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Fixed-Bearing Trabecular Metal Total Ankle Arthroplasty Using the Transfibular Approach for End-Stage Ankle Osteoarthritis

An International Non-Designer Multicenter Prospective Cohort Study

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Investigation performed at the University of British Columbia, Vancouver, Canada; IRCCS Istituto Ortopedico Galeazzi, Milan, Italy; Inselspital, Bern, Switzerland; University of California, Davis, Sacramento, California; Orthopaedic Associates of Michigan, Grand Rapids, Michigan; Krankenhaus St. Josef, Wuppertal, Germany; Spital Thun, Thun, Switzerland; OrthoCarolina Foot & Ankle Institute, Charlotte, North Carolina; Turku University Hospital, Turku, Finland; Rothman Institute, Philadelphia, Pennsylvania; Duke University Medical Center (DUMC), Durham, North Carolina

Background: This multicenter prospective cohort study assessed the safety and performance of the Trabecular Metal Total Ankle System (TM Ankle; Zimmer) for primary total ankle arthroplasty (TAA).

Methods: One hundred and twenty-one consecutive patients qualifying for primary TAA were enrolled in the study. All patients received the TM Ankle implant. Clinical outcome examinations and radiographic evaluations were conducted at 6 weeks, 6 months, 1 year, 2 years, and 3 years. Patient-reported outcome measures (PROMs) were evaluated with use of the EuroQol-5 Dimensions questionnaire (EQ-5D), Ankle Osteoarthritis Scale (AOS), American Orthopaedic Foot & Ankle Society questionnaire (AOFAS), and patient satisfaction at each time point. Complications were classified according to the Canadian Orthopaedic Foot and Ankle Society (COFAS) system.

Results: The average AOFAS, EQ-5D, AOS pain, and AOS difficulty scores showed significant improvement at 6 weeks, 6 months, 1 year, 2 years, and 3 years as compared with the preoperative baseline ($p < 0.001$). The Kaplan-Meier survival estimate for revision when used in primary cases was 97.35% at 3 years. During the 3 years of follow-up, 9 patients showed abnormal radiographic findings. Two ankles had intraoperative complications, 38 had complications that were non-surgical or device-related, and 3 ankles underwent revision.

Conclusions: The results of the present study indicated that patient well-being significantly increased following TAA with use of the TM Ankle. Radiographic parameters also demonstrated a low incidence of abnormal findings.

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

Total ankle arthroplasty (TAA) has been being increasingly used over the past 10 years as a result of substantial improvements in implant designs and increased survivorship[1].

The initial designs of TAA implants were associated with high rates of failure, which almost led to the complete abandonment of the procedure. However, newer-generation designs have demonstrated much improved results, which has led to a gradual increase in the number of TAAs being performed[2].

Given the substantial increase in the use of this procedure, a number of studies have analyzed the clinical, radiographic, and biomechanical outcomes associated with ankle prostheses. However, to our knowledge, no multicenter studies have been conducted with use of the Trabecular Metal implant (TM Ankle; Zimmer) for the treatment of ankle osteoarthritis[3].

The TM Ankle is a semiconstrained, fixed-bearing implant that is inserted with use of a lateral transfibular approach. With the leg immobilized in a frame, the center of rotation of the ankle

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is identified. The talus and tibia are then milled on the basis of the center of rotation to accommodate the implant. Traditionally, TAA has involved the use of flat tibial and talar resection through an anterior approach; however, the TM Ankle prosthesis is different because it preserves the normal arched contour of the ankle, thus maintaining bone stock[4].

The TM Ankle reproduces the frustum of a cone that is present in a normal ankle. The medial side of the prosthesis has a smaller radius of curvature than the lateral side, limiting the strain on the medial and lateral ligament complexes. This shape allows dorsiflexion with eversion and plantar flexion with inversion. The center point of contact shifts anteriorly with dorsiflexion and posteriorly with plantar flexion, mimicking normal ankle biomechanics[5].

