

Impact of Complications in Total Ankle Replacement and Ankle Arthrodesis Analyzed with a Validated Outcome Measurement

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Background: Major modifications in the design and techniques of total ankle replacement have challenged the perception that ankle arthrodesis is the treatment of choice for end-stage ankle arthritis. High complication and revision rates have been reported after both procedures.

Methods: We performed radiographic evaluations at a mean of thirty-nine months following 114 total ankle replacements done with use of commonly used implants and at a mean of thirty-seven months following forty-seven ankle arthrodeses. The mean age was sixty-four years for the patients (fifty-one female and sixty-three male) who underwent total ankle replacement and fifty-nine years in the patients (fifteen female and thirty-two male) who underwent ankle arthrodesis. The impact of complications was analyzed with use of the Ankle Osteoarthritis Scale (AOS), a validated outcome instrument.

Results: Both groups had significant improvement in the mean AOS score ($p < 0.001$). There was no significant difference in the mean improvement between the two groups ($p = 0.96$). The complication rate was 54% following total ankle replacement and 26% following ankle arthrodesis, which was a significant difference ($p = 0.003$). The impact of major complications on the AOS outcome score was significant in both the total ankle replacement group ($p = 0.031$) and the ankle arthrodesis group ($p = 0.02$).

Conclusions: At the time of follow-up, at a minimum of two years postoperatively, the outcomes of total ankle replacement and ankle arthrodesis, with regard to pain relief and function, were comparable. While the rate of complications was significantly higher following total ankle replacement, the impact of complications on outcome was clinically relevant in both groups.

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

End-stage ankle arthritis is a debilitating condition that causes functional limitation and poor quality of life¹⁻³. Ankle arthrodesis is the standard treatment when non-operative management has failed. Modern arthrodesis techniques have yielded good intermediate-term results⁴⁻⁷. In the longer term, ankle arthrodesis has been associated with the premature development of adjacent joint arthritis, pain, and dysfunction¹. Moreover, major modifications in the design of total ankle replacement have challenged the concept that ankle arthrodesis is the treatment of choice for severe arthritis⁸⁻¹¹.

High complication rates of >50% have been seen with both procedures at intermediate and long-term follow-up evaluations, and mean revision rates of 11% for ankle arthrodesis and 21% for total ankle replacement at the time of a five-year follow-up have been reported⁸⁻¹⁵. Aseptic loosening of implants, malalignment, and impingement are common complications following total ankle replacement¹⁵⁻¹⁷. Frequent complications after ankle arthrodesis include nonunion, malalignment, and later adjacent joint arthritis¹⁸. A recent literature review revealed comparable intermediate and long-term outcomes following

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total ankle replacement and ankle arthrodesis but indicated a major lack of objective data from controlled studies^{19,20}.

The purpose of the present study was to analyze the number and impact of complications associated with total ankle replacement and ankle arthrodesis, with use of a validated outcome instrument to measure pain and disability, and to assess the effect of case complexity on the outcome. We hypothesized that, after a minimum of two years of follow-up, the patients who had undergone ankle arthrodesis would have fewer complications and a lower revision rate and that complications would significantly impair the clinical outcome and satisfaction in both groups.

Materials and Methods

The study was approved by the institutional research ethics board, and all participants prospectively provided informed consent.

From February 2002 to August 2007, data collected from 516 patients following total ankle replacement or ankle arthrodeses were entered into the database. Nonoperative treatments for end-stage ankle arthritis had been unsuccessful for all patients. Indications for ankle arthrodesis were severe deformity and instability, poor ankle motion, no or mild adjacent joint arthritis, and a younger age. Indications for total ankle replacement were an older age, severe adjacent joint arthritis, a diagnosis of rheumatoid arthritis, and no or only mild deformity or instability. Patient preference was also a factor.

A total of 114 total ankle replacements in 112 patients and forty-seven ankle arthrodeses in forty-seven patients met our inclusion criteria—namely, a complete data set; a minimum duration of follow-up of twenty-four months; a diagnosis of rheumatoid arthritis, posttraumatic arthritis, osteonecrosis, or primary osteoarthritis; and a primary procedure. Exclusion criteria were a revision procedure, a custom-made total ankle replacement, or a takedown of an ankle arthrodesis. Patients with a primary total ankle replacement who subsequently underwent revision with exchange of components or conversion to an ankle arthrodesis remained in the study group since we were focusing on the impact of complications on outcome. Patient demographics are presented in Table I.

