Intermediate-Term Results of Total Ankle Replacement and Ankle Arthrodesis

A COFAS Multicenter Study

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Background: Surgical treatments for end-stage ankle arthritis include total ankle replacement and ankle arthrodesis. Although arthrodesis is a reliable procedure, ankle replacement is often preferred by patients. This prospective study evaluated intermediate-term outcomes of ankle replacement and arthrodesis in a large cohort at multiple centers, with variability in ankle arthritis type, prosthesis type, surgeon, and surgical technique. We hypothesized that patient-reported clinical outcomes would be similar for both procedures.

Methods: Patients in the Canadian Orthopaedic Foot and Ankle Society (COFAS) Prospective Ankle Reconstruction Database were treated with total ankle replacement (involving Agility, STAR, Mobility, or HINTEGRA prostheses) or ankle arthrodesis by six subspecialty-trained orthopaedic surgeons at four centers between 2001 and 2007. Data collection included demographics, comorbidities, and the Ankle Osteoarthritis Scale (AOS) and Short Form-36 (SF-36) scores. The preoperative and latest follow-up scores for patients with at least four years of follow-up were analyzed. Sensitivity analyses excluded ankles that had undergone revision. A linear mixed-effects regression model compared scores between the groups, adjusting for age, sex, side, smoking status, body mass index, inflammatory arthritis diagnosis, baseline score, and surgeon.

Results: Of the 388 ankles (281 in the ankle replacement group and 107 in the arthrodesis group), 321 (83%; 232 ankle replacements and eighty-nine arthrodeses) were reviewed at a mean follow-up of 5.5 ± 1.2 years. Patients treated with arthrodesis were younger, more likely to be diabetic, less likely to have inflammatory arthritis, and more likely to be smokers. Seven (7%) of the arthrodeses and forty-eight (17%) of the ankle replacements underwent revision. The major complications rate was 7% for arthrodesis and 19% for ankle replacement. The AOS total, pain, and disability scores and SF-36 physical component summary score improved between the preoperative and final follow-up time points in both groups. The mean AOS total score improved from 53.4 points preoperatively to 33.6 points at the time of follow-up in the arthrodesis group and from 51.9 to 26.4 points in the ankle replacement group. Differences in AOS and SF-36 scores between the arthrodesis and ankle replacement groups at follow-up were minimal after adjustment for baseline characteristics and surgeon.

Conclusions: Intermediate-term clinical outcomes of total ankle replacement and ankle arthrodesis were comparable in a diverse cohort in which treatment was tailored to patient presentation; rates of reoperation and major complications were higher after ankle replacement.

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

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End-stage ankle arthritis causes joint deformity, disability, and loss of income; has an effect on quality of life; and involves a younger age group compared with patients affected by hip or knee arthritis[1].

Accepted surgical treatment options for end-stage ankle arthritis include total ankle replacement and ankle arthrodesis. Although arthrodesis is a reliable procedure, ankle replacement is often preferred by patients. A systematic review of forty-nine

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studies involving either ankle replacement or arthrodesis indicated that intermediate-term outcomes appeared to be similar[2]. The authors identified a need for comparative studies to strengthen their conclusions. Four comparative studies have assessed the outcomes of both interventions[3-6]. A large clinical trial of the STAR prosthesis at twenty-four months of follow-up included a comparison with a small cohort of forty-seven patients treated with arthrodesis[4]. Another study indicated quality-of-life outcomes in 107 patients at one year after ankle replacement with multiple implant types or arthrodesis[5]. The other two studies indicated outcomes for a single implant type and for arthrodesis in small cohorts of fewer than sixty patients[3,6], with mean follow-up durations of three[6] and 3.5 years[3]. However, large comparative studies of the procedures with longer follow-up are still lacking.

The purpose of the present prospective cohort study was to quantify and evaluate the intermediate-term (four to ten-year) clinical outcomes of total ankle replacement and ankle arthrodesis in a large cohort of patients at multiple centers, with variability in the type of ankle arthritis[7], type of prosthesis, surgeon, and surgical technique, utilizing validated scoring instruments. We hypothesized that patient-reported clinical outcomes for the two procedures would be similar at intermediate-term follow-up.

