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CLINICAL RESEARCH

How Successful are Current Ankle Replacements?

A Systematic Review of the Literature

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Abstract Total ankle arthroplasty provides an alternative to arthrodesis for management of ankle arthritis. What is the outcome of total ankle arthroplasty implants currently in use? We conducted a systematic literature search of studies reporting on the outcome of total ankle arthroplasty. We included peer-reviewed studies reporting on at least 20 total ankle arthroplasties with currently used implants, with a minimum followup of 2 years. The Coleman Methodology Score was used to evaluate the quality of the studies. Thirteen Level IV studies of overall good quality reporting on 1105 total ankle arthroplasties (234 Agility™, 344 STAR, 153 Buechel-Pappas™, 152 HINTEGRA®, 98 Salto™, 70 TNK, 54 Mobility™) were included. Residual pain was common (range, 27%–60%), superficial wound complications occurred in 0% to 14.7%, deep infections occurred in 0% to 4.6% of ankles, and ankle function improved after total ankle arthroplasty. The overall failure rate was approximately 10% at 5 years with a wide range (range, 0%–32%) between different centers. Superiority of an implant design over another cannot be supported by the available data.

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

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

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Introduction

Total ankle arthroplasty (TAA) has been performed in selected patients with end-stage ankle idiopathic, post-traumatic osteoarthritis, and inflammatory arthritis since the 1970s [24]. Initial implant designs were associated with failures requiring revision or fusion as high as 72% at 10 years [10], raising substantial concern about the devices.

Studies of normal ankle biomechanics and review of previous implant failures have led to the development of new TAA designs [5, 8, 10]. First-generation implants were constrained, had an all-polyethylene tibial component, and used cement for implant fixation [9, 10]. Implants used today may have either two- or three-components with either fixed or mobile bearings. Cementless fixation is considered better by most implant manufacturers and surgeons [3, 5, 7, 10, 11, 14, 19, 20, 34]. The procedure is considered by some a reasonable alternative to ankle arthrodesis [12], and the demand by younger and more active patients likely will increase as failure rates diminish. Therefore, it is in the interest of clinicians and patients to evaluate the outcome of current TAAs for management of ankle arthritis.

We therefore systematically reviewed the literature to determine: (1) the quality of the literature reporting outcomes of TAA; (2) the indications for TAA (eg, inflammatory arthropathy, osteoarthritis) in different centers; (3) the clinical failure rate and survivorship for different implants; (4) the methods used to salvage failures; (5) the wound complication and deep infection rates; (6) the functional outcome and the ability to participate in sports after TAA; (7) the range of motion (ROM) after TAA; (8) whether pain is eliminated; and (9) the radiographic outcome.

Search Strategy and Criteria

We conducted a literature search of MEDLINE®, Cochrane, EMBASE™, and CINAHL® databases using the terms "total" and "ankle" and "arthroplasty" or "replacement". No language restrictions or date limits were applied to the search. In addition, the Google™ search engine and the electronic contents of several key journals were searched: *The Journal of Bone and Joint Surgery (American and British Volumes), Clinical Orthopaedics and Related Research, Foot and Ankle International, Foot Ankle Clinics of North America, Journal of Foot and Ankle Surgery,* and *Orthopäde* (German). Search of the German journals databases also was performed using combinations of the following keywords: "OSG", "Oberes Sprunggelenk", and "Sprunggelenkprothese". The date of the most recent search was October 24, 2008.

We excluded articles irrelevant to TAA (Fig. 1), articles not reporting outcomes (eg, reviews, letters to the editor, biomechanical and cadaveric studies), case reports, and studies reporting results of TAA implants that had been abandoned (St Georg, ICLH [Imperial College London Hospital], Irvine, Beck-Steffe, Mayo, Newton, Bath-Wessex, New Jersey prostheses) [10]. We also excluded data for prostheses that have been replaced by new versions of similar design but with fundamental differences as the older designs would not be relevant to current practice. The excluded devices include the LCS prosthesis replaced by the Buechel-Pappas™ [3], the shallow sulcus design of the Buechel-Pappas™ prosthesis replaced by the deep sulcus design [3], the early design of the Scandinavian Total Ankle Replacement (STAR) prosthesis for cemented implantation [20], and the early generation implants of the TNK prosthesis [29]. Finally we excluded data for prostheses without documented use in the last 10 years (Thompson-Richards prosthesis) [10].

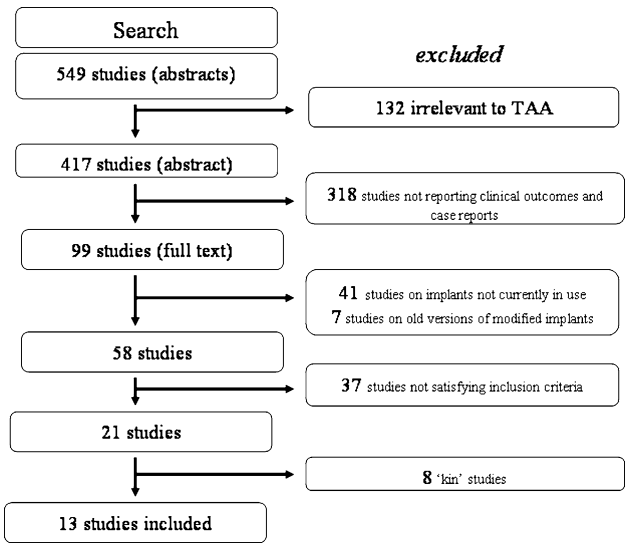

Fig. 1 A literature search was performed by two of the authors (NG, AK). We included studies published in peer-reviewed journals reporting on patients with more than 20 TAAs, followed for a minimum of 2 years. Several studies reported results from the same patient population (kin studies) at different intervals and with different numbers of patients; in these cases, only data from the most recent publication were included.

