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Mid-term results of total hip arthroplasty using a novel uncemented short femoral stem with metaphyso-diaphyseal fixation

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Abstract

Purpose: Short stems were developed with the promise of providing easier implantation, facilitating revision, reducing thigh pain and proximal stress shielding. The aim of this study is to present the mid-term clinical results of a titanium short stem with modular neck.

Methods: This is a prospective case series of 144 THAs performed on a series of 131 patients using the PROFEMUR Preserve Femoral Stem (MicroPort Orthopedics, Arlington, TN, USA). 2 surgeons, operated on the patients using a mini-posterior approach. The primary outcomes evaluated were stem revision for aseptic loosening and all-cause stem revision. Clinical and radiographic outcomes were also assessed.

Results: Of the 144 THAs, there were 43 males and 101 females, with an average age of 61 (range 22–92) years at surgery. After a mean of 78 (range 53–87) months follow-up, there were 2 (1.5%) femoral implant revisions; 1 for early femoral periprosthetic fracture and 1 for fatigue failure of the modular femoral neck. There were no cases of stem aseptic loosening and radiographic analysis demonstrated no cases of stem migration. The mean UCLA activity, WOMAC and Fogotten Joint scores were respectively 6.1, 10.7 and 86.6. 70% of prosthetic hips were observed as having no restriction and 99.2% of patients were satisfied with their THA.

Conclusions: This short modular stem produced satisfactory clinical and radiological results at mid-term, with 98.5% implant survival for any cause of stem revision and no revisions for aseptic loosening. Long-term results are required to further evaluate the stem's promising early results.

Keywords

Mini-stem, outcome, Preserve short stem, total hip arthroplasty

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Introduction

Total hip arthroplasty (THA) is 1 of the most successful and cost-effective operations with over a million performed annually worldwide.[1] A number of uncemented femoral stems have excellent long-term results, with stem survival at 25 years as high as 95%.[2–8] Despite these excellent long-term survival outcomes with conventional stems, some disadvantages have been described including proximal stress shielding, thigh pain and bone resorption.[9,10] The number of hip revisions has similarly increased, requiring arthroplasty surgeons to consider the possibility of a future revision surgery when performing the primary procedure, especially in younger, more active patients.

For these reasons, short stems (length <120 mm) have been increasing in popularity. They were developed with the promise of easier implantation, bone stock preservation for revision, the possibility of reduced thigh pain, and

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avoidance of proximal stress shielding.[11] The first short stems were used in the 1940s by Judet, with unsatisfactory results due to the relatively small surface area of the implant for anchoring in the metaphysis.[12] Since then, several other designs of short stems have been introduced with more encouraging results.[13–15]

The PROFEMUR Preserve Femoral Stem (MicroPort Orthopedics, Arlington, TN, USA) has been available since November 2011 (Figure 1). This femoral stem is shorter and more curved than traditional short stem designs and was developed with the aim of acquiring solid fixation in the meta-diaphyseal junction of the femur (Figure 2). At this level the femur has a more uniform ovoid shape, with less inter-individual variability than at the metaphysis.[16]

Figure 1. The Profemur Preserve stem.

This study presents the prospectively collected clinical and radiological results of the first 144 cases operated on by 2 surgeons using this short modular stem, after a minimum of 4 years follow-up.

Materials and methods

144 consecutive THAs performed on 131 patients were enrolled between January 2012 and August 2013. The inclusion criteria were all patients with hip pathology, clinical status and radiological analysis felt to be suitable for an uncemented primary THA. The mean clinical follow-up was 78 months (range 53–87 months). The main diagnosis was primary osteoarthritis (85.3%). Patient demographics are presented in Table 1.

Patients were treated by 2 of the stem's designer surgeons (ML and P-AV), utilising a mini-posterior approach. The femoral implant used was the PROFEMUR Preserve Femoral Stem with titanium alloy modular necks. The Preserve short stem is a trapezoidal titanium implant. It has a titanium plasma spray coating which thickness tapers from 1mm in the proximal region to 0.2mm in the distal region, aiding to achieve a proximal press-fit initial stability (Figure 1). Different uncemented acetabular components were used in combination with polyethylene, metal or ceramic liners (Table 2). During the period covered by this study, the initial modular neck version of the short stem was used and sizes 1 and 2 were not yet available.