Materials and Methods

Patient Enrollment

The Canadian Orthopaedic Foot and Ankle Society (COFAS) multicenter Ankle Arthritis Outcome Study was established in January 2003 and includes four study centers: Dalhousie University/Queen Elizabeth II Health Sciences Center, University of Toronto/St. Michael's Hospital, University of British Columbia/St. Paul's Hospital, and Vancouver Island Health Authority. This study was approved by the local hospital ethics boards. All patients provided informed consent for study enrollment and for the surgical procedure prior to questionnaire administration.

Patients enrolled in this study constitute a subgroup of the COFAS Prospective Ankle Reconstruction Database. This database includes all patients with symptomatic end-stage ankle arthritis of various etiologies who had undergone an unsuccessful trial of nonoperative treatment, gave informed consent for database enrollment, and were treated with total ankle replacement or ankle arthrodesis by one of six subspecialty-trained orthopaedic surgeons at the four centers. Inclusion in the present study required skeletal maturity, a complete preoperative data set, and ability and willingness to give informed consent. Exclusion criteria were substantial osteonecrosis of the talus, prior ankle arthrodesis or arthroplasty, active or prior infection, Charcot arthropathy, and obesity (a body mass index [BMI] of >35 kg/m^2).

Procedure Selection

The final decision regarding the surgical treatment selection (ankle replacement or arthrodesis) was reached by consensus between the surgeon and patient. Arthrodesis was recommended for younger patients and patients with comorbidities that compromised soft-tissue healing (e.g., diabetes or current smoking). Ankle replacement was recommended in patients who were sixty-five years of age or older.

Data Collection

Patient assessments were completed by the orthopaedic surgeon preoperatively, at one year following surgery, and annually thereafter. Patient demographics, comorbidities, and diagnoses were recorded preoperatively. Operative details were collected prospectively with use of the Halifax Joint Replacement Registry Form, which was developed for the COFAS database. Clinical outcomes were recorded preoperatively and at each follow-up visit with use of the Foot and Ankle Follow-up Questionnaire developed by a coalition of ten orthopaedic associations, including the American Academy of Orthopaedic Surgeons. This questionnaire includes the Ankle Osteoarthritis Scale (AOS)[8] and the Short Form-36 (SF-36) Standard Version 2.0 Health Survey[9]. Data collected at each study site were transferred to the central data site at the Queen Elizabeth II Health Sciences Center in Halifax, Nova Scotia, Canada.

Surgical Technique

Ankle arthrodesis was performed either open or arthroscopically, with no standard approach, utilizing modern techniques that included removal of the tibiotalar cartilage and penetration of subchondral bone, addition of autologous bone graft or bone graft substitute, and rigid internal fixation with compression. Ankle joint replacement involved one of four prostheses (Agility, STAR, Mobility, and HINTEGRA).

The Agility prosthesis (DePuy Orthopaedics, Warsaw, Indiana) is a semiconstrained ankle replacement with a cobalt-chromium talar component, a titanium tibial component, and a fixed polyethylene bearing[10]. The ingrowth surface consists of cobalt-chromium sintered beads. Fixation on the tibial side is aided by syndesmotic arthrodesis. Fixation on the talar side is achieved with use of a keel under a flat cut component. The only significant change in the Agility design during the study was the provision of a talar component with a larger surface area.

The STAR prosthesis (Scandinavian Total Ankle Replacement; Waldemar LINK, Hamburg, Germany; now distributed by Small Bone Innovations, Morrisville, Pennsylvania) is a cobalt-chromium mobile-bearing ankle replacement produced in a number of variations[11]. The STAR prosthesis used during the study was a cementless design with a plasma-sprayed titanium coat; no hydroxyapatite was used in this version. Fixation on the tibia was achieved with use of two barrels on the flat tibial component. The talar component was fixed with use of two side walls and a fin on the inferior surface.

