Outcomes of trabecular metal total ankle replacement: a longitudinal observational cohort study of 239 consecutive cases from the Swedish Ankle Registry

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Background and purpose — Information on outcomes after some modern total ankle replacement (TAR) designs is scarce. We therefore examined outcomes after trabecular metal (TM) TAR in Sweden by use of data from the national registry.

Patients and methods — On December 31, 2020, 239 primary TM TARs had been reported to the Swedish Ankle Registry. We analyzed prosthesis survival probability, using exchange or permanent extraction of components as endpoint for 239 protheses with mean follow-up of 2.2 years (0.1–6.6), risk of revision, as well as patient-reported outcome measures (SEFAS/EQ-5D/EQ-VAS) and satisfaction with surgery.

Results — 7/239 prostheses (3%) had been revised by December 31, 2020. We found an overall prosthesis survival probability of 95% (95% CI 89–98) after 3 years. 2 years after surgery 81% of the answering patients were satisfied or very satisfied with surgery and patients reported median SEFAS 36 (max 48), EQ-5D 0.90 (max 1), and EQ-VAS 80 (max 100).

Interpretation — We found short- to mid-term outcomes after TM TAR to be at least as good as after other TAR designs regarding prosthesis survival and patient-reported satisfaction.

Results of total ankle replacement (TAR) have gradually improved (1,2) but remain inferior to those after total hip and knee replacement (3). The most common cause of TAR revision is aseptic loosening (2,4,5). Trabecular metal (porous tantalum) coating has been used to improve fixation for various implants. Ingrowth and sufficient biological fixation in such implants have been shown both experimentally (6) and clinically in human specimens (7-9), and in long-term total knee replacement studies (10,11).

In relatively small short- and mid-term reports from different centers, the trabecular metal ankle (TM Ankle) has shown promising results (12-15). More data, preferably from independent, non-specialist centers is, however, needed.

We present real-world prosthesis survival probability and also PROM results for a large consecutive series of TM Ankles from a national cohort of patients by use of the Swedish Ankle Registry.

Patients and methods

Since 1993, Swedish hospitals performing TARs have reported information on date of index surgery and any revision surgery, together with data on the patient and the procedure, to the Swedish Ankle Registry. Reporting is made by the surgeon, except for PROMs and PREMs, which are reported by the patient. The current procedure-based coverage and completeness are both estimated at close to 100%.

The TM Ankle is a fixed-bearing 2-component total ankle prosthesis. The tibial and talar surfaces are coated with trabecular metal (porous tantalum). The surgical approach is transfibular, meaning that the fibular osteotomy must be fixated at the end of the procedure.

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Table 1. Preoperative demographics and characteristics for patients who underwent a primary TM Ankle procedure in Sweden (N = 239). Values are count (%) unless otherwise specified

Category	N (%)	Mean (SD) or n (%)
Age	239 (100)	65 (11) [a]
Sex	239 (100)	
Female		109 (46)
Male		130 (54)
BMI	204 (85)	28 (4.4) [a]
ASA	237 (99)	
1		57 (24)
2		149 (63)
3		31 (13)
Side	239 (100)	
Right		121 (51)
Left		118 (49)
Diagnosis	239 (100)	
Post-traumatic osteoarthritis		108 (45)
Primary osteoarthritis		72 (30)
Rheumatoid arthritis		38 (16)
Psoriatic arthritis		7 (3)
Other		14 (6)

[a] Mean (SD)

As at December 31, 2020, 239 TM Ankle (Zimmer Biomet, Warsaw, IN, USA) primary procedures in 233 patients were registered in the Swedish Ankle Registry. 6 patients underwent bilateral procedures, none simultaneously (Table 1). The procedures were performed at 11 different hospitals, 9 at 5 high-volume centers. In the 2 low-volume centers, most procedures were performed by, or with the aid of, a surgeon from a high-volume center.

Preoperatively most patients were invited to answer PROM questionnaires (SEFAS and EQ-5D/EQ-VAS) at the location of their caregiver. At 3 time points after surgery including 2 years postoperatively questionnaires for SEFAS, EQ-5D/EQ-VAS, and satisfaction with surgery were sent to all patients. The validated SEFAS score has 12 questions, each graded by the patient from 0 to 4 (16). A total score of 0 points represents the most severe disability and 48 points represents normal function. EQ-5D has 5 dimensions: mobility, hygiene, main activities, pain, and anxiety/depression, each graded by the patient on a scale from 1 to 3: no problem (1), some problems (2), and severe problems (3). The answers are converted to an overall score between 1 and 0, where 1 is full health and 0 is dead. EQ-VAS records the patient's self-rated health on visual analogue scale (0–100), with the endpoints "The worst health you can imagine" and "The best health you can imagine." Satisfaction with surgery was graded on a Likert scale with 5 levels: very satisfied, satisfied, neither satisfied or dissatisfied, dissatisfied, and very dissatisfied.

