Elective hinge and polyethylene exchange for lower limb tumor endoprostheses: is it a good idea?

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Background
Long-term survival of endoprosthetic implants is a major concern, with reported 20-year survival rates of lower limb tumor endoprostheses at only 25–38%. Mechanical failure of polyethylene (PE)-bearing surfaces may result in irreversible damage and contribute to osteolysis and aseptic loosening. The practice in our institution is to electively change replaceable parts of lower limb endoprosthesis ~7 years after index surgery.
Patients and methods
From 2014 to 2019, five patients underwent an elective change of parts at an average of 7 years from the initial surgery. All patients had rotating-hinge implants including one proximal tibia, three distal femurs, and one total femur prosthesis. Three had a fixed-poly (FP) with a rotating femur (Stryker GMRS), and two had a rotating mobile polyethylene (MP) design (Zimmer ZSS).
PE liners, hinge pin protectors, and bushings were retrieved for analysis. The parts were examined for macroscopic wear and under a light microscope at up to 40 times magnification. Linear wear was measured at standardized points.
Results
There were no major perioperative complications. MP inserts showed minimal burnishing. FP liners showed macroscopically visible surface pitting and posterior edge delamination. Submillimeter linear wear was noted on PE liners, bushings, and hinge pin protectors, with minimal evidence of macroscopic wear.
Conclusion
Elective PE exchange is a possible option for extending the longevity of tumor endoprostheses. The optimal timing of surgery is to be determined. Our retrieval study suggests that 7 years is appropriate for the FP design but may be early for the MP design. Further studies are required to determine implant survival benefits.

Keywords:
endoprosthesis, polyethylene, tumor

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Introduction

Tumor endoprosthesis (TEP) was introduced in the 1970s and has become a standard reconstruction method after the resection of malignant primary bone tumors. Endoprosthetic reconstruction is often performed in young patients for whom long-term implant survival is a major concern.

Despite advances in materials and implant designs, the rate of complication and failure remains high in comparison to conventional total knee replacement. Reported survival rates of lower limb TEP are 55–61% at 15 years and 25–38% at 20 years. Lower survival rates are reported for proximal tibial replacements compared with distal femoral implants [1–3]. Henderson *et al.* [4] classified the causes of endoprosthetic failure into six types (Table 1). Of these failure modes, aseptic loosening has been quoted in the literature as the most common long-term complication of these prostheses [5].

Higher mechanical failure rates compared with conventional arthroplasty may be attributed to high mechanical stresses that arise from highly constrained joints, long lever arms, and high levels of activity in the younger patient population [1]. When implants do fail, revision is challenging with a far higher complication rate than primary surgery; when reconstructive options have been exhausted, amputation may be required [6].

Apart from limiting physical activity, there are a few postoperative strategies for improving implant longevity. Implant servicing with the elective exchange of replaceable parts is one potential option for extending survival. At our unit, we have recommended that patients undergo elective exchange of replaceable

