Textile based medical devices and their role in sustainable health systems

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Abstract

The field of medical textiles is one of the fastest growing areas within the technical textiles sector of the textile industry. Part of this expansion is because of advances in technology, such as nanotechnology, electrospinning, and the ability to incorporate molecules (such as antimicrobials) into textile structures. Part is due to need. For example, the Covid-19 pandemic drove a surge of interest into the role that antimicrobial textiles may play in healthcare to prevent the spread of infection. The pandemic also highlighted the importance of resilience within the healthcare supply chain to ensure continuous supply.

As political agendas have focused upon the carbon footprint of society and creating a sustainable society, attention has turned towards the carbon footprint generated by the healthcare sector. Textiles account for a significant proportion of hospital waste and the use of disposable textiles rather than reusable textiles significantly alters the carbon footprint generated by the sector.

This critical commentary examines the body of work defining the medical textile field in current times. In turn it discusses current limitations within the evolving arena of antiviral and antimicrobial textiles. Attention is paid to the generation of medical waste and the textile constituents of waste before discussing how the implementation of a circular economy within the medical textiles sector could produce a positive impact upon the carbon footprint of healthcare and contribute to a sustainable healthcare system.

Background on Author

Ms Holly Morris holds dual professional registration across the medical and textile industries. Working as a hand surgeon, Holly has a special interest in the management of paediatric and congenital hand differences. Holly is a Fellow of the Royal College of Surgeons of Edinburgh, awarded following completion of higher surgical training in Trauma and Orthopaedic surgery.

Holly's childhood love of textiles led her to gain a formal textile qualification through a Master of Applied Science at the University of Otago, Dunedin, New Zealand. Her thesis, awarded a distinction, centred around the role of textile technology in implantable bioscaffolds used within regenerative medicine and was co-supervised by Professor Raechel Laing and Associate Professor David Gwynne-Jones.

In her clinical practice, Holly has a keen involvement with the utilisation of a circular economy model of medical textiles and is a member of the environmental committee of her hospital. Nationally, she has previously advised the Royal College of Surgeons Sustainability group, contributing guidance on textile use in surgery for the Green Surgery Report. In addition, Holly sits on the Technical Textile and Sustainability Special Interest Groups of the Textile Institute and the medical textile working group of the European Division of Health Care Without Harm.

Author of "Medical Textiles" for the forthcoming Bloomsbury Encyclopaedia on World Textiles, she has previously co-authored a substantial review of the sector for Textile Progress and the textbook "Medical Textiles" for the Textile Institute Professional Publications Series. Holly is a Fellow of the Textile Institute. She has been involved for some years with research within her fields and spoken internationally on both surgical and textiles matters relevant to her expertise.

Holly has experience supervising undergraduate and postgraduate students in medicine and medical device design. Previously Chief Medical Officer for Revolution-ZERO, Holly has a working knowledge of medical device regulations. Holly was previously the clinical director of ENG4, a charitable collaborative of professionals designing for the COVID-19 pandemic, that was awarded the 2021 Institution of Engineering Designers' Gerald Frewer Memorial Trophy for their collective work.

Holly enjoys mentoring juniors within the medical profession and has a healthy regard for fellow nonconformists.

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Portfolio of Publications and Presentations

Book	Medical Textiles. Morris H (50%), Murray R (50%) *Taylor and Francis. 2021 Dec. ISBN 9780367772734*
Chapter	Medical Textiles. Morris H (60%), Murray R (40%) In *Bloomsbury Encyclopaedia of World Textiles Volume 10: Textile Futures.* Accepted. Peer Reviewed. Publication anticipated December 2024.
Paper 1	Designing the Future of the Medical Textile Sector. Morris HV (100%) *Textiles 2018;(3):20-22.*
Paper 2	Bilateral congenital vertical talus in association with Beals contractural arachnodactyly. Morris HV (80%), Navarre P (20%). PMID: 30540606 *JBJS Case Connector 2018 Oct-Dec;8(4):e97.*
Paper 3	Medical Textiles. Morris HV (50%), Murray R (50%) *Textile Progress. 2020;52(1-2):1-127.*
Paper 4	Waste Not, Want Not: Assessing the impact of arthroscopic waste. Shah S (35%), Morris H (35%), Nicolau N (5%), MacInnes S (5%), Haslam P (5%), Shahane S (5%), Ali F (5%), Garcia J (5%). PMID: 36453070 *British Journal of Surgery 2023 Feb;110(2):275-6.*
Paper 5	The potential future role of antiviral fabrics within healthcare systems. Morris H (70%), Forrester-Soto N (15%), Ogrodnik P (15%) *Journal of the Textile Institute. 2023 March;1-7..* *https://doi.org/10.1080/00405000.2023.2193278*
Paper 6	The Carbon Footprint of Arthroscopic Procedures. Shah S (35%), Morris H (35%), Nicolau N (5%), MacInnes S (5%), Haslam P (5%), Shahane S (5%), Ali F (5%), Garcia J (5%) *Annals of the Royal College of Surgeons of England 2023 June;* *https://doi.org/10.1308/rcsann.2023.0036*
Paper 7	Waste Not, Want Not: Orthopaedic Waste Data. Shah S (35%), Morris H (35%), Thiagarajah S (5%), Gordon A (5%), Sharma S (5%), Haslam P (5%), Garcia J (5%), Ali F (5%) *British Journal of Surgery Open 2023 June;7(3):zrad062.*
Paper 8	Handling 'Carbon Footprint' in Orthopaedics. Shah S (35%), Morris H (35%), Thiagarajah S (5%), Gordon A (5%), Sharma S (5%), Haslam P (5%), Garcia J (5%), Ali F (5%) *Annals of the Royal College of Surgeons of England*
Paper 9	Improving Medical Textiles to Create a Greener Operating Theatre. Morris H (75%), Murray R (25%) Submitted to the Journal of the Textile Institute
Paper 10	Cotton in Healthcare – are we using the correct fibre? Morris HV (100%) *Textiles 2023(2):12-14.*

Policy Guidance The Role of Medical Textiles in Sustainable Healthcare.
Morris H (75%), Murray R (25%)
Submitted to the *Green Surgery Report (November 2023)* by UKHACC.

Supplemental Portfolio Contribution

Poster The development of a reusable, antiviral medical textile for PPE.
Smith M (70%), Ogrodnik PJ (10%), Morris HV (10%), Forrester-Soto N (10%)
BiomedEng Conference
September 2022

Presentation 1 Designing the Future of the Medical Textile Sector.
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July 2018

Presentation 2 Medical Textiles.
Grand Round, University Hospitals of Lincolnshire NHS Trust
September 2018

Presentation 3 The Development of Surgical Gowns and Use in Orthopaedics.
Department of Applied Science, University of Otago and *Southland Grand Round, Southland District Health Board*
August 2016

Presentation 4 The Role of Fibre Engineering in Incontinence.
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November 2017

Presentation 5 Crafting New Bone.
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Presentation 6 Medical Textiles.
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Presentation 7 Medical Textiles and the Sector.
Invited Lecture for *Pulvertaft Hand Centre Teaching*
September 2021

Presentation 8 The Role of Fibres in the Healthcare Setting.
Invited Lecture for *Biological Manufacturing Masters' Module, Loughborough University*
March 2022

Presentation 9 Sustainability. The 'Green' Operating Theatre.
Invited Lecture at the *British Orthopaedic Association Conference*
September 2022

Presentation 10 Sustainability in Surgery. Where are we at with textiles?
Webinar for *Healthcare Without Harm. European Division*
December 2022

Presentation 11 Interweaving a career in Orthopaedics and Technical Textiles.
Invited Lecture at the *Edinburgh University Trauma and Orthopaedics Society*
November 2022

Presentation 12 Medical Textiles in the Greener Operating Theatre.
Morris H (70%), Murray R (30%)
World Conference of the Textile Institute
July 2023

Author Contribution to Publications

Book	Initial draft (except i) the chapter on 'Ensuring Regulatory Compliance' by Peter Ogrodnik ii) the section 7.6 on 'Ophthalmic Uses' and Case Study Four 'Cataract' and iii) that Chapter 11 'Intelligent (SMART) Medical and Healthcare Textiles' which was co-authored with Simon King) then co-editing of the chapters on textile materials, medical textiles and their performance for the final version.
Chapter	Drafted initial chapter and editing of final chapter.
Paper 1	Full authorship.
Paper 2	Drafted paper with the section on five year follow up written by P Navarre.
Paper 3	Drafted the initial versions of both the clinical and textile content then co-edited the final version.
Paper 4	Methodology design, supervision of data collection, data analysis, drafted paper.
Paper 5	Methodology design, coordination/supervision of data collection, data analysis, drafted paper.
Paper 6	Methodology design, supervision of data collection, data analysis, drafted paper.
Paper 7	Methodology design, supervision of data collection, data analysis, drafted paper.
Paper 8	Methodology design, supervision of data collection, data analysis, drafted paper.
Paper 9	Drafted initial paper (both clinical and textile sections) then edited final version.
Paper 10	Full authorship.
Policy Guidance	Drafted initial paper (both clinical and textile sections) then edited final version.

All presentations were written and presented by Holly Morris.

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List of Abbreviations

ATLS®	Advanced Trauma Life Support
BOA	British Orthopaedic Association
CCT	Certificate of Completion of Training
CDC	Centers for Disease Control and Prevention
CPD	Continuing Professional Development
CVT	Congenital Vertical Talus
FDA	US Food and Drug Administration
HWOH	Healthcare Without Harm
ISO	International Organization for Standardization
NOTSS	Non-Operative Technical Skills for Surgeons
OECD	Organisation for Economic Co-operation and Development
PPE	Personal and Protective Equipment
RZ	Revolution-ZERO
UNEP	United Nations Environment Programme
WHO	World Health Organization

List of Definitions

Bioscaffold	Cells, scaffolds and growth-stimulating signals are generally referred to as the tissue engineering triad, the key components of engineered tissues. Scaffolds, typically made of polymeric biomaterials, provide the structural support for cell attachment and subsequent tissue development. (Chan and Leong, 2008)
Circular Design	The practice of creating durable, reusable, repairable and recyclable products that generate zero waste to support a circular economy. (Interaction Design Foundation, 2023)
Circular Economy	The circular economy is a model of production and consumption, which involves sharing, leasing, reusing, repairing, refurbishing, and recycling existing materials and products as long as possible. In this way, the life cycle of products is extended. In practice, it implies reducing waste to a minimum. When a product reaches the end of its life, its materials are kept within the economy wherever possible thanks to recycling. These can be productively used again and again, thereby creating further value. (European Parliament, 2023)
Decent Work	Involves opportunities for work that is productive and delivers a fair income, security in the workplace and social protection for all, better prospects for personal development and social integration, freedom for people to express their concerns, organize and participate in the decisions that affect their lives and equality of opportunity for all women and men. (International Labour Organization, 2023)
Elective	Operations planned in advance. (Royal College of Surgeons of England, 2023a)
Electrospinning	Electrospinning (polymer solution) and (melt). Electrospinning of nanofibers of 100nm or less in diameter from polymer solutions usually by capillary method, wherein a pendant droplet of the polymer solution at the capillary tip is subjected to the electric field created by the potential difference between the capillary and a grounded collector. (Textile Institute, 2021a)
Extracorporeal	Occurring or situated outside of the body.

Grand Round	A structured weekly educational and group learning activity used within continuing medical education as an instructional method for maintaining and improving clinical skills of practising physicians. (Lewkonia and Murray, 1995)
Kaizen	A philosophy that implies that small, incremental changes routinely applied and sustained over a long period result in significant improvements. It aims to involve workers from multiple functions and levels in the organization in working together to address a problem or improve a proves. It focuses on eliminating waste, improving productivity, and achieving sustained continual improvement in targeted activities and processes of an organisation. (United States Environmental Protection Agency, 2022)
Kanban	Key technique that determines a processes production quantities and facilitates just-in-time production and ordering systems. The "pull" system creates greater flexibility on the production floor, such that the organization only produces what is ordered. (United States Environmental Protection Agency, 2023)
Medical Textile	A general term which describes a textile structure which has been designed and produced for use in any of a variety of medical applications, including implantable applications. (Textile Institute, 2021b)
Moulage	The use of special effects makeup techniques to simulate illnesses, bruises, bleeding, wounds or other effects to a manikin or simulated patient, acting as visual and tactile cues for the learner. (Stokes-Parish *et al.*, 2018)
Orthotic	An orthotic is defined as an externally applied device, which modifies function by supporting or controlling a body part. (Kurup *et al.*, 2012)
Smart Textile	Textiles that are able to sense and respond to changes in their environment. (Koncar, 2016)
Technical Textile	Textile materials and products manufactured primarily for their technical performance and functional properties rather than their aesthetic or decorative characteristics. (Textile Institute, 2021c)

Textile	Fibres, filaments, and yarns, natural and manufactured, and most products for which these are a principal raw material. (Textile Institute, 2021d)
Trauma	Bony and soft tissue injuries. (Royal College of Surgeons of England, 2023b)

1. Introduction to Critical Commentary

1.1 Autobiographical Context

In providing a justification for the award of PhD by Publication, a principally chronological order will be adopted which allows for demonstration of incremental progression and development of research abilities and skills. Writing this body of work clarifies the milestones achieved and reviews and assesses how the work has been affected by career and personal experiences, not least the COVID-19 pandemic, as well as international political and societal agenda on Net Zero and sustainability.

Over a period of six years, since returning from New Zealand in 2017, there has been significant personal and professional development. A range of opportunities allowed for the acquisition of a breadth of skills. The award of Master of Applied Science in Clothing and Textiles with Distinction from the University of Otago, New Zealand, was the start of this journey and facilitated professional accreditation with the award 'Licentiateship of the Textile Institute'. This postgraduate course provided specialised training in technical textiles. The taught modules covered physical properties of clothing and textiles, research methods within textiles and the role of clothing and materials in workplace injury. A special study module focussed upon medical textiles with a dissertation on the role of protective and personal equipment in healthcare. The thesis centred on the role of bioscaffolds in bone regeneration. During the Master of Applied Science, I was awarded the University of Otago New Frontiers Scholarship at the level of Sustained Excellence. This funding awarded provided the opportunity to undertake an additional undergraduate module in basic computer programming which provided an introduction to understanding the role programming can have in applied science and medicine.

More recently, professional development opportunities have included being invited to present lectures at national conferences, membership of international panels and contributions towards national policy. For example, contributing the textile guidance to the UKHACC Green Surgery Report. These contributions facilitated professional accreditation with the award Fellowship of the Textile Institute. The Fellowship is awarded for an individual with a high level of knowledge and specialism, who has achieved a significant major personal creative contribution to their field (Textile Institute, 2023a).

Primarily, the last six years since my return to the United Kingdom have been dedicated to the completion of higher surgical training in the surgical speciality of trauma and orthopaedics. An intensive six year program which, in addition to clinical and surgical skills, places emphasis upon gaining skills in leadership, research, education, and management. The final professional examinations leading to the award of Fellowship must be passed before the Certificate of Completion of Training (CCT) can be awarded.

Trauma and orthopaedic surgery, whilst being the second largest surgical speciality, has a significant gender disparity with only 7% of consultant surgeons being female. Gender parity has been forecasted not to be achieved until 2070 (Newman *et al.*, 2022). Hence, mentoring juniors within the field has been a sound use of leadership skills acquired during my training, and has been a role often lacking due to the small numbers of female leaders within the field.

The body of work proposed for the PhD by publication includes a textbook, a chapter, ten papers and a report for policy guidance supplemented by a series of presentations to regional, national, and international audiences. These pieces of work cover the period following the award of Master of Applied Science. The research has combined pragmatism with opportunism and a notable progression and development of research skills. Initial steps commenced with a scope of the field and were followed by a comprehensive literature review, its historical and current developments, to update the field. Following this, applied research was undertaken. Theoretical research skills were enhanced with Cochrane Review Training which comprised in-depth modules covering protocol writing, analysis of medical studies and conducting a Cochrane review (Cochrane UK, 2023). These skills were beneficial when writing PPE Guidelines for the trauma and orthopaedic department at University Hospitals of Leicester NHS Trust under the supervision of Professor Joe Dias. A research methodology course covered medical statistics, systematic reviews, clinical trials, and meta-analyses. It also covered how to establish a study and critically evaluate a paper (North West Surgical Trials Centre, 2023). Skills gained on these courses allowed for the design of appropriate methodologies and data collection on operating theatre waste. These skills were also helpful in successfully obtaining a Medical Research and Development Centre Business Bridge Grant (Keele University, 2020).

An opportunity arose with the COVID-19 pandemic to study the role medical textiles have in creating a sustainable environment, as personal and protective equipment contributed significantly to healthcare waste. Good design is not just how an object appears; it also requires knowledge of underpinning principles behind its function. From a broader perspective, the importance of assimilation between the arts and science is being increasingly recognised and can be demonstrated by the linking of traditional art forms with modern science to push forward the boundaries of knowledge (Videla *et al.*, 2021). Supervision of postgraduate students undertaking a Masters in Medical Engineering Design at Keele University, reviewing how well considered design can reduce waste, has allowed for development of knowledge, teaching, and leadership skills such as mentorship.

Transferable teaching skills were also developed, not only via supervision of postgraduate students but also, during courses undertaken as part of higher surgical training and when working with sector leaders. For example, the ‘Advanced Trauma Life Support (ATLS®) Instructor’ course allows for instructing on ATLS® courses. Adopted in over 80 countries, ATLS® is a global

course, teaching a systematic process of trauma care for patients with life-threatening injuries. It is a hybrid course of e-learning and face-to-face learning via small group sessions of theory, moulage, and practical sessions, for example, inserting chest drains into sheep thoraces (Royal College of Surgeons of England, 2023c). Instructing on the ATLS® course granted the three-year tenure status of Educational Tutor for the Royal College of Surgeons of Edinburgh. The 'Teach the Teacher' course further developed knowledge in adult education theory, methods of establishing effective teaching sessions, and the role of different teaching styles and systems for coaching (ISC Medical, 2023a). Skills learnt from both courses have been beneficial in supervision of postgraduate students.

Following this, a series of leadership courses enabled the development of appropriate leadership skills used with industry professionals. First, the 'Transition to Leadership' programme, aimed at those working within a higher education setting, developed personal and team leadership skills required for leading during times of change (Advance HE, 2023). Secondly, the Cornell University 'Women in Leadership' Certificate targeted issues faced by women in leadership positions and offered strategies to adopt in response. Topics covered negotiation skills, how to effectively provide feedback, how to strengthen individual and team emotional intelligence and how to avoid the 'double bind' dilemma of exhibiting strong leadership qualities without being penalised for it (eCornell, 2023). Thirdly, 'Leadership and Management for Healthcare Professionals', delved into leadership styles with the NHS, managing teams, and mentoring and coaching of others (ISC Medical, 2023b). Finally, the 'Non-Operative Technical Skills for Surgeons' (NOTSS) course teaches skills required to perform safely in the operating room, focusing upon professionalism, interpersonal and communication skills, and systems of practice (Royal College of Surgeons of England, 2023d). These courses allowed me to develop the skill set used at the not-for-profit ENG4.

ENG4 is a collaboration of professionals and volunteers whose sole aim is to provide support to enhance health and wellbeing in times of need. It was established in response to the pandemic. Enrolling initially as a volunteer member, and later becoming Clinical Director, there was significant opportunity for collaborating with healthcare stakeholders across a range of disciplines. This developed interpersonal skills and provided the opportunity to understand how research in different fields is undertaken. The result of the ENG4 collaboration was a body of work undertaken on the role which antiviral fabrics may have in healthcare settings. As part of this, a methodology to allow testing of an antiviral fabric was devised to the available ISO standard. This provided opportunity to reflect and critical evaluate the weaknesses of the standard. During this COVID period, I became a member of the medical textile working party of the European Division of Healthcare Without Harm. This facilitated further collaboration with European professionals across allied specialities. Further memberships of the Textile Institute Sustainability Group, the Royal College of Surgeons Sustainability Group and the Sustainability Committee for University

Hospitals of Derby and Burton have provided further opportunity to undertake work on the sustainability of medical textiles, with a particular focus upon surgical gowns and drapes. As a result, this body of work culminated in a review of the role of medical textiles in sustainable healthcare submitted to the Green Surgery Report. This report, funded by UK Health Alliance on Climate Change and in collaboration with the Royal College of Surgeons of England, is an evidence-based guide and recommendation on how to mitigate carbon footprint associated with surgical practice (UK Health Alliance on Climate Change, 2023a). The guidance submitted to the Green Surgery report has been adapted and presented at the highly regarded World Conference of the Textile Institute in July 2023. Furthermore, it has been accepted (currently pending revision) as a formal paper to The Journal of the Textile Institute.

A further development of the work on sustainability included a body of work examining the amount of waste generated in the operating theatre. It was a combination of these works which gained attention such that I was headhunted to take the role of Chief Medical Officer for the start-up Revolution-ZERO, (RZ) (Revolution-ZERO, 2023). RZ aims to displace the global single-use PPE and related textiles market with more effective, economic, and sustainable alternatives. The company utilises circular economy principles where the objective is for resources to be continuously cycled and tightly controlled in an increasingly efficient system. It provides technology-enabled solutions for Net Zero reusable textiles which are both scalable and transferable across healthcare settings. Aa a named Co-Investigator on grants awarded to Revolution-ZERO amounting to £883,323, the Women Achiever rated the Chief Medical Officer role in "Top 10 Most Impactful Chief Medical Officers to Watch 2023" (The Women Achiever, 2023). Acknowledging a deficit in business and financial skills, the Certificate of MBA Essentials at London School of Economics and Political Science provided a basic overview of finance, strategy, and leadership skills in the business domain (London School of Economics and Political Science, 2023).

Having completed surgical training, I am currently undertaking a year of specialist surgical training in hand and microsurgery in Auckland Regional Centre for Plastic, Reconstructive and Hand Surgery. Developing the theme of waste generated during surgical procedures, I have commenced further work assessing the difference in generated waste when undertaking the same operation in a general operating theatre compared to a local anaesthetic procedure room.

1.2 Scientific Content

Archaeological expeditions discovered evidence of textiles being used in connection with medicine such as linen bandages used to splint broken bones and mummification in Egypt (Forrest, 1982). The first written references alluding to the use of textiles in medicine and healthcare date back to the Trojan War and the management of war wounds (Morris and Murray, 2021). Whilst these early

developments are significant, many of the major innovations date from the mid-1800s where great progress occurred within medicine generally and, in particular, surgery. Collections housed by the Royal College of Surgeons of Edinburgh in their Surgeons' Hall Museums demonstrate some of the great innovations and development of medical devices for procedures still undertaken in current times, for example, the development of surgical instruments for amputation and arthroscopic surgery (Surgeons' Hall Museums, 2023).

At around the turn of the 20th Century there was a paradigm shift from the use of textiles produced for other general purposes being used in the medical context, to textiles being specifically designed, produced, and treated to fulfil a medical need. As an example, the use of sterilised cotton to filter air and reduce contamination allowed for the development of the Lindbergh-Carrel perfusion pump and the subfield of external artificial organ support in the 1930s (Morris and Murray, 2021). The definition of medical textiles reflects this shift. Nanotechnology and the development of electrospinning has allowed witness to the development of an entirely new field within medical textiles; regenerative bioscaffolds for tissue replacement occurring in 1991 (Vacanti, 2006).

The field of medical textiles is one of the fastest growing areas within the technical textiles sector of the textile industry (Morris and Murray, 2020). Part of this expansion is because of advances in technology, such as nanotechnology, electrospinning, and the ability to incorporate molecules (such as antimicrobials) into textile structures. These advances have led to rapid progression with research in areas such as wound healing, pressure and bandaging garments, and implantable textiles. In the literature, a total of 3,238 papers about medical textiles were published between 2000 and 2021, of which over half emerged in the last five years (Morris and Murray, 2021).

Rajendran and Anand formally reviewed the field of medical textiles for the journal Textile Progress in 2002 following publication of conference proceedings the year previously (Anand SC, 2001; Rajendran S and Anand SC, 2002). Given the significant advances within the field, this review was updated for Textile Progress by Morris and Murray (Morris and Murray, 2020). This Textile Progress article was well received, reaching the "Top 10" read paper for the journals history within the first year of publication. Subsequently, it was converted and expanded into a formal textbook, Medical Textiles, for the Textile Institute Professional Publications Series (Morris and Murray, 2021). A literature review was undertaken as part of this process and used as the basis for the text. Collaboration with experts within medical and surgical subfields, medical device design and smart textiles ensured that the text was relevant to the clinical environment. This publication forms the literature review of this PhD thesis.

During the period of writing Textile Progress and the accompanying textbook, the first cluster of cases of "*a pneumonia of unknown cause*" were identified in Wuhan (British Foreign Policy Group, 2023). The World Health Organization declared a Public Health Emergency of International

Concern a month later and the outbreak of a pandemic of SARS-CoV2-virus, coronavirus, shortly after on the 11 March 2020 (World Health Organization, 2023). The quantity of contaminated waste created by used personal and protective equipment during the COVID-19 pandemic was significant. Combined with a new impetus from the surgical world on the importance of sustainability and Net Zero, and the United Nations Sustainable Development Goals, further applied research was undertaken by myself on the role of textiles in healthcare waste. This work forms some of the publications submitted for the PhD and includes the papers published on waste produced in the operating theatre and the role of antiviral fabrics in healthcare. The implementation of a circular economy model of textiles to the healthcare setting (Roa *et al.*, 2019) is critical in reducing the waste produced and the textile guidance submitted for the Green Surgery Report forms a further body of work contributing towards the PhD.

Whilst most of my research to date has been concerned with the textile waste generated by surgical gowns and surgical drapes, within my clinical practice, waste is also generated outside the operating room, for example, with orthotics. Paper 2 has been included to highlight the use of textiles, that are not gowns and drapes, within trauma and orthopaedics and, in this case study, the management of limb deformity. In this patient, textiles were used in two different ways. First, a textile suture anchor was used intra-operatively to transfer a tendon to alter biomechanical forces and correct the foot deformity. Secondly, the patient had already undergone extensive management using textile-based orthotics and splints for limb contracture and hip dislocation.

Contextualising the role of textiles in my own surgical practice has provided an opportunity to consider their environmental footprint. The surgical profession is also starting to critically examine the footprint of other medical devices, such as the orthotics discussed in this paper. Most orthotics are single patient use and discarded, many are only used for a short period of time and the materials used within them could be recycled as part of a circular economy model.

A fellow colleague, Mr James Bentley, presented an evaluation of the environmental impact of the aluminium used within wrist splints at Queens Medical Centre, Nottingham at the 48th Malkin Meeting, the East Midlands North Trauma and Orthopaedic research meeting. Over a period of 12 months, the fracture clinic purchased 1326 wrist splints which each contained an aluminium bar weighing 21grams. Consequently, 0.028 tonnes of non-recycled aluminium a year is used when providing wrist splints in fracture clinic and this contributes an annual carbon footprint of 0.134 tonnes (Bentley *et al.*, 2022). This work has been subsequently presented at the British Society for Surgery of the Hand, Spring Scientific Meeting 2023 and serves to highlight the impact of a seemingly innocuous device used in large quantities.

A PhD by publication, by its nature, is a personal claim to having produced some work of significance. In addition, it is an objective claim that the publications provide robust evidence for the award and are based upon research and originality. Whilst a personal claim, I would acknowledge that work of importance is, more often than not, undertaken by a team. During the past five years, I have enjoyed many collaborations which have allowed exchange of knowledge, challenge of thoughts and a stimulating environment within which to undertake research.

2. Introduction to the Field of Medical Textiles

Paper 1 Designing the Future of the Medical Textile Sector.
Morris HV (100%)
Textiles 2018;(3):20-22.

This publication, "Designing the Future of the Medical Textile Sector", (Paper 1), published in Textiles in 2018 was developed from a lecture presented at the 91st Textile Institute World. This is a rapid review of the medical textile field, based upon work undertaken for the Master of Applied Science before applying the knowledge of personal experience as a surgeon. It uses the opportunity to highlight problems with currently available textile based medical devices used within everyday practice.

One of the key learning points from the work undertaken for the award of Master of Applied Science, was the lack of collaboration between the textile and medical discipline. Not only can this hinder the progress of new ideas, but it can also mean that research opportunities, time, facilities, and funds are deployed incorrectly or inefficiently. The aim of the presentation and article was to highlight specifically to the textile community, the experiences of clinicians with the textile-based devices that they use and to try and foster a collaboration between the two fields. First, the article highlights current problems to allow for targeted research and development. Secondly, it demonstrates the lack of collaboration between fields. Thirdly, the technical aspects of medical device regulations were touched upon. Regulatory frameworks need to be considered at the design stage to ensure that design is efficient and that risk, and risk mitigation, is designed into the medical device.

Both the publication and lecture discussed the field of medical textiles and potential avenues for development, such as regenerative bioscaffolds and the role of smart textiles in monitoring patients remotely. It provided a platform to share key healthcare initiatives and practices with the textile audience, for example: the importance of patient safety and initiatives such as "Safe Surgery Saves Lives" and "Getting It Right First Time"; and how the healthcare profession structures clinical trials (NHS, 2023; World Health Organization, 2009). The importance of collaboration of both fields at the design and development stage was stressed.

Within the work, a clinician's insight was provided into the key role textiles play within the surgical field; hospital acquired infections; the role of personal and protective equipment; and the problems associated with wearing lead gowns whilst using radiation intra-operatively. Having undertaken charity surgical work in rural Vietnam, there was a discussion on the pitfalls of the current PPE in hostile environment, with further examples provided from the work of a colleague who had spent time in Liberia following the Ebola outbreak with Médicins San Frontières (Figure One).

Figure 1: Ebola Clothing in Liberia (Credits: An Vanthuyne)

The outbreak saw a drive towards understanding the role that individual garment items play when worn as a bundle. The Centers for Disease Control and Prevention, CDC, subsequently recommended bundles of clothing for healthcare workers, and the methods of donning and doffing, based upon the perceived level of exposure to the Ebola virus (Centers for Disease Control and Prevention, 2015). The same approach was used in the guidance released during the Covid-19 pandemic.

2.1 Methodology

This paper provides a rapid review of the medical textile field based upon work undertaken for the Master of Applied Science. The review then applied the knowledge to personal experience (as a surgeon), providing the opportunity to highlight problems with currently available textile based medical devices used within everyday practice.

The aim of the publication was to highlight, specifically to the textile community, the experiences of clinicians and the textile-based devices that they use including indications and complications. First, this highlights problems to allow for relevant research. Secondly, it demonstrates the importance of collaboration between fields. Thirdly, the technical aspects of medical device regulations were touched upon. Regulatory frameworks need to be considered at the design stage to ensure that design is efficient and that risk, and risk mitigation, is designed into the medical device.

2.2 Impact

This was the first occasion in which any clinician had presented at a Textile Institute World Conference and published within the journal Textiles. It demonstrated to the audience the importance of collaboration and sharing of experiences.

Following the presentation at the World Conference, an invite was extended to present the work at the medical grand round of the hospital where I was working (Presentation 2). Prior to this presentation, colleagues with knowledge of my developing interest in the field and who believed that interdisciplinary collaboration is of great importance, had extended invitations to present at both regional medical events (Presentation 3 and 5) and international conferences (Presentation 4 and 5).

Following the publication of this article, the Editor of Textile Progress requested a comprehensive review of the field Medical Textiles. This would be co-authored with a textile expert and the scope would include a review of each subfield of medical textiles, ensuring that the field was up to date before applying the textile knowledge to clinical practice to ensure relevance.

2.3 Conclusions

"Designing the Future of the Medical Textile Sector" comprised a brief review of the potential future directions which the medical textile field may take. It highlights the importance that should be placed upon ensuring regulatory guidelines and standards are regularly reviewed to ensure that they are up-to-date, relevant, incorporate the new and emerging technologies, and maintain patient safety.

Collaboration between experts from differing fields should be mandatory when comprising research and design panels. Not only will this allow for free-flowing information and the ability to draw upon a breadth and depth of experience across fields, but it offers the ability to use resources appropriately and reduce inefficiencies and waste.

3. A Review of Medical Textiles

Book	Medical Textiles. Morris H (50%), Murray R (50%) *Taylor and Francis. 2021 Dec. ISBN 9780367772734*
Chapter	Medical Textiles. Morris H (60%), Murray R (40%) In *Bloomsbury Encyclopaedia of World Textiles Volume 10: Textile Futures.* Accepted. Peer Reviewed. Publication anticipated December 2024.
Paper 3	Medical Textiles. Morris HV (50%), Murray R (50%) *Textile Progress. 2020;52(1-2):1-127.*

In this section, a review of medical textiles will be presented and discussed using the following sources as reference. A paper "Medical Textiles" (Paper 3), and a book 'Medical Textiles". The paper was published in Textile Progress in 2020 and made the Top 10 Most Read Papers in the journal within a year. Following publication, an invite was extended to convert and expand the paper into a reference book for the Textile Institute Professional Publications Series. This was published in 2021. An invited chapter, "Medical Textiles", to be published in the Bloomsbury Encyclopaedia of World Textiles Volume 10: Textile Futures in December 2023 supplements this work further.

The medical textile field had been comprehensively reviewed for the journal Textile Progress in 2002, by Rajendran and Anand (Rajendran and Anand, 2002) following publication of conference proceedings the year previously (Anand, 2001). The 42-page review discussed projected growth of the sector, fibres used within the medical textile sector, and applications of textiles within the clinical environment. In this publication, the medical textile field was classified into the following areas:

1. Non-implantable;
2. Implantable;
3. Health and hygiene products; and
4. Extracorporeal products.

The ***Textile Progress Paper***, "Medical Textiles", Paper 3, provided an updated review of the field when it was published in 2020. Textile Progress is the Textile Institute's critical review journal covering all aspects of textiles, clothing, and footwear (Textile Institute, 2023b). The final published review expanded upon the previous review by Anand. Within it, the publication reviewed currently available fibres, fabrics and their construction and the finishes that are applied to fabrics to impart various functional properties. Additionally, the necessary regulations and

standards to which medical devices must conform was included along with a description of how research is undertaken within the health sector. Finally, the areas of implantable, non-implantable, health and hygiene textiles and extracorporeal devices were each updated and a new chapter on intelligent (smart) healthcare textiles was added.

The ***Reference Textbook***, "Medical Textiles", aimed to update and greatly expand upon the collection of conference proceedings previously published by Anand in 2001 (Anand, 2001). Within the textbook, a new classification was proposed to reflect evolution of the field since the previous suggestions by Anand (Rajendran and Anand, 2002). The proposed 2021 classification expanded the work by Anand and incorporated three new areas to reflect development of the field, as follows:

1. Intelligent medical and healthcare textiles;
2. Furnishing fabrics and textiles in fixtures and fittings in healthcare establishments; and
3. Components of devices for environmental hygiene control (Morris and Murray, 2021).

The textbook contained a chapter on the historical development of textiles within healthcare focusing on textiles used to protect the patient, repair the patient and maintain the comfort of the patient. Attention was also given to advances in filtration which has allowed for the development of extracorporeal membrane oxygenation and haemodialysis. Following this, chapters in the textbook discussed fabric construction, the role fibres play in technical textiles and how finishes can be used to functionalise textiles.

A chapter was included on the regulations for medical devices and changes to these from the UK exiting the European Union. Each subfield of medical textiles was dedicated a separate chapter and relevant textiles were discussed with attention paid to the way the engineering of the textile affects human health. The underlying clinical pathologies were discussed at a level such that non-clinicians could understand the aim of treatment. A final chapter included a series of case studies of textiles in action and a discussion on some of the current limitations of commercially available textiles.

3.1 Methodology

Both of these publications were co-authored with Professor Richard Murray, Emiterus Professor of Manchester Metropolitan University, who provided guidance on the appropriate level of clinical knowledge to include to enable a textile audience to understand alongside advice on drafting, writing, and editing the review.

Initially, a systematic review of on medical textiles published between 2000 and 2020 in the two key textile journals, the Journal of the Textile Institute and the Textile Research Journal, was undertaken. A total of 267 papers were identified between 2000 and 2020. 203 of these concerned antimicrobial textiles.

Subsequently, Pubmed/Medline was searched to determine the research output and the topics addressed in the same time period of 2000 to 2020. 3,264 papers were identified. Again, antimicrobial textiles featured heavily. Their intended applications covered barrier fabrics, sutures, and implantable items.

Developing upon the work of Anand, the ***Textile Progress paper*** reviewed currently available fibres including the development of graphene and nanofibre technology. The construction of woven, knitted, braided and nonwoven fabrics was included as was a section on finishes, including antimicrobial finishes. Innovative to the Anand paper, and a direct offshoot of the work "Designing the Future of the Medical Textile Sector", was a section on the necessary regulations and standards to which medical devices must conform and how research is undertaken within the National Health Service. The aim of the Textile Progress publication was to provide information on the way devices are tested and the pathway they must follow for registered with the relevant authorities and clinical translation.

The areas of implantable, non-implantable, health and hygiene textiles and extracorporeal devices were updated and a new section on intelligent (smart) healthcare textiles was added. This was not demonstrated in previous reviews of the medical textiles sector, and hence, novel. Fundamental to the process was the concept of interweaving the two disciplines to allow and explanation of some of the limitations of currently available medical devices manufactured from textiles. This was the first time a clinician was co-authoring with a textile expert and allowed for a novel approach in discussing the subfields and textiles of the medical textile sector.

The ***Reference Textbook*** followed a similar process; literature review, critique, and expansion. It used the Medical Textile publication in Textile Progress journal as the basis for the overall structure and flow of chapters. New chapters were incorporated including a chapter on historical developments within the field and a chapter of case studies.

Following the literature search, invitations for collaboration in writing or reviewing sections of the textbook were extended to experts across a range of medical fields. This was novel and had not been undertaken in previous publications on the subject. Part of the intention of this was not only to ensure the textbook provided up-to-date and relevant material but also to raise awareness of the use of textiles in medical devices with colleagues. In addition, colleagues were invited to provide case studies of the textiles in action and discuss the challenges which they face. This allowed for the incorporation of a chapter of case studies towards the end of the textbook to illustrate to those

in the textile field how clinicians use the products in practice and highlight limitations with current designs, for example, the risk of infection and biofilms with implants. One of the case studies focused upon the lack of resilience within the supply chain of healthcare which was being highlighted during the pandemic with problems sourcing personal and protective equipment. This is discussed in further detail in Chapter Four.

An additional chapter included in the textbook concerned the development of the medical textile field over time. This chapter highlighted key figures, such as Sir Joseph Lister and Sir John Charnley, who pioneered change in the clinical environment which saw a subsequent response from the textile field with the development of personal and protective wear for the clinician. An update on the regulations, with a focus upon the way the regulations now apply post Brexit, for medical device licensing was included to highlight the necessary regulatory hurdles to those wishing to design and develop textile based medical devices. This chapter was authored by a Professor of Medical Device Design, Professor Peter Ogrodnik.

3.2 Impact

The ***Textile Progress Paper*** has enjoyed a rapid trajectory up the Most Read leader board of Textile Progress. As of the 21 December 2023, it holds the position of third most read article with 5,174 reads and 34 citations (Textile Progress, 2023). These citations include, *inter alia*, two within other Textile Progress issues, one within the Journal of the Textile Institute and a further paper assessing alternative ways of protecting healthcare workers from radiation - a problem alluded to in the Presentation at the 91st Textile Institute World Conference (Presentation 1). One citation from Textile Progress was referenced for an edition discussing the use of graphene in wearable textile sensor devices in healthcare (Ahmed *et al.*, 2022). The use of such devices potentially allows for monitoring of patients remotely which enables patients to be treated at home rather than as a hospital inpatient. The other Textile Progress citation is in the issue "Upcycling textile wastes: challenges and innovations" (Kamble and Behera, 2021). Given health systems generate 4% of the nation's greenhouse gases and textiles comprise up to 31% of healthcare waste, it is encouraging to see that healthcare textiles are addressed in this review (Shah *et al.*, 2023a, 2023b; Zlaugotne *et al.*, 2022). The citation in the Journal for the Textile Institute concerns antiviral textiles and will be discussed later within this thesis alongside the "Letter to the Editor" response to this article by Murray (Murray, 2022; Raza *et al.*, 2022).

From this, the Textile Institute extended an invitation to present a webinar as part of the "Tea with the Textile Institute" series to discuss the process of authoring an edition of Textile Progress (Presentation 6). This is open access and was promoted to members of the Textile Institute.

Within the ***Reference Textbook***, an updated and new classification of the medical textile subfields was proposed which was subsequently adopted and used within a Healthcare Without Harm lecture by an international speaker, Stefan Posner. This new classification is also reflected in the amendment to the definition of medical textile in Textile Terms and Definitions. The textbook has been cited in a journal paper reviewing plastic waste management and safety disinfection processes for reducing Covid-19 hazards in reference to the composition of FFP2 masks (Alkhursani *et al.*, 2023). Another citation concerns the manufacture of nonwovens for medical applications in a paper addressing the optimal combination of spunbond and meltblown processes for medical textiles (Čepič and Gorjanc, 2022). The textbook was cited within a discussion on the benefits of nonwoven textiles for patient care during the introduction of the paper.

Both of these publications generated requests for further work. One of the more significant requests was to submit an entry for the Medical Textile section of the Editors of Bloomsbury Encyclopaedia of World Textiles Volume 10: Textile Futures. The final article has been accepted for publication following peer review. In addition to this, there have been several requests for presentations and to act as a peer reviewer for other journals. These include an edition of Textile Progress on cosmetic textiles and an article reviewing the effects of different washing procedures on cleaning efficacy and fabric structure of medical textiles for the journal Fibres and Textiles.

Further invites during this period included delivering a lecture to the Pulvertaft Hand Unit and Loughborough University (Presentations 7 and 8).

3.3 Conclusions

Both reviews proposed updates to the field of medical textiles, in which a new classification of the field was proposed. Furthermore, by inviting collaboration with relevant clinicians, the bodies of work aimed to ensure that the publications were up-to-date and highly relevant to clinical practice.

It is challenging to find an accurate projection of the growth of the medical textile field. Many projections assess hygiene products and external medical textile products but neglect to include implantable products. Nevertheless, all projections show a trend of growth. Given the economic forecasting, ongoing advances in technology and renewed interest in sustainable alternatives to currently available products, the contents of Textile Progress will likely need a review and revision within five years. In a similar manner to Textile Progress, the Reference Textbook will require review and revision within five years to ensure it is providing current and relevant information. A section on a circular economy for healthcare textiles should also be included in the revision to reflect the significant amount of work being undertaken within this arena.

4. Personal and Protective Equipment

Paper 5 The potential future role of antiviral fabrics within healthcare systems.
Morris H (70%), Forrester-Soto N (15%), Ogrodnik P (15%)
Journal of the Textile Institute. 2023 March;1-7..
https://doi.org/10.1080/00405000.2023.2193278

This publication, "The potential future role of antiviral fabrics within healthcare systems", (Paper 5) was published in the Journal of the Textile Institute in 2023. The work stemmed from the ENG4 collaborative in response to the PPE supply chain crisis during the Covid-19 pandemic which was established to provide support to enhance health and wellbeing in times of need. The paper examines the role that fabrics with antiviral properties may have in allowing for re-use of personal and protective equipment.

During the period of writing for both the review for Textile Progress and the textbook "Medical Textiles", the first cluster of cases of "*a pneumonia of unknown cause*" were identified in Wuhan (British Foreign Policy Group, 2023). The World Health Organization declared a Public Health Emergency of International Concern a month later and the outbreak of a pandemic of SARS-CoV2-virus, coronavirus, shortly after on the 11 March 2020 (World Health Organization, 2023).

Whilst there has been uncertainty around the role of textiles as a fomite for transmission of infection, bacteria associated with hospital acquired infections have been found on hospital linens after extended periods of times (Fijan and Šostar Turk, 2012; Hochmuth *et al.*, 2005). More concerning, the parainfluenza virus has previously been demonstrated to survive four hours on a hospital gown (Brady *et al.*, 1990). It was therefore only a matter of time until the SARS-Cov2-Virus was found persisting on PPE and with dose dependent characteristics (Carraturo *et al.*, 2020; Chithra *et al.*, 2021; Kampf *et al.*, 2020).

An optimal solution to the PPE crisis would be the development of a fabric that reduces viral load yet can be laundered. The ability of PPE to proffer multiple uses thus reduces the burden of contaminated plastic waste generated by single use PPE.

Furthermore, the Covid-19 pandemic highlighted a lack of resilience within the healthcare supply chain regarding PPE, something discussed as a case study within the Reference Textbook. The first case study within the textbook "Medical Textiles" discusses the supply of PPE during times of emergency. There are many ways in which to improve and ensure a continuous supply. Simply put, for sufficient PPE there needs to be dedicated manufacturing capacity within each country, or at least region to satisfy ongoing needs as well as producing emergency levels. Heeding mistakes of the past is important yet is something that governments and policy writers/implementers do not appear to undertake readily or willingly. Prior to the coronavirus pandemic, there have been several significant epidemics such as Ebola, Severe Acute Respiratory Syndrome and H1N1. As

such, the coronavirus, whilst on a larger scale, was not a completely new and unanticipated event. The textile and the medical/surgical fields, however, had not previously collaborated to any great degree within this area.

There has been medical guidance available for some years on how to make an appropriate choice for PPE provision (Zins, 2006). Disposable devices ideally should not be used for items required in volume (Walton, 1986) but patient safety must remain a priority when reusables are utilised. Indeed, a full ten years ahead of the COVID-19 pandemic and just prior to the H1N1 outbreak, researchers from NIOSH in the United States together with members of staff from a highly respected US Federal Government contractor, USAAF researchers and an academic from the University of Nebraska repeated the warning given in 2006 by the US Institute of Medicine, Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic (Institute of Medicine, 2006). This was that supplies of PPE would run short in an epidemic. They also laid down a set of demonstration methods to form the basis for the development of N95 respirator decontamination and reuse. Reuse would help because despite the creation of a stockpile, the total quantities required would still be difficult to provide (Bergman *et al.*, 2010; Viscusi *et al.*, 2009).

Following this, the US Food and Drug Administration (FDA) commissioned Battelle to work on the respirator topic. In 2016, they reported on the development of a method of decontamination to allow for reuse. This was well ahead of the COVID-19 crisis (Battelle, 2016). Unfortunately, whilst recognising the COVID-19 emergency on February 4th, 2020, the Secretary of the Department of Health and Human Services did not authorise emergency use of medical devices until 24th March 2020 (Federal Register, 2020). This delay prevented the FDA releasing their 'Emergency Use Authorisation' any earlier (FDA, 2020).

Interestingly, the guidance released by the United Kingdom advised against undertaking decontamination and recommended using FFP2 respirators, with a lower level of filtration, instead (UK Health and Safety Executive, 2020). Given the strong and detailed guidance on decontamination and reuse of N95 respirators published ten years earlier by Bergman and Viscusi, one wonders whether any attention was paid to these published works (Bergman *et al.*, 2010; Viscusi *et al.*, 2009). Either way, there were clear shortages of appropriate PPE within the United Kingdom.

The United Kingdom does have a national stockpile of PPE. To function properly, however, it requires proper management of stock rotation, and withdrawal for use of product from the stockpile before the expiry date, rather than wasteful disposal. The supply chain management within the healthcare textile sector is neither as sophisticated nor as highly supervised as that modelled by fashion-retail companies. Yet another example of the textile and medical/surgical fields not collaborating. With rapid globalisation of supply chains not accompanied by similar rapidity in

the development of and insistence by governments on appropriate levels of corporate responsibility for business and industry, it is not sensible to rely on manufacturers and suppliers to self-assure quality. A check run by the Health & Safety Executive in the UK in 2017 demonstrated that 50% of the FFP3 masks (respirators) tested were defective (Health and Safety Executive, 2016). The European Safety Federation has also uncovered dishonesty and serious quality breaches (European Safety Federation, 2021). This overreliance on overseas manufacturers led to serious shortages of all kinds of PPE in Western countries. International effort is required here to improve both the resilience of the supply chain and the quality management systems in place.

There is a need for safe and effective personal and protective equipment which can be decontaminated appropriately to allow for re-use.

4.1 Methodology

This work stemmed from the ENG4 collaborative in a response to the PPE supply chain crisis during the Covid-19 pandemic. A quick search identified that Heathcoat Fabrics Limited (Tiverton, Devon, UK) had designed an antiviral launderable fabric in conjunction with Liverpool University. The fabric had been finished with a proprietary silver-based antiviral finish, Viroblock, NPJ03 (HeiQ, Zurich, Switzerland) and demonstrated >98.9% antiviral activities after laundering 15 times at 40ºC.

Originally designed for the purpose of manufacturing reusable masks which could be laundered at home, ENG4 were curious as to whether the fabric would sustain laundering at NHS standards. If it could then it may be able to be utilised for a range of healthcare applications.

Devising the methodology in line with NHS laundering standards, Heathcoat Fabrics Limited were approached who generously donated fabric for testing. James Heal (Halifax, United Kingdom) generously laundered to the appropriate International Organization for Standardization (ISO) standard. The samples were subsequently tested, according to the relevant ISO standard, for antiviral activity in the virology department at Keele University.

4.2 Results

The main finding from the work was that laundering in compliance with the NHS protocol significantly impacted the ability of the antiviral properties to remain effective. The protocol states that for conventional thermal disinfection methods, the washing process should have a cycle in which the temperature of the load is either maintained at 65°C for not less than ten minutes or 71°C for not less than three minutes. Further time, to allow for adequate mixing of the load, should be added on to the required disinfection period to ensure heat penetration and disinfection. For those

undertaking the laundering of workwear uniforms at home in domestic facilities, the treatment should be washing of the items for ten minutes at 60°C (Department of Health, 2016).

In addition to these results, other findings were identified during the experimental process. To begin with, the research group encountered an issue with ISO 18184:2019 – Textiles – Determination of antiviral activity of textile products. Fabrics exhibit different absorption properties depending upon the fibre, structure and finishes applied. As viral samples are, almost always, liquid based, different fabrics will absorb different amounts of the viral test. It was identified that the extent of absorption has a high impact on the results of the test. If the quantity of liquid applied to the fabric does not exceed the absorption of the fabric, then it is challenging to accurately recover enough liquid to sufficiently determine the antiviral properties exhibited by the fabric. As such, all testing regimes should determine the absorption of free liquid and calculate recovery of antiviral particles. The paper discussed the clinical relevance and importance of this. For example, a haemorrhagic fever, such as Ebola virus, often involves significantly more viral laden fluid than a respiratory disease transmitted in a sneeze. It was also suggested that this should be considered when the ISO standard is reviewed as it is of clinical relevance and applicable to other research and study groups using this standard.

In addition, the paper identified that standardisation of antiviral and antimicrobial testing of fabrics is critical to allow for accurate comparisons and meaningful results. This has also drawn attention in the textile field. Murray constructively critiqued the review paper on antibacterial finishes applied as antivirals to fabrics by Raza et al (Murray, 2022; Raza *et al.*, 2022). Very few antimicrobial-treated items have performed adequately against contamination in the practical setting, but this is often not mentioned as a limitation or area for further research. Therefore, there are some unsubstantiated claims about the prospects for treatment (Murray, 2022). For example, one of the criticisms of the Raza paper is that only two of the listed antiviral products were applied and tested on textile fabrics. The response from Murray as a letter to the editor confirmed what ENG4 had encountered; that the wetting of the fabric for the test does not bear resemblance to what happens in a clinical setting.

4.3 Impact

'The potential future role of antiviral fabrics within healthcare systems' demonstrates the experimental results, highlights shortcomings with the current ISO standards and provides recommendations for future work with antiviral and antimicrobial fabrics. Only recently published, it has currently not been cited but, as of 21 December 2023, has had 121 reads. To be included in the 30 Most Read articles from the journal within the last 12 months, 135 reads are required.

4.4 Conclusions

There is ongoing work standardising laundering protocols and reviewing current recommendations. Previous research has identified that healthcare workers laundering at home often use lower temperatures than the recommended 60°C (Riley *et al.*, 2015). This study was undertaken prior to the increase in energy prices seen recently. Considering the trend towards creating a Net Zero NHS and the advances seen in laundering technology, it is likely that there is a lower temperature solution which still provides adequate decontamination. This would be of significant benefit for current antiviral technology and would widen the range of potential antimicrobial agents suitable for application as a finish or to be included within household laundry detergents.

Further research is required to determine an appropriate ratio of absorption to free liquid for antiviral testing to allow for standardisation. Some clinical correlation needs to be introduced to the ISO standard; a viral haemorrhagic fever, such as Ebola, may result in contamination of the fabric with a significantly higher quantity of liquid than when compared to a virus spread by the respiratory route via small airborne droplets.

The Organisation for Economic Co-operation and Development recommended an approach in 2008 that stratified testing and results on antimicrobial treated articles (OECD, 2008) as a "Three-Tier Protocol". This divided testing into:

- Tier One Proof of Principle;
- Tier Two Simulation of Realistic Exposure Conditions; and
- Tier Three In-Use Evaluation.

The methodology developed for the experiment would classify as a Tier One according to the OECD "Three Tier Protocol". Further research is required to test to both Tier Two and Tier Three. On a broader level, there needs to be more awareness about reporting to the Three Tier Protocol, which would allow for improved ease of comparison between research groups and for meaningful decisions to be made by policy writers and those working within the healthcare sector and beyond.

There is still much work to be undertaken to ensure a resilient supply chain of PPE. The coronavirus pandemic highlighted many issues with the current system and the Good Law Project continue to investigate and uncover wrongdoing in the procurement of PPE. Strengthening the supply chain and increasing transparency is critical for future pandemics. Attention needs to be turned, however, to the entire life cycle of a medical device. Sustainability commences with the design of a device.

Policy writers, hospital management, those working in procurement and clinicians have the power to ensure that they are choosing not only sustainable products but also those manufactured using

ethical practices. Recently, there has been highlighting of labour-rights abuse of workers in the manufacturing of medical gloves for the National Health Service and this stresses the importance of transparent supply chains, even if these are challenging to create (British Medical Association, 2021).

Improvement in sustainability of the supply chain has an important gender equality effect as women comprise much of the low-wage and unskilled textile workforces (International Labour Organization, 2016). One of the main benefits of employment in the garment industry is the opportunity for women to earn an income, particularly where formal opportunities are limited, and social safety nets are weak. Formal employment also provides rights and protections to workers, as well as skilling opportunities. It increases women's bargaining power within the household and is critical for enhancing women's economic and social status and women's empowerment. Unfortunately, employment for women in the sector is frequently informal, home-based and with less income and social security. Whether technological deficits will exacerbate this imbalance or promote gender equality remains a critical question (International Labour Organization, 2022).

5. Medical Textile Waste

Paper 4	Waste Not, Want Not: Assessing the impact of arthroscopic waste. Shah S (35%), Morris H (35%), Nicolau N (5%), MacInnes S (5%), Haslam P (5%), Shahane S (5%), Ali F (5%), Garcia J (5%). PMID: 36453070 *British Journal of Surgery 2023 Feb;110(2):275-6.*
Paper 6	The Carbon Footprint of Arthroscopic Procedures. Shah S (35%), Morris H (35%), Nicolau N (5%), MacInnes S (5%), Haslam P (5%), Shahane S (5%), Ali F (5%), Garcia J (5%) *Annals of the Royal College of Surgeons of England 2023 June; https://doi.org/10.1308/rcsann.2023.0036*
Paper 7	Waste Not, Want Not: Orthopaedic Waste Data. Shah S (35%), Morris H (35%), Thiagarajah S (5%), Gordon A (5%), Sharma S (5%), Haslam P (5%), Garcia J (5%), Ali F (5%) *British Journal of Surgery Open 2023 June;7(3):zrad062.*
Paper 8	Handling 'Carbon Footprint' in Orthopaedics. Shah S (35%), Morris H (35%), Thiagarajah S (5%), Gordon A (5%), Sharma S (5%), Haslam P (5%), Garcia J (5%), Ali F (5%) *Annals of the Royal College of Surgeons of England*

This chapter discusses four publications which assess the impact of medical textile waste in trauma and orthopaedic surgery. The first publication, "Waste Not, Want Not: Assessing the impact of arthroscopic waste" (Paper 4) was published as a short research letter in the British Journal of Surgery in 2023 and the full study, "The Carbon Footprint of Arthroscopic Procedures" (Paper 6) was subsequently published in Annals of the Royal College of Surgeons of England. "Waste Not, Want Not: Orthopaedic Waste Data", (Paper 7) was also published as a short research letter in 2023 in the British Journal of Surgery Open and documented the findings of the second iteration of the project. The full publication, "Handling 'Carbon Footprint' in Orthopaedics", (Paper 8) is in Annals of the Royal College of Surgeons of England.

At an international level, there has been increased interest and movement towards the creation of a sustainable society (United Nations Development Programme, 2022), reduction in waste produced and promotion of a circular economy within both the textile and healthcare fields (United Nations Environment Programme, 2023). Healthcare has been increasingly concerned with the large carbon footprint it generates and this interest was further fuelled by the quantity of waste produced by PPE.

Even before the pandemic, the healthcare sector generated significant amounts of waste contributing to the carbon footprint. In 2020, it was reported that the NHS generates approximately 4-5% of the country's greenhouse gases and a quarter of all public sector waste (NHS England Press Release, 2020; Rizan *et al.*, 2020; Watts *et al.*, 2021). Textiles are the second greatest component of healthcare waste (Zlaugotne *et al.*, 2022) and between 20% and 33% of hospital waste originates from the operating room (Rizan *et al.*, 2020). Of this, up to 90% is improperly

sorted resulting in unnecessary and costly disposal methods (Lee and Mears, 2012). Studies demonstrating how much, and what type of, waste an operation generates are few and far between.

One of the benefits of choosing reusable textiles over disposable textiles where practicable is the impact on reducing waste and its carbon footprint. Both the healthcare and the textile industry have traditionally adopted a linear economic approach but there has been a recent drive towards a circular economy approach to reduce waste and create further value, see Figures Two and Three.

Supervising a Masters student at Keele University to undertake a literature review into the waste created by the PPE during the coronavirus pandemic, and the impact of considering waste production in the appropriate design of medical devices, revealed that the first and most crucial stage of reducing waste generation is by prevention. This commences at the design stage by designing medical devices appropriately and for reuse where appropriate (Rizan *et al.*, 2020). One obvious example would be in designing reusable PPE. Most accepted design models in medical device design include the stages: specifications and user needs; design input; design process; design output; and the final product (Ogrodnik, 2019). By incorporating sustainable goals within the specification, the likelihood that sustainability is considered at each future stage within the medical device design process is increased.

As part of this literature review, it became apparent that there was a lack of available literature on the amount of waste generated within the operating room. The publications within this chapter further assess the quantity of waste generated within trauma and orthopaedic surgery.

5.1 Methodology

The first iteration of this work was designed as a single site review where waste generated by two common orthopaedic arthroscopic procedures was weighed. Intraoperative waste from five of each of the surgeries was measured. The waste was separated into four bags: clean paper; contaminated paper; clean plastic; and contaminated plastic. Contaminated waste is any waste that has been directly used in patient care; it does not include wrappers of products but would include each item in a multipack surgical set, even if the item had not been used. Paper and plastic were measured as this comprises the largest quantity of waste; disposable gowns and drapes are manufactured from plastic (Zlaugotne *et al.*, 2022). Senior surgeons operated and anaesthetic waste was excluded.

The second iteration saw a roll out of the methodology to three other hospital sites thus providing a larger data set and to enable trends to be identified. Once the data had been collected, the waste contract for each hospital was scrutinised and a carbon footprint of the waste from the procedures

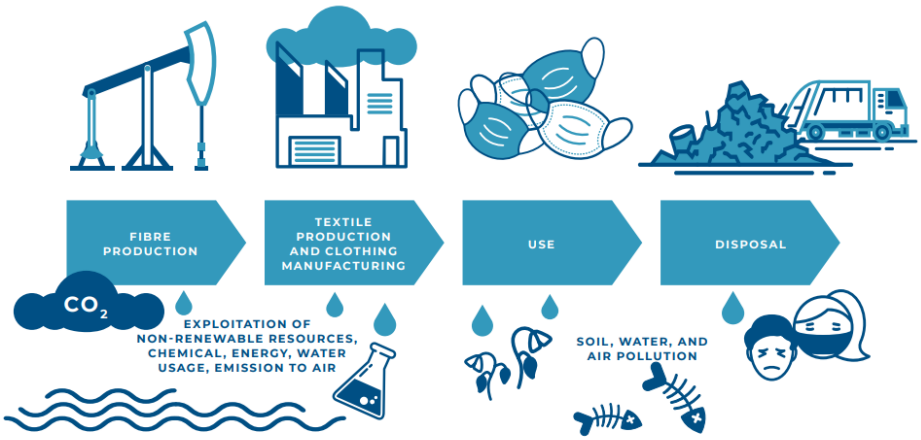

Figure 2: Linear Economy of Healthcare Textiles
(Credits: Healthcare Without Harm)

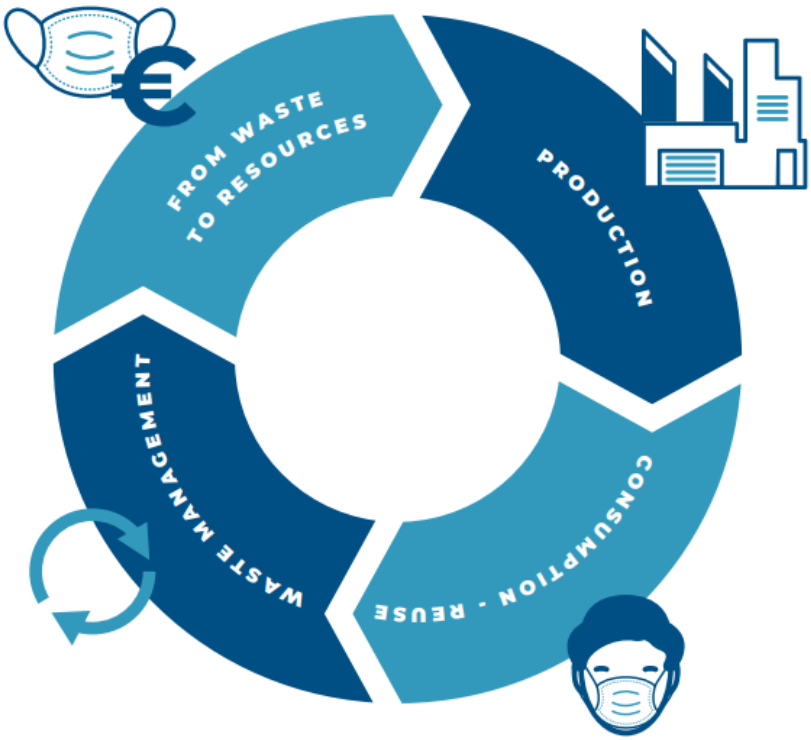

Figure 3: Circular Economy of Healthcare Textiles
(Credits: Healthcare Without Harm)

was generated. For just the two arthroscopic procedures over all the sites included in the study, the annual carbon footprint generated, 6.3 tonnes of carbon dioxide. This is the same as nearly 6.3 return flights from London Heathrow to J F Kennedy in New York.

Paper 4 published in the British Journal of Surgery, provides a short report on the data collated from the two arthroscopic procedures. The full publication, Paper 6, has been published by Annals of the Royal College of Surgeons of England.

The findings from this work led to third iteration and an expansion of the work across five separate hospital sites with an inclusion of a greater range of both trauma and elective surgeries. A similar methodology was employed except that waste was measured from ten of each type of surgery at each hospital site. Again, waste contracts were assessed, and an annual burden of carbon dioxide production calculated. A short report on the data collated has been published in the British Journal of Surgery, Paper 7 and a full publication by Annals of the Royal College of Surgeons of England, Paper 8.

As a final piece of work, at one of the hospital sites, a trial was designed where 1000 reusable surgical gowns were rented for four weeks and used in theatre in place of disposable gowns. These were laundered by a commercial company already holding a contract with the NHS. The carbon footprint for 1000 surgical gowns uses for reusable as against disposable was calculated using data based on the Overcash study of life-cycle-assessments for surgical gowns (Vozzola *et al.*, 2018). This work provided life cycle assessments of surgical gowns for 60 uses per gown. Whilst ISO testing standards allow for 75 uses per gown, the average actual use rate is lower, for example, due to losses or damage. The use of reusable gowns potentially, therefore, results in a 66% reduction in carbon emissions using calculations of Vozzola and Overcash.

5.2 Results

Analysis of the waste generated from arthroscopic surgeries revealed that the waste produced across the three hospital sites varied enormously. As an example, for arthroscopic anterior cruciate ligament repair plastic waste produced varied between 2.4kg and 9.6kg and for arthroscopic rotator cuff repairs plastic waste produced varied between 3.3kg and 15.5kg. One of the key factors identified in this variability was whether the site used reusable or disposable drapes and gowns. Indeed, this generated a mean difference of over 6kg in plastic waste between sites.

In addition, each hospital separately negotiated their waste disposal contracts and the companies contracted provided different methods of waste disposal. Incineration with harvesting of the energy generates a lower carbon contribution than landfill but not every contractor provided this option. None of the waste contractors were adequately equipped to fully separate the waste sent for recycling into paper, plastic and metals, instead opting to incinerate this in bulk and recapture

the energy produced. This was highlighted to the management team at each hospital site as a contract they may want to review.

The third iteration of the work expanded the procedures and sites included. That third iteration identified that, of the surgeries included, primary hip arthroplasty surgeries generated the greatest quantity of waste with a mean of 11.8kg of plastic waste per procedure. This is comparable to previous published literature; one two hospital site study in the East of England in 2011 found 12.1kg of waste was generated for a total hip arthroplasty, of which 6% was contaminated and not appropriate for recycling (Southorn *et al.*, 2013). More recently, in 2022, a study measuring total hip arthroplasty waste in Newcastle-upon-Tyne found the average waste produced for a single total hip arthroplasty was 10.9kg (Pegg *et al.*, 2022). Both studies reported that there was potential to recycle a greater percentage of the waste, without incurring additional harm from hazardous waste, than with the current practice. The studies also suggested that staff education is critical to ensure waste is being disposed of accurately.

Analysis of the results demonstrated a large range in plastic waste measured for procedures. For example, there was a range of 9.9kg for plastic waste in hip arthroplasty, 7.3kg for knee arthroplasty and 12.2kg for shoulder arthroscopy. Trauma operations also generated differences, though these were smaller; for example, 5.7kg for a dynamic hip screw, 3.3kg for a hip hemiarthroplasty and 3.8kg for an ankle fixation.

One of the reasons identified for the variability was the surgeon's preference for draping patients. There was significant discrepancy between surgeons for the same type of operation. One hospital site used a double draping system for elective procedures which involved utilising disposable drapes in the anaesthetic room and then re-draping the patient when they are in the main theatre. The mean total plastic waste generated for these procedures at this hospital site was the greatest across all the sites included in the study. This reinforces the effect of the surgeons' preference for draping and its impact upon waste generated.

The second reason identified was whether reusable or disposable gowns were used. The hospital site with the lowest mean total plastic waste was the only site to use reusable gowns but disposable drapes for most of their day case procedures. The other sites used disposable gowns and disposable drapes. Even when this was accounted for, however, the waste produced at this hospital site was still generally lower for the surgeries where disposable drapes and disposable gowns were used. It was hypothesised that this was due to an awareness and culture within the hospital towards sustainability.

The costs for using reusable and disposable gown over the pre-coronavirus period of 2019-2020 was calculated based on data supplied by the hospital. In 2019-2020 62,730 gowns were used at a cost of £60,698.67. In 2019-2020, the cost per use of a disposable gown was £0.97 and the cost

per use for a reusable gown was £0.75. If all 62,730 gowns that were used were reusable, the annual cost would be £47,214.78. This represents a cost saving of £13,483.89. The Trust have also estimated costs based on uplift predictions for 2022-2023. The cost for using disposable gowns would be £78,887.03 and the cost for using reusable gowns is £72,757.76. This represents a potential cost saving of £6,129.27 (Barnsley Hospital NHS Foundation Trust, 2022).

Recently, a team based in London substituted 3,051 disposable gowns for reusable over a six-month period and demonstrated a saving of 3,292 tonnes of CO_2 emissions and a cost saving of £366 from reductions in waste disposal and standard gown use (Beatty *et al.*, 2022). Directly scaling these figures up to 62,730 gowns, and not accounting for a likely reduction in costs from a higher throughput, the cost savings in the London study would be £7,525.13. The research undertaken in our work produced a cost saving of £13,483.89 and was based upon 2019-2020 data. Costs have increased due to the pandemic and using uplifted costs, our cost savings reduce to £6,129.27, similar to the London based team when one considers hospitals negotiate their own waste disposal contracts.

5.3 Impact

The data generated from these two studies has been presented regionally, nationally, and internationally, as well as published. Two notable presentations include discussing the results as part of a lecture on the "Greener Operating Theatre" at the annual congress for the British Orthopaedic Association in 2022 (British Orthopaedic Association, 2022) and with the Medical Textile Committee for Healthcare Without Harm, of which I am a member (Healthcare Without Harm, 2023). These presentations form two presentations within the supplementary portfolio contributions (Presentations 9 and 10).

The biography provided for the British Orthopaedic Association presentation generated interest within the profession and Edinburgh University Trauma and Orthopaedic Society extended an invite to provide a lecture to medical students and junior doctors on my career (Presentation 11). Following this presentation, a fellow presenter and surgeon based in Singapore offered to discuss further and said that he would potentially be keen for future collaborative work on sustainability.

The publications have added to the limited published database on waste within orthopaedic surgery and provide concrete data that can be used as evidence and examples for other clinicians, managers and policy makers wishing to create a greener operating theatre. At a local level, significant disparity between hospital sites and the contracts negotiated with waste contractors was identified. The work also exposed that none of the waste contractors were adequately equipped to fully separate the waste sent for recycling into paper, plastic or metals and instead incinerate this and

recapture the energy produced. Until industry and waste contractors have a viable solution, processing will continue with suboptimal and carbon heavy methods.

Now that healthcare has reached a stage where there are carbon calculations attributed to some of the procedures clinicians undertake, it is time to find solutions to reduce this significant footprint. An evolution of this work follows with the Policy Guidance written for the Green Surgery Report.

The collection of papers have yet to be cited due to the recent publication of them. Their impact has been in providing data for guiding national policy writing (see the following chapter) and for dissemination at conferences in sessions on sustainability.

5.4 Conclusions

Clinicians need to scrutinise what medical devices they use within their clinical practice. There has already been work undertaken within hand surgery on the use of multi packs in the operating room. One study in America concerning wide awake hand surgery cases had clinicians involved to slim down what was in the multipack. One unit removed fifteen items from their disposable plastic pack and seven from the hand pack with an estimated annual saving of US$17,381.05 in the unit from these changes alone (Albert and Rothkopf, 2015). Putting this into context, in 2016, the American Society for Surgery of the Hand estimated that there were approximately 2,000 active hand surgeons in the United States; if each were to do 100 "green" cases a year then there would be a cost saving of $2.13 million and a decrease in 506 tons of waste (Van Demark Jr *et al.*, 2018).

NHS procurement is fragmented and those working in procurement do not routinely interact with clinicians who use the products. In addition, decisions are made based on the cost of the product. The work on medical textile waste highlighted the significant cost differences from disposal methods. Those downstream costs are often externalised and not factored in when deciding which items to purchase. Further work should be undertaken in costing life cycles of products rather than just the upfront cost for purchase.

The work identified that there was potential to recycle a greater percentage of the generated waste, without incurring additional harm from hazardous waste, than with the current practice. Staff education is critical to ensure waste is being disposed of accurately. A culture of sustainable practice within the hospital also appears to influence staff practice.

The way in which a surgeon drapes their patients greatly affects the waste generated with those employing double draping generating the most waste. The use of reusable drapes rather than disposable drapes generates the lowest mean total plastic waste. There also appears to be a potential economic saving when reusable gowns are used as a substitution for disposable options.

Further work is required to assess whether reusable gowns and drapes are non-inferior to disposable options in preventing surgical site infection with a multi-site randomised controlled trial. Attention also needs to be given to the most appropriate methods of laundering and sterilisation of medical textiles.

6. Creating a Greener Clinical Practice

Paper 2	Bilateral congenital vertical talus in association with Beals contractural arachnodactyly. Morris HV (80%), Navarre P (20%). PMID: 30540606 *JBJS Case Connector 2018 Oct-Dec;8(4):e97.*
Paper 9	Improving Medical Textiles to Create a Greener Operating Theatre. Morris H (75%), Murray R (25%) Submitted to the Journal of the Textile Institute
Paper 10	Cotton in Healthcare – are we using the correct fibre? Morris HV (100%) *Textiles 2023(2):12-14.*
Policy Guidance	The Role of Medical Textiles in Sustainable Healthcare. Morris H (75%), Murray R (25%) Submitted to the *Green Surgery Report (November 2023)* by UKHACC.

As mentioned in the preceding chapter, Chapter Five, there is still much work required to reduce the carbon footprint of the NHS. This chapter concerns the policy guidance submitted to the Green Surgery Report and a series of three publications. "Improving Medical Textiles to Create a Greener Operating Theatre" (Paper 9) expanded on the policy guidance submitted to the Green Surgery Report, and has been recently published in The Journal of the Textile Institute. "Bilateral congenital vertical talus in association with Beals contractural arachnodactyly", (Paper 2), provides context of textiles used within trauma and orthopaedic surgery that are neither surgical gowns nor surgical drapes. "Cotton in Healthcare – are we using the correct fibre?", (Paper 10) discussed the impact of natural fibres on the environment.

The natural evolution of the work discussed in previous chapters is represented by the Policy Guidance. Co-authored with Professor Murray, the work aims to influence national and international policy in creating a more sustainable surgical practice. In addition, the work has been presented at the 92nd World Conference of the Textile Institute (Presentation 12). It has been converted into a paper, Paper 9, for formal publication.

As well as textiles used directly in patient care, textiles worn by healthcare providers are long overdue an overhaul. First, the fit of current uniforms is outdated compared to current body shapes which have changed since the work undertaken in the 1950s to produce the size chart used currently. Secondly, and as discussed previously in Section Four, those who launder their uniforms at home often do not follow Best Practice guidance. Consideration should be given as to whether the current polyester/cotton blend fabrics used could be changed for a fabric which may proffer a better life cycle assessment of the garment. Paper 10, discussing the role of cotton in healthcare suggests that further work is required in this regard. Whilst cotton is regarded as the "King of Fibres" it has a significant environmental impact from land use, water use and pesticides. One

study reported that the 2020/2021 cotton harvest produced a fibre yield of 40% (Picoli *et al.*, 2023). With new fibres in development, there may be a more appropriate alternative.

6.1 Methodology

The Policy Guidance document co-authored with Professor Murray for the Green Surgery report reviewed the role of the circular economy principles within the textile industry and how these can be incorporated within surgery and healthcare. The committee meetings involved experts in allied fields such as infection prevention, medical device design and procurement, in addition to representatives from the Royal Colleges of Surgeons within the UK and abroad - including the USA and Australasia.

The policy guidance commenced with a summary of the textile sector and sustainable practices within textile manufacturing. Following this, different items of PPE were reviewed individually. This section was an extension of the dissertation on PPE for the Master of Applied Science. A literature search was conducted to review developments of surgical protective clothing and current guidelines for safe clinical practice evidence. This was critically evaluated and a report generated which also provided suggestions of where future research should be directed.

Paper 9 offers a more comprehensive review of the policy guidance submitted to the "Green Surgery Report" with increased focus on international efforts during Covid with PPE and decontamination. It was written alongside the abstract submitted for the Textile Institute World Conference.

Paper 2 comprises a case report of a child with a rare condition. Whilst not directly related to creating a more sustainable clinical practice, it provides a background into the extensive use of medical textiles which are not PPE but still frequently used. The treatment and five-year outcomes are discussed alongside references to the textile-based products used in the management of the child.

Paper 10 converted work from the policy guidance for the "Green Surgery Report" into a short publication aimed at the textile community. Given the quantity of cotton used in healthcare as a polyester and cotton mix in scrubs, patient clothing and bedding, for example, it provided an opportunity to promote collaboration between the two fields by highlighting some of the problems associated with cotton production and identifying areas for further research and collaboration. There has been significant work in the textile industry to reduce the carbon footprint, particularly within the fashion sector and there is likely to be significant crossover into the technical healthcare textile sector. This would generate significant impact.