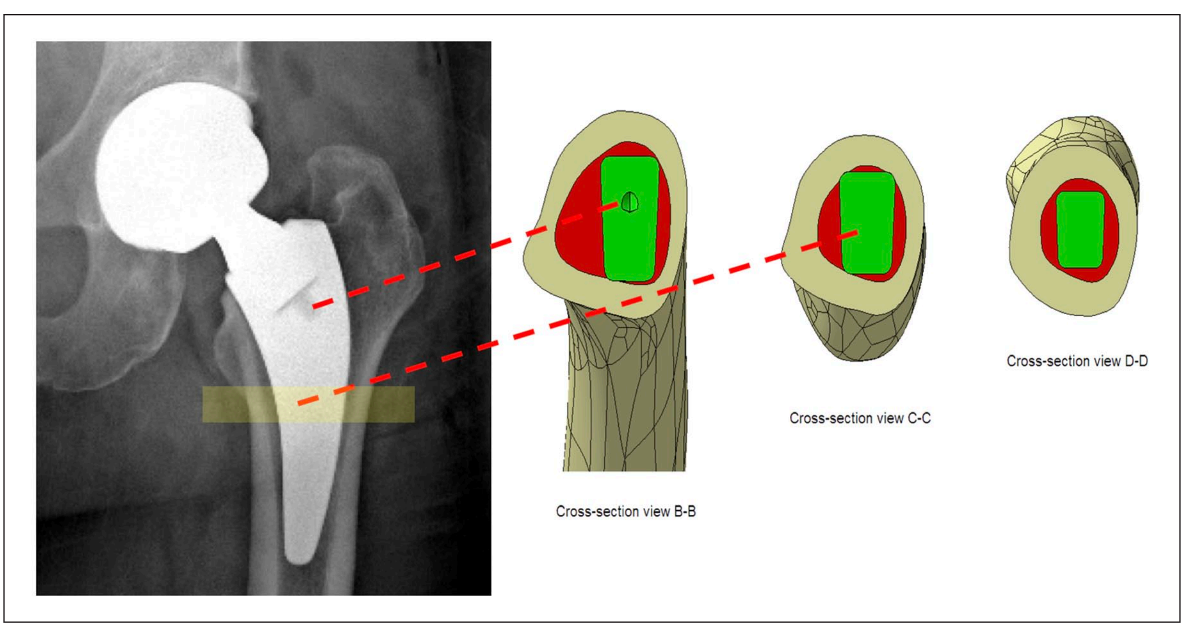

Figure 2. The Preserve stem aims for fixation at the meta-diaphyseal junction of the femur. At this level, the femur has a more uniform ovoid shape, with less inter-individual variability than at the metaphysis.

Table 1. Patient demographics.

Hips (*n*)	144
Age at surgery	60.6 (13.1, 22–92)
Gender (*n*, %)	
Female	101 (70.1)
Male	43 (29.9)
Height in cm	165.8 (9.4, 132–189)
Weight in kg	74.4 (16.8, 38.0–145.0)
Body mass index in kg/m^2	27.1 (5.4, 14.5–42.4)
Diagnosis (*n*, %)	
Primary osteoarthritis	116 (85.3)
Structural hip disorder	6 (4.4)
Avascular necrosis	5 (3.7)
Inflammatory arthritis	5 (3.7)
Legg-Calvé-Perthes disease	2 (1.5)
Post-traumatic arthritis	2 (1.5)

Note: Criteria mean (standard deviation [SD], min.–max.).

Table 2. Surgical parameters.

Surgical time in minutes	61.4 (26.1, 33–237)
Blood lost in mL	336.1 (202.2, 100–1200)
Cup abduction angle in degrees	43.6 (5.7, 31.1–60.0)
Cup anteversion angle in degrees	24.0 (8.9, 6.0–45.4)
Bearing surfaces (*n*, %)	
Ceramic-on-ceramic	95 (66.0)
Metal-on-polyethylene	45 (31.2)
Ceramic-on-polyethylene	4 (2.8)
Cup diameter in mm	52.2 (2.9, 46–60)
Head diameter in mm	37.58 (3.6, 28–44)
Modular neck length (*n*, %)	
Short	103 (71.5)
Long	41 (28.5)
Stem size (median, min.–max.)	5 (3–10)
Modular neck type (*n*, %)	
Varus/Valgus 8°	51 (35.4)
Straight	46 (31.9)
Ante/Retro – Varus/Valgus 1	24 (16.7)
Ante/Retro – Varus/Valgus 2	13 (9.0)
Ante/Retro 8°	9 (6.3)
Ante/Retro 15°	1 (0.7)

Note: Criteria mean (standard deviation [SD], min.–max.).

