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Foot Ankle Int 2013 34: 491 originally published online 15 February 2013
DOI: 10.1177/1071100713477610

The online version of this article can be found at:
http://fai.sagepub.com/content/34/4/491

Published by:
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On behalf of:

American Orthopaedic Foot & Ankle Society

AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY.

Foot & Ankle International
34(4) 491–497

DOI: 10.1177/1071100713477610
fai.sagepub.com

Clinical and Radiographic Outcomes of the Mobility Total Ankle Arthroplasty System: Early Results From a Prospective Multicenter Study

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Abstract

Background: The Mobility Total Ankle System is a third-generation design consisting of a 3-component, cementless, unconstrained, mobile-bearing prosthesis. This study reports the early results of a prospective multicenter study of the Mobility prosthesis.

Methods: Eighty-eight Mobility total ankle arthroplasties (TAAs) were implanted in 85 patients. The most common underlying diagnosis was posttraumatic arthritis (53%). Ankles were classified according to the Canadian Orthopedic Foot and Ankle Society (COFAS) end-stage ankle arthritis classification system. Coronal plane deformity was quantified preoperatively. Patients were reviewed at regular intervals postoperatively, with clinical and radiographic assessment. The mean follow-up time was 40 months (range, 30-60 months).

Results: Type 1 ankle arthritis was demonstrated in 44 ankles (50%). No patient had preoperative coronal plane angulation greater than 20 degrees. In 32 ankles (36%) the preoperative coronal alignment was neutral, and in 34 ankles (39%) the deformity was less than 10 degrees. The mean American Orthopaedic Foot & Ankle Society (AOFAS) Ankle-Hindfoot score improved from 38.2 (range, 12-59) preoperatively to 74.8 (range, 46-100) postoperatively. Bone-implant interface abnormalities were identified in 33 ankles with a retained prostheses (43%). Thirty (91%) of these involved zones around the tibial plate. In total, 8 TAAs required revision, 6 for aseptic loosening, 1 for talar migration, and 1 for deep infection. There was 1 conversion to arthrodesis for component malpositioning and 1 transtibial amputation for chronic regional pain syndrome. Six patients were being investigated for ongoing pain. The cumulative survival was 89.6% (95% confidence interval, 80.8-94.8) at 3 years and 88.4% (95% confidence interval, 79.3-93.9) at 4 years.

Conclusion: Early results of the Mobility TAA for independent researchers do not match those reported by other surgeons. Good pain relief and improved function were achieved postoperatively in 72 ankles (82%). High rates of bone-implant interface abnormalities around the tibial plate are concerning but require longer follow-up to determine their clinical significance.

Level of Evidence: Level IV, case series.

Keywords: ankle arthritis, arthroplasty, outcome, survivorship, radiolucency, complications

End-stage ankle arthritis is a debilitating chronic disease associated with joint pain, dysfunction, and, in advanced stages, muscle atrophy, joint contractures, and limb deformity. A recent study has shown that patients with end-stage ankle arthritis have severely affected health-related quality of life with Short Form 36 (SF-36) scores 2 standard deviations (SD) below a normal population.[7] Arthrodesis has been used to successfully treat disabling arthritis of the ankle since the late 19th century with good short-term results, but long-term data suggest that this treatment may result in deterioration of ipsilateral periarticular joints.[3,5,9,25]

The principles of joint replacement for the hip and knee were applied to the ankle in the 1970s, and more than 23

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prostheses have been developed. Many of the initial designs were mechanically flawed, leading to excessive talar bone resection, tibiotalar malalignment, and frictional forces between the fibular articular surface and tibial component. Early designs led to unsatisfactory results and a call for a complete hiatus of this procedure, as it failed to provide lasting pain relief or improved function.[8,9,13,26] Consequently, arthrodesis became the surgical standard of care for ankle arthritis.

In the 1990s, improved designs of total ankle arthroplasty (TAA) prostheses and surgical techniques, coupled with a continued high incidence of long-term ipsilateral periarticular arthritis subsequent to ankle fusion, initiated a resurgence of TAA. New TAA prostheses have shown positive short and medium-term results in North America and Europe over the last decade.[4,15,16,18,24,27-29] This prospective multicenter study, conducted across 3 sites in Canada, represents the first independent, noninventor clinical and radiographic outcome study on the Mobility TAA system (DePuy, Johnson & Johnson Co, Leeds, UK).