To minimize the influence of a single arthroplasty design, we included four implant designs: the Agility (DePuy Orthopaedics, a Johnson & Johnson Company, Warsaw, Indiana), Mobility (DePuy), STAR (Waldemar Link, Hamburg, Germany), and HINTEGRA (Newdeal, Lyon, France) implants. The selection of a

specific arthroplasty design evolved over time and was determined by surgeon preference. Both open and arthroscopic arthrodesis techniques were used. Arthroscopic arthrodesis was typically performed in patients with a potential for wound-healing problems, no or minor deformity, and minimal bone loss.

All surgical procedures were performed by, or under the direct supervision of, three fellowship-trained foot and ankle surgeons who had practiced foot and ankle surgery exclusively for more than six years. Standard contemporary operative techniques were used according to each surgeon's preference.

Postoperatively, a splint was applied and the patient remained hospitalized for two to five days. Until wound-healing occurred, usually at ten to fourteen days postoperatively, patients were kept non-weight-bearing. Then the patients walked with partial weight-bearing while wearing a weight-bearing fiberglass cast or walker boot for six weeks. There was minimal difference in the postoperative care among the various procedures.

The Ankle Osteoarthritis Scale (AOS) was used to evaluate all patients at six, twelve, and twenty-four months and 3.5, five, and ten years postoperatively. The AOS is a simple, reliable, and validated outcome measure for the clinical assessment of patients with ankle osteoarthritis (see Appendix)^{21,22}. This self-administered scoring system specifically measures symptoms and disabilities related to arthritis of the ankle and has shown excellent reliability for both pain and disability^{21,22}.

The complexity of each case was evaluated with use of the Canadian Orthopaedic Foot & Ankle Society (COFAS) end-stage ankle arthritis classification system (see Appendix)²³. The case complexity was correlated with the number of complications and the AOS score.

Standard weight-bearing anteroposterior and lateral radiographs of the foot and ankle were reviewed by the surgeons. Computed tomography (CT) scans were used to evaluate healing of the fusion.

Deep infection was confirmed by bacterial growth beneath the fascia or in the ankle joint, an elevated erythrocyte sedimentation rate, and an elevated C-reactive protein level. A patient was determined to have osteomyelitis when there was bacterial growth from bone samples.

Unvalidated criteria used to determine aseptic loosening of a total ankle replacement component were described by Doets et al.⁹ and included a change in the angular position of >3°, subsidence of >3 mm seen on any radiograph, or a complete radiolucent line >1 mm in thickness on both radiographs of the tibial component and on the lateral radiograph of the talar component. Technical errors included gutter impingement, malalignment, excessive polyethylene wear, and the wrong implant size. Malalignment was defined as varus or valgus

TABLE I Patient Demographics

	Total Ankle Replacement	Arthrodesis
No. of op./patients	114/112 (61 Agility, 22 HINTEGRA, 16 STAR, 15 Mobility)	47/47 (22 open, 25 arthroscopic)
Female/male	45%/55% (51/63)	32%/68% (15/32)
Body weight* (kg)	76.5 ± 12.3	78 ± 8.8
Height* (m)	1.69 ± 0.09	1.67 ± 0.08
Left/right (no.)	51/63	24/23
Diagnosis		
Posttraumatic arthritis	54% (62)	60% (28)
Rheumatoid arthritis	33% (38)	15% (7)
Primary osteoarthritis	12% (14)	26% (12)
Age at op.† (yr)	64.2 (36 to 88)	58.5 (28 to 82)
Duration of follow-up† (mo)	38.7 (25 to 68)	36.5 (28 to 109)