The primary outcomes were stem revision for aseptic loosening and all-cause stem revision. Patient follow-up was performed, at 6 weeks, 3 months, then annually post-surgery. The University of California at Los Angeles (UCLA) activity score, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, The Forgotten Joint score (FJS), patient joint perception (PJP) and patient satisfaction were assessed at last follow-up. Clinical assessment data was collected by 2 research assistants. Radiological analysis was performed by 2 arthroplasty fellows.

Radiological analysis was performed on anteroposterior and lateral radiographs using the DeLee and Charnley classification for the acetabular components,[17] and the Gruen classification for stems.[18] Implant loosening was defined as: a progressive radiolucent zone at the bone-implant interface >2 mm; implant migration >2 mm or; implant deviation in valgus or varus of >2°.

Data are presented with mean (standard deviation [SD], minimum-maximum) for continuous variables and frequencies for categorical variables. Statistical analysis was performed using SPSS version 24 (SPSS Inc., Chicago, Illinois, USA). For comparison of THAs with and without reported thigh pain, Student's *t*-test (2-tailed), Mann-Whitney U-test and the chi-squared test were used for continuous, ordinal and categorical data respectively. The significance level was set to 0.05.

Results

Of the 131 patients (144 THAs), 7 (5.3%, 8 THAs) were lost to follow-up, 8 (5.6%, 8 THAs) were deceased due to causes unrelated to the surgery. At a mean of 78 months (range 53–87 months), 128/144 THAs (88.9%, 116 patients) were clinically assessed and 104/128 THAs (81.2%) had complete functional questionnaires. At last follow-up, the mean UCLA activity scale was 6.1 (range 2–10), the mean WOMAC score was 10.7 (range 0–77) and the mean FJS was 86.6 (range 23–100, Table 3).

From the completed health questionnaires at last follow-up, thigh pain was reported for 11 THAs (10.6%) and was significantly associated with worse functional outcomes (Table 3). Thigh pain was reported significantly more often for hips with metal-on-polyethylene bearings (6/27, 22.2%) compared to ceramic-on-ceramic bearings (5/77, 6.5%, $p = 0.024$) and with long necks (6/25, 24.0%) compared to short necks (5/79, 6.3%, $p = 0.013$). Thigh pain was also associated with a significantly greater average stem size (6.6 compared to 4.7, $p = 0.037$). No other significant differences were observed for other demographic and arthroplasty parameters, such as gender, age, body mass index (BMI), preoperative diagnostic, surgeon, surgical time, bearing sizes and cup angles.

There were 14/144 (9.7%) fractures overall. These included 2/144 (1.4%) cases of intra-operative non-displaced peri-acetabular fracture with a stable cup left-*in situ*, 9/144 (6.3%) intraoperative proximal femur calcar fissures, treated with cerclage wiring with retention of the stem, and 1/144 (0.7%) immediate postoperative sub trochanteric fracture fixed with a peri-prosthetic plate. 5 of the 9 (55.6%) calcar cracks were in stem size 3- the smallest available stem at the time. There were 2/136 (1.5%) femoral implant revisions: 1 for early femoral periprosthetic fracture at postoperative day 10 revised for a standard-length stem with 5 femoral cerclage wires. The other revision was at 34 months for fatigue failure of the titanium modular femoral neck, while the patient was jogging. The femoral stem was a size 10 with a long and varus 8° neck. Additionally, there were 3 revisions not associated

Table 3. Functional outcomes.