The Mobility prosthesis (DePuy, Leeds, United Kingdom) is a mobile-bearing ankle replacement with cobalt-chromium components on the tibial and talar sides and a sintered bead ingrowth surface[12]. The tibial component has a stem placed into the tibia with an anterior bone window. The talar component has two fins on the inferior surface. No side walls are present on the talar component. The talar cut has three surfaces. The prosthesis underwent no design changes during the study.

The HINTEGRA prosthesis (Integra LifeSciences, Plainsboro, New Jersey) is a mobile-bearing ankle replacement with cobalt-chromium tibial and talar components[13]. The ingrowth surface is plasma-sprayed titanium with a hydroxyapatite coat. All inserted components have locking pegs on the talar component. The tibial component consists of a flat tray with raised spikes for bone fixation. The anterior side has a flange with holes for screw fixation. The talar component has medial and lateral walls and two fixation pegs; two screws may be used for added fixation if appropriate.

All components were inserted with use of standard cutting jigs and operative techniques as recommended by the manufacturers' surgical technique manual. Surgeons had appropriate training with the prostheses prior to use in patients.

Outcome Measures

The primary outcome measure was the total score on the AOS, which is a self-reported, ankle-specific functional outcome measure[8]. Secondary outcome measures included the AOS pain and disability subscales, the physical component summary (PCS) and mental component summary (MCS) subscales of the SF-36 (a generic measure of general health status[9]), and the need for revision. The AOS and SF-36 are responsive and show acceptable criterion validity in patients with end-stage ankle arthritis[14].

Revision following ankle replacement was defined as (1) reoperation requiring removal of one or both metal components of the prosthesis, or (2) amputation. Revision following ankle arthrodesis was defined as (1) reoperation for malunion or nonunion, or (2) amputation.

Major complications following arthrodesis were defined as malalignment requiring reoperation, nonunion requiring reoperation, or amputation. Major

TABLE I Baseline Characteristics for All Ankles Enrolled in the Study

	Total Cohort, N = 388	Arthrodesis, N = 107	Ankle Replacement, N = 281
Male sex	217 (56%)	64 (60%)	153 (54%)
Age* *(yr)*	61.5 ± 12.1	54.8 ± 12.4	64.1 ± 11.0
BMI* *(kg/m²)*	28.3 ± 4.9	28.7 ± 5.6	28.1 ± 4.7
Smoking history			
Never	174 (45%)	43 (40%)	131 (47%)
Not in the last 12 mo	154 (40%)	39 (36%)	115 (41%)
Within the last 12 mo	60 (15%)	25 (23%)	35 (12%)
Diabetes	42 (11%)	18 (17%)	24 (9%)
Inflammatory arthritis	65 (17%)	7 (7%)	58 (21%)
Right side	216 (56%)	61 (57%)	155 (55%)
Ankle replacement prosthesis			
Agility			69 (25%)
STAR			85 (30%)
Mobility			57 (20%)
HINTEGRA			70 (25%)
Preop. score†			
AOS total	51.3 ± 17.7 (383)	53.4 ± 18.1 (106)	50.6 ± 17.5 (277)
AOS pain	46.7 ± 18.7 (387)	48.6 ± 18.7 (106)	46.0 ± 18.7 (281)
AOS disability	56.1 ± 18.9 (383)	58.2 ± 19.7 (106)	55.3 ± 18.6 (277)
SF-36 MCS	49.3 ± 11.8 (374)	47.8 ± 12.9 (103)	49.9 ± 11.3 (271)
SF-36 PCS	31.7 ± 7.2 (374)	32.2 ± 7.1 (103)	31.6 ± 7.3 (271)

*The values are given as the mean and the standard deviation. †The values are given as the mean and the standard deviation, with the number of patients with score data in parentheses.

complications following ankle replacement were defined as implant failure or aseptic loosening leading to revision, a fractured polyethylene liner, deep infection requiring reoperation, or amputation[15].