6.2 Results

The transition towards a circular economy is afoot particularly within the fashion sector of the textile industry. These principles can and should be extended to the medical textile sector. One of the main problems the medical textile sector will have in adopting this change will be due to the highly globalised, complex, but crucially fragmented supply chain of textiles (Ki *et al.*, 2020). This will make full traceability of products for medical device regulatory bodies incredibly challenging, if not impossible. Another implication of the current system is that it makes accurate life-cycle-assessments of medical devices particularly challenging.

The policy guidance for the "Green Surgery Report" discussed the full cycle of a textile medical device from the initial design through to disposal. The design and procurement of items should focus on resource efficiency, circular design and designing for product life extension. Within the manufacturing stage there are several modifications to traditional processes which can impact significantly on aspects such as the use of pesticides, water, chemicals, and energy. For example, waterless technologies for dyeing methods such as air dye technology require 95% less water and 87% less energy than traditional dyeing methods (Dissanayake and Weerasinghe, 2021). These all affect the environmental impact of a product and its carbon footprint.

Further attention needs to be given to the reuse of medical devices. This requires effective sterilization and repurposing, so the products remain fit for purpose and further life cycles. Policy is changing to allow this. In Europe, according to Regulation (EU) 2017/745 of 5 April 2017 on medical devices (European Union, 2017), remanufactured "*single use*" medical devices must meet manufacturer standards and receive a CE mark ensuring they are as safe and as effective as the new equipment and are required to be sterilised to the level of the original device. The remanufacturing of "*single use*" medical devices will allow for disposable single use items to be sterilised and safely reused. It has already been adopted and in use in countries such as the USA and New Zealand (MedSalv, 2021).

Both decontamination and sterilisation require attention. Whilst there are no large-scale epidemiological studies demonstrating a direct link between healthcare-acquired infections and contaminated textiles, evidence of outbreaks given in case studies needs attention (Owen and Laird, 2020). A review undertaken at the behest of the Department of Health in 2007 found no robust evidence of a difference in efficacy of decontamination of uniforms/clothing between industrial and domestic laundry processes, nor that the home laundering of uniforms provides inadequate decontamination. Only a small number of relevant studies were, however, identified. Those identified provided limited evidence directly related to the decontamination of uniforms. Studies concerning domestic laundry processes were small scale and largely observational whilst practice current at those times and guidance for laundering uniforms was extrapolated from studies of industrial hospital linen processing (Wilson *et al.*, 2007). As previously mentioned, more recent work, in 2015, demonstrated that 44% of healthcare workers laundering at home do not launder

their uniforms at the 60°C stipulated by the national guidance (Riley *et al.*, 2015). As such, there is scope for improvement in the laundering of hospital textiles, both in the hospital and domestic setting. Attention should also be paid to the technologies employed.

The United Kingdom National Health Service has produced Best Practice guidance for the laundering of linens (Department of Health, 2016). Discussed earlier in this chapter, heating water to these temperatures requires significant energy. The guidance is historical, technology has advanced and there is likely a solution which effectively disinfects linen but with a lower environmental footprint. Another benefit of laundering at lower temperatures is a reduction in the rate of release of microparticles as higher rates of microparticle release correlate with laundering at higher temperatures (Cotton *et al.*, 2020). In the interim, filtration of effluent water used in the laundering process should be employed to reduce the escape and leach of microplastics into the environment by up to 80% (Napper *et al.*, 2020).

Finally, with regards to the disposal of medical devices, attention should be paid to the appropriateness of reuse, recycling or remanufacture. Figure Four demonstrates the waste hierarchy for healthcare. The work on medical textile waste discussed in the previous chapter influenced parts of the Policy Guidance. This expanded upon ways in which textiles can be recycled, for example, using near-infrared spectroscopy to determine fibre type in an initial sorting phase (Wei *et al.*, 2015) and the use of chemical, thermal or mechanical processes to separate fibre components from blended fabrics such as the polyester/cotton blend, used in surgical scrubs. Already used in the fashion sectors, there have been several studies reporting promising results, which suggest a recycling rate of more than 93-96%, a carbon footprint reduction of 1,440-1,534kg of CO_2 and an economic return of US$1,466-1,629 per tonne (Yousef *et al.*, 2020; Zamani, 2014).

6.3 Impact

In addition to proposing a broad overview of how a textile circular economy may be adopted within healthcare, the Policy Guidance separately addressed commonly used textile items within the operating theatre. The Green Surgery Report has not been formally published and so an assessment of the impact is not yet available. Following a committee meeting, the Director of Quality at the American College of Surgeons, Professor Clifford Ko, requested I separately provide him the guidance that I co-authored to assist his work in America.

The final guidance will be distributed internationally to the countries represented on the committee. It will also be disseminated at conferences, publications and used for policy change within the surgical world. Several aspects were identified which require attention such that healthcare can adopt an environmentally sustainable approach to the way in which it utilises textiles. Indeed, the European Commission Strategy for Sustainable and Circular Textiles acknowledges that advancing

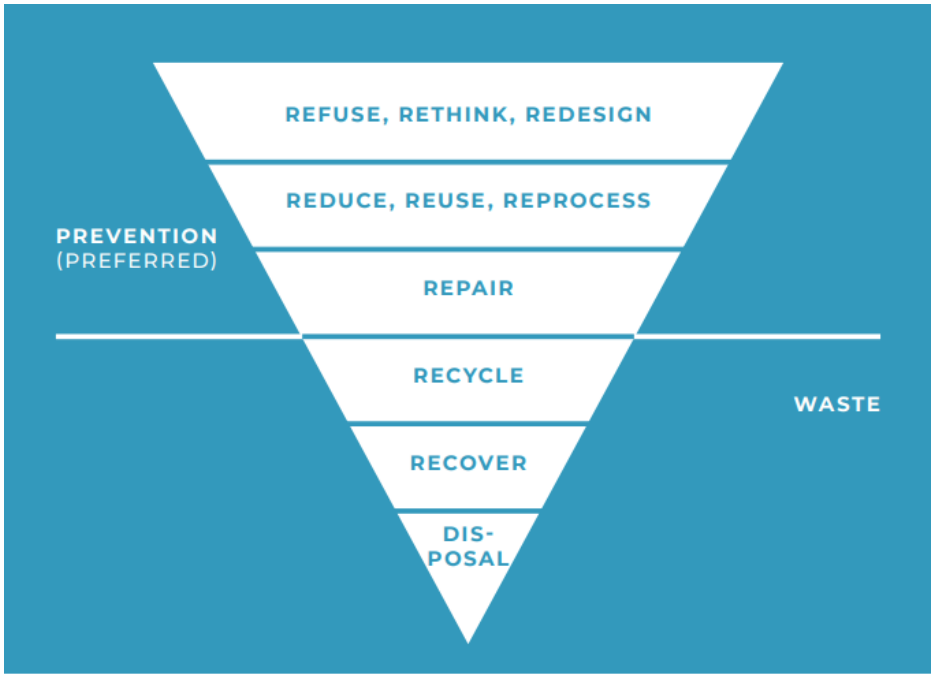

Figure 4: Waste Hierarchy in Healthcare (Credits: Healthcare Without Harm)

towards greater sustainability of the textile ecosystem requires deep changes in the currently prevailing linear economy (European Commission, 2022).

Paper 9 has been recently published.

Paper 2 presents the first published case study of a child with Beals contractural arachnodactyly and congenital vertical talus (CVT). CVT is a rare condition with a prevalence of only 1 in 10 000 live births and this case study described the surgical technique and outcome at five years following surgery in the child. This paper has been referenced twice, both times in relation to the management of paediatric foot deformity.

Paper 10 has also been recently published.

6.4 Conclusions

WHO Global Guidelines for the Prevention of Surgical Site Infection recommend the use of either reusable or disposable gowns and drapes (World Health Organization, 2016). The guidelines also acknowledge the paucity of evidence as to whether one is superior to the other; there have been no randomised controlled trials to assess surgical site infection with reusable or disposable gowns and drapes. Therefore, it cannot be conclusively stated that reusable and disposable gowns are equivalent at preventing surgical site infection until such work is undertaken in the future. Indeed, a recent review of surgical site infection in orthopaedic and spine surgery found no available evidence to support a difference between reusable and disposable gowns and drapes and called for further research (Kieser *et al.*, 2018). Nevertheless, small trials are showing cost benefits as well as environmental benefits for implementing reusable drapes and gowns over disposable.

The surgical world is starting to focus upon the waste and carbon footprint which medical devices generate. Collaborative work between material engineers, clinicians and designers is now required as there is great scope to incorporate sustainable materials into such devices and allow for clinical translation. Further consideration needs to be given to the fibres and materials used in textile based medical devices. Further work is required in the decontamination of medical devices and the efficacy of decontamination methods. Finally, life cycle assessments of textile products require updating and further standardisation as new fibres are developed and as innovative recycling and reprocessing methods are introduced. While the textile industry continues to explore eco-friendly textile fibres, such as bamboo, hemp, corn, pineapple, and banana leaf, and biosynthetic fibres it can be difficult to differentiate between a helpful development and one which offers little ecological advantage over an existing commodity fibre. The way in which fibres are processed to create fabrics and reprocessed after use should be addressed and sustainable options used where possible.

7. Conclusions and Recommendations for Future Work

The field of medical textiles is one of the fastest growing areas within the technical textiles sector of the textile industry. It is an exciting arena to work within and help craft. When I initially registered for the Master of Applied Science, I could not have envisaged the way in which my career, or the field, would develop. Driven by societal changes, technological advances, environmental concerns and political agendas, the field will continue to develop at a rapid pace over the next few decades. From the work presented in the previous chapters the following conclusions and recommendations for future work may be drawn.

Given the rapid expansion of the field, both the review for Textile Progress and the textbook for the Textile Institute Professional Publications Series will need to be reviewed and revised in the next five years. New chapters for incorporation should include sustainability, advances in fibres, advances in reprocessing and a review of the latest medical device regulations.

Both healthcare and the textile industry are significant global polluters. The recently released United Nations Environment Programme (UNEP) report "Sustainability and Circularity in the Textile Value Chain" highlights that the sector is struggling to address its impacts which include significant natural resource use and pollution. 215 trillion litres of water are consumed per year and the industry produces 9% of annual microplastic losses to oceans (United Nations Environment Programme, 2023). As clothing composes 81% of textile consumption in the EU, carbon footprints and environmental impact calculations usually comprise the textile clothing sector rather than the technical textile sector (Köhler *et al.*, 2021). The clothing industry emits 1.2 billion tons of greenhouse gas and if these emissions are not reduced, it is projected that the industry could use up to 25% of the global carbon budget by 2050 (Chen *et al.*, 2021; Ellen MacArthur Foundation, 2023). Reassuringly both the UNEP and NHS identify similar themes required to reduce the environmental impact of their respective sectors. It was a great pleasure to co-author the policy guidance for the Green Surgery Report and formally combine the two industries at a national level.

Going forwards, as well as reducing the environmental impact of the two sectors, it is critical that both fields collaborate, and work is undertaken to ensure a resilient supply chain of personal and protective equipment. This will be critical in future pandemics with current deficiencies highlighted during the coronavirus pandemic. The supply chain management for the healthcare textile sector is fragmented with an overreliance on overseas manufacturers. Lessons could be learned from the fashion-retail sector of the textile industry with mechanisms they utilise incorporated into the technical textile pathways used to supply healthcare. The use of AI, blockchain technology and manufacturing processes using Kaizen or Kanban principles to ensure a minimisation of waste offer sustainable and economically viable solutions whilst maintaining the ability to track components of individual medical devices.

Given the problems with the current supply chain model, the ability to decontaminate available PPE readily and rapidly to allow for reuse is essential. There are several publications on methods of decontamination, particularly in respect to filtering face masks, and more attention should be turned to these (Bergman *et al.*, 2010; Viscusi *et al.*, 2009). Adopting these techniques may prevent the crisis witnessed during the coronavirus pandemic of inadequate supplies and masks past their expiry date being delivered to healthcare providers in the event of another pandemic. My recommendation would be to target further research at decontamination, and in particular low-energy decontamination methods for PPE.

The huge output in research on antimicrobial (and more recently antiviral) textiles is of interest but probably only plays a limited and highly selective role within healthcare. The work undertaken as part of this PhD, and discussed in Section Four, highlighted that ISO 18184:2019 – Textiles – Determination of antiviral activity of textile products requires refinement to allow fabrics with different absorption properties to be adequately tested and to consider the nature of different viruses and modes of transmission to allow for adequate clinical correlation (Morris *et al.*, 2023). My recommendation is that this area of medical textiles requires standardisation of testing to prevent unsubstantiated claims about the prospects of treatment.

Pandemics aside, in day-to-day clinical practice as a surgeon there is still significant scope for improving the carbon footprint of healthcare with regards to the textiles and textile based medical devices used within the sector (UK Health Alliance on Climate Change, 2023b). There is no formal randomised controlled trial to demonstrate non-inferiority of reusable medical textiles when compared to disposable medical textiles in surgical site infections. Part of the resistance to fully adopting reusable options centres around a belief some surgeons' hold that they may increase infection rate in implant surgery. My recommendation is that the National Joint Registers should consider including the textiles used during surgery on their data entry form. Currently, there is no multi-centre randomised controlled trial comparing disposable and reusable textiles and subsequent infection rates in implant surgery. The time and money required to undertake such a trial is unlikely to provide results that allow time for adequate implementation of a change and reduction in carbon footprint before the international targets need to be achieved and I believe the profession should adopt a pragmatic approach and utilise currently implemented systems, such as the National Joint register, which collate large volumes of data based upon current clinical practice.

The work on medical waste, discussed in Section Five, highlighted a huge discrepancy existing between individual surgeons in the way they drape their patients and the types of drapes they use. There are ways in which to try and minimise these discrepancies which could be adopted. For example, reflection by individual clinicians on the way they drape their patients would potentially achieve a rapid reduction in the quantity of drapes consumed. Leadership within the operating theatre to prevent opening of packs 'just in case' is another simple way of reducing waste.

The carbon footprint of a gown could be reduced further if the number of uses per gown increased. Currently 75 uses, given the advances in technology for fabric manufacturing and laundering, it is likely that the limit of 75 uses could be extended. This requires change at an international level. As fibre technology has advanced, polyester manufactured from bio-oils rather than fossil fuels may potentially improve the footprint, provided the relevant testing technical test requirements can be met. It may be that other fibres are even more appropriate but there is still work to be undertaken on the creation of accurate life cycle assessments which can be easily and readily compared with others. My recommendation is that further research should be targeted towards the ideal fibre and fabric type used within a surgical gown and drape and durability over extended periods of use.

With regards to the laundering of reusable textiles, the National Health Service Best Practice guidance is historic and requires revision with attention paid to newer technologies. Some European countries currently launder their healthcare textiles at lower temperatures, using detergents which provide the same sterilising effect as higher temperatures. This is permitted, as in Europe hospital linens should be laundered to meet the standard EN14065: Textiles – Laundry processed textiles – Biocontamination control system. Research into ecolabelled detergents for low temperature laundering would be game changing as well as significantly reducing energy requirements and waste products.

The correct sorting and subsequent processing of waste dramatically affects the carbon footprint of a surgical operation (Lee and Mears SC, 2012). The work discussed in Section Five on medical textile waste confirms these earlier findings. Ensuring appropriate recycling facilities within the operating theatre and encouraging a culture that adopts using these is critical (UK Health Alliance on Climate Change, 2023b). The application of circular economy principles in the recycling of constituent fibres of medical textiles, once they have reached the end of their healthcare life back into the broader textiles industry is likely to have a significant positive impact upon the footprint of textile based medical devices.

Whilst consideration should be given to circular economy principles when disposing of textiles, a product design specification at the commencement of the medical device design process can ensure that sustainable criteria are built into the product design process from the outset (Ogrodnik, 2019). These may include designing for product life extension or reuse or considering aspects such as the method used in manufacturing the textiles, such as promoting the use of waterless methods for dyeing, or the reuse of waste products elsewhere in industry. My recommendation would be that medical device designers should routinely be incorporating sustainable criteria and demonstrating these in their technical files.

Workers in the textile industry face exploitation, systematic underpayment, forced labour, severe health risks, and verbal and physical abuse (United Nations Environment Programme, 2023). Women are particularly vulnerable as they represent the majority of the garment workforce. It

would be inappropriate not to offer consideration to the ethics and workplace practices for those employed within the textile industry. The International Labour Organization places importance on the need to address decent work (International Labour Organization, 2023). My recommendation is that further emphasis should be placed by those procuring medical devices upon the origin of raw materials and location of factories used in the manufacture. Enhancing supply chain transparency would be beneficial.

Finally, in my direct clinical practice as a congenital hand surgeon, I will use a variety of textile medical devices aside from surgical gowns and drapes. These include orthotics and splints to prevent deformity, implantable ligaments for joint reconstruction, and nanofibre bioscaffolds for cell regeneration and subsequent limb reconstruction. It is an exciting time for my practice in this field.

I hope to adopt and promote the use of sustainable and ethically sourced medical devices within my direct practice, collaborate with professionals from a diverse breadth of industries to design innovative solutions to some of the outstanding problems, and encourage the juniors whom I supervise to do the same.

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Medical Textiles – Chapter for Encyclopaedia

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Entry Text

As defined by The Textile Institute, a medical textile is "*a textile structure which has been designed and produced for use in any of a variety of medical applications, including implantable applications*" (The Textile Institute 2022).

Although there are references referring to the use of textiles in medicine by the ancient Greeks in their record-keeping on wounds sustained during the Trojan War, it is considered that the innovations began in in India particularly in the case of sutures, as listed by Susruta (Mackenzie D 1973). By the time of Hippocrates (460–375 BCE), a philosophical as well as a practical approach to medicine had developed (Fox RL 2020) but, in reality, most major innovations took place during the last 150 years.

Nanotechnology has provided much of the recent stimulus behind recent research and development in the medical textiles field. It has enabled several different but useful processes such as:

i) the incorporation of active agents in the form of nanoparticles into fibre-forming polymers before spinning them into filaments,
ii) nano-finishing treatments for adding nanomaterials to fabrics,
iii) electrospinning of fibre-forming polymers into nanofibres, and
iv) the incorporation of nano-particulate agents into nanofibres.

Nanofibres can be made from synthetic absorbable polymers (SAPs), which biodegrade at predictable rates. If manufactured to incorporate pharmaceutical molecules, they can yield implantable materials able to provide sustained drug/antibiotic release to assist patient recovery over a defined time period. Another characteristic of nanofibre yarns and fabrics, not achievable with microfibres or traditional fibres alone, is the manufacture of structures with pore sizes similar to those in native tissue. This enhances tissue regrowth, thereby forming excellent scaffolds to help tissue repair to progress. In such structures, nanofibres spun from an SAP are useful in enabling the production of a scaffold which provides support in

the early stages of tissue repair when it is most needed, but is then steadily absorbed so as not to require additional surgery for its removal. The use of SAP implants is not restricted to nanofibrous textiles; they can be used for the same reasons in fibrous, nano-fibrous, and continuous-filament form.

The performance of the materials intended to demonstrate antimicrobial action against bacteria, viruses and fungi now show substantial improvement over many of their traditional counterparts both in terms of their effectiveness and durability. Durability is typically high when nanoparticles are blended into the polymer prior to spinning, or with covalent bonding of the antimicrobial agent to the fibre surfaces. Such treatments appear to offer prospects for improved PPE (Personal Protective Equipment) for both healthcare personnel and patients and the recent COVID pandemic has further stimulated research, but the results for workwear in the healthcare setting are currently disappointing. Results for implantables and wound dressings are more promising, and added to this, strong, durable textile structures whose performance can be modelled and predicted, have been and are being developed. These could be braids for the replacement of tendons, knitted structures and spacer fabrics for the construction of wound dressings and both knitted fabrics and power nets for pressure garments to control blood flow and in the management of burns and lymphoedema.

Classification of Medical Textiles

A wide range of medical textiles are important to medicine and healthcare, and that range continues to grow. Morris and Murray (Morris H and Murray R 2021) neatly classified the areas within which medical textiles are applied as:

- implantable materials,
- non-implantable materials,
- healthcare/hygiene roles,
- extracorporeal devices,
- intelligent medical and healthcare textiles,
- furnishing fabrics and textiles in fixtures and fittings in healthcare establishments,
- components of devices for environmental hygiene control.

Implantable materials

An implantable medical device means any *active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain there after the procedure is completed* (Medicines and Healthcare products Regulatory Agency 2022). Such devices may be biologically active or biologically inert; those falling into the medical textile categories include sutures, vascular grafts, meshes, and resorbable polymer structures such as scaffolds to assist cell growth for tissue regeneration.

Implantable medical textiles can be used in almost every organ of the body but must be designed carefully to suit their end purpose. They need to be biocompatible, resist corrosion from bodily fluids and able to perform the intended task hence their biomechanical properties are also important. Implants that are biologically active may be required to be work at a particular rate over a fixed time so the means by which

the active molecule(s) are incorporated into the implant is critical. Resorbable implants that gradually disappear with time need to possess adjustable working profiles to be able to provide the structural support required for a given period. All of the products from their biodegradation must be non-toxic and non-carcinogenic.

Advances in sutures and grafts have seen a range of products enter the market over the past decade. Sutures structured to contain barbs to assist in maintaining wound closure and others containing antimicrobials have been trialled on patients and are used in clinical practice (Henriksen NA et al. 2017; Zhang W et al. 2016). Grafts and stents manufactured from nanofibres of absorbable or non-absorbable polymers appear to offer advantages over those made from conventional yarns, not least because they can be made to incorporate a high degree of porosity allowing integration into the tissue (Joseph J et al. 2018).

The method of construction of artificial tendons and ligaments is of key importance in the manufacture of grafts that mimic native anatomy and physiology. For example, braided ligaments, where fibre choice, braid angle, and the number of braids can be varied to predictably alter mechanical properties have shown promise. Laboratory trials showed artificial ligaments were able to mimic the normal viscoelastic loading cycles of a native anterior cruciate ligament (Turki S, Marzougui S, and ben Abdessalem S 2015). Artificial tendons that allow tissue ingrowth are currently available and used in clinical practice, ***as per Image One***.

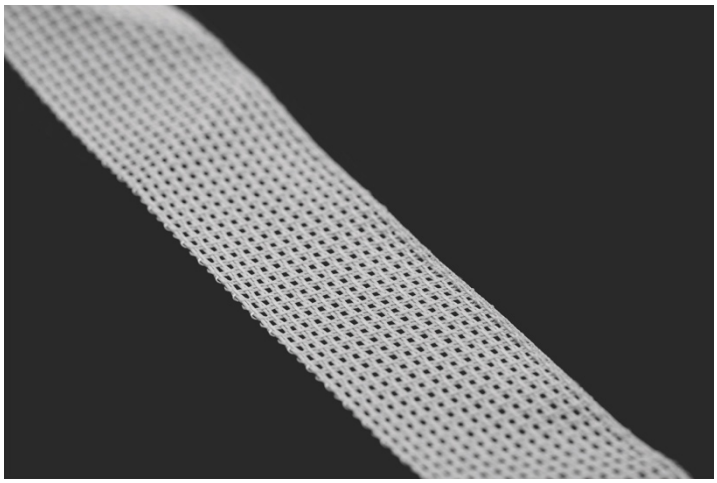

Image One: An example of a braided tape used in tendon reconstruction. The implant comprises a wide, open weave Poly-Tape. PatellaTape System™. Reproduced with kind permission granted by Neoligaments™, a division of Xiros, Leeds, UK, 2021.

In a similar manner, mesh is frequently used to bolster a hernial repair, ***Image Two***. Porosity of the synthetic mesh affects tissue ingrowth and needs to be carefully considered as increased scar tissue may cause pain from fibrotic tissue (Novitsky YW and Martin-del-Campo LA 2018). There is still room for research to improve what is currently available.

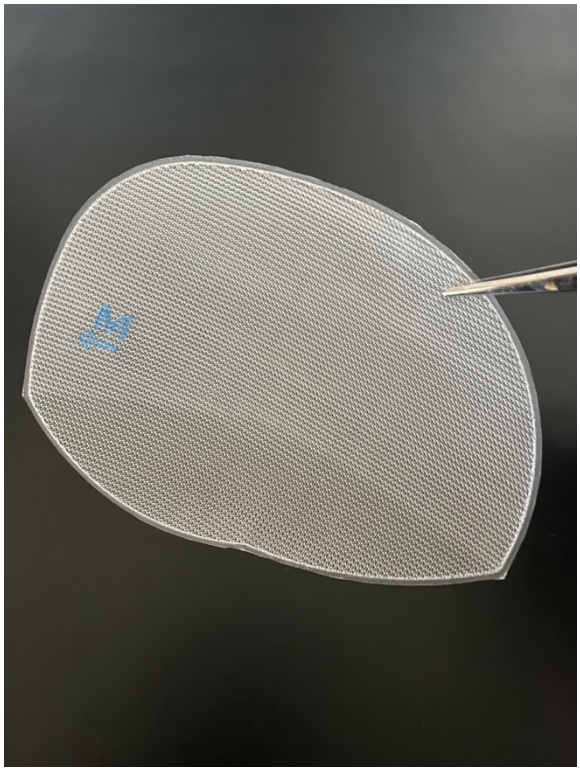

Image Two: An example of a hernial mesh augment used in hernial repair. Image kindly provided by Mr Steve Lindley, General Surgeon, UK, 2021.

The role of scaffolds in tissue regeneration is showing huge advances. Scaffolds serve as a substitute for the native extracellular matrix where they play a pivotal role by providing temporary support for cells during the time it takes for natural extracellular matrix to form. Scaffolds manufactured from natural and/or synthetic fibres have been used to generate a range of cells (Jafari M et al. 2017). Key features in the scaffold include surface features, such as roughness and hydrophilicity, and scaffold microstructures such as pore size, porosity, pore interconnectivity, and pore/fibre architectures (Morris H and Murray R 2021). The optimum pore size for each tissue type can be best matched by selective combination of nanofibres and microfibres.

Non-implantable materials

The category of non-implantable medical textiles includes dressings, pressure garments such as thromboembolic stockings and various braces, splints, and trusses. They are used for a variety of functions such as protection, augmenting normal anatomy, providing structural support, and enhancing aesthetics.

The role of the dressing in wound management has attracted significant attention over the past few decades. Surgeon Ambroise Pare stated in the 16th century that 'I dress the wound, God heals it', and whilst biological materials such as cobwebs, leaves, seaweed, silver, and honey were all used in dressings in the past, there is now interest in 'why' and 'how' dressings may aid the healing process (Hakimi O et al. 2007). As textile chemistry and engineering have progressed, the ability to manufacture fibres which impart rate-controlled delivery of active agents has begun to improve wound dressings. Fibres with haemostatic properties have proved invaluable in certain medical and surgical specialities, where they are used to influence haemostasis. Some products are

absorbable, thus lending themselves to internal usage, whilst others are non-absorbable and can be safely removed once a clot has been established. There is now significant reliance on the beneficial performance of such textiles in areas that are difficult to reconstruct or stitch.

Pressure garments are used clinically for a range of tasks including venous thromboembolism prevention, management of lymphoedema and in the treatment of burns and musculoskeletal injuries with recent work focussed on engineering the pressure garment to provide the desired pressure at the correct location (Liu R et al. 2018). Materials commonly used include the elastomeric spandex yarns (polymeric materials consisting of at least 85% segmented polyurethane) with the fabrics manufactured by warp knitting, weft knitting or weaving.

Orthotics and exoskeletons incorporating a range of medical textiles are regularly used across clinical practice and include hernia trusses, hip protectors, braces, and splints; a brace to treat scoliosis (curvature of the spine) is demonstrated ***in Image Three***. Design of a suitable orthotic begins with determination of the desired treatment objectives. Appropriate materials that can provide mechanical support are critical but rigid braces require a different selection of materials from a flexible insole for a shoe, for example, which may not only have to accommodate foot deformities but also support the foot and absorb shock and shear forces. The ability to maintain hygiene is critical as orthotics are usually used over a long period of time. Thermoforming plastics allow the orthotist to produce or customise an orthotic in the clinic itself, one that is specifically moulded to the requirements of the patient and their specific anatomy and to re-form it as necessary over time.

Image Three: A scoliosis brace used in managing scoliosis. Image kindly provided by Mr Wai Weng Yoon, Spinal Surgeon, UK, 2022.

3D printing has allowed for customisable braces and splints to be manufactured readily either from images taken of the patient or from radiographic imaging. Other novel innovations include exoskeletons designed for surgical applications. For example, a passive hand exoskeleton to provide passive assistance whilst operating (Nishida J et al. 2015). Prosthetics that allow osseous-integration, or integration to nerves and hence muscle units, also open the potential for development and design of prosthetics for amputees or those with congenital anomalies. Medical textiles are used at the interface of the prosthetic to the patient to allow for a seamless transition and prevent stump complications such as ulceration.

Healthcare and hygiene roles

Healthcare, hygiene, and personal protective equipment (PPE) in the medical textile sector covers a vast range from products used for disinfection such as disposable and reusable cleaning materials, sanitary wear, and dental floss through to reusable patient wear, staff clothing, and protective wear. This category of medical textiles includes many single-use disposable items, and whilst these proffer some advantages and may be the correct choice in some low-volume applications, they have enormous potential to incur high environmental costs in high-volume applications and in those cases should be urgently replaced by reusable or re-manufacturable items.

Cloths and Wipes

Cloths and wipes made from non-woven fabrics are commonly used on the ward for cleaning patients, staff, or equipment and usually contain antibacterial agents. Typically designed to be single use, fibre type makes a difference with hydrophilic wipes proving more effective in trials than polypropylene (which does not absorb moisture) (Edwards NW et al. 2019). Antimicrobial agents such as quaternary ammonium compounds are some of the most widely used disinfecting agents in such applications. In the case of wipes, it is ready release rather than adsorption which is required from the impregnated carrier fabric. The pH, temperature, and concentration of active ingredient all affect their release from cotton fibres and hence the disinfection achieved (Hinchliffe DJ et al. 2017; 2018).

Sanitary Wear

Sanitary wear, such as body-worn pads, diapers and flatform sheets, are used in cases of urinary and faecal incontinence. There has been a drive towards reusable products with the introduction of superabsorbent fibres and spacer fabrics. Ultimately, the product needs to be able to remove liquid from the surrounding skin, keep the skin clean and dry, and enclose the liquid safely within the product. Feminine hygiene products continue to attract interest in a growing industry sector with increased uptake of silicone menstrual cups and washable, reusable garments such as period panties in more recent years.

Healthcare workers' clothing

Healthcare workers' clothing has seen a phasing out of the traditional doctors' white coat for hygiene reasons. Uniforms have been found to become most-frequently contaminated below the waist and heavily contaminated after procedures that involve exposure to pathogens (Speers Jr R et al. 1969). However, it must be concluded at present that many items of workwear in the healthcare sector have little to offer in terms of enhancement of patient or healthcare worker safety. For example, the Antimicrobial Scrub Contamination and Transmission (ASCOT)

trial, a randomised controlled trial assessing the efficacy of antimicrobial-impregnated scrubs, demonstrated that such scrubs were ineffective at reducing contamination (Anderson DJ et al. 2017). Other studies have investigated bacterial transfer under dry conditions on the most common reusable fabrics for healthcare professional uniforms (those made from Tencel and PET/Cotton) (Rogina-Car B, Budimir A, and Katovic D 2017). Launderability, fabric and fibre choice and the type of seam were all found to be factors that play a role in microbial transfer. Case studies have demonstrated outbreaks of disease due to inadequate laundering which also suggests that textiles may play a role in pathogen transfer. There is a need for well-designed research in this area as there is little point in applying antimicrobial agents which may potentially damage the environment if they have no beneficial effect on patient and healthcare-worker safety.

Personal protective equipment (PPE)

Personal protective equipment is intended to protect both the patient and the healthcare worker and includes everything from gloves and masks to completely-enclosed protective outfits with independent air supply, face and eye shields, gloves and surgical facemasks or respirators. Much work has been undertaken on surgical gowns in attempts to reduce infection in arthroplasty and clean surgeries (World Health Organization 2016). Originally intended to reduce surgical-site infection, their role in proffering protection to the user is now recognised. Fibre type, fabric structure (woven vs non-woven), the addition of fibre finishes in the form of coatings and reinforcements all impact upon the performance of the gown, as does the glove-gown interface. There are strict testing regulations which differ depending upon the level of risk the gown has been designed to provide protection for. An FDA approved classification for gowns, now updated to ANSI/AAMI PB70:2012, places gowns in one of four categories depending upon the level of protection they provide. Level One is for minimal risk use and provides a slight barrier to the penetration of small amounts of fluid. Level Four is for high risk use and is used, for example, during fluid-intense procedures when pathogen resistance is required, or infectious diseases are suspected. For high-risk procedures, performance must be sufficient to prevent all fluid penetration for up to 1 hour and viral penetration for up to 1 hour. The guidance also specifies which areas of the gown should exhibit the necessary level of protection depending on the use of the gown (FDA 2021).

Surgical gloves have evolved. Powder on gloves increases the risk of starch peritonitis; an increase in latex allergy in healthcare workers has steered manufacturers to use other materials such as synthetic elastomers and there has also been concern over unethical manufacturing practices of latex gloves (British Medical Association 2021).

Surgical masks have undergone a considerable number of design modifications since their introduction in the 1800s when they consisted of a single layer of gauze (Spooner JL 1967). Currently, most masks are made from layered melt-blown non-woven polypropylene wherein fine diameter filaments are sandwiched between spunbonded cover layers sometimes containing a support layer. More recently however, because of the use in billions of single-use masks and respirators during the COVID-19 pandemic, cost and the environmental damage associated with their disposal has driven much of the best effort at their redesign towards reusable high-performance filtering face piece masks. One example, developed in Japan and Korea, incorporates a nanofibre web layer which dramatically improves performance. There are strict standards for testing and regulations around the level of filtration the mask proffers.

Patient clothing

Patient clothing remains an area where further development could prove to be very beneficial, especially with the advent of 'Smart Textiles', from which it is becoming possible to create garments to continuously monitor critical bodily functions whilst allowing patients greatly improved mobility and the potential to be monitored remotely at home.

Extracorporeal devices

Advances in technology have allowed clinicians to support organ function by using machines and techniques that supplement or mimic the outcomes of human physiology. Some of these incorporate textile materials, often for filtration purposes. Whilst there have been great advances in this field, attention always needs to be given to the biocompatibility of extracorporeal circuits, as they tend to activate the immune and coagulation systems leading to inflammatory response and coagulopathy, which in turn, leads to microvascular and macrovascular thrombosis.

Extracorporeal membrane oxygenation (ECMO) supports the gas-exchange function of the lung and cardiovascular systems in the event of reversible cardiovascular or respiratory pathology refractory to conventional therapies. In essence a modification of cardiopulmonary bypass utilised in the theatre environment (Bonacchi M 2016), ECMO is now a recognised level of support provided in highly specialised units around the world. Key components of the circuitry include cannulae, tubing, pump, oxygenator, and heat exchanger. It is within the oxygenator, as shown ***in Image Four,*** where gas exchange takes place across a membrane which serves to separate the blood and gas phases.

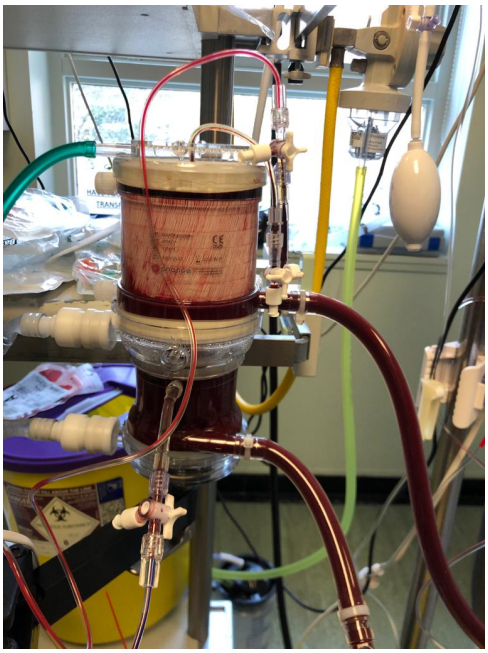

Image Four: An oxygenator used in an ECMO machine. Image kindly provided by Dr Matthew Charlton, Consultant Intensivist, UK, 2021.

Early generation membrane oxygenator devices included flat sheet silicone designs and hollow fibre configurations where the blood ran inside the fibres with the gas surrounding them. These devices used long blood paths and created high-pressure gradients which were not efficient. The first widely used fibre material was microporous polypropylene; however, the lifespan was limited due to plasma leaking into the gas phase side of the membrane. Design modification saw the introduction of polymethylpentene (PMP) hollow fibres which created a significant reduction in pressure gradients with markedly reduced plasma leakage and these are still used today (Morris H and Murray R 2021).

Dialysis machines, functioning as an artificial kidney, also incorporate fibrous membranes. The single most important part of a wearable artificial kidney is the closed-system self-regenerative dialysate. Traditionally filtration has been undertaken by activated carbon, but zeolites and polyethylene glycol-coated nano porous silica have shown promising results against uraemic toxins. The membrane must be biocompatible, non-thrombogenic and economic to use. Currently, polyester (PET) and viscose rayon are the two main fibre types used in mechanical kidneys. The ability to incorporate fibres with nanopores to allow diffusion (e.g., by using electrospun webs and scaffolds) has enabled advancement in this area, particularly in tissue scaffold creation (Attanasio C et al. 2016).

Regeneration of insulin-producing beta cells is a major goal for regenerative medicine. Islet cells can engraft and function within the liver allowing for injection into the portal vein. One method to reduce rejection, and the need for immune suppressants, has been achieved through encapsulating the islet cells such that diffusion of nutrients, insulin, and waste can occur but infiltration by immune cells and antibodies is prevented. Calcium alginate is commonly used for this purpose in a hydrogel sphere. Growth factors and medications may be added to engineer the properties favourably (Bochenek MA et al. 2018).

Intelligent medical and healthcare textiles

Applications of smart textiles in healthcare range from the use of a single fibre in a suture to complex wearable constructions and auxiliary systems for personalised care. The ability to identify declining health within a patient and subsequently alert healthcare providers creates the potential for smart textiles to be used in preventive medicine and in managing pre-existing disease, whether as an inpatient or within the wider community. To achieve the required performance, sensors may be embedded directly into the fabric or embedded into a coating applied to the fabric surface which allows production of devices that can capture a myriad of data, including physiological variables; the measurement of cardiorespiratory parameters, electromyography, and electroencephalography can be achieved with garments and fabrics already available (Coosemans J, Hermans B, and Puers R 2006).

Often, medical garments for monitoring and sensing movement have the potential to yield improvements to quality of life. As a result, attention has been directed at how smart textiles may improve prosthetics for amputees. For example, electronic skin can have sensory capabilities whilst textile-based sensors can be easily worn over prosthetics whilst retaining the appearance of being a regular garment. Flexible, stretchable piezoresistive fabrics are available for a range of pressure-sensing applications that can be incorporated into robotic limbs for direct feedback to the wearer (Leong J et al. 2016). Such textiles can also incorporate infection control management

systems aimed at preventing the onset of any infection by continuing wounds or use of the prosthetic, as well as conferring key benefits on a wider range of general medical garments, such as bandages, bedding, and dressings (Rajendran S and Anand SC 2016).

Further information can be sought from other articles within this volume.

Furnishing fabrics and textiles in fixtures and fittings in healthcare establishments

A wide range of textiles are used in healthcare and medical equipment, for example, the coverings of clinic couches and chairs, bedsheets and hospital bedding, padded augments to protect bony prominences and position patients when operating, and curtains that separate bed spaces upon the ward. Despite the vast range of these textiles, there are minimal standards for furnishings and furniture other than safety tests for electrically driven items and specification for bed castors (International Standards Organisation 2021), but it is worthy of note that antimicrobial finishes can be effective in these settings, particularly where patients are in contact with the textile items for longer periods of time. A series of British Standards do exist to which bedding can be designed including standards for mattress covers and pillows (British Standards Institution 1999).

Textiles in this category need to be designed with careful consideration given to the complete life-cycle assessment of environmental impact, particularly in the case of hospital bedding and the associated laundering process. The authors believe this should be a routine process; the reduced cost and carbon footprint of laundering high-volume-use items compared with single-use and disposal needs to be addressed, especially since the development of economical low-temperature laundry systems such as those which utilise ozone to clean, disinfect, and report on the achievement of disinfection after processing each load (JLA 2021).

Components of devices for environmental hygiene control

Maintaining a clean and hygienic environment is critical. In some circumstances, such as implant insertion, there has been significant work undertaken on ensuring a clean-air environment to reduce surgical infections. Disinfection does not always achieve sterility and further processing of the room air is required, for example by filtration, deploying aerosolised hydrogen peroxide or hydrogen peroxide vapour, ultraviolet-C light, pulsed-xenon ultraviolet, or ozone.

Filtration depends upon the ability of the filter to capture particles, and this depends on the particle size passing into its fibre mass as well as the velocity of the airflow passing through the filter. There are different mechanisms of filtration including direct interception, inertial impaction, diffusion, and electrostatic attraction. Where it is felt necessary to achieve high levels of decontamination of the air passing through the filter, the mechanical filtration provided by melt-blown non-woven fibre webs can be supplemented by UV-C irradiation, coupling the unit with a photocatalytic filter consisting of a filter fabric containing TiO2 nanoparticles (Woo DJ et al. 2012) or electrical discharge within the filtration device itself, and some models include activated carbon for removal of volatile organic compounds (VOCs). One system shown to be highly effective against avian flu aerosols, used an antimicrobial N-halamine finish on the filter fabric used within the filter itself.

Ultra-low particulate air (ULPA) filters are designed to remove 99.99% of particles down to 0.12 μm in size whilst HEPA filters are designed to remove up to 99.97% of contaminants of sizes down to 0.3 μm. As they demand more in maintenance and operating costs, ULPA filters are reserved for specialist treatment areas. Even when filtration is highly effective at removing particles, the positioning of the air-circulation device containing the filter remains critical. Modelling of airflow led to the introduction of vertical laminar flow in clean-air operating theatres. Work has also been undertaken on hospital wards with modelling of the effect of positioning of air inlets and outlets (HECOIRA 2021).

Pertinent issues to today

Standards, specifications, and clinical trials of medical devices must always remain at the forefront of the medical textile device designer's mind. Several of the currently-available ISO tests require an overhaul given the introduction of new technology; it is necessary to keep the test methods under constant review to ensure that they continue to relate to what happens in the clinical environment.

Collaborative research involving clinicians has the potential to reduce time and costs and allow for a seamless introduction of prototypes into the clinical world. Due consideration should be granted to the matter of data protection for information transmitted by smart garments, but we believe there is great value in being able to remotely monitor patients whilst maintaining maximum mobility.

Nanofibres produced by electrospinning are becoming an integral part of many medical textiles, particularly in those intended to assist in tissue engineering. High performance fibre types, such as electroactive fibres offer advantages through their ability to generate or conduct electricity, and those made from super absorbable polymers to provide dramatically-high levels of absorption are beginning to appear in currently-available products and we feel that interest in their wider application is likely to continue.

Due consideration should be given to developing countries where there are significant issues such as "Period Poverty" and a lack of access to feminine hygiene. Other issues include the lack of laundering facilities for medical textiles, such as PPE as shown ***in Image Five***, and overcoming such shortfalls could be of significant help in combatting their historical-high burden of infectious disease.

The single-use culture accepted and operating today needs to change quickly. Sensible decisions regarding reusable textiles are required and designers should be tasked with creating new forms of devices with improved performance, low cost and a minimised environmental impact. Life-cycle assessment that demonstrates appropriate consideration to sustainability should be a standard requirement.

Image Five: Doffing of PPE used during Ebola crisis in Sierra Leone in 2015. Image kindly provided by Dr An Vanthuyne, Consultant in Sexual and Reproductive Health, UK, 2022.

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See Also

Spider silk textiles into the future, An Introduction to Textile Recycling, Understanding Smart Textiles, What are Electronic Textiles, Textile interface for wearable sensors, Isotopia-knitted surfaces for soft membranes, Coating high performance textiles for functional and sustainable textiles, Therapeutic wearables and smart textiles, Laboratory ‘craft’ – Tissue Culture, Microbiology and the Production of BioTextiles,

Designing the future of the medical textile sector

At the recent 91st Textile Institute World Conference in Leeds, UK, Holly Morris MAppSc, MBChB (Hons), MRCSEd, FHEA, LTI, AMIMechE, an orthopaedic surgeon and medical textile engineer, based in the East Midlands, UK, looked at the future landscape of medical textiles.

Medical textiles are 'textile structures which have been designed and produced for use in any of a variety of medical applications, including implantable applications'. They date back to the birth of medicine. In Homer's Iliad, over 140 treatments of wounds are discussed, including the dressing of wounds. Whilst the fundamental principles of haemostasis, cleaning and dressing the wound have not changed to this date, the methods we utilise have been shaped by time, increasing knowledge and improving technology.

The Hippocratic statement of 'natura medicatrix', the healing power of nature, is well known, though often disregarded. Certainly, there are mentions of natural textile-based products being used for healing over the years. In the Medieval period, spider webs were often used as wound dressings because they appeared to reduce infection. There has been increasing interest in the use of spider silk with the development of nanotechnology. Not only are the antimicrobial properties being considered, but the structure of spider webs is being studied, demonstrating the overarching power of Mother Nature and the importance of biomimicry. In general, the development of nanotechnology has allowed for the development of dressings and bandages, containing small nanoparticles and microparticles of a targeted drug to reduce infection and promote wound healing.

Overall, development of the medical textile field is no different to any other scientific field and is through a combination of factors; an increasing knowledge base, technological advancement, warfare and economic reasons. Aside from wound dressings, the role in which medical textiles are utilised continues to expand.

The scope of the medical textile field

Medical textiles have roles both externally to the individual and internally, at a macroscopic and microscopic level. Implantable textiles include sutures, meshes, bio-scaffolds and grafts, such as the Dacron graft commonly used in vascular surgery. Externally, wound dressings and compression garments are all textiles with direct contact with the patient.

The role of medical textiles within the hospital setting includes patient bedding, patient gowns and garments designed for protective functions such as surgical gowns and gloves.

As technology has advanced, the remit of the medical textile field has increased. For example, the use of nanofibre bio-scaffolds in the laboratory setting is producing promising results in the field of regenerative medicine. In addition, the development of fibres and fabrics that can mimic human physiology has seen the development of materials that potentially could be used as artificial organs in the future.

The subfield of smart textiles has also expanded as technology to incorporate biosensors into fibres and fabrics has been developed. Investigations into fibres, yarns, fabrics and systems that can monitor human physiological and mechanical parameters are continuing. Currently, sensors can be printed directly on fabrics and the technology to manufacture conductive textile yarns (for example cotton fibres with a graphene coating) is continuing to develop. The ability to identify an individual who has declining health and subsequently alert healthcare providers, potentially allows smart textiles to be used in preventive medicine and in managing pre-existing disease, whether as an inpatient or in the wider community.

When designing medical textile products for implementation into the healthcare sector, it will be of great importance to understand not

The operating theatre; the author in Vietnam undertaking charity work in an operating gown

only physiology and pathology of the individual but also the constraints of the local and international healthcare systems. As legislation and fiscal pressures increase, it will be smart design that can produce products that allow for incorporation into both the healthcare and consumer markets.

Delivering effective healthcare at a nationwide level within the UK

Patient safety is defined as 'the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum.'

There are many different ways in which patient safety can be defined. Ultimately it is reducing errors, accidents, injuries and infections. The World Health Organization (WHO) broadly divides the field into the following categories:

- Reducing medication errors
- Reducing hospital acquired infections
- Reducing surgical complications, including surgical site infection
- Reducing exposure of patients and healthcare workers to ionizing radiation
- Reduction in administrative errors
- Increased efficiency in diagnosis and delivery of appropriate care

In addition to improving patient safety, the delivery of healthcare in a fiscally tight arena continues to be of utmost importance at a national level.

Medical textiles play a significant role in both patient safety and delivering effective healthcare. Drawing on the WHO areas of importance, medical textiles have direct relevance to reducing hospital acquired infections, improving the delivery of safe surgery and in protecting patients and healthcare workers by reducing exposure to ionising radiation.

Hospital acquired infections

A hospital acquired infection, or nosocomial infection, can be defined as 'an infection acquired in hospital by a patient who was admitted for a reason other than that infection'. Factors affecting a reduction in incidence are multiple. Those that are of relevance to the textile sector include developing and using appropriate gowns, gloves, masks and hats to reduce the direct spread of infection as well as the availability of appropriate facilities for disposal, laundry and sterilisation.

Delivery of safe surgery

'Safe Surgery Saves Lives' as the 2008 WHO initiative stated. An international campaign was instituted aimed at improving the many factors that are relevant to providing safe surgery. Relevant to the textile sector, was the literature that addressed surgical site infection. Again, this covered the use of textiles such as gloves, gowns, masks and hats but also extended to assess the role of medical textiles, such as wound dressings, in the post-operative period.

In Textile Terms and Definitions, The Textile Institute defines a wound dressing as 'materials, including textiles, whose functions are to provide protection to a wound against infection, absorb blood and exudate and promote healing'. Historically, biological materials such as cobwebs, leaves, seaweed, silver and honey have all been used as dressings. In recent times, there has been a revival in their use as the knowledge base behind 'why and how' they aid the healing process has increased. As a consequence, this has driven the development of new dressings with specialised properties to enhance wound healing.

Reducing exposure to ionising radiation

Ionising radiation sources may be found in a range of settings within the workplace. Within the healthcare field, it is used in both a diagnostic and therapeutic setting. Whilst advantageous to patient care, it is not without risk and there are guidelines regarding appropriate training of staff and the appropriate level of exposure to radiation.

Operating with radiation provides its own challenges for the surgical workforce. Operations may be lengthy and protecting the surgeon is important. The way in which this may be done is several fold and includes utilising ergonomic design for protective garments and ensuring that protective garments are regularly tested and replaced as necessary. It is not just the torso and reproductive organs that require protection; radiation increases the risk of thyroid cancer and cataracts of the eye.

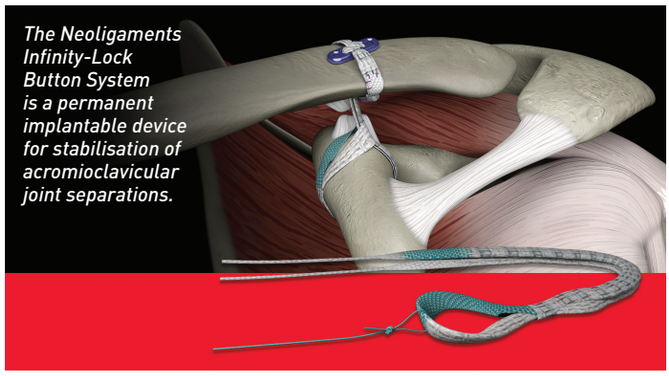
The interplay that garments have with surgical gowns is important. Lead gowns are typically cumbersome and there is evidence that the hot and sweating surgeon can compromise the sterility of the surgical gown and the surgical field. Time spent upon a clever design for healthcare may extend outside the field and interplay with safety garments for protecting those who venture into space and other hostile environments.

Delivering effective healthcare directly to the patient

The delivery of healthcare no longer stipulates that the clinician must be sat with the patient. The role of biosensors and smart textiles to monitor patients' physiological parameters and relay these to a central body may play a role in allowing patients to live remotely whilst still providing healthcare providers with key information on their health.

Increasing knowledge upon the morbidity risk of an increased hospital stay combined with the pressures upon hospital beds is driving the requirements to deliver effective care within a community based setting. The requirements for the patient will dictate the level and type of care that is required. This should not be seen as a challenge and there are already models in place that can deliver effective community care. For example, renal haemodialysis is already undertaken effectively in the community in several regions internationally. There potentially is a key role for biosensors and smart textiles to augment the delivery of care that can be provided, if appropriately designed and implemented.

The importance of delivering targeted treatment to tissues to reduce systemic side effects and complications is increasingly acknowledged. In addition to proffering benefits to the patient with reduced side effects, smaller drug dosages are required to achieve the



The Neoligaments Infinity-Lock Button System is a permanent implantable device for stabilisation of acromioclavicular joint separations.

The Neoligaments Leeds-Kuff Patch is a permanent implant constructed from knitted polyester fabric. It thus provides long term stability and encourages tissue ingrowth throughout the healing process.

Neoligaments (a division of Xiros) designs, develops, manufactures and markets innovative sterile medical devices for the sports medicine and orthopaedic markets.

same therapeutic effect. The formulation of the medication dictates whether the delivery is direct to the diseased tissues or whether release of the medication requires further processing once absorbed into the bloodstream. Implantable textiles, such as grafts or sutures, may have molecules of medication incorporated within them to undertaken roles such as reducing infection, preventing anastomosis of vessels and thus ultimately to enhance the natural healing process. In addition, the use of bioabsorbable scaffolds for cell growth in the field of regenerative medicine is pushing forward the boundaries of what is possible.

Providing care in hostile environments

The importance of protecting both the patient and the healthcare professional are well recognised. Hostile environments, such as the Ebola outbreak in Liberia, have challenged both experts and industry to create products that satisfy current safety standards in addition to meeting fiscal and environmental targets. With the threats of chemical and nuclear warfare, there is an increasing demand for personal and protective equipment that can withstand such attacks.

Personal and protective equipment utilised in such settings must not only offer protection, but must also do so in a scenario where temperature, humidity or the chemical constitution of the atmosphere may differ significantly. The degradation of fibres and fabrics in such settings must be understood fully such that a design and subsequent product offers the maximal benefit to the wearer. Finally, the 2014 Ebola outbreak saw a drive towards understanding the role that individual garment items play when worn as a bundle. The need to test garments as a 'bundle' is recognised in the laboratory setting and at a higher level with the Centres for Disease Control and Prevention (CDC) recommending bundles of clothing for healthcare workers, and the methods of donning and doffing, based upon the perceived level of exposure to the Ebola virus.

Delivering healthcare in the Western world in carefully climate-controlled environments is relatively easy to design textiles for. Delivering healthcare effectively in countries with high heat or humidity changes the parameters in which textiles must function effectively. Some of the factors that need to be accounted for in the design of such items include a higher rate of blood-borne infections, a higher rate of infections post-operatively and a relative lack of effective facilities for sanitisation of consumables. The economic climate should also be considered within the design and manufacture.

The consumer market for medical textile products

Medical textiles used within the healthcare industry are slowly filtering through to consumers as the general public become more aware of the advantages of living a healthy life. Products available to consumers span all age ranges, from infancy to the elderly population and genders. As the knowledge base continues to grow and technology develops there will be increasing scope for developing and producing products for the individual consumer, particularly when the consumer likes to take responsibility for their own health.

The use of graduated compression is used within sportswear and is endorsed by multiple sportsmen and sportswomen as enhancing the bodies repair processes post exercise. Clothing companies created for post-partum ladies are utilising the latest research in designing and creating products. Hot Mama creates lactation pads with antibacterial bamboo fibres and these may reduce the risk of mastitis. Infants are catered for with teething toys made from medical grade silicon. The increasing number of companies suggests that there is a market for these products.

The design team

The future scope of the medical textile sector is innovative. The application of potential designs continues to expand. In enabling successful implementation of credible design into the formal healthcare sector or the consumer market, one must address the structure of the design team.

A functioning design team will feature expert opinion from a breadth of specialities to enable collaborative design, manufacture and implementation. Not only will individuals with a design background sit on the team but industry needs to be represented to discuss the capabilities of current production lines and the likely expansions of these. Legal representatives with knowledge of national and international trade, health and textile laws will have a role. The healthcare sector should also be represented to ensure that items are appropriately targeted and designed for the needs of the patient and that patient safety is of utmost importance; clinical experience can never replace the knowledge of a textbook. Utilising key individuals who can draw on their experience should allow for successful development and later implementation of the initial design ideas with minimal loss of time and expenditure.

The relevance of regulations and standards

Medical textiles must serve the purpose and do so effectively whilst also being economically viable within the constraints of the relevant health care setting. A relatively new field, the ongoing development of products requires robust processes in place to allow for appropriate and relevant testing to ensure that patient safety is not compromised. In addition, the testing of textile products to national and international standards will provide local and national procurement departments with effective evidence to allow for careful selection and purchasing power of products. This is going to be of increasing importance as we drive forward with the delivery and restructuring of healthcare.

As this is a growth area, new standards need to be developed that are appropriate and practicable for the environment within which they govern. Indeed some historical standards may need to be withdrawn. Furthermore, increasing international collaboration and an overlap of various fields such as engineering, health and technology will add a layer of complexity. In addition, the ethical, environmental and social frameworks within which we practise also need to be considered.

What does the future hold?

This article comprises a brief review of the potential future direction and the scope with which the medical textile sector may take. As the sector develops, new regulatory guidelines and standards will need to be designed to ensure that products conform to current legislation and do not compromise the safety of the individuals that are using them. The use of a broad panel of experts will allow for appropriate design and implementation and potentially will prevent any waste of resources; time, material, economic or otherwise.

Ultimately, as Steve Jobs, famously said "Good design is not just what it looks and feels like. It is how it works". As an engineer in the surgical world, and a natural perfectionist, I cannot think of a more apt description of how to practice the craft of design as we start to innovate and push the boundaries of what is currently possible.

A full list of references is available for this article, please contact Georgia Affonso to request a copy

Silicone teething necklaces from Pebbles and Lace provide baby-friendly jewellery for modern parents (Photos courtesy of https://pebblesandlace.com)

Bilateral Congenital Vertical Talus in Association with Beals Contractural Arachnodactyly

A Case Report

Holly Morris, MAppSc, MBChB(Hons), MRCSEd, and Pierre Navarre, MDCM, FRCS(C)

Investigation performed at Southland Hospital, Invercargill, New Zealand

Abstract

Case: Congenital vertical talus (CVT) is a rare rigid flatfoot disorder with a rocker-bottom flatfoot appearance. It is characterized by hindfoot valgus and equinus, with associated midfoot dorsiflexion and forefoot abduction. We describe a patient who was born with dysmorphic features and subsequently was diagnosed with Beals contractural arachnodactyly. After the diagnosis of bilateral CVT was made, it was treated with a single-stage open reduction. There was a unilateral recurrence, which was treated with revision surgery. The patient had an excellent functional outcome.

Conclusion: CVT often requires surgical management and may recur. To our knowledge, this is the first reported case of CVT associated with Beals contractural arachnodactyly.

The recognition and management of congenital vertical talus (CVT) remains challenging, but outcomes may be good with early diagnosis and appropriate management. CVT is a rare rigid flatfoot disorder with a rocker-bottom flatfoot appearance[1,2]. The prevalence is estimated to be 1 in 10,000 live births, but this is felt to be an underrepresentation because there is a lack of recognition of the condition in newborns[1]. It may present either as an isolated deformity or in association with neuromuscular or genetic diseases. Common neuromuscular associations include distal arthrogryposis and myelomeningocele[3]; genetic associations include aneuploidy of chromosomes 13 and 18[4].

The classic appearance of CVT is that of a rocker-bottom foot with a convex plantar surface, the apex of which is at the talar head. A fixed dorsal dislocation of the talonavicular joint leads to hindfoot valgus and a calcaneus that is fixed in equinus with a contracted Achilles tendon. Midfoot dorsiflexion and forefoot abduction with associated taut peroneal and tibialis anterior tendons cause the foot to evert into a valgus, externally rotated position[2].

Although there is a high association with combined neuromuscular and genetic conditions, a thorough literature review failed to reveal a single report of CVT in a patient with Beals contractural arachnodactyly. We describe a patient with Beals contractural arachnodactyly and bilateral CVT that required surgical management; a unilateral recurrence required revision surgery.

The parents were informed that data concerning the case would be submitted for publication, and they provided consent.

Case Report

The child was a firstborn who had been delivered to healthy parents by cesarean section at 40 weeks after failure to progress. Clomiphene stimulation had been used because of maternal polycystic ovarian syndrome, but the pregnancy was otherwise unremarkable, and an ultrasound scan of the anatomy at 19 weeks' gestation was normal.

Dysmorphic features were noted at birth, including contractures of the fingers with an overlapping thumb and a little finger that overlapped the ring and middle fingers. There were dorsiflexion contractures of the feet, and both hips were dislocated. Furthermore, it was noted that there was limited extension of the knees and elbows and that the heels were prominent. An atrial septal defect was detected on echocardiography. The ears had a truncated superior helix and an overfolded appearance. Based on these clinical features, a diagnosis of Beals contractural arachnodactyly was made at 14 weeks postpartum by a pediatric geneticist.

The finger contractures were managed with gentle stretching and manipulation and had a good outcome. Management of the dislocated hips involved an attempt to treat with a Pavlik harness, which was unsuccessful as seen on sequential ultrasound scans that demonstrated persistent dislocation; subsequent bilateral open reduction was

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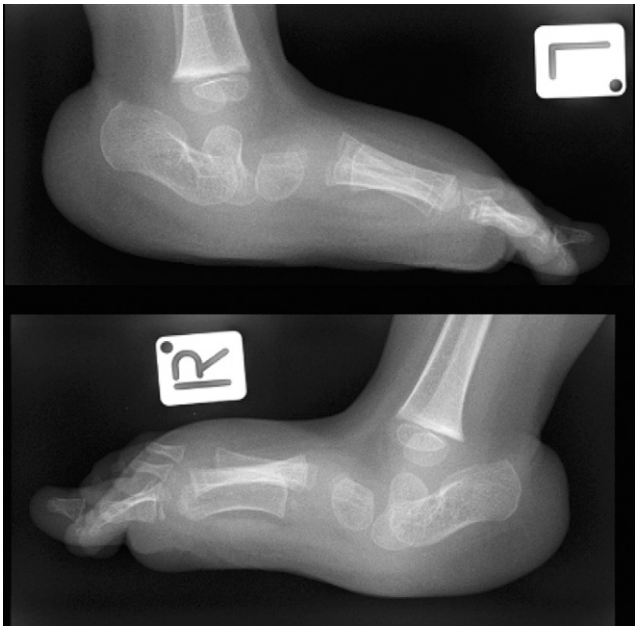

Fig. 1

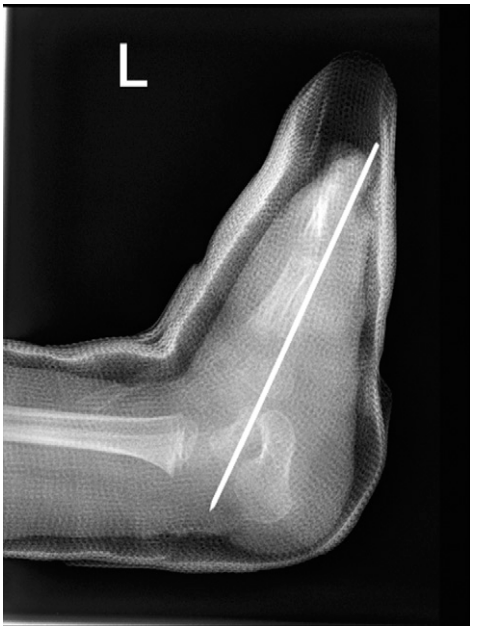

Fig. 2

Fig. 1 Lateral radiographs when the patient was 2 years old. **Fig. 2** Lateral radiograph following the initial surgery.

required when the patient was 1 year of age. Based on radiographs, the formal diagnosis of CVT was made when the child was 2 years old (Fig. 1).

At 2 years of age, the patient underwent correction of bilateral CVT in sequential operations. The talus was reduced in a single-stage operation that utilized 3 incisions: a lateral

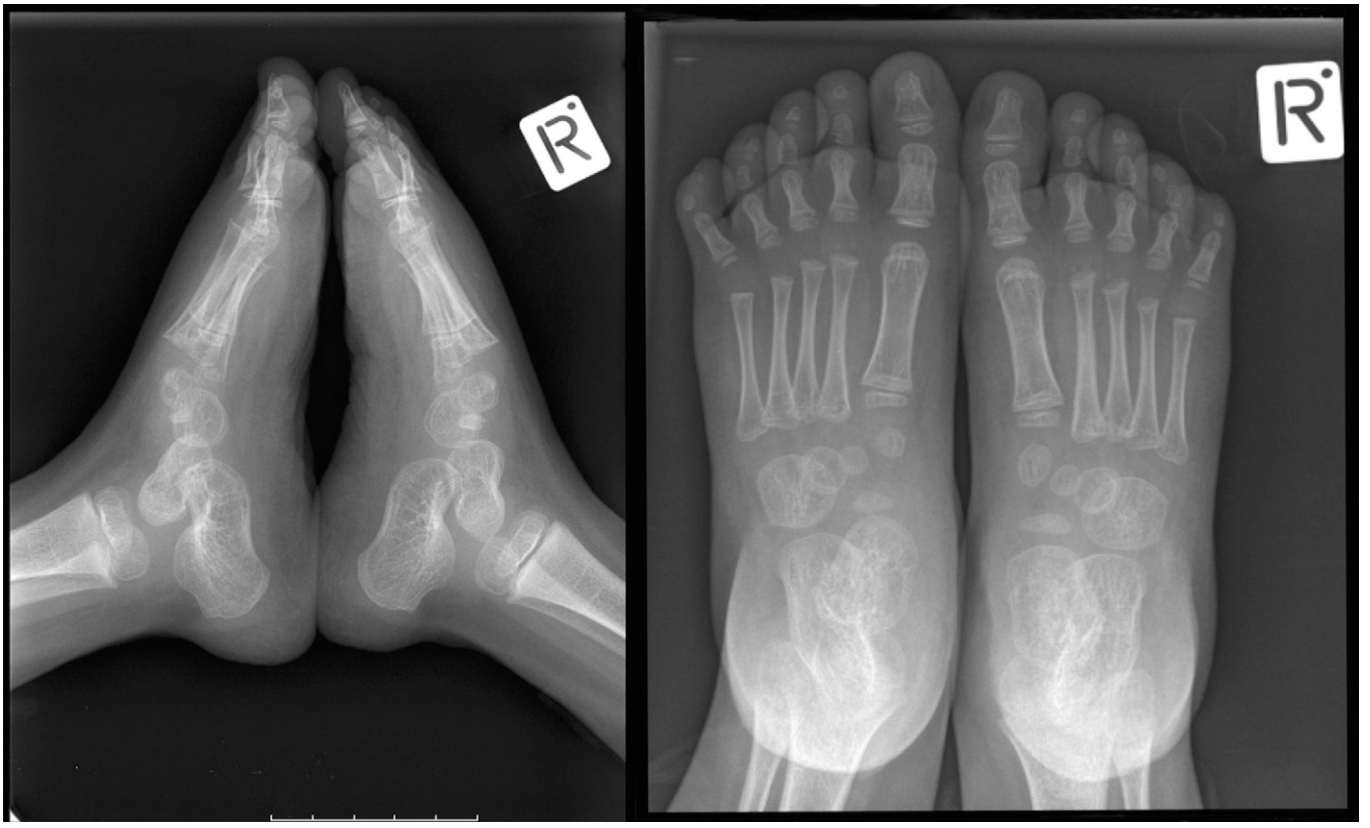

Fig. 3

Lateral (left) and anteroposterior (right) radiographs demonstrating the recurrence of the CVT in the left foot.

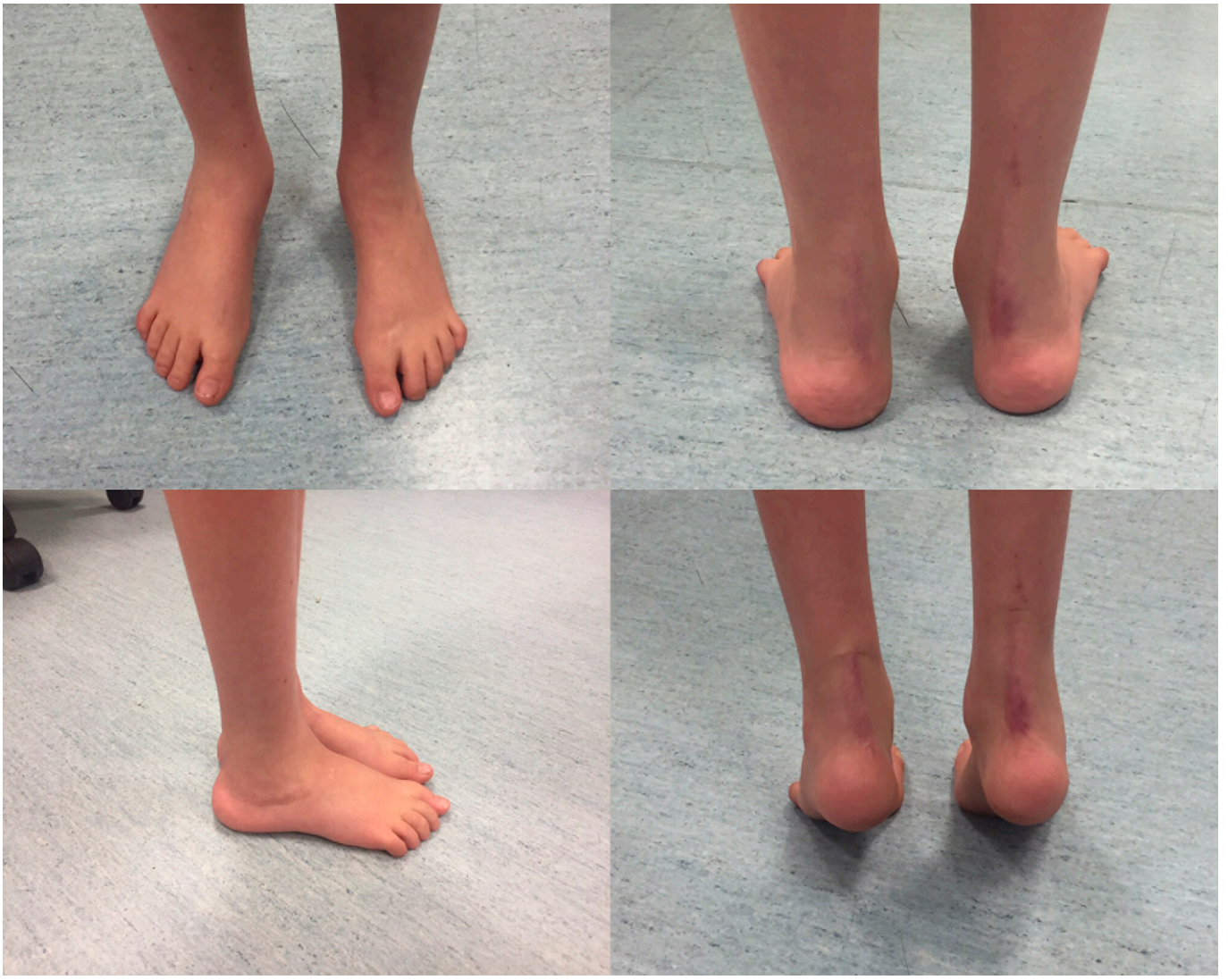

Fig. 4
Clinical photographs when the patient was 7 years old.

incision that was centered over the sinus tarsi, a medial incision that was centered over the head of the talus, and an incision medial to the Achilles tendon. Once the talus was reduced, a sling was created by splitting the tibialis anterior, passing it around the neck of the talus, and rejoining it to provide dynamic stability[5]. Z-lengthening of the peroneal tendons, the extensor tendons of the toes, and the Achilles tendon also was undertaken via an extension of the lateral incision (Fig. 2).

After a year, the malalignment of the left talus recurred (Fig. 3), and subsequent surgery was performed. During the revision operation, in addition to detachment of the tibialis anterior construct, extensive scarring was noted. After release, the navicular was mobilized onto the head of the talus, and a Kirschner wire was used to hold the position, as described by Dobbs et al.[6]. Furthermore, the tibialis anterior tendon was augmented with a tendon of the extensor digitorum longus. This was divided distally to maintain integrity of the muscle-bone unit, and it was transferred to the neck of the talus and held with a titanium suture anchor.

The most recent follow-up was when the patient was 7 years old. Although there was some slight residual planovalgus deformity, the child was walking independently with no notable gait disturbance, no substantial ankle and subtalar joint stiffness, and no functional limitation compared with peers. The final foot alignment is shown in Figures 4 and 5.

Discussion

Beals syndrome, also known as congenital contractural arachnodactyly, is an autosomal-dominant arthrogryposis that is characterized by kyphoscoliosis, abnormality of the external aspect of the ears, dolichostenomelia, arachnodactyly, and multiple contractures. Although the joint contractures are congenital, they have a tendency to lessen with age and with growth of the child, but interventions often are needed[7].

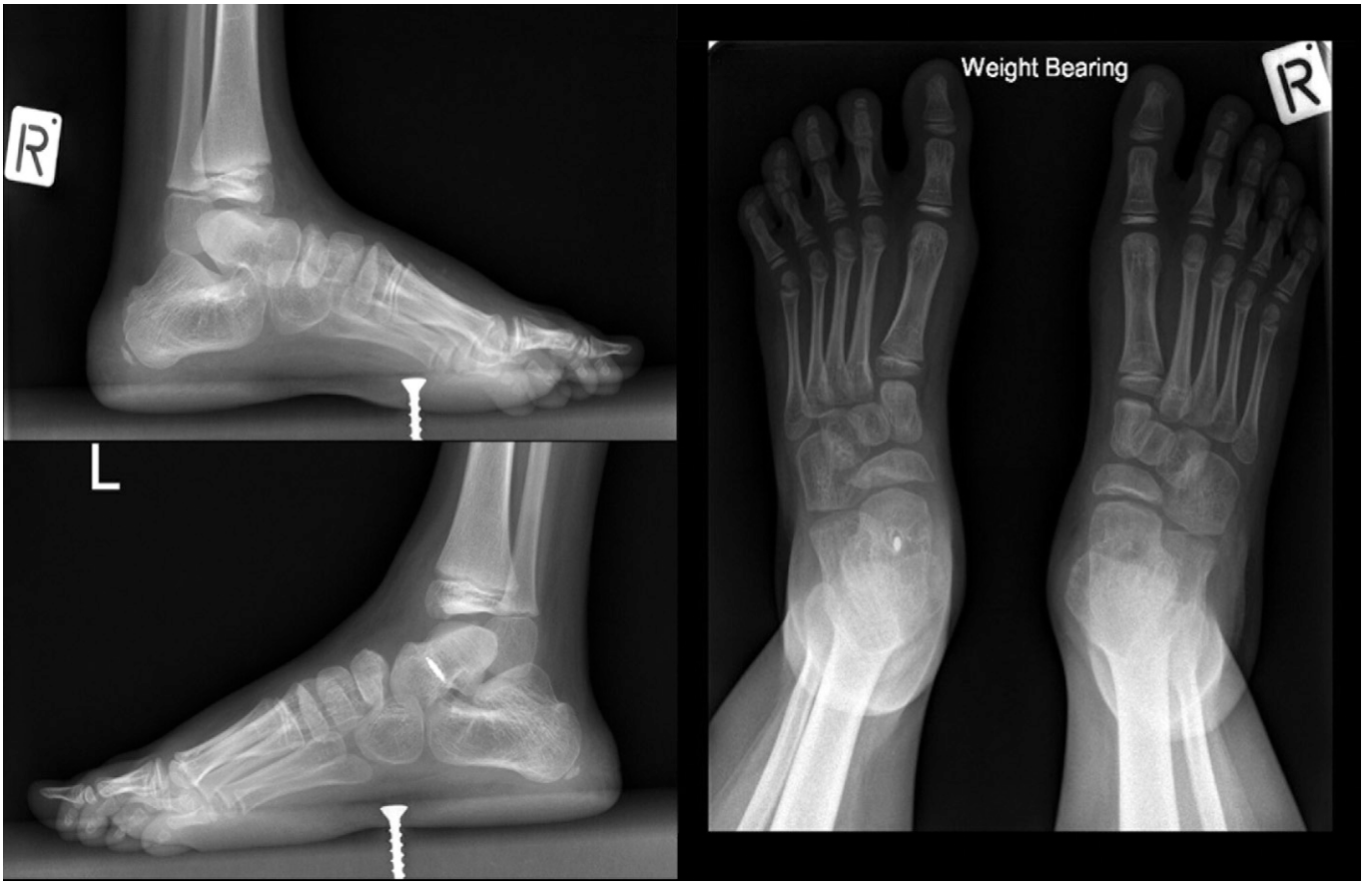

Fig. 5
Lateral (left) and anteroposterior (right) radiographs when the patient was 7 years old.

