Three-year rates of reoperation and revision following mobile versus fixed-bearing total ankle arthroplasty: a cohort of 302 patients with 2 implants of similar design

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A commentary by J. Chris Coetzee, MD, FAAOS, is linked to the online version of this article.

Three-Year Rates of Reoperation and Revision Following Mobile Versus Fixed-Bearing Total Ankle Arthroplasty

A Cohort of 302 Patients with 2 Implants of Similar Design

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Investigation performed at Geneva University Hospitals, Geneva; Lausanne University Hospitals (CHUV), Lausanne; and the Centre of Foot and Ankle Surgery, Clinique La Colline, Geneva, Switzerland

Background: Currently, the implants utilized in total ankle arthroplasty (TAA) are divided between mobile-bearing 3-component and fixed-bearing 2-component designs. The literature evaluating the influence of this mobility difference on implant survival is sparse. The purpose of the present study was therefore to compare the short-term survival of 2 implants of similar design from the same manufacturer, surgically implanted by the same surgeons, in fixed-bearing or mobile-bearing versions.

Methods: All patients were enrolled who underwent TAA with either the mobile-bearing Salto (Tornier and Integra) or the fixed-bearing Salto Talaris (Integra) in 3 centers by 2 surgeons between January 2004 and March 2018. All patients who underwent TAA from January 2004 to April 2013 received the Salto implant, and all patients who underwent TAA after November 2012 received the Salto Talaris implant. The primary outcome was time, within 3 years, to first all-cause reoperation, revision of any metal component, and revision of any component, including the polyethylene insert. Secondary outcomes included the frequency, cause, and type of reoperation.

Results: A total of 302 consecutive patients were included, of whom 171 received the mobile-bearing and 131 received the fixed-bearing implant. The adjusted hazard ratio for all-cause reoperation was 1.42 (95% confidence interval [CI], 0.67 to 3.00; p = 0.36); for component revision, 3.31 (95% CI, 0.93 to 11.79; p = 0.06); and for metal component revision, 2.78 (95% CI, 0.58 to 13.33; p = 0.20). A total of 31 reoperations were performed in the mobile-bearing group compared with 14 in the fixed-bearing group (p = 0.07). More extensive reoperation procedures were performed in the mobile-bearing group.

Conclusions: With the largest comparison of 2 implants of similar design from the same manufacturer, the present study supports the use of a fixed-bearing design in terms of short-term failure. We found a 3-times higher rate of revision among mobile-bearing implants compared with fixed-bearing implants at 3 years after TAA. Reoperations, including first and subsequent procedures, tended to be less common and the causes and types of reoperations less extensive among fixed-bearing implants.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Total ankle arthroplasty (TAA) is increasingly utilized to treat end-stage osteoarthritis because of the biomechanical advantages of arthroplasty over arthrodesis[1,2] and the promising mid-term and long-term outcomes[3-5]. Despite its success, TAA is historically associated with higher rates of early reoperation and revision compared with total

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/G666).

