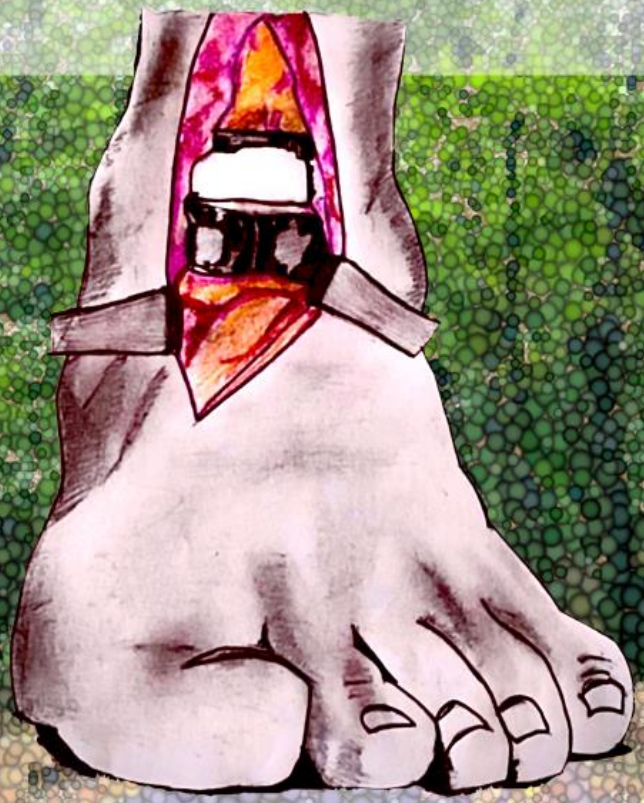
Joris P.S. Hermus

The pathway to optimal ankle replacement surgery

The pursuit of solutions



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PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit Maastricht,
op gezag van de Rector Magnificus, Prof.dr. Pamela Habibović
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in het openbaar te verdedigen
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door

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Stellingen behorende bij het proefschrift

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Joris Hermus

Maastricht 5 September 2025

The significance of the scientific findings from this thesis

1. Mobile-bearing total ankle replacements are associated with a higher reoperation rate than fixed-bearing implants, particularly due to impingement issues*. (Chapters 2 & 7)*
2. Incorporating patient stratification into surgical planning is crucial for optimizing outcomes, minimizing complications, and customizing treatments based on individual biomechanical and psychological characteristics. ***(Chapters 4 & 7)***
3. Continuous monitoring is essential for (self)improvement, as it allows us to learn from our "mistakes." ***(Chapters 3 & 4)***
4. Finite Element Analysis has identified the surgical steps required to improve outcomes by avoiding specific improper implant positioning *(**Chapter 5).***

The societal implications of this thesis.

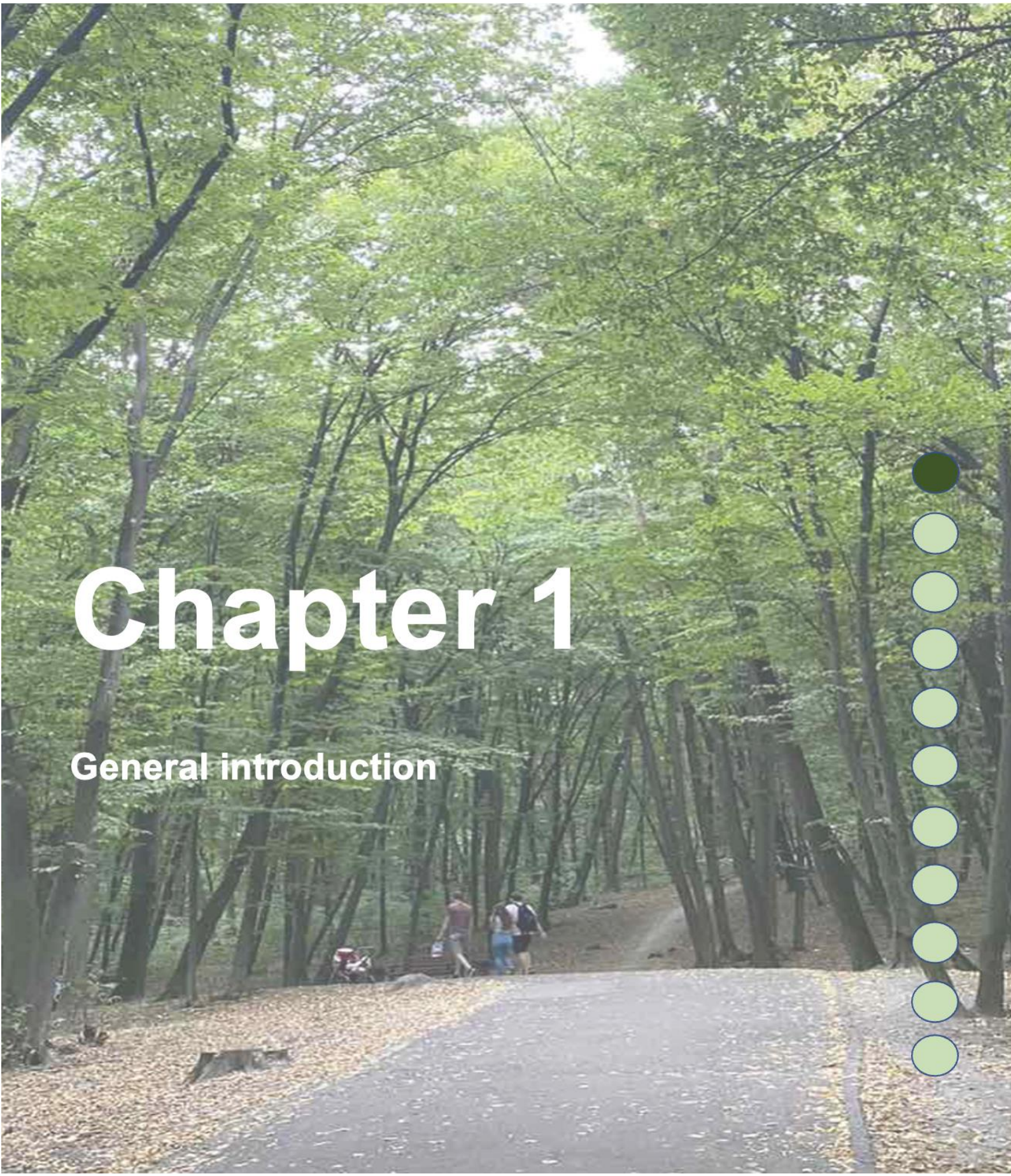
5. By centralizing total ankle replacement procedures in specialized centers, outcomes can be significantly improved through increased expertise and a reduced learning curve ***(Chapter 10)***.

Related to the doctoral candidate's field of expertise

6. True progress in surgery is not about avoiding challenges but about continuously seeking solutions that improve recovery and enhance quality of life. (**Joris Hermus**)
7. An orthopedic surgeon is not a podiatrist. (***Royal College of Podiatry)***
8. Good surgeons know how to operate, better when to operate, and the best when not to operate. ***(BMJ 1999; 318:0)***

Other statements related to the doctoral candidate

9. Ankles are nearly always neat and good-looking, but knees are nearly always not ***(Dwight Eisenhower)***
10. “Sometimes when you innovate, you make mistakes. It is best to admit them quickly and get on with improving your innovations.” ***(Steve Jobs)***
11. “Door de bomen het bos niet meer zien”. ***(Wieland 1733-1813)***


Chapter 1
General introduction

Introduction

OA is one of the most significant and widespread diseases that are becoming even more prominent as a public health issue especially in the elderly [1]. For instance, the Netherlands has a large number of people who suffer from OA, in 2023 alone 1.65 million patients visited their general practitioners for osteoarthritis complaints 605.500 men and 1.047.600 women. These figures are expected to increase dramatically by 2040 because of the population's growth.

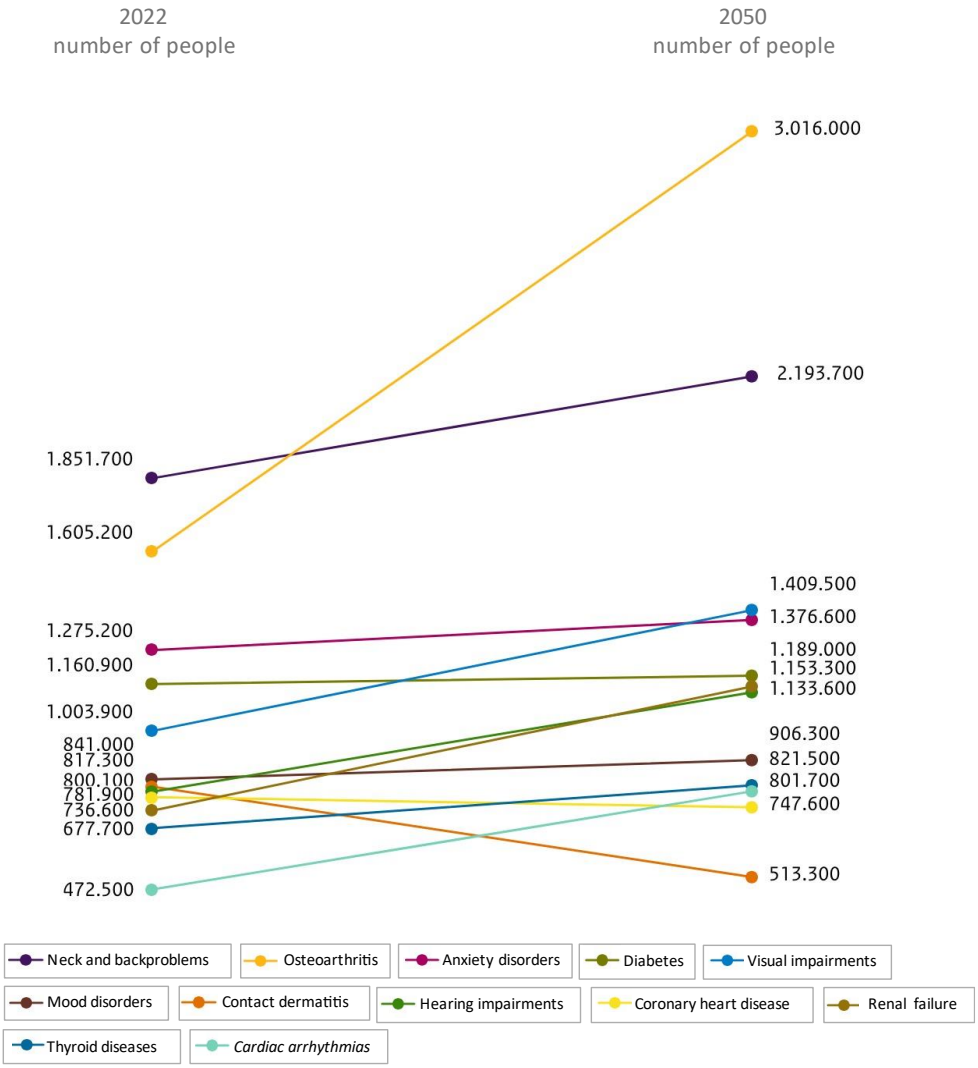


Figure 1. The distribution of the Dutch population with specific disorders for 2022 and 2050. The graph demonstrates a significant increase in osteoarthritis cases age in 2050 [1].

Similarly, in the United Kingdom about 29,000 cases of symptomatic ankle OA are referred each year to foot and ankle specialists and 3,000 of these will require ankle arthrodesis (AA) or total ankle replacement (TAR) [3,4].

Ankle osteoarthritis is different from other forms of OA that involve larger joints of the hip or knee joints, and it is mostly secondary in nature. 70% of cases are caused by post-traumatic factors including fractures and ligament instability as the causes of ankle arthritis [5-9]. These injuries lead to gradual deterioration of the joint with pain, stiffness and immobility that negatively affects the quality of life. Studies have shown that the health-related quality of life (HRQoL) with end-stage ankle osteoarthritis is as poor as that of a patient with hip osteoarthritis highlighting the need for effective treatments [10-12].

Conservative treatment is usually the first approach for managing ankle conditions. Methods such as physical therapy, intra-articular anti-inflammatory injections, pain medications, and orthotic devices are often helpful in reducing pain, though the effects are only short term [13,14]. When non-surgical measures are insufficient, surgical options may be necessary. Ankle arthrodesis (AA) has been the primary surgical treatment for functionally impaired ankles for the past three decades and is still regarded as the gold standard [15]. However, while arthrodesis is effective in alleviating pain, it can negatively affect gait [16,17].

Total ankle replacement (TAR) offers a promising alternative to arthrodesis. By preserving joint motion, TAR reduces the mechanical stress on adjacent joints, improves gait biomechanics, and allows patients to regain more natural movement patterns [18]. Moreover, TAR has been associated with a lower incidence of osteoarthritis in nearby joints compared to arthrodesis, addressing a significant concern for long-term outcomes [19]. The goal of TAR is to provide pain relief, restore ankle mobility, and improve the patient's quality of life, while minimizing complications and enhancing long-term functionality.

Goals in Total Ankle Replacement (TAR):

- Prevent avoidable complications.
- Ensure optimal positioning and fixation of the implant.
- Achieve limb alignment that feels natural to the patient, minimizing early wear and loosening.
- Establish a stable ankle joint.
- Minimize side effects, such as soft tissue damage and bleeding.

Strategies to Optimize Surgical Performance:

- Careful patient selection to match individual needs.
- Implementing pre-surgery exercise programs, particularly for frail patients.
- Optimizing peri-operative pain management.
- Providing patient-specific postoperative rehabilitation plans.

Enhancing Patient Satisfaction:

- Effectively manage and meet patient expectations.
- Emphasize shared decision-making processes.
- Streamline and optimize peri-operative procedures.

Choosing the most appropriate treatment requires careful evaluation of each patient's specific needs and the benefits and limitations of the available options.

The Biomechanics of Ankle OA: Implications of Posttraumatic Injuries

The ankle joint bears approximately four times the body weight during the stance phase, despite having a relatively small contact surface area of just 522 square millimeters—approximately one-third of the area seen in the hip or knee. This results in an exceptionally high load per unit of surface area [20].

Biomechanically, the ankle joint is highly congruent, with thinner cartilage (1.5 mm) compared to the hip and knee. Despite its thinness, this cartilage demonstrates strong resistance to tensile and shear forces, enabling it to endure substantial pressure. These characteristics could possibly explain why symptomatic ankle arthritis nine times is less frequent than symptomatic knee arthritis [21].

In contrast to hip and knee osteoarthritis (OA), which are primarily idiopathic or of primary origin [22], studies indicate that ankle OA is often posttraumatic [23-25,14]. Ankle OA can be attributed to post-traumatic causes such as fractures of malleoli, tibial plafond, isolated osteochondral lesions of talar dome and ligament injuries [25-27]. Such injuries may affect the joint's congruity and its mechanics and may increase the contact pressures and accelerate the cartilage degeneration.

History, Evolution, and Current Landscape of Total Ankle Replacement (TAR). In the last two decades, total ankle replacement (TAR) has gained increasing acceptance among foot and ankle surgeons as a valuable treatment option for patients with end-stage ankle osteoarthritis (OA). Compared to total hip and knee replacements, TAR has a shorter clinical history with many complications and a gradual development of implant design and surgical procedures [28].

First-Generation TAR. The early TAR designs that were available in the 1970s mainly had two-components with constraints or semi-constraint designs. These designs used cement for fixation of the talar as well as the tibial component. However, these systems had many complications and high early failure rates including aseptic loosening, implant subsidence and pain. These problems were compounded by excessive bone resections and non-anatomical designs of the prosthetic components which led to regular revisions and conversions to ankle arthrodesis. Because of the outcomes of the first-generation TAR, ankle arthrodesis became the treatment of choice for end-stage ankle arthritis for several decades [29-33].

Second-Generation TAR. Second-generation TARs were developed because the first-generation TARs had so many early failures. The improvements included Increasing the intrinsic stability, use of the cementless fixation with the biological surface to promote osseointegration and improving the techniques to reduce the wound complications such as wound healing disturbances and infection. These changes provided the basis for the second-generation TAR systems. Other prostheses include Agility, Buechel-Pappas, HINTEGRA, STAR, and TNK demonstrated encouraging mid- and long-term results. Second-generation TAR designs focused on preserving bone integrity, minimizing resection, and improving congruency between the prosthetic components and the bone. The introduction of meniscal-bearing, three-component systems was particularly notable. These systems provided better joint congruency, reduced polyethylene wear, and allowed for greater freedom of movement while maintaining stability [32-34]. Despite these advancements, the success of second-generation TAR depended heavily on precise surgical execution, particularly in achieving proper alignment and ligament balance. Even minor deviations could lead to complications such as instability, pain, or implant failure.

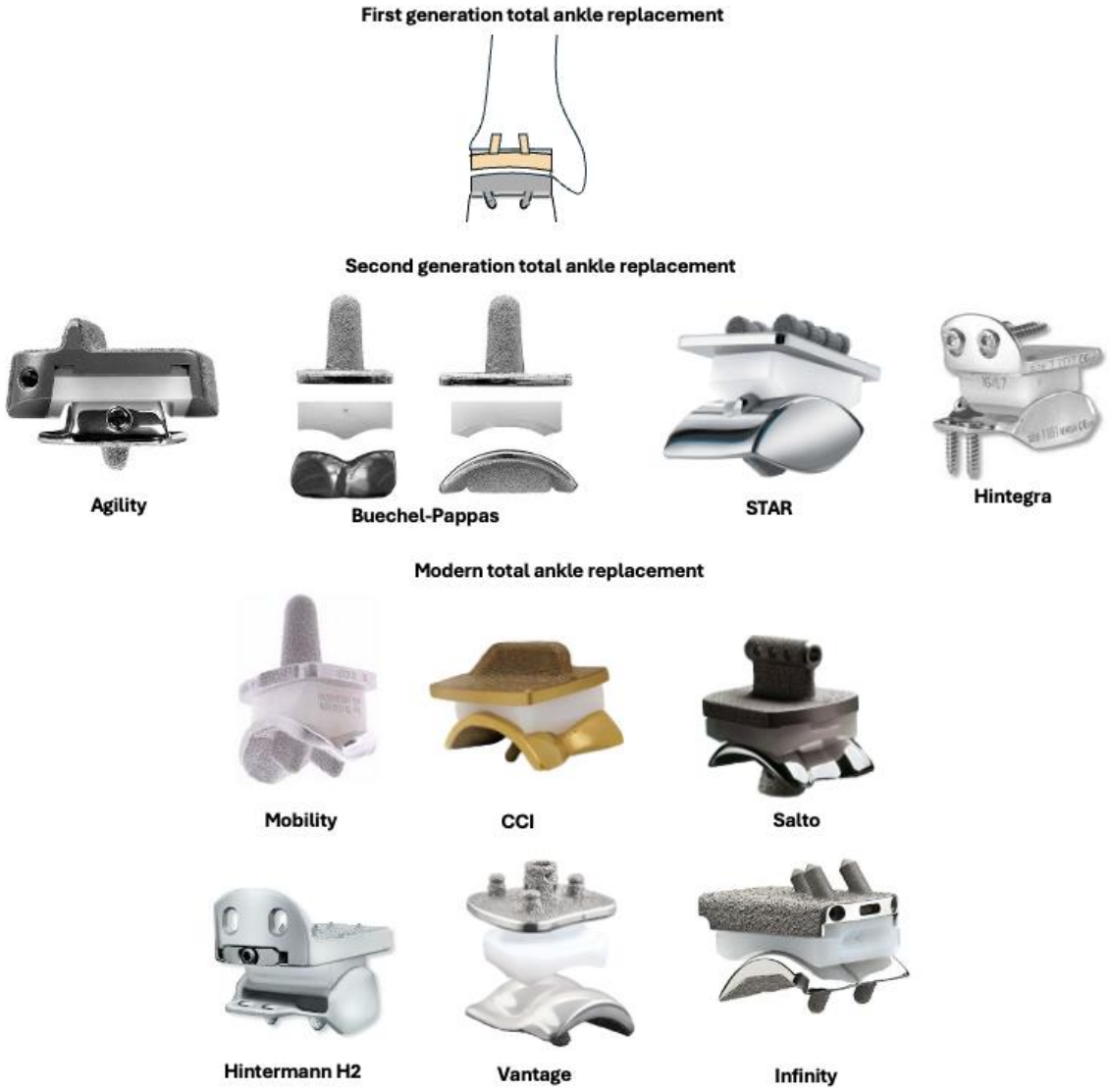


Figure 1. Evolution of total ankle replacement: From first-generation designs to second-generation models and modern total ankle replacement implants [28].

Modern TAR Designs. Building on earlier advancements, modern TAR systems be classified into two main types namely, two-component and three-component designs systems. These systems aimed at minimal bone resection, anatomical congruence, and optimized load distribution. Cementless fixation has become the standard, with surfaces designed to enhance bone ongrowth and reduce the risk of aseptic loosening [34-37] . Modern prostheses attempt at preserving the cortical rim and subchondral bone to provide robust support for the bone-implant interface. Meniscal-bearing, three-component prostheses have further evolved to offer complete congruency across a full range of motion, maintaining minimally constrained components that allow soft tissues to control physiological joint motion [38-41]. These improvements help to

reduce the stress on the bone-implant interface while at the same time enhancing the stability of the implant. However, the issues of proper ligament balance and alignment are still crucial. An improper alignment or imbalance of the ligaments can lead to issues such as pain, polyethylene wear, and joint instability. Ensuring intrinsic stability and optimal load transmission requires prosthetic surfaces that mimic the anatomy of the ankle joint as closely as possible.

Challenges in TAR

Despite the evolution of the design of the implants and the TAR surgical techniques, several technical challenges still affect its success:

1. **Bone Integrity and Implant Stability**: Excessive bone removal, particularly on the tibial and talar sides, can weaken the bone-implant interface, leading to implant subsidence under weight-bearing conditions. Adequate mechanical support relies on preserving the cortical rim and minimizing bone resection during surgery. The components of the prosthesis should provide complete covering of the subchondral bone to ensure proper load distribution and stability. Improper sizing or positioning of the implant can exacerbate these issues, resulting in early failure or revision.
2. **Surgical Complexity**: Achieving proper ligament balancing in TAR remains one of the most challenging aspects of TAR, as misalignment can cause joint pain, increased wear, and failure of the prosthetic components. Implant alignment and geometry are critical factors in achieving surgical success, as malalignment or instability can lead to implant failure. Achieving ligament balance and reducing deformities during surgery are essential goals to ensure durability and optimal function [42-45].
3. **Durability and Long-Term Complications**: Although, the second generation TAR systems have shown better results in the intermediate term, their longevity is still not as good as that of total hip and knee replacements. Survival rates of the TAR implant have been seen to have improved in the last few years with rates reaching up to 95% at 10 years for some designs [45-49].

The total ankle replacement (TAR) procedure typically uses a standard anterior approach to access the ankle joint. After exposure, minimal resection of the distal tibia and talar dome is performed to preserve subchondral bone integrity. Prosthesis designs vary, with mobile-bearing systems like the Ceramic Coated Implant (CCI) Evolution Total Ankle Replacement system developed to reduce implant-related stress and fixed-bearing systems such as the Infinity Total Ankle Replacement system designed to enhance mechanical stability. Depending on the degree of preoperative deformity, a combination of soft tissue procedures—such as Achilles tendon lengthening— and bony procedures—such as medial malleolus osteotomy—may be necessary to restore joint alignment and achieve soft tissue balance. A structured postoperative rehabilitation program is typically implemented to support recovery and restore function. Notably, the CCI Evolution Total Ankle Replacement system was withdrawn from the market in 2016 by Wright Medical Group (Memphis, USA).

This thesis outlines the chronological progression of TAR practice at our institution. Chapter 2 presents early clinical outcomes dating back to 2010 using the CCI implant system, which, although associated with a high complication rate, were consistent with findings reported in the broader TAR literature. Chapter 3 utilizes national registry data to examine patient- and procedure-related risk factors for implant failure. Chapter 4 details the transition to the Infinity implant system, which demonstrated improved outcomes compared to earlier designs despite complications such as impingement. This chapter also investigates the potential influence of preoperative anxiety on postoperative outcomes. Chapters 5 and 6 provide an overview of the most frequently reported complications, based on a systematic meta-analysis and an extensive literature review. Recognizing the importance of implant alignment, Chapter 7 explores the biomechanical consequences of malalignment through finite element modeling. In response to these findings, Chapter 8 introduces and validates a semi-automated radiographic tool for assessing three-dimensional TAR alignment from standard two-dimensional imaging. Chapter 9 integrates these insights to identify key factors associated with TAR success and failure, offering recommendations for improving clinical outcomes. Finally, Chapter 10 discusses future research directions and proposes practical strategies to enhance the safety, durability, and overall patient satisfaction of TAR procedures.

Aims of This Thesis

The research aims to advance the field of total ankle replacement surgery by focusing on several key objectives:

1. **Evaluating Clinical Outcomes:** Assess the effectiveness, functionality, and long-term durability of total ankle replacement (TAR) in light of advancements in implant design.
2. **Addressing Complications and Failures:** Examine the frequency, causes, and management strategies for complications and failures linked to TAR.
3. **Exploring Alignment and Biomechanics with the help of innovating technological solutions:** To examine the importance of alignment and biomechanical factors that influence implant failure and performance by using sophisticated measuring and modeling techniques.

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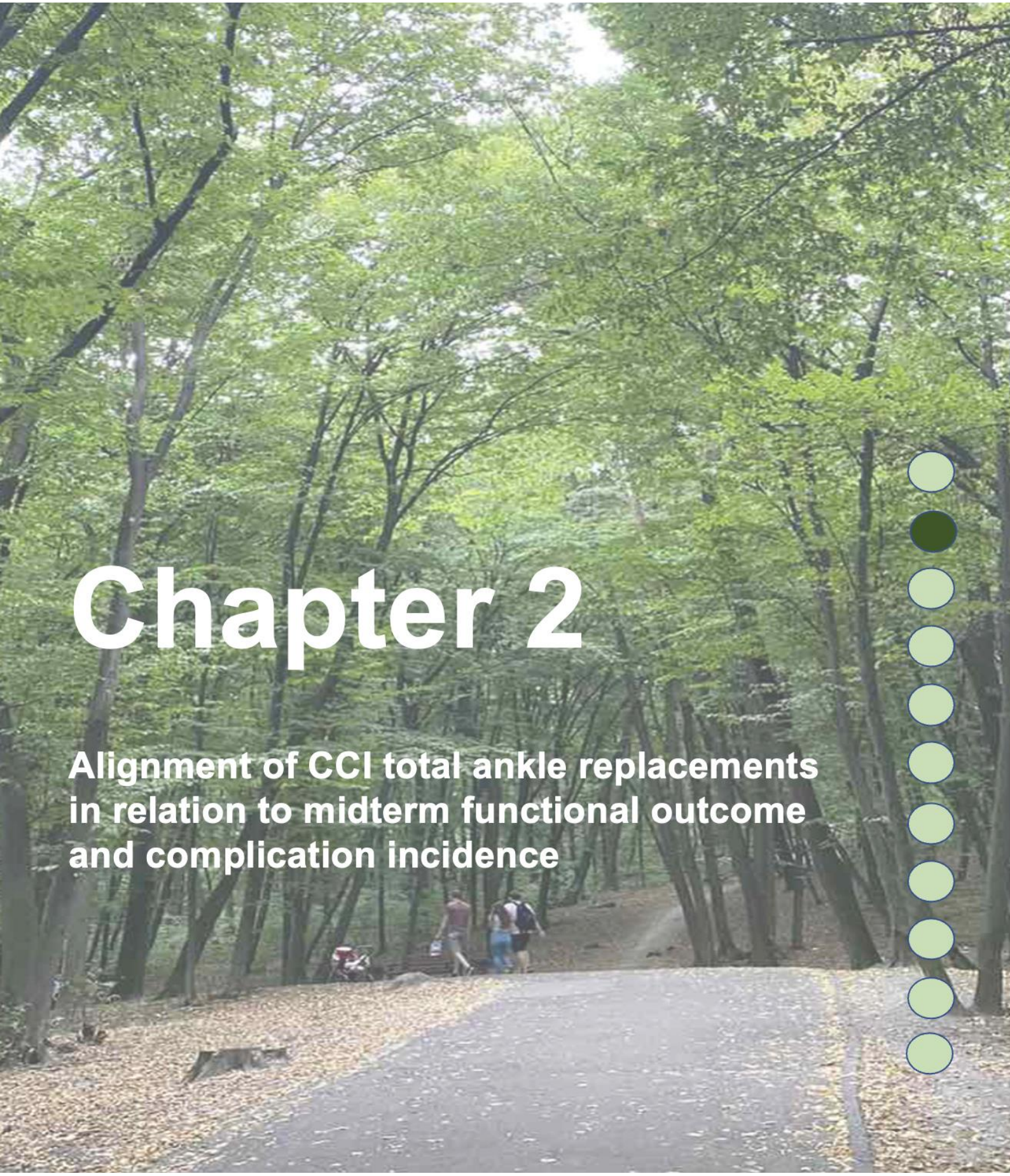

Chapter 2

Alignment of CCI total ankle replacements in relation to midterm functional outcome and complication incidence

Abstract

Background: Total ankle arthroplasty is increasingly used as a treatment for end-stage ankle arthropathy. The aim of this study was to report the mid-term clinical function and survival results of Ceramic Coated Implant (CCI) ankle replacements and assess the association between the alignment of the CCI total ankle replacements and early functional outcome and complication incidence.

Methods: Data of 61 patients, who received 65 CCI implants between 2010 and 2016, were obtained from a prospectively documented database. Mean follow-up time was 85.2 months (range 27–99 months). Clinical function was assessed with AOFAS questionnaire and passive range of motion (ROM). Survival analysis and elaborate radiographic analysis was performed. Furthermore, complications and reoperations were recorded for all patients.

Results: Progression in ROM was most seen in the first 10 months from 21.8 degrees of passive range of motion preoperative to 27.6 degrees postoperative ($p < 0.001$), while the mean AOFAS gradually increased during follow-up postoperative from a mean of 40.9 points preoperative to an average of 82.5 but shows a small decline towards the end of follow-up ($p < 0.001$). During follow-up, we recorded 8 failures (12.3%) resulting in a Kaplan-Meier survival analysis of 87.7% with a median follow-up of 85.2 months.

Conclusion: We observed excellent clinical results and survival after TAA with the CCI implant with only a low mid-term complication rate.

Level of evidence: Level III, prospective cohort study.

Keywords: Total ankle replacement, Total ankle arthroplasty, Complications, Failures

Introduction

End-stage arthritis of the ankle joint can substantially disrupt the Quality of Life (QoL) of a patient through functional limitations [1, 2]. Total ankle arthroplasty (TAA) and ankle arthrodesis (AA) are the two primary surgical treatment options for patients who fail conservative measures. Development of the total ankle arthroplasty is challenging because of the small contact area and high forces which can lead to high contact stresses [3–5].