Criteria Mean (SD, min.–max.)	All hips (104)	No thigh pain (93)	With thigh pain (11)	*p*-value
UCLA activity scale	6.1 (1.9, 2–10)	6.2 (1.9)	5.9 (1.5)	0.690
WOMAC score	10.7 (13.4, 0–77)	9.6 (12.9)	19.0 (14.7)	**0.027**
Forgotten joint score	86.6 (16.0, 23–100)	88.0 (15.5)	76.0 (15.9)	**0.018**
Satisfaction (*n*, %)				**<0.001**
Strongly satisfied	99 (95.2)	92 (98.9)	7 (63.6)	
Satisfied	4 (4.0)	1 (1.0)	3 (27.3)	
Neutral	1 (1.0)	0 (0.0)	1 (9.1)	
Dissatisfied	0 (0.0)	0 (0.0)	0 (0.0)	
Strongly dissatisfied	0 (0.0)	0 (0.0)	0 (0.0)	
Perception (*n*, %)				**0.014**
Natural hip	52 (50.0)	50 (53.8)	2 (18.2)	
Artificial hip without limitation	21 (20.2)	19 (20.4)	2 (18.2)	
Artificial hip with minimal limitations	31 (29.8)	24 (21.5)	7 (63.6)	
Artificial hip with important limitations	0 (0.0)	0 (0.0)	0 (0)	
Non-functional hip	0 (0.0)	0 (0.0)	0 (0.0)	

UCLA, University of California at Los Angeles; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.
Note: p-values were obtained from comparison of THAs with and without reported thigh pain.

with the stem. 2 of them were for early acetabular implant mobilisation and 1 was a late re-operation for femoral cerclage wire removal due to persisting pain.

There were no radiographic signs of femoral stem or acetabular cup aseptic loosening, periprosthetic osteolysis or progressive radiolucent line on either anteroposterior or lateral radiographs at final follow-up. 1 femur (1/128, 0.8%) had cortical hypertrophy in Gruen zone 4 and 5. There was no evidence of progressive subsidence of the femoral component >2 mm or a varus or valgus shift >2°. There were 2/128 (1.6%) cases of Brooker 1 heterotopic ossification and 1/128 (0.8%) of Brooker 2. There were no deep THA infections during the follow-up period.

Discussion

The results of this study demonstrate that the Profemur Preserve Stem has satisfactory survivorship at mid-term follow-up. There were no cases of aseptic loosening and an all-cause stem revision rate of 1.5% after a mean follow-up of 6.5 years. Functional and radiological outcomes were excellent.

Short stems were introduced with the aim of providing easier implantation, preservation of bone stock for revision, reduction of thigh pain and avoidance of proximal stress shielding. In the present series, the patients represent the first cohort treated by 2 designer surgeons (ML and P-AV) of the PROFEMUR Preserve Femoral Stem. The low number of complications is a testament to the short learning curve associated with this prosthesis. A number of conventional, uncemented femoral stems have excellent clinical outcomes including long-term survivorship.[2–8] For new short stems to be accepted, these must be equally safe and effective and offer something more to the surgeon, such as increased ease of implantation or easier revision. Molli et al.[19] found a lower rate of intraoperative complications, including fractures, in a series of 606 patients who underwent THA with a short stem compared with a conventional femoral prosthesis (0.4% vs. 3.1%, respectively). Short-stem femoral implants with standard neck resection do not have a steep learning curve, such as is seen in hip resurfacing.[20]

In the current study, there were no recorded cases of stem migration, confirming that the design of the prosthesis allows good primary stability with early osteointegration. Only 1 case of cortical hypertrophy was found in Gruen zones 4 and 5. The short modular stem used in this study is designed to acquire solid fixation in the metaphysis and the meta-diaphyseal junction of the femur. At this level the femur has a more uniform ovoid shape, with less inter-individual variability than at the metaphysis (Figure 2).[16] Short femoral stems can be classified into 3 categories according to the level of the osteotomy at the femoral neck:[21] first, femoral neck implants such as resurfacing prostheses;[22] second, implants that use the trochanteric flare to provide primary stability with axial compression resistance and;[23–25] third, implants <120 mm that are slightly curved in their principal axis and engage the lateral cortex,[26] and metaphysis of the proximal femur creating a physiological metaphyseal support.[13,27] Proximal stress shielding is rarely seen as the primary stability is achieved via proximal fixation and favourable stress distribution[28–30]

