Tibial fractures treated with mono-lateral fixation: principles of design and application.

Ogrodnik PJ[1,2], Thomas PBM[1,2], and Collingwood A[1]

[1]Orthopaedics and Biomechanics Research Group, Keele University, Stoke on Trent, UK

[2]Royal Stoke University Hospital, Stoke on Trent, UK

Keywords

Tibia, Fracture, External Fixation, Diaphyseal, Design Principles, RUST, Fixator, Unstable

Abstract

This paper presents the outcome of a data review of patients treated with the IOS external fixation system at the Royal Stoke University Hospital: a fixation designed to meet four requirements for external fixation proposed in this paper. Demographic data and outcome were collected and assessed.

From 69 initial patients, 64 patients (55 males and 9 females) had an average age of 35.9 years. The mean time to union was 127 days. There were no incidences of malunion, or refracture post fixation removal attributable to the treatment method. In addition, there was no incidence of pin tract infection resulting in osteomyelitis. Of all the factors assessed the only factor to have any significant effect on healing was smoking: an average delay of 31 days. An examination of RUST (radiographic union score tibia) and modified RUST scores illustrated a potential false negative of up to 80%. Hence, this study cannot support the use of either scoring system to diagnose fracture healing.

IOS external fixation was shown to be an effective method for the treatment of unstable tibial fractures. The reduction at fixation removal was shown to be very good. There was no incidence of osteomyelitis. It is, therefore, suggested that appropriately used external fixation is a viable alternative to intramedullary nailing if designed and surgically applied using four design principles outlined in this paper. Furthermore, it is proposed that external fixation be designed and applied to meet these four principles.

Introduction

Tibial fractures have an incidence of 34 per 100,000 per annum[1]. Patients presenting with a tibia diaphysis fracture tend to be male, with a mean age of 37.2. Injury is often secondary to high energy impact such as a fall, car crash or a sport injury. Fractures that are considered stable are commonly treated using Plaster of Paris casts: fractures are considered unstable if they experience shortening under an axial load. An unstable fracture will require invasive management such as an intramedullary nail or external fixation. Plating is an option but involves an open reduction and can be associated with high infection rates. Though intramedullary nails command some 80% of the treatment of tibial fractures recent research highlights significant side effects such as a high incidence of anterior knee pain [2]. In contrast the obvious competitor, external fixation, is rarely used: their complexity and patient compliance often cited as reasons as is the incidence of pin site infections. The common perception of external fixators, the Illizarov frame, compounds these preconceived ideas. There is, therefore, a need for simple external fixation that does not carry the same level of risk and difficulty.

From the work of Ogrodnik *et al.* [3,4], and in addition to the usual safety factors associated with maximum static load and fatigue at gait loading to at least 1 million cycles, we propose four principles by which external fixation should be designed (and applied):

1. At ¼ weight bearing (ca 200N) the axial dynamisation allowed / promoted by the fixator is ca 1mm.
2. The fixation provides a restoring force that returns the fracture to the steady state operating position (i.e back to reduced position) when unloaded.
3. The positioning of the fixator, in relation to the fracture, is symmetrical such that dynamisation is also symmetrical (thus minimising offset shear).
4. Dynamisation is controlled, there are no sudden jerks or jumps from one position to another due to frame instability.

The monolateral external fixator in this study - IOS™ - has been developed for management of unstable, diaphyseal tibial fractures using these principles (illustrated in Figure 1). The device is made of titanium alloy and designed so the elasticity of the fixator bar allows a specific amount of cyclical movement at the fracture site to promote healing. The fracture length is limited to 84mm or less from the proximal to distal extent. The degree of movement is dependent upon the degree of patient movement, therefore patients are encouraged to mobilise and weight-bear as soon as possible post operatively.

Following any intervention, but especially an external fixator, determining when to remove the device is key. Early removal can result in complications such as refracture and malunion, late removal results in higher costs and lower patient satisfaction. X-rays alone have been demonstrated to be poor indicators of union in tibia fractures[5]. It is generally accepted within the literature that biomechanical stiffness of a fracture is a safe and effective means of assessment of union, with 15 Nm/degrees deemed to be a safe threshold for union [3,5,6,7]. The literature has highlighted the need for devices measuring stiffness to operate in multiple planes and the necessity for a uniform loading rate[3] The IOS fixator has been developed taking these requirements into account by incorporating a visual guide for fracture healing end-point [4].

This study aims to investigate the outcomes from patients treated with a single design of mono-lateral external fixator over a 7 year period, thus confirming the principles of external fixation described earlier.

Description of the External Fixator

The IOS™ fixator[8] (Figures 1 and 2) is a single piece fixator with no moving parts (satisfying principle 4 - dynamisation is controlled, there are no sudden jerks or jumps from one position to another due to frame instability). Dynamisation is produced by mechanical loading across the fracture site produced by weight bearing or by muscle action from the patient performing dorsiflexion / plantar flexion. As the fixator is placed 60-65mm offset from the central axis of the tibia any loading through the bone creates a bending moment in the fixator and hence creates bending of the fixator. The combination of the bending of the fixator and the offset of the pins creates movement at the fracture site (Figure 2b). The overall length of the fixator is short (150 and 190 mm respectively for short and long versions) which allows it to be placed anywhere within the length of the diaphysis, thus allowing for the centre of the fixator to be aligned with the centre of the fracture (satisfying principle 3 - the positioning of the fixator, in relation to the fracture, is symmetrical such that dynamisation is also symmetrical (thus minimising offset shear).

In addition, the design allows the fixator to act as a spring, returning the fracture to its steady state operating position when unloaded (satisfying principle 2 - the fixation provides a restoring force that returns the fracture to the steady state operating position - i.e back to reduced position- when unloaded). The fixator has been mechanically tested and produces ca 1mm of axial deflection at an axial load of 200N (satisfying principle 1 - at ¼ weight bearing, ca 200N, the axial dynamisation allowed / promoted by the fixator is ca 1mm). The fixators have been cyclically loaded to 1.5million cycles at 115kgf and have been developed to withstand 200 kgf static body weight [8] – an important consideration in fixator design. In addition, the dynamisation is a combination of axial motion and angular motion (Figure 2b) providing a callus mass that develops to inhibit axial and bending actions [9,10]. However, this does make the need for symmetrical placement very important as asymmetric placement would lead to mechanical shear at the fracture site (Figure 2c). Indeed, this is an important consideration for all fixation.