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

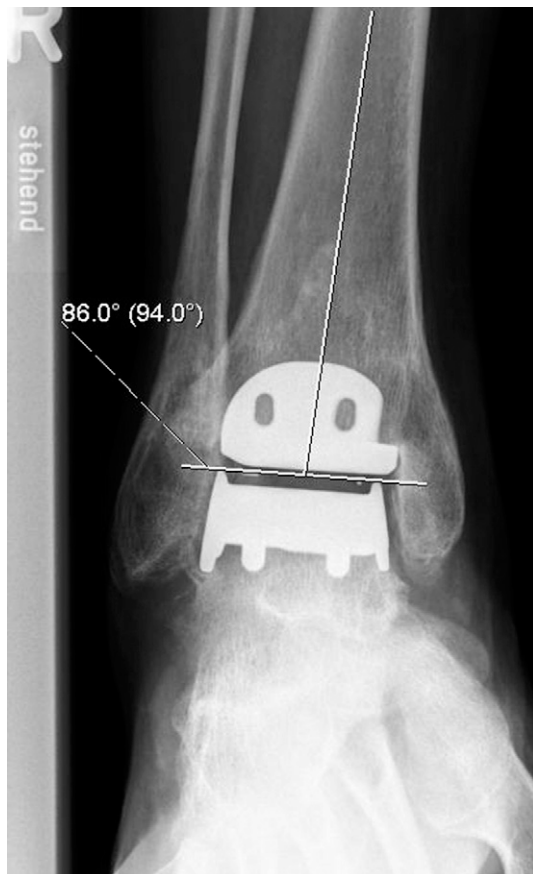


Fig. 1-A



Fig. 1-B

Figs. 1-A and 1-B Correct postoperative alignment of the HINTEGRA total ankle replacement components. **Fig. 1-A** Anteroposterior weight-bearing ankle radiograph showing the frontal angular position of the tibial component in relation to the long axis of the tibia (94° , slight varus). **Fig. 1-B** Lateral weight-bearing ankle radiograph showing the sagittal angular position of the tibial component in relation to the long axis of the tibia (4° positive slope) and the sagittal angular position of the talar component, which is created by a line drawn parallel to the talar component and a line drawn through the long axis of the talus.

angulation of the tibial component of $>5^\circ$ and an anterior slope of the tibial component of $>10^\circ$ or a posterior slope of $<0^\circ$ with respect to the longitudinal tibial axis as measured on anteroposterior and lateral radiographs, respectively (Figs. 1-A and 1-B).

Malalignment was the only technical error in ankle arthrodesis and was defined as varus or valgus angulation of $\geq 10^\circ$ at the intersection of a line drawn defining the talar shoulders and the longitudinal tibial axis on the anteroposterior radiograph (Fig. 2-A)²⁴. On the lateral radiographs, a variation of $>5^\circ$ from the 106° angle (neutral) created by a line drawn from the inferior aspect of the posterior tubercle of the talus to the most inferior aspect of the talar neck and its intersection with the longitudinal tibial axis was defined as malalignment (Fig. 2-B)²⁵.

The onset or progression of arthritis in the adjacent joints was defined as a change of at least one grade of impairment according to the system described by Kellgren and Lawrence²⁶.

The criteria used to determine the occurrence of a nonunion included the persistence of pain on manipulation and weight-bearing, a complete radiographic lucency with no visualization of trabeculae crossing the fusion site more than nine months after surgery, and failure of internal fixation¹⁴. The presence of a nonunion was always confirmed by CT.

Other major complications were intraoperative partial nerve lesions, nonspecific postoperative persistent pain, intraoperative fractures, and chronic regional pain syndrome.

In both study groups, minor complications that did not require an operative procedure and resolved without sequelae within six months were not considered to have an impact on the outcome. Medical complications were not studied.

Statistical Methods

Statistical evaluation of significance was performed with the two-sample Student t test for differences in AOS-score improvement and in the impact of complications on the outcome between groups; the one-sample Student t test for AOS-score improvement in either group; the chi-square test for differences in the number of complications between the total ankle replacement and ankle arthrodesis groups and for differences in the distribution of complex cases (COFAS classification) among the different total ankle replacement designs and between the open and arthroscopic ankle arthrodeses; the nonparametric Mann-Whitney U test for correlation of case complexity (COFAS classification) and the number of major complications; univariate analysis of variance (ANOVA) for the influence of different total ankle replacement designs and arthrodesis techniques on the number of major complications and their influence on the AOS score; and univariate ANOVA with the Bonferroni post hoc test for the impact of single complications on the AOS score (only in the total ankle replacement group; this calculation was not feasible for the ankle arthrodesis group because of the low number of complications), for correlations of case complexity and changes in the AOS score, and for the influence of the

