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Mid-Term Prospective Clinical and Radiographic Outcomes of a Modern Fixed-Bearing Total Ankle Arthroplasty

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ABSTRACT

The early outcomes of the Salto Talaris® Total Ankle Prosthesis have been promising, but information on its mid-term outcomes is still sparse. The purpose of this study was to evaluate the mid-term clinical and radiographic outcomes of this implant among a prospective cohort of patients who underwent total ankle replacement for various etiologies. Forty-six patients (50 ankles) were consecutively enrolled in the study. Our primary aim was to assess implant survivorship as determined by the removal or revision of the implant metal components or conversion to arthrodesis. Our secondary aim was to gauge patient outcomes by using commonly used outcome scores and assess ankle range of motion using goniometric and radiographic methods. We report 100% survivorship of the implant at a mean follow-up of 4.9 years. Compared with preoperative levels, all clinical outcome scores showed significant improvement at the 1-year, 2-year, and 5-year and longer follow-up. The mean clinical ROM improved from 27.7° ± 10.7° preoperatively to 40.0° ± 12.3° at the 2-year follow-up ($p < .001$). The mean radiographic ROM improved from 23.0° ± 10.2° preoperatively to 27.2° ± 9.1° at the 2-year follow-up ($p = .007$). Reoperations or secondary procedures were performed on 6 (12%) ankles, with the most common procedure being gutter debridement for impingement symptoms. The study confirms that the excellent survivorship seen with the implant in the early studies extends to mid-term follow-up as well. Patients could expect to see improvement in pain relief and activity well into 5 years after surgery and retain sufficient ankle range of motion for normal gait.

The ankle joint bears the highest load among all major joints of the lower extremity, for the least contact area. It is therefore surprising, almost paradoxical, that its susceptibility to symptomatic arthritis is much lower than that of the knee and the hip (1,2). A host of mechanical, biochemical, and anatomical factors unique to the ankle joint are thought to be responsible for this observation (1,3). Nevertheless, ankle arthritis is estimated to affect 1% of the global population and is associated with substantial loss of physical function and quality of life (2,4).

Ankle fusion, or arthrodesis, has been the mainstay for the treatment of ankle arthritis for several decades. Failing conservative management and other less invasive surgical options, arthrodesis is traditionally the next logical step, particularly for pain relief (5,6). However, it involves a trade-off in terms of reduced ankle range of motion (ROM), which could adversely affect gait and overall patient satisfaction (7). Moreover, complications associated with degenerative changes in the joints adjacent to the ankle are also common with ankle fusion (5–8). Introduced in the 1970s, total ankle arthroplasty (TAA) was meant to address some of the limitations seen with arthrodesis (8,9). Though initially marred by the disappointing outcomes of early implants, designs have evolved considerably since then—the implants of today feature more anatomic designs and offer better fixation with minimal bone resection (10). Early to mid-term results with current TAA implants show reliable pain relief, improvement in functional outcomes especially gait, and low failure rates (8,11–13). TAA is now considered a viable alternative to ankle fusion in select patients with studies showing equivalent pain relief and a slight advantage in restoring normal ankle function, although reporting of such advantage has been inconsistent (14–21).

The Salto Talaris® Total Ankle Prosthesis (Integra® LifeSciences, Plainsboro, NJ) was cleared for use by the US Food and Drug Administration in November 2006. Considered a modern, fixed-bearing implant, the idea for the Salto Talaris sparked when the Salto Total Ankle Prosthesis—its mobile-bearing, 3-component predecessor—was found to behave akin to a fixed-bearing implant, with little to no mobility between the polyethylene bearing and the tibial component (22). Design features of interest common to both the fixed- and

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mobile-bearing designs include a conical talar surface with 2 different radii of curvature and an anatomically shaped tibial component (10,22). A contrasting feature of the fixed-bearing counterpart is the polyethylene component being fixed to the tibial side during implantation. The instrumentation stage still incorporates the mobile-bearing concept with the tibial trial component allowed to rotate into proper position in relation to the talar trial component and thus, theoretically, conform to ankle anatomy (22,23).

The early results (1 to 3 years of follow-up) with the Salto Talaris® implant have been promising with excellent implant survivorship and improvement in patient outcomes (24–30). However, information on the mid-term outcomes of this device is still sparse (31–33). In this study, we sought to assess the mid-term outcomes of the Salto Talaris® implant. We hypothesized that the prosthesis would show good survivorship with patients experiencing an improvement in their functional outcomes in line with early to mid-term outcomes reported with the implant thus far. The primary aim of this investigation was to evaluate implant survivorship, and the secondary aim was to measure clinical and radiographic outcomes among patients who received the implant. For this purpose, we prospectively enrolled patients for implantation with the fixed-bearing Salto Talaris® prosthesis with the objective of reporting on outcomes based on mid-term follow-up.

