Complications and Failure After Total Ankle Arthroplasty

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Background: Second-generation total ankle arthroplasty has been reported to have good intermediate-term results. The purpose of the present study was to report on the cause and frequency of reoperation and failure after total ankle arthroplasty and to determine demographic and clinical predictors of reoperation and failure.

Methods: Three hundred and six consecutive primary total ankle arthroplasties were performed with use of the DePuy Agility Total Ankle System between 1995 and 2001. At a mean of thirty-three months after the arthroplasty, we retrospectively reviewed the records with regard to patient age, gender, the indications for the index procedure, adjuvant procedures, the timing and frequency of reoperation, and the indications for and the type of reoperations performed. Kaplan-Meier analysis was performed to determine the rate of prosthetic survival, and Cox regression analysis was performed to determine predictors of reoperation and failure.

Results: Eighty-five patients (28%) underwent 127 reoperations (involving 168 procedures) after primary total ankle arthroplasty. The most common procedures at the time of reoperation were débridement of heterotopic bone (fifty-eight), correction of axial malalignment (forty), and component replacement (thirty-one). Eight patients underwent below-the-knee amputation. Age was found to be the only significant predictor of reoperation and failure after total ankle arthroplasty. The five-year survival rate with reoperation as the end point was 54%. The five-year survival rate with failure as the end point was 80% for all patients and 89% for patients who were more than fifty-four years of age. The prosthesis could not be salvaged in nine ankles (2.9%); the inability to salvage the prosthesis was most often due to loosening or infection.

Conclusions: We noted a relatively high rate of reoperation after total ankle arthroplasty with this second-generation device. Younger age was found to have a negative effect on the rates of reoperation and failure. Most prostheses could be salvaged; however, the functional outcome of this procedure is uncertain.

Level of Evidence: Therapeutic study, Level IV (case series [no, or historical, control group]). See Instructions to Authors for a complete description of levels of evidence.

Second-generation prostheses have made total ankle arthroplasty a viable alternative to ankle arthrodesis in the treatment of severe arthrosis. The most commonly implanted device in the United States, and the only device approved by the Food and Drug Administration, is the Agility Total Ankle System (DePuy, Warsaw, Indiana), a semiconstrained two-component design. Pyevich et al.[1] studied the intermediate-term results associated with this system and reported that 93% of patients had little or no pain at an average of 4.8 years after implantation. However, they also noted high rates of component migration and delayed union or nonunion of the syndesmosis. Approximately 6% of the patients underwent a reoperation involving removal of components and arthrodesis (1%) or component revision (5%).

First-generation total ankle arthroplasties frequently failed[2-14]. For example, Kitaoka and Patzer[8] noted a high rate of complications and failure in association with the Mayo total ankle arthroplasty, with a 41% rate of reoperation. Most reoperations involved removal of components and arthrodesis for the treatment of persistent pain. Other investigators[15-17] also have reported high rates of salvage arthrodesis.

We noted a high rate of reoperation in a large series of total ankle arthroplasties performed with use of a second-generation implant design. The purposes of the present study were to determine the cause and frequency of reoperation and failure (defined as removal or replacement of components, ankle arthrodesis, or below-the-knee amputation) after a second-generation primary total ankle arthroplasty and to determine demographic and clinical predictors of reoperation and failure.

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Materials and Methods

Three hundred and six consecutive primary total ankle arthroplasties in 303 patients were performed at our insti-

TABLE I Demographic and Clinical Data

	All Patients	Patients Who Had Reoperation	Patients Who Did Not Have Reoperation
Number of ankles	303*	85	221
Age† *(yr)*	53.5 ± 14.2 (19 to 85)	49.7 ± 12.3 (26 to 76)	55.0 ± 14.6 (19 to 85)
Female *(%)*	48	45	49
Male *(%)*	52	55	51
Indication for total ankle arthroplasty			
Posttraumatic osteoarthrosis *(%)*	65	64	71
Primary osteoarthrosis *(%)*	25	26	24
Systemic joint disease *(%)*	4.2	3	5
Prior ankle fusion *(%)*	5.6	7	5
Complex total ankle arthroplasty *(%)*	58	52	59

*Three patients had bilateral total ankle arthroplasty, for a total of 306 prostheses. †The values are given as the mean and the standard deviation, with the range in parentheses.