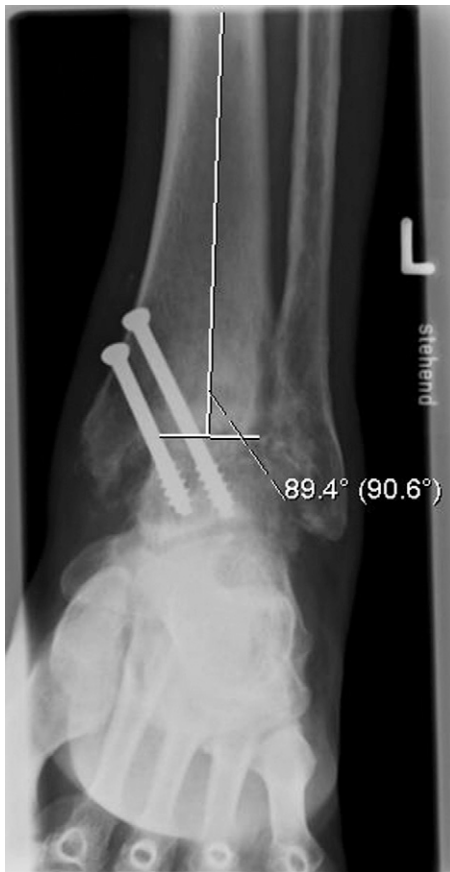


Fig. 2-A



Fig. 2-B

Figs. 2-A and 2-B Correct postoperative alignment of an ankle arthrodesis. **Fig. 2-A** Anteroposterior weight-bearing ankle radiograph showing the frontal alignment of the arthrodesis as defined by a line through the talar shoulders intersecting with the longitudinal tibial axis. **Fig. 2-B** Lateral weight-bearing ankle radiograph showing the sagittal alignment of the ankle arthrodesis as measured by a line drawn from the inferior aspect of the posterior tubercle of the talus to the most inferior aspect of the talar neck and its intersection with the longitudinal tibial axis (in this case 109.9°, indicating 4° of plantar flexion).

etiology of the arthritis (e.g., rheumatoid arthritis) on the outcome. The level of significance was set to $\alpha = 0.05$.

Source of Funding

The study was funded by Biomimetics, Wyeth, and Zimmer.

Results

The patients' results are listed in Tables II, III, and IV. The complication rate was 54% in the total ankle replacement group and 26% in the ankle arthrodesis group. Both groups had a significant and similar overall improvement in the mean AOS score (both $p < 0.001$), which was 30.9 points in the total ankle replacement group and 30.6 points in the arthrodesis group.

The rate of major complications was significantly higher in the total ankle replacement group (sixty-two of 114) than in the arthrodesis group (twelve of forty-seven, $p = 0.003$). The impact of major complications on the AOS score was significant in both the total ankle replacement group (34.8 versus 25.7 points for patients without and with a complication, respectively; $p = 0.031$) and in the arthrodesis group (32.8 versus 23.5 points; $p = 0.02$) (Table II).

Aseptic loosening occurred after 15% (seventeen) of the 114 total ankle replacements (Table III), with a mean improvement in the AOS score, between baseline and the time of follow-up, of 9.4 points in the seventeen cases. Eleven ankles with aseptic loosening (eight with an Agility implant, two with a Mobility implant, and one with a STAR implant) had revision surgery with exchange of at least one component (mean improvement in AOS score from baseline to the latest follow-up visit after the reoperation, 9.7 points), and five had been treated nonoperatively at the time of the most recent follow-up (mean improvement in AOS score, 8.1 points). One was converted to a tibiototalcalcaneal arthrodesis with use of a retrograde nail. With the numbers studied, the difference in the score improvement between the revised and non-revised cases was not significant ($p = 0.76$).

A technical error occurred in 15% (seventeen) of the 114 total ankle replacements (mean improvement in AOS score in the seventeen cases, 31.8 points): twelve ankles had medial or lateral gutter impingement (mean improvement in AOS score, 35.1 points), three had excessive polyethylene wear or breakage