From each article, two investigators (NG, AK) independently extracted the year of publication, type of study (randomized, controlled trial, prospective study or retrospective case series), number of patients and ankles treated, patients and ankles available for followup, length of followup, complications (superficial wound healing problems, deep infections), and prosthesis survival. Also, ankle ROM, validated outcome scores, numbers and proportions for patients' satisfaction (when available, although validated outcomes were not often reported), and residual pain in the ankle were recorded.

To evaluate the methods of studies reporting on TAA, we modified the score of Coleman et al. (commonly known as the Coleman Methodology Score or CMS) which initially was described to assess the quality of studies reporting outcomes of tendon disorders [6, 30] (Table 1). The CMS assesses methodology using 10 criteria, giving a total score between 0 and 100. A score approaching 100 indicates the study has a robust design and largely avoids chance, various biases, or confounding factors. The subsections that compose the CMS are based on the subsections of the CONSORT statement [25] (for randomized, controlled trials) but are modified to allow for other trial designs. Two investigators (NG, AK) scored the quality of the studies independently. Each investigator scored the quality of the studies twice with a 3-week interval between measurements. Intraobserver and interobserver reliability were examined. Where differences were encountered, agreement was achieved by consensus, for final data presentation (Table 2). To assess the reliability of quality scoring using the CMS, we used intraclass correlations for interobserver and the Spearman-Brown coefficient for intraobserver reliability. To compare means of CMS between the two examiners we used the Wilcoxon test. There was no difference (Wilcoxon test, $p = 0.066$, $z = -1.84$) between the mean CMS of the two examiners (71 versus 69). Intraobserver Spearman-Brown coefficient was 0.98, and the intraclass correlation was 0.98 (substantial agreement) [22]. Disagreement occurred in four studies (one parameter in each study). After disagreements were solved by consensus, the mean CMS was calculated (71; standard deviation, 11).

Confidence intervals (95% CI) were calculated where pooling of data was appropriate. The level of statistical significance was 0.05.

Table 1. Criteria used to compute the Coleman Methodology Score

Criterion	Category	Score
Part A: only one score to be given for each of the seven sections		
1. Study size		
	< 30 TAAs	0
	30–50 TAAs	4
	50–100 TAAs	7
	> 100 TAAs	10
2. Mean followup		
	< 2 years	0
	2–5 years	4
	5–10 years	7
	> 10 years	10
3. Number of different versions of implant used (eg, cemented versus cementless fixation)		
	Not stated, unclear, or < 90% of subjects receiving same implant version	0
	More than one implant version, but > 90% of subjects receiving one version	7
	One implant version used	10
4. Type of study		
	Retrospective cohort study	0
	Prospective cohort study	10
	Randomized, controlled trial	15
5. Description of indications/diagnosis (osteoarthritis, rheumatoid arthritis, etc)		
	No	0
	Yes	5
6. Descriptions of surgical technique		
	Inadequate (not stated, unclear)	0
	Fair (technique only stated)	3
	Adequate (technique stated, details of surgical procedure given)	5
7. Survivorship analysis		
	Yes	10
	No	0
Part B: scores may be given for each option in each of the three sections if applicable		
1. Outcome criteria		
	Outcome measures clearly defined	2
	Timing of outcome assessment clearly stated	2
	Use of outcome criteria that has reported reliability	3
	General health measure included	3
2. Procedure of assessing outcomes		
	Subjects recruited	5
	Investigator independent of surgeon	4
	Written assessment	3
	Completion of assessment by patients themselves with minimal investigator assistance	3
3. Description of subject selection process		
	Selection criteria reported and unbiased	5
	Recruitment rate reported > 90%	5
	Recruitment rate reported < 90%	0

TAA = total ankle arthroplasty. (The original description of the Coleman Methodology Score was published by Wiley Interscience in: Coleman BD, Khan KM, Maffulli N, Cook JL, Wark JD. Studies of surgical outcome after patellar tendinopathy: clinical significance of methodological deficiencies and guidelines for future studies. *Scand J Med Sci Sports.* 2000;10:2–11.)

