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Undén, Alexandra

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PO Box 117
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+46 46-222 00 00



End-stage Ankle Arthritis

Aspects on Surgical Treatment Outcomes and Diagnostics

ALEXANDRA UNDÉN

DEPARTMENT OF CLINICAL SCIENCES, MALMÖ | FACULTY OF MEDICINE | LUND UNIVERSITY



End-stage Ankle Arthritis

Aspects on Surgical Treatment Outcomes and Diagnostics

Alexandra Undén



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DOCTORAL DISSERTATION

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Faculty opponent

Michael Axenus, MD, Associate professor
Orthopaedics, Department of Clinical Sciences, Karolinska Institutet and
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Abstract

Background: Osteoarthritis (OA) is a major global cause of pain, disability, and socioeconomic burden. Prevalence of ankle arthritis varies in the literature, perhaps due to varying radiographic techniques and classification systems, but is often believed to be 1-2%. Ankle arthritis is to a large extent post-traumatic and causes significant functional impairment and reduced quality of life, often in younger individuals. Surgical management includes ankle arthrodesis (AA) and total ankle replacement (TAR), with no clear evidence of superiority of either one.

Aims: To evaluate prosthetic survival rate after TAR in general and for specific prosthetic designs (*Paper I-II*) as well as Patient Reported Outcomes (PROMs) after Trabecular Metal™ TAR and AA and factors associated with a better or worse outcome (*Paper II-III*). To evaluate the reliability of radiographs with varying degree of weight bearing for detection and classification of ankle arthritis (*Paper IV*).

Methods: Data for *Paper I-III* were collected from Swedankle which contains information on more than 7500 ankle replacements/ankle arthrodeses performed in Sweden since 1993. In *Paper IV*, we procured radiographs in patients with ankle arthritis in non-weight bearing (NWB), semi-weight bearing (SWB) and weight bearing (WB) positions, which were evaluated for signs of arthritis and classified according to the Kellgren-Lawrence (K-L), Van Dijk and Takakura systems, by two radiologists.

Results: Overall prosthetic survival rate at 5 years was 85%, at 10 years 74% and at 15 years 63%. Use of current prosthetic designs was associated with better prosthetic survival. Prosthetic survival 3 years after surgery with TM TAR was 95% and 2 years after surgery, 81% were satisfied with significant improvement of mean PROM scores. 2 years after AA 69% of patients were satisfied with significant improvement of mean PROM scores. After AA, a higher preoperative SEFAS score was associated with satisfaction, while a lower preoperative SEFAS score was associated with dissatisfaction. Comparing NWB with WB radiographs as well as SWB with WB radiographs regarding detection of signs of ankle arthritis, rendered almost perfect reliability. Comparing NWB with WB radiographs as well as SWB with WB radiographs regarding classification of ankle arthritis, rendered almost perfect reliability for K-L and Van Dijk, while moderate for Takakura.

Conclusion: Our results point to a positive time trend of prosthetic survival after TAR in Sweden. Improved designs and instrumentation, more experienced surgeons, and improved patient selection may all have contributed to this. AA seems a reasonable treatment for end-stage ankle arthritis and we speculate that preoperative SEFAS score may be useful for predicting surgical outcome and facilitate preoperative patient discussions on expected results. NWB as well as SWB radiographs appear reliable compared to WB radiographs, both in detecting and classifying ankle arthritis by K-L or Van Dijk, at least for moderate and severe grades.

Key words: Ankle arthritis, total ankle replacement, TAR, ankle arthrodesis, AA, PROMs, ankle radiograph.

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End-stage Ankle Arthritis

Aspects on Surgical Treatment Outcomes and Diagnostics

Alexandra Undén



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MADE IN SWEDEN 

*To my family
and to all the painful ankle joints out there.*

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Abstract

Background: Osteoarthritis (OA) is a major global cause of pain, disability, and socioeconomic burden. Prevalence of ankle arthritis varies in the literature, perhaps due to varying radiographic techniques and classification systems, but is often believed to be 1-2%. Ankle arthritis is to a large extent post-traumatic and causes significant functional impairment and reduced quality of life, often in younger individuals. Surgical management includes ankle arthrodesis (AA) and total ankle replacement (TAR), with no clear evidence of superiority of either one.

Aims: To evaluate prosthetic survival after TAR in general and for specific prosthetic designs (*Paper I-II*) as well as Patient Reported Outcomes (PROMs) after Trabecular Metal™ TAR and AA and factors associated with a better or worse outcome (*Paper II-III*). To evaluate the reliability of radiographs with varying degree of weight bearing for detection and classification of ankle arthritis (*Paper IV*).

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Results: Overall prosthetic survival rate at 5 years was 85%, at 10 years 74% and at 15 years 63%. Use of current prosthetic designs was associated with better prosthetic survival. Prosthetic survival 3 years after surgery with TM TAR was 95% and 2 years after surgery, 81% were satisfied with significant improvement of mean PROM scores. 2 years after AA 69% of patients were satisfied with significant improvement of mean PROM scores. After AA, a higher preoperative SEFAS score was associated with satisfaction, while a lower preoperative SEFAS score was associated with dissatisfaction. Comparing NWB with WB radiographs as well as SWB with WB radiographs regarding detection of signs of ankle arthritis, rendered almost perfect reliability. Comparing NWB with WB radiographs as well as SWB with WB radiographs regarding classification of ankle arthritis, rendered almost perfect reliability for K-L and Van Dijk, while moderate for Takakura.

Conclusion: Our results point to a positive time trend of prosthetic survival after TAR in Sweden. Improved designs and instrumentation, more experienced surgeons, and improved patient selection may all have contributed to this. AA seems a reasonable treatment for end-stage ankle arthritis and we speculate that preoperative SEFAS score may be useful for predicting surgical outcome and facilitate preoperative patient discussions on expected results. NWB as well as SWB radiographs appear reliable compared to WB radiographs, both in detecting and classifying ankle arthritis by K-L or Van Dijk, at least for moderate and severe grades.

List of papers

The thesis is based on the following papers:

- I. **Better implant survival with modern ankle prosthetic designs: 1,226 total ankle prostheses followed for up to 20 years in the Swedish Ankle Registry.**
Undén, A., Jehpsson, L., Kamrad, I., Carlsson, Åke, Henricson, A., Karlsson, M. K., & Rosengren, B.E. (2020).
Acta Orthopaedica, 91(2), 191-196.

- II. **Outcomes of trabecular metal total ankle replacement: a longitudinal observational cohort study of 239 consecutive cases from the Swedish Ankle Registry.**
Henricson, A., Undén, A., Carlsson, Åke, Jehpsson, L., & Rosengren, B.E. (2022).
Acta Orthopaedica, 93, 689-695.

- III. **Patient satisfaction and patient-reported outcome measures after primary ankle arthrodesis: 2-year results from the Swedish Ankle Registry.**
Undén, A., Jehpsson, L., Henricson, A., Karlsson, M.K., & Rosengren, B.E. (2026)
Acta Orthopaedica, 97, 171-176.

- IV. **Non-weight bearing, semi-weight bearing and weight bearing radiographs for the diagnosis and classification of ankle arthritis.**
Undén, A., Jehpsson, L., Taha, D., Karlsson, M.K., & Rosengren, B.E.
Manuscript

The papers are enclosed at the end of the thesis

Description of contributions

Paper I

Alexandra Undén, Lars Jehpsson, Ilka Kamrad, Åke Carlsson, Anders Henricson, Magnus Karlsson, and Björn Rosengren designed the study; Alexandra Undén and Åke Carlsson collected data; Alexandra Undén, Lars Jehpsson, and Björn Rosengren interpreted data and performed statistical analyses; Alexandra Undén and Björn Rosengren wrote the first version; all authors together finalised the manuscript.

Paper II

Anders Henricson and Björn Rosengren designed the study, Anders Henricson, Björn Rosengren, and Åke Carlsson collected data, Anders Henricson, Alexandra Undén, Lars Jehpsson, and Björn Rosengren interpreted data and performed statistical analyses, Anders Henricson and Björn Rosengren wrote the first version; all authors together finalised the manuscript (corrected compared to publication).

Paper III

Alexandra Undén, Lars Jehpsson, Anders Henricson, Magnus Karlsson and Björn Rosengren designed the study; Alexandra Undén and Björn Rosengren collected data; Alexandra Undén, Lars Jehpsson and Björn Rosengren interpreted data and did statistical analyses; Alexandra Undén and Björn Rosengren wrote the first version, all authors finalised the manuscript together.

Paper IV

Alexandra Undén and Björn Rosengren designed the study; Alexandra Undén and Dler Taha collected data; Alexandra Undén, Lars Jehpsson and Björn Rosengren interpreted data and did statistical analyses; Alexandra Undén wrote the first version, all authors finalised the manuscript together.

Abbreviations

AA	Ankle Arthrodesis
AUC	Area Under the Curve
CI	Confidence Interval
EQ-5D	EuroQol 5 Dimensions
IQR	Inter Quartile Range
(κ)	Kappa Value
NWB	Non-Weight Bearing
MRI	Magnetic Resonance Imaging
OA	Osteoarthritis
PROM	Patient Reported Outcome Measure
PtA	Post-traumatic Arthritis
QOL	Quality Of Life
ROC	Receiver Operating Characteristic
ROM	Range Of Motion
RA	Rheumatoid Arthritis
TAR	Total Ankle Replacement
TM TAR	Trabecular Metal Total Ankle Replacement
SD	Standard Deviation
SEFAS	Self-reported Foot and Ankle Score
SPECT	Single-Photon Emission Computed Tomography
STAR	Scandinavian Total Ankle Replacement
SWB	Semi-Weight Bearing
Swedankle	National Swedish ankle registry
WB	Weight Bearing
CT	Computed Tomography

Thesis at a glance

Paper	Aims	Methods	Results	Conclusions
I	To analyse the prosthetic survival rate after Total Ankle Replacement (TAR) in general and for specific prosthetic designs.	We analysed prosthetic survival rate in 1226 primary TARs reported to Swedankle 1993-2016. Differences between current and early prosthetic designs were examined by log rank test.	Overall prosthetic survival rate was 85% at 5 y, 74% at 10 y, 63% at 15 y and 58% at 20 y. For early prosthetic designs survival rate was 81% at 5 y and 69% at 10 y, while 88% and 84% for current designs.	We found a positive time trend of prosthetic survival, use of current prosthetic designs was associated with better survival.
II	To analyse the prosthetic survival rate and patient reported outcomes measures (PROMs and satisfaction) for Trabecular Metal (TM) TAR.	239 primary TM TARs were identified in Swedankle 2014-2020. Prosthetic survival rate, risk of revision and PROMs (SEFAS, EQ-5D index, EQ-5D VAS and satisfaction) were analysed.	7/239 prostheses had been revised by 2020. Prosthetic survival rate was 95% after 3 years. 2 years after surgery 81% of patients were satisfied and reported median SEFAS 36, EQ-5D 0.90, and EQ-5D VAS 80.	We found short- to mid-term outcomes after TM TAR to be at least as good as after other TAR designs regarding prosthetic survival rate and satisfaction.
III	To evaluate patient satisfaction 2 years after primary ankle arthrodesis (AA), changes in PROMs from before to 2 years after AA, and factors associated with the outcome.	In Swedankle, 2008-2020, 1145 patients reported on satisfaction and 662-702 on pre- and 2-year postoperative PROMs after AA. Changes in PROMs and associations between surgical and patient factors with outcomes, were analysed.	2 years after AA 69% of patients were satisfied. Satisfaction was associated with higher preoperative SEFAS and dissatisfaction with lower preoperative SEFAS score.	AA remains a reliable but not optimal treatment for ankle arthritis. We speculate that preoperative SEFAS score may facilitate preoperative patient discussions on expectations and expected results.
IV	To evaluate the reliability of non-weight bearing (NWB) as well as semi-weight bearing (SWB) compared to weight bearing (WB) radiographs, for detection and classification of ankle arthritis.	23 patients with ankle arthritis were included and underwent NWB, SWB and WB radiographs. Two radiologists classified and assessed the radiographs for signs of arthritis. Reliability of NWB/SWB compared to WB radiographs was analysed.	Reliability of NWB/SWB vs WB radiographs regarding detection of signs of arthritis was almost perfect. Reliability for classification of ankle arthritis on NWB/SWB compared to WB radiographs was almost perfect for K-L and Van Dijk, while moderate for Takakura.	NWB as well as SWB radiographs seem reliable compared to WB radiographs, both in detecting signs of arthritis and in classifying ankle arthritis by K-L or Van Dijk, at least in moderate and severe grades.

Introduction

Background

Osteoarthritis (OA) is a degenerative joint disease representing a major global cause of pain, disability, and societal cost [1, 2]. OA also represents the most common joint disease in Sweden [3]. In the Skåne region of Sweden, the proportion of doctor diagnosed OA has been found at 27% in the population aged ≥ 45 years and has been estimated to increase to 30% from 2012 to 2032 [4]. Ankle arthritis represents a smaller but clinically significant subset of OA, affecting approximately 1-2% of the population [5, 6]. The reported prevalence of ankle arthritis, however, varies in the literature [7, 8], perhaps related to differences in radiographic techniques used for identification and classification. Studies have utilised weight-bearing (WB), non-weight-bearing (NWB), or unspecified imaging approaches. Although WB radiographs are often considered the gold standard for assessing ankle arthritis, the actual degree of weight bearing during imaging can vary considerably [9], and the impact of this variation on detecting and classifying ankle arthritis remains unclear.