TABLE II Results

	Total Ankle Replacement	Arthrodesis
No. of cases	114 (61 Agility, 22 HINTEGRA, 16 STAR, 15 Mobility)	47 (22 open, 25 arthroscopic)
COFAS end-stage ankle arthritis classification		
Type 1	32% (37)	87% (41)
Type 2	16% (18)	4% (2)
Type 3	11% (13)	0%
Type 4	40% (46)	9% (4)
Mean AOS score (points)		
Baseline		
Overall score*	56.1 (11.1 to 96.3)	54.2 (18.5 to 94.4)
Pain domain	30.7	29.2
Disability domain	25.4	25.0
Latest follow-up		
Overall score*	25.2 (0 to 79.2)	23.6 (0 to 67.9)
Pain domain	14.5	10.3
Disability domain	10.7	13.3
Improvement		
Overall score†	30.9 (−20.4 to 96.3 [26.1 to 34.7])	30.6 (−11.9 to 80.4 [24.4 to 36.8])
Significance	p < 0.001	p < 0.001
Pain domain	16.2	18.9
Disability domain	14.7	11.7
Mean improvement in AOS score according to presence/absence of complication (points)		
Overall score		
No complication†	34.8 (−20.4 to 75.6 [5.5 to 64.1])	32.8 (−1.5 to 80.4 [7.1 to 58.5])
Complication†	25.7 (−18.2 to 96.3 [6.5 to 44.9])	23.5 (−11.9 to 49.4 [13.6 to 33.4])
Significance	p = 0.031	p = 0.02
Pain domain		
No complication	17.6	20.8
Complication	11.6	13.9
Disability domain		
No complication	17.2	12.0
Complication	14.1	9.6
Mean improvement in AOS score in patients with complication (points)		
Score improvement prior to reoperation	4.6 (n = 12)	Not available (n = 1)
Score improvement after reoperation	14.5 (n = 12)	Not available (n = 1)
Score improvement in patients with complication not treated with reoperation	27.9	23.5
Complication rate	54% (62)	26% (12)

*The values are given as the mean with the range in parentheses. †The values are given as the mean with the range in parentheses and the 95% confidence interval in brackets.

(mean improvement in AOS score, 20.6 points), and two had malalignment (mean improvement in AOS score, 13.9 points). The mean AOS-score improvement from baseline to the time of the latest follow-up after the reoperation in the four cases treated surgically for impingement was 37.2 points compared with a mean improvement of 33.4 points for the eight treated nonoperatively.

There were eight intraoperative fractures (7%), which were treated with internal fixation during the index operation. There were six lateral malleolar fractures, one medial malleolar fracture, and one talar neck fracture.

Deep infection occurred in association with 6% (seven) of the 114 total ankle replacements (mean improvement in AOS score in the seven cases, 41.2 points). Five cases were

TABLE III Comparison of Complication Rates of Total Ankle Replacement in the Present Study and the Literature*

	Present Study	Total Ankle Replacement Literature
No. of cases	114	2386
Mean duration of follow-up (mo)	38.7	63.3
Complication rate (%)		
Aseptic loosening	15	10.7
Intraop. fracture	7	4.2
Postop. fracture	3	1.3
Deep infection	6	1.5
Nonunion	4	1.4
Technical error	15	8.5
Other	4	0
All complications	54	29.5 (range, 4.4 to 98.1)

*The literature selection includes all relevant studies of total ankle replacement published in the last decade^{8-10,13,16,17,33-46}.

treated with antibiotics, irrigation, debridement, and a vacuum dressing, and one also required an exchange of the total ankle replacement components.

There were four cases of nonunion of an adjacent joint fusion (4%); these consisted of two talonavicular, one naviculocuneiform, and one syndesmosis fusion. The mean improvement in the AOS score from baseline to the time of the latest follow-up after the reoperations for these nonunions was 30.1 points. Revision was successful in each case at the time of the latest follow-up.

Other complications included the onset of subtalar arthritis in two patients (an increase from grade 0 to 2 in one and from grade 0 to 3 in the other) as well as the onset of talonavicular arthritis in one (an increase from grade 0 to grade 2). There were three postoperative stress fractures (one of the tibial diaphysis and one of the medial malleolus), which healed with nonoperative treatment. Two patients had an intraoperative deep peroneal nerve lesion: one of them had nonspecific ongoing pain, and the other had persistent chronic regional pain syndrome. The two nerve lesions were treated nonoperatively; one almost completely resolved within two years, and the other patient has ongoing hypesthesia.

The overall impact of complications on the outcome of total ankle replacement was significant ($p = 0.031$). Aseptic loosening had the highest impact, and this impact was significantly greater ($p = 0.039$) than that of deep infection and slightly, but not significantly, greater than that of technical error.

Among the patients treated with ankle arthrodesis (Table IV), three had the onset or progression of adjacent joint arthritis (mean improvement in AOS score, 32.1 points). At the five-year follow-up evaluation, two patients were found to have developed subtalar arthritis (an increase from grade²⁶ 0 to 2 in one and from grade 0 to 3 in the other). The remaining patient had progression of talonavicular arthritis (an increase from

grade 1 to 3), which was also noted at the five-year follow-up evaluation. No patient had been scheduled for surgical treatment of adjacent joint arthritis.