Patients and Methods

Patient Population

The study results reported here are part of an ongoing prospective, multicenter, observational cohort study designed to record the long-term (10-year) outcomes of the Salto Talaris® implant (NCT00503438). We report the mid-term outcomes from a single center (Medical College of Wisconsin), with implant survivorship and the assessment of clinical and radiographic outcomes as the primary and secondary aims of our study, respectively. The institutional review board approved the study protocol before study initiation. All patients gave informed consent before enrollment. Patients were enrolled in the study if they were 18 years of age or older and required an ankle replacement due to ankle arthritis or failed standard conservative management of their ankle condition (CPT Code: 27702-Total Ankle Replacement). Patients who presented with the following were excluded from the study: (1) known contraindications for ankle arthroplasty such as active infection, complete talar necrosis, insufficient quality of bone stock, severe fixed ligament laxity, severe osteopenia, or Charcot's arthropathy history of osteomyelitis, active nicotine use, poor soft tissue quality, or body mass index (BMI) >35 kg/m^2; (2) class IV or higher anesthetic risk; or (3) inability to comply with the study procedures. A total of 46 patients (50 ankles) were enrolled consecutively in the study and operated on between September 2007 and January 2015. The right ankle was operated on in 29 of the 50 cases; 4 patients underwent bilateral surgeries, all of which were staged. The following patient variables were recorded on enrollment: age (years), sex, BMI (kg/m^2), diagnosis (primary osteoarthritis, inflammatory arthritis, posttraumatic arthritis), presence of type 2 diabetes mellitus, and tobacco use (current, former, or never).

Operative Procedure

All surgeries were performed by the author (R.M.M.) with a general anesthetic supplemented by a popliteal regional block. A thigh tourniquet was used, and the manufacturer's recommended surgical technique was followed. Additional procedures were performed as necessary at the time of index surgery to restore neutral alignment, to correct ligament instability or deformity, or to manage any intraoperative complications. During the immediate postoperative period, patients were maintained in a splint in neutral position and were kept non-weightbearing. Sutures were removed 10 to 14 days postoperatively, and patients remained non-weightbearing in a cast for a total of 4 weeks. Gradual weightbearing was initiated at 4 to 6 weeks, with full weightbearing in a cast boot by 10 weeks. Physical therapy was used to monitor weightbearing status, as well as to restore ROM, strengthening, and proprioceptive exercises.

Endpoints

Postoperative visits for the assessment of clinical outcomes were scheduled at 3 months, 6 months, 1 year, and yearly thereafter. Patients completed the assessment questionnaires for the American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score, the Foot Function Index (FFI), and the Foot and Ankle Ability Measure (FAAM) preoperatively and at each of the postoperative visits. Both the FAAM (34) and FFI (35) are patient-reported validated outcome measures, whereas the AOFAS scale is a hybrid of clinician and patient assessments (36) and one of the most frequently used outcome scores in foot and ankle surgery (37). The clinical assessment portions of the AOFAS scale (gait abnormality, ankle-hindfoot stability, alignment, hindfoot motion, ROM) were typically performed by clinic staff trained in assessment techniques, both staff who had participated in surgery as well as staff who had not participated. Although its objective, clinician component has not yet been validated, the subjective component of AOFAS scale shows acceptable validity for conditions affecting the foot and ankle (38). Clinical ROM was evaluated by clinic staff preoperatively and during each of the postoperative visits (3 months, 6 months, 1 year, and yearly thereafter) with goniometer measurement using the long axis of the tibia and the lateral border of the foot (reported in degrees).

For assessment of radiographic outcomes, radiographs were obtained at the preoperative visit and at the 3-, 24-, 60-, and 96-month follow-up visits. All imaging assessments were performed by a qualified, independent radiologist. The reviewer had no access to the clinical outcomes of the study at any point during the clinical investigation. All measurements for the imaging assessments were conducted by using Quantitative Motion Analysis Software (QMA®) (Medical Metrics, Inc., Houston, TX). Full-foot sagittal radiographs at maximum dorsiflexion (weightbearing) and maximum plantarflexion (non-weightbearing) were used to calculate the total ROM. Radiographic ROM (reported in degrees) was calculated as the absolute difference between the angle measured between the line parallel to the long axis of the tibia and the line that bisects the talar neck as drawn on maximum plantarflexion and maximum dorsiflexion views. Radiographs were also analyzed for prosthesis changes such as device migration (subsidence or tilting) or aseptic loosening. Device subsidence was defined as the migration of the implant into the adjacent bone and graded based on the magnitude of the movement (in millimeters). Device tilting was defined as the rotation of the implant >4° in the craniocaudal direction away from the long axis of the tibia. Both device subsidence and tilting were recorded separately for the tibial and talar components. Similarly, periprosthetic radiolucency was evaluated separately for the tibial and talar components and classified into zones as established previously (39). Radiolucent lines >2 mm wide were analyzed for progressive changes. Global radiolucency was defined as lucency >2 mm present in all zones around either the tibial or talar component (25). Osteolysis was defined as the presence of progressive, scalloping lesions or bony lesions >5 mm at the bone–implant interface and graded separately for the tibial and talar components. Device loosening was defined as the presence of new or progressive radiolucency along the device–bone interface indicating a loss of fixation.