tution between April 18, 1995, and March 28, 2001. All arthroplasties were performed or directly supervised by the senior author (S.T.H. Jr.). Forty-eight percent of the patients were female, and 52% were male. The average age of the patients was 53.5 ± 14.2 years (range, nineteen to eighty-five years). The indication that had led to the total ankle arthroplasty was posttraumatic osteoarthrosis for 198 (65%), primary osteoarthrosis (including arthrosis due to chronic ligamentous laxity) for seventy-seven (25%), prior ankle arthrodesis for seventeen (5.6%), systemic joint disease for thirteen (4.2%), and both posttraumatic osteoarthrosis and systemic joint disease for one. Two patients with primary osteoarthrosis also had an underlying musculoskeletal affliction (hemochromatosis and Apert's syndrome in one patient each). Fifty-eight percent of the patients underwent adjuvant surgical procedures to treat axial malalignment or instability at the time of the total ankle arthroplasty and were therefore considered to have had a "complex" total ankle arthroplasty according to our criteria. These data are summarized in Table I. In all cases, the indication for primary total ankle arthroplasty was either (1) severe pain in the ankle joint that had been refractory to nonoperative measures and that was associated with radiographic evidence of degenerative joint changes or (2) patient dissatisfaction with a previous ankle arthrodesis.

The prosthesis that was used in all cases was the Agility Total Ankle System (DePuy), which is a semiconstrained implant with a titanium tibial component and a cobalt-chromium talar component, both of which are placed without cement. Implant fixation is secured by means of bone ingrowth, which requires an arthrodesis of the tibiofibular syndesmosis (performed at the time of the total ankle arthroplasty). The components were available in small, medium, and large sizes until February 1998. After that time, the prosthesis was available in six different sizes. The operative technique used for the total ankle arthroplasty was performed according to the principles dictated by the developers of the device[18].

In some patients, one or several adjuvant procedures (such as tibial osteotomy) were performed simultaneously with, or occasionally prior to, the total ankle arthroplasty in order to correct major malalignment, instability, muscle imbalance, or joint contracture. These adjuvant procedures included osteotomies, joint fusions, tendon transfers, and tendon-lengthening procedures involving the distal part of the tibia, the hindfoot, or the midfoot. In patients with varus malalignment of the hindfoot, the components were maximally medialized and a peroneus longus-to-peroneus brevis tendon transfer (or in extreme cases, a posterior tibial tendon-to-peroneus brevis transfer) often was performed to improve eversion strength. In some cases, a valgus-producing calcaneal osteotomy also was performed, sometimes with a dorsiflexion osteotomy of the first metatarsal. In patients with valgus malalignment of the hindfoot, the components were lateralized and correction of the alignment and stabilization of the medial column were achieved with medial and/or lateral column arthrodeses as well as augmentation of the posterior tibial tendon, usually with the flexor digitorum longus tendon. Occasionally, a subtalar or triple arthrodesis was performed to stabilize valgus or varus malalignment of the hindfoot that was not correctable with soft-tissue procedures or osteotomy. For patients with preexisting lateral ligamentous insufficiency with anterior extrusion of the talus, a lateral ligament reconstruction was performed[19] with or without a peroneus longus-to-peroneus brevis transfer, and cast immobilization or external fixation was used to maintain the position of the talus. Nearly all patients underwent an Achilles tendon lengthening or gastrocnemius recession procedure[20] to correct a tight heel cord or a gastrocnemius equinus contracture before or at the time of the total ankle arthroplasty. In some cases, a previous ankle fusion was resected in order to implant the prosthesis. This could be done only for patients who had had retention of certain anatomic structures, in particular, the lateral malleolus, the medial malleolus, and the deltoid ligament.