Prior to treatment, fractures are assessed for stability: those considered unstable and that meet the main criteria (fracture length no greater than 84 mm) are considered for treatment with the IOS fixator. Prior to definitive fixation the fracture is reduced, under general anaesthetic, using the STORM™ fracture reduction device [11] this provides consistency of anatomical reduction. Once reduced the IOS fixator is applied to the tibia using 6 x 6mm half-pins. The fixator acts as its own drill guide, ensuring that the half-pins are aligned and in the correct positions. This combination of anatomical reduction and consistent fixator application minimises confounding errors from variations in reduction and variations in fixator placement. Once the IOS has been applied the reduction device is removed. Patients are recommended to ambulate as soon as possible, often the day after surgery. Pin sites are treated using the RCN pin site care protocol [12]. Patients, and their carers, are given information on both pin-site care and on the importance of ambulation (weight bearing). Patients are encouraged to stop smoking and advised to avoid NSAIDs .

Because the fixator has no joints and no moving parts there is little chance of slippage. X-ray plates are taken pre-operatively and post-operatively. Apart from those deemed necessary, no further x-rays are required until fixation removal – there is no need for regular x-rays at each clinic.

The fixator is removed once the fracture is considered healed. The value of 15 Nm/degrees of stiffness in a fracture has been demonstrated to be a safe threshold indicating union[6,7] once a fracture has reached 15 Nm/degrees it is no longer possible to bend the tibia more than 1° by manual application of a bending force. The IOS fixator has this assessment built into the fixator body. Figure 1 illustrates an assessment in progress, if the clinician is able to deform the fracture such that the pins touch the sides of the body then the fracture is not healed. If, however, the fracture may be considered healed the pins will not touch the sides of the body. The justification for this assessment method is described in Ogrodnik and Thomas[4]. This provides a unique, quantifiable fracture healing end point.

The fixator is removed in fracture clinic and no anaesthesia is required. Pin sites are cleaned and dressed, and patients are given an information on how to care for the pin-site wounds. Patients are invited to return for a 2-week follow-up.

Materials and Methods

A retrospective evaluation of patients managed with the IOS external fixator at Royal Stoke University Hospital (RSUH) was conducted covering the years 2010-2017. The details of the patients' injuries and patient demographics were recorded to investigate if they influenced the performance of the IOS fixator. The data was gathered from patients treated at the RSUH. All data was collected using the iPortal (iPortal, UK) system and patient images were viewed via Sectra (Sectra, UK).

The patient database was formed using a prospective list of patients managed with the IOS fixator cross-referenced with the operation code for tibial external fixator application, W301, on the theatre database to ensure no patients had been omitted. The code for tibial external fixator removal was also searched, W303, to account for any potential errors in operation coding following application. 145 patients managed with IOS at RSUH were identified as eligible to be included in the service evaluation.

The data was collected using operation notes and clinic letters. The radiographs reviewed were the initial radiograph of the injury and the final radiograph, immediately before fixator removal. All data collected is shown in table 1. Time to union was calculated as date of external fixator removal minus date of external fixator application.

Data collection for this study was carried out in line with Keele Medical School's ethics committee and RSUH audit department's guidelines. No patient data was removed from the hospital site, and no patient data is identifiable from the data collected. All data was collected and stored on a hospital computer.

Data analysis

All data was analysed for normality using a Shapiro-Wilkes analysis (Table 2). As the data was illustrated to not be normally distributed, statistical significance between groups was determined using a Mann-Whitney analysis. A Kaplan-Meier non-parametric survival analyses was used to further determine Mean Time to Union - hypothesis testing for statistical significance was conducted using Wilcoxon and Log-Rank analyses.

The sample size was large, hence a Box-Cox transformation could be performed to normalise the raw data. Hypothesis testing between groups was determined using t-test on both the raw data and on the normalised data [13].

All analyses were conducted using SPSS and Minitab 19, as appropriate.

Results

Sixty-nine patients were identified - three patients were excluded as their treatment was interrupted. The outcomes of the remaining sixty-six patients with unstable tibial fractures managed with the IOS fixator were reviewed in this study, Table 2 demonstrates a demographic assessment of the cohort. It presents an analysis of the normality of the data using a Shapiro-Wilkes analysis. Further the table presents the descriptive statistics associated with the parameter. The results of the normality assessment demonstrates that most of the data sets cannot be judged as normally distributed. Median and average values are presented. A truncated average is also presented that excludes data from the bottom 5% and top 5%, this value illustrates the effects of outliers. Standard deviation is only presented for data that may be assumed to be normal ($p>0.05$). The range of data from minimum to maximum is also given.

The average age of the cohort was 36 with a median of 32 and a range from 12 to 78 years, but the data is not normally distributed ($p<0.01$). Fracture length (measured from distal tip to proximal tip) has a median of 30.75mm, with an average of 36.7 and a range of 4.4 to 90.5 mm. The distance from the fracture centre to the plafond has a median of 141.7 mm and an average of 143.5 mm with a range of 65-284 mm. The cohort consisted of 55 males and 9 females. Thus, this cohort correlates with the overall population noted by Larsen *et al.* [1] and may be considered indicative of the general population.

An assessment of alignment pre- and post-operative was conducted using data collected from digital x-ray plates. The results given in Table 2 illustrate the quality of reduction achieved. Using per-operative reduction before applying definitive fixation has, we suggest, eliminated this confounding factor from the study. The data is presented for information and will be used in an analysis of correlation between reduction and healing times later.

In this study days to fixation removal is the main data set and may not be considered to be normally distributed ($p<0.01$). The data is, in fact, skewed. This study illustrates an average time to union of 137 days. However, two patients, within this group, had exceptionally long healing times – more than triple the median value at 381 and 518 days respectively and greater than the median value compared to the next largest value - and may be considered as outliers. The average time to union for the cohort excluding the two outliers is 127 days (illustrated by the numbers in parentheses in Table 2). This data is further illustrated in Figure 3 – a Kaplan-Meier survival plot. For each analysis three lines are plotted, the survival plot itself (inner plot) and the 95% confidence limits of said survival plot (outer plots) – these are indicated on the figure for clarity. The Kaplan-Meier analysis, depicted in Figure 3, illustrates no significant difference between the Mean Time To Union (MTTU) ($P>>0.05$) between the analysis including the outliers versus that excluding the outliers. 64 patients remained in the study and their results were analysed and the results presented in Tables 3 and 4, and Figures 4-5. Their exclusion did not alter the results of hypothesis testing.

Table 3 depicts an analysis of the significance of sub-groups within the population, these subgroups included age, gender, surgeon, smoking, prescribed antibiotics, fracture classification, and open or closed fractures, and above and below average age. Table 2 illustrated that data is not normally distributed. As the data is continuous and is independent a Mann-Whitney analysis was used to test for statistical significance between groups. For comparison and confirmation, a Kaplan-Meier analysis was conducted. Finally, following a Box-Cox transformation, a t-test was performed on the normalised data.