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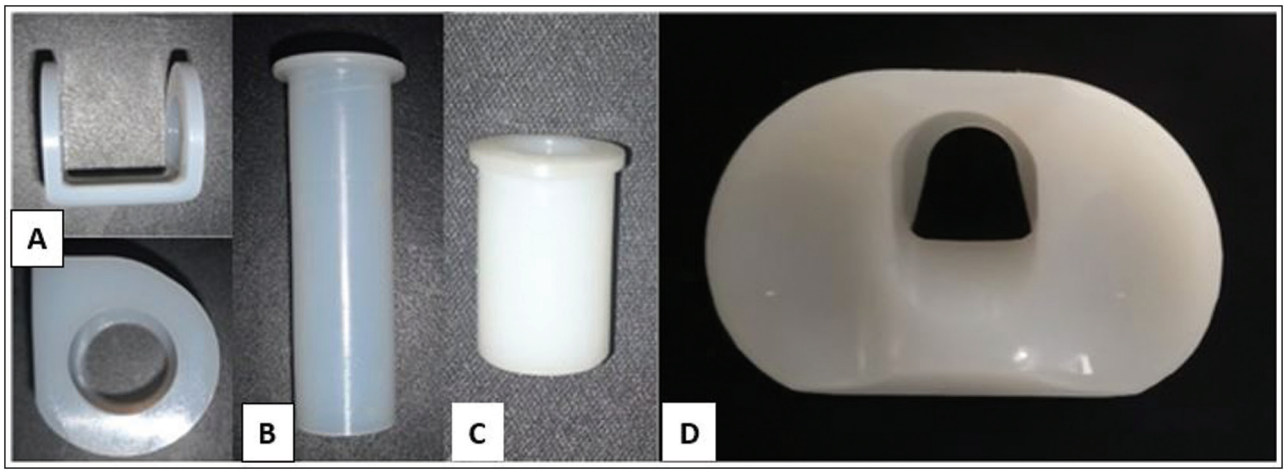
Table 1 Types of endoprosthesis failure by Henderson *et al*. [4]

	Type	Description
Low grade wear	Burnishing	Smooth or brightened surface without visible scratches, fracture or plastic deformation
	Abrasion	Low-stress wear which appears as a slight streak on the surface and can normally be observed only under the microscope
	Cold flow	Plastic deformation without change in the volumetric loss of material
High-grade wear	Scratching	Appears as a substantial streak
	Pitting	Usually causes a small cavity on the tibial insert
	Metal embedding	Occurs when third bodies such as metal wear particles or chips from the femoral component embed into the polyethylene
	Delamination	Appears as a subsurface crack and slice fracture of the material

Figure 1



(a) Segmental polyethylene insert. (b) Hinge pin protectors. (c) Bushings. (d) Polyethylene liner.

parts at ~7 years after index surgery. Replaceable parts include segmental polyethylene (PE) inserts, hinge pin protectors, bushings, and PE liners (Fig. 1). We hope that 'servicing' the implant may improve longevity by (a) reducing PE wear debris that contributes to aseptic loosening and (b) preventing complete mechanical failure that may result in irreversible damage to nonreplaceable parts. The primary concern of such elective surgery is the potential complication of introducing a prosthetic joint infection.

This study aims to report the clinical outcomes and safety of elective PE exchange and the results of a retrieval study. To our knowledge, this is the only report of this strategy for a well-functioning TEP.

Patients and methods

Between 2014 and 2019, five patients underwent elective exchange of replaceable parts for lower limb endoprostheses at our institution. These included one proximal tibia, three distal femurs, and one total femur prosthesis.

There were three males and two females. Primary surgeries were performed from 2007 to 2011. The age at index operation was from 12 to 23 years and the indications for primary surgery were osteosarcoma (n=3) and giant cell tumor (n=2). All five patients underwent elective surgery for a well-functioning prosthesis with no clinical or radiological evidence of problems before surgery. The revision surgeries were performed at 6.8–7.3 years from index surgery.

All patients had modular rotating-hinge design implants. Three had a fixed-poly (FP) with a rotating femur design (Stryker Global Modular Replacement System – GMRS, Kalamazoo, Michigan, United States) and two had a rotating mobile polyethylene (MP) design (Zimmer Segmental System – ZSS, Warsaw, Indiana, United States). Liners and inserts were available for review in four patients as one patient had an all-PE tibia and only bushings were replaced. The replaced parts were all manufactured from highly cross-linked ultrahigh molecular weight polyethylene (UHMWPE).

The liners, inserts, and bushings were visually inspected for macroscopic wear and damage, and also under light microscopy at up to 40 times magnification. Visible wear patterns were documented according to the classification of Lu *et al.* [7] (Table 2). Linear wear was measured using an electronic caliper to an accuracy of ±0.01 mm. The PE

tibia liners were divided into four quadrants: anterolateral, anteromedial, posterolateral, and posteromedial. Four points of reference were identified in each quadrant, and 10 measurements were done at each point, with the mean value ultimately used (Fig. 2).