Table 2. Coleman Methodology Scores for the 13 studies reporting on TAA

Study	Prosthesis	Coleman Methodology Score																			
		Part A							Part B												
		1	2	3	4	5	6	7	1				2				3				Total*
Knecht et al. [18]	Agility™	10	7	10	10	5	3	10	2	2	3	0	5	4	3	3	5	5	87
Anderson et al. [1]	STAR	7	4	10	10	5	5	10	2	2	3	0	5	4	3	3	5	5	83
Wood et al. [34]	STAR	10	7	10	10	5	3	10	2	2	3	0	5	0	0	0	5	5	77
Bonnin et al. [2]	Salto™	7	4	10	10	5	5	10	2	2	3	0	5	0	3	0	5	5	76
Hurowitz et al. [15]	Agility™	7	4	10	0	5	3	10	3	3	3	3	5	4	3	3	5	5	76
Valderrabano et al. [31]	STAR	7	4	10	10	5	5	10	2	2	3	0	5	0	3	0	5	5	76
Valderrabano et al. [32]	HINTEGRA®	10	4	10	10	5	3	0	2	2	3	0	5	4	3	3	5	5	74
Buechel et al. [3]	Buechel-Pappas™	10	10	0	10	5	3	10	2	2	3	0	5	0	3	0	5	5	73
Kofoed [20]	STAR	7	7	0	10	5	5	10	2	2	3	0	5	0	3	0	5	5	69
Takakura et al. [29]	TNK	7	7	7	10	5	5	0	2	2	2	0	5	0	0	0	5	5	62
Kopp et al. [21]	Agility™	4	4	7	0	5	3	0	2	2	3	3	5	0	5	5	5	5	58
San Giovanni et al. [27]	Buechel-Pappas™	4	7	1	0	5	5	10	2	2	3	0	5	0	3	0	5	5	57
Naal et al. [26]	Buechel-Pappas™, Mobility™	10	4	0	0	5	3	0	2	2	3	0	5	4	3	3	5	0	49

* Values set by consensus between the two investigators (NG, AK); studies are presented in descending order according to total Coleman Methodology Score.

Results

We identified 13 studies [1–3, 15, 18, 20, 21, 26, 27, 30–32, 34] published from 2003 to 2008 and reporting on 1105 TAAs (234 Agility™ [DePuy Orthopaedics, Inc, Warsaw, IN], 344 STAR [Waldemar Link, Hamburg, Germany], 153 Buechel-Pappas™ [Endotec, South Orange, NJ], 152 HINTEGRA® [New Deal, Lyon, France], 98 Salto™ [Tornier, Saint Ismier, France], 70 TNK [Kyocera, Kyoto, Japan], and 54 Mobility™ [DePuy International, Leeds, UK]) with a minimum of 2 years followup. There were no randomized trials. All included studies were graded as Level IV evidence [4]. Patients' recruitment rate in 12 of the studies was greater than 90% [1–3, 15, 18, 20, 21, 27, 30–32, 34].

The indications for TAA varied among different studies (Table 3). Trauma was the leading cause (34%) of arthritis in ankles undergoing TAA (Table 3).

With revision, arthrodesis, or amputation as an end point, we identified 108 failures of 1105 TAAs (9.8%; 95% CI, 3.1%–16.5%). The weighted followup for all prostheses was 5.2 years (95% CI, 3.9–6.5 years). Eight studies [1, 3, 15, 18, 20, 27, 31, 34] provided Kaplan-Meier survivorship analysis data [16] ranging from 67% at 6 years to 95.4% at 12 years (Table 4).

Failures were salvaged with revision of the TAA in the majority of ankles (62%), whereas amputations were rare (Table 5).

Superficial wound healing complications (including superficial infections, delayed healing, and skin necrosis) were documented in 66 of 827 (8%) TAAs, ranging from 0% to 14.7% in the individual studies, and deep infections in seven of 827 (0.8%), ranging from 0% to 4.6% [1–3, 15, 18, 21, 27, 30, 31].

The American Orthopaedic Foot and Ankle Society Ankle (AOFAS)-Hindfoot score [17] was used most commonly to assess ankle function after TAA (Table 6). Some of the designers of ankle implants have developed their own scores (Kofoed score [19] and New Jersey ankle score [3]). Ankle scores improved after TAA in all studies (Table 6).

Ankle range of motion (ROM) as an outcome measure was documented in nine studies [1–3, 18, 21, 27, 30–32] (Table 7). Several methods have been used to measure ROM (radiographic, clinical with the patient sitting or standing). Mean postoperative ROM was equal to preoperatively [1] or improved by approximately 4° to 14° (Table 7) [2, 3, 30, 31]. Two studies [26, 32] investigated the ability to participate in sports after TAA. In one study [32], 55 of 152 patients (36%) were active in sports before surgery compared with 85 of 152 after surgery (56%). The most common activities were hiking, swimming, and cycling. In another study [26], 62.4% of the patients were active in sports preoperatively. This was similar to the 66% who were active after surgery. The patients participated in 3.0 ± 1.8 different sports and recreational activities preoperatively and in 3.0 ± 1.6 activities after surgery. The sports frequency remained unchanged (2.0 ± 1.6 sessions per week before TAA and 2.3 ± 1.7 postoperatively). The