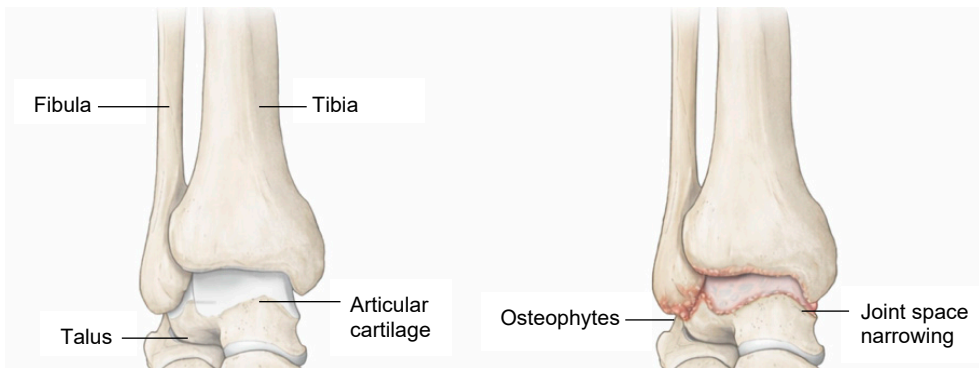
Although less prevalent than knee or hip OA [7, 10, 11], ankle arthritis, most commonly post-traumatic [12-14], leads to substantial functional impairment, reduced quality of life comparable to that related to hip OA [15], and a considerable socioeconomic burden, particularly among younger, working-age individuals [16]. Despite this, it has been found that total knee replacement (TKR) is performed 24 times more often than ankle arthrodesis (AA) and total ankle replacement (TAR) combined [10].

AA has traditionally been the gold standard for surgical treatment of end-stage ankle arthritis, though recent data show a growing use of TAR. Both procedures have been shown to improve function and patient reported outcome measures (PROMs), but each has distinct advantages and limitations. There is yet no consensus on superiority between the two methods [12, 17].

Brief anatomy and biochemistry

The ankle joint, or talocrural joint, is a hinged synovial joint formed through the articulations between the tibia, fibula and talus bones. The tibial plafond together with the medial and lateral malleoli, create a mortise that stabilises the talar dome.

The ankle joint is further stabilised by the joint capsule and supporting collateral ligaments medially and laterally. Main movements are plantarflexion and dorsiflexion, although the complex anatomy of the joint also allows for contribution to inversion/eversion as well as internal/external rotation. The cartilage lines the joint surface, acting as shock absorber and allowing for a smooth gliding motion [12]. Through the anterior talonavicular joint and the inferior talocalcaneal joint, the ankle connects with the foot. Together they build a complex structure that allows for basic daily activities such as standing, walking running and jumping.



AI generated image of a normal ankle joint (left) and an arthritic ankle joint (right).

Ankle arthritis

Osteoarthritis (OA) is a degenerative joint disease characterised by progressive cartilage loss, subchondral bone remodelling and synovial inflammation, ultimately leading to impaired joint function. OA can affect any joint, including the ankle. The ankle cartilage receives the greatest force per unit area of all hyaline cartilage in the human body [10] but is at the same time thinner than for example knee cartilage [18]. Despite this, ankle arthritis is less common than in other weight-bearing joints such as the hip or knee-joint [10]. This could perhaps be explained by a combination of anatomical, biochemical and biomolecular properties of the ankle joint cartilage. For example, load distribution in the ankle differs from other joints, such as the knee, resulting in compressive forces being distributed over a larger area [6] and cartilage in the ankle is also believed to have a greater capacity for self-repair [19] and to be less susceptible to mechanical damage [20].



Radiographs of a patient with ankle arthritis demonstrating advanced degenerative changes and deformity. Case courtesy of Mohammad Taghi Niknejad, Radiopaedia.org, rID: 98712. Reproduced under Creative Commons CC-NC-BY-SA 3.0.

Mechanical factors that change or increase stress in certain areas of ankle cartilage, such as incongruence, instability and malalignment, have been associated with the onset of arthritis [6]. Ankle cartilage is thus less prone to joint degeneration comparing to the knee or hip joint, but at the same highly susceptible to injuries/stress resulting in misalignment of the weight-bearing axis, be it asymmetric distribution of forces or joint fractures [21, 22].

Aetiology

Although literature on the aetiology of ankle arthritis is scarce [6] there is consensus that it is most often post traumatic i.e. related to a previous injury [12-14]. Post traumatic arthritis (PtA) accounts for between 70-90% of all ankle arthritis according to some studies [23-25], while 7%-9% is classified as idiopathic (OA) and 13% secondary to other causes such as rheumatoid arthritis, haemochromatosis, haemophilia, and osteonecrosis [6]. For PtA, the previous ankle trauma is often of rotational type [26] with a periarticular fracture (75%) or chronic, unresolved ligament instability (13%) [24]. Progression to advanced stages of ankle arthritis has been found to occur within 10 to 20 years of the onset [6], although clinical

studies show that the initial degenerative changes secondary to an ankle fracture develop within 12 to 18 months of the traumatic injury [21, 26].

Symptoms

Symptoms of ankle arthritis are typically stiffness, swelling, activity-related pain, and reduced range of motion (ROM) ultimately resulting in impaired gait [5]. As the condition progresses, deformity may arise, further decreasing ROM and most importantly increasing pain, not only activity-related but often interfering with night sleep. The mental and physical disability associated with end-stage ankle arthritis is considered at least as severe as that associated with end-stage hip arthritis [15] and comparable to other degenerative orthopaedic diagnoses [27] such as lumbar spinal stenosis, primary knee arthritis and hindfoot disorders [28-30].

Socioeconomic aspects

As ankle injuries often occur in contact sports or during imprudent activity, patients with PtA are more often male [28] and younger at diagnosis (18-44 years) [6] compared to hip- and knee arthritis. Mean age at ankle arthrodesis (AA) and total ankle replacement (TAR) has been reported at 56 and 63 years respectively [31, 32] compared to 65 and 67 years for total hip replacement and total knee replacement [33]. Patients with ankle arthritis are therefore likely to have another 10 work years before retirement and although less prevalent than hip- and knee arthritis [11], ankle arthritis can have great societal impacts by reducing vocational abilities and ultimately reducing employment productivity [16]. Surgical treatment of ankle arthritis has been shown to improve unemployment rates and be cost effective on a societal level [16].

Prevalence and disability

The prevalence and incidence of ankle arthritis is difficult to estimate as it is believed that many patients never seek medical care. Some literature suggest that ankle arthritis affects around 1%-2% of the population [5, 6, 27] and accounts for 2-4% of all arthritis [34]. The prevalence of ankle arthritis however varies substantially in the literature [7, 8], but studies generally indicate the prevalence of ankle arthritis to be lower than that of knee or hip arthritis [7, 10, 11]. The demand incidence of ankle arthritis in the UK has been reported at 47,7/10000 [34].

There are studies which report that knee arthritis is 8 to 9 more prevalent than ankle arthritis, however ankle arthritis is associated with substantial functional disability and reduced quality of life, comparable to that of hip arthritis [15]. Despite this, it has been found that approximately 24 times more total knee replacements are performed annually compared to the combined numbers of ankle arthrodesis (AA) and total ankle replacement (TAR) [10].

Although prevalence data can facilitate health-system planning, resource allocation and could justify investment in research related to both joint-preserving and surgical techniques [35], presently, no epidemiological data on ankle arthritis based on the Swedish population exists.

Radiology and ankle arthritis

Ankle arthritis is primarily a clinical diagnosis, based on a thorough patient history (anamnesis) and physical examination. As previously mentioned, typical clinical findings include pain, stiffness, swelling, reduced range of motion, and gait impairment. While clinical assessment is central to diagnosis, imaging can play an important complementary role when evaluating disease severity, confirming the diagnosis, monitoring progression, and in particular when planning surgical or joint-preserving interventions. Radiological examination can provide valuable information on joint space narrowing, osseous deformity, alignment, and involvement of adjacent joints that may not be fully appreciated on clinical examination alone.



Radiographs of a normal ankle joint. AP (left), Mortise (middle) and Lateral (right) views. Case courtesy of Andrew Murphy & Dr Ian Bickle, Radiopaedia.org, rID: 37950, 48079. Reproduced under Creative Commons CC-NC-BY-SA 3.0

Non-weight bearing and weight bearing radiographs

Despite the widespread use of radiography in the assessment of ankle arthritis, there is no universally accepted standard regarding radiographic classification or imaging technique in the literature [24].

The preferred radiographic technique varies, although weight-bearing (WB) radiographs are generally regarded as more reliable for assessing ankle arthritis [9, 36-38]. Radiographic assessment is commonly based on a combination of WB anteroposterior, mortise and lateral views [24]. WB imaging allows evaluation of the joint under physiological loading conditions and can reveal joint space narrowing, malalignment, and instability that may not be apparent on non-weight bearing (NWB) images. However, it has been shown that the true degree of WB varies considerably in WB radiographs of the foot and ankle [9] but the implication of this for assessing ankle arthritis, is unknown.

Nevertheless, non-weight bearing (NWB) radiographs are still frequently used in both clinical practice and some research, often due to logistical considerations, patient discomfort, or the retrospective nature of radiographic datasets. The lack of standardisation regarding WB status complicates comparison across studies and may influence the detection and grading of ankle arthritis.

Several radiological classification systems have been proposed, most of which are based on structural features such as joint space narrowing, osteophyte formation, and subchondral sclerosis. Among these, the most commonly used systems include the Kellgren-Lawrence classification [39], the Van Dijk classification [40] and the Takakura classification [41] (Figure 1).

Figure 1. Classification systems for ankle arthritis according to Kellgren-Lawrence [39], Van Dijk [40] and Takakura [41].

Kellgren-Lawrence	1	2	3	4
	Minute osteophyte of doubtful significance	Osteophytes on the medial malleolus, no joint space narrowing	Osteophytes, moderate diminution of joint space <50%	Osteophytes on medial and lateral malleoli, severe joint space narrowing >50%, tibiotalar sclerosis
Van Dijk	0	1	2	3
	Normal joint or subchondral sclerosis	Osteophytes without joint space narrowing	Joint space narrowing with or without osteophytes	(Sub) total disappearance or deformation of the joint space
Takakura	1	2	3	4
	Early sclerosis and formation of osteophytes without narrowing of the joint space	Narrowing of the medial joint space	3A. Obliteration of the medial joint space with subchondral bone contact limited to the medial malleolus 3B. Subchondral bone contact extending to the roof of the dome of the Talus.	Obliteration of the entire joint space, resulting in bone contact throughout the ankle

Advanced imaging modalities

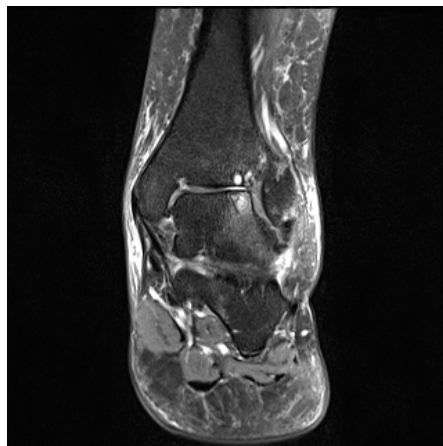
For evaluation and treatment planning in ankle arthritis, plain radiographs may be supplemented by advanced imaging modalities. These techniques can provide additional information regarding the extent and distribution of disease, osseous deformities, joint alignment, involvement of adjacent joints, and the condition of surrounding soft tissues [24].

Computed tomography (CT) allows for three-dimensional assessment and is particularly useful for detailed evaluation of bony anatomy. It enables accurate visualisation of bone erosion, subchondral cysts, loose bodies, and degenerative changes in adjacent joints, which can be critical in surgical decision-making [42]. CT is useful when plain radiographs are inconclusive or when complex deformities require detailed osseous assessment [25]. However, the higher exposure to ionising radiation, greater cost, and limited availability in some settings restrict routine use of CT, particularly in younger patients and for repeated or longitudinal evaluations.

Weight-bearing CT (WB-CT) is a relatively recent imaging modality that also allows for three-dimensional assessment of the ankle and hindfoot, but under physiological load. This technique enables evaluation of joint alignment and congruency in the standing position and may reveal deformities, such as rotational malalignment or subtle instability, that are not evident on non-weight bearing imaging [24]. Nevertheless, WB-CT remains limited in availability, is associated with higher costs, and lacks standardised diagnostic thresholds.

Magnetic resonance imaging (MRI) also has a role in the evaluation of ankle arthritis, particularly when assessment of cartilage, ligaments, tendons, or other soft-tissue structures is required. MRI can also be useful in earlier disease stages or when alternative diagnoses are considered. However, MRI is less effective for detailed assessment of bony alignment and joint congruency and is generally performed in a non-weight bearing position. High cost, limited accessibility, longer acquisition times, and contraindications in certain patient populations further restrict the routine use.

Single-photon emission computed tomography combined with CT (SPECT-CT) integrates functional and anatomical imaging. This enables accurate localisation of the part of the tibiotalar joint most affected by arthritis as well as demonstrate arthritis in adjacent joints [43]. This modality can be valuable in complex or unclear clinical scenarios, such as when pain distribution does not correlate with conventional imaging findings. However, SPECT-CT involves relatively high radiation exposure, limited spatial resolution compared to CT and MRI, and higher costs. Interpretation may also be challenging, as increased tracer uptake is not specific to arthritis and may reflect other pathological processes.



MRI showing ankle arthritis with joint space narrowing and subchondral cysts. Case courtesy of Henry Knipe, Radiopaedia.org, rID: 87869. Reproduced under Creative Commons CC-NC-BY-SA 3.0.

Treatment

Non-surgical treatment

Non-surgical treatment of ankle arthritis includes physical therapy, activity and footwear modification, weight reduction, and the use of orthotics or gait aids [12, 44]. Pharmacological treatment options include analgesics, anti-inflammatory medications, and intra-articular injections such as corticosteroids, newer therapies such as PRP (Platelet-Rich Plasma) or stem cell therapy are lacking sufficient evidence to recommend [24]. Together, these interventions aim to alleviate symptoms, preserve mobility and function, and potentially delay the need for surgical intervention [24].