We chose to analyze the number of prostheses rather than the number of patients (including bilateral cases), in line with our previous study (17), as this approach has been found to have a negligible effect on the survival estimates (18).

We defined revision as exchange or removal of 1 or more components except incidental exchange of the polyethylene insert (19). Follow-up started on the day of primary TAR and ended on the day of revision, death, or December 31, 2020, whichever came first.

Statistics

Even though the data is collected from a complete or almost complete National Quality Registry (NQR) we chose to consider the study as sample based. We thus present measures of uncertainty to facilitate generalization to probable future outcomes in Sweden and to other similar populations.

We used the Kaplan–Meier estimator to visualize the prosthesis survival probability and used 95% confidence intervals (CI) to describe uncertainty.

For estimation of risk of revision, cases that underwent surgery at least 1, 2, or 3 years before end of study were used as population at risk and revision cases within 1, 2, or 3 years as events (disregarding deaths).

As PROM scores were not normally distributed, they are presented as medians with interquartile ranges (IQR). Changes in scores were, however, approximately normally distributed (with some ceiling effects). We therefore (under the central limit theorem) used a t-test (with non-parametric bootstrapping, using simple case resampling with 10,000 iterations) to estimate mean changes with 95% confidence intervals (interval percentiles from the ordered bootstrap values).

Ethics, data sharing, funding, and potential conflicts of interest

The study protocol was approved by the Ethical Review Board of Lund University (Dnr 2009:698, 2014/448) and the study was conducted in accordance with the Helsinki Protocol.

The registration of data and the study was performed confidentially and according to Swedish and EU data protection rules. All authors had access to the anonymous database delivered by Register Centrum Syd, Region Skane Sweden. This study is based on sensitive individual-level data protected by the Swedish personal data act. Data sharing is not possible according to Swedish law.

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The authors declare no conflict of interest.

Results

Before the end of follow-up, 5 of the 233 patients died (mean 24 months [range 11–52)] after surgery) and 7 (3%) under-

Table 2. Concomitant procedures in patients who underwent a primary TM Ankle procedure in Sweden (N = 239)

Concomitant procedure	n
Calcaneal osteotomy	15
Lateral ligament reconstruction	13
Subtalar arthrodesis	12
Achilles tendon lengthening	12
Extraction of metal device	9
Osteotomy metatarsal I	5
Deltoid release	5
TMT I arthrodesis	5
Gastrocnemius lengthening	3
Navicular–cuneiform arthrodesis	3
Flexor digitorum longus transfer	2
Augment screw medial malleolus	2
Total	86

Table 3. Pre- and postoperative PROM/PREM scores in patients who underwent a primary TM Ankle procedure in Sweden (n = 239) answering any (pre- and/or postoperative [a]) questionnaire

	Individuals answering preoperative questionnaire		Individuals answering postoperative [a] questionnaire	median (IQR) [b] or n (%)
	n (%)	median (IQR) [b]	n (%)	
SEFAS	168 (70)	15 (10–19)	107 (72)	36 (26–43)
EQ-5D	165 (69)	0.68 (0.58–0.73)	106 (71)	0.90 (0.83–0.97)
EQ-VAS	160 (67)	60 (40–76.5)	107 (71)	80 (70–90)
Satisfaction			108 (72)	
Very satisfied				61 (5)
Satisfied				27 (25)
Neither satisfied nor dissatisfied				12 (11)
Dissatisfied				3 (3)
Very dissatisfied				5 (5)

[a] ≥ 1.5 years' follow-up, alive and unrevised, n = 149 eligible patients.
[b] See Statistics.

