**Title Page**

**Title: Low failure rate at short term for 40mm heads and second generation triple annealed HCLPE liners in hybrid Hip Replacements**

**Running Title: Thin Second Generation Highly cross linked Polyethylene low revision rate and large diameter heads**

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**ABSTRACT**

**INTRODUCTION**

40mm large diameter heads offer the advantages of lesser dislocation rates and better stability while highly cross linked polyethylene have lower wear rates than ultra high molecular weight polyethylene. Studies of the survivorship of 40mm heads in hybrid hip replacements with Exeter stem and second generation highly cross linked polyethylene are limited. The purpose of the study is to report the short term of survivorship of the large diameter heads (40mm) with Exeter stem with the secondary aim being the survival analysis of the thinnest second generation highly cross linked polyethylene.

**METHODS**

Retrospective case series of survivorship of patients with hybrid hip replacements of Exeter stems with 40mm heads articulating with second generation triple annealed highly cross linked polyethylene liner on a uncemented acetabular shell was performed. As a subset, survival of thinnest second generation highly cross linked polyethylene survival (3.8mm) at short term was assessed. Survival of the implants was confirmed from the hospital records and National joint registry as of 2015. Revision for any cause was taken as end point.

**RESULTS**

324 hybrid hip replacements with 40mm heads had been performed for primary hip osteoarthritis. Of the 324 hip replacements, 154 hip replacements had thinnest second generation highly cross linked polyethylene (3.8mm). Two patients had revision of components, one for periprosthetic fracture and one for deep infection. Mean age of the patients was 70.5 years (range 42-88 years, median 71, SD 8.3 years). None of the patients had revision due to trunion wear or loosening of components. The overall 5-year implant

survival probability of hips with 40mm heads was 99.4% (95% CI 98 to 100%) while the subset group of hip replacements with thinnest second generation highly cross linked polyethylene (3.8mm) had 5-year implant survival probability of 99.3% (95% CI 97.1 to 100%).

**CONCLUSION**

Short term survivorship does not show significant evidence of early failure or higher rate of revision in our series of hybrid hip replacements with large diameter heads and second generation triple annealed highly cross linked polyethylene. Dislocation rate at the short term is none. Results from this series have to be carefully interpreted due to the relatively short follow up but so far results are encouraging. Long term follow up is required to conclude whether there is early or higher rate of failure. It is our intention to follow up this cohort and further publish our results at longer term.

**Keywords:** Large diameter heads, highly cross linked polyethylene, sequentially processed polyethylene, second generation HCLPE, Revision, Low Failure

## INTRODUCTION

Around 700,000 hip replacements and 80,000 revision hip replacements have been performed since 2003 according to the 2015 Annual Report of the National Joint Registry(1). With better understanding of material properties and development of manufacturing principles, hip components continue to evolve. The NJR Annual Report for 2015 shows an increase in (1)hybrid hip replacement. The use of large diameter heads has increased due to (2,3)favourable evidence in the recent years. Metal on polyethylene articulation accounts for 87.8% of all cemented hip replacements performed, but only 37.6% of uncemented hip replacements and 63.9% of hybrid hip replacements have metal on polyethylene articulation(1).

Though pain relief had been the primary aim of hip replacement for arthritis, stability, better range of motion and longer survival of prostheses are being sought as younger patients with arthritis are being treated and older patients are more active and have better life expectancy. When boundaries are pushed, new problems are encountered. For instance, not long ago, there was an upsurge towards metal on metal articulation to prevent wear, hailed as a next step in improved articulation. Fast forwarding, new problems in the form of metal debris with subsequent ALVAL reaction and pseudo tumour resulted in less than 1% hip replacements being performed with metal on metal articulation as per NJR 2015(1).

Large diameter heads have higher wear rates due to their larger sliding distances(4,5). Success of Charnley's low frictional torque arthroplasty(4,5) is due to the use of smaller 22mm diameter heads, as the higher frictional torque generated by the larger heads due to increased sliding distance caused higher wear of the polyethylene manufactured in Charnley's era, resulting in early loosening of the components. The disadvantage of the smaller heads has been the dislocation and reduced primary range of motion. With the availability of highly cross linked polyethylene with presumed better wear properties, orthopaedic surgeons around the world have been increasingly using larger heads to achieve better primary arc range of motion and stability and to reduce dislocation rate. Recent studies from the joint registry(6) has shown no higher rate of failure when large diameter heads were used with highly cross linked polyethylene. Recent evidence(7–11) have shown satisfactory clinical outcome with low dislocation rate, better range of motion, improved stability with large diameter heads.

Improvement in the manufacturing of polyethylene and the production of highly cross linked polyethylene has aided production of polyethylene with superior wear property, facilitating the use of larger heads. Compared to ultra high molecular weight polyethylene (UHMWPE), the highly cross linked polyethylene (HCLPE)(12–17) is considered to have better surface wear properties and has a larger surface hardness, making it more scratch resistant and is proven in (18)clinical studies as well. The first generation HCLPE(19–22) has shown satisfactory clinical performance with good midterm survival and satisfactory survival with (2)large heads.

The production of HCLPE is now in the second generation with different manufacturers having different principles producing HCLPE with different mechanical properties, although their effect on the tribological properties of the bearing surface is questionable(23). (24)In vitro studies show similar properties of first and second generation HCLPE in molecular structure and mechanical properties. (25)In vitro studies show that HCLPE was better in withstanding higher frictional torque when 40mm heads were used than conventional UHMWPE. Though HCLPE shows less wear, clinical studies have shown that it is not better than conventional PE when osteolysis or wear-related revision rates are compared(21,26).

