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REVIEW ARTICLE

A systematic review of outcome and failure rate of uncemented Scandinavian total ankle replacement

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Abstract
Purpose The purpose of this study was to provide cumulative data about the intermediate to long-term outcome of Scandinavian total ankle replacement (STAR) in the literature and to provide a summary of survival rate, implant failure rate and reasons.
Methods A comprehensive search for all relevant articles published in English and German from January 1995 to May 2011 was conducted. Two reviewers evaluated each study to determine whether it was eligible for inclusion and, if so, collected data of interest. The intermediate to long-term outcomes were determined. Evidence-based meta-analytic pooling of results across studies was performed to determine survival and failure rates.
Results Sixteen primary studies with 2,088 implants were identified. The mean American Orthopaedic Foot and Ankle Society (AOFAS) score was 77.8 points, and the mean Kofoed ankle score was 76.4 points. The pooled mean five year survival rate was 85.9% [95% confidence interval (CI) 80.9–90.3], and the pooled mean ten year survival rate was 71.1% (95% CI 60.9–81.5). Pooled failure rate was 11.1% (95% CI 7.6 –14.9), with a mean follow-up time of 52 months; 41% failed within one year of initial operation. The first three reasons associated with implant failure were aseptic loosening (5.2%), malalignment (1.7%) and deep infection (1.0%).
Conclusions We found that STAR prosthesis achieved encouraging results in terms of intermediate to long-term outcome. The five and ten year survival rates were acceptable. However, the failure rate was still high. The major reasons for implant failure were aseptic loosening and malalignment. Maybe the increase of surgeons' experience and patient selection could improve outcomes and decrease failure rate.

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Introduction

Arthrodesis has been the gold standard treatment for severe ankle arthrosis since it was first described by Albert in 1879. However, whereas isolated ankle arthrodesis might address immense pain at the ankle, it might not sufficiently address the associated problems and ongoing changes in the neighbouring joints, and this procedure is also associated with a high complication rate. Cumulative data of 649 ankle arthrodesis in 16 studies with a mean follow-up of ten years showed the major complication (deep infection, nonunion, amputation) rate was 30%, with continuing hindfoot pain in 51% of patients and subtalar joint degeneration in 66% [1]. Total ankle arthroplasty (TAA) was developed to provide an alternative to ankle arthrodesis for treating severe ankle arthrosis, with the inherent advantage of preserving joint motion, reducing limp and protecting other joints [2–4]. Initially introduced with much optimism in the 1970s, first-generation cemented ankle arthroplasties were subsequently found to be plagued with unacceptably high complication and failure rates and were largely abandoned [5]. Enthusiasm for TAA has been renewed with the development of newly designed total ankle devices, which require less bone resection, leaving stronger subchondral bone to secure the prosthesis. In addition, mobile-bearing prostheses offered the distinct possibility of less wear and loosening, which was attributable to improved component conformity and minimal constraint. To date, second- and third-generation TAA devices have been reported to have promising intermediate-term results [6, 7].

At least 20 different TAA systems have been designed worldwide, with new systems continually being developed .

Mobile-bearing prostheses were mainly used in Europe, and fixed-bearing implants were mainly used in the USA [8]. The Scandinavian Total Ankle Replacement (STAR) device (Waldemar Link, Germany) was one of the most used mobile-bearing total ankle prosthesis devices used worldwide. Developed by Kofoed in 1978 and first used in 1981>, it received tentative US Food and Drug Administration (FDA) approval in April 2007 [9]. This total ankle prosthesis received FDA approval for use in May 2009, making it the only mobile-bearing design available in the United States [10]. The earlier design consisted of a metallic talar component that covered the medial and lateral talar surfaces, articulating with a polyethylene tibial component (two-component congruent unconstrained design). Both components were fixed with bone cement. Clinical results showed that cement fixation was less successful [11]. A polyethylene meniscus was introduced in 1986 [12]. From 1990, a bioactive surface coating for cementless implantation was introduced, and from 1999 a double coating. The uncemented STAR prosthesis was a three-part, mobile-bearing replacement designed to permit motion at two interfaces: one above and one below the polyethylene bearing. The upper interface was a flat planar surface, permitting internal and external rotation as well as translation in the anterior–posterior and medial–lateral directions. The inferior articulating surface was shape like a cylinder, allowing dorsiflexion and plantarflexion. The combined potential of the two articulating surfaces was to allow a moving axis of motion that theoretically reduces shear stresses at the bone–implant interfaces, thus promoting fixation and long-term stability [13]. As the STAR ankle prosthesis was widely used, clinical studies evaluated long-term safety and performance, which contained cohort studies and National Joint Register reports. Survival and failure rates were highly variable between these studies. For experienced surgeons, >5-year failure rate was <5% and exceeded 95% [11, 14]. However, some studies reported a much higher failure rate and lower survival rate [15–17]. To date, no evidence-based meta-analysis has evaluated the outcome of STAR total ankle replacement. We therefore systematically reviewed the literature to determine the quality of outcomes of total ankle replacement and to provide evidence-based cumulative data of clinical failure rate, survivorship and the functional outcomes.

