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Salto Talaris Fixed-Bearing Total Ankle Arthroplasty: Long-Term Results at a Mean of 10.7 Years

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Abstract

Background: Total ankle arthroplasty (TAA) has become increasingly popular in the treatment for end-stage ankle arthritis in recent decades. However, there is limited evidence regarding the long-term clinical outcomes and complication rates of modern TAA implants.

Methods: This study presents a follow-up on a previous cohort involving 78 patients (81 ankles) who underwent Salto Talaris fixed-bearing TAA to treat end-stage arthritis, with a mean postoperative follow-up of 5.2 years. The aim of this follow-up study was to assess the radiographic (33 patients, 35 ankles) and clinical (48 patients, 50 ankles) results from the original cohort at a mean of 10.7 years (range, 7.8-14 years).

Results: At a mean of 10.7 years, the Kaplan-Meier estimated survivorship was 84.2% (95% CI, 71.9%-98.6%). For the patients reviewed, we did not find any change in patient-reported outcomes between an average 5- and 11-year follow-up. Measured total range of motion and plantarflexion did not change between 1 and 11 years, but dorsiflexion was measured as decreasing by an average of 4 degrees ($P < .02$).

Conclusion: In this longer-term follow-up of a limited cohort, we found that Salto Talaris fixed-bearing TAA demonstrated good long-term survival with relatively low rates of revision or other complications. Patient-reported outcome and range of motion measures revealed good stability.

Level of Evidence: Level III, therapeutic.

Keywords: total ankle arthroplasty, concise follow-up study, retrospective study, long-term outcomes study, implant survival

Background

A recent systematic review of 18 studies found that the prevalence of ankle arthritis in community-dwelling older adults was 3.4%.[23] The surgical techniques for the treatment of ankle arthritis have been a topic of ongoing debate.[28] For many years, the gold standard surgical care was ankle arthrodesis (AA).[9] Although a reliable procedure, AA is associated with various sequelae such as gait abnormalities and adjacent joint arthritis.[18,21] In a recent randomized controlled trial, a significant improvement was observed in walking/standing domain outcome scores of the Manchester Oxford Foot & Ankle Questionnaire (MOXFQ) from preoperation to 52 weeks postoperation in fixed-bearing total ankle arthroplasty (TAA), as compared to AA.[12] Consequently, with advancements in

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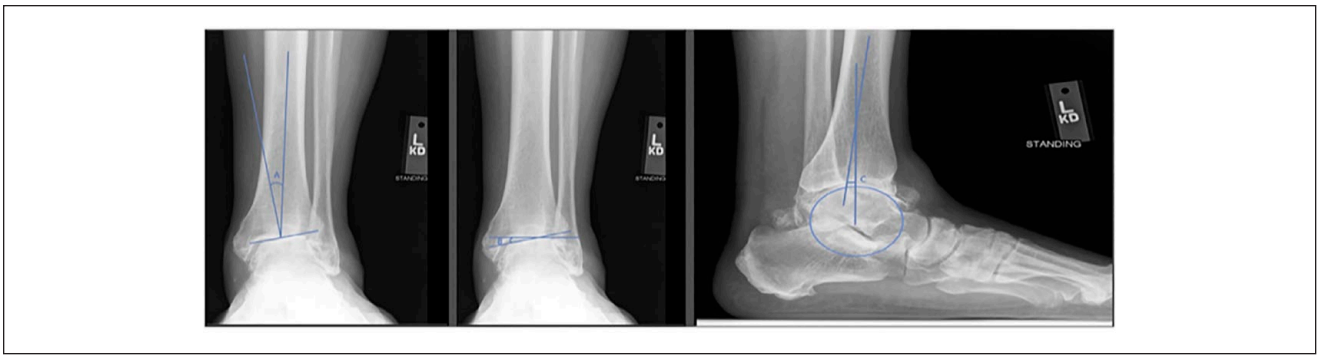

Figure 1. Preoperative radiographic measurements. Left: tibiotalar coronal alignment. Middle: talar tilt. Right: tibiotalar sagittal translation.[13]

implant design and postoperative outcomes, TAA rates have significantly increased.[18] One study reported a 431% rise in TAA incidence from 2007 to 2013.[6] However, TAA is not without potential complications, including higher reoperation and infection rates.[15,30] Despite the growing popularity of TAA, there is limited data on the long-term clinical outcomes.