Table 3. Patients' ages, causes of arthritis, and implants

Study	Prosthesis	Number of ankles	Age (years)*	Cause of ankle arthritis			
				Trauma	Idiopathic	Autoimmune	Other
Knecht et al. [18]	Agility™	132	61 (27–89)	61 (46%)	38 (29%)	31 (24%)	2 (1.5%)
Hurowitz et al. [15]		62	54.5 (28–77)	37 (60%)	12 (19%)	10 (16%)	3 (5%)
Kopp et al. [21]		40	63 (32–85)	24 (60%)	8 (20%)	8 (20%)	0
Valderrabano et al. [31]	STAR	68	56.1 (25–81)	48 (71%)	9 (13%)	11 (16%)	0
Kofoed [20]		25†	58 (29–81)	22 (88%)		3 (12%)	0
Anderson et al. [1]		51	57 (29–76)	10 (20%)	13 (26%)	28 (55%)	0
Wood et al. [34]		200	59.6 (18–83)	25 (12%)	56 (28%)	119 (60%)	0
Buechel et al. [3]	Buechel-Pappas™	75‡	49 (25–78)	55 (73%)	8 (11%)	9 (12%)	3 (4%)
San Giovanni et al. [27]		31	61 (28–79)	0	0	31 (100%)	0
Naal et al. [26]	Buechel-Pappas™	47	59.4 (24–85)	47 (48%)	35 (36%)	19 (19%)	0
	Mobility™	51					
Valderrabano et al. [32]	HINTEGRA®	152	59.6 (28–86)	115 (60%)	21 (14%)	16 (11%)	0
Takakura et al. [29]	TNK	70	71 (50–87)	36 (51%)		31 (44%)	3 (5%)
Bonnin et al. [2]	Salto™	98	56 (26–81)	43 (44%)	22 (22%)	29 (30%)	4 (4%)
All		1105	58.9 (95% CI, 56.2–61.7)	343/1010§ (34%)	244/1010§ (24.2%)	345/1105 (31.2%)	12/1105 (1%)

* Values expressed as means, with ranges in parentheses; †only STAR implants designed for cementless implantation have been included; ‡only deep sulcus Buechel-Pappas™ prostheses have been included; §two studies [20, 29] did not distinguish between idiopathic and posttraumatic osteoarthritis; in the remaining 11 studies [1–3, 15, 18, 21, 26, 27, 31, 32, 34] (including 1010 arthritic ankles), trauma was the causative factor in 343 (34%) and idiopathic osteoarthritis in 244 (24.2%); CI = confidence interval.

most common disciplines after TAA were swimming, cycling, and fitness/weight training.

Residual pain in the hindfoot after a TAA ranged between 23% and 60% in seven studies (Table 8) [2, 18, 21, 27, 31, 32, 34].

Patients' satisfaction after TAA was documented in eight studies [1, 2, 21, 26, 27, 30–32]. Naal et al. [26] used a visual analog scale to assess satisfaction with surgery. The mean score was 8 (± 2.5) of 10. Other authors did not use rigorously validated scales to evaluate patients' satisfaction. They stated patients were questioned regarding their satisfaction with the outcome (Table 9).

Ten studies [1–3, 18, 21, 26, 27, 30, 34] reported radiographic evaluation of TAAs. Most studies evaluated the presence of radiolucency and prosthesis subsidence or migration (Table 10), with heterogeneity in methods used and in definitions of radiographic loosening. One study evaluated alignment of the TAA [34]. Progression of osteoarthritis in adjacent joints was examined in two studies [18, 34]. Knecht et al. [18] reported progression at the subtalar joint in 22 of the 117 ankles (19%) and in 17 of 117 (15%) at the talonavicular joint, whereas Wood et al. [34] reported "deterioration" of subtalar joint arthritis in 15% of 95 ankles without arthritis in this joint before TAA.

Discussion

Early attempts of TAA with implants have been disappointing [10, 23]; however, implant designs have evolved [5, 7, 10]. What can we learn from the literature regarding the outcome of TAA with implants currently in use?

We note numerous limitations in the literature reviewed. (1) The level of surgeons' experience and variability in patients' selection may have influenced results in the individual studies. (2) Heterogeneity in study design and outcome measures did not allow direct comparisons of much of the data. It therefore is not possible to show superiority of certain implants or directly compare TAA with alternative management options (eg, arthrodesis). A multicenter trial comparing the outcomes of fixed- versus mobile-bearing implants, and a trial comparing TAA with arthrodesis, would be clinically relevant. However, comprehensive cohort studies reporting on the long-term effects of interventions (eg, TAA), although not providing treatment effect estimates, are useful estimates of prognosis, can detect adverse effects and complications, and are indicative of daily clinical practice achievements [9]. (3) The length of followup varied among studies, thus reported outcomes are not directly comparable. (4) Different scales and methodologies of assessment (patient recruitment,