X3 HCLPE (Stryker, USA) is produced by the second generation manufacturing of sequential processing, whereby the process of irradiation and low heat annealing is done three times. By sequential (triple) annealing or heating and cooling three times to sub melting temperature, (27)cross linking is aided and free radicals are abolished to a low level at which they do not cause polyethylene scission, strongly reducing (27)the possibility of oxidation.

By improving the wear properties of polyethylene, thinner liners can be used against the large diameter heads. The minimum thickness of triple annealed highly cross linked polyethylene to prevent significant wear is unknown, but evidence of fractures of early generation HCLPE when its thickness was less than 4.8mm at the rim have been reported(28). On the other hand, the locking mechanism of the thinner first generation HCLPE when used with large diameter heads are considered strong enough, without major concern (29). The safety of the thin liners has been questioned but current (30)clinical evidence and (31)laboratory studies supports satisfactory survival at short term.

With the increase in uncemented acetabular shells for fixation and large femoral heads(1,6), the thickness of the liner plays an important role for two reasons. It is extremely difficult to determine the progress of the wear radiologically as the metal shell's shadow overlaps the liner and even if there was a significant wear, an uncemented shell may not show significant evidence of loosening until late. Second, if the polyethylene wears out completely, the Co-Cr metal head will start to articulate with the titanium metal shell, generating large amounts of metal debris potentially causing a metal adverse reaction and pseudo-tumour formation if the polyethylene wear is not detected early.

Evidence for the satisfactory survival of second generation HCLPE in the short to midterm has been published in recent years(12–15,32–34) but survival of a very thin liner alone has not been reported to our knowledge. Though retrieval studies have shown evidence of oxidation in annealed HCLPE(35), no correlation between oxidation and clinical failure has been found. Although biomechanical changes in the HCLPE(36,37) have been noted, whether these will translate to a clinical early failure is unknown.

With modular hip systems, there is a concern from secondary articulating surfaces between the trunion and femoral heads(38–45). The trunion is a morse taper and the head is wedged on to the trunion. No motion should occur between the surfaces but in reality it is difficult to prevent the micro motion. The micro motion in the smaller heads is not of major concern as the frictional torque generated at the surface is low. As frictional torque is directly proportional to the radius of the head, larger the head, higher is the frictional torque. As the articulation surfaces are metal, the higher frictional torque generates metal debris. Multiple factors like design of the trunion, improper seating of the head, head diameter, metal surface roughness, hardness, soft tissue stiffness, patient factors, time from the index procedure(46–50)can influence the trunion related metal debris and wear. The major concern is the metal debris from trunion (38–40,51) causing a metal reaction in the form of ALVAL formation or pseudo tumour formation and early failure of the implants. The diagnosis is difficult though recently it had been noted that (52)elevated cobalt levels compared to chromium levels is suggestive of trunion wear. Corrosion from the trunion has also been a concern when large diameter head articulating with a small trunion(38,39,41,49,53) but recent retrieval study has shown the head size(50) has no effect on corrosion. Apart from higher frictional torque(38,51,53), corrosion can also be a cause for metal ion release and metal debris. Head length(41,42), size, material (46–48,54) are thought to influence the fretting and corrosion at the trunion. Though highly cross linked polyethylene has a better wear rate(55), recent evidence has shown higher volumetric wear with large diameter heads. Finite element analysis(44) has shown increase wear potential from trunion with large diameter heads. There has been conflicting evidence questioning the use of large heads with advantages and disadvantages, especially, in relation to trunion wear(33,56,57). There have been concerns due to trunion wear for a long time(40–42,45,53,58,59) with case reports, systemic reviews and retrieval studies being published on failure requiring revision and metal reaction due to debris from trunion articulation. As far as we are aware there are no major clinical studies with large number of patients to suggest the revision rate is higher in an Exeter stem with large diameter head.

The Exeter double taper collarless polished stem is one of the most common implant(1) to be implanted in United Kingdom. The Exeter V40 Taper is a patented design of the Exeter stem and is unique. The material property, design, size, trunion angle are different from other manufacturers and it is unclear whether large diameter 40mm heads have a negative outcome. Recent studies on the blood metal ion levels from Exeter stem has shown no major concern when used with 36mm heads(60). The thinnest second generation highly cross linked polyethylene (3.8mm) is implanted on a 50 or 52mm trident uncemented acetabular shell (Stryker, USA) and will articulate with a 40mm heads while the liners in the smaller shells less than 50mm will only articulate with 36mm heads and are thicker. The trident uncemented acetabular shell (Stryker, USA) of size 54mm or more have thicker second generation highly cross linked polyethylene (3.8mm).

The primary aim of this study is to assess if any early failure is noted when large diameter 40mm heads are used against second generation triple annealed highly cross linked polyethylene acetabular liners in hybrid hip replacements with Exeter stems and to assess survival at short term. As a secondary aim we also assessed the survival of the thinnest second generation highly cross linked polyethylene (3.8mm). As far as we are aware, this is the thinnest polyethylene manufactured and we felt that this has to be reported as a subset of our cohorts.

**METHODS**

A retrospective case series of patients who had hybrid hip replacements with 40mm heads on an Exeter stem articulating against second generation triple annealed highly cross linked polyethylene liner on an uncemented hydroxy apatite coated Trident acetabular shell was performed. Ethical approval was obtained (IRAS id no. 198853, 198872) for the project. All patients had hybrid hip replacements for primary osteoarthritis.