Ever since TAA surgeries have been undertaken for osteoarthritis, patient satisfaction, pain relief and function have changed for the better [6], however, potential risks of only small improvement of range of motion, persistent pain, and low functional outcome following TAA still remain high [7–9]. TAA may be more susceptible to complications, failure and subsequent re-operation as compared to other surgical interventions of the ankle, especially compared to ankle arthrodesis [10]. For example, a study conducted by Spirt et al. [11] observed that 28% of the patients that underwent ankle arthroplasty were re-operated due to complications with a follow-up time of 5 years. Watts et al. [12] documented in their systematic review a 2.5 times higher re-operation rate in TAA compared to ankle arthrodesis. Nonetheless, the perioperative major complications in ankle arthrodesis occurred 1.8 times more often but had a 29% lower risk of a minor complication after adjusting for patient and hospital factors, such as gender, age, and health-status [13]. These findings are confirmed by the higher 30-day re-admission rate for ankle arthrodesis, which has an independent risk factor with an odds ratio of 2.51 [14].

Salvage arthrodesis after failed ankle arthroplasty has an overall complication rate of 18.2% whereas the overall non-union rate was 10.6%, and it has also inferior results to primary arthrodesis [15, 16]. Therefore, minimal bone resection is necessary in the surgical procedure of TAA to enhance the union rate [17].

Until January 2023 there were no non-designer studies presenting short-term clinical results of exclusively the CCI ankle prosthesis. The group of Doets et al. reported two designer studies. First report presented both the Buechel-Pappas and the CCI ankle prosthesis showing a survival of 87% in the post fracture group and 79% in the instability group at 6 years of follow-up [18]. The other designer study reported a survival rate of 67.5% at 10-year follow-up, with a complication rate of 54% and 37% patients underwent reoperation [19].

This is the first non-designer study to report the mid-term clinical results of the Ceramic Coated Implant (CCI) ankle replacements. The aim of this study was to report the first clinical results and survival of 65 consecutive CCI ankle replacements with a median follow-up time of 85.2 months. Secondly, to report the complication and failure rate. Thirdly, to ascertain if associations could be observed between implant migration during follow-up, as measured according to the Rippstein protocol [20], and subsequent failure of the implant.

Material and methods

Sixty-five consecutive CCI total ankle replacements were placed between June 2010 and June 2016 and included in this prospective follow-up study. In January 2021, the last clinical follow-up was performed. The study was approved by the local ethical committee of Maastricht University (METC 2018-0709), and all patients provided written informed consent prior to participation in the study. All TAA's surgeries were performed by a non-designer single surgeon (JH) in Maastricht University Medical Centre (MUMC +), using the CCI ankle replacement (Wright Medical Technology, Arlington, TN, USA).

The importance of single surgeon studies may allow better comparison, because of consistent diagnosis and different experience levels of surgeons.

The following standard surgical protocol and standardized post-op rehabilitation was followed. Postoperative patients had an aftertreatment with a cast for 2-3 weeks, 50%weightbearing till 6 weeks and from 10 weeks onward, the patients were allowed to advance to full weightbearing. Achilles' tendon lengthening was performed when perioperative an ankle dorsalflexion of 10 degrees couldn't be reached. Additionally, these patients received a cast as aftertreatment for 6 weeks. Afterwards these patients followed standard aftertreatment protocol. Thromboembolic prophylaxis with low-molecular-weight heparin was given until 6 weeks postoperative. Patients were assessed pre-op and postoperatively at 1 day, 6 weeks, 3-6-12 months and thereafter yearly. The American Orthopedic Foot and Ankle Score (AOFAS) questionnaire and passive range of motion (ROM) were assessed. During every follow-up moment all complications and re-operations were recorded, Radiographic evaluation was performed at follow-up moments of 6 weeks, 3-6-12 months and thereafter yearly according to the Rippstein protocol [20]. Failure of the implant was defined as the need of revision surgery of one of the metal components or

(pan)arthrodesis, according Henricson et al. [21]. They define the term revision as removal or exchange of one or more of the prosthetic components except for incidental exchange of the polyethylene insert (e.g., due to infection).

Radiographic Evaluation assessment consisted of the estimation of prosthesis alignment, migration, translation, and radiolucent lines using the Rippstein protocol (Fig. 1) [20].

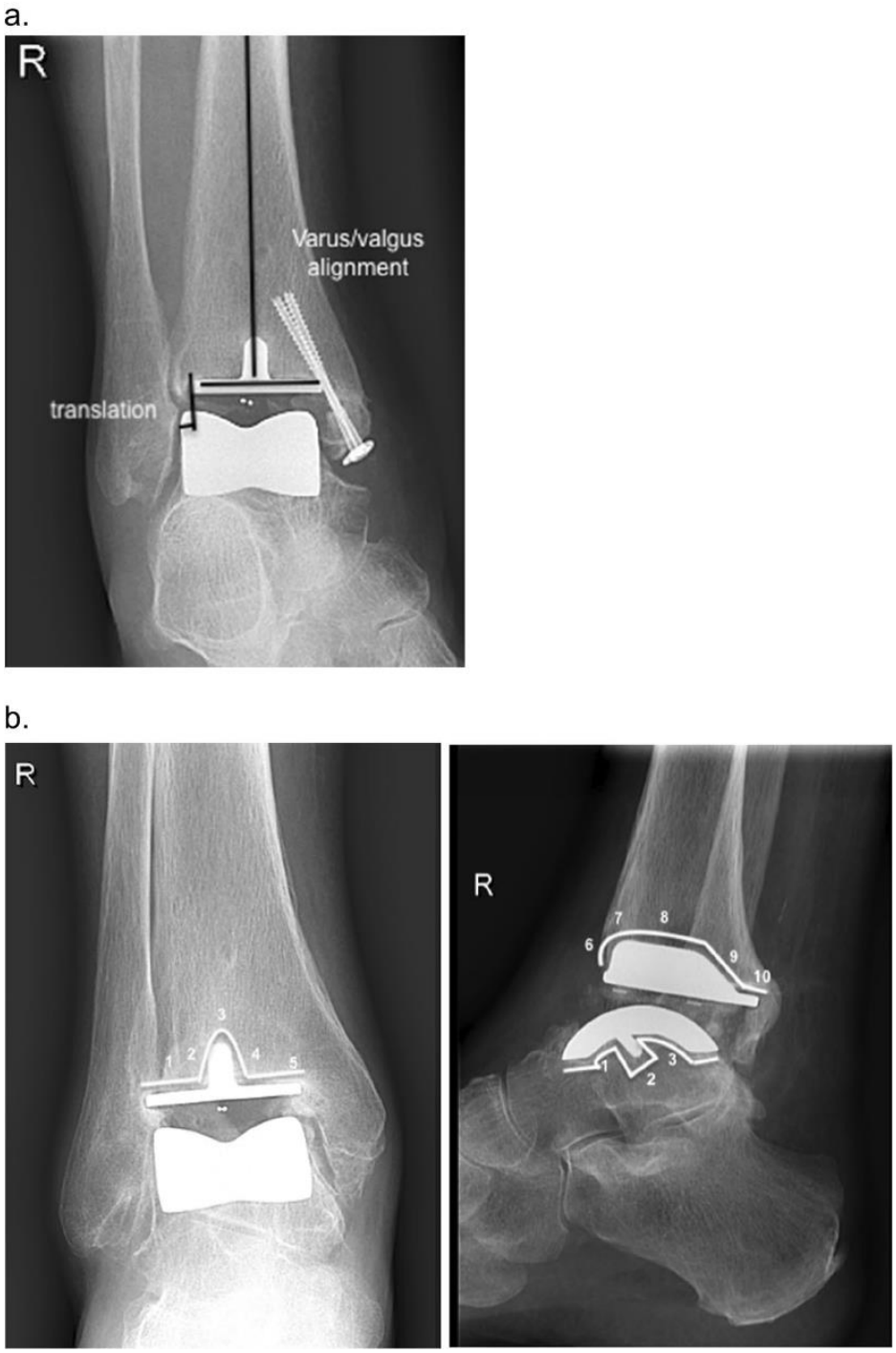

Fig. 1 Visualisation of X-ray angle measurement for alignment and migration assessment according to Rippstein protocol (18). a Measurement varus/valgus aligment and translation. b Zones of radiolucency

These assessments were evaluated by two independent reviewers (JV, PV) who did not perform an operation on any of the patients.

Standing anteroposterior (AP) and lateral (LAT) radiographs of the ankle were made preoperatively and at each follow-up visit. Ankle alignment was determined on the anteroposterior radiograph by measuring the angle between the talar and the tibial component. An angle of 0° is considered ideal, and > 5° was defined as varus or valgus ankle alignment compared to the tibial anatomical axis. The posterior slope of the tibial component was measured on the lateral radiograph. The components were considered to be improperly aligned on the anteroposterior radiograph if the medial or the lateral border of the talar component extended more than 2 mm beyond the border of the tibial component.

Tibial radiolucencies > 1 mm in width were assessed in five zones around the implant on the anteroposterior radiograph and in five zones on the lateral radiograph.

Talar radiolucencies were assessed in three zones around the implant on the lateral radiograph. Migration of the tibial component was defined 121 as a change of an angle of > 3°. Migration of the talar component was defined as > 2 mm of subsidence into the talar bone. In addition, we recorded the presence and location of periprosthetic cysts and osteophytes [20].

CCI design rationale

The CCI Evolution mobile-bearing prosthesis design (Wright Medical Technology, Arlington, TN, USA) combines three principles: Preservation of bone stock, cement free fixation and reduction of abrasion (Fig. 2).

Fig. 2 The CCI Evolution mobile-bearing prosthesis design

The three components, including mobile bearings, allow minimal bone resection of the tibia as well as of the talus. The tibial component requires only a 2.8 mm resection of the distal tibia. The talar component, with its triple V-design, will requires a resection as little as possible.

The CCI Evolution prosthesis has a trapezoid tibial component with the same AP ratio of 1.4 to 1 as the human tibial surface. In contrast to the Buechel-Pappas prosthesis, the CCI ankle uses a fin instead of stem on the tibial side. The talar component requires a triple-V-shaped resection of the talar dome instead of a curved resection.

The cement-free fixation is made possible by a titanium surface (CoCrMo metal) with a plasma spray coating of a biomimetic BONIT®calcium phosphate coating with a thickness of 20 ± 10 µm and a Ca/P ratio: 1.1 ± 0.1 (DOT, Rostock, Germany). The metal parts of the CCI Evolution ankle prosthesis are coated with a titanium nitride (TiN) coating. The design of the talar component includes a deep sulcus, conforming the distal articulating surface of the polyethylene bearing, providing medial-lateral stability.

Statistical methods

Patient baseline characteristics were described as mean and standard deviation (SD) or median and range for continuous variables that were distributed normally or were skewed respectively. Categorical characteristics were summarized as count and percentage. Similar descriptive statistics were used to describe characteristics of the procedures, complications, and clinical outcomes.

To quantify a potential learning effect, the ankles were dichotomized into the first half by calendar time and the second half. Subsequently, Fisher's Exact test was used to test for a difference in occurrence of perioperative complications.

A Kaplan-Meier curve was used to assess the cumulative survival of the ankle replacement. As a sensitivity analysis, a second Kaplan Meier curve was plotted including also insert changes as failures.

Results

Patient and demographics

Between April 2010 and June 2016, a single foot and ankle surgeon (JH) performed 65 consecutive primary TAA's with the CCI implant in 61 patients. Gender distribution

was 18 female (29.2%) and 43 male (70.8%), with a mean age at first ankle replacement of 65.4 years (± 7.3, range: 52.5 to 81.7). The median follow-up time was 85.2 months (range 54.1 – 128.4 months). One patient had a failure of the total ankle replacement within seven months of follow-up because of migration of the tibia component caused by a postoperative fracture. The demographic information of the study cohort is displayed in Table 1.

Characteristic	Total cohort ($N=61$)
Gender	
female	18 (29.2%)
male	43 (70.8%)
Age at first procedure (years)	65.4 (7.3)
BMI (kg/m^2)	27.4 (3.6)
Bilateral ankle replacement	4 (6.6%)
Side[a]	
right	38 (58.5%)
left	27 (41.5%)
Indication for operation[a]	
arthritis	51 (78.5%)
rheumatoid arthritis	8 (12.3%)
hemochromatosis	4 (6.2%)
hemophilia	1 (1.5%)
tuberculosis	1 (1.5%)
Follow-up time (months)	47.8 (24.5)
Adjacent disease[b]	49 (80.3%)
talonavicular joint	13 (21.3%)
subtalar joint	27 (44.3%)
Chopart	16 (26.2%)
midfoot	6 (9.8%)
other	3 (4.9%)
Subtalar arthrodesis prior to procedure	2 (3.3%)
Double arthrodesis prior to procedure	3 (4.9%)

Data are presented as mean (sd) or count (percentage)

[a] Summary over all 65 procedures

[b] Sum of categories is larger than the total number of affected patients due to multiple locations in some patients

Table 1 Patient baseline characteristics

Adjacent joint disease was present in 53 171 (81.5%) of the 65 ankle joints.
Six weeks prior to the TAA some cases required additional surgery, such as subtalar (3.1%) and double arthrodesis (7.7%). The time frame was chosen to reduce the immobilization time in a plaster.

On pre-operative conventional standing X-rays, a mean varisation was seen of 10.0 (SD = 3.4) degrees in 23 (35.4%) ankles on the anteroposterior view, and valgisation of 8.9 (SD = 2.6) degrees in 11 (16.9%) ankles.

A perioperative medial malleolus osteotomy was necessary in 9 out of 65 procedures (13.8%) because of ligament balancing caused by a varisation of the talus pre-operative according to the technique described by Doets et al. [22]. Additional Achilles tendon lengthening was performed in 28 of 65 ankles.

Clinical results and functional outcomes

After TAA, the Range of Motion improved preoperative from mean 21.8 degrees (SD = 9.0) to 27.6 degrees (SD = 7.0) at final follow-up postoperative ($p < 0.001$).

The AOFAS hindfoot score improved significantly from a mean of 40.9 (SD = 12.9) points preoperative to an average of 82.5 (SD = 13.1) over the whole follow-up period of 7.1 years ($p < 0.001$). Figure 3 shows the post-operative changes of both the Range of Motion and the AOFAS score.

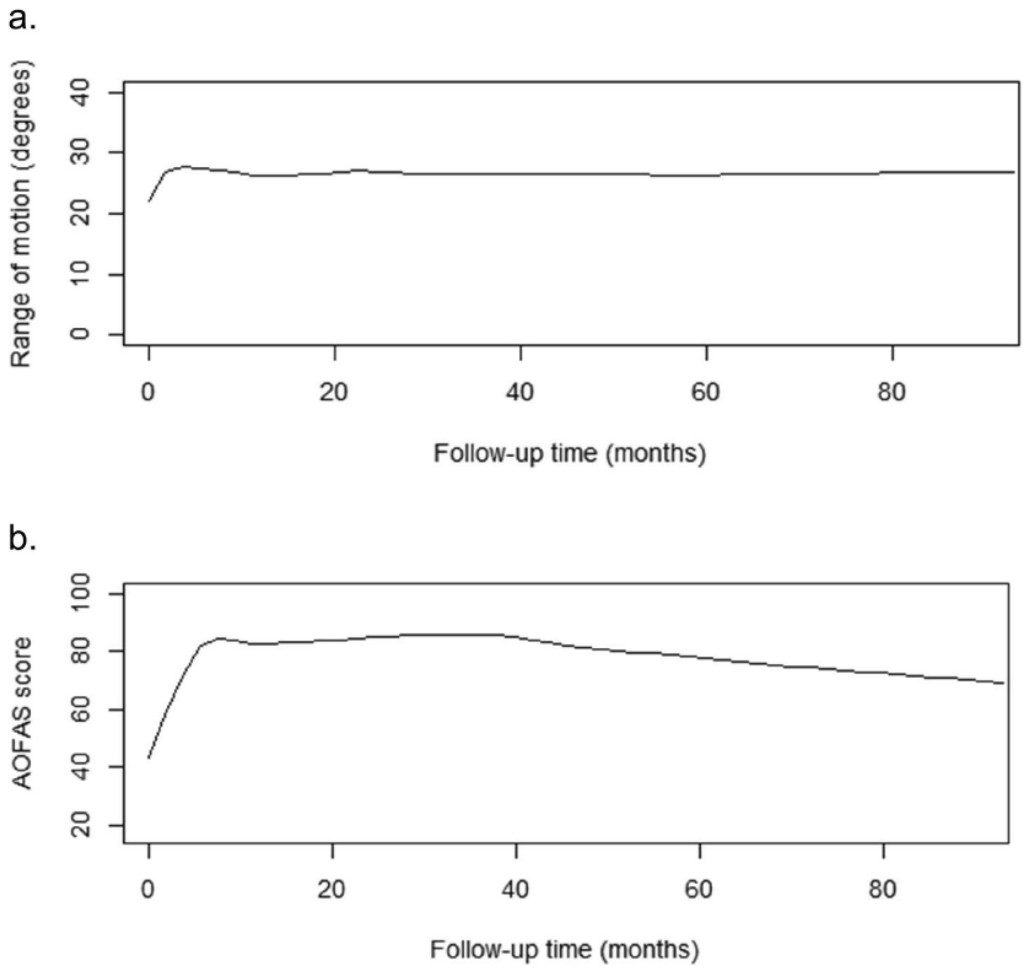

Fig. 3 a Range of motion during follow-up. **b** AOFAS during follow-up

The most progression in ROM was observed in the first 10 months while the AOFAS gradually increased till 16 months postoperative.

Per-operative complications and failures

Ten intra-operative complications (15.4%) of which 7 were medial malleolar fractures (70.0%) were observed.

One or more post-operative complications occurred in 23 ankles (35.4%). Impingement (8 ankles 196 (12.3%)) and deep infection (7 ankles (10.8%)) were the most frequently recorded. All the perioperative complications occurred in the first thirty surgeries, none occurred in the later surgeries. Twenty-three ankles (35.4%) required one or more re-operations. Gutter impingement was the primary reason for a reoperation in 4 ankles (4 revisions to a thicker UHMWPE insert of the 7 impingements (57,1%)).

During follow-up, we recorded 8 (12.3%) failures and 6 insert changes (2 because of a DAIR procedure in case of an infection [23] and 4 for impingement). Of those 8 failures, 6 were (pan)arthrodesis, and 2 ankles required revision surgery of all components. The median time to failure was 12.2 months of follow-up (IQR 6.1, 14.9).

Survival analysis

Kaplan–Meier curves of the survival probability of ankle replacements excluding and including insert changes are shown in Fig. 4. Kaplan-Meier survival analysis of the CCI ankle implant at mid-term follow-up showed a survival rate of 87.7% with a median follow-up of 85.2 months. Table 2 shows associations between patient characteristics before surgery and failure of the TAA. Due to the small number of failures, we were unable to estimate the association between valgisation/varisation and the risk of failure. We did observe a significant association with pain duration and the risk of failure (HR = 0.87, 95% CI: 0.78 – 0.97).

Radiologic outcomes

Radiologically, 11.3% of the TAA's were positioned in varus (mean 6.5 degrees; SD = 1.2) and 0% in valgus.

Migration in the frontal plain was measured on conventional X-rays in three ankles and in the sagittal plane in two ankles respectively.

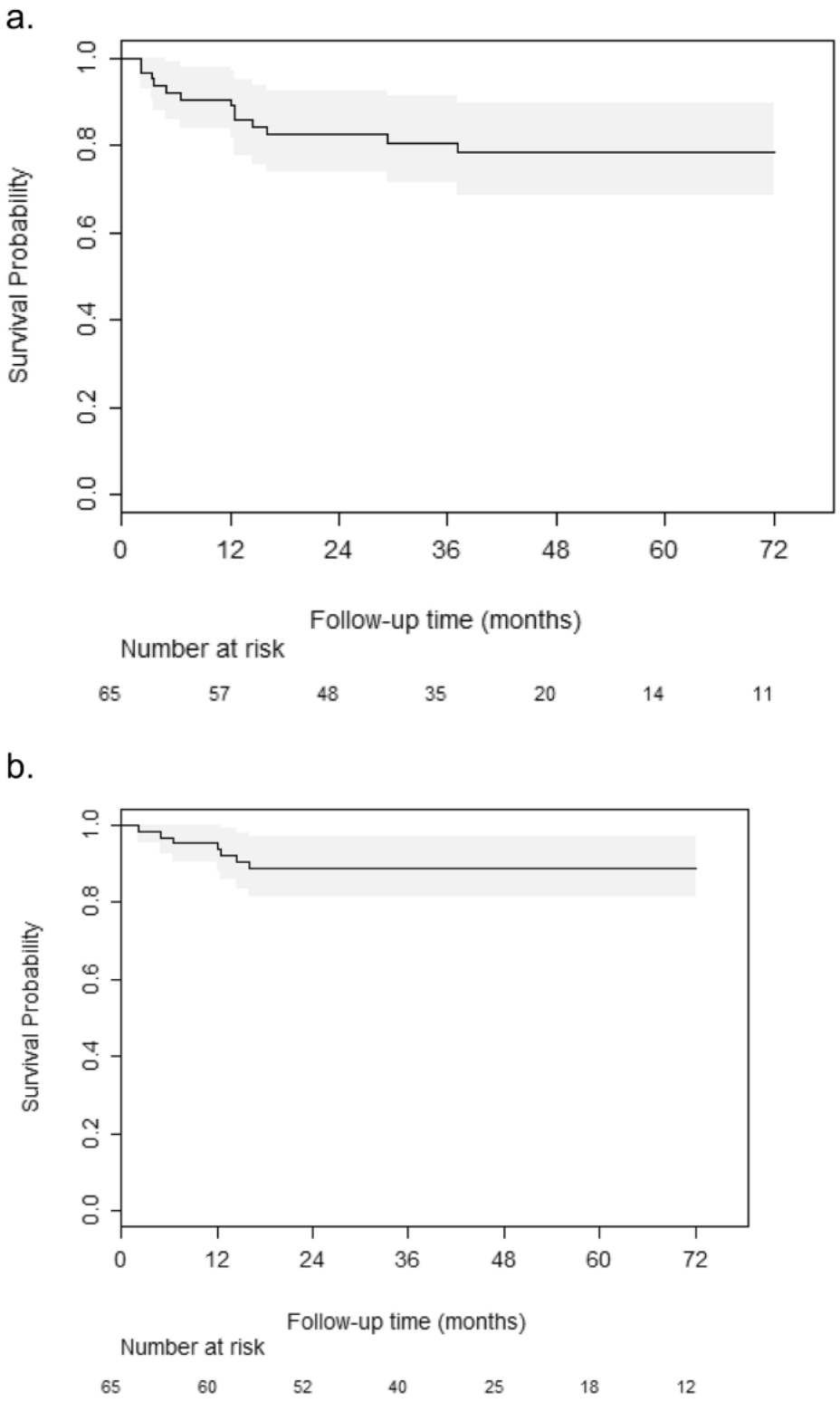

Fig. 4 a Kaplan -Meier curve of the survival probability of an ankle implant, including insert change as failure. **b** Kaplan-Meier curve of the survival probability of an ankle implant, disregarding insert change as failure

Radiolucency is significantly increasing with the follow-up time ($p = 0.02$). At the mean follow-up of 85.2 months 54 patients had radiolucency of more than 1 mm, of which

only 15 in the talus. No trends were seen as to how much radiolucency occurred in the talar or tibial component.

Characteristic	Hazard ratio (95% CI)	*p*-value
Varisation (degrees)	1.19 (0.28-5.10)	0.811
Valgisation (degrees)	u.e	u.e
AOFAS hindfoot score	1.02 (0.97 – 1.08)	0.449
Weight (kg)	1.02 (0.96 – 1.09)	0.512
BMI (kg/m^2)	1.14 (0.96 – 1.34)	0.136
Diabetes Mellitus	0.88 (0.11 – 7.33)	0.908
Pain duration (years)	0.87 (0.78 – 0.97)	**0.013**
ASA score	0.86 (0.26 – 2.81)	0.803

u.e unable to estimate, *CI* confidence interval, *BMI* body mass index

Table 2 Associations between characteristics before surgery and subsequent failure after surgery

According to the Rippstein protocol radiolucency was not seen in 11 of the 65 ankle replacements (16.9%).

The radiolucency zone 3 (Fig. 1), for the CCI ankle replacement, was associated higher risk for failure; HR 6.4 (95% BI:1.4, 29.0; p = 0.0152). On the last follow-up with a mean follow-up of 85.2 months the X-ray showed in 15 ankles (23.1%) a cyst in the talus with a mean diameter of 17.8 cm (range 8.9-29.5 cm) and in 13 ankles 20%) in the tibia with mean diameter of 15.2 cm (range 9.1-22.1 cm). In total, cyst formation in ankle replacement was found in 26 of 65 ankle replacements (40%). Only in two failures cyst formation was found in the talus. No significant correlation was found between failure and varus /valgus malpositioning or a gap between the bone and prosthesis.

Discussion

In this study, we report the first mid-term clinical out- come results of the Ceramic Coated Implant (CCI) ankle replacements after a median follow-up time of 85.2 months. The functional outcome "Range of Motion", improved after ankle replacement from 21.8 preoperative to 27.6 degrees postoperative. The AOFAS hindfoot score improved significantly from a mean of 40.9 points preoperative to an average of 82.5 over the entire follow up period of 7.1 years. Valderrabano et al. [24] showed that these

changes in gait were accompanied by a significant improvement in AOFAS, SF-36 and ROM [24].

The results of the CCI Evolution Total Ankle System, presented in this study, can be compared to the designer study of Doets [17]. In this study, the 5-year follow-up results of 75 CCI ankle prosthesis and 15 Buechel-Pappas ankle prostheses showed a survival rate of 87% in the postfracture group and 79% in the instability group [18].

Recently the group of Doets reported even a lower survival rate of 67.5% at 10-year follow-up [19].

In this non-designer study the reported Kaplan-Meier survival analysis of the CCI ankle implant at mid-term follow-up showed a survival rate of 87.7% with a median follow-up of 85.2 months. 1,226 prostheses were analyzed in the Swedish Ankle Registry with a mean follow-up of 7 years. An overall survival rate at 5 years was found of 0.85 (95% CI 0.83-0.87), at 10 years 0.74 (CI 0.70-0.77) [25] which is comparable with our presented results.

TAA is an emerging treatment and might be an alternative to ankle arthrodesis in the treatment of end-stage ankle arthroplasty. However, there are also disadvantages to this intervention. TAA may be more sensitive to complications, failure and subsequent re-operations compared to ankle arthrodesis [26]. Simonson et al. [27] showed that 44,2% of 2453 total ankle replacements had a complication. These complications could lead to failure. Usuelli et al. [28] showed that most of the operative variables as well as clinical and radiological outcomes stabilized after a surgeon had performed 28 cases. We have reported all our perioperative complications in our first thirty ankle replacements. The median time to failure was 12.2 months of follow-up (IQR 6.1, 14.9). Kamrad et al. [29] showed that mean time from primary TAR to revision surgery was about two years.

Intra-operative complications occurred in 10 ankles (15.4%) and one or more post-operative complications in 23 ankles (35.4%). Excluding the failures, there were 15 postoperative complications in the remaining 57 ankles (26.3%). The most postoperative complications were impingement and deep infection. In the 8 impingements a gradual postoperative coronal translation of the talus was seen 7 cases with a mean translation of 3.8 mm. In the group of impingements, the median was (IQR): 3.0 (2.2-5.0) compared to the group without impingement 271 (IQR): 2.2 (0.0 – 3.4). Similar complication and reoperation rates were found in the designer study which presented results of the Buechel-Pappas and CCI prosthesis [18]. The

10-year follow-up study of the same group 45% of the total ankle replacements had developed a complication of which only 16% was treated conservatively [19].

Causes for impingement could be component malrotation that will always lead to gutter impingement [30, 31].

Nunley et al. [32] noticed that the reoperation rate was higher in mobile-bearing total ankle replacements compared to fixed bearing total ankle replacements, and in most cases to relieve impingement.

In this study, it was also assessed if associations could be observed between implant migration during follow-up, as measured according to the Rippstein protocol [20], and subsequent failure of the implant. According to the Rippstein protocol analysis, progressive radiolucency was seen in 8 ankle replacements (12.5%). The radiolucency zone 3, for the CCI ankle replacement, was associated with a higher risk for failure; HR 6.4 (95% BI:1.4, 29.0; p = 0.0152).

Therefore, we advocate to specify these values for TAA patients on X-ray evaluation during clinical follow-up.

The association between total ankle component alignment and biomechanical contact stresses and clinical outcome has been extensively studied [6, 8–11, 33–37].

Pyevich et al. [38] found higher rates of pain in tibial components placed in more than 4° of valgus and 19 cases of migration of a component of TAA. We could not find a significant correlation between failure and varus /valgus malpositioning or a gap between the bone and prosthesis.

In the prospective cohort study of Dalat et al. [39] 29.8% had symptomatic cysts which required treatment at a mean 59.8 months. Of which 16.7% of their patients were treated by curettage and grafting, 13.9% ended up in an arthrodesis. Najefi et al. [40] reports that in 78% of the patient's bone cysts were not removed by implant resection, of which 30% of the cases were larger than 5 mm.

The description of osteolysis as the first "mechanical" type of radiolucency is probably incorrect, as this most likely refers to the presence of pre-existing cysts that had not been observed, or progression of pre-existing cysts due to stress shielding. We reported that 40% of our 65 ankle replacements in our cohort had cyst formation while only two failures showed cyst formation.

This study has a number of limitations that have to be considered. First, this study includes a relatively small number of patients. Making generalizations from a small

sample size is a cognitive bias. Second, the AOFAS score combines a clinician-reported and patient-reported parts. Forty of the possible 100 points are determined by clinical examination and, therefore, the evaluator can be biased when grading the clinical results [41]. Third, the learning curve of the CCI Evolution Total Ankle System was part of this prospective follow-up, as we have reported all our perioperative complications in our first thirty ankle replacements. Finally, this study reports on the CCI TAR, a prosthesis that was withdrawn from the market in 2016 by Wright Medical Group (Memphis, USA). However, mid-term outcomes of this 3-component prosthesis remains relevant and will contribute to the limited literature available.

Conclusion

The mid-term results of the CCI Evolution Total Ankle System cohort are comparable to literature of other TAA designs with a survival of 87.7% at 7.1 years of follow-up [18, 25].

Functional recovery is two-fold with most progression in ROM seen in the first 10 months, while the mean AOFAS gradually increased during follow-up postoperative.

Additional studies with larger cohorts and longer follow-up are warranted to determine which patient specific factors, surgical technique and designs are a higher risk for failure to improve the patient satisfaction, clinical outcome and survival rate of ankle replacement.