Historically, Beals contractural arachnodactyly often was misdiagnosed as Marfan syndrome because of an overlap of characteristic features[7]. While both syndromes are due to a defect in the fibrillin gene, each syndrome is caused by a defect at a differing genetic locus. Marfan syndrome is caused by a defect in the fibrillin-1 gene at 15q15-21, whereas Beals syndrome is caused by a defect in the fibrillin-2 gene at 5q23-31[8,9]. Fibrillin-2 is a component of microfibrils, which are found in tissues that are associated with the elastin system[10]. Fibrillin-2 appears with elastogenesis early in development, and it is predominantly located in elastic tissues (e.g., elastic cartilage and the tunica media of the aorta)[11]. In mice, it has been shown that an absence of the fibrillin-2 gene alters the constituents of tendons and causes an abnormality in bone growth, thus suggesting that fibrillin-2 influences the biochemical and morphological processes in connective tissue[12].

CVT has been described in a range of neuromuscular conditions, including myelodysplasia and arthrogryposis[3]. The literature on CVT reveals conflicting pathoanatomy and recommended management of the abnormality. Nevertheless, a unifying feature among reported cases is substantial pathology that is located at the level of the subtalar joint[13]. If untreated, the natural history is pain, abnormal callus formation, issues with shoe wear, and an abnormal gait. Treatment aims to restore normal relationships between the talus, the navicular, and the calcaneus, and to provide a plantigrade weight-bearing surface on the sole of the foot[14].

There are characteristic radiographic appearances with CVT. Standard views include an anteroposterior view and 3 lateral views: with the foot in maximal dorsiflexion, maximal plantar flexion, and neutral[1]. Standing views can be made with older children; on a weight-bearing lateral view, the talus appears in a nearly vertical position, almost parallel to the tibia[2]. Hamanishi defined criteria for the radiographic diagnosis of CVT[15]. In maximum plantar flexion, a talar axis-first metatarsal base angle (TAMBA) of >30° is diagnostic of CVT[15,16]. Ultrasonography may be used to diagnose CVT in infancy, and there are reports of the use of magnetic resonance imaging (MRI) for studying the pathoanatomy of the condition[13,17].

Traditionally, correction in patients who are <2 years old has been by surgical methods with a 1 or 2-stage extensive soft-tissue release. The first stage of the 2-stage approach included lengthening of the dorsolateral tendons, and the second stage involved lengthening of the Achilles and peroneal tendons. The 1-stage approach was a combination of these 2 stages. Complications include stiffness and degenerative osteoarthritis, which may require salvage procedures such as subtalar and triple arthrodeses. There have been reports of additional

procedures that include excision of the navicular and arthrodesis of the subtalar joint[18,19].

In 2006, a new method referred to as the reverse Ponseti, or Dobbs, technique was described. This involves serial manipulations and casting, followed by limited surgery with temporary stabilization of the talonavicular joint and release of the Achilles tendon[1,6]. This minimally invasive approach has obvious advantages, and medium-term follow-up data are promising, with a reduced recurrence rate and improved range of motion of the ankle and the foot compared with extensive surgery[20].

For those who are ≥2 years old, correction with extensive release and tendon transfers remains the preferred treatment option. If this is unsuccessful, talectomy or naviculectomy with extensive release and tendon transfer can be performed[21]. Children between the ages of 4 and 8 years may be treated with a combination of open reduction and extra-articular arthrodesis[19]. A triple arthrodesis can be considered in those who are >8 years old[21].

A late complication is restricted range of motion of the foot and ankle, which can contribute to calf-muscle atrophy and easy fatigability of the affected limb[22]. Recurrence of CVT is a common problem, and a higher recurrence rate has been reported in patients with spina bifida and other neurologic abnormalities[14]. Osteonecrosis of the talus is a unique complication of CVT surgery, although, to our knowledge, there have been no reported occurrences since the introduction of minimally invasive techniques[22].

In summary, this report describes bilateral CVT deformity in association with Beals contractural arachnodactyly. Correction was undertaken with a single-stage open surgical procedure when the patient was 2 years old. Recurrence occurred unilaterally, and revision surgery was needed when the child was 3 years old. At the 5-year follow-up, the patient had a very good functional outcome. ■

Note: The authors thank Mr. Murray Fosbender for his management of this patient prior to retirement.

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Medical textiles

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ABSTRACT

Medical textiles is an emerging specialist field within the textile industry showing substantial growth in the amount of research attention it has attracted over the past ten years and it is becoming a rapidly-growing part of the textile industry. Much of the stimulus for its growth has arisen from the establishment of nanotechnology enabling the incorporation of nanoparticles into fibre-forming polymers before spinning into filament form, nanofinishing treatments allowing nanomaterials to be added to fabrics and electrospinning enabling the preparation of fibre-forming polymers into nanofibres and also the incorporation of nano-particulate agents into the electrospun nanofibres. The performance of the emergent materials, particularly of those relating to antimicrobial action, have shown substantial improvement over many of their traditionally-prepared counterparts, not least in relation to their durability, which is typically high for those where the nanoparticles were blended into the polymer prior to spinning, or where covalent bonding to the fibre surface was involved. Absorbable polymer implants in fibrous, nano-fibrous and continuous-filament form have also been the focus of considerable research attention because they reduce/eliminate the need for further invasive surgery for their removal, whilst strong, durable textile structures whose performance can be modelled and predicted, have been and are being developed for the replacement of tendons and for the construction of pressure garments and wound dressings. This review serves to categorise the various domains, explore the range of textile materials and devices either emerging or now in use in healthcare and offers recommendations for future project areas to move healthcare and the medical textile sector forward. A critical review is provided of single-use items of PPE and the lack of preparedness for the recent pandemic; solutions for circumventing the shortcomings of single-use items are presented.

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1. Introduction

Medical textiles is one of the fastest growing parts of the technical textiles sector of the textile industry, with products ranging from personal protective equipment (PPE), bandage and dressing materials through to implantable prosthetics and bioscaffolds for tissue engineering. Due to advances in technology, and mainly, but not only in

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nano-technology, the technical medical textile sector is undergoing rapid progression and expansion particularly in fields such as wound healing, pressure and bandaging garments and implantable textiles. In addition there is growth in medical devices aided by incorporation of a growing range of durable and effective antimicrobial agents. Population growth, an ageing population and rising standards of living will all continue to fuel the growth of this sector.

The following review aims to provide an update and overview on the role in which textiles can be used in the healthcare sector as well as reviewing current developments within the field. As part of that process, the papers on medical textiles published between the year 2000 and 2020 in the two key textile journals, namely the Journal of The Textile Institute [1] and the Textile Research Journal [2] have both been checked individually to determine not only the levels of research output on medical textiles but also the topics being addressed. For a more-overarching view, the record provided by Pubmed®/Medline® for papers on medical textiles was also checked. What the exercise revealed was that between the years 2000 and 2020, a total of 494 papers were published in the two textile journals on topics relating to medical textiles; of these, over half (267) were published within the last 5 years and of the papers published, antimicrobial textiles was by far the largest category across the whole 20-year period, accounting for 203 papers in total. For Pubmed®/Medline®, from 2000 to 2020, a total of 3,264 papers about medical textiles were published and once again, over half of the total (1713) emerged in the last 5 years; the largest category for the past 20 years, antimicrobial textiles, accounted for 1,122 papers in total. The papers were reporting research on both the development and incorporation of the antimicrobial agents to bring about the desired antimicrobial effects and on the efficacy of the resultant textiles/garments. The intended applications of the antimicrobial textiles ranged from barrier fabrics in uniforms for health-care personnel and in their Personal Protective Equipment (PPE), through sutures and implantable items, to wipes, dressings for wound care and hospital textiles in general. The surge in published research on antimicrobial topics over the past 5 years can be attributed, at least in part, to advances in nanotechnology [3] enabling the incorporation of the active antimicrobial agent in nanoparticle form into the textile either during spinning of the fibre-forming polymer or through finishing treatments. Helpfully, the nanoparticles can be applied to fabrics intended for medical use without detrimental effects on their textile properties. Regarding effectiveness, such treatments with antimicrobial agents in the form of nanoparticles can demonstrate high levels of antimicrobial activity coupled with excellent durability (both in use and through repeated cycles of laundering), much better than metal salts or adsorbed quaternary ammonium compounds for example, which work by leaching from the treated fabric and therefore become diminished by laundering. The fully-developed versions of antimicrobial nano-finishes can therefore find widespread application. In this regard, *Nano-silver (Nano-Ag)* treatments can be thought of as leading the way. Despite concerns (even in this case) over possible leaching of the nano-silver from the garment onto the skin of the wearer (which it would be wise to keep under review), skin contact has been shown to be not so great a problem [4, 5]. As for loss into the environment at the end of the textile's useful life, given consideration of the complete lifetime assessment, concerns are reduced, and

nanosilver treatments can be seen to have continued to contribute to health and to establish a secure and substantial niche in the market for antimicrobial textiles [6]. That may be so, but there are now several other nano-particulate agents and combinations of agents demonstrating similarly-high levels of effectiveness, and pre-treatments for example with chitosan or carbon nanotubes are being shown to enhance not only uptake of the active agents, but also their effectiveness and durability. Overall however, the antibacterial treatments that show the most benefit in practice are multifunctional finishes which combine antimicrobial action with surface modification to enable the fabric to repel/shed hazardous liquids such as bodily fluids.

Within this issue of Textile Progress, antimicrobial treatments on textiles will be addressed in the context of each particular application. What is interesting to note is that whilst there might have been a substantial surge in the development of antibacterial treatments for textiles, the same level of activity does not explicitly apply to viruses. Although there was a single reference to virus removal by liquid filters (for water treatment) [7] and a small number to surgical respirators, there was only one reference to work engaged specifically in the development of an antiviral barrier item to form part of the healthcare workers' Personal Protective Equipment (PPE). Great credit must therefore go to the two researchers from PSG College in Coimbatore, Parthasarathi & Thilagavathi [8] for trying to more-fully address improved protection from potential infection by viruses, which are somewhat more difficult to research and to test.

Electrospun nanofibres are relatively slow to produce compared to outputs from traditional wet, dry or melt-spinning processes, but worth the effort because of the very particular properties they possess on account of their fineness, and consequent extremely high surface areas together with great flexibility. The electrospinning process is well-established and can be applied to a wide range of polymers given suitable solvents and sufficient polymer-chain entanglement. Although they can be collected and used in the form of a web, such webs are very weak and tricky to handle, so most interest lies in collection in the form of continuous bundles or yarns of nanofibres, bundles which can be of very neat construction and may be twisted together to yield two-fold nanofibre yarns for example. Also, yarns can be created by coating a conventional filament yarn with nanofibres to bring together in that core-spun yarn characteristics not achievable alone; such core-spun yarns have the strength of the conventional yarn combined with the surface characteristics of the nanofibres. Moreover, dissolving that core can yield hollow yarns (of interest as reservoirs for drug delivery). Electrospun yarns made from synthetic absorbable polymers (SA polymers) now play a significant role in medical textiles; this has occurred not least because of the way the massive surface areas and the porosities of electrospun fibrous assemblies/fabrics provide such excellent scaffolds for cell proliferation and growth during the period that the steadily-degrading polymer is needed to continue to offer support. The sought-after performance from these particular materials arises therefore, not only from the nano-fibrous nature of the textile support, but also from the properties conveyed into the structure by the SA polymer. Accordingly, there has been a significant amount of work carried out on candidate SA polymers and the best ways of preparing the fibrous materials in order to achieve repair without the need to engage in further

surgical procedures to remove the support once it has achieved the desired effect. Mokhtari et al (2016) [9] provide a long list of the candidate polymers for biomedical applications in their review of advances in electrospinning and its applications. It not only includes details about bioactive nanofibres and their biomedical applications, but also the use of nanofibrous assemblies in filtration and the applications of electrospun materials in sensor and actuator structures, all of which are relevant to the topic being reviewed here. In this issue of Textile Progress therefore, detailed reference to electrospun bundles, yarns or webs will mostly be made in the context of particular types of medical textile.

1.1. Textiles in medicine and the medical environment

As defined by The Textile Institute, a medical textile is "a textile structure which has been designed and produced for use in any of a variety of medical applications, including implantable applications" [10]. The first references to the use of textiles in medicine and healthcare date back to Ancient times. Over 130 wounds sustained during the Trojan War, and the management of them, are discussed by Homer in his poem, the Iliad. Prior to this, the Egyptians used bandages to splint broken bones and to wrap around bodies in the mummification process [11]. In ancient times, it appears that leaves, grasses and flaxes were used as wound dressings. It has also been hypothesised that bandages may have been made from wool or linen, though evidence of these has long since degraded [12].

The Hippocratic statement of "*natura medicatrix*", the healing power of items from nature is well known though often disregarded [13]. Indeed, natural textile-based products continue to be used in current times and the progression of technology has allowed for careful engineering of nature to our advantage; for example, the antimicrobial properties and structure of spider webs being used in nanotechnology [14]. Whilst the Hippocratic Oath, once sworn as entrance into the medical profession, has been replaced by the Declaration of Geneva, the fundamental principle that the health of the patient will be the first consideration remains [15]. Certainly, patient safety is of paramount importance and due consideration needs to be granted as there can often be a very fine line between causing considerable harm and undertaking considerable good, hence medical practitioners need not only to be equipped with the means to help the patient but also adequate personal protection to help them to keep working effectively.

The area of medical textiles can be subdivided into sections based upon the end use of the fibre, garment or product. Wang [16] neatly classified the areas within medical textiles as

- Implantable materials, e.g. sutures, grafts, scaffolds
- Non implantable materials, e.g. wound dressings, pressure garments
- Healthcare/hygiene roles, e.g. clothing, disposable products such as wipes
- Extracorporeal devices, e.g. artificial kidney, liver, pancreas
- Intelligent medical and healthcare textiles

Each subdivision will be considered in turn.

1.2. Properties sought from textiles for medical and healthcare applications

Medical and healthcare textiles must exhibit certain properties and these will depend upon the overall purpose for which the textile has been designed and manufactured [16]. Generally speaking, the textiles should be non-toxic and biocompatible. They should be hypoallergenic and non-carcinogenic. Stability of the product is important, particularly if implanted as degradation and the degradation products need to be non-toxic and must not accumulate in body tissues.

Depending upon the role of the medical textile, the textile may need to be biologically inert. Alternatively, it may need to be biologically active; for example, delivering a drug to a target organ at a controlled rate. The textile may need to demonstrate

- Strength e.g. an implantable scaffold or suture
- Flexibility e.g. a vascular graft
- Air permeability e.g. a wound dressing
- Moisture absorption and permeability e.g. a wound dressing

Some textiles need to be sterile and the sterilization process must not alter the mechanical properties, chemical composition or biological function, if any. For example, artificial joints sometimes contain components made from polyethylene; different sterilisation methods each have their own advantages and disadvantages; sterilisation with high-dose irradiation produces a highly cross-linked polyethylene with better wear resistance but a decreased fatigue compared to standard polyethylene [17]; see also Section 1.3.2.2. For textiles aimed at consumers, treatments need to be both affordable and socially acceptable. Finally, with increasing environmental legislation, production and disposable of products should be in line with current guidance, either nationally or internationally, depending upon the target market.

1.3. Candidate textile materials for medical applications

The next section provides details about fibres and filaments that are used for medical and healthcare applications. It is not an exhaustive list but aims to cover the common fibres.

1.3.1. Natural fibres and filaments

1.3.1.1 Animal-based protein fibres. ***Wool*** fibres form the fleece that is there to protect sheep from the extremes of heat, cold and rain. Wool and animal hairs are of similar composition. They are all keratin fibres with two distinct components:

i. overlapping tile-shaped cuticular cells on the fibre surface, and
ii. long, thin cortical cells arranged lengthwise along the middle of the fibre.

Whilst the keratin in the cortical cells contains a substantial proportion of the fibre's cysteine, each of the outer layers of the cuticular cells contain progressively more and more, and being composed of very-highly, cross-linked protein the cuticular cells are therefore both physically hard and resist water penetration [18]. The cortex of the fibre

in both cases is composed of the protein keratin which is typified by long helical protein chains cross-linked at regular intervals through the disulfide bonds in the amino acid cystine. The helical protein chains confer on wool its substantial extensibility, especially when wet, and the regular cross-linkages from cystine assist it to return to its original dimensions, again especially when wet, see for example, the CSIRO summary of wool structure [19].

Keratin can be extracted from natural sources and regenerated in the form of films, sponges and hydrogels [20] and it improves the production of anti-inflammatory cytokines and decreases the quantity of pro-inflammatory cytokines [21]. Its high cystine content differentiates keratin from other structural proteins such as collagen and elastin and this influences its mechanical and chemical properties due to the inter- and intra-chain cross-links formed by the cystine disulphide bonds which cause a higher stability and lower solubility. Ionic bond formation is pH dependent and is greatest at the isoelectric point of pH 4.9 [22]. Keratin extracted from wool fibres can be used as scaffolding for fibroblasts and osteoblasts due to its inherent ability to facilitate cell adhesion, proliferation and regeneration [23]. Indeed, sheep's wool has been used in tissue-engineering scaffolds [24, 25]. The key properties of such scaffolds is that the sponges demonstrated highly interconnected porosity and contain intrinsic sites of cellular regeneration that mimic the extracellular matrix [26].

Modification of wool fabrics with zinc oxide nanoparticles increases the UV light absorbance compared to untreated wool [27]. Studies have shown that modification with graphene/titanium dioxide nanocomposites produce a fabric with antibacterial properties towards both *Staphylococcus aureus (S. aureus) and Escherichia coli (E. coli)* [28]. A similar treatment is also effective on cotton fabrics [29] and given the advent of antibiotic-resistant bacteria, its potential for developing dressings that outsmart resistant bacteria is particularly attractive. Work undertaken by Laing et al demonstrated that socks composed primarily of wool can positively affect observable measures of skin health. In addition, merino wool socks maintained their energy-absorbing properties better than cotton socks suggesting they may be beneficial in individuals requiring cushioned socks [30]. This has many potential applications throughout the clinical and consumer healthcare market and is not a new concept; using animal hair in clothing which began to establish a comfort/hygiene trend in the late 1800s, particularly with the idea of moving away from the more extremely-restrictive women's fashion garments of the time, saw the award of a gold medal to Jaeger at the International Health Exhibition in the 1880s [31].

Silk fibroin in continuous form is derived from *Bombyx mori* cocoons with a single cocoon yielding 600–1500 m. It demonstrates biocompatibility, has controllable degradation and can be chemically modified to alter its surface properties or to immobilize growth factors [32].

Silk has been used as a suture material for centuries [33], though for this application to be a success, the fibres are often coated in wax to prevent fraying and to avoid invoking an immune response to sericin, which consists of soluble glycoproteins that cover the surface of the fibroin core [34, 35]. As technology has progressed, the ability to produce recombinant silk and engineer silk fibroin in the form of hydrogels, sponges, nanospheres and scaffolds has seen the uses expand into the

pharmaceuticals and regenerative medicine [36, 37]. Attractive mechanical properties of *Bombyx mori* silk for medical textiles include its toughness, with a breaking energy of 6 x 10^4J/kg [38]; tougher than Kevlar (DuPont) [39] at 338 N, the strength-to-density ratio is up to ten times higher than that of steel. It also demonstrates a high ultimate tensile strength of 740mPa [40]; by contrast, collagen has an ultimate tensile strength of 0.9–7.4 MPa [41]. Silk however, degrades with time, the rate affected by implantation site, mechanical environment and the way in which silk is processed.

There are other types of silk including those produced by spiders [42] and they possess different mechanical properties; for example, spider silk fibres exhibit high extensibility and strain-hardening (an increase in the stress required to bring about further extension as a fibre is extended within the plastic region beyond the yield point). Strain-hardening is important in energy-absorbing materials hence this particular behaviour has proved to be attractive to those involved in regenerative medicine particularly when designing implants for use in load-bearing tissue, but products are still under development and not yet in clinical practice [43].

The SERI Surgical Scaffold, a surgical mesh, is used in abdominal wall reconstruction and plastic surgery applications in the United States. There is published data available reporting the clinical use but no long-term data is currently available and some of the published data may not be considered independent [44]. Externally, silk is gaining increasing interest as a hydrogel for wound dressing. It can also be sterilized; different methods causing a change to functional and mechanical properties [45]. Silk is already used in clothing to treat dermatological conditions including atopic dermatitis and acne vulgaris; the long, smooth filaments/few fibres ends in the filament fabrics minimising mechanical irritation of the skin. Finishing of the silk has allowed for chemical modification and finishing treatments to achieve antibacterial properties [44].

1.3.1.2 Plant-based cellulose fibres. Seed hairs. **Cotton** fibre grows on the seed of a variety of plants of the genus *Gossypium* [46] and 95% of the world's cotton is from *G. hirsutum,* which originated in Central America. However, over two thirds of the world's cotton grown today is genetically-modified (GM) cotton, containing genes from the bacterium *Bacillus thuringiensis (B. thuringiensis)* aimed to act as an insecticide (Bt cotton) and/or genes that confer herbicide tolerance [47]. Cotton fibre is traded in more than 150 countries with around 270 million farmers living by growing cotton [48]. A natural cellulose fibre, it has 1,4 D-glucose pyranose as its repeating unit along the polymer chain, a chemical structure which offers the opportunity for its polymer chains to become firmly hydrogen-bonded to one another, for some crystalline regions to form and for moisture absorption to take place in the less well-ordered regions. Fibre length varies from approximately 10–65 mm with a diameter from 11 to 22 μm; those fibres with a length greater than 12 mm can be used in the production of nonwovens.

Cotton has been nicknamed the 'King of fibres' and has a wide variety of applications. Being naturally permeable due to its twisted fibres and their hollow interior, together with its ability to withstand sterilisation/high temperature laundering and bleaching means that within the healthcare sector it is used for bedding, gowns and uniforms as well as for more specialist purposes, such as baby diapers, feminine

hygiene products and nursing pads [49]. One of the key properties of scoured and bleached cotton is its hydrophilic nature which enables absorbent textiles to be produced, but care therefore needs to be taken in healthcare applications as it may serve as a nutrient reservoir for microbes and contaminated fibre fragments can be lost from garments into the surrounding air. Indeed, there has been much work directed towards the manufacture of antimicrobial cotton fabrics and in particular, a focus on the production of cotton finishes with silver nanoparticles; a variety of manufacturing processes have been utilised including impregnation [50] and sonochemical deposition [51].

Excellent antimicrobial activity against *Escherichia coli (E. coli)* in vitro trials was exhibited. Furthermore, the inclusion of silver nanoparticles into cotton fibres improved thermal stability and this may be beneficial in the sterilisation process [52]. Finishing cotton with nanocomposites of zinc-oxide can produce a fabric that displays enhanced protection against ultraviolet rays in addition to antimicrobial properties against *Staphylococcus aureus (S. aureus)* and *Klebsiella pneumoniae (K. pneumoniae)* [53]; the potential uses for this overlap into the consumer market.

Kapok fibres enclose the seeds of the kapok tree, *Ceiba pentandra*. It is a typical cellulosic fibre with a round microtube with smooth surface and a thin wall. The diameter is approximately 10 micrometres and length around 1.6 centimetres [54]. It is the least-dense natural fibre and exhibits both hydrophobic and oleophilic properties provided by a waxy cutin on the fibre surface [55, 56]. Conventionally, kapok has been used as stuffing for bedding and upholstery as well as for insulation against sound and heat because of its air-filled lumen [56]. It is a brittle fibre with low cohesivity and strength and as such, cannot easily be spun like cotton fibre, although it has been successfully blended with cotton fibre to form yarns, reducing the tenacity but providing an increase in extensibility. There are few areas of general application for the fibre in medical textiles, but kapok can be used to engineer microtubes on a large scale; essentially the kapok forms a hollow, removable form around which a synthetic polymer may be cast; experiments showed that the surface morphology and wall thickness of the microtubes were easily modulated by controlling processing conditions [57]. Coated with polyaniline, the kapok can be removed by treatment with NaOH solution to leave polyaniline microtubes suitable for use as supercapacitors, energy-storage components in Smart Textiles [58, 59], see Section 7. In regenerative medicine, the ability to create a microtubule structure, may be of benefit for those requiring scaffolds for cell growth. Silver nanoparticles can be combined with the fibre with good antibacterial performance in in vitro trials [60].

Bast fibres. A widely utilised biofibre, ***flax***, *Linum usitatissimum*, has been found in graves in Egypt dating back to 5000BCE [61].

The growing cycle of flax is short with just 100 days between sowing and harvesting in the Western European region [62].

The flax fibres, produced as one of the structural components of the stems of the flax plant, are composed of cellulose in a structure that is more crystalline than that in cotton, which makes the fibres stiffer and more rigid. The fibres are extracted by partial rotting to enable removal of the outer parts of the plant stems followed by opening out and cleaning of the fibres of the stem so their structure is complex with

several concentric cylinders of cells and layers of cellulose microfibrils of various lengths [62]. Flax fibres demonstrate a non-linear stress strain curve with a transition point to a lower tangent modulus at strains between 0.3% and 0.5%. This is due to several phenomena including, plastic yielding of some components of the elementary fibres, shear yielding of the bonding layer between them and reorientation of the elementary fibres. The stiffness of flax compares well with that of glass, 55-75GPa compared to 70-74GPa for glass. It has a tensile strength greater than jute, at 800-1500 MPa and also demonstrates hydrophilic properties, though such moisture absorption affects mechanical properties; as the fibre swells, stiffness and strength both decrease [63].

Regarding its medical textile applications, flax is increasingly used in bio-composites, for example, as the reinforcing fibre in biocomposites for tissue engineering because of its biocompatibility. Fibroblasts are known to proliferate well on scaffolds made from flax fibre blended with polylactide or polycaprolactone [64]. *In-vitro* trials have seen silver-nanoparticle-coated linen fabric demonstrate good antibacterial capability against both Gram positive and Gram negative bacteria [65] which, combined with its hydrophilic properties makes it attractive for use in wound dressings. The fibres have also been used experimentally as sutures but further work is required [66].

Hemp has a long history of cultivation for various purposes including fibre, medicine, recreational drugs and food. It is one of the oldest fibres to have been used in textiles, having been discovered in tombs in Mesopotamia dating back to approximately 8000 BC. A bast fibre, hemp is the second most-widely used natural fibre in composites, after sisal; its fibres are contained within the tissues of the stems and they impart strength and stiffness to the shrub, which is what makes them useful as a textile fibre, but one of its drawbacks is the variability between crops [67]. With a cellulose content of 57-77%, not dissimilar to that of flax, but with a higher lignin content of 3.7-13% compared to 2.2% for flax, hemp offers a density similar to that of flax and jute, with a tensile strength of 550-900 MPa and a Young's Modulus of 70 GPa [68].

Over 500 natural compounds have been identified in hemp; a number of these exhibit antibacterial properties which makes hemp one of the most studied of the bast fibres [69]. The concentrations of the bioactive compounds depend upon many factors including plant tissue type, age, variety, growth conditions, harvest time and storage conditions [70–72]. Cannabinoids and the phenolic component of lignin have demonstrated antimicrobial activity against a range of bacteria and fungi, some of more clinical relevance than others [69]. Hemp oil is already used topically for skin conditions in the consumer market. Drawing on this, the fibres may be able to be utilised in a safe and effective way for medical dressings and bandages. In addition hemp fibres could prove to be a useful component in bio-composites in a wide range of prosthetics, including implantables, given their radio-opacity [73].

Leaf fibres. ***Sisal*** fibre is obtained from the leaves of *Agava sisalana* [74]. Native to tropical and sub-tropical North and South America, it is now widely grown in tropical parts of Africa, the West Indies and the Far East [75]. A plant produces approximately 250 leaves and each leaf contains 1000-1250 fibre bundles composed of 4% fibre, 0.75% cuticle, 8% dry matter and 87.25% water [76]. The leaf contains three types of cellulose fibres; mechanical, ribbon and xylem. It is the mechanical fibres that are the

most commercially useful and these are extracted predominantly from the periphery of the leaf by retting (partial degradation) followed by scraping or by mechanical means with decorticators [75]. In a similar manner to hemp, the composition of the fibre varies with age, source, growth, harvesting and storage conditions, and figures quoted vary widely, with a cellulose content between 43-99% and a lignin content of 8% [77]. A fibre is between 1-1.5 m in length and the diameter ranges from 100-300 μm [75]. Mechanical properties vary between fibres; strength and stiffness depend upon the cellulose content and the angle made between the bands of microfibrils in the inner secondary cell wall and the fibre axis [78]. Furthermore, tensile properties are not uniform along its fibre length with that from towards the lower part and root exhibiting a low tensile strength and modulus but high fracture strain, whereas the mid portion fibre is stronger and stiffer. Tensile strength quoted in the literature ranges from $347 - 700$ MPa and the tensile modulus, 7-22 Gpa [77]. Sisal is biodegradable and recyclable and can be treated during textile finishing to adjust its functional properties in the same way as other cellulose fibres and in the consumer healthcare market, sisal has been used to manufacture scrubbers for removing dead skin cells [79]; for the future, sisal may prove to be a useful natural fibre for the manufacture of surgical drapes given growing environmental legislation and requirement for safe disposal.

Manila is obtained from abaca, *Musa textilis* [80]. The plant is closely related to the banana plant but the fruit is not for human consumption and so the abaca plant is grown only for its fibre [81]. The fibre has one of the highest densities amongst the natural fibres at 1.5 g/cm^3. A strand typically has a length between 1 and 3 m composed of fibre ultimates of around only 5 mm in length and a width around 20 μm. Tensile strength is quoted at 430-813Mpa and a Young's Modulus of 32 GPa [82]. Interestingly, abaca fibres exhibit a strong resistance to saltwater and can be used in saline environments which may be of use in complex wound management where the wound needs to be kept moist for healing [80].

1.3.1.3 Natural polymer. Regenerated protein fibres. ***Casein*** is a completely biodegradable natural polymer consisting of the phosphoproteins extracted from raw skimmed milk by acidification [83]. It is able to be formed into filaments or film and shows good heat resistance. Casein filaments can be wet spun by dissolving the casein in dilute sodium hydroxide solution and extruding the solution into a coagulating bath containing formaldehyde; their production in filament form was first reported in the 1940s [84]. Various formulations have been designed for drug-delivery purposes [85, 86], including combinations with zein in electrospun nanofibres [87]; the proteins demonstrate open and flexible conformations consisting of both hydrophilic and hydrophobic segments. In general, they have a highly hydrophobic nature and thus individual caseins are most stable for use when formed into micelles [88]. One of the benefits of utilising casein in healthcare products is that as a food grade protein it is digestible if ingested. It is relatively economical to produce, and it offers a good capability to interact with a wide variety of compounds and nutrients, for example, drugs and vitamins [89].

Collagen fibres are natural macromolecular protein assemblies that play a vital role in structures that support tensile mechanical loads in the human body/animal bodies. There are different subtypes of collagen but the most abundant form is type I

collagen, the primary structural motif in tendon and ligament [90]. The structure of collagen is complex; right-handed triple helical structures are assembled into microfibres by hydrogen bonds. Cross-linking aggregates the chains into a triple helix to provide stability to the molecule and then several molecules aggregate in a quarter-staggered array to form microfibrils, which further aggregate to form the fibres [91, 92]. Collagen can be extracted from connective tissues, purified and reconstituted into gels and scaffolds. Purified collagen remains a preferred base for ligament and tendon tissue engineering due to its low antigenicity, a chemotactic surface structure for fibroblasts, biocompatibility and proteolytic degradation pathways; collagen-based fibres are in contemporary clinical use as sutures, though these cannot be used for scaffolding due to inflammatory tissue reactions [93].

Regenerated cellulose fibres. ***Viscose rayon*** and its associated industry is the oldest of the existing man-made fibre businesses (slightly older and more extensive than that of cuprammonium rayon) with roots stretching back to the late 19th century. A fibre made from regenerated cellulose, the starting material is purified wood pulp from spruce or eucalyptus trees, but it can also be produced from parts of other plants with a high cellular cellulose content such as soy plant stems, bamboo and sugar cane; when used, these other cellulose sources are often mentioned in the promotional literature presumably with the purpose of making the resulting viscose rayon products sound more acceptable. In fact the process, once the cellulose fibre pulp has been prepared, is the same as for wood pulp from trees. As for wood pulp, the original pulp is purified to remove lignin and undesirable colourants then temporarily chemically modified into sodium cellulose xanthate to render it soluble in sodium hydroxide solution prior to spinning; the syrupy so-called viscose solution is extruded into an acidic coagulating bath (wet-spun) to regenerate the cellulose and yield continuous filaments of viscose rayon. The filaments are then drawn and washed before winding, and depending upon the method of manufacture and extent of drawing, different physical and mechanical properties can be provided to the resulting fibre [94].

For example, subjecting the emerging filaments as they are being extruded to very high levels of extension, causes the regenerated-cellulose molecules to become better orientated along the filament axis and results in a more highly-crystalline filament. This yields a somewhat stronger filament with reduced extensibility but despite the improvement and although in filament form it may resemble silk, with a breaking tenacity of 25cN/tex, elongation of 20% and moisture absorption of 11%, the mechanical properties of the regenerated cellulose are still no match for silk fibroin [95]. In the case of modal viscose rayon, the method of manufacture is altered and further improvement in the mechanical properties is gained by retaining some of the original crystallinity present in the original source of the cellulose, thereby improving the breaking strength and wet modulus [10]. Viscose rayon is an absorbent fibre and this property is utilised already within the healthcare industry for wound-care, as absorbent pads or base materials in advanced dressings, bandages and gauzes [96].

Lyocell, named in 1989, owes its genesis to the Greek word lyein which means 'dissolve' [94, 97], and it is the generic name for a regenerated cellulosic fibre obtained by spinning cellulose dissolved in an organic cyclic polar solvent, N-methyl morpholine-N-oxide [10, 98, 99]. The first commercial product, Tencel^{TM} (Lenzing AG, Austria),

was originally released by Acordis in 1988. The starting material for lyocell, as for viscose rayon, is wood pulp, but the manufacturing process used to take the cellulose into solution is different; temporary chemical modification to render the cellulose soluble in the case of viscose rayon but only dissolution for lyocell, where the dissolution involves using the organic cyclic polar solvent N-methylmorpholine-N-oxide (NMMO) hydrate under intensive shear forces and simultaneous evaporation of water. The solution of cellulose in NMMO hydrate is subsequently filtered and then extruded into a water bath through fine jets. As the solvent is washed out, the fibres form into fine filaments which can be collected and a very-high proportion of the solvent recycled for a further round of dissolution [97]. The lyocell fibre has a high degree of orientation with a crystalline to amorphous ratio of approximately 9:1. This offers good wet and dry tensile strength and that makes the fibre readily washable. In addition, the fibre has good dimensional stability and its fabrics shrink less on wetting than those made from cotton and viscose rayon [98], but one of the issues of lyocell is that the fibres fibrillate along their length and produce microfibres when wetted due to the highly crystalline structure of the fibre. Whilst there has been work aimed at reducing the fibrillation, it can be used to advantage during the production of nonwoven fabrics but it could cause issues in products intended for implanting in the body because the shedding of microfibres could potentially cause harm [100].

The fibre can be blended with other fibres and it has industrial applications in wipes, medical swabs and gauzes. For example, lyocell blended with bamboo charcoal yarn creates antimicrobial properties raising the possibility of utilising blended lyocell in hospital clothing, bedding and surgical gowns. Hydrocell® (Integra LifeSciences Corp, Plainsboro, New Jersey, America), based on lyocell technology, offers similar properties to calcium alginate (discussed later in this section). It forms a coherent gel in a moist environment and is utilised in wound care products [97].

Other natural fibres. ***Calcium alginate*** is a polymer extracted from brown seaweed, *Phaeophyceae,* by treatment with sodium hydroxide solution, then extruded into a coagulating bath (wet-spun) containing calcium salts to form calcium or mixed calcium/sodium salts to form filaments [101], which, in one of its more-routine applications is used in hospitals in the form of water-soluble alginate bags for 'used' (soiled) linen, as the first layer of protection for the health-care worker before being put in a clear plastic bag which can then be safely tagged for place and date. The polymer does however, possess several properties that make it highly-suitable for wound dressings; for example, it has the ability to swell and retain water and wound exudate, thus contributing to the moist wound environment. Furthermore, the gel-forming property allows the dressing to be removed with ease, thus reducing tissue trauma. Calcium alginate is also a natural haemostat and is non-degradable in mammals due to their lack of the enzyme alginase [101–103]. The effect of alginate fibre on wound healing was discussed in journal articles over thirty years ago; when used in dressings for both partial and full thickness wounds, the histology after fourteen days confirmed not only that the alginate was well-tolerated by body fluids and cellular components but also that it was an efficient haemostatic agent [104].

With the advent of silver nanoparticles and interest in their biological applications, coupled with sophisticated attachment/delivery mechanisms (See Section 1.3.2.2),

modifications to the alginate fibre have been trialled; researchers at Shinshu University demonstrated that even a minimum silver concentration used for coating the calcium alginate fibres of 1 mg/g showed measurable antibacterial properties and that increasing the silver content could completely inhibit the growth of Gram-positive *S. aureus* and Gram-negative *E. coli* [105]. Zinc oxide is a more economical substance to use than silver and also demonstrates antimicrobial properties. In 2016, zinc oxide-sodium nanoparticles were incorporated into alginate/cellulose fibres and their antibacterial properties compared to that of a blend of alginate/cellulose fibres with no modification. When tested against *E. coli*, the fibres containing nanoparticles showed good antibacterial properties [106].

In addition to nanoparticles, commonly-available drugs are being incorporated into wound dressings to promote wound healing. Simvastatin, traditionally used as a lipid-lowering drug, has been shown to be anti-inflammatory, have the ability to promote wound healing and be a good inductor of bone growth. In 2016, Simvastatin was combined into an alginate-based composite-film wound dressing. Pre-formulation studies demonstrated desirable wound-dressing properties and superior mechanical properites alongside the ability to maintain a controlled-release drug profile. The cell-viability assay demonstrated the film to be non-toxic [107]. The preparation of alginate in a gel form has allowed for the incorporation of tissue factors such as bone morphogenetic proteins. Modifying the gel to allow for sequential delivery has shown enhanced differentiation of osteoprogenitor cells in the bone marrow on testing *in vitro* [101]. Given that cartilage can now be grown *in vitro*, the ability to regenerate bone such that it can be implanted into the human body will push forward the field of regenerative medicine.

Chitosan is a polycationic biopolymer derived from chitin, a major component of the outer skeletons of crustaceans, by treatment with alkali [102]; its polymer backbone chain is composed of randomly-distributed β-linked D-glucosamine and N-acetyl-D-glucosamine and it is often used to modify the surface properties of cellulose fibres. Chitin and chitosan are both biocompatible materials highly suitable for use in medical applications intended to treat, augment or replace certain tissue, organs, or functional components of the human body, and recent studies suggest that chitosan and its derivatives are promising as supporting materials in tissue-engineering applications [108]. It possesses bacteriostatic and fungostatic properties and, like calcium alginate, is haemostatic, and it also affects the function of macrophages and stimulates wound healing. Chitosan has a similar structure to cellulose and can therefore be used as a coating on cotton fabrics to provide antibacterial performance in an economical way [103]. For example, in one study, chitosan applied as a finishing agent to bamboo-cellulose viscose rayon demonstrated antibacterial activity against Gram-positive and Gram-negative bacteria and this activity remained for 30 washes [109]; in another, non-woven fabric made from wool/viscose rayon treated with chitosan at various concentrations by pad-dry-cure was explored to determine its potential in wound dressings. Low concentrations (0.3%) of chitosan were effective in conferring both good absorbency and antibacterial properties whilst higher concentrations led to undesirable stiffness of the dressing material [110].

Chitosan has also been successfully electrospun with silk fibroin to create nanofibrous membranes that have demonstrated antibacterial activities against *E. coli*

and *S. aureus* [111]. Furthermore, coating a Tencel®/cotton nonwoven fabric with chitosan was shown to control evaporation and provide a barrier to microorganisms in a laboratory setting [112].

Chitosan can be manufactured into fibres, nanofibres, hydrogels, membranes, scaffolds and sponges for use in a variety of situations, such as tissue engineering, enzyme immobilisation, drug delivery, control over the rate of absorption in synthetic absorbable sutures and wound care (see Section 3.1, Section 4, and Section 7 for further practical examples). Commercially, chitosan and its derivatives are currently used in wound care in the form of Tegasorb® and Tegaderm® (3M, Maplewood, Minnesota, USA) [113]. Chitosan has been demonstrated to display properties advantageous in wound dressings. The ability to blend it with other readily-available fibres increases its potential applications, as was already mentioned for other fibres such as cotton and viscose rayon. For example, combining alginate and chitosan has been of interest. The material formed remains biodegradable and has preferable mechanical properties to a single fibre of chitosan; in particular, it is mechanically stronger when exposed to acidic conditions [114]. The alginate/chitosan fibres produced have a core of calcium alginate and an outer coating of chitosan [103] and show acceptable tensile properties for the manufacturing of bandages. In addition, the hydrophilic nature of the fibre allowed for absorption of bodily fluids and, potentially this phenomenon could be utilised to preferentially displace antibiotics or other molecules [114].

Rubber is one of the most-extensible polymers; it is naturally produced and used in more than 400 medical devices. The sole commercial source of natural isoprene is natural rubber that is harvested from the Brazilian rubber tree, *Hevea brasiliensis* [115]. The high molecular weight of the rubber (and the consequently very long polymer chains) leads to high performance properties including resilience, elasticity, abrasion resistance, efficient heat dispersion and impact resistance and its elastic properties/rigidity can be enhanced via the cross-linking process called vulcanization to allow use over a wider range of applications and temperatures [115]. Rubber can be combined with other fibres to create fibre-reinforced rubber composites that may be improved by appropriate combinations of fibre orientation, chemical treatment of the fibre and vulcanisation of the rubber [116] and of fibre ratio [117] to exhibit the combined behaviour of the soft, extensible and elastic rubber matrix together with stiffness from the strong fibrous reinforcement. A wide variety of fibre and filament types have been explored and employed as reinforcement in rubber, not least because of their value in tyre manufacture, and these include cellulose natural fibres, natural polymer man-made fibres such as viscose rayon and synthetic polymer fibres such as nylon and polyester (polyethylene terephthalate, PET) or, where higher performance is needed, aramid fibres such as Kevlar™, the high-performance polyester polyethylene naphthalate (PEN - Teonex®;Teijin Ltd, Tokyo, Japan and PENTEX®, Honeywell International, Inc , Virginia USA) or carbon fibre. A useful summary of combinations of reinforcement fibres, filaments and rubber is available online [118]. Whilst rubber is utilised extensively in the healthcare industry, one of the major drawbacks is IgE-mediated latex allergy caused by the presence of proteins in the latex [115].

1.3.2. Synthetic polymer fibres and filaments

Acrylic (polyacrylonitrile, PAN) was first developed and marketed under the trade name Orlon by Dupont in the 1940s [119]. PAN fibres do not consist solely of polyacrylonitrile, but are copolymers wherein *over* 85% of the monomer used consists of acrylonitrile and *less than* 15% is a vinyl monomer selected to improve processing and properties. For example, vinyl alcohol may be employed as the co-monomer to improve absorption. If the fibre contains *more than* 15% of a copolymer, it is described as a modacrylic [10]. The filaments are usually wet spun from aprotic solvents such as dimethyl sulfoxide into a coagulating bath, though when a higher resistance to abrasion is required, they can be dry spun. For commodity acrylic fibre products themselves, the material is used predominantly in fibre form, and tow-to-top conversion is carried out mainly by stretch-breaking of the filament tows, but it is fair to say that PAN fibres themselves have little profile at present in the medical textiles field; however, PAN filaments are the main precursor chosen for the preparation of carbon fibres which find use in braces and artificial limbs. The internal structure of the PAN filament used can significantly affect the properties of the resultant carbon fibre. For example, it has been shown that air-gap wet spinning can yield an improved PAN precursor with reduced numbers of voids and yield the preferred circular or close-to-circular cross section for the carbon fibre [120].

Nylon was the first synthetic-polymer man-made fibre to be produced commercially, and this was achieved rapidly following its discovery in 1935 by Carothers; Dupont brought it into production in late 1939 [119]. Although never a particularly cheap fibre to make, because it was the first synthetic polymer man-made fibre to appear on the textile market, nylon became commercialised very quickly with womens' stockings made of nylon appearing from 1940 and rapidly replacing silk in this application; the term 'Nylon' became synonymous with ladies hosiery providing an indication of its commercial success. Nylon is a polymer made by condensation polymerisation brought about by the reaction of di-functional monomers containing equal numbers of amine and carboxylic acid groups such that amide links can be formed at both ends of each monomer residue [121]. Nylon is therefore a synthetic linear polyamide consisting of repeating lengths of hydrocarbon chains joined together by amide links and this results in the different nylons being classified according to the number of carbon atoms in the sections of hydrocarbon chain between the repeating amide groups [10]; applying this approach, three of the more important members are known as nylon 6.6 and nylon 6 (the most common types used in fibre or filament form) and nylon 11 (which uses castor oil as the starting point and is mainly used in resin form).

The nylon polymer is converted into filament form by melt spinning, which involves the polymer chips being melted and subsequently extruded through a spinneret then drawn to produce continuous filaments or, after a further step involving cutting or stretch-breaking, staple fibres [122]. Melt spinning as a process does allow for the incorporation of other polymers/molecules into the polymer melt if desired. Melt spinning of the nylon is followed by drawing of the newly-formed filaments (extending the filament by 4-5 times its length to help to align the polymer chains along the lengthwise direction of the filament and improve crystallinity), a common requirement in spinning processes; both spinning and drawing can be adjusted to alter the final

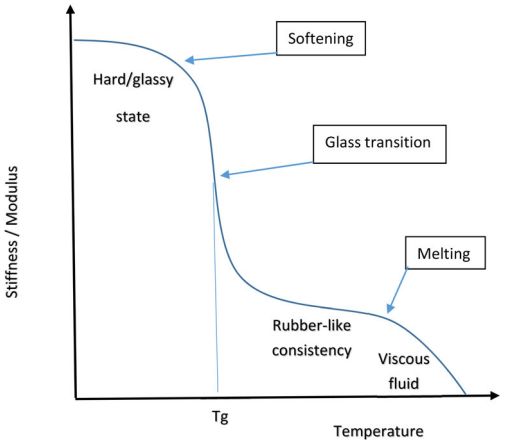

Figure 1. The effect of temperature on the stiffness and consistency of a semi-crystalline thermoplastic fibre.

filament properties to render them more-suitable not only for general use, but also for more-demanding purposes [123]. In the case of tyre cord for example, where high modulus and high strength are imperative, and for demanding medical applications, higher levels of extension are required and the temperature at which the drawing is carried out may need to be raised to enable enhanced alignment of the polyamide chains to be achieved.

In common with other melt-spun polymers, the drawing of the nylon filaments immediately following extrusion improves its tensile properties by bringing about a reduction in extension to break and raising the initial modulus to acceptable levels by increasing the degree of crystallinity of the filament. Typically, the tenacity of commercially-produced nylon 6 and nylon 66 is 0.4-0.6 N/tex with a breaking extension 20-30% for Nylon 6.6 and 20-40% for Nylon 6. Initially, there is a linear relationship between molecular mass and tenacity but it reaches a point where further increases in the length of the polyamide chain show little further benefit in terms of improved tenacity and would in any case lead to too-high a viscosity in the molten polymer in the extrusion stage. Apart from improving its stiffness, a higher degree of crystallinity in the nylon yarn reduces creep (the tendency of a material to slowly deform under persistent stress) which improves its dimensional stability. The elastic recovery from deformation of nylon is greater than that of many other fibres. For example it exhibits 90% recovery from a 1% extension and 89% recovery from a 10% extension whereas viscose rayon offers only 67% recovery from a 1% extension and a mere 23% recovery from a 10% extension [124].

Thermoplastic polymers such as the nylons, PET, polypropylene and polyethylene, soften and become rubbery before they melt; the point at which the transformation takes place is the glass transition temperature, T_g, see Figure 1.

Details of the melting points and glass transition temperatures for a range of polymers are available online [125]. Melting points of nylon 6.6, nylon 6 and nylon 11 at 250 °C, 210 °C and 185 °C respectively, glass transition temperatures are also correspondingly high at 50-60 °C (nylon 6.6.), 40-60 °C (Nylon 6) and 30-45 °C for Nylon 11

which makes them potentially useful in medical textiles [126]. Given the presence of polar groups within the polyamide polymer structure, it is not surprising that nylon absorbs some moisture into its structure from the atmosphere to a level of around 4.0-4.5% under standard conditions of temperature and humidity and on immersion in water, absorption of 9-10%. Moisture absorption reduces the tenacity and initial modulus, and brings about a lowering of the glass transition temperature whilst causing the extension to break to become greater. Not inherently conductive itself, the application of silver as a fabric coating to nylon can provide it with both electrical conductivity and antimicrobial properties [127]. Whilst antimicrobial activity is of obvious benefit in preventing infection, the additional ability to connect to an electrical power supply to generate heat from the fabric produced with silver-coated nylon yarn may be of use to those in expedition and wilderness medicine in the form of clothing [128].

Some of the current applications of nylon in the healthcare field are in support/compression stockings, hosiery and wound dressings. In addition, nylon is commonly used as a non-absorbable surgical suture as well as being utilised in the form of nylon mesh membranes in regenerative medicine for cell aggregation and filtration [129].

Polyesters are a category of polymers that contain the ester group as the linking group along their polymer chain. Although there are several other fibres and polymers within the group which are of significant interest for medical textiles, the polyester most-commonly employed in commodity products is ***poly(ethylene terephthalate)*** often referred to as ***PET***. Developed in England in 1940 by Whinfield and Dixon of the Calico Printers Association, PET is manufactured by the condensation polymerisation of ethylene terephthalate (itself produced by the esterification of terephthalic acid and monoethylene glycol), extruded by melt spinning, hot-drawn, then used alone or in blends as a textile fibre or filament. The polymer molecules in PET are stiffened by the presence of the aromatic groups within each of the repeat units along the polymer chain (aliphatic polyesters will be relatively more flexible and some of them are elastomeric) [130].

PET for medical applications involving implanting needs to be improved compared with the commodity product suitable for apparel, particularly in regard to it needing to possess high tenacity, high modulus and low elongation [131]. Whilst PET can show enhanced properties when higher molecular weight polymer is used to improve strength and the extruded filaments are subjected to hot drawing treatments similar to those used in the production of tyre cord to fully orient the polymer, there is a higher-performance polyester, ***polyethylene naphthalate (PEN)*** coming into use. Although PEN is more expensive, it is inherently stiffer and shows better thermal performance and barrier properties to chemical agents than PET [132].

Another, the simplest linear polyester of all is ***polyglycolic acid*** (PGA), which, because its hydrophilic nature leads it to become rapidly degraded, is most often used in medical applications such as absorbable sutures (see below under *Polyglycolides*).

It may be of interest that in plant tissue, natural polyesters can be found composed mostly of oxygenated fatty acids in cutin, where they serve as the framework for the plant cuticle and in suberin, a waxy substance which acts as a barrier to the passage

of water and solutes [133]. Frequently ingested in food, they safeguard the plant cell wall polysaccharides from degradation by colonic bacterial enzymes and are also potent *in vitro* absorbers of hydrophobic carcinogens [134]. Such properties could be of interest in medical textiles, but before these materials could be used, their allergenic potential would need to be assessed (especially given that they are natural polymers). The use of suberin in wound management for example, may prove to be of use due to its barrier functions.

As a melt-spun synthetic polymer fibre, just as is the case with nylon, modification of the production process of PET can allow for the manufacture of fibres with different properties and the incorporation of additional nano-materials or molecules into the molten polymer, but this is not done so much with PET as it is with other fibre-forming polymers, see for example Palza's paper [135], but it is amenable to surface treatment, for example with copper/copper oxide nanoparticles, following relatively-gentle aminolysis with triethanolamine, copper sulfate as the source of the metal, sodium hypophosphite as the reducing agent and polyvinylpyrrolidone as a stabilizer. The treated fabric in this case was hydrophilic and flame-retardant with high tensile strength [136].

Polyester shows a very low moisture regain and as a consequence does not readily absorb finishing agents or other chemicals from aqueous solutions; it can therefore only be dyed using disperse dyes and its oleophilicity can result in staining of the fabric and fibre by oily substances both in use and in laundering. However, advantageously, polyester has a relatively-high glass transition temperature at 70-80 °C and melting point (260 °C) and it is amenable to sterilisation; fabrics made from polyester do demonstrate good resistance to extension and typically possess excellent dimensional stability plus good resistance to abrasion, but polyester is thrombogenic (demonstrating a tendency to cause thrombosis) which needs to be considered in vascular grafts to prevent occlusion [137]. More recently, problems of lack of incorporation and scarring have been highlighted in vaginal mesh repair [138]. Healthcare applications of PET include non-absorbable, braided sutures, for example, Ethibond^{TM} (Ethicon Inc, a subsidiary of Johnson and Johnson, Belgium) in which it proffers minimal tissue reaction and has good handling and a high tensile strength [92]. It has also been in use for many years in vascular grafts, for aneurysm and vascular repair [139], ligament and tendon reconstruction, in implantable mesh, prosthetic heart valves and in hygiene products, such as incontinence pads.

PET itself is non-conductive so, considering the requirements of home health care and the associated need for intelligent textile medical applications, efforts have been undertaken to create blended yarns made from polyester and stainless steel to allow electrical charges to be conducted, and trials have been undertaken to create clothing such that physiological measurements may be recorded [140]. Blended with cotton, polyester is widely used in garments for use within the healthcare industry, for example, in stockings, surgical gowns, caps, masks and bedding [141].

Polyglycolide, or polyglycolic acid, PGA, is a biodegradable linear thermoplastic polymer. The basic structure is glycolide and once polymerized, the polymer can be shaped by extrusion into filaments, pins or rods, melt moulded or shaped by compression moulding. Fibre-reinforced composites have been used to strengthen the mechanical properties of this polymer [142].

Polylactide-polyglycolide antibiotic implants were a development undertaken because the mechanical strength of the first-generation screws made from PGA was insufficient for orthopaedic applications. However, the creation of a fibre-reinforced composite in which the polymer matrix was reinforced with suture fibres of the same material improved the strength of the rods and screws [143]. PGA has a melting temperature of 225 °C and a Tg of 37 °C, a tensile strength of 1 GPa and a Young's Modulus of 4-14 GPa. Elongation at break is 30-40% [144].

Introduced as the first synthetic absorbable suture in the 1970s as Dexon® (now produced by Medtronic, Dublin, Ireland), the PGA in many products is coated with another polymer to improve its ease of use in forming stitches and its passage through tissue [145]. Antibiotic-impregnated polymer-coated components have been manufactured to allow for antibiotic delivery in cases of osteomyelitis (bone infection); they are used for absorbable sutures, screws and implants, for example to provide aperture fixation in anterior cruciate ligament reconstruction, and additionally, in cell scaffolding. Of note, there have been reports of localised reactions developing at the site of implantation in some patients even though the products of biodegradation are naturally occurring [146].

Polyethylene is produced by free-radical addition polymerisation of ethylene, a process which is carried out under high pressure (ca 2000 atmospheres) at 200 °C in the presence of some oxygen. Initiation of the polymerisation reaction occurs due to the presence of oxygen which forms very reactive peroxides under these reaction conditions. Free-radicals form which produce the growing length of polymer chain as each new ethylene residue becomes attached and creates a new free-radical at the chain end. Termination occurs when two of these come together, and because that is a random process, chain lengths can vary considerably. Moreover, unfortunately, unless prevented, polymer-chain growth may not simply be linear, as it may also be initiated part way along the length of the growing polymer chain. The product, when such chain branching is allowed to occur under the polymerisation conditions spelt out above, has a degree of crystallinity below 75% and is called low-density polyethylene (LDPE). When chain branching is prevented, say by the use of Ziegler-Natta catalysts at low pressure (a few atmospheres) and a reduced temperature of 60°C, the polymer chains are linear and their packing together/crystallinity is much improved, resulting in the product known as high-density polyethylene (HDPE). Typically it is very-highly crystalline (95% or above), and hence both stiffer and stronger than LDPE, but even so, HDPE is only between 3% and 6% more dense than LDPE. A usefully brief description of the various types of polyethylene is available online [147].

Being a non-polar polymer, the individual macromolecular chains in polyethylene are attracted to their neighbours only by London dispersion forces (the weakest of the intermolecular forces) but even so, it is typically semi-crystalline (crystallites surrounded by amorphous regions) with a higher degree of crystallinity achievable when the polymer chains are unbranched. Polyethylene is known for being remarkably resistant to degradation but even so, studies have been undertaken to characterise its degradation [146]. For example, oxidation is one cause of degradation, and ideally the storage of polyethylene products should be conducted in an oxygen-free environment; oxygen in the surrounding atmosphere can diffuse into the polyethylene and promote

oxidation. Maximum oxidation occurs 1-2 mm below the surface in what is termed the 'subsurface white band' and whilst all mechanisms for degradation are not understood in detail, it is recognised that enzymes can cause the initial oxidation of polyethylene chains. It has been suggested that metabolic pathways for degradation of hydrocarbons can be used once the size of polyethylene molecules decrease to an acceptable range for enzyme action, and because of their easier accessibility, the polymer chains in the amorphous regions are more prone to microbial attack than those in the crystalline regions.

Polyethylene can also be subject to deterioration in performance caused by mechanical wear, and work to combat such degradation problems has led to the development of high-performance versions of polythene known as:

i. Ultra-high molecular weight polyethylene (UHMWPE), and
ii. Highly-cross-linked polyethylene (HXLPE)

UHMWPE is prepared by polymerisation of ethylene in the presence of a zirconium-based metallocene catalyst which enables the creation of very long polymer chains with a degree of polymerisation of 100,000 to 250,000 compared with a value around 80,000 for HDPE. It is converted into filament form by gel spinning - preparing a very-dilute gel which is carefully heated to the point where the polymer chains become almost completely separated, then extruding through a spinneret, drawn in the air then passed into a cooling water bath to harden. HXLPE is most-often prepared by exposing UHMWPE to gamma radiation giving rise to polymer chain cleavage and C and H free-radical formation followed by:

a. recombination along the polymer-chain backbone limiting the level of chain cleavage,
b. combination between polymer chains leading to the desired cross-linking, and
c. entrapped free radicals which, over time, react with oxygen to form per-oxy free radicals which themselves establish a damaging chain of events by creating further free radicals able to react with oxygen.

The cross links that have been introduced into the polyethylene prove beneficial by acting as molecular constraints and help to improve its mechanical properties, see also Section 1.3.2.2. [148], but a high degree of resistance to continued penetration of free radicals into the polyethylene more generally is important because, in the presence of oxygen, they cause it to degrade. The melting point of polyethylene is 135 °C and raising the temperature of the polyethylene towards this point causes the polymer chains to become separated which allows relatively easy access for free radicals to all parts of the polymer chains. Below the melting point but above the glass transition temperature, the polymer chains in the crystalline regions remain rigid and well-packed together, restricting access by free radicals, but those in the less well-ordered regions are mobile, so some degradation (a reduced level) can still occur. Annealing, heating to just below the melting point, increases the degree of crystallinity and raises the softening point, which preserves the desirable mechanical properties to a higher

temperature, but leads to less-efficient removal of free radicals. Melting then reforming of the HXLPE does enable the elimination of free radicals, but there have also been searches for quenching methods, and Vitamin E doping has proved successful in improving oxidative stability, resistance to wear and fatigue beyond that achievable by melting and reforming [149].

Polypropylene is a thermoplastic polymer that is produced by free-radical addition polymerization of propylene; there are three types of polypropylene wherein the degree of crystallinity varies depending on the direction in which the $-CH_3$ side groups are arranged; randomness in the direction of their arrangement along polymer chain can be controlled by the application of Ziegler/Natta catalysts during polymerisation:

i. Atactic polypropylene: irregularly arranged side groups
ii. Isotactic polypropylene: $-CH_3$ side groups arranged regularly to one side of the polymer chain
iii. Syndiotactic polypropylene: the $-CH_3$ side groups are arranged regularly but alternately first to one side of the polymer chain then to the other

Typically it is the isotactic form which is used for filaments and fibres; the syndiotactic version is softer and finds use in medical bags and pouches.

Polypropylene in fibre or filament form possesses many useful characteristics, such as low density, low hydrophilicity, and good preservation of shape (dimensional stability) when wet, plus its fabrics exhibit high resistance to creasing and are durable to wear making them a good choice for healthcare clothing; for example, nonwoven polypropylene fabric is used in the BARRIER® surgical gown (Mölnlycke, Gothenburg, Sweden). Medical applications continually increase as the polymer possesses the advantage of being able to be manufactured and sterilised by a wide range of techniques and in fabric form, products for the healthcare industry include wipe-able covering fabrics over pillows with polypropylene filling, waterproof non-woven polypropylene pillowcases, non-woven bedding covers, items of clothing, bandages and medical dressings [150–152]. Sutures, for example Prolene® (Ethicon Inc, a subsidiary of Johnson and Johnson, Belgium) can be manufactured from polypropylene and a considerable range of mesh products, either woven or nonwoven, which can be readily cut to shape, many including polypropylene, are widely used for example to enhance the ease of hernia repair (see Section 3.3). The first hernia repair mesh used in 1958 was made from polypropylene. It is estimated that over 18 million hernia operations per year now involve the use of synthetic, non-degradable mesh [153], and polypropylene mesh is the most widely used, but there have been both problems (for example, chronic pelvic pain) and lawsuits. The problems are said now to have been overcome [154].

Research has therefore been undertaken at a European level with the stated aim:

> *"to fabricate a nano-fibrous mesh with well-defined nano-topography using cellulose; human recombinant collagen, derived from transgenic tobacco plants; and biodegradable poly-ε-caprolactone or polylactic/polyglycolic acid as raw materials,"*

to enable a move away from polypropylene to more biologically-acceptable/biomaterial alternatives [155]. The project claimed success in reaching a stage that would allow clinical trials to begin in 2020. For implants requiring fine detail (between

800 nm and 70 μm) with nanofibre support, 3-dimensional digital printing methods combined with melt electrospinning, melt micro extrusion or laser sintering of polypropylene have been developed [156].

1.3.2.1 Synthetic polymer high-performance and specialist fibres/structures. ***Aramids*** are a group of polyamides that are composed of aromatic groups joined together by at least 85% amide linkages through the para position or the meta position; it is the presence of the aromatic rings that confers the much higher stiffness to the aramid compared with the linear hydrocarbon chain present between the amide groups in nylon 66 and nylon 6. Filaments are produced by gel spinning and extruded from solutions in strong acids or solvents. Of the many types of aramid that are known, only a few have become commercially available in filament or fibre form and they can be broadly grouped as follows: meta-aramids such as Nomex® and para-aramids such as Kevlar® 29 - the high toughness type, Kevlar® 49 - the high-modulus type and Kevlar® 149 - the ultra-high-modulus type (all Dupont, Wilmington, Delaware, USA) and Twaron® (Teijin, Arnhem, Netherlands) [157].

The p-aramid fibres have a very high tensile modulus and tensile strength, are five times stronger than steel and lose little strength during repeated abrasion, flexing and stretching. They also demonstrate excellent dimensional stability, which is why they are used in demanding applications such as for tyre reinforcement and in structural composites in high-performance cars. As components for improving the properties of composite structures they are of significant help in the creation of anti-ballistic and stab-resistant items of clothing, useful in personal and protective equipment for police and soldiers when operating in the field [157].

The m-aramid fibres are used in applications where their excellent heat resistance including low shrinkage is helpful in firefighter's protective clothing, and for medical textiles this would make them ideal for heat-sterilisable items, but as yet, in the healthcare sector, aramid fibres have failed to find much of a role as yet although bio-compatibility tests were undertaken several years ago [158] and surface coating with m-aramids can confer improved bio-compatibility and enable antimicrobial applications when m-aramid coated fabrics are chlorinated; such materials were demonstrated to inactivate *E coli* and *S. aureus* through chlorine release with a 7 log reduction in ten minutes. The original level of antimicrobial action can be restored by subsequent chlorine treatment of the coated fabric following exposure [159].

Ultra-High Molecular Weight Polyethylene (UHMWPE) is a type of polyethylene in which the degree of polymerisation is extremely high, yielding long polymer chains of molecular weight between two and six million Daltons. UHMWPE is used as a bearing surface in joint arthroplasty. In this form, it is a semicrystalline with the polymer exhibiting a degree of crystallisation of around 50%, hence the human body temperature is:

a. Above the UHMWPE's glass transition temperature (quoted figures vary, from as low as -160 °C to -80 °C compared with the values for PE at -110 to -120 °C [160], but it is the figure of -80 °C for UHMWPE that makes more sense as it is expected to be higher than for PE because of restricted freedom of movement owing to fewer polymer chain ends) [161] and
b. Below the polymer's melting point (132.7 °C) [162, 163]

and it therefore exhibits both the rigidity expected in solids and some mobility in the non-crystalline chain segments yielding other attributes more characteristic of a liquid. Crosslinked, it is used in the liners of joint replacements as it has better wear characteristics than polyethylene [164] and also it has been shown to perform excellently well when incorporated together with polycaprolactone in a partially-absorbable suture for tendon and ligament repair [165].

Cross-Linked Polyethylene (PEX, XPE or XLPE) is high-density polyethylene within which covalent bonds have been formed either by chemical modification through attachment of silanes, by heating in the presence of peroxide crosslinking agents or by irradiation with an electron beam to interconnect its polymer chains to form 3-dimensional polymers with high molecular weights and improved physical properties. The molecular structure that is formed by crosslinking provides greater resistance to stress cracking, improved toughness, stiffness, and chemical resistance compared to the HDPE used as the precursor, but the likelihood of such improvements may be improved by increasing crystallinity in the precursor prior to its crosslinking. Improvements in both tensile strength (50% increase) and Young's Modulus (36% increase) were reported in UHMWPE fibres by virtue of cross-linking compaction at elevated temperatures in the presence of peroxide [166]. It is certainly a high-performance fibre but there are concerns that highly-cross-linked polyethylene (HXLPE), made by forming cross linkages in UHMWPE may be too unforgiving to the host in some medical applications, although these observations related to liners made from HXLPE rather than the filament forms [148].

Highly-branched/ Dendritic polymers have a centre formed by what was originally a multifunctional compound which has made a link with each of the polymer-chain branches spreading out from the centre. The dendritic structure is characterised by a surface of functional groups (either those of the amine end-group of the growing polymer chain or an acidic agent attached to the amine group - other groups could be used in place of an amine group) and voids between the branches. In terms of its functional groups, it is a layered structure, see Figure 2.

Each new layer of polymer attached is called a generation and addition of further generations can be undertaken to determine the optimum number required to retain a particular molecule within the structure; the voids between branches have the capacity to hold molecules within the structure that are not part of the structure itself. In these circumstances, the dendritic structure can be considered to be the host, and the molecules held within its structure the guest molecules. There is the possibility for a range of molecules to be held as guests, such as fragrances, drugs or antibiotics, which can be slowly released over time, or antimicrobial agents such as silver nanoparticles [167, 168].

1.3.2.2. Synthetic polymer elastomers. ***Spandex yarns*** such as Lycra® (Dupont) are segmented-polyurethane elastomers in the form of fibres, filaments and films, also sometimes called elastane. They are long-chain synthetic polymers that are comprised of at least 85% by weight of segmented polyurethane [10]; the filaments are produced by dry spinning. Polyurethane yarns demonstrate extremely high extensibility and complete recovery from deformation, able to be extended by up to five times the original

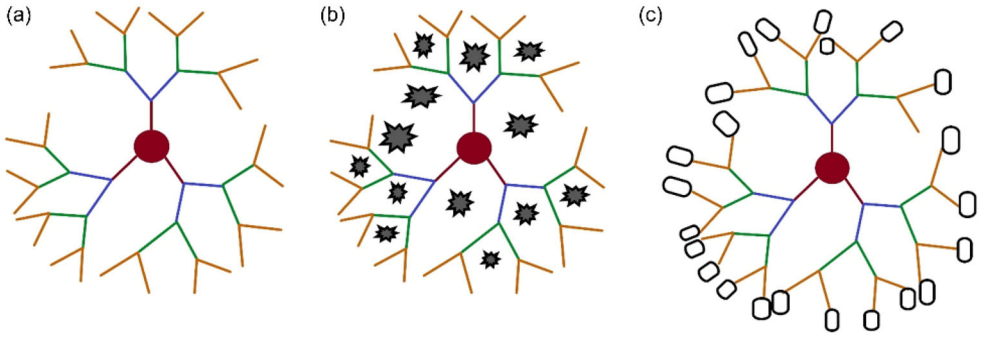

Figure 2. Dendritic structure a) 3rd generation structure, b) 3rd generation structure loaded with entrapped guest molecules, and c) 3rd generation structure with guest molecules attached to the surface [168]. With kind permission of Taylor & Francis.

length and returning to the original length on release (rubber-like elasticity), a high tensile strength and good abrasion resistance. Should they be contaminated with oil-based products, such as emollients, following contact with the skin, their resistance to many cosmetic oils and solvents allow textiles containing polyurethane to be laundered [169]. Spandex yarns can be manufactured as filaments, staple fibre yarns or as composites and their excellent elastomeric performance has led to their use not only in fashion products, but also in compression garments in the healthcare sector, such as the stockings used for controlling oedema [170].

1.3.2.3. Electroactive polymer fibres. There are four main categories of electroactive biomaterials: conductive polymers, piezo-electric polymers, photovoltaic materials, and electrets.

Conductive polymers show electrical conductivity typically less than most metals, but not dissimilar to that of semiconductors. The major advantage of conductive polymers over metals is that they can offer the type of flexibility and recovery from deformation expected from a textile material. However, because these types of polymer are highly insoluble, it is necessary to add a dopant (a charge carrier), such as dodecylbenzene sulfonic acid, to enable spinning of the polymers into filaments and make the resultant fibres/filaments less stiff. Not only does this improve handling, the retained dopant is essential in providing an enormous boost in electrical conductivity. Smaller dopants such as chloride ions are more-readily lost from the fibres, and that action can be used to both assist and control drug delivery from the fibre. The most-widely researched conductive polymers are polyaniline (PANi), poly-pyrrole (PPy), and polythiophene (PTh), but more often as its derivative, poly (3,4-ethylenedioxythiophene) (PEDOT), which possesses better all-round properties than PTh including improved chemical, electrical, environmental, and thermal stabilities and better electrical conductivity. They all exhibit good biocompatability, hence particularly in the form of nanofibres, these polymers are used in biosensors, neural implants, drug delivery devices and in tissue engineering scaffolds [171, 172], see also Section 7 (Intelligent (SMART) Medical and Healthcare Textiles).

Piezoelectric polymers become electrically polarised in response to the application of mechanical stress, and the reverse is also true, they will deform on the application

of an electric charge. Such responses are rapid and the power requirements to achieve them are small, so this makes them attractive for the generation of electrical signals in sensors, and also as nano-generators in the case of electro-spun versions of the piezoelectric polymer. There are subsets of piezoelectric materials, some of which may demonstrate pyroelectric properties (by responding to changes in temperature by emitting an electric signal) and others, ferroelectric polymers, whose polarisation can be reversed by the application of an electric field. PVDF, Poly (vinylidene fluoride), falls into the last category and it is currently the most-important piezoelectric polymer with the highest electromechanical response over a broad temperature range of all known synthetic polymers; the fact that having been electrospun to yield nanofibres, it can be adjusted to match its surface properties to that of the host environment whilst retaining its piezoelectric properties [173], makes it an attractive material to employ in nanofibrous-textile-based bone bio-implants [174].

Electrets are polymers that have been caused to adopt a substantial semi-permanent electric charge either by corona charging or triboelectric charging. The polymer acts as a dielectric hence if the polymer contains little of any moisture, this will help the retention of the charge by the polymer. Polypropylene fibres therefore, because of their very low electrical conductivity and low regain values at most humidity levels, are very good at retaining electrical charge, hence they are widely deployed in electret filters. Electret filters are used in high-efficiency filtration because in addition to the usual mechanical means of particle capture, they have the ability to trap airborne particles through coulombic attraction of charged particles and/or induced polarization (dielectrophoresis) of uncharged particles, and by virtue of the resultant deflection of the particles, enhanced capture at the surface of the electret [175] (see also Section 5).

1.3.3. Other materials

Carbon fibres (fibres that contain at least 90% weight carbon) are manufactured by thermally treating a precursor fibre in an inert atmosphere in a process termed carbonization. The precursor most-used is PAN followed by pitch (less than 10% of the precursors used); graphite fibres, produced by heating to a graphitising temperature of around 2,500 °C and containing at least 99% weight carbon, are much more unusual. The precursor PAN fibres in filament form are subjected to thermo-stabilization at 200-400 °C (a process that causes cross-linking in the precursor polymer prior to carbonization), followed by carbonisation in an inert atmosphere at around 1,000 °C. Flaws within the fibre fine-structure greatly influence the tensile strength of the fibres as does the temperature used for carbonization (due to effects at an atomic level on bonding) [176] and also the (beneficial) existence of an air gap during wet spinning of the PAN precursor [177].

Carbon fibres are able to provide lightweight fabrics that can demonstrate high strength, flexibility and fatigue resistance and they may be classified as either general purpose or high performance; the fibre may be cut short or kept as continuous filaments, and may be highly-crystalline, amorphous or partly-crystalline, structural variations which affect their tensile properties - a high modulus of elasticity is demonstrated if the crystalline carbon layers within the fibre structure lie parallel to the fibre axis [178]. For PAN-based carbon fibres, the conditions of temperature/time

and tension applied during stabilisation during the heat treatment prior to carbonisation have important influences, caused, it is suggested, by their effects on crystallisation. Prolonging heat pre-treatment time improved both tensile strength and modulus for carbon fibres produced by low-temperature carbonisation (800°C rather than the more usual 1300-1500°C) whereas increasing applied tension improved their tensile strength only up to a particular limit (15 mg per filament in the reported work), above which it deteriorated [179].

Carbon fibres can be manufactured into a range of textile structures as well as being incorporated into composites. In the healthcare sector, they have a structural role in orthotics, artificial limbs [180] and medical equipment. Related nano-materials such as carbon nanotubes have potential in drug delivery and in radiation therapy by targeted cellular internalization and hence may revolutionize medical care, though their safety profile in nanotube form needs to be fully elucidated [181]. It has proven to be possible to cause carbon nanotubes to become interlocked and aligned into single continuous-filament form which is expected to enhance their applicability by seamlessly connecting the nano- to the micro- and macro- levels [182, 183].

Graphene is a form of carbon that consists of a single sheet of carbon atoms, so, although like carbon nanotubes, not itself in fibre form, may offer special properties such as electro-conductivity if applied as a finish or coating to a polymer in its preparation to become a useful medical textile. Isolated in 2004, graphene demonstrates strength 200 times that of steel, is an excellent electrical and thermal conductor and is transparent to visible light [184]. In addition to providing electroconductivity in smart clothing, graphene has been trialled as artificial retinas [185], demonstrating its potential as an implantable component; both its bacteriostatic and bacteriocidal effects are found advantageous in this setting [186].

Ceramics are inorganic, non-metallic and crystalline structures wherein ionic bonding contributes to their strength. There are many ceramics available and these are broadly grouped into those based upon glass-matrices, polycrystalline and resin-matrices; a classification system has been developed to assist in defining different types and gaining some information about their likely structural characteristics [187]. Orthopaedic implants, e.g. hip prostheses, are one of the well-known healthcare uses of ceramics and in such applications, ceramics are known for their resistance, strength, biocompatibility, wettability and high resistance to wear and corrosion [188]. However, there are also a large number of other applications such as in dental and bone reconstruction. Ceramic matrix composites are of medical interest in dentistry and hydroxyapatite has been used on bio-scaffolds to encourage bone ingrowth. A detailed review of ceramic biomaterials has been undertaken which includes the materials, their manufacture, products and their clinical applications [189].

Glass is a non-crystalline and amorphous solid for which additives in the manufacturing process can be used to create bioactive glasses, and there are several types available based upon silicates, phosphate and borate [190]. Bioactive glass is a brittle type of material that demonstrates a unique set of properties such as the ability to degrade at a controllable rate and convert to a hydroxyapatite-like structure [191, 192]. Bioactive sol-gel glasses were first synthesised in the 1990s. They have been used in regenerative medicine for osseous growth. In addition to creating a structure

that mimics the trabecular architecture of cancellous bone, the sol preparation can be foamed to create a structure that demonstrates porosity and mimics biology more accurately. In addition to use in bone tissue engineering, uses extend to wound dressings, ocular implants and clinical imaging [192]. Other glass compounds can be created into yarns that can be manufactured into fabrics, the bioresorbable compounds being particularly attractive for the prospect of development of medical devices [193]. The original Bioglass® was created into a middle ear prosthesis and 10 year follow-up studies demonstrated that 4 out of 21 had failed but that the others maintained their original function [190].