Table 4. Survivorship of implants

Study	Prosthesis	Followup (years)*	Failures†	Kaplan-Meier [16] Survivorship analysis	Survivorship analysis pooled data
Knecht et al. [18]	Agility™	9 (7–16)	14/132 (10.6%)	63% at 14 years (95% CI, 35–90)	Agility™ [14, 17]: 86% at 6 years (95% CI, 60%–99%)
Hurowitz et al. [15]	Agility™	3.3 (2–5.9)	21/62 (32.3%)	67% at 6 years (95% CI, 53–82)	
Kopp et al. [21]	Agility™	2.8 (2.2–5.3)	2/40 (5%)		
Buechel et al. [3]	Buechel-Pappas™ (deep sulcus)	5 (2–12)	6/75 (8%)	92% at 12 years (95% CI, 55–100)	Buechel-Pappas™ [3, 27]: 92% at 12 years (95% CI, 89%–95%)
San Giovanni et al. [27]	Buechel-Pappas™	8.3 (5–12.2)	2/31 (6.5%)	93.4% at 12 years (95% CI, 83–100)	
Naal et al. [26]	Buechel-Pappas™	4.5 (2–7)	0/47		
	Mobility™	3 (2–4)	0/54		
Valderrabano et al. [31]	STAR	3.7 (2.4–6.2)	9/68 (13.2%)		STAR [1, 31, 34]: 89% at 5 years (95% CI, 74%–99%)
Kofoed [20]	STAR (uncemented)	9.5 (> 2)	1/25 (4%)	95.4% at 12 years (no CI given)	
Anderson et al. [1]	STAR	4.3 (3–8)	12/51 (23.5%)	70% at 5 years (95% CI, 54–86)	
Wood et al. [34]	STAR	7.3 (5–13)	24/200 (12%)	80.3% at 10 years (95% CI, 71–90)	
Takakura et al. [29]	TNK	5.2 (2–11.2)	3/70 (4.3%)		
Bonnin et al. [2]	Salto™	2.9 (2–5.7)	2/98 (2%)		
Valderrabano et al. [32]	HINTEGRA®	2.8 (2–4)	13/152 (8.6%)		

* Values expressed as means, with ranges in parentheses; †reaching end point: arthrodesis, revision, or amputation; CI = confidence interval.

Table 5. Failures of total ankle arthoplasties

Prosthesis	Followup (years)	Failures	Revision	Arthrodesis	Amputation	Osteochondral allograft
Agility™ [15, 18, 21]	6.6	37/234 (15.8%)	24 (65%)	11 (30%)	1 (2.5%)	1 (2.5%)
STAR [1, 20, 31, 34]	6.3	45/344 (13.1%)	26 (58%)	19 (42%)	0	0
Buechel-Pappas™ [3, 26, 27]	5.5	8/106 (7.5%)	4 (50%)	4 (50%)	0	0
HINTEGRA® [32]	2.8	13/152 (8.6%)	13 (100%)	0	0	0
Salto™ [2]	2.9	2/98 (2%)	0	2 (100%)	0	0
Mobility™ [26]	3.7	0/54 (0%)	0	0	0	0
TNK [30]	5.2	3/70 (4.3%)	0	3 (100%)	0	0
All implants	5.2 (95% CI, 3.9–6.5)	108/1105 (9.8%) (95% CI, 3.1–16.5)	67/108 (62%)	39/108 (36%)	1 (1%)	1 (1%)

CI = confidence interval.

questionnaires, independent examiner or not) were used in different studies. (5) Clinical outcome measures frequently were not validated, whereas some TAA implant designers have produced their own outcome scales (Kofoed [19], New Jersey [3]). Results reported in the individual studies therefore could be biased. (6) Patient satisfaction was not assessed using rigorous validated methods. (7) Definitions of the radiographic variables used in the assessment were not identical in different studies, and the radiographic examinations were not always standardized.

We evaluated the quality of studies using the CMS [6, 29]. The substantial interobserver and intraobserver agreement is indicative of the reliability of the CMS, although formal validation was not performed. The reader can easily compare the total score, with the maximum possible of 100 points, to get an impression of the study quality. It shares some similarities with the STROBE (Strengthening of Reporting of Observational trials in Epidemiology) [33] guidelines (study design, type and size, data collection, and recruitment of participants), although

Table 6. Functional outcome

Study	Prosthesis	Score	Preoperative*	Postoperative*	Followup (years)†
Knecht et al. [18]	Agility™	AOS [18]		2.5 ± 2.3 (different from age-matched control subjects; $p < 0.0001$)	> 7
Kopp et al. [21]	Agility™	AOFAS [17]	34 (12–70)	83 (65–100)	2.8 (2.2–5.3)
Takakura et al. [29]	TNK	AOFAS [17]	OA: 49 ± 11	OA: 86 ± 11	5.2 (2–11.2) (all ankles)
			RA: 44 ± 10	RA: 74 ± 12	
Bonnin et al. [2]	Salto™	AOFAS [17]	32 ± 10	82 ± 16	2.9 (2–5.7)
Buechel et al. [3]	Buechel-Pappas™ (deep sulcus)	NJOH [3]		(66/75) 88% good/ excellent	5 (2–12)
				(4/75) 5% fair	
				(5/75) 7% poor	
San Giovanni et al. [27]	Buechel-Pappas™	AOFAS [17]		81 (40–92)	8.3 (5–12.2)
Valderrabano et al. [31]	STAR	AOFAS [17]	25 (3–44)	84 (44–100)	3.7 (2.4–6.2)
Kofoed [20]	STAR (uncemented)	Kofoed [19]	30 ± 12	92 ± 7	9.5 (> 2)
Anderson et al. [1]	STAR	Kofoed [19]	39 (14–61)	70 (14–96)	4.3 (3–8)
		AOFAS [17]		74 (21–100)	
		Mazur [24]		74 (28–91)	
Wood et al. [34]	STAR	AOFAS [17]		70 (20–94)	7.3 (5–13)
Valderrabano et al. [32]	HINTEGRA®	AOFAS [17]	36 (10–74)	84 (28–100)	2.8 (2–4)
Naal et al. [26]	Buechel-Pappas™, Mobility™	AOFAS [17]	46 ± 17	84 ± 13	4.5 (2–7)