Abbreviations

CCI Ceramic Coated Implant
AOFAS American Orthopaedic Foot and Ankle Society
ROM Range of Motion
TAA Total Ankle Arthroplasty
AA Ankle Arthrodesis
METC Medical Ethics Assessment Committee
AP Anteroposterior
LAT Lateral
TiN Titanium nitride
SD Standard deviation
SF-36 Short Form Survey-36

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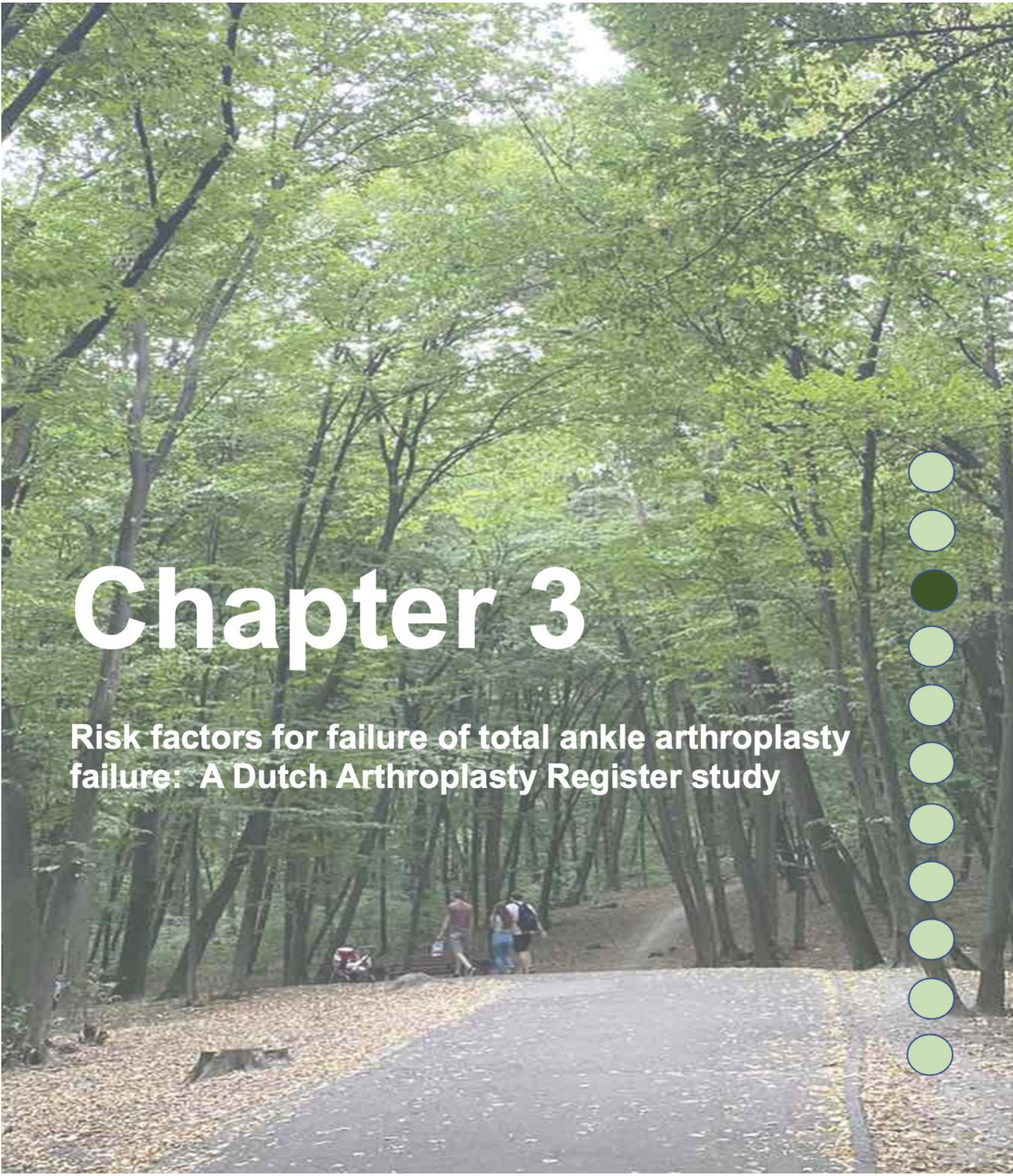

Hermus JPS, van Kuijk SMJ, Spekenbrink-Spooren A, Witlox MA, Poeze M, van Rhijn LW, Arts JJ.

Foot and Ankle Surgery (2022) 28(7): 883-886

Abstract

Background: Studies concerning total ankle arthroplasty could be influenced by several forms of bias.

Independent national arthroplasty registries represent objective data on survival and patient-reported outcomes. The aim of this study was to determine survival and identify risk factors for early failure in a nationwide series of total ankle arthroplasties from the Dutch Arthroplasty Register (LROI).

Patients and methods: Data of 810 patients, who received 836 total ankle arthroplasties between 2014 and 2020 were obtained from the Dutch Arthroplasty Register (LROI) with a median follow-up of 38 months (range 1–84 months). Survival was expressed in Kaplan-Meier analysis and associated hazard ratios for implant failure were determined. Implant failure was defined as the need for revision surgery for any reason or (pan)arthrodesis.

Results: During follow-up, we recorded 39 failures (4.7%) resulting in an implant survival of 95.3% with a median follow-up of 38 months (range 1–84 months). Medial malleolus osteotomy (HR = 2.27), previous surgery (HR = 1.83), previous osteotomy (HR = 2.82) and previous ligament reconstruction (HR = 2.83) all showed potentially clinically meaningful associations with a higher incidence of implant failure, yet only previous OCD treatment (HR = 6.21), BMI (HR = 1.09) and age (HR = 0.71) were statistically significant.

Interpretation: Excellent short-term survival (95.3%) with a median follow-up of 38 months was reported for TAA patients from the Dutch Arthroplasty Register. Patients with a lower age, a higher BMI or who had a prior surgical OCD treatment before TAA surgery appear to have a higher risk for revision after short-term clinical follow-up. Thorough patient selection with emphasis on risk factors associated with early implant failure might be essential to improve TAA survivorship.

Keywords: National register, Ankle replacement, Survival**,** Risk factors**,** OCD

1. Introduction

Total ankle arthroplasty (TAA) has been developed to preserve mobility of the ankle joint in end-stage arthritis. Since TAA has been incorporated in the treatment of osteoarthritis of the ankle joint, patient's satisfaction, pain relief and function outcomes have improved [1,2]. However, the risks of only small improvement of range of motion, persistent pain following TAA still remain [3]. TAA may be more susceptible to complications, failure and subsequent re-operation as compared to other surgical interventions of the ankle joint, especially compared to ankle arthrodesis [4].

To be able to improve long-term TAA results, e.g., functional outcome and survival rate and reducing the complication rate, more knowledge is necessary about the factors that negatively affect complications and failure rates. Labek et al. stated that joint registersprovide a good overview of the true revision rate and causes of revision, without relying on extrapolation from a smaller cohort sample [5]. Literally, long-term follow-up is currently non-existing in the joint registries, except the 10 year-follow-up of the Swedish national registry [6]. Therefore, Gross et al. noted that more research is necessary to report functional outcomes, complication rates and failures to become a parameter for new ankle implants that have entered the ankle arthroplasty market [7]. Undèn et al. presented with their follow-up till 20 years that use of current prosthetic designs was associated with better prosthetic survival [8].

The Dutch Arthroplasty Register (LROI) is a nationwide population-based registry in which all joint arthroplasties (hip, knee, ankle shoulder, elbow, wrist and finger) in the Netherlands are prospectively collected and include patient and surgery characteristics.

However, our LROI data does not include the TAA implant design.

The LROI started registering total ankle arthroplasty in 2014. In this first study on total ankle arthroplasties of the LROI the cumulative revision rate for ankle replacements and assessed risk factors for failure were investigated during the period 2014 and 2020. The aim of this study is to determine survival rate and identify risk factors for early failure in a nationwide series of total ankle arthroplasties from the Dutch Arthroplasty Register (LROI).

2. Material and methods

The Dutch Arthroplasty Register was set up by the Netherlands Orthopaedic Association (NOV) in 2007. It is a nationwide, population-based register, which collects

data about joint arthroplasty in the Netherlands. Prostheses characteristics are derived from an implant library within the LROI, where all characteristics of prostheses used in the Netherlands are available [9].

For the present study, we included all primary 836 TAAs performed in 807 patients registered in the LROI between 01 January 2014 and 31 December 2020. There were no exclusion criteria. We then extracted all subsequent revision procedures from this cohort to study the early results of a nationwide series of total ankle arthroplasties from the Dutch Arthroplasty Register (TAA).

Within the LROI, a revision procedure is defined as an exchange of at least 1 of the components of the prosthesis. 3 different types of revision procedures are distinguished: (1) a total revision, where all components (tibial, talar and insert) are exchanged; (2) a partial revision procedure, where only the tibial or talar or insert component is exchanged; (3) an arthrodesis, where all components are removed and converted to an arthrodesis. Patients who died during follow-up were censored at the time of death. In survival, or time-to-event analysis when a patient is censored, they stop contributing to the numerator.

2.1. Ethics

Ethical approval was not required as all data were received completely anonymous. Data are available from the LROI (Dutch Arthroplasty Registry), but restrictions apply to the availability of these data, which were used under licence for the current study. In this way patient anonymity is ensured and compliance with Dutch AVG (AVG = Algemene Verordening Gegevensbescherming, meaning privacy legislation) and European General Data Protection Regulation (GDPR) legislation is corroborated.

3. Statistical analysis

Baseline characteristics of all included patients were provided. Continuous variables were described using means and standard deviations (SDs), or median and interquartile range, where appropriate. Categorical data were described using counts and percentages.

Demographic characteristics of the patients included in the LROI TAA cohort were summarised using mean and standard deviation (SD) for continuous variables, and count and percentage for categorical variables. Follow-up time was summarised as median and interquartile range (IQR). Kaplan-Meier curves were calculated to display

TAA implant associated patient survival at median follow-up of 38 months (range 1–84 months). Survival time of primary TAA was calculated as time between the moment of implantation and revision procedure, death of the patient, or the end of study follow-up (31 December 2020). Number at risk are the patients who are at specific follow-up which decreases over time, caused by death, failure and a too short follow-up time.

Univariable Cox proportional hazards regression was used to assess the association between characteristics of the hospital (low (< 10 TAAs per year) versus high-volume centres (> 10 TAAs per year)) and of the patients and revision surgery. Subsequently, significant characteristics were entered into a multivariable, or adjusted, model. As the vast majority of patients received only unilateral ankle replacement, no multilevel modelling for clustered data was employed. The proportional hazards assumption was verified by testing an association between follow-up time and the scaled Schoenfeld residuals. An alpha of 0.05 was used for statistical testing. All analyses were performed in R version 3.6.1.

4. Results

4.1. Patient and demographic characteristics

The study data were obtained from the Dutch Arthroplasty Register (LROI) and the TAA study cohort encompassed 807 patients, who received 836 TAA implants between January 1st 2014 and December 31st 2020.

	n = 836
Gender (Male)	468 (51.1%)
Age (year)	66.1 (9.0)
Body Mass Index (kg/m^2)	27.8 (4.2)
ASA classification	
• ASA I	165 (20.5%)
• ASA II	546 (67.8%)
• ASA III-IV	94 (11.7%)
Diagnosis[a]	
• Osteoarthritis	650 (77.8%)
• Inflammatory arthritis	8 (1.0%)
• Osteonecrosis	1 (0.1%)
• Posttraumatic	93 (11.1%)
• Rheumatoid arthritis	65 (7.8%)
• Primary tumour	1 (0.1%)
• Other	17 (2.0%)
Previous surgery (yes)[a]	264 (32.4%)
Perioperative medial malleolus osteotomy[a]	49 (5.9%)

Data are presented as mean (standard deviation) or as count (percentage).
[a] Computed on the ankle-level (n = 836).

Table 1 Baseline characteristics of the total ankle arthroplasty (TAA) patient cohort included between 2014 and 2020 in the Dutch Arthroplasty Register (LROI).

The mean age at first TAA was 66.1 years (± 9.0). The median follow-up time was 3.0 year (IQR: 1.6 – 4.7). The diagnosis was primary or secondary arthritis (OA) in 650 ankles (77.8%), posttraumatic arthritis in 93 cases (11.1%), rheumatoid arthritis in 65 cases (7.8%), inflammatory arthritis in 8 cases (1.0%) and various diagnosis including e.g., osteonecrosis, primary tumour in 19 cases (2.2%). Previous surgery was performed in 264 ankles of the 836 ankle replacements (32.4%), i.e., ligament repair, hindfoot arthrodesis, alignment osteotomy. More specific data of the type of hindfoot arthrodesis is not registered in the LROI. The demographic in- formation of the TAA study cohort is displayed in Table 1.

4.2. Ankle replacement failures

During the follow-up time 2014–2020, the 38 months survival rate was 95.7% (95% CI: 93.9–97.5). Fig. 1 shows the Kaplan-Meier curve of the survival of the TAA implants over time.

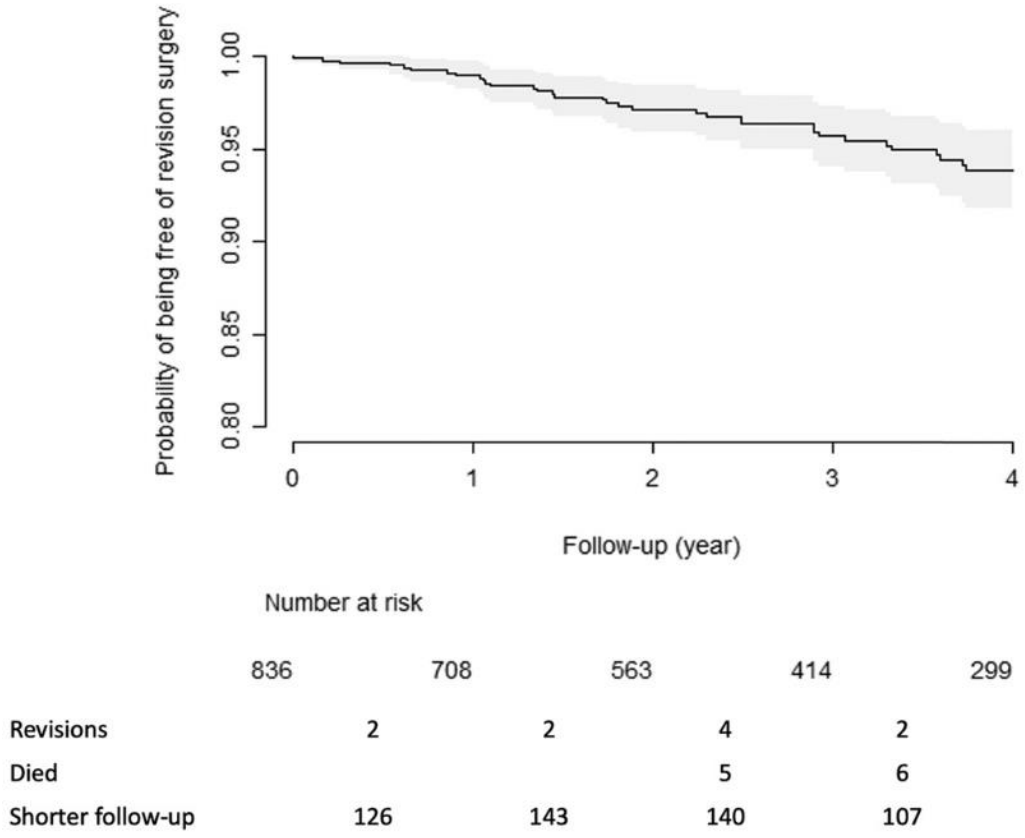

Fig. 1. Kaplan-Meier curve of the cumulative incidence of ankle implant revision. The grey band denotes the 95% confidence interval around the survival estimate. The whole range of follow-up times have not been reported as the number of patients who are still available and at risk becomes very low, which would have a profound influence on the precision of the estimates.

In total 39 (4.7%) TAA implants were revised in our TAA cohort with a mean follow-up of 2.21 years. Of which seven TAA (17.9%) of thirty-nine were revised because of loosening of the tibial and/or the talar component, and another three (7.7%) because of instability with or without dislocation of the polyethylene (PE) meniscus. Six (15.4%) ankles were judged as technical failures by the surgeons performing the revisions caused by malpositioning of the tibial component. In addition, one ankle (2.6%) was revised because of severe wear/fracture of the mobile bearing component. Numbers at risk are also shown in Fig. 1. 29 patients (3.5%) of the TAA cohort died at a mean follow-up of 2.96 years.

In five (12.8%) revisions, a medial malleolus osteotomy was performed in the primary ankle replacement. The hazard ratio (HR) after a medial malleolus osteotomy was 2.27 (p = 0.087) (Table 2).

Characteristic	HR (95% CI)	p-value
High volume unit (> 10 TAAs)	1.71 (0.84–3.45)	0.137
Year of operation	1.00 (0.80–1.25)	0.995
Gender (female)	1.12 (0.60–2.10)	0.726
Age (per 10 years)	0.71 (0.50–1.00)	0.049
ASA classification		
ASA I	ref	ref
ASA II	1.62 (0.67–3.90)	0.283
ASA III-IV	1.62 (0.46–5.77)	0.455
Side (right)	0.53 (0.28–1.01)	0.054
BMI (kg/m^2)	1.09 (1.02–1.16)	0.016
Medial malleolus osteotomy	2.27 (0.89–5.82)	0.087
Osteoarthritis	1.00 (0.49–2.05)	0.993
Previous surgery	1.83 (0.96–3.49)	0.068
Previous osteotomy	2.81 (0.85–9.29)	0.091
Previous osteosynthesis	0.35 (0.11–1.18)	0.092
Previous synovectomy	1.18 (0.66–7.25)	0.203
Previous arthroscopy	1.42 (0.58–3.52)	0.444
Previous ligament reconstruction	2.83 (0.67–12.01)	0.158
Previous OCD treatment	6.21 (2.15–17.95)	< 0.001
Previous hindfoot surgery	1.44 (0.55–3.77)	0.462
Previous forefoot surgery	0.92 (0.12–6.82)	0.936
Previous arthrodesis	0.94 (0.22 – 3.96)	0.932

Table 2 Associations between characteristics of the hospital, patient, and medical history, and the occurrence of ankle implant revision.

No statistically significant difference was found in the revision rates between the high volume and low volume units (n = 261 (HR 1.71 (95%CI 0.84 – 3.45); p = 0.137). In 264 (32.4%) of ankles previous surgery was performed (HR = 1.83; p = 0.068): previous osteotomy (HR = 2.82; p = 0.091), previous ligament reconstruction (HR = 2.83; p = 0.158) and previous OCD treatment (HR = 6.21) all showed potentially

clinically meaningful associations with a higher incidence of implant failure, yet only previous OCD treatment was statistically significant ($p < 0.001$). Two patient characteristics showed an association with a higher implant failure: patients with a lower age (HR 0.71 (95%CI 0.50 −1.00; $p < 0.049$).and a higher BMI (HR 1.09 (95%CI 1.02 – 1.16; $p < 0.016$) appear to have a higher risk for revision after short-term clinical follow-up (Table 2).

5. Discussion

The aim of this study was to document and evaluate the short-term follow-up of a nationwide series of total ankle arthroplasties from the Dutch Arthroplasty Register (LROI) to determine survival and identify risk factors for early failure. We determined that a higher incidence of implant failure was statistically significant when patients have had previous OCD treatment (HR 6.21 (95%CI 2.15–17.95; $p < 0.001$). Whereas previous ligament reconstruction, previous osteotomy and medial malleolus osteotomy showed potentially clinically meaningful associations with a higher incidence of implant failure, but no significance. Two patient characteristics were associated with a higher implant failure: patients with a lower age (HR 0.71 (95%CI 0.50 −1.00; $p < 0.049$).and a higher BMI (HR 1.09 (95%CI 1.02 – 1.16; $p < 0.016$) (Table 2).

In the Dutch Arthroplasty Register (LROI) 835 TAA implants were entered from 2014 till 2020 with a three-year survival rate of 95.7% (95% CI: 94.1–97.3). Muir [10] highlighted the bias between the designers reporting an average 9–10-year survival of 84–95% and the data reported in the national registers. D'Ambrosi et al. reported a failure rate of 16.1% (369 ankle revisions of 2285 ankle replacements) extracted from the Swedish, Norwegian, Finnish and New Zealand registers. The mean survival rates for primary TAR resulted 0.94 at 2 years, 0.87 at 5 years, and 0.81 at 10 years extracted from five thousand one hundred and fifty-two primary and 591 TAR revisions over a 2–13-year period [11]. The learning curve can lead to a higher failure rate creating bias between the data of the designers, non-designers and national registers. The survival rate of the 5-year implants of the Swedish Register improved significantly when the first 30 cases were excluded, and the authors considered these first cases as learning curve [12].

Most common causes for revision surgery were aseptic loosening (38%), instability (8.5%), septic loosening (9.8%), periprosthetic fracture (2%), wear (8%), pain (12%),

implant breakage (5.3%) and technical error (15%). National registers can provide a more an unbiased insight about the failure risks and clinical functional results of total joint implants [10]. The definition of revision is not so explicit as already pointed out by Henricson et al. They define the term revision as removal or exchange of one or more of the prosthetic components except for incidental exchange of the polyethylene insert (e.g., due to infection). However, the LROI and the national joint registry of the UK define revision as every component exchange or removal. Therefore, the failure rate could have been lower according to the definition of revision by Henricson et al. by two [13].

In this study, failure of the implant was defined as the need for revision surgery (insertion, replacement and/or removal of one or more components of the prosthesis) including (pan)arthrodesis. The data from the Dutch Arthroplasty Register can be compared to the results with other studies from hospitals in the Netherlands and with other joint registers. We report a failure rate of 4.7%, within the median follow-up time of 38 months ± 2.0. Previously, Krishnapillai et al. reported 13 revisions of the 101 ankle replacements (12.9%) in a 10-year follow-up and revision was performed at mean time of 3.3 years after primary surgery (0.2–9.1 years) [14]. Faber et al. reported revision of the tibial component and 4 conversions to an arthrodesis of the 52 ankle replacements (7.7%) with a mean follow-up time of 4.2 years [15]. Schimmel et al. reported 3 conversions to an arthrodesis of the 50 ankle replacements in a 2-year follow-up (6.0%) [16]. Kerkhoff et al. noted that in their cohort of 67 ankle replacements 4.5% of the TAA had a failure with a mean follow-up time of 40 months [17]. Before 2014, failure rates were reported of 11.9% and 16% [18,19] These results from the Netherlands match the results reported in the literature, where the survival rate ranges between 0.88 and 0.94 with follow-up between 2.0 and 3.0 years [19,20].

The low failure rate of 4.7% with a median follow-up of 3.2 years from our national register could suggest an underreporting of revision procedures in the data compared the data last mentioned [11–20]. The Dutch Arthroplasty Register shows a completeness of primary ankle arthroplasty of 98% resulting in an overall completeness of the LROI ankle arthroplasty register of 84.6% [21]. The Norwegian register already reported in 2006 lack of completeness in e.g., ankle register of 82% [22]. Skyttä suggests that underreporting of failures can be caused by not reporting the implants of the conversions of a failed TAA to an arthrodesis [23].

Scientific publications from national joint registers for total ankle replacement can be useful in gathering information on implant survivorship, implant models and risk factors. Sadoghi et al. reported from the Norwegian arthroplasty register no significant difference between any of the failure modes that are pertinent to the ankle [24]. In contrast, in the Swedish register there was a significantly higher risk of failure in case of patients (especially women) younger than 60 years of age with osteoarthritis or posttraumatic arthritis [6]. Concerning our reported patient characteristics, patients with a lower age (HR 0.71 (95%CI 0.50 −1.00; $p < 0.049$).and a higher BMI (HR 1.09 (95%CI 1.02 – 1.16; $p < 0.016$) appear to have a higher risk for revision after short-term clinical follow-up (Table 2). Similar findings are also reported in national joint registry of the United Kingdom by the cumulative revision of TAA by gender and age [25].

Gaul et al. found that revision and reoperation rates for salvage procedures following failed osteochondral allograft transplantation of the ankle are higher compared to published data for primary AA and TAA procedures [26]. Lee et al. published that TAA would be a reliable treatment in ankles with ligamentous post-traumatic osteoarthritis in neutrally aligned stable ankles [27]. Considering surgical factors, we found previous surgery, previous osteotomy, previous ligament reconstruction and previous OCD treatment all showed potentially clinically meaningful associations with implant failure. However, only previous OCD treatment was statistically significant.

Limitations of this study include the short-term follow-up and the probable underreporting of revision surgery. More research is necessary to obtain the missing data of arthrodesis as revision surgery of TAA.

6. Conclusion

In this study, short-term survival of TAA was excellent. Patients with prior OCD surgery seem to have a higher risk for implant failure. A higher BMI and a lower age were also determined as a risk factor for implant failure. We suggest that a more thorough patient selection with emphasis on risk factors associated with early TAA implant failure, might improve the survivorship by reducing complication rates. Patients need to be made aware of the risk factors of treatment failure prior to choosing an ankle replacement as treatment for end-stage ankle osteoarthritis.

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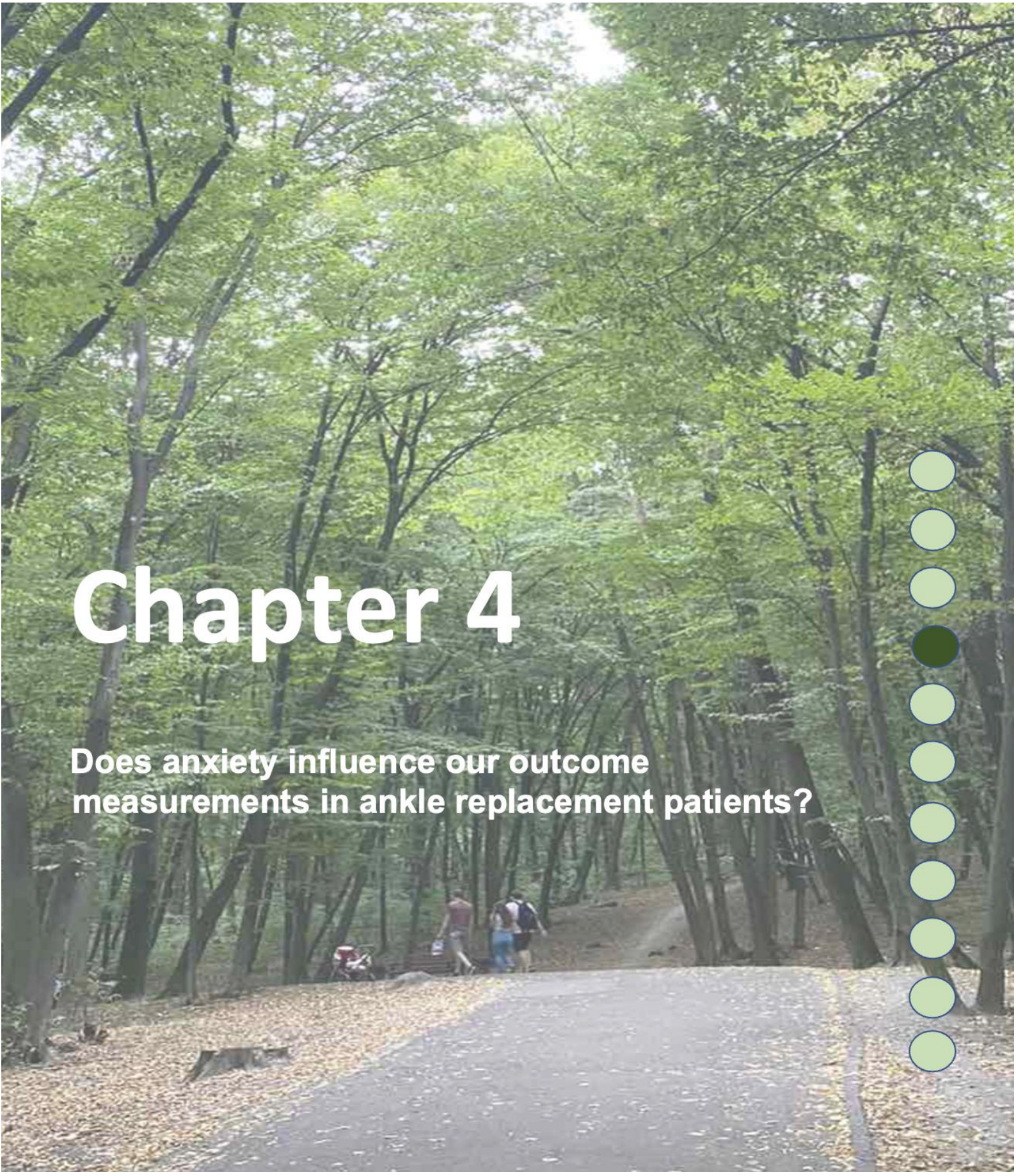

Hermus JPS, Stam P, van Kuijk SMJ, Witlox MA, van Rhijn LW. Arts JJ, Poeze M

Foot and Ankle Surg (2024) 30(3): 231-238

Abstract

Background: Total ankle arthroplasty (TAA) is increasingly used to treat end-stage ankle arthritis to restore ankle functional outcomes and alleviate pain. This treatment outcome may be influenced by pre-morbid patient anxiety.

Methods: Twenty-five Infinity TAA implants were prospectively followed post operatively with a mean follow-up time of 34.18 months. Demographic, clinical, and functional outcomes were assessed. Analysis was performed on the effect of anxiety, reported by the HADS, on patient-perceived postoperative pain, functioning, and quality of life.

Results: Postoperative the PROMs and Range of Motion (ROM) improved significantly. Linear regression analysis and Pearson correlation showed a significant negative effect of anxiety on the postoperative patient-reported outcome measurements (EQ-5D-5L, VAS, and MOxFQ) at the end of follow-up.

Conclusion: Good functional, clinical, and radiographic results were observed in this prospective cohort study. Anxiety had a negative influence on the outcome of the patient-reported outcome measurements (EQ-5D-5L and MOxFQ) postoperatively.

Level of Evidence: Level III, prospective cohort study

Keywords: Ankle replacement;Anxiety; Patient satisfaction

1. Introduction

Degenerative pathologies of the ankle joint may cause substantial pain and functional limitations, which negatively affects patients' health-related quality of life [1,2]. According to the study by Glazebrook et al., this reduction in quality of life and the limitation in physical functioning are at least as severe as compared to patients suffering from end-stage osteoarthritis of the hip joint [3].

Ever since total ankle arthroplasty (TAA) surgeries have been performed in osteoarthritis, patient satisfaction, pain relief and ankle function changed for the persistent pain, and the low functional outcome following TAA remains high [4,5]. TAA may be more susceptible to complications, failure and subsequent re-operation as compared to other surgical interventions of the ankle, particularly compared to ankle arthrodesis [6]. The study conducted by Spirt et al. observed that 28 % of the patients who underwent ankle arthroplasty were re-operated due to complications [7].

Although the TAA has a better functional American Orthopedic Foot and Ankle Score (AOFAS) and Range of Motion (ROM), there is no significant difference in pain relief, gait analysis or patient satisfaction compared to ankle arthrodesis [8]. By focusing not only on the increasing survival rates of TAA but also on the overall patient experience, healthcare providers can enhance patient satisfaction in the context of TAA procedures. Patient satisfaction is influenced by multiple factors, such as functional outcome, postoperative pain and anxiety. Ongoing symptoms of depression and anxiety can have a significant negative impact on patients' post-surgical recovery in total joint replacement (TJR) surgery [9]. Depression and anxiety can lead to poorer functional improvement, limiting a patient's ability to regain mobility and engage in daily activities.