The indication for reoperation after the primary total ankle arthroplasty was substantial ongoing ankle pain that was refractory to pain-management measures and that was associated with radiographic and/or clinical evidence of various complications or failure. Components were replaced when there was pain and no radiographic sign of osseointegration within the expected time-course or when the components were malpositioned or loose as indicated by subsidence, migration, or tilting. Removal of impinging osseous overgrowth within the joint was indicated when there was painful impingement or ankylosis and radiographic evidence of osseous overgrowth in the medial gutter, lateral gutter, and/or posterior tibiotalar articulation. Repair of the site of the tibiofibular syndesmotic arthrodesis was performed when there was radiographic evidence of nonunion of that area, with substantial pain. Extra-articular realignment procedures were indicated when there was a new or recurrent gross axial deformity that prevented the foot from achieving a plantigrade position. These procedures included periarticular osteotomies (e.g., tibial, calcaneal, and midtarsal osteotomies), tendon transfers and lengthenings, and arthrodeses (e.g., subtalar and midfoot arthrodeses). The indication for irrigation and débridement of the joint with retention of the components was acute deep infection within the joint (that is, a deep infection occurring within three months after the procedure). For late infection (that is, an infection occurring more than three months after the procedure), the implants were removed and an antibiotic spacer was inserted. In the one patient in whom a late infection occurred, an ankle arthrodesis was performed with use of structural bone graft from the posterior iliac crest. Open reduction and internal fixation was performed when the talus fractured intraoperatively during component exchange or during the postoperative course. The decision to undergo an amputation was made by the patient, after consultation with our limb viability and amputation team, when the foot remained dysfunctional following numerous failed reconstructive attempts.

The data on each patient were obtained from a review of the preoperative clinical notes, primary surgical report, follow-up reports, and reoperation reports. The evaluation was carried out independent of the surgeon who had performed the operative procedure. The chart review took place at a mean of 33 ± 18 months (range, four to seventy-five months) after the index total ankle arthroplasty.

Regression analyses using Cox proportional-hazards modeling were performed to determine whether patient age at the time of primary total ankle arthroplasty, gender, the indication for total ankle arthroplasty, and a factor that we termed the "complexity" of the total ankle arthroplasty had an impact on the hazard of reoperation or failure (that is, the instantaneous probability of reoperation or failure at any time). The primary total ankle arthroplasty was considered to be "complex" if adjuvant procedures other than heel-cord lengthening or gastrocnemius recession were performed to correct axial malalignment or instability, as previously described. Kaplan-Meier survivorship analyses were performed with reoperation and failure (defined

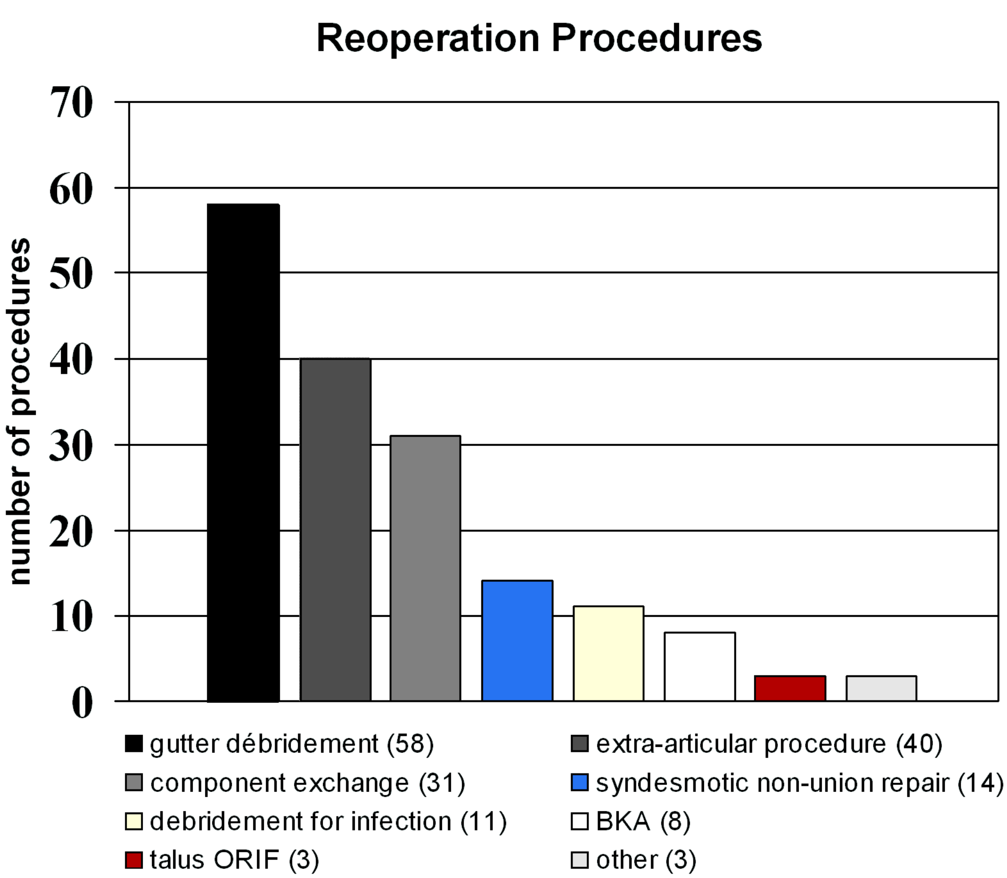

Fig. 1

Illustration depicting the 168 surgical procedures that were performed during 127 reoperations in eighty-five patients.