Nonunion of the ankle fusion occurred in two cases. Revision of each was successful at the most recent follow-up evaluation.

There was one technical error—a case of ankle varus malalignment, which was corrected with a lateral sliding calcaneal osteotomy.

Other complications included two cases of medial-gutter-related discomfort and two cases of nonspecific ongoing pain. All patients experiencing discomfort declined additional surgery. One intraoperative lesion of the superficial peroneal nerve occurred. One intraoperative fracture of the medial malleolus also occurred and was fixed during the index operation. No deep infections or cases of osteomyelitis were seen.

Case Complexity

The distribution of COFAS classification types²³ is outlined in Table II. There were significantly more complex cases in the total ankle replacement group ($p = 0.002$) (see Appendix). Increasing complexity correlated significantly with the rate of complications in both the total ankle replacement group ($p = 0.032$) and the ankle arthrodesis group ($p < 0.001$, Fig. 3), but it did not correlate with poor AOS scores in either group (both $p > 0.05$).

The distribution of complex cases (COFAS classifications) correlated significantly with the different total ankle replacement designs ($p = 0.011$). Type-3 and 4 cases were treated most frequently with an Agility arthroplasty, with 61% (thirty-seven) of the sixty-one Agility prostheses used for types 3 and 4, followed by the STAR arthroplasty (56% [nine] of the sixteen STAR prostheses were used for types 3 and 4), the Mobility arthroplasty (40% [six of fifteen]), and the HINTEGRA arthroplasty (23% [five of twenty-two]) arthroplasties. Similarly, the highest rate of complications was recorded for the Agility

TABLE IV Comparison of Complication Rates of Arthrodesis in the Present Study and in the Literature*

	Present Study	Arthrodesis Literature
No. of cases	47	606
Mean duration of follow-up (mo)	36.5	134.7
Complication rate (%)		
Adjacent joint arthritis	6	28.3
Nonunion	4	5.2
Deep infection	0	1.2
Technical error	2	2.5
Other	9	12
All complications	21	49.2 (range, 15-63)

*The literature selection includes all relevant studies of ankle arthrodesis published in the last decade^{1,14,20,27,28,31,32,47-50}.

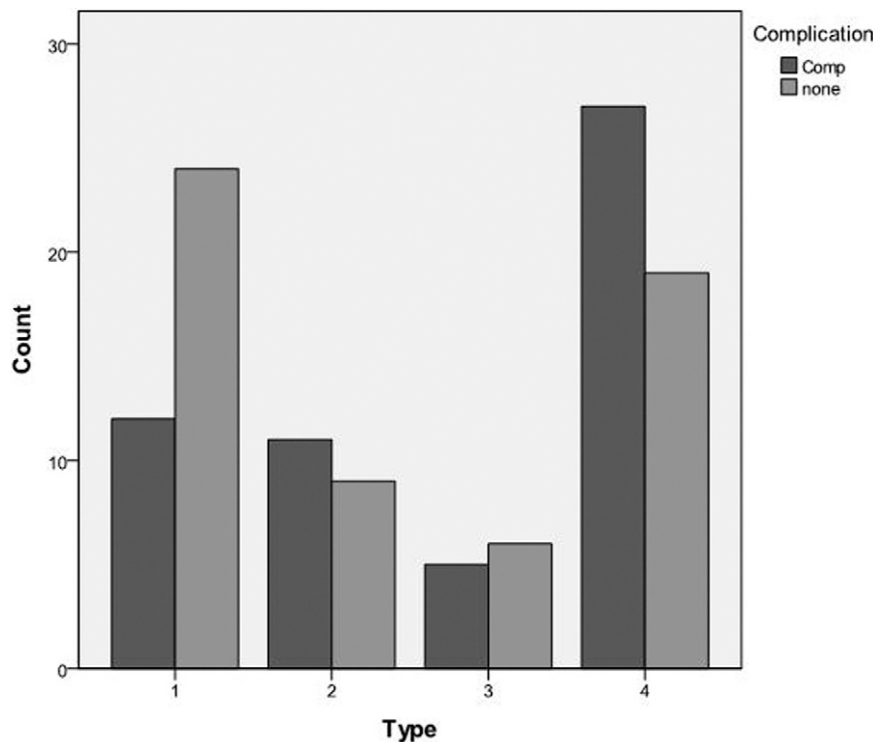


Fig. 3

The complication rate among cases with increasing complexity (types 1 through 4) according to the COFAS end-stage ankle arthritis classification system for all 161 cases combined.

arthroplasty (61% [thirty-seven] of the sixty-one Agility implants), followed by the Mobility arthroplasty (47% [seven of fifteen]), the STAR arthroplasty (44% [seven of sixteen]), and the HINTEGRA arthroplasty (18% [four of twenty-two]).