Figure 1. Photograph of the Mobility Total Ankle Arthroplasty (TAA) prosthesis.

Methods

Between November 2005 and February 2008, the senior authors (T.D., A.Y., M.G.) implanted 88 Mobility prostheses in 85 patients. The underlying diagnosis was primary osteoarthritis in 24 ankles (27%), posttraumatic arthritis in 47 ankles (53%), and inflammatory arthritis in 17 ankles (20%). There were 41 males, with a mean age of 67 years (range, 51-87 years), and 44 females, with a mean age of 60 years (range, 29-72 years). The mean body mass index (BMI) for male patients was 28 (range, 22-36) and for female patients was 28 (range, 20-39). Prior ankle operations were performed in 24 patients (28%), and in 22 of these patients, the intervention was for internal fixation of ankle fractures.

The Mobility prosthesis is a third-generation, mobile-bearing ankle replacement made with a cobalt chrome component on both the tibial and talar side. The tibial component has a short conical tibial post, long anteroposterior (AP) length, and a thick tibial plate. The long AP length permits slight posterior overhang of the posterior tibial cortex, thereby minimizing the risk of nonuniform bone loading and supporting the cortex of the tibia. The short conical tibial post prevents tibial component rotation and provides primary fixation into the tibia while aiding stress distribution. The thick tibial plate reduces the risk of plate failure. The articulating surface of the talar component has a deep talar sulcus and a triplane underside with 2 short deep fins, to provide medial, lateral, and rotational instability. The polyethylene insert has 2 congruent articulating surfaces allowing an unconstrained range of motion (Figure 1).

Operative Technique and Postoperative Care

The surgical procedure began with an anterior approach through a 10- to 15-cm incision centered over the middle of the talus carried down deep through the extensor hallucis longus tendon sheath to allow exposure of distal tibial plafond and talus. Bone resection jigs were then positioned using a tibial rod positioned parallel to the long axis of the tibia. The tibial and talar bone cutting jigs were then used to guide resection of the distal tibial and proximal talar articular surfaces. The tibial component was inserted with the stem placed into the tibia through an anterior bone window. The talar component was inserted onto the talus with 2 fins on the inferior surface. No side walls were present on the talar component and the cortical sidewalls of the talus remained intact. The bone ingrowth surface was porous-coated.

In this study, there were 44 simultaneous procedures performed in 29 (33%) ankles. These included 10 subtalar fusions, 8 gastrocnemius recession procedures, 7 triple arthrodeses, 7 calcaneal osteotomies, 5 dorsiflexion osteotomies of the first metatarsal, 3 talonavicular arthrodeses, 2 first tarsometatarsal arthrodeses, and 2 hallucal interphalangeal arthrodeses.

Postoperatively, a well-padded plaster cast was applied below the knee. The foot was elevated for 24 to 48 hours to reduce swelling. The plaster cast was exchanged for an air cast boot at 4 weeks, and weight-bearing to tolerance was commenced. The boot was removed periodically for range of motion exercises under the guidance of a physical therapist. The boot was discontinued after 4 weeks.

Table 1. COFAS Classification System for End-Stage Ankle Arthritis[17]

Type 1	Type 2	Type 3	Type 4
Isolated ankle arthritis	Ankle arthritis with intra-articular varus/valgus deformity or a tight heel cord, or both	Ankle arthritis with hindfoot deformity, tibial malunion, midfoot abductus or adductus, supinated midfoot, plantar flexed first ray, etc	Types 1-3 plus subtalar, calcaneocuboid, or talonavicular arthritis