Table 4. Pre- and postoperative PROM scores and changes in PROM scores in patients who underwent a primary TM Ankle procedure in Sweden and answered both pre- and 2-year [a] postoperative questionnaires

	n (%)	Preoperative median (IQR) [b]	Postoperative [a] median (IQR) [b]	Change from pre- to postoperative mean (95% CI) [b]
SEFAS	79 (53)	16 (10–20)	35 (25–41)	18 (15–20)
EQ-5D	77 (51)	0.68 (0.58–0.73)	0.83 (0.83–0.96)	0.19 (0.15–0.22)
EQ-VAS	76 (51)	65 (46–80)	80 (70–90)	15 (9.6–20)

[a] ≥ 1.5 years' follow-up, alive and unrevised, n = 149 eligible patients.
[b] See Statistics.

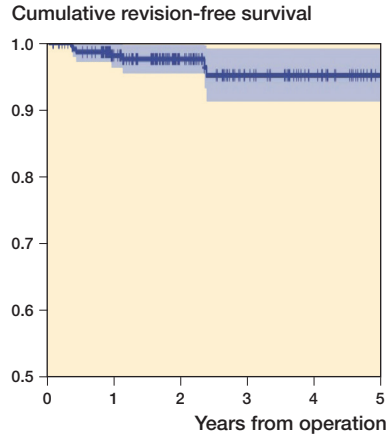

Figure 1. Estimated cumulative prosthesis survival probability for primary TM Ankle procedures in Sweden (N = 239). The purple band represents the 95% confidence interval.

went revision (mean 13 months [4–28] after surgery). The mean follow-up was 26 months [1–79].

Of the 7 patients who underwent revision, 4 were due to deep infection; of these 3 were treated with removal of components and arthrodesis in a 2-stage procedure and 1 with arthrodesis in a 1-stage procedure. 2 patients with valgus malalignment after fracture close to the prosthesis both underwent ankle fusion, and 1 patient with medial pain underwent cleaning of the medial gutter and change to a higher meniscal bearing.

During the 239 TM Ankle procedures 86 concomitant procedures were performed in 85 patients. Calcaneal osteotomy was the most common (Table 2).

Postoperative major complications occurred in 7 patients. 6 of these were related to infection; 1 was treated with debridement, antibiotics, and implant retention (DAIR), and the other 5 with removal of the lateral plate. 1 patient suffered a fracture and underwent a re-osteotomy of the fibula.

10 patients underwent secondary non-revision surgery, 2 due to valgus malalignment (1 of these underwent calcaneal osteotomy, FDL transfer, and deltoid reconstruction, and the other underwent navicular–cuneiform arthrodesis and tibial osteotomy). 1 patient, due to varus malalignment, underwent osteotomy of both tibia and fibula. Due to medial pain 4 patients underwent cleaning of bony overgrowth in the medial gutter and insertion of an augmenting screw in the malleolus. The 3 remaining patients for unspecific reasons underwent talo-navicular arthrodesis (1 patient), TMT I arthrodesis (1 patient), and extraction of a medial screw (1 patient).

Preoperatively, 168/239 completed the SEFAS questionnaire, 165 (69%) the EQ-5D, and 160 (67%) completed the EQ-VAS. 149 patients were available (≥ 1.5 years' follow-up, alive and unrevised) for the 2-year questionnaires and 107 (72%), 106 (71%), and 107 (72%) completed the respective above-mentioned questionnaire. Median scores were higher after surgery. Not all patients answered all questionnaires but for those that reported both pre- and 2-year postop scores, changes were statistically significant. 108 (72%) patients also reported their satisfaction with surgery in the 2-year questionnaires; 81% were very satisfied or satisfied with their prosthesis (Tables 3 and 4).

Table 5. Life table of primary TM Ankle procedures in Sweden (N = 239)

Interval (year)	Entering interval	Censored [a]	Exposed to risk	Terminal events	Cumulative proportion surviving at end of interval (CI)
0–1	239	51 (1)	213.5	4	0.98 (0.95–0.99)
1–2	184	81 (3)	143.5	1	0.97 (0.94–0.99)
2–3	102	43 (0)	80.5	2	0.95 (0.89–0.98)
3–4	57	22 (0)	46	0	0.95 (0.89–0.98)
4–5	35	20 (1)	25	0	0.95 (0.89–0.98)

For further details see Figure 2 (in Supplementary data).
[a] Deaths or follow-up not long enough. Number of deaths in parenthesis.