Materials and methods

Study selection

Standard systematic review methods were used. Initially, a prospective protocol was written to describe objectives, search criteria, study selection criteria, elements of interest and plans for analysis. According to the protocol, a broad search of the English and German language literature from January 1995 to May 2011 was conducted. MEDLINE was searched through PubMed using the search terms ankle and arthroplasty or replacement or prosthesis. Article titles and abstracts were reviewed and the articles of interested were selected for the full text. Other databases, such as EMBASE and Cochrane Review, and the main orthopaedic journals were also searched. A manual reference check of all accepted papers and recent reviews was performed to supplement the electronic searches and to identify any additional potentially relevant studies. Search results were screened independently by two reviewers (ZHM and YYF) and determined as relevant, irrelevant or uncertain according to study eligibility criteria, and conflicts were resolved by consensus discussions.

Inclusion and exclusion criteria

To satisfy inclusion criteria, the study must have reported: (1) outcome and failure rate and reasons for TAA, (2) use of uncemented STAR, (3) at least 20 patients with a STAR prosthesis in the treatment group and (4) mean follow-up of at least two years. Exclusion criteria consisted of studies in which: (1) all patients had severe ankle or hindfoot deformities, (2) the study population was diabetic, (3) ankle arthrodesis or arthroplasty failed, (4) multiple publications on the same patient population were pooled, to the extent possible, as one study (kinship) to counting patients more than once. Two reviewers (ZHM and YGR) had to agree on all accepted and rejected studies. All study designs were eligible, including randomised controlled trials, prospective and retrospective nonrandomised controlled trials and case series, according to the *Journal of Bone and Joint Surgery* criteria level I–IV [18]. The methods of studies reporting on STAR prosthesis were evaluated by a modified Coleman Methodology Score (CMS), (Table 1) [19], which indicates a total score between 0 and 100; 100 indicates the study has a robust design and largely avoids chance, various biases or confounding factors.

Data sampling and statistical methods

Patient characteristics, number of cases, mean follow-up, patient-reported functional outcome scales and scores, ankle joint range of motion (ROM), failure rate and reasons and prosthesis survival rates were recorded. TAA failure was defined as the need to change prosthesis components, change to ankle arthrodesis or TAA-related amputation. All selected studies were reviewed carefully by two orthopaedic surgeons (ZHM and ZJQ). Protocol-defined data from each eligible study were extracted and confirmed by the

Table 1 Criteria used to compute the modified Coleman Methodology Score (CMS)

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 follow-up	<2 years	0
	2–5 years	4
	5–10 years	7
	>10 years	10
3. Number of different versions of implant used (e.g. cemented versus cementless fixation)		
	Not stated, unclear, <90% of patients receiving same implant	0
	>90% of patients receiving one version	7
	One implant version used	10
4. Type of study	Retrospective cohort study	0
	Prospective cohort study	10
	Randomised 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, have surgical procedure details)	5
7. Survivorship analysis	No	0
	Yes	10
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		
	Patients recruited	5
	Investigator independent of surgeon	4
	Written assessment	3
	Completion of assessment by patients, 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

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same two researchers. Differences were resolved prior to data entry. Failure and survival rates were calculated using meta-analytic pooling group results across studies [20]. Data are shown as median and range or mean and 95% confidence interval (CI). For the different functional outcome scales, the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale and Kofoed ankle score were the most commonly used evaluation systems in the studies of TAA. As score-reported method was not unified, only a mean score was calculated in our study. All statistical analyses were performed with the SAS 9.1.3 (SAS Institute Inc., NC, USA) and STATA 7.0 (StataCorp LP, TX, USA).

Results

The initial search yielded 335 citations: 25 full publications met all eligibility criteria for inclusion into the database,

four studies met criteria for exclusion and five were kinship studies. As a result, 14 studies in English and two in German with a total of 2,088 TAAs were eligible for inclusion into further analysis [11, 13–17, 21–30]. Results of the modified CMS of each study are shown in Table 2, and demographic data are shown in Table 3. The mean follow-up was 52 (1–158) months. Mean patient age was 60 (17–89) years. Preoperative diagnosis was rheumatoid arthritis (RA) for 681 ankles (33%) posttraumatic osteoarthritis (TA) or primary osteoarthritis (OA) for 1,177 (56%) and other for 230 (11%).