Surgical treatment

General considerations

Joint preserving surgical treatment

Joint debridement is by some considered an alternative in early stages of ankle arthritis and involves removal of impinging osteophytes and loose bodies [44]. In advanced disease, however, osteophyte removal may exacerbate pain and joint instability rather than provide symptomatic relief.

Realignment osteotomies aim to shift the mechanical axis from an affected portion of the ankle joint and increase the surface contact, decreasing the load per unit area [44]. Depending on the deformity, the osteotomy can be intra-articular (plafondplasty) or extra-articular (supramalleolar) or a combination of osteotomies [45].

Distraction arthroplasty is a technique where an external ring fixation unloads the force on the ankle joint to provide pain relief and possibly delaying or even reversing osteoarthritis. The mechanism of action is still unclear and evidence to support general use is insufficient [24, 46].

Joint sacrificing surgical treatment

When non-surgical alternatives and/or joint preserving surgical treatments are exhausted, there are two main surgical methods; Ankle Arthrodesis (AA) and Total Ankle Replacement (TAR) [12, 15]. AA is performed more frequently than TAR with a current trend toward increasing numbers of TAR [1, 12]. There is only one head-to-head randomised controlled trial comparing AA and TAR, which contributed with important but limited information [12] and the choice of procedure largely remains in the hands of the surgeon and patient.

Currently, AA is often recommended in younger patients with high demands on their ankle joint. TAR has been recommended in older patients with lower demands on their ankle joint, and no systemic conditions affecting wound healing [20].

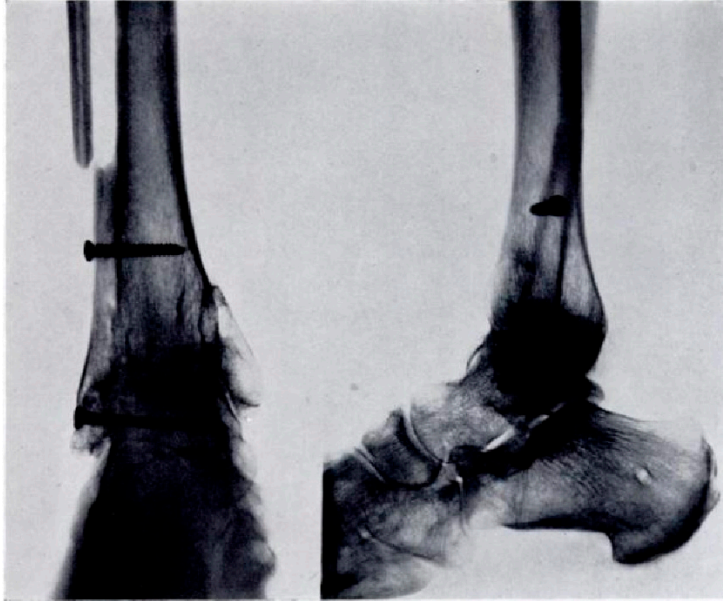


FIG. 8

From Adams, J. C. (1948). "Arthrodesis of the ankle joint; experiences with the transfibular approach." *J Bone Joint Surgery Br* 30B (3): 506-511. Reproduced with permission by British Editorial Society of Bone & Joint Surgery.

Ankle arthrodesis

Arthrodesis or joint fusion, was first described by Albert [47] for the knee joint almost 150 years ago. Ankle arthrodesis was initially considered an exceptional procedure primarily performed to treat infections or severe traumatic injuries. Results were however varying as surgical technique and understanding of bone biology were rudimentary. Methods gradually evolved, partly due to lessons learned from surgery during World War 2 including fixation by intramedullary nail or screws [48]. In the 1950s Sir John Charnley contributed with describing the importance of compression across the fusion to achieve a bony union [49].

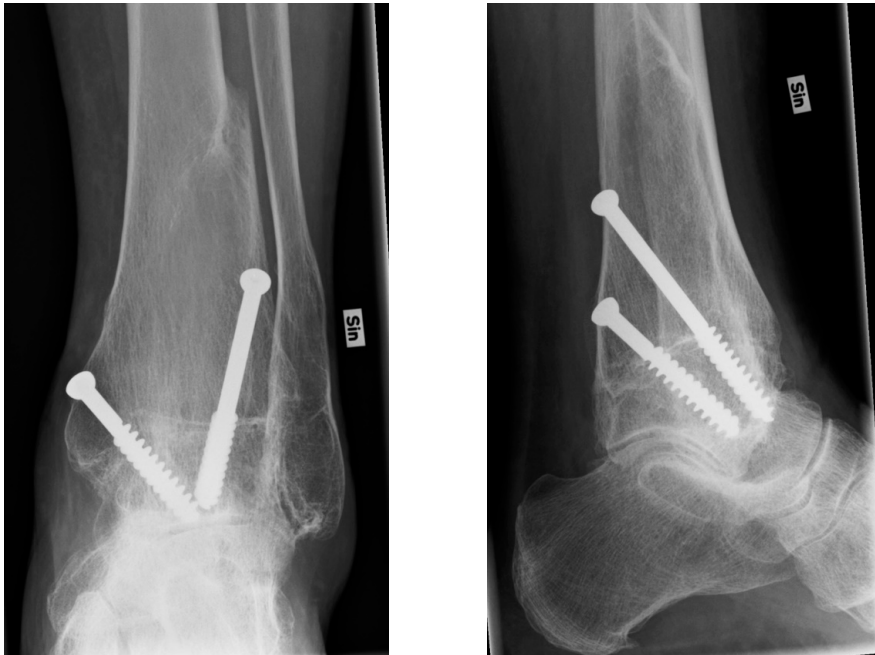


Radiograph of ankle arthrodesis fixed with plates and screws. Fractured staples are seen over the syndesmosis. AP view (left), lateral view (right).

Today AA is considered standard surgery with the goal to achieve a pain-free plantigrade foot during weight bearing [50]. Many approaches have been described and can roughly be divided into 2 categories, open or minimally invasive/arthroscopic [51]. Benefits of the most prevalent, open approach [52], include easier access for correction of malalignments and applying plates and bone grafts [53, 54]. Minimally invasive or arthroscopic approaches have grown popular but are often reserved for patients with mild or no deformity but may also be the only option for patients with comorbidities compromising wound healing. Benefits compared to open techniques include smaller incisions and dissections as well as shorter operation time and lower risk for wound complications [24]. However, the objective in both categories is debrided fusion surfaces free of cartilage, well apposed and compressed with stable fixation [20].

Fixation methods

AA can be performed using a variety of internal and external fixation techniques, with the choice of method influenced by patient characteristics, local bone and soft-tissue conditions, deformity severity, and surgeon preference [51]. Internal fixation is the most common fixation for AA including plate(s), screws or retrograde intramedullary nailing. [51, 52, 55, 56]. External fixation is nowadays uncommon and is usually reserved for more complex clinical scenarios such as active infections, poor bone quality or open wounds [57].



Radiographs showing ankle arthrodesis fixated with two screws. AP view (left), lateral view (right).

Indications and contraindications of Ankle Arthrodesis

Ankle arthrodesis (AA) remains a well-established surgical option for end-stage ankle arthritis. Indications include severe pain and functional impairment when joint-preserving procedures are not enough. AA is often considered in younger, more physically active patients such as manual workers [58], in cases of severe deformity, poor bone stock, instability, neuropathy, or compromised soft tissues. Other indications include failed prostheses, neoplasms, avascular necrosis or when TAR is contraindicated [25]. Contraindications to AA are few but include active infection and, significant arterial insufficiency, insufficient bone stock, in some

cases, severe bilateral ankle disease or significant pre-existing arthritis in adjacent joints, where arthrodesis may exacerbate symptoms.

Outcomes after Ankle Arthrodesis

Commonly used outcomes after AA are union-rate, complication rate and various patient reported outcome measures (PROMs). Several studies have shown favourable short- and medium-term outcomes in terms of union and complication rates [20, 24, 52, 59, 60], with average union rates of approximately 89% for open arthrodesis and 94% for arthroscopic arthrodesis [51].

Most patients demonstrate improved gait following AA [61] and achieve satisfactory functional outcomes, including pain relief, allowing them to remain active postoperatively. Many patients however tend to transition to less physically demanding activities [62].

Complications following ankle arthrodesis (AA) include superficial or deep infections, persistent pain, functional limitations, malalignment [52] and non-union. Reported risk factors for non-union include prior open fractures, diabetes mellitus, renal disease, tobacco and alcohol use, and rheumatoid arthritis. Historically, studies have shown average non-union following primary AA of 8% (range 0% to 40%) [63], with more recent reviews, as mentioned above, showing better results [51].

In cases of non-union associated with persistent pain, revision surgery may be necessary. The most common option is revision arthrodesis (re-arthrodesis), whereas conversion to total ankle replacement (TAR) is less frequently performed, and transtibial amputation remains a last-resort option.

After AA, in the long term, many studies describe an increased risk of developing adjacent joint arthritis, attributed to increased stress transfer and compensatory motion in adjacent joints [63-68].

To better understand the patient's perspective after AA, the use of patient reported outcome measures (PROMs), both generic and region specific, have become popular [69, 70]. Although scarce, some smaller studies have indicated reasonable patient satisfaction after AA [71-73] while others have found that a substantial proportion of dissatisfied patients [64, 74].



Radiographs of ankle arthrodesis fixated with an intramedullary screw. AP view (left), lateral view (right). Case courtesy of Craig Hacking, Radiopaedia.org, rID: 79941. Reproduced under Creative Commons CC-NC-BY-SA 3.0.

Total Ankle Replacement

In order to keep motion in the ankle and address complications and limitations associated with ankle arthrodesis, particularly altered gait mechanics, alternative treatment strategies were pursued, leading to the development of total ankle replacement (TAR). The principal aim and theoretical advantage of TAR compared with AA is the preservation of ankle joint motion, thereby facilitating a more physiological gait pattern while providing effective pain relief [24]. The first TAR procedures were performed by Lord and Marotte [75] and included talus resection and used an inverted hip stem implanted in the tibia and a cemented acetabular cup in the calcaneus. Results were discouraging [76]. Currently, an ankle prosthesis often consists of a tibial component (metal), a talar component (metal) and in between the two, a meniscal component (polyethylene). Prostheses can be fixed bearing (2-component, meniscal component is often fixed to the tibial component) and mobile bearing (3-component, meniscal component is a free component) and have various degrees of constraint.



Radiograph of Total Ankle Replacement "Rebalance". Lateral view (left) AP view (right)

Prosthetic design

1st generation

Specific TAR prostheses were developed in the 1970s, designs varied but were mainly cemented 2-component prostheses with both constrained and unconstrained systems [23], which required extensive bone resection. These early designs had high rates of loosening (29-90% at 10 years), rendered low satisfaction scores, and poor prosthetic survivorship [77-81].

2nd generation

2nd generation prostheses were introduced in the mid-1980s as a response to the complications associated with 1st generation prostheses. Cementless prostheses and porous coating were designed to promote osseous integration and decrease high rates of loosening [23]. There were both fixed bearing (2-component) and mobile bearing (3-component) prostheses, with varying degrees of constraint and varying outcomes [82].

Modern generations (3rd & 4th)

After the first two generations of TAR, modern prostheses were designed to minimise bony resection and to a greater extent respect ankle joint anatomy. Aside from advancements in prosthetic design, surgeons developed a greater appreciation for mechanical alignment and balancing the ankle with additional bony and soft tissue procedures to ensure a stable ankle and foot around the replacement [23].

Modern prostheses still include both fixed-bearing and mobile-bearing designs and are typically uncemented and of lower constraint.



Total ankle replacement prostheses. CCI (left) Mobility (right).

Trabecular Metal Total Ankle Replacement (TM TAR).

Indications and contraindications of Total Ankle Replacement

Similarly to AA, total ankle replacement (TAR) is primarily indicated for patients with end-stage ankle arthritis who experience severe pain and functional limitations, despite adequate non-surgical treatment [23, 83]. Absolute contraindications include active joint infection, severe peripheral vascular disease, neuropathy (including Charcot arthropathy), poor soft-tissue conditions, significant bone loss or severe deformity that cannot be adequately corrected [23].

Relative contraindications have traditionally been high physical demand and younger age due to concerns regarding prosthetic survival [84] and non-optimal results after TAR revision surgery [85, 86]. Surgeons have become more liberal with

their indications as adequate outcomes across a wider range of subjects, including younger patients have been presented [87-89].

There is however conflicting evidence regarding the relationship between age and outcomes following TAR. While some studies report no significant association between age and risk of revision [23, 84, 87, 90], others identify age as a predicting factor [91, 92]. Nevertheless, the mean age at primary TAR seems to have remained similar over time [31].

Outcomes after Total Ankle Replacement

Commonly used outcomes after TAR are prosthetic survival rate, revision rate and PROMs, but long-time follow-up data are scarce. In the modern era, TAR is associated with promising short term outcomes regarding pain relief and functional improvement, and during the recent 20 years, research has shown substantial advances in clinical and functional results, including greater prosthetic survivorship, lower complication and reoperation rates [23]. A recent meta-analysis which focused on TAR designs still available on the market, found a total overall survivorship of 93% at a mean follow up of 5.3 years [84] and an inverse relationship between follow-up duration and survivorship. Another meta-analysis based on national registries, found overall prosthetic survival rate of 82% at 5-years follow-up [93]. Reports focusing on specific prostheses generally report prosthetic survival rates of more than 80% at 10-year follow-up [94], while average 10-year rates from national registries was 77%. Reports on patient experience have found significant improvements after TAR in terms of pain relief and function, as well as quality of life, with satisfaction rates ranging between 80-97% but typically exceeding 90% [23].