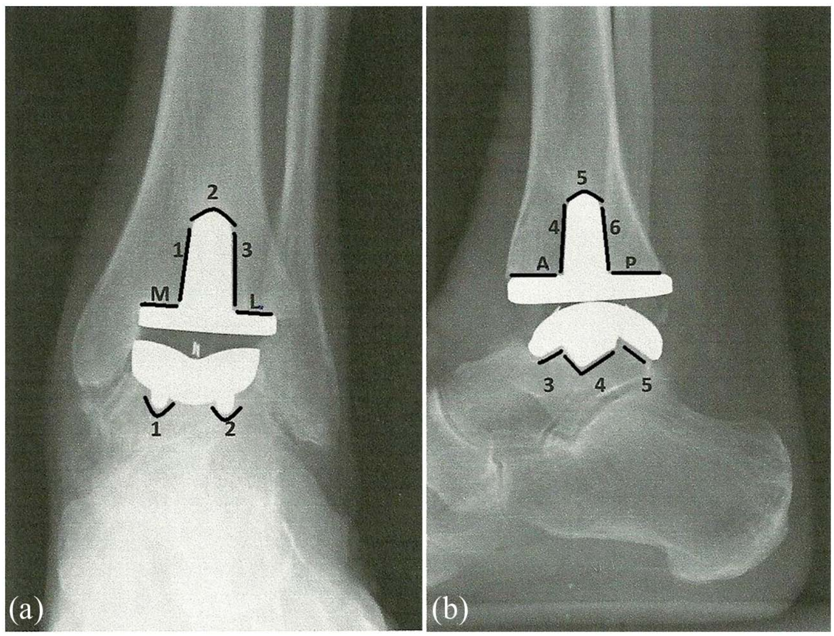

Figure 2. Postoperative (a) anteroposterior and (b) lateral radiographs demonstrating the 10 tibial and 5 talar zones assessed for bone-implant interface abnormalities.[27] A, anterior; L, lateral; M, medial; P, posterior.

Clinical and Radiographic Assessment

All data were collected prospectively at an average of 40 months (range, 30-60 months) postoperatively. The primary outcome measure was joint-specific clinical outcome using the American Orthopaedic Foot & Ankle Society (AOFAS) Ankle-Hindfoot score, measured preoperatively and at regular intervals postoperatively.[14] Secondary outcome measures included radiographic assessment, implant survival, and complications.

The radiographic assessment was based on weight-bearing AP, lateral, and mortise views. All radiographs were assessed by the primary author and an independent musculoskeletal radiologist (G.B.). Ankles were classified according to the Canadian Orthopedic Foot and Ankle Society (COFAS) classification system for end-stage ankle arthritis (Table 1).[17] Coronal plane deformity (varus/valgus) was quantified preoperatively. The tibiotalar ratio was measured on pre- and postoperative radiographs. This represents the proportion into which the midlongitudinal axis of the tibial shaft divides the longitudinal length of the talus, and it is a measure of the AP tibiotalar alignment.[27,28] The mean tibiotalar ratio found in normal ankles is 40%, and significant anterior subluxation is deemed to be present when the tibiotalar ratio is less than 34%, that is, greater than 2 SD from the mean. Postoperative radiographs were also assessed for prosthetic alignment, component migration, edge-loading (loss of congruency between the bearing surfaces), osseous integration, and periarticular ossifications. Pertaining to the appraisal of osseous integration, the tibial bone-implant interface was divided into 10 zones and the talar bone-implant interface into 5 (Figure 2).[27] It was considered that osseous integration in any particular zone had failed if there was a lucent line along the entire length of the zone or if the width of the lucency was greater than 2 mm at any 1 point. It was conceded that talar assessment was limited due to the complex contours of the talar component. Regardless of the appearance of the bone-implant interface, migration of components was deemed to be a failure of osseous integration.[27]

Survival analysis was calculated according to the Kaplan-Meier method. Failure was defined as exchange of any component of the TAA, conversion to arthrodesis, or amputation. Complications were tracked using previously published TAA complication classification systems.[6]

Results

During the study, 1 patient died 10 months postoperatively. This patient's outcome from surgery at this juncture was satisfactory and uncomplicated. A total of 87 TAAs (84 patients) were available for review at a mean of 30 months. Of these patients, 70 (83%) stated that they were satisfied with the outcome from their surgery.

AOFAS Ankle-Hindfoot Scores

The AOFAS Ankle-Hindfoot score improved from a mean of 38.2 (range, 12-59) preoperatively to 74.8 (range, 46-100) postoperatively.