Six studies with a total of 529 TAAs used the AOFAS ankle and hindfoot scale, and the mean score was 77.8 with a mean follow-up time of 66 months (Table 4). Six studies (225 TAAs) used Kofoed ankle score, with a mean score of 76.4 in a mean 53 months' follow-up. Ten studies with 1,278 TAAs reported the five year survival rate, and five studies with 806 TAAs reported ten year survival rate. The meta-analytic pooled 5-year survival rate was 85.9% (95% CI 80.9–90.3), and the pooled 10-year survival rate was 71.1% (95% CI 60.9–81.5). Five studies reported ankle joint ROM [15–17, 25, 30], and the mean ROM was 26.8° (0–55°) in 242 STAR total ankle replacement with a mean follow-up of 49 months.

For the 2,088 STAR with a mean follow-up of 52 months, 232 were considered to have failed results and with a pooled failure rate of 11.1% (95% CI 7.6–14.9). Eleven main complications were reported in the literature as the reasons of STAR implant failure: intraoperative fracture, wound-healing problems, postoperative fracture, subsidence, instability, aseptic loosening, deep infection, malalignment and edge loading, broken or torn prosthesis, stiffness and residual pain and others (Table 5). The first three reasons associated with implant failure were aseptic loosening (5.2%, 59–107), malalignment (1.7%, 19–107) and infection (1.0%, 11–107). Seven studies with 357 TAAs and 34 failures reported the time and reason of each failure [11, 14, 15, 17, 22, 26, 30]. Among those patients, 14 (41%) experienced failure within one year after initial operation: six implant loosening, three postoperative fractures, three deep infections and two residual pain. In these seven studies, if failure cases within one year were eliminated, the failure rate decreased from 10.6% (95% CI 3.6–17.6) to 5.6% (95% CI 0.2–11.3).

Discussions

According to our study, functional outcomes were difficult to determine in combination because of the different methodologies used in the studies analysed. The most frequently used evaluation scale was AOFAS score, with a

Table 2 Modified Coleman Methodology Score (CMS) for studies of the Scandinavian total ankle replacement (STAR)

Study	Coleman Methodology Score										Total
	Part A							Part B			
	1	2	3	4	5	6	7	1	2	3	
Skyttä [21]	10	4	10	0	5	0	10	5	9	10	63
Karantana [15]	7	7	10	0	5	5	10	7	8	10	69
Saltzman [13]	10	4	10	10	5	5	0	7	15	10	76
van der Heide [22]	0	4	10	0	5	3	10	7	11	10	60
Wood [14]	10	4	10	15	5	5	10	7	15	10	91
Schönherr [23]	4	4	10	10	5	3	0	7	11	10	64
Wood [24]	10	7	10	10	5	5	10	7	11	10	85
Schutte [25]	4	4	10	0	5	3	0	4	11	10	61
Hosman [26]	4	4	10	0	5	0	10	7	15	10	65
Henricson [27]	10	7	10	0	5	0	10	4	9	10	65
Fevang [28]	10	4	10	0	5	0	10	4	9	10	62
Carlsson [29]	7	4	10	10	5	5	10	7	15	10	83
Murnaghan [30]	0	4	10	0	5	5	0	7	11	10	52
Valderrabano [16]	7	4	10	10	5	5	10	7	15	10	76
Kofoed [11]	0	7	10	10	5	5	10	7	11	10	75
Anderson [17]	7	4	10	10	5	5	10	7	15	10	83

Values set by consensus between the two investigators (ZHM and ZJQ)