Silicon has a wide range of uses in the healthcare sector ranging from clothing through to lubricants and indwelling catheters for which it is widely employed. Silicon is more electropositive and lipophilic than carbon making it attractive in drug design and devices for drug delivery [194]. Silicon-based electronics provide unparalleled performance in data-processing devices and that makes silicon an attractive material for use in smart textiles (silicon may be engineered by a variety of methods such as fabrication onto a wafer, integration into a chip or by printing onto a surface, the latter offering a wide range of applicability in the healthcare sector particularly in the case of flexible items) [195].

Whilst silicon-based bio-microelectromechanical systems are becoming increasingly attractive for medical implants due to their relatively-low cost and capacity for fabrication, they are not without issue. When silicon surfaces encounter blood, the coagulation cascade is activated causing thrombosis. There is ongoing work directed towards modification of the silicon surface to prevent this and thus increase the lifetime of such implants, for example by coating with polymers which possess better compatibility [196].

1.3.4. Nanofibres

Electrospinning can be used to produce fibres with widths from the sub-micrometre range to just a few nanometres across. Their great flexibility arises because fibre rigidity to bending is proportional to the fibre radius to the power four (for a perfectly circular elastic fibre), so reducing its radius by a factor of 2 means that bending rigidity is reduced by a factor of 16. By appropriate choice of the spinning arrangement, nanofibrous yarns can be made rather than simply fibre bundles or nanofibre webs and these are of particular interest because whilst highly flexible, they have sufficient integrity and strength to be woven or knitted, and given particular care, this may be done in such a way as to yield three-dimensional fabrics. Of considerable interest for implanted medical textiles are the synthetic absorbable electrospun polymers, of which there are a growing list, whereas for Smart electronic wearables and high-performance filtration it is the highly-flexible electrospun electroactive biomaterials (Section 1.3.2.4) which are of particular interest [9] (see also Section 7).

1.4. Fabrics

1.4.1. Woven fabrics

Woven fabrics are widely used in hospital bedding, clothing, wound dressings, gauzes and in some of the hygiene products. With structures wherein yarns are interlaced at

right angles to one another, woven fabrics in various interlacing designs can be created to satisfy a wide range of end uses requiring flat, strong sheet-like structures capable of demonstrating significant flexibility [10]. Whilst the ultimate goal of woven fabric designers is to develop a construction that has predetermined properties to fit the specific application they also need to achieve the highest possibly fabric quality and weaving efficiency [197]; even so, given those constraints, many variables can be altered during the creation of a woven fabric to modify its mechanical performance ranging from the yarn used to the type of yarn interlacing and density of weave [198], whereas many of the clothing and bedlinen requirements can be satisfied with standard traditional woven fabrics.

Most usually, after weaving, the 'grey' woven fabrics will undergo mechanical or chemical finishing to confer more of the required characteristics to the woven product. For example, lamination and impregnation with substances demonstrating antimicrobial activity have both been used to create a sterile barrier [199, 200]. Plasma modification can be used to impart hydrophilicity to fabrics [201], whilst some of the more-recent treatments involve those that may allow the mounting of biosensors within the fabric, technology which is enabling advancement in the field of smart textiles [202, 203]. In one study, the preparation of organic electrochemical transistors on nylon fibres demonstrated stable performance during bending tests due to the introduction of a metal/conductive polymer multilayer electrode onto the fibre. When the fibres are then woven with cotton, flexible and extensible fibre biosensors can be produced [202]. Another study patterned microchannels and reservoirs by combining a photoresist polymer with a nonwoven fabric which then allowed for lactate levels to be measured [203].

3-D Woven fabric applications in healthcare are mostly to be found in wound dressings, implants and in items intended for regenerative medicine [204]. The ability to create 3 D structures out of several different yarns arranged on a X-, Y- and vertical Z- axis allows for the production of different types of textiles that display a range of mechanical properties which go beyond those expected from the two-dimensional products and allow for the opportunity to produce structures that can follow and mimic the body's anatomy, for example, tendons/ligaments and vessels. 3-D woven textiles can be produced in multilayer form, hollow shapes, nodal or dome structures, each of which has its own distinctive range of characteristics. For example, many hollow structures exhibit high-energy absorption capabilities whilst a solid 3-D structure can exhibit high dimensional stability providing substantial resistance to shear and deformation [205].

1.4.2. Knitted fabrics

Industrially, knitted fabrics are produced by one of two methods: weft knitting and warp knitting. The fabrics are typically more extensible than woven fabrics, because rather than the yarns being tightly interlaced under and over one another as in woven fabrics, they consist of rows or columns of interlinked loops of yarn. Their extensibility has enabled various knitted meshes to be used for the treatment of hernias, pelvic organ prolapse and body wall defects. In addition, knitted structures are being utilised in regenerative medicine as scaffolds for cell growth [206].

Warp Knitted fabrics are produced from a set of warp yarns that are knitted parallel to each other down the length of the fabric. Each new row of loops is drawn through the previous row of loops in the fabric such that each loop in the horizontal direction is made from a different thread [207]. This produces a fabric of intermediate extensibility, but with tensioned elastane as one of the lengthwise threads, it offers greater extensibility and better durability than a weft-knitted structure.

3 D Warp knitted structures can be created that are like sandwich constructions. They consist of two surface layers connected by resilient yarns in between that hold the layers at a distance. This 3 D structure exhibits high porosity and allows for moisture transmission. They also demonstrate high air permeability and are comparatively lightweight because of this. In addition, different materials can be used to create the different layers of the fabric [208]. In the healthcare sector, they are used to create artificial vessels and innovative compression bandages and for pressure-sore management [206, 209, 211].

Weft Knitted fabrics consist of loops formed in succession one loop at a time across the fabric, hence to form one horizontal row of interlinked loops, a minimum of only one thread requires to be inserted. Whereas weft knitted fabrics for most purposes may be produced on flat or circular machines, stockings including compression stockings are manufactured by 3 D weft knitting. Weft knitting produces a fabric that demonstrates extensibility and elasticity which can be modified further by altering the weft knitted pattern of loops. Weft knitted fabrics are not as extensible as the particular warp-knitted fabrics designed to extend lengthways, such as power nets, but even so, some can provide and sustain high levels of compression and support [211, 212]. Just as is the case for weaving and warp-knitting, fabrics with two parallel faces joined by connecting threads (spacer fabrics), can be prepared by weft knitting.

1.4.3. Nonwoven fabrics

Given the capacity for very-high production rates for nonwoven fabrics, and therefore the possibility of generating low-cost garments, nonwoven fabrics have been used extensively in the healthcare setting for many years to create disposable protective clothing such as surgical gowns, drapes, caps and masks [96]. The way in which the fibres are arranged affects both pore size and capillary dimensions [213] so they are also, because of the ability to create a wide variety of nonwoven fabric structures from most fibre types, widely used in the more-technically demanding fields of dressings, hygiene products and filters [96].

Nonwoven techniques allow for textile fibre webs to be prepared then assembled into layered structures wherein several layers are bonded to create a fabric, a step which can be carried out at high rates of production by a variety of processes [10, 213] including:

i. Wet laying, used to produce wipes such as eye pads and wound wipes and surgical gowns [214]
ii. Air layering, also used to produce wipes [214]
iii. Needle punching which has been used to produce absorbent dressing products and scaffolds for tissue engineering [215, 216]

iv. Thermal bonding used to produce sterile wraps and fabrics used in compression management [217]
v. Chemical bonding which has been used in the manufacture of medical masks and more recently in creating drug-encapsulated textile structures [214]

Alternatively, the fabric can be produced directly as a web utilising polymer extrusion methods, such as:

i. Melt-blowing [218] used in filters in surgical masks
ii. Creation of flash spun microfibre webs [219] which has been used in medical sterile packaging [220],
iii. Electrospinning for the preparation of nanofibre webs [9] which have been used in burn and wound management [221]
iv. Spunbond (or spunlaid) methods (for creating webs from very long filaments) [96], used as the absorbent sanitary pad's outer covering [214].

1.4.4. Braided fabrics

A braid (or plait) is a narrow fabric made by interlacing three or more threads diagonally to create flat, tubular or solid constructions [1, 222]. Artificial ligaments can be made from braided structures because they afford the opportunity to engineer tensile properties and include the desired degree of extensibility into the replacement structure [223] and for other medical applications where the implant is expected to undergo repeated extension, but sutures (see Section 3.1) and stents (See Section 3.2) are the most common braided medical textile items. Alongside key structural features such as the braiding angle, the polymeric material used in a braided device is one of the numerous variables that affect the mechanical properties of the braid. PET, polyamides, polypropylene, polytetrafluoroethylene and UHMWPE are used as are biodegradable and absorbable polymers such as poly(L-lactic acid) or polyglycolide and metal wires such as nitinol or stainless steel. For more-sophisticated applications, drawn-filled tubes or composite braids are made by combining polymer filaments and wire. The non-absorbable braids are not without issues however, such as bacterial proliferation aided by their surface structure, so inherently antibacterial (coated) polyamide braids have been developed [224].

1.5. Finishes

Textile finishing is the final stage in textile manufacture at which the characteristics of the textile item are able to be adjusted or determined. Apart from bleaching and sterilising, for medical textiles finishing may mean conferring to the textile surface hydrophilicity or super-hydrophobicity depending on whether moisture absorption or repellency is required by the particular application. In some cases it may be preferable to have the two sides of the fabric behave differently, particularly in the case of wound dressings [225, 226]. Finishing may also involve the process of impregnating or coating the textile with an agent or agents intended to confer specific properties or to assist in the uptake or retention properties of the active agent.

1.5.1. Antimicrobial finishing

There has long been interest in improving the performance of textiles intended for medical use against bacteria, fungi and viruses, to protect both patients and healthcare professionals from contamination and spread. Some methods for achieving antibacterial and antifungal activity involve incorporating the active/protective agent in the fibre-forming polymer, but others work on the basis of being applied as a finish to the textile material. A manual check of the topics published in either The Journal of The Textile Institute or the Textile Research Journal since the year 2000 and including all papers accessible online up to the end of June 2020 showed:

- A total of 548 papers concerned with textiles for medical purposes of which over 42% (232) were focussed on antimicrobial treatments; 189 of these claimed successful achievement of antibacterial activity through the application of a textile-finishing treatment, whereas 50 accomplished it through incorporation of the antibacterial agent into the fibre-forming polymer.
- ***Only a single paper*** reported the application and testing of a fabric to demonstrate its ***antiviral activity*** [8].
- The great majority of the papers concerned with the achievement of antibacterial action were published since 2010 (192), and the surge continues in this particular area with 118 papers published since 2015.

Nanotechnology and antimicrobial textiles. Despite recent interest in the application and effectiveness of naturally-occurring antimicrobial agents [227] and the environmental acceptability of agents and processes (so-called 'green' treatments), the real catalysts behind the surge in research outputs on the development of effective antimicrobial textiles are attributable to successes in nanoscience/technology [3]. Of the 189 papers concerned with the achievement of antimicrobial action through finishing treatments, 105 were reliant on the application of nanoparticles for their effectiveness. However, another approach is also proving successful - there were a further 50 papers which were reporting good results, particularly in terms of durability, from incorporation of the active/protective agent in nano-particulate form into the fibre-forming polymer itself.

Nanotechnology has enabled the application of nanometals such as nano silver, nano metal oxides such as zinc oxide and nano titanium dioxide, copper oxide, iron oxide and to a lesser extent as yet, boron, zirconium oxide, graphene oxide and carbon nanotubes, either as the active agent itself or to enhance durability of the agent. Added to this is the emergence of chitosan as a widely-used fibre pre-treatment to enhance both uptake and adhesion of the finish and as an antibacterial agent in itself (a total of 26 papers). Interest in nanofibres treated to yield antibacterial action, more in the form of electrospun yarns [9] as scaffolds for tissue growth for example, rather than as webs, have grown steadily over just the past ten years (a total of 32 papers).

1.5.2. Additional methods to assist in achieving antimicrobial textiles

Plasma treatments applied to modify surface properties and confer antibacterial action itself or enhance uptake and retention of various antimicrobial finishing

agents [228], whilst both successful and environmentally-acceptable, and useful in preparing multifunctional finishing treatments [229], have been less-widely employed for those purposes (a total of 13 papers) than treatment with chitosan (26 papers) although nitrogen-plasma treatment has been used to enhance chitosan's antibacterial effectiveness and render it rechargeable as is the case for N-halamines (see below) [230].

Chitosan applied at low concentrations is often used to modify the surface properties of cellulose fibres and confer some antibacterial action (see Section 1.3.1.3). [231]. It is antimicrobial and non-toxic and the antimicrobial action is attributed to the free amino groups on the chitosan; binding of the chitosan to the fibres by covalent linkages to permanently attach it is a compromise: it is necessary to carefully judge the extent of binding so as not to reduce the number of amino groups too much and affect the antimicrobial action. However, the chitosan will need to be crosslinked to the cellulose to improve its durability to laundering processes if it is intended to be used for bedlinen or protective clothing. In other applications it can be useful that its attachment to the surface is reversible, for example if it is required that the antimicrobial chitosan is intended to be released from the textile beside a wound or from a textile implant [232]. Chitosan may be applied alone, or used in conjunction with other agents such as silver nanoparticles [233] or zinc oxide [234] to enhance its antibacterial action or to create additional functionality.

Cyclodextrins may be used as an alternative approach to the use of metal or metal-oxide nanoparticles. Cyclodextrins can be used for their ability to hold and control the release of active agents, drugs and other partly-hydrophobic molecules at the fibre surface and release them at a particular rate; their use has continued steadily over the whole period (11 papers alongside applications for aroma release and in textile dyeing). Cyclodextrins are oligosaccharides in which glucose residues are linked together to form ring structures, most commonly consisting of 6 (α-cyclodextrin), 7 (β-cyclodextrin), or 8 (γ-cyclodextrin) glycopyranose units. They are derived from starch by enzymatic action, and it is β-cyclodextrin that is most used (95% of consumption) [235]. The ring structures of cyclodextrins have their hydroxyl groups arranged around the outer edges of the ring, which makes them hydrophilic on the ring edges, but by contrast, the inside of the ring structure is lipophylic. Because of this arrangement, cyclodextrins can form inclusion complexes with some drugs and with surfactants by entrapping lipophilic sections of the molecules within the centre part of the ring structure [236].

The host-guest entrapment is reversible and obeys Le Chatelier's principle [237], so it is possible for the entrapped species to be released at a predictable steady rate with no great initial surge, which is useful for drug release from a variety of medical textile materials such as sutures and scaffolds. Although cyclodextrins themselves may not be strongly attached to the fibre, modified forms such as the triazinyl complex become covalently attached to cellulose fibres and are therefore firmly held and durable to repeated wet treatments in the same way as reactive dyes [238].

Many surfactants show considerable affinity for certain types of textile fibres and as is the case for drugs with a lipophilic section to the molecule, cyclodextrins can form inclusion complexes with surfactants where often a delicate balance exists

between the lipophilic and hydrophilic segments of the molecule, particularly for non-ionic surfactants [239]. Surfactant retained by fabrics can cause problems not only in dyeing processes conducted after scouring and bleaching operations, but also following normal domestic laundering of clothing and bedlinen. The characteristics of the surfactants (surface-active agents) in domestic detergents are not dissimilar to those of a direct dye with poor wash fastness. On rinsing, some but not all of it is removed and it behaves similarly if rinsed again and again, with surfactant still being released after 20 or more rinse cycles. This can cause problems for eczema sufferers as some surfactant retained in the fabric is released on contact with the moist skin surface during wear and may act as a skin irritant. Cyclodextrins should therefore have the potential to serve as a rinse-aid following domestic laundering, because by forming inclusion complexes with the adsorbed surfactants they can assist in their removal [239]; the surfactant/cyclodextrin complex will have lower affinity for the fibre because it is not surface active and should be easily rinsed away.

Quaternary ammonium compound use in recent applications has focussed on ensuring their firm attachment to the fibre whilst retaining a high level of antimicrobial action. A variety of attachment mechanisms have been used. For example, a betaine was used as the finishing agent for preparing antibacterial fabrics through ester linkage between the carboxyl group of the betaine and the hydroxyl groups of the cellulose fibres of fabrics; the quaternary ammonium moiety of this compound exerted the antibacterial effect. Analyses showed that the antibacterial efficiencies of betaine-modified cotton fabrics against *E. coli* and *S. aureus* were 99.0% and 99.3%, respectively and that the fabrics were durable to laundering with antibacterial action remaining greater than 91.5% after 20 washing cycles; cytotoxicity tests showed the modified fabrics were safe to wear [240]. In other successful cases, antibacterial action and its durability was achieved with a quaternary ammonium salt plus a sulfopropylbetaine [241, 242], or by an isocyanate group using a dip-pad-dry application process [243], or they were coupled with perfluorination to yield both superhydrophobicity and antimicrobial effects [244, 245], or were applied in nanoparticulate form [246], and they may also be used in combination with N-halamines [247].

N-Halamines offer another option; a major issue in using chlorine-, bromine or iodine as disinfectants is one of stability, but there is no such problem with their organic derivatives, the N-halamines, a diverse class of rechargeable biocides in the form of amines, amides or imides, which can form covalent bonds with halogens [248]. The oxidative halogen ion (chlorine, bromine or iodine) in the N-halamine is stabilized but biocidal [249]. They are inexpensive and unlike many other biocides used for antimicrobial applications, N-halamines show rapid inactivation of a broad spectrum of microorganisms (gram-positive and gram-negative bacteria, yeasts, fungi and viruses) and do not exhibit any evidence of bacterial resistance. It is surprising therefore that so few papers (13 over the past 20 years) across both the Journal of The Textile Institute and the Textile Research Journal were reporting their application and testing of their effectiveness; having said that, there were a further 30 research papers published in the journal 'Cellulose'.

N-halamines can be applied as a coating by synthesising using the sol-gel process then applying by pad-dry-cure [250], and it is possible by careful choice of coating or

by covalent attachment to surfaces that the treatment will show great durability; also the oxidative halogen effect can be long-lasting. It did not prove necessary, for example, following epoxide tethering attachment of three different heterocyclic N-halamines to cotton, to recharge any of the three N-halamine coatings even after 50 wash cycles [251]. Covalent attachment was achieved for cotton by reaction with methylene-bis-acrylamide then its conversion into a non-cyclic N-halamine by dilute sodium hypochlorite solution. The agents used were inexpensive and readily available commercially, treatment was mild and did not cause damage to the cotton, it was highly effective against both gram + ve and gram-ve bacteria and it was rechargeable. Antimicrobial testing showed that the treated cotton inactivated 5.78×10^7 CFU/mL of *S. aureus* and 7.58×10^8 CFU/mL of the serotype of *E. Coli* named *E. coli* O157:H7 completely within 1 minute of contact, and following 50 wash cycles, although the remaining oxidative chlorine fell from 0.43% to 0.06%, it was able to be recovered to 0.30% via a simple re-chlorination using dilute NaOCl [252]. Similarly good results have been achieved by UV-photo-initiated thiolene click chemistry to apply the halamine precursor [253, 254].

Considering N-halamines as a group, the long-term nature of their halogen stability and antimicrobial functionality does depend on their chemical composition, but they have been successfully grafted onto cellulose, polyester and polyamide fibres, and the mechanism of action of stable N-halamines involving direct contact of the N-halamine with the bacterial cell during which process the oxidative halogen is transferred to the microbial cell rather than dissociating into free oxidative chlorine before its transfer, is highly effective. Features that are of particular benefit apart from their low cost are:

- Once the oxidative halogen inactivates the microorganisms and is exhausted, N-halamines can be easily recharged for example by a dilute solution of NaOCl and can then continue to be effective in inactivating pathogens.
- They can be used for the production of textiles which will be able to kill pathogenic microorganisms with high resistance to many antibacterial agents.
- Skin irritation is low so N-halamines can be used in wound dressings to prevent infection [255], and
- N-halamines can be combined with other agents to yield multifunctional finishes, although there may be some reduction in oxidative chlorine-retention properties [256]

Given their expected effectiveness against a wide range of pathogens, it comes as a surprise that the application of test methods on the antiviral effectiveness of N-halamine treated fabrics to confirm their broad-spectrum effectiveness has not become the accepted routine in research reports.

Polyhexamethylene bigaunides (PMHB) are polycationic amines wherein the cationic biguanide repeat units are separated by hydrocarbon chains. The most common is polyhexamethylene biguanide, $(C_8H_{17}N_5)_n$ where n, the degree of polymerisation, is typically selected to be between 11 and 16; the amine groups in PHMB are spaced out between sections of hydrocarbon chain six carbon atoms in length. The higher the degree of polymerisation, the stronger the attachment to the

fibre surface and the more-effective the antibacterial action. Their development and application for use in healthcare workers' uniforms was reported [257] and their application has been reviewed [258]. Effective PHMB-based finishing agents are reported to be commercially available [259]. Research activity on guanidine-based antibacterial treatments continues, with the accent on their durability [260, 261].

Molecular imprinting of polymers involves casting with the polymer in one of several available ways to encapsulate a selected molecule, then removing that molecule so that a site is generated on the polymer surface which will accept further molecules of the same shape. Films of such imprinted polymers have proved successful in acting as detectors for specific molecules [262]. It has taken longer to become able to prepare useful molecular imprinted electrospun nanofibres [263], but there are good reasons for doing so as shown by a recently-successful example: the imprinted nanofibres held a greater drug load and released the drug at a steadier rate than with 'naked' electrospun nanofibres, and based on the choice of polymer adjusting the nature and strength of drug/polymer interactions, the drug-release time could be greatly extended [264]. The approach used here was based on soft molecular imprinting [265, 266].

Multifunctional finishing of medical textiles has drawn considerable attention as shown by reported research [241, 242, 244, 245], with the purpose of capturing a series of beneficial improvements in fabric properties alongside antimicrobial action. One recent piece of research involved applying a thin, elastic xerogel coating as a finish by padding on woven 67% PET/33% cotton fabric by the sol-gel method to achieve antibacterial (vs both gram + ve and gram –ve bacteria) and antifungal effects, combined with photocatalytic cleaning, a high ultraviolet protection factor (over 50) and high abrasion resistance. The sol used was a hybrid Al_2O_3/SiO_2 sol modified with metallic nanoparticles of Ag/Cu powder and TiO_2 P25; this is a significant combination of nanoparticles, one set selected for its antimicrobial action (Ag/Cu) and the other for photocatalytic self-cleaning and UV-protection effectiveness (TiO_2 P25) [267]. Such multifunctional finishes may not always be achieved only with nanoparticles; in another case it was with a quaternary ammonium salt plus a sulfopropylbetaine [241, 242]. A detailed review of the roles of apparel in the transfer of pathogens in healthcare, drew attention to the greatly-enhanced effectiveness of antibacterial finishing treatments when combined with fluid repellancy [268]. (Finished fabrics fulfilling the preferred requirements of healthcare settings as expressed in the review, such as those possessed by 'Daltex® Smart Barrier', are commercially available [269]).

Naturally-occurring antimicrobials for textile treatments have potential as some can demonstrate effectiveness and consideration is also given to their environmental acceptability, with some treatments making claims to aspects being 'green' [52]. There has also been attention given to the antibacterial properties of plant extracts [227], and those of natural dyes, which arise from the presence of tannins, flavonoids and quinonoids [270].

1.5.3. Durability testing of antimicrobial and antiviral finishes

It is encouraging to be able to report on thorough testing of the durability of the effects of antibacterial treatment with silver nanoparticles, not least because it

demonstrated continued high levels of antibacterial effectiveness after 50 cycles of laundering [233, 271], and similarly a guanidine-functionalised cotton fabric [260] whereas just 10 Launder-Ometer® (SDL Atlas, Rockville, S. Carolina, USA) washings used to be thought indicative of durability [272]; whilst 20 laundry cycles may be a helpful indicator in the early stages of trials [240], 50 cycles is better for making a more-realistic, final-performance claim. With 30-50 laundry cycles becoming more common in test reports, it is time for the higher number of treatments to be clearly specified and agreed upon as a minimum standard for durability claims, and where the treated fabrics are expected to be laundered in a hospital or commercial laundry, for the testing regime to match (or be shown to be comparable to) that type of laundry process.

Although there was hope that nanosilver-treated fabrics might be able to exhibit broad-spectrum antimicrobial effectiveness, including antiviral action, nothing has emerged to indicate such antiviral action at a useful level, at least not by adequate testing of that or any other finishing treatment (or by incorporation of an active agent in the fibre-forming polymer), except in a single case. Despite little use of the term antiviral alongside claims for antibacterial action, it ***was*** made for a 'tri-laminate fabric' with a nano-finished PET outer layer, a microporous membrane sandwiched between that and an inner layer made of a nonwoven viscose rayon fabric (see also Section 5.2). It was also claimed that the applied nano-composite finish of nano-titanium dioxide/methylene blue exhibited light-activated antiviral properties as measured using the bacteriophage X174 specified in ASTM F1671/1671M-13 as a surrogate for Hepatitis B virus, Hepatitis C virus and HIV [8] and it is considered to be an excellent choice for the testing of barrier materials [273]. This work [8] is alone in making claims for antiviral action by a fabric alongside it providing an antiviral barrier and it is disappointing that the test regimes applied to the N-halamines, which should be expected to be able to demonstrate antiviral effectiveness, did not include the antiviral test regime [247, 248, 250–252]. Antiviral finishing and testing are topics worthy of much more attention by textile research groups; in the absence of antiviral finishing treatments or antiviral fibres, reliance must otherwise be placed solely upon the barrier aspect, resulting in a continuing slide towards single-use barrier fabrics, masks and respirators for viral protection, the consequential financial and environmental costs and the well-known high risks of supply-chain failure under the stresses of epidemic events.

1.6. Standards and specifications

In the United Kingdom, the Medicines and Healthcare products Regulatory Agency, the MHRA, are the designated competent authority that administer and enforce the law on medical devices to ensure their safety and quality. Devices must comply with the Medical Devices Regulations 2002 and the General Product Safety Regulations 2005. In addition to these, the device must also currently conform to the requirements of European directives such that a CE (Conformité Européenne) mark may be placed on the device if the product is to be marketed in the United Kingdom or European Union. Of note, in the European Union, medical devices have to undergo

a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. In the United States, the Food and Drug Association (FDA) regulate medical devices under a 510(k), also referred to as a premarket notification. Further information can be found from the relevant bodies' websites [274, 275]

Medical devices within the United Kingdom fall into one of three categories. Class I medical devices have a low to moderate risk to the patient. Class II medical devices pose a moderate to high risk to the patient/user whilst Class III medical devices are those with a high risk to the patient/user. As the risk to the patient/user increases then the regulatory requirements for licensing and the end product also increase. Regardless of the risk level, each of these categories is governed by a different European Union directive:

i) Medical Devices

Medical devices are covered by the Medical Devices Directive, 93/42/EEC [276],and define a medical device as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, (including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application), intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception.

Examples of medical devices involving textiles are orthotics, exoskeletons, bandages and sterile gloves.

ii) In vitro diagnostic medical devices

In vitro diagnostic medical devices are covered by the In Vitro Diagnostic Medical Devices Directive 98/79/EEC [277].

An *in vitro* diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purposes of providing information:

- Concerning a physiological or pathological state or
- Concerning a congenital abnormality or
- To determine the safety and compatibility with potential recipients or
- To monitor therapeutic measures

Examples of *in vitro* medical devices involving textiles include blood glucose monitors and those used in near-patient testing devices.

iii) Active implantable medical devices

Active implantable medical devices are covered by the Active Implantable Medical Devices Directive 90/385/EEC [278].

An active implantable medical device means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Examples of active implantable medical devices involving textiles are implantable glucose monitors, implantable fusion pumps and associated accessories.

On 5 April 2017, two new regulations on medical devices and in vitro diagnostic medical devices were adopted by the EU. They entered into force on 25 May 2017 and will progressively replace the existing directives. Within the EU, the new regulations will be fully applicable in May 2020 for medical devices and May 2022 for *in vitro* diagnostic medical devices [277]. Regulation (EU) 2017/745 will govern medical devices and Regulation (EU) 2017/746 will govern *in vitro* diagnostic medical devices. Key changes and updates include a new risk classification system, improved transparency, reinforcement of criteria for designation and processes for oversight, reinforcement of the rules on clinical evidence and the introduction of an 'implant card'[279].

For determining conformance of medical devices to national and international regulations, products and devices may be tested to establish how well they perform under controlled conditions in the laboratory against a series of standards governed by the International Standards Organization, namely ISO 13485. ISO 13485 is a stand-alone quality management standard to regulate medical device manufacturing environments. There are also separate standards for technical specifications that can be used including British Standards, ASTM International, Standards Australia and Japan Medical Device and Pharmaceutical Regulations.

In addition to determining conformance, medical devices are subject to post-market surveillance. This is a collection of processes and activities used to monitor the performance of a medical device and is required immediately upon commercialization of the device. Examples of the processes involve vigilance, complaint handling and reviews of clinical literature and databases [280].

2. Research involving human participants

It is well recognised that research involving human participants is an essential part of developing an understanding of the factors that underpin health and disease. It also allows for assessment of the safety and effectiveness of biomedical and social interventions [281].

The World Health Organization defines research with human subjects as 'any social science, biomedical, behavioural or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge in which human beings:

- are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment; or

- become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records.' [282]

2.1. The Nuremberg Code

Historical events have shaped the evolving legislation and regulation that are in place today. Many prominent medical researchers in the 19th and 20th centuries conducted experiments on patients without their consent and with little regard to the patient's well-being.

Physicians in Nazi Germany and elsewhere performed research on subjects that clearly violated fundamental human rights, so following the Second World War, some of the physicians were tried and convicted at Nuremberg and the basis of the judgement, the Nuremberg Code, has since served as one of the fundamental documents of modern research ethics [283].

Although the Nuremberg Code has not been adopted officially in its entirety either as law by any nation or as ethics by any major medical association, its influence on global human-rights law and medical ethics has been profound. The basic requirement of informed consent has been universally accepted and articulated in international law in Article 7 of the United Nations International Covenant on Civil and Political Rights (1966) [284]. In addition, informed consent, with specific reliance on the Nuremberg Code, is also the basis of the International Ethical Guidelines for Biomedical Research Involving Human Subjects – the most recent guidelines by the Council for International Organizations of Medical Sciences, CIOMS [285].

2.2. Research in the United Kingdom

In the United Kingdom, the UK Research Integrity Office (UKRIO) provides independent, expert and confidential support across all disciplines of research. It covers all research sectors including Higher Education, the National Health Service, private sector organizations and charities, and to aid researchers, the UKRIO have produced a Code of Practice for Research to promote good practice and prevent misconduct [286].

All practising clinicians in the United Kingdom require registration with a license to practise with the General Medical Council [287]. The General Medical Council have guidelines on good practice in research that discuss the framework of research, necessary ethics and inclusion of people who may be categorised as vulnerable, e.g. adults without capacity [288]. All individuals in the United Kingdom who are involved in the conduct of clinical research must be competent to perform their tasks, qualified by education, training and experience. Good Clinical Practice (GCP) training is the international ethical, scientific and practical standard under which all clinical research is supposed to be conducted. Compliance provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable [289].

Clinical trials require to be registered so that the results are made available to all those involved in health-care decision-making and to assist in that regard the World

Health Organization has an International Clinical Trials Registry Platform, WHO ICTRP [290]. Within the United Kingdom, the National Institute for Health Research, NIHR, offers a 'Clinical Trials Toolkit' to provide practical advice to researchers in designing and conducting publicly-funded clinical trials [291], and there is further information available from the National Health Service Health Research Authority, NHS HRA [292], and the Medical Research Council, MRC [293]. By comparison, in the USA, trials are registered via a website that is maintained by the National Library of Medicine and the National Institutes of Health [294]; Australia [295] and New Zealand [296] register their trials in a similar manner.

2.2.1. Structure of research team in the United Kingdom

The NHS HRA have released information on the structure of an adequate research team.

A sponsor takes responsibility for initiation, management and financing of the research. This may be an individual, company, institution, organization or group of organizations. All research falling under the remit of the Secretary of State for Health and Social Care must have a formal sponsor.

A legal representative of the sponsor is required if the sponsor is based outside the European Economic Area and the research covers a clinical trial of an investigational medicinal product. There are different regulations for medical devices.

The Chief Investigator, CI, is responsible for the conduct of the whole project in the United Kingdom. They should be professionally based in the United Kingdom and able to supervise the research effectively. In addition, they should be readily available to communicate with the Research Ethics Committee and other review bodies during the application process and where necessary during the conduct of the research.

The Principal Investigators, PIs, are individuals responsible for the conduct of the research at the research site. There should be one PI for each research site. Finally, the Data Controller will be the organisation responsible for the management and oversight of the data [298].

Other countries, such as the USA, Australia and New Zealand, have similar structures with regulatory bodies overseeing trials, ensuring compliance to rules and that trials are ethically run. Those involved are organised in a similar manner though with some variation depending on the nature of the trial that is being undertaken.

2.2.2. Establishing a clinical trial in the United Kingdom

The design of a clinical trial is usually undertaken by a team comprising doctors, specialist and a wide variety of others, including patients. Initially, the current evidence base requires review to establish what is already known – this is called a systematic review - it also helps identify important questions that still require addressing. A Cochrane Systematic Review is considered the gold standard. Each Review is prepared and supervised by a Cochrane Review group. Explicit, systematic methods are used to conduct the review and the reviews are updated to reflect the findings of new evidence when it becomes available [297].

Following the review, a trial protocol is designed, and it is at this stage that biostatisticians and trial managers may be involved in addition to clinicians, patients and

other relevant parties. Once the trial protocol has been written, it is sent to the relevant research ethics committee. This may be within the local hospital, University or a national group but is an independent group that includes doctors, nurses, members of the public and sometimes lawyers. It is their duty to assess whether the trial is ethical. Once the trial protocol has been passed by the research ethics committee and sufficient funding is in place to support the work, the trial may begin - investigators are recruited at the research sites, training is undertaken and the trial is commenced [298].

2.3. Types of clinical trials

Clinical trials may be conducted at a number of stages during research and development. Whilst the detail below concerns drugs, with the development of the medical textile sector, many of the newer medical textiles exhibit biological activity and thus exert a physiological or pharmacological effect.

Phase 1 trials are the first stage and usually involve small groups of healthy people or patients. They are aimed at finding out how safe a drug is.

Phase 2 trials test the new drug in a larger group of individuals to better measure the safety and side effects. These trials also identify whether the drug has a positive effect in patients.

Phase 3 trials are larger again and may include hundreds or thousands of patients. They may be multi-national trials. They compare the effects of the newer drug or treatment with the standard treatment. In addition, they identify how well the drug works and how long the effects last. More information is gathered at this stage about common and serious side effects or risks and any possible longer-term problems that may develop.

Phase 4 trials are carried out after a new drug has been shown to work and given a licence. These determine how well the drug works when it is used more widely and the long-term risks and benefits. In addition, they assess possible rare side effects.

Trials may be designed to compare different treatments. Broadly speaking, there may be a control group who receives no treatment or the current treatment and an intervention group who receives the new treatment.

Trials may be blinded to improve the accuracy of the results and evidence. Blinding reduces conscious and unconscious bias in the design and execution of a clinical trial [299]. In a blind trial, participants are not told whether they are receiving the new treatment or the alternative. In a double-blind trial, the clinicians treating or data collects and the patients are unaware of the treatment the participant receives. In a triple blind trial, participant, clinicians/data collectors and the outcome adjudicators/data analysists are all unaware of the treatment the participant receives. Randomisation allocates participants randomly to a trial. This may be undertaken by a computer programme. It may be done such that each group within the trial contains a similar mix of individuals of different ages, sex and state of health to allow for meaningful data analysis. As one can see, trials are regulated to ensure that they are safe to participants and comply with ethics yet still produce meaningful results that can be used to optimise human health.

3. Implantable medical textiles

As discussed in Section 1, an implantable medical device means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain there after the procedure is completed [278]. Such devices may be biologically active or biologically inert. Those that fall under the medical textile remit include sutures, vascular grafts, meshes and resorbable polymers such as scaffolds for cell growth.

3.1. Sutures

The history of sutures in the medical field dates back over 4000 years when fibres of the flax plant were used to close or cover wounds. In reference to more-recent medical innovations, the first internal use of sutures is credited to French physicists Lapuyade and Sicre who used metal wires to set a broken humerus in Toulouse in 1775, whereas today, interest has grown in the application of *biodegradable* metal sutures made from alloys of iron magnesium and zinc; they are used predominantly for vascular stent or osteosynthesis applications, but could have wider applications, and although they would have to compete with biodegradable polymers for soft-tissue sutures, they are thought to have the potential to replace stainless steel and titanium alloys for hard-tissue sutures [300].

By the 1930s, catgut (made from the cleaned and sterilised intestinal tube walls, mostly of sheep) and silk dominated the suture market [301] whereas after World War II and the development of synthetic polymers, nylon, polyester and polypropylene led to them becoming the predominant non-absorbable sutures [302]. Both absorbable and non-absorbable sutures are used in surgery, see Figure 3; they may be natural or synthetic polymer materials in monofilament or in a multifilament form [302]. Synthetic absorbable or SA sutures made from bio-degradable polymers such as poliglecaprone 25 and polyglactin 910 undergo degradation by enzymatic digestion or hydrolysis. Various different materials are used for their different length of time for absorption and different strength retention profiles (for example, poliglecaprone 25 degrades rapidly whereas polyglactin 910 degrades more slowly), knowledge of which is key in preventing wound dehiscence (wound opening owing to suture failure before healing). Poly(l-lactic acid), PLLA, is another biodegradable material which, although too stiff and inflexible itself for monofilament suture purposes due to its high glass transition temperature and crystallinity, can be modified by combining it with another polymer. The properties of PLLA are able to be adjusted by blending PLLA (90%) with poly (lactide-co-ϵ-caprolactone), PLCL, (10%) thereby lowering the Tg with consequent reduction in stiffness and improvement in flexibility and knotability in monofilament sutures [303].

Absorbable suture materials are also used in specialist applications such as the so-called ‘Catgut Embedding Acupoint’ for which the ideal embedding materials are required to have excellent swelling, mechanical, and antibacterial properties; two absorbable polymers have been assessed and regarded as suitable, namely

Figure 3. Examples of commonly used sutures.

polyglycolic acid and polylactic acid in the form of monofilaments. Various ways of optimising their performance have been explored:

- Chitosan Coating: for chitosan-coated polyglycolic acid and chitosan-coated poly (lactic acid) monofilaments, the treatment of polyglycolic acid with chitosan altered its rate of degradation offering the possibility of control over this feature, hence polyglycolic acid filaments were preferred for this type of embedding treatment [304].
- Coating Method: The method used to apply the chitosan coating was important and this consisted of pre-treatment, spray-coating and rolling and drying [305]. The application of a 3% chitosan coating proved most effective [303].
- Hydrophilicity and swelling behaviour: surface modification of polygycolic acid monofilaments either by ultrasonic treatment in a 50/50 v/v solution of ethanol / H_2O_2 at 250 W ultrasonic power for 30 minutes or by cold oxygen plasma treatment, improved both key properties for acupoint embedding therapy [307–309].

Sutures need to demonstrate a number of characteristics, and there are some useful papers which set these requirements down in great detail [300, 310] but they can be summarised as follows:

- Tensile strength – the ability of the suture to resist damage and deformation
- Shape Memory – the ability of the material to return to or maintain its original shape

- Capillarity – the extent to which the suture material allows the passage of adsorbed fluid
- Pliability – the ease of handling of the suture material
- Knot security – sutures must be able to be tied effectively such that the knots do not slip
- Low coefficient of friction – the ease with which a suture passes through the skin

Some of the related properties need to have standard methods for their measurement as values can vary substantially depending on, for example, rate of extension when testing knot strength [311] and in braided structures, it was found that the variation of braid angle had an important influence on breaking load/elongation of the suture and slippage ratio for the knots was defined and measured. The presence of a knot lowered the breaking load and the rupture occurred consistently at the knot region [312].

With regards to poor clinical outcomes in wound repair, the most common outcomes studied are surgical site infection and wound healing, cosmetic outcome, incisional hernia formation and perineal pain [313]. It may be that development of new sutures and biomaterials should be directed towards these avenues. Suture materials must fulfil specific roles which are dictated by factors such as the location they are used in, the type of tissue being closed and the type of surgery being undertaken. There are some roles where their function is more critical than others, for example, the failure of a suture in the anastomosis (join) of a large vessel may be fatal whilst the dehiscence of a subcutaneous (inner part of the skin) fat plane or overlying skin may cause an unsightly scar but not a fatality. Traditionally, skin is often closed with a non-absorbable nylon or absorbable poliglecaprone 25 or polyglactin 910. Non-absorbable sutures require removal which necessitates a health care attendance whilst the absorbable will gradually dissolve without the need for removal.

Tendon repair is another aspect to consider. For example, the Achilles tendon is the thickest and strongest tendon in the body and withholds stress approximately 12.5 times the individual's body weight when running. Repair of a defect can be undertaken as a primary procedure or augmented with autologous tendon, such as that of flexor hallucis longus, which increases load to failure. This remains a topic of interest in the foot and ankle community [314, 315].

3.1.1. Human biology

Different tissues within the body exhibit different characteristics; mechanical and biological. Fascial planes are comparatively tough and aid in keeping structures in various compartments within the body. Condensations of fascia can form ligaments, for example the palmar fascia in the hand condenses to form the carpal tunnel ligament. Pathology here can create carpal tunnel syndrome. In comparison, subcutaneous fat is a relatively soft tissue to close and the quantity that can close varies widely between individuals. In stronger tissues, a stronger suture is required.

Acute wounds undergo faster healing than chronic wounds and thus for the acute wound, a suture that loses its mechanical integrity at a fast rate may be appropriate.

In the healing of an acute wound, there is an orderly progression through inflammation, fibroblast proliferation and maturation.

i) Inflammation

In the acute inflammatory phase, there is local vasodilatation of vessels allowing an influx of inflammatory cells and growth factors. These trigger a cascade that ultimately tell platelets to clot to prevent blood loss, immune cells to upregulate and move from a dormant to active phase to fight infection and finally to stimulate relevant cells to proliferate to aid in wound closure.

ii) Fibroblast proliferation

Within two to three days, fibroblasts appear and relevant extracellular matrix. Collagen and glycosaminoglycans are produced to aid in wound healing. There is also angiogenesis to produce capillaries required for scar formation.

iii) Maturation

By three weeks, wound remodelling begins. This can last up to two years in the healthy individual. During this phase, there is reorganization of new cells into a more organised structure, determined by mechanical factors and an increase in tensile strength.

Chronic wounds are all unique and heal in a different manner from that of acute wounds. One of the unique features is that wounds contract. This does serve a useful role in that it reduces the size of the wound but can cause disorganized structural integrity, loss of function and cosmetic deformity. Chronic wounds also produce granulation tissue (which acute wounds do not) composed of numerous capillaries and a support matrix rich in fibroblasts, inflammatory cells, endothelial cells, pericytes and myofibroblasts that all have their own function. The problem with granulation tissue is that it converts from a cell-rich, highly-vascular medium to a relatively-avascular and acellular matrix of collagen. Finally, in chronic wounds there is a dysregulation of growth factors in comparison to acute wounds [313].

Different tissues heal at different rates, therefore, any successful suture must maintain a sufficient strength over the time taken for the wound to heal and not interfere with the native biology. The healing of stomach and colon tissue in dogs for example, has been demonstrated to differ from that of their skin wounds. The gastrointestinal tissues are more metabolically active with a markedly elevated rate of both collagen and non-collagenous protein synthesis so that after 21 days, the breaking strength of the wound does not increase significantly [316].

Most surgical wounds heal by what is known as primary intention, where wound edges are re-approximated using sutures, staples, clips or glue. Some wounds are left open to heal by secondary intention, where they heal from the 'bottom up'. This may be because wound closure is not appropriate due to infection or wound edges cannot be approximated. Some wounds break down following closure and may partially or completely reopen.

Surgical site infection is a serious global health issue that can lead to significant morbidity, need for re-intervention and treatment and, in very serious infections, the possibility of fatality [317–319].

Different types of surgical wounds carry different risks for surgical site infection (SSI). Wound class is assessed using the classification system adopted by the Centres

of Disease Control and Prevention [320]. For example, dirty wounds such as a bowel perforation or a known infected wound carries an increased risk compared with wounds in clean surgery, such as a thyroid or arthroplasty operation. Whilst there is a view that the method of surgical wound closure may impact on SSI risk, there is limited background evidence on mechanisms for SSI prevention. It has been suggested that the better the seal the closure method obtains, the better the barrier to microbial contamination [321].

In plastic surgery, the most common wound complications are tissue reactivity, infections and wound dehiscence. It is well known that choice of suture material is imperative to appropriate wound closure. The 'perfect' suture material should be of uniform calibre (possess uniform linear density), be readily available, be reasonably inexpensive and easy to sterilize, elastic, supple and have good tensile strength. In one study of 1000 plastic surgical wounds [322], the wounds were evaluated at days 3, 7 and 14 post operation for three outcomes of interest: tissue reactivity, wound dehiscence and local infection. Monofilament non-absorbable sutures used in the study included nylon. Multifilament absorbable sutures of catgut, polglycolic acid and polyglactin (a copolymer of glycolic and lactic acid) were used. Multifilament non-absorbable synthetic sutures of braided polyamide and polyester and natural sutures of silk were used.

There was no significant difference between commonly-used sutures in terms of tissue reactivity and wound site did not make a significant difference. In two-layer wounds, silk demonstrated an increased risk of tissue reactivity when compared with the monofilament sutures. With regard to internal suture materials, polyglactin 910 showed a 66% increase in risk of tissue reactivity when compared with polyglycolic acid. Thinner sutures showed a statistically-significant protective effect.

With regard to wound dehiscence, the type of suture material in one- and two-layer wounds did not make a significant difference. Patient characteristics, for example co-morbidities did play a role. Suture material also did not appear to make a difference on rate of infection, although the overall infection rate was only 1.7% and thus this is a small sample size.

In gastrointestinal surgery, a Cochrane Review assessed the best way of closing a laparotomy wound. The review asked the question 'does the type of suture material, or type of closure prevent complications?' With regard to sutures, there was no difference at one year or more of follow up of the incidence of incisional hernia between absorbable and non-absorbable sutures. Nor was there any difference in risk of wound infection. However, absorbable sutures did reduce the risk of sinus or fistula tract formation when compared to non-absorbable sutures and the review suggested that absorbable sutures could be used to reduce the risk of chronic drainage from the wound and monofilament sutures considered for abdominal closure to reduce the risk of incisional hernia [323]. For obstetrics, a Cochrane Review assessed the role of absorbable sutures for repair of perineal damage at the time of childbirth. Women stitched with synthetic materials had less pain in the first three days after delivery and required fewer pain-relieving drugs in the 10 days after giving birth compared to those stitched with catgut. However, there was evidence that synthetic sutures were not always readily absorbed and some women required the sutures to be removed [324].

As mentioned earlier in this section, in addition to sutures, wounds and lacerations may be treated with adhesive glue. One study on traumatic wounds demonstrated no difference at 1 year between wounds treated with octylcyanoacrylate (glue) and sutures. In a busy Emergency Department, adhesive glue is quicker to apply than suturing and does not require local anaesthetic, making it appealing for use on combative or paediatric patients and with a premorbid patient, speed is vital, hence these may be influencing factors in this situation when clinicians have to decide what to use [325].

3.1.2. Recent advances in sutures

More recently, there has been interest in developing bio-active and bio-inert polymers for closing surgical incisions and wounds. This has modified the function of the suture to an active medical device that biologically interacts with the host environment to prevent suture failure and to promote a positive healing response. Modifications to sutures that alter their overall function include coating the suture to achieve, for example, advantageous bio-activity, creating sutures with barbs to obviate the need for knots, or creating sutures where the knot may be adjusted to achieve different degrees of tightness of wound closure.

In 2003, antimicrobial-coated Vicryl® Plus, (Ethicon) - made from polyglactin 910 was introduced. The coating contains a broad-spectrum antimicrobial agent based upon Triclosan and has been shown to reduce surgical site infection by up to 30% [326, 327]. Other sutures have been trialled with biologically-active modifications such

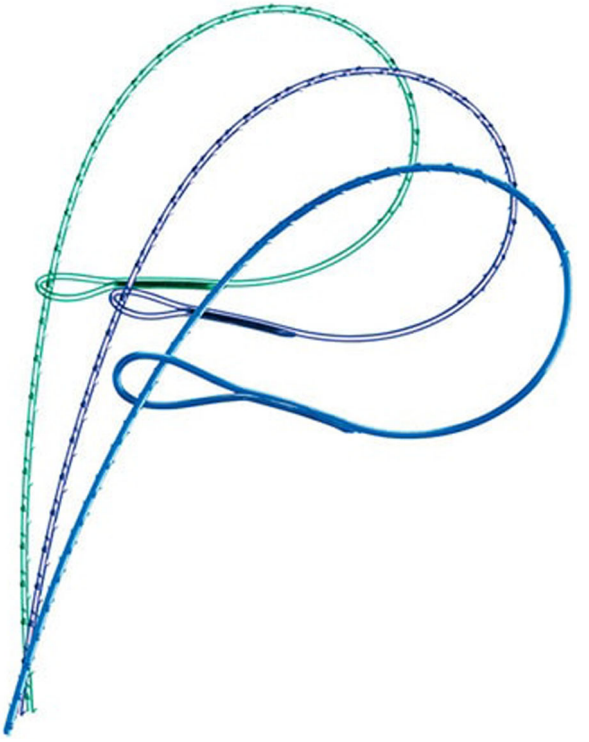

Figure 4. Barbed Sutures (Reproduced with permission from Medtronic, Watford, United Kingdom).

as the addition of antimicrobial grapefruit seed extract [328], growth factors such as BMP-12 [329] and even stem cells [330].

Barbed sutures are sutures that have barbs or projections on the surface which penetrate into the tissues and hold them without necessitating the need for knots. The knotless, barbed suture was first described in 1967 by McKenzie in tendon repair in the hand [331]. In an orthopaedic study, it has been shown to lead to a shorter operation time and lower total cost when used instead of standard sutures and yielded similar postoperative function and a lower total complication risk (see Figure 4) [332]. Animal studies of gastrointestinal closure confirm that the speed of closure was significantly faster than that achieved by traditional sutures with no significant increase in complication rate [333]. Finally, a Cochrane Review explored whether adjustable sutures may be of benefit in ophthalmological surgery for strabismus but could reach no reliable conclusion due to the lack of data in this area [334] showing there is still tremendous scope for innovation in the design of sutures and further trials may elucidate the potential benefits.

3.2. Vascular grafts, stents

The primary purpose of the vascular system is to serve as a non-thrombogenic conduit for blood flow. The structure and function of the vascular tree varies depending upon location. As well as providing the human body with 'plumbing', the vessels are also biologically active and can regulate blood flow, blood pressure and the focus the delivery of blood to tissues according to their metabolic requirements.

There are three types of vessels: arteries, veins and capillaries. Arteries and veins are composed of three distinct layers; tunica intima, tunica media and tunica adventitia. In arteries, the intima is composed of a single layer of epithelial cells (endothelium) supported by a basement membrane and elastic lamina. The media contains circular smooth muscle cells and an elastin-rich cellular matrix whereas the adventitia is composed of loose connective tissue, fibroblasts, nerve endings and vasa vasorum (blood supply to the vessel) [335]. Arteries can be divided into large elastic arteries, medium muscular arteries and small arteries. Veins are capacitance vessels that operate under low-pressure conditions and are larger and thinner-walled than arteries. There are fewer smooth muscle cells in the tunica media. The basic structural components allow for the vasculature to regulate blood flow by changing luminal area and wall thickness. As the vessels are living tissues, damage to them or the introduction of foreign material results in endothelial dysfunction leading to an inflammatory response resulting in atherosclerosis.

Grafts can be used to 'replumb' whole or parts of diseased vessels. They can be used to bypass sites of occlusion or to strengthen weakened vessels, for example, an aneurysm (enlargement of an artery due to weakness in the arterial wall). They may be made by weaving, knitting or braiding, but whatever construction method is used, they need to be able to withstand the pressures generated in the vessel they are grafted into and it is also believed that the success of a textile vascular graft, in the healing process after implantation, is due to the porous micro-structure of the wall. It has been shown that the type of fabric in textile vascular grafts and the degree of porosity and

permeability affect both the local fluid dynamics and the level of penetration of platelets through the wall, thus indicating their importance as design parameters [336].

Grafts can be very sophisticated in terms of their design and performance and they can be made to be seamless by knitting [337], weaving [338, 339] or braiding [340, 341], with bifurcations or trifurcations (see Figure 5) [342]; their performance can be modelled (not least to explore flow at bends in the stent) to enable informed choices to be made [343] and in a comparison between knitted and braided structures made from polypropylene, it was concluded that the braids performed better in that instance [344] but stents of all constructions are used. Whilst medical practitioners may usually refer to stents according to their function/application, a useful summary of the different types of construction methods was assembled some time ago and it remains a useful reference in this regard [345].

In another example, to minimize radial compliance mismatch between native arteries and vascular prostheses over the entire blood pressure range, a biomimetic woven prosthesis sample with a bilayer wall was developed using poly(trimethylene terephthalate) (PTT) filaments as the circumferential yarns in the inner layer (to increase the radial compliance of the inner wall), and poly(ethylene terephthalate) (PET) filaments to form the outer layer (to provide a strong and more-rigid external prosthesis wall). The two layers were joined together axially along the sample's length by a stitched weave. By means of its woven design, the cross-section of the tubular sample consisted of a circumferentially-crimped outer layer woven around the inner layer. The bilayer wall structure allowed only the inner layer of the sample to deform radially under small loads equivalent to low normal physiological (diastolic) blood pressures. As the load increased, the inner layer stretched until it came into contact with the outer layer. At higher (systolic) pressures, further loading caused both layers of the wall to deform together. As a result, the prosthesis showed high pressure-induced compliance when the load was within the normal diastolic pressure range and appropriately lower compliance at higher systolic pressures [345].

Attention is being paid to the suitability of biodegradable materials for stents, to circumvent the need for removal, but particular attention is needed to ensure, through optimisation, that a stent (knitted in this case) made from such a material (polylactic acid in this instance) can withstand the radial forces likely to be exerted over the required length of time [346]. Grafts/stents made from nanofibres which may be made from absorbable or non-absorbable polymers depending on the application [9] also appear to offer many advantages over those made from conventional yarns, not least because of their high degree of porosity, which, in the case of a tubular woven nanofibre graft could be adjusted by controlling thread density [347]. The yarns made from bundles of nanofibres are relatively fragile so great care had to be taken not to damage them during the (novel robotic) weaving process, but the resulting graft was robust, suturable, kink-proof, and non-thrombogenic. The woven nanofibre graft is claimed to possess significant advantages over nano-fibrous nonwovens owing to its regular and controlled hierarchy of nanofibres which yields super-hydrophilicity from an otherwise hydrophobic polymer material; it was considered that characteristic contributed to the observed enhanced protein adsorption, cell attachment and spreading. Grafts may be inserted by a traditional open method or

Figure 5. Vascular Graft (Image provided courtesy of W.L Gore 7 Associates, Arizona, United States).

by an endovascular approach. In an endovascular approach, the site of interest is approached via the vessels from a distant site. The graft is preoperatively sized and fenestrated to allow blood flow to branches of the main vessel. It is put in place under radiological guidance.

NICE guidelines from 2018 do not advocate the use of endovascular repair due to long term complications and higher costs to the National Health Service for unruptured aneurysms. Current guidelines support open surgery rather than endovascular [348].

3.2.1. Problems with grafts/stents

Revision of vascular intervention is frequently required beyond the first six weeks and up to 40% of femorodistal bypass surgery grafts (a vessel that bypasses a blockage and connects the femoral artery with an artery in the leg) require re-intervention within 5 years. Although, there has been considerable enthusiasm for endovascular aortic aneurysm reconstruction (EVAR) [349], the same issue arises for endovascular intervention where up to 30% of patients need a re-intervention within 5 years after EVA [350]. This may be due to a variety of problems. Graft -related problems include occlusion and infection. EVARs also suffer from aneurysm sac expansion due to type II endoleak, back-flow of blood from aortic collaterals into the sac (other blood vessels that connect to the aorta nearby and can allow blood to 'backflow' into the repair).

Graft thrombosis is influenced by both general and local factors. Infra-inguinal bypass patency of autologous vein is better than Dacron (PET) or PTFE [351]. For femoropopliteal bypass grafts (a graft connecting the femoral artery to the popliteal artery), patency at 5 years is similar when Dacron or PTFE are used [352]. A heparin-bonded PTFE graft significantly reduced the overall risk of primary graft failure by 37% in a 1 year multicentre randomised clinical trial (RCT) in Scandinavia. The heparin bonded graft was superior to PTFE and with no difference in primary graft patency at 5 years for above knee bypass [353, 354]. The risk for ischaemic complications and the need for emergency limb revascularisation are greater with occlusion of prosthetic grafts compared to venous grafts as the thrombus in the prosthetic graft extends into the outflow artery and are at a higher risk of breaking off resulting in distal infarction [355].

A Cochrane Review in 2018 demonstrated a clear primary patency benefit for autologous vein when compared to synthetic materials for above-knee bypasses. In the long term (5 years), Dacron confers a small primary patency benefit over PTFE for above-knee bypass. More research is required to determine which graft is superior for a below-knee bypass [356].

Graft infection is relatively uncommon but has a high amputation and mortality risk [357]. Treatment is aimed at patient survival, eradication of infection and revascularisation by a method that is durable and does not itself become infected. Grafts have been manufactured that incorporate antimicrobials. At present, Rifampicin bonding of Dacron grafts does not appear to reduce graft infection, nor does silver-coating of the graft [358, 359].

The development of aneurysms was frequent with early PTFE grafts. Adjustments in manufacturing appear to have eliminated this. Dacron undergoes late degradation and dilatation and this becomes clinically significant in 2-3% of cases. After 5-10 years, disruption can occur at points of stress, for example, under a ligament, and cause a false aneurysm [360]. Distraction of the graft may cause spontaneous rupture or anastomotic disruption of PTFE axillofemoral grafts [361].

3.2.2. Future developments with grafts/stents

In small diameter vessels, synthetic grafts are of limited use due to poor patency rates [362]. Whilst there has been some improvement in patency by seeding autologous

endothelial cells onto the luminal surface of synthetic grafts, the grafts have been unable to exceed the performance of autologous vessels [363]. Synthetic polymer scaffolds have been used to create vascular grafts. A porous scaffold produced from a biodegradable copolymer mesh of poly-L-lactide and poly-caprolactone reinforced with polyglycolide has been seeded with cells prior to inflammation. The grafts were implanted into large vessels and results were somewhat promising though not without room for improvement [364, 365]. A variety of other fibre types, both synthetic and natural, have been used to create scaffolds on which to seed cells. Current understanding of the underlying molecular process in replacing the engineered graft by host cells is limited. Better understanding of this process will enable the construction of grafts with the potential for long term graft success.

3.3. Implantable mesh

Implantable mesh is used to treat hernias, a protrusion of all or part of an organ through the body wall of the cavity that contains it. Hernias are a common general surgical problem; there are several types of groin hernias. Abdominal wall hernias can occur post-operatively, or primarily, around the umbilicus and parastomal hernias around stoma openings. In gynaecology and urology, protrusions of the bladder or rectum into the vagina, cystoceles and rectoceles respectively, are a common problem with significant morbidity to individuals involved.

The development of synthetic meshes has resulted in the advancement of surgical technique away from bolstering the tissue with sutures towards using a mesh to close a defect. Details of the first synthetic polymer mesh (a woven polypropylene mesh) were published in 1958 and the researchers swiftly moved to using knitted polypropylene mesh instead because of its improved flexibility. A significant advantage is that a synthetic mesh placed over the defect can repair a hernia without the need undertake extensive tissue dissection to release enough tissue to perform a tension-free repair. To perform adequately, the mesh needs to be able to withstand the tensions and extensibility experienced within the abdominal wall; these can be calculated and measured. The hernia-repair mesh needs to be able to withstand at least 180 mmHg (20 kPa) before failing, indicating a tensile strength requirement of 16 N/cm and extensibility in males of 23% ± 7% and 15% ± 5% and 32% ± 17% and 17% ± 5% in females when tissue is stretched in the vertical and horizontal directions respectively [366].

In groin hernias, mesh repair reduces the risk of hernia recurrence compared to non-mesh repair resulting in a shorter hospital stay and quicker return to normal activity [367]. The risk of hernia recurrence is also reduced in mesh repair of parastomal hernias and laparoscopic repair of inguinal hernias [368]. A lightweight mesh in the repair of inguinal hernias does not appear to alter the risk of hernia recurrence but is associated with a reduced incidence of chronic groin pain, groin stiffness and foreign body sensation than a heavy weight mesh [369].

Current practice involves the use of polypropylene mesh products such as Prolene® (Johnson & Johnson Medical Ltd, Wokingham, United Kingdom) in open repair and laparoscopic Trans-Abdominal Pre-Peritoneal hernia repair (TAPP). Laparoscopic Totally

Extra-Peritoneal mesh repair (TEP) uses self-fixating mesh, which reduces post-operative pain and bleeding resulting in early mobilisation and return to normal activities. A randomised multicentre study found that at five years, chronic pain in TEP repair was 9.4% versus 18.8% in open repair [370].

Using mesh has been shown to provide a statistically significant better anatomical outcome when used in anterior vaginal wall prolapse repair in comparison to native tissue with no deleterious effects on functional outcome. The multicentre, prospective and randomised PROSPECT trial compared using native tissue to either synthetic or biological mesh repair in vaginal prolapse surgery and showed no short-term effect on outcomes such as effectiveness and quality of life but an increase in complications [371, 372].

Synthetic meshes have been made from a variety of materials that have evolved with experience and technology. Meshes may be manufactured from PTFE, polypropylene or polyester. Expanded PTFE, whereby a sheet of PTFE is created first and then stretched to create micropores, is an inert, microporous hydrophobic material that can be used intra-peritoneally due to the low risk of host inflammation reaction that is often associated with mesh. However, incorporation into the abdominal wall is limited. Polypropylene and polyester can be made in the form of microporous meshes that allow a good integration in the abdominal wall by colonization of the prosthesis with collagen fibres from the host. Polypropylene absorbs little if any moisture and in these applications is usually knitted or woven to the required design. Polyester is also woven into a variety of designs for similar purposes; it is slightly less hydrophobic than polypropylene. Composite meshes made of two sheets of differing materials have also been used in abdominal surgery but are more expensive [373]. Synthetic meshes are often characterised by 'weight' and porosity; varying between ultralightweight at approximately $<30\,g/m^2$ and heavyweight $>90\,g/m^2$. Porosity is characterised by the size of the pore; microporous being $<100\mu m$ and large pores being 1000-2000μm. Biocompatibility appears to be proportional to the pore size of the mesh [374].

There are resorbable meshes available, typically composed of copolymerized forms of polylactic acid, polyglycolic acid, polyglactin and/or polycaprolactone; with these, one of the issues that needs to be taken into account is that the degradation rate needs to be slower than the native healing to ensure sufficient reinforcement of tissue walls while that takes place [375].

Biologic meshes derived from porcine or bovine tissue are also used and provide an ideal scaffold for tissue penetration but these are very expensive and so they are usually reserved for use in abdominal wall reconstruction.

3.3.1. Problems with mesh

Mesh repair is not without problems. In groin hernias, a Cochrane Review showed that wound infection and seroma (collection of fluid) rate was more common than in a hernia repair without mesh [376].

Permanent mesh for vaginal prolapse was associated with a higher rate of de novo stress incontinence and bladder injury [377]. Furthermore, there were reports of vaginal mesh erosion and chronic pain. In 2011, transvaginal permanent mesh was

voluntarily withdrawn from the market, though lightweight transvaginal permanent mesh was still available until banned in 2018. Hitting the headlines of national newspapers in the United Kingdom in 2017, NICE in updated advice in December 2017 said that evidence on the safety of the procedure showed there were serious, but well-recognised safety concerns and recommended that the use of mesh in prolapse should be restricted to research only [378]. The latest update is that mesh can be implanted but that a register must be maintained to track patients and outcomes [379].

3.3.2. Future developments with mesh

In an effort to decrease fibrotic response and to prevent adhesions that can occur with meshes, both polyester and polypropylene meshes have been coated with a range of anti-adhesive barriers including collagen, titanium, polyglactin and omega-3 fatty acids [374]. The use of coating has been associated with less postoperative pain in short-and long- term follow up but this may be attributed to the weight of the mesh rather than the coating [374]. The currently used materials have also been coated with polyethylenimine with promising results [380].

There has also been work directed at the process of manufacture of the mesh. Most meshes are woven but one type is made from randomly-orientated microfibres of polypropylene, which is theoretically more biocompatible than a mechanical weave.

The addition of drugs and cells to meshes is also being trialled. Fibroblast cells and mesenchymal stem cells have been coated onto three commercial meshes and demonstrated a positive integration, though this research is still largely in the infancy stages [381].

3.4. Resorbable scaffolds for cell growth

Scaffolds serve as a substitute for the native extracellular matrix and play a pivotal role in tissue regeneration as they provide temporary support for cells whilst natural extracellular matrix forms. They have been used to generate a range of cells. Scaffolds may be made from natural fibres, such as collagen, elastin, silk or alginate or they may be manufactured from synthetic fibres, such as polylactic acid, polycaprolactone or polyetherurethane [382]. Resorbable scaffolds for providing temporary support during cell growth are particularly interesting. Both the surface topographic features such as roughness and hydrophilicity and the scaffold microstructures, such as pore size, porosity, pore interconnectivity and pore/fibre architectures influence the cell-scaffold interactions with architecture playing a pivotal role.

A scaffold needs to meet certain criteria for tissue regeneration. For example, it needs to have a surface and internal structure that support cellular behaviours, have mechanical properties similar to the native tissue being repaired, be biocompatible and degrade at a rate to match tissue regeneration. The advent of electrospinning has been pivotal in the development of scaffolds, but whilst electrospun scaffolds typically possess a high porosity, they lack the appropriate mechanical properties for load-bearing properties [383]. Pore size can also be problematic; too small and vascular ingrowth is restricted. One modification to solve some of these ‘problems’ is to

combine electrospinning with other scaffold fabrication techniques, for example, wet spinning, melt spinning, microfluidic spinning, extrusion and fibre bonding [384]. Scaffolds and regenerative medicine are very much a new area of medicine and there is still much scope for development within the field.

4. Non-implantable medical textiles

Non-implantable medical textiles include dressings and pressure garments, such as thromboembolic stockings. The broad categories will be discussed below.

4.1. Wound dressings

The Textile Institute defines wound dressings as "materials, including textiles, whose functions are to provide protection to a wound against infection, absorb blood and exudate and promote healing" [385]. Historically, biological materials such as cobwebs, leaves, seaweed, silver and honey have all been used as dressings. In more recent times, there has been a revival in their use as the knowledge base behind 'why and how' they aid the healing process has increased [386–388].

It is not the dressing that heals a wound. However, a properly selected dressing will prevent further harm to the wound and also promote healing. In an ideal situation, the wound dressing should prevent micro-organisms from reaching the wound and should also maintain a moist environment at the wound interface) [103]. A moist environment allows cells to move unhampered by the formation of an eschar (scab) [389]. Other factors to consider when selecting a wound dressing include gas exchange, maintaining appropriate tissue temperature, adherence to the wound and any debridement action [390]. Wounds can be created by a variety of methods; from the surgical knife to trauma or tissue breakdown due to disease. In clinical practice, an acute wound requires different treatment from a chronic wound. As discussed previously in Section 3.1.1, primary closure of a wound differs significantly from allowing a wound to heal by secondary intention, where the wound edges are not approximated.

Dressings may be classified as passive, interactive or bioactive. Dressings such as gauze are the traditional passive dressings. Interactive products are those that provide a barrier to microbes but are permeable to air and water. Bioactive dressings are those that deliver substances active in wound healing [391] and this field has expanded immensely in the past thirty years due to advances in immunology and understanding of the science of wound healing [392]; they shall be discussed in turn but being part of a broader review of medical textiles this is by no means a fully comprehensive review of the subject matter.

4.1.1. Passive wound dressings

These wound dressings involve gauzes and secondary wound dressings such as wool and crepe that are used over a smaller wound dressing (see Figures 6 and 7). They often provide additional padding and compression and may be used post-surgery to prevent haematoma formation. The secondary dressings are often debulked around 48-72hours after surgery.

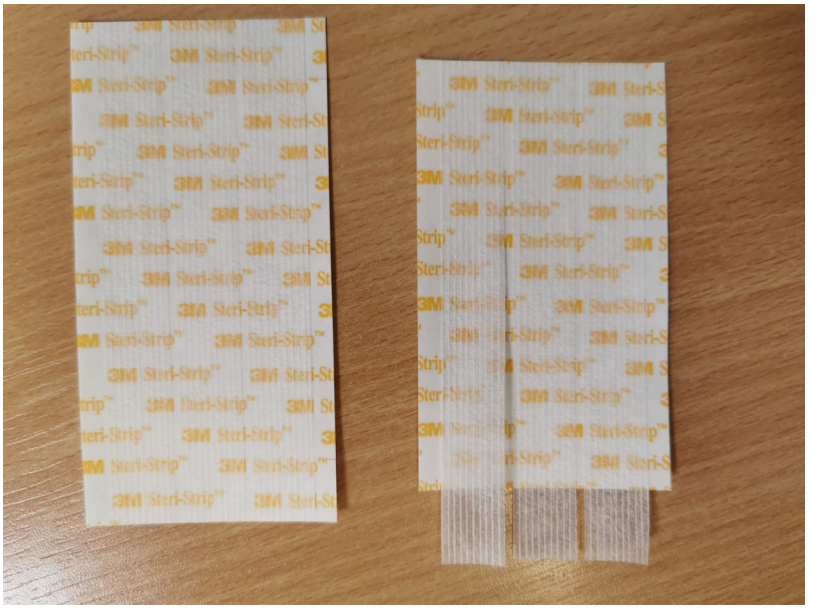

Figure 6. Example of Steristrips.

Figure 7. Gauze swab.

Gauze dressings may be manufactured from woven and non-woven fibres of cotton, rayon and polyester and provide a barrier to the wound and thus some protection against bacterial infection. They are also intended to be absorbent and aid in absorbing exudate and fluid in a wound [390].

Gauze dressings can also be made to be superhydrophobic and durably antibacterial. For example, cotton gauze was endowed with superhydrophobic and antibacterial properties by a dip-coating method that involved sequential deposition of positively-charged chitosan, negatively-charged gallic acid-modified silver nanoparticles and 1H,1H,2H,2H-perfluorodecanethiol (PFDT). The wettability of the gauze surface was converted from superhydrophilic to superhydrophobic with a water contact angle of $158 \pm 2.2^{\circ}$ and sliding angle of $5.2 \pm 1.8^{\circ}$, exhibiting water repellency plus antifouling ability as well as bacterial-anti-adhesive action. The coated fabric exhibited antibacterial activity against both *E. Coli* and *S. Aureus*, which was mainly attributed to the synergistic effect of contact-killing by the chitosan together with continuous release of Ag^{+}. In addition, it was found that the outer PFDT deposition could act as a barrier to prevent leaching of the silver nanoparticles during laundry, enhancing the durability of the antibacterial activity [393].

Impregnated gauzes are commonly used in surgery on incisions and traumatic wounds. These typically consist of a fine or open mesh gauze that is impregnated with a petroleum emulsion. This allows the dressing to be nonadherent and this prevents disruption of the incision site at dressing change. They can often be used to help maceration of exudative wounds as they transfer exudate to the outer layer [394]. Gauzes may be impregnated with antiseptics, such as iodine, which creates a dressing that is bactericidal in nature. These are of particular use in wounds that are contaminated or superficially infected.

4.1.2. Interactive wound dressings

Interactive wound dressings may be divided into different classes based on their composition.

Transparent film dressings are made of a self-adhesive polyurethane film and are semi-permeable. These allow gas and water-vapour exchange but prevent the absorption of wound exudates. As they are occlusive to fluids, they are used on drier wounds where they may help to provide a moist environment and prevent desiccation of underlying tissue, though maceration may result if a film dressing is used on wounds with a moderate amount of drainage. They may promote autolysis of necrotic tissue [394]. Initially, such films were manufactured from nylon derivatives with an adhesive polyethylene frame [390]. Transparent films tend to conform and cling well to the surface of the wound and thus reduce friction and shear and blister formation on inflamed surrounding skin [394].

Semi-permeable foam dressings are manufactured by combining hydrophobic and hydrophilic foams. This dual constituency serves different purposes. The hydrophobic outer layer protects the wound from liquid but allows gaseous exchange. The foam in the dressing can absorb varying quantities of exudate making the dressings ideal for ulcer care [390].

Janus Fabric dressings have the potential to fulfil similar requirements to those of semi-permeable foam dressings. The characteristic of a Janus Fabric is that it possesses very different properties on each side (hence the name) and their potential has been known for some time [225]. A useful example as a wound dressing to suppress blood flow consists of a superhydrophobic outer surface and a super-hydrophilic inner [226] and it is also possible to include silver nanoparticles into the textile to confer antibacterial

properties [395], or to rely on chitosan to achieve the required antibacterial effect [396] or quaternary ammonium nanoparticles for multifunctional effects including antibacterial performance and rendering the dressing both interactive and bioactive [397].

Spacer fabrics, because of their structure, which in general terms consists of two adjacent woven or knitted layers connected by threads or yarns which hold the layers separate, have an open central region which offers the prospect of being able to absorb wound exudates. Given sufficiently stiff fibres or filaments connecting the two layers, which may be woven, warp or weft-knitted, the spacer fabric also has the potential to offer some cushioning effect. Their resistance to pressure can be adjusted and depends on the type of connecting fibres, their angle in the structure, and the stitch density [398, 399]. Consequently, they have been considered as possibly useful for heavily-exudative wounds, and in particular two three-layer spacer fabrics were proposed as suitable [400, 401].

Hydrogel dressings are available in the form of a gelatinous sheet or an amorphous wound filler. They can be used to fill wound defects, such as loss of tissue creating a cavity, and also conform well to wound surfaces. They are non-adhesive, permeable to gases and have a high water content which aids granulation and also provides a cooling and thus soothing effect. As they provide little absorption, they should be used on a dry or lightly-exudative wound to maintain a moist surface; indeed burns appear to heal quicker with hydrogel dressings than with standard care [402]. Use on a heavily-draining wound may lead to maceration and bacterial overgrowth [394, 403].

Hydrocolloids are occlusive dressings that are composed of two layers; the inner layer is a wafer of a gum-like substance (carboxymethylcellulose, gelatin or pectin) that adheres to the wound surface. The outer layer is a water-resistant film or foam that allows patients to bathe with the dressing in place and prevents bacterial overgrowth. They adhere and conform well to the wound and do not require a further dressing.

As the wound produces exudate, it interacts with the inner wafer and forms a gel-like substance. The gel then helps to keep the wound surface moist and provides protection against microbes and any further trauma. The dressings can absorb a moderate amount of exudate before maceration of the underlying tissue becomes a problem.

Alginate dressings are made from the sodium and calcium salts of the mannuronic and guluronic acid residues in the alginate polysaccharide which is absorbent and biodegradable and derived from seaweed. The dressings accelerate wound healing by activating the immune system to produce inflammatory signals. When applied to the wound, ions in the alginate are exchanged with blood to form a protective film. As they potentially dehydrate the wound, they require a secondary dressing [400].

4.1.3. Bioactive wound dressings

Bioactive dressings are manufactured from biomaterials which promote healing. They are sometimes incorporated with growth factors or antimicrobials [403]. The dressings are manufactured from natural or artificial sources including collagen, hyaluronic acid, chitosan, alginate and elastin [400]. The natural polymers such as gelatin, collagen, silk fibroin, cellulose, alginate and chitosan have been employed to construct wound dressings due to their non-cytotoxicity and hydrophilicity. Additional functionalities such as antimicrobial properties, growth factor or drug-release abilities and

biodegradable properties have the potential to hasten the healing process. Chitosan, the polycationic linear polysaccharide derived from chitin, is currently receiving a great deal of attention, not only in the form of textile products for bioactive wound dressings [404], but also in the competing form of sponges [405].

Honey has been regarded as a natural healing agent due to its antimicrobial activity, debriding activity and anti-inflammatory effects. This is felt to be due to its acidity, which may prevent biofilm formation, lower water content which creates a hostile environment for microbial growth and presence of antimicrobial substances [406–409].