Swedankle - The national Swedish ankle registry

The importance of national registry data as a source of information for comparing outcomes after joint replacement has been well documented [1]. In Sweden information on date of primary TAR, AA and supramalleolar osteotomy (SMO) surgery and revision surgery, including data on the patient and the procedure are recorded by the surgeon in Swedankle [95]. The registry was founded in 1997 and was then administered from Falu Central Hospital. Initially only primary Total Ankle Replacements (TARs) and TAR revisions were reported to the registry (including retrospectively from 1993), to cover all 3rd generation ankle prostheses implanted in Sweden. In 2007 the administration of the registry moved to Skåne University Hospital. The following year, in 2008, reporting of primary Ankle Arthrodesis (AA), re-arthrodesis and supramalleolar osteotomy (SMO) was

introduced. The same year, the registry introduced three Patient Reported Outcome Measures (PROMs); SF-36 (discontinued 2015), EQ-5D and Self-Reported Foot and Ankle Score (SEFAS). Postoperatively the patients are also asked to answer a question on satisfaction. Since 2024, the questionnaires are available via the official 1177 caregiver app, with the goal of decreasing administrative work and increasing patient participation. Coverage and completeness is currently estimated at 95% for AA and 100% for TAR [95].

PROMs

To better understand the patient's perspective, both before and after surgery, the use of patient reported outcome measures (PROMs) has become popular [69, 70]. PROMs are standardised, validated questionnaires completed by patients to provide information about outcomes such as pain, function, mobility and overall quality of life. This information can help assess the benefits of surgical intervention from the patient's point of view. PROMs can be divided into (i) generic PROMs that allow comparison across different conditions, represented by EQ-5D in the Swedish Ankle Registry, and (ii) region-specific or disease-specific PROMs that provide more detailed insight into specific condition, represented by SEFAS in the Swedish Ankle Registry.

EQ-5D

The EQ-5D is a standardised instrument developed by the EuroQol Group [96] to measure health-related quality of life. It is widely used in both clinical studies and registries, including orthopaedic registries [97]. The EQ-5D consists of two parts: the descriptive system and the visual analogue scale (EQ-5D VAS).

The descriptive system evaluates five dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated by the patient at one of three (EQ-5D-3L) or five (EQ-5D-5L) [98] levels of severity. These responses are then converted into a single summary index value (EQ-5D index) using a country-specific value set, where 1 represents full health and 0 represents death (with negative values indicating health states considered worse than death).

The EQ-5D VAS is a vertical visual analogue scale ranging from 0 to 100, where the patient rates their overall health status on the day of assessment, with 0 being the worst imaginable health and 100 the best imaginable health.

Together, EQ-5D index and EQ-5D VAS provide an overview of a patient's subjective health and are considered valuable tools in evaluating outcomes following medical or surgical interventions [99, 100].

SEFAS

The Self-Reported Foot and Ankle Score is a validated, patient-reported outcome measure (PROM). [101], It was developed in Sweden and is based on the Oxford Hip and Knee Scores, but adapted to the functional demands and symptoms associated with foot and ankle disorders. SEFAS contains 12 questions with 5 response options, and each question scores from 0 to 4 points. A total score of 0 represents the most severe disability, and 48 represents normal function. The score covers different constructs such as pain, function, and quality of life. The performance of SEFAS is at least similar compared to the American Orthopaedic Foot and Ankle Society (AOFAS) score [102] and the Manchester-Oxford Foot Questionnaire (MOXFQ) [103], and has been translated into and validated for several other languages [103-107]. For SEFAS, Minimal Clinically Important Difference (MCID) is 5 [108] for foot and ankle procedures.

Satisfaction

The question on satisfaction reads “how satisfied are you with the operated ankle joint” and is answered on a 5 grade Likert scale [109] with the options very satisfied, satisfied, neither satisfied nor satisfied, dissatisfied or very dissatisfied.

History of registry research

Orthopaedic registries were established to track prosthetic performance, complications, and long-term outcomes in joint replacement surgery. The first national arthroplasty registry was the Swedish Knee Arthroplasty Registry, founded in 1975 [110], followed by the Swedish Hip Arthroplasty Registry [111]. Survivorship analyses became popular in the 1980s and were implemented for outcome evaluation [112, 113]. Registries demonstrated that large-scale, prospective data collection could identify poorly performing prostheses early and significantly reduce revision rates. The Swedish model led to the establishment of additional national registries in Sweden and across the globe. At least six countries have joint registries with ankle joint data, Sweden [95], Finland [114], Norway [115], New-Zealand [116], Australia [117] and the UK [118].

Aims

The main aim of the thesis was to improve and optimise aspects of diagnosis, procedure selection and patient information for severe ankle arthritis.

Specific research aims

- I. To analyse the prosthetic survival rate after Total Ankle Replacement (TAR) in general and for specific prosthetic designs (*Paper I and Paper II*).
- II. To analyse the prosthetic survival rate and patient reported outcomes measures (PROMs and satisfaction) for Trabecular Metal Total Ankle Replacement (TM TAR) (*Paper II*).
- III. To evaluate patient satisfaction 2 years after ankle arthrodesis (AA), changes in PROMs from before to 2 years after AA, and factors associated with a better or worse outcome. (*Paper III*).
- IV. To evaluate the reliability of non-weight bearing (NWB) compared to weight bearing (WB) radiographs and semi-weight bearing (SWB) compared to WB radiographs, both for detection and classification of ankle arthritis. (*Paper IV*).

Methods

Paper I-III

Study design

Papers I-III are nationwide registry-based observational cohort studies using data from Swedankle. The registry holds information on primary TARs implanted since 1993 and primary AAs since 1998, with PROMs available since 2008. Surgical and demographic data are prospectively recorded, and patient-reported outcome measures (PROMs) are collected pre- and postoperatively. Reporting is performed by the surgeon, except for PROMs which are reported by the patients. Registry coverage and completeness are currently estimated to be 100% for TARs and 95% for AAs.

Data collection

Data on patient characteristics, surgical details, and revisions were reported to the registry by the surgeon. Revision was defined as removal or exchange of 1 or more of the prosthetic components with the exception of incidental exchange (exchange of the polyethylene insert during a secondary procedure undertaken because of a different indication) of the polyethylene insert [119]. PROMs (SEFAS and EQ-5D index/EQ-5D VAS) were filled out by patients preoperatively and 2 years postoperatively, including a postoperative question on satisfaction with the surgery. The foot and ankle specific SEFAS score ranges from 0 (worst) to 48 (best). EQ-5D assesses health-related quality of life across five dimensions and is converted to an index score between 0 and 1, while EQ-5D VAS records self-rated health on a 0-100 scale. Surgical satisfaction was graded using a five-point Likert scale.

Paper IV

Study design

This was a cross-sectional observational study evaluating radiographic assessment of moderate to severe ankle arthritis (AA) using non-weight bearing (NWB), semi-weight bearing (SWB), and weight bearing (WB) radiographs.

Data collection

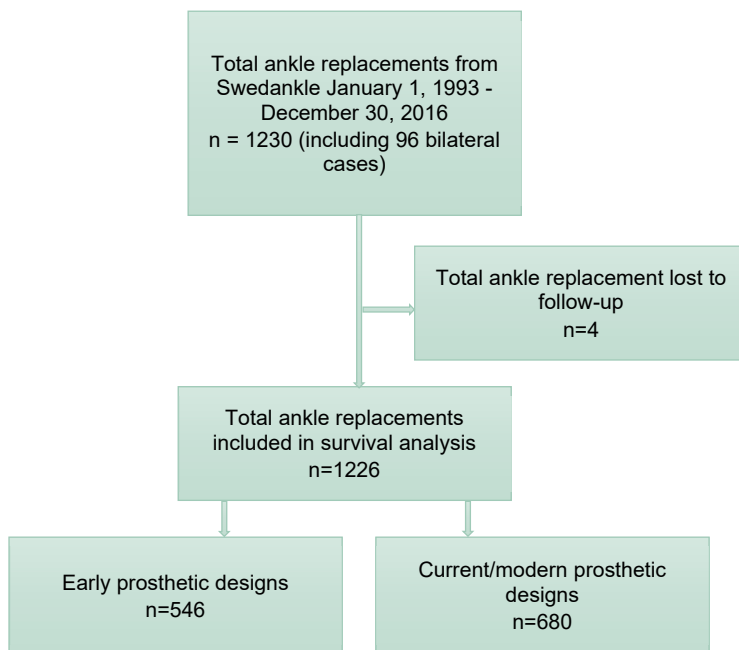
All radiographs were obtained at the same radiology unit by experienced radiographers using standardised protocols. Each participant underwent three radiographic series (NWB, SWB, and WB), each consisting of frontal, mortise, and lateral views. NWB and WB radiographs followed routine clinical protocols, while SWB radiographs were acquired using a protocol designed to simulate sitting weight load. Two radiologists independently assessed all images for radiographic features of ankle arthritis and graded disease severity using the Kellgren-Lawrence, Van Dijk, and Takakura classification systems. Assessments were performed without clinical information, with reclassification defined as any change in arthritis grade between NWB and WB or SWB and WB images. Intra-observer reliability was evaluated through repeat assessments performed three months later by one radiologist.

Inclusion flow charts

Paper I

Participants

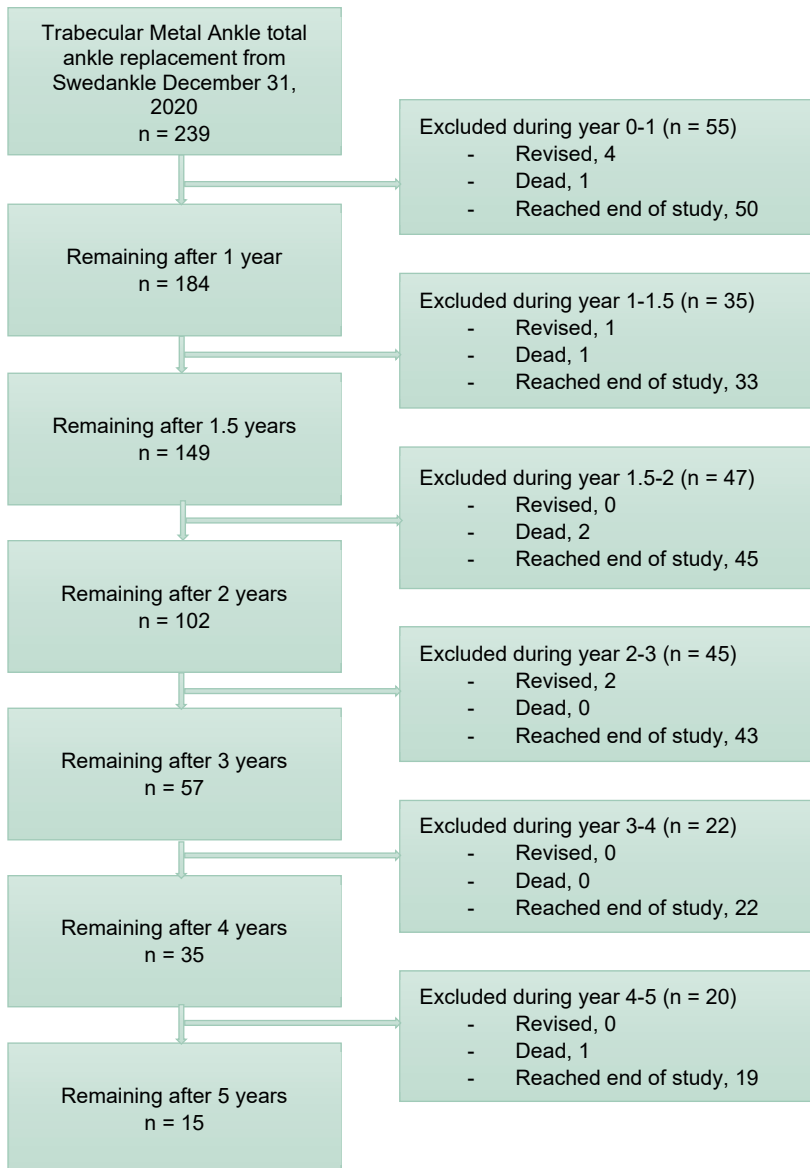
Until December 31, 2016, 1,230 primary TARs had been registered in 1,132 patients. The mean follow-up time was 7 years. 4 cases lost to follow-up were not included in the survival analyses. 546 of the remaining 1,226 cases we referred to as “early prosthetic designs” (STAR, BP, and AES) as these designs have not been implanted in Sweden since 2008; the other 680 we referred to as “current prosthetic designs” (Hintegra, Mobility, CCI, Rebalance, and TM TAR).



Paper II

Participants

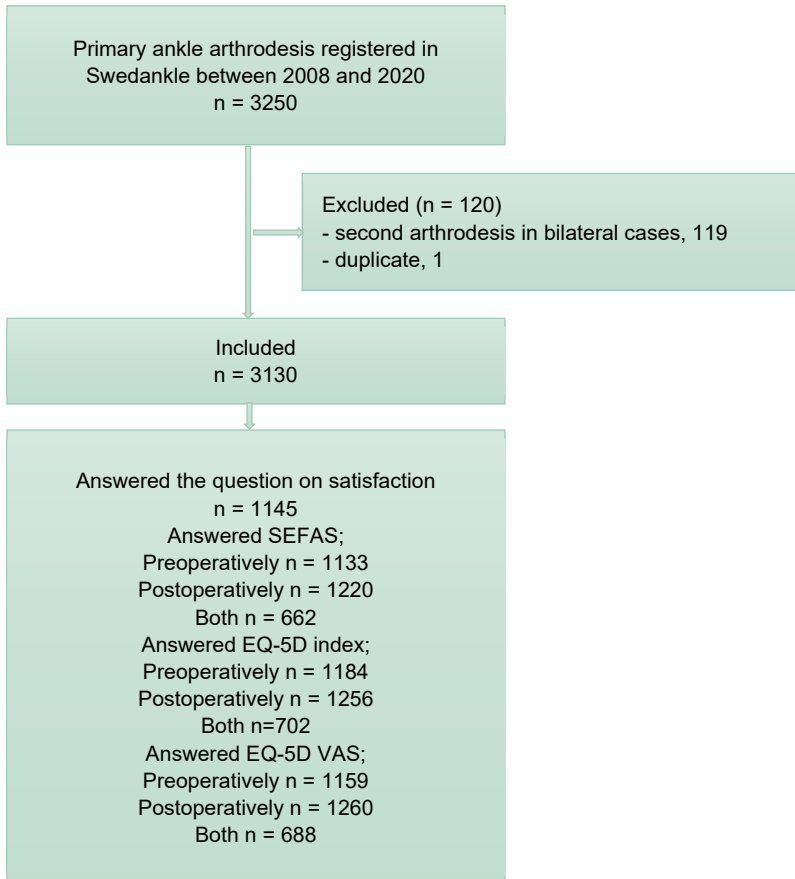
All patients who underwent primary total ankle replacement with the TM TAR prosthesis between registry inception and December 31, 2020 were identified. In total, 239 primary procedures in 233 patients were included; six patients underwent bilateral procedures, none simultaneously.