The primary purpose of the present study was to analyze the implant survival and revision rate; the secondary aim was to evaluate clinical and radiographic parameters. Finally, safety was assessed by monitoring the frequency and incidence of complications.

Materials and Methods

Study Design

This multicenter, prospective, consecutive cohort study involved non-designer orthopaedic surgeons skilled in TAA procedures and experienced with the TM Ankle implant[4]. Eleven centers were involved in the study (University of British Columbia, Vancouver, Canada; IRCCS Istituto Ortopedico Galeazzi, Milan, Italy; Inselspital, Bern, Switzerland; University of California, Davis, Sacramento, California, U.S.A.; Orthopaedic Associates of Michigan, Grand Rapids, Michigan, U.S.A.; Krankenhaus St. Josef, Wuppertal, Germany; Spital Thun, Thun, Switzerland; OrthoCarolina Foot & Ankle Institute, Charlotte, North Carolina, U.S.A.; Turku University Hospital, Turku, Finland; Rothman Institute, Philadelphia, Pennsylvania, U.S.A.; and Duke University Medical Center [DUMC], Durham, North Carolina, U.S.A.); all patients were enrolled in the centers where their surgery then took place. Patient enrollment started on March 21, 2014, and the last patient was enrolled on March 17, 2017. The study was conducted following the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines[6].

Ethics committee approval was obtained for each site prior to the study. The study was registered at ClinicalTrials.gov (identifier: NCT02038140)[7]. All potential study participants were required to participate in an informed consent process and to sign the institutional review board/ethical committee-approved written informed consent form prior to study enrollment. All patients underwent preoperative, intraoperative, and immediate postoperative assessments, including radiographic evaluation and collection of quality-of-life metrics. Follow-up evaluations were conducted at 6 ± 1 weeks, 6 ± 1 months, 1 year ± 2 months, 2 years ± 2 months, and 3 years ± 2 months postoperatively.

Study Population

The inclusion criteria were a minimum age of 18 years, severe ankle pain and disability requiring primary unilateral or bilateral TAA, the ability to cooperate in the required postoperative therapy, and the ability to complete scheduled follow-up evaluations as described in the informed consent form.

The exclusion criteria were the inability to give consent or comply with the follow-up program; pregnancy; the presence of acute or chronic local or systemic infection; severe muscular, neural, or vascular disease; lack of osseous structures proximal or distal to the joint; total absence of an ankle muscle or ligament ; allergy to implant material; local bone tumors and/or cysts; and skeletal immaturity.

Study Outcome Measures/End Points

Survivorship

Implant survival was calculated with use of the Kaplan-Meier method. Revision was defined as the removal of ≥1 of the TM Ankle System metal or polyethylene components, including partial revisions such as polyethylene exchange[8].

Clinical Outcomes

Pain, functional difficulties, and alignment were measured with use of the Ankle Osteoarthritis Scale (AOS) and the American Orthopaedic Foot & Ankle Society questionnaire (AOFAS). Quality of life was measured with use of the EuroQol-5 Dimensions (EQ-5D) score[9-11]. Patient satisfaction was assessed with use of a questionnaire asking patients whether or not they were satisfied with the result of the procedure and whether the involved ankle was in better or worse condition than preoperatively[12].

Radiographic Assessment

Radiographic assessment was performed at each center by a skilled musculoskeletal radiologist who evaluated each patient with respect to the incidence, extent, and nature of radiolucent lines, osteolysis, hypertrophy, and subsidence[13].

Complications and Adverse Events

The complexity of each case was evaluated with use of the Canadian Orthopaedic Foot and Ankle Society (COFAS) end-stage ankle arthritis classification system[14]. Undesirable clinical developments that were not present at baseline or that increased in severity after treatment were classified as adverse events[15]. Surgical device-related complications were defined as any deviation from the normal postoperative course due to the implants[16].