Radiographic Assessment

The COFAS classification system for end-stage ankle arthritis was used. Type 1 was identified in 44 (50%) ankles, type 2 in 12 (14%) ankles, type 3 in 9 (10%) ankles, and type 4 in 23 (26%) ankles. Pertaining to preoperative coronal plane alignment, 32 (36%) ankles were neutral. In 34 (39%) ankles, the deformity was less than 10 degrees; 20 of these were in valgus, and 14 were in varus. In 22 (25%) ankles, the deformity was 10 to 20 degrees; 10 of these were in valgus, and 12 were in varus. There were no ankles with a deformity of greater than 20 degrees in the coronal plane.

In 80 (91%) ankles, prosthetic components were implanted within 5 degrees of the optimal position in both coronal and sagittal planes.[21,24] Twenty-four (27%) ankles demonstrated evidence of preoperative anterior subluxation (tibiotalar ratio <34%). The mean preoperative tibiotalar ratio was 31 (range, 24-34). Twenty-two (92%) improved postoperatively. Two (8%) remained the same. The mean postoperative tibiotalar ratio was 39 (range, 32-42). The average correction of the tibiotalar ratio achieved was 8 (range, 0-17).

Bone-implant interface abnormalities were identified in 33 (43%) ankles with retained prostheses. Thirty (91%) of these involved zones around the tibial plate. In 6 (20%) ankles the abnormality involved 1 zone, in 6 (20%) ankles it involved 2 zones, in 8 (27%) ankles it involved 3 zones, and in 10 (33%) ankles it involved all 4 zones around the tibial plate. In 2 ankles, bone-implant interface abnormalities were demonstrated around the tibial stem, and in 1 ankle, they were demonstrated around the talar component. All bone-implant interface abnormalities were less than 2 mm and appeared nonprogressive in nature for the duration of the study. Thus far, these patients were asymptomatic.

Cystic radiolucencies were observed in 4 (5%) ankles. All were located in the medial malleolus and were 5 to 10 mm in size (Figure 3). None extended to involve the bone-implant interface. Once again, patients were asymptomatic.

The anterior cortical window created for insertion of the stem of the tibial component healed uneventfully in all ankles.

Implant Survival

In total, 10 (11%) TAAs failed (Table 2). Of the 8 that required revision, 6 were for aseptic loosening of the tibial component, 1 was for talar migration, and 1 was for deep infection. The latter underwent a successful 2-stage procedure. There was 1 conversion to an arthrodesis for component malpositioning with edge-loading and 1 transtibial amputation for chronic regional pain syndrome. The average BMI in those who sustained a mechanical failure (see Table 2—exclusive of patients 2 and 6) of their prosthesis was 33 (range, 29-39), with all patients but 1 falling within the obese category (BMI >30). This compares with 11 obese patients with an average BMI of 34 (range, 31-39) who successfully retained their prostheses. In addition, 4 of these mechanical failures occurred in patients whose prosthetic components were not implanted within 5 degrees of the optimal position in both coronal and sagittal planes.

The Kaplan-Meier survival analysis (Table 3) showed a 3-year cumulative survival of 89.6% (95% confidence interval, 80.8-94.8), and 88.4% (95% confidence interval, 79.3-93.9) at 4 years.

Reoperations and Complications

There were 8 reoperations (9%), most commonly for impingement due to periarticular ossifications (4 ankles—50%). Intraoperative and postoperative complications were noted in 13 ankles (15%). Delayed wound healing occurred in 3 ankles. One of these required split thickness skin grafting. Another had a concurrent superficial wound infection that responded well to local wound care and antibiotics. Asymptomatic subsidence involving the talar component was noted in 2 ankles. In both, it stabilized within 1 year, and successful osseous integration was achieved. Edge-loading was noted in 3 ankles, 1 of which required revision. The remaining 2 patients were asymptomatic. Five ankles sustained a fracture of the medial malleolus : 2 were intraoperative and underwent internal fixation. The 3 delayed medial malleolar fractures were successfully treated nonoperatively. Six patients were being investigated for ongoing pain without an obvious cause to date.