Paper III

Participants

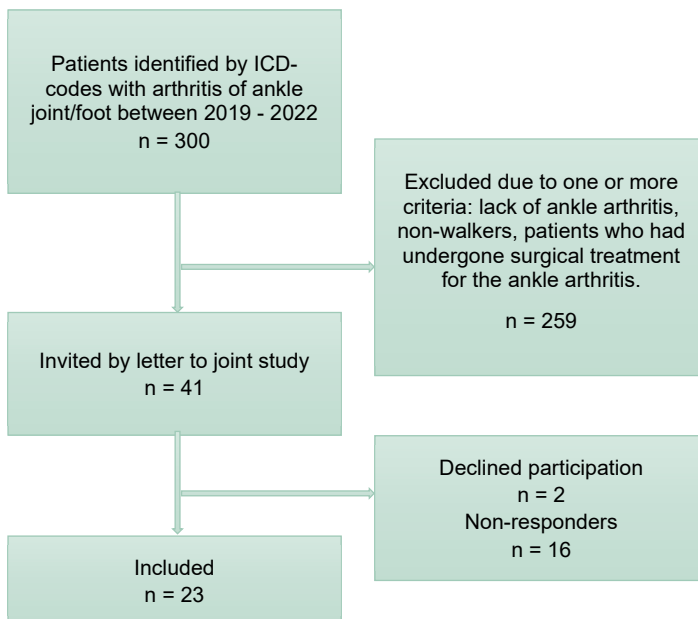
Patients who underwent primary ankle arthrodesis between 2008 and 2020 were identified. After exclusion of one duplicate and the second procedure in bilateral cases, 3130 procedures were included.



Paper IV

Participants

Patients with suspected moderate to severe ankle arthritis were identified through a search of waiting lists at the orthopaedic department, Skåne University Hospital, Malmö, from 2019 – 2022, using ICD-10 codes for ankle and foot arthritis (M19.0H, M19.1H, M19.2H, and M36.2). A musculoskeletal radiologist (the author) reviewed the identified cases to confirm ankle arthritis diagnosis and eligibility, including residence in Skåne or nearby regions. Of 300 patients identified, 259 were excluded due to lack of ankle arthritis, inability to undergo WB radiography or prior surgical treatment. Forty-one eligible patients were invited, 24 consented to participate, and 23 were ultimately included after exclusion of one patient due to recent ankle surgery.



Statistics

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), versions 23-26. For all papers, results are presented as absolute frequencies, proportions (%), medians with interquartile ranges (IQR) or means with 95% confidence intervals (95% CI).

Kaplan-Meier estimator

In *Paper I and II*, prosthetic survival rate was estimated using time-to-event data. Survival probabilities were estimated and visualised using the Kaplan-Meier estimator, a non-parametric approach that does not require assumptions about the underlying distribution of survival times. This method was chosen because it allows handling of censored observations, which are common in registry-based survival data, and provides an intuitive graphical representation of survival over time. A key assumption of the Kaplan-Meier method is non-informative censoring, meaning that the probability of censoring is independent of the probability of experiencing the event. In addition, survival probabilities are assumed to be constant within each time interval, which may oversimplify complex real-world survival patterns. As Kaplan-Meier analysis is primarily descriptive, it does not allow adjustment for potential confounding variables.

Log-rank test

In *Paper I*, differences in prosthetic survival rate between early and current prosthetic designs were assessed using the log-rank test. This is a non-parametric test which evaluates the null hypothesis of no difference in survival functions between groups and is often used for group comparisons in survival analysis. The log-rank test was selected because no strong evidence of non-proportional hazards was anticipated. The method is simple to apply and has high statistical power when the proportional hazards assumption is met and when survival differences are consistent over time. However, performance may be reduced if hazards are non-proportional or if survival curves cross. Furthermore, the log-rank test does not account for covariates and therefore cannot adjust for potential confounding factors.

Multivariable survival regression methods, such as Cox proportional hazards models, were considered but not used. These models require proportional hazards and sufficient number of events per covariate. Given the limited number of events and the primarily descriptive aim of comparing prosthetic design generations, unadjusted non-parametric methods were considered more appropriate.

Risk of revision

In *Paper II*, risk of revision was calculated at 1, 2, and 3 years postoperatively. For each time point, the population at risk consisted of patients who had undergone surgery at least 1, 2, or 3 years before the end of the study period, respectively, while revision surgeries occurring within the corresponding time frame were treated as events. Deaths were disregarded in these analyses.

Patients Reported Outcome Measures (PROMs)

PROM scores were assessed for distribution properties. As pre- and postoperative PROM scores were not normally distributed, results were presented as medians with interquartile ranges (IQR).

Paired-samples t-test

In *Paper II and III*, changes in PROM scores between baseline and follow-up, were approximately normally distributed, although some ceiling effects were observed. Under the assumptions of the central limit theorem, mean score changes were therefore estimated using a t-test. To account for potential deviations from normality and to provide robust estimates of uncertainty, non-parametric bootstrapping with simple case resampling (10,000 iterations) was utilised. Mean changes and corresponding 95% confidence intervals were derived using percentile intervals from the ordered bootstrap distributions.

Imputation and Logistic regression analysis

Imputation is a statistical technique used to handle missing data by replacing missing values with plausible estimates. Rather than discarding cases with incomplete data, which can reduce statistical power and introduce bias, imputation allows all available data to contribute to the analysis. Because a substantial proportion of patients in *Paper III* had only one observation (either preoperative or postoperative), multiple imputation was applied. Five imputed datasets were generated using age, sex, diagnosis, procedure, available pre- and postoperative PROM scores, and satisfaction/dissatisfaction as predictors.

Logistic regression

This is a statistical method used to examine the relationship between one or more predictor variables and a binary outcome. In *Paper III*, Logistic regression analyses were performed on the imputed data (described above) to evaluate associations between satisfaction or dissatisfaction and preoperative PROM scores, age, sex, diagnosis, and procedure. Patients who had completed either a preoperative or postoperative PROM as well as the satisfaction question were included. Two regression models were fitted per PROM (six models in total), all adjusted for age, sex, procedure, diagnosis, and the relevant preoperative PROM score. Model fit was evaluated using the Nagelkerke pseudo-R².

Mixed-effects models

Mixed-effects models is a statistical method used to analyse clustered or repeated data (such as pre- and postoperative PROMs) which can accommodate unequal numbers of observations per individual and missing follow-up data under the missing-at-random assumption.

It was utilised in *Paper III*, to examine the associations between the 3 PROMs (outcome) and age, sex, and diagnosis. 3 mixed-effects models were fitted (1 for each PROM), each with a subject-specific random intercept and no additional random effects. Models were adjusted for age, sex, diagnosis, timepoint, and a sex-by-timepoint interaction. Model adequacy was assessed through residual diagnostics, including residuals vs predicted values and normal probability plots, with no major violations of assumptions observed. Due to the study design, floor and ceiling effects as well as regression to the mean were considered potential sources of bias. Random slopes were tested to address possible floor and ceiling effects; however, model fit did not improve and these were therefore not retained. Any regression to the mean would likely have reduced rather than produced the observed associations and is unlikely to have affected the overall findings.

Inter- and intra-observer reliability

In *Paper IV*, inter- and intra-observer reliability were assessed using Cohen's kappa (κ) coefficient, which is a statistical measure of agreement for categorical data. It quantifies how much two observers agree beyond what would be expected by chance alone. Agreement was interpreted according to Landis and Koch criteria [120] where <0 indicates poor agreement, 0.00-0.20 slight, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, and 0.81-1.00 almost perfect agreement.

Receiver Operating Characteristic (ROC)

ROC analysis is a statistical method used to evaluate the diagnostic performance of a test or model in distinguishing between two conditions. In *Paper IV* this was utilised to evaluate the ability of non-weight bearing (NWB) and semi-weight bearing (SWB) radiographs to discriminate between grades in the Kellgren-Lawrence, Van Dijk, and Takakura classification systems. To accomplish this, binary outcome variables were created for each grade. Weight bearing (WB) radiographs were considered the reference standard. Sensitivity and specificity were calculated when both positive and negative WB cases were present. (AUC) summarises the overall ability of the test to discriminate between diseased and non-diseased cases.

Ethical considerations

The studies in this thesis were approved by the Ethical Review Board of Lund University (Dnr 2009/698, 2014/448, Dnr 2010/590), and were conducted in accordance with the Helsinki Protocol.

The studies are based on sensitive individual-level data protected by the Swedish personal data act. Data sharing is not possible according to Swedish law.

Funding

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Main results

Paper I

Overall prosthetic survival rate after TAR in the Swedish Ankle Registry at 5 years was 85% (95% CI 83-87), at 10 years 74% (CI 70-77), at 15 years 63% (CI 58-67), and at 20 years 58% (CI 52-65) (Figure 2). Use of current prosthetic designs was associated with better prosthetic survival rate. (Figure 3).

Cumulative revision-free survival.

Estimated cumulative prosthetic survival for all designs, early vs current designs, early designs and current designs.

Figure 2

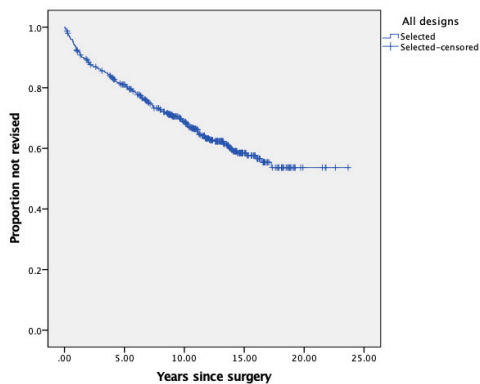
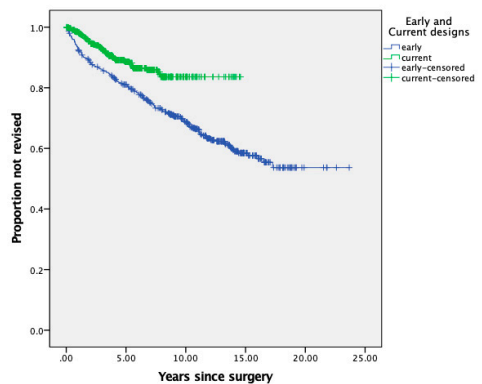


Figure 3



Paper II

Prosthetic survival rate 3 years after TM TAR was 95% (95% CI 89-98) (Figure 4) and the 3-year risk of revision was 3%. 2 years after surgery, 81% of patients were satisfied, and all mean PROM scores had increased significantly compared to preoperatively (all $P < 0.001$) (Table 1).

Figure 4. Cumulative revision-free survival

Estimated cumulative prosthetic survival for TM TAR.

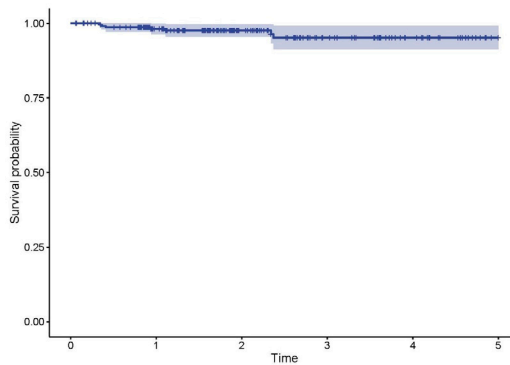


Table 1. PROMs in patients who underwent TM TAR.

	n (%)	Preoperative median (IQR)	Postoperative median (IQR)	Change from pre- to postoperative mean (95% CI)
SEFAS	79 (53%)	16 (IQR 10 to 20)	35 (IQR 25 to 41)	+17.5 (15.1 to 19.8)
EQ-5D	77 (51%)	0.68 (0.58 to 0.73)	0.83 (0.83 to 0.96)	+0.19 (0.15 to 0.22)
EQ-VAS	76 (51%)	65.0 (46.25 to 80.0)	80.0 (70.0 to 90.0)	+14.6 (9.6 to 20.1)

Paper III

2 years after AA 69% of the patients were satisfied. All mean PROM scores improved from pre- to 2 years postoperatively (all $P < 0.001$) and all mean changes were clinically relevant ($>MCID$ values). Higher preoperative SEFAS score was associated with postoperative satisfaction (Table 2) and lower preoperative SEFAS score was associated with dissatisfaction (Table 3). In the mixed-effects model, we found that male sex and diagnoses OA and “other” (compared with RA) were associated with higher SEFAS score. Male sex, diagnoses PtA and OA (compared with RA), as well as higher age, were associated with higher EQ-5D index score. Male sex, diagnoses PtA, OA and “other” (compared with RA), as well as higher age, were associated with higher EQ-5D VAS (Table 4).

Table 2. Associations between satisfaction 2 years postoperatively and preoperative PROM, age, sex, diagnosis and procedure. Logistic regression on imputed data.