TABLE I Patients Included, Undergoing Revision Surgery, and Lost at Each Study Follow-up

Follow-up	No. of Visits Completed	Total No. of Revisions	No. of Patients Lost to Follow-up
Preop.	121	0	0
6 wk	121	0	0
6 mo	120	0	1
1 yr	117	2	2
2 yr	91	3	27
3 yr	53	3	65

TABLE II Concomitant Surgical Procedures Performed During TAA

Subtalar arthrodesis	9
Achilles tendon lengthening	14
Gastrocnemius recession	1
Distal tibiofibular fixation	7
Total	31

Surgical Technique

The surgical technique was carried out with use of the original TM Ankle instrumentation as per the manufacturer's guidelines[17].

Statistical Analysis

Survival analysis was performed with longitudinal Kaplan-Meier curves. The mean clinical scores were compared at different times of assessment with a repeated-measures analysis of variance. A Toeplitz, autoregressive, or unstructured covariance matrix within the subject residuals was selected on the basis of how well it fit with the model (according to the Akaike information criterion). The Wilcoxon signed-rank test was used if there were deviations from the assumptions of the model. A 2-tailed p value of <0.05 was considered to be significant. The statistical analyses were performed with use of SAS (version 9.4; SAS Institute).

Sample Size

The primary driver of the sample size was survivorship. The study was designed to have an alpha error of no greater than 0.1. Based on an assumed survivorship of 79.1% at 3 years, a sample size of 72 at 3 years was determined to have at least 80% probability to yield a 90% confidence interval (CI) for the device survivorship with a half-width precision of 0.09. Sample size calculation was computed with use of the ProcPower routine in SAS 9.4. The half-width precision of 0.09 allowed us to set a CI on survivorship of 9% above and below the expected survivorship performance of 79.1% at 3 years. This detectable change of 9% is analogous to noninferiority margins that approach 10% in regulated studies. Assuming a loss-to-follow-up rate of 30% over 10 years, the study would require a minimum of 103 patients. However, to allow for the possibility of >30% attrition due to loss to follow-up, 121 patients were enrolled in this study.

Source of Funding

The study was fully funded by Zimmer-Biomet. Funds provided were for the cost of clinical and radiographic examinations of patients and dedicated operating room instrumentation.

Results

Of 154 patients who were screened for eligibility, 121 satisfied the inclusion and exclusion criteria and were enrolled in the study. Of the 33 excluded patients, 10 had a local or systemic infection, 8 reported a metal allergy, 8 were pregnant, and 7 declined to participate.

The 121 patients were enrolled into the study at 11 study centers. The study population comprised 60 men and 61 women. The patients had a mean age of 60 years (range, 18 to 82 years), a mean weight of 84.2 kg (range, 60 to 153 kg), and a mean height of 169.9 cm (range, 149.9 to 180 cm). The primary diagnoses were posttraumatic arthritis in 61 participants, primary arthritis in 18, and rheumatoid arthritis (RA) in 42. All 121 patients returned for follow-up at 6 weeks, 120 returned at 6 months, 117 returned at 1 year, 91 returned at 2 years, and 53 returned at 3 years (Table I). Twenty-three patients (19%) underwent 31 concomitant procedures (Table II).

Survivorship

The Kaplan-Meier survival estimate for the TM Ankle, when used in primary procedures, was 98.32% at 1 year and 97.35% at 2 and 3 years (Table III). There were 3 revisions in this cohort, including 2 within the first year and the third within 2 years. One revision was due to an infection, resulting in a polyethylene exchange, and 2 were due to valgus malalignment (with aseptic loosening), resulting in the removal of 1 talar, 1 tibial, and 2 polyethylene components.

Clinical Results

The average AOFAS, EQ-5D, AOS pain, and AOS difficulty scores showed significant improvement at 6 weeks, 6 months, 1 year, 2 years, and 3 years, as compared with the preoperative baseline (Table IV).