In 2006, the US Food and Drug Administration approved the use of Salto Talaris TAA system (Tornier, Bloomington, MN).[26] Previously, we reported the midterm results of the modern fixed-bearing Salto Talaris TAA system as a treatment for end-stage tibiotalar arthritis. The study included 78 patients (81 ankles) treated between September 2007 and June 2012 at a tertiary referral center by a single surgeon. The surgical technique followed the manufacturer's recommended protocol, with final components impacted into place without the use of bone cement.

At a mean follow-up of 5.2 years postoperatively, the prosthesis survival rate was 97.5%, with one revision each of the talar and tibial components.[13] Seventeen patients in this cohort underwent additional procedures after the index surgery, with gutter debridement being the most common. The total range of motion (dorsiflexion and plantarflexion) increased significantly from preoperative to postoperative (35.5 to 39.9 degrees, $P = .02$). Twenty-five ankles (31%) showed evidence of lucency around a metallic component at the final radiographic evaluation. Patient-reported outcome measures (PROMs) revealed promising results, with a visual analog scale (VAS) for pain of 21.3, and a Foot and Ankle Disability Index (FADI) of 79.2. The purpose of this study was to evaluate the long-term results of the same cohort at a mean of 10.7 years, focusing on the survivorship of the metallic components, clinical outcomes, and radiographic analysis.

Methods

This retrospective study was approved by our Institutional Review Board. For the long-term evaluation, patients obtained new weightbearing radiographs, completed PROMs, and underwent a physical examination by the senior surgeon, including active ankle range of motion. PROMs were assessed by VAS for pain, the 36-Item Short Form Health Survey, the Short Musculoskeletal Function Assessment (SMFA), and FADI.

Preoperative radiographs included weightbearing anteroposterior (AP), mortise, and lateral ankle views. Coronal alignment of the tibiotalar joint, the degree of talar tilt, and the degree of sagittal translation of the talus were measured.[2,16,19] Postoperative radiographs included weightbearing (AP), mortise, lateral ankle, dorsiflexion lateral, and plantarflexion lateral views. Coronal alignment of the tibial prosthesis, sagittal alignment of the tibial and talar components, and the height of the talar component with respect to the talonavicular joint and the superior aspect of the posterior facet of the calcaneus were measured.[14] All parameters were calculated using our institution's digital PACS (picture archiving and communication system, Viztek Opal-RAD). Postoperative measurements were compared to preoperative and final measurements at the time of the previous study. Preoperative and postoperative radiographic measurements are described in detail in the previous study and are shown in Figures 1 and 2, respectively.[13] Radiographs were analyzed for signs of subsidence, aseptic loosening, or lucency, and evaluated by 2 fellowship-trained orthopaedic surgeons according to previously described zones.[28,31] Subsidence refers to longitudinal movement of an implant with respect to the bone in which it is imbedded over time.[10] It signifies a continuous migration of the implant beyond an acceptable early migration.[20] Although specific quantified data on pathologic migration is lacking, a study using a fixed-bearing TAR indicated that mean implant migration was 0.7 mm at 1 year and 1.0 mm at 2 years.[4] We sequentially measured tibial and talar implant translation on follow-up radiographs, using the initial postoperative radiographs as a baseline. Aseptic loosening was confirmed during the revision surgery by observing implant loosening from the embedded bone without signs of infection. Mason