* Values expressed as means, with ranges in parentheses, or as mean ± standard deviation; †values expressed as means, with ranges in parentheses; AOS = Ankle Osteoarthritis Scale; AOFAS = American Orthopaedic Foot and Ankle Society; NJOH = New Jersey Ohio; OA = osteoarthritis; RA = rheumatoid arthritis.

Table 7. Range of motion

Study	Prosthesis	Preoperative*	Postoperative*	Followup (years)†	Method
Knecht et al. [18]	Agility™		18 (2–40)	9 (7–16)	Radiographic
Kopp et al. [21]	Agility™	34 of 40 ankles had improved range of motion postoperatively		2.8 (2.2–5.3)	Clinical
Anderson et al. [1]	STAR	28	28 (10–55)	4.3 (3–8)	Clinical
Valderrabano et al. [31]	STAR		38 (10–60)	3.7 (2.4–6.2)	Clinical weightbearing
			30 (10–50)		Clinical nonweightbearing
			28 (4–42)		Radiographic
Buechel et al. [3]	Buechel-Pappas™	24 (0–50)	29 (10–50)	5 (2–12)	Clinical
San Giovanni et al. [27]	Buechel-Pappas™	17 (5–40)	23 (10–40)	8.3 (5–12.2)	Clinical
Bonnin et al. [2]	Salto™	23 ± 12	33 ± 13	2.9 (2–5.7)	Clinical
		15 ± 10	28 ± 7		Radiographic
Takakura et al. [29]	TNK (OA)	28 ± 9	33 ± 10	5.2 (2–11.2) (all ankles)	Clinical
	TNK (RA)	22 ± 6	22 ± 5		Clinical
Valderrabano et al. [32]	HINTEGRA®	21 (0–45)	35 (10–55)	2.8 (2–4)	Clinical

* Values expressed as means, with ranges in parentheses, or as mean ± standard deviation; †values expressed as means, with ranges in parentheses; OA = osteoarthritis; RA = rheumatoid arthritis.

these are not a study quality scoring tool. They were developed to provide a checklist and recommendations that could aid authors to conduct and present observational studies [33].

Rheumatoid arthritis was the primary indication for TAA (reported rates of 39% and 37.5%) in two previous meta-analyses [12, 28]. Our data (Table 3) showed trauma was the leading cause (34%), with a wide range (range,

Table 8. Residual pain after total ankle arthroplasty

Study	Prosthesis	Painful ankles	Ankles examined	Percent	Followup (years)
Knecht et al. [18]	Agility™	17	63	27%	> 7
Kopp et al. [21]	Agility™	24	40	60%	2.8 (2.2–5.3)*
Valderrabano et al. [31]	STAR	30	65	46%	2.4–6.2
Wood et al. [34]	STAR	65	200	33%	7.3 (5–13)*
San Giovanni et al. [27]	Buechel-Pappas™	7	28	25%	> 5
Bonnin et al. [2]	Salto™	21	93	23%	> 2
Valderrabano et al. [32]	HINTEGRA®	47	152	31%	2.8 (2–4)*

* Values expressed as means, with ranges in parentheses.

Table 9. Patients' satisfaction rates

Study	Prosthesis	Satisfied patients	Patients who responded	Percent	Followup (years)
Kopp et al. [21]	Agility™	37	38*	97%	> 2.2
Anderson et al. [1]	STAR	33	39†	85%	> 3
Valderrabano et al. [31]	STAR	63	65*	97%	> 2.4
San Giovanni et al. [27]	Buechel-Pappas™	25	28*	89%	> 5
Bonnin et al. [2]	Salto™	86	93	92%	> 2
Takakura et al. [29]	TNK	49	62*	79%	> 2
Valderrabano et al. [32]	HINTEGRA®	Excellent: 49 Good: 77 Moderate: 17 Poor: 9	152	Excellent: 32% Good: 51% Moderate: 11% Poor: 6%	2.8 (2–4)‡

* Not reported why some patients did not respond (eg, lost to followup, failed results); †12 patients with failed TAAs were excluded; ‡values expressed as means, with ranges in parentheses.