All intraoperative and postoperative complications were documented along with any procedures that were required to address them. Removal or revision of ≥1 of the metal implant components was defined as the endpoint for implant survivorship. Nonrevision surgical procedures performed subsequent to the index surgery at or surrounding the original operative site and related to the index procedure were defined as reoperations or secondary procedures.

Statistical Analysis

Normality of the data were checked by using the Shapiro-Wilk test. Normally distributed data were analyzed by using the paired-sample *t* test. Non–normally distributed data were analyzed by using the Wilcoxon signed-rank test. A value of $p < .05$ was considered statistically significant. A Kaplan-Meier survival curve was created for survivorship of implant with revision of metal components or arthrodesis as an endpoint. Data are reported as the mean ± standard deviation for continuous variables and as percentages for categorical variables. All statistical analyses were performed using SAS (version 9.4; SAS Institute, Cary, NC).

Results

A total of 46 patients (50 ankles; 4 bilateral cases) underwent total ankle replacement with a mean follow-up of 4.9 (range 0.9 to 8.6) years (Table 1). One-year follow-up data were available for 48 (96.0%) of 50 ankles; 2-year follow-up data were available for 47 (94.0%) of 50 ankles, and 36 (72.0%) of 50 ankles had follow-up ranging from 5 to 8.6 years. As of the final follow-up, 8 patients had withdrawn from the study, 3 were lost to follow-up, and 2 patients (3 ankles; 1 patient with bilateral implants) had died from causes unrelated to the implant or the surgical procedure. The mean age of the study population at the time of surgery was 65.3 (range 49.4 to 81.6) years, and the mean BMI was 29.4 (range 21.4 to 36.3) kg/m^2. All operations were primary arthroplasty procedures; posttraumatic arthritis (62.0%) was the most common preoperative diagnosis, followed by primary osteoarthritis (34.0%) and rheumatoid arthritis (4.0%). The mean length of hospital stay was 2.2 ± 1.1 (range 1 to 7) days.

Survivorship and Concurrent Procedures

We report a 100% implant survivorship (Fig. 1); none of the patients required removal or revision of any metal implant component or conversion to ankle arthrodesis after implantation of the prosthesis. Seventeen

Table 1
Demographic characteristics of the patients included in the study (N = 50 ankles in 46 patients)

Patient Demographics*	
Mean age, y (range)	65.3 (49.4 to 81.6)
Sex, n (%)	
Male	25 (54.3)
Female	21 (45.7)
Side, n (%)	
Right	29 (58.0)
Left	21 (42.0)
Diagnosis, n (%)	
Primary osteoarthritis	17 (34.0)
Rheumatoid arthritis	2 (4.0)
Posttraumatic arthritis	31 (62.0)
Tobacco use, n (%)	
Current	2 (4.0)
Former	25 (50.0)
Never	23 (46.0)
Type 2 diabetes mellitus, n (%)	4 (8.0)
Mean body mass index, kg/m^2 (range)	29.4 (21.4 to 36.3)
Mean follow-up, y (range)	4.9 (0.9 to 8.6)
Mean length of hospital stay, d (range)	2.2 (1.0 to 7.0)

* All demographic characteristics, except sex, are presented on a per-ankle basis. Sex is expressed per patient. All procedures were primary arthroplasty; no prior failed arthroplasty (Salto or not Salto) was identified.

Table 2
Concurrent procedures performed at the time of index total ankle replacement (N = 13 ankles in 12 patients)

Procedure	n (%)*
Hardware removal	6 (12.0)
Tendon Achilles lengthening	2 (4.0)
ORIF for intraoperative malleolar fracture	2 (4.0)
Subtalar fusion	2 (4.0)
Decompress malleolar impingement	1 (2.0)
Bone debridement exostectomy	1 (2.0)
Peroneal debridement relocation and retinacular repair	1 (2.0)
Os trigonum resection	1 (2.0)
Deltoid release	1 (2.0)

Abbreviation: ORIF, open reduction and internal fixation.
* Rate of occurrence calculated on a per-ankle basis.

concomitant procedures were performed in 12 patients (13 ankles) at the time of the index surgery (Table 2). The most common procedure was hardware removal, which was performed in 6 (12.0%) ankles.

Clinical Outcomes

All clinical outcome scores showed significant improvement compared with their preoperative values (Table 3), with a trend of