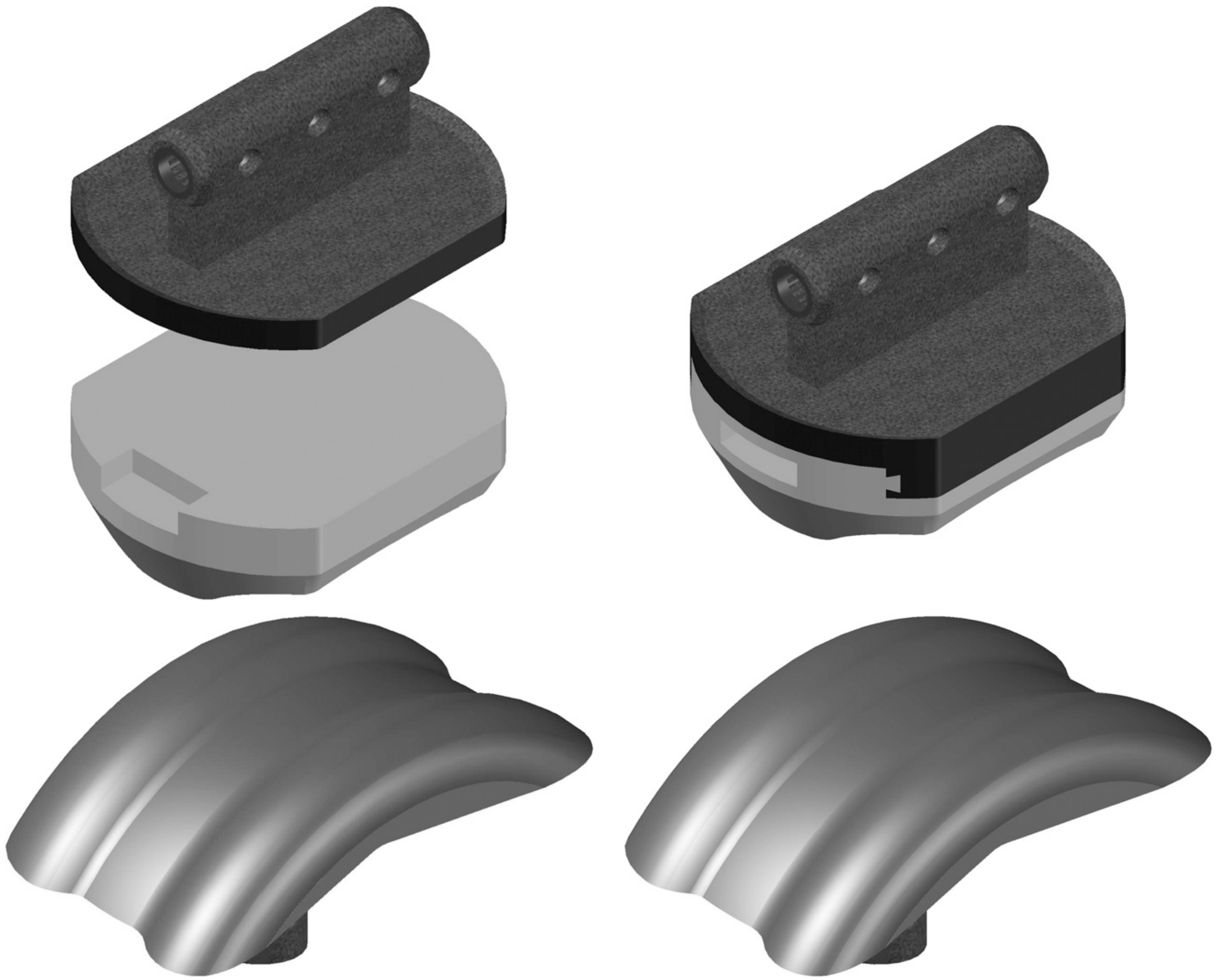

Fig. 1-A Fig. 1-B

Figs. 1-A and 1-B Images of the Salto mobile-bearing (**Fig. 1-A**) and Salto Talaris fixed-bearing (**Fig. 1-B**) implants.

hip and knee arthroplasty[6-9], which demonstrates the difficulty of replacing the relatively complex ankle joint[9,10].

Nevertheless, continuous advances in implant design have improved outcomes and survival rates of TAA[11,12]. Current implants are divided between mobile-bearing 3-component and fixed-bearing 2-component designs. Most comparative clinical studies and meta-analyses have not demonstrated differences in reoperation and revision rates between implant designs[13-16]. However, the latest registry reports and a systematic review have demonstrated a new trend toward the superiority of fixed-bearing 2-component designs in terms of the rates of reoperation and revision[17-19].

Mobile-bearing implants have exhibited increased rates of instability and subluxation of the polyethylene component[20], whereas fixed-bearing implants have been associated with a higher rate of tibial loosening and polyethylene wear, likely as a result of shear forces[16,21]. However, a finite-element analysis found no differences in bone strain or bone-implant interfacial stress between 2 comparable fixed-bearing and mobile-bearing implants[22]. Fixed-bearing designs have benefited from a series of design improvements over the years, and a recent study reported no major strain differences between mobile-bearing and fixed-bearing designs[22]. Furthermore, newer designs have corrected many of the flaws of previous generations, casting doubt on the relevance of these older observations in the context of modern TAA implants[23]. Therefore, early identification of complications related to implant design remains a major challenge in the field of ankle arthroplasty[11,24].

The purpose of the present study was therefore to compare the short-term survival of 2 implants of similar design from the same manufacturer, surgically implanted by the same surgeons, in fixed-bearing or mobile-bearing versions, and to evaluate the frequency, cause, and type of procedures associated with reoperations.

Materials and Methods

Patients and Study Design

All patients were enrolled who underwent TAA with either the mobile-bearing Salto (Tornier and Integra) or the fixed-bearing Salto Talaris (Integra) at 3 centers (Geneva University Hospitals; Clinique La Colline Hirslanden, Centre of Foot and Ankle Surgery in Geneva; and Lausanne University Hospital) between January 2004 and March 2018. Two surgeons (M.A. and X.C.) performed all of the TAA procedures together. All patients who underwent TAA from January 2004 to November 2012 received the mobile-bearing Salto implant, and all patients who underwent TAA after April 2013 received the fixed-bearing Salto Talaris implant, with patients treated in the short intervening period receiving one of these implants according to availability. No deaths occurred within the first 3 years postoperatively, and no patients were excluded from the study. The study was approved by the relevant national ethics boards (Swiss Ethics, project ID 2016-00065).