The lead surgeon conducted 16 procedures; the remaining 28 surgeons conducted the remaining 48 procedures. The results of the Mann-Whitney and Kaplan-Meier analyses do not show an significant difference between the groups - medians of 117.5 and 116.5 with a p>>0.05, and Mean Time to Union (MTTU) of 126.6 and 127.7 with p>>0.05. The result of analysing normalised data using a t-test illustrates a value of p>>0.05 – again not significant. This multi-pronged approach has been conducted to ensure that any lack of significance between groups, or indicated significance between groups, is robust. The survival plots (Figure 4) for the lead surgeon and the remaining surgeons all lie within each other's 95% confidence limits, hence it is confirmed they are indistinguishable as groups. This suggests that it is possible to ignore the effects of the surgeon on further analysis, and the cohort may be treated as a whole.

Table 3 illustrates there was no significant difference between patients presenting closed (N=50) and open (N=14) fractures, with MTTU of 124 and 137 days respectively and all values of p>>0.05. The same applies for Male patients (N=55) and female patients (N=9) – MTTU being 127 and 140 days respectively and all values of p>>0.05.

Age and treatment for infection are often cited as a contributory factor. Table 3 illustrates no significance between groups of patients of below the average age of 36 (N=35) and those above the average age (N=29) – MTTU being 125.5 and 128.7 days respectively and all values of p>>0.05. Equally, Table 3 illustrates no significance between patients prescribed antibiotics (N=22) to those with no treatment (N=42). – MTTU being 130.5 and 125 respectively and all values of p>>0.05

This study included 20 smokers and 44 non-smokers. This is the only factor where any statistical significance between the groups was identified. Table 3 illustrates that the Mann-Whitney analysis and Wilcoxon analysis suggest no significance (p=0.062 and 0.066 respectively), but the log-rank analysis and t-test results illustrate significance (p=0.008, 0.05 and 0.036 respectively). Figure 5 illustrates the Kaplan-Meier survival plot for these groups. The survival plot for the smoking groups lies outside that of the 95% confidence limits of the non-smoking group, and vice-versa, this supports the evidence from the log-rank and t-test analysis that the groups are different, and that the difference between the values of MTTU is statistically significant. This suggests there is a delay in union from smoking and this can be as much as 31 days – or over 4 weeks, and this compares with previous findings[14,15].

The fracture classification may be considered to be an indication of fracture complexity. Table 3 illustrates the results from those patients presenting with fractures classified as 42-A (50) and those in 42-B and 42-C (collated to give a large enough group for analysis). Again, there is no significant difference between the groups with MTTU of 127.5 and 124.9 days respectively and all values of $p>>0.05$: this is further illustrated by Figure 6.

Table 4 examines the correlation between orthopaedic outcomes and time to union. In all cases the value of p should be less than 0.05 to illustrate significance. In all cases $p>>0.05$ and hence no significant correlation may be claimed. In this table all measurements were taken from pre-operative and post-operative x-rays. Interestingly there is no evidence of any correlation of healing time with age ($p=0.471$), fracture length ($p=0.989$), or distance to plafond (0.315). Nor is there any correlation with final reduction as exemplified by AP and lateral angulation and translation data ($p>>0.05$ in all cases).

An important consideration may not be the final reduction, but the amount the fracture had to be manipulated to achieve said reduction. The correlation between change in translation and time to union is presented for both AP and lateral manipulations, again there is no correlation ($p>0.05$ in all cases).

The final row of this table is to check if the surgeons' skill of application improved as the time passed. This row checks correlation between when the patient was treated with respect to the first patient treated. If any skills, tips, or lessons had been learned as time passed this should exhibit itself as a negative correlation. But as the data shows the Pearson correlation coefficient is 0.054 with a $p=0.67$, hence there is no correlation. Therefore, patients treated early in the latter period had no significant benefit over those treated later. This, once again, supported the ability to analyse the cohort as a whole.

Table 4 illustrates the results of an analysis of fracture union assessment using RUST (Radiographic Union Score Tibia) and mRUST scoring systems[16]. The first two rows illustrate RUST scores determined immediately post-operative, and at the point of fixation removal. The average RUST scores at treatment and at union are 4.1 and 7.7 respectively, and they are significantly different ($p<<0.05$). The final two rows are similar but using the mRUST scoring system. The average mRUST scores at treatment and union are 4.2 and 9.8 respectively, again there is significant difference with $p<<0.05$. The accuracy of diagnosis was investigated. Firstly, the average "healed" RUST and mRUST scores were used as thresholds, this resulted in 34% and 39% of the group being diagnosed as not healed when, in fact, they were. Using the Litrenta *et al.* [16] scores of RUST>9.5 and mRUST>11.4 resulted in a misdiagnosis of not being healed for 77% and 80% of the population respectively.

Discussion

This study reviewed the results of 69 patients presenting with unstable fractures of the tibia who were treated with IOS external fixation. 29 surgeons were involved in the study. Three patients were excluded as they required further surgical intervention to treat the fracture. In this study this is termed as a non-union as the primary treatment methodology has been replaced and, hence has not led to union. This represents a 4.3% incidence rate, which compares favourably with the 11% maximum suggested by Ekegren *et al.* [17]. The Mean Time to Union (MTTU) for the remaining 66 patients was 136.7 days, but two outliers were identified and when these were excluded MTTU was 127 days, which compares - favourably - with: 175 days for a similar study by Beltsios *et al.* [18] for monolateral fixation; Checketts and Young[19] reported a range of averages of 68 to 168 days dependent on fracture severity; and 181 days for frame fixation by Watts *et al.* [20]. No patient suffered a refracture post fixation removal, there was no incidence of malunion attributable to the treatment method. There was no incidence of pin-tract infection leading to osteomyelitis.

The reduction of the fractures was assessed post-operatively. The average malalignment being 1.58 degrees AP angulation, 0.78mm AP translation, 0.71mm shortening, degrees lateral angulation, and 0.16mm lateral translation. Because the IOS fixation system has no joints, these reduction values were maintained throughout the healing process. This is an important aspect for two reasons. The first reason is that the values demonstrate the quality of reduction achieved, which is much less than typical accepted maxima. The second is that the quality and consistency of reduction removes this as a confounding factor.

The average fracture length was 36.7 mm, the maximum fracture length is dictated by the indicated use of IOS, the fractures ranged from being highly transverse (4.4mm) to the maximum length (90.5mm). This maximum length has been stipulated by the manufacturer[8], in the IOS documentation it is stated that fractures longer than 90mm may not suitable for treatment with mono-lateral fixation. The average distance from the fracture to the plafond was 142.9 mm, not surprisingly being approximately mid-shaft. The range, however, illustrates that the IOS fixator was not solely applied to mid-shaft fractures but to distal and proximal fractures also (range 65-284 mm). The population contained fractures of classification 42-A, 42-B and 42-C (N - 51, 15 and 3 respectively). Furthermore, the data set contained males and female subjects (N=57 and 9 respectively) with ages from 12 to 78 years. Thus, the population covered the range of fracture complexity and the results presented and discussed in this paper can be generalised to tibial fractures within the ranges and classifications.