Radiographic Results

At 3 years of follow-up, 9 patients (17.0%) showed abnormal radiographic findings, including radiolucency (5 patients), osteolysis (1 patient), heterotopic ossification (2 patients), and

TABLE III Kaplan-Meier Survival Estimates for All Patients

Years of Follow-up	No. of Cases at Risk	Cumulative No. of Cases Revised	Kaplan-Meier Survival Estimate	95% CI
1	121	2	0.9832	0.9345-0.9958
2	115	3	0.9735	0.9197-0.9914
3	98	3	0.9735	0.9197-0.9914

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TABLE IV Clinical Outcomes at Each Follow-up*

	Preop.		6 Wk			6 Mo			1 Yr			2 Yr			3 Yr		
	N	Mean (SD)	N	Mean (SD)	P Value Compared with Preop.	N	Mean (SD)	P Value Compared with Preop.	N	Mean (SD)	P Value Compared with Preop.	N	Mean (SD)	P Value Compared with Preop.	N	Mean (SD)	P Value Compared with Preop.
AOFAS	121	39.0 (16.2)	119	68.2 (15.4)	<0.001	119	80.8 (13.7)	<0.001	113	82.7 (12.9)	<0.001	91	84.8 (12.8)	<0.001	53	85.2 (15.2)	<0.001
EQ-5D	121	0.4 (0.3)	121	0.6 (0.3)	<0.001	120	0.8 (0.2)	<0.001	117	0.8 (0.2)	<0.001	90	0.8 (0.2)	<0.001	53	0.8 (0.3)	<0.001
AOS pain	119	59.7 (20.6)	60	27.2 (21.1)	<0.001	120	22.0 (18.1)	<0.001	117	18.2 (19)	<0.001	90	17.5 (20.9)	<0.001	51	16.0 (21.0)	<0.001
AOS difficulty	119	70.3 (18.8)	75	41.9 (27.8)	<0.001	120	30.0 (21.6)	<0.001	117	23.6 (21.4)	<0.001	90	22.4 (21.9)	<0.001	51	23.5 (25.8)	<0.001

*AOFAS = American Orthopaedic Foot & Ankle Society ankle-hindfoot scale, EQ-5D = EuroQol-5 Dimensions questionnaire, AOS = Ankle Osteoarthritis Scale, SD = standard deviation.

possible subtalar impingement (1 patient). One subject showed delayed union of the fibula, which was later found to be fully healed at the time of plate removal. Three subjects showed subsidence (Table V). Figures 1 and 2 show preoperative and 2-year radiographic findings, with no evidence of implant loosening or migration.

Satisfaction

The rate of patient satisfaction was 92.5% (49 of 53) at 3 years, 89.0% (81 of 91) at 2 years, 90.6% (106 of 117) at 1 year, and 90.0% (108 of 120) at 6 months. At 3 years, 2 patients (3.8%) stated that the status of the ankle was worse when compared with the previous visit, compared with 3 patients (3.3%) at 2 years, 5 patients (4.3%) at 1 year, and 4 patients (3.3%) at 6 months.

Complications and Reoperations

Two ankles (1.7%) had intraoperative complications, including a partial tear of the peroneal tendons and a partial cut on the tibialis posterior tendon. Thirty-eight ankles (31.4%) had postoperative complications that were not related to the TM Ankle (Table VI) or that resulted in a secondary reoperation within or around the primary operative site (Table VII). Table VIII provides a breakdown of the COFAS Reoperation Coding System (CROCS)[7]; a majority (12%; 55%) of the reoperations were due to fibular plate issues.

Discussion

The present report outlines the initial outcomes of a prospective non-designer multicenter study of laterally placed fixed-bearing TM Ankle implants, with 53 implants available for analysis at a minimum follow-up of 3 years. Our results demonstrated an encouraging implant survival rate of 97.35% at the initial follow-up period.

Barg et al. reported similar outcomes in a study of patients who had been treated with TAA through a lateral transfibular approach[18]. The 24-month implant survival rate was 93%, with 3 revisions of the tibial component due to aseptic loosening. In 10 cases, a secondary procedure was performed during follow-up.

In our cohort, patients demonstrated statistically significant and clinically important improvements in all clinical parameters, as well as minimal concerns regarding multiple radiographic parameters, during the follow-up period.