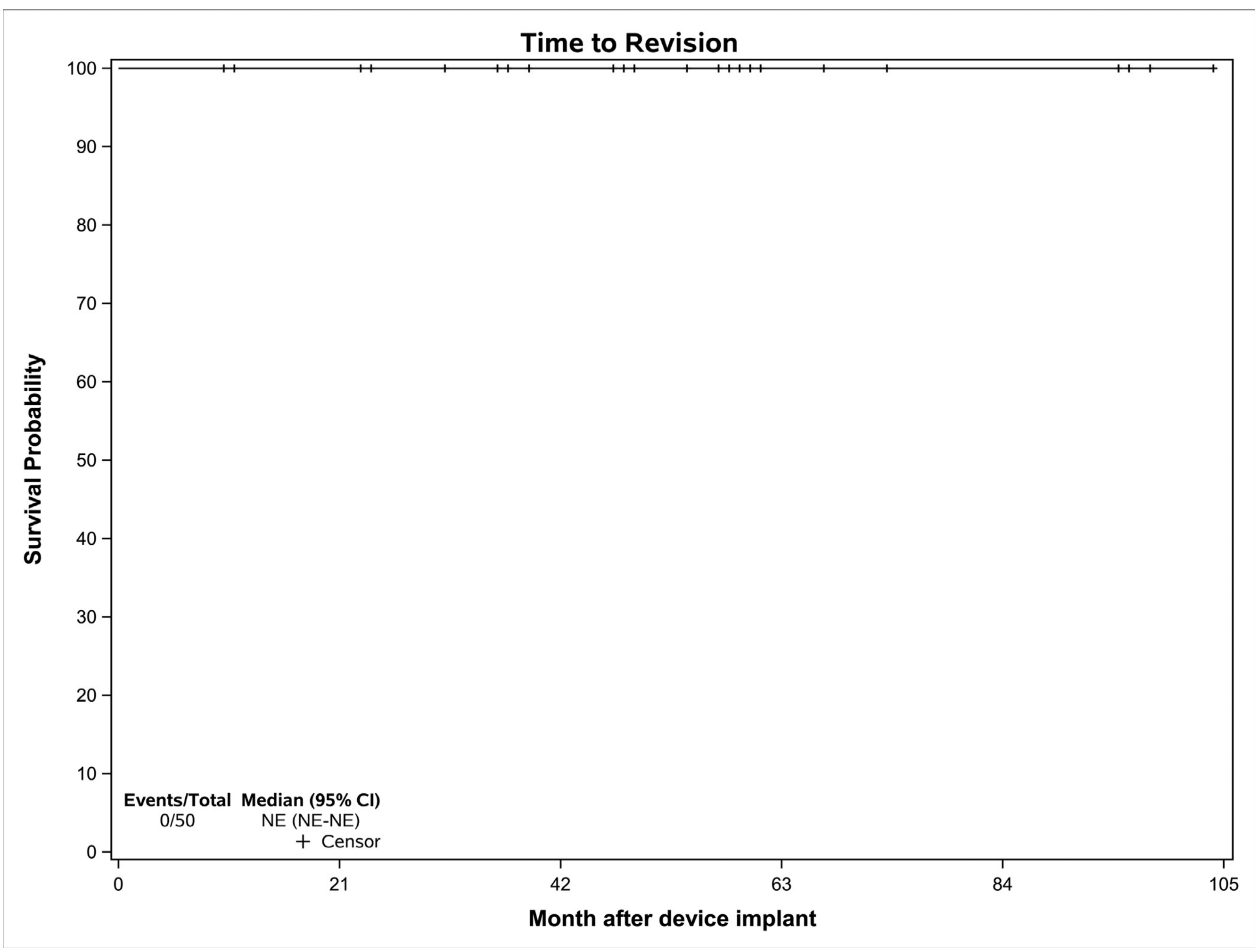

Fig. 1. Kaplan-Meier survival curve for the study (N = 50 ankles in 46 patients). Kaplan-Meier survival curve with revision of metallic components or conversion to arthrodesis as endpoints. We report 100% survivorship at a mean follow-up of 4.9 years.

Table 3
Clinical outcome scores at baseline and follow-up (N = 50 ankles in 46 patients)

Mean Score	Preoperative	Follow-Up* 1 y	Follow-Up* 2 y	Follow-Up* 5+ y†	*p* Values I: Preoperative vs 1 y II: Preoperative vs 2 y III: Preoperative vs 5+ y IV: 1 y vs 2 y V: 2 y vs 5+ y
AOFAS	69.6 ± 12.6	82.1 ± 13.9	85.0 ± 8.9	82.7 ± 12.2	I: <.001 II: <.001 III: <.001 IV: .110 V: .078
FFI	51.8 ± 15.9	14.0 ± 13.3	15.1 ± 16.4	15.7 ± 20.0	I: <.001 II: <.001 III: <.001 IV: .774 V: .875
FAAM-ADL	53.8 ± 17.0	80.9 ± 18.9	85.4 ± 14.8	86.0 ± 11.5	I: <.001 II: <.001 III: <.001 IV: .200 V: .943
FAAM-Sports	24.3 ± 18.8	66.7 ± 28.1	66.6 ± 27.3	66.3 ± 24.2	I: <.001 II: <.001 III: <.001 IV: .711 V: .844

Abbreviations: AOFAS, American Orthopedic Foot and Ankle Society Ankle-Hindfoot Score; FFI, Foot Function Index; FAAM, Foot and Ankle Ability Measure; ADL, activities of daily living
* The mean follow-up scores are significantly different ($p < .05$) than the mean preoperative scores.
† This follow-up ranged from 5 years to 8.6 years.

improvement seen across the follow-up period. The mean AOFAS score improved significantly from 69.6 ± 12.6 preoperatively to 82.7 ± 12.2 at the 5+-year (range 5- to 8.6-year) follow-up ($p < .001$). The 5+-year FFI scores also showed significant improvement compared with the preoperative levels (51.8 vs 15.7; $p < .001$). Finally, as part of the FAAM questionnaire, patients reported significantly improved activities of daily living (ADLs) and sports outcomes compared with preoperative levels. The ADL scores improved from a preoperative score of 53.8 ± 17.0 to 86.0 ± 11.5 at the 5+-year follow-up ($p < .001$). The sports scores improved from a preoperative score of 24.3 ± 18.8 to 66.3 ± 24.2 at the 5+-year follow-up ($p < .001$). As seen in Table 3, statistically significant improvement was also evident at the 1-year and 2-year follow-ups for all the clinical outcome scores evaluated in this study ($p < .001$ for all 1-year and 2-year follow-up analyses).