The primary aim of this prospective cohort study was to determine if anxiety influences patient-reported outcome measurements (PROM) after ankle replacements. Secondary aims include the assessment of clinical results and survival.

2. Material and methods

2.1. Cohort description and clinical follow-up schedule

Twenty-five consecutive Infinity total ankle replacements were placed between January 2017 and May 2021 in this prospective cohort study. In August 2021 the last clinical follow-up was performed.

The study was approved by the local ethical committee of Maastricht University (METC 10–3–072), and all patients provided written informed consent before participation in the study. All TAA's surgeries were performed by one non-designer surgeon (JH), using the Infinity ankle replacement (Wright Medical Technology, Arlington, TN, USA). A standard surgical protocol and standardized post-op re- habilitation were followed. Postoperative patients had an aftertreatment with a cast for 2–3 weeks with 50 % weight bearing till 6 weeks, and from 10 weeks onwards full weight bearing was allowed.

Achilles tendon lengthening was performed when perioperative ankle dorsiflexion of 10 degrees couldn't be reached, these patients received a cast as after-treatment for 6 weeks. Afterwards, these patients followed the standard after-treatment protocol.

Thromboembolic prophylaxis with low-molecular-weight heparin was given for 6 weeks postoperatively. Patients were assessed pre-op and postoperatively on 1 day, in 6 weeks, 3–6–12 months, and thereafter yearly.

Two patients were excluded since they had a shorter clinical follow-up of less than 12 months (Fig. 1).

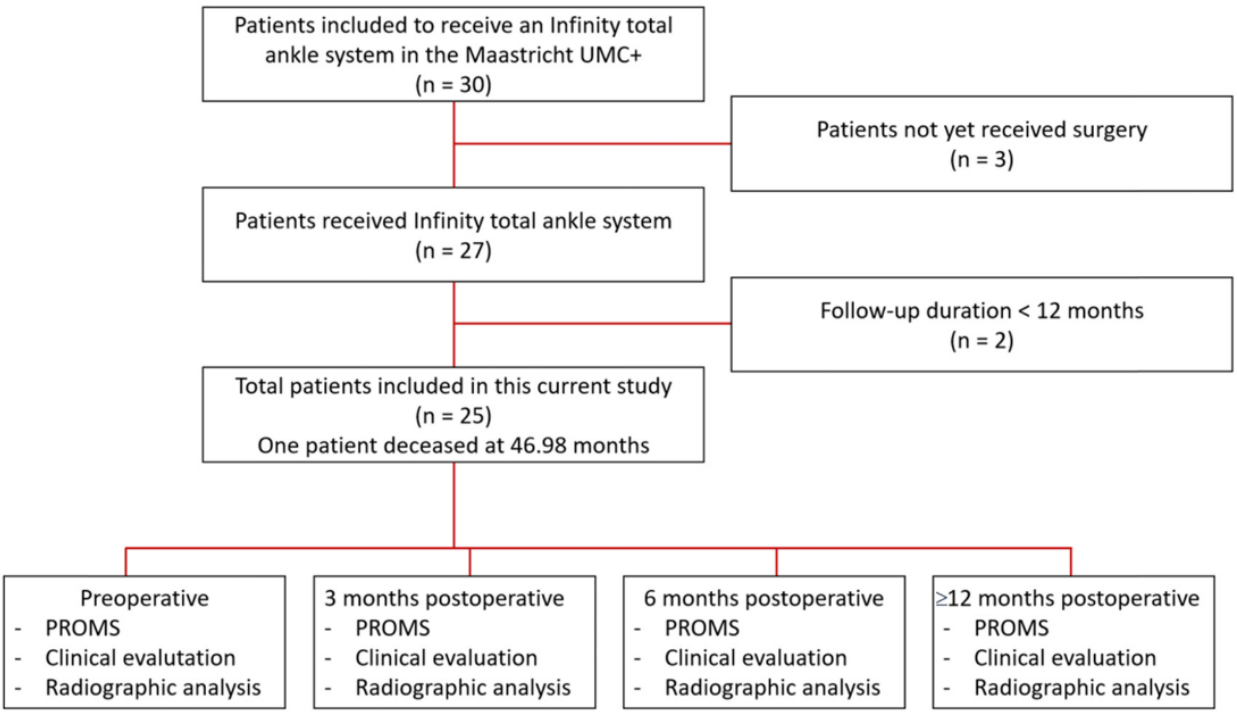

Fig. 1. Flowchart of the participant inclusion in this present study and performed measurements at each time point. All patients with an infinity ankle replacement and a follow-up of more than 12 months were included.

After a follow-up of 46.98 months, one patient died because of COVID-19. The data on the Infinity TAA was gathered at regular outpatient visits during a median follow-up period of 34.18 months (range 14.75–58.45) through physical examination of ankle function and passive ROM, PROM questionnaires and radiographs (Table 1).

Name of questionnaire		
RAND36	Research and Development 36	Mental wellbeing
HADS	Hospital Anxiety and Depression Scale	Mental wellbeing
PCS	Pain Catastrophising Scale	Mental wellbeing
AOFAS	American Orthopaedic Foot & Ankle Society	Function and pain
FAOS	Foot Ankle Outcome Score	Function and quality of life
EQ-5D-5L	EuroQol 5 Dimension 5 Level	Function and pain
VAS	Visual Analogue Scale	Pain
MOxFQ	Manchester-Oxford Foot Questionnaire	Quality of life

Table 1: Name, abbreviation and function of the used patient-reported outcome measures on pain, functioning, quality of life, and mental well-being.

2.2. Radiographic evaluation

The radiographic assessment consisted of the estimation of prosthesis alignment, migration, translation and radiolucent lines according to the Rippstein protocol (Fig. 2 and 3) [10].

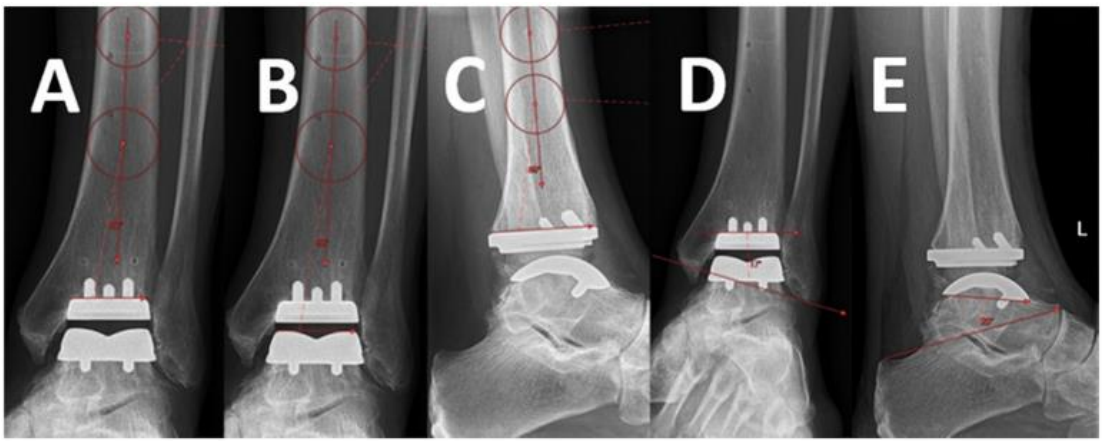

Fig. 2. Measurement technique of tibia CA (A), talus CA (B), tibia AP-CA (C), LMA (D) and gamma angle (E). Abbreviations: CA; component angle. AP-CA; anteroposterior component angle. LMA; lateral-medial malleolar angle.

These assessments were evaluated by two independent reviewers (PV, CA), not involved in clinical treatment or clinical follow-up.

Preoperative standing long-leg X-rays were evaluated to determine the mechanical axis; the size of pre-existing cysts was measured by computed tomography (CT) of the ankle. CT was performed with the use of the SOMATOM Definition AS (Siemens). This scanner contains an 80-kW generator and Ultra-Fast Ceramics detector with a rotation time of 1 s (tube voltage, 120 kV; tube current range, 35 mA; pitch, 0.6; 128 slices; slice thickness, 1.0 mm; slice increment, 0.5 mm). Standing anteroposterior (AP) and lateral (LAT) radiographs of the ankle were made preoperatively and at each follow-up visit. Ankle alignment was determined on the anteroposterior radiograph by measuring the angle between the talar and the tibial component. An angle of 0° is considered ideal, and > 5° was defined as varus or valgus ankle alignment. The posterior slope of the tibial component was measured on the lateral radiograph.

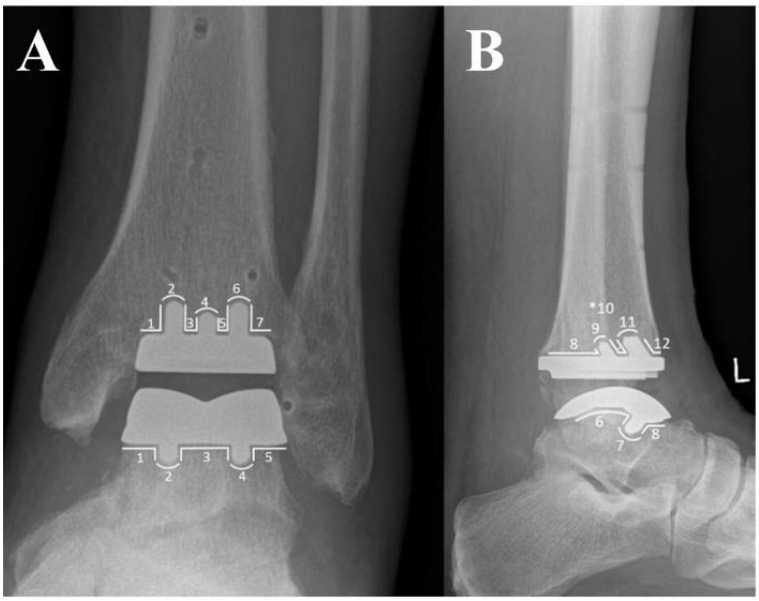

Fig. 3. Zones in which radiolucency is assessed, according the Rippstein protocol, on both the tibia (12 zones) and talus (8 zones) component [20].

Tibial radiolucencies > 2 mm in width were assessed in seven zones around the implant on the anteroposterior radiograph and in five zones on the lateral radiograph. Talar radiolucencies were assessed in three zones around the implant on the lateral radiograph and in 5 zones on the anteroposterior radiograph [17]. Migration of the tibial component was defined as a change of an angle of > 3°. Migration of the talar component was defined as > 2 mm of subsidence into the talar bone.

2.3. Clinical assessment

Patients were assessed preoperatively and postoperatively on 1 day, in 6 weeks, 3–6–12 months, and yearly thereafter. The AOFAS questionnaire, the Foot and Ankle Outcome score (FAOS), the Visual Analogue Scale (VAS), the EQ-5D-5 L score, the Manchestor-Oxford Foot Questionnaire (MOxFQ), ROM and the Hospital Anxiety and Depression Scale (HADS) were assessed at these follow-up examinations [11–14].

The Hospital Anxiety and Depression Scale (HADS) is considered part of the (British) National Institute for Health and Care Excellence (NICE) recommendation for the diagnosis of depression and anxiety and was employed to determine the level of preoperative anxiety and depression [15].

The cohort was divided into two separate groups based on HADS anxiety outcomes. Groups were classified based on HADS anxiety scores: 0 – 7 “no anxiety disorder”; 8 – 21 “possible and probable anxiety disorders”.

All complications and re-operations were recorded, and a radiographic evaluation was performed. Complications were defined according to the classification system of Glazebrook et al., but other complications were also recorded [6]. Failure of the implant was defined as the need for revision surgery of one of the ankle re- placement components or (pan)arthrodesis. Revision of TAA was defined as the removal or exchange of one or more of the prosthetic components except for the incidental exchange of the polyethylene insert (e.g., due to infection) [16].

2.4. Statistical Methods

Normal distribution was checked using the Shapiro-Wilk test.

Descriptive statistics were used to report demographics, complications, and failures. Continuous variables were reported as mean, range and standard deviation (SD), and categorical variables as count and percentage. Differences between the two groups based on HADS anxiety score were tested using the independent-samples t-test and Pearson’s chi-square test.

Repeated measures ANOVA with Bonferroni post hoc analysis were used to calculate the statistical difference in the measured parameters over time. The Greenhouse-Geisser correction was used in the assessment of the change in a continuous outcome with three or more observations over a period of time or within subjects. The larger the F-statistic, the more likely it is that the independent variable will have had a significant effect on the dependent variable.

Correlations were tested using Pearson correlation coefficient, or the Spearman's Rho when data was not normally distributed. Linear regression analysis was performed to assess the association between the effect of anxiety reported by the HADS and the PROMS. Results were expressed as regression coefficients including a 95 % confidence interval (CI).

Statistical analysis was performed in IBM SPSS Statistics, with the accepted level of significance at 0.05 (α = .05).

3. Results

3.1. Patient and demographics

From January 2017 to May 2020, one surgeon (JH) performed 27 consecutive primary Infinity TAAs in 27 patients, with 25 included with a minimal follow-up of 12 months. Demographic information of the study cohort is displayed in Table 2.

	(n = 24)	Range	SD
Age	69.8	61–86	6.93
Gender			
Male (%)	88		
Female (%)	12		
BMI (kg/m^2)	27.09	22.4–31.4	3.13
Follow-up (months)	34.18		12.24
Range of motion (degrees)	25.80	10–40	7.59
Alignment (degrees)	90.44	84 – 96	2.63
Varus (%)	24.00	84–88	1.63
Neutral (%)	20.00		
Valgus (%)	56.00	91–96	1.31
Side			
Left (%)	36.00		
Right (%)	64.00		
Indication			
Post-traumatic arthritis (%)	36.00		
Osteoarthritis (%)	60.00		
Rheumatoid arthritis (%)	4.00		
Symptoms preoperative (years)	6.57	0.50 – 40.00	8.14
Diabetes			
Yes (%)	8.00		
No (%)	92.00		

Table 2: Demographic data listed below as mean or percentage, range and standard deviation (SD) of Infinity TAA patient cohort with minimal 12 months follow-up.

Indications were posttraumatic OA (36 %), primary OA (60 %) and rheumatoid arthritis (4 %). Gender distribution was 3 female (12 %) and 22 male (88 %) patients, with a mean age at first ankle replacement of 70.1 years (± 6.9, range: 60–85). The median follow-up time was 34.18 months (range 14.75 – 58.45). No surgery was done before TAA to correct any hindfoot deformity. An Achilles tendon tenotomy was performed perioperatively in 14 patients.

3.2. Impact of anxiety on clinical results and functional outcomes

After TAA, the ROM improved preoperatively from 25.8 degrees of range of motion (SD = 7.6) to 35.0 degrees (SD = 6.2) at 12 months follow-up postoperatively ($p < 0.001$). The EQ-5D-5 L, AOFAS hindfoot, FAOS, VAS and MOxFQ scores improved significantly over time compared to baseline (pre-operative) (Table 3). Pre- and post-operative mean outcome scores on PROMs and ROM are reported in Tables 3 and 5 (Tables 3,4; Fig. 4).

	Mean	SD
ROM preoperative	25.80	7.59
ROM 3 MFU	31.00	9.01
ROM 6 MFU	33.95	7.36
ROM 12 MFU	35.00	6.17

Table 3: Passive range of motion (degrees) of the ankle in mean and standard deviation at baseline(pre-operative) and at 3-, 6-, and 12-months follow-up.

		Baseline		3 MFU		6 MFU		12 MFU		
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
EQ-5D-5L		0.78	0.06	0.84	0.10	0.86	0.11	0.91	0.10	P = .001
AOFAS	Pain	14.17	9.29	29.57	8.77	29.50	9.44	34.00	7.64	
	Functioning	26.83	9.32	39.30	7.34	44.00	6.00	45.80	6.05	
	Alignment	7.29	3.29	9.78	1.04	10.00	0.00	9.80	1.00	
	Total	48.29	17.12	78.65	14.64	83.50	14.72	90.71	11.94	P = .000
FAOS	Symptoms	49.85	21.08	65.99	15.22	69.64	18.19	78.43	22.53	
	Pain	43.98	18.00	74.76	16.09	77.36	18.52	83.33	19.23	
	Daily functioning	56.13	19.66	78.84	17.66	82.79	17.18	86.00	16.46	
	Sports and recreation	25.00	15.46	50.65	29.86	60.75	29.84	60.20	29.74	
	Quality of life	30.73	18.05	50.27	21.93	60.63	27.88	67.75	24.45	
	Total	41.14	15.23	64.10	17.14	70.23	18.88	76.97	18.83	P = .000
VAS		5.61	2.32	2.61	2.30	2.00	2.36	1.54	1.64	P = .000
MOxFQ	Walking/ standing	74.00	21.34	41.61	23.92	36.25	30.53	30.29	30.10	
	Pain	65.60	22.70	31.30	22.32	33.75	29.19	25.80	24.22	
	Social interaction	73.50	22.55	54.08	27.86	44.06	32.54	41.00	26.46	
	Total	73.99	15.73	42.33	22.44	38.02	29.50	30.38	24.31	P = .000

Table 4: Outcome scores of PROMs on pain, functioning, and quality of life. Outcomes in mean and standard deviation. Repeated measures ANOVA corrected using Greenhouse-Geisser concluded statistical significant difference for AOFAS scores ($F(2.155, 32.325) = 37.340$, $P = .000$), FAOS scores ($F(1.810, 27.146) = 22.917$, $P = .000$), ROM ($F(2.722, 51.710) = 18.054$, $P = .000$), EQ-5D-3 L scores ($F(1.978, 29.673) = 9.585$, $P = .001$), VAS scores ($F(1.805, 27.071) = 12.911$, $P = .000$) and MOxFQ scores ($F(1.373, 20.600) = 28.207$, $P = .000$). Post hoc tests using het Bonferroni correction revealed that TAA elicits its significant increase in mean AFOAS scores at 3-months postoperative (46.75 ± 18.13 vs 78.38 ± 15.89, $P = .000$).

HADS anxiety scores ranged between 0 and 7 (mean=2.83; SD=2.23) in the “no anxiety”-group (n = 19) and 8–13 (mean=10.66; SD=1.86) in the “anxiety”-group (n = 6). No major differences between the two groups were found based on group demographics. No statistically significant differences were found in the two groups between mean preoperative AOFAS ($p = 0.579$), FAOS ($p = 0.498$) scores and ROM

(p = .541) between groups. However, statistically significant differences were found between preoperative mean EQ-5D-5 L (p = 0.001), VAS (p = 0.014) and MOxFQ scores (p = 0.024). 12 months postoperatively the AOFAS (p = .049), EQ-5D-5 L (p < .001), and FAOS (p = .037) scored significantly higher in the “no anxiety”-group. VAS (p = .009) and MOxFQ (p < .001) scored significantly lower at 12 months postoperatively in the “no anxiety”-group. ROM at 12 months postoperatively scored higher in the “no anxiety”-group, yet not statistically significantly (p = .451). (Tables 4,5, Fig. 5)

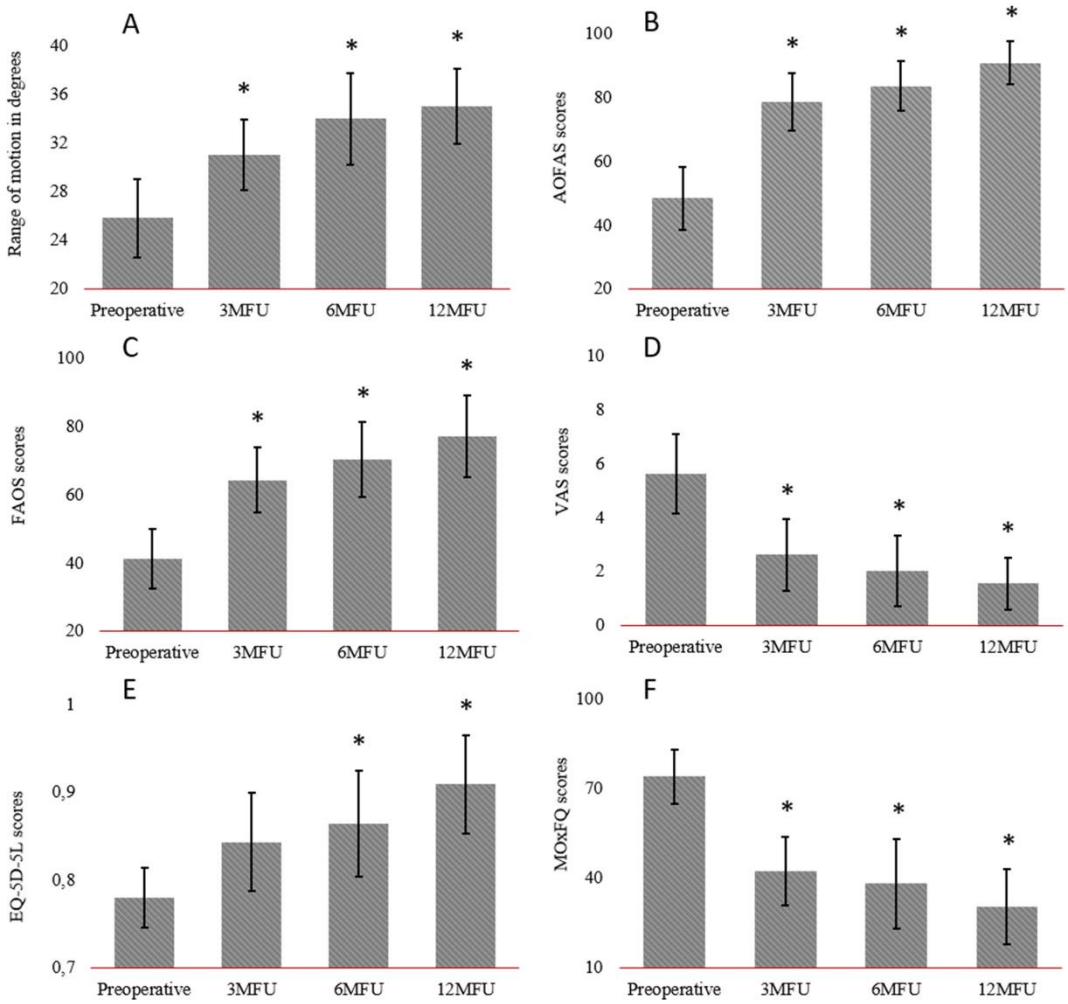

Fig. 4. Visual representation of (A) ROM, (B) AOFAS, (C) FAOS, (D) VAS, (E) EQ-5D-5L, and (F) MOxFQ scores at baseline (pre-op) and 3-, 6-, and 12-months follow-up. Significant differences compared to baseline are marked * . MFU = median follow-up time.

		R	R-squared	F	t	p-value
HADS – Anxiety	AOFAS	.214	.046	4.191	-2.047	.044*
	FAOS	.357	.127	12.680	-3.561	.001*
	EQ-5D-5L	.538	.289	35.388	-5.949	.000*,**
	VAS	.131	.017	1.513	1.230	.222
	MOxFQ	.488	.239	27.262	5.221	.000*,**
	ROM	.059	.003	.310	-.557	.579

Table 5: Linear regression analysis on the relationship between preoperative anxiety reported by the HADS and postoperative patient-perceived pain, functioning and quality of life reported by the AOFAS, FAOS, EQ-5D-5L, VAS, MOxFQ and ROM. T-values indicate whether anxiety reported by the HADS contributes significantly to the prediction model using *(P < .05). When the regression analysis predicts the dependent variables significantly well, values are indicates using ** (P < .0005).

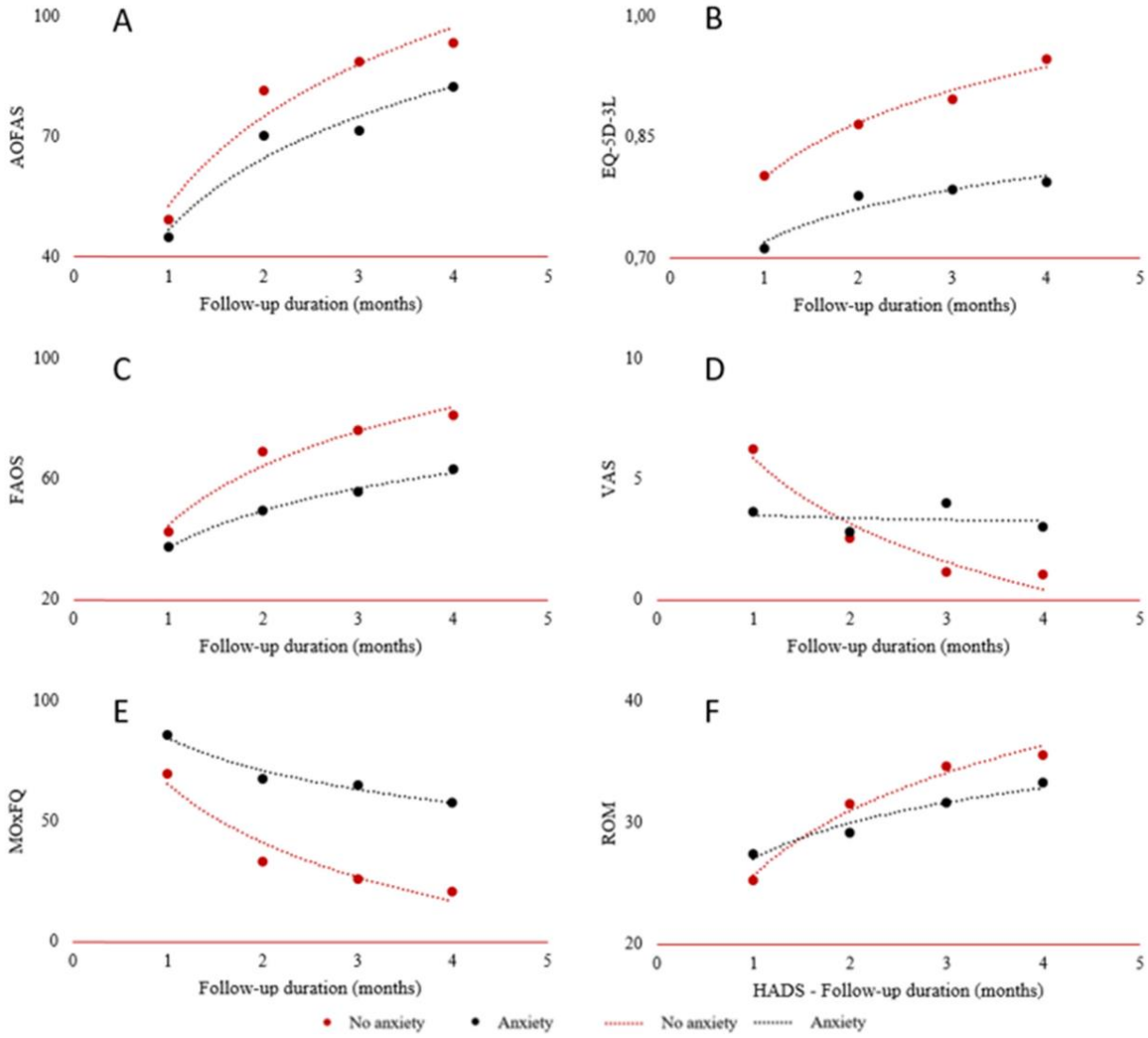

Fig. 5. Visual representation on the influence of anxiety on the AOFAS (A), EQ-5D-5 L (B), FAOS (C), VAS (D), MOxFQ (E) and ROM (F). An increase in AOFAS, FAOS, and EQ-5D-5 L scores increased till 12-month endpoint. The VAS and MOxFQ decreased till 12-month endpoint postoperatively. The ROM seemingly plateaus after 12 months postoperative.

3.3. Peri-operative complications and failures

We observed two intra-operative complications, one of them being a medial malleolar fracture which was fixated with two cannulated screws; and the other one being a nerve tibialis injury which required microscopic repair conducted by a plastic surgeon.

Three post-operative complications occurred in twenty-five ankle replacements (12 %). Impingement in two ankles (8 %) and deep infection in one ankle (4 %) were recorded. According to the definition by Henricson, no failures were reported in our study [16]. Therefore, the survival was 100 % during a median follow-up time of 34.18 months (range 14.75 – 58.45.

One patient with a deep infection was treated by a DAIR procedure within three months after the TAA. A polyethylene liner exchange was performed as a DAIR procedure in combination with extensive irrigation, debridement, and prolonged antibiotic use postoperatively [17]. The wound-healing problem of this patient was caused by an underlying chronic venous insufficiency.

3.4. Radiologic outcomes

On pre-operative conventional standing X-rays, the mean axial alignment of the tibia was 90.4 degrees (SD 2.63; range 84–96). The mean varisation of the talus was 86.7 (SD = 1.63) degrees in 6 (24 %) ankles on the anteroposterior view, and the valgisation was 92.2 (SD = 1.31) degrees in 14 (56 %) ankles.

The radiographic assessment consisted of the estimation of prosthesis alignment, migration, translation and radiolucent lines according to Rippstein protocol (Figs. 2–3) [10]. No radiolucency was found in the course of a 12-month follow-up.

No change was found in the postoperative alignment of the Infinity TAA system indicating the absence of component migration and subsidence (Fig. 6).

Heterotopic ossifications developed in 8 % of patients after 3 months postoperatively and increased to 52.2 % and 64.0 % after 6- and 12 months respectively (Table 6). There are no coherent significant correlations between heterotopic ossifications and ROM after 3 months ($r = .074$, $p = 0.727$), 6 months ($R=-.446$, $p = 0.033$) and 12 months ($R=-.038$, $p = 0.871$) postoperatively.