Demographics and Outcomes

Demographic variables were noted at the time of patient inclusion, with the exception of the body mass index and American Society of Anesthesiologists (ASA) score, which were collected retrospectively from patient files so as to assess the possible heterogeneity of the baseline characteristics.

The primary outcome was the time to first all-cause reoperation, defined as any procedure on the ankle and/or any of the adjacent joints following the index procedure. The 2 end points relating to revision reflect 2 common definitions of revision in the literature: (1) revision for the exchange of metal components or for conversion to salvage arthrodesis[25,26] and (2) revision of any component, including isolated polyethylene exchange, or for conversion to salvage arthrodesis[18].

Secondary outcomes were the frequency (number of first and subsequent reoperations), cause, and type of reoperation, graded in accordance with other published work[26,27]. All patients had standard radiographs at 3 months and 1 year postoperatively, and then every other year thereafter. In addition, patients with painful prostheses were further assessed with use of computed tomography. Patient symptoms and imaging results were assessed to determine the necessity of a reoperation.

Implants

The mobile-bearing Salto implant was introduced to the European market in 1997, and the fixed-bearing Salto Talaris implant was introduced in 2012 (Figs. 1-A and 1-B). The tibial and talar components of both prostheses are made of cobalt-chromium alloy. The coating of the Salto mobile-bearing prosthesis consists of plasma spray titanium and hydroxyapatite. Hydroxyapatite was not utilized in the coating of the Salto Talaris. Both prostheses are of anatomical design and are implanted cementless with a standard bone resection of 7 mm. In both prostheses, the talar component is conical in shape with 2 different radii of curvature to match the normal morphology of the talus. Fixation of the talar component is press-fit and enhanced by a central peg. The tibial part utilizes a central press-fit keel for fixation. In the fixed-bearing design, the polyethylene is fixed to the tibial component, whereas in the mobile-bearing design, the polyethylene is positioned between the tibial and talar components, thus creating 2 articulating surfaces. Regarding the learning curve for implantation, both surgeons had extensive experience utilizing the Salto implant during TAA since the year 2000. Further, because the surgical technique and the instrumentation of both models are identical, there was no learning curve adapting to the new fixed-bearing model.

Surgical Technique and Rehabilitation

The prosthesis was implanted through an anterior approach between the tibialis anterior and extensor hallucis longus tendons. A pneumatic thigh tourniquet was utilized in all cases, being inflated immediately prior to the skin incision and kept until closure. Attention was paid to create a plantigrade foot and a balanced ankle, as achieved with use of selected adjunctive procedures. Patients were allowed to walk with partial weight-bearing (20 kg) on postoperative day 3. A protective cast was utilized for 6 weeks postoperatively, after which passive and active range of motion were begun.

Statistical Analyses

Data were summarized with use of descriptive statistics. For the primary outcome, Kaplan-Meier survival analysis was performed for 3 different end points: (1) all-cause reoperation, (2) revision for the exchange of metal components or for conversion to salvage arthrodesis, and (3) revision of any component, including isolated polyethylene exchange, or for conversion to

TABLE I Patient Demographics*

	Mobile-Bearing (N = 171)	Fixed-Bearing (N = 131)
Age *(yr)*	62 ± 12	68 ± 9
Body mass index *(kg/m²)*	28.0 ± 7.0	27.6 ± 5.1
Male sex male	87 (51%)	63 (48%)
Indication, posttraumatic arthritis	139 (81%)	109 (83%)
Diabetes	5 (3%)	7 (5%)
ASA score		
1 or 2	107 (87%)	95 (85%)
3 or 4	16 (13%)	17 (15%)
Hindfoot alignment		
Neutral	133 (78%)	71 (54%)
Varus	14 (8%)	24 (18%)
Valgus	24 (14%)	36 (28%)

*Values are given as the mean ± standard deviation or as the count with the percentage in parentheses. Body mass index had missing data for 55 patients in the mobile-bearing group and 16 in the fixed-bearing group. ASA score had missing data for 48 patients in the mobile-bearing group and 12 in the fixed-bearing group.