All patients treated at our unit under a single surgeon (RDP) were identified from hospital records and the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR). Survival of the implants was confirmed from the NJR as any revision of the component were reported and recorded in this registry. Individual records, electronic patient records and radiographs of all included cases were reviewed. Radiographs were reviewed to assess for any significant progressive loosening of components. Complications in term of leg length discrepancy, infection, dislocation, neurological damage and any other complication were noted. We searched for cases of failure due to any reason in both hospital records and the NJR data base with revision for any cause being considered the end point. Hospital records were reviewed to assess if any case had developed metal reaction or pseudotumour as this might signify catastrophic wear, with the metal head most likely articulating with the titanium shell, producing large amounts of metal debris. Implant survival was determined using the Kaplan-Meier method and Peto estimates of the 95% confidence intervals, which take account of the effective sample size. All statistical analyses were performed using R vs 3.0.2, using the "survival" package.

**RESULTS**

324 hybrid hip replacements with 40mm large diameter metal Co-Cr alloy heads on a cemented Exeter femoral stem articulating with second generation highly cross linked polyethylene on an uncemented trident acetabular shell had been performed through posterior approach for primary hip osteoarthritis between 2006 and 2014. Of the 324 patients, 165 were female and 159 were male patients. Age range was from 42 to 88 with an average of 70.5 years (+/- 0.9 years at 95% CI) at the time of procedure [Median 71, SD 8.3 years].

154 of the 324 hip replacements had the thinnest second generation highly cross linked polyethylene (3.8mm). There were 128 female and 26 male patients. There were more female patients in this subset due to relatively smaller acetabular size in females. The average age at the time of surgery was 71.8 years (7.3SD, range 42-88 years).

At the time of the data collection for the study, none of the patients had dislocation. None of the implants had been revised for aseptic loosening or significant wear or due to trunion related wear. None of the hip replacements had been revised for pseudo tumour formation or ALVAL reaction. Examination of radiographs found no evidence of noticeable osteolysis. 34 patients had died due to non orthopaedic causes of cardiac or disseminated malignancy.

Revision for any cause was considered as end point. 2 patients had revision of the components. 1 patient had deep infection requiring 2 stage revisions. This patient had large diameter 40mm head with thinnest second generation highly cross linked polyethylene. One patient had a fall and sustained pelvic fracture involving the columns and the acetabular shell lost the fixation and had to be revised following the column fixations and head was changed to 36mm. An analysis of the NJR data confirmed that this was indeed the only two cases that had revision in this series as of end of 2015.

Other complications noted in our series were as below but none of them had revision of the components. 1 patient had foot drop which recovered. 1 patient had sciatic nerve damage and had nerve repair and later foot procedure for the foot drop under the foot and ankle team. One patient had CVA in the post operative period. 2 had superficial infection treated with oral antibiotics but did not require revision. 6 had limb length discrepancy requiring heel rises. 19 had back pain due to spinal degenerative causes. 7 developed trochanteric pain due to trochanteric bursitis. One settled with steroid injection but others did not require any treatment and symptoms settled with conservative management.

The patient (58/F) who had a steroid injection had no further symptoms. Comparison of immediate postoperative radiograph (Fig. 1) and 7-year follow up radiograph (Fig. 2) showed no evidence of osteolysis or loosening. A further example of radiographic follow up is a 70 year old female with a follow up of over 7 years, which again show no signs of osteolysis when comparing between immediate postoperative (Fig. 4) and latest follow up (Fig. 7).

Kaplan-Meier survival analysis of the 324 hip replacements with 40mm large diameter metal Co-Cr alloy heads on a cemented Exeter femoral stem articulating with second generation highly cross linked polyethylene on an uncemented trident acetabular shell showed the 5-year survival probability of the implant was 99.4% (95% CI 98 to 100%), corresponding to a failure probability of 0.6% (95% CI 0.0 to 2%; Figure 3). At latest follow up (7.8 year) the probability of survival was the same but with a wider 95% confidence interval (88.8 to 100%).

Kaplan-Meier survival analysis of 154 hip replacements with thinnest second generation highly cross linked polyethylene (3.8mm) showed the 5-year survival probability of the implant was 99.3% (95% CI 97.1 to 100%), corresponding to a failure probability of 0.7% (95% CI 0.0 to 2.9%; Figure 3).

**DISCUSSION**

The study had shown satisfactory survival of 40mm large diameter metal Co-Cr alloy heads on a cemented Exeter femoral stem articulating with second generation triple annealed highly cross linked polyethylene [X3 HCLPE]on an uncemented trident acetabular shell for primary hip osteoarthritis at short term. The subset of hip replacements with the thinnest (3.8mm) HCLPE liner at short to midterm also shows satisfactory survival at short term.

Concerns of wear due to increased frictional torque generated by the large sliding distances of the large diameter heads at primary and secondary articulation surfaces had restricted the use of large diameter heads and our series had shown satisfactory survival at short term. Though trunion related wear has been considered a problem to deal with the modern modular femoral stems, the V40 taper of the Exeter femoral stem has shown satisfactory resilience against trunion wear in spite of higher frictional torque produced by the large diameter heads as none of hip replacements in this series had been revised for trunion related problems at short term.