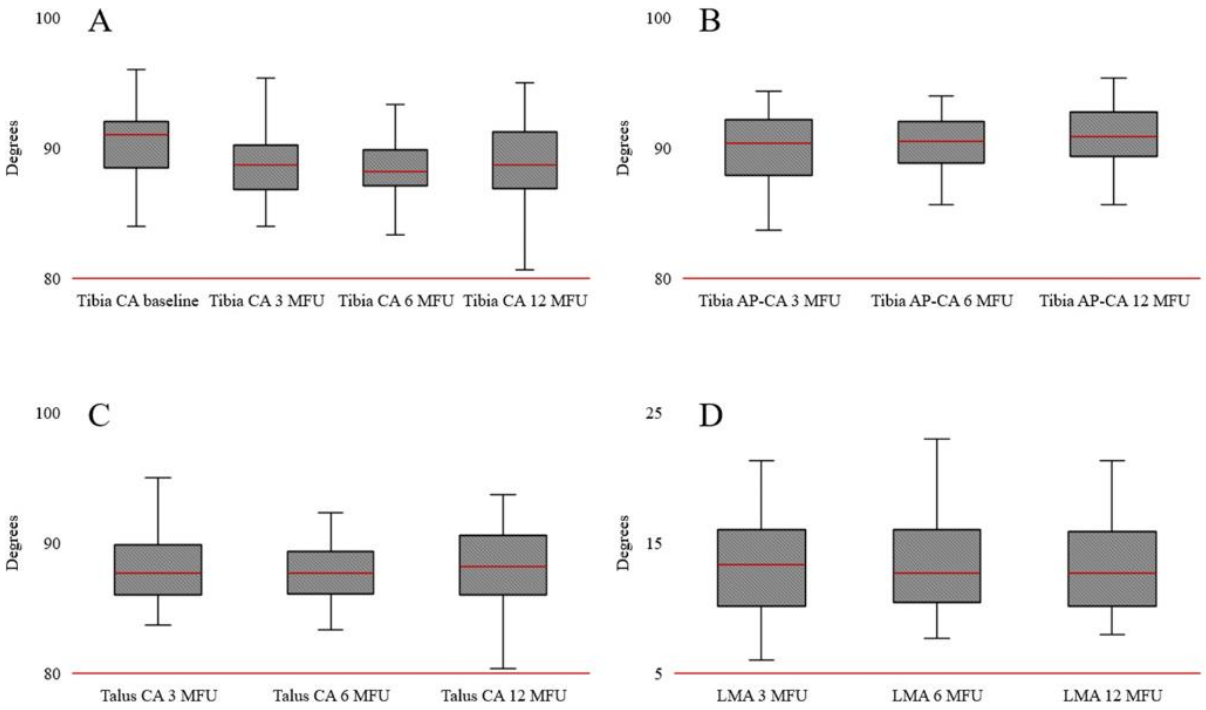

Fig. 6. Boxplots of alignment in degrees plantar- and dorsiflexion of the Infinity components on sagittal and coronal radiographs. Tibia CA preoperatively and at subsequent follow-up (A), tibia AP-CA postoperatively (B), talus CA postoperatively (C), and the LMA postoperatively (D). Abbreviations: CA; component angle. AP-CA; anteroposterior-component angle. LMA; lateral-medial malleolar angle.

Class	PAO 3 MFU		PAO 6 MFU		PAO 12 MFU	
	Frequency	%	Frequency	%	Frequency	%
0	23	92.0	11	44.0	6	24.0
I	1	4.0	8	32.0	7	28.0
II	1	4.0	4	16.0	8	32.0
III	-	-	-	-	1	4.0
IV	-	-	-	-	-	-

Table 6: Heterotopic ossification frequencies at 3-, 6-, and 12-months follow-up according to the modified Brooker classification. Abbreviations: MFU; months follow-up. PAO; peri-articular ossification.

4. Discussion

In this study, we report the first correlation between anxiety and short-term clinical outcome of an ankle replacement. We concluded that patients without anxiety (HADS anxiety scores 0–7) had significantly higher AOFAS ($p = .049$), EQ-5D-5 L ($p < 0.001$) and FAOS ($p = 0.037$) scores and significantly lower MOxFQ ($p < 0.001$) and VAS ($p = .009$) scores. ROM ($p = 0.451$) showed better scores in the “no anxiety” group but not significantly (Table 5).

We report a significant increase in ROM after surgery achieved after 3 months, with a further increase till 6 months and plateauing after 12 months, from 26 degrees preoperatively to 35 degrees postoperatively. Previous reports have shown similar improvements in ROM till 12 months postoperatively ranging from 22 to 40 degrees postoperatively [18]. A positive correlation was found between the increase in ROM and the self-reported functional and physical improvement postoperatively assessed by PROMs [18,19]. We identified a negative correlation between ROM and anxiety, however not significant (Fig. 5).

In our cohort, we have had no failures according to the definition of a revision by Henricson et al. [16]. The United Kingdom National Joint Registry reported a 99 % survival rate in 895 Infinity TAAs at a mean follow-up of 14 months [20]. Since we have had no failures in our cohort, a correlation between anxiety and depression could not be found. Only one article by Jämsen et al. reported an association between depression and early hip prosthesis failure by multivariate analysis. This analysis found no correlation between depression and knee prosthesis failure [21].

In the literature it is noted that TJR has a high survival rate, but is it also a predictor of satisfaction? Price et al. suggest that the survival rate or revision rate alone as a sole index of failure is probably an underestimation of the problem [22]. Bourne et al. show that 49 % of the total knee replacements did not live up to patients' expectations compared to 6 % that did [23].

Selecting patients who would benefit from a TJR would seem reasonable as suggested by Dowsey et al. [24]. It has been estimated that one-quarter of the candidates for a TJR are inappropriate because of an insufficient improvement of a validated pain and functional threshold after surgery [24–26]. One in five patients undergoing total joint replacement shows significant levels of depression prior to and up to six months after surgery. Depression and anxiety can influence the outcome of surgery. Anxiety symptoms in TJR are being ranged between 9 % and 95 %. Wood et al. state that preoperative pain and poor function are predictors of catastrophizing, anxiety, and/or depression in TJR. Patients at risk for catastrophizing, anxiety, and/or depression include those with increased pain but generally good clinical function along with younger women with comorbidities [27].

Valdes et al. found a relation between high levels of catastrophizing and increased likelihood of opioid use to treat chronic pain after TJR. However, this does not mean that patients are less satisfied [28], only that the increase in satisfaction is lower [29].

The presence of emotional disorders preoperatively raises the chance of persistent postoperative pain. Patients with depression and anxiety symptoms had also higher expectations of surgery [30,31]. Wood et al. have shown that patients who are anxious, depressed or catastrophize pain demonstrate inferior self-reported outcomes. Postoperatively these patients also experience higher levels of pain and inferior subjective function (Oxford hip and knee score) while this difference was not observed in postoperative objective function scores (Harris Hip Score/Knee Society Score) [9]. In elective foot and ankle surgery, Nixon et al. noted similar results stating preoperative emotional anxiety could predict worse pain and function in the early follow-up period [32].

In our cohort, the presence of anxiety negatively influences postoperative patient-perceived outcomes, which correlates with the results in the aforementioned literature [32]. Our findings encourage the discussion of whether patients experiencing considerable disease-related and general anxiety should receive TAA surgery.

Although patient-perceived postoperative outcomes may be worse in patients experiencing anxiety, objective functioning, complications and failures are not different in this subgroup. In total knee replacement prehabilitation brings significant difference regarding the Knee Score preoperatively and 6 months postoperatively while in 12 months no difference was to be observed [33]. In our report, we have seen a difference in AOFAS, FAOS, EQ-5D-5 L, VAS and MOxFQ scores in 12 months of follow-up. Raju et al. support that pre-operative and postoperative counseling produces positive effects on a patient's physical recovery, coping and anxiety reduction [34].

5. Conclusion

Our short-term results of the Infinity Total Ankle System are comparable to other studies with good clinical and functional outcomes. Anxiety in TAA patients has a negative influence on patient-reported outcome measurements, such as AOFAS, FAOS, EQ-5D-5L, VAS and MOxFQ scores. Providing counseling for patients suffering from anxiety could enhance patient satisfaction after TAA.

Additional studies with larger cohorts and longer follow-up periods are warranted to determine if anxiety still plays an important role in having a negative influence on patient satisfaction.

Additional knowledge is required to determine whether anxiety can be trained to improve patient-reported outcome measurements and clinical outcomes.

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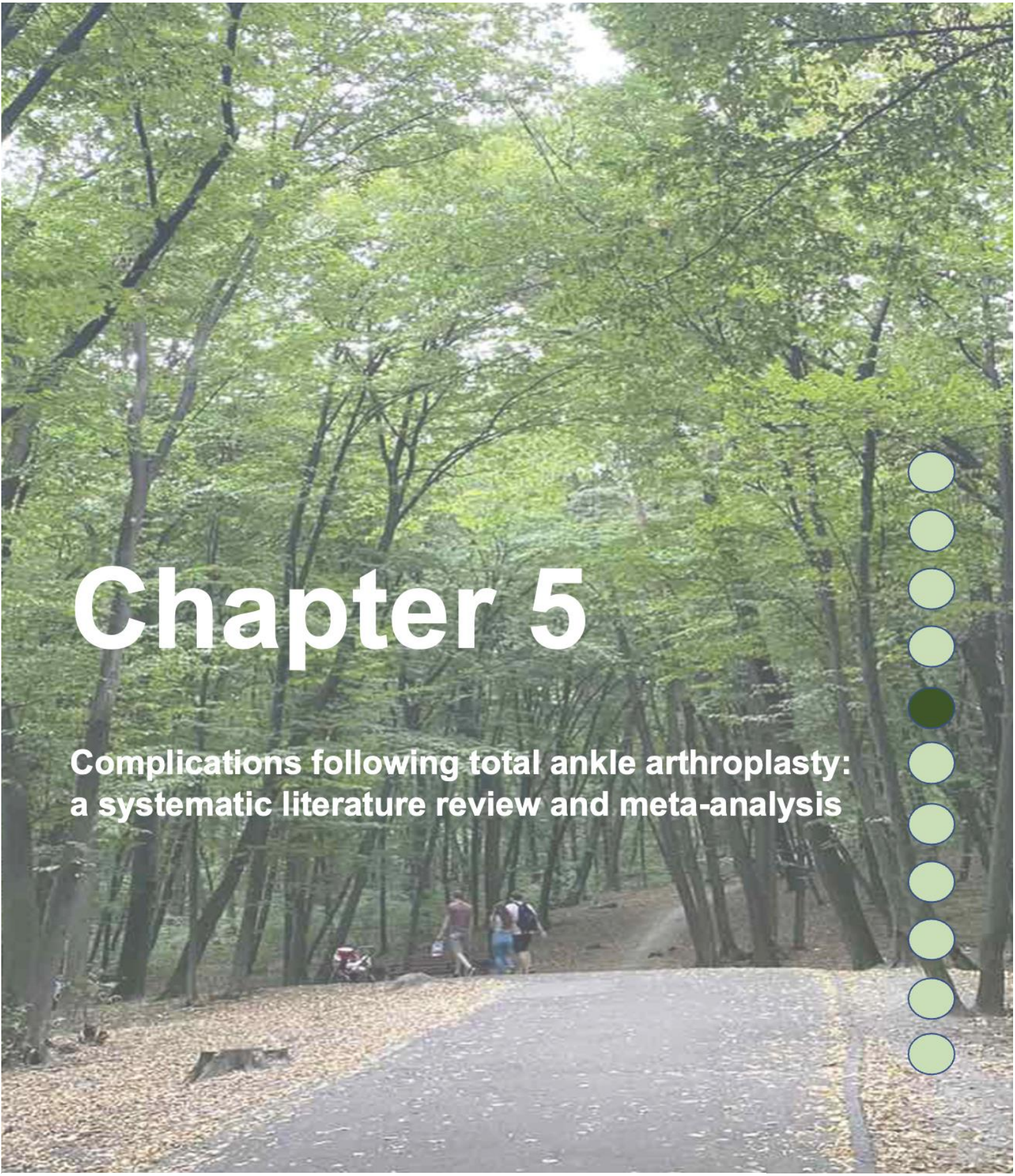

Hermus JPS, Voesenek JA, van Gansewinkel EHE, Witlox MA, Poeze M, Arts JJ.

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Abstract

Background: Total ankle arthroplasty (TAA) is increasingly used as a treatment for end-stage ankle arthropathy. However, TAA may be more sensitive to complications, failure and subsequent re-operations compared to ankle arthrodesis. The aim of this systematic review and meta-analysis is to generate an overview of complications of TAA surgery.

Methods: PubMed, EMBASE and the Cochrane library were searched between 2000 and 2020 to identify all papers reporting on complications in TAA surgery. Meta-analysis was conducted based on type of complication in TAA surgery. Pooled estimates of complications were calculated using a random effects model.
Risk of bias and quality was assessed using the Cochrane risk of bias and ROBINS-I tools. The confidence in estimates was rated and described according to the recommendations of the GRADE working group.

Results: One hundred twenty-seven studies were included in this systematic review. All combined, they reported on 16.964 TAAs with an average follow-up of 47.99 ± 29.18 months. Complications with highest reported pooled incidence were intra operative fracture 0.06 (95 %CI 0.04–0.08) (GRADE Very low) and impingement 0.06 (95 %CI 0.04–0.08) (GRADE low) respectively.

Conclusion: Reported complication incidence of TAA surgery is still high and remains a significant clinical problem that can be severely hampering long-term clinical survival of the prosthesis. The results of this systematic review and meta-analysis can help guide surgeons in informing their patient about complication risks. Implementation of more stringent patient selection criteria might contribute to diminishing TAA complication rates.

Keywords: Total ankle replacement, Ankle arthroplasty**,** Complications**,** Impingement**,** Fracture

1. Introduction

In the last two decades, total ankle arthroplasty (TAA) has been increasingly used in clinical practice as an alternative to arthrodesis [1]. The preserved mobility of the ankle joint in TAA might be accompanied by a more successful functional outcome and a better protection of adjacent articulations [2,3].

Ever since TAA surgeries have been performed, patient satisfaction, pain relief and functional outcomes have changed for the better [4]. However, there are also disadvantages for TAA may be more sensitive to complications, failure and subsequent re-operations when compared to ankle arthrodesis [5]. A study conducted by Spirt et al. shows that 28 % of the patients that underwent ankle arthroplasty had to undergo one or more reoperation(s) due to complications [6]. The perioperative major complications in ankle arthrodesis occurred 1.8 times more often compared to TAA but had a 29 % lower risk of a minor complication after adjusting for patient and hospital factors, such as gender, age, and health-status [7].

Glazebrook et al. proposed a classification system for complications of total ankle replacement based on clinical outcomes. Insight in the risk of complications is important, since the risk of failure that is associated with the occurrence of complications [8].

The aim of this meta-analysis is to generate an overview of complications of TAA surgery and perform a meta-analysis on complication incidence. In this meta-analysis we defined a complication as any undesirable, unintended and direct result of the ankle replacement according to the definition by Sokol and Wilson [9].

Failure was defined in this meta-analysis as during interpretation of revision rates, revision of TAA was defined as removal of either the tibial or talar component or both components with subsequent placement of an antibiotic spacer, reimplantation of metal components, conversion to an arthrodesis, or amputation [10].

2. Materials and methods

2.1. Protocol

The protocol for this systematic review and meta-analysis was prospectively registered in PROSPERO (https://www.crd.york.ac.uk/prospero/ , ID: CRD42018105062). This study was performed and reported according to the PRISMA-statement for reporting systematic reviews [11].

2.2. Eligibility criteria

Retrospective and prospective cohort studies, case series and randomized controlled trials reporting on complications of TAA were eligible for inclusion in this study. Only studies written in English and Dutch languages were included, and publication date inclusion was set at studies published 2000–2020. Participants of any age and gender undergoing TAA were eligible for inclusion. Other exclusion criteria were systematic reviews and/or meta-analysis, studies about only first-generation total ankle arthroplasty implants and studies which focused on revision TAA. All other generations of ankle replacement and all types of systems were eligible for inclusion.

2.3. Information sources and search strategy

The electronic databases of PubMed, Cochrane and EMBASE were systematically searched to find relevant articles. Keywords used to develop our search strategy were ‘ankle’, ‘joint replacement’. The literature search of published papers was performed on 31 December 2020. The search terms and methodology were checked by a librarian.

2.4. Study selection

Selection of relevant studies was independently performed by three reviewers (JV, EG, JH). The retrieved studies from the search were first screened on title. Selected studies abstracts were subsequently assessed based on the eligibility criteria previously mentioned. The full text was read when there was any doubt about inclusion or exclusion of a study. In case of a difference of opinion for inclusion, the judgment of the fourth reviewer (CA) was used for the final decision.

2.5. Data collection process

A data file was composed (JV, JH) to register extracted complications from the selected studies. Database was checked for completeness for all patients in dual assessment (JV/JH; EG/CA) Next to the outcome measures, also the sample size, demographics, TAA indication, follow-up duration, failure rate, functional outcome, type of implant used, including generation and bearing type, were extracted from the studies.

2.6. Level of evidence

For each included article, the level of evidence was assessed using the CEBM levels of evidence guideline of March 2009 document compiled by the Oxford Centre of Evidence-based Medicine [12].

2.7. Risk of bias

The ROBINS-I tool was used for assessing risk of bias in non- randomized studies of interventions [13]. This tool assesses seven domains through which bias might be introduced. The first two domains, covering confounding and selection of participants into the study, address issues before the start of the interventions. The third domain addresses classification of the interventions themselves. The other four domains address issues after the start of interventions: biases due to deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result.

Because all studies used a retrospective or prospective cohort method, assessing bias according to random sequence generation, allocation concealment and blinding for the allocated intervention are irrelevant.

The confidence in estimates was rated according to the recommendations of the GRADE working group as each outcome was assessed for potential risk of bias, inconsistency, imprecision, indirectness, and publication bias [14].

2.8. Statistical analysis

A meta-analysis was performed for the ten most reported complications. Meta-analyses were performed whenever three or more studies reported on a complication. When study populations overlapped, the study with the most recent data was used in the meta-analyses.

Despite anticipated heterogeneity, the individual study proportions were pooled. Pooled proportions with their corresponding 95 % confidence intervals were calculated using Freeman-Tukey double arcsine transformation within a random effects model framework.

Heterogeneity of combined study results was assessed by visual inspection of forest plots, use of the I2 statistic and connected $\chi 2$ test, and 95 % prediction intervals (PIs) were calculated to present the expected range of true effects in similar studies. Between-study variance was quantified using the $\tau 2$ statistic, estimated using the

Sidik-Jonkman estimator. The Hartung–Knapp method was used for adjustment of the estimates and confidence intervals (CIs).

Publication bias was assessed only if 10 or more studies were included in the meta-analysis using funnel plots and Peters' test (for proportions) for funnel plot asymmetry [15].

Statistical analyses were performed using R version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria) with package 'meta'.

2.9. Source of funding

None.

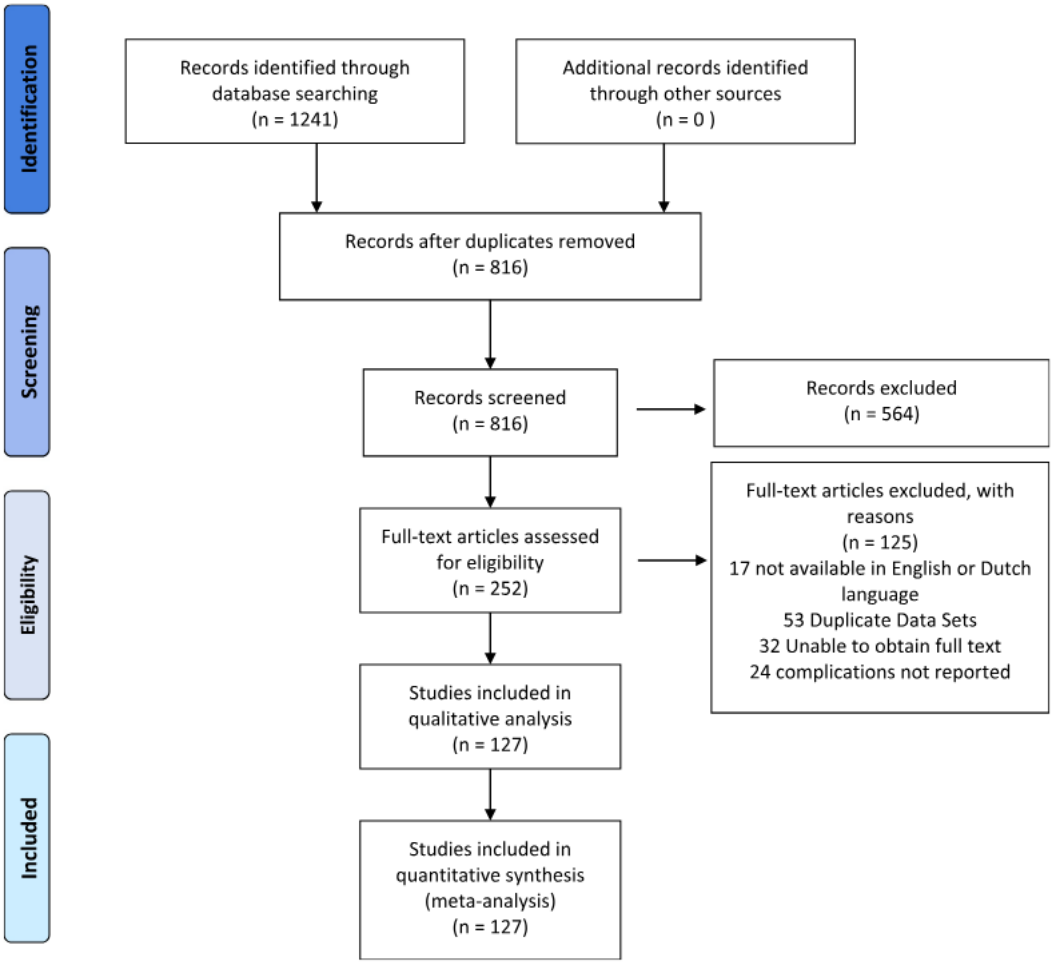

Fig. 1. Flow-chart of the study PRISMA selection process

3. Results

3.1. Selected studies

A total of 816 reports were identified through PubMed, EMBASE, ScienceDirect, Clinical registries and Cochrane Library, and after removal of duplicates 816 remained.

Based on title screening, 564 of those reports were discarded, since it was clear that these articles did not adhere to the inclusion criteria leaving 252 reports. After reading the full text, 127 articles were included in this meta-analysis (Fig. 1).

3.2. Methodology assessment

Results level of evidence: Using the CEBM levels of evidence guideline of 2009, the level of evidence for each article was assessed [12]. Most included studies were cohort studies, with mostly a 4 on the level of evidence assessment because of poor methodological quality or the lack of control group (74.7 %). The studies that included a control group (25.3 %) were 2b level of evidence studies.

Results risk of bias: The results of the ROBINS-I risk of bias assessment are summarized in Table 1 and they indicate that the overall ROBINS-I score for most studies was subject to serious or critical risk of bias.

3.3. Study characteristics

One hundred twenty-seven studies were included in this systematic review. All combined, they reported on 16.964 TAAs with an average follow-up of 47.99 ± 29.18 months. A variety of aetiologies were reported as an indication for TAA with posttraumatic osteoarthritis, primary osteoarthritis and rheumatoid arthritis being the most prevalent aetiologies. The age of subjects ranged between 17 and 95 years, with an average of 60.04 years. So according to the indication for TAA and the range in age, the population of present review is very heterogeneous.

3.4. Complications

A total of 127 articles reported on complications (Table 2). With 67 papers reporting on intra-operative fracture and 48 papers on impingement, these were the most frequently reported complications among the included papers.

A meta-analysis was performed for the ten most reported complications (Fig. 2).

The pooled complication rates for the ten most reported complications were according the classification by Glazebrook: deep infection 0.02 (95%CI 0.01–0.02 in 221 events in 12,963 ankles, 77 studies), aseptic loosening 0.05 (CI 0.03–0.06 in 486 events in 9425 ankles, instability 0.02 (95 %CI 0.01–0.04 in 103 events in 3297 ankles, 23 studies), post-operative fracture 0.03 (95 % CI 0.02–0.03 in 437 events in 6388 ankles, 56 studies), component subsidence 0.04 (95 %CI 0.02–0.06 in 154 events in 3915

Table 1 ROBINS-I assessing risk of bias in non-randomized studies of interventions.

		Domain 1: Confounding	Domain 2: Selection of participants	Domain 3: Classification of interventions	Domain 4: Deviation from interventions	Domain 5: Missing data domain	Domain 6: Measurement of outcomes	Domain 7: Selection of reported results	ROBINS-I overall
Adams et al.	2014	2	2	1	1	1	1	2	2
Ahn et al.	2020	2	1	1	2	1	2	1	2
Anderson et al.	2003	3	2	2	2	1	2	2	3
Asencio et al.	2014	3	3	1	1	1	1	2	3
Bai et al.	2010	2	2	1	1	1	1	2	2
Barg et al.	2011	2	3	1	2	1	1	2	3
Barg et al.	2011	2	2	1	1	1	1	1	2
Barg et al.	2018	2	1	1	1	2	2	1	2
Benich et al.	2017	2	1	1	2	2	2	1	2
Bennett et al.	2018	2	2	1	1	3	1	1	3
Berlet et al.	2020	1	1	1	1	1	1	1	1
Besse et al.	2009	3	3	2	1	1	1	2	3
Bianchi et al.	2012	2	2	1	1	1	2	3	3
Bonnin et al.	2011	2	2	3	1	2	1	3	3
Borenstein et al.	2018	2	1	1	1	2	1	2	2
Bouchard et al.	2015	3	3	2	1	2	3	3	3
Brunner et al.	2013	2	1	1	1	2	1	1	2
Buechel et al.	2003	2	1	1	1	1	3	2	3
Chao et al.	2015	2	1	1	1	1	1	1	2
Choi et al.	2013	3	2	2	1	1	1	2	3
Choi et al.	2014	3	3	2	1	1	1	2	3
Claridge et al.	2009	3	1	2	2	2	2	3	3
Cody et al.	2019	2	3	1	2	3	1	1	3
Cody et al.	2019	2	1	3	2	4	1	1	4
Currier et al.	2019	3	2	1	4	3	2	1	4
Daniels et al.	2015	2	1	1	1	1	1	1	2
Day et al.	2020	2	1	2	2	3	1	1	3
Demetracopoulos et al.	2015	2	1	1	2	1	1	2	3
Demetracopoulos et al.	2019	2	1	2	2	1	1	2	2
Di Iorio et al.	2017	1	1	1	2	2	1	1	2
Doets et al.	2006	2	1	2	1	2	2	1	2
Eckers et al.	2017	3	2	2	1	3	1	1	3
Escudero et al.	2020	3	1	2	2	1	1	1	3
Esparragoza et al.	2011	3	1	2	2	1	1	2	3
Faber et al.	2018	1	1	1	1	1	1	1	1
Gaudot F et al.	2014	2	2	1	1	1	1	2	2
Giannini et al.	2010	2	1	1	1	1	1	2	2
Giannini et al.	2011	2	1	1	1	1	1	2	2
Gramlich et al.	2018	2	1	1	2	3	1	1	3
Gross et al.	2015	3	2	1	1	1	1	1	3
Gross et al.	2016	2	1	2	1	1	1	2	2
Gross et al.	2017	3	3	1	2	1	2	1	3
Harston et al.	2017	2	1	1	2	2	1	1	2
Heida et al.	2017	2	2	1	2	1	1	1	2
Henricson et al.	2010	3	1	1	1	2	1	2	3
Henricson et al.	2015	2	1	1	1	1	1	1	2
Henricson et al.	2020	2	2	1	2	3	1	1	3
Hintermann et al.	2004	2	1	1	1	2	1	1	2
Hobson et al.	2009	2	2	2	1	1	2	1	2
Hofmann et al.	2016	3	2	1	2	2	2	1	3
Hsu et al.	2015	3	1	1	2	1	1	1	3
Hurowitz et al.	2007	2	1	1	1	2	1	1	2
Johnson-Lynn et al.	2018	2	1	1	2	4	2	1	4
Jung et al.	2015	2	2	3	1	2	2	1	3
Kamrad et al.	2017	1	2	3	1	4	1	2	4
Karantana et al.	2010	2	1	1	2	2	1	1	2
Kerkhoff et al.	2016	3	2	1	1	3	2	1	3
Kerkhoff et al.	2016	3	1	1	1	2	2	1	3
Knecht et al.	2004	2	1	1	2	3	4	1	4
Kofoed et al.	2004	2	3	2	1	3	1	1	3
Koivu et al.	2017	1	3	1	2	3	1	1	3
Koo et al.	2018	1	1	1	2	3	1	1	3
Kopp et al.	2006	2	1	1	2	2	2	1	2
Kraal et al.	2013	3	1	1	1	1	4	1	4
Lagaay et al.	2010	1	2	3	1	1	1	1	3
Lampley et al.	2016	3	2	2	1	2	1	1	3
Lee et al.	2008	1	1	1	1	1	1	1	1
Lee et al.	2020	1	1	1	1	1	1	1	1
Lewis et al.	2015	1	3	2	2	3	3	1	3
Loewy et al.	2019	2	2	1	2	1	1	1	2

(*continued on next page*)

Table 1 (*continued*)

		Domain 1: Confounding	Domain 2: Selection of participants	Domain 3: Classification of interventions	Domain 4: Deviation from interventions	Domain 5: Missing data domain	Domain 6: Measurement of outcomes	Domain 7: Selection of reported results	ROBINS-I overall
Mann et al.	2011	2	1	1	1	2	2	1	2
McConnell et al.	2017	1	1	3	1	1	2	2	3
Morgan et al.	2010	2	1	1	1	2	2	1	2
Mosca et al.	2020	2	1	1	2	4	1	1	4
Muir et al.	2013	3	1	1	2	3	2	1	3
Myerson et al.	2003	2	1	1	1	2	2	1	2
Natens et al.	2003	2	1	1	1	2	1	1	2
Nieuwe Weme et al.	2015	1	1	2	2	2	1	1	2
Noelle et al.	2013	3	1	1	2	3	2	1	3
Oliver et al.	2016	3	2	2	1	4	3	2	4
Pangrazzi et al.	2018	3	2	1	2	1	2	1	3
Pedersen et al.	2014	1	1	3	2	4	4	1	4
Penner et al.	2018	2	1	1	2	1	1	1	2
Preis et al.	2017	2	1	1	1	1	2	1	2
Preis et al.	2017	3	2	1	1	1	2	1	3
Queen et al.	2013	2	1	3	1	2	2	1	3
Ramaskandhan et al.	2014	1	2	1	2	1	3	2	3
Reuver et al.	2010	1	2	1	1	1	1	1	2
Richter et al.	2020	2	2	1	1	2	1	1	2
Rodrigues-Pinto et al.	2013	2	2	1	1	2	1	1	2
Rodriguez et al.	2010	3	1	1	1	3	2	1	3
Roselló Añón et al.	2014	3	4	1	1	3	2	2	4
Rushing et al.	2020	1	2	2	1	3	2	1	3
Saito et al.	2018	1	1	1	2	3	1	1	3
Saltzman et al.	2009	2	3	2	2	1	1	2	3
San Giovanni et al.	2006	2	1	1	1	2	1	1	2
Schenk et al.	2011	2	3	1	1	3	1	1	3
Schipper et al.	2016	2	1	1	2	1	2	1	2
Schuberth et al.	2006	1	2	1	1	2	2	2	2
Schuberth et al.	2020	2	1	1	2	1	1	1	2
Schutte et al.	2008	2	1	1	2	1	2	1	2
Schweitzer et al.	2013	2	1	1	2	3	1	1	3
Shi et al.	2015	3	1	3	1	2	2	2	3
Skyttä et al.	2010	3	2	1	1	2	2	2	3
Spirt et al.	2004	1	3	2	1	2	1	2	3
Sproule et al.	2013	1	1	1	1	1	1	1	1
Stewart et al.	2017	2	2	1	2	1	2	1	2
Strauss et al.	2014	2	1	1	1	1	1	1	2
Summers et al.	2012	2	1	1	1	3	4	3	4
Sung et al.	2014	3	2	3	1	2	2	1	3
Tan et al.	2016	2	1	1	1	3	3	1	3
Tan et al.	2018	2	2	1	2	3	1	1	3
Tedder et al.	2018	3	2	1	1	2	3	1	3
Tenenbaum et al.	2016	2	1	1	1	2	2	1	2
Tiusanen et al.	2020	1	1	1	1	2	2	1	2
Trajkovski et al.	2013	1	1	1	1	1	1	1	1
Usuelli et al.	2016	3	2	1	1	3	1	1	3
Usuelli et al.	2017	3	1	1	1	2	1	1	3
Usuelli et al.	2019	1	2	1	1	2	4	1	4
Valderrabano et al.	2004	2	2	1	2	1	1	1	2
Wood et al.	2000	1	3	1	1	2	3	1	3
Wood et al.	2003	3	1	1	1	1	2	1	3
Wood et al.	2008	3	1	1	1	1	2	1	3
Wood et al.	2010	2	3	1	1	2	2	2	3
Zafar et al.	2020	2	2	1	2	2	1	1	2