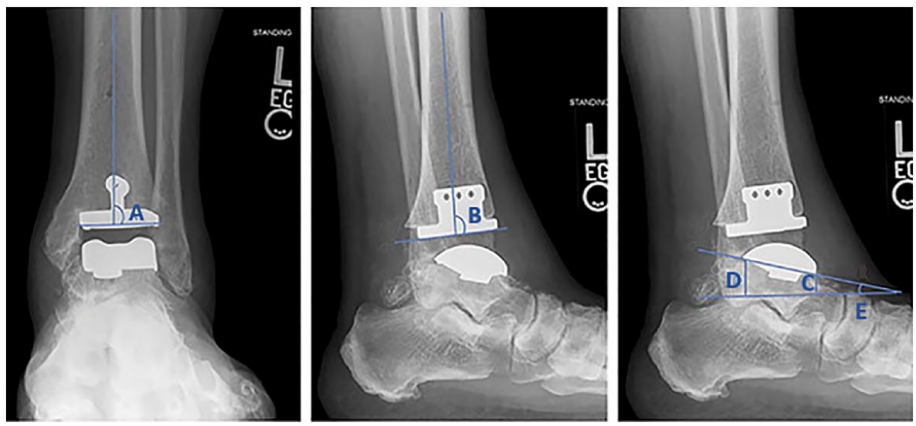

Figure 2. Postoperative radiographic measurements. Left: (A) Tibial component coronal alignment. Middle: (B) Tibial component sagittal alignment. Right: (C) Talar component anterior height. (D) Talar component posterior height. (E) Talar component sagittal alignment.[13]

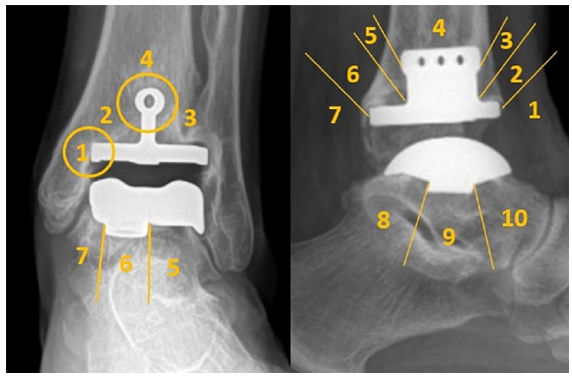

Figure 3. Radiographic lucency zones.

et al[22] suggested that angular measurement changes of 5 degrees, talar component subsidence of 5 mm on lateral radiographs, radiolucent lines >2 mm, or a progressive increase in radiolucency may indicate loosening. Lucency was defined as any periimplant radiolucent area of the tibia and/or talus on the postoperative radiographs, irrespective of size. The locations of the lucency zones described in Table 6 can be seen in Figure 3. High-grade complications after TAA were defined as one of the following that would lead to failure of the TAA greater than 50% of the time: deep infection, aseptic loosening, or implant failure.[10]

Statistical Analysis

All statistical analysis was performed using R statistical software (version 4.2.2; R, Vienna, Austria). The normality of the data was assessed using the Shapiro-Wilk test. Normally distributed data were compared using paired *t* test or repeated measures analysis of variance. Nonnormally distributed data were analyzed using Mann-Whitney *U* test or paired Wilcoxon signed rank test. Survival analysis was conducted using R survival analysis function.

Results

Since the previous reported study on 78 patients, 14 patients (15 ankles) passed away, and 16 additional patients were lost to follow-up. The mean follow-up for the remaining 48 patients (50 ankles) was 10.7 years (range, 7.8-14 years) (Figure 4). Eight patients were contacted by telephone, 6 of whom denied any additional complications or surgery to the ankle. Two patients required an outside revision TAA from another surgeon. Of the remaining patients, 32 (33 ankles) returned for clinical and radiographic evaluation. The mean age of the 48 remaining patients (50 ankles) at the index TAA was 64 years (range, 44-81 years). The most common diagnosis was primary osteoarthritis (22 patients), followed by posttraumatic arthritis (21 patients). Additional demographic data are summarized in Table 1.