Table 6. Primary TM Ankle procedures in Sweden (N = 239) with revisions for estimation of revision risk. All individuals who have undergone the primary procedure are thus considered at risk of revision during the follow-up (not discarding deaths). For a traditional flowchart see Figure 2 (in Supplementary data)

TAR performed years before EoS	n	Revisions during follow-up year [a] 1	2	3	> 3	Revisions at EoS
0 to < 1	50	(0) [a]	–	–		0
1 to < 2	81	1	(1) [a]	–		2
2 to < 3	48	2	0	(1) [a]		3
> 3	60	1	0	1	(0) [a]	2

[a] Revisons during incomplete follow-up years in parenthesis.
EoS = end of study (December 31, 2020).
Revision rate within 1 year: (1+2+1) / (81+48+60) = 2%
Revision rate within 2 years: (2+1) / (48+60) = 3%
Revision rate within 3 years: (1+1) / 60 = 3%
Revision rate overall: 7 / 239 = 3%

The estimated prosthesis survival probability was 95% (CI 89–98) after 3 years (Figure 1, Table 5). The risk for revision was 3% at 3 years (Table 6).

Discussion

In this study, the so far largest published consecutive series of the TM Ankle, we found a 3-year prosthesis survival probability of 95% and a 3-year risk of revision of 3%. After 2 years the satisfaction rate and the clinical score (SEFAS) were high.

Trabecular metal components have properties that seem to facilitate bony ingrowth and stable biological fixation (7,8,10,11). We found no aseptic loosening of components, and few have been reported in the literature. Mosca et al. (15) reported 1 aseptic loosening among 73 cases. This case had, however, already been revised 21 days postoperatively due to malrotation of the tibial component and may thus rather be a technical error than a true aseptic loosening. Barg et al. (12) reported 3 cases of loosening (the tibial component) out of 55 cases. Long-term studies of the Trabecular Metal Tibia in total knee replacement have not shown aseptic loosening (10,11,20).

The complexity of total ankle replacement is well known and is reflected in the high rate of concomitant procedures in this study (86 concomitant procedures during 239 primary TARs). To attain good balancing of the foot and ankle complex during TAR surgery a range of simultaneous procedures may be necessary. DeVries et al. (21) had 7 concomitant procedures in their short-term study, i.e., in nearly half of their patients. Barg et al. (12) reported 58 concomitant procedures in their 55 cases and Bianchi et al. (22) 14 in their study of 30 cases.

Problems related to the lateral plate in TM Ankles are not uncommon. Plate removal was undertaken in 5 patients with superficial infections in this study, all of which healed. The most reported complications with the lateral plate are either superficial infection or discomfort and tenderness from the hardware. Tiusanen et al. (14) reported problems with the lateral hardware in 12% of cases and Gagné et al. (23) in 23%. The rate of superficial infections decreased when these authors changed lateral fixation to screws and rods respectively. On the other hand, Usuelli et al. (24) found similar infection rate in 81 TARs through an anterior approach and 69 TARs through a transfibular approach. DeVries et al. (21), in a series of 16 patients, reported 3 cases of non-union after plate fixation of the fibula, and Bianchi et al. (22) had 1 such case in 30 patients. No non-union of the fibular osteotomy was reported to the Swedish Ankle Registry.

On a 5-category scale, 81% of the patients indicated that they were satisfied or very satisfied with the surgical results. Other reports of the TM Ankle have found nine-tenths very satisfied or satisfied patients using a 3-category rating (22) and two-thirds very satisfied patients with a 4-category rating (14). With mobile bearing TARs, Jung et al. (25), in their small short-term study and with a 4-grade score, had nine-tenths very satisfied or satisfied patients with the Hintegra and Mobility prostheses, respectively.

We found a high satisfaction rate and a statistically significant and clinically relevant mean improvement in EQ-5D as well as in the foot- and ankle-specific SEFAS after surgery. The mean increment in SEFAS (max. 48) of 18 points for those who answered both questionnaires was also clinically significant, well beyond the minimal important change (MIC) of 5 points (26). Our results are thus in line with Bianchi et al. (22), who found statistically significant improvements postoperatively using the FFI, the AOFAS, and the VAS pain scores. Mosca et al. (15) used the AOFAS, SF-36, and VAS scale and all improved statistically significantly. In the study by Usuelli et al. (13), the AOFAS, VAS, and Short Form-12 also improved statistically significantly as did the VAS, and the physical and pain domains of the PROMIS scores in the

study by Barg et al. (12). Clifton et al. (27) analyzed 55 procedures with Hintegra designs after 7 years and found an AOS score of 35, MOX-FQ score of 36, and EQ-5D score of 0.69, the latter in line with our result of 0.80.