1 low risk of bias, 2 moderate risk of bias, 3 serious risk of bias, 4 critical risk of bias.

ankles, 37 studies), ongoing pain 0.04 (95 %CI 0.03–0.06 in 396 events in 5794 ankles, 45 studies), post-operative malalignment or deformity 0.04 (95 % CI 0.03–0.06 in 180 events in 4936 ankles, 38 studies), 71 studies), impingement 0.06 (95 %CI 0.04–0.08 in 333 events in 5203 ankles, 47 studies), wound healing problems 0.04 (95

Table 2 Overview of all clinical outcomes and complications reported by the included studies

Study	N ankles	age (yrs)	Follow-up (mo)	TAA generation type	AOFAS		VAS		SF-36		ROM (°)		Failure (%)	Pain	Wear	Impinge-ment	Aseptic loosening	PAO	Infection		Malalign-ment/ deformity	Fracture		Insta-bility	Wound-problem	Other (n[type complication])
					Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op							Deep	Superf		Intra-op	Post-op			
Adams 2014	194	64	44.4	2	39.7	78.0	7.02	1.36	50.0	68.1		22,5	11				*		5	4		4	3		6	6[1], 4[2], 1[3], ?[4], ?[5]
Ahn 2020	16	44.1	81.6	3,4			5.5	0.9			30.8	37.3	0													314
Anderson 2003	39	57	52	2		74						28	23.5	1			7				2				2	26
Asencio 2014	32	44	52.8	3,4	40.2	83.4					23.6	35.9		1												1[7], 1[8], 1[9]
Bai 2010	67	52	38	3	49	86.5						37.5	2.7			1		5	1			8			8	3[1], 4[2], 2[10]
Barg 2011d	19	65.2	61.2	3	38	75	7.5	1.2			29.5	37.8	10.5				2				1					
Barg 2011e	123	62.4	62.4	3	35	70	7.0	1.4			26.9	35.3	7.0	7		5					4	7		1	8	2[2], 8[3]
Barg 2018	55	67	26.6	4			7.9	0.8			22.9	40.2	7.0				3			2		2			2	
Benich 2017	103	65.9	36	3						157																
Bennett 2018	173	62.5	24	4									1.7	1		7	1		3			1	2		1	
Berlet 2020	121	62.88	28.51	4									5.0				2		3	9		3	1		1	1[1], 9[5], 1[42]
Besse 2009	50	56	40	3	36.9	85.4					33.7	44.8	8.0									4	1		1	1[2], 1[5], 1[11], 1[12], 1[13], 1[14]
Bianchi 2012	62	57.3	42.5	3	35.1	78	6.8	2.0					8.1	2			2		1			2				1[14], 1[4]
Bonnin 2011	87	56	106.8	3	26.7	79.3						26.7	15	3		2	1		1							5[6], 19[14], 1[15]
Bouchard 2015	39	62.44	46	3,4					84.7	92.3			6.7				3		1							26
Borenstein 2018	65	62.4	16.6	4									3.0				4		1					1	1	
Brunner 2013	77	56.9	148.8	2	25	73	3.9	1.8			18.2	22.8	38	17	1	4			1	1	7			2		11[6], 5[5], 1[14]
Buechel 2003	50	49	60	2							27	28	6.5		1		1		2			2	1		7	2[16], 1[5]
Chao 2015	23	68.6	36	3	42.7	88	76	13					4.4							5		3				15
Choi 2013	67	63	43.5	3,4	47.8	82.8					25.8	30.7	7.5				2					6	3		3	5[1], 13[2]
Choi 2014	173	66	58	4	55.8	82.7							13.9				5		1			1			13	
Claridge 2009	28	68.5	59.8	2	34.9	76.4							0				2		4	2		2	3			2[5], 2[2], 1[17], 1[18]
Cody 2019	159	63	20	4									10				6		6							
Cody 2019	533	62	84	3,4									6.4				7		3		4					2, 2[19], 5[14]
Currier 2019	70	59.5	54	2,3,4											3		22							2		13[14], 10[6]
Daniels 2014	281	64.1	62.4	2,3									17				41		3							4[9], 12[8]
Daniels 2015	281	61.9	108	2									18		2				3	1			1			1[9], 1[3], 2[6], 1[14], 1[10]
Day 2020	85	63.5	85.2	3									2.4			12	1		1		1		3			1[15], 1[10], 18[14]
Demetracopoulos 2015	395	62.3	41.2	3,4									5.1						3	4					19	119
Demetracopoulos 2019	80	66.5	42	4									8						1						2	
Di Iorio 2017	50	56	120	4	36	75				69			32	2					2							1514
Doets 2006	93	57.6	91.2	4,2	26.5	77					26.3	31.9	16				6		5		5	27	18	1	7	7[5], 3[20]
Eckers 2017	17	43	115.2	2,3,4		81					16	26	17.6		1		3					2				5[8], 5[24], 2[26], 3[32], 1[1], 1[11]
Escudero 2020	67	61.5	35,4	4									3.0													2714
Esparragoza 2011	14	64	25.2	3	33	62			33,6	59,8			0							2		2				
Faber 2018	52	70	50.4	3		85							6	1			2		1			3			3	
Gaudot 2014	56	64	24	3	34.5	87.5					23.5	31.5	1.5				1			1		8			2	1[2], 1[21], 6[13], 9[14]
Giannini 2010	51	62	29.7	4	38.5	79							3	1							1	1			3	
Giannini 2011	158	60.5	17.7	3	36.3	79					16.1	24.6	1.3	4		1					1	3	2		4	
Giannini 2017	76	62	78	4	37.4	78.9					16.1	24.6	1.3	3		1			1			2			3	
Gramlich 2018	60	56	59	3		55.2							42			3										12[14], 2[38]
Gross 2015	105	59.6	37.5	3,4	42.8	81.1	6.5	1.4	63.9	64.8			3.8			5	2				2				1	15,214
Gross 2016	455	61.8	44.2	3	40.7	77.7			48.0	71.2			3.1			38										
Gross 2017	762	62.7	13.2	3,4									23.1						8						16	219
Harston 2017	149	63.2	71	4	40.1	76.2	7.1	1.4	51.9	71.9			9.4			21	7		4			1		4		4[5], 14[4], 1[19]
Heida 2017	404	65.1	*	*															1	2						1[33], 3[34], 2[35], 1[36]
Henricson 2010	93	57	42	3									10			7	3		4	3	2	5	1			314
Henricson 2015	324	*	*	2									53	10	19		62		14		17		2	1		
Henricson 2020	267	61	50.4	4	49	80							7.9						1	4		8	6			13
Hintermann 2004	122	56.4	18.9	3	40	85						39	6.6	1		2	4	4		1	11		1		4	21,113
Hobson 2009	123	64	48	4		79.3						19.4	14.6	2		1	1	3			1	4	9	7	12	2[13], 1[6]
Hofmann 2016	81	64.3	62.4	3				1.7			35.5	39.9	2.5			12	4			3		5	6		7	25
Hsu 2015	59	57.2	35	1,2	44.1	87.3	8.1	1.6			29	38	7									1	2			15[5], 9[22]
Hurowitz 2007	62	54.5	39.6	2									34			1	8		3	1	3				9	5[5], 1[19], 1[23], 1[14]
Johnson-Lynn 2018	76	63	60	4									4	1			1			3		2	2	2		
Jung 2015	54	62.9	30.4	3,4	45.5	85.1	8.1	2.4			40.6	51.7	9.3			11			3	6	3	5			3	8[1], 2[24], 1[13], 1[14], 1[14]
Kamrad 2017	241	62	24	4									1.7													
Karantana 2010	52	62	80	2		78						23	16	1		2	1	1	1	3	5	5	3			2[6], 1[5], 1[14]
Kerkhoff 2016	134	59	90	2									22			7			3	7	9		5		1	9[14], 15[6], 2[1]
Kerkhoff 2016	64	63	40	4				2.0					5	2		4			2	1		1	1			2[2], 1[14], 1[1], 1[29], 1[5], 1[14], 1[19]
Knecht 2004	132	61	109	2								18	11.9			1	4		3	3	1					1[3], 1[4], 4[14], 2[6]
Kofoed 2004	58	59.1	112.8	1									27.3		3	2	5			1	2					1[5], 2[1], 1[13]
Koivu 2017	130	56.4	38.4	4							31	30	25.1				1		2			24			8	7[13],9[14], 5[1], 3[21]
Koo 2018	55	70	60	3		50							5.5	1			1		1							1[37], 1[14]
Kopp 2006	40	62.7	44.5	2	33.6	83.3				50			2.6				1				7	4		5	3	3[18], 1[3], 1[9]
Kraal 2013	93	57.6	121.2	4,2	26.5	80.4							20		3		9	1	2		7		1		1	2[13], 2[14], 1[6]
Lagaay 2010	95	59	*	2									1						1	1				7	8	3[5], 5[18], 12[14]

Study	N ankles	age (yrs)	Follow-up (mo)	TAA generation type	AOFAS		VAS		SF-36		ROM (°)		Failure (%)	Pain	Wear	Impinge-ment	Aseptic loosening	PAO	Infection		Malalign-ment/ deformity	Fracture		Insta-bility	Wound-problem	Other (n[type complication])
					Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op							Deep	Superf		Intra-op	Post-op			
Lampley 2016	642	61.9	35.6	3	40.4	78.8			48.4	73.6			3.1			53	11		6						26	3^{5}, 8^{14}
Lee 2008	50	57.35	3	3									2			1		3	1			5			6	3^{1}, 2^{2}
Lee 2020	195	64.4	90	3	51.6	86.4	6.9	1.8	44.0	60.9	32.2	34.9	4.9				4		1						1	17^{14}, 5^{5}, 11^{40}
Lewis 2015	249	63.2	34.8	1,2	40.2	79.2	7.2	1.4	48.8	71.5			8.4			2	10		6			9	5		16	1^{4}, 8^{5}, 7^{21}
Loewy 2019	139	61.5	105.6	4									15.2						4	8	8				4	2^{10}, 9^{6}
Mann 2011	84	61.4	109.2	2	42.7	81.9					32	39.2	14		0		2		3	2		4	3			3^{5}, 2^{14}, 1^{6},
McConnel 2017	140	63.5	57.8	3	42.8	78.3	6.8	1.0	48.4	71.4																
Morgan 2010	45	64.6	57.8	3		88.1							5.3				1						1		1	2^{5}, 10^{28}
Mosca 2020	73	61.7	31.2	4	45	88.9	8.2	1.2			16.7	35.6	2.6				1		5							399
Muir 2013	129	64	48	4									5.6	11		3			3		4		1			15
Myerson 2003	25	55.5	*	2																6		7			2	2^{1}, 2^{2}
Natens 2003	27	53.9	15.8	4			8.4	2.8			13.6	25.4	0			11				1		1	2		2	125
Nieuwe Weme 2015	90	56	60	2,4	36	85,2					32.8	40.3	16.6				8		1		4	11			7	10^{20}, 11^{14}
Noelle 2013	114	63	36	3	36.9	76							18.4	1		10	6		4	6		2				
Oliver 2016	245	65.5	38.9	*	41.1	84.6	6.7	1.8					3.1	5		10	3		4			1		1	13	111
Pangrazzi 2018	104	65	46	3									15.6			6	4		3			1	2		9	2^{7}, 2^{5}, 3^{1}
Pedersen 2014	100	58.5	64.7	4,3,4,2									12				9		1		5				1	26
Penner 2018	67	61.5	35.4	3					33.7	45.9			3				2		1							
Preis 2017	6	53.3	40.8	3	15.8	68.7	8.7	1.5	27	74	-5.8	35.7	0							1						
Preis 2017	14	51.4	69.4	3	23.0	76.6	8.5	1.3			9.9	28.4	7.1	2								1			2	
Queen 2013	103	*	*	3,4	32.9	81.4	5.4	0.9	39.7	73.9									1	1		1	1		13	45
Ramaskadhan 2014	112	58.5	24	4	29	77.2							1			2				2			7			113
Reuver 2010	59	57	36	3		75						33	11.9	2			5		3	3		3				
Richter 2020	1074	62	105.6	4									12		14		34		11					41		1214
Rodrigues-Pinto 2013	119	55.6	38.7	3	27.7	90.1					16.3	35.4	1.7						2		1	6		1	4	2^{20}, 1^{14}, 1^{13}
Rodriguez 2010	18	57.6	39.4	4	52.2	86.6							9.5			1		1			1					2214
Roselló 2014	18	58	37	3	31	83					27.5	34.4	0	1		3				1		2		1		
Rushing 2020	55	59	22	4									5.5	1					2	2		1	2		4	15
Saito 2018	64	60.8	24.5	4									4.7			5				1	1		1		1	45,114
Saltzman 2009	593	63.1	24	2			7.5	1.7					0	218					8	19		36	44		124	1^{19}, 130^{1}, 47^{26}, 33^{27}
San Giovanni 2006	31	61	99.6	2		81					17	23	6.6	1					1			10	4		4	17
Schenk 2011	218	56.8	42.3	3	50.9	82.2	7.4	2.0			25.2	33.1	13	19			4		3		2	5	5		5	1^{1}, 4^{5}
Schipper 2016	97	56.5	95.4	2,3									37.1			11	6		4	8	13		3	1	9	6^{14}, 4^{10}, 2^{18}, 4^{30}, 31^{5}, 9^{14}
Schuberth 2006	50	57.6	24.2	2									16						1	9	8	19				4^{5}, 6^{18}, 6^{7}, 1^{19}
Schuberth 2020	77	58.9	99.6	2,3,4,3,4	33	75	8	3			16.5	20.1	14.3			9			1	10		8	2			55
Schutte 2008	49	57.1	28	4							23	27	8.2			1	2		2		4	11	1		2	1^{1}, 1^{14}, 1^{7}
Schweitzer 2013	67	63	33.7	3	39.1	78.7	7.0	1.5	41.4	74.5			4			4	3			3	3	2	1			1^{1}, 1^{3}, 3^{10},
Shi 2015	22	58	29.3	4,4,3,4	38.9	70.1	5.3	2.1	40.6	67.6			0	2								1			3	1^{1}, 1^{14}
Skytta 2010	489	55	38.4	3									17				23		4		5		1	23		36
Spirt 2004	306	53.5	33	2									20	4			22		8				3			14^{18}, 8^{19}, 1^{5}, 1^{26}
Sproule 2013	88	63.5	40	3	38.2	74.8							11.6	7		4	6	4	1	1	1	2	3		2	2^{5}, 1^{19}, 1^{24}, 3^{28}
Stewart 2017	106	61.9	81.1	3	43.4	79.4	7.0	1.2	45.1	69.8	16	26	4.2	2		9	2								1	2^{10}, 2^{20}, 1^{14}, 3^{31}
Strauss 2014	11	49	36	3	21.5	68	7.6	1.9			23.2	25	9.1						2							
Summers 2013	58	65	32	4	42.6	64.6							12			16	7	2		1		8	2	2		7^{1}, 1^{2}, 1^{9}
Sung 2014	103	63.2	31	3,4	45.8	80.3	8.4	3.5			37.9	39.5	4.9	1			1					10			1	1^{1}, 2^{2}, 2^{21}, 1^{13}
Tan 2016	19	63.7	18	4			7.5	2.2			21.4	51.5	0	2		1			1							
Tan 2018	41	59.4	29.4	4	35	72	7.0	3.0					9.7			14	2		1	1		2				
Tedder 2018	591	64.7	1	*															1	3						
Tenenbaum 2016	42	65	26.8	4	31.2	80.8	7.9	1.7			16.2	19.3	0													
Tiusanen 2020	104	60.7	43.6	4							30	33	2.9	18		3			3	9	4	2	1		1	8^{1},1^{18}, 3^{41}
Trajkovski 2013	72	63	34.7	3,4,4	27.6	81.5							8.3	1	1	5			2		5	1		1		1^{5}, 1^{20}, 1^{13}, 3^{28}, 2^{14}
Usuelli 2016	31	60.1	24	3	43.4	69.9	8.5	2.4				25.1	3.2	1					1			6				
Usuelli 2017	76	56	12	3	32.8	72.6	8.7	2.2																		
Usuelli 2019	89	53.2	12	4	33.8	88.5	8.1	1.4			15.8	42.3	1.1						1						2	
Valderrabano 2004	68	56.1	44.4	4	24.7	84.3		3.2					13		3	2	5			1	2					2^{1}, 1^{5}, 1^{13}
Wood 2000	13	60.7	86.4	4									14.3	3								1			1	
Wood 2003	200	59.6	46	4									7.3	7			14	1	1		1	9	10		28	1^{5}, 9^{28}, 1^{7}, 7^{24}
Wood 2008	200	*	88	4									19.7	6			25					9	10		5	1^{6}, 9^{28}, 1^{24}
Wood 2010	100	66	43	4			8.5	2.1					6.4	6		1			1		2	2	5		6	7^{28}, 5^{14}, 1^{5}, 1^{13}
Zafar 2020	322	60	144	2,3									32	3			34		7		6		3			7

1. Nerve injury, 2. Tendon injury or tendinitis, 3. Thromboembolic event, 4. Metallic component fracture, 5. Subsidence, 6. Polyethylene liner fracture, 7. Fixation failure or fracture non-union, 8. Per-operative cardiogenic shock, 9. Bleeding episode or vascular complication, 10. Tarsal tunnel syndrome, 11. Hematoma, 12. Plantar scab related to an analgesic popliteal nerve block, 13. Polyethylene liner displacement or (sub)luxation, 14. Bone cysts or osteolysis, 15. Synovial cysts, 16. Reflex sympathetic dystrophy, 17. Artery injury, 18. Syndesmosis non-union, 19. Amputation, 20. Arthritis or infection elsewhere, 21. Osteonecrosis, 22. Arthrofibrosis, 23. Failure of ingrowth prosthesis, 24. Migration, 25. Achilles tendinitis, 26. Soft tissue edema, 27. Bony changes, 28. Edge-loading, 29. Neurinoma, 30. Tendon adhesion. **** Denotes inconclusive or missing data.***

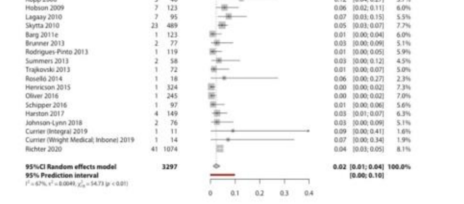

Figure 2: Forest plots of the included studies reporting on (a) Aseptic loosening, (b) deep infection, (c) intra-operative fracture, (d) impingement, (e) wound healing problems, (f) postoperative fracture, (g)malalignment or deformity, (h) component subsidence, (i) ongoing pain and (j) instability. Forest plots display the mean proportion of complications (a-j), 95% confidence interval and the relative weight of the individual studies. The diamond indicates the pooled estimate and its 95% confidence interval. The red bar indicates the 95% prediction interval. Prediction intervals illustrate the range of true effects expected to occur in similar studies in future settings.

% CI 0.03–0.06 in 443 events in 7988 ankles, 61 studies) and intra-operative fracture 0.06 (95 %CI 0.04–0.08 in 348 events in 6100 ankles, 64 studies).

There was considerable heterogeneity (Fig. 2). The 95 % prediction intervals (PIs) present heterogeneity in the same metric as the original effect size measure, illustrating the range of true effects that can be expected in future settings [16].

Results GRADE assessment: The confidence in the estimates from the meta-analyses according to the GRADE assessment concerning the complications was low to very low (Table 3) [14].

Table 3 Summary of reported complications and conclusion of GRADE assessment.

Complication	No. of studies	Number of TAA	Effect estimate (95 %CI)	Quality of evidence (GRADE)
Deep infection	77	12.963	0.02 (95 % CI 0.01–0.02)	⊕⊕⊙⊙ LOW
Instability	23	3.297	0.02 (95 %CI 0.01–0.04)	⊕⊙⊙⊙ VERY LOW
Postoperative fracture	56	6.388	0.03 (95 %CI 0.02–0.03)	⊕⊙⊙⊙ VERY LOW
Component subsidence	37	3.915	0.04 (95 %CI 0.02–0.06)	⊕⊙⊙⊙ VERY LOW
Ongoing pain	45	5.794	0.04 (95 %CI 0.03–0.06)	⊕⊙⊙⊙ VERY LOW
Wound healing problems	61	7.988	0.04 (95 %CI 0.03–0.06)	⊕⊕⊙⊙ LOW
Postoperative malalignment /deformity	38	4.936	0.04 (95 %CI 0.03–0.06)	⊕⊙⊙⊙ VERY LOW
Aseptic loosening	71	9.425	0.05 (CI 0.03–0.06)	⊕⊙⊙⊙ VERY LOW
Intra-operative fracture	64	6.100	0.06 (95 %CI 0.04–0.08)	⊕⊙⊙⊙ VERY LOW
Impingement	47	5.203	0.06 (95 %CI 0.04–0.08)	⊕⊕⊙⊙ LOW

GRADE Working Group grades of evidence [17].
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

4. Discussion

TAA is an emerging treatment and might be a valid alternative to ankle arthrodesis in the treatment of end-stage ankle arthroplasty.

The aim of this systematic review was to generate an overview of complications of TAA surgery and perform a meta-analysis on complications incidence.

The definition of a complication is debatable. Ricketts et al. emphasized that there need to be some clarity about the definition of a complication. The National Health Service defined a complication as any less than perfect outcome that increases the cost of treatment [18]. Sokol and Wilson defined a complication as any undesirable, unintended and direct result of the ankle replacement [9]. Henry et al. suggests using an algorithm detailing evaluation and management of a painful total ankle replacement but does not propose to report pain as a complication. Therefore, it could be suggested to report this in further research as a complication as it is an unintended, undesirable result of its initial treatment [19]. McKenna et al. defined failure as removal of either the tibial or talar component or both components with subsequent placement of an antibiotic spacer, reimplantation of metal components, conversion to an arthrodesis,

or amputation [10]. In our meta-analysis we only reported complications inherent to the ankle replacement.

In our meta-analysis the most occurred complications in ankle replacements were intra-operative fracture 0.06 (95 %CI 0.04–0.08) (GRADE Very low) and impingement 0.06 (95 % CI 0.04–0.08) (GRADE low) respectively. Clough et al. reported a rate of intraoperative fractures of 9.7 % of the medial malleoli and 1.4 % of the lateral malleoli [20]. Most intra-operative fractures are iatrogenic, associated with inadequate exposure by the jig itself or size of the resection guide, together with inadvertent use of the saw blade [21].

Our meta-analysis shows a rate of intra-operative fractures of 5.6 % (range 0–40 %); 4.9 % medial malleoli and 1.7 % lateral malleoli.

Only seventy-seven percent of the intra-operative fractures were operated; 65.6 % of the medial malleoli and 60.3 % of the lateral malleoli. Therefore, the suggestion by Lazarides et al. that in all periprosthetic TAR fractures fixation is recommended seems debatable.

Another frequent complication in ankle replacement is impingement, also called gutter pain. The pain is derived from either soft-tissue or bony impingement in one of the gutters in ankle replacement. The largest study of impingement after TAA by Schuberth et al. reported that impingement can be caused by component design and sizing issues, subsidence and avascular necrosis, hypertrophic bone, and uncontrolled varus or valgus thrust. They performed prophylactic widening of the medial and lateral gutters to diminish the prevalence of impingement [22]. Najefi et al. changed their axial rotation of ankle, after their learning curve, by reducing the impingement occurrence to 1.9 %. CT scanning confirmed their internal rotation of the tibial component and medial impingement [23].

Nunley et al. noticed that the reoperation rate was higher in mobile-bearing total ankle replacements compared to fixed-bearing total ankle replacements to relieve impingement [24]. Our meta-analysis could not certify this hypothesis, because most included studies did not make a distribution of impingement between the different types of ankle replacement.

Glazebrook et al. proposed a classification system for complications of total ankle replacement based on clinical outcomes. In which they divided the complications in high-grade (deep infection, aseptic loosening, and implant failure), medium-grade (technical error, subsidence, and postoperative bone fracture) and low-grade (intra-op

bone fractures and wound healing problems) [8]. Simonson et al. stressed out that 16.2 % were unclassified [25]. The unclassified complications included nerve and tendon injuries and were not explicitly defined by Glazebrook et al. Gadd et al. simplified the complication system of Glazebrook to two types: high and low. They found it unlikely that intra-operative bone fractures and wound healing problems would lead to TAA failure [26]. While Lazarides et al. has proven that intra-operative talar fractures were related to a higher failure rate. Consensus in the literature is necessary and the use of a coding system, as reported by Glazebrook et al., and Vancouver foot and ankle WNS classification system could according to the authors be a vast improvement [8,27].

In our meta-analysis the population was very heterogeneous according to the indication for TAA and age of the patients. Spirit et al. mentioned that age was the only significant predictor of re-operation [6]. Additionally, the Swedish national register of 780 TAA's and as our Dutch national register of 810 TAA's showed a higher hazard ratio in older patients [17,28]. A limitation of the present systematic review is that because of the heterogeneity of the included studies no correlation between age and complications could be established. This finding is in contrast with Steck et al. who reported that patient selection, surgeon experience, implant features, and prosthetic device selection all could influence the incidence of complications [29].

While that there are several reports showing that TAA has a higher complication rate than arthrodesis [30,31], the meta-analyses of Fanelli et al. and Li et al. showed no difference in complications and reoperation rate between TAA and arthrodesis [32,33]. Future research needs to identify which risk factors cause complications, reoperations, and failure, and therefore could lower patient satisfaction.

As a result of the high variable of the definition of a low- and high-level center across the studies, we could not discriminate between the occurrence rate of complications in high and low volume centers. Zaidi et al. found in the NJR database that early revision rates are significantly higher in low volume centers, while this was contrasted with a Norwegian registry study that examined 257 TARs and found no difference in survival by unit volume [34,35]. This is also confirmed by our study of the Dutch national registry which could not find a difference in high and low volume centers [28]. However, whether this relationship could be assessed at surgeon volume instead of center volume, as suggested by Baker et al., remains to be proven [36].

As for all systematic reviews, this study is limited by the quality of evidence available. In most meta-analyses of reported complications, the evidence according to GRADE working group methodology was graded as low to very low. Apparently, there is a higher level of evidence concerning complications in TAA according to our meta-analysis. Nonetheless, it was not possible to draw any conclusions on these factors which influence the complication rates. In addition, we could not account for the assumed abbreviated learning curve period of current-generation TAR systems as opposed to older generations that likely involved a higher incidence of various complications during the surgeon learning curve period.

Furthermore, only studies written in English or Dutch were included in this systematic review which could be a potential limitation of this study.

Moreover, considerable variation was identified between studies in (the choice of) the complications reported and in their definitions.

In addition, this systematic review and meta-analysis showed considerable heterogeneity. To account for the encountered heterogeneity, a random effects model was used, especially the range in age, type of prosthesis and aetiology as indication for TAA differs greatly across studies.

These factors might be of importance in determining which patient subgroups benefit the most from this treatment and could steer the potential benefit of more stringent patient selection.

5. Conclusion

TAA is a proven effective procedure to relief pain and preserve function in end-stage ankle arthritis. The complications rate of TAA is highly variable across studies. The evidence according to GRADE working group methodology was graded as low to very low. In this study multiple factors, such as the surgeon’s experience, patient’s specific health factors and activity pattern, that could be additional determinants of TAA outcome, were not assessed. Awareness of these complications which occur in TAA is necessary, to achieve a decrease in complication rates in TAA surgery. Further research should focus on a more thorough patient selection to preserve the functional outcome improvements while reducing the complication and revision rates to increase long-term clinical survival.

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Supplementary information:

Appendix 1. Search strategy
Last search was performed on 31 December 2020

PubMed
(((((((replacement, total ankle[MeSH Terms])) OR (ankle replacement[Title/Abstract])) OR (ankle arthroplasty[Title/Abstract])) OR (ankle joint replacement[Title/Abstract])) OR (ankle prosthesis[Title/Abstract])) OR (ankle prostheses[Title/Abstract])) AND ((((((cohort study[MeSH Terms])) OR (cohort[Title/Abstract])) OR (prospective[Title/Abstract])) OR (retrospective[Title/Abstract])) OR (((((randomized controlled trial[MeSH Terms])) OR (RCT[Title/Abstract])) OR (randomized controlled trial[Title/Abstract])) OR (clinical trial[Title/Abstract])) OR ((case study[MeSH Terms]) OR (case study[Title/Abstract]) OR (case report[Title/Abstract])))

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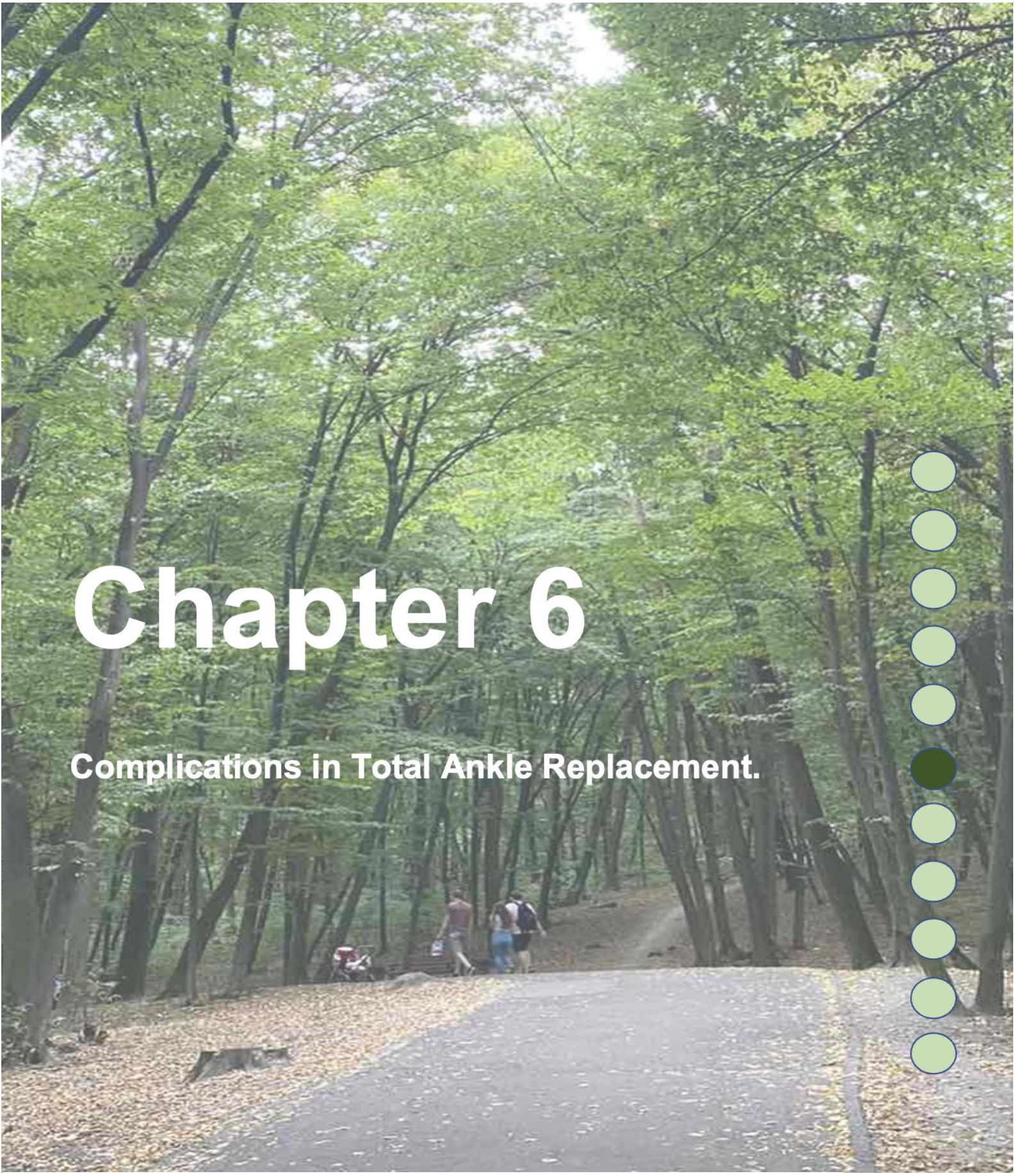

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KEYWORDS

• Total ankle replacement • Complications • Risk factors • Patient selection

KEY POINTS

- TARVA study shows no superiority between ankle arthrodesis and total ankle replacement.
- Defining complication is necessary to have accurate registration of complications.
- Complications with highest reported pooled incidence were intraoperative fracture 6% (95% CI 4%–8%) (GRADE very low) and impingement 6% (95% CI 4%–8%) (GRADE low), respectively.
- The risk of complications is much higher during the learning curve of a total ankle replacement.
- Lucency or cyst formation around the talar component was observed more frequently in mobile-bearing total ankle replacements.