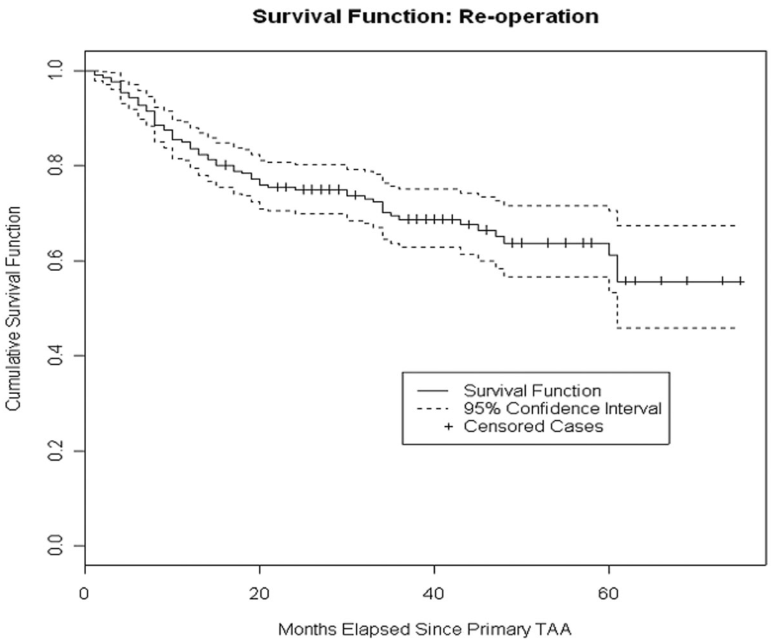

Fig. 2
Kaplan-Meier survivorship curve, with reoperation as the end point. All ankles that did not have the outcome of interest (reoperation) before the last follow-up are censored. The final reoperation occurred at sixty-one months, and all subsequent ankles were censored. TAA = total ankle arthroplasty.

as removal or replacement of components, ankle arthrodesis, or below-the-knee amputation) as end points. All patients who did not have the outcome of interest (reoperation or failure) before the end of follow-up were censored.

Results

During the study period, eighty-five ankles in eighty-five patients (28%) required a total of 127 reoperations (see Appendix). Forty-five percent of the patients who required a reoperation were female, and 55% were male. The average age of these patients at the time of the primary procedure was 49.7 ± 12.3 years (range, twenty-six to seventy-six years). The indication for total ankle arthroplasty was posttraumatic osteoarthrosis for fifty-four patients (64%), primary osteoarthrosis for twenty-two (26%), previous ankle fusion for six (7%), systemic joint disease for two, and posttraumatic osteoarthrosis and systemic joint disease for one. Fifty-two percent of the primary total ankle arthroplasties in the patients who required a reoperation were considered to have been "complex."

Fifty-seven patients had one reoperation at a mean of 17.8 months (range, 0.5 to sixty-one months) after the primary procedure. Eighteen patients had two reoperations; the mean time between the primary procedure and first reoperation was 13.7 months (range, one to forty-three months), and the mean time between first and second reoperations was 10.6 months (range, 0.1 to thirty-two months). Nine patients had three reoperations; the mean time between the primary procedure and the first reoperation was 10.8 months (range, two to thirty-four months), the mean time between first and second reoperations was 7.2 months (range, 0.1 to thirty-two months), and the mean time between second and third reoperations was five months (range, 0.2 to twenty-six months). One patient required seven reoperations at four, twelve, eight, one, 0.1, one, ten-month intervals, respectively.