Stem fixation in the meta-diaphyseal junction has several potential advantages over longer femoral stems. It reduces the risk of "three point" stem fixation due to proximal femoral bowing, and the associated risk of undersizing

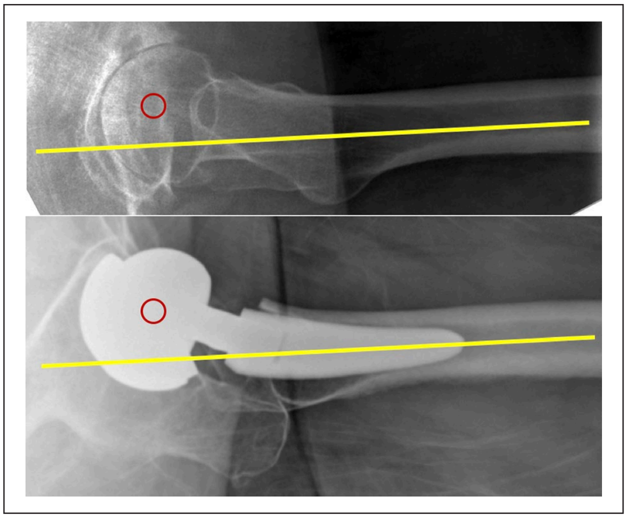

Figure 3. Radiographs demonstrating that the Preserve stem replicates the natural anteroposterior offset of the femoral head.

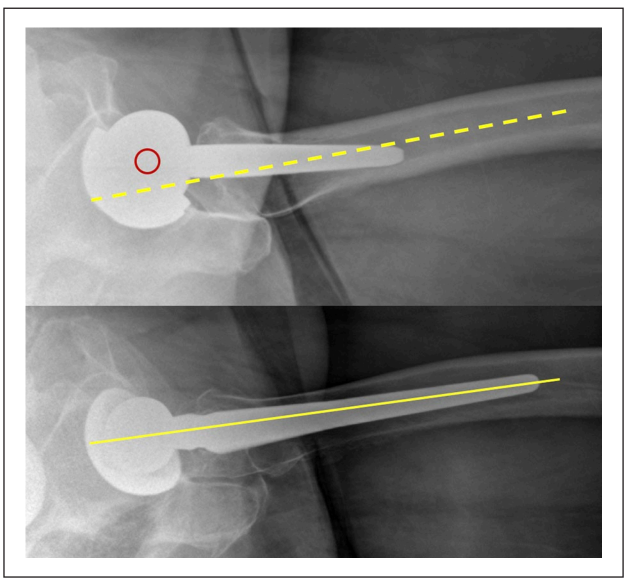

Figure 4. Radiographs demonstrating translation of the centre of rotation posteriorly with a long femoral stem in comparison to the Preserve stem.

the stem. By centring the stem at its mid-portion, it also reduces the risk of varus stem implantation – seen with short stems aiming for a femoral neck fixation. Finally, following the proximal femoral bow may help preserve the anatomic centre of rotation of the femoral head (Figure 3). Longer stems tend to translate the centre of rotation posteriorly (Figure 4).

The rate of reported thigh pain in this series (11/104, 10.6%) was equivalent to that observed in our previous series with a traditional cementless stem (CLS Spotorno, Zimmer, Warsaw, Indiana, USA; 21/177, 11.9%). Thigh pain is a frequent complication in THA and it was associated with significantly worse functional outcomes in our series.[31,32] Potential causes of this complication are a mismatch in the Young's modulus of elasticity between the bone and the implant with excessive load transfer to the femur. This is seen with the conventional cementless stems (with length >150 mm).[31] A meta-analysis by Huo et al.[33] identified 6 randomised clinical trials (RCTs) with 572 hips comparing short stem prostheses with conventional implants.[34–39] In contrast to our observations, they demonstrated significantly reduced thigh pain in the small stem prostheses (risk ratio 0.15, 95% confidence interval [CI], 0.04–0.49, $p=0.002$;), but with no significant differences in the functional outcomes (Harris Hip Scores and WOMAC). The present study does not support the theory that smalls stems reduce thigh pain. We found a higher rate of thigh pain in the patients with metal-on-polyethylene versus ceramic-on-ceramic bearings (22% vs. 7%, $p=0.024$). This may be linked to the differing patient profiles for each bearing: older, less active, more osteopenic and with thinner femoral cortices. The other finding is the higher thigh pain rate with long femoral modular necks versus short ones (24% vs. 6%, $p=0.013$). In the longer necks, the increased offset and moment arm may increase the femoral stresses and related thigh pain.