Similarly, measurements for the rest of the replaceable parts were done at 10 points along their circumference. These included the hinge pin protectors and internal bushings for the ZSS implants, and the femoral bushings for the Stryker GMRS implants. Values were compared against new implants of the same size to calculate the reduction in overall thickness.

Ethics

This research has been approved by the IRB of the authors' affiliated institutions.

Results

The age of patients during the first surgery ranged from 12 to 23 years. Their BMI ranged from 19 to 27 (mean, 23).

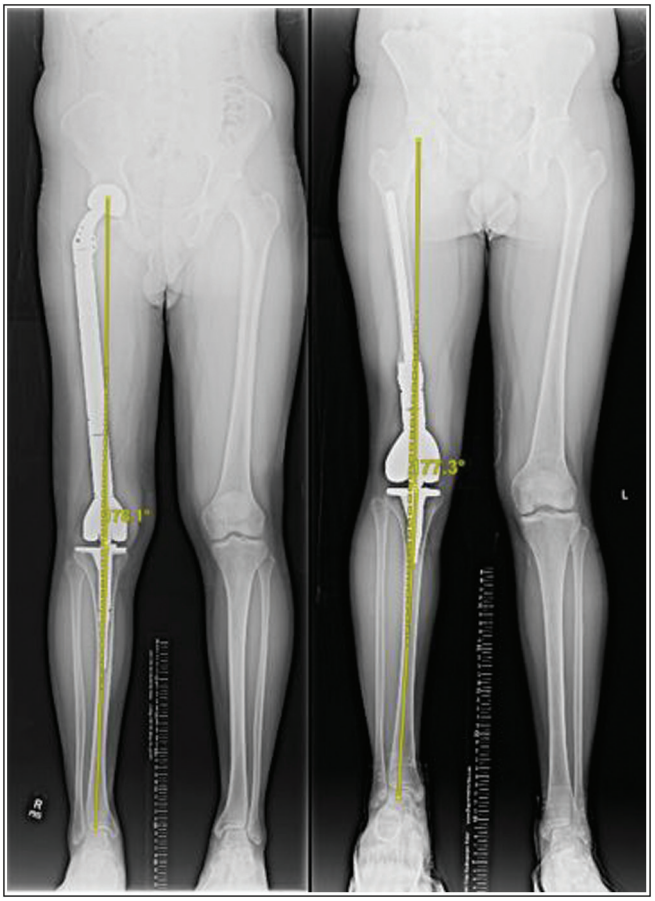
Four out of five of the patients maintained a moderate level of daily activity postoperatively but did not do any sports. One patient with a distal femur GMRS implant was very active, participating in hiking and even rock climbing. There were no complaints of restrictions in daily activities for all the patients. The range of movement averaged at 10–110°. All the patients were able to reach full extension passively, but there was an average extensor lag of 10°, likely due to quadriceps deficiencies. On long lower extremity films, the mechanical axes ranged from neutral to 3° of valgus (Fig. 3). Lower limb radiographs were repeated

Table 2 Types of wear patterns as described by Lu *et al*. [7]

Quadrant	Wear on GMRS (FP) liners (mm)	Wear on ZSS (MP) liners (mm)
Anterolateral	0.2	0.76
Anteromedial	0.22	0.6
Posterolateral	0.26	0.05
Posteromedial	0.11	0.06
Average	0.20	0.37