TABLE II Unadjusted and Adjusted HRs for Reoperation and Revision

	Patient	Survival					
	N (%)	Unadjusted HR (95% CI)	P Value	Adjusted HR* (95% CI)	P Value	Adjusted HR† (95% CI)	P Value
Reoperation							
Mobile-bearing	22 (12.9%)						
Fixed-bearing	11 (8.4%)	1.57 (0.76-3.24)	0.22	1.42 (0.67-3.00)	0.36	NA‡	
Revision (polyethylene exchange included)							
Mobile-bearing	14 (8.2%)						
Fixed-bearing	3 (2.3%)	3.70 (1.06-12.86)	0.04	3.31 (0.93-11.79)	0.06	3.70§ (1.06-12.86)	0.04
Revision (polyethylene exchange excluded)							
Mobile-bearing	8 (4.7%)						
Fixed-bearing	2 (1.5%)	3.14 (0.66-14.82)	0.12	2.78 (0.58-13.33)	0.20	2.79# (0.59-13.12)	0.20

*Analysis adjusted for covariates with substantial baseline imbalance (i.e., age and alignment). †According to best-fit model (determined by smallest Akaike information criterion). ‡The null model was the model with the lowest Akaike information criterion (373.2). NA = not available. §The unadjusted model was the model with the lowest Akaike information criterion (189.8). #The model adjusted for alignment showed best fit (Akaike information criterion: 113.1).

salvage arthrodesis. Charts were audited for any patient who did not undergo a reoperation in order to confirm that no reoperation had occurred within 3 years postoperatively. Corresponding p values were calculated with use of the log-rank test. To compare the 3-year outcomes of the 2 types of implants, unadjusted hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated with use of Cox regression analysis. To account for baseline imbalances in age[9] and alignment[28], an additional Cox regression analysis was performed adjusting for these variables. In addition, we identified the best regression model by testing all possible combinations of the predictor variables age, sex, alignment, and posttraumatic or other indication. The model with the lowest Akaike information criterion was considered to be the best-fit model. Finally, the incidence of reoperation was calculated with use of Poisson regression analysis, with reoperation per person-year as the outcome. All analyses were performed independently by a senior statistician (A.L.) and an epidemiologist statistician (J.H.) with use of R (version 3.5.0; R Foundation for Statistical Computing), SPSS (version 25; IBM), and Stata (version 15; StataCorp).

Source of Funding
We received internal funding from our institutions and external funding in the form of a research grant from the Swiss Foot and Ankle Society, which did not play a role in the investigation.

Results

Overall, a total of 302 consecutive patients were included, of whom 171 received a mobile-bearing implant and 131 received a fixed-bearing implant. Patient demographics were comparable between groups in terms of patient sex, body mass index, diabetes, and ASA score distribution. A greater proportion of patients had valgus-aligned ankles in the fixed-bearing group, and the fixed-bearing group had a higher mean age (Table I). No patient was lost to follow-up at the time of the 3-year evaluation.

Regarding the primary outcome, 22 patients (12.9%) in the mobile-bearing group underwent ≥1 reoperation compared with 11 (8.4%) in the fixed-bearing group (Table II). The 3-year rate of survival free from any reoperation was 87.1% (95% CI, 82.3% to 92.3%) in the mobile-bearing group compared with 91.6% (95% CI, 87.0% to 96.5%) in the fixed-bearing group (log-rank test, p = 0.21) (Fig. 2). The adjusted HR for any reoperation was 1.42 (95% CI, 0.67 to 3.00; p = 0.36) (Table II). The most common reoperation procedures were cyst debridement, gutter debridement (i.e., the removal of impinging bone at the medial or lateral side of the implant), salvage arthrodesis, wound debridement, and polyethylene

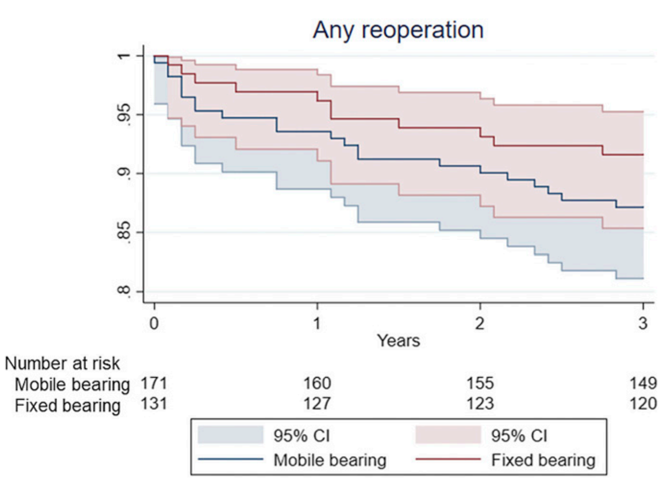

Fig. 2
Three-year Kaplan-Meier survival analysis of the mobile-bearing and fixed-bearing groups, with any reoperation as end point.