There was a high rate of intraoperative fracture seen in this series, with calcar cracks requiring a cerclage wire in 6.3% of hips. This is much higher than seen in our institution's series of conventional CLS stems (2/225, 0.9%). The majority of these calcar cracks were seen in stem size 3. At the time this study was performed, stem sizes 1 and 2 were not available, which may have contributed to the higher number of fractures. These were also the first prostheses implanted by the surgeons and may demonstrate a learning curve.

Few trials have reported on long-term outcomes with short stem THAs. Kim et al.[14] reported 15-year results for a metaphyseal-fitting short stem in 630 hips of patients under the age of 65. There were no revisions for aseptic loosening and no thigh pain reported. 15-year survival rates were 99.4% (95% CI, 0.97–1.00) for the femoral component. Santori et al.[13] also reported satisfactory results at 8-year follow-up for custom made short stem prosthesis, suggesting that the absence of a diaphyseal portion of the stem does not necessarily affect the stability of the prosthesis. Von Lewinski et al.[15] reported on 1953 Metha short stem THAs performed over a 10-year period. 38 (1.9%) required revision due to mechanical complications. There were 12 cases where the modular titanium neck adapter failed, 19 cases of aseptic loosening (of which 11 cases were due to major stem subsidence), 5 cases of periprosthetic fracture and 2 cases of cortical penetration. All of these studies present excellent results for short stems, which have not been entirely replicated in registry results. The Australian Orthopaedic Association

National Joint Registry reported on 2877 procedures using a short stem prosthesis, undertaken for osteoarthritis.[40] The 10-year cumulative revision rate for the total conventional hip replacement using a short stem is 6.2% compared to 5.1% for other femoral stems (although this difference is not statistically significant). The cumulative incidence of revision for loosening in short stems, however, was more than double that of conventional femoral stems at 10 years (2.7% compared to 1.3%). This may be the result of a learning curve typically seen with surgeons adapting to new devices. Many of the reported studies are conducted by designer surgeons.

In our series, we report a failure rate due to stem fracture of 0.7% (1 case out of 136) at mid-term follow-up. The incidence of modular neck fractures with similar titanium alloy modular necks has been reported to be 0.13% worldwide over a period of 20 years.[41] There is a higher risk of neck fractures for the varus and long modular neck designs (as was our fracture case). In 2015, an overall failure rate of 6.6% was reported in a series of 277 subjects, 2.1% (7/277 hips) of those were due to femoral neck fracture. All necks in the fracture cases were long necks produced from titanium alloy.[42] A large number of the failures were due to fracture of the neck at the modular junction. These results contradict other long-term data for the titanium necks in the PROFEMUR stem family.[43–46] After these results were published, the manufacturer decided to switch the material of the "long" neck from titanium (Ti) to cobalt chrome (CrCo). The benefits of modularity in THA, however, may be outweighed by the additional risks that modularity begets.[47,48] As of 2016, a monobloc version of the short stem, PROFEMUR Preserve Classic Femoral Stem [MicroPort Orthopedics, Arlington, TN, USA]) has become available. This stem variant eliminates the cross-sectional area reduction and stress riser associated with the modular neck junction, thus minimising the risk of prosthetic fatigue failure.

The current study has some limitations. Radiographic analysis performed with standard films is inferior to radiostereometric analysis for accurate measurement of component migration and to dual-energy x-ray absorptiometry analysis for bone remodelling around the prosthesis. A control group with a conventional stem would have been a good comparator, but instead we have relied on the well-published results of these stems and our institution's comparative results. The results presented are relatively short-term for this stem, but it is important to present the early results of new stems to identify those performing well and alert surgeons to those performing poorly.

Conclusion

The Profemur Preserve stem, produced satisfactory clinical and radiological results at mid-term follow-up, with 98.5% implant survival for all-cause revision and no revision for aseptic loosening. Long-term results are required to further evaluate the stem's promising early results.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: P-AV and ML: were developers of the Preserve stem and receive royalties.

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