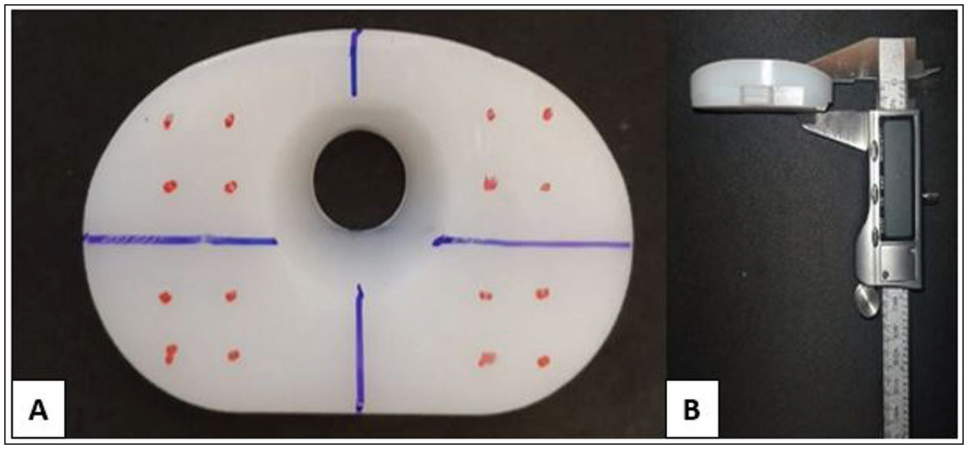
FP, fixed-poly; MP, mobile polyethylene.

Figure 3



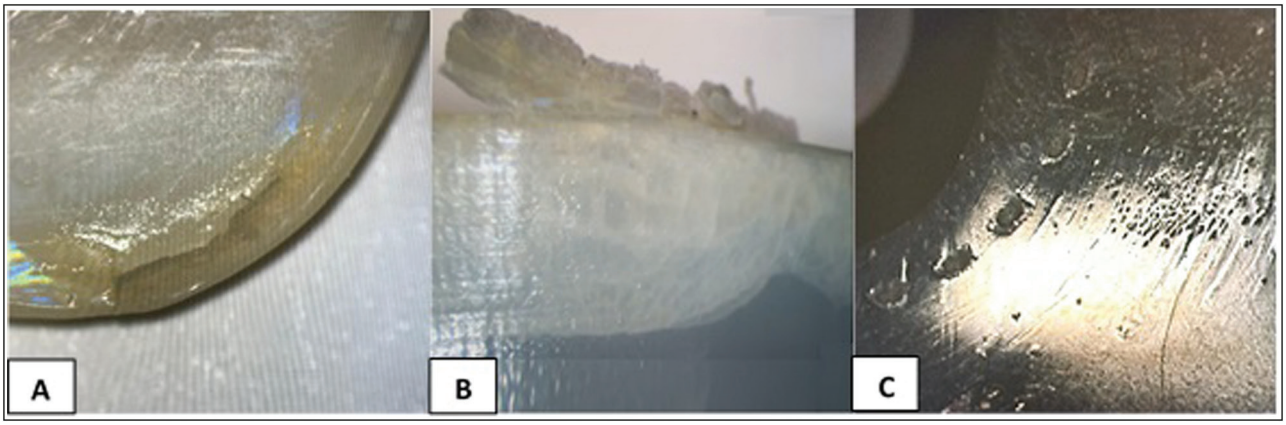
Long leg extremity films. (a) Total femur endoprosthesis (mechanical axis 2°). (b) Distal femur endoprosthesis (mechanical axis 3°).