Mānuka honey inhibits the growth of a broad range of microorganisms and prevents biofilm formation at the site. Gram-positive organisms such as Methicillin Resistant *Staphylococcus Aureus* (MRSA) and *Streptococcus pyogenes* are inhibited. Gram-negative strains such as *Escherichia coli, Proteus mirabilis, Enterobacter cloacae* and *Pseudomonas aeruginosa* are inhibited [410]. Indeed, a Cochrane Review demonstrated high-quality evidence to support honey dressings in healing partial-thickness burns at a faster rate than conventional dressings, though it was unclear if there was a difference in rates of adverse events or infection. Furthermore, honey heals infected post-operative wounds more quickly than antiseptic washes and heals pressure ulcers at a faster rate than saline soaks [411]. Animal trials comparing a honey dressing, milk dressing, combined honey and milk dressing, and 5% sulfadiazine dressing showed that the combination of honey with milk proved the most effective followed by the 5% sulfadiazine [412]. Manuka honey has been incorporated in an electrospun membrane of silk fibroin and demonstrated to show antibacterial activity against both gram positive and gram-negative bacteria [413].

Chitosan, as discussed in Section 1.3.1.3, exhibits antimicrobial activity and it can be electrospun to create a variety of nano-fibrous structures that can be incorporated into wound dressings. The ability to manufacture nano-fibrous webs by electrospinning also allows for the incorporation of other molecules, such as antibiotics, through their addition to the spinning solution. Antibiotics for example can be incorporated during fabric finishing into nanofibres or nanofibrous yarns or webs by a variety of methods: by soaking the textile in a solution, by coating the textile or by incorporating the molecule as mentioned above, at the spinning stage [103].

Silver and its antimicrobial properties are long established. Silver can be incorporated into fabrics by physical treatments, chemical treatments such as ion exchange or by the blending of fibres [103]. There is a wide range of silver dressings already in clinical use and the more-recent move towards the incorporation of silver nanoparticles into fibres has gained popularity as a result of the emergence of resistance of some bacteria towards antibiotics [414]. Work has also been undertaken into the topical delivery of silver for controlling wound infections; for example, through using a bilayer chitosan wound dressing [415]. A 2010 Cochrane Review has concluded that there is insufficient evidence to establish whether silver-containing dressings or topical agents promote wound healing or prevent wound infection [416].

4.2. Pressure garments

Pressure garments that provide external pressure to the human form may be used in medicine for a range of purposes including to prevent venous thromboembolism and

venous ulceration, in the treatment of burns and in the management of fractures or other soft tissue injuries.

4.2.1. Thromboembolic devices

A thrombus, or clot in the venous system may be formed due to an alteration in one of the triad named after German physician Rudolf Virchow (1821-1902). The triad includes

1. Damage to vessel endothelium
2. Hypercoagulability
3. Stasis of blood flow

Venous thromboembolism, (VTE), comprises both Deep Vein Thrombosis, (DVT), and Pulmonary Embolism, (PE). Hospital-acquired VTE is a common complication and a leading cause of mortality and morbidity in hospitalized surgical patients. Those occurring during hospitalization or within the three months after hospitalization have been shown to underlie more than 50% of all cases of the population burden of VTE [417]. Similarly, PE is a serious postoperative complication that represents a source of preventable morbidity and mortality; in the United States it is responsible for 5-10% of all hospital inpatient deaths [418]. Whilst there are other causes of DVT and PE at the perioperative period, and treatments to be directed at these, the use of pressure garments to prevent stasis of blood flow remains an accepted practice. Indeed, consideration is also given to hospital inpatients that are not under the surgical directorate, although there are contraindications to their use and, thus, are not suitable for everyone.

Whilst it may appear that the use of compression stockings is beneficial, evidence is conflicting, though large meta-analyses accept that large well-designed trials are still needed [419–421]. Indeed, further evidence is required to distinguish whether thigh-length or below-knee stockings proffer the maximum benefit to patients [422]. Compression stockings may also be used to prevent venous leg ulceration and there is a small amount of evidence to support its effectiveness, more so for high-compression rather than medium-compression hosiery. However, the rates of patient intolerance to compression hosiery generally were high (see Figure 8) [423].

In the consumer sector, compression stockings have been shown to reduce the incidence of symptom-less VTE in airline passengers [424] (e.g. Flightsocks©, Scholl, Reckitt Benckiser, Slough, UK) and there has been uptake in the health and exercise industry as stockings have been shown to improve endurance performance by increasing proprioception muscle coordination and propulsive force [425]. Bandages and stockings may also be used as retention bandages, to retain dressings, in place, or for support, to provide retention and prevent development of a deformity [103]. Of note, there are contraindications to the use of anti-embolism stockings and these include individuals who have suspected or proven arterial disease, peripheral arterial bypass grafting, peripheral neuropathy or sensory impairment, local conditions such as gangrene or recent skin grafts, known allergy to the material of manufacture or severe leg oedema [426].

Medical compression stockings can be manufactured in a variety of ways including circular or flat-bed knitting and using woven fabrics [427]. Adjusting the raw fibre, yarn and knit structure can produce stockings of varying compression. Maleki et al. [428]

Figure 8. Thromboembolic Stockings.

investigated the influence of stitch length, strain, washing operation and repeated usage on the pressure behaviour of knitted fabrics; all of which are important factors for the stocking. Further studies have demonstrated that the elastane yarn count is the most effective parameter affecting pressure characteristics [429] and that the tensile energy, tensile strain, shearing stiffness and bending rigidity are all key mechanical properties for compression stockings [430].

In clinical applications, it is important to know the pressure profile, dosage of compression and the pressure distribution of the stocking. As such, compression bandages are classified according to the level of compression that they provide: Class 1 bandages offer light support at 14-17 mmHg to control varicose veins and mild oedema, Class II medium support at 18-24 mmHg for the treatment of severe varicose veins, mild oedema and prevention of ulcer recurrence with Class 3 offering strong support at 25-35 mmHg for severe varicose veins, post-phlebitic limbs, the prevention of ulcer recurrence and chronic venous insufficiency [431].

There is still no universal standard for graduated compression and so there are three classification systems in use in Europe: British, French and German. For bandages and stockings used other than in the role of VTE prevention, the bandage may be combined with other dressings or in a multilayer format. Indeed, there has been interest from the sports industry to assess the effect of number of fabric layers, fabric composition and fabric direction in sport compression garments [432, 433].

Of interest, there is also a role for intermittent pneumatic compression devices in reducing the incidence of VTE in hospital patients. There are several different devices available with variations in their design, including the rate and means of compression [434].

The devices work by simulating the normal calf pump mechanism by causing external compression of the deep veins and therefore creating a pulsatile blood flow and venous return. In addition to their use as VTE prophylaxis, they have also been used to treat limb swelling, for example in patients with lymphoedema or venous leg ulcers [435].

4.2.2. Pressure garments in the management of fractures and soft tissue injuries

The use of casts in fracture management is probably the most worldwide method of managing fractures throughout the world today and dates back to Ancient times where a variety of methods were utilised to stiff bandages. For example, the Egyptians used glue to stiffen bandages to provide support to the cast whilst the Greeks used cerate [436].

Casts may be applied for a variety of reasons; to aid prevent movement in the short term to provide pain relief, to provide pressure around the fracture site to aid in healing in an optimal position, to protect underlying surgical repair of tendons or in combination with traction to name but a few [436]. There are a range of different types of casts that may be applied depending upon the reason. For example, total contact casting may be used in the management of neuropathic foot ulcers to offload the foot and these casts are applied in a modified way to the fracture casts that most will commonly imagine [437]. Regardless of that, application of a cast is a specialist topic with the British Orthopaedic Association offering comprehensive courses [438].

Sir John Charnley described the three-point fixation method of applying a moulded plaster to hold a fracture in position. The fracture is reduced to the optimal position and then plaster cast subsequently applied. The plaster is then moulded to apply pressure at the site of the fracture and the sites proximal and distal. The optimal positions of moulding dependent upon the type and location of the fracture [439]. All casts are applied in a similar manner whether using the traditional plaster of Paris or more modern fibreglass

Figure 9. Casting of limb.

materials (see Figure 9). Slabs or a roll of cast material are applied over a layer of protective stockinette and layers of synthetic staple fibre 'wool' padding. In addition, foam may be used over bony prominences to prevent skin breakdown (see Figure 10). Judging the layer of padding is important as too much permits secondary fracture displacement and too little causes skin problems and an increased risk of compartment syndrome [436].

Plaster of Paris remains the time-honoured material of choice for the treatment of acute fractures. It is named after a large gypsum deposit at Montmartre in Paris and was traditionally used in the construction industry. Its use predates this and it has been found on the insides of pyramids. It was first incorporated into bandages to use in fracture management in the 1850s by two surgeons, Antonius Mathijsen and Nikolai Ivanovich Pirogov [440]. Plaster of Paris is manufactured from gypsum ground to a fine powder by milling. When water is added, the more-soluble form of calcium sulphate returns to the relatively-less soluble form and heat is produced. The big advantage of using Plaster of Paris in casting materials is that it allows itself to be moulded [440]. The Plaster of Paris is combined with a woven inextensible bandage and then wrapped in the final layer of the cast around the limb. There are a variety of other materials that can be used in place of Plaster of Paris. Some of these are water activated and are stronger and more durable than Plaster of Paris. Others are thermoplastic and can be worked by heating in a water bath or oven and then can be directly moulded to the patient. These tend to be more expensive but have their place [440].

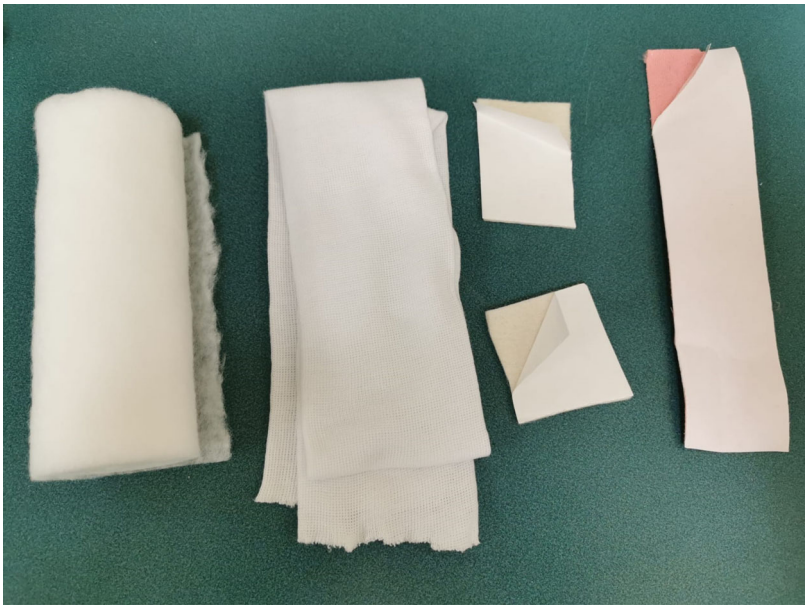

Figure 10. Components used when casting.

Finally, a range of orthotics such as braces, slings etc can be used in fracture management and the management of soft tissue injuries and these are discussed in more detail in Section 5.

4.2.3. Pressure garments in the management of burns

In 2004, it was estimated that nearly 11 million people worldwide suffered burns severe enough to warrant medical attention [441].

Whilst there have been advances in burn care, abnormal scarring remains one of the most common complications and may occur in up to 70% of cases. Scarring is a healing process of the skin in response to the burn injury. A prolonged inflammatory phase may increase the risk of scarring [442].

Jackson produced the 'burn wound model' which divides a burn into zones related to their overall potential for healing:

- Inner zone – dead tissue
- Middle zone – the "zone of stasis" which is the target of good burns care
- Outer zone – the "zone of hyperaemia", a zone of inflammation in response to the injury

Burns are classified according to the components of the skin which are damaged, which in turn reflects the expected time for healing to occur. An epidermal burn, typified by sunburn, does not require dressing but is treated with emollients and moisturisers. It usually heals in less than 14 days and does not scar. A superficial dermal burn may require a dressing to absorb fluid and thus prevent maceration, reduce the risk of

infection and prevent secondary deepening of the wound. This also provides an element of pain control. Usually a superficial dermal burn heals within two weeks, if kept clean and free of infection. A deep dermal, or full-thickness burn, often requires a dressing to debride or temporise the remaining tissue prior to surgery [443].

In deeper burns, dermal appendages are removed so re-epithelialisation occurs primarily from the edges of the burn. Unless very small, these deeper burns take over two weeks to heal and are more likely to leave undesirable scars.

Prolonged healing or genetic predisposition may result in a hypertrophic or a keloid scar. Both are characterised by the deposition of collagen fibres and bundles within the dermis. Pressure garment therapy is considered an effective strategy for the prevention and management of abnormal scarring and to assist with scar maturation by preventing scar contraction and improving scar biomechanics [444]; this has been the main method of treating hypertrophic scars since the 1970s and can include complicated garments such as gloves [445]. The garments are designed to exert a pressure of approximately 25 mmHg on the underlying tissue in order to exceed the inherent capillary pressure and a soft, flexible and extensible fabric with a thickness of 3.81 mm has been recommended previously [446].

Extended use of the garment and its use in conjunction with moisturisers and oils may reduce the pressure that the garment exerts [447]. Problems with the garments include increased pain, intolerance to heat and skin breakdown in some patients [448], and these may impact upon patients' adherence to the treatment plan, with rates of 41-70% reported in the literature. Indeed heat and associated perspiration have been demonstrated to alter the pressure the garment delivers according to the way the fibre interacts with moisture. Indeed, fabrics tested in one study all exerted less pressure when wet; the fabrics included a warp-knitted sleeknit made from nylon and elastane, a weft-knitted tubigrip made from cotton with nylon-covered elastodiene, two different powernet fabrics made from nylon and elastane [447]. A protocol for a Cochrane Review to assess the effect of pressure-garment therapy in the treatment of burns has recently been published; the outcomes are awaited [442]. In addition, there has been a call for a formal RCT to be undertaken in this field [449]. The 'ideal' pressure garment remains elusive [447].

4.2.4. Engineering the pressure garment

The same statement about the elusive 'ideal' pressure garment made at the end of Section 4.2.3, could be made here at the beginning of Section 4.2.4, in this case about compression garments in general. However, a considerable amount of work has being undertaken to improve understanding about essentials in the engineering of pressure garments, not least in relation to being able to model, predict and measure the pressure actually being exerted at the intended point(s) on the body, with focus on making choices or adjustments to provide the desired pressure at the correct location. The materials most-commonly used in the compression garments contain the elastomeric spandex yarns, sometimes called elastane yarns, (polymeric materials consisting of at least 85% segmented polyurethane), for their rubber-like elasticity; standard fabric constructions can be used (warp knitting, weft knitting or weaving). There are several possible approaches to designing and modelling the properties and performance the

compression garments. Maklewska et al. [450] proposed a model for designing knitted compression garments that would exert a pre-set pressure on the human body using the Laplace Law, and Hong et al. worked with the Young's modulus of the fabric and a finite element model in a study of pressures exerted by tight-fitting clothing [451] whereas Senthilkumar et al. [452] related the stretch and recovery properties of the cotton/elastane knitted fabrics with the elastane linear density, tension on the elastane yarn during knitting and cotton yarn loop length.

Even so, the engineering situation being addressed is somewhat messy for the following reasons:

i. Little information regarding the properties of fabrics used in the construction of existing pressure garments exists in the literature and the pressure that is exerted by the pressure garments is not routinely measured with suitable instruments, at least not in UK hospitals. So, the real pressures exerted by each pressure garment, currently used to treat hypertrophic scars, are not normally known [453].
ii. During pressure-garment application in UK hospitals, there is no awareness of the impact that the various fabric types will have on the different pressures exerted by pressure garments, nor is there a standard test method for the evaluation of fabrics for their use in pressure garments - pressure garments are normally exempt from Conformité Européenne (CE) marking under the Medical Devices Directive because they are custom made and, therefore, fall into a gap in standards legislation [453].

Starting with modelling of compression garments following burns [453, 454], in this case, the Laplace equation was used to model a pattern-cutting chart refined to predict the sub-garment pressure more accurately, irrespective of the shape and size of the limb. The model's accuracy was validated by constructing garments for the arms and legs of a male volunteer and measuring the actual pressures by using a Kikuhime pressure-measuring device.

As mentioned previously, comfort or the lack of it with compression garments can be a major issue. The thermo-physiological properties of the compression garment which provide comfort by preserving body temperature and moisture output close to their normal levels, together with the dimensional, mechanical and thermo-physiological properties of four fabrics intended for pressure exertion applications, were therefore compared to determine their suitability to be utilised for the management of hypertrophic scarring. One of the desirable properties of compression garments is that the pressure exerted by the garment on the limb should be uniform in all directions; mechanical properties, such as fabric stiffness, extension and recovery, should be close to isotropic to prevent the skin from stretching in the direction where the fabric extension is highest, particularly important when the pressure garment is used on areas of limbs with bony protrusions and areas with a small radius of curvature. It was a power net, the bulkiest one of the four fabrics tested (three power nets and one solid warp-knitted fabric) that was found to possess the best properties for the purpose, but it was also found to be capable of improvement [453].

For an investigation into the effects of elastane linear density, thread density, and weave float length on the extensibility, recovery, and compression properties of

bi-stretch woven fabrics for compression garments, various fabric samples were produced using elastane core-spun cotton yarns both in the warp and weft. The elastane linear density, fabric thread density, and weave float size were used as input variables while fabric contraction, sub-garment pressure, fabric stretch, and recovery were taken as response variables. The coefficients of determinations (*R*-sq values) of the regression equations showed good prediction ability of the developed statistical models [455].

Following through on that exercise, the compression properties of bi-stretch woven fabrics were compared with knitted fabrics of the same areal density, all constructed from core spun elastane yarns with cotton as the sheath, to determine their practical suitability in compression garments using a Kikuhime pressure sensor; durability of their performance after washing was also assessed. It was found that the bi-stretch woven fabrics possessed better compression properties before and after washing and retained their durability after repeated use, whereas the knitted stretchable fabrics lost their compression ability after repeated use and the sub-garment pressure of the knitted structures after 15 washes was almost half that of the woven bi-stretch fabrics. The simplest woven structure, the plain weave, was the fabric which exerted the highest pressure [456].

The subsequent action was to undertake a study on the optimisation of the mechanical and comfort properties of the bi-stretch woven fabrics, an appropriate step given that a high proportion of patients may discard the compression garments because of discomfort [457].

Very recently, a new practical engineering approach to modelling, measuring and predicting the compression from a compression garment used a cut-strip method to develop two new mathematical models based on 'true Young's modulus' and 'engineering Young's modulus'. Through comparison with Hooke's law and Laplace's law and previous models of Leung et al. [458] and Dubuis et al [459], using linear regression to assess the experimentally-measured compression pressure results, it was found that the newly-developed models were more precise and accurate than the previous models [460].

Taking a more-comprehensive view, the effectiveness of the compression garment was rightly considered to depend not only on the correct technical functioning of the compression item, (which is difficult to achieve in itself as can be seen from the sequence of investigations being carried out on the bi-stretch woven fabrics), but also on physiology, pathophysiology, biomechanics [427]. The group undertaking the review which was formed by researchers from The Hong Kong Polytechnic University, the Chinese University of Hong Kong and North Carolina State University, would have done better in this critical review to have paid more attention to psychology as well.

That group's attention has moved on to anthropometry in an attempt to improve fit by 3-D scanning of 208 subjects and cluster analysis enabling the stratification of lower limb shapes into 3 morphologies, which they named diamond, inverted trapezoid, and balanced leg shapes from the determined anthropometric landmarks along the lower extremities. Responding to such a stratified shape-led sizing system was thought to allow the possibility of catering better for both shape and size together hence also the possibility of improving both fit and more-accurate compression treatment for the patient [461]. Subsequently the same group has moved on to address

the problem with homogeneous compression garments which apply pressure unevenly, cause discomfort and fail to administer the necessary pressure with any accuracy to the area where it is required. To counteract those problems, a heterogeneous compression bandage/stocking was knitted and pressure measurements on the wearer showed that heterogeneous compression shells designed for the lower limbs could redistribute skin pressures around the leg cross-section and be higher for the muscle-dominated posterior calves where it was intended to be. It was thought that user compliance in practice might improve if heterogeneous compression stockings with such "bi-axial" pressure profiles for improved compression performance were to be developed [463], and the research group has moved on to try to refine the shape profiles for compression stockings by further application of shape measurement, again in the hope that this might help to improve patient compliance with the compression garment requirement [463].

5. Healthcare and hygiene products

Healthcare and hygiene products in the medical sector covers a vast range of items including products used in the operating theatre or on the hospital ward. It therefore ranges from wipes and sanitary wear through to surgical gowns, masks, respirators and uniforms. The types of fibres commonly used include polyester; polypropylene; viscose rayon, lyocell and cotton, and may be woven (for re-usable items) or non-woven (for disposables); in the case of the manufacture of nonwovens, hydro-entanglement is considered to offer advantages in terms of reducing the microbiological burden to such a level as to offer a good base from which more-taxing hygiene requirements can be developed [464]. Other items that fall within this category include orthotic devices and the wide range of equipment used in healthcare from operating table covers through to chair covers and the curtains used in the medical bays.

5.1. Disposables

Incontinence products such as body worn pads and diapers and flat-form sheets used in the bed are commonly used as methods of dealing with urinary and faecal incontinence. With increasing concerns over sustainability and environmental impact, there has been a drive back towards re-useable products [465]. Ultimately the product needs to remove liquid from the surrounding skin, to keep the skin clean and dry, and enclose it safely within the product. The layer that is in direct contact with the skin needs to be non-irritant [466]. The disposable diaper is a composite nonwoven article that contains an outer (protective) layer, and an inner covering layer supporting the absorbent layer in the middle part of the diaper; the inner covering layer may be manufactured from a polyester-fibre web or a spunlaid polypropylene-fibre nonwoven material [96]. Although the materials in the central layers need to be absorbent, the permeable non-absorbent outer layer may be manufactured from polyethylene [467]. The methods of construction and manufacture of composite nonwovens such the Coform Process (Kimberley-Clark) which mixes melt-blown polypropylene with absorbents such as wood pulp as used for diapers and wipes, were

detailed by Das, et.al [213] in a review which also includes details about the Spunbond + Meltblown + Spunbond or SMS Process (Kimberley-Clark) as used for the manufacture of non-woven composites for protective covers, barrier fabrics, sanitary products and facemasks; their characteristic good lengthwise and transverse strength arises from the central meltblown component whilst the spunbonded outer layers provide the soft handle suitable for these applications. There is a move towards developing spacer fabrics that may be suitable both for disposable and re-useable products [400, 401].

Cloths and wipes made from nonwoven fabrics [213], see Section 1.4.3, are commonly used on the ward for cleaning patients, staff or equipment and typically contain antibacterial and cleaning agents; preferably they are flushable [468] and biodegradable [469]. It appears that not all wipes are similarly effective, but also they do need to be used in a particular manner to work effectively. The efficacies of two types of nonwoven wipe have been assessed by dynamic wiping, and it was found that of the two, the hydrophilic wipes (those composed of lyocell) were more consistently effective than those made from polypropylene. Use of a high-density lyocell fabric ($150\,g.m^{-2}$), at high pressure ($13.8\,kN.m^{-2}$) was considered best practice [470]. Antimicrobial agents such as quaternary ammonium compounds are some of the most-widely used disinfecting agents, and in the case of wipes, it is ready release rather than adsorption and retention which is required from the impregnated carrier fabric. Quaternary ammonium compounds can be strongly adsorbed on to cotton, but it was shown that whereas raising the alkalinity of their solutions increased the amount of alkyl-dimethyl-benzyl-ammonium chloride (ADBAC) adsorbed onto cotton nonwoven fabrics, a more-acidic solution reduced ADBAC adsorption, as did increasing the temperature and concentration of salts in the solution. Nonionic surfactants or low molecular weight quaternary ammonium compounds reduced ADBAC adsorption onto cotton fabrics in a concentration-dependent manner. Because their adsorption behaviour was dependent on the composition of the solution, incorporation of the additives that promote ADBAC release into the antimicrobial solution was able to be optimised so as to enable ready release of the ADBAC from the wipe onto the surface required to be disinfected [471, 472].

Successful disinfection of a hard surface can be impeded by the presence of a soil load in the form of protein, fat or other material, so the use of greige cotton as the nonwoven wipe material improved the performance of the disinfecting wipe over other fibre types. It was shown by dynamic wiping assays that successful disinfection of a hard surface was greatly enhanced by a wipe fabric that also effectively removed organic contaminants and was strong enough to resist structural failure; the use of griege cotton also reduced water wastage when the disinfecting solution was being applied [473].

A useful and detailed review of the efficacy of disinfectant-impregnated wipes used for surface disinfection in hospitals has been undertaken recently [474]. In the EU, the disinfectant efficacy test is regulated and issued by the European Committee for Normalization (CEN), Technical Committee 216 (TC 216) under the work programme "Chemical Disinfectants and Antiseptics" and it is Standard EN 16615 that is the most suitable. For the United States, it is the Environmental Protection Agency (EPA) which

undertakes that kind of regulation. Even so, as yet, there are few test methods for assessing the efficacy of impregnated wipes, the main ones being EN 16615:2015, the modified AOAC International method 961.02 and ASTM E2896–12 and ASTM E2967–15 all of which fall short in terms of variations that may occur during in their application and/or the limited range of surfaces embraced by the standard. Also, according to the reviewers, several information gaps have to be filled to obtain consistent and exhaustive knowledge about the interaction between textile and substrate, in particular regarding material compatibility (combination of wipe and disinfectant), liquor ratio (wipe mass/disinfection solution volume), contact time (of disinfectant and wipes) and durability to storage [474]. Even so, despite shortcomings, the ASTM test has been put to use [475].

A different approach to disinfection is detailed in an attempt to combat the growing threat of hospital-acquired infections; it relies on a dry non-woven wipe composed of viscose rayon containing sufficient beneficial bacteria or spores which, on wetting and using the wipe, are released and spread over the wiped surface, The released beneficial bacteria inhibit pathogens by growing and colonizing on the wiped surfaces [476].

5.2. Personal protective equipment

In a hospital or other health-care setting, the personal protective equipment used by health-care workers may include protective clothing, face and eye shields, gloves and surgical facemasks or respirators. For the UK, the health and safety regulations that apply in the case of the presence or likely presence of biological agents (such as viruses, bacteria, fungal spores etc) are those of the Control of Substances Hazardous to Health (COSHH) Regulations 2002, which are designed to provide a framework of actions to control risk from exposure to hazardous substances [477].

The central approach in COSHH is one of risk assessment, and in their recent 'Rapid Evidence Review' [478] the Health and Safety Executive (HSE) stressed that no PPE is 100% effective. The HSE also stressed that the level of protection offered is dependent on the outcome of a thorough risk assessment based on the inherent characteristics of the hazard, including routes of transmission and the type(s) of activities being performed as well as the correct selection, training, donning, use, doffing, storage, decontamination (of reusable items) and waste disposal. COSHH Regulation 7 and its associated Approved Code of Practice (ACOP) to [479] state that where employers cannot prevent exposure to a biological agent, they should take steps to ensure that it is controlled adequately (by consideration of the requirements set out in Regulation 7(3), (4), (6) and (7), applying good practice; the need is stressed to use each requirement where, and to the extent that it is applicable (the assessment carried out under Regulation 6 shows that it will lead to a reduction in risk).

5.2.1. Surgical gowns, aprons and gloves and healthcare workers' clothing

An excellent review of the requirements for adequately functional healthcare workers' clothing contains sufficient detail to provide the information needed to enable textile and apparel specialists to develop their specifications for improved products; this is particularly the case because of a developing need to provide protection in the

widening variety of working environments that healthcare personnel are now likely to experience. The review draws attention to the need to address the role that the textiles used in healthcare settings might play in the acquisition and retention of pathogens (e.g. privacy curtains, bedlinen, upholstery, furniture and furnishings), textiles which include uniforms, scrubs and other apparel (see Figure 11). There is also a need to give appropriate consideration to variations in laundering and sterilising practices. The review acknowledges that the textiles employed in healthcare settings can play a significant role in protecting healthcare workers and that there has been limited adoption of available textile technologies such as fluid repellency and antimicrobial action by healthcare institutions; this is in part because of their failure to recognise the impact such treatments can have on risk reduction, and a failure to become engaged in the necessary research and publication about their effectiveness in healthcare settings [480].

Surgical gowns were introduced primarily as a protective barrier to reduce surgical-site infection and protect the patient from the surgical team. They achieve this by controlling skin flakes and bacteria shed by the user and by preventing the direct transmission of microbes. Finally, a surgical gown must also demonstrate good wearing comfort whilst keeping the surgeon and team comfortable, particularly in longer operations [481, 482]. Currently, for the UK, there are a series of standards applied to protective clothing items such as surgical gowns namely:

Standards relating to items and materials [483]:

Figure 11. Examples of Personal and Protective Equipment.

i. BS EN 13795-1:2019: Surgical clothing and drapes. Requirements and test methods. Surgical Drapes and Gowns
ii. BS EN 13795-2:2019: Surgical clothing and drapes. Requirements and test methods. Clean air suits
iii. BS 3314:1982: Specification for protective aprons for wet work, and
iv. BS EN 455-1, 2, 3, 4 :2020, 2015, 2015, 2009: Medical gloves for single use,

The latter relate to non-textile latex, nitrile and vinyl products, so only included for completeness.

Standards relating to performance requirements and test methods:

i. BS EN ISO 22610:2006/2018: Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment. Test method to determine the resistance to wet bacterial penetration
ii. BS 3546:2001 Coated fabrics for use in the manufacture of water penetration resistant clothing
iii. BS EN 14126:2003: Protective clothing. Performance requirements and tests methods for protective clothing against infective agents

For the United States, standards from ASTM [484] and AATC [485]
ASTM International, Standards and Specifications:

i. ASTM F1670/F1670M-17a: Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
ii. ASTM F1671/F1671M-13: Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

AATCC Test Method:
iii. AATCC TM127-2017, Water Resistance: Hydrostatic Pressure Test

International standards

i. ISO 16603:2004 Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood [486]
ii. ISO 16604:2004 Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X 174 bacteriophage [487]

A literature review was undertaken by the National Health Service Scotland for their '*National Infection Prevention and Control Manual*' which provides a useful context on the range of protective equipment, what evidence there is for its effectiveness and its proper use; the review recommended full-body, fluid-repellant gowns for situations where splashing might occur and pointed out that superiority of plastic gowns has been questioned whilst noting that there was little evidence identified

as to when re-useable aprons/gowns might be appropriate [488]; the report should provide a useful basis from which textile and apparel specialists might engage in the next phase of product development, not least in terms of improving the prospects for reusability. There is also guidance on infection control measures regarding PPE/healthcare worker's protective clothing and its use, not only from the WHO given the COVID-19 pandemic [489], but also through organisations focused on practitioner levels, such as the Association for Perioperative Practice [490], where there is guidance adapted from *'Pandemic Influenza: Guidance for Infection prevention and control in healthcare settings, 2020'* issued jointly by the Department of Health and Social Care (DHSC), Public Health Wales (PHW), Public Health Agency (PHA) Northern Ireland, Health Protection Scotland (HPS) and Public Health England as official guidance.

Traditionally, one or more layers of sterile woven cotton cloth were used as an aseptic barrier, however, in 1948, an article in the Lancet highlighted a problem with these surgical gowns; when a gown became 'wet', it acted as a sieve and allowed bacteria to pass through the fabric [491]. Cotton fabric used at this time had a pore size of 80-100μm, too large to prevent the passage of skin cells and bacteria [492]. Further work in this period showed that an interposition with a waterproof layer reduced the passage of bacteria [493].

Implant surgery further drove the development of surgical gowns. Charnley, the grandfather of modern day orthopaedic surgery, developed Ventile fabric made from long-staple cotton [494], and designed the total body exhaust gown [495]. Whilst not without problems, for example, it had to be connected to a power source; when utilized in a laminar flow theatre, the rate of surgical site infection has been shown to be significantly less than when an ordinary gown is used [496]. There has been continual work directed at the ideal fibre, construction of fabric and construction of the garment and garment design recommendations have been made, particularly related to the ease of hygienic doffing [497].

The pore size in woven fabrics is an important factor in microbial transmission [498], as is the repellency of the fabric; testing and modelling showed that more-compact structures achieved by shorter thread floats and higher thread densities made the fabrics more water-resistant but less-permeable to air; the statistical models were thought to be of help in determining the appropriate compromise between protective properties and comfort [499].

A laminated fabric with a nano-finished PET outer layer, a microporous membrane sandwiched between that and an inner layer made of nonwoven viscose rayon was considered to be one way of creating a barrier to the ingress of viruses; tested according to the ASTM F1671: 2003 viral penetration test, it achieved level 4 protection according to the classification system of the American Association for the Advancement of Medical Instrumentation (AAMI). It was also claimed that the applied finish of titanium dioxide/methylene blue exhibited antiviral properties. This work is alone in making claims for antiviral action alongside providing an antiviral barrier [8].

There has been a move towards disposable nonwoven gowns that do not require laundering and thus reduce the requirement for a laundering facility, although it has

been determined that disposable nonwoven fabric gowns made from polypropylene or 55/45 cellulose/PET were less-comfortable than re-usable woven fabric gowns made from micro-fibre polyester reinforced with a permeable membrane or 65/35 PET/cotton [500], an important consideration in hospital operating theatres [501]. The nonwoven fabrics being used can be modified by laminating the fabric [502] and by using plasma treatments [503]. In addition, multilayer fabrics such as those supplied by Gore® (WL Gore and Associates, Newark, Delaware, USA) and Rotecno® (Rotecno® AG, Switzerland) have also been trialled [199].

Whether the surgical gown is of the disposable or re-usable type, it was demonstrated using synthetic blood, isopropanol and artificial sweat, that wetting by any such liquid from the wearer or the surgical environment may compromise the barrier properties of the gown material. Gown replacement protocols should take this into account [504]. The transfer of bacteria through contact between fabrics was found to be aided by the presence of moisture and the application of friction. Of seven different fabrics (cotton, silk, viscose, wool, polyester, polypropylene and a polyester-cotton blend), bacterial transfer was found to be highest for polyester followed by viscose rayon, whilst polypropylene showed the least transfer [505].

Such studies confirm why it has been judicious for antimicrobial agents to have been incorporated into gown fabrics for many years [506]; given the rise of antimicrobial resistance this line of thought and technique might have become questionable, however, more recent developments in nanotechnology have shown that:

- Silver release from treatments to incorporate nano-silver into fabrics is safe to the skin [507]
- Silver incorporated into fabrics can withstand challenge by a variety of chemical agents (such as artificial sweat to represent in-use exposure),
- Silver incorporated into fabrics can withstand a mimic for landfill leachate to simulate end-of-life exposure), and
- Silver incorporated into fabrics can maintain high antibacterial efficacy down to levels on fabrics as low as $\sim$10 μg Ag (g fabric)$^{-1}$ under conditions of normal use (below this concentration, efficacy significantly decreases) [508].

Attractive characteristics such as these have led to the development of improved antibacterial fabrics based on silver release for their effectiveness, for example:

i. A recently-reported method for large-scale economic and high-speed production of antibacterial fabrics based on silver applied by liquid flame spray followed by plasma coating, suitable for single-use PPE items in a hospital environment [509]; whilst very promising, it would now require further testing on site to determine its suitability and performance in the intended environment and its durability to laundering to enable re-use, and,
ii. Durable nano-silver treatments achievable in a variety of ways, for example
    - By a finishing treatment on cotton fabric, first applying single-walled carbon nanotubes (CNTs) then microwave heating to deposit silver nanoparticles onto the CNTs [510], or

- By anchoring silver ions to PET fabric by coordination bonding using tannic acid by alternately immersing in an aqueous solution of silver nitrate followed by tannic acid for five cycles. Durability to laundering and residual antibacterial activity was investigated and the results appeared to be very good. After 30 cycles of accelerated washing, the silver loadings were found to have decreased from 5.0 wt% to 2.2 wt% but the remaining coordinated silver ions continued to make the sample highly antibacterial against *S. aureus* (99.99 ± 0.03%), *E. coli* (99.99 ± 0.05%), and *S. albicans* (99 ± 0.14%) [511], or
- By enhancing its durability by combined finishing with silver nanoparticles and carboxymethyl chitosan binder on a cotton fabric surface through what was described as a 'simple mist modification process'. Durability in terms of bacterial reduction rates against both *S. aureus* and *E. coli* were high; effectiveness remaining at over 95% after 50 wash cycles was attributed to the carboxymethyl chitosan binder being covalently linked to the cotton fabric via esterification and the silver nanoparticles being tightly held onto the fibre surface through coordination with the amine groups on the carboxymethyl chitosan. It was considered to be as a result of these methods of attachment, that the coating of AgNPs on the cotton fabric showed excellent antibacterial properties and laundering durability [512].

There is ongoing research into the elusive 'ideal' surgical gown with research on seam type, the glove-gown interface and the ideal fabric and design [513].

The recent COVID pandemic has highlighted the importance of robust protection for both the patient and the health-care professional [514]. Whilst fabric type is important for the barrier function, the need for safe disposal and safe donning and doffing are also of equal importance as a mistake at this step can have significant consequences. One hospital protocol involved not tying the inner tie of the surgical gown such that the gown could be removed easily with a quick tug and folded on itself as it was doffed prior to disposal. Some hospitals reported wearing a surgical gown as a 'human skin' and thus donned and doffed the aprons being worn on top between patients whilst leaving the gown in situ. This had the benefit of protecting the user as well as reducing the requirement on stretched PPE resources. The need for air and moisture-vapour permeability of fabric for the gown is clearly critical. Other day-to-day scenarios, where such permeability becomes increasingly important are in surgeries where radiation is used, as surgeons are required to wear lead aprons throughout, which increases the 'heat' generated within the gown. Some work has been done to reduce weight and improve comfort whilst maintaining effective shielding [515–517].

The large body of work to date on surgical gowns has been concerned with assessing transmission of bacteria. With the increasing incidence of pandemics, it is becoming clear that more attention should be paid to viral transmission, and protection from prions should also be considered, as they too pose a potential future problem.

Surgical masks and respirators. Surgical masks date back to the late 1800s and in 1897, Radecki described a surgical mask that was composed of a single layer of gauze [518]. Following on from a paper published by Hamilton in 1905 which advocated the use of masks by nurses performing dressings and by doctors at the time of surgery

[519], Weaver in 1918, discussed the value of a facemask in preventing spread of infectious disease. In subsequent years, different types of mask have been tested including gauze, paper and filter masks. Currently, most masks are made from layered nonwoven polypropylene within which the nonwoven filter layer is meltblown to produce fine diameter fibres and this is sandwiched between spunbonded cover layers sometimes containing a support layer [520]. In addition, Kimberley Clark produce a Fluidshield Fog Free Surgical mask [521] with a clear visor to offer protection to the eyes (from personal experience, user application error and a fogging up of the mask may complicate the 'protection' offered to the eyes). The length of time that a mask provides protection for has also been questioned and in fact, whether a mask needs to be worn at all has also been scrutinised [519, 522]; a recent Cochrane trial was unclear as to whether wearing a surgical face mask by members of the surgical team had any impact on surgical wound infection rates for patients undergoing clean surgery [523]. The situation is more complicated however, when masks have to protect the healthcare team from the patient, particularly when there is a likelihood of aerosols or spray being generated.

The terms *Surgical Mask or Facemask* when used in the United States, refer to Food and Drug Administration (FDA)-cleared surgical-, laser-, isolation-, dental-, and medical-procedure masks with or without a face shield. They are approved on the basis of test results for particle-filtration efficiency, bacterial-filtration efficiency, fluid resistance, differential pressure, and low flammability. Used by health care personnel during surgical and nonsurgical procedures to protect both the patient and the health-care worker, the Surgical Mask is intended in particular, to cover the user's nose and mouth and provide a physical barrier to splashes/sprays of large droplets of blood or body fluids. There are of course, also European Standards for masks (EN 14683:2019 + AC:2019; Medical face masks - Requirements and test methods), approved by CEN, the European Committee for Standardisation and available through many European countries' standards organisations [524].

The need for *Filtering Face-piece Respirators (FFRs)* with *Surgical Mask* capabilities such as fluid resistance and low flammability, was first addressed by the FDA in 1996 through the introduction of *Surgical N95 Respirators*. These National Institute for Occupational Safety and Health (NIOSH) -approved Surgical N95 FFRs, cleared by the FDA for fluid resistance and flammability and intended to offer the combined protection of both an N95 FFR and a Surgical Mask to health-care personnel [525], are recommended in the United States during the care of patients with diseases such as tuberculosis and measles and during aerosol-generating procedures on patients with various infectious diseases such as seasonal influenza, novel influenza A, and Ebola. NIOSH tests and certifies the adequacy of performance of FFRs according to requirements outlined in the US Title 42 Code of Federal Regulations (CFR) Part 84; for N95 FFRs, the primary tests are filtration efficiency and airflow resistance [526]. By contrast, in the European Union, the recommended FFR has to meet the requirements of the more-demanding European standard for filtering half masks, EN 149:2001 + A1:2009, wherein the need is to be able to withstand additional challenge by an oily substance and to demonstrate (slightly) higher efficiency levels than the N95 respirator. Guidance on the use of respirator and facial protection equipment has been

developed and published by The Healthcare Infection Society Working Group on Respiratory and Facial Protection [527]. It has been pointed out that the use of surgical N95 FFRs in both surgical and non-surgical environments increases markedly during outbreaks involving a known or suspected respiratory pathogen, and scarcities of respirators were said to occur during the spread of SARS in 2003, [528] and H1N1 influenza in 2009 [529].

With the advent of a growing number of pandemic threats, such as Ebola (originating in 1976 but still recurring, most recently in West Africa in 2014-2016 and sporadic cases being reported in 2020), SARS CoV-1 (2003), Influenza A (H1N1) (2009-2010) and Middle East Respiratory Syndrome caused by the MERS Coronavirus (MERS-CoV) (2010-on) there has been interest in finding the 'best mask' to prevent infection amongst health care workers.

During the 2009 H1N1 influenza pandemic, contradictory recommendations were given by leading authorities. The WHO recommended the use of surgical masks [530] whereas the US National Academy of Sciences recommended N95 respirator masks (see Table 1 for differences between the masks} [531, 532]. In 2020, for the case of the COVID-19 pandemic, the United States recommended that those coming into contact with patients in a healthcare setting should use an N95 respirator. In Europe, the N95 respirator has not been tested against European Standards and does not carry CE approval. The WHO recommends an FFP2 mask or respirator, whilst in the UK the recommendation is to use an FRSM (Fluid-Resistant Surgical Mask) in the lower risk environments but an FFP3 respirator in high-risk situations, unless there is shortage in supply in which case, according to the UK Health and Safety Executive, an FFP2 can be used instead of an FFP3; apparently, such judgements must always be based on a risk assessment rather than the hazard [478] whereas the Guidance from America's Occupational Safety and Health Administration (OSHA) were that judgements on the protection to use should be based on a hazard analysis [533]. It would seem reasonable to suggest that, rather than pedantically abiding by just one or the other, organisations such as the HSE and OSHA should recommend using both risk and hazard analysis.

Guidance from America's Occupational Safety and Health Administration (OSHA) in the past has however, been similarly pragmatic to that recently issued by the HSE in the UK, more so than that from other regulatory bodies, It considered FFRs to be one-time-use devices when used in the presence of infected patients but advised employers and employees to reuse FFRs during a pandemic but only if FFRs were in short supply and the device had not been obviously soiled or damaged (e.g. creased or torn), and retained its ability to function properly. NIOSH has provided detailed

Table 1. Comparison of key requirements of N95, FFP2 and FFP3 respirators.

Requirement	N95	FFP2	FFP3
Assigned Protection factor (APF)	10	10	20
Filter efficiency	≥95% (85 l/min)	≥94% (95 l/min)	≥99% (95 l/min)
Test agent used	NaCl	NaCl & Paraffin oil	NaCl & Paraffin oil
Total inward leakage (TIL)	N/A	≤8%	≤2%
Inhalation resistance	≤343 Pa (85 l/min)	≤240 Pa (95 l/min)	≤300 Pa (95 l/min)
Exhalation resistance	≤245 Pa (85 l/min)	≤300 Pa (160 l/min)	≤300 Pa (160 l/min)
Re-breathed CO_2	N/A	≤1%	≤1% T

guidance on 'extended use' and 'limited re-use' [534] and the Centers for Disease Control and Protection (CDC) have given extensive guidance on the decontamination and re-use of filtering facepiece respirators, details of methods available and their applicability, with the focus primarily on N95 respirators (with attention also paid to three oil-proof P100 types), plus guidance on methods not to apply [535].

The respective EU and American test standards (European standard for filtering half masks EN 149:2001 + A1:2009 and NIOSH 42CFR84) detail key requirements as shown below, where N95 meets the requirements of NIOSH42CFR84, but the FFP2, FFP3 respirators are designed to meet EN149:2001 + A1:2009.

Apart from the above data taken from the UK Health and Safety Executive 'Rapid Evidence Review, March 2020' [478], useful tables of equivalences between respirators from different countries are also given elsewhere [536, 537].

To combat transmission of diseases, respirators need to be able to filter out fine particles. Such particles are classified into three categories PM10 (less than 10 μm), PM2.5 (less than 2.5 μm) and PM1 (less than 1 μm) by BS EN ISO 16890 [538], which was based on the "National Air Quality Standard for Particulate Matter" of the US Environmental Protection Agency (EPA); the main attention of the standard is towards High-Efficiency Particulate Air (HEPA) the efficiency standard for air filters for large spaces. BS EN 149:2001 + A1:2009 on the other hand, is the British Standard to which respiratory protective devices are tested using sodium chloride and paraffin oil at 95 l/min. Transmission of influenza can occur by sneezing or heavily exhaling the infectious particles, some of which may be aerosols, so size is variable and ranges from 0.1 to 100 μm, whereas the Ebola virus is smaller, with a diameter of 80 nm and the Coronavirus SARS-CoV-2 is about 120 nm in size [537] but exists primarily in aerosol droplets from 0.05 – 16 μm [539].

Filtration mechanisms. A useful review of the main physical mechanisms that apply generally to small particles in air filtration [540] lists them as:

- Direct Interception, where the particle follows a flow path to within a particle radius of a filter fibre and is captured
- Inertial Impaction, where the (larger) particle does not deviate with the flow so collides with the filter fibre, and
- Diffusion, where the very-fine particles are jostled by collisions with molecules of gas (Brownian motion) and caused to collide with filter fibres and become trapped.
- Electrostatic Attraction, which occurs when opposites charge exist or charges are generated between the filter fibres and particles. Particles therefore collect on the fibre surfaces.

A filter's ability to capture particles depends on the particle size passing into its fibre mass as well as the velocity of the flow passing through the filter. In looking at the range of sizes applicable to bacteria and viruses, (all of which would be classified by BS EN ISO 16890 as PM1), the larger particles in the range, that is, particles above 0.4 μm in diameter, will be captured due to both the impaction and interception mechanisms. Medium particles, in the 0.1 to 0.4 μm diameter range, turn out to be the

most penetrating, despite being captured by both the diffusion and interception filtration mechanisms. Small particles, below 0.1 μm in diameter, are captured mostly by the diffusion mechanism, but more effectively than those in the medium size in the range [540, 541] For such as the Coronavirus aerosol droplets, which will vary in size, there will be many of a size which will fall within the range $0.1 - 0.4\,\mu m$ where the filter is operating at low effectiveness, at least insofar as these physical mechanisms are concerned.

Research to produce a 'better' mask has taken several different avenues. For example, a useful and detailed set of criteria were set down by the Department of Veterans' Affairs project: "Better Respiratory Equipment using Advanced Technologies for Healthcare Employees" (BREATHE). The working group, 'BREATHE', was brought together to design a new and improved respirator specifically for health care personnel, beyond the N95 (and reusable up to 10 times), which would be called the B95 [542]. Nothing further seems to have emerged from this initiative, but other work has continued. For example, how a mask is working and its ability to fit closely has been studied, particularly by a group at Shinshu University in Japan, for example by assessing the fitting patterns of masks for closed and open mouths [543], because, pleated masks may allow mouth movement. The movement of the mouth can alter the pleats and can still create an air gap. To allow for the shape variation of the face with the mouth open and to achieve good fitting performance for a larger population, a mask sheet made from knitted fabric was proposed [544], but good mask fit which will also allow for the mouth to open and close still poses problems [545], as do the particular requirements in the design of masks for young people (with closed mouth) as explored by researchers from the same group; it proved difficult to achieve good fit for all face shapes [546].

For the outer filter layer in masks, the addition of a fluorochemical repellent finish [520] and the use of an antimicrobial nanoparticle covering finish has been explored [547], as has, most recently, the use of nanofibre webs in the filtration layers to improve both filtration effectiveness and comfort [548]. Attention was also paid to other ways of helping the filtration material to work more effectively; for example, the development of electrets for improving the performance of fibrous filters was reported as early as 1976 [549]. Indeed, the feature of N95 and FFP2- and FFP3-type filters which substantially enhances their effectiveness is the incorporation of an electret in the form of polypropylene microfibres charged through exposure by corona charging. Nonpolar polymers such as polyolefins can become good electret materials for use in air filtration especially if the polymer is loaded with a high-dielectric additive before spinning such as barium titanate (1%) with a particle size mostly below 2.1 μm [550].

Electret filters are used in high-efficiency filtration particularly because they are effective at low pressure drops, a critical metric in PPE design, since it directly affects breathing comfort and the length of time a respirator can be worn. The electret filter as opposed to the mechanical filter displays enhanced ability to capture airborne particles due to coulombic attraction and induced polarization and therefore tend to exhibit a higher quality factor (QF), that is, the ratio of relative efficiency to unit pressure drop Because of their electrical conductivity and low regain values at most humidity levels, polypropylene fibres are very good at retaining their electrical charge;

this allows them to continue to attract particles passing into the filter medium even following considerable periods of ageing. It has been shown for example that N95 masks (which do contain an electret layer) retain their performance through storage for periods of at least 10 years [551].

There is still however, not only a lack of research in the area of how long a mask remains effective in actual use (critical in surgical applications and infectious disease transmission) but also a problem with acceptance of possible treatments for the decontamination of respirators and a lack of official certification rather than emergency permission to enable their re-use after exposure to viruses, despite useful baseline research conducted ten years ago by Viscusi, Bergman and co-workers.

Various decontamination treatments were explored and reported in 2009 by Viscusi et al. [552] and in 2010 by Bergman et al. [553] following the H1N1 outbreak in the United States because health officials in the United States had expressed concerns about possible shortages of N95 respirators during pandemics such as the H1N1 influenza crisis on 2009. To improve on the information gained earlier by Viscusi et al. [536] from the successful single application of a number of different decontamination procedures, Bergman et al. [553] investigated three-cycle (3X) processing using eight different methods on six FFR models: ultraviolet germicidal irradiation, ethylene oxide, hydrogen peroxide gas plasma, hydrogen peroxide vapour, microwave-oven-generated steam, bleach, liquid hydrogen peroxide, and moist-heat incubation (pasteurization). A four-hour 3X submersion of FFR in deionized water was performed for comparison to act as a control. Only the hydrogen peroxide gas-plasma treatment resulted in reduced performance with mean penetration levels $>$ 5% for four of the six FFR models; FFRs treated by the seven other methods and the control samples had expected levels of filter aerosol penetration ($<$ 5%) and filter airflow resistance. However, there was some physical damage to the respirators which varied by treatment method and it was considered that further research was still needed before any specific decontamination methods could be recommended.

Ten years later, on 1 April 2020, at the height of the COVID-19 pandemic, the Stanford Anesthesia Informatics and Media Lab in the School of Medicine at Stanford University [554] established a rapidly-growing group called N95decon.org [555] to create a set of best practices on the decontamination and reuse of N95 respirators. They appear to have resurrected several of Viscusi et al [552] and Bergman et al.'s [553] decontamination methods and, most creditably, applied many more cycles of treatment to check how many re-uses might become possible, investigating, in their words: 'multiple commonly-used and easily-deployable, scalable disinfection schemes on media with a particle filtration efficiency of 95%'. Among these, heating ($\leq$85 °C) under various humidities ($\leq$100% RH) was considered the most promising, non-destructive method for the preservation of filtration properties in melt-blown fabrics as well as for N95-grade respirators. Heating could be applied up to 50 cycles (85 °C, 30% RH) without degradation of meltblown filtration performance. Ultraviolet (UV) irradiation was a second possible choice as it was able to withstand 10 cycles of treatment and showed only a small degree of degradation after 20 cycles, but with the potential for impact on the material strength and fit of the respirators [556, 557]; their article was published ahead of a

significant flurry of related papers appearing throughout May 2020, regarding masks, respirators, respirator shortages and reuse, and other ways of decontamination such as the use of a high-level disinfection cabinet [558] and a practical system for decontamination and re-use commendably put into operation in a hospital setting on a large scale in St Louis, USA, during the COVID-19 epidemic [559], but few others offered such a complete set of guidance as Liao et al. [557]; details about many of these papers can be accessed from the United States National Institute of Health's National Library of Medicine [560] for example: [561–564].

Having contracted COVID-19 in late March 2020, unable to be at work and in isolation, one of the authors of this issue of Textile Progress (HM) developed a protocol for testing, to British Standards, a set of scalable decontamination processes that could be used locally on surgical FFP3 respirators, namely:

1. Disinfection method 1: Hot air (75 °C)

1. Take fifteen masks.
2. Test three for filtration efficiency and pressure drop via EN149:2001.
   (Note: This is what the University Hospital Leicester mask is tested to. The Stanford paper tests to TSI 8130A)
3. Preheat oven to 75 °C.
4. Place remaining twelve samples into the oven.
5. After heating for 30 minutes, remove the samples and cool at room temperature for 10 minutes.
6. Repeat step 5 for a total of 20 cycles.

a. After every 5 cycles, pick 3 samples to test as per Step 2.

2. Disinfection method 2: Ultraviolet Light

1. Take fifteen masks.
2. Test three for filtration efficiency and pressure drop via EN149:2001.
3. Place samples into a UV sterilizer (254nm wavelength, 8W UV lamp).
4. Irradiate under the UV light for 30 minutes.
5. Remove the samples, allow to stand under ambient conditions for 10 minutes.
6. Repeat Steps 3-5 for a total of 20 cycles.

a. After every 5 cycles, pick 3 samples to test as per Step 2.

3. Disinfection method 3: Microwave

1. Take fifteen masks.
2. Test three for filtration efficiency and pressure drop via EN149:2001.
3. Place samples into a microwave heating device at 1250W for 2 minutes.
4. Remove the samples, allow to stand under ambient conditions for 10 minutes.
5. Repeat Steps 3-4 for a total of 20 cycles.

b. After every 5 cycles, pick 3 samples to test as per Step 2.

As can be seen, there are similarities with the Stanford AIM team's selection of treatments, and as with them, an emphasis on a larger number of treatment

cycles than was the case in Bergman et al.'s [553] earlier attempts in 2009, but in this case the treatments were to be applied to the surgical FFP3 type respirators used in the UK rather than the N95 surgical respirator favoured in the United States.

Implementation of the protocol was inhibited because significant numbers of identical respirators would be required to accomplish the tests; it proved to be impossible to assemble the required set, even from already-used items, because of the wide variety of different makes and ages of FFP3 surgical respirators that were having to be used in UK hospitals just then, drawn from stores made up from diminishing collections of small batches of different types. Contact was therefore made with the AIM Group at Stanford to determine whether any assistance could be given there, but the reply indicated that they were having to focus solely on the N95 Respirator decontamination procedures at that time. As a consequence, HM's efforts to establish the possible usefulness of the selected decontamination treatments have had to be put into abeyance until such time as supplies may allow implementation of such trials, and HM has returned to the more-usual work of a surgeon.

In the meantime, a research paper has been published referring to decontamination of the FFP2 Type respirators as approved by the EU, by a process involving treatment of used FFP2 respirators – Model 3 M Aura™ 1862 + which were sterilized using a low temperature process involving vapourised hydrogen peroxide (H_2O_2), using the V-PRO® maX Low Temperature Sterilization System (STERIS, Mentor, Ohio, USA), a US Food and Drug Administration approved method to decontaminate FFP2 respirators). The sterilisation process maintained filtration efficiency to EN 149 [565]. A starting set of 5,000 respirators were sorted into two groups: re-processable (clean, undamaged) and discards (10% of the batch). The re-processable set was decontaminated using the low-temperature hydrogen peroxide treatment. Despite the large size of the starting set, for some reason only 10 new and 10 'used and decontaminated' respirators were tested for their filtration efficiency, but even so, it was concluded that the sterilisation process maintained filtration efficiency to EN 149. What should also be of interest for future consideration are the overall cost considerations of collection, decontamination and handling calculated here to be at 0.5 Euros [549], about one tenth of the cost of each new FFP2 device as quoted on line by Hive Pharmacy in the UK for example for FFP2 certified (N95) Covaflu™ and almost one 30th that quoted for a new FFP3 surgical mask on 21 June 2020 (but down to one 16th on 21 July 2020) [566], and also how decontamination might help to address difficult questions about the sustainability of the routine adoption of single-use practices.

Interestingly, all of these more-thorough attempts at determining suitable decontamination techniques to allow the safe re-use of surgical respirators appear to have been carried out during the actual COVID-19 pandemic crisis, despite early warnings having been issued about possible shortages of respirators during a pandemic: according to a 2006 report from the National Academies' Institute of Medicine in the United States, over 90 million N95 FFRs would be needed to protect their workers in the healthcare sector during a 42-day influenza pandemic outbreak [567].

Clearly, making possible the safe-reuse of respirators was not given an appropriate level of priority in some countries; certainly that was the case not only in the UK

but also in Canada and the USA, however, the FDA by mid-April 2020 had issued several factsheets on decontamination of N95 respirators by various methods. These were put forward on the basis of "*Emergency Use Authorisation (EUA)*" [568]. The Stryker decontamination of compatible N95 respirators was approved using the Stryker Sterizone VP4 N95 Respirator Decontamination Cycle in the Sterizone VP4 Sterilizer (compatible N95 respirators are those that do not contain cellulose-based or paper materials, natural rubber, or latex). The device uses vaporised hydrogen peroxide as the decontaminant followed by ozone and this only enable decontamination for "*single-user reuse up to two times*" as was the case for the ASP STERRAD Sterilization, another hydrogen peroxide vapour system, whereas decontamination with the Sterilucent HC 80TT Vaporized Hydrogen Peroxide (VHP) Sterilizer allowed for a maximum of 10 decontamination cycles; a new EUA for Technical Safety Services LLC, Berkeley, CA. which allows decontamination and reuse 20 times was the latest to be issued at the time of writing. It is clear from outcomes such as these that blanket approval cannot be given for treatments simply because they make use of the sterilising effects of a particular agent or type of agent. It is the controlled application of the whole treatment procedure that is required to achieve the desired extent of reusability

The STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers also allowed for a maximum of 10 decontamination cycles but the Duke decontamination system, also based on vapour-phase hydrogen peroxide and also allowing for a maximum of 10 decontamination cycles, had not been approved by CDC/NIOSH. The best of the methods in the FDA *Emergency Use Authorisation* list, in terms of number of decontamination cycles allowed, was the Battelle Decontamination System for Compatible N95 Respirators, based on exposure to vaporised hydrogen peroxide for 150 minutes, which would allow for up to a maximum of 20 decontamination cycles and was the earliest to be approved under the EUA (29 March 2020). For whatever reasons, the FDA (5th June 2020) had not yet seen fit to approve Liao et al's preferred system for decontamination and re-use despite it being able to offer 50 cycles of decontamination and reuse [556, 557].

Surgical gloves have references dating back to 1758 in the literature when a primitive glove was made from the caecum of a sheep in an attempt to reduce tissue laceration during obstetrics [569]. Following this, the materials used to make gloves evolved through cotton, leather, silk and rubber [570]. It is, however, Sir William Halsted who tends to be credited with the introduction of surgical gloves in 1889 [569]. Rather than to protect the patient, the gloves were introduced to protect the hands of the scrub nurse, working for him, who was developing dermatitis from the sterilization solutions. This was 'true love' and he later married her [570]. Subsequently, Halsted's junior commenced wearing rubber gloves during hernia operations and noticed a 100% drop in surgical site infection [569]. With the advent of knowledge of blood-borne diseases, gloves are now also used to protect the healthcare worker. Indeed, *in vivo* studies have demonstrated that glove material can reduce the transferred blood volume in a needlestick injury by 46-86% [571].

Over time, the materials from which surgical gloves are manufactured has changed. An important event was the association between the powder on the gloves and the

Figure 12. Examples of surgical gloves.

development of starch peritonitis [572]. Furthermore, the increase in latex allergy in healthcare workers during the 1990s has also steered the manufacturing of gloves away from latex [573]. The range of common gloves materials has widened to include not only latex but also synthetic polymers such as neoprene, polyisoprene and nitrile (see Figure 12) [574].

A subject of interest is that of surgical glove perforation and the associated risk of infection to the healthcare worker or the patient. The risk of perforation has been shown to increase with the duration of operating time (increasingly so after 90 minutes) and also with the fit of the glove; a poorly fitting glove is more likely to perforate. Studies have shown that the frequency of glove perforation during surgery ranges from 8% to 50% [575, 576].

The decision to use an additional layer of glove protection is influenced by a range of factors including 'risk' status of the patient, personal preference and the surgery involved. For example, orthopaedic surgery is considered to have a higher risk of perforation. From personal experience, double layering of gloves can cause reduced sensation and dexterity to the surgeon which can be a problem when delicate work is required. This is supported in the literature [577, 578]. A Cochrane Review has compared single gloving with double gloving and the risk of perforation. It was found that there were more perforations in the single layer of glove than there were in the inner layer of the double-layered gloves. Interestingly, when pooling data from multiple trials, this was consistent regardless of which of outer-glove was worn [579]. A UK trial

in orthopaedics found that wearing a knitted outer glove, as opposed to a standard latex glove, significantly reduced the risk of perforation to an inner latex glove ($p < 0.0001$) [580], whereas, to the contrary, a further trial with an outer glove made from a polyester/stainless steel wire weave glove found no statistical difference in inner layer perforations when compared to an outer latex glove [581].

The permeation of chemicals through the glove, for example glutaraldehyde used to fix histological specimens, can also cause problems. One trial demonstrated that latex gloves had the quickest permeation rate (less than an hour at 3.4% glutaraldehyde solution) whilst gloves manufactured from butyl rubber had the longest permeation rate (greater than eight hours at 3.4% solution). In addition, neoprene and polyvinyl chloride gloves should not be used with glutaraldehyde because the gloves retain or absorb the solution [582].

The glove-gown interface has been a subject of interest following the 2010 joint registry study in New Zealand which showed increased infection rates with use of the modern surgical helmet systems when compared with conventional gowns [583]. More work could be directed into this area.

Healthcare worker uniforms also require consideration, and methods have been developed to enable rapid quantitative testing with the real-time polymerase chain reaction (qPCR) to check for the presence of nosocomial pathogens [584]. Whilst the majority of contamination is from the wearer of the uniform, uniforms have been found to become frequently contaminated below the waist and heavily contaminated after procedures that involve exposure to pathogens [585]. Using a plastic apron significantly reduces contamination at the front of the uniform [586].

Bacterial transfer under dry conditions has also been investigated on the most common re-usable fabrics for healthcare professional uniforms (Tencel® and PET/Cotton) [587]. A three-layer laminate (PU/PET/PU) for surgical drapes that meets the European Standard for surgical drapes (EN 13795) was used as the reference. The relative performances of each of the other fabrics and their seams in terms of bacterial transfer were checked against this fabric, plus their ability to maintain performance for up to 50 laundering and disinfection cycles which was carried out using hospital laundering and steam-sterilisation services. The PU/PET/PU laminate proved to be the best barrier fabric followed by the Tencel® then the PET/cotton; barrier performance by the Tencel® improved with repeated laundering and sterilisation. Although, with their greater thickness, bacterial penetration was lower at the seams, the two most-commonly used seam types for the manufacture of healthcare uniforms were found not to have a significant influence on microbial barrier efficacy. Having said that, the seam type 1.01.05/504.504.301 was considered more suitable than type 1.01.02/ 301.504, which is more susceptible to gaping on the application of tension to the seam [587]; (seam-type terminology here is in line with ISO 4916:1991, Textiles-Seam Types-Classification and Terminology; see [588] for an illustrated explanation of seam types). Doctors' white coats become progressively more contaminated as they are worn and it is for this reason that hospitals have now made them obsolete in their uniform policy [589, 590].

Whilst little attention generally has been turned to un-scrubbed members of the staff, a substantial reduction in airborne contamination occurs when

un-scrubbed staff wear non-woven fabrics. This highlights the importance of the protective barrier the clothing offers during the day. It was found that the efficacy of non-woven clothing was superior to that of woven clothing, even at the end of the working day when clothing was showing a frayed appearance. Indeed, as much as a 72% reduction in bacteria dispersal is noted for male surgeons wearing non-woven clothing. When rubber bands were worn over the shirt sleeves of males, the bacterial dispersion was reduced by 35% compared to that without, demonstrating the importance of axillary dispersion of bacteria in contamination of the surrounding environment [591].

One must also consider laundering of the uniforms and whether this should be undertaken in a professional laundering facility or whether it can be undertaken at home. It has been shown that a 10 minute wash at 60 °C with the addition of either a biological or non-biological detergent was effective in removing MRSA from experimentally-contaminated swatches and that low levels of recontamination of uniforms could be effectively removed by (hot) ironing [592].

Healthcare workers' uniforms tend to be washed industrially in washer-extractors and dried in tunnel driers rather than by batch or continuous washing machine and tumble drying. It is thought that this method gives a substantially greater dilution of contamination than either batch or continuous washing machines, though the review was inconclusive [593, 594].

With the development of new fabrics and multifunctional finishes, the potential for development of uniforms expands. More consideration should be given to both the maintenance and disposal of uniforms in an economical and enviromentally-friendly manner.

Patients. Consideration should also be given to clothing for patients. Some work has been carried out on clothing for children in the hospital environment [595] but it should be expected that the clothing worn by patients could play a more-active role in patient care in the future. For example, in terms of drug delivery from hollow fibres controlled by thermal stimuli [596] and see also Section 7 for more developments of this type.

5.3. Orthotics

An orthosis is defined as an externally applied device, which modifies function by supporting or controlling a body part [597]. There are a wide range of orthotics available for all aspects of the body ranging from hernia supports through to hip protectors and more recently, exoskeletons. Modifications of these have made it through to the commercial and consumer markets; for example, the Fitflop™ (London, United Kingdom), Masai Barefoot Technology® (Barcelona, Spain) and Earth Shoe® (New York, United States of America). A few different orthoses will be discussed below.

Hernia trusses have been used for centuries with reports of Sir Astley Cooper using a truss successfully back in the 1820s. They are a mechanical support that assists in maintaining the hernia; "a bandage by which ruptures are restrained from lapsing [598]. Trusses are generally used in elderly patients where the risks of surgery are

excessive. A range of trusses are available for patients to maintain a reduced hernia. A study in the British Medical Journal suggested that trusses are not without problems, some of which include discomfort when wearing. The study also reported that poor hernia control can be exacerbated by incorrect truss placement and that a truss increases the probability of complications such as strangulation of the hernia, atrophy of the spermatic cord and atrophy of the fascial margins [599]. There is scope for improved designs for the benefit of those not wanting to undergo the surgeon's knife.

Hip protectors consist of plastic shields or foam pads fitted in pockets of specially designed underwear that aim to reduce the impact of a fall onto the hip and thus the risk of a hip fracture [600]. Over 70 0000 hip fractures occur annually in the United Kingdom and the total cost of care is over £2 billion with 10% mortality at 30 days and up to 30% mortality at one year [601]. A Cochrane Review found accumulating evidence casting some doubt on the effectiveness of the provision of hip protectors in reducing the incidence of fragility hip fracture. Many people stop wearing hip protectors because they find them uncomfortable and impractical [602]. That said, there are recent publications investigating methods of protecting the hips that may lend themselves to clever design, improved comfort and fit and higher levels of acceptance [603–606].

Braces and Splints are common methods of managing many musculoskeletal injuries as a treatment option as well as having use in providing support in the post-operative period. In recent years there has been an increasing interest in customizing medical and orthopaedic products to provide individual treatment for the patient concerned [607]. Generally speaking, braces may offer protection or assist in protected mobilization. They can assist in pain relief, improve normal alignment, stretch contractures and facilitate normal movement and function depending upon their design (see Figure 13) [608].

Braces and splints are readily available in two forms; either prefabricated off-the-shelf orthoses or custom-moulded orthoses [609]. They are used in a variety of specialities and commonly so in orthopaedics as treatment or as an adjunct to aid post-operative recovery. Despite improved design and materials, there are still limitations with using braces and splints [610]. Indeed, several Cochrane Reviews have been inconclusive as to the benefits of braces and splints in managing a variety of conditions [611–613]. That said, they remain a treatment option in the management of acute and chronic orthopaedic issues e.g. wrist splints for osteoarthritis, post distal radius fractures, boots to protect weight bearing following foot and ankle surgery.

3-D printing technology will permit the creation of a personalized cast and brace for the individual patient which may improve their outcomes.

Scoliosis Braces have been used as nonoperative treatment of adolescent idiopathic scoliosis, curvature of the spine, for approximately 60 years. Over this period of time, a variety of orthoses have been utilised with more in development [614]. There are many different brace designs but all have the same common objective; to restore normal contours and align the spine by means of external forces (see Figure 14). In some designs the simulation of active correction occurs as the patient moves the spine away from pressures within the braces [615]. Studies of bracing in adolescent idiopathic scoliosis suggested that bracing decreases risk of curve progression but

Figure 13. Commonly used orthotics and splints.

Figure 14. Scoliosis Brace.

results were inconsistent, observational and compliance can be an issue. A multicentre randomised controlled trial conducted in the United States and Canada concluded that bracing significantly decreased the progression of high-risk curves to the threshold for surgery in patients with adolescent idiopathic scoliosis. Furthermore, longer hours of brace wear were associated with greater benefit [615]. More recently, a Cochrane Review assessed the different types of braces – broadly, rigid or elastic, and quantified which brace is most suitable for which degree of curvature [616]. Brace wear varies across clinicians and may range from 12 to 23 hours a day until skeletal maturity is reached. There are recognised practical issues with braces including limited clothing choice, interference with sport and activity and self-consciousness about the brace [617].

Exoskeletons are a distinctive kind of robot to be worn as an overall. They effectively support or substitute the owners' own movements [618].

They can be divided into three broad categories depending upon use.

1. Human performance augmentation
2. Assistive devices for those with disabilities
3. Therapeutic exoskeletons for rehabilitation [619]

They may assist all four extremities or just the lower limbs only. The interest in the medical and healthcare use of exoskeletons has been driven by the benefits that the use of a human exoskeleton is closer to 'normal' mobility than using a wheelchair. They have also been perceived as more effective than the traditional assistance and support of therapists and rehabilitative devices [620].

A key driver in the development of exoskeletons is the limited access to rehabilitation clinicians and facilities [621]. Body weight-support robot-assisted treadmill training has been shown to lead to comparable or improved functional outcomes in stroke survivors. In the same vein, manually assisted or robot-assisted locomotor training can result in beneficial effects, even for subjects with complete spinal cord injury [622–624]. Upper-limb exoskeletons are considered safer than lower-limb exoskeletons because gravity and the potential for falling is eliminated. Another consideration is the risk of fracture from incorrect fitting of exoskeletons that then apply a force to a bone that may have disuse osteopenia [625, 626]. With the advances in nerve stimulation, the possibility of functioning and life like exoskeletons/prosthetics that can sense nerve conduction and integrate with the human are also a distinct possibility.

Exoskeletons have also been designed for surgical applications. For example, a passive hand exoskeleton to provide passive assistance [627]. This may have uses in microsurgery and fine neurosurgical operations where any false movement can have severe consequences.

Prosthetics for amputees are critical in rehabilitation. There have been several advances over the years. There are broad categories; passive devices, body-powered designs and externally powered designs. Take for example, the hand. In a hand, the thumb provides approximately 40% of hand function, the index and middle finger 20% and the ring and little finger 10%. Opposition is critical for normal hand function and the reason why loss of a thumb is so detrimental to hand function. With advances

in biomaterials and engineering design, the ability to provide critical grips, such as opposition, three-digit hands and multi grasp anthropomorphic hands have seen evolutions in upper limb prosthetics [628, 629]. Electrodes placed on functioning muscle units allows prosthetics to be driven by myoelectric activity which allows a prosthesis to mimic the previous functioning limb. Prosthetic fingers can then be covered with materials resembling natural skin. Examples of prosthetics include ProDigits (Optimus Prosthetics, Columbus, OH, USA) and iLIMB (Touch Bionics, Mansfield, MA, USA). Research has been directed at the use of direct brain-wave control for operating prosthetics. Cerebral control has the major advantage that it bypasses the peripheral nervous system in the remaining limb, which may be damaged [630]. Another avenue of interest is whether prosthetics can be directly implanted into a stump.

5.4. Healthcare equipment

Furniture, furnishings and coverings

A wide range of textiles are used in healthcare and medical equipment. For example, the coverings of clinic couches and chairs through to the curtains that separate bed spaces upon the ward and there are no significant international standards for such items except for the electrically-driven items although these do exist for disposables such as surgeons' gloves (see figure 15) [631].

Figure 15. Healthcare Equipment; Ward Bed.

Hygiene and ease of cleaning are key considerations to reduce the risk of transmission of infection, not least the padding and coverings of operating tables and of supports used to protect pressure points for the patient; infection transmission needs to be minimised and, in addition, the ability of materials to protect the skin without being causative in a pressure sore is a key requirement.

The sheets and bed coverings on inpatient beds need to be designed within the current economic and environmental context where life-cycle assessment of all items should be routinely undertaken and the reduced carbon footprint of laundering versus disposal needs to be addressed (see also Section 5.2 for a related point about the high cost of single-use respirators). A series of British Standards do exist to which bedding can be designed and these include standards for mattress covers and pillows [632, 633].

Air filters

In a modern hospital environment there is an expectation that apart from heating and ventilation there will also be provision made for filtration of the air being circulated, particularly but not exclusively in operating theatres and intensive-care units. By contrast with the personal protective devices such as surgical masks and respirators, although such filters are described as High-Efficiency Particle Arrestance (HEPA) air filters, they are expected to treat significant volumes of air, many times the amount taken in by a single individual, so they cannot easily achieve the degree of entrapment of most virus–sized particles by mechanical filtration or attraction by charged electret fibres to the extent that would be routinely achieved by a N95, FFP2 or FFP3 respirator. Instead, wherever it is felt necessary to achieve high levels of decontamination of the air passing through the filter, the mechanical filtration provided by melt-blown nonwoven fibre webs is supplemented by UV-C irradiation which may be coupled with a photocatalytic filter (filter fabric containing TiO_2 nanoparticles as used in photocatalytic self-cleaning fabrics and/or ionisation) [634] or electrical discharge within the filtration device itself, plus in some models, activated carbon for removal of volatile organic compounds (VOCs). Appropriately administered, such additional treatments should prove effective, but recent claims that such devices would remove/destroy SARS-Coronavirus2 have had to be withdrawn because the necessary tests have not yet taken place on this particular virus. In some cases such as for clean rooms or demanding hospital setting, the HEPA filter will be coupled with devices which bring about a slight reduction in air pressure in the area to help to limit the transfer of contaminants. There are examples which span a great range, from fixed or large mobile installations for hospitals, through more-mobile but still substantial devices for hospitals, care homes, schools and factories, and those which may be described as medical but are actually intended for domestic or small-office/reception area use. [635–637].

There are also Ultra-Low Particulate Air (ULPA) filters and whereas HEPA filters are designed to remove up to 99.97% of contaminants of sizes down to 0.3 μm, ULPA filters are designed to remove 99.99% of particles down to 0.12 μm in size which does therefore include virus-sized particles. However, the ULPA filters are much more demanding both in terms of maintenance and operating costs, so they are intended to be reserved for specialist treatment areas.

6. Extracorporeal devices

6.1. Artificial organs

6.1.1.1 The kidney and renal function. The *kidney* is a complex organ that is involved with filtration and excretion of waste substances in the body. They are critical in the overall maintenance of fluid balance and also contribute to endocrinological function of the body with a role in erythrocyte production, bone homeostasis and the regulation of blood pressure. The role of filtration and excretion is undertaken by a series of ion pumps that can transport, actively or passively, ions and metabolites from blood flow into a waste system that creates urine [638].