Table 3 Demographic data on the studies of Scandinavian total ankle replacement

Study	Year	Years implanted	Centre	Cases	Follow-up (months)	Mean age (years)	Etiology	Failure Number
Skyttä [21]	2010	1997–2006	Multi-centre	217	58 (1–115)	55 (17–86)	RA 128; Other 89	31
Karantana [15]	2010	1999–2002	Single-centre	52	80 (60–110)	62 (33–81)	OA 34; RA 14	8
Saltzman [13]	2009	2000–2006	Multi-centre	593	24	63	OA 157; TA 345; RA 51; Metabolic 40	28
van der Heide [22]	2009	1996–2004	Single-centre	29	29 (6–78)	55 (27–82)	RA 29	4
Wood [14]	2009	2000–2003	Single-centre	100	54 (36–85)	65 (23–83)	OA 69; RA 31	4
Schönherr [23]	2008	2000–2004	Single-centre	49	30 (6–51)	63 (42–79)	TA 25; OA 17; RA 7	5
Wood [24][a]	2008	1993–2000	Single-centre	200	88 (60–156)	60 (18–83)	OA 81; RA 119	24
Schutte [25]	2008	1999–2004	Single-centre	49	28 (12–67)	57 (37–81)	RA 29; TA 12; OA 5; other 3	4
Hosman [26]	2007	2000–2005	Multi-centre	45	43 (12–74)	65 (32–83)	OA 71%; TA 17%; RA 12%	3
Henricson [27]	2007	1993–2005	Multi-centre	318	83 (1–158)	58	RA 41%; OA 22%; TA 33%; Other 4%	73
Fevang [28]	2007	1996–2005	Multi-centre	212	48 (1–144)	59 (18–89)	OA 106; RA 97; Other 13[b]	21
Carlsson [29][c]	2006	1999–2005	Single-centre	58	37 (11–64)	56 (26–83)	RA 24; OA or TA 29; Other 3	1
Murnaghan [30]	2005	1999–2003	Single-centre	22	26 (8–46)	60 (31–77)	OA 14; RA 6	2
Valderrabano [16]	2004	1996–1999	Single-centre	68	44	56 (22–85)	TA 48; RA 11; OA 9	11
Kofoed [11]	2004	1990–1995	Single-centre	25	108	58 (29–81)	OA 22; RA 3	1
Anderson [17]	2003	1993–1999	Single-centre	51	52 (36–97)	57 (27–76)	OA 13; RA 28; TA 10	12

OA osteoarthritis, *RA* rheumatoid arthritis or inflammatory arthritis, *TA* traumatic arthritis

[a] Some information was extracted from another paper, which was excluded as a kinship report [31]; [b] includes four cemented STAR prosthesis; [c] series 1 with 51 cases in this study was excluded as a kinship report

mean of 77.8 points, which was comparable with a previous report of 78.2 points for mixed prostheses [32]. Some scores, such as the Kofoed ankle score and Buechel–Pappas ankle score, were also used to evaluate functional outcomes of TAA. As the clinical outcome measures frequently were not validated, results reported in the individual studies therefore could be biased [19].

Pooled mean survival rates of STAR were acceptable. The five and ten year survival rates were 85.9% and 71.1%, respectively, although the survival rates varied among different institutions. TAA survivorship data should be interpreted with caution. The results of our analysis were lower than reported by some studies, but they more closely represented the average surgeons' outcomes. Overall STAR failure rate was 11.1%, with a wide range between centres. The most common reason for failure was aseptic loosening (55%). Implant malalignment or edge loading was another common reason for failure (18%). Infection was a major reason for TAA revision. As many as 41% TAAs failed within one year, which might mean surgeons' experience was an important factor. If failure within the first year were eliminated, the rate decreased significantly. Swedish Joint Registry data reported three experienced surgeons' five year survival rates increased from 0.70 for the first 90 cases to 0.86 for the following 132 cases [27]. Carlsson et al. [29] reported two series of STAR: series two (1.7%) achieved a much lower failure rate that did series one (23.5%). Wood was one of the most experienced STAR surgeons, who reported a failure rate of 12% for 200 TAAs between 1993 and 2000; that rate decreased to 4% for 100 TAAs between 2000 and 2003 [14, 24]. Haskell et al. [33] compared the perioperative complication rate of the first ten and subsequent ten STAR operations performed by ten different surgeons. Patients in the early group had a 3.1 times greater chance of having perioperative adverse events than those in the late group.

The surgical challenge of performing a TAA and the long learning curve are well known, and STAR is especially technically demanding [17, 27, 29, 31]. Knowing how and when to perform additional pre- or postoperative surgery is crucial to achieve stability and alignment. Henricson et al. [27] reported a higher revision rate for the STAR prosthesis than other prostheses: they explained that STAR was introduced earlier and at a time when most surgeons were in the early learning phase, that STAR was technically demanding and that instrumentation during the first years was unsatisfactory. Hosman et al. [26] concluded that longer operative time for the primary procedure was associated with subsequent failure and determined that the reasons for longer operative time were ankle condition preoperatively, surgeon inexperience and the difficulty of the surgical procedure.