Figure 2



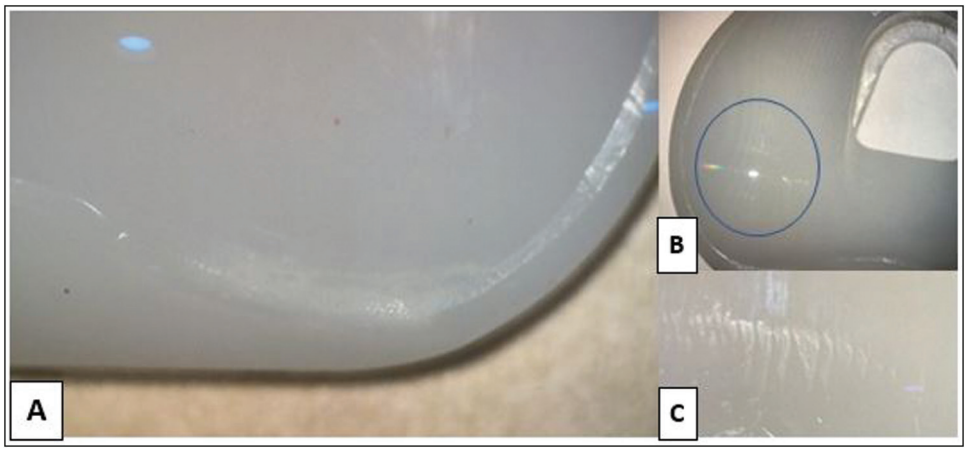
(a) Liners were divided into four quadrants. Four points of reference were identified in each quadrant for consistency of measurement. (b) Measurements performed with an electronic millimeter caliper.

Figure 4



FP tibial liners. (a, b) Severe posterolateral edge delamination. (c) Surface pitting. FP, fixed-poly.

Figure 5



MP tibial liners. (a) Minimal edge delamination. (b) Posterior quadrant burnishing (circled). (c) Microscopic appearance of transverse burnishing. MP, mobile polyethylene.

during yearly follow-up until the date of the elective revision surgery. None of the patients exhibited signs of radiographic loosening, fracture, or implant migration.

The patients with osteosarcoma underwent a course of chemotherapy as part of standard treatment. None of the patients underwent radiotherapy to the affected limb.

Intraoperatively, all fixed implants were assessed to be stable before and after the exchange of replaceable parts. There were no major perioperative complications. One patient had a superficial wound complication with a small area of skin necrosis that was treated with simple excision and resuturing. To date, all patients have retained their implants at an average of 3.3 years postrevision with no prosthetic joint infections.

Visual inspection

FP inserts showed macroscopically visible high-grade topside wear with surface pitting and major delamination that was most significant at the posterior edges. No backside wear was noted (Fig. 4).

MP inserts showed minimal macroscopic topside burnishing at the posterior quadrants corresponding to the contact points of the femoral component. Backside streaking was noted in a circular pattern corresponding to the rotation of the PE against the tibial tray. Microscopic evaluation showed subsurface fissure lines at the posterior edges (Fig. 5).

Bushings and rotating-hinge pin sleeves showed minimal burnishing and microscopic streaking. There was no cracking or delamination.

Linear wear

The average tibial insert thickness reduction was 0.29 mm (range, 0.05–0.76 mm). The calculated average linear wear rate was 0.04 mm per year. Thickness reduction was 0.20 mm for the FP inserts, and 0.37 mm for the MP inserts (Table 3).

Stryker GMRS femoral bushings showed 0.10 mm average thickness reduction. ZSS hinge pin protectors and internal bushings showed 0.02 and 0.08 mm thickness reduction, respectively (Table 4).

Discussion

Isolated tibial polyethylene insert exchange (ITPIE) is not a new concept and has been reported for conventional primary total knee replacements with variable results. ITPIE for well-functioning joints is not commonly done and the procedure is usually undertaken for patients with evidence of wear or osteolysis, stiffness, instability, or prosthetic joint infections [8].

Table 3 Linear wear measurements on liners

	Average measure (mm)	Linear wear (mm)	Average linear wear (mm)
Stryker GMRS			
Bushings			
Patient 1	2.93	0.04	
Patient 2	2.82	0.15	0.10
Patient 3	2.86	0.11	
Model	2.97		
Zimmer ZSS			
Hinge pin protectors			
Patient 1	1.13	0.02	
Patient 2	1.14	0.01	0.02
Model	1.15		
Internal bushings			
Patient 1	8.15	0.08	0.08
Model	8.07		

Literature has shown that ITPIE performed for symptomatic joints is of limited value. The procedure is unable to correct problems related to a poorly aligned or poorly balanced arthroplasty with expectedly poor results in this group. The results of ITPIE are best in patients with an initially well-functioning arthroplasty, who suffer from problems related to isolated PE wear [9–11].