Statistical Analysis

The time to revision surgery in each group was summarized with use of a Kaplan-Meier cumulative incidence plot. For patients who did not undergo revision, time was censored at the last follow-up score collection. All patients with a postoperative follow-up score were included in this analysis. For the analysis of outcome scores, only the preoperative and final follow-up (i.e., most recent) values were used. In keeping with the aim of characterizing intermediate-term results, the primary analysis included only patients with follow-up scores obtained at least four years after surgery; patients who underwent revision within four years after surgery were not excluded. Two subgroup analyses were conducted: (1) a sensitivity analysis that excluded patients who underwent revision and did not have an outcome score at least two years after the revision (to assess the impact of including data for patients requiring revision, who may not be good proxies for longer-term outcomes, in the primary analysis), and (2) an analysis that excluded all patients who underwent revision (to assess outcomes in only those patients not needing revision). To assess potential bias due to differential attrition in the two cohorts, all three of the preceding analyses were repeated for patients who had at least two years of follow-up (instead of four years). Patients who were missing data required for a given analysis were excluded.

A paired Student t test was used to assess improvements in AOS and SF-36 scores from baseline to final follow-up in each cohort. A linear mixed-effects regression model was used to compare outcome scores at final follow-up between the two groups, with adjustment for patient age, sex, operatively treated side, smoking status, BMI, inflammatory arthritis diagnosis, and baseline score. The surgeon was included as a random (cluster) effect. Results were reported with use of point estimates with corresponding 95% confidence intervals (CIs).

Source of Funding

Direct or indirect research funding for this study was received from Integra LifeSciences Corporation and DePuy. An unrestricted research grant from DePuy supported data collection involving the Mobility prosthesis for each patient entered in the COFAS database. Some patients receiving a Mobility ankle replacement at the Dalhousie site were also part of an independent radiostereometric analysis study supported by an unrestricted research grant from DePuy.

Results

From November 1, 2001, to July 31, 2007, 107 ankles in 107 patients underwent arthrodesis and 281 ankles in 262 patients underwent ankle replacement at one of the four participating sites. Baseline characteristics of the full cohort and the two patient subgroups are summarized in Table I. The arthrodesis group included ankles in sixty-four men (60%) and forty-three women. The ankle replacement group included 153 ankles in men (54%) and 128 in women. Patients in the arthrodesis group were younger (mean age, fifty-five compared with sixty-four years), more likely to be diabetic (17% compared with 9%), less likely to have inflammatory arthritis (7% compared with 21%), and more likely to have smoked during

TABLE II Baseline Characteristics of Ankles Evaluated at Least Four Years After Surgery

	Total Cohort, N = 321	Arthrodesis, N = 89	Ankle Replacement, N = 232
Follow-up* *(yr)*	5.5 ± 1.2 (4.0-9.8)	5.2 ± 0.9 (4.0-8.0)	5.6 ± 1.3 (4.0-9.8)
Male sex	171 (53%)	53 (60%)	118 (51%)
Age† *(yr)*	60.9 ± 12.0	53.7 ± 12.3	63.6 ± 10.7
BMI† *(kg/m²)*	28.2 ± 5.0	28.7 ± 5.5	28.0 ± 4.8
Smoking history			
Never	144 (45%)	34 (38%)	110 (47%)
Not in the last 12 mo	129 (40%)	35 (39%)	94 (41%)
Within the last 12 mo	48 (15%)	20 (22%)	28 (12%)
Diabetes	35 (11%)	15 (17%)	20 (9%)
Inflammatory arthritis	56 (17%)	6 (7%)	50 (22%)
Right side	176 (55%)	50 (56%)	126 (54%)
Ankle replacement prosthesis			
Agility			62 (27%)
STAR			73 (31%)
Mobility			44 (19%)
HINTEGRA			53 (23%)
Surgeon			
1	88 (27%)	18 (20%)	70 (30%)
2	25 (8%)	16 (18%)	9 (4%)
3	43 (13%)	26 (29%)	17 (7%)
4	39 (12%)	9 (10%)	30 (13%)
5	8 (2%)	2 (2%)	6 (3%)
6	118 (37%)	18 (20%)	100 (43%)

*The values are given as the mean and the standard deviation, with the range in parentheses. †The values are given as the mean and the standard deviation.

the past year (23% compared with 13%). Baseline AOS and SF-36 scores in the two groups were similar.