The distribution of more complex cases also correlated significantly with the two ankle arthrodesis techniques (open and arthroscopic, $p = 0.02$). All complex cases (types 3 and 4) were treated with an open ankle arthrodesis (six [27%] of the twenty-two open procedures were done for types 3 and 4), while no complex cases were treated with the arthroscopic technique. With the numbers studied, we could not identify a significant correlation between either the specific total ankle replacement design or the specific ankle arthrodesis technique and the AOS score (all $p > 0.05$). Nor could we identify differences in the AOS score with regard to the specific etiology of the ankle arthritis.

Minor complications that were not considered in the statistical calculations were eighteen cases of superficial wound dehiscence, four cases of wound-edge necroses, and one hematoma. Twelve cases of dehiscence, one case of wound-edge necrosis, and the hematoma were revised surgically. All resolved within six months. Implants (screws and plates) were removed in nineteen cases.

Discussion

Ankle arthrodesis is considered the standard treatment for end-stage ankle arthritis, even though it has disadvantages. Potential complications in the short term include nonunion (in

<10% of cases^{14,27,28}), malalignment, and deep infection. Disturbed gait following ankle arthrodesis has been documented^{29,30}. A substantial risk of deterioration of the adjacent joints over the long term has been described^{1,31,32}.

Total ankle replacement has certain theoretical advantages over ankle arthrodesis^{9,15,19}. Gait is affected less, and adverse effects on the adjacent joints are not expected⁹. An acceptable failure rate of 7% at five years and a revision rate of 6% were first reported for the second-generation, two-component Agility prosthesis¹¹, whereas current unconstrained three-component, mobile-bearing prostheses have demonstrated superior early and long-term results^{33,34}.

Our study revealed that the rate of major complications following total ankle replacement was significantly higher than that after arthrodesis at the time of early follow-up. In an evaluation of reoperation rates following 4705 ankle arthrodeses and 480 total ankle replacements, arthroplasty was found to be associated with a higher risk of complications³. Total ankle replacement revision rates were 9% at one year and 23% at five years, compared with rates of 5% and 11% following ankle arthrodesis.

The complication rate associated with the total ankle replacements in our study was substantially higher than that reported in the literature (54% versus 30%, Table III), while the distribution of complications, with aseptic loosening and intraoperative fracture being the most common, was comparable⁷. Most studies during the last decade have demonstrated total ankle replacement complication rates similar to those following ankle arthrodesis^{8-10,13,16,17,33-46}.

The percentage of arthroplasties done with the Agility prosthesis, which was found to be associated with the highest complication rate, was 28% in the reviewed literature^{8-10,13,16,17,33-46} but was 54% in our study. Moreover, many arthroplasties were performed for complex cases (COFAS classification types 3 and 4), and increasing complexity correlated significantly with the complication rate. Not all intraoperative and postoperative adverse events were defined as complications in the reviewed literature, as most authors did not report nonunion of a failed adjacent-joint fusion as a complication.

The ankle arthrodesis complication rate in our study was nearly half of the mean rate reported in studies of ankle arthrodeses in the last decade (26% versus 49%)^{1,14,20,27,28,31,32,47-50}. The most distinct difference was in the rates of adjacent joint arthritis (6% versus 28%), which was probably due to the difference in the mean duration of follow-up (thirty-seven versus 135 months).

The occurrence of early subtalar arthritis and later transverse tarsal arthritis has been reported to be relatively frequent (after up to 60% of ankle arthrodeses) in mid-term and long-term follow-up studies^{1,31,32,47}. However, the majority of the patients with this complication were satisfied with the overall outcome of the ankle arthrodesis^{1,29,31,51}. Radiographic changes of arthritis do not necessarily correlate with symptoms, and only a few patients undergo adjacent joint arthrodeses to treat the arthritis^{6,14,51}.