In the case of TEP, however, there are additional factors to consider such as the amount of soft-tissue coverage, type of resurfacing required, adjuvant therapy, prostheses type, and overall alignment. Furthermore, these prostheses were implanted into a significantly younger patient population who, by default, are more active and have higher lifestyle demands. With modern 5-year survival rates of osteosarcoma patients at 66–77%, maintaining the longevity of these implants throughout the patients' lifespan needs to be a consideration [12].

As of today, there are no reports of elective exchange of parts specifically for lower limb TEP. This is despite a relatively high rate of implant failure and the fact that 36% of these failures are mechanically related [5]. Hence, we propose an elective exchange of replaceable parts in a well-fixed endoprosthesis before irreversible damage occurs to the PE and other components that may contribute to aseptic loosening and eventual failure [13].

There is a paucity of data in the literature to have an ideal timing as to when to proceed with this elective

Table 4 Linear wear measurements on bushings and hinge pin protectors

General category	Mode	Subcategory	Description
Mechanical	Type 1 soft-tissue failure Dysfunctional or deficient soft tissues resulting in compromised limb function	A. Functional	Limited function owing to insufficient musculo-ligamentous attachments
		B. Coverage	Aseptic wound dehiscence
	Type 2 aseptic loosening Clinical and radiological evidence of peri-prosthetic loosening	A. Early	Aseptic loosening <2 years after implantation
		B. Late	Aseptic loosening >2 years after implantation
	Type 3 structural failure Breakage, fracture or wear-related failure resulting in deficient support structure	A. Implant	Implant breakage or wear, expandable implant lengthening malfunction
		B. Bone	Peri-prosthetic osseous fracture
Nonmechanical	Type 4 infection Infected reconstruction not amenable to retention	A. Early	Infected implant <2 years after implantation
		B. Late	Infected implant >2 years after implantation
	Type 5 Tumor progression Recurrence or progression of tumor with endoprosthesis contamination	A. Soft-tissue	Soft-tissue progression of tumor with endoprosthetic contamination
		B. Bone	Bony progression of tumor with endoprosthetic contamination
Pediatric	Type 6 Pediatric failures	A. Physeal arrest	Growth arrest resulting in longitudinal or angular deformity
		B. Joint dysplasia	Dysplastic joint resulting from articulation with implants

change. The 7-year mark in our study was based on reported distal femoral endoprosthetic survival rates and incidence of aseptic loosening. Based on a recent systematic review, general distal femur replacement overall implant survival has been reported as 78% at 5 years and 70% at 10 years. This is lower for proximal tibial implants [3]. Specific to the GMRS implant, Pala *et al.* [2] reported an implant survival of 70% at 4 years and 58% at 8 years. While there is no specific survival data for ZSS, there have been reported cases of bumper breakage resulting in hyperextension failure at a median time of 30 months (range, 14–60) [14].

With regard to aseptic loosening, this was reported in the literature as a 'mid-to-long-term complication,' with the average time of loosening ranging from 3 to 12 years, increasing over time. Risk factors for this specific complication include younger aged patients and distal femoral location among others, both of which are applicable to our patient population [3,15]. In view of all these data, we postulated that 7 years was an acceptable 'mid-term' time frame for the surgery.

Retrieval study

Four tibial PE inserts were available. Macroscopic damage was clearly visible on the two FP tibial inserts and minimal damage to the two MP inserts. The reasons for the difference may be related to the specific kinematics of each implant or the properties of the PE itself.

In the FP design, the insert is locked to the metal tibia and the femoral component rotates over the saddle-shaped top surface. We postulate that repetitive mounting of the PE edge may be responsible for the observed cracking and delamination concentrated around the posterior lip of the PE. In contrast, the top surface of the MP liner experiences only congruent flexion and extension movement relative to the femoral component; the flat underside of the insert contacts with the polished tibial tray and only experiences rotation around a central postresulting in circular abrasion streaking on the underside.