The estimated prosthesis survival probability in this study was 95% after 3 years, which corroborates other mid-term reports of other TAR designs. Sproule et al. (28) found a 90% prosthesis survival probability after 3 years with the Mobility design, and with the same prosthesis Kerkhoff et al. (29) and Lefrancois et al. (30) found 95% and 89% prosthesis survival probabilities respectively. Using the Salto mobile bearing design, Faber et al. (31) and Wan et al. (32) report prosthesis survival probabilities of 94% and 95% respectively. With the TM Ankle, Barg et al. (12) found a prosthesis survival probability after 2 years of 93%, in line with our 2-year results of 97% (CI 0.94–0.99) (Table 5).

2 other fixed-bearing designs have been introduced quite recently, the Cadence and the Infinity. For Cadence, short- to mid-term results are promising but studies are few and small (33,34). For Infinity, promising results have been shown in one mid-term study (35); potential problems around the tibial component have, however, been observed (36,37).

There are some limitations to this study. The proportion of patients completing both measurements could have been higher than the approximately 50% achieved. Even though dropout analyses revealed similar PROMS in those who answered only the baseline or only the 2-year follow-up compared with those who answered both (data not shown) we cannot rule out selection bias. More patient-specific information would also benefit the study, but, due to the register-based nature, detailed patient-level data was not available. As in all registry studies, there is always uncertainty regarding the completeness and validity of data. The current procedure-based coverage and completeness are, however, both estimated as close to 100% in the register. The registry regularly compares data with the Swedish National Patient Registry and the validity of variables is, due to automatic input controls at registration, high. The strength of the study is that it is the so far largest series published and that it represents non-designer results in a real-world complete national cohort of patients.

In conclusion, this study of TM Ankle outcomes in Sweden found a high prosthesis survival probability (95%) after 3 years without any aseptic loosening, and a high patient satisfaction rate. The results justify further use of this prosthesis but also indicate that studies with head-to-head comparisons with other designs are necessary.

AH and BR designed the study, AH, BR, and ÅC collected data, AH, LJ, and BR interpreted data and performed statistical analyses, AH and BR wrote the first version; all authors together finalized the manuscript.

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Supplementary data

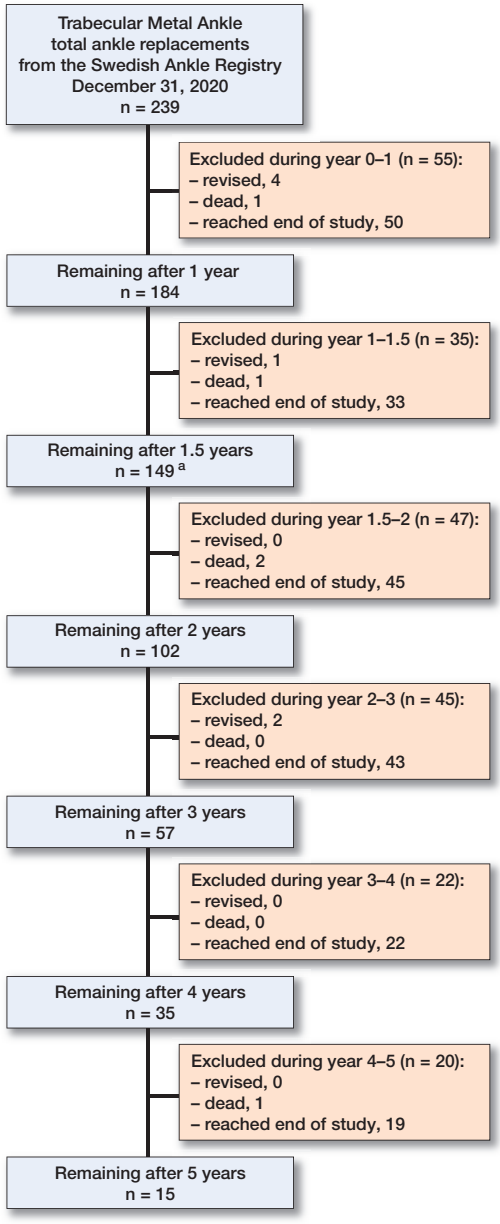

Figure 2. Flowchart of TM Ankle procedures in Sweden with revisions and death. [a] Available (≥ 1.5 years' follow-up, alive and unrevised) for the 2-year questionnaires.