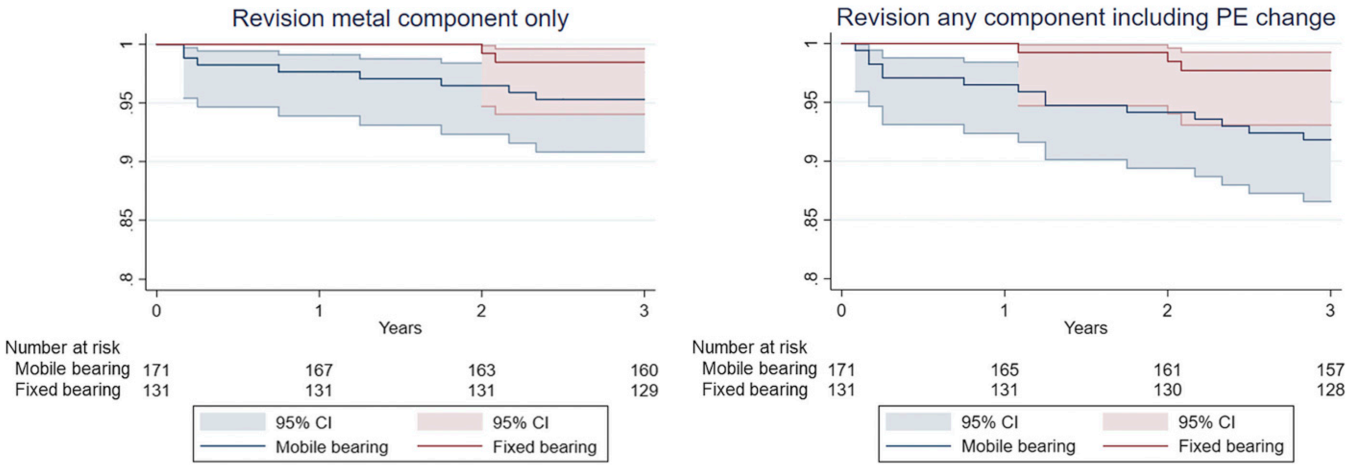

Fig. 3-A

Fig. 3-B

Fig. 3-A Three-year Kaplan-Meier survival analysis of the mobile-bearing and fixed-bearing groups, with revision of any metal components as the end point.
Fig. 3-B Three-year Kaplan-Meier survival analysis of the mobile-bearing and fixed-bearing groups, with revision of any component, including isolated polyethylene (PE) exchange, as the end point.

exchange in the mobile-bearing group and gutter debridement, wound debridement, salvage arthrodesis, and ligamentoplasty in the fixed-bearing group.

Fourteen patients (8.2%) in the mobile-bearing group underwent revision of any component, including polyethylene exchange, compared with 3 (2.3%) in the fixed-bearing group (Table II). The 3-year rate of survival for revision of any component was 91.8% (95% CI, 87.8% to 96.0%) in the mobile-bearing group compared with 97.7% (95% CI, 95.2% to 99.9%) in the fixed-bearing group (log-rank test, p = 0.03) (Fig. 3-A), and the adjusted HR was 3.31 (95% CI, 0.93 to 11.79; p = 0.06). At the time of the latest follow-up, an additional 2 patients in the mobile-bearing group had planned revision for polyethylene exchange compared with none in the fixed-bearing group.

Eight patients (4.7%) in the mobile-bearing group underwent revision of a metal component compared with 2 (1.5%) in the fixed-bearing group. The 3-year rate of survival for revision of any metal component was 95.3% (95% CI, 92.2% to 98.5%) in the mobile-bearing group compared with 98.5% (95% CI, 96.4% to >99.9%) in the fixed-bearing group (log-rank test p = 0.13) (Fig. 3-B). The adjusted HR for revision of any metal component was 2.78 (95% CI, 0.58 to 13.33; p = 0.20). When visualizing the Kaplan-Meier survival analysis (Figs. 3-A and 3-B), the immediate drops in survival could be attributed to 5 patients: 2 with an early deep infection, 2 with polyethylene subluxation, and 1 with an atraumatic medial malleolar fracture.

Regarding the secondary outcomes, 33 (10.9%) of the 302 patients in the study group underwent ≥1 reoperation (10.9%), of whom 12 (4.0%) underwent ≥2 reoperations. A total of 31 reoperations, including both first and subsequent reoperations, were performed in 22 patients (12.9%) in the mobile-bearing group compared with 14 reoperations in 11 (8.4%) in the fixed-bearing group (HR, 1.70; 95% CI, 0.94 to 3.06; p = 0.07) (Table III). A total of 54 procedures were performed during those 31 reoperations in the mobile-bearing group compared with 16 procedures during 14 reoperations in the fixed-bearing group. The mobile-bearing