Of the 388 ankles enrolled in the study, 382 (276 in the ankle replacement group and 106 in the arthrodesis group) were reviewed during at least one follow-up visit. Of the remaining six cases (five ankle replacements, one arthrodesis) without at least one follow-up score, one patient died within two years for reasons unrelated to the ankle replacement, two treated with ankle replacement declined to participate postoperatively, and two treated with ankle replacement and one treated with arthrodesis were lost to follow-up. The mean follow-up duration (and standard deviation) was 5.2 ± 1.6 years (range,

TABLE III Complications for All Ankles Enrolled in the Study (N = 388)*

Complication	Total Cohort, N = 388	Arthrodesis, N = 107	Ankle Replacement, N = 281
None	329 (85%)	100 (93%)	229 (81%)
Implant failure or aseptic loosening, leading to revision	41 (11%)	0	41 (15%)
Fractured polyethylene liner	12 (3%)	0	12 (4%)
Deep infection requiring reoperation	3 (1%)	0	3 (1%)
Malalignment of fusion or nonunion, requiring reoperation	7 (2%)	7 (7%)	0
Amputation	5 (1%)	1 (1%)	4 (1%)

*The percentages total >100% because four ankles in the ankle replacement group and one in the arthrodesis group had multiple complications, with amputation performed as a result of the other complications.

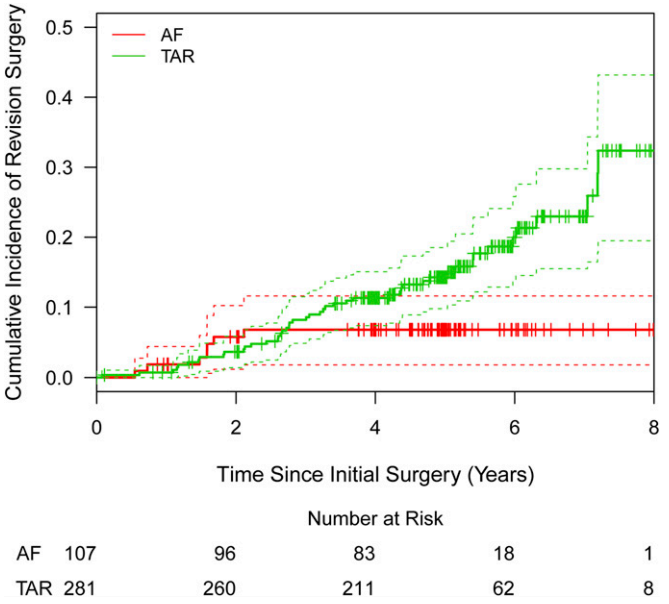

Fig. 1

Kaplan-Meier curve showing cumulative revisions after ankle arthrodesis (AF) and total ankle replacement (TAR). The dashed lines indicate the 95% confidence intervals.

0.1 to 9.8 years) for the ankle replacement group and 4.8 ± 1.5 years (range, 0.5 to 8.0 years) for the arthrodesis group. Of the 388 ankles, 382 had at least one follow-up score, and 321 (83%; 232 in the ankle replacement group and eighty-nine in the arthrodesis group) had at least four years of follow-up. The sixty-one ankles in which the latest follow-up score was less than four years postoperatively included forty-four in the ankle replacement group and seventeen in the arthrodesis group. The characteristics of the ankles evaluated at least four years postoperatively (Table II) were similar to those of the full cohort.

Eight major complications (7%), including one amputation, were observed in seven (7%) of the 107 ankles treated with arthrodesis (Table III), all of which required revision. Sixty major complications, including four amputations, were observed in fifty-two (19%) of the 281 ankles treated with ankle replacement (Table III); these led to revision in forty-eight ankles (17%). In the arthrodesis group, all revisions occurred within 2.5 years of the initial surgery. In the ankle replacement group, revisions were spread throughout the entire follow-up period (Fig. 1). Of the fifty-five ankles that underwent revision, twelve (22%; all in the ankle replacement group) had no follow-up scores after revision, and the latest follow-up scores for the remainder were obtained at least two years after the revision. There was no indication that complication rates were related to surgeon experience.