	Imputed data with preoperative SEFAS	Imputed data with preoperative EQ-5D index	Imputed data with preoperative EQ-5D VAS
Variable	Odds ratio for satisfaction (CI) n = 1,117	Odds ratio for satisfaction (CI) n = 1,117	Odds ratio for satisfaction (CI) n = 1,117
Preoperative PROM	1.04 (1.01 to 1.07)	1.38 (0.79 to 2.42)	1.01 (1.00 to 1.01)
Age	0.99 (0.98 to 1.01)	0.99 (0.98 to 1.01)	1.00 (0.98 to 1.01)
Sex			
Female	Reference	Reference	Reference
Male	1.03 (0.78 to 1.35)	1.07 (0.81 to 1.40)	1.07 (0.82 to 1.41)
Diagnosis			
RA	Reference	Reference	Reference
PtA	1.05 (0.66 to 1.67)	1.07 (0.68 to 1.70)	1.06 (0.67 to 1.68)
OA	1.72 (1.06 to 2.80)	1.75 (1.08 to 2.83)	1.72 (1.06 to 2.79)
Other	0.75 (0.44 to 1.25)	0.81 (0.49 to 1.35)	0.82 (0.49 to 1.35)
Procedure			
Open screw	Reference	Reference	Reference
Plate	0.80 (0.54 to 1.20)	0.82 (0.55 to 1.22)	0.81 (0.54 to 1.21)
Intramedullary nail	1.13 (0.79 to 1.62)	1.11 (0.77 to 1.59)	1.10 (0.77 to 1.58)
Arthroscopic screw	1.13 (0.78 to 1.66)	1.18 (0.81 to 1.72)	1.17 (0.80 to 1.71)
Pseudo R Square (Nagelkerke)	0.042	0.029	0.031

Table 3. Associations between dissatisfaction 2 years postoperatively and preoperative PROM, age, sex, diagnosis and procedure. Logistic regression on imputed data.

	Imputed data with preoperative SEFAS	Imputed data with preoperative EQ-5D index	Imputed data with preoperative EQ-5D VAS
Variable	Odds ratio for dissatisfaction (CI) n = 1,117	Odds ratio for dissatisfaction (CI) n = 1,117	Odds ratio for dissatisfaction (CI) n = 1,117
Preoperative PROM	0.96 (0.93 to 0.99)	0.99 (0.38 to 2.55)	1.00 (0.98 to 1.01)
Age	0.99 (0.98 to 1.01)	0.99 (0.98 to 1.01)	0.99 (0.98 to 1.01)
Sex			
Female	Reference	Reference	Reference
Male	1.14 (0.81 to 1.60)	0.07 (0.76 to 1.49)	1.08 (0.77 to 1.51)
Diagnosis			
RA	Reference	Reference	Reference
PtA	0.86 (0.49 to 1.51)	0.83 (0.47 to 1.45)	0.86 (0.49 to 1.51)
OA	0.66 (0.37 to 1.19)	0.64 (0.36 to 1.15)	0.66 (0.37 to 1.19)
Other	1.09 (0.59 to 2.03)	0.99 (0.54 to 1.83)	1.02 (0.55 to 1.87)
Procedure			
Open screw	Reference	Reference	Reference
Plate	1.15 (0.70 to 1.89)	1.17 (0.72 to 1.91)	1.14 (0.70 to 1.86)
Intramedullary nail	0.99 (0.64 to 1.53)	1.01 (0.65 to 1.56)	1.02 (0.66 to 1.57)
Arthroscopic screw	0.88 (0.55 to 1.42)	0.86 (0.53 to 1.37)	0.86 (0.54 to 1.38)
Pseudo R Square (Nagelkerke)	0.030	0.014	0.016

Table 4. Associations between PROMS and age, sex, and diagnosis

Mixed model	SEFAS coefficient (CI) n = 1,749/6,260	EQ-5D index coefficient (CI) n = 1,840/6,260	EQ-5D VAS coefficient (CI) n = 1,803/6,260
Age	0.03 (-0.003 to 0.05)	0.003 (0.002 to 0.004)	0.09 (0.02 to 0.17)
Sex			
Female	Reference	Reference	Reference
Male	1.71 (0.94 to 2.47)	0.08 (0.04 to 0.11)	3.29 (0.74 to 5.83)
Diagnosis			
RA	Reference	Reference	Reference
PtA	1.02 (-0.21 to 2.24)	0.08 (0.03 to 0.12)	8.46 (5.17 to 11.75)
OA	1.35 (0.09 to 2.61)	0.09 (0.04 to 0.14)	9.27 (5.87 to 12.67)
Other	1.56 (0.16 to 2.96)	0.01 (-0.04 to 0.07)	5.56 (1.82 to 9.30)
Timepoint			
Primary	Reference	Reference	Reference
Secondary	13.81 (12.81 to 14.81)	0.35 (0.32 to 0.38)	14.41 (12.07 to 16.76)
Sex/timepoint interaction	1.36 (0.04 to 2.69)	-0.03 (-0.07 to 0.02)	-0.52 (-3.62 to 2.57)

Paper IV

Comparing non-weight bearing (NWB) with weight bearing (WB) radiographs (Table 5) as well as semi-weight bearing (SWB) with WB radiographs (Table 6) regarding detection of signs of AA, when applicable, rendered almost perfect reliability. Comparing NWB with WB radiographs as well as SWB with WB radiographs regarding classification of AA, we found almost perfect reliability using the K-L and Van Dijk systems, while moderate reliability using the Takakura system.

Table 5. Reliability, sensitivity and specificity of NWB compared to WB radiographs in detecting signs of ankle arthritis according to radiologist 1 (R1) and radiologist 2 (R2).

N=23	Cohen's Kappa (κ), R1	Sensitivity	Specificity	AUC for NWB	Cohen's Kappa (κ), R2	Sensitivity	Specificity	AUC for NWB
Reduced joint space	*	*	*	*	*	*	*	*
Osteophytes	*	*	*	*	*	*	*	*
Subchondral sclerosis	0.83 ($p < 0.001$)	0.95	1.00	0.98	0.89 ($p < 0.001$)	0.94	1.00	0.97
Subchondral cysts	1.00 ($p < 0.001$)	1.00	1.00	1.00	0.90 ($p < 0.001$)	0.94	1.00	0.97

*Reliability (κ) and diagnostic performance cannot be estimated

Table 6. Reliability, sensitivity and specificity of SWB compared to WB radiographs in detecting signs of ankle arthritis according to radiologist 1 (R1) and radiologist 2 (R2).

N=23	Cohen's Kappa (κ), R1	Sensitivity	Specificity	AUC for SWB	Cohen's Kappa (κ), R2	Sensitivity	Specificity	AUC for SWB
Reduced joint space	*	*	*	*	*	*	*	*
Osteophytes	*	*	*	*	*	*	*	*
Subchondral sclerosis	1.00 ($p < 0.001$)	1.00	1.00	1.00	0.89 ($p < 0.001$)	0.94	1.00	0.97
Subchondral cysts	1.00 ($p < 0.001$)	1.00	1.00	1.00	1.00 ($p < 0.001$)	1.00	1.00	1.00

General discussion

End-stage ankle arthritis presents a clinical challenge as patients are typically younger at the time of diagnosis (compared to hip- and knee arthritis) [6] and therefore face many remaining years of work and active life, often with substantial functional demands. The socio-economic implications are considerable [16], but equally important are individual consequences such as pain, impaired mobility, and limitations during a highly productive phase of life. In this context, the choice between total ankle replacement (TAR) and ankle arthrodesis (AA) is particularly complex.

Collecting outcomes - the Role of Registries

Papers I-III are based on data from Swedankle, the Swedish national ankle registry. The importance of National joint registries for comparing prosthetic survival rates and examining prosthetic safety, has been well documented [1, 121, 122], as they can facilitate early detection of trends in prosthetic survival, revision risk, and complication patterns. This may be especially important for treatments that are rare. Presently, at least six countries have dedicated national joint registries with ankle joint data, Sweden [95], Finland [114], Norway [115], New-Zealand [116] Australia [117] and the UK [118]. Swedankle participates in the International Ankle Arthroplasty Consortium where a recent publication compares outcomes after TAR between different countries [93]. Since national registries collect data from multiple units, studies represent real-world results from clinical practice, often with larger sample sizes and longer follow-up, compared to single-centre or single-surgeon reports [123]. Compared to clinical trials, registry studies are more cost-effective as they utilise existing data.

Nevertheless, registries, including Swedankle, are observational by design and therefore inherently subject to selection bias. They are restricted to predefined variables and only data that are selected for collection can be analysed. Consequently, important clinical factors, such as degree of deformity, bone quality, soft tissue status, radiographic findings, rehabilitation protocols, or surgeon-specific technical variations, may be incompletely recorded or entirely absent. Similarly, patient-related factors such as expectations, psychological status [124], work demands, and social support are rarely included, despite their known influence on outcomes and satisfaction.

Furthermore, data quality of registries depends on accurate and consistent reporting. Although procedure-based coverage and completeness are high in Swedankle, revision is used as the endpoint and clinical or radiological follow-up is not registered. Patients who for some reason are not surgically revised, will therefore not be included as failures, which may underestimate the true burden of complications. Thus, a surviving ankle prosthesis or ankle arthrodesis is not necessarily a successful one from the patient's perspective.

In *Paper I-II*, we used an established definition of revision, i.e., exchange or removal of one or more components except incidental exchange of the polyethylene insert [119]. However, the definition of revision varies in the literature which can make comparison of results between different studies challenging.

The only follow-ups in which the patients directly participate after surgery in Swedankle are the questionnaires (PROMs) that include a question on satisfaction. During the years, participation has sometimes been low, at least compared to some other Swedish orthopaedic registries [28]. This may partly be explained by varying compliance of the operating units (responsible for preoperative PROMs) as well as technical issues within the registry postal system. Patient participation will hopefully increase as the questionnaires are available via the national Swedish healthcare app, 1177, since 2024.

Despite the many challenges of national registries, they play an essential role in healthcare, contributing to research and continuous quality improvement. Their maintenance and further development warrant continued recognition and economical support. It is important that healthcare providers continuously learn from both their own data and national data in order to ensure and further develop the quality of care.

Patient-Reported Outcomes and Satisfaction

Although prosthetic survival rate and union rate are important outcomes after TAR and AA surgery, a surviving TAR or a healed AA, is not synonymous with patient satisfaction, which ultimately should be the goal of surgery. From an orthopaedic surgeon's perspective, a complication-free procedure with radiographic union or surviving prosthesis may constitute success. From the patient perspective, however, pain relief, restored function, and fulfilment of preoperative expectations are important. Therefore, PROMs, both generic and region-specific, are increasingly recognised as important outcome measures, as they may capture dimensions of health that are invisible in radiographs and operative reports. However, factors influencing PROMs may extend beyond the surgery itself and can include the patient-surgeon relationship, pre- and perioperative care, rehabilitation, and perhaps most importantly, expectations. These factors are difficult to bypass, emphasising

the importance of utilising validated PROMs with high reliability and responsiveness.

Papers II-III use data from Swedankle which includes both generic (EQ-5D) and region specific (SEFAS) PROMs. EQ-5D is commonly used in orthopaedic registries which facilitates comparison between countries and diseases. SEFAS is not the only or most common foot and ankle PROM but was developed in the Swedish context in collaboration with Swedankle. SEFAS has been validated and translated into several languages and MCID values are available.

In Swedankle, patients are also asked a question on how satisfied they are with the surgical result. The goal of this question is for the patient to give an overall evaluation of the operated ankle, combining factors like pain and function. Satisfaction is however a subjective outcome, and as mentioned above with PROMs, may be affected by other factors. Expectation management appears central to PROMs including patient satisfaction [74]. Therefore, incorporating measures of “preoperative expectations” as well as “expectations met” into registries, may enhance the understanding of surgical success.

PROMs after primary TAR, revision TAR, bilateral AA and salvage arthrodesis after failed TAR have previously been analysed in data from Swedankle [71, 85, 86, 125, 126]. Although scarce, some smaller studies have indicated reasonable patient satisfaction after AA [71-73] while others found that a substantial proportion of patients remain dissatisfied [64, 74]. To add to the existing knowledge, we therefore, in *Paper II and III*, analysed PROMs after the currently most used TAR prosthesis in Sweden, TM TAR, and after primary AA. We found that 81% of the patients were satisfied or very satisfied with the surgical results after TM TAR when using a 5 grade Likert scale. Other reports of the TM TAR have found 90% satisfied patients (using a 3-category rating) [127] and 67% very satisfied patients with a 4-category rating [128]. *Paper III* demonstrated reasonable satisfaction 2 years after AA (69%), which was lower than 75% satisfaction after AA in 88 patients in Sudan [73], 89% in 122 patients after mean 7 years in the Netherlands [62] and 91% in 60 patients after mean 9 years also in the Netherlands [72]. Our results were comparable to 71% satisfaction after primary TAR in Swedankle [125] and somewhat lower than the 81% satisfaction after TM TAR in *Paper III*.

In *Paper III*, we found an association between preoperative SEFAS score and postoperative satisfaction. We hypothesise that the preoperative SEFAS score may serve as a predictor of surgical outcomes and help guide preoperative discussions with patients regarding anticipated results. Previous reports have found that preoperative pain levels and psychological status, including depression and anxiety, can predict long-term functional outcomes following hip- and knee arthroplasty [124] and that anxiety has a significant negative effect on postoperative PROMs also after TAR [129]. These findings and our findings in *Paper III* underline the importance of the preoperative assessment of the patient and may support more

individualised preoperative counselling to help align expectations with probable outcomes. We were unable to find an association between sex and satisfaction in adjusted analyses, despite the fact that we and others, have found that men in general score better than women on some PROMs including SEFAS [130] and EQ-5D index [131]. Male sex was however associated with higher PROMs (SEFAS, EQ-5D index, and EQ-5D VAS), in line with previous reports, which have shown that men score better on PROMs compared to women [29, 130-132].