Table 10. Radiographic loosening

Study	Prosthesis	Radiolucencies	Subsidence/ migration	Followup (years)*
Knecht et al. [18]	Agility™	89/117 (86%)	16/117 (14%)	4.6 (2–13.5)
Kopp et al. [21]	Agility™	34/40 (85%)	18/40 (45%)	3.7 (2.2–5.3)
Anderson et al. [1]	STAR		18/39 (46%)	4.3 (3–8)
Valderrabano et al. [31]	STAR	13/68 (19%)	10/68 (15%)	3.7 (2.4–6.2)
Buechel et al. [3]	Buechel-Pappas™	8/75 (11%)	3/75 (4%)	5 (2–12)
San Giovanni et al. [27]	Buechel-Pappas™	1/28 (4%)	5/28 (18%)	8.3 (5–12)
Bonnin et al. [2]	Salto™	0/93	1/93 (1%)	2.9 (2–5.7)
Takakura et al. [29]	TNK		23/67 (34%)	5.2 (2–11.2)
Naal et al. [26]	Buechel-Pappas™, Mobility™	35/101 (35%) tibia, 8/101 (8%) talus (Buechel-Pappas™ > Mobility™)		3.7 (2–7)

* Followup was calculated for the implants examined radiographically; values expressed as means, with ranges in parentheses.

12%–73%) in reports from different centers. This may reflect extension of the indications by some surgeons.

An overall 9.8% of ankle replacements required revision or conversion to ankle fusion at 5.2 years. The wide CI (CI range, 3.1%–16.5%) shows inconsistency in the presented data from individual studies, and should be interpreted with caution. A meta-analysis comparing TAA with ankle arthrodesis [11] that included studies published from 1990 to 2005 reported a TAA survival rate of 78% (95% CI, 69.0%–87.6%) at 5 years and 77% (95% CI, 63.3%–90.8%) at 10 years. The data in the current investigation are not directly comparable to those by Guyer and Richardson [11], as more recent publications have been included and different methods for data analysis were used

in the two studies. Another meta-analysis [28], which reviewed 18 studies on mobile-bearing prostheses published from 1997 to 2002, found the weighted survival rate was 90.6% at 5 years. This is comparable to the survival rate of mobile-bearing implants in our study (Table 4). TAA survivorship data, however, should be interpreted with caution. Results from the prosthesis' inventors can be biased and may reflect the higher familiarity with the implant. Knecht et al. [18] included the surgeries performed by the designer of the Agility™ prosthesis, evaluated by independent authors, and reported a 95% survival rate at 6 years, whereas others achieved only 67% [15]. Similarly, the designer of the STAR [20] reported a 95% survivorship rate at 10 years, whereas an independent high-volume surgeon [5] was reported to have a survivorship rate of 80% at 10 years. Others [1] reported a better survival rate in their latter 31 TAAs compared with the initial 20. The Swedish Joint Register [13], possibly representing more closely the average surgeon's outcomes, reported a 77% survival rate. Their data [13] showed the 5-year survival rate increased from 70% before to 86% after the surgeon had performed 30 TAAs. The designer of the Buechel-Pappas™ prosthesis reported a 92% survivorship rate at 12 years in 75 TAAs with the newer, deep sulcus implant. These results were reproduced by an independent surgeon [27], however, in patients with rheumatoid arthritis (low demand). Differences therefore may be symptomatic and reflect the surgeon's familiarity with the procedure, or selection of patients, rather than the effect of the intervention and the implant.

Comparing functional outcomes of different implants requires caution because of the different methodologies used, as described earlier. Haddad et al. [12] reported the mean AOFAS score was 78.2 points, which is comparable to the reported outcomes in our study (Table 6). Two studies [26, 32] suggested participation in certain sports is possible after TAA. It is not known, however, whether this is advisable and how it would affect failure rates in the long term.

The improvement in ankle ROM was relatively small (0°–14°) (Table 7). This is in agreement with the results of others [12, 28]. Our patients therefore should be informed preoperatively, improvement in ankle motion is not one of the expected benefits from TAA.

Furthermore, residual pain after TAA is relatively frequent (23%–60%) (Table 8), whereas the methodologic flaws in assessing patients' satisfaction in the individual studies raise concerns regarding the high satisfaction rates reported (Table 9).

Current TAAs improve ankle function; however, residual pain is common and wound complications can occur. The overall failure rate is approximately 10% at 5 years with a wide range from different centers.