The population was reduced by excluding the 3 non-unions and the 2 delayed union patients, as described previously. The following discussion, hence, relates to the results from the remaining 64 patients. A comparison of MTTU for the lead surgeon against all remaining surgeons showed no significant difference (MTTU = 117.5 and 116.5 respectively, and $p>>0.05$). This suggests that the application of IOS is a readily transferrable skill between orthopaedic surgeons that requires minimal specialist training to achieve equivalent results. Furthermore, this outcome meant that the population could be treated as a whole for all subsequent analyses. There was no significant difference in time to unions for complexity of fracture (42-A versus 42-B and C), nor if the fracture was open or closed. There was no difference in healing times between males and females, or between age groups. Some patients were prescribed antibiotics as a part of their treatment, open fracture or pin site infection. There was no significant difference in healing times between those prescribed antibiotics and those who were not. Although antibiotics were prescribed there was no incidence of a pin-site infection leading to osteomyelitis.

The only factor that did illustrate a significant difference was smoking. Patients who smoked showed an average delay of approximately 31 days. There was some disagreement between the hypothesis tests as conducted by Mann-Whitney and Wilcoxon tests (p marginally >0.05) and those conducted using Log-Rank and t-tests ($p < 0.05$). However, the trend and the survival plot illustrated in Figure 4 suggests that patients be advised to, and be given support to, stop smoking as a part of their treatment regime. Unfortunately, there is no evidence in the data that may be used to infer any reduction in MTTU if a patient quits smoking during treatment. There is anecdotal evidence that patients who stop smoking during treatment progress to union, but if this is an effect of quitting smoking or would have occurred anyway is open to debate. Equally, when smoking has ceased may also be important. For example, for there to be an effect should smoking have stopped before the end of the callus phase, or can they quit at any time? Hence, the effect of quitting smoking against continuing smoking during the treatment of a fracture on MTTU is worthy of further study. In contrast, this study does not support the use of RUST or mRUST to assess the healing endpoint of tibial fractures (Table 5), and as a consequence their use in allied research studies.

An investigation of any correlation between age, fracture length, distance to plafond and reduction did not demonstrate any correlation. An important consideration, however, is this does not mean there is no correlation between time to union and reduction. In this study all reductions were near anatomical and there were no patients with reduction that could be classed as being at the extrema of acceptable. Hence, an important point is that this study showed no correlation between healing time and reduction where the reduction values are less than maxima given in Table 2.

An important aspect is the learning curve for the procedure. Do patients treated later have the benefits of lessons learned from earlier patients? This has been investigated by comparing any correlation between those patients first to those treated last. There was no correlation found illustrating that the IOS system is simple to use and the operating technique is easily transferrable between surgeons.

The outcome of the results suggest that the four principles provided earlier, should be used for the design and application of fixation systems for the treatment of unstable diaphyseal fractures of the tibia.

The study does have limitations. The data set does not include other factors that may be of importance such as bone quality, diet, and general habits. Further, it did not enable the investigation of long-term Quality Accumulated Life Years (QALY), nor could the data directly relate the outcomes to another treatment regime (intramedullary nailing). However, the results presented do not provide a reason to not use such an external fixator. Therefore, a prospective study investigating the long-term outcomes of this fixation versus intramedullary nailing would be timely and could greatly influence the treatment of tibial fractures.

Conclusions

From the results presented and discussed the following conclusions may be drawn. From the 64 patients examined the Mean-Time-To-Union was 127 days. The overall incidence of antibiotic administration was 34%, within which 26% of the population had open fractures. There was no incidence of a pin tract infection leading to osteomyelitis: any infections were successfully treated with pin site care and oral antibiotics. The fracture reduction was classed as near anatomical, and this was maintained to fixation removal. There was no incidence of malunion post fixation removal. Two refractures occurred, but these were due to trauma immediately following fixation removal and hence were deemed not to have been due to the treatment method. Therefore, IOS was demonstrated to be a safe and effective means for the treatment of unstable tibial fractures.

There was no difference in healing times between the lead surgeon and that of the other surgeons, nor was there any correlation between healing times and the period when they were treated. This suggests that the fixation system and its application is readily transferrable from one surgeon to another and the learning curve is relatively flat. It is possible, in conjunction with the above, to suggest that IOS external fixator is a potential alternative to Intra-Medullary Nailing as any reticence related to fears of pin tract infection leading to osteomyelitis or complexity of application are allayed. Furthermore, the profile of the fixator enabled proximal and distal fractures to be treated as well as simply mid-shaft.

There was only one factor that illustrated any significant effect on healing times, and that was smoking. The average delay in healing for a patient who smokes was 31 days. This suggests that patients who present as smokers should be advised to quit smoking and offered support to do so. The study could not determine what the effect was if a patient quit smoking during treatment, nor the optimum time by when smoking should have ceased. However anecdotal evidence suggests that this does improve the prognosis.

In addition to due consideration of pin site care, and failure due to static and dynamic loading, it is suggested that external fixation be designed and surgically applied considering the following four principles:

1. At ¼ weight bearing (ca 200N) the axial dynamisation allowed by the fixator is is ca 1mm.
2. The fixation provides a restoring force that returns the fracture to the steady state operating position (i.e back to reduced position) when unloaded.

3. The positioning of the fixator, in relation to the fracture, is symmetrical such that dynamisation is also symmetrical (thus minimising offset shear).
4. Dynamisation is controlled: there is not potential for sudden jerks or jumps from one position to another due to frame instability.

In addition to monoliteral fixation, the four design principles may be applied to frame fixation - such as Illizarov frames.

In this study neither RUST nor m-RUST were useful indicators for time to union. In both cases the incidence of misdiagnosis of union was greater than 75% (3 out of 4 misdiagnosed). As a consequence, their use to determine fracture healing end-point in fracture clinics is not supported: their use in research studies is not recommended.

References

[1] Larsen P, Elsoe R, Hansen SH, Graven-Nielsen T, Laessoe U, Rasmussen S. Incidence and epidemiology of tibial shaft fractures. *Injury*. 2015 Apr 1;46(4):746-50.

[2] Katsoulis E, Giannoudis PV. Incidence and aetiology of anterior knee pain after intramedullary nailing of the femur and tibia. *The Journal of Bone & Joint Surgery British Volume*. 2006 May 1;88(5):576-80.

[3] Ogrodnik PJ, Thomas PB, Moorcroft CI, Mohammed KN. A multidirectional fracture stiffness model to determine the principal stiffness properties of a healing human tibia. ***Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine.*** 2013 Oct;227(10):1125-34.