Implant survival was 88% when metallic component revision or resection was used as a primary endpoint at a mean of 10.7 years from the index TAA. The implant's probability of survival, calculated using the Kaplan-Meier curve, was 84.2% (95% CI 71.9%-98.6%) (Figure 5). A total of 6 patients underwent revision TAA at a mean implant failure of 77 months, ranging from 21 months to 129 months. Notably, 4 of these revisions took place after the last 5-year report with a mean implant failure of 98 months, ranging from 58 to 129 months. One patient since the last report had 2 subsequent revision procedures following the index TAA, ultimately requiring an explant and an antibiotic spacer due to a deep infection from the

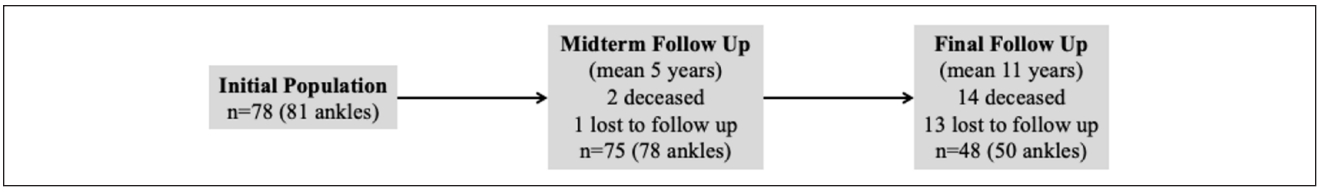

Figure 4. Inclusion flowchart.

Table 1. Patient Demographics (n=48 Patients, 50 Ankles).

Age at surgery, y, mean (range)	64 (44-81)
Female sex[a], n (%)	31 (65)
Laterality[b], right, n (%)	28 (56)
Body mass index, mean (range)	30 (21-49)
Immunosuppressed[a], n (%)	8 (17)
Primary diagnosis[b], n (%)	
Osteoarthritis	22 (44)
Posttraumatic arthritis	21 (42)
Rheumatoid arthritis	6 (12)
Psoriatic arthritis	1 (2)
Smoking status[a], n (%)	
Current	4 (8)
Former	8 (17)
Never	36 (75)
Follow-up, y, mean (range)	11 (8-14)
Length of stay, d, means (range)	2 (1-5)

[a]Calculated per patient.
[b]Calculated per ankle.

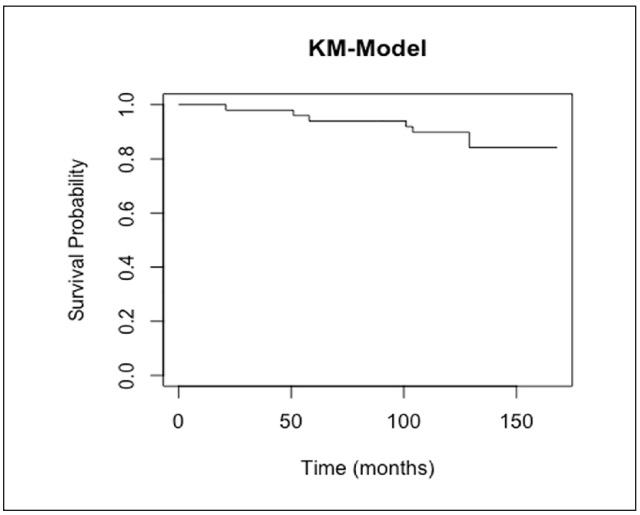

Figure 5. Kaplan-Meier survival curve of Salto Talaris metallic components.

revision procedure. Two of the other revisions were performed by outside surgeons because of patient relocation. There have been 4 revisions since the original report. Three patients displayed lucency leading to subsidence and loosening of the implant. Two of these 3 patients displayed progression of radiolucency from the prior report. Only 2 of these 4 displayed lucency at the last report, with 13 of the 33 patients who had radiographs in this report having lucencies in the prior report. There was no strong predictive value of implant failure with respect to radiographic lucency. Of these 4 patients who underwent revision surgery, 3 displayed aseptic loosening, whereas 1 patient developed a tibial cyst leading to implant failure. Additionally, 3 patients required an exchange of the polyethylene liner at a mean of 8 years postoperatively. No additional reoperations are described in this cohort.

