High Revision and Reoperation Rates Using the Agility™ Total Ankle System

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Abstract

Background Total ankle arthroplasty (TAA) is an evolving treatment for end-stage ankle arthritis, however, there is controversy regarding its longevity.

Questions/purposes We determined survival of the Agility™ TAA, the overall reoperation rate, and function in patients who retained their implant.

Methods We retrospectively reviewed 64 patients who had 65 TAAs between June 1999 and May 2001. Information was gathered through chart reviews, mailed-in questionnaires, and telephone interviews. Nine patients had died; data were available for 41 of the remaining 55 patients. Survival was based on revision as an end point.

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The minimum followup was 0.5 years (median, 8 years; range, 0.5–11 years).

Results Sixteen of the 41 patients (39%) needed revisions. The average time to revision surgery was 4 years with six of the revisions (38%) occurring within 1 year of the TAA. Of the 25 patients who retained their implants, 12 required secondary surgery for an overall reoperation rate of 28 of 41 (68%) at an average of 8 years followup. The average VAS pain score was 4, the average Foot and Ankle Ability Measure (FAAM) sports subscale score was 33, and the average FAAM activities of daily living subscale score was 57.

Conclusion TAA had high revision and reoperation rates. Patients who retained their implant had only moderate pain relief and function. TAA must be approached with caution. More research is needed to elucidate the role of contemporary TAA.

Level of Evidence Level IV, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

End-stage ankle arthritis is a debilitating problem with a substantial impact on patients' quality of life [2]. Initially, nonoperative modalities are attempted to prolong the life of the native ankle. When these modalities fail, ankle arthrodesis is a reliable surgical intervention for treatment of severe ankle arthritis to provide excellent pain relief and return to activities of daily living [13, 22]. However, since the introduction of contemporary total ankle arthroplasty (TAA) in the 1970s [4, 9, 15, 19], there has been controversy regarding its role in the treatment of end-stage ankle arthritis. Numerous studies with first-generation arthroplasty implants

show high failure rates, ultimately requiring some form of surgical revision in 27% to 52% of cases [3, 4, 6, 9, 12, 15, 20]. Second-generation devices have been developed to address the issues that resulted in high failure rates of early implants, yet intermediate-term outcomes have mixed results with revision rates ranging from 11% to 20% and total reoperation rates ranging from 33% to 54% [8, 10, 19].

The Agility™ Total Ankle System (DePuy, Warsaw, IN, USA) is a semiconstrained two-component design that has been the most commonly used implant in the United States [23]. Until the introduction of a second-generation three-component mobile-bearing device in 2007, the Agility™ was the only device approved by the FDA in 1992. Pyevich et al. [16] reported 93% of patients had little or no pain with the Agility™ at an average of 4.8 years and a revision rate of 6% after 5 years of followup [16]. In followup of the study of Pyevich et al., Knecht et al. [10] reported on an additional 32 patients and 5 years more of followup showing a higher revision rate of 11% after a mean followup of 9 years [10]. Other studies have reported 5-year survival rates of 80% and 77% with major revision as an end point [18, 19].

To confirm previous reports on revision (defined as arthrodesis, revision arthroplasty, or below-knee amputation) and reoperation rates of TAA we determined (1) the survival of the Agility™ implant, (2) the overall reoperation rate, (3) if age or the presence of rheumatoid arthritis had an effect on implant survival, and (4) the function in patients who retained their implant.

Patients and Methods

We retrospectively identified 65 TAAs performed on 64 patients using the DePuy Agility™ prosthesis by one surgeon (KDJ) from June 1999 until May 2001. During that time no other patients had a TAA by that surgeon. Indications for TAA were intractable pain owing to advanced ankle arthritis or severe hindfoot arthritis with a prior ankle arthrodesis not responsive to nonoperative treatments. The only absolute contraindication in these patients was signs of active infection. Relative contraindications for surgery were young age (younger than 60 years) and severe deformity. Nine patients had died since their surgery, with no deaths related to the surgery. Of the remaining 55 patients (56 TAAs), 12 were unable to be contacted, one refused to participate, and one was critically ill at the time and unable to participate. We obtained updated data via medical records, mailed-in questionnaires, and telephone interviews for the remaining 41 patients (42 TAAs, one patient had bilateral TAAs). The minimum followup was 0.5 years (median, 8 years; average, 8 years; range, 0.5–10.8 years).