[4] Ogrodnik PJ, Thomas PB. A practical, quantitative, fracture healing endpoint assessment criterion for tibial fractures treated with external fixation. ***Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine***. 2019 May;233(5):497-505

[5] McClelland D, Thomas PB, Bancroft G, Moorcroft CI. Fracture healing assessment comparing stiffness measurements using radiographs. *Clinical Orthopaedics and Related Research*. 2007 Apr 1;457:214-9.

[6] Richardson JB, Kenwright J, Cunningham JL. Fracture stiffness measurement in the assessment and management of tibial fractures. *Clinical biomechanics*. 1992 May 1;7(2):75-9.

[7] Richardson JB, Cunningham JL, Goodship AE, O'connor BT, Kenwright J. Measuring stiffness can define healing of tibial fractures. *The Journal of Bone & Joint Surgery British Volume*. 1994 May 1;76(3):389-94.

[8] Metaphysis LLP, *IOS Surgical Technique*. 2021.

[9] Moorcroft, C. I. *Control and monitoring of movement in fractures of the human tibia*. PhD Thesis, Staffordshire University, 1999.

[10] Goodship AE, Kenwright J. The influence of induced micromovement upon the healing of experimental tibial fractures. *The Journal of Bone & Joint Surgery British Volume*. 1985 Aug 1;67(4):650-5.

[11] Moorcroft CI, Thomas PB, Ogrodnik PJ, Verborg SA. A device for improved reduction of tibial fractures treated with external fixation. ***Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine****.* 2000 May 1;214(5):449-57.

[12] RCN (2022), *Guidance on Pin Site Care*, RCN 009 907.

[13] Campbell MJ, Machin D, Walters SJ. Medical statistics: a textbook for the health sciences. John Wiley & Sons; 2010 Oct 26.

[14] Verborg S, Jones PW, Gregson PA, Tandon S, Thomas PB. Tibial fracture healing in smokers. *Journal of Orthopaedic Trauma*. 1999 May 1;13(4):314-5.[

[15] Patel RA, Wilson RF, Patel PA, Palmer RM. The effect of smoking on bone healing: a systematic review. Bone & Joint Research. 2013 Jun 1;2(6):102-11.

[16] Litrenta J, Tornetta III P, Mehta S, Jones C, O'Toole RV, Bhandari M, Kottmeier S, Ostrum R, Egol K, Ricci W, Schemitsch E. Determination of radiographic healing: an assessment of consistency using RUST and modified RUST in metadiaphyseal fractures. Journal of Orthopaedic Trauma. 2015 Nov 1;29(11):516-20.

[17] Ekegren CL, Edwards ER, De Steiger R, Gabbe BJ. Incidence, costs and predictors of non-union, delayed union and mal-union following long bone fracture*. International journal of environmental research and public health.* 2018 Dec;15(12):2845.

[18] Beltsios M, Savvidou O, Kovanis J, Alexandropoulos P, Papagelopoulos P. External fixation as a primary and definitive treatment for tibial diaphyseal fractures. *Strategies in trauma and limb reconstruction.* 2009 Oct;4:81-7.

[19] Checketts RG and Young CF. (iii) External fixation of diaphyseal fractures of the tibia. *Current Orthopaedics.* 2003 Jun 1;17(3):176-89.

[20] Watts A, Sadekar V, Moulder E, Souroullas P, Hadland Y, Barron E, Muir R, Sharma H. A comparative evaluation of the time to frame removal for tibia fractures treated with hexapod and Ilizarov circular frames. *Injury*. 2023 Mar 1;54(3):996-1003.

Acknowledgements

The authors of this paper recognise the contribution of the Royal Stoke University Hospital and Keele University.

Declarations of interest

This study did not receive funding. Ogrodnik and Thomas are co-inventors of IOS.

.

Table 1. Data points collected from patients treated with IOS fixator.

Patient demographics	Data collected from patient follow up	Data collected from x-rays
Age	Date of fixator application	AO classification of fracture
Gender	Length of stay post application	
Smoking status	Time to full weight bearing	
Mechanism of injury	Time to return to work	
	Incidence of infection (Abx)	
	Time to union (removal of IOS)	
	Incidence of delayed union	
	Incidence of non-union	

Table 2 – Descriptive statistics of the population indicating normality, median, mean/average, truncated mean /average, standard deviation and range. The numbers in square parentheses indicate means for normally distributed data, otherwise it is the average. The numbers in circular parentheses indicate vales where the two delayed unions (at 381 and 518 days) have been excluded. The truncated mean/average is the value where the lower and upper 5% have been excluded. All measurements were made from digitally stored pre-operative, per-operative and post-operative x-ray plates.

	Normality		**Median**	**Average [Mean]**	**Truncated Average [Mean]**	**St. Dev**	**Range**
Age	p<0.01	No	32	35.9	35	-	12.0-78.0
Fracture length	p<0.01	No	30.75	36.7	36	-	4.4-90.5
Fracture to Plafond	p=0.026	No	141.7	143.5	142.9	-	65-284
Pre-operative data							
Xrays (initial position) - AP Angulation	p=0.025	No	6.34	7.1	6.9	-	0.4-19.7
Xrays (initial position) - AP Translation (%)	p>0.1	yes	33%	[33.80%]	[33.30%]	19%	0-77%
Xrays (initial position) - AP Translation (mm)	p>0.1	yes	9.2	[9.28]	[9.04]	5.4	0-24.7
Xrays (initial position) - Shortening (mm)	p=0.02	No	6.9	8.27	7.47	-	0-35.2
Xrays (initial position) - Lateral Angulation	p=0.021	No	6.2	7.2	6.9	-	0-24.3
Xrays (initial position) - Lateral Translation (%)	p<0.01	No	23%	31%	29%	-	0-100%
Xrays (initial position) - Lateral translation (mm)	p=0.024	No	5.6	7.2	6.8	-	0-27.1
Post-operative data							
Xrays (reduced) - AP Angulation	p>0.1	Yes	1	[1.58]	[1.43]	1.83	0-6.9
Xrays (reduced) - AP Translation (%)	p<0.01	No	0	3.30%	2.10%	-	0-35%
Xrays (reduced) AP translation (mm)	p=0.046	No	0	0.78	0.55	-	0-7.3
Xrays (reduced) – Shortening (mm)	p<0.01	No	0	0.21	0	-	0-11.5
Xrays (reduced) – Lateral Angulation	p<0.01	No	0.8	1.7	1.37	-	0-13.3
Xrays (reduced) - Lateral Translation(%)	p<0.01	No	0.70%	1.70%	1.33%	-	0-13.3%
Xrays (reducted) Lateral Translation (mm)	p<0.01	No	0	0.16	0.02	-	0-4
Time To Union							
Days to fixation removal (Time To Union)	p<0.01	No	118.5 (116.5)	136.7 (127)	127	-	57-518 (57-259)

Table 3 – A statistical analysis of the significance of the differences between time to union of specific groups from within the total population (this data excludes the two delayed unions as described earlier). In the first main column the data is treated as being non-parametric, the results from Mann-Whitney and Kaplan Meier analyses are presented. For comparison the second main column presents an analysis assuming normal data and following a Box-Cox transformation, the results of a t-test are presented. To illustrate any significance the values of p should be less than 0.05. In this table MTTU replaces the usual MTTF, and stands for Mean Time To Union.