Table 2. Complications.[a]

Type of Complications	No.
High-grade	
Deep infection	1[b]
Aseptic loosening	10
Implant failure	6
Medium-grade	
Technical error	0
Subsidence	10
Postoperative bone fracture	5[c]
Low-grade	
Intraoperative bone fracture	5
Wound-healing problem	7

[a]Sample size refers to n = 48 patients (50 ankles); some ankles had more than 1 complication.
[b]One case of deep infection after a revision surgery led to an explant of the prosthesis.
[c]No additional fractures since the midterm (mean 5 years) report.

Table 2 summarizes the overall complications of this cohort. The most common immediate postoperative complication was wound healing issues (n = 7), followed by bone fracture (n = 5). Each of the postoperative bone fractures occurred early in the course and was diagnosed radiographically during a follow-up visit. They consisted of 4 medial malleolar fractures, 1 fibular fracture, and 1 tibial stress fracture above the tibial prosthesis. Three of the malleolar fractures were treated with open reduction and internal fixation (ORIF), and the rest of the fractures were treated nonoperatively. Radiographically, 10 ankles displayed evidence of aseptic loosening, 4 of which remained asymptomatic with no additional surgery. The

Table 3. Patient-Reported Outcome Measures (n=35).

Outcome	Midterm Follow-up (Mean 5 y)	Final Follow-up (Mean 11 y)	*P* Value
VAS pain	21 ± 19 (0-67)	17 ± 17 (0-60)	.64
SF-36			
Physical function	39 ± 10 (21-55)	41 ± 10 (19-55)	.65
Role physical	47 ± 10 (18-57)	47 ±10 (25-57)	.73
Body pain	46 ± 10 (20-62)	47 ± 9 (29-62)	.53
General health	51 ± 8 (33-64)	52 ± 9 (35-64)	.78
Social function	50 ± 9 (30-57)	48 ± 10 (24-57)	.56
Role emotional	47 ± 11 (17-56)	48 ± 11 (13-56)	.43
Vitality	50 ± 10 (21-65)	53 ± 8 (30-68)	.15
Mental health	52 ± 9 (30-64)	52 ± 9 (36-64)	.79
MCS	53 ± 8 (33-67)	53 ± 8 (36-66)	.86
PCS	43 ± 9 (27-57)	45 ± 9 (30-59)	.38
SMFA			
Function index	19 ± 14 (1-57)	21 ± 15 (1-56)	.56
Bother index	20 ± 14 (0-46)	19 ± 13 (0-46)	.83
FADI	79 ± 16 (39-98)	78 ± 18 (32-100)	.43

Abbreviations: FADI, Foot and Ankle Disability Index; MCS, mental component summary; PCS, physical component summary; SF-36, 36-Item Short Form Health Survey; SMFA, Short Musculoskeletal Function Assessment; VAS, visual analog scale.

Table 4. Clinical Range of Motion (n=32 Patients, 33 Ankles).

Measurement	Preoperative	One-Year	Final	*P* Value[a]
Dorsiflexion (degrees)	9 ± 6 (–5 to 20)	11 ± 6 (0 to 20)[b]	7 ± 5 (0 to 20)[b]	.018*
Plantar flexion (degrees)	27 ± 9 (10 to 40)	28 ± 6 (0 to 20)	29 ± 10 (15 to 65)	.49
Total range of motion (degrees)	36 ± 12 (15 to 60)	39 ± 9 (20 to 55)	36 ± 11 (20 to 65)	.23

[a]*P* value represents preoperative and final measurement comparison.
[b]Post hoc test revealed that dorsiflexion for 1 year was significantly greater than final DF ($P < .001$).
*Statistically significant ($P < .05$).

remaining 6 patients showed evidence of aseptic loosening leading to subsidence (2 tibial, 4 talar) and underwent revision. Since our first report, there has been 1 additional event of deep infection, 6 additional events of aseptic loosening, and 4 additional events of implant failures.