The most frequent causes of arthritis in the 41 patients (42 TAAs) for whom we were able to obtain definitive

followup were posttraumatic in 25 of 41 (42 TAAs; 61%) and rheumatoid arthritis in five of 41 patients (six of 42 TAAs; 12%) (Table 1). Other diagnoses included an osteochondral defect (one patient), hindfoot deformity (three patients), avascular necrosis (one patient), primary osteoarthritis (two patients), lateral ligamentous laxity (two patients), and residual clubfoot deformity (two patients).

An anterior approach using the interval between the tibialis anterior and the extensor tendons was used in all of the TAAs. An external fixator was used for distraction of the joint. After the ankle was prepared and the appropriate implants were selected, the syndesmosis was prepared through the same anterior incision and local bone graft was used to assist with this fusion; the implants then were placed. Through a separate lateral incision the fibula was drilled with a 3.5-mm drill bicortically and the tibia was drilled with a 2.5-mm drill bicortically, then two 3.5-mm titanium screws were placed over washers in a lag-type fashion for fixation of the syndesmotic fusion.

Table 1. Demographic data

Demographic data collected	Distribution of patients and average ages
Age at time of TAA	
18–50 years	16
50–60 years	9
60–70 years	10
70–90 years	6
Average age of patients who retained implant (years)	58
Average age of patients who underwent revision (years)	48
Average age of all patients (years)	54
Sex	
Male	20
Female	21
Cause of ankle arthritis	
Posttraumatic	25
Rheumatoid arthritis	5
Nonrheumatoid inflammatory arthritis	0
Hindfoot deformity	3
Osteochondral defect	1
Avascular necrosis	1
Residual clubfoot deformity	2
Primary osteoarthritis	2
Lateral ligamentous laxity	2
Diabetes	
Yes	4
No	37

TAA = total ankle arthroplasty.

Postoperatively the patients wore a splint and were non-weightbearing. Patients were seen 2 weeks postoperative for wound check, suture removal, and transition to a short-leg nonweightbearing cast. At 6 weeks postoperative, AP, lateral, and oblique ankle radiographs were obtained and the patients were transitioned to a walker boot, allowed to bear weight as tolerated, and physical therapy two to three times per week was initiated for ROM and strengthening. At 12 weeks postoperative, radiographs were obtained, physical therapy was discontinued, and the patients could transition to a normal shoe. The patients then were seen at 6 months, 12 months, and then yearly with radiographs being taken at each followup. The patients who did not have a revision procedure documented in the medical records were contacted by mailed-in questionnaire or by telephone to determine a Foot and Ankle Ability Measure (FAAM) score [14] and a VAS pain score [1]. The FAAM was designed to assess physical performance of individuals through a self-reported evaluative instrument. FAAM scores range from 0 to 100 with higher scores indicating higher function. Slight difficulty performing activity is scored 75, moderate difficulty 50, and extreme difficulty 25 using this scoring system [14].

Thirty-eight additional procedures were required at the time of the 42 arthroplasties, including 30 gastrocnemius recessions or Achilles tendon lengthenings, six triple arthrodeses, two subtalar arthrodeses, one talonavicular arthrodesis, one lateral ligament repair, one calcaneal osteotomy, one plantar fascia release, two bunionette corrections, and one hallux valgus correction. Five patients who had a prior ankle arthrodesis had conversion surgery to ankle arthroplasties in conjunction with a hindfoot fusion to address their severe hindfoot arthritis.