The 127 reoperations involved 168 surgical procedures, including fifty-eight gutter débridements, forty extra-articular procedures, thirty-one component replacements, fourteen syndesmotic nonunion repairs, eleven irrigation and débridement procedures for the treatment of infection, eight below-the-knee amputations, three talar fracture fixations, one ankle arthrodesis, one split-thickness skin-grafting procedure for the treatment of wound breakdown, and one prosthetic removal and spacer implantation (Fig. 1). Kaplan-Meier analysis as a function of time since the primary total ankle arthroplasty revealed that the cumulative five-year (sixty-one-month) survival rate (and 95% confidence interval) with reoperation as the end point was 54% ± 11.5% (Fig. 2).

Thirty-three ankles (10.8%) were considered to have had a failed total ankle arthroplasty (defined as removal or replacement of components, ankle arthrodesis, or below-the-knee amputation). Kaplan-Meier analysis revealed that the cumulative five-year (sixty-one month) survival rate (and 95% confidence interval) with failure as the end point was 80% ± 8.7% (Fig. 3). Ultimately, all but nine joints (2.9%) were salvaged with reoperation. The leading cause of inability to salvage a prosthesis was loosening of the talar component, which could not be corrected in six of the twenty-two joints in which it was evident. The next most common reason for failure was infection, which led to failure in three of the five ankles in which it was evident.

Seven of the eight patients who underwent below-the-knee amputation had a history of severe trauma and multiple surgical procedures prior to the total ankle arthroplasty. All but one of these patients had been considering an amputation as a surgical option before undergoing total ankle arthroplasty. The total ankle arthroplasties in these patients failed because of persistent pain associated with osseous overgrowth and failure of the talar component (four patients) or because of infection

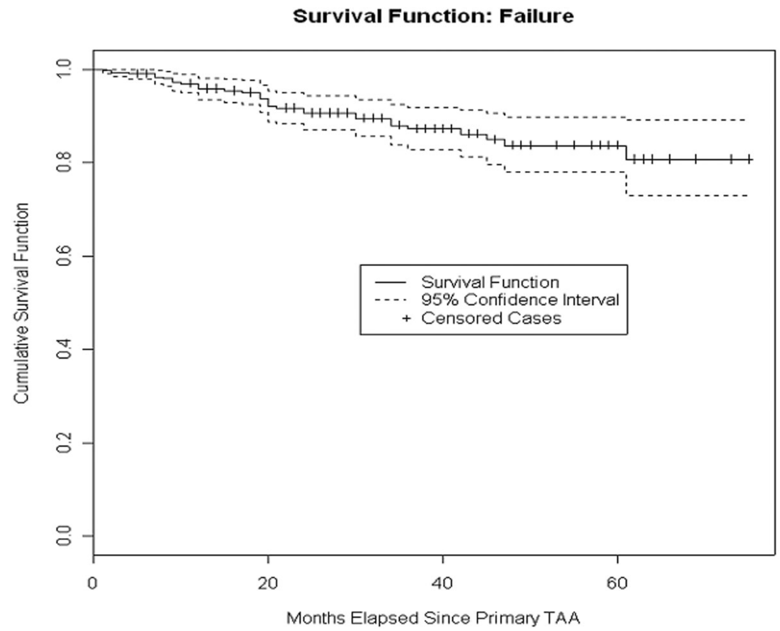

Fig. 3
Kaplan-Meier survivorship curve, with failure (replacement of components, ankle arthrodesis, or below-the-knee amputation) as the end point. All ankles that did not have the outcome of interest (failure) before the last follow-up are censored. The final failure occurred at sixty-one months, and all subsequent ankles were censored. TAA = total ankle arthroplasty.

(three patients). An amputation also was performed in a patient who had had a severe cavovarus clawfoot deformity before surgery that was difficult to correct. This patient had subsidence of the talar component and inexplicable persistent severe edema without proven infection. No patient with normal preoperative alignment underwent an amputation.

Only one patient had an ankle arthrodesis. In this patient, an ankle fusion was resected at the time of the total ankle arthroplasty. Osseous impingement and loosening of the talar component developed, and the patient underwent a second operation. Postoperatively, a deep infection developed and the patient was treated with removal of the components and arthrodesis with use of structural bone graft from the iliac crest. At the time of the last follow-up, the ankle was successfully fused.

Cox regression analysis revealed that age at the time of the primary total ankle arthroplasty was the only covariate that had an impact on the hazard of reoperation and failure after total ankle arthroplasty. Each one-year increase in age corresponded with a 1.9% relative decrease in the hazard of reoperation ($p < 0.05$) and a 3.5% decrease in the hazard of failure ($p < 0.05$). The one patient who had a diagnosis of both posttraumatic osteoarthrosis and systemic joint disease was excluded from the analysis.