The total clinical ROM increased from 27.7° ± 10.7° at the baseline to 37.6° ± 10.9° at the 5+-year follow-up (Table 4), which was a statistically significant difference ($p < .001$). Furthermore, significant differences in total ROM were seen at the 2-year follow-up as well ($p < .001$). Both dorsiflexion and plantarflexion were improved at the 2-year and 5+-year follow-ups compared with the preoperative values; the improvement in dorsiflexion was statistically significant at both postoperative time-points ($p = .011$ for the 2-year follow-up, $p < .001$ for the 5+-year follow-up), whereas plantarflexion showed significant improvement at the 2-year follow-up alone ($p < .001$).

The true tibiotalar ROM obtained from radiographs improved from the mean preoperative value of 23.0° ± 10.2° to 27.2° ± 9.1° at the 2-year follow-up and 24.6° ± 10.5° at the 5+-year follow-up, the effect being significant at the 2-year follow-up ($p = .007$) (Table 4). Statistically significant differences were also seen in the dorsiflexion values, which had decreased at the 2-year follow-up compared with baseline ($p = .003$) but showed improvement at the 5+-year follow-up ($p = .024$) compared with the 2-year values.

Radiographic Outcomes

Radiographic analysis was available for 48 (96.0%) of 50 ankles (Fig. 2). Radiolucent lines >2 mm were observed in 10 (20.8%) ankles; however, 6 did not extend beyond 1 zone. Four (8.3%) ankles showed nonprogressive lucent lines involving >1 zone that were radiographically and clinically stable as of the last follow-up (Fig. 3). None of the ankles exhibited global radiolucency.

Nonprogressive cystic changes were observed in 8 (16.7%) ankles and were benign in all except 1 case. One patient exhibited clinically significant balloon cysts around the tibial and talar component with lucencies ranging from 3.8 to 24.0 mm across implant zones (tibial anteroposterior zones 2, 3, 4, 5, and 6; tibial lateral zones 2, 3, 4, 5, 6, and 7; talar lateral zone 10). Cystic changes were first noted in this patient at the 5-year follow-up, quite possibly due to a malpositioned talar component. However, the cysts had not progressed as of his most recent follow-up at 8 years and the patient is clinically asymptomatic.

Radiographic signs of mild talar component migration was noted in two patients, both of which were clinically insignificant. The patient with the balloon cysts described previously showed anterior migration and caudal subsidence (>2 to ≤4 mm), whereas another patient showed talar subsidence (≤2 mm) with a dorsal tilt. No aseptic loosening was observed in the study. Radiographic signs of tibial component loosening without any signs of device migration were observed in the left ankle of a bilateral patient at her 2-year follow-up visit, but the implant was not thought to be loose based on her 5-year follow-up radiographs. She demonstrated no clinical signs of loosening at either follow-up, and both implants continue to be stable.

Complications and Reoperations

Thirteen complications were observed in 9 (18.0%) ankles/patients. No high-grade complications as defined by Glazebrook et al (40) such

Table 4
Clinical and radiographic range of motion at baseline and follow-up (N = 50 ankles in 46 patients)

ROM	Preoperative	Follow-Up 2 y	Follow-Up 5+ y‡	p Value I: Preoperative vs 2 y II: Preoperative vs 5+ y III: 2 y vs 5+ y
Mean total clinical ROM, ° (N = 50)	27.7 ± 10.7	40.0 ± 12.3*	37.6 ± 10.9a*	I: <.001 II: <.001 III: .190
Mean dorsiflexion	1.2 ± 8.4	4.8 ± 5.3*	5.1 ± 5.3a*	I: .011 II: <.001 III: .622
Mean plantarflexion	27.5 ± 10.3	35.1 ± 10.6*	32.5 ± 8.5	I: <.001 II: .053 III: .115
Mean total radiographic ROM, ° (N = 48)	23.0 ± 10.2	27.2 ± 9.1*	24.6 ± 10.5	I: .007 II: >.999 III: .342
Mean dorsiflexion	112.4 ± 9.5	107.7 ± 7.4*	110.7 ± 9.0†	I: .003 II: .284 III: .024
Mean plantarflexion	135.3 ± 9.9	134.8 ± 11.5	135.3 ± 9.5	I: .790 II: .457 III: .066

Abbreviation: ROM, range of motion.
* The mean score is significantly different ($p < .05$) compared with the mean preoperative score.
† The mean score is significantly different ($p < .05$) compared with the mean score at the 2-year follow-up.
‡ This follow-up ranged from 5 years to 8.6 years.