Patient-reported outcomes were completed by 35 of the patients (72% of eligible patients) who returned for follow-up. Analysis revealed that there was no significant difference in outcomes reported by the patients in any of the assessed categories between the 5- and 10-year marks (Table 3).

With the serial clinical range of motion (ROM) assessment, the total ROM preoperatively (36 degrees), 1 year postoperatively (39 degrees), and at final follow-up (36 degrees) revealed no significant difference ($P = .23$) (Table 4). Only dorsiflexion decreased significantly between any of the 3 time points, from 11 degrees at the 1-year mark to 7 degrees at the 10-year statistical estimate ($P < .001$) of the survival function, particularly useful in situations where some data are censored.[11]

Postoperative radiographic measurements are summarized in Table 5. Significant variations of the preoperative tibial coronal alignment (range from 18 degrees valgus to 17 degrees varus) improved postoperatively and remained consistent at the final follow-up (range from 4 degrees valgus to 5 degrees varus). Other parameters, such as postoperative tibial/talar sagittal angle and anterior/posterior talar height, showed only small, non–clinically significant variations between the midterm and final follow-up.

The final postoperative radiographs often showed radiolucency around the implants (Table 6). Out of 33 cases, 22 (67%) had at least 1 area of radiolucency, and 13 of those 22 also displayed lucency in the original report. The majority of the radiolucency discovered was around the tibial component, especially in zones 2 and 3 on AP views and zones 6 and 7 on lateral views.

Table 5. Radiographic Measurements (n=32, 33 ankles).

Measurement	Preoperative	Midterm	Final	*P* Value[a]
Tibial coronal angle (degrees)	1 ± 8 (–18 to 17)	2 ± 2 (–3 to 6)	1 ± 2 (–4 to 5)	.33
Tibial sagittal angle (degrees)	–	6 ± 4 (–1 to 13)	5 ± 4 (–4 to 14)	.002*
Talar sagittal angle (degrees)	–	3 ± 5 (9 to 12)	7 ± 6 (–8 to 17)	<.001*
Anterior talar height (mm)	–	10 ± 3 (3 to 15)	7 ± 4 (–1 to 15)	<.001*
Posterior talar height (mm)	–	12 ± 4 (5 to 20)	12 ± 4 (4 to 19)	.49

[a]All *P* values represent comparison between midterm and final measurements.
*Denotes statistical significance with alpha risk of .05.

Table 6. Radiographic Zones of Lucency (n=32, 33 ankles).

Anteroposterior radiograph	No. (%)
Tibia	
Zone 1	12 (46)
Zone 2	22 (67)
Zone 3	22 (67)
Zone 4	2 (6)
Talus	
Zone 5	10 (30)
Zone 6	4 (12)
Zone 7	12 (46)
Lateral radiograph	
Tibia	
Zone 1	10 (30)
Zone 2	16 (48)
Zone 3	2 (6)
Zone 4	3 (9)
Zone 5	2 (6)
Zone 6	21 (64)
Zone 7	19 (58)
Talus	
Zone 8	9 (27)
Zone 9	3 (9)
Zone 10	10 (30)