	Non-Parametric						**Assuming normal data**		
	Mann-Whitney			**Kaplan Meier**					
	N	**Median**	**Test Statistic, p**	**MTTU**	**Wilcoxon test statistic, p**	**Log-rank test statistic, p**	**Mean**	**St.dev**	**t-test result (Box-Cox normalised value) p**
Lead surgeon	16	117.5	0.944	126.6	0.94	0.792	126.6	43.2	0.97 (0.933)
Others	48	116.5		127			127	41.5	
Non-Smoker	20	131	0.0616	148.3	*0.066*	*0.008*	148.3	56.4	*0.05 (0.036)*
Smoker	44	113		117.2			117.2	28.5	
42-A	50	115	0.691	127.48	0.9254	0.691	127.5	44.6	0.837 (0.87)
42-B and 42-C	14	122		124.85			124.9	29.6	
Closed	50	114	0.359	124	0.37	0.29	124	39.6	0.301 (0.296)
Open	14	122		137.1			137.1	47.9	
Male	55	115	0.664	126.9	0.656	0.461	126.9	51.3	0.417 (0.468)
Female	9	119		140			140	41.5	
Abx treatment	22	119.5	0.646	130.5	0.6441	0.7916	130.5	40.93	0.62 (0.526)
No Abx treatment	42	114		125			125.5	42.23	
Below average age	35	112	0.207	125.5	0.2068	0.797	125.5	48.76	0.762 (0.272)
Above average age	29	122		128.7			128.7	31.48	

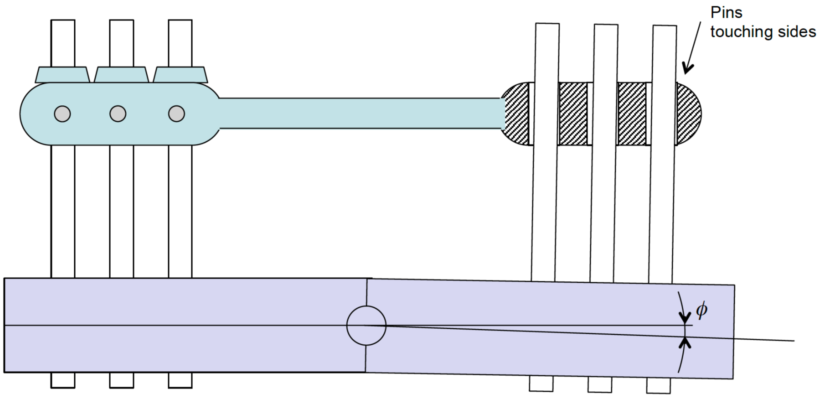
Table 4 – An analysis of the correlation between time to union and specific clinical outcome measurements. To be considered correlated p should be less than 0.05.

Correlation with time to fixation removal	Pearson Correlation Coefficient	p
Age	0.092	0.471
Fracture length	-0.002	0.989
Distance to Plafond	-0.128	0.315
AP angulation (reduced)	0.102	0.426
AP translation (reduced)	-0.024	0.852
Lateral Angulation (reduced)	0.032	0.805
Lateral Translation (reduced)	-0.12	0.357
Change in AP translation	0.102	0.42
Change in lateral translation	0.053	0.679
Time from first surgery	0.054	0.67

Table 5 – Comparison of Rust and mRust scores at start of treatment and at point of fixation removal. The table further illustrates the number of patients misdiagnosed as not healed (fale negative) when average RUST and mRUSt scores, and when the accepted values of RUST> 9.5 and mRUST>11.4 (Litrenta *et al.*) are used. The result of a t-test between initial and final scores is presented – to be significant $p<0.05$..

	Average	**St.Dev.**	**%misdiagnosed using average score**	**%misdiagnosed using accepted scores Rust>9.5 mRUST>11.4**	**t-test result, p**
Initial RUST score	4.1	0.44	-	-	<<0.05
RUST score at union	7.7	1.35	34%	77%	
Initial mRUSTscore	4.2	0.61	-	-	<<0.05
mRUSTscore at union	9.8	2.06	39%	80%	

(a) Stiffness assessment *in vivo*



(b) Diagrammatic representation of the result when the fracture may not be considered healed

Figure 1 – Fracture stiffness assessment using IOS. If, when manipulated, the pins touch the sides of the holes then the fracture stiffness is not greater than 15Nm per degree, and the fracture is not healed.