INTRODUCTION

The debate between ankle arthrodesis and total ankle replacement for patients with end-stage arthritis of the ankle joint is an ongoing topic in orthopedic surgery.

Ankle arthrodesis, or fusion, has been the traditional treatment for ankle arthritis. It involves fusing the bones of the ankle joint together, eliminating the joint and creating a solid bony union. Arthrodesis is effective in reducing pain in the ankle, but it results in a loss of ankle motion. This can increase the load on adjacent joints, such as the subtalar joint, which may lead to accelerated degeneration and arthritis in those joints over time [1–3].

Total ankle arthroplasty, on the other hand, involves replacing the arthritic ankle joint with a prosthetic implant. This allows for preservation of some degree of ankle motion and potentially more normal gait patterns compared with ankle fusion [4]. Total ankle replacement aims to provide pain relief while maintaining or restoring joint function.

The total ankle replacement versus ankle arthrodesis (TARVA) study, which compared total ankle replacement to ankle fusion, did not find clear superiority of either procedure.

However, a post-hoc analysis of the study showed that the fixed-bearing total ankle replacement resulted in significantly lower Manchester-Oxford Foot and Ankle Questionnaire (MOXFQ) scores compared with ankle arthrodesis and mobile-bearing total ankle replacement at 52 weeks [5]. This suggests that fixed-bearing total ankle replacement may provide better functional outcomes in the short term.

It is important to note that the TARVA study had a relatively short follow-up period of 1 year, which may limit the ability to assess long-term outcomes and complications of the procedures. Long-term studies with extended follow-up are needed to evaluate the durability and effectiveness of both ankle arthrodesis and total ankle arthroplasty.

Ultimately, the choice between ankle arthrodesis and total ankle arthroplasty depends on various factors, including the patient's age, activity level, overall health, severity of arthritis, and surgeon expertise. It is crucial for patients to have a thorough discussion with their orthopedic surgeon to understand the potential risks, benefits, and expected outcomes of each procedure before making a decision.

Defining What Is a Complication?

The definition of a complication is debatable. Ricketts and colleagues emphasized that there needs to be some clarity about the definition of a complication. The National

Health Service defined a complication as any less than perfect outcome that increases the cost of treatment [6]. Sokol and Wilson defined a complication as any undesirable, unintended, and direct result of the ankle replacement [7].

According to Mahmoud and colleagues' study, adverse events related to total ankle replacement are defined as unintended injuries or complications resulting from medical management that cause measurable disability, prolonged hospital stay, or even death [8]. It is important to note that not all adverse events are reported as complications, such as delayed wound healing. They found that 8.33% of the 648 reports in the Manufacturer and User Facility Device Experience database were not able to ascertain the specific complication or adverse event.

On the other hand, Van der Griend and colleagues emphasize the importance of distinguishing complications that require reoperation, not only in terms of numbers but also types [9]. This suggests that not all complications may necessitate reoperation, and it is crucial to understand the specific complications that lead to subsequent surgical interventions.

Glazebrook and colleagues proposed a more detailed classification based on the chance of failure [10]

Low grade: Very unlikely to cause TAA failure

1. Intraoperative bone fracture
2. Wound healing problems

Medium grade: Leads to failure less than 50% of the time

1. Technical error
2. Subsidence
3. Postoperative bone fracture

High grade: Leads to failure greater than 50% of the time

1. Deep infection
2. Aseptic loosening
3. Implant failure

By categorizing adverse events and complications and understanding the ones that require reoperation, healthcare professionals and researchers can gain a better understanding of the risks and outcomes associated with total ankle replacement.

This information can ultimately contribute to improved management and decision-making related to this procedure.

Which Complications Can Occur in Total Ankle Replacement Surgery

Pubmed search found six English-written meta-analyses, which solely orientated on complications in total ankle replacement. In our own meta-analysis, we have reported the 10 most reported complications according the classification by Glazebrook: deep infection 2% (95% CI 1%–2% in 221 events in 12,963 ankles, 77 studies), aseptic loosening 5% (95% CI 3%–6% in 486 events in 9425 ankles), instability 2% (95% CI 1%–4% in 103 events in 3297 ankles, 23 studies), postoperative fracture 3% (95% CI 2%–3% in 437 events in 6388 ankles, 56 studies), component subsidence 4% (95% CI 2%–6% in 154 events in 3915 ankles, 37 studies), ongoing pain 4% (95% CI 3%–6% in 396 events in 5794 ankles, 45 studies), postoperative malalignment or deformity 4% (95% CI 3%–6% in180 events in 4936 ankles, 38 studies, 71 studies), impingement 6% (95% CI 4%–8% in 333 events in 5203 ankles, 47 studies), wound healing problems 4% (95% CI 3%–6% in 443 events in 7988 ankles, 61 studies), and intraoperative fracture 6% (95% CI 4%–8% in 348 events in 6100 ankles, 64 studies) [11]. Complications with highest reported pooled incidence were intraoperative fracture 6% (95% CI 4%–8%) (GRADE very low) and impingement 6% (95% CI 4%–8%) (GRADE low), respectively. Impingement could be prevented by prophylactic widening of the medial and lateral gutters to diminish the prevalence of impingement [12]. Najefi and colleagues suggests that impingement could be caused by component malrotation [13].

Most intraoperative fractures are iatrogenic, associated with inadequate exposure by the jig itself or size of the resection guide, together with inadvertent use of the saw blade [14]. Lazarides and colleagues suggest that all periprosthetic total ankle replacement fractures need to fixate [15].

Jennison and colleagues reported a meta-analysis exclusively on thromboembolic events in total ankle replacements [16]. The incidence of reported postoperative DVT was 0.07% (95% CI 0.001%–0.59% in 81 events in 30,829 ankles, 18 studies). The pooled risk of a patient suffering a postoperative pulmonary was 0.01% (95% CI 0.001%–0.03% in 55 events in 28,335 ankles, 8 studies).

Is It Justified to Perform Ankle Replacement Surgery When There Is a High Risk of Complications and a Failure Rate?

Fanelli and colleagues performed a meta-analysis where they compared 5448 total ankle replacements with 13,175 ankle arthrodesis with a mean follow-up of 42.3 ± 16.8 months [17]. No significant differences were found in complication rate between total ankle replacement and ankle arthrodesis (OR 0.936, 95% CI 0.826–1.060; I2 5 87.44). Patients undergoing a total ankle replacement did not have a higher risk of reoperation for all causes compared with patients having an ankle arthrodesis (OR 1.720, 95% CI 0.892–3.316; I2 5 77.65).

Goldberg and colleagues performed a randomized clinical trial comparing the results of the total ankle replacement and ankle arthrodesis group [5]. The total ankle replacement group had a higher incidence of wound healing complications (13.8% compared with 5.5% in the ankle arthrodesis group). In addition, nerve injuries were more prevalent in the total ankle replacement group compared with the ankle arthrodesis group (4.3% vs <1%). On the other hand, thromboembolic events (such as blood clots) were less common in the total ankle replacement group (3%) compared with the ankle arthrodesis group (5%). It is clear that nonunions only occurred in the ankle arthrodesis group (11.3%). Nonetheless, there was no significant difference found in the improved MOXFQ-W/S scores between the total ankle replacement group and Complications in Total Ankle Replacement the ankle arthrodesis group at 52 weeks postoperatively. A post-hoc analysis showed better outcomes in the fixed-bearing total ankle replacement compared with the ankle arthrodesis at 52 weeks of follow-up.

How Can We Minimize the Risk of Complications?

While reporting our results with the CCI total ankle replacement system, we noted that all our perioperative complications in our first 30 ankle replacements [18]. Schimmel and colleagues advised in their article that stricter patient selection for total ankle replacement especially during the first 50 total ankle replacements [19]. During the learning curve period, careful surgical indications and surgeries are desired. A meta-analysis of 25 articles by Simonson and colleagues reports the risk of complications during the learning curve of a total ankle replacement [20]. A total of 1085 complications occurred during their learning curve in 2453 total ankle replacements, yielding an overall incidence of complications of 44.2%. In addition, Kurokawa and

colleagues advised that involving experienced surgeons as assistants can lead to favorable results, even when the primary surgeon lacks experience [21]. This further supports the notion that the involvement of experienced surgeons during the learning curve can help mitigate complications and improve outcomes.

Albright and colleagues found in their meta-analysis that inpatient surgery had a fivefold higher risk of short-term complications compared with outpatient surgery [22]. On the other hand, Tedder and colleagues reported that their inpatient population was significantly older, had longer operative times, and higher rates of diabetes. Nonetheless, it could suggest that a healthy patient without comorbidity can be treated outpatient for total ankle replacement [23].

Are There Implant-Related Factors at Risk for Complications?

The randomized clinical trial by Goldberg and colleagues showed with a post-hoc analysis that the fixed-bearing total ankle replacement resulted in significantly lower MOXFQ scores compared with ankle arthrodesis and mobile-bearing total ankle replacement at 52 weeks [5]. Nunley and colleagues performed a randomized clinical trial comparing the outcomes between mobile- and fixed-bearing total ankle replacement with an average follow-up of 4.5 years [24]. Visual analogue scale (VAS), 36 item short form health survey (SF-36), foot and ankle disability index (FADI), short musculoskeletal function assessment (SMFA), and American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot scores demonstrated no statistically significant differences between the mobile bearing- and fixed-bearing total ankle replacement cohorts. Although lucency or cyst around the talar component was observed more frequently in the mobile bearing group (P 5 .01). Malalignment occurred also more significantly in the mobile-bearing group as well for the tibial as the talar component. Reoperations were also performed more often in the mobile bearing group, with most procedures being to relieve impingement or treat cysts. Arcângelo and colleagues confirmed similar results in their meta-analysis that nonanatomic, mobile-bearing, hydroxyapatite-coated and non-tibial-stemmed total ankle replacements were positively associated with more periprosthetic bone cysts (430 developed periprosthetic cystic osteolysis in 2430 total ankle replacements in 21 articles) [25].

Are There Patient-Related Factors at Risk for Complications?

Most articles relate the patient-related factors to failures instead of complications. So, the Swedish register, there was a significantly higher risk of failure in case of patients (especially women) younger than 60 years of age with osteoarthritis or post-traumatic arthritis [26]. Our own Dutch Arthroplasty Register study showed that patients with prior osteochondral defect (OCD) surgery seem to have a higher risk for implant failure and a higher body mass index (BMI) and a lower age were also determined as a risk factor for implant failure [27].

Althoff and colleagues performed a cohort study of 6977 patients. 294 patients (4%) had the diagnosis of, or had undergone a procedure for, periprosthetic joint infection. Risk factors found for periprosthetic joint infection included age less than 65 years (OR 1.44; P 5 .036), body mass index less than 19 kg/m2 (OR 3.35; P 5 .013), body mass index greater than 30 kg/m 2 (OR 1.49; P 5 .034), tobacco use (OR 1.59; P 5 .002), diabetes mellitus (OR 1.36; P 5 .017), inflammatory arthritis (OR 2.38; P < .0001), peripheral vascular disease (OR 1.64; P < .0001), chronic lung disease (OR 1.37; P 5 .022), and hypothyroidism (OR 1.32; P 5 .022). Most reported patient-related risk factors for complications were concerning periprosthetic joint infection and wound problems [28].

Recently, Lewis and colleagues propose a five-factor-modified frailty index as a predictor of complications following total ankle replacement [29]. The modified 5-item frailty index (mFI-5) is composed of five risk factors: history of diabetes mellitus, history of hypertension, history of congestive heart failure (with an exacerbation within 30 days before surgery), history of severe chronic obstructive pulmonary disease (COPD) or current pneumonia, and nonindependent functional status (requiring some or complete assistance with activities of daily living).

Patients with an mFI-5 score of 0 had a wound complication rate of 0.24%. In comparison, patients with an mFI-5 score of ≥2 had a higher wound complication rate of 1.55%. Patients with an mFI-5 score of 0 had a complication rate of 5.24%, whereas those with an mFI-5 score of ≥2 had a significantly higher complication rate of 19.38%. This suggests that patients with higher frailty scores are more likely to experience complications.

SUMMARY

Total ankle replacement is a proven effective procedure to relief pain and to preserve function in end-stage ankle arthritis. The complications rate of total ankle replacement

is highly variable across studies. Multiple factors, such as the surgeon's experience, patient's specific health factors, and activity pattern, could be additional determinants as a risk factor for complications in total ankle replacement. Awareness of these complications which occur in total ankle replacement is necessary, to achieve a decrease in complication rates in total ankle replacement surgery. Further research should focus on a more thorough patient selection to reducing the complication of total ankle replacements.

CLINICS CARE POINTS

- Intraoperative fracture and impingements are the most reported complications in total ankle replacement.
- Rotation of the component could be a reason for impingement.
- A more thorough patient selection is necessary to reduce he complication rate of total ankle replacements.

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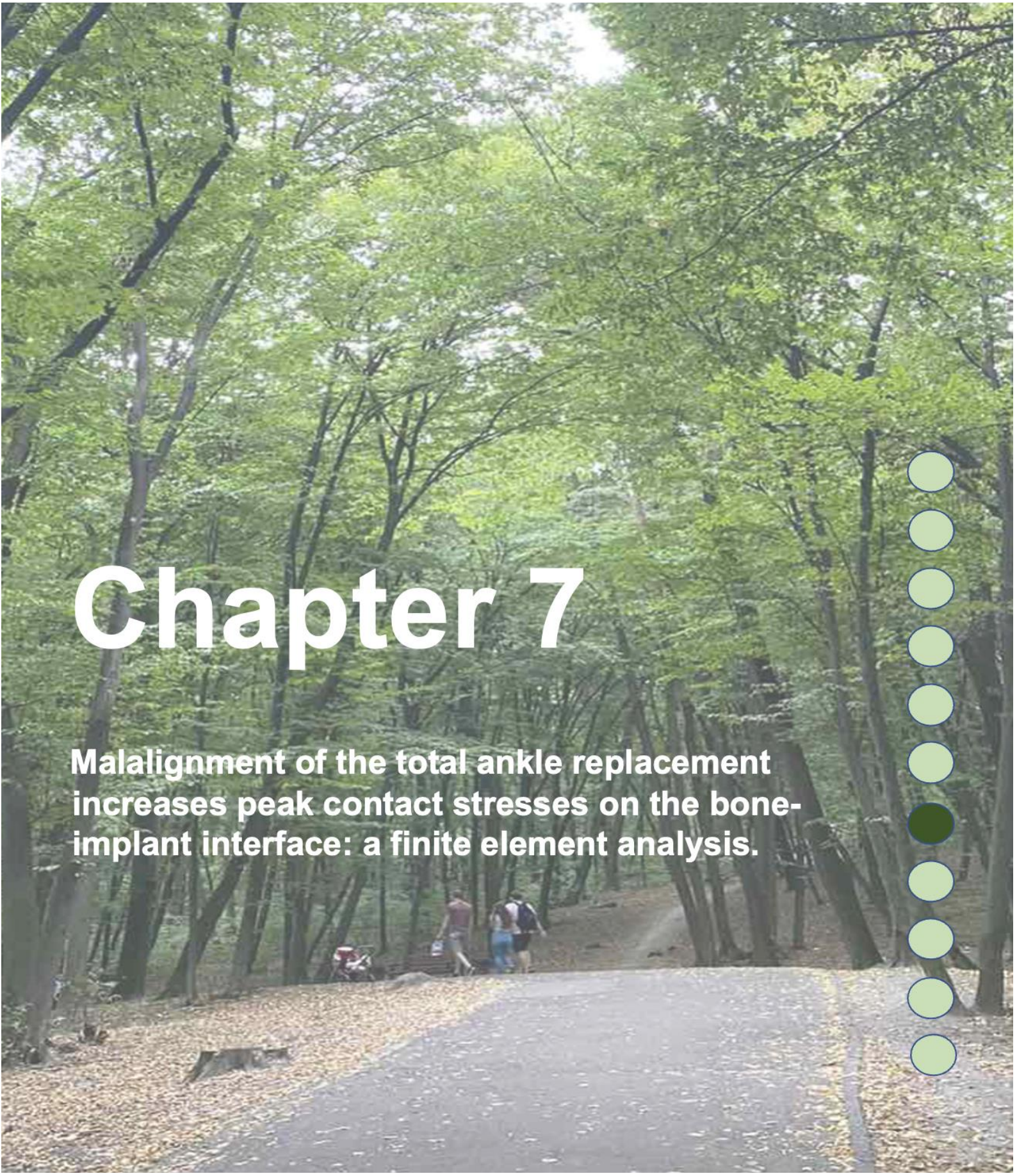

Van Hoogstraten SWG, Hermus JPS, Loenen ACY, Arts JJ, van Rietbergen B.

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Abstract

Introduction: Malalignment of the Total Ankle Replacement (TAR) has often been postulated as the main reason for the high incidence of TAR failure. As the ankle joint has a small contact area, stresses are typically high, and malalignment may lead to non-homogeneous stress distributions, including stress peaks that may initiate failure. This study aims to elucidate the effect of TAR malalignment on the contact stresses on the bone-implant interface, thereby gaining more understanding of the potential role of malalignment in TAR failure.

Methods: Finite Element (FE) models of the neutrally aligned as well as malaligned CCI (Ceramic Coated Implant) Evolution TAR implant (Van Straten Medical) were developed. The CCI components were virtually inserted in a generic three-dimensional (3D) reconstruction of the tibia and talus. The tibial and talar TAR components were placed in neutral alignment and in 5° and 10° varus, valgus, anterior and posterior malalignment. Loading conditions of the terminal stance phase of the gait cycle were applied. Peak contact pressure and shear stress at the bone-implant interface were simulated and stress distributions on the bone-implant interface were visualized.

Results: In the neutral position, a peak contact pressure and shear stress of respectively 98.4 MPa and 31.9 MPa were found on the tibial bone-implant interface. For the talar bone-implant interface, this was respectively 68.2 MPa and 39.0 MPa. TAR malalignment increases peak contact pressure and shear stress on the bone-implant interface. The highest peak contact pressure of 177 MPa was found for the 10° valgus malaligned tibial component, and the highest shear stress of 98.5 MPa was found for the 10° posterior malaligned talar model. High contact stresses were mainly located at the edges of the bone-implant interface and the fixation pegs of the talar component.

Conclusions: The current study demonstrates that TAR malalignment leads to increased peak stresses. High peak stresses could contribute to bone damage and subsequently reduced implant fixation, micromotion, and loosening.
Further research is needed to investigate the relationship between increased contact stresses at the bone-implant interface and TAR failure.

Keywords: Total ankle replacement, Malalignment, Finite element modeling, Contact stress, Bone-implant interface

Introduction

An increasingly used treatment for end-stage ankle osteoarthritis is total ankle replacement (TAR). With TAR, a prosthetic implant between the tibia and talus replaces the ankle joint, maintaining tibiotalar articulation. Over the past decade, TAR has been increasingly used in the clinic and has challenged ankle arthrodesis as the treatment of choice for end-stage ankle osteoarthritis as patient satisfaction, pain relief, and ankle function continued improving [1]. Unfortunately, primary concerns for TAR are still present including longevity and rate of revision. A study by Spirt et al. showed that 28% of the patients that received a total ankle arthroplasty, underwent at least one reoperation due to complications [2].

Subsidence and aseptic loosening are the most common clinical reasons for TAR failure, as they occur in 10.7 and 8.7% of all patients with a TAR [3]. TAR has unsatisfying long-term outcomes, with a survival rate of 70% after 10 years and less than 50% after 14 years [4–6]. Despite the development and improvement of four generations of TAR designs, the potential risk of persisting pain and low functional outcome after TAR surgery remains high.

Malalignment has been often postulated as one of the main reasons for the high failure rate of TAR. The surgical procedure of a TAR is challenging, and it is especially complicated to achieve the correct alignment of the TAR components. Also, the survival rate of the TAR increases significantly with increasing surgical experience, showing the presence of a significant learning curve [7, 8]. Furthermore, restoring alignment in patients with a pre-operative deformity of the ankle is even more challenging. Proper alignment is essential for a successful TAR surgery as a slight degree of malalignment has been claimed to result in higher failure rates [9–12].

The ankle joint has a contact area approximately three times smaller than that of the hip or knee joint, but it experiences higher forces [13]. Peak forces of 2.5-, 4-, and 6-times body weight were found for respectively the knee, hip, and ankle [14]. Together, the small contact area and large forces result in high contact stresses in the ankle joint [14]. The implant material, often cobalt-chrome-molybdenum (Co-Cr-Mo) alloys, is substantially stiffer than cortical and trabecular bone, so transmission of force

from the implant to the bone can give stress peaks on the bone-implant interface [15]. High stress peaks can contribute to bone damage and subsequently reduced implant fixation, micromotion, and loosening [16].

In several studies, Finite Element (FE) modeling has been used to investigate the biomechanical consequences of TAR malalignment and the role of these biomechanical parameters in TAR failure [17–21]. FE models of different TAR designs have been developed and showed that TAR malalignment can result in increased contact pressure on the polyethylene liner, leading to wear particles and implant loosening [21]. It was also found that malalignment increases micromotion, which can lead to improper fixation of the TAR [20]. Furthermore, tibial bone strains alter upon malalignment of the TAR, leading to local overloading and stress shielding which can contribute to implant loosening [18].

The effect of TAR malalignment on the contact stresses on the bone-implant interface, however, has not been investigated using FE modeling. Therefore, it remains unclear to what extent malalignment of the TAR affects the stresses at the bone-implant interface. Gaining insight into the contact stresses on the bone-implant interface in neutrally and malaligned TARs might lead to a better understanding of the high failure rate of TAR. Therefore, this study aims to elucidate the effect of TAR malalignment on the contact stresses on the bone- implant interface of a TAR, by developing a generic FE model of the neutrally and malaligned TAR and calculating the resulting contact stresses under physiological loading conditions.

Methods

Geometrical reconstructions

FE models of the neutrally aligned and malaligned CCI Evolution TAR [22] (Van Straten Medical, The Netherlands; Fig. 1) were created, by virtually inserting the tibial and talar CCI component in respectively a tibia and talus. The CCI Evolution TAR consists of a tibial and talar cobalt-chrome-molybdenum (Co-Cr-Mo) component and a polyethylene liner (Fig. 1). The Co-Cr-Mo components in contact with the bone were included in this study and the geometries of the standard-sized tibial and talar components of the CCI Evolution TAR design were obtained by three-dimensional (3D) scanning using the ATOS Scanport (Zebicon a/s; Billund). From 2010 to 2016, 65 CCI Evolution TAR implants were placed at Maastricht University Medical Centre.

A pre-operative CT scan with a slice thickness of 0.6 mm of a randomly selected,

Fig. 1 The CCI Evolution TAR implant (Van Straten Medical). The three components from top to bottom: tibial CoCrMo component, polyethylene liner, talar CoCrMo component

anonymized patient from this cohort (male, age 72 years) with a clinically well-performing TAR was used. The CT scan was obtained during clinical follow-up in the past and no additional interventions or radiographical assessments were needed for this retrospective study. This CT scan was used for virtual reconstruction of the tibia and talus. Using medical image processing software (MIMICS® version 21.0; Materialise NV, Leuven, Belgium), the tibia and talus of the left foot were segmented and 3D reconstructions were obtained. In MIMICS, the CCI components were virtually inserted in the tibia and talus, following surgical guidelines and with guidance from an orthopedic surgeon specialized in TAR surgery. The CCI was placed in neutral alignment, which is defined as perpendicular to the anatomical axis of the tibia measured from the tibial TAR plateau.

Besides the neutrally aligned implant, reconstructions of the malaligned TAR components were created. The tibial and talar TAR components in 5° and 10° varus, valgus, anterior, and posterior malalignment were modeled, as can be seen in Fig. 2. These are the malalignment cases measured and observed in the clinic [20, 21, 23, 24]. For the anterior-posterior malaligned implants, the sagittal angle deviated from the neutrally aligned CCI, where the anteriorly malaligned implant is in plantarflexion relatively to the foot and the opposite for the posterior malaligned implant. In total, 9 reconstructions were developed for both the tibial and talar component, resulting in a total of 18 models.

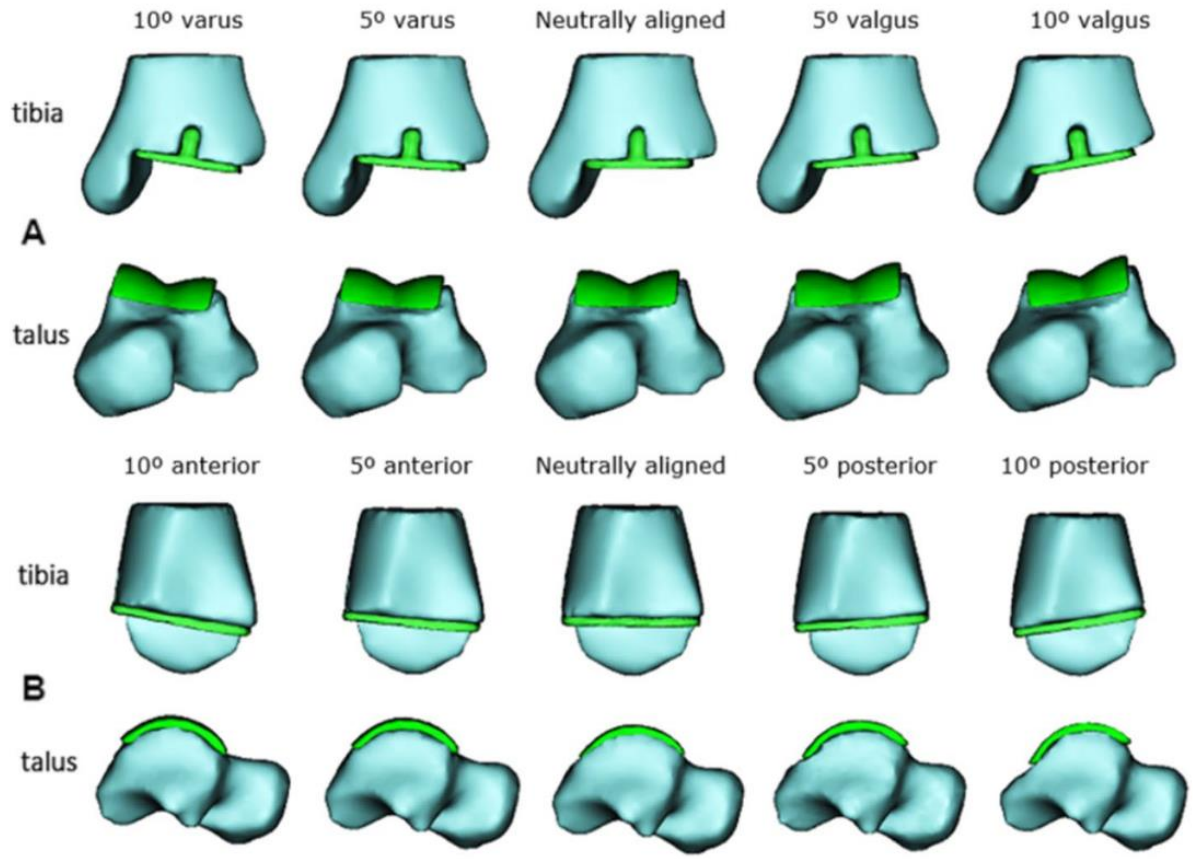

Fig. 2 Coronal and sagittal (mal) alignment of the CCI Evolution TAR

Material properties

All the materials were modeled as homogenous, isotropic, and linear elastic, with material properties as reported in Table 1. The cortical shell and the trabecular bone of the tibia and talus were assigned separate material properties. For the genericity of the model, the trabecular bone was modeled as a continuum.

Contact

To model the direct post-operative interaction after TAR surgery, a contact condition with a coefficient of friction of 0.5 at the bone-implant interface was chosen [31].

'Hard' linear contact with a penalty method and automatically calculated contact stiffness was used to simulate the contact behavior in the normal direction at the bone-implant interface. Small-sliding formulation with the surface-to-surface discretization method was used.

	Young's Modulus [MPa]	Poisson's ratio [–]
Co-Cr-Mo [25, 26]	$210 \cdot 10^3$	0.29
Cortical bone [27, 28]	$17 \cdot 10^3$	0.3
Trabecular bone [29, 30]	500	0.3

Table 1 Material properties

Boundary conditions and meshing

For the tibial models, the bottom of the distal plateau of the tibial TAR component was constrained in all directions. For the talar models, the distal part of the talus was fixed to all motions (Fig. 3). Using medical image processing software (3-Matic® version 16.0; Materialise NV, Leuven, Belgium), automatic meshing was performed using 10-node tetrahedral elements (C3D10). A maxi- mum triangle edge length of 5 mm was chosen, with a denser meshing near the bone-implant interface using a maximum edge length of 1.5 mm. This edge length was assumed acceptable based on previous models [20, 32].