The AOS total, pain, and disability scores and SF-36 PCS scores of the patients with at least four years of follow-up all improved between the baseline and final follow-up time points in each group; the changes in the SF-36 MCS scores were minimal (Fig. 2, Table IV). The mean improvement in the AOS total score in the arthrodesis group was 19.5 points (95% CI, 15.2 to 23.8 points), from 53.4 to 33.6 points, where a lower score reflects less pain and better function. The AOS total score in the ankle replacement group improved by a mean of 25.7 points (95% CI, 23.1 to 28.3 points), from 51.9 to 26.4 points. A power calculation based on the eighty-nine ankles in the arthrodesis group and 232 in the ankle replacement group that met the inclusion criteria for comparison of the AOS total scores (omitting consideration of clustering by surgeon) and an observed standard deviation of 25 points in the change from baseline to follow-up

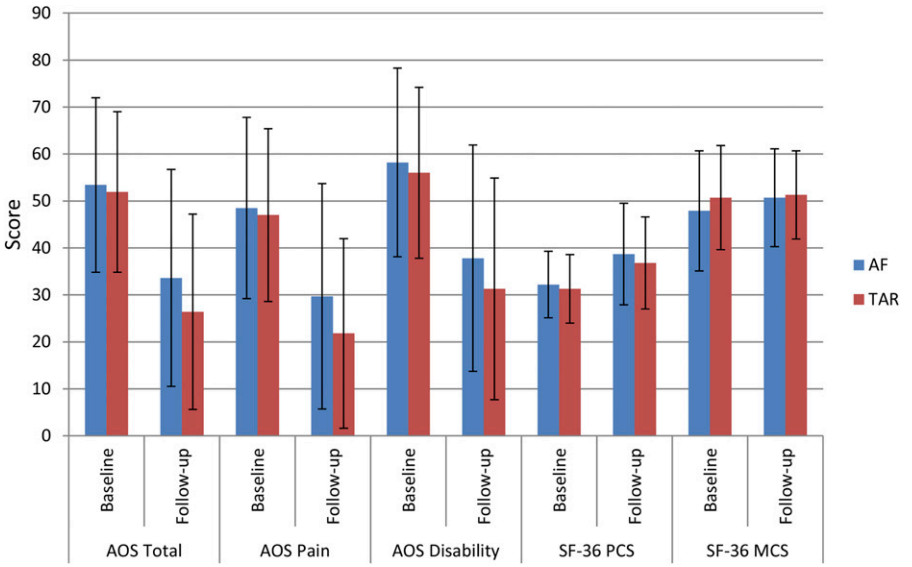

Fig. 2

Outcome scores at baseline and at the time of final follow-up (minimum, four years) in the ankle arthrodesis (AF) and total ankle replacement (TAR) groups are graphed as the mean and the standard deviation. The number of patients who answered individual questions varied from eighty-seven to eighty-nine in the arthrodesis group and from 218 to 232 in the ankle replacement group.

TABLE IV Change in Outcome Scores from Baseline to Final Follow-up

	Arthrodesis, N = 89*		Ankle Replacement, N = 232*	
	Mean and Std. Dev.	95% CI	Mean and Std. Dev.	95% CI
AOS				
Total	−19.5 ± 24.3	−23.8 to −15.2	−25.7 ± 23.5	−28.3 to −23.1
Pain	−18.6 ± 25.6	−23.1 to −14.0	−25.4 ± 23.4	−27.9 to −22.8
Disability	−20.3 ± 25.9	−24.8 to −15.7	−25.6 ± 26.7	−28.5 to −22.6
SF-36				
PCS	6.6 ± 11.7	4.5 to 8.7	5.4 ± 10.9	4.2 to 6.6
MCS	2.9 ± 11.5	0.8 to 4.9	0.5 ± 10.2	−0.6 to 1.6

*The number of patients who answered individual questions varied from eighty-seven to eighty-nine in the arthrodesis group and from 218 to 232 in the ankle replacement group.