TABLE III Causes and Types of Reoperation Procedures Performed

	Mobile-Bearing Group (N = 171)	Fixed-Bearing Group (N = 131)
No. of patients	22	11
No. of reoperations	31	14
Cause for reoperation*		
Wound-healing problem	7 (4.1%)	4 (3.0%)
Infection	3 (1.7%)	2 (1.5%)
Gutter impingement	8 (4.7%)	5 (3.8%)
Fracture	1 (0.6%)	0 (0.0%)
Polyethylene subluxation	2 (1.2%)	0 (0.0%)
Polyethylene wear	5 (2.9%)	1 (0.8%)
Cyst	9 (5.3%)	1 (0.8%)
Loosening	2 (1.2%)	1 (0.8%)
Adjacent joint arthrosis	5 (2.9%)	0 (0.0%)
Reoperation procedure*		
Wound debridement	7 (4.1%)	4 (3.1%)
Osteosynthesis	1 (0.6%)	0 (0.0%)
Polyethylene exchange	7 (4.1%)	1 (0.8%)
Gutter debridement	8 (4.7%)	5 (3.8%)
Cyst debridement	11 (6.4%)	1 (0.8%)
Adjacent joint fusion	5 (2.9%)	0 (0.0%)
Ligamentoplasty	2 (1.2%)	2 (1.5%)
Metal component exchange	6 (3.5%)	1 (0.8%)
Salvage arthrodesis	7 (4.1%)	2 (1.5%)

*Some reoperations were performed for multiple causes and included multiple procedures.

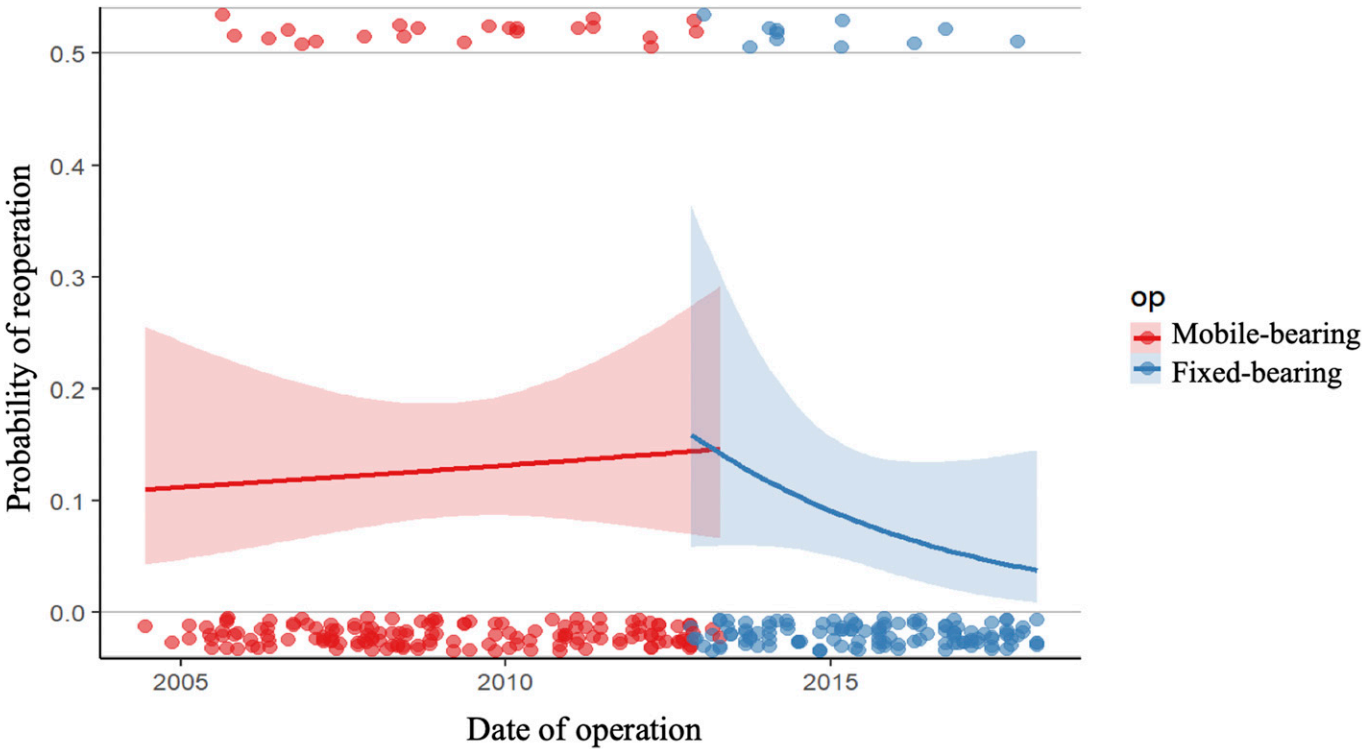

Fig. 4
Probability of reoperation over time for the mobile-bearing and fixed-bearing groups, calculated with use of a Poisson regression model, with reoperations per person-year as the outcome.

group underwent proportionally more polyethylene exchange (4.1%) and cyst debridement (6.4%) than the fixed-bearing group (0.8% for both procedures). Finally, although the probability of reoperation marginally increased over time in the mobile-bearing group, it decreased in the fixed-bearing group (Fig. 4).