A Kaplan-Meier survival curve [7] was compiled to estimate the cumulative survival over 9 years of all 64 patients (65 TAAs), censoring for death or loss to followup before implant removal. Furthermore, patients were censored if the end of the followup period was reached before implant removal. Survival curves also were constructed for patients with and without rheumatoid arthritis. Differences in survival of patients with rheumatoid arthritis versus patients without rheumatoid arthritis were determined with a log-rank test using Statistical Software R (Version 1.11.0; www.r-project.org, Institut für Statistik und Mathematik, Wirtschaftsuniversität Wien, Vienna, Austria). Differences in age in patients who had their implants removed versus those who retained their implants were analyzed with Student's t-test.

Results

At an average of 8 years of followup after TAA, 16 of 41 patients (42 TAAs; 39%) required revision surgery.

Kaplan-Meier analysis revealed that the cumulative 9-year survival rate (and 95% confidence interval) with failure as the end point was $62\% \pm 15\%$ (Fig. 1). Ten patients had ankle fusions, three had revision ankle arthroplasties, and three had below-knee amputations. The average time to revision surgery was 4 years with six of the revisions (38%) occurring within 1 year of the TAA (Table 2). Of

Fig. 1 A Kaplan-Meier survival curve is shown for all implants with an end point as revision, arthrodesis, or below-knee amputation (BKA). The hatched lines represent the 95% confidence interval.

Table 2. Revision and reoperation data

Revision and reoperation data	Distribution of patients: numbers and percentages
Patients who required foot and ankle surgeries after TAA	
No more surgeries	27%
One more surgery	37%
Two more surgeries	33%
Three or more surgeries	3%
Complications	
Infection requiring reoperation	3 (one had loosening, treated with antibiotics, culture was contaminated)
Revision surgeries	
Revision TAA	3
Ankle fusion	10
Below-knee amputation	3
Time until revision surgery	
Less than 1 year	6
1 to 2 years	1
2 to 5 years	2
5 to 10 years	7
Average number of years until revision surgery	4

TAA = total ankle arthroplasty.

Fig. 2 Kaplan-Meier survival curves are shown for patients with rheumatoid arthritis and patients without rheumatoid arthritis. Patients with rheumatoid arthritis are represented by the solid line. Having rheumatoid arthritis did not influence ($p = 0.89$) implant survival.

the 16 patients who required revision surgery, 11 (69%) had posttraumatic arthritis, two (13%) had rheumatoid arthritis, and three (19%) had other etiologic causes: one osteochondral lesion of the talus, one subtalar coalition, and one severe flatfoot. Patients with rheumatoid arthritis had a similar ($p = 0.89$) rate of implant removal (Fig. 2). The average age of patients requiring revision surgery was similar ($p = 0.17$) to that of patients who retained their implant: 49 years versus 59 years, respectively.

Of the patients who we were able to contact who retained their implant, 12 of 25 patients (26 TAAs; 48%) required secondary surgery for an overall reoperation rate of 28 of 41 patients (42 TAAs; 68%) at an average of 8 years of followup. Secondary surgeries included six syndesmotic nonunion repairs, five removals of hardware, four tendon transfers, four open reductions and internal fixations for postoperative fractures, three irrigations and débridements for infections, two calcaneal osteotomies, two débridements for impingement, and one of each of the following: percutaneous Achilles lengthening, gastrocnemius lengthening, triple arthrodesis, peroneal tendon repair, neuroma excision, and split-thickness skin graft.

Of the 25 patients who retained their prostheses, the average VAS for patients using a scale of 1 to 10 was 4, the average FAAM sports subscale score was 33, and the average FAAM activities of daily living subscale score was 57 (Table 3).

Discussion

Since the introduction of TAAs, there have been multiple studies evaluating the role of TAA for the treatment of

Table 3. Followup data for patients with retained prostheses

Followup data for patients who retained their prostheses	Distribution of patient data
Average VAS score of patients who retained prostheses	
All patients	4
Patients with rheumatoid arthritis	3
Patients with posttraumatic arthritis	4
Average FAAM% daily subscore	
All patients	57%
Patients with rheumatoid arthritis	64%
Patients with posttraumatic arthritis	51%
Average FAAM % sports subscore	
All patients	33%
Patients with rheumatoid arthritis	30%
Patients with posttraumatic arthritis	35%
Number of nonrevision surgeries after TAA	
None	0
One	10
Two	1
Three or more	1

TAA = total ankle arthroplasty; FAAM = foot and ankle ability measure.

end-stage ankle arthritis [3–6, 8–12, 15–21, 23, 24], but few report results with more than 5 years of average followup [8, 10, 21]. We report the revision and reoperation rates for TAA with the Agility™ prosthesis and the function of patients who retained their prostheses after an average followup of 8 years, and our results are not as favorable as those in other studies [18, 19] (Table 4).