Total ankle replacement survival

Although PROMs are increasingly used to complement outcome assessment after TAR, prosthetic survival rate remains a fundamental endpoint in research. Reports have shown a steady improvement in prosthetic survival rates for TARs during the recent decades [23], however for TAR to be considered a true alternative to AA in younger patients, prosthetic survival rates must approach those reported for total knee and hip replacements.

To put our numbers into perspective, recent meta-analyses of registry data found 90% prosthetic survival for total knee replacement (TKR) [133] and 85% for total hip replacement (THR) at 20 years [134]. In *Paper I*, we found an overall prosthetic survival rate after TAR, of 85% after 5 years, 74% after 10 years, 63% after 15 years and 58% after 20 years but with long-term results based on few cases. For early prosthetic designs the 5- and 10-year prosthetic survival rates were 81% and 69% respectively, while the corresponding rates for current designs were better at 88% and 84%.

Paper I also showed better overall prosthetic survival rates compared to a previous report from Swedankle, which demonstrated overall prosthetic survival rate of 81% at 5 years 69% at 10 years [91] corresponding to our results for early designs, supporting the notion that prosthetic survival rates are improving. This is further supported by our *Paper II*, where we found short-term prosthetic survival for the currently most popular prosthesis in Sweden, TM TAR, with an estimated prosthetic survival rate of 95% after 3 years.

Other recent studies also show promising results for TAR in short- and medium-term follow-up, with national registries reporting mean 5-year prosthetic survival rates of 86% (range 80% to 91%) and 10-year prosthetic survival of 77% (range 66% and 84%) [93]. In a large study from the French exhaustive discharge database on 4748 TARs, 5-years prosthetic survival was 84% and 10-year prosthetic survival 78% [135]. Similarly, in a study from United Kingdom, out of 5562 TARs, 199 were followed at least 10 years with a prosthetic survival of 86% [136]. Even higher results are reported in a Korean study from a national database of 5619 cases, with 5-year prosthetic survival of 95% and 10-year prosthetic survival of 91% [137]. The currently used third and fourth generations of TAR prostheses, have implemented

improvements in bone fixation, mechanical alignment, and soft tissue balance that may have contributed to increasing prosthetic survival rates [138]. However, as previously mentioned, improvements may be related to many other factors such as surgeon experience, improved instrumentation and patient selection and expectation management, and TAR still has a long way to go to approach prosthetic survival rates for hip and knee arthroplasty.

Fusion rate, choice of fixation and approach for Ankle Arthrodesis

As for AA, several studies have shown favourable short- and medium-term outcomes in terms of union and complication rates [20, 24, 52, 59, 60], with average union rates of approximately 89% for open arthrodesis and 94% for arthroscopic arthrodesis [51]. In the long term however, a complication after AA may be adjacent joint arthritis, [63-68], although this notion has been questioned [139]. In *Paper III*, we found reasonable satisfaction and PROMs after AA, however our results only cover the first 2 years postoperatively. An important question thus remains, does PROMs and satisfaction decline with time, as potential adjacent arthritis progresses? A systematic review from 2015 showed that a correlation between postoperative imaging findings of adjacent joint arthritis and clinical presentation in the patients, could not be conclusively demonstrated [139].

Internal fixation methods include plates, which is currently the most common method in Sweden [95], screws, intramedullary nails, or combinations thereof. Screws are preferred by some due to ease of use, minimal soft tissue disruption, and low cost, while plates can offer greater construct stiffness and versatility [51]. Retrograde intramedullary nails are uncommon and external fixation is generally reserved for complex cases and overall union rates and outcomes are inferior compared to internal fixation [57]. Open approaches in general allow better correction of deformity and easier use of plates and bone grafts. Arthroscopic arthrodesis is less invasive, with shorter operative time and comparable union rates, and is preferred for minimal deformity or patients at higher risk of wound complications [51]. In *Paper III*, we found no association between open screw fixation or arthroscopic screw fixation with satisfaction. In a previous study from Swedankle, arthroscopic screw fixation was associated with higher risk (15%) of re-arthrodesis compared with open screw fixation (8%), this report however was based on older data up to 2015, when arthroscopic approach was fairly new [60].

Surgical skills and learning curve

Prosthetic design alone does not determine outcome. Surgeon experience and the learning curve are also important factors. The complexity of TAR is well known and is for example reflected in the high rate of concomitant procedures found in our *Paper II* (86 concomitant procedures during 239 primary TM TARs). Consequently,

in Sweden, as in many other countries, TAR procedures are increasingly centralised to fewer centres and performed by a limited number of surgeons, resulting in larger volumes per surgeon [95]. This concentration of expertise likely contributes to improved results. At the same time, market dynamics and procurement policies may influence prosthetic availability, sometimes limit surgeon preference and potentially affect outcomes. Continuous evaluation of prosthetic performance in real-world settings is therefore essential.

Patient selection

With growing experience, orthopaedic surgeons have refined their understanding of which patients will benefit from surgery and which are more suitable for TAR respectively AA. There are however still no definite guidelines. Improvements in prosthetic technology and surgical technique have broadened indications for TAR, but careful selection remains central to achieving favourable outcomes.

The role of age in the decision-making process to perform a TAR is debated, with variations in the literature on the topic. While some studies report no significant association between age and risk of revision [23, 84, 87, 90], others identify age as a predicting factor [91, 92]. Despite significant clinical improvements after TAR shown in both younger and older patients, median age at surgery for patients undergoing TAR during the recent two decades has been 63 years, with no significant changes between 1999 and 2023, according to a systematic review by Bernasconi [31]. In *Paper III*, we found that higher age in fact was associated with higher EQ-5D index and EQ-5D VAS scores, consistent with the association between preoperative EQ-5D and higher age reported after TAR in a previous study from Swedankle [125] but contrary to the pattern observed in the general Swedish population [131].

Indications for both AA and TAR are end-stage ankle arthritis with persistent pain and functional limitation despite adequate non-operative management. Aetiology of end-stage ankle arthritis is often post-traumatic. In Sweden, a declining occurrence of Rheumatoid arthritis (RA) has been reported as the main diagnosis for surgery [95], which may be due to improvements in medical therapy. In *Paper I* we found similar prosthetic survival rates (ranging from 57% to 69% at 15 years) for different diagnoses, although few cases were available for long-term follow-up. In *Paper II* analyses based on diagnosis were not performed. In *Paper III* we found that osteoarthritis (OA) and “other” diagnoses (compared with RA) were associated with higher SEFAS score. Post-traumatic arthritis (PtA) and OA (compared with RA), were associated with higher EQ-5D index score. Diagnoses PtA, OA and “other” (compared with RA), were associated with higher EQ-5D VAS.

The latest annual report from Swedankle shows differences in Sweden regarding the incidence of surgery for severe ankle arthritis between regions and an uneven

distribution of type of surgery (TAR and AA) both between regions and between sexes. Similar findings have also been reported in the US [140]. Based on this, we can suspect that the type of surgical treatment a patient receives, if any, partly depends on geographical location. This, in turn, may be due to variations in the availability of orthopaedic surgeons with a subspecialty in foot and ankle surgery, as well as differences in resources and regional priorities [95].

Total Ankle Replacement or Ankle Arthrodesis - Current Evidence

There is a trend of increasing use of TAR as treatment for end-stage arthritis, globally [12] and in Sweden [95]. Despite substantial progress, the fundamental question, whether TAR or AA is the superior treatment for end-stage ankle arthritis, remains unresolved. At present, only one large randomised controlled trial, the TARVA study conducted in the United Kingdom, directly compares the two procedures. Early results suggest comparable short-term outcomes in several domains, but longer follow-up is required before definitive conclusions can be drawn [12].

The data presented in *Paper I and II* indicate a gradual improvement in prosthetic survival rates for modern TAR prostheses, supporting the notion that technological and procedural advancements are translating into better outcomes. *Paper III* highlights that AA remains a valuable and satisfactory treatment option.

Prosthetic survival rate after primary TAR is especially important considering the inferior results previously found by Kamrad (based on data from Swedankle) regarding the two main surgical options after TAR failure, revision TAR and salvage arthrodesis (SA) [85, 86]. Prosthetic survival rate was 76% after 5 years and 55% after 10 years for revision TAR [86], compared to 85% and 74% after primary TAR, *Paper I*.

After revision TAR 52% were satisfied compared to 71% for primary TAR in general [86] and 81% after TM TAR, *Paper II*. Mean scores postoperatively after revision TAR were SEFAS 22, EQ-5D index 0.60, and EQ-5D VAS 64 [86] compared to SEFAS 36, EQ-5D index 0.90 and EQ-VAS 80 after primary TAR [125]. After SA, Kamrad et al found that 47% were satisfied [85], compared to 69% after primary AA in *Paper III*. After SA, mean SEFAS was 22, EQ-5D index 0.57, EQ-5D VAS 59 [85] compared to SEFAS 30, EQ-5D index 0.69 and EQ-5D VAS 69 after primary AA in *Paper III*.

It is likely that the future will see a broader indication for TAR, particularly if prosthetic survival improves further and surgical expertise continues to increase. However, AA will probably remain an important surgical option, especially for younger patients with high physical demands or complex deformities where durability is paramount.

Evaluation and classification of ankle arthritis

Ankle arthritis is primarily a clinical diagnosis, based on a thorough patient history (anamnesis) and physical examination, including alignment and stability. While clinical assessment is central to diagnosis, imaging can play an important complementary role when evaluating disease severity, confirming the diagnosis, monitoring progression, and in particular for choosing or planning surgical interventions [24]. In assessing ankle arthritis, weight bearing (WB) radiographs are considered gold standard by most [9, 36-38, 141]. Although, WB radiographs can be technically more challenging to acquire compared to non-weight bearing (NWB), and potentially more time-consuming, as well as more painful for the patient. Furthermore, it has been shown that the true degree of WB varies considerably in WB radiographs of the foot and ankle [9], however the implication of this for assessing ankle arthritis, is unknown.

Osteophytes, subchondral sclerosis and subchondral cysts all appear in the bony parts of the joint and their detection should not be related to WB. It is joint space narrowing, which ought to be related to WB. In *Paper IV*, we found that reliability of NWB compared to WB radiographs for detection of signs of ankle arthritis was almost perfect. However, most subjects in the study had moderate or severe ankle arthritis, but in one case, reduced joint space became detectable on WB (while not on NWB) radiographs, thus, NWB radiographs may not be sufficient to exclude milder forms of joint space narrowing. However, in clinical practice when a patient's symptoms do not align with the radiological findings, further imaging should be considered, for example WB radiographs or more advanced imaging such as CT or MRI.

In *Paper IV* we found that the reliability of NWB compared to WB radiographs as well as SWB compared to WB radiographs, was almost perfect according to K-L and Van Dijk, while moderate for Takakura. Disregarding the Takakura classification (as it was developed mainly for ankle arthritis with medial joint space narrowing and our cohort was not chosen according to those criteria), these findings further support that variability in the true degree of WB on foot and ankle radiographs [9], may have limited or manageable implications for detection of ankle arthritis.

Our findings can also be compared to an older study from Malmö (Bauer, Bergstrom et al. 1979) that analysed 220 ankles on WB (only AP view) and NWB radiographs and found that the WB radiograph only contributed with additional information in 2 patients, leading to upgrade in ankle arthritis grade (according to the classification Magnusson and Cedell) in 1 case. However, it is possible that improvements in radiographs since the mentioned paper may allow for detection of subtle load-dependent joint space reduction.

Why is this thesis important

In the present information landscape, patients and the public may be exposed to an overwhelming amount of health-related content. While a significant portion of this information may be grounded in scientific research, much of it is also shaped by personal opinions, anecdotal experiences, and unverified claims. The coexistence of scientific research and subjective perspectives can make it difficult for non-scholars to distinguish reliable knowledge from misinformation.

Furthermore, commercial interests play a significant role in how health information is distributed and presented to the public. This can be seen on platforms such as YouTube and other social media where advertisements and sponsored content often appear alongside informational videos, sometimes blurring the line between education and promotion. These commercial messages are often designed to appeal to patients concerns, fears, and hopes, which may complicate the patients ability to critically evaluate the information.

This thesis is important as there is still no simple algorithm helping patients and orthopaedic surgeons choose between AA and TAR. Our findings support the continuous use of AA and TAR, based on prosthetic survival rates, PROMs as well as satisfaction. However, careful patient selection continues to be of importance as is continuous quality monitoring and further research.

Strengths and limitations

The strengths of *Paper I-III* include the large patient cohorts, although even larger cohorts could reduce the risk of type II errors. *Paper I and II* present non-designer results for TAR in a real-world complete national cohort of patients, in contrast to reports from single or specialised units or surgeons.

While the response rate on questionnaires in *Paper II and III* was non-optimal the data reflect both the Swedish population and the national Swedish health care system, with many different caregivers and surgeons of varying experience. Another strength was the combination of generic (EQ-5D) and region specific (SEFAS) PROMs.

Strengths of *Paper IV* include the standardised imaging protocol with a set order for the radiograph acquisition, facilitating standardised SWB and WB conditions. Another strength was the use of multiple classification systems, and assessment of both inter- and intra-rater reliability, showing substantial/almost perfect reliability. The inclusion of two raters with different levels of experience also enhanced the generalisability of the findings, although raters of varied experience can also be considered a weakness. Furthermore, to our best knowledge, there are few or no previous reports of this kind.

Given the observational study design in *Paper I-III*, causality cannot be established, and results should be regarded as exploratory. It is also plausible that choice of method (AA or TAR) and surgical approach may have been influenced by both preference of the surgeon as well as specific patient factors, none of which we were able to take into account.