Tiusanen et al. recently investigated the safety of a TM ankle prosthetic system with use of the transfibular approach and found that 89% of the patients reported improved functioning and 66% were very satisfied with the procedure[19].

The results of the current study confirm the promising good outcomes associated with the use of a transfibular approach. Previous authors have found that lateral incision placement is preferred because it is associated with better prospects for postoperative wound-healing[20-22]; this finding was confirmed in our cohort, in which only 4 patients reported wound dehiscence.

The lateral approach allows direct visualization of the tibiotalar joint once the fibula is reflected distally. This approach allows the surgeon to accurately assess the normal arc of rotation

TABLE V Radiographic Findings at Different Time Points

Radiographic Findings	No. of Patients
Heterotopic ossification	
6 mo	1
1 yr	3
2 yr	4
3 yr	2
Osteolysis	
2 yr	3
3 yr	1
Radiolucency	
6 wk	1
6 mo	2
1 yr	5
2 yr	7
3 yr	5

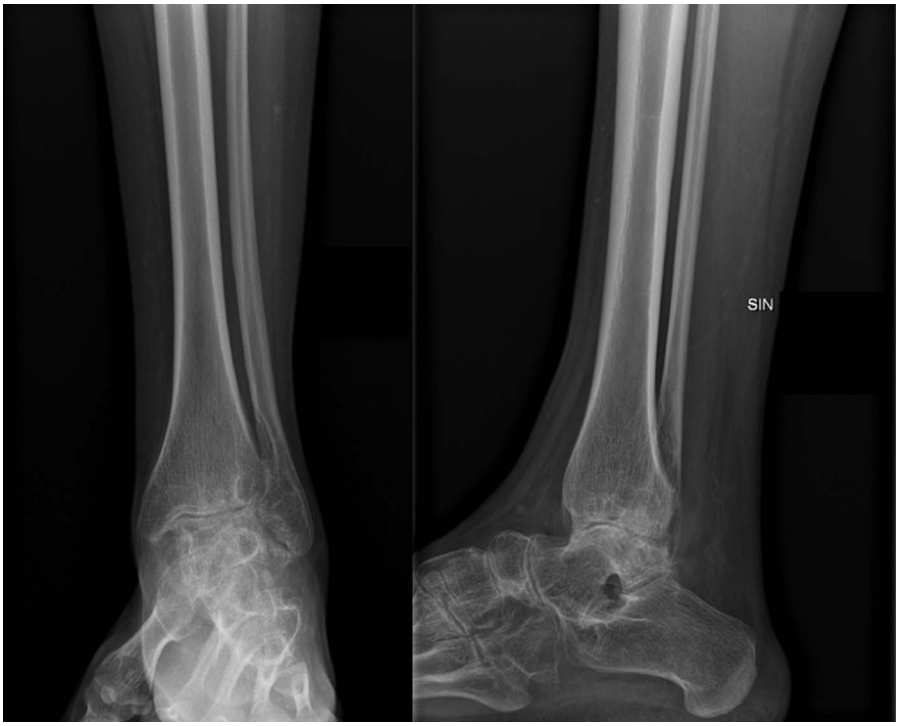

Fig. 1

Anteroposterior and lateral weight-bearing radiographs of a left ankle, showing preoperative osteoarthritis of the ankle and subtalar joint.

and precisely identify the center axis of the ankle joint. The alignment guide can be rotated around the center axis to perform accurate osseous resection and facilitate subsequent implant placement. Soft-tissue balancing procedures are paramount to ensure TAA stability and successful reduction of varus/valgus malalignment[23].