Despite testing in its thinnest form against the largest available head, producing the largest sliding distance with a maximum frictional torque, so far the survival of second generation triple annealed highly cross linked polyethylene [X3 HCLPE] is satisfactory. We had no dislocation in our series. This combination of a low dislocation rate and good survival at short term suggests this liner might be an option for use of 40mm heads in elderly patients as an alternative to dual mobility or constrained liner. No case has been revised so far for aseptic loosening, nor have we seen noticeable osteolysis suggesting impending failure. The only revision done was for infection in a patient in two stages and for periprosthetic fracture.

Our results looked at the survival of this polyethylene at its currently thinnest level which reflects the clinical performance. Its low failure rates in this form suggest that the material will also perform well when used with thicker liners for larger uncemented shells. However, it will be difficult to predict if these findings extend to cemented acetabular shells as their fixation is different. It is our intention to follow up this group further and publish the longer-term results to investigate the survival of these thin polyethylene liners.

There is significant restriction in the study. The study is a retrospective case series with short term results. At the study time, revision rate has been extremely low but as years progress there might be higher revision rate due to unknown or known factors. The Kaplan Meier survival analysis in figure 1 shows satisfactory survival at 8 years but towards the right side of the curve there is significant widening of the confidence interval.

The study is not without its weaknesses. Firstly, to assess revision rates we relied mainly on the NJR. The time to follow up in the clinic varied because local policy and guidelines had changed during the study period, with patients increasingly followed up at primary care centres for financial reasons. For this reason, the authors relied on the NJR data for the survival of implants. The authors feel that this is justified as all revisions in England, Wales, Northern Ireland and the Isle of Man, are meticulously reported, and our patients have not moved outside the NJR area. Obviously it is not clear whether the high survival found in this study holds in the long run. Other limitation is the lack of patient related outcome scores.

Unfortunately, we were not able to determine the wear rate as this is difficult to achieve with an uncemented shell in situ. However, we did not find noticeable osteolysis around the femoral or acetabular bone interface when reviewing the radiographs at the latest follow up. A final weakness is that we only studied patients with primary osteoarthritis. It is unclear if the results are reproducible if the above components are used for secondary osteoarthritis.

As hip prostheses continue to develop with advances in material science, bearing technology and manufacturing processes, vigorous monitoring regarding the performance of the newer technologies with publication of results is needed. At the moment, the hybrid hip replacements with large diameter 40mm heads on an Exeter stem articulating with second generation sequentially processed HCLPE has shown satisfactory survival but longer term follow up is required. It is our intention to further follow this cohort of patients to study the longer term clinical results and safety of the large 40mm Co-Cr metal heads and second generation sequentially annealed highly cross linked polyethylene and publish our results.

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**FIGURE LEGENDS**

Fig 1 Kaplan -Meier Survival curve of 40mm Heads on cemented Exeter stem articulating with all HCLPE X3 on uncemented trident acetabular shell showing 99.4% at 7.8 years but a widened confidence interval towards the right side - grey shaded area shows confidence interval.

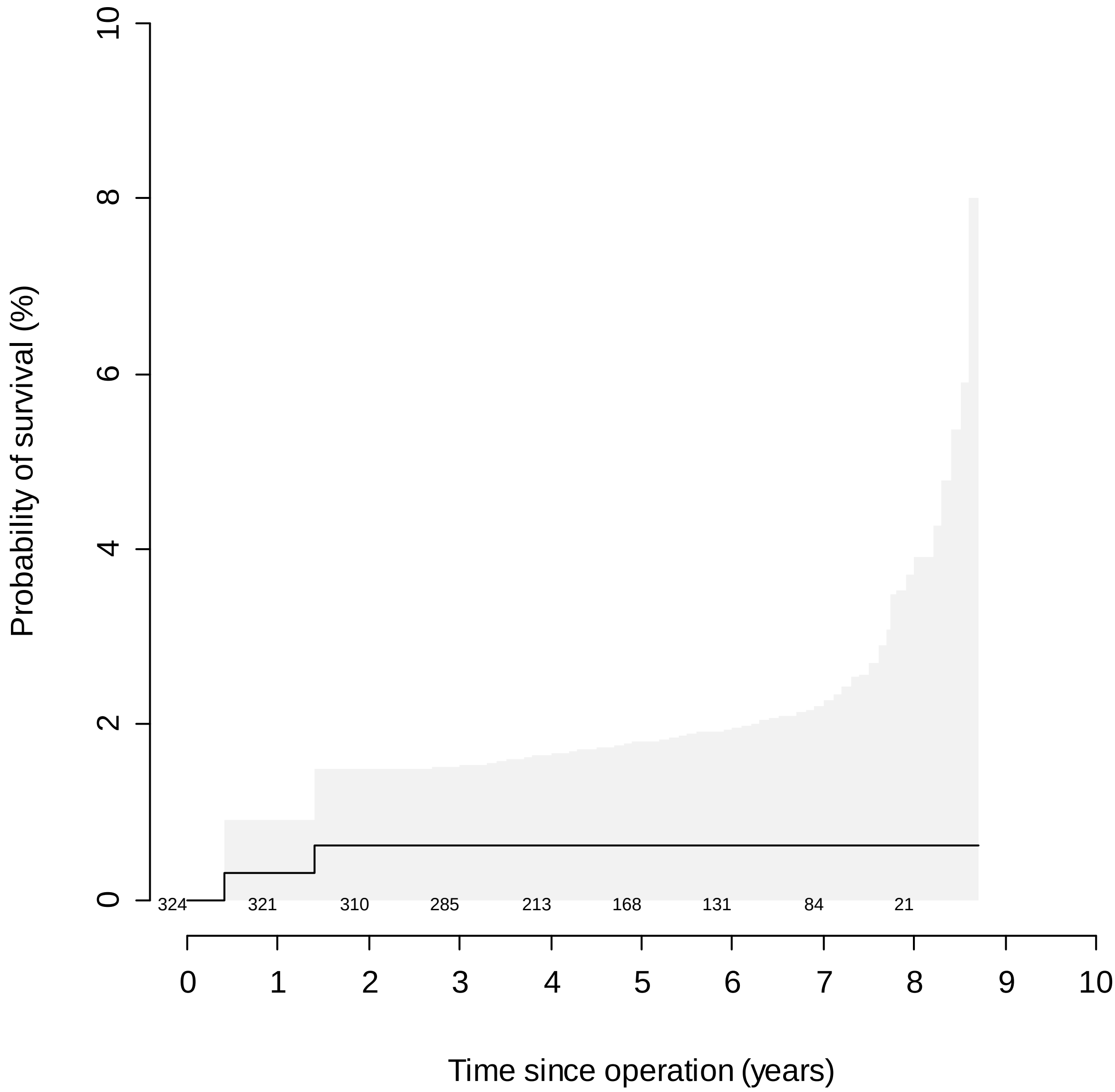
Fig 2 Kaplan -Meier Survival curve of thinnest (3.8mm) HCLPE X3 on uncemented trident acetabular shell articulating with 40mm Heads on cemented Exeter stem showing 99.3% at 7.8 years but a widened confidence interval towards the right side - grey shaded area shows confidence interval.