Our results confirm the <10% nonunion rate following ankle arthrodesis that has been reported in the current literature^{1,14,20,27,28,31,32,47-50}. Previous studies have demonstrated that, even with an established nonunion, there is a high rate of patient satisfaction, with acceptable pain relief and little functional limitation^{50,52}.

Our initial hypothesis that major complications have a significant impact on outcome was confirmed for both groups. A higher proportion of the patients who underwent total ankle replacement had complications, yet the mean improvement in the overall AOS score was almost identical in the two groups. Despite the numerous major complications, the patients with a total ankle replacement were as satisfied as the patients with an ankle arthrodesis at a mean of 37.7 months postoperatively, a finding that may be due to better postoperative function and a selection bias. If the preoperative ankle range of motion is maintained, patients' gait after total ankle replacement is less disturbed, and they obtain better functional scores on the disability subscale than those with an ankle fusion. This was reflected in the AOS subscales. While the scores on the subscales were balanced for the patients with a total ankle replacement, those with an arthrodesis had generally worse disability scores than pain scores, although the difference was not significant. Complications did not influence this proportion.

There may have been a general selection bias, with older and less demanding patients more likely to receive a total ankle replacement and younger and more active patients more likely to undergo an ankle arthrodesis. Moreover, patients who are presumed to be less likely to comply with postoperative instructions and those with complex hindfoot deformities or tenuous soft tissue in the ankle are more likely to undergo

arthrodesis. The results of our study support the idea of a selection bias among patients with end-stage ankle arthritis in terms of age and activity. There was a higher mean patient age and a higher percentage of patients with rheumatoid arthritis in the total ankle replacement group. In contrast, there was a higher percentage with complex hindfoot deformities (COFAS classification types 3 and 4) in the total ankle replacement group than in the ankle arthrodeses group.

With or without revision, aseptic loosening had the highest impact on the outcomes of total ankle replacement, whereas deep infection almost always resolved without residual problems at the time of the latest follow-up. Interestingly, patients who had undergone a successful exchange of at least one total ankle replacement component because of aseptic loosening scored only slightly better than those with ongoing aseptic loosening and impending revision of the total ankle replacement. This finding indicates that the satisfaction level after a revision total ankle replacement is distinctly lower than that after a primary total ankle replacement. Probably because of our relatively short mean duration of follow-up, adjacent joint arthritis had only a low impact on the outcome of the arthrodesis, whereas the outcome was substantially adversely affected by nonspecific ongoing pain and discomfort caused by an intraoperative nerve lesion. The two patients with nonunion of the fusion underwent a successful revision, and they had superior scores at the time of the latest follow-up. Generally, complications that have resolved at the time of follow-up do not adversely affect outcome as much as ongoing complications⁴³.

Numerous approaches should be considered to reduce the complication rate. A meticulous soft-tissue dissection and preparation of the osseous surfaces is important. Intraoperative evaluation of joint motion may identify gutter impingement. An aggressive approach to achieve correct alignment should be pursued to avoid wear and loosening of the prosthesis or ongoing hindfoot discomfort following an ankle arthrodesis. The new mobile-bearing prosthetic designs may reduce the risk of aseptic loosening, but this possibility must be explored in prospective comparative long-term studies. Because of the high complication rate, we have stopped using the Agility prosthesis.

The strength of this retrospective cohort study is its comparative design and use of a validated outcome instrument for evaluation of the patient data. A limitation is the short duration of follow-up; long-term studies are required to further evaluate the course following total ankle replacement and ankle arthrodesis, particularly with regard to the impact of aseptic loosening and subtalar arthritis. Our study groups were similar with regard to demographics but dissimilar with respect to the number of procedures and the preoperative conditions, which may limit the quality of the analysis. The statistical analysis of the subgroups was limited by the small number of patients in each subgroup. Finally, the substantially higher rate of complex cases in the total ankle replacement group limits the comparability of the two groups.

In conclusion, the early outcomes of total ankle replacement and ankle arthrodesis are comparable with regard to pain relief and function. While the complication rate is significantly higher after total ankle replacement, the impact of

complications on the outcome is significant in both groups. Despite more complications following total ankle replacement, its preservation of ankle motion combined with a selection bias for older and less active patients may result in outcomes that are similar to those of ankle arthrodesis.

Appendix

eA Tables describing the AOS and the COFAS classification system and additional procedures according to the COFAS classifications in the total ankle replacement and ankle arthrodesis groups are available with the online version of this article at jbjs.org. ■

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