as deep infection, aseptic loosening, or implant failure were observed in the study population at a mean follow-up of 4.9 years (Table 5). Two (4.0%) patients sustained intraoperative fractures of the medial malleolus, which were treated successfully with open reduction and internal fixation. Radiographic signs of device subsidence were seen in 2 (4.0%) ankles, 1 (2.0%) of which also had clinically significant cysts. As described in the previous section, both patients were asymptomatic, and neither of the signs were associated with loosening or required any intervention. Three (6.0%) ankles had postoperative wound healing complications: one had delayed wound healing and another had a superficial wound infection, and both resolved with wound care and oral antibiotics, respectively. Wound dehiscence requiring plastic surgery was observed in the third ankle. One (2.0%) patient developed postoperative cardiomyopathy related to the anesthesia, which resolved. Another patient (2.0%) developed postoperative deep vein thrombosis, which resolved with anticoagulants. Two (4.0%) patients had prolonged hospital stays—one had complications from bronchitis and a urinary tract infection and was hospitalized for 7 days, and the other developed pain at the nerve block site, which prolonged his stay by 1 day.

Six (12.0%) ankles/patients underwent 10 secondary procedures or reoperations related to the index surgery (Table 6). The most common procedure was gutter debridement performed to address symptomatic gutter impingement in 4 (8.0%) ankles. One of these patients also underwent subtalar fusion and tendon Achilles lengthening for symptoms of subtalar arthritis. Another patient underwent exchange of the

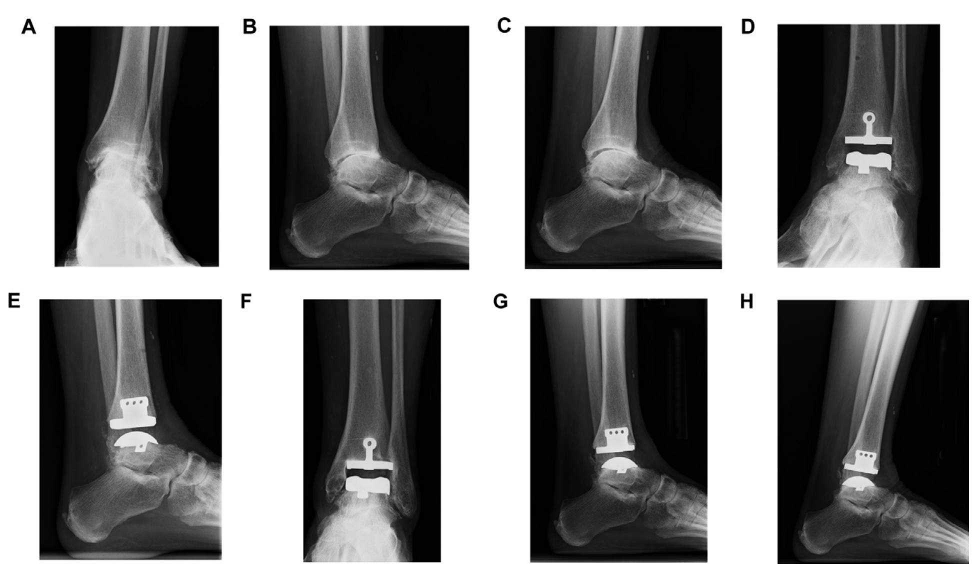

Fig. 2. Representative preoperative and postoperative radiographs. Preoperative anteroposterior (AP) (*A*), lateral (*B*) and lateral dorsiflexion (*C*) radiographs. Six-week AP (*D*) and lateral radiographs (*E*). Twenty-four–month AP (*F*), lateral (*G*), and lateral dorsiflexion (*H*) radiographs.

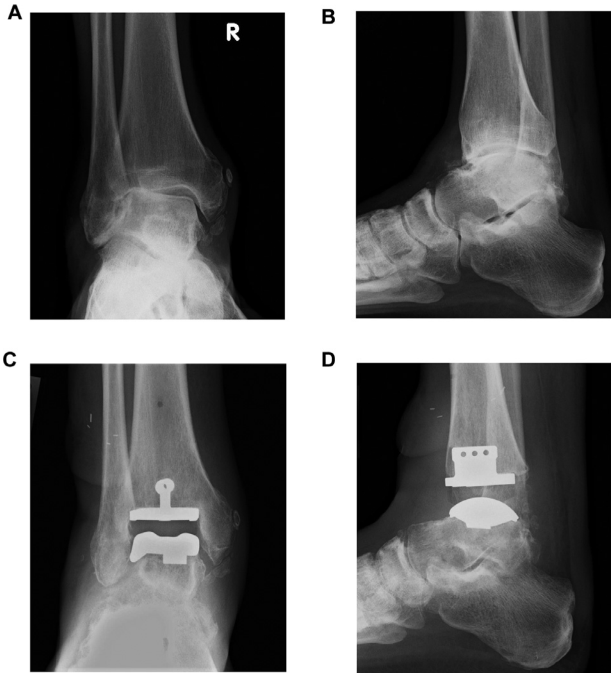

Fig. 3. Postoperative radiolucency observed in a patient. Preoperative anteroposterior (AP) (*A*) and lateral (*B*) radiographs. Three-month AP (*C*) and lateral (*D*) radiographs. Twenty-four–month AP (*E*) and lateral (*F*) radiographs. Note radiolucency in AP tibia zones 2, 3, 5, and 6. Sixty-month AP (*G*) and lateral (*H*) radiographs. There is no progression of radiolucency, with stable components.