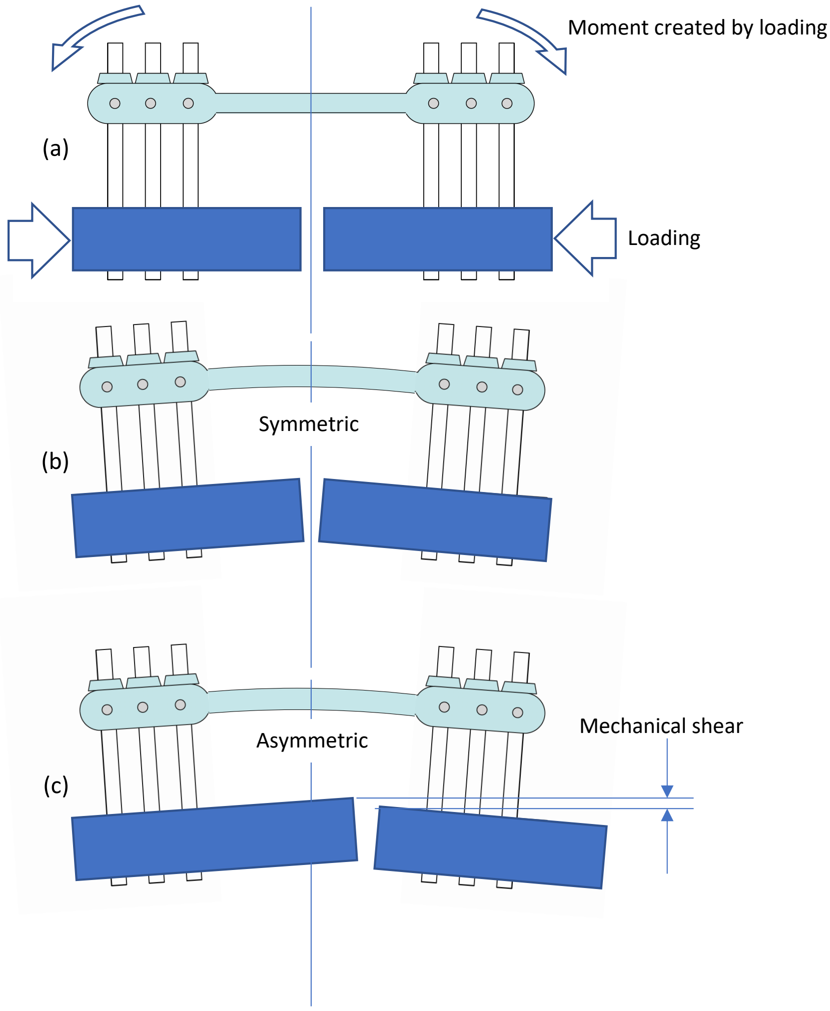


Figure 2 – Diagrammatic representation of external fixator under axial loading illustrating (a) loading regime, (b) dynamisation when positioned symmetrically, and (c) mechanical shear produced when positioned asymmetrically.

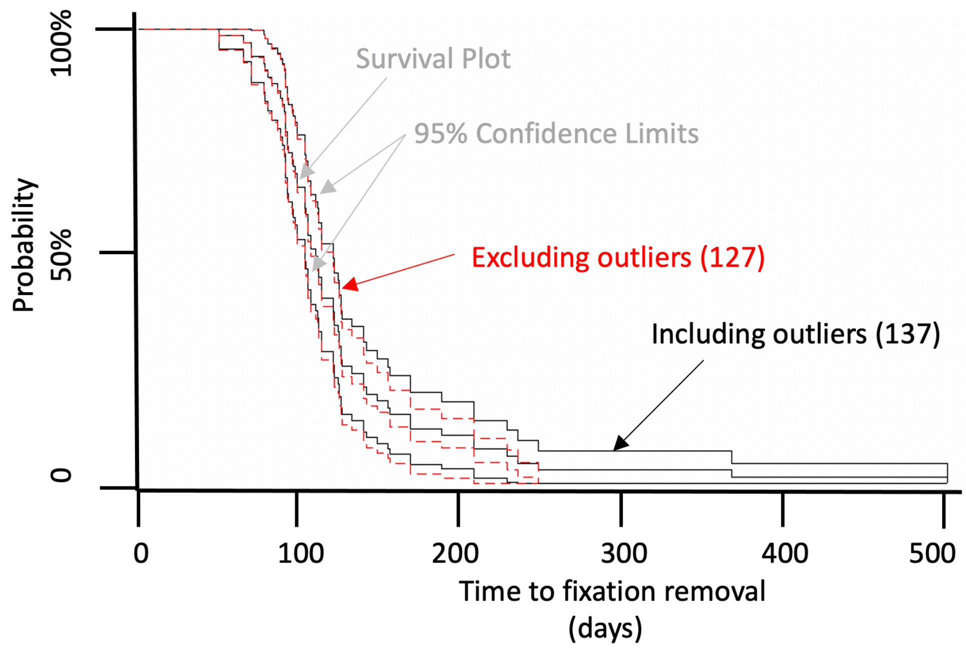


Figure 3 – Kaplan Meier survival plot for the analysis of significant difference between the outcomes from time to union including outliers (Black lines) and excluding outliers (red lines). The Mean Time To Union was 127 and 136.6 in both cases, the outcome of hypothesis testing was Wilcoxon p=0.77 and Log-Rank p=0.5.

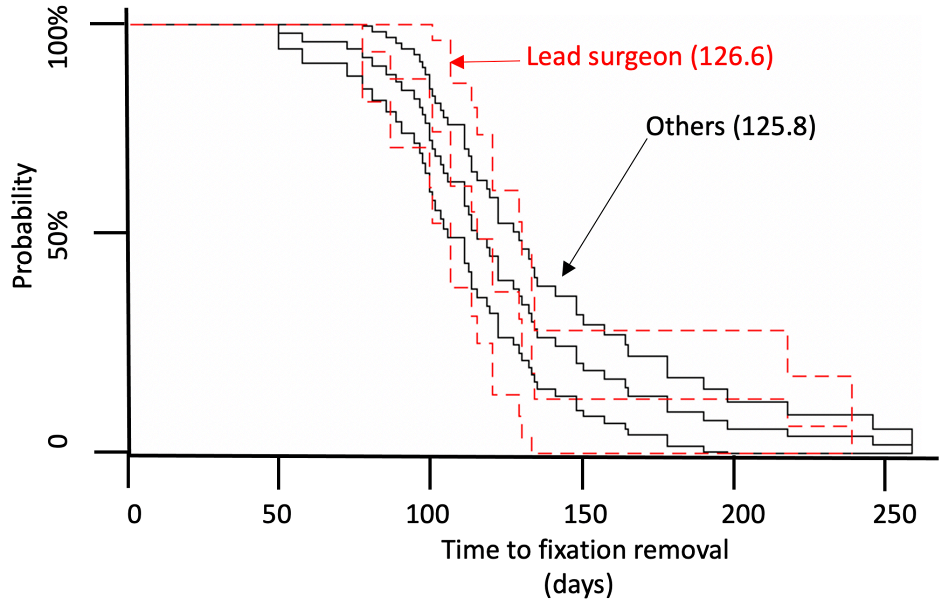


Figure 4 – Kaplan Meier survival plot for the analysis of significant difference between the outcomes from that of the lead surgeon and that of the other surgeons. The data in red is for the lead surgeon, the data in black for all other surgeons. The outer lines for both are the 95% confidence limits for the survival analysis.

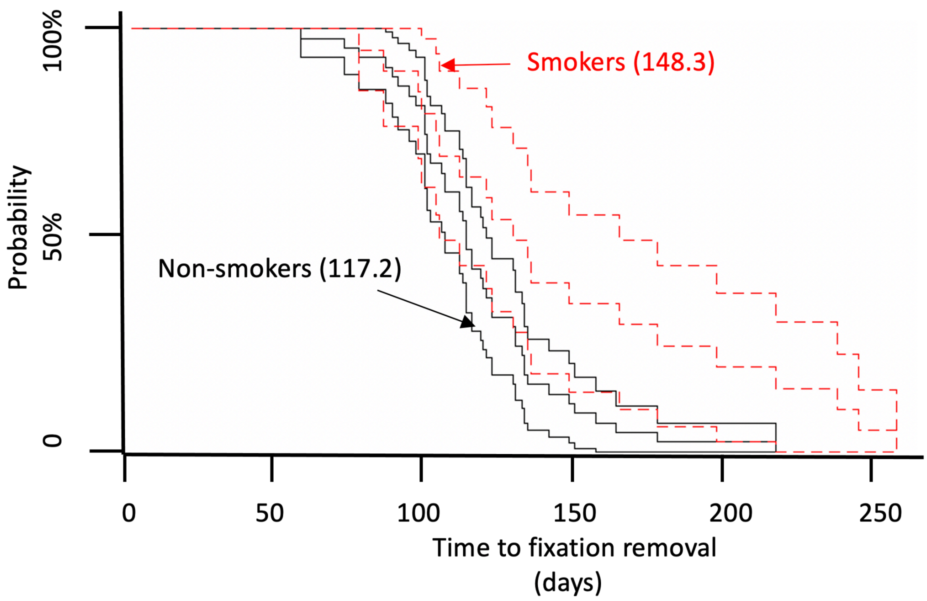


Figure 5 – Kaplan Meier survival plot for the analysis of significant difference between the outcomes from that of patients classed as non-smokers (black lines) and those classed as smokers (red lines). The Mean Time To Union for a smoker is over 31 days greater than that for a non-smoker.