Discussion

The present study has demonstrated good implant survivorship for the fixed-bearing Salto Talaris TAA system at a mean follow-up of 10.7 years. Out of 50 ankles, 44 (88%) maintained their implants, and the Kaplan-Meier estimated survivorship was 84.2% (95% CI, 71.9%-98.6%). These findings align with other mid- to long-term follow-up studies on the Salto Talaris TAA system. For instance, a 7-year follow-up study on 82 patients (85 ankles) reported a survivorship of 97.6% with only 2 revisions.[8] Another study with an average follow-up of 6.9 years on 19 total ankle arthroplasties showed a 10.5% reoperation rate with a 100% survivorship of the implants.[31] Although direct comparisons with these studies are challenging because of differences in surgical indications, patient populations, follow-up rates, study periods, and sample sizes, our results are similarly promising in terms of longer-term follow-up. To our knowledge, the current study represents the largest cohort with the longest follow-up period for the fixed-bearing Salto Talaris TAA system.

To our knowledge, there have been 4 revisions since the original report with an average follow-up of 5.2 years. Among these, 3 patients exhibited lucency resulting in subsidence and loosening of the implant. Progression of radiolucency from the original report was observed in 2 of these 3 patients. At the last report, only 2 of these 4 patients displayed lucency. In the current report, 13 of our 33 patients who underwent radiographs demonstrated lucencies as per the prior report. Among the 4 patients who underwent revision surgery, 3 displayed aseptic loosening, whereas 1 patient experienced implant failure due to a tibial cyst. Of the 4 revisions, implant failure was observed in 1 of the tibial and 3 of the talar components. Figure 6 further details a specific revision case.

Long-term outcomes of other implant systems were also investigated. The Scandinavian Total Ankle Replacement (STAR) has the longest history in TAA surgery. A recent study examining STAR reported an implant survival of 76.2% at a mean follow-up of 15.8 years for 84 patients (87 ankles).[5] In a larger systematic review of 16 primary studies and 2088 STAR implants, a survival rate of 85.9% at a mean follow-up of 5 years, and 71.1% at a mean of 10 years was reported.[32]

The STAR system, however, is mobile-bearing, which could potentially lead to different outcomes because of the different biomechanics compared to the fixed-bearing Salto Talaris implant. A recent study reported the short-term rates of reoperation and revision of both mobile-bearing Salto Talaris (Tornier and Integra) and fixed-bearing Salto Talaris (Integra) systems after 3 years. The authors reported a 3 times higher rate of revision among mobile-bearing implants compared with fixed-bearing implants 3 years postoperatively,[1] suggesting that fixed bearing might be superior to mobile bearing in the short term.

In this study, we chose 4 patient-reported outcome measures (PROMS) including VAS pain, 36-Item Short Form Health Survey, SMFA, and FADI to evaluate outcomes. We found excellent stability of the PROMS measures between an average of 5 and 11 years for the patients included in our current report.

Regarding postoperative radiographs, we observed somewhat high rates of radiolucency (22 of 33 cases, 67%). In a