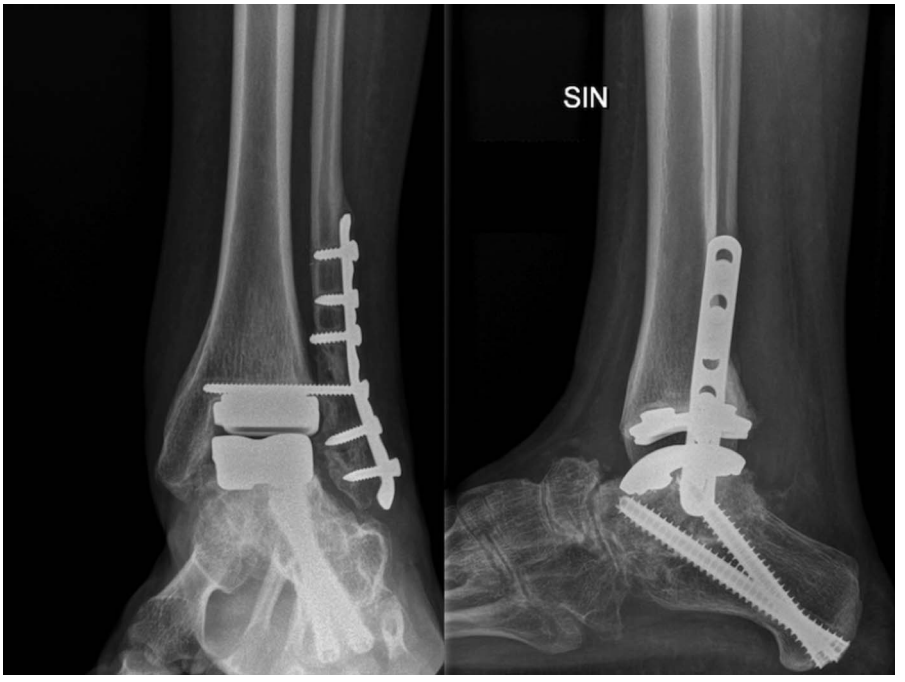

Fig. 2

Anteroposterior and lateral radiographs of a left ankle, showing the TM Ankle implant and subtalar arthrodesis at 2 years after surgery, with no implant loosening or migration or osteolysis.

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While the lateral transfibular approach has many benefits, it also has certain drawbacks. Previous reports in the literature have shown that the rate of syndesmotic nonunion or fibular osteotomy nonunion can range from 0.6% to 1.6%[24]. Although there were no cases of malunion in our series, there was 1 case of syndesmotic nonunion (0.8%). Although the risk of nonunion is minimal, postoperative protocols must be adjusted to allow for osteotomy healing.

Gagné et al., in a single-center study, reported that the use of nails instead of fibular plates provided improved surgical outcomes[25]. In another recent study, the length of the fibular osteotomy was also observed to have an effect on outcomes, with a long oblique osteotomy being associated with better results than a short osteotomy[26].

Although our patients had good to excellent clinical outcomes, the rate of complications in our multicenter non-designer study was 31%. Clough et. al. found overall complication rates ranging from 12.8% to 46% in a review of outcomes of TAA[27]. Newer devices, such as the TM Ankle, are designed to maintain physiological transfer of forces between the distal part of the tibia and the talus through arthroplasty without inducing excessive edge-loading that can lead to device failure[13].

Some authors have listed complications according to the frequency of occurrence. In the study by Lee et al., 62% of TAAs were associated with radiographic evidence of complications[28]. Specifically, periprosthetic radiolucency was seen in 34% of their cases; hardware subsidence, in 24%; peri-hardware fracture, in 11%; syndesmotic screw loosening, in 10%; and screw fracture, in 6.5%[28].

Aseptic loosening is the most common complication following TAA and is the most common indication for prosthetic revision[29]. Reports in the current literature have indicated that approximately 40% of TAA revisions are due to aseptic loosening. Furthermore, subsidence represents another common postoperative complication associated with TAA failure. Subsidence was reported in nearly 11% of failed TAAs[29]. The third most frequent cause for revision is infection, which occurs

TABLE VI General Non-Device-Related Complications

Complication	No. of Patients
Deep infection at >6 weeks	1
Impingement	2
Musculoskeletal (non-ankle)	1
Other ankle-related complication	7
Skin slough	1
Subsidence	2
Wound dehiscence	2
Total	16