Alteration of the normal function of the kidney can lead to renal failure and this may be acute or chronic in nature. In end stage renal disease, treatment options for renal replacement therapy include haemodialysis, peritoneal dialysis (either continuous ambulatory peritoneal dialysis or continuous automated peritoneal dialysis) or transplantation. Worldwide, the prevalence of end-stage renal disease exceeds two million individuals [639].

Haemodialysis relies on the principal of solute diffusion across a semipermeable membrane. The movement of metabolic waste products occurs down a concentration gradient from the circulation to a dialysate. The rate of diffusion is affected by the concentration gradient, membrane surface area, pump speed and the mass transfer coefficient of the membrane. The dialysate can be artificially manipulated depending upon the current state of the patients' blood and what needs to be filtered. This allows for finer control. Blood is extracted from a filter and passed through a dialysis machine before returning to the patient (see Figure 16). Haemodialysis is undertaken several times a week depending upon the severity of the renal disease and requirements of the patient. This is often performed at hospital in-centre haemodialysis units though may be undertaken at a satellite unit; both mean time away from friends and family. Occasionally it may be performed at home.

Peritoneal dialysis differs in that a dextrose-containing, or amino-acid based solution is infused into the peritoneal cavity for a period of time before being removed. Dialysis occurs across a concentration gradient by diffusion and relies upon the balance between the movement of solute and water into the peritoneal cavity and absorption from the peritoneal cavity. As equilibrium is reached, the rate of diffusion diminishes.

Transplantation of the kidney is undertaken for advanced chronic renal failure. The aim is to transplant a functioning kidney such that dialysis is no longer required. Lifelong immunosuppression is used to prevent rejection [608]. There are problems with all forms of renal replacement therapy. Haemodialysis hinders mobility and limits activities of daily life. Peritoneal dialysis does the same but tends to affect quality of life more than mobility. Both carry a risk of infection and failure of dialysis. Transplantation requires a carefully matched kidney and life-long immunosuppression. Thus, the ability to design an artificial functioning kidney would have great promise [640].

6.1.1.2 The artificial kidney and associated role of textiles. An artificial kidney would be one that functions continuously, is able to remove toxic waste products indiscriminately, is portable, wearable, and light-weight, at low cost [641].

Figure 16. Dialysis Machine.

The single most important part of a wearable artificial kidney is the closed-system self-regenerative dialysate. To be able to achieve such a design, the removal of diffused toxins from the dialysate would require nanoporous adsorbents with high adsorption capacity [642].

Traditionally filtration has been undertaken by activated carbon. More recently, zeolites and polyethylene glycol-coated nanoporous silica have shown promising results against uraemic toxins. As the blood runs over the artificial filtration membrane, it is vitally important that the filter does not cause activation of the clotting cascade which would be a disaster for the patient. The development of hollow fibres to allow filtration [643], has allowed for further development within this area. Polyester and viscose rayon are the two main textiles that are used for mechanical kidneys. The textile needs to be biocompatible, non-thrombogenic and economic for use. The ability to create fibres with nano-pores, for example by electrospinning webs and scaffolds, to allow diffusion, has allowed for advancement in this area, particularly in that of tissue scaffold creation [644]. With the progress in artificial intelligence, the role of smart textiles that can continually adapt to the internal physiological environment increases the likelihood of a personalised haemodialysis design [645]. There are some interesting developments in slightly–different applications on thermal-stimuli effects for drug delivery in self-care garments, utilising nonwoven fabrics made from crimped, synthetic-polymer, staple hollow fibres (for their drug-holding ability) and incorporating silver-coated fibres into the nonwoven fabric (for thermal stimulation), that may provide some ideas (in terms of finding an appropriate stimulus and a fibre/fibre formable to respond) about how to move forward [595].

6.1.2. The pancreas

The *pancreas* is an exocrine and endocrine organ that is involved in releasing digestive enzymes and secreting hormones that regulate blood glucose. Damage to the pancreas, such as in pancreatitis, can damage the cells that constitute the pancreas and impair its function. If the pancreas is globally affected, then pancreatic insufficiency occurs and both exocrine and endocrine functions are impaired. Diabetes mellitus, due to an inability to secrete insulin and regulate blood glucose occurs. In addition, malabsorption due to an inability to digest food occurs and the enzymes need to be replaced.

Diabetes mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycaemia. There are different types of diabetes mellitus based upon the causative factor. The two broad categories are type I and type II, though there are other types increasingly recognised. Type I diabetes mellitus develops as a result of autoimmunity against the insulin producing beta cells of the pancreas. It results in near or total insulin deficiency. Type II diabetes mellitus is a group of disorders characterised by variable degrees of insulin resistance, impaired insulin secretion and increased hepatic glucose production [646]. Those with type I diabetes mellitus are managed with exogenous insulin administration. Type II diabetes mellitus may be managed with lifestyle modification, medications or insulin. Long term complications include macrovascular and microvascular complications such as an increased risk of myocardial infarction, cerebrovascular accident, diabetic nephropathy, diabetic retinopathy and diabetic neuropathy [629]. Tight blood glucose control reduces the risk of long-term diabetes related complications although is limited by hypoglycaemia [647].

6.1.2.1. The artificial pancreas and associated role of textiles. The artificial pancreas addresses the unmet clinical need for improved glucose control. It is a closed-loop system that senses glucose blood levels and uses control algorithms to direct insulin

delivery. It aims to improve glucose control whilst reducing the burden of hypoglycaemia and diabetes self-care [647]. One of the advantages it offers over the conventional injection regime is that it can respond to day-to-day and within-day glucose variability [648].

Regeneration of insulin producing beta cells is a major goal for regenerative medicine. Scaffolds and tissue constructs may serve as adjuncts to allow cell growth and culture prior to transplantation. Interestingly, however, islet cells have the ability to engraft and function within the liver which thus means that they can be injected into the portal vein to lodge in the liver [649].

One method to reduce rejection, and the need for immune-suppressants, has been encapsulating the islet cells such that diffusion of nutrients, insulin and waste can occur but infiltration by immune cells and antibodies is prevented. Alginate is commonly used for this purpose in a hydrogel sphere. Growth factors and medications may be added to engineer the properties favourably [650, 651].

Regenerative medicine has been directed at other tissues such as heart muscle, liver, trachea, skin. Scaffolds have been used to grow cells. This is a growing area of medicine with huge scope for application clinically and the discovery of new materials with improved mechanical and biological function, for example clay-polymer nanocomposites, offer new scope for design. Clay nanoparticles are biocompatible at doses significantly higher than most other nanoparticles and have non-toxic and absorbable degradation products. Studies have also demonstrated direct, beneficial and concentration-dependent effects of clay nanoparticles on cellular adhesion, proliferation and differentiation. This does, however, remain a field at the forefront of science and as was the case ten years ago, there are still challenges that need to be overcome [649].

6.2. Devices for the support of homeostasis

In addition to those briefly mentioned above, a range of textiles are used in extracorporeal devices used to support homeostasis in the human body. For example, microporous polypropylene is used to create an artificial lung that supports respiratory exchange [652], and a textile heart-valve has been constructed and tested [653]. There are a whole range of filters and detectors used within medical devices that involve the use of textile materials. For example, anaesthetic machines contain a range of filters (which may be ULPA or HEPA types, see Section 5.4, depending on the treatment being delivered) to ensure appropriate ventilation and a mixture of NaOH and CaO (soda lime) is used to remove carbon dioxide from the ventilatory system [654].

7. Intelligent (SMART) medical and healthcare textiles

Smart textiles/garments are textiles that can perform all or one of several functions; sensing the environment they are surrounding as well as the surrounding environment, and responding to environmental stimuli by integrating functions from the textile structure. Energy required to 'drive' the textile function may be derived from a mechanical, thermal, magnetic, chemical, kinetic or electrical stimulus [655].

Smart textiles and e-textiles, textiles with specified electronic properties included in the textile fibres/yarn, differ from wearables, which are in wide use (e.g. the Fitbit,

Fitbit Inc., San Francisco USA), as emphasis in the smart textile is on the integration of sensors and electronics in the textile/finished product itself rather than that being carried as a separate electronic device. Currently, power-generating devices, sensors and transmitters can be woven or knitted into the fabric, stitched onto the garment, embroidered or printed directly onto fabrics, with various degrees of success. The accent is not only on their physical flexibility, but on their correct positioning, effectiveness, consistency in the sensing, recording and transmitting of physiologically-important data and their durability.

Given that electro-conductive textiles have applications not only as medical textiles, but also in electromagnetic shielding, in heating pads and in a range of sensors, technology has been developed to manufacture conductive textile yarns in various ways [171], such as:

i. Inherently-conductive metallic filament materials such as stainless steel, used alone or embedded in a non-conductive substrate for its protection [656]
ii. Non-conductive fibres such as polyethylene or polypropylene incorporating conductive fillers such as metal powders, metal nanowires or CNTs during melt spinning or solvent spinning, with solvent spinning providing the best outcomes [171]
iii. Carbon fibres [657]
iv. Intrinsically-conductive polymers such as polythiophene or its more-easily processable derivative, poly(3,4-ethylene dioxythiophene)-poly(styrene sulfonate) or (PEDOT:PSS) [658], polypyrrole (PPy) [659], or polyaniline (PANI) [660] are used as coatings on non-conductive fibres because in filament form these polymers are very stiff.
v. Non-conductive or weakly-conductive fibres given a conductive coating with a dispersion such as carbon black, a metal coating or treatment with CNTs, or cotton fibres given a graphene coating is continuing to develop [661]

Each of these approaches has its strengths and weaknesses [662].

Applications of smart textiles in healthcare range from surgical uses of a single fibre to complex wearable and auxiliary systems for personalised care [663]. The ability to identify that an individual has declining health and subsequently alert healthcare providers, potentially allows smart textiles to be used in preventive medicine and in managing pre-existing disease, whether as an inpatient or in the wider community. Sensors may be embedded directly into the fabric or embedded into a coating applied to the fabric [664].

The first smart shirt was developed in the 1990s for use by medical staff in combat situations: optical fibres woven through the fabric connected to sensors that monitored vital signs and detected and assessed wounds [665].

Since the release and successful use of this smart shirt, much research has been directed towards smart textiles and potential uses that sensors embedded in garments may have in healthcare. For example, the EU project, BIOTEX, developed a range of e-textile sensors that can measure sweat rate and the electrolyte concentration and pH of the sweat, allowing for potential monitoring of both the fluid and electrolyte status of patients [666, 667] and a multi-layered flexible braided structure (consisting of

120 μm enamelled copper wire as the conductor and 19 tex air-jet spun singles viscose rayon yarns as the hygroscopic dielectric) has been developed which acts as a moisture sensor based on capacitance changes within the braid caused by changes in relative humidity in the adjacent environment. Enamelled copper wires (6) were braided as the central core, then overbraided with 12 of the viscose rayon yarns and that assembly openly overbraided by 6 of the enamelled copper wires to form an outer conductor; this was open enough to allow moisture to penetrate through to the viscose rayon dielectric and control its position whilst not so densely packed as to reduce the overall electrical capacitance too significantly. Unlike thin film devices, the properties of the braided structure were such as to enable it to be compatible with the other textiles in bandages or clothing and it was found to be highly sensitive for relative humidities between 22% and 94% [668].

Organic electrochemical transistors (OECTs) are devices composed of a stripe of conductive polymer that works as a channel and another electrode that works as a gate. Between them is an electrolyte solution. The channel current can be modulated by the gate voltage through electrochemical reactions that change the charge-carrier concentration in the transistor channel material and thus alter the conductivity of the channel. An OECT was developed which consisted wholly of the flexible conductive polymer PEDOT:PSS [658] and this was screen-printed onto/embedded into a flexible fabric made of woven cotton/Lycra® to enable the non-invasive monitoring of biomarkers in external body fluids [669, 670].

Measurement of cardiorespiratory parameters, electromyography and electroencephalography can be achieved with garments and fabrics already available [671, 672]. These consist of a sensor to monitor physiological parameters, conductive yarns and an interface that can interpret and collect incoming data prior to transmission to a remote location, for example, by Bluetooth [673].

In addition, an American company produced one of the earlier garments released that allowed for physiological measuring. The garment called the LifeShirt® (VivoMetrics, Vivosense, San Diego, USA) had attachments that monitored blood pressure, EEG, temperature and pulse oximetry. Whilst no longer available for sale, production of this garment did highlight the possibilities for future design and the breadth of clinical application for which design and manufacture may be suitable [674].

Other garments produced have been used for a range of applications, including home monitoring for episodes of sleep apnoea [675]. Compression garments used in sport and vascular pathology have already attracted interest from experts in the field [676]. In orthopaedics and sports medicine, a knee sleeve with in-built goniometers was trialled. These consisted of developing a textile goniometer that coupled two knitted piezoresistive layers through an electrically-insulating layer. This would appear to have many potential applications for post-operative physiotherapy in orthopaedics and sports medicine [677–679]. Optical fibre Bragg-Grating sensing was developed some time ago [680] and proves to be a useful technique for monitoring posture and pressure [681]. Attention has also been directed at how smart textiles may improve prosthetics for amputees. For example, electronic skin has sensory capabilities whilst textile-based sensors can be worn over prosthetics. Flexible, stretchable piezoresistive fabrics are available for a range of pressure-sensing applications that can be incorporated into robotic limbs [682].

Research at the University of Otago has already highlighted the importance of fibre type, yarn and the fabric structure used in socks and underlying skin health. The key determinant on cyclic loading was whether the fabric was dry or damp; damp fabrics absorbed less energy, retained less thickness during compression and recovered less than dry fabrics. The structure of the fabric was deemed less important in comparison [83]. Incorporation of sensors in the form of fibre optics, into a garment has further allowed for the development of socks which can be used to monitor pressure changes and temperature, and thus measure pre-ulcerative inflammation and possibly predict the likelihood of diabetic foot ulceration [684].

Entry into the field of psychological medicine is possible as biofeedback systems incorporated into textiles that can sense emotions and alert the user to negative emotions have been trialled. These consist of textile electrodes and hardware platform integrated into a belt that is worn by the individual. Novel and innovative, with the current support to increase mental health awareness from high profile individuals, there is likelihood that biosensors will continue to be developed for arena of psychological medicine [685].

Being able to monitor physiological variables and communicate the relevant information has the potential to revolutionise healthcare by enabling remote monitoring of patients, thus reducing overall admissions to hospital, the duration of stay, and perhaps identifying early onset of disease. In a fiscally-tight public health care sector, these enhancements proffer benefits. In 2018, the global smart textile industry was estimated to show a projected compound annual growth rate of 4.9% by 2025 [686], owing to a combination of the rising geriatric population, ongoing technological advancements and stringent legislative framework mandating the use of medical textiles. Indeed, a further analysis of the market suggests that compound annual growth rate may be higher, at approximately 9.5%, during the period 2018 – 2027 [687].

In a similar manner, the market for smart textiles continues to grow as applications across several industries are found. The global smart textiles market is expected to exhibit a compound annual growth rate of 30.4% through to 2025 and rise to a valuation of US$5.5 billion by 2025. This is expected to be driven by growth in medical, sport and fitness and military and defence applications [688].

There are several issues to be resolved:

i. Acceptance by both patient and health professional needs to be achieved
ii. Sterility and the efficacy of the sensing function in the presence of any form of moisture such as bodily fluids, needs to be considered
iii. Efficacy following cleaning requires investigation when the product is designed for re-use
iv. The security of the data being collected and (possibly) transmitted
v. Finally, what happens when the smart textile malfunctions?

All five factors are critical to the success of smart textiles. Important ethical considerations surround the information/data collected and forwarded. For example, who will own the data, how will it be stored, and who will have access to it? If data from patients in the community are sent to a central point, will there be sufficient

adequately-trained staff to collect and interpret this? Who will have responsibility for making decisions on identification and management of abnormal parameters? From a clinicians' point of view, bedside skills and the importance of a thorough history and examination ought not to be negated for readily-accessible and measurable data.

8. Conclusions and recommendations

Medical textiles is an emerging specialist field within the textile industry showing substantial growth in the amount of research attention it has attracted over the past ten years and it is becoming a rapidly-growing part of the textile industry. Much of the stimulus for its growth has arisen from the establishment of nanotechnology enabling the incorporation of nanoparticles into fibre-forming polymers before spinning into filament form, nanofinishing treatments allowing nanomaterials to be added to fabrics and electrospinning enabling the preparation of fibre-forming polymers into nanofibres. The performance of the emergent materials, particularly of those relating to antimicrobial action, have shown substantial improvement over their traditionally-prepared counterparts, not least in relation to their durability, which is typically highest for those where the nanoparticles are blended into the polymer prior to spinning, or where covalent bonding to the fibre surface is involved.

8.1. Antimicrobial treatments

A group of 'preferred agents' has emerged which include, nano Ag, nano ZnO, nano TiO_2 and nano CuO either alone or in combination with other agents such as CNTs to enhance their attachment, and graphene oxide has entered into the frame as well. This is not to say that everyone is in favour of the use of antimicrobial finishes for textiles; for example, in the Global Organic Standards, '*prohibited in general is the use of synthetic inputs for anti-microbial finishing (including bio-cides)*' [689], a message supposed to be well-meaning perhaps, but with no appropriate recommendation, high-handed, and lazy-looking when set beside that of Janine Jagger, Director of the International Healthcare Worker Safety Center at the University of Virginia School of Medicine:

> 'The basic measures for protecting Health Care Workers from the life-threatening risk of blood-borne pathogen infection should be viewed everywhere as essential and included in the national health priorities of all nations. The resources for this task are unlikely to be forthcoming unless we re-assess the value we place on Health Care Workers. They are not merely a service commodity; they are an invaluable asset to their countries and to the world community. Without them there would be no health care. All of us benefit from protecting their lives and health.' [690].

In any case, the argument could not be said to be about researchers ignoring the environment per se; 'synthetic' environmentally-friendly antibacterial finishing agents were developed some time ago [691]. Chitosan retains value as an antibacterial agent and biocompatibility enhancer and there is a re-emergence of research interest in quaternary ammonium compounds and their derivatives which have found new use in combination with nanoparticle finishing agents.

Recommendations for further antimicrobial research and development work would be:

i. To continue to seek combinations of agents to yield multifunctionality and broad-spectrum activity against both gram+ve and gram-ve bacteria, resistant strains and fungi. In addition, to urgently address the need for antiviral agents with which to treat textiles and textile components of the filtration and purification equipment necessary to protect against viral contamination. There is also a need to work on protection against prions.
ii. To engage routinely with greater determination in testing to establish 'durability' with practical meaning. For example, for multiple-use items intended to provide antimicrobial action, the laundering regime applied to the items should be representative of those which would be applied by/for hospitals/care homes and other healthcare establishments and follow patterns similar to those set in test regimes for hospital textiles more generally. Whilst it is encouraging to see that some research teams are now subjecting the treated fabrics to 25, 30 or less-often to 50 wash cycles [257, 511, 512], the number of complete laundering cycles applied in the test regime that follow on from the early exploratory work, should always be required to mimic the number and type an item of that kind would be expected to be subjected to over the period of its useful life, be it hospital linen [692] or a smart textile object [658] and if not (it was not in this case) it would represent a shortcoming. Otherwise the term 'durable' lacks useful meaning; even so, it is still being used with reference to just 10 laundry cycles [693]. Of course, durability does not relate only to repeated cycles of laundering, so the same principle of adopting enough repeat cycles of treatment to mimic what happens in practice should apply to other wear/use factors as well.
iii. To work on ways of eliminating single-use items of PPE to improve reliability in supply and save money without compromising safety. Governments should indeed fund this work and their projects on re-usable PPE product design should all include the need to demonstrate the ability of the designed item to be decontaminated and re-used.
iv. For promising candidate antibacterial, antiviral and antifungal treatments such as N-halamines, which are capable of being low-cost and not only environmentally-acceptable in terms of their application and their rechargeability, but also highly effective against a broad spectrum of pathogens including viruses. They show no signs of allowing resistance to develop so there should be much more enthusiasm for research into their further development and wider application on textiles just as there has been for surface treatments for their application in the food industry [694]. Crucially, when work beyond initial exploration is being reported on the application of N-halamines to textiles, it should always include the results of tests undertaken to establish the extent of its antiviral potency alongside its effectiveness against bacteria and fungi and the treated fabric's durability to repeated laundry cycles mimicking what will happen in the hospital, clinic or care-home laundry [692]. There is also a clear need to determine ways of incorporating a chemical indicator into N-halamine-treated textiles, to show when they

need to be laundered and recharged with dilute sodium hypochorite to return to effectiveness; with these enhancements to research papers, perhaps the true value of N-halamines will become more-widely understood and appreciated.

v. To work to improve environmental acceptability in the design and disposal of items currently described as 'disposables' and to establish what would constitute adequate checks to ensure that 'disposable' items properly perform the task they are supposed to achieve. There is a challenge here in that with the 'disposable product', if it did not perform the promised task, the evidence that it did not match the requirement is likely to have already been disposed of. Once again, such research and development initiatives are unlikely to come from the suppliers of disposable items, so will have to be brought to fruition through Government-funded research together with backing for production of the improved goods and the means for quality assurance of the fruits of that work.

8.1.1. Absorbable polymers

Drug-loaded synthetic-absorbable polymers are finding application for drug delivery, as they can be used as sutures or meshes for example in which applications they can be prepared so as to provide antibacterial/antibiotic action and other treatments at a controlled rate of drug release. Absorbable polymer implants in fibrous, nano-fibrous and continuous-filament form have also been the focus of considerable research attention because they can be engineered so as to provide support for just the time necessary for enough healing to occur before being absorbed and therefore reduce/eliminate the need for further invasive surgery for their removal. By contrast, strong, durable textile structures whose performance can be modelled and predicted, have been and are being developed for the replacement of tendons and for the construction of pressure garments and wound dressings. These are all maturing areas of research which continue to open up interesting new avenues for exploration but will need continued support to widen their applicability.

8.1.2. Drug delivery

Regarding textile drug-delivery arrangements through the use of medical textiles, there has been and continues to be a considerable amount of research into a wide variety of methods such as loading with non-steroidal, anti-inflammatory drugs covalently-bonded via an amide link, followed by coating with silica nanoparticles to render the cotton fabric hydrophobic and to entrap selected enzymes chosen for their ability to selectively cleave the amide link to control drug release [695].

Others involve drug-loaded hollow fibres acting as the reservoir for its supply, conductive fibres (involving their stimulation to bring about dopant release as a means of controlling drug delivery), the incorporation of drug-containing dendritic polymers where the dendrites are engineered to be of the correct dimensions to act as host for the guest drug, drug-encapsulation and incorporation during finishing, coating (particularly for meshes), CNTs for precision delivery to chosen points within a cell, the drug loading of chitosan, or collagen and casein natural-absorbable polymers for steady rates of drug delivery from that absorbed within the polymer as it degrades. There are a host of opportunities to explore and this area attracts a hive of research activity to which the

precise delivery by molecularly-imprinted electrospun polymer nanofibers can now be added [263, 264].

8.2. Orthotics

A range of orthotics such as braces, slings and hip protectors can be used in fracture management/prevention, deformity and for the management of soft tissue injuries. Developing a stronger research-based focus on patient comfort with such medical textile garments/devices may have the potential for changing the outcomes of treatment (the same point applies to PPE for healthcare staff in the case of FFP3 respirators in particular; breathing is hard work and cannot be sustained for extended periods of time and the versions with exhaust valves with which breathing is easier, are not suitable in situations involving close interactions with a patient; such matters are not without their effect). Textile structures and their performance in such devices do still have the potential to be significantly adjusted to enhance their acceptance and such work does need to be pursued further and projects intended to accomplish better compliance in the use of such items should perhaps be more-strongly supported by research grant-awarding bodies. The fact that several papers do address client acceptability as a major strand in their work deserves full credit - the design and development of a garment/dressing or device that performs well technically but is not adequately utilised by the patient because it makes them feel uncomfortable cannot be regarded as good practice. The nutritionist's mantra is a helpful aide memoire here for the medical textile researcher: "Nutrition is not what is put in front of you on the plate, it is what is eaten that matters."

8.3. Smart textiles

Smart textiles and garments continue to attract attention, not least because of growing popularity in the consumer-market. Currently, power-generating devices, sensors and transmitters can be woven or knitted into the fabric, stitched onto the garment, embroidered or printed directly onto fabrics, with various degrees of success. Flexibility is a key issue and particularly for the data-transmission device (aerial) where affixing flexible strips, weaving, printing, or embroidering have all been tried with varying degrees of success; the accent is not only on physical flexibility (and not only for the transmitter - Bluetooth for example), but also the other components of the system and their correct positioning, effectiveness, consistency in the sensing, recording and transmitting of physiologically-important data and their durability, not least to laundering [696]. Piezoelectrics for strain/pressure sensing, and as used in a fabric-based goniometer sandwich arrangement, continue to be promising components and in sensing patient movements can play a useful role in the monitoring of key health indicators.

8.4. Pandemics and PPE

In any pandemic-type emergency, each country will have to put its own nation's needs first. What this means is that for PPE, there needs to be sufficient PPE-dedicated manufacturing capacity within the country itself not just to satisfy its ongoing needs

but its likely emergency levels of requirement as well. It is essential that government bodies pay attention to warnings about what will happen when a substantial epidemic occurs. Not all types of respirator for example are suitable for use everywhere [697]. A full ten years ahead of the COVID-19 pandemic and just prior to the H1N1 outbreak, researchers from NIOSH in the United States together with members of staff from a highly-respected US Federal Government contractor, USAAF researchers and an academic from the University of Nebraska repeated the warning given in 2006 by the US Institute of Medicine, Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic [698]. In their own papers [552, 553] they warned that supplies of PPE would run short in an epidemic (90 million N95 surgical respirators would be needed) and laid down a set of demonstration methods to form the basis for the development of N95 respirator decontamination and re-use; re-use would help because despite the creation of a stockpile the total quantities required would still be difficult to provide. The US, Canada and the UK for example do have national stockpiles, but they require proper management; stock rotation and use of product before the expiry date, rather than wasteful disposal, should be the norm, as Canada at least seems to be learning late in the day, and similarly about reuse of PPE [699, 700]. The authors of the papers recommending decontamination and re-use appear to be people of good standing [552, 553] so what attention was paid to their published work, in their own country or yours? This can be determined from whether there were severe PPE shortages in your country as the pandemic progressed. In the UK, Canada and the US, and in parts of Europe especially in Italy, there were shortages. So whatever attention *was* paid, it was clearly inadequate. Maybe it is worth trying again to get the essentials of the message across, and perhaps it would be helpful if the following could be brought to the attention of the government health ministers and health officials in each country:

To provide protection for citizens, not least those involved in healthcare:

i. Provision should be made for stockpiling as is already done for example, in the US, Canada and the UK. It has been demonstrated that N95 respirators can be stored for 10 years and still meet their performance requirements; the electret, a key component, maintains its charge for a lot longer than might be expected. A routine needs to be established for testing (similar to that carried out on N95 respirators) to determine the longevity of every existing type of approved FFP3 and FFP2 Surgical Respirator together with another routine for storage trials to be begun automatically for each newly-developed device as it enters the market.
ii. It is difficult to know from a website whether the facemasks or surgical respirators that are being sold online are at all trustworthy; indeed, non-compliance was recorded as an issue arising from '*lack of accountability for non-compliance*' in 2013 in the paper published by the 'BREATHE' Project [542], so for the EU a 'Trusted Source' table of FFP3 respirators should be prepared and made openly available to the public by a reliable government body, as is now the case in the USA [701]. For the UK, there is a site (stating that it is only available to health professionals) providing details of 'Suppliers Approved by the British Industry

Federation', which lists *'PPE suppliers that have signed up to its safety scheme and have been independently audited to make sure the service and products they provide conform to standards'* [702]. It would be much more reassuring had it stated that the PPE suppliers were continually being audited at frequent intervals to ensure full compliance with the required standards. Whilst across Europe it may be thought that most manufacturers who label their respirators as complying with EU PPE Directive 89/686/EEC (i.e. compliance with standard EN149:2001 + A1:2009) are acting responsibly, this may not be the case. According to the UK Health and Safety Executive RR1087 research report - *market surveillance of FFP3 Disposable Respirators* [703], when 10 different models of FFP3 respirators on the UK market were tested, only half of the models passed all tests with no faults or failures. Imagine the outrage if the items being referred to as failing to perform in such large measure were other items on which you (maybe more-obviously) depend on for your personal protection, such as car seat belts, crash helmets or parachute harnesses. CE certification is supposed to show that the items certificated meet the required EU standard; reliance to assure compliance with the requirements of the standards is placed upon manufacturers or, if the manufacturer is outside the EU, on the distributor bringing the items into the EU [704]. Perhaps not surprisingly, the outcomes from those naive reliance mechanisms have proved to be abysmal. The EU recently published details of CE 'certificates' that were in use for PPE but not of the legally-valid type [705]. It is to their credit that the European Safety Federation has issued details enabling the identification of many of the offenders. Their findings were that:

a. A total of 15 organisations based in Europe and appearing on 'certificates' were listed as '*not a notified body competent for PPE*' and falsified certificates fraudulently using the name, logo and/or layout of 5 'Notified Bodies for PPE' had also been discovered.
b. One organisation based in Canada and one in India appearing on 'certificates' were listed as '*not a notified body competent for PPE*'.
c. The 'certificates' issued by a total of 28 organisations based in China or Hong Kong had no legal basis for CE marking nor for placing the PPE on the EU market.
d. For two organisations, one in Greece and one in China, their logos or names/declaration of conformity had been falsely used
e. A total of 12 organisations based in China had their names falsely used on certificates.

Such lack of trustworthiness does not only affect countries and regions, it affects reliable companies as well. For example, 3 M has become involved in unwanted law suits and related activities to try to protect the good name of its PPE products, including revealing detail about over-charging for products, particularly N95 respirators [706] and a group called Project N95 has become established with the expressed aim of partnering with local and state governments in the USA to support their community's PPE and critical medical supply needs, providing details of products vetted by them and pricing information [707]. There is a clear issue of trust here created by the

unreliability of some manufacturers and suppliers of PPE, hence, where organisations such as Project N95 do not exist, for manufacturers' products to be included on any list of approved suppliers, *regular* independent testing would be essential. Moreover, it should always be seen as the duty of the manufacturer to commission the necessary tests and to be required to provide the testing information to those engaged in procurement. However, given the prevalence of sharp practice, additional independent testing to determine that the content achieved the standard would still have to be carried out on each incoming consignment; the whole consignment would need to be rejected if faulty product was found and the manufacturer would have to be told that no more product could be ordered from them. For product commissioned from manufacturers abroad, the buyer/procurer needs to visit the manufacturer on a very frequent but not entirely predictable basis to check that the product being made is up to standard, and to be empowered to reject consignments as not meeting the prescribed standard, something which could have been learned from fashion-retailer practices regarding their supply-chain management processes [708]. Unless checks like this are put in place, what should be a 'Trusted Source' listing simply becomes a 'Preferred Source' listing, with insufficient reassurance of compliance with the required standards. Just because a company is trusted by its customers, does not mean that it will respect that trust, as evidenced by the 'Volkswagen Emissions Scandal' of 2015 which began in the USA [709]. Litigation against Volkswagen in England was filed in 2016 and in December 2019 the High Court was asked to decide whether software installed in VW cars was a 'defeat device' under EU regulations. Volkswagen lodged an appeal, but the High Court ruled in August 2020 that Volkswagen, Skoda, Audi and Seat engines were deliberately fitted with a 'defeat device' [710]. It makes it difficult to maintain respect for this company and its management in particular, but it also undermines the idea that it would prove sensible to adopt approaches with any companies which rely solely on them to adhere to decent corporate social responsibility practices and ensure that their products meet the required standards. There will always be the possibility of tension between the profit motive and ethical behaviour. For some unknown reason, the UK Health and Safety Executive RR1097 report is not open regarding the identities either of the manufacturers whose devices complied with standard EN149:2001 + A1:2009 and should be safe to use, or those from slipshod/cavalier manufacturers whose devices not only did not comply, but were also masquerading as being up to standard and no doubt priced accordingly. Currently the Health and Safety Executive (HSE) is warning against the use of KN95 facemasks as Personal Protective Equipment (PPE) for the same reasons of unreliability [711].

iii. Methods should be developed for decontamination and re-use of PPE wherever possible, and there should be an approved routine established in each healthcare unit for used PPE recovery and re-use wherever possible. In the case of respirators, the successful methods established for N95 decontamination and re-use should be urgently examined and tested to determine their suitability for FFP3 and of course, FFP2 surgical respirators. When a suitable method is found, it should be implemented forthwith, as FFP3 surgical respirators are very expensive items to treat as disposables (at ca 25 US Dollars each currently), whereas the

overall cost for decontamination was calculated to be less than 1 US Dollar; substantial savings within health services can accrue.

iv. The government, as the organisation responsible for the care of a country's citizens, needs to ensure that PPE is available to them when problem situations such as epidemics/pandemics arise, and this is particularly the case for their healthcare workers. The majority of the manufacture of PPE should therefore take place in the home country, something which has recently been recognised by Canada [699, 700]. No matter how much one might support the notion of globalisation, it is a mistake to believe that supply chains not closely managed in a way similar to those developed for the just-in-time provision of fashion textiles to fashion retail organisations [708], could be the appropriate tool for ensuring a guaranteed adequate supply of health-and-safety equipment for citizens in a time of crisis, most-especially, for healthcare workers and medical professionals.

The possible contribution that certain types of HEPA filters such as those equipped with Far-UV or UV-C irradiation and electrical discharge could make to the elimination of the SARS-CoV-2 and other viruses in enclosed spaces needs to be determined, as does the contribution that HEPA filters not equipped in this way might make to its circulation and spread in enclosed spaces. There is a need for research to address the two issues as they relate to the circulation and spread of viruses more generally, and for the establishment of improved and extended test methods and standards that explain the targets which will need to be met for approval to be conferred on such devices; these will have to be determined in relation to the size and shape of the space in which the device is intended to be installed. Research also needs to be undertaken to determine ways of improving/broadening the effectiveness and the useful life of the filter materials; coupling their application with Far-UVC [712] light in place of UV-C; Far-UVC light, being safer to humans, less damaging to filter fabrics and more-quickly effective in destroying viruses and other pathogens, may have the potential for more-widespread application than current devices, particularly in making it easier to retro-fit the light source and thereby upgrade the performance of standard HEPA filters. Commercial aircraft and high-speed trains represent two of the most challenging environments for ensuring ventilation whilst filtering to remove problematic small particles, bacteria and viruses, so it is useful to see what has been achieved in that regard to date and to use this as the benchmark.

From a study reported in The New England Journal of Medicine following the SARS epidemic in 2003, of:

a. A flight with 120 passengers of whom one was symptomatic resulting in 22 passengers becoming infected, and
b. Another with four symptomatic passengers but no infection of others,

it was concluded that transmission of SARS may occur on an aircraft when infected persons fly during the symptomatic phase of illness, and that measures to reduce the risk of transmission were warranted [713].

Considerable work has since been undertaken on the difficult challenge, to determine ways of making the aircraft-cabin environment both safer and more comfortable for the passengers, particularly at Purdue University by a team led by Qiyang Chen, for example by assessing three types of ventilation arrangements: mixing ventilation, conventional displacement ventilation, and personalized displacement ventilation. Because the personalized ventilation system performed the best in maintaining cabin thermal comfort and could also reduce infection risk, this system was recommended for aircraft cabins [714], and positioning of the air supply to the passengers at a low level with a set number of exhausts was shown to be effective in reducing exposure to contaminants. The work serves to illustrate that whilst the textile in the filtration design is an important component in the removal of contaminants, the overall three-dimensional design of the ventilation system within which it is incorporated is also crucial to its effectiveness (and the difficulties can be appreciated from the dramatic visual output from that team's work on modelling the effect of coughing [715]).

Other work led by Chen at Purdue has been engaged with modelling ventilation arrangements for indoor spaces; although the design objective was a thermally-comfortable, healthy, productive, and energy-efficient indoor environment, it does illustrate the possibility of replacing haphazard trial-and-error methods for determining system requirements for filtration and purification, and replacing them with data-informed choices instead [716]. What could be considered complementary work by Brenner's group at the Center for Radiological Research, Columbia University Medical Center, New York, focussed on the use of Far Ultra-Violet light (207-222 nm wavelength) to enhance the quality of the air by reducing the number of viruses and other pathogens in interior environments [717] also needs to be followed through. They used a krypton-chlorine (Kr-Cl) excimer lamp producing 222 nm UV light with a bandpass filter to remove the lower- and higher-wavelength components. The 222 nm wavelength ultraviolet light was shown to kill bacteria efficiently but unlike the usual 254 nm wavelength UV-C was not significantly cytotoxic or mutagenic to human cells [718, 719]. They concluded that used appropriately, Far UV light could have the potential for safely and inexpensively reducing surgical-site infection rates, including those of drug-resistant origin and it may be that combining the outputs of the kind emerging from Chen's team on the challenging task of designing suitable filtration and ventilation systems for airliner cabins with Far UV radiation treatment of contaminated air in confined spaces or emerging from filters, indicate the way ahead. The textile components of the filtration devices will remain crucial components in determining their efficiency. Positive outcomes would, of course have wider application than to healthcare establishments alone, in fact to all enclosed places where people are brought together such as reception areas, offices, meeting rooms, waiting areas, public transport, airliner cabins, high-speed trains, restaurants, hotels and educational establishments.

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Research Letter

Waste not, want not: assessing the impact of arthroscopic waste

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Health systems generate as much as (or at least) 4 per cent of the nation's greenhouse gas emissions[1–4]. Between 20 per cent and 33 per cent of healthcare waste originates from the operating theatre, with up to 90 per cent waste unsorted (or improperly sorted) and sent for unnecessary 'hazardous' processing[5–8]. The World Health Organization has made recommendations to separate healthcare waste into different coloured, clearly labelled bags for disposal according to contents. Appropriate items should be recycled, while contaminated waste can be incinerated (ideally, with energy-harvesting methods) or sent to landfill. The choice of waste stream has up to a 50-fold impact on a procedure's carbon footprint.

Intraoperative waste from five each of arthroscopic anterior cruciate ligament (ACLR) and arthroscopic rotator cuff repair (RCR) procedures from four centres was measured. All procedures were undertaken by senior surgeons and data were collected prospectively. Clinical waste created by anaesthesia colleagues was excluded. The waste was separated into four bags: clean paper, contaminated paper, clean plastic, and contaminated plastic. Contaminated waste includes any waste directly used in patient care; it does not include product wrappers but includes each item in a multipack surgical set, even if unused. At the end of each procedure, each bag of waste was weighed using a theatre scale (DIGI® DS-502; Marsden Weighing Machine Group, Rotherham, UK). The mean measurement of waste was calculated for each procedure from each centre and is shown in *Table 1*.

The waste-management policy of each hospital was requested alongside the tariff of waste management and CO_2 emissions for processing waste. The cost of processing clean waste varied between €120 and €303 per tonne, and the cost to process contaminated waste between €247 and €819 per tonne. Despite the hospitals separating out clean plastic and paper waste, none of the hospital waste contractors provided a full recycling service—this waste tends to be incinerated with energy recapture. Of the contaminated waste, waste was either landfilled or incinerated. Carbon emissions were calculated using these figures (*Table 1*).

A calculation was undertaken based on the annual surgical figures (pre-COVID-19 pandemic) from the hospital sites to calculate their annual burden of CO_2 emissions for ACLR and RCR. The annual burden for ACLR was 7.53 tonnes of clinical waste and 1.7 tonnes of CO_2, while the burdens for RCR were 15.4 and 4.5, respectively. The higher proportion of

Table 1 Mean plastic and paper waste, carbon emissions, and processing costs across individual hospital sites per anterior cruciate ligament (ACLR) or rotator cuff repair (RCR) procedure

	Site	Textiles	Clean waste (kg)	Contaminated waste (kg)	Total plastic waste (kg)	Total annual waste (kg)	Annual carbon emissions (tonnes)	Annual processing costs (€)
ACLR	A	Reusable gowns, disposable drapes	1.0	2.1	2.4	3 100	0.34	1089
	B	Disposable	1.4	3.5	3.6	4 900	0.87	3261
	C	Disposable	5.4	5.6	9.6	11 000	2.6	3084
RCR	A	Reusable gowns, disposable drapes	1.2	3.4	3.5	4 600	0.53	1010
	B	Disposable	4.2	10.3	13	14 500	2.6	9709
	D	Disposable	2.3	13.2	14.7	15 500	6.4	4830

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plastic waste in RCR generated a proportionally larger carbon footprint.

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Conflict of interest

Ms Holly Morris is Chief Medical Officer for Revolution-ZERO. She co-authored the textile guidance provided to the Green Surgery Report.

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RESEARCH ARTICLE

The potential future role of antiviral fabrics within healthcare systems

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ABSTRACT

Health care-associated infection is acquired by patients while receiving care and represents the most frequent adverse event with a prevalence internationally ranging from 5.7% to 19.1%. Whilst the role of textiles as a fomite in infection has been questioned, the increasing body of evidence showing microbes persisting on textiles and increasing interest into developing antimicrobial textiles has been further driven by the Covid-19 pandemic. The aim of the experiments reported here was to determine whether the antiviral coating remained effective after laundering at national healthcare laundering standards. Secondly, we discuss whether the available testing regime for antiviral treatments on fabric is appropriate for judging the effectiveness of the treatment. There is still significant work that needs to be undertaken in standardising and ensuring the suitability of test methods within this area of technical textiles. Trials in the relevant workplace environment are essential as these may produce very different results to those undertaken as a proof of principle within a laboratory.

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Antiviral; coronavirus; healthcare textiles; laundering

Introduction

Much attention has been given in recent years to the development of antimicrobial textiles, in particular to antibacterial and antifungal materials. The role of cotton as a fomite in healthcare was addressed in academic literature at the end of the nineteenth century where it was noted that clothing could carry and transmit yellow fever. During the plague of 1835 cotton shipments from Egypt to the United Kingdom had needed to perform long periods of quarantine to 'purify' the cotton on board (Plunket, 1879). Cotton is hydrophilic, and studies have shown that the survival of microorganisms on cotton is longer than on fibres which absorb little moisture such as polyester (Riley et al., 2017).

More recently a review, in 2012, questioned the role of textiles, in general, as fomites for transmission of infection (Fijan & Turk, 2012). Indeed, Methicillin Resistant *Staphylococcus Aureus* (MRSA) and Vancomycin Resistant *Enterococci* (VRE), both bacteria associated with hospital acquired infections, have been found on hospital linens after extended periods of time. Certain VRE strains can survive for up to 11 weeks on bedlinen thus allowing for transmission to those handling the textile (Hochmuth et al., 2005). Furthermore, the parainfluenza virus has been demonstrated to survive four hours on a hospital gown with increasing concentrations becoming more readily available to culture with time. Interestingly, laundering the gown using an anhydrous sodium metasilicate -based detergent with a monoalkyl trimethyl ammonium chloride base meant that the virus was unable to be cultured from the fabric (Brady et al., 1990).

There has been a surge in research outputs on the development of effective antimicrobial textiles due to the successes seen within the field in nanoscience and technology. These advances have enabled the application of nanometals and their compounds, such as nano silver, nano titanium dioxide, copper oxide, and to a lesser extent agents such as graphene oxide and carbon nanotubes (Morris & Murray, 2021). Microorganisms can be transmitted from contaminated textiles through either direct or indirect contact (*via* a third party) and thus pose a risk to both patients and health care workers.

The Covid-19 pandemic has driven a further flurry of activity with efforts concentrated on textiles exhibiting antiviral properties against the SARS-CoV-2 virus. The main modes of transmission of Covid-19 are via 'droplet transmission', (the transfer of droplets of saliva or respiratory mucus generated whilst coughing, sneezing or talking) and 'contact transmission', (contact with body fluids or contaminated surfaces) (World Health Organization, 2020). The coronavirus can remain viable on various surfaces such as metal, glass, wood and textiles for several hours to several days, allowing transmission by contact (Chithra et al., 2022).

Recently there has been attention directed to the benefits that could be derived from incorporating antiviral fabrics in personal and protective equipment (PPE) (Raza et al., 2022) but the potential application of antiviral textiles extends further within healthcare. For healthcare workers, the potential benefits of antiviral fabrics include a reduction in risk of transmission particularly for high risk hospital environments, such as intensive care units or wards treating patients with confirmed, or suspected, coronavirus. Furthermore, for those

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working in laundering facilities, the ability to reduce viral load would reduce the risk of transmission from soiled laundry. There has already been some work exploring the role and effectiveness of cotton treated with a naturally occurring antimicrobial agents and the effect that laundering had on their antimicrobial properties (Gesese et al., 2022).

The ability to launder antimicrobial fabrics and retain the effectiveness of the antimicrobial actions would allow for the design and development of reusable textile products. This would reduce hospital waste and the potential infection risk associated with healthcare textiles. The ability to create antimicrobial textiles which can withstand domestic laundering has significant implications for those working in community health and social care. Currently, domestic laundering of healthcare worker uniforms is of particular concern due to the lack of control and monitoring of decontamination (Owen & Laird, 2020).

The United Kingdom Department of Health has produced Best Practice guidance for the laundering of linens {linens including bed linen, bibs, blankets, canvases, curtains, hoist slings, patient clothing, staff clothing, and towels} (Department of Health, 2016). Traditionally, disinfection has been by thermal methods although chemical methods at a lower temperature may also be employed. For conventional thermal disinfection methods, the washing process should have a cycle in which the temperature of the load is either maintained at 65 °C for not less than ten minutes or 71 °C for not less than three minutes. Alternative time/temperature relationships may be used provided the efficacy of the process chosen is equal to the 65 °C or 71 °C processes. Mixing time should be added on to the required disinfection period to ensure heat penetration and assure disinfection. For those carrying out the laundering of workwear uniforms at home in domestic facilities, the treatment should be washing of the items for ten minutes at 60 °C (Department of Health, 2016).

For heat-labile items, chemical disinfection is preferred; Best Practice suggests that the exact process should be chosen in discussion and agreement with the infection control team, such that the entire process, should be capable of passing the required microbiological tests (Department of Health, 2016).

The current paper seeks to test a newly developed, and commercially available, antiviral cotton against the laundering standards of the NHS to assess how this type of cleaning process affects the antiviral actions of the cotton. The commercially available fabric was initially developed for use as a domestically launderable face mask and results from commercial tests were available to us and included below.

Materials and methods

Fabric preparation

English spun Supima cotton (English Fine Cottons, Manchester, UK) was woven into a fabric by Heathcoat Fabrics (Tiverton, Devon, UK) and subsequently finished with a wash-durable antiviral treatment. The fabric had an area density of 124 g/m^2. Warp tensile strength was 550 N/50 mm and weft tensile strength was 550 N/50 mm. The manufacturer applied a proprietary silver-based antiviral finish, Viroblock NPJ03, {HeiQ, Zurich, Switzerland} post-weaving (Hei Q, 2022).

The manufacturer tested the fabric during development of the finishing treatment to ISO 18184:2019—Textiles—Determination of antiviral activity of textile products, by an external-accredited laboratory (Microbiological Solutions Ltd, Bury, UK). A control fabric of 100% cotton and no antiviral, the 100% cotton woven fabric treated with antiviral, and the 100% cotton woven fabric treated with antiviral then laundered were tested. The laundered fabric was prepared as per BS EN ISO 6330:2012 Textiles—Domestic washing and drying procedures for textile testing, 15x4G/40/TD; washed at 40 °C with gentle agitation for 3 min ± 20 s. There were two rinse cycles followed by a two minute spin cycle then a third rinse followed by a six minute spin cycle. The samples were subsequently tumble dried. The laundering process was repeated for 15 cycles. A feline coronavirus, Munich strain, with a contact time of 2 h ± 10 s was applied to each sample of laundered fabric. The test temperature was 25 °C ± 1 °C and the incubation temperature was 37 °C ± 1 °C.

Testing under healthcare-approved laundering conditions

This experiment was designed as a two-factor design. The first factor was the number of laundering cycles that the fabric undergoes (0, 15, 30 or 50 cycles). The second factor was the virus used. Following laundering these fabrics were subjected to testing using two enveloped viruses. A CL2 virus (Semiliki Forest Virus) was used to identify the correct protocols followed by further testing using the SARS-CoV-2 virus at CL3. These viruses were chosen because, like the feline coronavirus, they are both enveloped viruses.

Laundering of fabric

The fabric was laundered based upon the UK Department of Health Best Practice guidelines (Department of Health, 2016). The choice of wash procedure at local hospitals is based upon local microbiology advice. The choice of standard test was made such that essential finishes could be respected and results could be compared across other studies. The laundering involved washing to the Standard washing procedure (Type A) of BS EN ISO 10528:1995 Textiles—Commercial laundering procedure for textile fabrics prior to flammability testing. The fabric was heated to 75 ± 3 °C in 15 ± 3 mins with reduced agitation then run at 75 ± 3 °C and normal agitation for a further 15 ± 3 mins. The fabric was subsequently tumble dried at a temperature not exceeding 60 °C to BS EN ISO 6330:2012 Textiles—Domestic washing and drying procedures for textile testing, then conditioned in accordance with BS EN ISO 139:2005 Textiles—Standard atmospheres for conditioning and testing, to a standard atmosphere of temperature 20.0 °C and a relative humidity of 65.0%.

Deviations from the Standard included use of ECE (A) Non-Phosphate detergent without optical brightener. This conformed to the Department of Health Best Practice

guidelines. The laundering process was repeated for 15, 30 and 50 wash cycles. BS EN ISO 6330:2012 Textiles—Domestic washing and drying procedures for textile testing, Type III 100% Polyester makeweights were used to maintain the wash load at 2 kg.

Antiviral testing of fabric

The fabric was tested using the ISO 18184:2019 standard as a guide. The fabric was cut into circles of 15.9 cm^2 that fit within a petri dish to allow for ease of analysis. Each piece of fabric was treated with Semliki Forest Virus (SFV) in a final volume of 100 ul and left for 5 mins before harvesting the fabric. Since all the liquid was absorbed by the fabric, an additional 100 ul of media was added to the fabric; of the total amount applied to the fabric, 20 ul was recovered. All samples were run in triplicate.

Semiliki Forest Virus, a CL2 virus, was chosen as it had the highest titre and conformed most closely to the standard. All samples were titred using standard plaque assays (Beaty et al., 1995) to determine the amount of virus. The original viral sample used to treat the fabric was also included as a control to determine the loss of viral titre from the experimental protocol.

A second round of testing was undertaken. The fabric was cut into circles of 3.4 cm^2 and placed in standard 12 well plates. Six replicates were performed. Each fabric was treated with 250 ul of liquid added containing 10^6 pfu/ml of virus. Following a 5 min incubation, liquid was removed from the wells and stored until further processing. Fabrics were tested with both Semliki Forest virus (SFV) and Severe Acute Respiratory Syndrome (SARS) Coronavirus 2 (SARS-CoV-2). All the recovered liquid was titred using standard plaque assays (Beaty et al., 1995). SARS-CoV-2 has a lower titre and is not as close to the standards, but is more biologically relevant to healthcare.

Results

Test results: antiviral fabric finish development

In order to independently establish whether treated fabrics were able to demonstrate antiviral activity after laundering, testing of the treated fabric was undertaken by an external accredited laboratory (Microbiological Solutions Ltd, Bury, UK). The fabric was tested to ISO 18184:2019 Textiles—Determination of antiviral activity of textile products.

The test demonstrated a 1.94 log (98.96%) reduction in Feline Coronavirus on the unlaundered fabric and that there was a 1.78 log (98.33%) reduction in Feline Coronavirus on the laundered fabric, showing that the antiviral treatment remained effective after repeated domestic laundering.

Test results: healthcare-approved laundering

Testing with complete absorption of liquid

During the first test run with the fabric, it was found that the fabric absorbed all the applied liquid containing SFV and additional liquid had to be added to extract the virus-carrying liquid following its exposure to the fabric. The exposure was 5 min and during this time, all the liquid was absorbed by the fabric. All tests were carried out in triplicate.

There was a reduction in the viral titre from the original stock for all samples, as demonstrated in Figure 1. However, only the 'treated not laundered fabric' showed evidence of complete viral kill in 2 out of 3 repeats. The washed fabrics showed a small reduction in viral titre compared to the original virus. The reduction in titre was significant for the 'treated not laundered fabric' compared to the 'untreated fabric' ($p = 0.0053$) and for the 'Washed 50′ compared to the 'untreated fabric' ($p = 0.0171$).

Results when liquid exceeds the absorption of the fabric

A second test was undertaken ensuring that the liquid absorption capacity of the fabric was exceeded. This was undertaken in part to ensure that the results we saw were a result of correct recovery of the liquid in Figure 1, but also to determine if the antiviral properties were sufficient when the virus was present in much larger amounts than the fabric could absorb. The results are demonstrated in Figure 2.

In a similar manner to when the fabric was tested with complete absorption of the liquid containing the viral stock, it was possible to demonstrate a reduction in titre for the treated but not laundered fabric. However, unlike the original test, there was a larger amount of virus still present despite the antiviral treatment of the fabric. The reduction in titre was significant for the treated but not laundered fabric for both SARS ($p < 0.0001$) and SFV ($p = 0.0005$).

Discussion

Health care-associated infection is infection that is acquired by patients while receiving care and represents the most

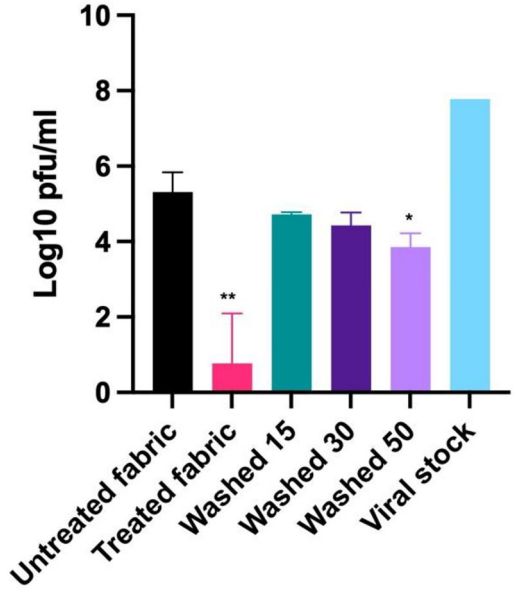

Figure 1. Testing with complete absorption of all liquid containing virus. Showing the results from the liquid harvested from fabrics that absorbed all the liquid. Statistical significance was determined using Student's t-test for the treated fabrics against the 'Untreated fabric' as a control. (** $p < 0.01$, * $p < 0.05$).

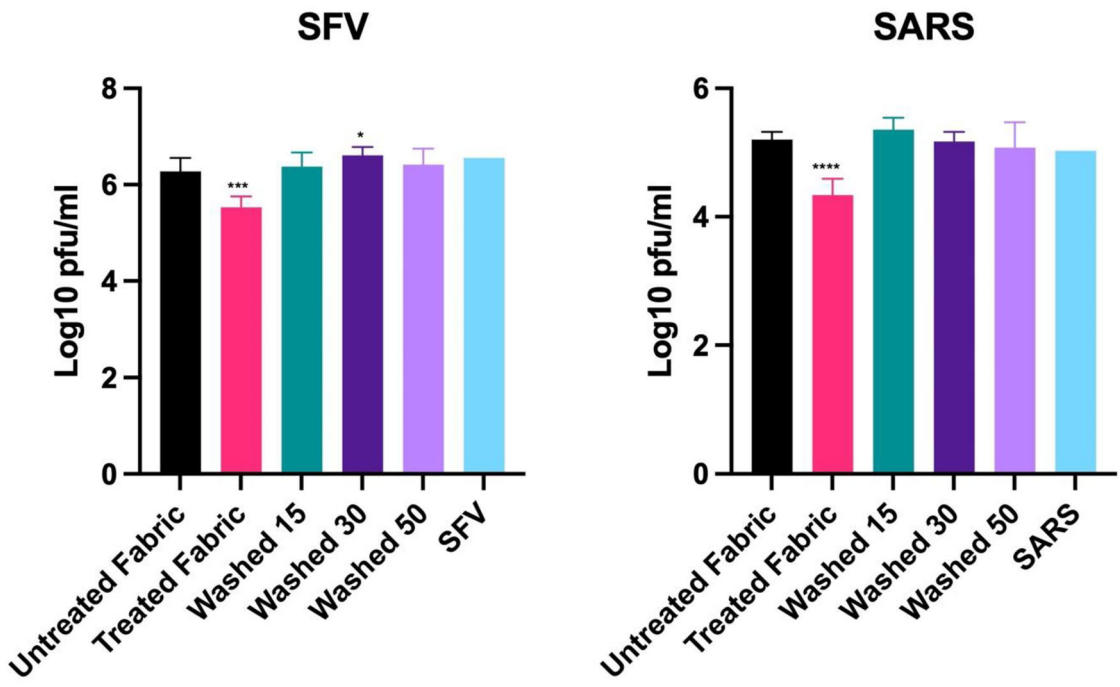

Figure 2. Test results when liquid exceeds absorption of the fabric. Showing results with (A) Semliki Forest Virus (B) SARS. Statistical significance was determined using a T-test against the Untreated fabric as a control. (**** $p < 0.0001$, *** $p < 0.001$, * $p < 0.05$).

frequent adverse event with a prevalence internationally ranging from 5.7% to 19.1% (World Health Organization, 2011) Whilst the role of textiles as a fomite in infection has been questioned, the increasing body of evidence showing microbes persisting on textiles and increasing interest into developing antimicrobial textiles has been further driven by the Covid-19 pandemic.

In 2015, the 'CDC Prevention Epicenters Program,' a research program established in the US over 20 years ago to implement innovative strategies to improve healthcare quality and patient safety commissioned the Antiseptic Scrub Contamination and Transmission Trial (ASCOT). The purpose of the ASCOT trial was to determine the effectiveness of antimicrobial-impregnated polyester-cotton scrubs that had been treated with either a silver alloy (within the fibres) or fabric finished by treatment with a silane plus quaternary ammonium compound (to allow durable binding of the silane to the fibre) together with a hydrophobic fluoroacrylate copolymer emulsion as a fluid-repellent treatment. Carried out by Duke University, this was a well-designed randomised controlled trial with crossover design that investigated contamination of healthcare clothing worn by nurses on intensive care units. Neither of the treatments were effective at reducing contamination from the bacteria tested (the CDC Prevention Epicenters Program, 2017). However, another RCT did find a significant reduction of 4–7 log colony forming units of MRSA using an organosilane-based quaternary ammonium antimicrobial agent and a fluoroacrylate copolymer emulsion as a fluid-repellent (Bearman et al., 2012).

The first paper reporting the application of an agent and testing of the treated fabric to demonstrate its antiviral barrier activity to internationally accepted standards was in 2015. The research saw the development of a trilaminate surgical gown using a polyester nonwoven fabric as an outer layer, microporous polytetrafluroethylene as a middle layer and viscose rayon nonwoven fabric as an inner layer. Antiviral activity was conferred by titanium dioxide nanoparticles coupled with methylene blue. The fabric was tested against the antiviral standard ATSM F1671 and passed (Parthasarathi & Thilagavathi, 2015). Other work has demonstrated the effectiveness of N-halamines as a potent antiviral agent. The concentration of the antiviral agent on the nonwoven affected the time to a significant reduction in viral load but both concentrations used showed significant reductions in load within two hours (Ren et al., 2018).

The agents responsible for antimicrobial action in medical textiles operate based on one of the following mechanisms.

1. Leaching – Prolonged release of agents from treated textile into any moisture encountering the material or by slow evaporation if the agent is a volatile organic compound.
2. Contact – The agent is chemically bonded, directly or via a selected carrier, to the fibre and exert their effect only when microbes come directly into contact with the fabric.
3. Photocatalytic oxidation – The agent is chemically bonded, directly or via a selected carrier, to the fibre. On exposure to light, the substance is activated (Morris & Murray, 2021).

Substances that may be used to impart antiviral behaviour to textiles fall broadly into one of the following three categories

1. Metallic compounds – This group includes the use of nanoparticles such as silver, gold, tin, gold, copper, and zinc that are applied to the fabric.

2. Non-metallic organic compounds – This group includes the N-halamines, halogenated phenols, quaternary ammonium compounds and polyhexamethylene biguanides.
3. Compounds of Natural Origin – This group includes naturally occurring substances such as curcumin and other extracts containing phytochemicals that offer antiviral activity. Around 150 plants have been identified as sources of antimicrobial compounds (Raza et al., 2022).

There is still much work to be undertaken to develop robust antimicrobial and antiviral textiles suitable for a healthcare environment with current authors often making over-enthusiastic claims about fabrics with antimicrobial properties (Murray, 2022). The aim of the experiments reported here was to determine whether an antiviral treatment applied to workwear could withstand laundering to the NHS protocol and remain effective.

Our work demonstrated that laundering at NHS standards significantly impacted the ability of the antiviral properties to remain effective. Given that the laundering regime occurs at 65 °C or 71 °C, this will likely inactivate any enzymes used in finishing treatments and may also destabilise bonds attaching coatings to the fabric. In contrast, laundering to the ISO standard temperature of 40 °C in the testing by the manufacturer demonstrated ongoing antiviral activity after repeated launderings. Thus, the use of antiviral fabric is currently incompatible with NHS laundering protocols. Currently, there is ongoing work on standardising laundering protocols within healthcare, and previous research has shown that healthcare workers laundering at home often use lower temperatures than the recommended 60 °C (Textile Services Association, 2022; Owen et al., 2022). Further work into formally assessing microbial and viral load at lower wash temperatures using currently-available technology should be welcomed. After all, the idea behind using an antiviral finish should not be just to prevent the transfer of contaminants during wear, but also for it to be able to demonstrate that role during laundering and thereby to eliminate/reduce the need for high temperature laundering. In addition, to using less energy and providing a sustainable solution, lowering the temperature on laundering may widen the range of agents suitable for application as antiviral and antimicrobial textile finishes.

During the study, we encountered a major issue with the ISO standard for antiviral testing and the fabric used here. The viral samples in this case, and almost always, are liquid based. Depending on their composition and structures, different fabrics exhibit significantly different absorption properties. All testing therefore needs to account for the absorption properties of the fabric. This requires all testing regimes to determine the amount of liquid absorbed and use this to calculate the amount of virus particles that are used in the testing. It is imperative that further research determines an appropriate ratio of absorption to free liquid for antiviral testing because the results presented here suggest that the extent of absorption has a high impact on the results. Even so, it is important to determine the optimum level of absorption to realistically match what occurs on exposure of a fabric in its intended use and identify a standard method to accommodate different levels of absorption to enable assessment of antiviral properties across different fabrics and treatments.

This is critical for clinical translation; a virus spread by the respiratory route may be spread by small airborne droplets that are fully absorbed by the fabric. In contrast, a viral haemorrhagic fever, such as Ebola, may result in contamination of the fabric with significantly higher quantities of liquid (due to the haemorrhagic nature of the disease process) such that the fabric is fully saturated with liquid and there remains liquid present on the surface. Currently, such variations are not addressed by the ISO standard, hence one needs to be careful in translating results that indicate antiviral action within a particular test setting into clinical practice.

Thirdly, any technical textile in contact with skin should be tested for biocompatibility. The aim of this experiment was not to test for biocompatibility but this would need to be undertaken prior to commercial release.

Finally, the authors consider it important in this type of research and development work to adopt the OECD 'Three-Tier Protocol', which involves applying more-realistic contamination and other significant treatment methods associated with the product in mind and recognise the significance of the several OECD publications on these matters. The full OECD-recommended approach was published some 15 years ago (Organisation for Economic Co-operation & Development, 2007; Organisation for Economic Co-operation and Development, 2008). However, because of a particularly weak response to Tier 2 testing, namely the lack of development and application of laboratory-based methods which more-closely mimic the conditions to which the fabrics would be exposed in the clinical setting, a new guidance document focussed specifically on how to address Tier 2 has been published more recently (Organisation for Economic Co-operation and Development, 2018).

The OECD 'Three Tier Protocol' has been described and discussed in detail elsewhere (Morris & Murray, 2021), but briefly (Murray, 2022) it consists of:

Tier 1 *Proof of Principle*

(For any medical textile this would have to include not only identifiable antimicrobial action but activity following successful attachment of the agent as a finish to a textile material suitable for the intended application. The test can only be said to be valid for the particular virus or other microbial species under test, and only for the particular fibre/fabric type(s) being tested).

Tier 2 *Simulation of Realistic Exposure Conditions*

(For workwear such as gowns, aprons or scrubs for healthcare personnel, exposure conditions within the laboratory which leave the fabric mostly dry, but with some splashing, some pressure-transfer of contaminants and some drying out of the bodily fluids containing the pathogen or a suitable surrogate).

Tier 3 *In-Use Evaluation*

(For workwear such as gowns, aprons or scrubs, a randomised controlled trial (RCT) of its performance in the workplace of a type similar to that applied the ASCOT Trial mentioned earlier).

Taking account of these matters, the authors would classify their research in terms of the OECD 'Three Tier Protocol' as Tier 1. In addition, by addressing aspects related to laundering conditions simulating those which would be experienced by fabrics in garments of workwear in the NHS, the results reported here demonstrate that there is now reason to believe that this particular antiviral fabric finish can remain active following repeated laundering of the treated cotton fabric under conditions typical of those applied in the workplace.

Conclusion

There has been a surge in enthusiasm for antimicrobial protective workwear since the Covid-19 pandemic. However, very few papers have undertaken testing according to the OECD Three Tier Protocol which allows for tests to be classified from proof of principle through to in-use evaluation (Murray, 2022). There is a role for antiviral textiles for the protective workwear worn within healthcare and the scope extends to other industries, for example, health and beauty, and hospitality. However, there is still significant work that needs to be undertaken in standardising and ensuring the suitability of test methods within this area of technical textiles.

With the increasing number of publications investigating antiviral and antimicrobial textiles, authors adopting the OECD Three Tier Protocol and citing to which level they are testing and achieving positive results would allow standardisation and comparison. An antiviral fabric in the laboratory (Tier 1) may behave very differently when used in a simulated or actual clinical environment (Tier 2 and Tier 3 respectively). In addition, it should also be made clear which virus was used in the test procedure as they all possess different characteristics. Trials in the relevant workplace environment are essential as these may produce very different results to those undertaken as a proof of principle within a laboratory.

Laundering methods and temperatures may affect antiviral fabrics and attention should be paid to this to ensure that reusable textiles that provide ongoing function after laundering are being adopted in the workplace.

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Disclosure statement

Previously, Holly Morris was the textile advisor to the Royal College of Surgeons Sustainability Group and co-authored guidance on sustainable textile use in surgery for the Green Surgery Report. She is a member of ENG4 and Chief Medical Officer for Revolution-ZERO. Peter Ogrodnik is the founder of ENG4. ENG4 is a not-for-profit collaboration of professionals and volunteers whose sole aim is to provide support for other not for profit healthcare organisations in times of need.

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The carbon footprint of arthroscopic procedures

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ABSTRACT

Introduction The healthcare sector contributes the equivalent of 4.4% of global net emissions to the climate carbon footprint; between 20% and 70% of healthcare waste originates from a hospital's operating theatre and up to 90% of waste is sent for costly and unneeded hazardous waste processing. This study aimed to quantify the amount and type of waste produced during an arthroscopic anterior cruciate ligament reconstruction (ACLR) and an arthroscopic rotator cuff repair (RCR), calculate the carbon footprint and assess the cost of the waste disposal.

Methods The amount of waste generated from ACLR and RCR procedures was calculated across a range of hospital sites. The waste was separated primarily into clean and contaminated, paper or plastic. Both carbon footprint and cost of disposal across the hospital sites was subsequently calculated.

Results RCR generated 3.3–15.5kg of plastic waste and 0.9–2.3kg of paper waste. ACLR generated 2.4–9.6kg of plastic waste and 1.1–1.6kg of paper waste. The cost to process waste varies widely between hospital sites, waste disposal contractors and method of waste disposal. The annual burden of the included hospital sites for the arthroscopic procedures undertaken was 6.2 tonnes of carbon dioxide.

Conclusions The data collected demonstrated a significant variability in waste production and cost for waste disposal between hospital sites. At a national level, consideration should be given to the procurement of appropriate products such that waste can be efficiently recycled or disposed of by environmentally sustainable methods.

KEYWORDS
Sustainability – Environment – Orthopaedics – Arthroscopy

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Introduction

The health sector's mission is to promote and protect health. However, it makes a major contribution to the greatest health threat of the 21st century, the climate crisis. Climate change has been labelled as 'the biggest global health threat of the 21st century'.[1] The climate footprint of the healthcare sector is equivalent to 4.4% of global net emissions, and if it were a country, would be the fifth-largest emitter on the planet.[2]

In 2018, the Intergovernmental Panel on Climate Change announced that to limit global warming to 1.5°C, greenhouse gas emissions must decrease 45% by 2030 compared with 2010 and reach net zero by 2050.[3] In the United Kingdom, Public Health England and the National Health Service (NHS) have estimated the health and social care climate footprint within England in 2017 to be around 6.3% of the country's climate footprint.[2]

The United Nations Sustainable Development Goals strive to protect the planet and end poverty by 2030. These goals emphasise the need to strengthen health systems by building service-delivery capacity and ensuring sustainability; they have already been addressed by the surgical community, but attention has been paid to service delivery as opposed to waste management.[4] Adequate hospital waste management contributes to success in several of the goals; in particular, health and wellbeing, clean water and sanitation, decent work and economic growth, responsible consumption and production, and climate action.[5]

The Health Technical Memorandum for the safe management of healthcare waste, published in 2013, provides an update to that previous published in 2006.[6] It has been suggested that between 20% and 70% of healthcare waste originates from a hospital's operating theatre. Up to 90% of operating theatre waste is improperly sorted and sent for costly and unneeded hazardous waste processing.[7] Between individual hospitals and trusts, there is still significant variation in the way in which healthcare waste is disposed of which, in turn, affects the cost of waste disposal and the environmental burden.

There is a lack of published data on the proportion of waste disposed via the different waste streams, yet the choice of waste stream has up to a 50-fold impact on a procedure's carbon footprint.[8,9] The purpose of this study

was to quantify the amount and type of waste produced during two common orthopaedic arthroscopic operations: arthroscopic rotator cuff repair (RCR) and arthroscopic anterior cruciate ligament reconstruction (ACLR). Initially undertaken in a single unit, subsequent data were captured from surrounding hospitals that highlighted the variability in practice.

Methods

Prospective data collection was undertaken. All procedures were undertaken by senior surgeons.

Five each of ACLR and RCR from each centre were included. Clinical waste created by anaesthetic colleagues was excluded.

Hospital site A is a district general hospital that uses reusable gowns and disposable drapes. Hospital site B is a district general hospital utilising disposable drapes and gowns. Hospital sites C and D are specialist tertiary level centres that also utilise disposable drapes and gowns. It is worth noting that one of the hospital sites, site A, used reusable tray packs, drapes and gowns, and did not use disposable options.

Intraoperative waste from ACLR and RCR procedures was measured. The waste was separated into four bags: clean paper, contaminated paper, clean plastic and contaminated plastic. Contaminated waste is any that has been used directly in patient care; it does not include product wrappers but would include each item in a multipack surgical set, even if the item had not been used. At the end of each procedure, each bag of waste was weighed using a theatre scale DIGI® DS-502 (Marsden Weighing Machine Group Ltd, Rotherham, UK). The mean measurement of waste was taken for each procedure from each centre.

Subsequently, the waste management policy of each hospital was requested alongside the tariff for waste management and carbon dioxide (CO_2) emissions for different types of waste from each waste management contractor. Each waste management contractor is obliged to provide data on carbon emissions, cost and the way in which they process the waste. The cost and carbon emissions for processing each type of waste were calculated for each centre.

Finally, a calculation was undertaken based on the annual surgical figures (before the COVID-19 pandemic) from the hospital sites to calculate their annual burden of CO_2 emissions for ACLR and RCR surgeries using the data on carbon emissions provided by the waste contractor.

Results

Overall waste data

Table 1 demonstrates the range of total waste across the hospital sites and the mean total weight of clean and contaminated paper and plastic waste across the hospital sites. Figure 1 shows commonly disposed plastic items and their weights.

Table 1 Mean weight of clean and contaminated waste across hospital sites per procedure

	Paper waste (kg)			Plastic waste (kg)		
Procedure	**Total**	**Clean**	**Contaminated**	**Total**	**Clean**	**Contaminated**
ACLR	1.1–1.6	1.1	0.28	2.4–9.6	3.3	2.9
RCR	0.9–2.3	0.9	0.45	3.3–15.5	2.2	4.7

ACLR = arthroscopic anterior cruciate ligament reconstruction; RCR = rotator cuff repair

Figure 1 Suction tubing (0.31kg), suction bag (0.1kg), plastic disposable medical devices and plastic saline bags (0.84kg)

Individual hospital sites

Table 2 and Table 3 demonstrate the mean plastic and paper waste generated across individual hospital sites for an ACLR and RCR, respectively.

Carbon emissions and processing costs

Each hospital has a contract for waste management that is negotiated on an individual basis.

- Hospital A pays £124 per tonne for the management of clean recyclable waste and £215 per tonne for the management of contaminated recyclable waste. The contract involves the use of specific waste bags that allow identification and sorting such that contaminated waste is incinerated and the energy released during this process is harvested and reused.
- Hospital B pays £264 per tonne for the management of clean recyclable waste and £714 per tonne for the management of contaminated recyclable waste. The contaminated waste is disposed of into landfill.
- Hospitals C and D pay £103 per tonne for the management of clean recyclable waste and £301 per tonne for the management of contaminated recyclable waste. Contaminated waste is disposed of into landfill.

Despite the hospitals separating out clean plastic and paper waste, none of the hospital waste contractors provide a recycling service and so this waste is incinerated with energy recapture. Of the contaminated waste, waste was either disposed of into landfill or by incineration. The carbon emissions of processing a tonne of waste via these methods were taken from information provided by each waste contractor. Subsequently, the carbon emissions were calculated using these figures.

Table 4 and Table 5 demonstrate the mean total waste per ACLR and RCR procedure, respectively, for each individual site, the cost of processing this and the carbon emissions produced.

National figures

Pre-COVID-19, the hospital sites had an annual burden for ACLR of 7.53 tonnes of clinical waste generated and 1.7 tonnes of carbon dioxide. For RCR surgeries, the annual burden from the hospital sites was 15.4 tonnes of clinical waste generated and 4.5 tonnes of carbon dioxide. The higher proportion of plastic waste in RCR surgeries generated the proportionally larger carbon footprint.

To put this into context, flying from London Heathrow to New York John F Kennedy airport generates 986kg of carbon dioxide. The combined annual contribution for arthroscopic ACLR and RCR surgeries at these three sites is the equivalent of 6.3 return flights.[10]

Table 2 Mean plastic and paper waste across individual hospital sites per arthroscopic anterior cruciate ligament reconstruction procedure

Hospital	Textiles	Clean waste (kg)	Contaminated waste (kg)	Total plastic waste (kg)
A	Reusable gowns, disposable drapes	1.0	2.1	2.4
B	Disposable	1.4	3.5	3.6
C	Disposable	5.4	5.6	9.6

Table 3 Mean plastic and paper waste across individual hospital sites per rotator cuff repair procedure

Hospital	Textiles	Clean waste (kg)	Contaminated waste (kg)	Total plastic waste (kg)
A	Reusable gowns, disposable drapes	1.2	3.4	3.5
B	Disposable	4.2	10.3	13
D	Disposable	2.3	13.2	14.7

Table 4 Mean waste, processing costs and carbon emissions for 1,000 arthroscopic anterior cruciate ligament reconstruction procedures across individual hospital sites

Hospital	Textiles	Total waste (kg)	Carbon emissions (tonnes)	Processing costs (£)
A	Reusable gowns, disposable drapes	3,100	0.34	949
B	Disposable	4,900	0.87	2,842
C	Disposable	11,000	2.6	2,668

Table 5 Mean waste, processing costs and carbon emissions for 1000 rotator cuff repair procedures across individual hospital sites

Hospital	Textiles	Total waste (kg)	Carbon emissions (tonnes)	Processing costs (£)
A	Reusable gowns, disposable drapes	4,600	0.53	880
B	Disposable	14,500	2.6	8,463
D	Disposable	15,500	6.4	4,210

Discussion

In the Health Technical Memorandum, clinical waste is defined as '... any waste which unless rendered safe may prove hazardous to any person coming into contact with it ... and any other waste arising from medical practice.'[6] Healthcare waste is divided into non-hazardous and hazardous waste and is strictly controlled with regulations; for European Union Member States, this includes healthcare waste classification from Annex III of Directive 2008/98/EC and a List of Waste established by Commission Decision 2014/955/EU.[11,12]

The main components of healthcare waste are plastic (39.3%–50%), textile (14%–31%), paper (11.2%–25%), glass (0.3%–22.7%), woodware (3.2%–20%), rubber (3.4%–6.6%), metal (0.3%–5%) and other waste (1.4%–18.6%).[13]

The World Health Organization (WHO) estimates that 80%–85% of all healthcare waste is non-hazardous and 15%–20% is hazardous.[14] It has been estimated that over half of the global population is at risk from environmental, occupational or public health threats resulting from improperly treated healthcare waste.[15] Improper healthcare waste management may occur for a variety of reasons including a lack of awareness about health hazards from healthcare waste, inadequate training in proper waste management, lack of infrastructure or energy, lack of appropriate regulations or a failure to enforce existing regulations.[16] To enable appropriate waste care management, the WHO has made recommendations to separate healthcare waste into different coloured trash bags with labels. These then undergo a range of disposal methods depending upon their contents. Recyclable waste should be recycled, whereas contaminated waste undergoes processing by incineration, with or without energy-harvesting methods, or by landfill. Single-use metals, disposed of in a sharps bin, are processed by incineration.[6]

Reducing waste and application of a circular economy to healthcare

There are several ways in which to reduce clinical waste; for example, applying a circular healthcare economy model: reducing, reusing, recycling.