We acknowledge limitations of our study. First, our surgical data were obtained retrospectively and our functional outcomes were determined with a mailed-in FAAM and VAS pain score questionnaire. The patients were not reexamined in clinic to objectively assess functional ability which could have led to a lower functional score. The FAAM is a validated self-reported evaluative instrument that reproducibly measures changes in an individual's status and reliably assesses functional abilities in activities of daily living and sports activity [14]. Second, we report data for only 41 of 64 patients (42 of the 65 TAAs; 64%). The 12 patients who could not be contacted, one who refused to participate, and one who was too critically ill to participate potentially could have required revision surgeries or reoperations but sought care at an outside facility without our knowledge, which could have caused our rates to be falsely lowered. We attempted to account for this with censoring of subjects while constructing the survival plots. Third, there was no radiographic review performed that could have identified radiographically loosened implants to help explain the poor functional outcomes and

Table 4. Summary of comparative studies

Study	Prostheses used	Followup (years)	Posttraumatic arthritis (%)	Rheumatoid arthritis (%)	Age at surgery (years)	Revision surgery (implant removal)	Reoperation excluding revision
Doets et al. [5]	LCS/Buechel-Pappas	8	Not available	75	58	16%	Not available
Karantana et al. [8]	STAR™	8	23	29	62	16%	17%
Knecht et al. [10]	Agility™	9	46	23	61	11%	40%
Pyevich et al. [16]	Agility™	5	52	22	63	6%	Not available
Saltzman et al. [17]	STAR™	2	58	9	63	5%	7%
Spirt et al. [19]	Agility™	5	64	4	54	20%	26%
SooHoo et al. [18]	Not available	5	58	10	59	23%	Not available
Van der Heide et al. [24]	STAR™/Buechel-Pappas	3	0	100	55	8%	Not available
Current study	Agility™	8	61	12	54	39%	48%

STAR™ (Small Bone Innovations, Morrisville, PA, USA); Agility™ (DePuy, Warsaw, IN, USA); LCS (Low Contact Stress) (DePuy, Warsaw, IN, USA); Buechel-Pappas (Endotec, South Orange, NJ, USA).

continued pain in patients who retained their implants. Followup data were obtained through mailed-in questionnaires or telephone interviews, therefore, radiographs were not obtained to allow us to correlate reported poor functional outcomes with radiographic loosening. Fourth, in our functional assessment there was no return-to-work analysis. The FAAM activities of daily living score has one question that addresses the patient's perspective on his or her ability to work. The majority of the questions focus on walking, personal care, ability to work, and the ability to perform activities of daily living, and on average, patients who retained their implants had moderate difficulty performing these tasks. Patients who have moderate difficulty with these basic functions would be more likely to have a low rate of return to work. Fifth, this is a relatively small series of TAAs with 64% followup which could have caused higher revision and reoperation rates owing to the steep learning curve associated with the procedure. Perhaps with more patients included in this study the revision and reoperation rates could have decreased as the surgeon's familiarity with the implant increased.