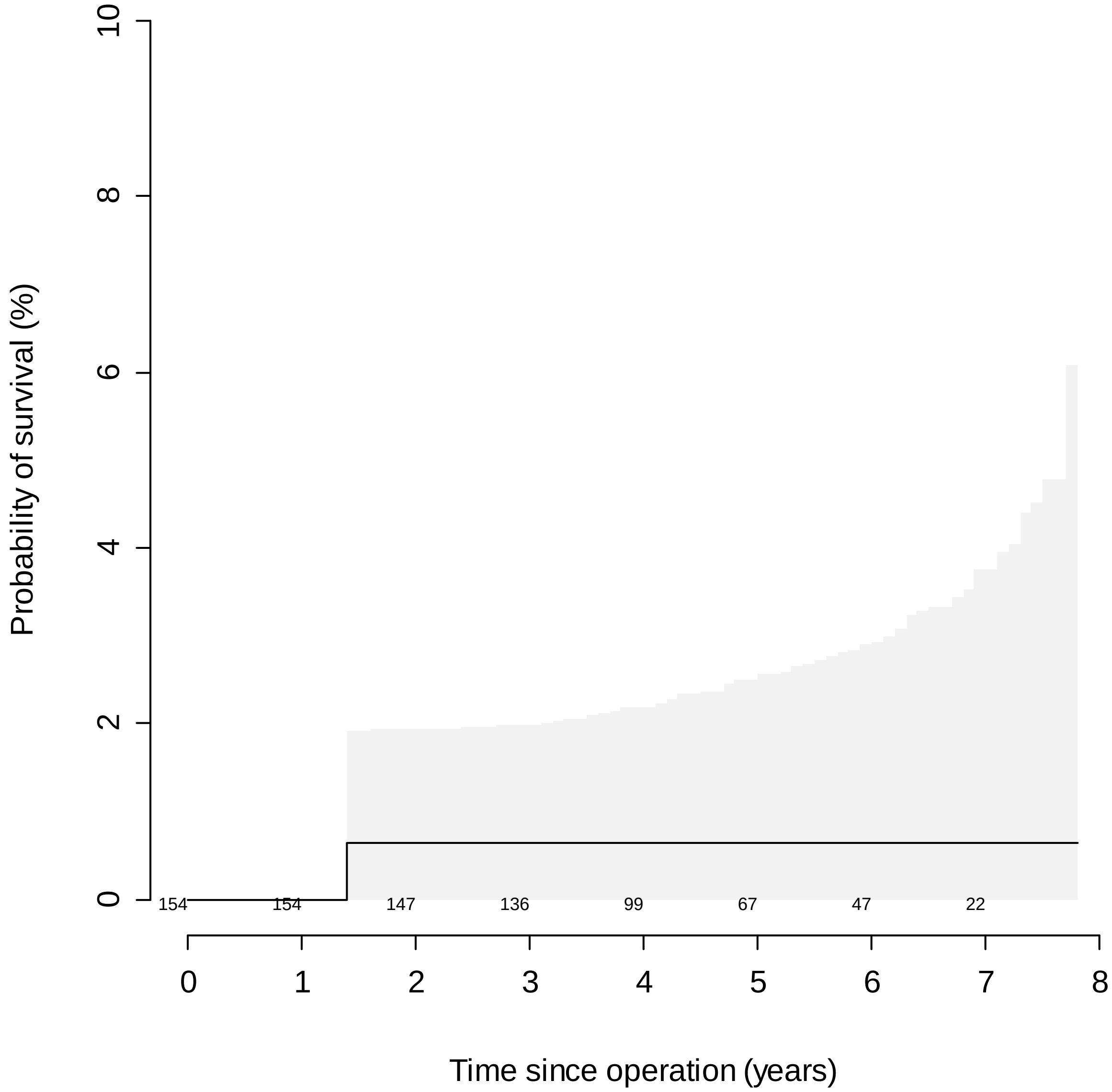
Fig 3 58y/F had right THR for Primary OA. Patient had trochanteric pain settled following steroid injection.