The use of national registry data in *Paper I-III* has drawbacks including missing data, data quality issues, as reporting is done by many different persons as well as limited number and complexity of variables and risk of selection bias. In *Paper I* the aggregation of different prosthesis designs into groups may obscure advantages and disadvantages of certain designs and results may have been different if groups were set up in another way.

In *Paper II and III*, our results only cover a limited postoperative period. The proportion of patients completing PROMs could have been higher, rendering some degree of selection bias probable. More patient-specific information would also benefit *Paper I-III*, however due to the registry-based nature, detailed patient-level data were not available. Another limitation is lack of detailed information on non-responders, as trends of poorer results from this group have been described after other orthopaedic procedures [142, 143]. 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, estimated at 95% for AA and 100% for TAR in Swedankle. Although translated into and validated for several other languages [103-107], the SEFAS score has only been used in few other papers related specifically to AA which impedes putting our results into a larger perspective. Another limitation is that information on patients with severe end stage arthritis who do not undergo surgery, is missing in our studies and within the field.

Imputation in *Paper III*, that was used to address missing data, may also be deemed a weakness as it may introduce bias, underestimate variability, mask data collection problems and possibly distort relationships between variables. Even though type I errors thereby may be more frequent, the similarities between results from analyses on imputed data and the original (unimputed) dataset make this less probable.

Paper IV is based on a small sample size. The study population also predominantly consisted of patients with moderate to severe ankle arthritis, potentially limiting applicability to early-stage disease where WB may have a greater impact on radiographic appearance. The SWB and WB radiographs were acquired without a scale, rendering the true degree of weight applied by the patient, unknown. The fact that the radiographs were assessed in a fixed order (NWB, SWB, WB) may also have introduced bias, as information from the prior radiograph (e.g., NWB) was known during assessment of the subsequent radiograph (e.g., SWB); however, we have no indications that this had any substantial impact.

Finally, WB radiographs were treated as the reference standard, although clinical diagnosis of ankle arthritis is multifactorial and not based on radiographs alone.

Conclusions

- Prosthetic survival rate after Total Ankle Replacement (TAR) was 85% after 5 years, 74% after 10 years, 63% after 15 years and 58% after 20 years.
- Prosthetic survival rate after TAR for early prosthetic designs was 81% after 5 years and 69% after 10 years, while the corresponding rates for current designs were 88% after 5 years and 84% after 10 years.
- Current prosthetic designs had better prosthetic survival (log rank test $p < 0.001$).
- Prosthetic survival rate after Trabecular Metal (TM) TAR was 95% after 3 years.
- Satisfaction 2 years after TM TAR was 81%.
- All mean Patient Reported Outcome Measure (PROM) scores improved from before TM TAR to 2 years postoperatively (all $P < 0.001$). Mean PROMs after TM TAR were SEFAS 36, EQ-5D index 0.90, and EQ-5D VAS 80.
- Satisfaction 2 years after ankle arthrodesis (AA) was 69%.
- All mean PROM scores (SEFAS, EQ-5D index and EQ-5D VAS) improved from before primary AA to 2 years postoperatively (all $P < 0.001$).
- Higher preoperative SEFAS score was associated with satisfaction after AA and lower preoperative SEFAS was associated with dissatisfaction.
- After primary AA, male sex and diagnoses OA and “other” (compared with RA) were associated with higher SEFAS score. Male sex, diagnoses PtA and OA (compared with RA), as well as higher age, were associated with higher EQ-5D index score. Male sex, diagnoses PtA, OA and “other” (compared with RA), as well as higher age, were associated with higher EQ-5D VAS.
- Comparing non-weight bearing (NWB) with WB (weight bearing) radiographs and SWB (semi-weight bearing) with WB radiographs regarding detection of signs of AA, reliability was almost perfect.

- The reliability for classification of ankle arthritis according to two different radiologists on NWB compared to WB radiographs and SWB compared to WB radiographs, was almost perfect for Kjellgren-Lawrence and Van Dijk classifications, while almost perfect for one radiologist and moderate for the other regarding the Takakura classification.
- Inter-rater reliability for NWB, SWB and WB radiographs was substantial/almost perfect for all three classifications.

Clinical perspectives

Although generalisation of our results is limited due to the study designs, this thesis contributes important information.

- Our findings support further use of Trabecular Metal (TM) Total Ankle Replacement (TAR), when TAR is the treatment of choice.
- In the preoperative patient doctor discussion, we can inform that few patients (12-16%) undergoing surgery with modern TAR require revision the first 5-10 years.
- In the preoperative patient discussion, we can inform that a vast majority (TM TAR 81%, AA 69%), but not all, patients are satisfied 2 years after TM TAR as well as after AA.
- Preoperative SEFAS may facilitate predicting surgical outcome, and can have a role in the preoperative patient discussion on expected results.
- NWB as well as SWB radiographs seem reliable compared to WB radiographs, both in detecting signs of AA and in classifying AA by K-L or Van Dijk, at least in moderate and severe grades.

Future perspectives

I believe that it is important for future research to accept the complexity of treating end-stage ankle arthritis. We should stop asking “which procedure is better” and focus on personalised treatment strategies, rather asking “which procedure is better for which patient”, allowing PROMs to play a central role in answering these questions.

There will always be a need for continuous development of prosthetic designs and instrumentation, a task for which we mainly have to rely on the industry. In line with a more personalised approach to patient selection, a recent review discusses advancements of custom-made prostheses for total knee replacement [144], and we will probably see increasing utilisation of 3D printing techniques and customised prostheses in ankle surgery as well. However, as prosthetic designs develop, it is important that neutral actors such as national registries continue with large cohort outcome evaluations to provide long-term follow-up, both regarding prosthetic survival and revision rates as well as patient reported outcomes.

There are few qualitative studies within this area. In the future, we may consider more qualitative studies, for example exploring surgeon experiences or going more deeply into what could be improved in the ankle arthritis care according to patients.

Another important missing piece of this puzzle is long-time follow-up regarding PROMs, both after AA and TAR. This could potentially be future projects for our research group. Another area of importance is acquiring epidemiological data on ankle arthritis based on the Swedish population, which is currently lacking. This kind of data may help health-care planning and justify future research directions. We hope to facilitate future epidemiological studies on ankle arthritis through completion and publication of *Paper IV*.

Populärvetenskaplig sammanfattning (Summary in Swedish)

Bakgrund

Fotleden, som också kallas den talokrurala leden, är en gångjärnsled som gör att vi kan böja och sträcka på foten. Den bildas av skenbenet (tibia), vadbenet (fibula) och språngbenet (talus). Leden stabiliseras av en ledkapsel och starka ledband på både insidan och utsidan. Tillsammans med foten skapas ett avancerat system som gör det möjligt att stå, gå, springa och hoppa. Brosket i fotleden täcker ledytorna och fungerar som stötdämpare. Det gör också att benen glider smidigt mot varandra.

Artros (ibland kallat ledsvikt) karaktäriseras av långsamt ökande ledförändringar med broskförlust och nybildning av ben vid ledkanterna, så kallade pålagringar. Artros är en av de vanligaste orsakerna i världen till smärta, funktionsnedsättning, nedsatt livskvalité och medför stora kostnader för samhället. Hur vanligt det är med artros i fotleden är osäkert och varierar mellan olika studier, bland annat eftersom man använder olika röntgenmetoder och bedömningsystem. Ofta anges cirka 1-2% av befolkningen ha fotledsartros. Oftast uppstår artros i fotleden efter en skada, till exempel en fraktur eller stukning. Studier av fotledsartros har ibland använt belastade och ibland obelastade bildtagningsmetoder eller till och med metoder där graden av belastning inte angetts. Även om belastade röntgenbilder ofta betraktas som den bästa metoden för att bedöma fotledsartros, kan den faktiska graden av belastning under bildtagningen variera avsevärt, och hur denna variation påverkar upptäckt och klassificering av fotledsartros är oklart.

Artros i fotleden leder ofta till nedsatt funktion och sämre livskvalitet, inte sällan hos ganska unga personer. Som ett första steg och om besvären inte är uttalade, används icke-kirurgiska behandlingsmetoder. Dessa innefattar till exempel träning, viktminskning, ortopediska skor/inlägg, receptfria mediciner och gånghjälpmedel. I vissa fall kan kortisoninjektioner i leden tillfälligt minska besvären. När dessa alternativ inte längre ger tillräcklig effekt kan behandling med operation övervägas.

Ett mindre ingrepp som använts tidigare är borttagning av pålagringar, vilket kan ge förbättrad rörlighet under en period, oftast kommer dock både besvären och pålagringarna tillbaka. Om fotleden är felvinklad men ledbrosket är bevarat, finns alternativ där man sågar av benet, ovanför fotleden, och vinklar om leden. Detta kan även användas om bara en del av leden är drabbad.

Är besvären däremot uttalade och ledbrasket utplånat, återstår i stort sett två operationsalternativ, steloperation av fotleden eller fotledsprotos. Steloperation är den mest välbeprövade metoden medan fotledsprotos representerar ett modernt alternativ. Båda metoder är numera vedertagna och det finns för- och nackdelar med var och en av dem. På senare tid har fotledsprotos börjat användas i allt större utsträckning.

Steloperation innebär att man tar bort brosket, sätter ihop de ben som tidigare utgjorde ledens begränsning och låter de läka ihop. Steloperation fungerar oftast komplikationsfritt och behöver sällan opereras om. Patienter upplever i stor utsträckning smärtfrihet och man har uppmätt en relativt hög grad av nöjdhet. Rörelsemönstret i komplexet fot/fotled förändras dock till följd av operationen, vilket kan leda till ökad belastning och förslitningar av andra närliggande leder. Steloperation rekommenderas ofta till yngre patienter som är fysiskt aktiva och har många levnadsår framför sig, eftersom fotledsprotoser i de studier som finns inte verkar hålla tillräckligt länge.

Fotledsprotos å andra sidan fungerar också oftast komplikationsfritt initialt, men har en risk för att lossna på längre sikt, vilket kan kräva om-operation. Efter protesoperation upplever de flesta patienter smärtfrihet och relativt hög grad av nöjdhet, på liknande sätt som efter steloperation. Då fotledens ursprungliga rörelsemönster bevaras bättre, finns indikationer på att närliggande leder drabbas av ledsvikt i mindre utsträckning. Fotledsprotos har traditionellt rekommenderats till äldre, normalviktiga patienter med god läkningsförmåga och benkvalité.

Metod

Data till *Artikel I–III* hämtades från Swedankle, ett nationellt svenskt kvalitetsregister med information om över 7500 fotledsprotoser och steloperationer som utförts sedan 1993 i Sverige. I *Artikel IV* togs röntgenbilder utan belastning, med viss belastning och med full belastning. Två röntgenläkare bedömde bilderna för att se tecken på artros och klassificerade graden av artros enligt tre olika system; Kellgren-Lawrence, Van Dijk och Takakura. För att utvärdera resultat efter fotledsprotos kan man använda protesöverlevnad, vilket avser andelen protoser som fortfarande fungerar (och inte har behövt opereras om) vid uppföljningstillfället. Även patientrapporterade utfallsmått (så kallade PROMs) via enkäter är viktiga för att förstå patientperspektivet.

Resultat

I *Artikel I* fann vi att protesöverlevnaden var 85% efter 5 år, 74% efter 10 år och 63% efter 15 år. Vi fann även att nyare protesmodeller hade bättre protesöverlevnad jämfört de äldre. I *Artikel II* fann vi att protesöverlevnaden för protesen ”TM TAR” var 95% efter 3 år och att 81% av patienterna nöjda med den opererade fotleden 2 år efter operationen. I *Artikel III* fann vi att 2 år efter steloperation av fotleden var 69% av patienterna nöjda, och även här sågs tydliga förbättringar i funktion och livskvalitet. Vidare fann vi att patienter som hade bättre funktion före operationen oftare var nöjda efteråt, medan de som hade sämre funktion före operationen oftare var missnöjda. I *Artikel IV* fann vi att röntgenbilder tagna utan belastning eller med viss belastning visade sig vara nästan lika tillförlitliga som bilder tagna med full belastning, när man skulle upptäcka fotledsartros. För två av tre bedömningssystem (Kellgren-Lawrence och Van Dijk) var överensstämmelsen mycket hög, medan den var måttlig för det tredje systemet (Takakura).

Slutsats

Våra resultat visar att överlevnaden för fotledsproteser har förbättrats över tid i Sverige. Det kan bero på bättre protesdesign, förbättrade operationsmetoder, mer erfarna kirurger och bättre urval av patienter. Vidare fann vi att steloperation i fotleden är en rimlig behandling vid svår fotledsartros, men kanske inte den optimala lösningen för alla. Resultaten tyder också på att patientens funktionsnivå före steloperation kan hjälpa till att förutsäga hur nöjd personen blir efteråt och kan vara ett stöd i samtal inför operationen. Röntgen utan eller med viss belastning verkar fungera bra för att upptäcka och bedöma åtminstone måttlig till svår fotledsartros, jämfört med röntgen med full belastning.

Framtid

Framtida forskning bör fokusera på ”vilken metod passar bäst för vilken patient?”. Behandlingen behöver alltså anpassas mer efter individen. Här är patienternas egna upplevelser av resultatet, patientrapporterade utfallsmått, mycket viktiga för att kunna ge rätt behandling till rätt person. Idag saknas långtidsuppföljning av hur patienterna själva upplever resultatet, både efter steloperation och fotledsprotes. Det skulle kunna bli ett framtida projekt för vår forskargrupp. Det saknas även statistik över hur vanligt fotledsartros är i Sverige och vi diskuterar inom forskargruppen hur vi kan bidra med sådan kunskap framöver. Det finns också behov av att fortsätta utveckla proteser och operationsinstrument. Detta arbete görs främst av företag som tillverkar proteser, men resultaten bör granskas och följas upp av oberoende aktörer som Swedankle.

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All original text was written by the author(s). Generative artificial intelligence (AI) tools (ChatGPT) were used for language refinement and style improvement, as well as for some images and figures.

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