References

1. Anderson T, Montgomery F, Carlsson A. Uncemented STAR total ankle prostheses: three to eight-year follow-up of fifty-one consecutive ankles. *J Bone Joint Surg Am.* 2003;85:1321–1329.
2. Bonnin M, Judet T, Colombier JA, Buscayret F, Graveleau N, Piriou P. Midterm results of the Salto total ankle prosthesis. *Clin Orthop Relat Res.* 2004;424:6–18.
3. Buechel FF Sr, Buechel FF Jr, Pappas MJ. Twenty-year evaluation of cementless mobile-bearing total ankle replacements. *Clin Orthop Relat Res.* 2004;424:19–26.
4. Centre for Evidence-Based Medicine. Levels of evidence and grades of recommendation. Available at: http://www.cebm.net/index.aspx?o=1025. Accessed May 18, 2009.
5. Chou LB, Coughlin MT, Hansen S Jr, Haskell A, Lundeen C, Saltzman CL, Mann RA. Osteoarthritis of the ankle: the role of arthroplasty. *J Am Acad Orthop Surg.* 2008;16:249–259.
6. Coleman BD, Khan KM, Maffulli N, Cook JL, Wark JD. Studies of surgical outcome after patellar tendinopathy: clinical significance of methodological deficiencies and guidelines for future studies. Institute of Sport Tendon Study Group. *Scand J Med Sci Sports.* 2000;10:2–11.
7. Cracchiolo A 3rd, Deorio JK. Design features of current total ankle replacements: implants and instrumentation. *J Am Acad Orthop Surg.* 2008;16:530–540.
8. Giannini S, Leardini A, O'Connor JJ. Total ankle replacement: review of the designs and of the current status. *Foot Ankle Surg.* 2000;6:77–88.
9. Glasziou P, Vandenbroucke JP, Chalmers I. Assessing the quality of research. *BMJ.* 2004:328:39–41.
10. Gougoulias NE, Khanna A, Maffulli N. History and evolution in total ankle arthroplasty. *Br Med Bull.* 2009;89:111–151.
11. Guyer AJ, Richardson G. Current concepts review: total ankle arthroplasty. *Foot Ankle Int.* 2008;29:256–264.
12. Haddad SL, Coetzee JC, Estok R, Fahrbach K, Banel D, Nalysnyk L. Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis: a systematic review of the literature. *J Bone Joint Surg Am.* 2007;89:1899–1905.
13. Henricson A, Skoog A, Carlsson A. The Swedish Ankle Arthroplasty Register: an analysis of 531 arthroplasties between 1993 and 2005. *Acta Orthop.* 2007;78:569–574.
14. Hintermann B, Valderrabano V, Dereymaeker G, Dick W. The HINTEGRA ankle: rationale and short-term results of 122 consecutive ankles. *Clin Orthop Relat Res.* 2004;424:57–68.
15. Hurowitz EJ, Gould JS, Fleisig GS, Fowler R. Outcome analysis of Agility total ankle replacement with prior adjunctive procedures: two to six year follow up. *Foot Ankle Int.* 2007;28:308–312.
16. Kaplan EL, Meier P. Nonparametric estimation from incomplete observations. *J Am Stat Assoc.* 1958;53:457–481.
17. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int.* 1994;15:349–353.
18. Knecht SI, Estin M, Callaghan JJ, Zimmerman MB, Alliman KJ, Alvine FG, Saltzman CL. The Agility total ankle arthroplasty: seven to sixteen-year follow-up. *J Bone Joint Surg Am.* 2004;86:1161–1171.
19. Kofoed H. Cylindrical cemented ankle arthroplasty: a prospective series with long-term follow-up. *Foot Ankle Int.* 1995;16:474–479.
20. Kofoed H. Scandinavian Total Ankle Replacement (STAR). *Clin Orthop Relat Res.* 2004;424:73–79.
21. Kopp FJ, Patel MM, Deland JT, O'Malley MJ. Total ankle arthroplasty with the Agility prosthesis: clinical and radiographic evaluation. *Foot Ankle Int.* 2006;27:97–103.

22. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* 1977;33:159–174.
23. Lord G, Marotte JH. [Total ankle prosthesis: technic and first results. Apropos of 12 cases] [in French]. *Rev Chir Orthop Reparatrice Appar Mot.* 1973;59:139–151.
24. Mazur JM, Schwartz E, Simon SR. Ankle arthrodesis: long-term follow-up with gait analysis. *J Bone Joint Surg Am.* 1979;61:964–975.
25. Moher D, Schulz KF, Altman DG; CONSORT. The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *BMC Med Res Methodol.* 2001;1:2.
26. Naal FD, Impellizzeri FM, Loibl M, Huber M, Rippstein PF. Habitual physical activity and sports participation after total ankle arthroplasty. *Am J Sports Med.* 2009;37:95–102.
27. San Giovanni TP, Keblish DJ, Thomas WH, Wilson MG. Eight-year results of a minimally constrained total ankle arthroplasty. *Foot Ankle Int.* 2006;27:418–426.
28. Stengel D, Bauwens K, Ekkernkamp A, Cramer J. Efficacy of total ankle replacement with meniscal-bearing devices: a systematic review and meta-analysis. *Arch Orthop Trauma Surg.* 2005;125:109–119.
29. Takakura Y, Tanaka Y, Kumai T, Sugimoto K, Ohgushi H. Ankle arthroplasty using three generations of metal and ceramic prostheses. *Clin Orthop Relat Res.* 2004;424:130–136.
30. Tallon C, Coleman BD, Khan KM, Maffulli N. Outcome of surgery for chronic Achilles tendinopathy: a critical review. *Am J Sports Med.* 2001;29:315–320.
31. Valderrabano V, Hintermann B, Dick W. Scandinavian total ankle replacement: a 3.7-year average followup of 65 patients. *Clin Orthop Relat Res.* 2004;424:47–56.
32. Valderrabano V, Pagenstert G, Horisberger M, Knupp M, Hintermann B. Sports and recreation activity of ankle arthritis patients before and after total ankle replacement. *Am J Sports Med.* 2006;34:993–999.
33. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *PLoS Med.* 2007;4:e296.
34. Wood PL, Prem H, Sutton C. Total ankle replacement: medium-term results in 200 Scandinavian total ankle replacements. *J Bone Joint Surg Br.* 2008;90:605–609.