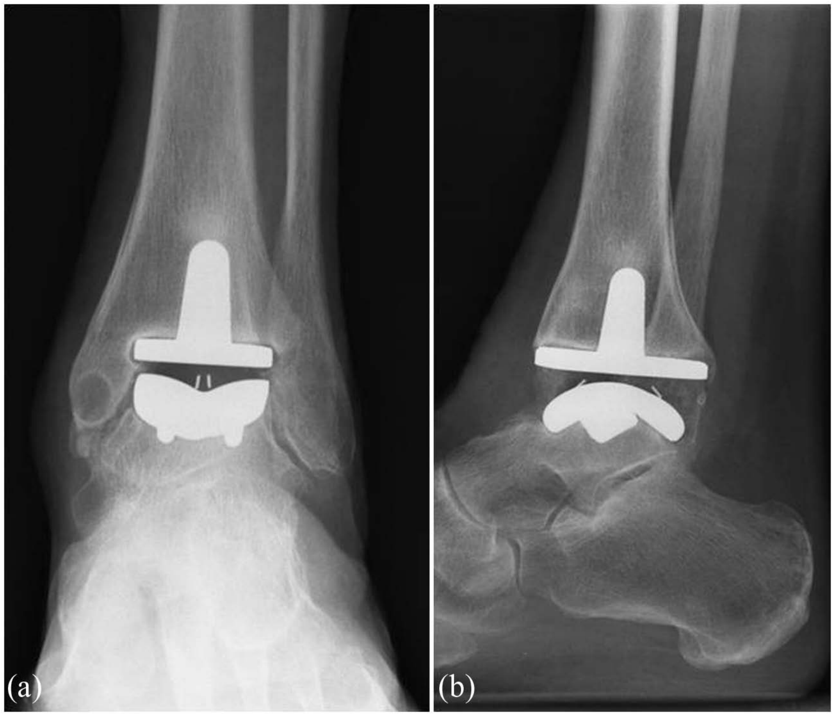

Figure 3. (a) Anteroposterior and (b) lateral radiographs at 3 years postoperative detailing a 5- to 10-mm cystic radiolucency in the medial malleolus. Lucent lines less than 2 mm are also evident in the anterior, medial, and lateral zones around the tibial plate. These abnormalities appeared stable, and the patient was asymptomatic.

Table 2. Details of Mobility TAA Failures

Patient	Age/ Gender	Body Mass Index	Diagnosis	Coronal Deformity, Pre-/Postoperative	Failure Reason	Procedure	Time to Failure, y
1	69/F	39	Primary OA	19 degrees valgus/6 degrees varus	Talar migration	Revision	0-1
2	48/F	27	RA	Neutral/neutral	Infection	2-stage revision	1-2
3	62/M	31	Secondary OA	13 degrees valgus/8 degrees varus	Varus/edge-loading	Arthrodesis	1-2
4	71/F	31	Secondary OA	Neutral/neutral	Tibial loosening	Revision (tibia)	1-2
5	64/M	37	RA	Neutral/8 degrees varus	Tibial loosening	Revision	2-3
6	53/M	34	Secondary OA	Neutral/4 degrees varus	CRPS	Transtibial amputation	2-3
7	63/M	29	Secondary OA	6 degrees varus/ neutral	Tibial loosening	Revision	2-3
8	56/F	33	Primary OA	7 degrees varus/2 degrees varus	Tibial loosening	Revision (tibia)	2-3
9	54/F	32	RA	12 degrees valgus/ neutral	Tibial loosening	Revision	2-3
10	51/M	32	Secondary OA	11 degrees valgus/6 degrees varus	Tibial loosening	Revision	3-4

Abbreviations: CRPS chronic regional pain syndrome; OA, osteoarthritis; RA, rheumatoid arthritis; TAA, total ankle arthroplasty.

Table 3. Kaplan-Meier Survival Data

Year	At Risk	Censored	Failure	Survival, %	95% CI Lower	95% CI Upper
0-1	88	1	1	98.8	92.9	99.9
1-2	86	0	3	95.4	88.0	98.5
2-3	83	8	5	89.6	80.8	94.8
3-4	70	44	1	88.4	79.3	93.9

Abbreviation: CI, confidence interval.