TABLE V Difference Between Raw and Adjusted Outcome Scores at the Time of Final Follow-up

	Arthrodesis − Ankle Replacement*			
	Raw	Adjusted†		
	Total Cohort, N = 89:232	Total Cohort, N = 89:232	Excluding Revised Ankles with <2 Years of Follow-up After Revision, N = 89:218	Excluding All Revised Ankles, N = 85:195
AOS total	6.7 (1.0 to 12.3) in 89:223	3.8 (−2.1 to 9.8) in 88:221	4.9 (−1.0 to 10.8) in 88:207	4.9 (−1.1 to 10.9) in 84:186
AOS pain	7.6 (2.0 to 13.2) in 89:229	3.8 (−2.1 to 9.8) in 88:229	4.8 (−1.1 to 10.8) in 88:215	4.6 (−1.4 to 10.5) in 84:193
AOS disability	5.8 (−0.4 to 12.0) in 89:224	3.9 (−2.6 to 10.5) in 88:224	5.0 (−1.6 to 11.5) in 88:208	5.2 (−1.5 to 11.9) in 84:187
SF-36 PCS	1.1 (−1.5 to 3.8) in 88:225	−0.2 (−3.2 to 2.7) in 87:218	−0.6 (−3.5 to 2.4) in 87:205	−0.4 (−3.4 to 2.7) in 83:185
SF-36 MCS	−2.3 (−4.7 to 0.2) in 88:225	0.5 (−1.9 to 3.0) in 87:218	−0.3 (−2.1 to 2.8) in 87:205	−0.1 (−2.5 to 2.3) in 83:185

*The N values are given as arthrodesis:ankle replacement, and the scores are given as the mean, with the 95% CI in parentheses. †Adjusted for age, sex, side, inflammatory arthritis, smoking, diabetes, BMI, preoperative outcome score, and surgeon.

across these patients indicated that the minimum detectable difference between the groups would have been 8.7 points at a significance level of 0.05 and 80% power.

Raw and adjusted mean differences in outcome scores between the groups at the final follow-up were also evaluated in the ankles with a minimum of four years of follow-up (Table V). For the unadjusted AOS total score, patients treated with arthrodesis scored 6.7 points (95% CI, 1.0 to 12.3 points) higher on average (i.e., had a worse score) compared with patients treated with ankle replacement. However, after adjustment for baseline patient characteristics (age, sex, operatively treated side, smoking status, BMI, inflammatory arthritis, and baseline AOS score) and surgeon, the difference between the final AOS total scores in the arthrodesis and ankle replacement groups was attenuated substantially (3.8 points; 95% CI, −2.1 to 9.8 points). The difference was also attenuated in the sensitivity analyses that excluded revised ankles without follow-up scores at least two years after revision (4.9 points; 95% CI, −1.0 to 10.8 points) and that excluded all revised ankles (4.9 points; 95% CI, −1.1 to 10.9 points). Differences between the arthrodesis and ankle replacement groups were small for both the SF-36 PCS (1.1 points; 95% CI, −1.5 to 3.8 points) and MCS (−2.3 points; 95% CI, −4.7 to 0.2 points) in the analysis of the raw scores and near zero after adjustment in both the primary and subgroup analyses.

Discussion

This prospective, multicenter cohort study evaluated multiple outcomes of ankle arthrodesis and ankle replacement in 382 patients at intermediate-term follow-up, with variability involving surgeon, surgical approach, and type of prosthesis used. Detailed analysis of both groups indicated that clinical outcomes after both ankle replacement and ankle arthrodesis were satisfactory at a mean of five years postoperatively. It is important to note that these procedures were performed by subspecialty-trained foot and ankle surgeons who selected carefully and performed the procedure that they felt to be most appropriate for each individual patient. A review of the raw data suggested that intermediate-term AOS scores were better in the ankle replacement group. However, an adjusted analysis showed that a substantial portion of this difference was explained by differences in patient characteristics and surgeon.