Both implant designs use highly cross-linked UHMWPE; however, differences in manufacturing methods, sterilization, and storage may result in different wear and failure characteristics. The GMRS implant was introduced in 2002 and uses duration-stabilized PE, in which the material undergoes cyclical irradiation and annealing, followed by crosslinking. This was the first UHMWPE to employ heat stabilization following irradiation [16]. In comparison, the ZSS system was introduced in 2010 and uses a vitamin E-infused cross-linked PE [17,18].

The average linear wear of the tibial PE insert was 0.29 mm (~0.04 mm/year). Linear wear was higher in the MP inserts; however, the significance of any difference between implant designs should be treated with caution given the small numbers available and potential variability between patients. High rates of linear PE wear (>0.1 mm/year) are associated with osteolysis and aseptic loosening in total hip arthroplasty; however, there are no equivalent studies on knee arthroplasty or TEP replacement [19]. All the inserts retrieved in our study fell within these acceptable linear wear rates. UHMWPE is more resistant to wear and generates smaller particulate debris than conventional PE, but is more susceptible to brittle failure [20].

Incidentally, it was noted that the PE with the largest amount of macroscopic wear was from the patient with the highest BMI of 27. Also, the patient who was the most physically active only had minimal burnishing of implants. A larger sample size of patients will be required to analyze if this is indeed significant.

There was no visible damage and minimal measurable change in the thickness of the axle or hinge bushings. We were unable to find any reports of implant failure caused by wear or damage to these components; however, there are reports of failure due to breakage of the PE bumper that acts to prevent implant hyperextension and we suggest that the exchange of these parts may also be beneficial [14,21].

With the significant macroscopic damage seen on FP inserts, the time frame may be appropriate for these implants. As there was less damage on MP implants, potentially, the elective liner exchange surgery for these patients could have been stretched to a later period.

An alternative to this solution would be to monitor for symptoms or radiological evidence of aseptic loosening before proceeding with intervention. However, our concern is that of instability, falls, or fracture should an acute catastrophic failure occur when the implant reaches the point of fatigue. At that point, revision may be more challenging as the tibial and femoral components themselves may be involved (progressive loosening and osteolysis from third body wear). Rather than waiting for that to occur, we would rather intervene at an earlier stage with a short and safer elective procedure. Despite this, we do acknowledge that there is no specific data as to when that can occur, or have sufficient knowledge of how much macroscopic wear can occur in these parts before 'fracture' or failure occurs. Furthermore, there is always the risk of an iatrogenic prosthetic joint infection that would result in more morbidity. Hence, counseling the

patient extensively on the pros and cons and obtaining informed consent is essential before proceeding with the surgery.

Limitations

Our study is limited by a small patient population, as well as variability in the type of implants, preoperative indication/diagnosis, and presence of adjuvant therapy. The question also remains as to the corelation between the degree of macroscopic wear and how this affects the patient clinically and radiologically, seeing that our patients did not show any signs of clinical or radiographic loosening at the time of surgery. This is a pilot study and we hope to obtain a larger sample pool to analyze the extent of damage to each implant over time and decide on the most appropriate time for elective exchange.

Conclusion

This study introduces the idea of elective PE exchange as a possible strategy for improving the longevity of TEP. While our retrieval series is small, it suggests that change at 7 years may be appropriate for the FP design; a longer period may be suitable for the MP design. Further studies with a larger number of patients are required to confirm our findings and establish the optimal timing of PE exchange. A large randomized controlled trial with a long-term follow-up would be required to establish the long-term benefits of this active intervention approach.

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Authors' contributions: L.W.M.C. and M.H.W.C. were the primary surgeons for the initial and subsequent surgeries and conceived the idea for the study. M.F.C. developed the methodology for the retrieval study, performed analysis of the implants, and wrote the manuscript with support and supervision from L.W.M.C. and M.H.W.C.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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