Discussion

This prospective multicenter study, conducted across 3 sites in Canada, represents the first independent, noninventor outcome study on the Mobility Total Ankle System. The results demonstrated that good pain relief and improved function were achieved postoperatively in 72 ankles (82%) undergoing a TAA with the Mobility prosthesis. Exclusive of failures, a reoperation rate of 9% and a complication rate of 15% highlight the importance of attention to surgical technique. Wood et al[27] reported their inventor series results of 100 Mobility TAAs performed at their institution, with a 93.6% survivorship at 4 years. Similarly, Rippstein et al[21] reported their inventor series results of 233 Mobility TAAs performed at their institution, with a 97.7% survivorship at 4 years. Patient demographics and selection were similar to the current study, which demonstrated an inferior survivorship of 88.4% at 4 years. The senior authors (T.D., A.Y., M.G.) in our study were all experienced, fellowship-trained orthopedic foot and ankle surgeons, and consequently our results were not unduly biased by the early learning curve, which has been shown to adversely affect the outcome of TAA.[1,8,9,12] Furthermore, these results may offer a more accurate reflection of survivorship outside inventor surgeons' institutions.

We had 10 failures in this study, with 7 cases of aseptic loosening. Some important trends were noted with these patients. First, 6 of these patients with aseptic loosening were obese. A direct relationship between obesity and failure of TAAs has yet to be established, and conflicting evidence exists in the hip and knee arthroplasty literature.[19,22] Probably because of the existence of many other variables, we were not able to correlate the two. Second, 6 of these patients with aseptic loosening had tibial component loosening, as opposed to talar migration, which has been a more common mode of failure of TAAs.[10,27] This may be related to lack of osseous integration of the tibial plate during the early phase, with subsequent micromotion predisposing to pain. Progression to overt loosening inevitably ensues. Third, 3 of the 8 patients who sustained a mechanical failure of their prosthesis had preoperative valgus deformities of more than 10 degrees. Although an absolute preoperative coronal plane threshold has not been defined, deformities exceeding 10 degrees are associated with higher failure rates, in particular valgus deformities, where reconstitution of a deficient deltoid ligament can be difficult even following adequate joint tensioning.[10,27] Wood et al[27] had 5 failures in their study, with 3 patients having valgus deformities of more than 10 degrees. Finally, 4 of these patients did not have their prosthetic components implanted within 5 degrees of the optimal position in both coronal and sagittal planes. The importance of optimal prosthetic component implantation on implant longevity has been emphasized previously.[1,24,28]

Using the radiographic criteria as described by Wood et al,[27] we found that 33 ankles (43%) with retained prostheses had bone-implant interface abnormalities. This finding is in contrast to those of Wood et al, who detected abnormalities in only 14 ankles (14%). The majority of these radiolucencies were less than 2 mm and stable thus far. They were almost exclusively located around the tibial plate. Due to the short-term follow-up of this study, it was difficult to accurately ascertain whether they were truly progressive and to interpret the significance of their presence. Nevertheless, their existence is a source for concern. Periprosthetic radiolucency, and ultimately osteolysis, can progress without symptoms until catastrophic structural failure or mechanical loosening of the implant occurs.[1,11,20,23]

We had 6 patients with persistent unexplained pain who were being investigated at the time of final follow-up. None of these patients had gross evidence of aseptic loosening or progressive radiolucencies. Whether these patients should be included in the analysis as failures with data presented as best-case and worst-case scenarios remains contentious. Previous studies have reported the need to convert to arthrodesis in select patients with a well-fixed prosthesis but unexplained pain.[2,27] We did not have any patients pending revision at the time of final follow-up, whom we would have included as failures. However, we are aware of the evolution of such patients since the completion of this study. These issues highlight the importance of pursuing medium and long-term results. Thus, it is our intention to report on the progress of this series of patients again in the next couple of years.

We used the AOFAS outcome score to evaluate our patients, with an improvement noted (38.2-74.8) comparable to other studies.[1,20,23,27-29] We reported this outcome score because it was most reliably collected across each site, although the Ankle Osteoarthritis Scale, the Foot Function Index, and the SF-36 were also recorded. Using all 3 additional scores could have strengthened this study.

Conclusion

Early results of the Mobility TAA for independent researchers do not match those reported by designer surgeons. Good pain relief and improved function were achieved postoperatively in 72 ankles (82%). Notable reoperation (9%) and complication (15%) rates emphasize the importance of attention to surgical technique. High rates of bone-implant interface abnormalities around the tibial plate are worrisome but require longer follow-up to determine their clinical significance. Suboptimal component implantation may negatively affect outcome.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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