- Reducing what is consumed can be achieved by identifying whether the item needs to be opened for the set. Do we need to use multipack options of surgical tools when single-packed items may suffice? Reducing the amount of plastic used is critical because the recycling and processing of clean plastic waste generates a greater carbon footprint than the processing of clean paper waste, even though the financial cost to the trust was the same in the contracts we analysed.[17]
- Reusing items by selecting items that can be laundered reduces the production and subsequent consumption of items; for example, the use of reusable kidney bowls, light handles and drapes. Our data suggest that 7kg of waste is from drapes and gowns for an ACLR or RCR. Given that a recent review could not support disposables as more effective in orthopaedic or spinal surgery in reducing surgical site infection, as professionals we should be questioning whether we are making appropriate decisions with the surgical textiles we are using.[18]
- Recycling allows for a reduction in waste going to incineration and landfill.
- If waste has to be disposed of, then utilising ways in which energy can be harvested and reused is preferable to landfill.

The clean waste generated by an arthroscopy includes the wrappers of items such as drapes, giving sets and saline bags; effectively things that are wasted before any patient contact. The remainder of the waste is deemed clinical waste because it is involved in direct patient care. In the NHS, clinical waste is hazardous waste unless it is from a municipal source not in any way associated with healthcare (eg cosmetic body art or piercing) or it is segregated non-cytotoxic and non-cytostatic medicine.[6]

Hazardous clinical waste can be broadly classified into one of three categories: that containing an infectious substance, that which is a chemical hazard or that containing a pharmaceutically active agent.[6] The authors would challenge whether more consideration should be given to the guidance for disposal. For example, for the waste to be deemed infectious, when applied to arthroscopy, the main concern is that of contamination from synovial fluids and the potential risk of infection from these. Interestingly, the same guidance counts sanitary waste including incontinence pads as non-infectious and non-clinical waste unless the patient has a documented infection such as *Clostridium difficile*[6] yet these potentially pose a far greater risk of infection transmission given the nature of faeces.

The NHS guidance suggests that medicinal waste includes discarded items contaminated with medicinals, such as connecting tubing or drug vials.[6] The saline used to infiltrate the joint during arthroscopy is not a

medicinal product and would pose little harm to an individual during disposal if not classified as medicinal waste. The implication of this is that the saline bags and connecting tubing could then be recycled as clean, not contaminated waste, thus increasing the amount of waste for recycling and reducing the quantity for disposal by incineration or landfill.

If further consideration was given to the national guidelines, it is likely that significantly more items (eg giving sets, connecting tubing, drapes not soaked with bodily fluids) used within arthroscopy could be processed as clean waste and recycled without harm to those involved in the processing. This has both environmental and economic implications given the cost of waste management for clean and contaminated waste.

The waste produced over the four hospital sites varied enormously, with one key factor being whether the site used reusable or disposable drapes and gowns. There is work currently underway, via the Royal College of Surgeons of England Green Surgery Oversight Committee, to identify ways in which surgery can be made greener and more environmentally friendly. One of these aspects is assessing waste, including whether medical textile waste, such as gowns and drapes, can be minimised without incurring patient harm.

The costs of waste disposal varied widely depending on the contractor, contract negotiated and the methods of waste disposal used. Site A had on-site processing by incineration with harvesting of the energy generated. Because they used reusable drapes and gowns, the quantity of waste was less at this site. Site B utilised a combination of off-site processing by incineration with harvesting of the energy generated alongside landfill options. Sites C and D used landfill for waste processing. Standardisation of contracts may reduce variability between hospitals with regards to the cost of waste processing.

Procurement also has a role to play because they source the items that we, as clinicians, use. There has already been some work on the multipacks used in the operating theatre. One study in the United States concerning wide-awake hand surgery cases had clinicians involved in slimming down what was in the multipack. The study reported a 13% reduction in waste per case and a cost saving of $125.[19] A further unit removed 15 items from their disposable plastic pack and 7 from the hand pack with an estimated annual saving of US$17,381.05 in the unit from these changes alone.[20] Putting this into context, in 2016, the American Society for Surgery of the Hand estimated that there were approximately 2,000 active hand surgeons in the United States; if each were to do 100 ‘green’ cases a year, there would be a cost saving of $2.13 million and a decrease in 506 tons of waste.[21]

Study limitations

This study did not assess waste created by anaesthetic procedures. In addition, only a small data set was examined with five patients for each of the two procedures at each site. Further research should be directed at assessing waste production from other orthopaedic procedures and consideration given to waste produced by anaesthetics. One study assessing waste from primary hip arthroplasty had similar findings: excess waste being produced and not being placed in the correct waste streams.[22] Some types of plastic are more readily recycled than others, which cannot be recycled. Further investigation into the type of plastic disposed of during procedures would be valuable to assess whether we are using appropriate plastic types to create a greener operating environment. Finally, more work is required to assess the cost of laundering reusable gowns and the environmental impact this has compared with disposable gowns and drapes.

Conclusions

To conclude, the data collected during this study demonstrated significant variability in waste production between hospital sites and a highly variable cost for waste disposal dependent upon the nature of the contract and method of disposal used by the waste management company. Clinicians should be working with hospital management and procurement to create an environmentally more sustainable operating theatre with consideration given to the methods in which waste is managed. At a national level, consideration should be given to both the guidance for and procurement of appropriate products such that waste can be efficiently recycled or disposed of with attention paid to environmentally sustainable methods.

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Research Letter

Waste not, want not: orthopaedic waste data

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Dear Editor

The National Health Service (NHS) contributes 4–5 per cent of the UK's greenhouse gases and one-quarter of all public-sector waste. The main components of healthcare waste are plastic (39.3–50 per cent), textile (14–31 per cent), paper (11.2–25 per cent), glass (0.3–22.7 per cent), woodware (3.2–20 per cent), rubber (3.4–6.6 per cent), metal (0.3–5 per cent), and other waste (1.4–18.6 per cent)[1]. It has been suggested that between 20 and 33 per cent of healthcare waste originates from the operating room of a hospital[2]. Up to 90 per cent of operating-room waste is improperly sorted and sent for costly and unneeded hazardous-waste processing, which can increase the carbon footprint of each procedure by up to 50-fold[3–5].

One tertiary and four district general hospitals participated in this study, with all surgery undertaken by senior surgeons. Surgical waste generated for ten procedures each over a variety of elective and trauma procedures was separated primarily into clean and contaminated, paper or plastic, then weighed using a theatre scale (DIGI® DS-502; Marsden Weighing Machine Group, Rotherham, UK). The mean weight was calculated for each procedure at each centre. The annual carbon footprint for each procedure at each site was subsequently calculated based on retrospective pre-COVID-19 surgical numbers for the year 2019–2020 and data provided by each waste contractor on carbon emissions and cost for disposal.

Over the procedures analysed, the mean total plastic waste at the hospital sites varied from 6 to 12 kg. *Table 1* details the number of procedures, costs, and carbon emissions for the orthopaedic procedures at each site. Each hospital site uses a separately negotiated waste contract and waste contractor.

Tables S1–S3 detail the operations included, range of paper and plastic waste, and mean waste for four trauma and four elective procedures.

The preference for reusable or disposable medical textiles, and the way surgeons draped, was the main contributing factor for the witnessed variation in waste produced between sites and corresponds with earlier published work[6]. One hospital site used reusable gowns and disposable drapes for most of their day-case procedures and disposable gowns and drapes for non-day-case procedures. The remaining hospital sites all used disposable gowns and drapes for all procedures. Of note, one hospital site used a double draping system for elective procedures. These practices contributed to overall carbon emissions.

Despite the hospitals separating out clean plastic waste, it was combined with clean paper waste, and none of the hospitals' waste contractors provides a recycling service that can separate the two and recycle them, and so this waste is incinerated with energy recapture. It is likely that other trusts may have a similar issue where the potential for recycling in theatres is not realized because of a lack of sorting in the hospitals or a lack of facilities at the waste contractors. Some types of plastic are more readily

Table 1 Plastic waste, disposal costs, and carbon emissions across hospital sites

	Hospital site				
	A	B	C	D	E
Total number of procedures	2826	2921	4981	2791	12 562
Plastic waste per procedure (kg)	9	6	9	10	12
Total annual plastic waste (tonnes)	25.4	17.5	44.8	27.9	150.7
Processing cost/tonne (euro)	665	516	860	855	596
Total cost incurred (euro)	16 915	9044	38 552	23 874	89 882
Total annual carbon emissions (tonnes)	6.1	3.6	10.8	6.7	49.0
Carbon emission/ procedure (tonnes)	0.002	0.001	0.002	0.002	0.004

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recycled than others and attention should be turned to medical-device packaging to see whether there is scope for improvement.

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Disclosure

H.M. is Chief Medical Officer for Revolution-ZERO. The authors declare no other conflict of interest.

Supplementary material

Supplementary material is available at *BJS Open* online.

Data availability

Data are available on request.

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Handling 'carbon footprint' in orthopaedics

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ABSTRACT

Introduction The National Health Service contributes 4%–5% of England and Wales' greenhouse gases and a quarter of all public sector waste. Between 20% and 33% of healthcare waste originates from a hospital's operating room, and up to 90% of waste is sent for costly and unneeded hazardous waste processing. The goal of this study was to quantify the amount and type of waste produced during a selection of common trauma and elective orthopaedic operations, and to calculate the carbon footprint of processing the waste.

Methods Waste generated for both elective and trauma procedures was separated primarily into clean and contaminated, paper or plastic, and then weighed. The annual carbon footprint for each operation at each site was subsequently calculated.

Results Elective procedures can generate up to 16.5kg of plastic waste per procedure. Practices such as double-draping the patient contribute to increasing the quantity of waste. Over the procedures analysed, the mean total plastic waste at the hospital sites varied from 6 to 12kg. One hospital site undertook a pilot of switching disposable gowns for reusable ones with a subsequent reduction of 66% in the carbon footprint and a cost saving of £13,483.89.

Conclusions This study sheds new light on the environmental impact of waste produced during trauma and elective orthopaedic procedures. Mitigating the environmental impact of the operating room requires a collective drive for a culture change to sustainability and social responsibility. Each clinician can have an impact upon the carbon footprint of their operating theatre.

KEYWORDS
Orthopaedics – Sustainability – Carbon footprint – Net Zero

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Introduction

Climate change has been labelled as "the biggest global health threat of the 21st century".[1] In 2020, it was reported that the National Health Service (NHS) generates approximately 4%–5% of England and Wales' greenhouse gases and a quarter of all public sector waste.[2–4] The United Nations Sustainable Development Goals strive to protect the planet and end poverty by 2030. Adequate hospital waste management contributes to success in several of the goals; in particular, health and wellbeing, clean water and sanitation, decent work and economic growth, responsible consumption and production, and climate action.[5]

In 2018, the Intergovernmental Panel on Climate Change announced that to limit global warming to 1.5°C, greenhouse gas emissions must decrease 45% by 2030 compared with 2010 and reach Net Zero by 2050.[6] In the United Kingdom (UK), Public Health England and the NHS have estimated the health and social care climate footprint within England in 2017 to be around 6.3% of the country's climate footprint.[7]

In 2020, the NHS launched its campaign For a Greener NHS and commissioned an expert panel to set out a practical, evidence-based and quantified path towards a "Net Zero NHS". This report sets out a strategy and two clear targets to respond to this challenge:

- Net Zero by 2040 for the emissions the NHS controls directly
- Net Zero by 2045 for the emissions the NHS can influence.[8]

Key areas identified in this report include waste management and the procurement of lower carbon options. The main components of healthcare waste are plastic (39%–50%), textile (14%–31%), paper (11%–25%), glass (0.3%–23%), woodware (3%–20%), rubber (3%–7%), metal (0.3%–5%) and other waste (2%–19%).[9] It has been suggested that between 20% and 33% of healthcare waste originates from a hospital's operating room.[3] Up to 90% of operating room waste is incorrectly sorted and sent for costly and unneeded hazardous waste processing.[10] Contaminated or hazardous waste includes waste that has been used directly within patient care. In

addition, there is often significant variation in the way in which healthcare waste is disposed of between trusts.

Although there are annual reports detailing the proportion of waste disposed of via the different waste streams, there is a lack of published data on the proportion of waste for individual operations, yet the choice of waste stream has up to a 50-fold impact on a procedure's carbon footprint.[11,12] The purpose of this study was to quantify the amount and type of waste produced during common trauma and elective orthopaedic arthroscopic operations across different centres.

Methods

Prospective data collection was undertaken. All procedures were performed by senior surgeons.

Both elective and trauma operations were included (Table 1). Data were collected for ten operations of each type (eg, total hip joint replacement, arthroscopy of knee) at each individual hospital site, provided the hospital undertook the surgery. Five hospital sites were included: one tertiary and four district general hospitals. Clinical waste created by anaesthetic colleagues was excluded.

The intraoperative waste from the surgeries was measured. The waste was separated into four bags: clean paper, contaminated paper, clean plastic and contaminated plastic. Contaminated waste is any that has been used directly in patient care; it does not include product wrappers but would include each item in a multipack surgical set, even if that item had not been used. Paper and plastic were measured because they comprise the largest amount of waste; disposable gowns and drapes are manufactured from plastic. At the end of each procedure, each bag of waste was weighed using a theatre scale DIGI® DS-502 (Marsden Weighing Machine Group Ltd, Rotherham, UK). The mean measurement of waste was taken for each procedure from each centre.

Subsequently, estimated annual carbon emissions of the waste disposal for each procedure were calculated. This calculation used retrospective case numbers from pre-COVID surgery for the year 2019–2020, identified by searching with clinical codes, and data provided by each waste contractor on the carbon emissions, cost and way in which they process the waste.

Following this, hospital site A undertook a trial in which 1,000 reusable surgical gowns were rented for four weeks and used in theatre in place of disposable gowns. The gowns were laundered by a commercial company that already held a contract with the NHS. The carbon footprint for 1,000 uses of reusable and disposable surgical gowns was calculated using data based on the Overcash study of life-cycle assessments for surgical gowns.[13] The costs for using reusable and disposable gowns over the 2019–2020 period were calculated based on data supplied by the hospital.

Results

Trauma and elective waste

Table 1 lists the operations included in the study, which were divided into elective or trauma. Waste was measured over ten procedures for each operation. The range of total paper and plastic waste within the two groups, and for selected elective and trauma operations within the study, is demonstrated in Table 2. The mean waste for four trauma and four elective procedures is also shown.

Table 3 shows four elective and four trauma operations commonly undertaken at each hospital site and lists the mean total plastic waste over ten of these procedures at each hospital site.

Annual plastic waste, costs for waste disposal and carbon emissions

Mean total plastic waste per procedure in orthopaedics was calculated for each hospital.

Table 1 List of elective and trauma operations included in the study

Elective	Trauma
Total hip joint replacement	Dynamic hip screw
Total knee joint replacement	Cannulated screws
Total shoulder joint replacement	Hip hemiarthroplasty
Arthroscopy of knee	Intramedullary femoral nail
Arthroscopy of ankle	ORIF femur (including periprosthetic)
	ORIF tibial plateau
	Intramedullary tibial nail
	ORIF distal tibia
	External fixation/TSF tibia
	ORIF ankle
	ORIF foot
	ORIF proximal humerus
	Intramedullary humeral nail
	ORIF distal humerus/proximal humerus
	TENS nail forearm
	ORIF forearm
	ORIF distal radius
	MUA ± K-wire distal radius
	ORIF hand
	MUA ± K-wire hand

MUA = Manipulation under Anaesthetic; ORIF = Open Reduction and Internal Fixation; TENS = titanium elastic nail; TSF = Taylor Spatial Frame

Table 2 Range of paper and plastic waste for elective and trauma surgery

	Paper waste (kg)		Plastic waste (kg)	
Procedure type	**Mean**	**Range**	**Mean**	**Range**
Trauma		0.4–2.2		2.4–12.6
Dynamic hip screw	0.9	0.4–0.9	11.4	6.9–12.6
Hip hemiarthroplasty	1.2	0.8–1.4	10.8	8.9–12.2
ORIF ankle	1.0	0.8–1.2	7.4	5.9–9.7
ORIF distal radius	0.8	0.6–0.8	6.3	4.9–7.1
Elective		1.1–3.2		3.3–16.5
Hip arthroplasty	2.4	1.8–2.9	11.8	6.6–16.5
Knee arthroplasty	2.4	1.8–2.8	10.7	6.5–13.8
Knee arthroscopy	1.3	1.1–1.6	8.6	3.4–9.6
Shoulder arthroscopy	1.4	1.2–2.3	10.6	3.3–15.5

ORIF = open reduction and internal fixation

Table 3 Mean total plastic waste (kg) for selected operations across hospital sites

	Hospital site				
Procedure	**A**	**B**	**C**	**D**	**E**
Trauma					
Dynamic hip screw	11.2	9.6	12.1	11.6	12.2
Hip hemiarthroplasty	10.6	9.2	11.4	10.9	11.8
ORIF ankle	6.9	6.2	7.3	8.6	7.8
ORIF distal radius	6.1	6.2	6.4	6.2	6.6
Elective					
Hip arthroplasty	11.2	10.2	11.9	11.8	13.9
Knee arthroplasty	9.9	9.8	11.2	10.8	12.2
Knee arthroscopy	9.1	5.8	8.8	5.8	10.4
Shoulder arthroscopy	10.1	7.2	9.2	7.6	15.1

ORIF = open reduction and internal fixation

The number of procedures undertaken at each site in 2019–2020 was obtained and used to calculate the annual waste for these procedures. The cost for each hospital site to process the plastic waste was calculated. This is shown in Table 4. Of note, each hospital site uses a separately negotiated waste contract and contractor. The processing cost per tonne of plastic waste at each site is also shown.

The hospitals in the study separated clean plastic and paper waste put into the same bag. Unfortunately, the hospital waste contractors provide a recycling service but are unable to separate combined waste into its individual plastic and paper components and so this waste is incinerated with energy recapture. Contaminated waste was disposed of either to landfill or by incineration. The carbon emissions of processing a tonne of waste via these methods was taken from information provided by each waste contractor. Carbon emissions were calculated using these figures for the disposal of plastic, and the data are given in Table 4.

Table 4 Plastic waste, disposal costs and carbon emissions across hospital sites

	Hospital site				
	A	**B**	**C**	**D**	**E**
Total number of procedures	2,826	2,921	4,981	2,791	12,562
Plastic waste per procedure (kg)	9	6	9	10	12
Total annual plastic waste (tonnes)	25.4	17.5	44.8	27.9	150.7
Processing cost/ tonne (£)	580	450	750	746	520
Total cost incurred (£)	14,752	7,887	33,622	20,821	78,387
Total annual carbon emissions (tonnes)	6.1	3.6	10.8	6.7	49.0

Hospital site B used reusable gowns and disposable drapes for most of their day case procedures and disposable gowns and drapes for non-day case procedures. The remaining hospital sites used disposable gowns and drapes for all procedures. Of note, hospital site E used a double-draping system for elective procedures. This involves utilising disposable drapes in the anaesthetic room and then re-draping the patient when they are in the main theatre.

Reusable vs disposable gowns

Finally, published work by Overcash on life-cycle assessments of surgical gowns was used to estimate the difference in carbon emissions of using 1,000 reusable gowns, for 60 uses per gown, and 1,000 disposable gowns over a four-week period at hospital site A. The figures taken from the work by Overcash are shown in Table 5. Of note, International Organization for Standardization standards allow for 75 uses per gown, although the average use rate is lower because of losses, damage and so on. The Overcash work had a gown use rate of 60 cycles to account for this.[13] The use of reusable gowns potentially results in a 66% reduction in carbon emissions.

Costings were requested from the trust of hospital site A and used to estimate cost savings over a year using the number of operative procedures within the trust for the period 2019–2020. During 2019–2020, some 62,730 gowns were used at a total cost of £60,698.67. In 2019–

Table 5 Carbon footprint of 1,000 gowns

	Carbon footprint ($kgCO_2$)	
	Reusable (>60 uses)	Disposable
Gown manufacture and supply chain	143.0	1,495.0
Packaging and supply chain	76.7	121.0
Laundry	278.0	0
Sterilisation	19.8	6.3
Use phase transport	38.7	3.5
End of life	1.4	10.9
Total carbon footprint	557.6	1,636.7
Carbon footprint per gown	0.56	1.64

2020, the cost per use for a disposable gown was £0.97 and the cost per use for a reusable gown was £0.75. If all 62,730 gowns that were used were reusable, the annual cost would be £47,214.78. This represents a cost saving of £13,483.89. The trust also estimated costs based on uplift predictions for 2022–2023. The cost for using disposable gowns would be £78,887.03 and the cost for using reusable gowns is £72,757.76. This represents a potential cost saving of £6,129.27.[14]

Discussion

This study aligns with the Royal College of Surgeons England (RCS England) Sustainability in Surgery Strategy 2021 and the plastics reduction pledge of the NHS "Net Zero" report, highlighting the importance of addressing waste and waste processing in producing a greener operating theatre.[8,15] It has been estimated that over half of the global population are at risk from environmental, occupational or public health threats resulting from incorrectly treated healthcare waste.[16]

There are several ways of reducing clinical waste and particular attention has been paid to implementing a circular healthcare economy model: reducing, reusing, recycling.

- Reducing what is consumed can be achieved by identifying whether the item needs to be opened for the set. Do we need to use multipack options for surgical tools when single-packed items may suffice? Reducing the amount of plastic used is critical because the recycling and processing of clean plastic waste generates a greater carbon footprint than the processing of clean paper waste, even though the financial cost was the same to the trust in the contracts we analysed.[17]
- Reusing items, and selecting items that can be laundered, reduces the production and subsequent consumption of items; for example, the use of reusable kidney bowls, light handles and drapes.
- Recycling allows for a reduction in waste going forward to incineration and landfill.
- If waste must be disposed of, utilise methods that allow for energy harvested and reuse over landfill.

As clinicians, we are at the end of the medical device life cycle. Medical device designers, manufacturers and procurement also have a role to play in waste production. Over 80% of the environmental impact of a product is determined at the design stage.[18] Using resources efficiently by considering the use of renewable and sustainable raw materials, reducing the amount of resources consumed in a device's manufacture, delivery and operation, and waste minimisation all affect the environmental impact. Medical devices should be designed for circularity (a product suitable for several life cycles), durability, disassembly and reuse. Finally, product life should be extended to keep the product in use for the greatest number of safe-use cycles rather than disposing of it after a single use.

Reducing our consumption is critical. There has already been interest in this area with consideration given to what is in a multipack in theatre. An American study including wide-awake hand surgery cases had clinicians involved in deciding what was in the multipack with a subsequent 13% reduction in waste per case and a cost saving of $125.[19] A further unit removed 15 items from their disposable plastic pack and seven from the hand pack, with an estimated annual saving of US$17,381.05 in the unit from these changes alone.[20]

Plastic constituted the greatest amount of waste, in line with other studies and our expectations. Despite the hospitals separating out clean plastic waste, it was combined with clean paper waste and none of the waste contractors provide a recycling service that can separate the two and recycle, and so this waste is incinerated with energy recapture. It is likely that other trusts have a similar issue where the perception of recycling in theatres is not realised because of a lack of sorting in the hospital or a lack of facilities at the waste contractors.

In our study, primary hip arthroplasties generated a mean of 11.8kg of plastic waste per procedure. This is comparable with previous published literature; a two-hospital study in the East of England in 2011 found 12.1kg of waste was generated for a total hip arthroplasty, of which 6% was contaminated and not appropriate for recycling.[21] More recently, in 2022, a study measuring total hip arthroplasty waste in Newcastle upon Tyne found that the average amount of waste produced for a single total hip arthroplasty was 10.9kg.[22] Both studies reported that there was the potential to recycle a greater percentage of the waste, without incurring additional harm from hazardous waste, compared with the current practice, and suggested that staff education is critical to ensure waste is being disposed of accurately.

We noted a large range in the plastic waste measured for different procedures; for example, 9.9kg for hip arthroplasty, 7.3kg for knee arthroplasty and 12.2kg for

shoulder arthroscopy. Trauma surgery also generated differences, although these were smaller: 5.7kg for a dynamic hip screw, 3.3kg for a hip hemiarthroplasty and 3.8kg for an ankle fixation. One reason identified was the surgeon's preference for draping patients. There was significant discrepancy between different surgeons undertaking the same operation. The second factor identified was whether reusable or disposable gowns were used.

The results show that hospital site B had the lowest mean total plastic waste. This site uses reusable gowns and disposable drapes for most of their day case procedures, such as knee or shoulder arthroscopy and distal radius fixation, and disposable gowns and drapes for non-day case procedures such as hip and knee arthroplasty, and hip hemiarthroplasty. Taking this into account, their figures were still generally lower even for those surgeries where disposable textiles were used. This may be because of an awareness and culture within the hospital towards sustainability.

Interestingly, one surgeon at hospital site B uses reusable gowns and drapes because of an allergy to the disposable gowns. Previous unpublished work at this hospital site has demonstrated that the amount of textile waste produced in arthroscopic surgery is 6kg.

Hospital site E uses a double-draping system for elective procedures. This involves utilising disposable drapes in the anaesthetic room and then re-draping the patient when they are in the main theatre. The mean total plastic waste generated for these procedures at this hospital site was the greatest across all the sites included in the study, reinforcing the importance of surgeon preference for draping and its impact on waste generated.

The use of reusable or disposable drapes and gowns appeared to be a key factor in the differences in waste produced between hospital sites. Work is currently underway via the: Sustainability in Surgery Strategy and partners of The Centre for Sustainable Healthcare's Green Surgery Challenge Oversight Committee to identify the ways in which surgery can be made greener and more environmentally friendly. One of the areas being addressed within the surgical community is waste production, and this includes whether medical textile waste, such as gowns and drapes, can be minimised without incurring patient harm. There have been no randomised controlled trials to assess the incidence surgical site infections (SSIs) with reusable or disposable gowns and drapes. Despite great enthusiasm being shown for investigating the best types of fabric for a surgical gown, replication of results in vivo and in vitro often differ.[23] A recent review of SSIs in orthopaedic and spine surgery found no available evidence to support a difference between reusable and disposable gowns and drapes, and called for further research.[24] World Health Organization Global Guidelines for the Prevention of Surgical Site Infection recommend the use of reusable or disposable gowns and drapes, and acknowledge the paucity of evidence in this domain.[25] Given the lack of evidence directly comparing the incidence of SSIs with reusable and disposable gowns, we cannot conclusively state that the two are equivalent at preventing SSIs in clean surgery; it is suspected, however, that there is little difference in clean-contaminated surgery and no difference in dirty or contaminated surgeries.

Our pilot study substituting disposable gowns for reusable ones demonstrated a 66% reduction in carbon emissions when calculated using data published by Overcash.[13] This was by no means an in-depth life-cycle assessment. However, most life cycle studies focusing on medical devices in surgical settings compare single-use items with their equivalent reusable solutions, and find that reusable options generally perform better across a broad range of environmental impact categories, including climate change.[26] For example, a recent life-cycle analysis of scrub suits found that a reusable scrub suit has a 31% reduced impact on climate change compared with a disposable scrub suit system. This study considered a day's use of 1.8 scrub suits and found these had a 62% lower impact when reusables were used compared with disposables.[27]

Recently, a team based in London replaced 3,051 disposable gowns with reusable ones over a six-month period and demonstrated a saving of 3.292 tonnes of CO_2 emissions and a cost saving of £366 from reductions in waste disposal and standard gown use.[28] Scaling these figures up to 62,730 gowns, the cost savings in this study would be £7,525.13. Our cost saving of £13,483.89 was based on 2019–2020 data. Costs have increased because of the pandemic and using uplifted costs, our savings reduce to £6,129.27, which is similar to the London-based team's findings when taking into account that hospitals negotiate their own waste disposal contracts.

Study limitations

This study did not assess the waste created by anaesthetic procedures nor did it assess the total amount of waste per procedure, the percentage that was recycled or the percentage sent to landfill. Surgeons were aware that the study was being undertaken and as such the results may show bias. Although it involves a small sample size of five hospitals, raw data in the published field are still relatively scarce and this could be a benchmark for others to use and add to.[29] Figures for carbon emission reduction were based upon the Overcash study, which makes several assumptions on gown use and is based on US rather than UK data.[13]

Further research should be directed at assessing waste production and processing. Some plastics are recycled more readily than others, and further investigation into the type of plastic disposed of during procedures would be valuable to assess whether we are using appropriate plastics in our packaging types to create a greener operating environment. Accurate and in-depth life-cycle assessments are costly and time-consuming but we would benefit from producing life-cycle assessments of medical devices, such as surgical gowns, using items in circulation and current practices for laundering and disposal. Finally, attention should be paid to qualitative

work exploring the education and beliefs of staff concerning the recycling of theatre waste; educating staff on what to recycle has demonstrated an increase in the overall recycling of theatre waste.[30] Exploring surgeons' beliefs regarding the draping of patients for procedures and comparing this with infection rates would also be valuable for providing an understanding behind some of the discrepancies in practice we encountered.

Conclusions

This study sheds new light on the environmental impact of waste produced in trauma and elective orthopaedic procedures. Given the national and international targets, it is timely to draw this to the attention of the clinician. Mitigating the environmental impact of the operating room requires a collective drive for a culture change to sustainability and social responsibility. At a national level, consideration should be given to the design, manufacture and procurement of appropriate products with attention paid to environmentally sustainable options. Clinicians should be working with hospital management and procurement to create an environmentally more sustainable operating theatre, and consideration should be given to the methods in which waste is managed.

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Conflicts of interest

Holly Morris is Chief Medical Officer for Revolution-ZERO.

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REVIEW ARTICLE

Improving medical textiles to create a greener operating theatre

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ABSTRACT

By generating almost 5% of the world's carbon emissions, healthcare, if it were a country, would be the world's fifth biggest polluter and for the UK in 2017, the health sector alone was responsible for 4.4% of its net global greenhouse gas emissions and 6.3% of that country's carbon footprint. In 2020, the UK National Health Service became the first health service to announce its intention to achieve Net Zero emissions. Between 20% and 33% of health care waste is thought to originate from a hospital's operating rooms and up to 90% of this is sent for unnecessary hazardous-waste disposal. Current practice allows the use of disposable or re-usable textile items but textile products can still account for up to 30% of the waste generated within an operating theatre. This paper explains the steps that those working in textile product development and those working in healthcare can take to reduce the textile-related carbon footprint and, in particular, to how medical textile items, such as gowns and drapes can be selected to produce a lower carbon footprint. Attention is also paid to how reusable textiles can be microbiologically decontaminated and laundered in the most economical and ecologically-acceptable fashion. The paper draws attention to the need for willingness to implement already-existing solutions for environmentally-acceptable personal protective equipment (PPE) and low carbon-footprint laundry processes for the cleaning and microbiological decontamination of all types of re-usable textiles employed within the operating theatre. Where redesign of PPE is required, the need is stressed for sensitive adjustment of standards to support the implementation of reusable forms, whilst maintaining the original high performance requirements expected in actual use.

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Introduction

Climate change has been labelled as 'the biggest global health threat of the twenty first century' ('Editorial. A Commission on climate change,' Lancet, 2019) and in 2018, the Intergovernmental Panel on Climate Change (IPCC) announced that to limit global warming to 1.5 °C, greenhouse gas emissions must decrease 45% by 2030 (compared with 2010) and reach Net Zero by 2050 (Intergovernmental Panel on Climate Change, 2018). One of the most-widely-used ways of estimating the impact of an item or activity on the environment is to determine its carbon footprint through life-cycle assessment; international standards provide guidance in the ISO 14000 series (International Organization for Standardization, 2006a, 2006b).

The magnitude of the various negative environmental impacts of healthcare were established through research into the carbon footprint generated by that sector by Pichler et al. (2019), and these were built on and further developed by the non-government organisation Health Care Without Harm, who calculated that the world's health-care climate footprint in 2014 was 2.0 $GtCO_2e$, an amount equivalent to 4.4% of global net emissions meaning that, if it were a country, it would be the world's fifth biggest polluter. The top three emitters were the United States 546 MtCO2e, China 342 MtCO2e, and the European Union 248 MtCO2e, which together contributed over half (56%) of the world's total health-care climate footprint (Health Care Without Harm, 2019a). The values which emerge on a country or regional basis consist of a combination of emissions per patient treated and numbers of patients treated in that country. For developed countries, both the total and relative contributions can vary widely between countries, demonstrated by substantial differences in the per-capita climate footprint per patient treatment. For example, comparing the per-capita climate footprint per patient treatment across the countries which make major contributions to global net emissions, they emerge as: USA- 1.72 tCO_2e, Australia, Canada and Switzerland over 1.0 tCO_2e, Japan, Korea, Russia and the UK between 0.5 and 1.0 tCO_2e and the EU (with between the global average 0.28 tCO_2e and 0.5 tCO_2e) at the upper end of the spectrum, whereas China and India with below average emissions lie towards the lower end.

Overcash and co-workers have argued for environmental impact reduction to be applied as a quality measure in healthcare (Esmaeili et al., 2018). The main contributors to the carbon footprint were identified as:

i. *Energy use*: energy accounts for over half of health care's carbon footprint; this includes on-site consumption by heating/ventilation/environmental control

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systems taken together with that used by suppliers in the provision of goods and services.

ii. *The health care supply chain*: over 70% of emissions are primarily derived from the health care supply chain through the production, transport, and disposal of goods and services, such as pharmaceuticals and other chemicals, food and agricultural products, medical devices, hospital equipment, and instruments.

The procurement of low-carbon products is critical for reducing the carbon footprint of healthcare. Indeed, manufacturing and distribution of medical and non-medical supplies, devices and pharmaceuticals account for up to 71% of healthcare's global greenhouse gas emissions (Health Care Without Harm, 2019b). Whilst these emissions are beyond the direct control of a healthcare organisation, they can be influenced by healthcare professionals and procurement teams by product selection and use. It is therefore imperative that industries supplying the healthcare sector are aware of the principles applied to sustainability within healthcare such that they can supply appropriate products. There are other conditions which must also be satisfied during procurement. Alongside the negative impact of surgery on greenhouse gas emissions, there have been reports of labour rights abuses in the manufacture of products used in healthcare. Some of these include the manufacture of textile-based products such as forced labour in the manufacture of masks and gowns in China (British Medical Association, 2021) and labour rights violations in the manufacture of surgical masks in Mexico (British Medical Association, 2011), nurse uniforms in India (Bjurling, 2007) and surgical drapes in Thailand (OECD Watch, 2021).

A greener health-care system

In the United Kingdom, Public Health England and the National Health Service estimated the health and social care carbon footprint within England in 2017 to be around 6.3% of the country's carbon footprint (Public Health England, 2018) and in 2020, it was reported that the NHS in the UK generates between 4 to 5% of the country's greenhouse gases and a quarter of all public-sector waste (NHS England Press Release, 2020; Rizan et al., 2020; Watts et al., 2021). In 2020, the NHS launched its campaign for a 'Greener NHS' with a report aimed at setting out a practical, evidence-based, and quantified path to a 'Net Zero NHS' (NHS England, 2022) with targets of Net Zero by 2040 for the emissions the NHS controls directly and by 2045 for emissions that the NHS can influence. Key areas identified in this report include the procurement of lower-carbon options and appropriate waste management. Despite the emphasis of the 2022 report, no attention was paid to lower-carbon options and very little to appropriate waste management for the newly-designed 'NHS National Healthcare Uniform' introduced in 2023 (National Health Service Supply Chain, 2023).

The operating theatre is an area of the hospital with a particularly high medical-product use and consumption and a recent Green Surgery Report emphasises the need to procure low-carbon options, to reuse medical devices and to manage waste appropriately to reduce carbon emissions but with little attention paid to the textile items employed in the surgical setting (UK Health Alliance on Climate Change, 2023). However, included in the list of items with the highest greenhouse gas emissions that are used in operating theatres, are textile-based items such as surgical caps, gowns and surgical drapes (Sustainable Development Unit, 2017).

Auditing waste allows for the identification of opportunities to reduce use upstream and thus reduce waste production. The main components of healthcare waste are plastics (39.3–50%), textiles (14–31%), paper (11.2–25%), glass (0.3–22.7%), wood-ware (3.2–20%), rubber (3.4–6.6%), metals (0.3–5%) and other waste (1.4–18.6%) (Zlaugotne et al., 2022). It has been suggested that between 20% and 33% of health-care waste originates from a hospital's operating room, see Figure 1 (Rizan et al., 2020). Whilst some of this waste is badly contaminated, up to 90% of operating room waste is improperly sorted and sent for costly and unnecessary hazardous waste processing (Lee RJ and Mears SC, 2012). In addition, there is often significant variation in the way in which health care waste is disposed of between different operational groupings (NHS Trusts) across the UK which impacts upon the carbon footprint (Shah et al., 2023a). Alongside plastic, major contributors to the waste generated in the operating room are textile-based items and in particular the workwear of the operating personnel and personal protective equipment (PPE) such as surgical gowns and drapes (Shah et al., 2023b). Recent research suggests that for arthroscopic shoulder and knee surgery, 7 kg of waste consists of disposable surgical drapes and gowns (Shah et al., 2023a).

Whilst surgical gowns and drapes were originally reusable, an attitude initiated in the mid-1950s labelled at that time by LIFE magazine as 'Throwaway Living', became adopted in the hospital and healthcare settings by the 1970s and more widely ever since (Strasser & Schlich, 2020). The advantages in terms of the convenience of disposable items had been strongly marketed to the healthcare sector with attention drawn to similarities in cost and the possibility of moving away completely from the management responsibilities involved with in-house decontamination and sterilisation of metal and plastic items and the institutional laundering of textiles. There were those who provided their strong professional support to move away from reusable gowns and drapes, suggesting that using a new item every time would be more reliable and require less testing than laundered reusable items (Gruendemann, 2002) an assumption which was demonstrably not supported by market surveillance of single-use respirators by the UK Health & Safety Executive (Health & Safety Executive, 2016) or by the European Safety Federation (European Safety Federation, 2021). Reliance on single-use disposable items also leaves health systems vulnerable to supply-chain interruptions (Rowan and Laffey, 2021; Sherman et al., 2023). A spirit of compromise does exist, in that some regions are prepared to accept that devices intended for 'single-use' can be reused

Figure 1. Operating theatre waste – authors own.

given that they can, and have been, appropriately decontaminated. For example, in Europe, according to Regulation (EU) 2017/745 of 5 April 2017 on medical devices (European Union, 2017), remanufactured 'single-use' medical devices must meet manufacturer standards and be able to receive a CE mark to indicate that they are as safe and effective as the new equipment. They are therefore required to be sterilisable to the same level as the original device.

Medical textiles in a greener health system

A wide range of medical textiles are important to medicine and healthcare, and that range continues to grow. As defined by The Textile Institute, a medical textile is 'a textile structure which has been designed and produced for use in any of a variety of medical applications' (Textile Institute, 2021). Morris and Murray updated the subcategories within the field to:

1. Non-implantable;
2. Implantable;
3. Health and hygiene products;
4. Extracorporeal products;
5. Intelligent medical and healthcare textiles;
6. Furnishing fabrics and textiles in fixtures and fittings in healthcare establishments; and
7. Components of devices for environmental hygiene control (Morris & Murray, 2021).

Given that the focus of attention in the current review is on the operating theatre, most attention is paid to the health and hygiene products but with some reference also on the

textile filtration components of devices for environmental hygiene control, namely heating, ventilation and air-conditioning systems (HVACS).

The World Health Organisation defines sustainability, as applied to health systems as a process to 'improve, maintain, or restore health while minimizing negative effects on the environment'. As discussed in the previous section, operating rooms are the most energy- and resource-intensive part of the hospital, and thus, Net Zero health systems cannot be achieved without green surgery (Nepogoodiev and Bhangu, AAMI, 2022). A study examining operating suites in Canada, the USA, and the UK found that a typical operation has a carbon footprint of 146–232 kg carbon dioxide equivalents (MacNeill et al., 2017). Other work identified consumable equipment as one of the carbon hotspots in an operation (Rizan and Bhutta, 2021). Alongside the need to ensure the reliable performance of the medical textile item in performing the action expected in its subcategory, there are growing concerns about the negative impacts that the use, maintenance and disposal of medical textiles are having on the environment. Practice Greenhealth™ (Reston, VA, USA) has developed the business case and step-by-step guidance documents to give practical help in developing a sound basis from which to reach decisions about what choices to make for the operating room to improve environmental acceptability (Practice GreenHealth, 2022). Adaption of their work should prove of significant assistance in the development of improved processes, procedures, and equipment to suit other regions and other areas of healthcare and enhance their environmental acceptability.

Medical textile items for use in the greener health system should be designed to fit within a circular economy. Designing for circularity, where products or their components are reused or recycled at the end of the current product's lifecycle means that factors such as in-built durability, ease of disassembly and the ability to reuse need due consideration. Alongside satisfying the existing performance and reliability criteria, in future, the design and procurement of items must additionally focus on using renewable and sustainable raw materials, reducing the amount of resource consumed, using sustainable manufacturing processes, and minimising waste (resource efficiency), designing for ease of maintenance, disassembly, and reuse (circular design) and ensuring the possibility of repeated safe use of a textile product (product-life extension).

Medical supply chains are a major source of greenhouse gas emissions. Whilst the production and transport of items and their disposal are not under the direct control of healthcare providers, the decisions about what should be purchased, its specification and the approval of suitable suppliers does rest with those involved in procurement within healthcare organisations. A complicating factor in achieving a medical-textile circular economy is that the textile industry has not yet developed the ways and means to achieve the overarching aim of a circular economy for itself, and this will have implications for those working towards sustainable healthcare procurement, particularly as many of the textile items are medical devices and must meet strict regulatory standards (Claxton & Kent, 2020; United Nations Development Programme, 2022). The extent to which circularity is being achieved can be obscured by the highly globalized, complex and extremely-fragmented nature of the supply chain (Ki et al., 2020). Many medical textile manufacturing firms are located outside the Western consumer markets; ethical corporate governance is often an unresolved issue hence it can be challenging to access sufficient reliable information either for full traceability or to determine a procurement footprint. It would be easy to dismiss fashion-clothing retail supply chains as unrelated and irrelevant, but important lessons can be learned from fashion retailers about the intensity of supervision necessary to ensure that product designs are followed through and that items meet the required specifications. Every significant operation is checked through the meticulous application of over 300 specified supply-chain-management supervisory steps (Chen et al., 2007). Retailer representatives visit the suppliers' design, production, and warehousing facilities to run checks on a weekly basis. Nothing operates only on the basis of trust.

One of the first matters to consider to assist transitioning to a greener health system is the value, both environmentally and financially, of moving away from disposable to reusable textile items. Sun recommended that when considering disposable and reusable medical textiles those involved in procurement should seek to improve protective performance, reduce cost, and minimise the environmental impact from medical textiles, the most appropriate of which might be disposable or reusable (Sun, 2011). Whilst single-use disposables do have some attractive features and are the sensible choice in certain settings where the number of items being used is small and/or treatments are being applied in emergency situations, in most situations they have the potential to incur high recurrent costs and to make a substantial contribution to pollution. How to make the decision about which type to use was already well-addressed by the 1980s by Walton, who recommended that the use of disposables should be reserved for low-volume applications. These were applications where it was not going to be economical either to contract out or equip for future decontamination or for sterilisation (Walton, 1986).

Instant reductions in environmental impact are achievable at the site of surgery through eliminating the consumption of unnecessary items and by choosing to use reusables where possible. Repairing reusable textiles, such as surgical gowns and surgical drapes, allows them to be retained within the system and complete their full life cycle. Pleasingly, there is a small study demonstrating that repairing drapes with patches does not appear to increase microbial load (Sharplin & Hooper, 2019), otherwise disassembly of the item, recovery of useful component parts then reassembling them to make new items (for use within healthcare or other settings) is worthy of consideration. Whilst remanufacture is often a cost- and resource-effective treatment method compared to recycling (which often requires energy and chemical-intensive treatment processes), intelligent design of the original item can further facilitate easy disassembly and remanufacture by incorporating bonding and stitch types that assist with disassembly (Dissanayake & Weerasinghe, 2021).

If a garment or its constituent fabric is not in a condition to be reused, consideration should be given to the recycling of fibres wherever possible. Recycling facilities in hospitals may be highly variable, but good recycling systems are usually both environmentally and financially preferable to disposal (Campion et al., 2015). The proportion of operating-theatre waste that is potentially recyclable has been estimated at 55% by weight (McGain et al., 2015). This proportion can be increased if infectious or biologically-contaminated waste is decontaminated prior to recycling. One potential problem that currently exists with recycling in the hospital environment is the mixing of textile wastes such as polyester/cotton blends with 100% cotton, 100% polyester or with other fibre types. Technologies such as near-infrared spectroscopy which is a fast, non-destructive, and efficient method of determining fibre type could provide a solution for mixed textile waste separation (Wei et al., 2015).

Recycling technologies are divided broadly into mechanical and chemical recycling. Mechanical recycling pulls apart the fabric to reduce it to short fibres which then need to be separated physically to allow further processing. Thermal recycling applied to thermoplastic waste materials is perhaps the simplest recycling process; it involves melting of the fibres then extrusion of the molten polymer to obtain new filaments able to be used in filament form or to be cut/broken into fibres and re-spun into yarns. Chemical processes are also available to enable the separation of the fibre components from fabrics made with fibre blends such as the polyester/cotton blend used in some types of healthcare apparel. Already used in the fashion sector, there have been studies reporting promising results; these suggest that a recycling rate of more than 93–96% is achievable leading to a carbon-footprint reduction of 1440–1534kg of CO_2 and an economic return of US$1466-1629 per tonne (Yousef et al., 2020; Zamani, 2014). Rather than reusing the fibrous material as fibre, fibres from the medical textile could be regarded instead as a useful source of organic chemical compounds and converted to yield products which may be used in other industry sectors thereby avoiding the need for disposal by incineration or landfill, for example, cellulose being converted to glucose or nano-cellulose (Li et al., 2019; Ling et al., 2019). Currently, however, recycling markets are often unreliable, and contamination of recycling streams leads to much material intended for recycling being thrown away.

Disposal should be the last option to consider once all the above options have been exhausted, but even at this stage, there are actions which are more acceptable, for example by using waste contractors who provide more-preferable methods of disposal, such as incineration with energy recapture rather than landfill.

Medical textiles in a greener operating theatre

A range of items are recommended for personal protection in the healthcare and surgical environment have been neatly summarised by Park and include those considered necessary during an epidemic or pandemic. Park's comparison includes the recommendations of the Korean Centers for Disease Prevention and Control (KCDC), the World Health Organisation (WHO), The US Centers for Disease Prevention and Control (CDC) and the European Centres for Disease Prevention and Control (ECDC) as shown in Table 1 (Park, 2020).

Surgical masks and filter facepieces

The medical facemask is a loosely-fitting item intended to act as a barrier to help protect the wearer from liquid splashes and sprays, such as blood, that they may be exposed to during certain medical procedures and to help capture some particles and droplets expelled by the wearer, such as those that may contain viruses and bacteria. A typical structure and composition is shown in Figure 2.

The terms *Surgical Respirator, Surgical Mask* or *Facemask* when used in the United States, refer to Food and Drug Administration (FDA)-cleared surgical-, laser-, isolation-, dental-, and medical-procedure masks with or without a face shield. They are approved in the US based on their performance under test for particle filtration efficiency, bacterial filtration efficiency, fluid resistance, differential pressure, and flammability specified by NIOSH (National Institute for Occupational Safety and Health); the N95 is the most-commonly used. Higher performance types are available but they resist the breathing action of the wearer more severely. Elsewhere the Surgical Respirator may be described as a filtering half mask, but more commonly a Filter Facepiece (FFP). The FFP2 is broadly similar in performance terms to the N95. Both are designed to fit tightly to the face to prevent airborne contaminants from being inhaled by the wearer, with the facepiece comprised entirely of the filter material. By comparison, the surgical or medical mask fits loosely over the face and is designed to prevent the emission of respiratory droplets and aerosols from the wearer and to prevent the exposure of droplets or spray onto the mouth or nose of the wearer (Brosseau et al., 2021; Godoy et al., 2020).

A typical structure for a N95 filtering facepiece respirator fitted with a ventilator for easy release of the air being breathed out is illustrated in Figure 3. It will protect the wearer but not the patient. Models without the ventilator serve to protect both the wearer and the patient, but breathing in and out through the respirator requires more energy. In the surgical area, models without the ventilator are required.

The standards applied to Filtering Facepiece Respirators and Surgical Masks and their key features are shown in Table 2.

The need for Filtering Facepiece Respirators (FFRs) with Surgical Mask capabilities such as fluid resistance and flammability, with the capacity to act as one form of personal protective equipment (PPE), was first addressed by the FDA in 1996 through the introduction of the Surgical N95 Respirator. In the European Union, the recommended FFR must meet the requirements of the more demanding European standard for filtering half masks, EN 149:2001 + A1:2009, wherein there is also a need to be able

Table 1. Comparisons of personal protective equipment recommendations (Park, 2020).

Settings	KCDC (March 2020)	WHO (April 2020)	CDC (May 2020)	ECDC (May 2020)
Triage: patient examination with direct contact	• KF94 mask or equivalent respirator • Eye protection[a] • Gown[b] or coveralls with foot covers • Gloves	• Medical mask • Eye protection[a] • Gown[b] • Gloves	• N95 respirator (or facemask if a respirator is not available) • Eye protection[a] • Gloves	• Surgical mask or, if available, FFP2 respirator • Eye protection[a] • Gown[b] or apron • Gloves
Usual inpatient care	• KF94 mask or equivalent respirator • Eye protection[a] • Gown[b] or coveralls with foot covers • Gloves	• Medical mask • Eye protection[a] • Gown[b] • Gloves	• N95 respirator (or higher-level respirator) or facemask (if a respirator is not available) • Eye protection[a] • Gown • Gloves	• Surgical mask or, if available, FFP2 respirator • Eye protection[a] • Gown[b] or apron • Gloves
Aerosol-generating procedures[c]	• KF94 mask, equivalent respirator, or PAPR • Eye protection[a] • Gown[b] or coveralls with foot covers • Gloves	• N95, FFP2, or FFP3 respirator • Eye protection[a] • Gown[b] • Gloves • Apron (if gowns are not fluid-resistant)	• N95 or higher-level respirator • Eye protection[a] • Gown[b] • Gloves	• FFP3 respirator • Eye protection[a] • Gown[b] • Gloves
Collecting specimens (not involving aerosol-generating procedures)	• KF94 mask, equivalent respirator, or PAPR • Eye protection[a] • Gown[b] or coveralls with foot covers • Gloves	• Medical mask • Eye protection[a] • Gown[b] • Gloves	• N95 respirator or higher-level respirator (or facemask if a respirator is not available) • Eye protection[a] • Gown[b] • Gloves	Enclosed spaces: • Surgical mask or, if available, FFP respirator • Eye protection[a] • Gown[b], gloves Drive-through or outdoor facilities: • Surgical mask

PAPR, powered air-purifying respirator; FFP, filtering facepiece.
[a]Eye protection includes goggles or a face shield.
[b]Gown refers to a long-sleeved, fluid-resistant gown.
[c]Aerosol-generating procedures include endotracheal intubation, non-invasive ventilation, tracheostomy, cardiopulmonary resuscitation, manual ventilation, bronchoscopy, open suctioning, sputum induction, nebulizer therapy.

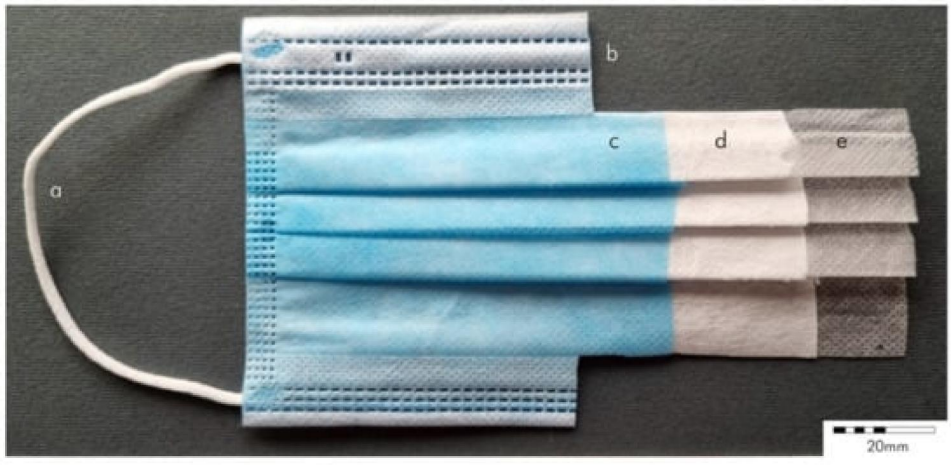

Figure 2. Components of a surgical-type single-use face mask. (a) Elastic ear loop; (b) heat-wielded seam; (c) outer layer of spunbond polypropylene fabric; (d) Central core of melt-blown polypropylene fabric; (e) inner layer of spunbond polypropylene fabric (spennemann, DHR, 2022).
Spennemann, DHR. 2022. 'COVID-19 Face Masks as a Long-Term Source of Microplastics in Recycled Urban Green Waste' *Sustainability* 14, no. 1: 207. https://doi.org/10.3390/su14010207

to withstand additional challenge by an oily substance and to demonstrate higher efficiency levels than the N95 respirator (although the difference in efficiency between the N95 and the widely used FFP2 is only slight). Korean standards for their KF80, KF94, and KF99 respirators follow the European standards (Park, 2020). BS EN 149:2001 + A1:2009 is the British Standard to which respiratory protective devices are tested using sodium chloride and paraffin oil at 95 l/min.

High filtration efficiency is essential, but typically, higher efficiency comes with increased difficulty in drawing the air through the filter as the wearer breathes in, pointing to the need for great care to ensure completeness of fit to ensure that unfiltered air is not drawn in from the sides. Guidance on the use of respirators and facial protection equipment was therefore developed and published by the Healthcare Infection Society Working Group on Respiratory and Facial Protection (Coia et al., 2013).

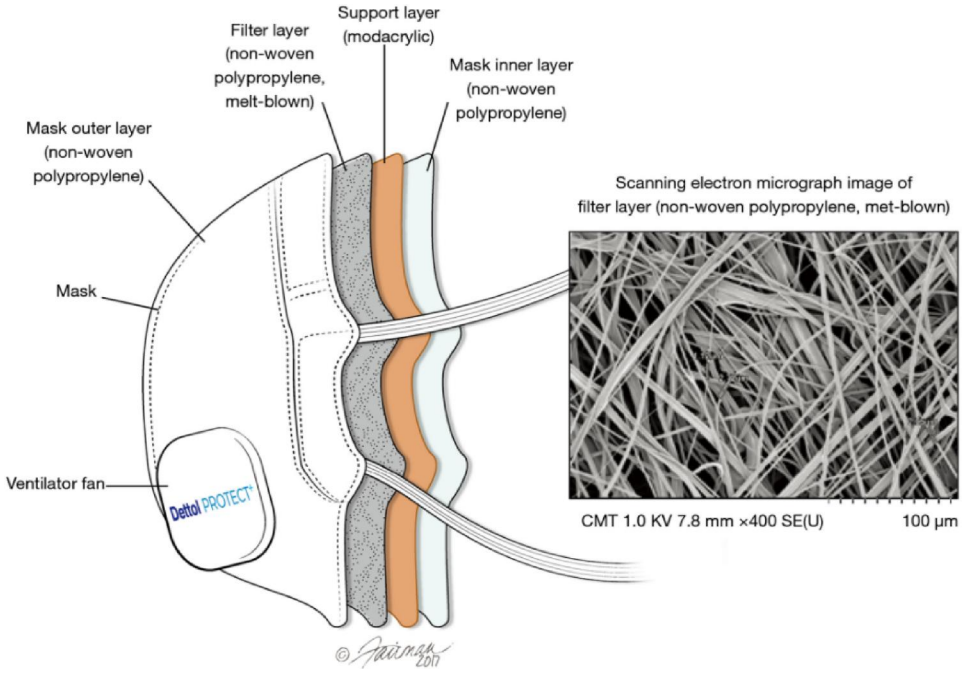

Figure 3. Layered construction of the N95 respirator (Zhou et al 2018).
S. Steve Zhou1, Salimatu Lukula1, Cory Chiossone1, Raymond W. Nims2, Donna B. Suchmann1, M. Khalid Ijaz
Journal of Thoracic Disease
Vol 10, No 3 (March 31, 2018) Assessment of a respiratory face mask for capturing air pollutants and pathogens including human influenza and.

Table 2. Standard test methods for filtration efficiency (Jones Rm & Rempel D, 2021).

	Filtering facepiece respirators			Surgical masks		
Standard	TEB-APR-STP-0059 (NIOSH, 2019)	EU EN 13274-7	GB 2626-2006	ASTM F2299	ASTM F2101	EU EN 14683 + C1
Particle material	Sodium chloride	Sodium chloride	Sodium chloride	Latex spheres	*S. aureus* bacteria	*S. aureus* bacteria
Particle size	Polydisperse CMD = 0.075 ± 0.020 µm GSD ≤ 1.86	Polydisperse CMD = 0.06–0.1 µm GSD 2.0 to 3.0	Polydisperse CMD = 0.075 ± 0.020 µm GSD ≤ 1.86	Monodispersed in range 0.1–5 µm	Mean 3 ± 0.3 µm	Mean 3.0 µm
Particle charge	Neutralized	Not specified	Neutralized	Neutralized	Unneutralized	Unneutralized
Item tested	Entire facepiece	Entire facepiece	Entire facepiece	Material sample, 100 cm^2	Material sample, size unspecified	Material sample, at least 100 mm^2
Flow rate	85 L/min	95 L/min	85 L/min	28.3 L/min	28.3 L/min	28.3 L/min
Particle measurement	Particle count by light-scattering laser photometers	Particle count by light-scattering laser photometers	Particle count by light-scattering laser photometers	Particle count by light-scattering laser photometers	Colony Forming Units by the 6-stage sampler	Colony Forming Units by the 6-stage impactor

Jones RM, Rempel D. Standards for Surgical Respirators and Masks: Relevance for Protecting Healthcare Workers and the Public During Pandemics. Ann Work Expo Health. 2021 Jun 12;65(5):495-504. doi: 10.1093/annweh/wxab008. PMID: 33942848; PMCID: PMC8135753.

Research to produce a 'better' mask has taken several different avenues including the fit of the mask and the style of the mask, with other work assessing the effectiveness of finishing the fabrics with antimicrobial and antiviral compounds to improve filtration (Li et al., 2006; Shen H and Leonas KK, 2005) and attention was also paid to improving filtration not just by the physical properties of the fabric but by the inclusion of electrets to attract particles and aerosols and more-recently, because of their potential to improve filtration performance, the incorporation of nanofibre webs (Rossin et al., 2023; Suen et al., 2020; Wang et al., 2018). It has been shown that N95 masks (which do contain an electret layer) retain their performance through storage for periods of at least ten years, which is something to be considered when planning the stocks for future pandemics (Viscusi et al., 2009a). The use of surgical N95 FFRs, in both surgical and non-surgical environments, increases markedly during outbreaks involving a known or suspected respiratory pathogen. To combat transmission of such diseases, respirators need to be able to filter out extremely-fine particles of dimensions equivalent to those of the responsible viruses or their aerosols. Such particles are classified by BS EN ISO 16890 into three categories PM10 (less than 10 µm), PM2.5 (less than 2.5 µm), and PM1(less than 1 µm).

With the advent of a growing number of pandemic threats, there has been continued interest in finding the 'best mask' to

prevent infection amongst healthcare workers. The 2009 H1N1 influenza pandemic and 2020 COVID-19 pandemic saw contradictory recommendations given by leading authorities depending upon whether the authority wrote guidance based upon a risk or a hazard analysis. It would seem reasonable to suggest that, rather than pedantically abiding by just one or the other, organisations such as The Health & Safety Executive in the UK, and The Occupational Safety and Health Administration in the US, should recommend using both risk and hazard analysis.

COVID-19 pandemic

The limited supply of masks in the COVID-19 pandemic saw guidance released upon reuse and decontamination of masks. There is still, however, not only a lack of research around how long a mask remains effective in actual use but also a problem with acceptance of possible treatments for the decontamination of respirators and a lack of official certification to replace the emergency permission which was temporarily put in place to enable their re-use after exposure to the COVID-19 virus during the first phase of the pandemic. Lack of official engagement with the development and certification of re-useable respirators remains the current situation despite useful baseline research conducted ten years ago by Viscusi, Bergman, and co-workers (Bergman et al., 2010; Viscusi et al., 2009b). Their work was undertaken following concerns in the USA by health officials about a potential shortage of masks following the H1N1 outbreak in 2009. Another group in the United States, the Department of Veteran's Affairs, established the 'BREATHE' project which intended to develop an improved, re-useable N95 respirator design for health care personnel to be called the B95, but nothing has entered into use from this project (Gosch et al., 2013). Ten years after the H1N1 epidemic, when COVID-19 had been spreading for six months, it was clear that lessons about the danger of shortages caused by dependence on single-use PPE had not been fully accepted, and that preparations for the pandemic were seriously inadequate. Responding to the worsening situation, Stanford University established a rapidly growing volunteer group called N95DECON to create a set of best practices on the decontamination and reuse of N95 respirators (N95DECON., 2020). Several decontamination methods were proposed, some of which were based on the earlier work published by Viscusi et al. and Bergmann et al. and although several decontamination methods were allowed by the FDA during the height of the COVID-19 pandemic, none of the N95DECON methods were included. The FDA brought its Emergency Use Authorisation for decontamination and reuse to a close at the end of June 2021, so once again only single-use respirators were approved in the US.

During the early stages of the COVID-19 pandemic, because of developing shortages, there was a need for a special category of decontamination and cleaning arrangements to be applied to filter facepieces and facemasks originally intended for single-use only, and these were determined on a country or regional basis:

United States The Battelle CCDS Critical Care Decontamination System™ was an early example of the systems which received EUA (Emergency Use Authorisation) from the US Food and Drug Administration at that point, i.e. in March 2020 (Batelle Media Relations, 2020). EUA is not necessarily without its problems. That system, based on the application of vapour-phase hydrogen peroxide, was widely used but came under criticism from users for its claim to be able to be applied 20 times. The original permission was revoked by the FDA in January 2021. Given the restriction on its application to only the Battelle Institute and with the numbers of repeated applications being reduced to four times (US Food & Drug Administration, 2021) the system was voluntarily withdrawn from EUA by Batelle in April 2021. Fewer such difficulties would be encountered with the filter facepiece designs equipped with removable filters because only the removable filter would need to be able to survive the rigours of the decontamination treatment, not the whole of the facepiece. In fact, in the early stages of its introduction, it may prove impractical to try to make the filter reuseable in which case a replaceable filter of conventional composition could be employed to begin with (as it happens, having any type of replaceable filter will in itself yield most of the potential savings in resources, cost and benefit to the environment).

Two of the longer-term benefits realised because of the inadequacy of the response to the COVID-19 crisis were the need for the development and dissemination of reprocessing guidance, and recognition of the benefits of providing more advice about how to proceed with the development of new medical devices. For example,

> *Canada*: the Government now provide thorough guidance on medical devices for Covid including how to recognise products which have passed the correct medical device regulations (Government of Canada, 2023a). In addition, they provide a technical specification for a transparent mask to enable improved communication by those who are hard of hearing (Government of Canada, 2023b) plus information on strategies to use in times of shortage, including how to reprocess single-use masks and respirators (Government of Canada, 2023c, 2023d).
>
> *Japan* also has guidance on reprocessing and necessary regulatory paperwork (Director of the Medical Device Evaluation Division, 2017) and in Australasia, the Therapeutic Goods Administration released guidance on the reprocessing of masks during the pandemic to allow for safe reuse (Department of Health and Aged Care, 2021). By contrast, NZ did not support mask reprocessing (New Zealand Sterile Sciences Association, 2020).

Considerable work on the development of reusable filter facepieces has already been reported, much of it stimulated by the shortages in supply during the COVID-19 pandemic particularly in the:

> *Europe and Switzerland:* As was the case for the FDA in the United States, the European Centre for Disease Prevention and Control published extensive guidance via their 'Options for decontamination and reuse of respirators in the context of the COVID-19 pandemic' (European Centre for Disease Prevention & Control, 2020) which gave details of the methods it considered appropriate, as shown below in the section 'Reusable Filter Facepieces'.

Their list was extensive and included details of the various treatments' considered suitable for application in a healthcare environment, including

i. Biocidal Ultraviolet Irradiation,

ii. Ethylene Oxide Irradiation,
iii. Moist Heat Incubation,
iv. Dry Heat Treatment, and
v. Reuse by the same individual of the used respirator after storage for a minimum of 5 days,

They also suggested the following caused too much damage to the respirators or were inappropriate to be applied in the hospital setting.

i. Steam sterilisation,
ii. Gamma Irradiation,
iii. Microwave Irradiation,
iv. Autoclaving,
v. Alcohol Solutions, and
vi. Chlorine-based Solutions,

In Switzerland efforts were made to explore the possible benefits from the decontamination and reuse of FFP2 respirators, and to determine the savings accruable from the processes. The treatment they adopted was the V-PRO® maX Low Temperature Sterilization System which uses low temperature gaseous hydrogen peroxide (STERIS 5960 Heisley Road Mentor, OH 44060, USA), one of the United States FDA Emergency-Approved decontamination methods. This enabled 10 cycles of decontamination and reuse to be applied at an overall cost of 0.5 Euro per cycle, a significant saving over the practice of single-use (Widmer & Richner, 2020).

United States. The accent was on decontamination to enable the reuse of N95 masks with the aim of stimulating interest so that successful procedures could be included in the then limited Food and Drug Administration list of treatments approved under the EUA, 'Emergency Use Authorisation of Decontamination Systems for Personal Protective Equipment' namely:

i. Vaporised hydrogen peroxide
ii. Vaporised hydrogen peroxide followed by ozone
iii. Steam sterilisation

What was clear from examination of the exact systems that were approved was that the design of the decontamination delivery system and its ability to be precisely controlled were of key importance alongside the agent or physical treatment being applied.

Independently, the N95DECON consortium of volunteer scientific specialists (N95DECON., 2020) independently prepared a useful list of decontamination and reuse processes during the COVID-19 pandemic under three headings:

i. Methods being implemented in hospitals (H_2O_2 vapour, H_2O_2 gas plasma, UV-C, moist heat).
ii. Methods not well-established but under investigation (microwave-generated steam, room-temperature storage, liquid H_2O_2, steam autoclave, dry heat, immersion in boiling water, multicooker, chlorine dioxide and ozone).
iii. Methods that are not recommended for use (alcohol submersion, bleach submersion, soapy water submersion, exposure to daylight, ethylene oxide, formaldehyde vapour and gamma ray irradiation).

A valuable cost analysis applied to cover the first six months of the COVID-19 epidemic in the United States indicated that the redesign of the respirator to include an exchangeable filter was by far the most resource- and cost-effective option (Chu et al., 2021).

United Kingdom. Early on in the pandemic, the National Engineering Policy Centre released a commentary on reprocessing of PPE based upon international experience (National Engineering Policy Centre, 2020) and the Scientific Advisory Group for Emergencies considered the processing of PPE for re-use. Re-use was only to be considered as a temporary measure in supply-chain failures. In addition to material issues with reprocessing, such as weakening of nose bands on masks, ineffective sterilisation and degradation of elastic in elastic straps, cultural dissonance was also recognised as a factor that may prevent reprocessing (Environmental & Modelling Group, 2020). More detail about the prospects for successful decontamination and reuse was provided by the Nuffield Centre for Evidence-based Medicine which undertook a rapid systematic review. It tabulated the Review's own conclusions about particular treatments applied to extend the life of a single-use respirator against those of the Centers for Disease Control in the United States, the European Centre for Disease Prevention and Control, and the World Health Organisation's (Toomey et al., 2020). A short list of procedures which could be extracted from the review was:

i. *Effective sterilisation while maintaining mask integrity*
   - Vapourised hydrogen peroxide
ii. *Effective sterilisation while maintaining mask integrity (some models)*
   - Microwave heating; dry or moist (60–90 °C)
   - Other heating (60–90 °C)
   - Ultraviolet germicidal irradiation
iii. *Further research needed*
   - liquid hydrogen peroxide
iv. *No systematic review evidence*
   - Ozone
   - Gamma Irradiation
   - Disinfectant wipes
v. *Not recommended*
   - Autoclaving/heat >90 °C (damages mask)
   - Ethylene oxide (health hazard)
   - Ethanol/isopropyl alcohol
   - Sodium hypochlorite (affects function)

Japan/South Korea. Attention was focussed on the development and testing of nanofibre filters by a team from Korea and Japan. The nanofibre filters were able to be washed in alcohol then reused with no loss in performance (Ullah et al., 2020). In follow-up work in Korea, in one particular

example, the need for the electret component typically included in the currently-available N95 and FFP2 single-use respirators was eliminated. Instead, it made use of a filter pad created by precisely arranging nanofibres by block electrospinning to more-closely control the pore size and reduce the chance of virus particles passing through the filter to a much-greater extent than that achievable by a random fibre arrangement. That filter was shown to be able to retain its high filtration performance for 20 washes in alcohol (Kaist, 2020).

Environmental impact of surgical masks/filter facepieces

As mentioned earlier, one of the most-widely-used ways of estimating the impact of an item or activity on the environment is to determine its carbon footprint through life-cycle assessment; international standards provide guidance in the 14000 series+ (International Organization for Standardization, 2006a, 2006b). Detailed descriptions have been reported about how the life-cycle assessment of textile items can be conducted and used to determine their impact on the climate; the need to establish the uncertainties at each stage of the assessment because of the paucity of data available, then to integrate them in the full assessment to be able to gain an understanding of its reliability has also been explained (Bevilacqua et al., 2011; Lo et al., 2005; Moazzem et al., 2018). A number of attempts have been made to determine the environmental impacts of single-use respirators and facemasks, driven particularly by the COVID-19 pandemic. It was determined that the single-use surgical mask had a carbon footprint of 0.059 kg CO_2-eq and a N95 respirator 0.05 kg CO_2-eq (Klemeš et al., 2020); the value for the N95 respirator did not include transport but whilst not determined in exactly the same way, serves to show that the carbon footprints are of similar magnitude. The numbers of users are vast, so when these values are multiplied by numbers used, the total carbon footprint is extremely (Luo et al., 2023).

Reducing the environmental impact of filter facepieces

Interest has been shown in determining practical methods by which the degree of environmental impact and the financial cost of filter facepiece protection might be reduced. Several approaches have been explored:

i. *Reuse of disposable respirators*
The filter facepieces currently available are designed to be single-use items, but under the supply pressures brought about by the COVID-19 pandemic, searches were conducted to identify sufficiently gentle but effective decontamination treatments to enable reuse. Several have been identified, but their suitability will depend on what equipment is or could be made available to the hospital. An analysis of the benefits of applying the low-temperature gaseous hydrogen peroxide method (Widmer & Richner, 2020), which enables reuse for 10 times illustrated its significant financial benefits compared with single-use only. It would be reasonable to assume that there would be comparable levels of environmental benefit, but those calculations were not made. Using another acceptable but different decontamination method, it was found that applying steam sterilisation to used FFP2-type single-use respirators reduced the carbon footprint by 58% given that the respirators were able to be reused 5 times (van Straten et al., 2021).

ii. *Redesign of the surgical respirator*
For surgical filter facepieces, a cost and modelling analysis applied to the first 6 months of the COVID-19 epidemic in the United States (Chu et al., 2021) showed: Significant savings could have been made from respirator reuse in terms of the numbers of respirators required and the associated costs whichever of the two most-common types of decontamination system was applied. H_2O_2 vapour decontamination to enable reuse reduced the number of respirators required and the associated costs and waste by about 40% whereas ultraviolet germicidal irradiation treatment to decontaminate and enable reuse was even more cost-effective achieving about a 50% reduction. Redesign would be most beneficial. The most outstanding savings would be achieved by a redesigned re-useable respirator equipped to take either disposable or re-useable filters intended to be replaced daily, which would reduce the number of respirators required by 94%. Adopting the model with the re-useable replaceable filter would be the cheapest option with the least waste of all because that would halve the (small but significant) remaining cost per use compared with the disposable removable filter option (Chu et al., 2021). The main casing holding the replaceable filter in the redesigned re-usable respirator would need to be treated with a fast-acting antimicrobial finish, so that the changing of the filter could safely carried out before its next use. A rechargeable, fast-acting, non-volatile and odour-free N-halamine called MC was found to be effective against the avian influenza virus in a chicken hatchery when applied as a finish to the nonwoven filter fabric (Ren et al., 2018). Its potential should be further explored. The need for such a fast-acting treatment has been amply demonstrated by a flawed design developed to try to overcome respirator-supply problems in one area in Canada (CBC News, 2023). Also, whatever approach is used to generate reusable respirators, it will be essential to include a means of tracking and recording numbers of decontamination cycles to which they are exposed to determine their end of life as a useful PPE device and take them out of service.

Reducing the environmental impact of surgical masks

The benefits in financial terms and on environmental of making the surgical mask so that it can be decontaminated

and reused multiple times are expected to be similar to those for the FFP respirator.

Surgical gowns and surgical drapes

Surgical gowns were introduced primarily as a protective barrier to reduce surgical site infection and protect the patient from the surgical team by limiting the escape of skin squames shed by the user and by preventing the direct transmission of pathogens. The gown is also intended to offer protection to the surgical team from the patient whilst keeping the surgeon and team comfortable, particularly when worn for lengthier periods of time (Aibibu et al., 2003; Aslan et al., 2013). To these ends, the ANSI/AAMI PB70:2012 standard classifies surgical gowns and drapes into four levels in terms of their liquid barrier performance, see Table 3. The standard also provides details about the design, construction and the increasing performance requirements needed to achieve the required performance at each level (AAMI, 2012).

A recent update (AAMI, 2022), ANSI/AAMI PB70:2022 (PB70) includes additional categories:

- Surgical Gown–E: A specialized gown which provides extended protection of critical zones—defined as the areas where direct contact with blood, bodily fluids, and other potentially infectious material is most likely to happen.
- Non-surgical Protective Gowns: including procedure gowns and decontamination gowns which also include protective full-coverage gowns, protective gowns with non-protective backs, and protective gowns with open backs.
- Protective hoods and togas were also added along with a general category of other protective apparel items such as aprons, footwear covers and sleeves.

For Europe, the standard which applies is EN 13795-1:2019, and in the UK, BS EN 13795-1:2019; this standard recognises two performance levels: 'standard performance' and 'high performance' based on the barrier performance of the gown in critical areas. Unlike ANSI/AAMI PB70, EN 13795 does not specify critical areas, but leaves it to the surgical practitioner to decide, based on their risk assessment relating on the procedure being undertaken (British Standards Institution, 2023).