polyethylene liner because it was inadvertently damaged during the ankle debridement procedure. The patient with the wound dehiscence complication described previously underwent repair with peroneal artery fasciocutaneous perforator pedicle flap and a split-thickness skin graft. Finally, a Strayer gastrocnemius recession and posterior capsulotomy release was performed on another patient to improve her ROM. Secondary procedures unrelated to the ankle replacement surgery included a case of hallux interphalangeal fusion and surgery to correct a fifth metatarsal bunionette.

Table 5
Complications after index total ankle replacement (N = 9 ankles)

Complication	n (%)a*
Intraoperative medial malleolus fracture†	2 (4.0)
Subsidence	2 (4.0)
Clinically significant cyst	1 (2.0)
Wound-healing complication‡	3 (6.0)
Deep vein thrombosis	1 (2.0)
Cardiomyopathy	1 (2.0)
Prolonged hospital stay	2 (4.0)

* Occurrence rate calculated on a per-ankle basis; 4 of 9 ankles had multiple complications.
† Treated with open reduction and internal fixation.
‡ One of these patients had delayed wound healing, the other had a superficial wound infection, and the third had wound dehiscence requiring plastic surgery.

Table 6
Secondary procedures performed after index total ankle replacement (N = 6 ankles)

Procedure	n (%)a*
Gutter debridement	4 (8.0)
Subtalar fusion	1 (2.0)
Tendon Achilles lengthening	1 (2.0)
Strayer gastrocnemius recession	1 (2.0)
Ankle posterior capsulotomy	1 (2.0)
Peroneal artery fasciocutaneous perforator pedicle flap and split thickness skin graft	1 (2.0)
Incidental polyethylene liner exchange	1 (2.0)

* Occurrence rate calculated on a per-ankle basis; 3 the 6 ankles underwent multiple procedures.

Discussion

Implant survivorship is the primary indicator of the success of an arthroplasty procedure. High failure rates have been the cause for concern with ankle replacement, especially with earlier designs. Though modern implants have demonstrated good early survivorship, there is still uncertainty vis-à-vis their mid- and long-term outcomes. The early to mid-term survivorship of the Salto Talaris® implant has been reported previously and ranges from 95.7% to 98% (25,28–33). Our study demonstrated 100% implant survivorship for the implant at mid-term follow-up. Patients experienced pain relief and restoration of ankle function as evidenced by the significant improvement in outcome scores and the ankle ROM. The incidence of complications and reoperations was low and comparable to that seen with other modern implants (14,41,42).

To the best of our knowledge, 3 studies have reported the mid-term outcomes of the Salto fixed-bearing implant thus far (31–33). The earliest was the study by Nodzo et al (32), which reported 98% survivorship (using a Kaplan-Meier curve) at a mean follow-up of 43 months. Hofmann et al (31) reported 97.5% survivorship at a mean follow-up of 62.4 months. The most recent study by Stewart and colleagues (33) with the longest follow-up to date (mean 81.1 months) had a 95.8% implant survival rate. The current study corroborates the high implant survivorship seen in these studies and further builds on the existing knowledge by (1) evaluating both clinical and radiographic ROM, (2) assessing clinical outcomes by using a mix of clinician- and patient-oriented scores, and (3) analyzing the rate of reoperations as a more relevant estimate of patient morbidity compared with assessing perioperative complications in isolation.

Ankle motion occurs primarily around the tibiotalar joint in the sagittal plane as a combination of dorsiflexion and plantarflexion. A combined ROM of about 25° is thought to be sufficient to maintain normal gait on a flat surface (43). An estimate of the expected ROM after a TAA procedure is important to orient patients' expectations of the replacement procedure and to plan for the postoperative physiotherapy regimen. The modes of reporting ROM outcomes in the literature have often been inconsistent (10,44). A combination of clinical and radiographic ROM was used in this study to obtain a reliable picture of ankle function. Although clinical ROM is a global measure and incorporates adjacent joint motion, especially the midfoot, the radiographic ROM provides information on the true tibiotalar ROM. We saw significant improvement in both clinical and radiographic ROM compared with the preoperative ankle motion, albeit at different time-points. Mean clinical ROM improved significantly from 27.7° ± 10.7° preoperatively to 37.6° ± 10.9° at the 5+-year follow-up, which is consistent with the quantum of improvement in global ankle motion noted in other studies that used goniometric measurement (32,45). Mean radiographic ROM, on the other hand, showed a modest, yet statistically significant, improvement from the preoperative 23.0° ± 10.2° to 27.2° ± 9.1° at the 2-year follow-up, after which it did not show improvement and seemed to plateau at 24.6° ± 10.5° at the 5+-year follow-up. This marked difference between the clinical and radiographic ROM was anticipated and serves to highlight the fact that clinical measurements may not be truly reflective of actual ankle motion (46). The temporal pattern of initial ROM improvement followed by a plateau observed in our study has also been confirmed by others (27,43), although they noticed improvement within 1 year after surgery. Whether our patients demonstrated an earlier spurt in ROM is unclear, as we did not analyze radiographs from the early postoperative period.