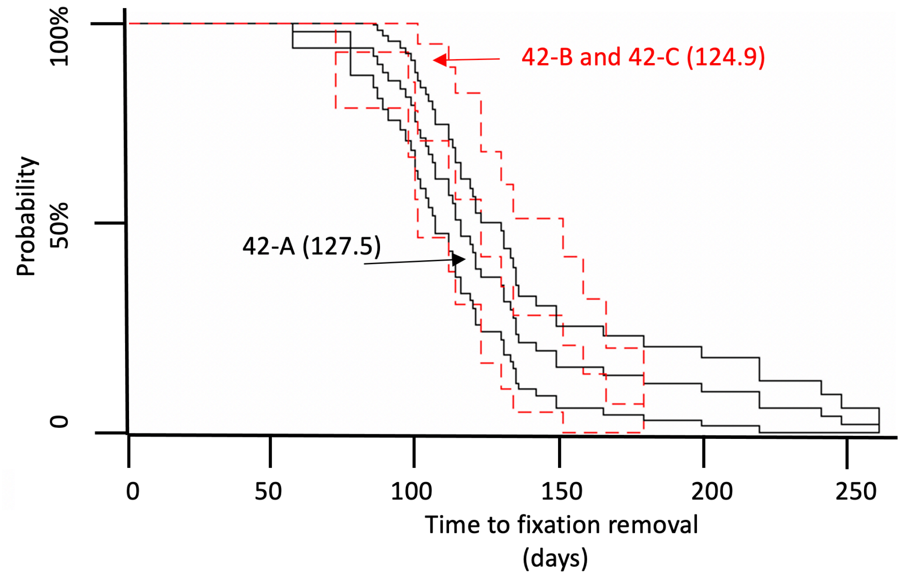
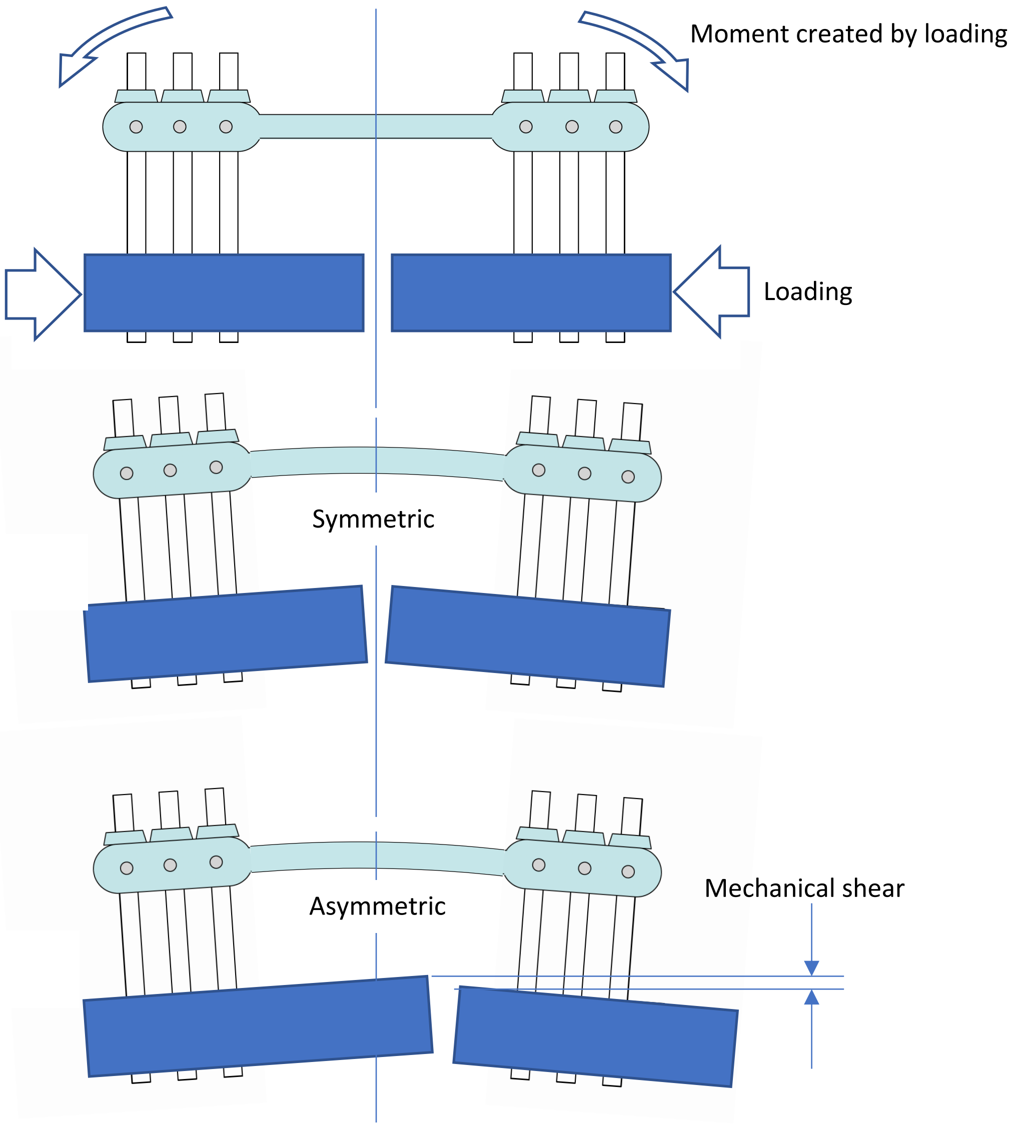


Figure 6– Kaplan Meier survival plot for the analysis of significant difference between the outcomes from patients with fractures in 42-A classification (black lines) to those with fractures in 42-B and 42C classifications (red lines).



Principles of External Fixation Design
In action

Graphical Abstract