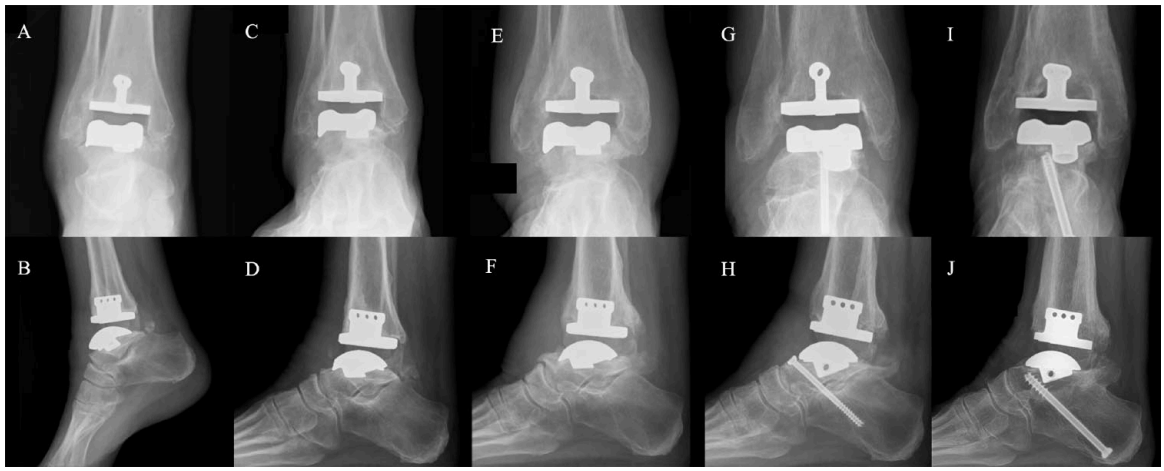

Figure 6. (A and B) Nonweightbearing ankle anteroposterior (AP) and lateral radiographic views at 7 weeks postoperation following primary right total ankle replacement. (C and D) Weightbearing ankle AP and lateral radiographic views at 6 months postoperation following primary right total ankle replacement. (E and F) Weightbearing ankle AP and lateral radiographic views at 3 years and 2 months postoperation following primary right total ankle replacement. Patient reported having increased right ankle pain at this visit. Radiographs show a talar component which had subsided. (G and H) Weightbearing ankle AP and lateral radiographic views at 3 months postoperation following revision right total ankle replacement, talar component and right subtalar fusion. (I and J) Weightbearing ankle AP and lateral radiographic views at 8 years postoperation following revision right total ankle replacement. Radiographs show an intact revision Salto-Talaris total ankle replacement. Patient at this visit reports minimal pain and has a total range of motion of 30 degrees.

similar study with a mean of 7 years and 82 patients (85 ankles) who received the same Salto Talaris TAA, 18 cases (21%) showed radiolucent cysts.[3] In that study, the cyst was defined as a hypodense zone greater than 5 mm in diameter, as reported in a previous study.[3] Our radiolucency evaluation included even smaller diameters, likely contributing the higher incidence. Furthermore, most radiolucency was located around the tibial component, consistent with findings in previous studies.[25,27] This osteolysis could be a result of stress shielding, polyethylene particles in the synovial fluid, or a combination of both.[7,17,24]

Our study has some limitations. First, we were only able to follow up with 48 patients (62% of the original cohort of 78 patients) regarding complications. Additionally, of these 48 patients, we only obtained physical examination, radiographic analysis, and patient-reported outcomes for 32 patients (33 ankles) or 41% of the original patients in the cohort. These limitations are partly due to the advanced age of the patients (mean 64 years) at the time of the index surgery, and as a result, 14 patients died during the study period. Our adjusted follow-up rate is thus 32 of 64, that is 50%, and what has happened to the other half remains unknown at the time of this study. Lack of follow-up in this cohort weakens our understanding of survivorship and long-term function of our patient's ankle replacements. Second, our patient-reported outcome measures (PROMs) were only available postoperatively, making it challenging to perform a detailed evaluation of postoperative outcomes without knowing the preoperative baseline. However, our postoperative scores are at least comparable to a recent study using the same Salto Talaris TAA system with similar outcome measures.[29] For example, our mean final VAS pain was 17 vs 12, SMFA function index was 21 vs 17, and SMFA bother index was 17 vs 19. And we had stable postoperative PROMS between 5.2 and 10.7 average years' follow-up reviews. Finally, another limitation regarding this study is the use of radiographs instead of CT scans, as radiolucency and osteolytic cysts are not reliably detected in radiographs as compared to CT. Despite these limitations, we believe that our study provides valuable information regarding long-term outcomes of total ankle arthroplasty.

Conclusion

In our cohort, we found the Salto Talaris fixed-bearing TAA had acceptable long-term survival with relatively low rates of revision and other complications. Patient-reported outcomes remained stable, as well as the general preservation of preoperative range of motion. Observed failures were commonly associated with aseptic loosening and subsidence.

Ethical Approval

This study was approved by the Institutional Review Board of the New England Baptist Hospital (project number 1821503).

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. ICMJE forms for all authors are available online.

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