Cox regression modeling also was done to determine the impact of a categorical predictor representing age on the hazard of failure, with time elapsed since the primary total ankle arthroplasty as the dependent variable of interest. The validity of including an age-group variable was verified with use of the technique described by Kalbfleisch and Prentice[21]. The results of this analysis showed that patients with a median age of fifty-four years or less had a 1.45-times greater risk of reoperation and a 2.65-times greater risk of failure than did patients who were older than fifty-four years, at any time, with all other covariates being held constant ($p < 0.05$). The estimated five-year survival rate with reoperation as the end point was

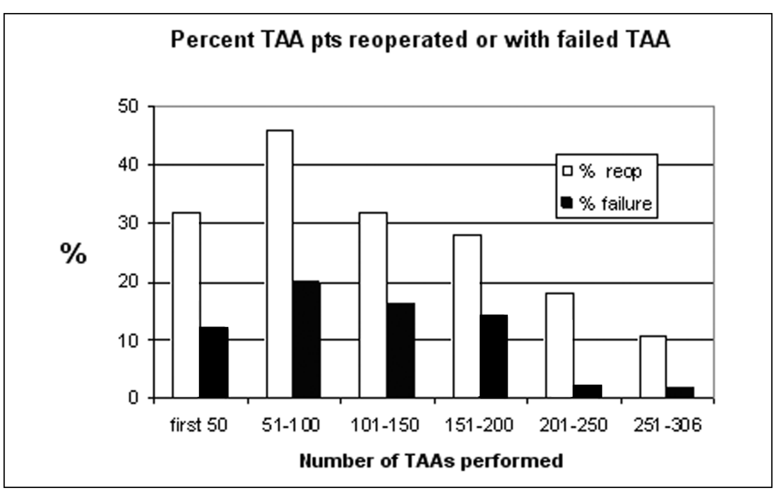

Fig. 4
The first fifty patients who underwent total ankle arthroplasty (TAA) fared as well as the next 150 patients did in terms of the rates of reoperation and failure, indicating the lack of a learning-curve effect. A decline in the rates of reoperation and failure is seen after the first 200 total ankle arthroplasties because of the shorter duration of follow-up. These results were confirmed by Cox proportional-hazards modeling ($p < 0.05$).

TABLE II Age-Dependent Five-Year Cumulative Survival Rate for 306 Total Ankle Arthroplasties

Age	Survival Free of Reoperation*	Survival Free of Failure*
≤54 years	0.51 (0.37-0.70)	0.74 (0.60-0.91)
>54 years	0.65 (0.52-0.82)	0.89† (0.80-0.99)

*The 95% confidence interval is given in parentheses. †The rate of survival free of failure for patients who were more than fifty-four years old is reported at forty-seven months.

0.51 (95% confidence interval, 0.37 to 0.70), at sixty-one-months, for patients who were fifty-four years old or younger and 0.65 (95% confidence interval, 0.52 to 0.82), at sixty months, for those who were more than fifty-four years old. The estimated five-year survival rate with failure as the end point was 0.74 (95% confidence interval, 0.60 to 0.91), at sixty-one months, for patients who were fifty-four years old or younger. In comparison, the estimated forty-seven-month survival rate with failure as the end point was 0.89 (95% confidence interval, 0.80 to 0.99) for those who were more than fifty-four years old. This function stops at forty-seven months because no failures were observed in this age-group beyond that time, which led to difficulty in predicting five-year survival. This finding is depicted in the cumulative survivorship curves in the Appendix and is summarized in Table II.

No evidence of a learning-curve effect was noted when the results for the first patients who underwent total ankle arthroplasty were compared with the results for later patients. The first fifty patients fared no worse than the next 150 patients in terms of the proportion who had a reoperation and/or failure (Fig. 4). Beyond the first 200 patients, a decreased proportion of reoperation and failure is evident because of a shorter duration of follow-up. These observations were statistically confirmed with use of Cox proportional-hazards modeling, which demonstrated that the hazard of reoperation or failure was not increased in the earlier patients compared with the later patients, with all other covariates held constant.