TABLE VII Secondary Reoperations

Reason for Secondary Reoperation and Related Device	Total
Deep infection at <6 wk	
Fibular plate	2
Impingement	
Fibular plate	1
Screw-related	1
Other	1
Infection (non-ankle)	
Fibular plate	1
Malalignment	
Other	1
Musculoskeletal (non-ankle)	
Fibular plate	1
Other ankle-related complication	
Fibular plate	1
Screw-related	1
Tendinosis	1
Persistent fibular pain	
Fibular plate	1
Skin slough	
Fibular plate	1
Other	1
Syndesmotic nonunion	
Other	1
Wound dehiscence	
Fibular plate	4
Revision: device removal	3
Total	22

TABLE VIII Breakdown of the COFAS Reoperation Coding System (CROCS)

Code	Reoperation Category	No. of Subjects (N = 121)
1	No reoperation	106 (87.6%)
2	Isolated implant removal	8 (6.6%)
3	Reoperation outside initial operative site	3 (2.5%)
4	Gutter or heterotopic ossification debridement	5 (4.1%)
5	Polyethylene liner exchange	1 (0.83%)
6	Debridement of osteolytic cyst	1 (0.83%)
7	Deep infection requiring debridement	1 (0.83%)
8	Revision of arthrodesis	Not applicable
9	Revision of metal components	2 (1.7%)
10	Infection requiring revision of metal components	0 (0.0%)
11	Amputation	0 (0.0%)

in up to 10% of patients with TAAs and includes superficial wound infections that could lead to delayed wound closure and deeper periprosthetic infections[13].

Finally, the radiographic data at 3 years showed some radiolucency and osteolysis; however, the clinical relevance of these findings is still unclear[30,31]. In our cohort, we observed no associations between radiographic findings and persistent pain, failure, or revision surgery.

Subsidence remains a common problem after TAA. Hirao et al. suggested that this problem may be due to a decrease in blood supply to the talar dome after subtalar joint arthrodesis[32].

Limitations

The present study had limitations. The follow-up was relatively short and the series was small for determination of the survivorship of this implant. The study also lacked a control group to assess clinical and radiographic differences with other ankle arthroplasties with different bearings and surgical approaches[33].

Furthermore, in our cohort, a high percentage of patients (35%) were affected by RA; this can have a relevant impact on outcomes (including a higher risk of infection and reduced global activity)[32].

Currently, there is no clear consensus on the most appropriate outcome measures for assessments in patients who have undergone TAA. Although it has not yet been validated, we used the AOFAS scale to evaluate ankle function. Hunt and Hurwit, in a review of the literature, found that the AOFAS scale is the most commonly used scale in articles dealing with foot and ankle abnormalities[34].

Another limitation of the current study is the lack of analysis regarding patient ethnicity, which may play a role in the development of immunologic disorders. Recent studies have demonstrated that nearly tenfold more non-Hispanic white patients underwent TAA when compared with other racial/ethnic groups[35,36]. Finally, we noted a meaningful loss to follow-up after 3 years. Perhaps one of the reasons for this loss to follow-up was that the patients were unhappy; in many cases, patients who drop out are different from those who do not. Loss to follow-up is very important in determining a study's validity because patients who are lost to follow-up often have a different prognosis than those who complete the study. Some studies have suggested that <5% loss leads to little bias, whereas >20% poses serious threats to validity[37]. This may be a good rule of thumb, but one should keep in mind that even small proportions of patients lost to follow-up can cause substantial bias[37]. One way to determine if loss to follow-up can seriously affect results is to assume a worst-case scenario with the missing data and to see if the results would change. For this reason, further multicenter studies are needed to confirm our promising results

Conclusions

This study assessed the functional outcomes associated with the TM Ankle implant at 6 weeks, 6 months, 1 year, 2 years, and 3 years of follow-up. The results indicated that patient well-being significantly increased following TAA with use of the TM Ankle. Radiographic analysis also demonstrated a low rate of abnormal findings. ■

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