The rate of revision surgery for our patients was higher than that for patients who received the Agility™ prosthesis reported by Knecht et al. [10]. However, there were important differences that could account for our larger revision rate. The average age of our cohort was 54 years compared with 61 years for the patients of Knecht et al. The average ages of patients in our study requiring revision versus no revision were 49 years and 59 years, respectively. Posttraumatic arthritis was the reason for TAA in 61% of our patients compared with 46% in the study of Knecht et al. [10]. Our findings and patient population are similar to those of the study by Spirt et al. [19], who reviewed 306 primary TAAs using the Agility™ prosthesis

and reported a 5-year cumulative survival of 80%. Their patient population had an average age of 54 years and posttraumatic arthritis was the reason for TAA in 64% of patients. Furthermore, rheumatoid arthritis was the cause of arthritis in five of 41 patients (six of the 42 TAAs; 12%) compared with 23% of the patients in the study by Knecht et al. [10]. Several studies have suggested patients with posttraumatic arthritis are less successful regarding outcomes when compared with patients with rheumatoid arthritis [5, 11, 21]. Van der Heide et al. [24] reported a revision rate of 8% in patients with rheumatoid arthritis treated with TAA.

Another consideration for the higher revision rate is the learning curve associated with ankle arthroplasty. Knecht et al. [10] reported outcomes for patients who were treated by one surgeon who was the inventor of the Agility™ prosthesis and likely would have a considerably high familiarity with the implant. Saltzman et al. [17] reported on outcomes comparing the STAR™ (Small Bone Innovations Inc, Morrisville, PA, USA) implant versus fusion and showed that patients who had a TAA by surgeons with an average of 43 TAAs performed before the study had less secondary major surgeries compared with surgeons with an average of 16 TAAs performed before the study. We report on one surgeon's complete series of patients. Of the first 43 patients who had a TAA performed (43 TAAs) by our surgeon (KDJ), 12 were lost to followup and 13 had revision surgery for a revision rate of 42% (13 of 31 patients). Of the last 21 patients who had a TAA performed (22 TAAs, one patient with bilateral TAAs), 11 were lost to followup and three had revision surgery for a revision rate of 30% (three of 10 patients). Our findings are consistent with a steep learning curve for TAA and could explain our higher revision rate.

In the current study, 12 of the 25 (48%) patients (12 of 26 TAAs) who did not require revisions required a secondary surgery. The overall reoperation rate including revisions was 68% at an average of 8 years followup. The need for secondary surgery in patients with retained implants in our study is consistent with other Agility™ implant studies [10, 19]. Knecht et al. [10] reported the need for a secondary procedure in 32 of the 81 (40%) patients followed clinically who were living and who did not have revision surgery after an average 9-year followup. Spirt et al. [19] reported the reoperation rate excluding removal of the Agility™ implant was 26% after 5-years of cumulative followup with an overall cumulative 5-year reoperation rate of 54%. Six of the 12 (50%) secondary surgeries in the current study were attributable to syndesmosis nonunion. This complication is unique to this implant design as it requires syndesmotic fusion for stability and fixation. These six patients (six TAAs) accounted for 15% of the 41 patients (42 TAAs). This rate was slightly higher than in other studies with syndesmotic nonunion rates of 5% to 8% [10, 19].

Of the patients in the current study who retained their implants, the average pain score was 4 and the average FAAM sports and activities of daily living scores were 33 and 57, respectively. With a FAAM sports score of 33, patients on average reported moderate to extreme difficulty with running, jumping, low impact activities, and ability to participate in sports. An average FAAM activities of daily living score of 57 represents moderate difficulty with walking, squatting, ability to work, activities of daily living, and personal care. These results indicate that patients who retained their prostheses had continued pain and functional issues.

Our data show high revision and reoperation rates with the second-generation Agility™ total ankle prosthesis at an average followup of 8 years. Only one other study [10] to our knowledge has reported outcomes with a similar length of followup in a slightly different patient population using the Agility™ implant. That study and ours show that with longer followup, the need for reoperation and revision increases and the longevity of second-generation total ankle prostheses may need to be assessed further. Our results are consistent with those of the current literature in that younger patients with posttraumatic arthritis undergoing TAA tend to have higher rates of revision surgery and more frequent secondary surgeries. Older patients with inflammatory arthritis may be the population that would benefit most from TAA. The role of newer TAAs also has not been well elucidated. A randomized controlled trial of TAAs versus ankle arthrodesis would provide a great amount of information regarding the use of TAAs and who might benefit the most from their use.

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