Discussion

A variety of reoperations were performed after primary total ankle arthroplasty, in slightly more than one-fourth of the patients. The types of procedures that were performed were dictated by the indications. The most common procedure was joint débridement for osseous impingement; the next most common procedures were extra-articular procedures for axial malalignment and component replacements (usually involving the talar component). These three types of procedures accounted for 77% of the total procedures performed and were roughly fourfold more common than all reoperations for syndesmotic nonunions, infection, talar fractures, and wound-healing problems combined. In contrast with the high rate of wound-healing complications requiring operative intervention that is associated with first-generation devices, only one wound-healing problem that required surgical treatment was incurred in our patient population.

Component failure involving migration or subsidence nearly always involved the talar component. Osseous overgrowth often was associated with a loose talar component and was discovered at the time of gutter débridement or, occasionally, at a later date. The component often was found to have subtle signs of loosening rather than gross loosening. In these cases, the component was not well bonded to the talus, allowing a thin elevator to be inserted in the interface and the component to be detached without difficulty. This sort of loosening was not recognized in many of the early débridements but was noted later in some patients who underwent multiple débridements. It may have been missed initially, or it may not have developed until a later date. If it was missed and the osseous overgrowth was a consequence of a loose talar component, then perhaps an early exchange of the component would have avoided further débridements for overgrowth. Few problems were encountered with the tibial component.

The revision rate in the present study was higher than that in the study by Pyevich et al.[1], but there were important differences between the patient populations. The revision rate in that study was 5%, with a 1% rate of component removal and arthrodesis, at an average of 4.8 years. In the present study, 10% of the patients underwent component revision at an average of twenty-one months. However, the patients in the present study were younger than those in the study by Pyevich et al. (average age, 53.5 compared with sixty-three years). Apparently, none of the patients in that study had substantial malalignment that required correction before or at the time of total ankle arthroplasty, although this factor may not have affected the rate of revision, as discussed later in this section. The percentage of patients who underwent total ankle arthroplasty because of posttraumatic arthrosis was higher in the present study than it was in the other study (66% compared with 45%). In addition, the study by Pyevich et al. focused on the results of procedures performed by the inventor of the Agility ankle prosthesis, who had intimate familiarity with the implant. Any combination of these factors may have led to a higher rate of revision in our patient population.

Interestingly, the performance of adjuvant procedures for substantial malalignment or instability, or the resection of a fusion, did not increase the risk of reoperation or failure. This finding indicates that total ankle arthroplasty can be performed just as successfully in patients with complex reconstructions to correct preexisting malalignment and instability or in patients who have undergone a previous ankle arthrodesis and have an intact deltoid ligament.

It is possible that additional patients in this study may have gone elsewhere for reoperation without our knowledge. We are not aware of any such cases, but the possibility exists nevertheless. For this reason, the reoperation and failure rates that we have reported should be regarded as the lower limits of such rates, with the actual rates perhaps being somewhat higher.

The adverse effect of age on the risk of reoperation and failure after total ankle arthroplasty is consistent with the well-known effect of age on these rates after total knee and total hip arthroplasty[22,25]. However, the present study also indicates that the rates of reoperation and failure after primary total ankle arthroplasty are substantially higher than those associated with most modern total hip and knee designs. Berry et al.[22] noted that the five-year survival rate after Charnley total hip arthroplasty was 96% with reoperation as the end point and 98% with component removal or revision as the end point. High survival rates (>95% at ten years) also have been reported in association with other types of total hip prostheses[23,24]. Rand et al.[25] noted an overall five-year survival rate of 96% for later-generation total knee arthroplasty designs, although some designs had much lower survival rates in younger patients. The complex kinematics of the ankle joint and the small weight-bearing surface of the prosthesis are likely to be major contributing factors to the lower survival rate after total ankle arthroplasty and therefore present important design challenges.

In conclusion, we noted a relatively high rate of reoperation due to complications that arose after total ankle arthroplasty. Age was the only patient-related factor that was found to have an adverse effect on both the reoperation rate and the failure rate. In most patients with complications, the prosthesis could be salvaged. The functional outcome of these salvaged prostheses remains to be seen.

Appendix

eA A table showing specific data on all patients undergoing reoperation as well as illustrations showing Kaplan-Meier survival curves are available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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The authors did not receive grants or outside funding in support of their research or preparation of this manuscript. One of the authors (S.T.H Jr.) works as a consultant for DePuy on a "piece-work" basis (expenses and an honorarium for teaching). That work is unrelated to the present study. They did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

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