Fig 4 6 year postoperative radiograph – patient has no symptoms with hip with satisfactory outcome. Components show no significant loosening.

Fig 5 70Y/F had right THR for primary OA. Postoperative radiograph after the surgery. Patient had no pain and satisfied. Patient had one of the longest follow up in our series. Patient had left THR with 28mm head in the past

Fig 6 7 year postoperative radiograph – patient has no symptoms with hip and satisfactory outcome. Minor asymptomatic heterotopic ossification noted but components are not loose.


Probability of survival (%)
0
2
4
6
8
10
324
321
310
285
213
168
131
84
21
0
1
2
3
4
5
6
7
8
9
10
Time since operation (years)


Probability of survival (%)
0
2
4
6
8
10
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154
147
136
99
67
47
22
0
1
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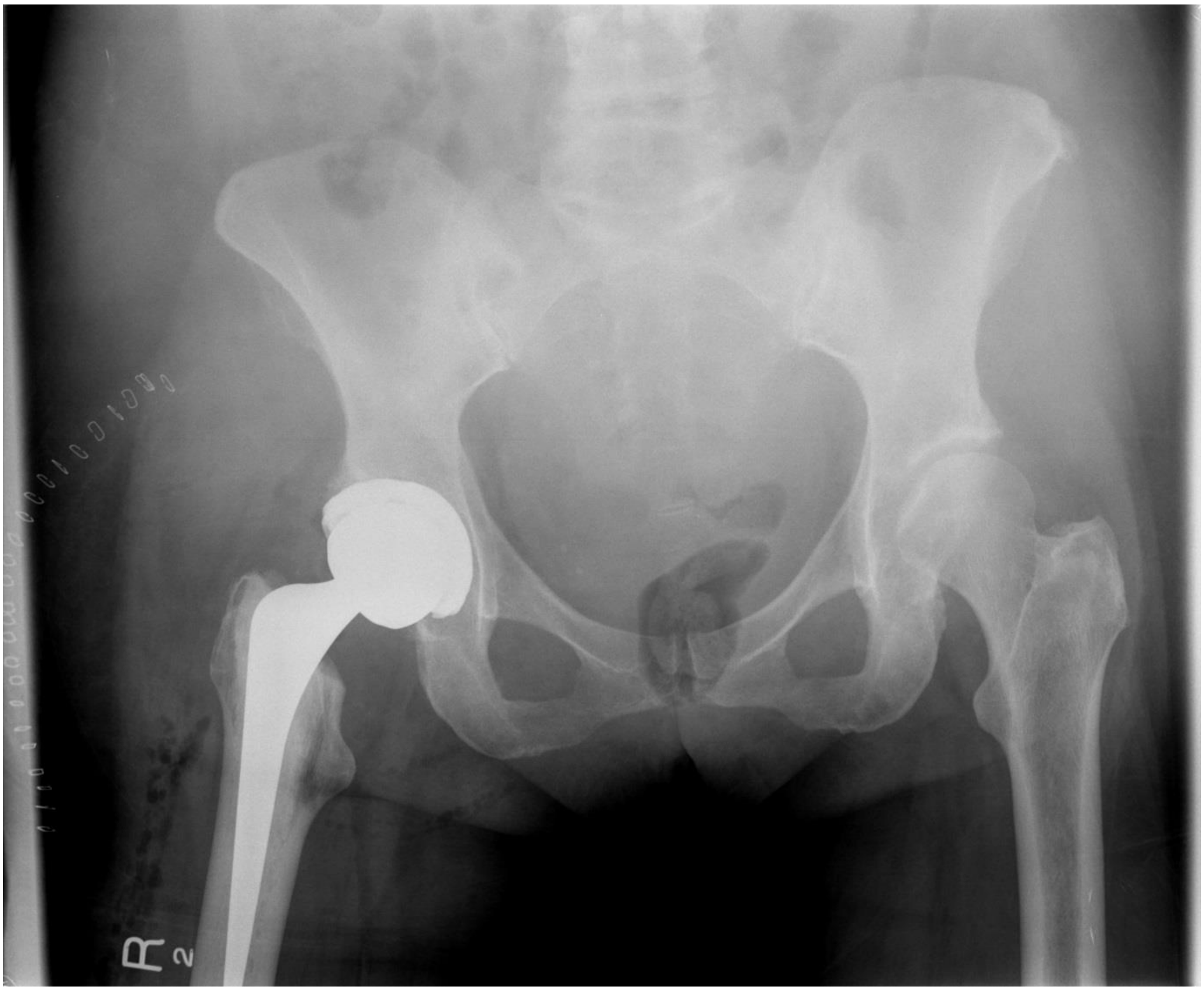
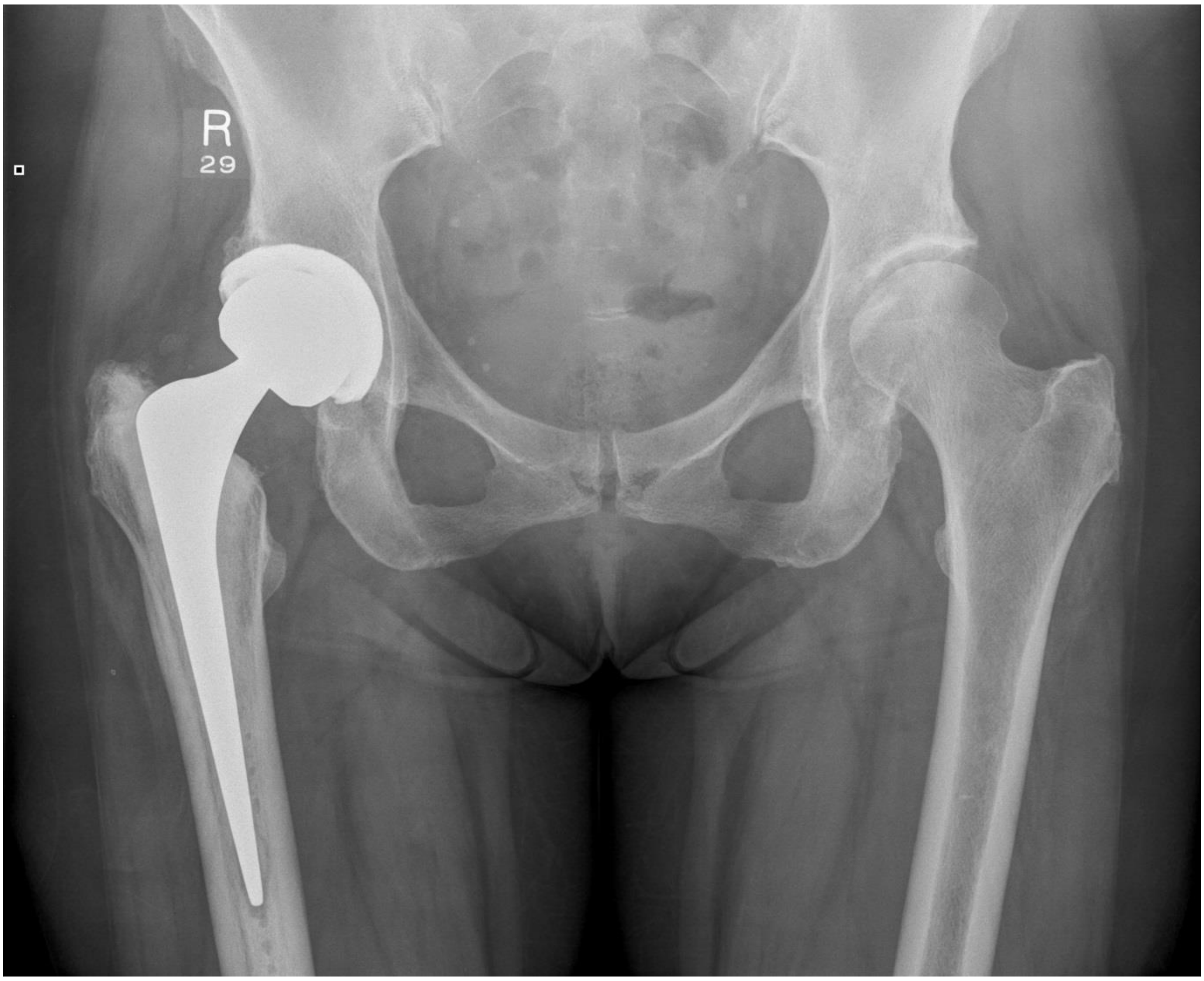
7
8
Time since operation (years)