There has long been recognition of the importance of pore size between fibres in the gown fabric in enabling/preventing transmission of microbes, the differences in the ease of their transmission between the wet and dry fabric states, and the effect of pressure on the fabric on microbial transmission. More recently, the effects of yarn float size and thread density in woven surgical gowns on moisture penetration and air permeability have been modelled, and that demonstrated that tightly-woven fabrics with shorter floats, such as plain weave structures, were better able to provide moisture-penetration resistance but were less able to provide sufficient air permeability (Maqsood et al., 2016). Even so, despite great enthusiasm being shown for investigating the best types of fabric for a surgical gown, replication of results *in vivo* and *in vitro* often differ (Gulihar et al., 2009). A similar situation applies in establishing the benefits (or otherwise) of antimicrobial finishing treatments for fabrics used in PPE.

There are other challenges. Well-intentioned changes to the design of the gown rather than the fabrics used, their fibre composition and finishing treatments, such as the introduction of total body exhaust suits by Charnley, have not proved to be successful, showing instead to increase wound contamination and surgical site infection in arthroplasty (Hooper et al., 2011); the glove-gown interface remains a source of potential contamination (Fraser et al., 2015).

Reusable and disposable surgical gowns and drapes

Both reusable and disposable types of gown and drape are available, see Figures 4 and 5. According to the World Health Organization, sterile surgical drapes are used during surgery to prevent contact with unprepared surfaces and maintain the sterility of environmental surfaces, equipment and the patient's surroundings. Similarly, sterile surgical gowns are worn over the scrub suit of the operating team during surgical procedures to maintain a sterile surgical field and reduce the risk of the transmission of pathogens to both patients and staff. Surgical gowns and drapes are fabricated from either multiple- or single-use materials. In addition, there is a considerable variation in design and performance characteristics within each of these two broad categories, which reflects the necessary trade-offs in economy, comfort and degree of protection required for particular surgical procedures. During surgical procedures, the risk of pathogen transmission increases if the barrier materials become wet. Consequently, the multiple- or single-use materials of the drapes and gowns used in a surgical procedure should prevent the penetration of liquids. Reusable materials are typically composed of different tightly-woven textiles

Table 3. Levels of surgical apparel and drapes as per ANSI.AAMI PB70:2012 standard (AAMI, 2012).

Level	Description
1	Minimal fluid barrier protection – not suitable for surgical procedures
2	Low fluid barrier protection suitable for procedures with low risk of liquid exposure
3	Medium fluid barrier protection suitable for most procedures
4	High fluid barrier protection suitable for procedures with high volume liquid exposure

Authors own work based upon AAMI Standard.

Figure 4. Reusable surgical gowns and drapes – authors own.

Figure 5. Disposable surgical gowns and drapes – authors own.

and/or knitted cotton or other fabrics possibly blended with polyester and/or chemically treated; these products have to be durable and provide protection after many cycles of processing and treatment (World Health Organization, 2016). A typical fabric for a gown or drape for the standard performance class in the UK might consist of 100% polyester woven filament fabric with a carbon thread every 100 threads to reduce electrostatic build up with a fluorocarbon finish, whereas those for high performance would incorporate a multi-layer laminates with PTFE, polyethylene or polyurethane microporous membranes to prevent liquid penetration in the areas most likely to be exposed to splashing and pressure Figure 6.

Disposable surgical drapes and gowns are typically composed of non-woven material of synthetic and/or natural origin, possibly combined with chemical treatment; such gowns are most often constructed from nonwoven polyester or polypropylene fabrics (World Health Organization, 2016). A brief outline of different types, how to select the type needed and the standards which apply in Europe are available online (Euronda, 2023). For example, a spunbonded/meltblown/spunbonded (SMS) 3-layer arrangement can be used to provide the necessary durability. Spun-laced nonwoven fabrics created by the hydro-entanglement of card webs consisting of polyester fibres, can be combined with an outer web consisting of cellulose pulp to improve wearer comfort. Typically, the cellulose outer layer would need to be treated with a liquid/soil-repellent finish to improve its resistance to the penetration of bodily fluids.

For greater fluid protection, high performance types can be created by laminating the outer layer with a microporous polyethylene film, whilst for virus protection, a three-layer arrangement can be used with the microporous film at the centre. Examples of such arrangements would be found for example in Barrier® surgical gowns (Mölnlycke, Gothenburg, Sweden) which are FSC certified (Molnlycke, 2023). Oher fabric structures may be employed, such as, polyester tricot fabric combined with a polyethylene barrier membrane intended to be able to be worn for long periods and certified to BS EN13795:2019 and ISO 16604:2015 Standards (Survitec Group Ltd. Ellesmere Port, UK).

There do not appear to be any tangible differences in terms of performance between reusable and disposable gowns and drapes in practice. WHO Global Guidelines for the Prevention of Surgical Site Infection recommend the use of either/both reusable or disposable gowns and drapes but acknowledged the paucity of evidence in this domain (World Health Organization, 2016) and a recent review of surgical-site infection in orthopaedic and spine surgery found no available evidence to support a difference between reusable or disposable gowns and drapes, and called for further research (Kieser et al., 2018).

Progressing towards environmental acceptability with drapes and gowns

One of the most-widely-used ways of estimating the impact of an item or activity on the environment is to determine

Figure 6. Scrub suits – authors own.

its carbon footprint through life-cycle assessment; international standards provide guidance in the 14000 series+ (International Organization for Standardization, 2006a, 2006b). Detailed descriptions have been reported about how the life-cycle assessment of textile items can be conducted and used to determine their impact on the climate; the need to establish the uncertainties at each stage of the assessment because of the paucity of data available, then to integrate them in the full assessment to be able to gain an understanding of its reliability has also been explained (Bevilacqua et al., 2011; Lo et al., 2005; Moazzem et al., 2018). Whilst estimates of the carbon footprint may vary depending on the methods applied in practice and the software systems employed, when identical reliable systems are employed, they clearly indicate the magnitude of the impact and enable reliable comparisons to be made. Overcash, in 2012, completed an analysis that combined the findings from six independent lifecycle assessments for gowns and drapes, carried out in terms of cost-effectiveness analyses and life-cycle testing. That analysis showed there was little cost difference to the hospital/institutional user between using disposable gowns and drapes compared with using reusables, but there were significant differences in terms of environmental impact (Overcash, 2012). The environmental impact differences arise because disposables require proportionately much greater amounts of energy and water per single use than the reusables which, whilst they require more energy and water initially, in the manufacturing stage, consume much less overall despite their need for laundering after each use, because they are used multiple times.

From an assessment involving the estimation not only of global warming, but also the environmental impacts of energy, water use, and solid waste consumption, it was shown that the reusables demonstrated a 30% reduction in greenhouse gas emissions, a 28% reduction in energy consumption, a 41% reduction in blue-water consumption and a 93% reduction in solid-waste generation when compared with the disposables. The estimates were generated for a 63 g nonwoven polypropylene gown, chosen as representative of disposable isolation gowns and a 240 g woven polyester gown chosen as representative of reusable gowns; they also reported that if the weight of the disposable gown could be reduced to around 45 g, the energy consumption and global warming potential for the disposable and reusable isolation gowns would be about even (Vozzola et al., 2018). Even so, water use and solid waste would remain higher; despite the water and energy requirements of the laundering of reusable gowns, because the repeated manufacture of new single-use items created significantly more impact on the environment than the consumption per use for the reusable item. Life-cycle assessment estimated that choosing reusable surgical gowns over disposable gowns reduced energy consumption by 64% and the carbon footprint by 66% (Vozzola et al., 2020). (Their calculations were based on the application of the US CDC decontamination and laundering recommendations which require heating of the laundry load and liquid to 71 °C. Application of low-temperature ozone laundering would swing the advantages further towards disposable items if they were laundered in this way (see *Decontamination and Laundering*).

Reprocessing of textile items originally intended for single use (*via* schemes designed to process, clean, and test the item to the relevant standard to enable re-use), already takes place in countries such as the USA and New Zealand (MedSalv, 2021) an activity which will serve to close the gap in environmental impact. There had been a misconception that the single-use items would be a better choice in terms of hygiene but that is not the case as was neatly summarized by the RACS Position Statement (Royal Australasian College of Surgeons, 2023) which stated that it had been shown that reusable surgical gowns are either equivalent or superior to disposable gowns in terms of:

i. sterility and infection prevention (World Health Organization, 2016),
ii. water resistance (McQuerry et al., 2021),
iii. comfort (Conrardy et al., 2010; Ross B and CICM FM, 2023)

and also

iv. that they are cost-effective (Ross B and CICM FM, 2023), and
v. have a vastly lower environmental impact as demonstrated in several life cycle analyses (Vozzola et al., 2020), and
vi. that implementing the routine use of reusable surgical gowns is a tangible and effective way that surgeons and hospitals can reduce the impact of surgery on the environment (Vozzola et al., 2018).

Switching to reusable surgical linens was also recommended in a joint report by the Royal Colleges of Surgeons of England, Edinburgh and Glasgow (Royal College of Surgeons of England, 2022), but this action may not provide the complete answer. Analyses of the economic and environmental benefits have already been undertaken across a range of surgical specialities (Tan & Lim, 2021; Van Demark et al., 2018) but again there remains a paucity of evidence; no randomised controlled trials aimed at assessing the occurrence of surgical-site infection in clean surgery with reusable and disposable gowns and drapes have been undertaken (Kieser et al., 2018). It may seem that compared with facemasks, ecological-acceptability in healthcare workers' protective clothing such as surgical gowns and drapes should prove easier to achieve. The introduction of synthetic fibres and the development of effective finishing treatments may have enabled a variety of beneficial changes to be made in the construction, durability, impenetrability, and soil repellency of the fabrics used in surgical gowns over many decades (Leonas and Jinkins, 1997), but whilst semi-permeable films incorporated as the central layer in laminated fabrics have proved successful in achieving Level 4 barrier protection (Parthasarathi & Thilagavathi, 2015), they are difficult to recycle.

A useful description of the factors to consider in the manufacture of surgical gowns has been prepared (King & Liang, 2020) and this could prove to be of considerable help

to those interested in its redesign for improved environmental acceptability. Compared with the standard gown, the design for the surgical gown is enhanced using barrier fabrics covering the front panel and the cuffs and lower sleeves to provide enhanced protection in those critical zones. In design terms, such requirements are not totally restrictive; it is the performance requirement which is the overriding criterion. The surgical gown is classified as a medical device hence it needs to satisfy approval standards set by the US Food and Drug Administration (FDA), but it is the performance of the gown rather than its design which is the overriding criterion for the FDA and the FDA has the facility to be flexible about how the performance criteria are met so long as it can be demonstrated that it is at least as safe and effective as a legally-marketed device (FDA., 2014). A similar situation applies with regard to the European/British standard, but in this case reliance is placed on the knowledge and experience of the surgeon to make the appropriate decision about the type of gown to deploy to provide the necessary protection for any particular procedure, rather than depending on some overarching body to specify what should be deployed (British Standards Institution, 2023).

Healthcare workers' clothing

Operating theatre scrub suits

As is the case with gowns and drapes, scrub suits may either be reusable or disposable, and the environmental benefits achievable from the reusable suits is therefore expected to be similar to that of those other types of protective wear. This particular type of healthcare workers' clothing requires separate attention because despite being reserved as operating-theatre attire, it differs from the sterile gown in that its primary objective is to reduce contamination of the air by skin squames and microorganisms shed by healthcare personnel. One observational study found that single-use polypropylene scrub suits reduced the median quantity of bacterial CFU/m^3 compared to two different reusable scrub suits (Kasina et al., 2016) whereas more recently it was considered to be the same for both types (Burguburu et al., 2022). However, there is still no study assessing the impact of the scrub suit on surgical-site infection rate. That said, if WHO guidance on surgical-site infection with reusable and disposable drapes and gowns is extrapolated, then the impact is likely to be minimal (World Health Organization, 2016).

Considerable research attention has been directed over the past 10 years towards the production of antimicrobial and antiviral fabrics, driven most recently by the COVID-19 pandemic and earlier epidemics, which stimulated widespread interest in PPE protection and its further development to help to guard against infection. Included in these activities were antimicrobial finishing treatments such as those based on the application of nanosilver/nanometal oxides, quaternary ammonium compounds, polyhexamethylene biguanide or N-halamines. One of the papers which emerged during the early stages of the COVID-19 pandemic (Karim et al., 2020), provided timely and helpful details of products already available for use in PPE with particular reference to antimicrobial agents, but it failed to explain why so few treatments with such agents have exhibited any beneficial effect in the practical setting. That shortcoming can largely be explained by failure to engage adequately in experimental design. The resulting uninformed selection of test methods means that the *in vitro* test results may have no value in predicting the effectiveness of antimicrobial fabric treatments intended to confer antimicrobial properties to items of PPE in the practical setting (Anderson et al., 2017; Murray, 2022; OECD., 2019, OECD, 2008). One exception is the antiviral barrier fabrics for gowns to prevent pressure transfer of contaminants (Parthasarathi & Thilagavathi, 2015) but separating and recycling of the barrier laminates from gowns at the end of their useful life remains problematic.

Properly designed trials undertaken in realistic situations are few and far between, but the trials which have been carried out have shown that existing antimicrobial treatments are ineffective in the practical setting. For example, the treatment of protective workwear with antimicrobial agents coupled with soil repellents was shown in the ASCOT Trial to be largely ineffective in terms of the elimination of cross contamination (Anderson et al., 2017). It is therefore important to be cautious about requiring protective workwear to be treated with antimicrobial agents; wherever the agents are applied, it is essential to be able to demonstrate their effectiveness in practice, otherwise they should not be used because of potentially negative environmental effects on eventual disposal. Despite the difficulties, there is potentially a role for fabrics that can deactivate pathogens in particular circumstances, so robust research needs to continue into the role that antimicrobial textiles may play in the workplace. For those involved in research and development of protective workwear involving the application of antimicrobial agents, it is important for them to be careful in the selection of standard test methods to adopt during their research, otherwise they may become over-optimistic about how well the treatment might perform in practice (Murray, 2022). Solid groundwork was established in the 'Three-Tier' protocol published by the OECD in 2008 in their Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects (OECD, 2008).

i. Tier 1 concerns 'Proof of Principle'
ii. Tier 2 'Simulated Use'
iii. Tier 3 'In-Use Evaluation'

What is required now is for those intent on developing antimicrobial workwear for healthcare workers is to take the necessary steps in their research planning to put the protocol into effect. It is at Tier 2 where current test methods currently fall seriously short. Realistic, reliable, laboratory-based Tier 2 test methods now need to be developed for medical textiles and validated for their alignment with practice before they could be considered for acceptance as

suitable standards. The OECD does give guidance on the development of appropriate Tier 2 test methods in their 2019 document 'Guidance Document on Use and Development of Tier-2 Laboratory Based Tests Used to Substantiate Claims for Efficacy of Biocide Treated Articles', (OECD., 2019) and although some progress has been made (Hardwick M, n.d.) this is what more researchers now need to address and build on to develop effective antimicrobial PPE (Murray, 2022). Research interest has now moved on to determine the advantages of incorporating electrospun nanofibre membranes onto nonwoven fabrics, such as a PAN-silica-aerogel membrane onto a viscose rayon nonwoven fabric to improve moisture-vapour management (Bhuiyan et al., 2020) and various electrospun nanofibre mats onto a polypropylene nonwoven fabric to improve antiviral activity (Hamoda et al., 2023).

Progressing towards environmental acceptability with healthcare workers clothing

The perspective is very different when considering environmental impact. A life-cycle assessment published in 2022 of reusable and disposable scrub suits has demonstrated that the reusable solution had a 62% lower impact on climate change compared to the disposable (Burguburu et al., 2022). This supports previous publications and would support recommending using reusable scrub suits wherever practicable. The recently issued details for the NHS England National Healthcare Uniform which will be on-stream in 2024 is one example following this line and this includes the requirements for scrubs to be made using only cotton sourced through the 'Better Cotton Initiative' and for the polyester content to be 100% recycled, stating that their suppliers can provide NHS Trusts with details of a third party provider who can compliantly recycle redundant garments and provide details of its cost (National Health Service Supply Chain, 2023). Maybe so, but the main issue for the future is that, as with other items made from fibre blends, when the new design of suit has reached the end of its useful life it will still be difficult to separate the component fibres from the blend well enough to make them suitable for reuse. Considerable work will be needed, therefore, either to improve separation methods or to develop a fully recyclable/reusable alternative fibre composition that would be able to match the combined comfort and durability of the traditional polyester/cotton blend currently used in scrub suits.

Decontamination and laundering

Reuse of products in healthcare requires cleaning, followed by microbial inactivation through disinfection and/or sterilisation to allow for safe use (Department of Health, 2013). Worthy of note is that reuse of the textile item may not be as per the original intention but may have value in a different setting such as the reuse of a surgical gown as protective wear in a non-sterile environment (MacNeill et al., 2020). Whilst significant carbon footprint reductions can be seen by switching from single-use to reusable products, once a reusable item is in place the majority of carbon footprint is from the reprocessing phase (UK Health Alliance on Climate Change, 2023); for textiles, reprocessing means laundering/sterilising and whereas sterilising is unnecessary in most cases laundering is always required. Sterilisation of reusable products has been shown to be responsible for 20% of the carbon footprint of all products in the five most common operations in England (Rizan et al., 2023).

The United Kingdom National Health Service produced its Best Practice guidance for the laundering of linens some time ago (Department of Health, 2016). Traditionally, disinfection has been by thermal methods, although chemical methods using a lower temperature may also be employed. For thermal disinfection methods, the washing process should have a cycle in which the temperature of the load is either maintained at 71 °C for not less than three minutes or at 65 °C for not less than ten minutes or (but alternative time/temperature relationships may be used provided the efficacy of the process is equal to the 65 °C or 71 °C processes). Mixing time should be added to ensure heat penetration and assure disinfection across the wash load. Healthcare workers laundering workwear uniforms at home in domestic laundry equipment should be washing the items for ten minutes at 60 °C (Department of Health, 2016). In order to assure that the laundered items can continue to perform their protective function and have not reached the end of their useful life, the commercial or in-house hospital laundry needs to be able to track the number of processes the gown has been subjected to. This can be achieved by either using a label, barcode or a RFID tag, and the process needs to certified as able to assure the integrity of the gown and hygienic levels of processing; operational standards for healthcare laundries, in the EU and UK include EN 14065 and the DHSC HTM 01-04; surgical gowns are required to be processed in line with BS/EN13795.

For heat-labile items, chemical disinfection is preferred, and the NHS Best Practice suggests that the exact process should be chosen in discussion and agreement with the infection control team, such that the entire process, should be capable of passing the required microbiological tests (Department of Health, 2016). Attention should also be paid to how best the chemicals used in chemical disinfection should be disposed of. Whichever of the decontamination processes are applied to reusable protective workwear and healthcare workers' clothing, they should also be able to cover the whole range of those types of medical textile. Whilst the chemicals used in laundering require safe disposal, the actual laundering of synthetic textiles is a significant cause of microplastics release into the environment (Palacios-Marin and Tausif, MedSalv, 2021). Both natural cellulosic microparticles and microplastics have been identified in the environment and in the stomachs of wild species (Parton et al., 2020). Washing at higher temperatures increases the rate of release of microparticles (Cotton et al., 2020) and whilst filtration of laundry effluent can reduce the escape of microplastics into the environment by up to 80% (Napper et al., 2020), further research is required into the most effective methods of large-scale laundering. A

review undertaken at the behest of the Department of Health in 2007 found no robust evidence of a difference in efficacy of decontamination of uniforms/clothing between industrial and domestic laundry processes, or that the home laundering of uniforms provides inadequate decontamination. However, only a small number of relevant studies were found, and they provided only limited evidence directly related to the decontamination of uniforms. Studies concerning domestic laundry processes were small scale and largely observational whereas the large-scale practice current at the time, together with the related guidance for laundering uniforms, was extrapolated from studies of industrial hospital linen processing (Wilson et al., 2007). More-recent work, in 2015, demonstrated that 44% of healthcare workers laundering at home do not launder their uniforms at the 60 °C stipulated by the national guidance (Riley et al., 2015).

A recent review concluded that a number of studies had indicated that microorganisms survive on textiles for extended periods of time and can transfer onto skin and other surfaces hence raising the possibility that they might be transferred through contact between staff or patients and contaminated textiles. A number of case studies linked small outbreaks with inadequate laundering or poor infection-control processes for healthcare laundry. Others demonstrated the survival of potential pathogens during the laundering of healthcare textiles, which might possibly increase the risk of infection. Although there are no large-scale epidemiological studies demonstrating a direct link between healthcare-acquired infections and contaminated textiles, the evidence of outbreaks that was provided in the case studies needs further attention (Owen and Laird, Kaist, 2020) as do the systems most-widely employed for the decontamination and laundering of reusable medical textile items in general. Both effectiveness and environmental impact need to be included in any assessment.

Progressing towards environmental acceptability with decontamination and laundering

The most interesting improvement in laundry technology in recent years, both in terms of cost and environmental acceptability is ozone laundering. Ozone laundering uses aqueous ozone to achieve disinfection during the wash process rather than using the traditional thermal disinfection method. The result is low-energy decontamination and laundry systems which monitor and record the achievement of pathogen removal during each cycle of use, and these are already available, but need to be more-widely adopted by the healthcare sector (JLA., 2021; Ozone Industries, 2023).

Systems began to emerge in the 1980s and by the early 2000s their reliability and effectiveness enabled their use for decontamination and cleaning in the healthcare sector. For Europe, $EUO_3TA.org$, the European Ozone Trade Association (EUO3TA.org, 2021) works to guide its member manufacturers and suppliers of ozone-generating equipment to operate safely and effectively. Despite multiple benefits in terms of cost, performance, and materials their implementation was slow; by 2009 it was estimated that there were only around 2000 ozone laundries in operation in the UK and the same number in the US. In the UK, the Department of Health, under its Healthcare Associated Infections Technology Innovation Programme undertook an assessment of the patented OTEX Laundry System (JLA™ Group, Ripponden, West Yorkshire, UK). The outcomes were very positive and resulted in the award of a Rapid Review Panel (RRP) 'Recommendation 1′ in September 2009 by the Department of Health and a report which included a 'Template business case for use by any Trust considering using this product'; that report is available through the UK Government website (GOV.UK., 2011).

The OTEX ozone laundering system utilises an oxygen concentrator which takes in air and converts it to 90% pure oxygen. Electrical arcs separate the paired atoms in oxygen (O_2) which reassemble into ozone (O_3) with each molecule containing three oxygen atoms. The patented 'interfusor' developed by JLA Group provides a mechanism to dissolve an effective concentration of ozone into the water automatically during the wash process allowing disinfection to be carried out at ambient temperatures. As a safeguard the OTEX equipment contains within it a manganese oxide honeycomb destruct unit which acts as an ozone scavenger converting ozone to oxygen. Background levels of ozone are monitored though the OTEX combined room monitor and validation system and comply with Health and Safety Executive (HSE) guidelines (Health & Safety Executive, 2014). The water is at ambient temperature (this is because the ozone breaks down at elevated temperatures, providing heat during the laundry cycle hinders rather than improving the disinfection process) so there are savings in both energy costs and water compared with the traditional thermal processes which raise the temperature to 71 °C, and the quantity of detergent used is around half. OTEX is considered to be an effective method of disinfection including hardy environmental bacteria such as Clostridium difficile spores as are other ozone laundry systems (Ozone Industries, 2024). Added to good disinfection performance and the environmental benefits from reduced utility and detergent use, the water drained away at the end of the process is beneficial to the environment because of its increased oxygen content. Due to the continued savings during use, recovery of the initial outlay from making the change is said to be achievable within 1–2 years. The performance of ozone-cleaned items has been shown to match that of conventionally laundered items in the case of microfibre cleaning cloths and wipes (Humphreys et al., 2012) and the Department of Health has recommended their use across the healthcare sector (GOV.UK., 2011). The statement made in the 2023 Green Surgery Report (UK Health Alliance on Climate Change, 2023), that the opportunity 'to optimise the environmental impact of healthcare linen laundering has received little attention' is clearly not the case, but does indicate how important it is to ensure effective dissemination of information and advice, not only to users but also to those positioned to inform decision-makers.

Surface hygiene

Conventional cleaning and disinfection methods used in hospitals and other healthcare settings depend for their

effectiveness on the disinfectant products used and the way they are applied, including allowing sufficient contact time with the disinfectant for the active agent to work. There are alternative systems which are intended to eliminate errors in the application of cleaning and disinfection and improve reliability by automated room disinfection; the disinfection level achieved by such devices can be high but does not achieve sterility (Otter et al., 2020) and it is the use of microfibre cloths for environmental cleaning that has become ubiquitous in healthcare environments. Their re-use depends on their ability to be sterilised and to maintain their original level of cleaning performance.

Cloths and wipes made from non-woven fabrics (Das et al., 2012) are commonly used for cleaning patients, staff, or equipment and typically contain antibacterial and cleaning agents; preferably they would be able to be decontaminated and reused, otherwise, it is thought that they would be better if they were flushable (Kim and Hergeth, 2012) and biodegradable (Soukupova et al., 2007). It appears that not all wipes are similarly effective, but also, they do need to be used in a particular manner to work effectively. The efficacies of two types of non-woven wipe have been assessed by dynamic wiping, and it was found that of the two, the hydrophilic wipes (those composed of lyocell) were more consistently effective than those made from polypropylene. Use of a high-density lyocell fabric (150 g.m-2), at high pressure (13.8 kN.m-2) was considered best practice (Edwards et al., 2019).

Antimicrobial agents such as quaternary ammonium compounds are some of the most-widely used disinfecting agents and in the case of wipes, it is ready release rather than adsorption which is required from the impregnated carrier fabric. Quaternary ammonium compounds can be strongly adsorbed on to cotton, but it was shown that whereas raising the alkalinity of their solutions increased the amount of alkyl-dimethyl-benzyl-ammonium chloride (ADBAC) adsorbed onto cotton non-woven fabrics, a more-acidic solution reduced the agent's adsorption, as did increasing the temperature and concentration of salts in the solution. Non-ionic surfactants or low molecular weight quaternary ammonium compounds reduced the agent's adsorption onto cotton fabrics in a concentration-dependent manner. The incorporation of the additives to promote ADBAC release into the antimicrobial solution can be optimised to enable its ready release from the wipe onto the surface required to be disinfected (Hinchliffe et al., 2018, 2017). It was shown by dynamic wiping assays that successful disinfection of a hard surface was greatly enhanced by a wipe fabric that also effectively removed organic contaminants and was strong enough to resist structural failure; the use of greige cotton also reduced water wastage when the disinfecting solution was being applied (Hron et al., 2019). A useful and detailed review of the efficacy of disinfectant-impregnated wipes used for surface disinfection in hospitals has been undertaken recently (Song et al., 2019).

In the EU, the disinfectant-efficacy test is regulated and issued by the European Committee for Normalization (CEN), Technical Committee 216 (TC 216) under the work programme 'Chemical Disinfectants and Antiseptics' and it is Standard EN 16615 that is the most suitable. For the USA, it is the Environmental Protection Agency (EPA) which undertakes that kind of regulation. Even so, as yet there are few test methods for assessing the efficacy of impregnated wipes, the main ones being EN 16615:2015, the modified AOAC international method 961.02 and ASTM E2896–12 and ASTM E2967–15, all of which fall short in terms of variations that may occur during their application and/or the limited range of surfaces embraced by the standard. Also, according to the reviewers (Song et al., 2019), several information gaps must be filled to obtain consistent and exhaustive knowledge about the interaction between textile and substrate, in particular regarding:

i. material compatibility (combination of wipe and disinfectant)
ii. liquor ratio (wipe mass/disinfection solution volume)
iii. contact time (of disinfectant and wipes)
iv. durability to storage

Even so, despite shortcomings, the ASTM test has been adopted (Sattar et al., 2015).

A different approach to disinfection to combat the growing threat of hospital-acquired infections relies on a dry non-woven wipe composed of viscose rayon containing sufficient beneficial bacteria or spores which, on wetting and using the wipe, are released, and spread over the wiped surface. The released beneficial bacteria inhibit pathogens by growing and colonising on the wiped surfaces (Dural-Erem et al., 2019).

Overcash undertook a re-evaluation of reported research concerning the effectiveness of cleaning products made from nylon/polyethylene terephthalate wedge-shaped microfibres measuring about 4–6 µm across (Overcash, 2022). The revised results showed that for hospital surface cleaning with reusable microfibre products, no detectable levels were found for two of the most challenging organisms for hospital-acquired infections, namely MRSA and *S aureus* and *C difficile*. The reusable microfibre products improved with use. Coincidentally, the successful use of ozone laundering and decontamination for microfibre cleaning cloths and wipes at the hospital in Southampton (UK) formed part of the Department of Health approval case study for the OTEX system (GOV.UK., 2011).

Heating, ventilation and air conditioning (HVAC)

In a modern hospital environment, particularly, in operating theatres and intensive care units there is an expectation that apart from heating and ventilation, there will also be provision made for filtration of the air being circulated. A useful review of the main physical mechanisms that apply generally to small particles in air filtration (Maduna & Patnaik, 2017) lists them as:

i. Direct Interception, where the particle follows a flow path to within a particle radius of a filter fibre and is captured.

ii. Inertial Impaction, where the (larger) particle does not deviate with the flow so collides with the filter fibre.
iii. Diffusion, where the very fine particles are jostled by collisions with molecules of gas (Brownian motion) and caused to collide with filter fibres and become trapped.
iv. Electrostatic Attraction, which occurs when opposites charge exists or charges are generated between the filter fibres and particles. Particles therefore collect on the charged fibre surfaces.

A filter's ability to capture particles depends on the particle size passing into its fibre mass as well as the velocity of the flow passing through the filter. In looking at the range of sizes applicable to bacteria and viruses, (all of which would be classified by BS EN ISO 16890 as PM1), the larger particles in the range, that is, particles above 0.4 µm in diameter, will be captured due to both the impaction and interception mechanisms. Medium particles, in the 0.1 to 0.4 µm diameter range, are thought to be the most penetrating, despite being captured by both the diffusion and interception filtration mechanisms; small particles, below 0.1 µm in diameter, captured mostly by the diffusion mechanism, are captured more effectively than those in the medium size in the range (Maduna & Patnaik, 2017; TSI., 2012). By contrast with the personal protective devices such as surgical masks and respirators, although filters designed for use in the hospital environment are described as high-efficiency particulate air (HEPA) air filters, they are expected to treat significant volumes of air, many times the amount taken in by a single individual, so they cannot easily achieve the degree of entrapment of most virus-sized particles by mechanical filtration or attraction by charged electret fibres to the extent that would be routinely achieved by an N95, FFP2, or FFP3 respirator. Instead, wherever it is felt necessary to achieve high levels of decontamination of the air passing through the filter, the mechanical filtration provided by melt-blown non-woven fibre webs can be supplemented by UV-C irradiation in units such as the Steriwhite Air M and related units which may be retrofitted (Dr Hönle AG, UV-Technologie, Gräfelfing/MunicH, Germany) or units coupled with a photocatalytic filter consisting of a filter fabric containing TiO2 nanoparticles as used in photocatalytic self-cleaning fabrics and/or ionisation (Woo et al., 2012) or electrical discharge within the filtration device itself. Some models include activated carbon for removal of volatile organic compounds (VOCs).

For demanding hospital settings such as the operating theatre, the HEPA filter can be coupled with devices which bring about a slight reduction in air pressure in the area to help to limit the transfer of contaminants. Details of examples accessible at the Hepacart, Dust Arrest, and Airvia sites span the range, from fixed to mobile-but-substantial installations intended for use in hospitals (Air Purified, 2024; Dust Arrest, 2024; Hepacart, 2024). There are also ultra-low particulate air (ULPA) filters; whereas HEPA filters are designed to remove up to 99.97% of contaminants of sizes down to 0.3 µm, ULPA filters are designed to remove 99.99% of particles down to 0.12 µm in size which does therefore include virus-sized particles. However, the ULPA filters are much more demanding both in terms of maintenance and operating costs, so they are intended to be reserved for the most-specialist treatment areas. Whilst textile filtration design is an important component in the removal of contaminants, the overall three-dimensional design of the HVAC system within which it is incorporated is also crucial to its effectiveness. It can be seen from modelling exercises that positioning of inlets and exhausts are critical (HECOIRA, 2021) but there is reason to believe that optimum positioning coupled with effective filtration by the textiles within the filters and disinfection of the emergent air by exposure to far ultraviolet, will provide the necessary protection against infection from airborne pathogens in the operating theatre and elsewhere. There is also evidence that treatment of the air-filter textile with an antimicrobial agent can be successful against airborne pathogens; a fast-acting, non-volatile and odour-free N-halamine called MC was found to be effective against the avian influenza virus in a chicken hatchery when applied as a finish to the nonwoven filter fabric (Ren et al., 2018).

Conclusions and recommendations

The reusability of medical textiles has been shown not only to have the capacity to provide a major contribution to the reduction of greenhouse gas emissions by the healthcare sector but also the potential to mitigate critical shortages of PPE such as those which occurred during the COVID-19 pandemic. Progression towards the achievement of low carbon emissions in the operating theatre will remain slow until those responsible for procurement in the healthcare sector (which can vary from individual surgeons/hospitals to groups of hospitals across a region) recognise that environmental acceptability need not be difficult or costly to achieve. Several incentives have been shown to exist which should help all involved to decide to take the necessary steps to ensure widespread implementation.

With their focus on performance rather than structural details, standards for surgical gowns and drapes are already sufficiently flexible to allow significant scope for redesign to improve their environmental acceptability, as is evidenced by variety amongst the effective re-usable items currently available amongst that group of products. There are also significant financial savings to be made by health-care providers who are prepared to make the ecologically-advantageous change to reusable surgical drapes and gowns. Added to this, low temperature laundering and decontamination systems have the potential to further enhance all of the advantages of moving to the routine use of the reusable items in surgery. Such systems have already demonstrated their effectiveness with cleaning wipes and mops. It would be helpful in the case of such laundry systems to undertake further projects on such systems' decontamination and laundering abilities for PPE garments such as gowns, drapes and scrubs in particular to determine their ability to maintain

the integrity of key performance requirements of the PPE through multiple cycles of application.

The situation is different for filter facepieces. Although decontamination and reuse of filter facepieces was demonstrably a successful tactic during the early stages of the COVID-19 pandemic, approval was eventually withdrawn by the FDA in the US. Reuse does remain an acceptable approach in the EU, so long as the treated items can be shown to be as effective as the new device. However, reusable filter facepieces have not yet entered the market in either region. What needs to happen now is that the items need to be redesigned to be suitable for reuse in the first place, and care taken to ensure easy reprocessing or recycling at the end of their repeated use. A serious attempt needs to be taken to capitalise on the analyses that have already been carried out which show that the most effective design will be a reusable filter facepiece with a replaceable filter. Once sustainable items have been developed, it is of great importance that regulatory standards and approval organisations adjust their requirements to ensure that their standards and approval procedures are adapted to be suitable for re-useable items rather than just for those intended to be for single use. This is not to suggest that standards should be compromised, simply that the adapted standard should specify the performance requirements of any necessary decontamination and sterilisation treatment that might need to be applied. The performance requirements for the treated item should be the same as for the new item.

Disclosure statement

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Cotton in Healthcare – are we using the correct fibre

Cotton has been nicknamed the 'King of fibres' and has a wide variety of applications within the healthcare field. Holly Morris, a hand surgeon, Chief Medical Officer for Revolution-ZERO and Fellow of The Textile Institute explores the use of cotton in this sector along with ways in which its environmental impact could be reduced.

Cotton is a naturally permeable fibre due to both its twist and hollow interior. Whilst absorbent, care does need to be taken as it can serve as a nutrient reservoir for microbes. That said, it can withstand sterilisation and high temperature laundering and bleaching, lending itself to current healthcare laundering practices. Thus, cotton is widely used within the healthcare sector from bedding, surgical scrubs, and healthcare workers uniforms through to more specialist uses such as diapers, nursing pads and feminine hygiene products. To put this into perspective, bandages alone accounted for USD$8.58billion of world trade in 2019. As a natural cellulose fibre, cotton is biodegradable which proffers advantages over synthetic fibres.

Production and Processing

Cotton fibre grows on the seed of a variety of plants of the genus Gossypium and remains the most important natural fibre around the globe. After polyester, it is the second most consumed fibre in the world and responsible for 25% of global fibre production in 2019. Whilst production occurs in over 100 countries, currently it is China, India, the USA and Pakistan who produce more than 60% of the worlds cotton. Over two thirds of the worlds cotton is the genetically transformed variety of cotton (Bt cotton) which contains genes from the bacterium Bacillus thuringiensis that act as an insectide and allows for production with less risk of pest attack.

After harvest, cotton seeds undergo a process called ginning; this separates the cotton fibre from the cotton seeds. Following this, the fibres may be blended during yarn manufacturing. A popular blend is polyester with cotton, used in surgical scrubs and hospital uniforms, because the polyester offers better performance and durability whilst the cotton proffers good comfort characteristics.

Life cycle assessment studies on cotton from fibre to fabric have been undertaken. Fibre processing, dyeing and laundering of end products carry the highest environmental impact. Herbicides and insecticides can be hazardous to human health and the large amount of water necessary for cotton fibre production has affected both water supply and quality in areas of production. The use of fertilisers and nitrates in production and the associated soil degradation from intensive farming have contributed to climate change.

However, there are examples of sustainable practice in cotton production that are already employed including multi-cropping, reduced or no use of pesticides, soil management and sustainable irrigation. More work is required as currently these often have high harvest losses. Organic cotton, whilst carrying a premium, claims to reduce soil erosion, water consumption and primary energy demand by up to 25%, 91% and 62% respectively. Fibres are often far better quality than non-organic cotton and there is a reduced risk of skin irritation due to a lack of chemicals. However, organic cotton currently only represents around 1% of global cotton production.

Ethical Considerations

75% of cotton worldwide is handpicked and this tends to be the predominant method in developing countries. Processing creates noise, cotton dust and some aspects require high humidification. All of these may impact workers health if the environment is not well-designed and air-conditioned. Furthermore, dyeing and printing require chemicals which can cause eczema, occupational asthma, allergies, and cancer.

Cotton fibre grows on the seed of a variety of plants of the genus Gossypium and remains the most important natural fibre around the globe. Image supplied by Cotton Council International

In addition to the occupational hazards, there have been controversies regarding forced labour and the use of child labour which have attracted the attention of industrial and human rights organisations.

New Initiatives

There has been significant progress to improve both the environmental and ethical issues associated with the production of cotton with the establishment of several initiatives.

The Better Cotton Initiative is the world's largest Cotton Sustainability Program with over 2300 members; more than a quarter of the worlds cotton is now produced under the Better Cotton Standard. This Standard comprises six components including producing cotton in a way that cares for the environment. Better Cotton Farmers also commit to decent work principles and conditions that support workers' safety and wellbeing.

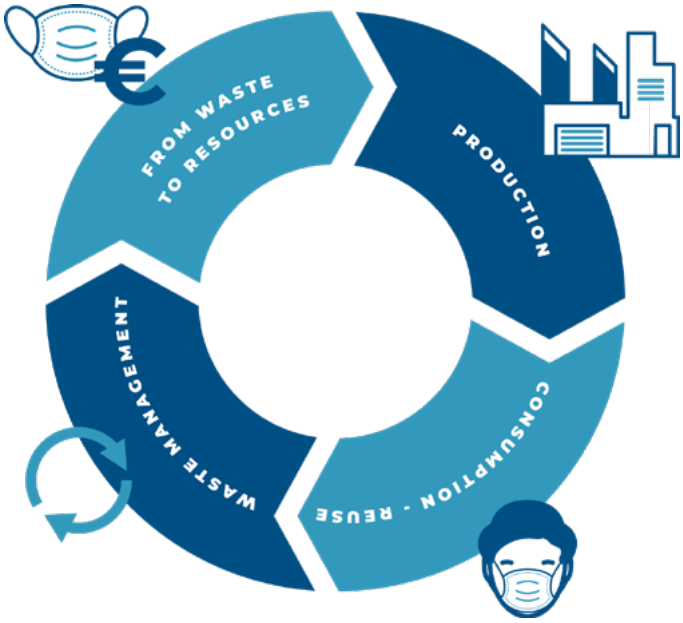
The US Cotton Trust Protocol has a wide membership with over 525 mills and manufacturing members and over 300 grower members all working towards goals that are aligned with the United Nations Sustainable Development Goals. In addition to sustainable goals, the initiative sets out strict guidelines for worker well-being.

Fairtrade Cotton works with small-scale cotton farmers through Asia and Africa to assist building stronger farmer-owned organisations. It encourages sustainable cotton production and provides economic benefits, through a guaranteed Fairtrade Minimum Price and additional Fairtrade Premium for seed cotton farmers. Fairtrade currently works with almost 44,480 cotton farmers who grow seed cotton; global sales in 2020 generated over GBP147 million in Fairtrade Premium.

The Circular Economy Within Healthcare

It has been predicted that the total textile waste in the year 2030 will be 148 million tonnes. After the apparel industry, hospital textile waste is the second largest sector of textile waste. From a healthcare perspective, The NHS contributes 4-5% of the countries greenhouse gases and a quarter of all public sector waste. After plastic, textile waste is the second biggest waste product from healthcare, representing 14-31% of all healthcare waste. Between 20% to 33% of all health care waste originates from a hospital's operating room. Aware of the contribution of healthcare to the carbon footprint, healthcare professionals are moving towards applying the principles of the circular economy to healthcare in an attempt to reduce waste.

The use of cotton, and the associated textile waste created, from single-use and reusable devices is alarming. We found that a single paediatric Achilles tendon tenotomy in a UK hospital, an operation that takes less than five minutes, generated 10 separate pieces of single use textiles (ten pieces of gauze) and 20 separate pieces of launderable textiles (hospital bedding (two sheets, one pillowcase, two blankets), one set of patient clothing and seven sets of scrubs). This did not include any waste from the anaesthetic procedure.



Reduce

A standard surgical set up often involves opening items as a 'just in case'. One way to reduce the use of textile products would involve health care professionals critically evaluating the devices they use for each procedure and questioning whether they are really required. For example, surgical gauze is packaged and opened in batches of five pieces. In many surgeries there is gauze that is surplus to requirements that has been opened and is subsequently disposed of. We should be assessing how items are packaged and whether bulk packaging is the best method.

Reuse

Our reliance on single use products stems to a large extent from concerns of infection risk. However, in the COVID-19 pandemic, single use surgical gowns were widely used within hospitals, yet community workers were still home laundering their cotton and polycotton uniforms due to shortages. A pragmatic approach needs to be taken to assess whether high risk aspects of reuse can be mitigated, for example, there are already organizations internationally who launder and process single use items for reuse and other countries who launder at lower temperatures.

Reuse rather than disposal is often, though not always, the better option for reducing environmental harm. Further research is required into the laundering and sterilisation/disinfection of healthcare textiles. Traditionally, NHS laundering standards use heat as the primary method of disinfection and state that the garment must be processed at a temperature of 71°C for not less than three minutes or 65°C for not less than ten minutes. Further mixing time is then added depending on the quantity of items being laundered. Home laundering requires the garment to be washed at the hottest temperature it can sustain, guidance recommending a ten-minute wash at 60°C. Properly designed trials undertaken in realistic settings are few and far between and further research is required into other methods of sterilisation, such as the use of ozone, ultraviolet or gamma-irradiation, ethylene oxide gasification or the application of spray-on disinfectants in laundering of healthcare textiles and the affect they have upon the physical and mechanical properties of the fibres within the textile.

Technology has advanced and the life span of technical textile products has increased. ISO standards deeming the number of safe uses of an item should be reviewed. An increase from a 75-wash life cycle to a 100-wash life cycle would gain a further 33% use out of the garment. Furthermore, the incorporation of nanotechnology and plasma-based treatments as finishing items for textiles may allow for laundering at significantly lower temperatures whilst maintaining sterility and with no reduction in quality or functionality of the textile product. Good quality studies are required.

There is much potential for reuse of healthcare devices. Manufacturers should be encouraged to produce equipment designed for reprocessing, a critical and balanced view of infection risk should be applied. Whilst we are not advocating for reuse of all items, in developing countries where resources are scarce, reuse is a requirement. Some countries already redistribute single use items that no longer meet the necessary legislative requirements for use in their country, but are still safe and functional, and send these to understocked developing nations.

Recycle

Potentially, almost all textiles are recyclable. Cotton decomposes as it is a natural fibre. However, when recycled, it becomes a more sustainable fibre as the need for virgin cotton and associated water, pesticides and insecticides

Aware of the contribution of healthcare to the carbon footprint, healthcare professionals are moving towards applying the principles of the circular economy to healthcare in an attempt to reduce waste. Graphic supplied by Healthcare Without Harm

reduces. It has been estimated that one tonne of reused cotton saves 765m^3 of water; 98% of which would be used in the processing of virgin cotton. Other recycling processes allow for the conversion of the cellulose to glucose or nanocellulose which can then be utilised in other industry sectors and there have been reports of the recovery of biogas from medical cotton waste.

A potential problem of recycling in the hospital environment is the mixing of textile wastes e.g. polycotton, cotton and other fibre types. Near-infrared spectroscopy, which is fast, non-destructive, and efficient has been used in textile waste separation to reduce the need for manual sorting, which is both time and effort consuming. Chemical processes have been developed to separate the fibre components from waste blended fabrics such as polycotton (polyester and cotton), used in surgical gowns and drapes.

Results from the recycling of waste fashion items are exceptionally promising and technologies here may be beneficial to the healthcare sector. Whilst recycling facilities in hospitals are highly variable, good recycling systems are usually environmentally and financially preferable.

Conclusion

The responsibility and potential for change requires engagement and support from healthcare professionals, governmental organisations and procurement. The textile industry also has a role to play. Fast fashion has already seen significant work undertaken to create a circular economy model. The way in which fibres and fabrics are recycled in this sector of the textile industry could be tweaked and subsequently adopted within healthcare textiles.

Key research questions, such as sustainable textile processing and the effectiveness of different methods of laundering need to be addressed with good quality studies. Life cycle assessments of textile products require updating as new fibres are developed and as novel recycling and reprocessing methods are introduced. Whilst the textile industry continues to explore eco-friendly textile fibres, such as bamboo, hemp, corn, pineapple, and banana leaf, it can be difficult to differentiate between a helpful development and one which offers little ecological advantage over an existing commodity fibre. It may be that cotton remains the 'King of Fibres', particularly with the environmental and ethical initiatives seen over the last decade within the cotton industry. Alternatively, it may be that another fibre is more advantageous, or it may be that we need to incorporate cotton within the health sector in a more balanced manner. Regardless, any change requires careful consideration and a phase in period so as not to cause significant impact to the 270 million farmers worldwide who are dependent, directly or indirectly, on cotton production.

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Top; A standard surgical set up often involves opening items as a 'just in case'
Bottom: Whilst we are not advocating for reuse of all items, in developing countries where resources are scarce, reuse is a requirement

UKHACC Green Surgery Report – Medical Textiles

A wide range of medical textiles are important to medicine and healthcare, and that range continues to grow. Morris and Murray (1) classified the areas within which medical textiles are applied as:

- Implantable materials, e.g., sutures, grafts, scaffolds
- Non-implantable materials, e.g., wound dressings, pressure garments
- Extracorporeal devices, e.g., artificial kidney, liver, pancreas
- Healthcare/hygiene roles, e.g., clothing, disposable products such as wipes
- Furnishing fabrics and textiles in fixtures and fittings in healthcare establishments
- Components of devices for environmental hygiene control
- Intelligent medical and healthcare textiles

This Green Surgery guidance focuses upon textiles used for their healthcare and hygiene roles and predominantly, surgical gowns and drapes, linen, and healthcare worker uniforms. Items described as 'linen,' as defined by the UK Department of Health, include bed linen (blankets, counterpanes, cot sheets and blankets, duvets, duvet covers, pillowcases, and sheets including those which are woven, knitted, half sheets, draw and slide sheets); bibs; blankets; canvases; curtains; hoist slings; patient clothing (gowns, nightdresses and shirts, pyjama tops and bottoms); staff clothing (coats, scrub suits, tabards, uniforms); and towels. (2)

Sun recommended when considering disposable and reusable medical textiles that individuals should seek improved protective performance, low cost, and minimised environmental impact from medical textiles which could be disposable or reusable. (3) Whilst single-use disposables do have some attractive features and are the sensible choice in certain settings where the numbers of particular types of medical textile items being used is small, in others, they have the potential to incur high costs and to make a substantial contribution to pollution. How to make the decision about which type to use was well-addressed by Walton, who recommended that the use of disposables should be reserved for low-volume applications, where it was not going to be economical to equip to be able to decontaminate and sterilise them. (4) We seek to expand upon these foundations with recommendations on how textile products should be procured, used, reused and disposed of using currently available technology.

Regarding their relative impacts on the environment in the modern day, textiles are in fourth place for quantity of use of primary raw materials and water used, after transport, housing and food, and in fifth place for greenhouse gas emissions. (5) Attention should be paid to the full lifecycle of the product from procurement through to disposal. The fashion industry traditionally follows a linear model consisting of three key stages: take (the harvesting of raw materials), make (the production of garments), and waste (the wearing and subsequent disposal of garments). (6) Change is afoot within the fashion sector of the textile industry to move towards a circular economy for textile products and these principles can be extended to the medical textile sector.

There are several definitions of a circular economy. (7) When related to medical textiles, the definition proposed is a 'system that moves towards a regenerative model with an improved use of sustainable and renewable resources, reduction of non-renewable inputs, pollution and waste generation, while facilitating long product life and material circulation via sustainable medical-device design strategies'. The European Commission Strategy for Sustainable and Circular Textiles acknowledges that advancing towards greater sustainability of the textiles ecosystem requires deep changes in the currently prevailing linear economy. (8)

Design and Procurement of Medical Textile Items

The textile industry has not yet developed the ways and means to achieve the overarching aim of a circular economy, and this will have implications for those working towards sustainable healthcare procurement. (9,10) A further issue which poses challenges to transparency is the highly globalized, complex and extremely fragmented supply chain. (11) Many medical textile manufacturing firms are located outside the Western consumer markets; corporate governance is an issue hence it can be challenging to access sufficient reliable information either for full traceability or to determine a procurement footprint. It would be easy to dismiss fashion clothing retail supply chains as unrelated and irrelevant, but important lessons can be learned from fashion retailers about the intensity of supervision necessary to ensure that product designs are followed and that items meet the required specifications. Every significant operation is checked through the meticulous application of over 300 specified supply-chain-management supervisory steps. (12) Retailer representatives visit the supplier design, production and warehousing facilities to run checks on a weekly basis. Nothing operates only on the basis of trust.

Within a medical textile circular economy, alongside satisfying the existing performance and reliability criteria, the design and procurement of items must also focus on

- Resource efficiency
- Circular design
- Product life extension

Resource efficiency includes the use of renewable and sustainable raw materials, reduction in the amount of resource consumed in a device's manufacture, delivery and operation, and waste minimization. Selection of sustainable fibres can substantially contribute to reducing the environmental impact at the raw material stage. Strategies that may make a fibre more sustainable vary depending upon fibre type; for example:

- For natural fibres reducing water, land and chemical use during farming is key, whilst
- For synthetic fibres, energy consumption and the use of fossil fuels in their manufacture should be minimized. (13) There is significant work directed at creating synthetic fibres from bio-based products to reduce the industry's dependence upon fossil fuels.

Manufacturing methods by which textile fibres are produced and processed must be tailored to phase out toxic chemicals and energy efficient machineries and processes should be employed. Using renewable energy sources, recovering waste heat and using natural cooling systems are all helpful in improving the carbon footprint. (14) Recovery of the polymer or its monomers at the end of the medical textiles item's life should also be utilised.

Around 20% of industrial water pollution is due to textile dyeing and finishing, so efforts should be made to find sustainable alternatives that reduce water contamination with toxic chemicals and capture and purify wastewater. (15) Waterless technologies that conserve or greatly reduce water usage should be considered and such dyeing methods that do exist which can achieve major improvements:

- Air dye technology uses air rather than water to impart dye to garments and requires 95% less water and 87% less energy than traditional dyeing methods. (15)
- Colorzen® is a pre-treatment for cotton that enables it to attract dye more readily. Dyeing time is reduced significantly and water consumption by up to 90%. (16)
- Dyecoo® uses no water and instead uses supercritical CO_2 in a closed recovery loop to impart dye to fibres. (17)

- Mass Pigmentation, where pigment is mixed into the polymer prior to spinning into filaments, uses no water. Whilst it commits the fibre to a particular colour at an early stage, this should not be a problem for a commodity product.
- Sublimation uses no water but instead uses heat to transfer dye to a product.

Circular design is crucial given that over 80% of the environmental impact of a product is determined at the design stage. (18) In the conventional design process, designers have the power to select materials, trims, colours, quality, and other design features which could significantly affect the environmental impact of the product. Improved design and reuse can reduce not only the environmental and economic cost of raw materials, but also end-of-life disposal whilst creating new business models and useful products.

Designing for circularity intends that the design of a product is suitable for several life cycles. Designing for durability allows product life to be extended and includes using good quality materials, durable seams and long lasting dyes that can withstand several cycles of use and laundering. Designing long-lasting products needs to take into account what the consumer is seeking from the product and may involve tailoring products for specific requirements e.g. adding tabs to a surgical drape to allow ease of suspension.

Products should be designed for disassembly and reuse. Designing for disassembly ensures that component parts can be readily deconstructed for refurbishment, reassembly and further use. Considerations include the shape and types of components, the fibres used, the methods of deconstruction to be used and potential reuse options. For example, the polyester and cotton fibre constituents of surgical drapes and gowns could be reused within healthcare in surgical scrub suits which do not need to meet the same rigorous ISO standard testing given the nature of their use.

There should be transparency between the manufacturer, the customer and the public regarding the design process and how it lends itself to a circular economy. Procurers should also recognise the impact they have in this process by ensuring that they only purchase products where sustainable design has been both implanted and openly declared by the producer.

Product life extension aims to keep the product in use for the highest amount of safe-use cycles rather than disposing after a single use. Increasing the number of times that a textile can be used leads to increased material value, reduction of waste, lower pollution and a reduced number of items that need to be procured. Offering services that repair existing products provides an alternative way to extend product life and reduce the demand for both the finished product and the virgin materials from which it is made. (19) With this in mind, attention should be paid to revision of the relevant standards available for gowns, drapes and other medical textiles. Many of these require an extensive overhaul, and attention should be paid to enabling extension of the product life of the medical devices when reviewing and writing standards.

Reuse of Textile Items

Waste minimisation in a circular economy can be achieved by a variety of methods including

- Reuse of products
- Product life extension (discussed in previous section)

Reuse of products in healthcare requires effective sterilization and repurposing such that the product remains fit for purpose and a further life cycle. In Europe, according to Regulation (EU) 2017/745 of 5 April 2017 on medical devices (20), remanufactured ‘single-use’ medical

devices must meet manufacturer standards and receive a CE mark ensuring they are as safe and as effective as the new equipment and are required to be sterilised to the level of the original device. Healthcare units keen to save on resources and address the growing need to generate less waste, but concerned about the expense of decontamination and sterilisation, are now able to find systems and products to help them to achieve those aims. Practice Greenhealth™ (Reston, VA, USA) has developed the business case and step-by-step guidance documents to give practical help in developing a sound basis from which to reach such a decision about what choice to make for the operating room. (21) Adaptations should be possible for the other areas of healthcare.

For reusable items, laundering requires attention. A recent review concluded that a number of studies had indicated that microorganisms survive on textiles for extended periods of time and can transfer onto skin and other surfaces hence raising the possibility that they might be transferred through contact between staff or patients and contaminated textiles. A number of case studies linked small outbreaks with inadequate laundering or poor infection-control processes for healthcare laundry. Others demonstrated the survival of potential pathogens during laundering of healthcare textiles, which might possibly increase the risk of infection. Although there are no large-scale epidemiological studies demonstrating a direct link between healthcare-acquired infections and contaminated textiles, evidence of outbreaks given in case studies needs attention. (22)

The United Kingdom National Health Service has produced Best Practice guidance for the laundering of linens. (2) Traditionally, disinfection has been by thermal methods although chemical methods at a lower temperature may also be employed. For thermal disinfection methods, the washing process should have a cycle in which the temperature of the load is either maintained at 65°C for not less than ten minutes or 71°C for not less than three minutes. Alternative time/temperature relationships may be used provided the efficacy of the process chosen is equal to the 65°C or 71°C processes. Mixing time should be added to ensure heat penetration and assure disinfection. Those laundering workwear uniforms at home in domestic facilities should be washing for ten minutes at 60°C. (2)

For heat-labile items, chemical disinfection is preferred, and the Best Practice suggests that the exact process should be chosen in discussion and agreement with the infection control team, such that the entire process, should be capable of passing the required microbiological tests. (2)

Heating water to 65°C or 71°C requires significant energy. Attention should be turned towards more sustainable practice including scrutinising whether this temperature could be lowered without undue effect on the cleaning of the textiles. Attention should also be paid to the chemicals used in chemical disinfection including how they are disposed of. A system for decontamination and disinfection at low temperatures involving the generation of ozone within the washing machine which automatically provides the data demonstrating its efficacy required for use in audit trails has been shown to be cost-effective within both hospitals and care-home settings and deserves serious attention and implementation on a wider scale. Details about such a system approved in accordance with the Biocidal Products Regulations (EU) 528/2012 (23) are available from one UK based provider. (24) Of note, not all hospital linen was laundered.

A review undertaken at the behest of the Department of Health in 2007 found no robust evidence of a difference in efficacy of decontamination of uniforms/clothing between industrial and domestic laundry processes, or that the home laundering of uniforms provides inadequate

decontamination. However, only a small number of relevant studies were found; those found provided limited evidence directly related to the decontamination of uniforms. Studies concerning domestic laundry processes were small scale and largely observational whilst practice current at the time and guidance for laundering uniforms was extrapolated from studies of industrial hospital linen processing. (25) More recent work, in 2015, demonstrated that 44% of healthcare workers laundering at home do not launder their uniforms at the 60°C stipulated by the national guidance. (26) There is scope for improvement in the laundering of hospital textiles, both in the hospital and domestic setting given advances in laundering abilities.

The laundering of synthetic textiles is a significant cause of microplastic release to the environment. (27) Natural cellulosic microparticles, alongside microplastics, have also been identified in the environment and stomachs of other species. (28) Washing at higher temperatures increases the rate of release of microparticles, another reason to reconsider the laundering process. (29) Filtration of effluent water used in the laundering process can reduce the escape and leach of microplastics into the environment by up to 80%. (30)

Disposal of Textile Items

Rather than the disposal of items, consideration should be given to the circular economy and the appropriateness of reuse, recycling or remanufacture either for the item or its constituent parts or by harvesting the constituent fibres for recycling and reuse elsewhere. Reuse of single use textile items via schemes to process, clean and test the item to the relevant standard for use are already in use in countries such as the USA and New Zealand. (31) Reuse of the textile item may not be as was originally intended, but may have value in a different setting; for example, reusing a surgical gown as protective wear in a non-sterile environment. (32)

Remanufacturing which allows disassembly of the item, recovery of useful component parts, redesigning and reassembling them to make new items (to be used within healthcare or elsewhere) should be considered. Whilst this is often a cost and resource effective treatment method compared to recycling (which often requires energy and chemical intensive treatment processes), the design process can further facilitate easy disassembly by incorporating suitable bonding and stitch types. (15)

Whilst recycling facilities in hospitals are highly variable, good recycling systems are usually environmentally and financially preferable. (33) A potential problem of recycling in the hospital environment is the mixing of textile wastes e.g. polyester/cotton blends with 100% cotton or with other fibre types. Near-infrared spectroscopy is a fast, non-destructive and efficient method of determining fibre type for textile waste separation. (34) Chemical processes are already available to enable the separation of the fibre components from blended fabrics such as the polyester/cotton blend, used in surgical gowns and drapes. Already used in the fashion sectors, there have been several studies reporting promising results, which suggest a recycling rate of more than 93-96%, a carbon footprint reduction of 1440-1534kg of CO_2 and an economic return of US$1466-1629 per tonne. (35,36)

If a garment or fabric is not in a condition to be reused, consideration should be given to the recycling of fibres wherever possible. Recycling technologies are divided broadly into mechanical and chemical recycling. Mechanical recycling pulls about fabrics to their fibre constituents whilst thermal recycling involves melt-extrusion to obtain fibres from waste materials which are then subsequently respun into yarns. In chemical recycling, synthetic-polymer materials are depolymerized into the constituent monomers and then repolymerized back into fibres. Recycling does not only apply to synthetic fibres; for example, although

cotton can decompose, if it is recycled it becomes a more sustainable fibre as the requirement for virgin cotton, with all the associated water, pesticides and insecticides is reduced. (37) One tonne of reused cotton has been estimated to conserve 765m^3 of water of which 98% would otherwise have been used in the production of virgin cotton. (38)

Rather than reusing the fibre as fibre, fibres from the medical textile can also be converted to yield other products which may be used in alternative industry sectors; for example, cellulose can be converted to glucose or nanocellulose. (39,40) This may offer possible routes for reuse that avoid the need for incineration or landfill disposal.

Textiles Within Surgery

High volume textiles used within the surgical directorate include surgical gowns and drapes and the workwear of the operating personnel. There was an attitude initiated in the mid-1950s that was labelled at the time by LIFE magazine as 'Throwaway Living', and this became adopted in the hospital and healthcare settings by the 1970s and more widely ever since. (41) The advantages in terms of the convenience of disposable items had been strongly marketed to the healthcare sector with attention drawn to similarities in cost and the possibility of moving away completely from the management responsibilities involved with in-house or outsourced institutional laundering and sterilisation.

Overcash, in 2012, completed a useful analysis that combined the findings from six independent lifecycle assessments for gowns and drapes, carried out in terms of cost-effectiveness analyses and life-cycle testing. The analysis showed there was little cost difference to the hospital/institutional user between using disposable gowns and drapes compared with using reusables but there were significant differences in terms of negative environmental impact. (42) The environmental impact differences arise as disposables require proportionately much greater amounts of energy and water per single use than the reusables which require the energy and water for only one manufacturing stage and then are subsequently cleaned 50 times. Reusables demonstrate a 28% reduction in energy consumption, 30% reduction in greenhouse gas emissions, 41% reduction in blue-water consumption and a 93% reduction in solid-waste generation than disposables. (43) Even considering just the water and energy requirements of the laundering of reusable gowns, the manufacturing of disposables creates significantly more impact to the environment than using a reusable. That said, it would be presumptuous to assume that a reusable gown is appropriate in every setting.

Surgical Gowns

Surgical gowns were introduced primarily as a protective barrier to reduce surgical site infection and protect the patient from the surgical team. They accomplish this by one of two means

- by controlling the skin and bacteria being shed by the user, and
- by preventing the direct transmission of bacteria.

In current practice, the gown now also offers protection to the surgical team from the patient. A surgical gown must also demonstrate good wearing comfort whilst keeping the surgeon and team comfortable, particularly when worn for lengthier periods of time. (44,45)

There have been significant advances in both the design and construction of surgical gowns since the time of the frock coat donned in the mid 19th Century. Recognition of the importance of pore size between woven fibres in terms of enabling the transmission of microbes, the difference in transmission of bacteria through wet and dry fabric, the effect of pressure on the fabric for microbial transmission, the introduction of synthetic fibres and the development of

effective finishing treatments have seen a variety of changes in the construction, durability, impenetrability and surface repellency of the fabrics used over the decades. (46)

Changes to the design of the gown, such as the introduction of total body exhaust suits for arthroplasty by Charnley have since been shown to increase wound contamination and surgical site infection in arthroplasty. (47) The glove-gown interface also remains a source of potential contamination. (48) There is room for further research into the improved surgical gown.

Despite great enthusiasm being shown for investigating the best types of fabric for a surgical gown, replication of results in vivo and in vitro often differ. (49) A recent review of surgical site infection in orthopaedic and spine surgery found no available evidence to support a difference between reusable and disposable gowns and drapes and called for further research. (50) WHO Global Guidelines for the Prevention of Surgical Site Infection recommend use of reusable or disposable gowns and drapes and acknowledge the paucity of evidence in this domain. (51) There have been no randomised controlled trials to assess surgical site infection with reusable or disposable gowns and drapes. As such, we cannot conclusively state that reusable and disposable gowns are equivalent at preventing surgical site infection in clean surgery; it is suspected however that there is little difference in clean-contaminated surgery and no difference in dirty or contaminated surgeries.

The FDA-approved classification scheme for gowns, now updated to ANSI/AAMI PB70:2012 places gowns into one of four categories depending on the protection they provide. Procurement and clinicians should be ensuring that the correct category of gown is used within each particular workplace environment. (52)

- Level 1: Minimal risk, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit. It provides a slight barrier to small amounts of fluid penetration. One type of test is used to determine its effectiveness level by means of water impacting the surface of the gown material to assess barrier protection performance.
- Level 2: Low risk, to be worn, for example, whilst taking a sample of blood, inserting a suture, in the Intensive Care Unit or a pathology laboratory. It provides a better barrier to larger amounts of fluid penetration through splatter than a Level 1 gown and to fluid exposure through soaking. Two tests are conducted in this case to assess barrier protection performance, water impacting the surface of the gown material as for the Level 1 material and subjecting the material to the possibility of penetration of liquid under hydrostatic pressure.
- Level 3: Moderate risk, to be used, for example, during arterial blood draw, inserting an intravenous line, in the Emergency Room, or for trauma cases. The same two types of tests are used to determine barrier protection performance as for Level 2 but with more impact force and greater hydrostatic pressure. The Level 3 material provides a barrier to larger amounts of fluid penetration through splatter and greater fluid exposure through soaking than Level 2.
- Level 4: High risk, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed, or infectious diseases are suspected (non-airborne). Requirements are higher for all of the types of tests conducted to determine performance to Levels 1-3 and barrier level performance must be sufficient to prevent all fluid penetration for up to 1 hour and virus penetration for up to 1 hour, the latter being tested with a simulated blood containing a virus/surrogate virus. If no virus/surrogate is found at the end of the test, the gown material has shown the required performance.

Clinicians should be critically evaluating how to drape patients and to consider whether quantity of drapes used for operations can be reduced. Analyses of the economic and environmental benefits have already been undertaken across a range of surgical specialities. (53,54) Again, however, there remains a paucity of evidence and no randomised controlled trials assessing surgical site infection in clean surgery with reusable and disposable drapes have been undertaken. (50)

Surgical Masks

Following on from a paper published by Hamilton in 1905 which advocated the use of masks by nurses performing dressings and doctors engaging in surgery, Weaver in 1918, discussed the value of a facemask in preventing the spread of infectious disease. (55) In subsequent years, different types of masks have been tested including gauze, paper, and filter masks. Currently, most masks are made from layered non-woven polypropylene within which the non-woven filter layer is melt blown to produce fine diameter fibres and this is sandwiched between spunbonded cover layers sometimes containing a support layer. (56) The length of time that a mask provides protection for has also been questioned and in fact, whether a mask needs to be worn at all has also been scrutinised, (55,57); a recent Cochrane trial was unclear as to whether wearing a surgical face mask by members of the surgical team had any impact on surgical wound infection rates for those undergoing 'clean' surgery. (58) The situation is more complicated, however, when masks have to protect the healthcare team from the patient, particularly when there is a likelihood of aerosols or spray being generated.

The terms *Surgical Mask* or *Facemask* when used in the United States, refer to Food and Drug Administration (FDA)-cleared surgical-, laser-, isolation-, dental-, and medical-procedure masks with or without a face shield. They are approved based on test results for particle filtration efficiency, bacterial filtration efficiency, fluid resistance, differential pressure, and flammability. In addition, there are also European Standards for masks; EN 14683:2019+AC:2019. (1)

The need for Filtering Facepiece Respirators (FFRs) with Surgical Mask capabilities such as fluid resistance and flammability, was first addressed by the FDA in 1996 through the introduction of the Surgical N95 Respirator. In the European Union, the recommended FFR must meet the requirements of the more demanding European standard for filtering half masks, EN 149:2001+A1:2009, wherein the need is to be able to withstand additional challenge by an oily substance and to demonstrate higher efficiency levels than the N95 respirator (although the difference in efficiency between the N95 and the widely-used FFP2 is only slight). High filtration efficiency is essential, but typically, with higher efficiency comes increased difficulty in drawing the air through the filter as the wearer breathes in, pointing to the need for great care to ensure completeness of fit to ensure that unfiltered air is not drawn in from the sides. Guidance on the use of respirators and facial protection equipment has been developed and published by the Healthcare Infection Society Working Group on Respiratory and Facial Protection. (59)

The use of surgical N95 FFRs in both surgical and non-surgical environments increases markedly during outbreaks involving a known or suspected respiratory pathogen. To combat transmission of diseases, respirators need to be able to filter out fine particles. Such particles are classified by BS EN ISO 16890 into three categories PM10 (less than 10μm), PM2.5 (less than 2.5μm), and PM1(less than 1μm). BS EN 149:2001 + A1:2009 is the British Standard to which respiratory protective devices are tested using sodium chloride and paraffin oil at 95 l/min.

With the advent of a growing number of pandemic threats, there has been interest in finding the 'best mask' to prevent infection amongst healthcare workers. The 2009 H1N1 influenza pandemic and 2020 COVID-19 pandemic saw contradictory recommendations given by leading authorities depending upon whether the authority wrote guidance based upon a risk or a hazard analysis. It would seem reasonable to suggest that, rather than pedantically abiding by just one or the other, organisations such as The Health & Safety Executive in the UK, and The Occupational Safety and Health Administration in the US, should recommend using both risk and hazard analysis.

Research to produce a 'better' mask has taken several different avenues including the fit of the mask and the style of the mask. There has been work assessing finishing the fabric with antimicrobial and antiviral compounds to improve filtration. (56,60) Attention has been paid to improving filtration not just by the physical properties of the fabric but by the inclusion of electrets to attract particles and aerosols and nanofibre webs. (61,62) It has been shown for example that N95 masks (which do contain an electret layer) retain their performance through storage for periods of at least ten years, which is something to be considered when planning for future pandemics. (63) This is an area of evolving interest.

The limited supply of masks in the COVID-19 pandemic also saw guidance released upon reuse and decontamination of masks. There is still, however, not only a lack of research around how long a mask remains effective in actual use but also a problem with acceptance of possible treatments for the decontamination of respirators and a lack of official certification rather than emergency permission to enable their re-use after exposure to viruses. This remains the current sitatuion despite useful baseline research conducted ten years ago by Viscusi, Bergman, and co-workers. (64,65) Their work was undertaken following concerns in the USA by health officials about a potential shortage of masks following the H1N1 outbreak in 2009. Ten years later, when COVID-19 had been spreading for six months, it was clear that preparations for such a pandemic were seriously inadequate. Responding to the worsening situation, Stanford University established a rapidly growing group called N95DECON to create a set of best practices on the decontamination and reuse of N95 respirators. (66) Several decontamination methods were proposed, some of which were based on the earlier work published by Viscusi et al. and Bergmann et al. Whilst other papers have emerged, there is no review assessing the best method of decontamination of a facemask with consideration given to number of cycles of decontamination, environmental impact of repeated decontamination or the ease to by which decontamination could be upscaled in a future pandemic.

Surgical Gloves

The materials from which surgical gloves are manufactured has changed over the decades. The association between the powder on gloves and the development of starch peritonitis being an important driving force. (67) Similarly, the increase in latex allergy amongst healthcare workers during the 1990s also steered the choice of material. (68) The range of common glove materials has widened to include not only latex but also synthetic polymers, such as neoprene, polyisoprene and nitrile rubber. (1)

Recent highlighting of labour-rights abuse of workers in the manufacturing of medical gloves for the National Health Service stresses the importance of transparent supply chains. Allegations include forced labour, exploitation, debt bondage, violence and intimidation. Quite clearly, this is not acceptable and as a profession the way in which we utilise and procure goods lies within our control. (69) Women make up the majority of the low-wage and unskilled

textile workforces, so improvement in sustainability of the supply chain has an important gender equality dimension. (70) Both workers employment conditions and gender opportunity are included in the United Nations Sustainable Development Goals.

Clinicians should use gloves judiciously and only in appropriate clinical situations where there is a risk of infection and contamination rather than for routine everyday interaction. Clinicians should wear the correct size of glove; the risk of perforation is more likely with a poorly fitting glove. (71) Double gloving reduces the risk of perforation but at a trade-off against sensation and potential dexterity. (72,73)

Changing gloves during the procedure should be at the clinician's discretion; there is an increased risk of perforation as the operating time increases. (74)

Surgical Hats

Surgical hats have been routinely worn in operating suites since the 1950s when they were introduced with the intention of covering the hair to reduce the risk of hair and skin squame shedding.

Currently available hats include disposable bouffant style hats, disposable skullcaps and reusable cloth hats. One prospective study conducted in a mock surgical environment found that disposable bouffant hats yielded higher levels of 0.5μm and 1.0μm particles and a significantly higher microbial shed than the other head coverings. The fabric of the disposable bouffant hat had larger average and maximum pore sizes compared to the cloth skull caps and were significantly more permeable. (75) Reusable hats should be considered where possible. It would be prudent to change these, as a minimum, either daily or when visibly dirty.

A randomised controlled trial assessing cap design and comparing bouffant caps and skull caps found the style of hat makes no significant impact on surgical site infection rate. (76) Another larger study confirmed no difference to surgical site infection rate with a change in style of hat from a skull cap to a bouffant hat. (77) Given the function of a hat, it would seem appropriate that a hat that appropriately covers the hair should be worn. This will differ between individuals. More work is required to identify whether a hat should also cover the ears. (78)

Healthcare Workers' Clothing

Healthcare workers' clothing also requires separate attention as operating theatre attire differs from the sterile gown. The objective of wearing an operating theatre scrub suit is to reduce contamination of the air by healthcare provider skin squames. One observational study found that single use polypropylene scrub suits reduced the median quantity of bacterial CFU/m^3 compared to two different reusable scrub suits. (79) However, there is no study assessing the impact of scrub suit on surgical site infection rate. That said, if WHO guidance on surgical site infection with reusable and disposable drapes and gowns is extrapolated, then the impact is likely to be minimal. (51)

A life-cycle assessment published in 2022 of reusable and disposable scrub suits has demonstrated that the reusable solution had a 62% lower impact on climate change compared to the disposable. (80) This supports previous publications and would support recommending using reusable scrub suits where practical. Further work is needed to determine whether there is a more appropriate fibre that could replace the traditional polyester and cotton blend used in scrub suits currently.

Work has been undertaken to assess the impact of wearing a jacket over the scrub suit in the operating theatre to reduce dispersion of skin squames. One study including 30 493 procedures found no difference in surgical site infection when long sleeves were worn compared to not worn. (81) We would recommend that jackets should not be mandatory.

Methods have been developed to enable rapid quantitative testing with the real-time polymerase chain reaction (qPCR) to check for the presence of nosocomial pathogens. (82) Whilst most of the contamination is from the wearer of the uniform, uniforms have been found to become frequently contaminated below the waist and heavily contaminated after procedures that involve exposure to pathogens. (83) Using a plastic apron significantly reduces contamination at the front of the uniform (84) but the apron itself with its slick surface must become a highly-effective contamination transfer item and this needs to be investigated. As contamination of theatre attire increases during the day, scrub suits should be changed, as a minimum, daily. (85)

When leaving the operating theatre, surgeons should cover their attire or change their clothes. One randomised study showed a closed gown exterior worn outside the operating theatre reduced the bacterial contamination of the scrub suit worn underneath. (85) Whilst evidence is lacking, it seems sensible to reduce overall contamination by covering the scrubs outside of the operating complex.

There has been much attention turned towards the production of antimicrobial and antiviral fabrics, driven recently by the COVID-19 pandemic. Properly designed trials undertaken in realistic situations are few and far between but the trials which have been carried out show that existing antimicrobial treatments are ineffective in the practical setting. However, there will always be a need for fabrics able not only to act as barriers but also to deactivate pathogens and therefore to keep staff and patients safe despite contamination during their treatment.

Further robust research is required into the role that antimicrobial textiles may have in the workplace. The groundwork was established in the 'Three-Tier' protocol published by the OECD in 2008 in their Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects. (86)

- Tier 1 concerns 'Proof of Principle'
- Tier 2 'Simulated Use'
- Tier 3 'In-Use Evaluation'

It is at Tier 2 where current test methods fall seriously short. Realistic, reliable, laboratory-based Tier 2 test methods now need to be developed for medical textiles and validated for their alignment with practice before they could be considered for acceptance as standards. The OECD does give guidance on the development of appropriate Tier 2 test methods in their 2019 document Guidance Document on Use and Development of Tier-2 Laboratory Based Tests Used to Substantiate Claims for Efficacy of Biocide Treated Articles, (87) and this is what more researchers now need to build on to develop effective antimicrobial PPE.

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