Patient selection might be an influencing factor in TAA failure. Whether younger patient age and severe ankle

Table 4 Functional outcomes and survival rate of Scandinavian total ankle replacement (STAR)

Study	Functional outcome		Survival rate (mean and 95% CI)	
	Scale	Score[a]	5-year	More than 5-years
Skyttä [21]	NR	NR	83% (81–86)	7 years 80% (73–88)
Karantana [15]	AOFAS	78±18	87% (73.8–94.1)	8 years 84% (68.9–92.2)
Saltzman [13]	BP subscale	83±21	NR	NR
van der Heide [22]	Kofoed	73 (21–92)	78%[b]	NR
Wood [14]	AOFAS	79	95% (87.2–98.1)	6 years 95% (87.2–98.1)
Schönherr [23]	Kofoed	86±18	NR	NR
Wood [24]	AOFAS	75	93.3% (89.8–96.8)	10 years 80.3% (71.0–89.6)
Schutte [25]	Kofoed	68±19	NR	NR
Hosman [26]	NR	NR	86% (78–94)	NR
Henricson [27]	NR	NR	78% (74–82)	10 years 62% (52–72)
Fevang [28]	NR	NR	89% (84–94)	10 years 76% (63–89)
Carlsson [29]	AOFAS	81 (63–100)	93.7% (90–97)	NR
Murnaghan [30]	Kofoed	75 (19–96)	NR	NR
Valderrabano [16]	AOFAS	84 (44~100)	NR	NR
Kofoed [11]	Kofoed	92±7	100%	10 years 95% (91–100)
Anderson [17]	Kofoed/AOFAS	70/74	70% (54–85)	10 years 60.4% (53–68) [30]

[a] Mean and 95% confidence interval (CI), mean or mean and range; [b] excluded for pooled five year survival rate, as no information on 95% CI
BP subscale Buechel–Pappas ankle score, *Kofoed* Kofoed ankle score, *AOFAS* American Orthopaedic Foot and Ankle Society Ankle–Hindfoot Scale, *NR* not reported

malalignment are associated with earlier failure is still under debate. In a Swedish study, younger age was associated with an increased risk of later revision [27]. Valderrabano et al. [16] reported younger age correlated with lysis and loosening. Spirt et al. [6] retrospectively reviewed 306 TAAs and reported age was the only significant predictor of reoperation and failure after TAA.

Table 5 Scandinavian total ankle replacement (STAR) failure rate and reasons

Reasons[a]	Cases	Total	Rate (%)
Intraoperative fracture	2	1,128	0.2
Infection	11	1,128	1.0
Wound-healing problems	1	1,128	0.1
Subsidence	1	1,128	0.1
Postoperative fracture	5	1,128	0.4
Instability	9	1,128	0.8
Loosening	59	1,128	5.2
Malalignment	19	1,128	1.7
Broken prosthesis	9	1,128	0.8
Stiffness and pain	10	1,128	0.9
Others	5	1,128	0.4
Total	232	2,088	11.1

[a] Three studies contained 960 total ankle arthroplasties; 125 failure cases did not report reasons

However, Kofoed et al. [34] reported TAA results were of equal quality in patients younger than 50 years and those who were older. Other studies also reported age had no statistically significant effect on survival [21, 28]. Doets et al. [35] reported an increased failure rate was encountered in ankles with a preoperative deformity of >10° in the frontal plane. Other authors agreed with performing realignment procedures at the same time as implant arthroplasty [14, 24, 25, 27]. Cenni et al. [36] reported ankles with larger preoperative anterior subluxation showed the talar component positioned more posteriorly over the talus postoperatively. However, Hobson et al. [37] compared patients with a preoperative hindfoot deformity <10° to a group with greater deformity (11–30°) and found no difference in ROM, complication and survival rate. Although some studies reported good results in younger and preoperative malalignment patients, TAA should be performed with caution in this population, especially when being performed by inexperienced surgeons.

Postoperative ankle ROM was relatively small (mean 26.8°). This was in agreement with results of other authors [19, 32, 38]. Dyrby et al. [39] evaluated ankle joint function during walking before and after STAR and reported a significantly improved ROM postoperatively but a reduced ROM compared with normal controls. Tochigi et al. [40] reported inaccurate STAR was associated with a decreased ROM. Patients should therefore be informed preoperatively

that improvement in ankle motion is not one of the expected benefits from STAR.

According to our study, the midterm functional outcome and five and ten year survival rates were acceptable, which demonstrated that STAR might be a reasonable alternative to fusion. However, the total STAR failure rate was still high. Perhaps an increase in surgeons' experience and appropriate patient selection could improve outcomes and decrease the failure rate. Furthermore, as Pfeiff supposed [41], if longer-term follow-up studies continue to show favourable outcomes, STAR would likely become the new gold standard for surgically treating disabling ankle joint arthritis.

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