Discussion

The purpose of the present study was to compare the short-term survival of 2 implants of similar design from the same manufacturer, surgically implanted by the same surgeons, in fixed-bearing or mobile-bearing versions. We observed an approximately 3-times greater rate of all-cause revision in the mobile-bearing group compared with the fixed-bearing group at 3 years after TAA. There were fewer reoperations, including first and subsequent reoperations, in the fixed-bearing group, with reoperations involving fewer procedures performed for less severe complications.

To our knowledge, the present study is the first comparative clinical study to evaluate the influence of bearing type on implant survival in prostheses of similar design from the same manufacturer. Previous case series have shown a large variability in the rates of revision and reoperation associated with these implants (Table IV). The present results are consistent with the those reported in the 2019 annual report of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)[18], which indicated a 3-year cumulative percent revision of 1.8% (95% CI, 0.7% to 4.3%) for the Salto Talaris fixed-bearing implant (n = 344) compared with 6.1% (95% CI, 4.1% to 9.0%) for the Salto mobile-bearing implant (n = 415). The registry showed that the Salto Talaris had the best 3-year survival among all of the included implants. The overall 3-year cumulative incidence of revision was 2.2% (95% CI, 1.1% to 4.5%) for all of the included fixed-bearing implants and 7.3% (95% CI, 6.4% to 12.8%) for all of the included mobile-bearing implants. Moreover, the New Zealand Registry reported no revisions in 98 TAAs performed with the Salto Talaris (rate per 100 component years, 0) compared with 53 revisions in 721 TAAs performed with the Salto (rate per 100 component years, 1.34)[17].

In the present study, the most common reoperation procedures were cyst debridement, gutter debridement (i.e., the removal of impinging bone at the medial or lateral side of the implant), salvage arthrodesis, wound debridement, and polyethylene exchange in the mobile-bearing group and gutter debridement, wound debridement, salvage arthrodesis, and ligamentoplasty in the fixed-bearing group. The greater proportion of isolated polyethylene exchange observed in the mobile-bearing group was in accordance with the 2019 annual report of the AOANJRR[18], which identified isolated polyethylene exchange as the cause of >50% of the revisions associated with these prostheses. We also observed that the mobile-bearing group underwent a greater number of reoperations for cyst de

TABLE IV Literature Review of the Reported Reoperation and Revision Rates of the Salto and Salto Talaris Implants*

	Study	Journal	No. of Procedures	Minimum Follow-up *(mo)*	Reoperation Rate *(%)*	Revision Rate (Polyethylene Exchange Included)	Revision Rate (Polyethylene Exchange Excluded)
Salto	Present study	-	171	36	12.9%	8.2%	4.7%
	Mehdi[34], 2019	OTSR	25	40	25.0%	10.0%	10.0%
	Koo[35], 2019	FAI	55	24	9.8%	6.7%	6.7%
	Wan[10], 2018	FAI	59	6	11.9%	5.1%	5.1%
	Gaudot[13], 2014	FAI	33	4	12.1%	0.0%	0.0%
	Rodrigues-Pinto[36], 2013	FAS	119	18	5.9%	2.7%	2.7%
	Schenk[37], 2011	FAI	218	24	11.0%	-	5.5%
	Reuver[38], 2010	FAI	59	12	16.9%	-	11.9%
	Bonnin[39], 2011	CORR	98	81.6	35.0%	20.1%	15.0%
	Bonnin[40], 2004	CORR	93	24	4.3%	2.2%	2.2%
Salto Talaris	Present study	-	131	30	8.4%	2.3%	1.5%
	Nunley[14], 2019	FAI	43	24	7.0%	7.0%	2.3%
	Marks[41], 2019	JFAS	50	11	12.0%	2.0%	0.0%
	Cody[42], 2019	FAI	79	60	-	8.8%	8.8%
	Pangrazzi[43], 2018	FAI	104	20	11.0%	5.0%	5.0%
	Stewart[44], 2017	FAI	72	60	19.0%	5.1%	3.8%
	Hofmann[45], 2016	JBJS	81	41	21.0%	-	2.5%
	Oliver[46], 2016	FAI	321	24	6.2%	-	2.8%
	Chao[47], 2015	FAI	23	24	17.4%	-	4.6%
	Nodzo[48], 2014	FAI	75	24	17.3%	-	2.0%
	Gaudot[13], 2014	FAI	33	11	3.0%	3.0%	3.0%
	Schweitzer[49], 2013	JBJS	67	24	12.0%	3.0%	3.0%
Both (mixed)	Gramlich[50], 2018	IO	60	24	42.0%	15.0%	15.0%