To accurately gauge the patients' perception of their surgery, we incorporated patient-reported outcomes along with the more conventional clinician-based assessments (37). There was a significant improvement both in the patient-reported FFI and FAAM scores and in the clinician-based AOFAS scores with the trend of improvement seen across the follow-up period. The AOFAS score is the most widely used and therefore amenable to comparison between studies. Although its objective component is not yet validated, its subjective component provides quality-of-life information with acceptable validity for conditions affecting the foot and ankle (38). The postoperative AOFAS scores were in alignment with others (28,33,47), but we did notice that our patients were at a better preoperative status compared with these studies. FFI and FAAM outcomes have been reported with the Salto mobile-bearing implant at a mean follow-up of 54 months. The activity limitation (4.5 ± 8.9 vs 13.7 ± 17) and disability (20.4 ± 18.7 vs 31.7 ± 23) FFI subscores observed in our study compared favorably to those reported by Bonnin and colleagues (48), whereas the pain scores were similar (15.4 ± 19.7 vs 16.9 ± 19). Likewise, both the ADL and the sports outcomes were better in the current study (ADL: 86.0 ± 11.5 vs 74.9 ± 18; sports: 66.3 ± 24.2 vs 48.9 ± 28).

Radiolucency was observed in 10 (20.8%) of 48 ankles in our study, with a majority of them limited to 1 zone. There were no cases of progression. There were no significant device migrations (>5 mm) and no component loosened as of the last follow-up. These results echo the findings of others (25,31) and reinforce the notion that partial radiolucencies do not seem to affect implant stability. Cystic changes observed in our study were benign in all except 1 case. Balloon cysts were observed predominantly around the tibial keel in one ankle but were clinically asymptomatic and did not require any intervention. Although a common radiographic finding, there continues to be some ambiguity around osteolytic phenomena. Some suggest that they could be a stress-shielding response (39), whereas others believe that abnormal micromotion at the bone–implant interfaces or altered fluid pressure dynamics around the implant could be responsible (49). In our single case, it could be attributed to a technical error in positioning the talar component.

There is remarkable diversity in the manner in which complications are reported after ankle replacement surgery, which often leads to confusion about their interpretation and their ultimate clinical significance. Glazebrook et al (40) devised a method for classifying complications, which, while useful to gauge their relative risk of resulting in implant failure, does not encapsulate events that could send the patient back to the operating room for reasons other than failure. We agree with Younger et al (50) that analyzing the reoperation rate instead presents a more unified approach to assessing complications and renders itself to comparisons across studies. The reoperation rate in this study (12%), is the same as that reported by Schweitzer et al (29) at a mean follow-up of 2.8 years and compares favorably to rates reported by Hofmann et al (31) and Stewart et al (33) at mid-term follow-up (21% and 19%, respectively). Gutter debridement for the treatment of painful ankle impingement was the most common reason for reoperation among our patients, which was also the case in the studies by Hofmann et al (31) and Stewart et al (33). The etiology of gutter impingement has not been clearly elucidated, but a few of the predisposing factors include inadequate bone resection, oversizing of implant components, implant malpositioning and heterotopic bone formation. Schuberth et al (51) noted a 12% incidence of secondary debridement among patients treated with the Salto Talaris® implant. Gross et al (52) reported a much lower incidence in their Salto cohort (2.7%) but also indicated that the finding needs to be tempered with the fact that the Salto patients in this study had a relatively short follow-up. Our gutter debridement rate (8%) lies somewhat in between these 2 studies, with none of the patients requiring a repeat debridement procedure as of the last follow-up.

One of the strengths of this study is that it adds to the relatively scarce body of evidence on mid-term survivorship and functional outcomes of this fixed-bearing implant. Moreover, it bridges some of the gaps in the other mid-term studies by assessing the progression of both clinical and radiographic ROM. Owing to its prospective design, it offers the advantage of a more accurate means of data collection not subject to recall biases inherent in retrospective studies. Finally, being a single-center study conducted by a single surgeon, this study was not subject to procedural bias, which could be a potential confounding factor in multicenter studies. Our study limitations include a small sample size and the lack of a control or comparator group. We had data on relatively fewer patients at the 5+-year stage, which might have weakened the reliability of our 5+-year findings. Also, it is still uncertain whether the results of our study would hold true on long-term follow-up.

In conclusion, our results indicate that the Salto Talaris® implant is highly durable and provides good pain relief with retention of ankle function on mid-term follow-up. We believe that these results would provide impetus for larger studies on this implant with longer follow-up. In addition to implant survivorship and clinical outcomes, studying patient gait mechanics would be an interesting avenue for future investigations.

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