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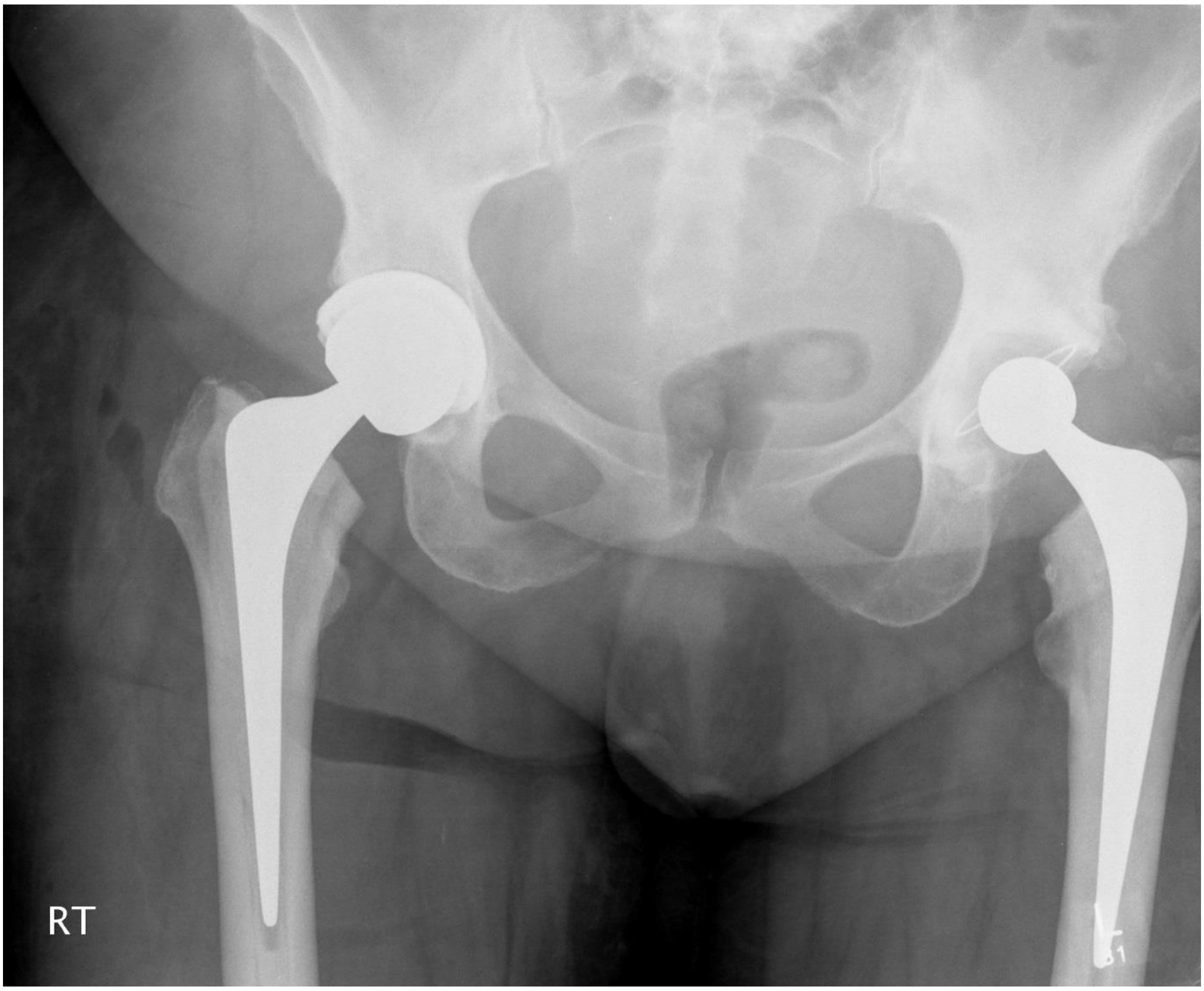
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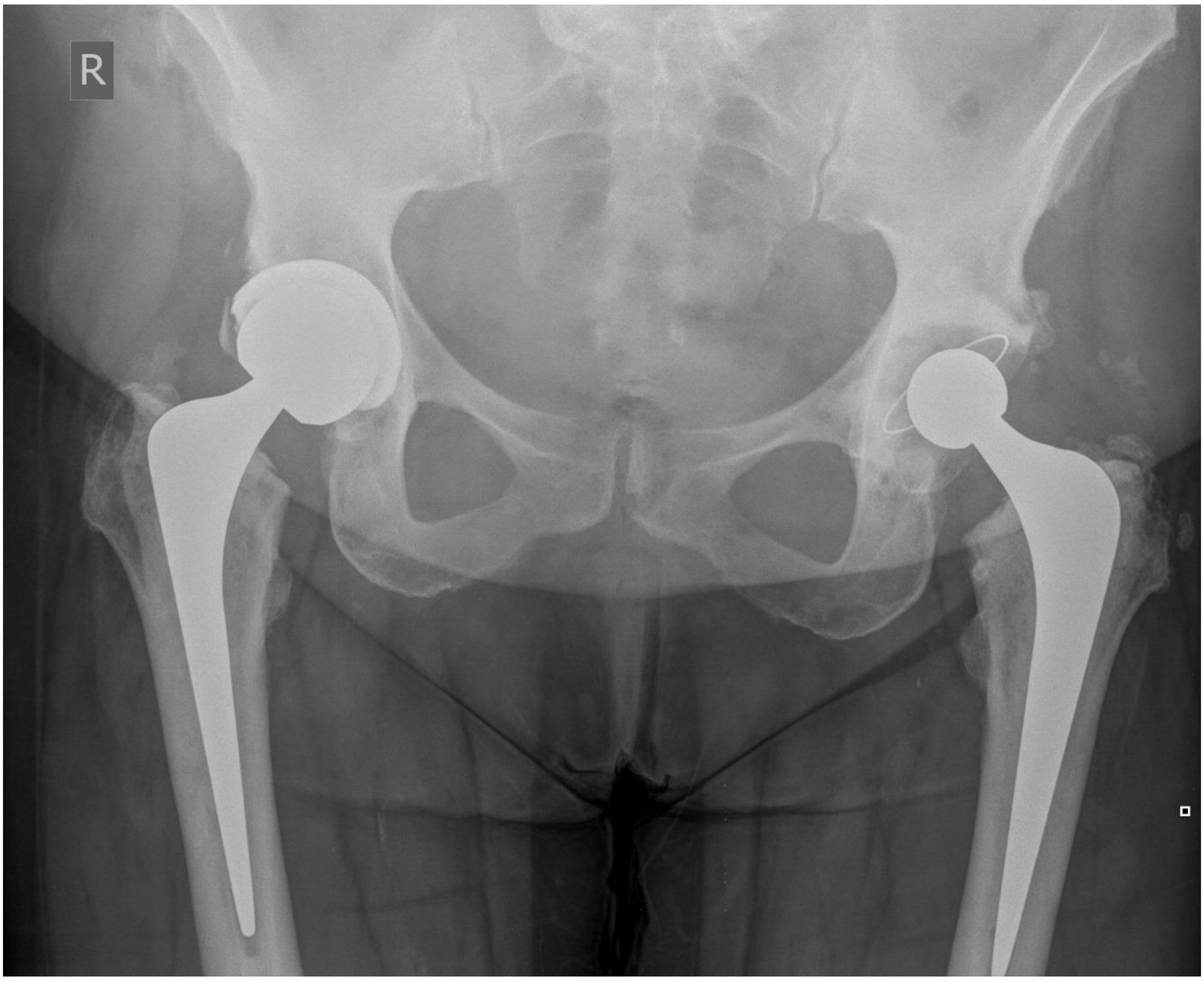
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