Only a few clinical trials have compared the outcomes of ankle arthrodesis and ankle replacement. Saltzman et al.[4] reported on a prospective, controlled clinical trial comparing

the efficacy of ankle replacement (with a STAR prosthesis) in 456 patients with ankle arthrodesis in forty-seven patients. They reported a better Buechel-Pappas function score following ankle replacement and equivalent Buechel-Pappas pain scores at twenty-four months postoperatively. Slobogean et al.[5] demonstrated similar mean SF-6D health state values in sixty-one patients treated with ankle replacement and forty-six treated with arthrodesis at one year postoperatively.

In the present study, the revision rate observed in the ankle replacement group (17%) was approximately twice as high as that in the arthrodesis group (7%). A systematic review of the literature revealed revision rates ranging from 0% to 32% at five years after ankle replacement, with an overall failure rate of 10%[16]. A review of national registry data from Norway, Sweden, and New Zealand revealed mean revision rates of 21.8% and 43.5% at five and ten years, respectively, after ankle replacement with STAR, Agility, Buechel-Pappas, HINTEGRA, Mobility, and Ramses prostheses[17]. Another literature review revealed nonunion rates ranging from 3% to 15% after ankle arthrodesis[18]. The higher revision rate after ankle replacement is likely due, in part, to the complexity of ankle replacement surgery and the unique biomechanics of the ankle joint. As prosthesis designs and surgical techniques continue to improve, there is a potential for revision rates after ankle replacement to decline.

The present comparative clinical study has several strengths. The study population was large, with a cohort of 382 ankles (276 ankle replacements, 106 arthrodeses). Only two previously published comparative studies have had cohorts of more than 100 patients[4,5]. Another strength is the duration and completeness of follow-up (with 83% of patients having at least four years of follow-up), providing an opportunity to accurately evaluate intermediate-term outcomes of ankle surgery. Furthermore, this study presents an unbiased evaluation of the current status of ankle arthrodesis and ankle replacement, with variability in surgical approach and type of implant. It reflects the actual clinical use of these procedures based on what was felt to be most appropriate following consultation with each individual patient. It is therefore not surprising that both procedures produced large improvements in clinical outcome scores.

The ankle replacement prostheses used in this study have been evaluated for safety, intermediate-term outcomes, and revision rates in single-design clinical trials[16]. In our experience with these designs, no substantial prosthesis-related issues have arisen that would lead to bias due to variability among prostheses in the present study.

Surgeon judgment and selection were a part of the process in the present study and may have led to bias. The indications for ankle replacement were not the same as those for ankle arthrodesis. In general, arthrodesis is considered in younger patients; those who have physically demanding jobs or played impact sports; those with isolated ankle arthritis, diabetes, or compromised soft tissues and integument; and those with a recent history of infection. Ankle replacement is a viable option in patients with more extensive arthritis, advanced age, ipsilateral hindfoot arthritis, and less strenuous physical demands[19-21]. The significant differences in patient characteristics (age, diabetes, smoking status, and inflammatory arthritis diagnosis) between the study groups were expected and may have contributed to the better outcome scores observed after ankle replacement in the analysis of the raw scores. In the linear mixed-effects regression model, adjustments were made for patient age, sex, operatively treated side, smoking status, BMI, inflammatory arthritis diagnosis, and baseline score to minimize potential bias, and these adjustments resulted in a substantial attenuation of the difference between the final AOS scores in the arthrodesis and ankle replacement groups. Another limitation of this study is the fact that we did not differentiate among implant types, etiologies leading to surgery, or preoperative or intraoperative COFAS classifications[7,22]. Designation of cohorts according to these variables may be a consideration for future studies. Finally, we reported only major complications requiring revision, reoperation, or amputation and did not include postoperative complications that, in our opinion, would not influence intermediate-term patient outcomes (e.g., delayed wound-healing that resolved without surgical intervention, minor sensory nerve injury, and stress fracture).

In conclusion, the intermediate-term clinical outcomes of ankle replacement and arthrodesis in a diverse cohort of patients were comparable, even when patients who required revision ankle replacement were included; however, the rates of additional surgery and major complications were higher after ankle replacement than after arthrodesis. Both ankle replacement and arthrodesis had the capacity to provide acceptable results when the treatment was tailored to the patient's condition, as defined in this study by six surgeons in four sites across Canada. ■

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