*OTSR = Orthopaedics & Traumatology: Surgery and Research, FAI = Foot and Ankle International, JFAS = Journal of Foot & Ankle Surgery, CORR = Clinical Orthopaedics and Related Research, JBJS = Journal of Bone and Joint Surgery, IO = International Orthopaedics, and FAS = Foot and Ankle Surgery.

bridement over 3 years compared with the fixed-bearing group; this observation is in accordance with previous reports comparing mobile- and fixed-bearing implants[13,14]. In our practice, the presence of a symptomatic cyst is confirmed with use of computed tomography[29]. The cysts are then treated surgically by debridement and grafting, usually in combination with adjunctive surgical procedures, which may include component exchange. Although the reason for the formation of such cysts following TAA remains unclear, it is likely multifactorial, including an interaction with the particles resulting from polyethylene wear, micromotions, and hydroxyapatite coating[30-32]. Previous studies have shown that polyethylene particles are not the primary cause of osteolytic cyst formation but are a secondary factor that might contribute to the acceleration of osteolysis[30,33]. The 2019 report from the AOANJRR[18] indicated that there was presently no evidence that the coating of an implant affects the rate of revision following TAA.

In the present study, patients who received a mobile-bearing implant were more likely to undergo reoperations for a more severe complication than those who received a fixed-bearing implant, including higher rates of metal component exchange and salvage arthrodesis. The 3 most common reasons for reoperation were symptomatic cysts, gutter impingement, and wound-healing complications in the mobile-bearing group and gutter impingement, wound-healing complications, and deep infection in the fixed-bearing group.

When visualizing the Kaplan-Meier survival analysis (Figs. 3-A and 3-B), the immediate drops in survival could be attributed to 5 patients: 2 with an early deep infection, 2 with polyethylene luxation (which is a complication that is specific to the mobile-bearing design), and 1 with an atraumatic medial malleolar fracture. The rate of infection was similar between groups (1.7% in the mobile-bearing group and 1.5% in the fixed-bearing group), but infections occurred earlier in the mobile-bearing group.

One strength of the present study was that it represented the largest direct comparison of 2 implants of similar design from the same manufacturer, surgically implanted by the same surgeons, in fixed-bearing or mobile-bearing versions, which allowed us to analyze the effect of design on short-term implant survival. However, 1 limitation of the study was that the study design did not allow for randomization because the fixed-bearing implant was not being manufactured at the beginning of the recruitment process. Although we could not exclude the possibility of a learning effect, we believe that any such effect would be small because the 2 operating surgeons had substantial experience in TAA prior to the commencement of the study, specifically with the Salto implant as they started using this prosthesis in 2000 and the study period began in 2004. Additionally, in the mobile-bearing group, 10 of 86 patients in the first chronological half of the study underwent ≥1 reoperation compared with 12 of 85 patients in the second chronological half. Figure 4 shows that the probability of reoperation in the mobile-bearing group was consistent over the duration that this implant was utilized.

After adjusting for the baseline differences in age and alignment, the HR slightly changed and the CI included 1, indicating a loss of statistical significance. However, 2 patients in the mobile-bearing group had planned revision for polyethylene exchange compared with none in the fixed-bearing group. Overall, the number of events was relatively small, affecting the precision of our analyses. The analysis may also have been slightly affected by the younger age and greater proportion of valgus-aligned ankles in the fixed-bearing group. An effect of these parameters on the risk has been described in the literature[9,28], although other studies have suggested that alignment does not substantially affect the rate of failure in TAA[11,28]. Nonetheless, neither adjustment for age and alignment nor for other sets of covariates had a noteworthy effect on point or interval survival estimates. Finally, the decision to perform a reoperation following TAA is complex and likely surgeon-dependent; however, the same 2 surgeons performed all of the index procedures and reoperations throughout the study period.

Conclusions

On the basis of the largest comparison of survival between 2 implants of similar design from the same manufacturer, the present study supports the use of a fixed-bearing implant in TAA. We found a 3-times higher rate of revision for TAAs performed with the Salto mobile-bearing implant compared with the Salto Talaris fixed-bearing implant at 3 years after TAA. There were fewer reoperations, including first and subsequent reoperations, in the fixed-bearing group, with reoperations involving fewer procedures performed for less severe complications. ■

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