The models consisted of 55,000 to 64,000 nodes.

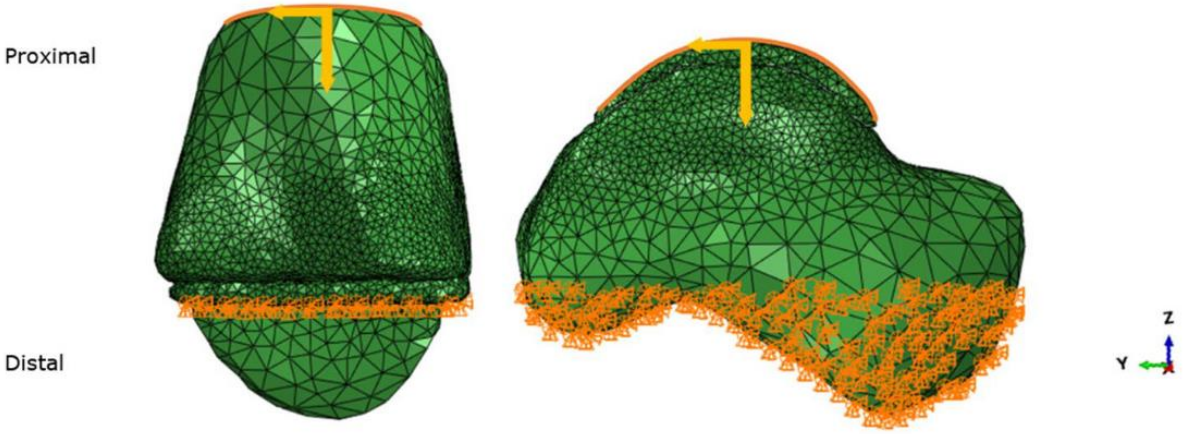

Fig. 3 Boundary and loading conditions of the neutral aligned tibial (left) and talar (right) TAR models. Load distributed along surface indicated by the orange line. The yellow arrows indicate the loading components

Loading

Loading was applied as a point force evenly distributed between the nodes of the proximal tibia and the proximal surface of the talar TAR component, for respectively the tibial and talar models. For all models, the bone-implant interface stresses were

investigated during the terminal stance, when the ankle joint is subjected to the highest axial reaction force during a normal gait cycle (5.2 times bodyweight). A bodyweight of 82 kg was assumed (corresponding to the patient from the CT scan) so an axial load of − 4183 N was applied through the tibial axis (z-axis). During terminal stance, however, bodyweight is not transmitted through the tibial axis but at a 15° angle in anterior direction from the tibial axis meaning a shear component is present. Therefore, a shear load of 1121 N was applied in the direction of the tibial plateau (y-axis) [19, 33–35].

Numerical method and outcome measures

The models were processed using Abaqus® Standard/ Implicit FE solver (ABAQUS CAE, ver. 2019, SIMULIA, Providence, RI, USA). The models had a runtime of approximately 21 hours, using a computer with a CPU Intel core Xeon X5550 2.6 GHz 4-cores and 20 GB RAM.

A customized MATLAB® script (version 2020, Math-Works Inc., Natick, MA, USA) was coded to extract output parameters from the output file from Abaqus and to obtain the peak contact stress on the bone-implant interface. Contact pressure and shear stress were obtained (CPRESS and CSHEAR in Abaqus). For the models showing the most indicative quantitative results, stress distribution plots were made. These images were created by plotting the bone-implant interface contact stresses on the TAR surfaces, as shown in Fig. 4.

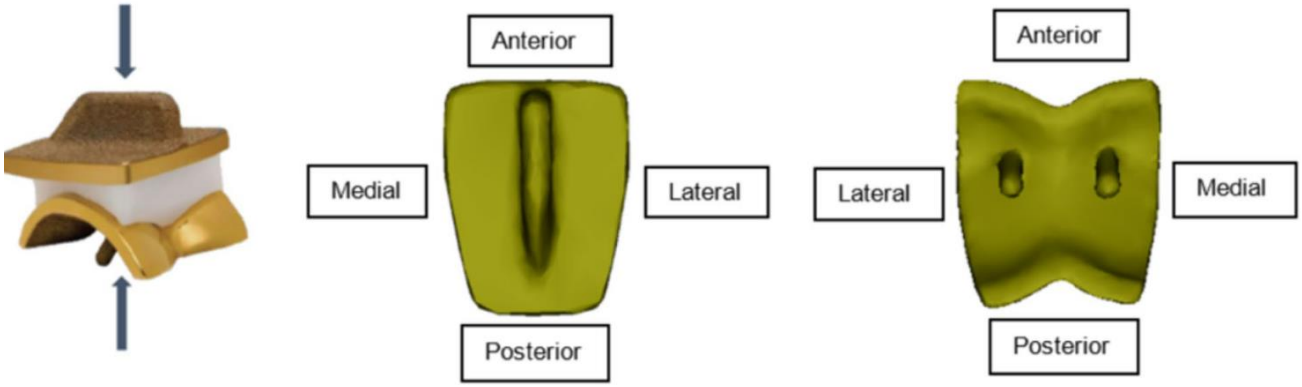

Fig. 4 Views of visualization for the stress distribution images

Results

Malalignment of the tibial TAR component

In Fig. 5, peak contact pressures and shear stresses of the malaligned and neutrally aligned tibial TAR models are plotted. For the neutrally aligned tibial TAR component,

a peak contact pressure of 98.4 MPa and a peak shear stress of 31.9 MPa is found.

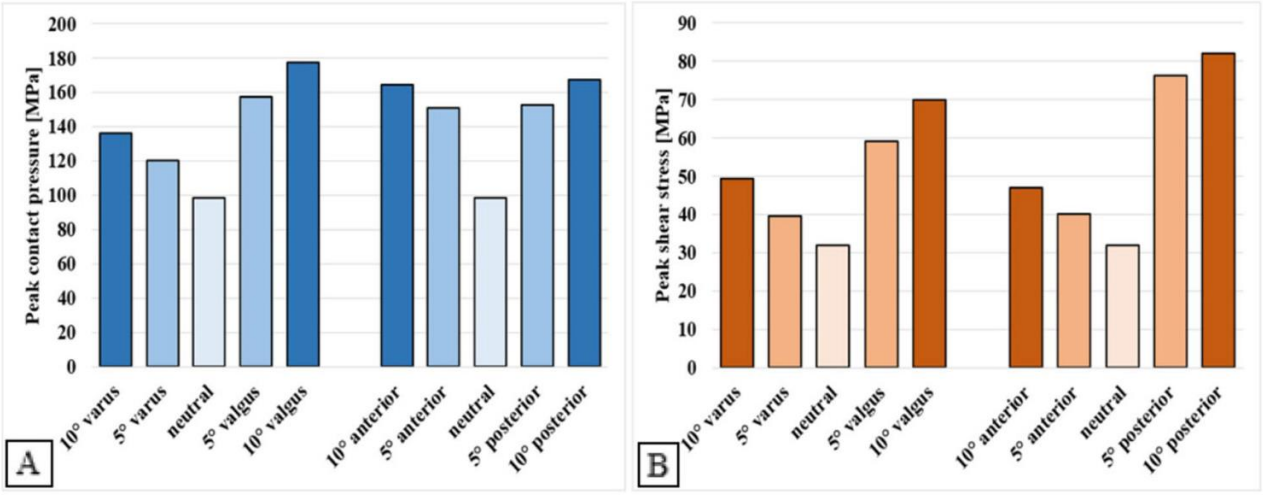

Fig. 5 Peak contact pressure (A) and shear stress (B) for the neutrally aligned and malaligned tibial TAR components

Peak contact stresses increase upon TAR malalignment, where valgus and posterior malalignment show the largest increases. A maximum peak contact pressure of 177 MPa was found for the 10° valgus malaligned tibial component and the highest shear stress found was 82.2 MPa for the 10° posterior malaligned tibial model. For both the tibial and talar models, stress distribution plots were made for the 10° posterior and valgus malaligned models, as the quantitative results of these models provide the most insights. Clear changes in shear stress distribution on the tibial interface are visible upon malalignment, as can be seen in Fig. 6. Shear stresses expectedly shift towards the medial and posterior side of the interface for respectively the valgus and posterior malaligned models.

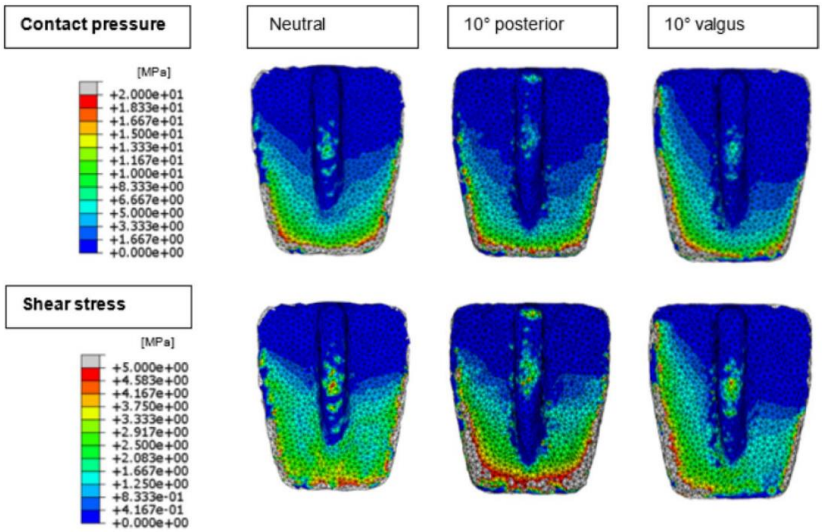

Fig. 6 Contact pressure and shear stress distribution images of the neutral, 10° posterior, and 10° valgus malaligned tibial models

Malalignment of the talar TAR component

Peak contact pressures and shear stresses on the talar bone-implant interface are plotted in Fig. 7.

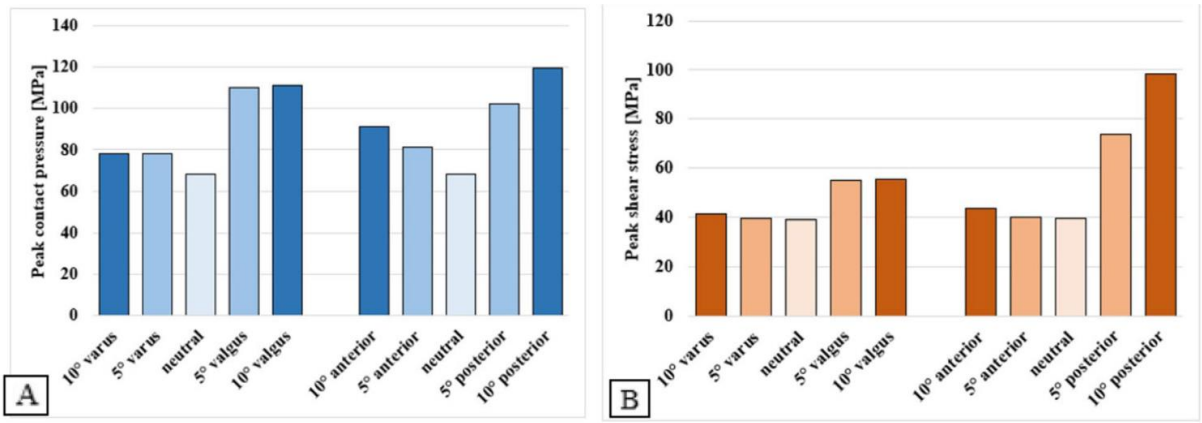

Fig. 7 Peak contact pressure (A) and shear stress (B) for the neutrally aligned and malaligned talar TAR components

In neutral alignment, a peak contact pressure of 68.2 MPa and a peak shear stress of 39.0 MPa were found. As with the tibial models, peak contact stresses increase upon TAR malalignment. Also corresponding to the tibial models, valgus and posterior malaligned TAR components showed the largest increase in contact stress. Both maximum peak contact pressure and shear stress were found for the 10° posterior model of respectively 120 MPa and 98.5 MPa. Peak shear stresses on the talar bone-implant interface show fewer changes upon TAR malalignment than observed for the tibial interface, except for the posteriorly malaligned models, where a large increase was seen in peak shear stress. Changes in stress distributions are visible in Fig. 8. Expected shifts in shear stress distribution towards the lateral and posterior side of the bone-implant interface are visible on the talar bone- implant interface, upon respectively valgus and posterior TAR malalignment. Contact pressure distributions show less pronounced changes upon TAR malalignment, compared to the tibial models.

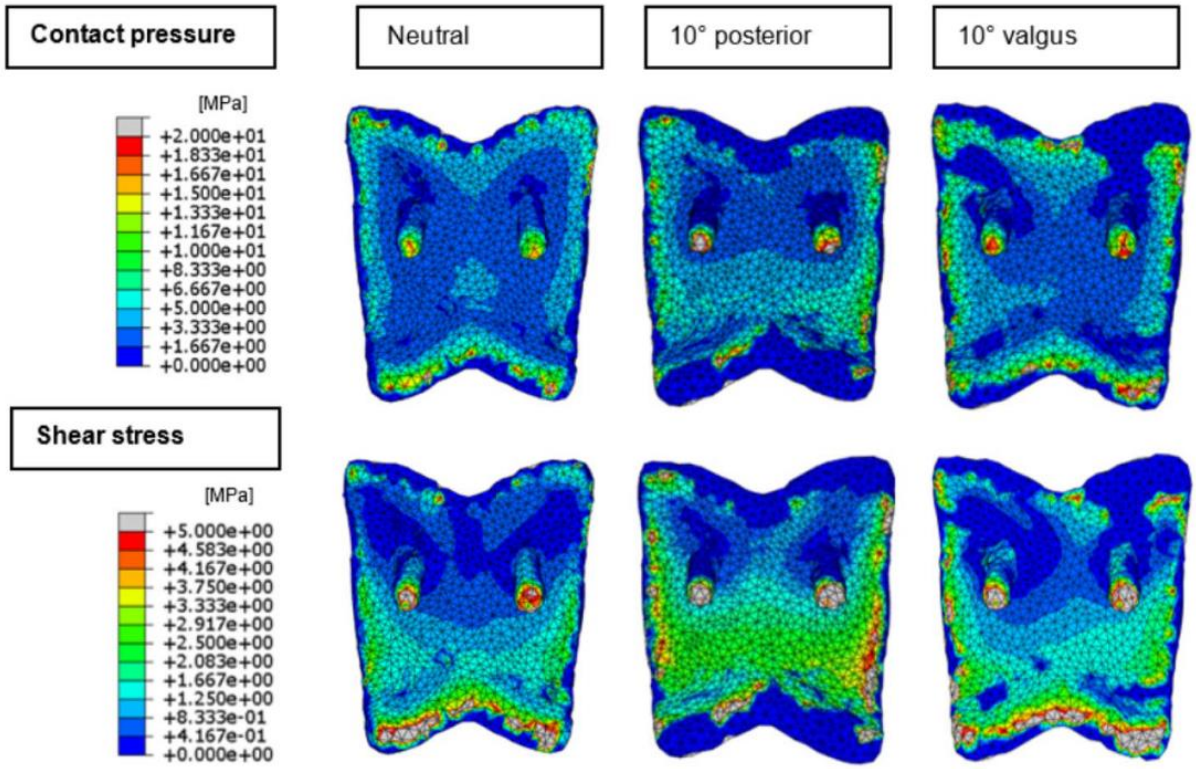

Fig. 8 Contact pressure and shear stress distribution images of the neutral, 10° posterior, and 10° valgus malaligned talar models

Discussion

The purpose of this study was to elucidate the effect of TAR malalignment on the contact stresses on the tibial and talar bone-implant interface. The results of this study show that TAR malalignment can substantially increase local peak stresses (by up to 158%) on the bone-implant interface and that proper positioning of the TAR thus is necessary to reduce contact stresses on the bone-implant interface. Peak contact pressures up to 177 MPa were found which are exceeding the ultimate yield point of trabecular bone, and thus presumably leads to bone damage [36]. Bone damage, in turn, can lead to implant loosening, subsidence, and subsequent TAR failure. Even though the generic character of the presented models cannot lead to clinical recommendations, it was shown that contact pressure on the bone-implant interface can be dangerously high and that contact stresses on the bone-implant interface are important parameters to include in future FE studies which evaluate the correlation between biomechanical load on the construct and the eventual clinical TAR performance.

The neutrally aligned TAR components showed lower contact stresses than the malaligned models. Similar results, although for other output parameters, were

obtained by other FE studies investigating the biomechanical consequences of TAR malalignment for other TAR designs [18, 20, 21]. Contact pressure on the poly-ethylene liner, micromotion, and the occurrence of strain shielding are lower when the TAR is placed in neutral alignment. In previous research, however, it was shown that large variation in results can be found when investigating different TAR designs [20, 32]. As every study models different implant types with varying loading regimes and boundary conditions, it is not trivial to make a direct comparison with previous literature.

The stress distribution images show that in neutrally aligned as well as malaligned TARs, contact pressures, and shear stresses are unequally divided over the bone-implant interface during terminal stance and that high stresses are present on the edges of the bone-implant interface and on the talar fixation pegs. Uneven distribution of loads can contribute to component subsidence, one of the most common complications of TAR failure, due to local overloading [37, 38]. Furthermore, the high stress peaks located on the talar fixation pegs, which serve as the anchor of the talar component resisting it from rotating on the talar surface, might result in fixation problems and subsidence of the talar component.

Valgus and posterior malalignment of the CCI Evolution TAR components showed the largest increase in contact stress on the bone-implant interface, higher than varus and anterior malalignment. Also, the tibial TAR component showed higher contact pressure peaks than the talar component. This is in accordance with Sopher et al., which reported higher micromotion and strain outputs for the tibial component than for the talar component [20]. Besides the cases of malalignment modeled in the current study, Sopher et al. showed that a malalignment with a gap between the implant and bone led to high micromotions. Therefore, in future studies, it might be interesting to assess the effect of a gap between the implant and the bone on the bone-implant interface stresses, as focal loading is expected due to a decrease in the contact area of the implant.

A main limitation of the presented study is the lack of experimental validation. A cadaver study of the differently aligned CCI Evolution TAR using for example the K-scan Joint Analysis System (TekScan Inc., Boston, MA), could be of great value and should be included in a future validation study. Some other limitations must be highlighted as well. Soft tissues, such as ligaments, were not considered in the model, but as these do not carry much load during the loading conditions applied in the

present model it is expected that this omission does not affect the results. Furthermore, the polyethylene liner was not taken into account in the presented FE models. Loading on the talar TAR component was applied by distributing a point force on the proximal talar TAR component surface, but loads will actually be transmitted through the moving polyethylene liner located in between the tibial and talar component.

This liner has a small surface, so stress distributions at the implant surface are expected to be more focused.

Nevertheless, as the implant is very stiff compared to the bone, this should not affect the results at the bone-implant interface. Furthermore, we only analyzed the direct post-operative case, where no bonding between bone and implant has taken place. After such bonding occurs, the stresses may be reduced. The results

presented here are thus more representative for early failure. Also, the amount of elements was limited due to computational resources and number of model variants. This limitation, however, was assumed acceptable based on previous models and the use of consistent element size throughout all model variants [20, 32]. Lastly, we focused solely on the terminal stance phase of the gait cycle since the highest axial load is present during this phase. The highest peak contact pressures are expected during this phase of the gait cycle, but analysis of the complete gait cycle might further elucidate the effect of TAR malalignment on the overall stress distributions on the bone-implant interface.

Conclusions

In conclusion, the presented results show that TAR malalignment leads to a considerable increase in peak contact stresses on the bone-implant interface, which may lead to bone damage and subsequent TAR loosening or subsidence. It was found that valgus and posterior malalignments induce the largest increase in peak stress for the CCI Evolution TAR design. We further elucidated the possible failure mechanism of the CCI Evolution TAR, and this study showed that contact stresses on the bone-implant interface are an important parameter to include when investigating TAR malalignment and performance.

Abbreviations

TAR : Total Ankle Replacement; FE: Finite Element; CT: Computed Tomography; 3D: three-dimensional; 2D: two-dimensional; CCI: Ceramic Coated Implant; Co-Cr-Mo: Cobalt-Chrome-Molybdenum.

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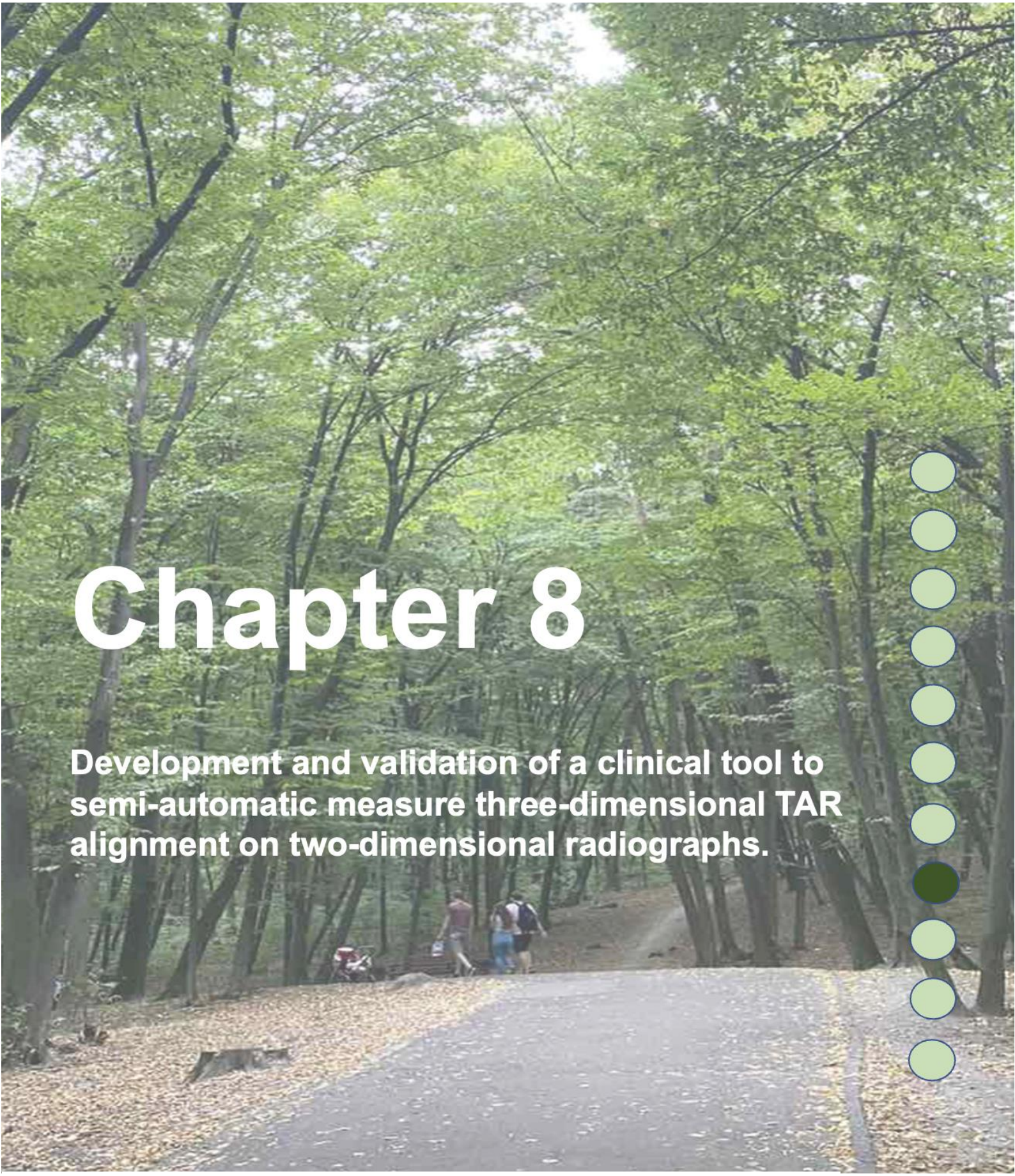

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Abstract

Background: Malalignment is often postulated as an important reason for the high failure rate of total ankle replacements (TARs). The correlation between TAR malalignment and clinical outcome, however, is not fully understood.
Improving and expanding radiographic TAR alignment measurements in the clinic might lead to a better insight into the correlation between malalignment and the clinical outcome. This study aims to develop and validate a tool to semi-automatic measure TAR alignment, and to improve alignment measurements on radiographs in the clinic.

Methods: A tool to semi-automatically measure TAR alignment on anteroposterior and lateral radiographs was developed in MATLAB. Using the principle of edge contouring and the perpendicular relationship between the anteroposterior and lateral radiographs, the exact configuration of the TAR components can be found. Two observers validated the tool by measuring TAR alignment of ten patients using the tool. The Intraclass Coefficient (ICC) was calculated to assess the reliability of the developed method. The results obtained by the tool were compared to clinical results during radiographic follow-up in the past, and the accuracy of both methods was calculated using three-dimensional CT data.

Results: The tool showed an accuracy of 76% compared to 71% for the method used during follow-up. ICC values were 0.94 ($p < 0.01$) and higher for both inter-and intra-observer reliability.

Conclusions: The tool presents a reproducible method to measure TAR alignment parameters. Three-dimensional alignment parameters are obtained from two dimensional radiographs, and as the tool can be applied to most TAR designs, it offers a valuable addition in the clinic and for research purposes.

Keywords: Total Ankle Replacement, Malalignment, Radiographic measurements, Subsidence, Migration

Background

The Total Ankle Replacement (TAR) has been increasingly used over the past years, as it has been shown to relieve pain while maintaining ankle function [1]. Despite the development of four generations of TAR designs, primary concerns regarding revision rates remain present. Studies reporting on the short-term outcome of TAR 3 years after surgery report a reoperation rate of up to 36%. After 14 years, only 46% of the TARs did not undergo revision surgery or conversion to arthrodesisand this high revision rate is of major concern [2–6]. Malalignment is an important predictor for the long-term outcome of TAR, and a very steep learning curve for TAR surgery is present as the functional outcome of the TAR increases significantly with increasing surgical experience [7–9]. Also, correcting pre-operative deformity of the ankle is extremely challenging, and proper alignment is the key to a successful TAR surgery [10–13].

After TAR surgery, patients undergo follow-up appointments regularly to monitor TAR performance.

During standard follow-up, TAR alignment is measured on an anteroposterior (AP) and lateral radiographs [14, 15]. Even though malalignment is often postulated as the main reason for TAR failure, a standard, and accurate TAR alignment measurement method lacks and measurable parameters on radiographs are limited. Only a few studies investigated the correlation between TAR alignment and clinical outcome, but different measurement methods were used, and varying output parameters were investigated [16–18]. No significant correlations between several TAR alignment parameters and the clinical outcome were found. Due to the inconsistency in methodology, comparison between the studies is difficult, and more importantly, the different TAR alignment measurement methods come with varying accuracy [19–21]. Furthermore, only little is known about TAR malalignment in the transverse plane, including relative axial alignment of the tibial and talar components. A study reported large inter-individual variability of axial rotation of the TAR components, which may impose an unknown contribution to TAR failure due to malalignment [22]. To gain more insight into the correlation between TAR malalignment and failure, large-scale measurements using a consistent and accurate method that is applicable in the clinic, allowing TAR alignment measurement on all rotational axes, are necessary.

In a previous study by Kitzen et al. (2020), a tool to measure three-dimensional (3D) parameters of a total disk replacement on two-dimensional (2D) spinal radiographs was developed [23, 24]. 3D alignment information of the total disk replacement could

be obtained and correlated to clinical outcomes. Such a tool, when adjusted to TAR application, would be valuable in the clinic as it would expand the set of measurable TAR alignment parameters on plain radiographs, as 3D alignment parameters would be available without the use of a CT scan, saving health care costs and reducing the radiation dose. Radiographic TAR alignment measurements are always restricted to measuring parameters in the coronal and sagittal plane, while rotation in the transverse plane might as well be an interesting parameter.

Such a semi-automated tool is expected to offer a more accurate method to measure TAR alignment. Therefore, the goal of this study was to develop a clinical tool to semi automatic measure TAR alignment on radiographs, using the framework developed by Kitzen et al. (2020) and to validate the results relative to measurements based on CT scans that are taken as the gold standard.

We compared the accuracy of this method compared to the alignment measurements that were performed using a standard manual method during follow-up. This tool is expected to expand TAR alignment measurements using radiographs and standardize research on correlating TAR malalignment to clinical outcomes. This will lead to a better insight into the role of malalignment in the failure mechanism of the TAR.

Methods

Patient selection

An anonymized cohort consisting of 61 patients that received the CCI Evolution TAR (Fig. 1) cohort at Maastricht University Medical Center was reviewed, and cohort demographics are shown in Table 1.

Fig. 1 The CCI Evolution TAR implant (Van Straten Medical). The three components from top to bottom: tibial CoCrMo component, polyethylene liner, talar CoCrMo component

To test the accuracy and reliability of the tool, specific data needed to be available, and the patients meeting the following criteria were selected from the cohort:

1. A postoperative computed tomography (CT) scan was present
2. An anteroposterior and lateral weight-bearing radiograph obtained within a week from this CT scan was present
3. TAR alignment of the patient was measured during follow-up, and measurement outcomes were registered in the database. In this database, coronal and sagittal alignment of the tibial component and coronal alignment of the talar component was registered.

Ten patients fulfilled these criteria and were included in this study.

Table 1 Exclusion criteria and characteristics of included patients from the CCI Evolution TAR cohort at MUMC

Total number of patients in CCI cohort	**61**
Number of patients after applying the following exclusion criteria:	
1. Follow-up data including manual measurement results available	59
2. Number of patients with post-operative CT scan available	18
3. Radiographs corresponding to post-op CT scan available	10
Characteristics of study population	
Study size	10/10 ankles/subjects
Gender	7/3 male/female
Mean age at operation	68.6 ± 4.2 years
Operation side	3/7 right/left
Operation date	23/04/2010—16/03/2016
Mean follow-up	57.6 ± 33.1 months

Tool development and usage

3D reconstructions of the standard-sized tibial and talar components of the CCI Evolution TAR design were obtained by 3D scanning the individual components using the ATOS Scanport (Zebicon a/s; Billund). Using a custom-developed software package implemented in MATLAB (MATLAB; R2019b, MathWorks, Natick, MA, USA), these 3D reconstructions in neutral alignment were visualized in a graphical user interface (GUI). Secondly, a custom-developed software package based on the work of Kitzen et al., (2020) [24] was implemented in MATLAB, to simultaneously display both lateral and AP radiographs in the same GUI (Fig. 2).

After the radiographs are loaded in the GUI, the user is asked to select the tibial axis by aligning two circles on the tibial shaft, one most proximally and one most distally

(Fig. 3). The tibial axis will serve as a reference line for rotation measurements in the weight-bearing radiographs. After selecting the tibial axis, images are cropped around the TAR for visualization purposes during the contouring process.

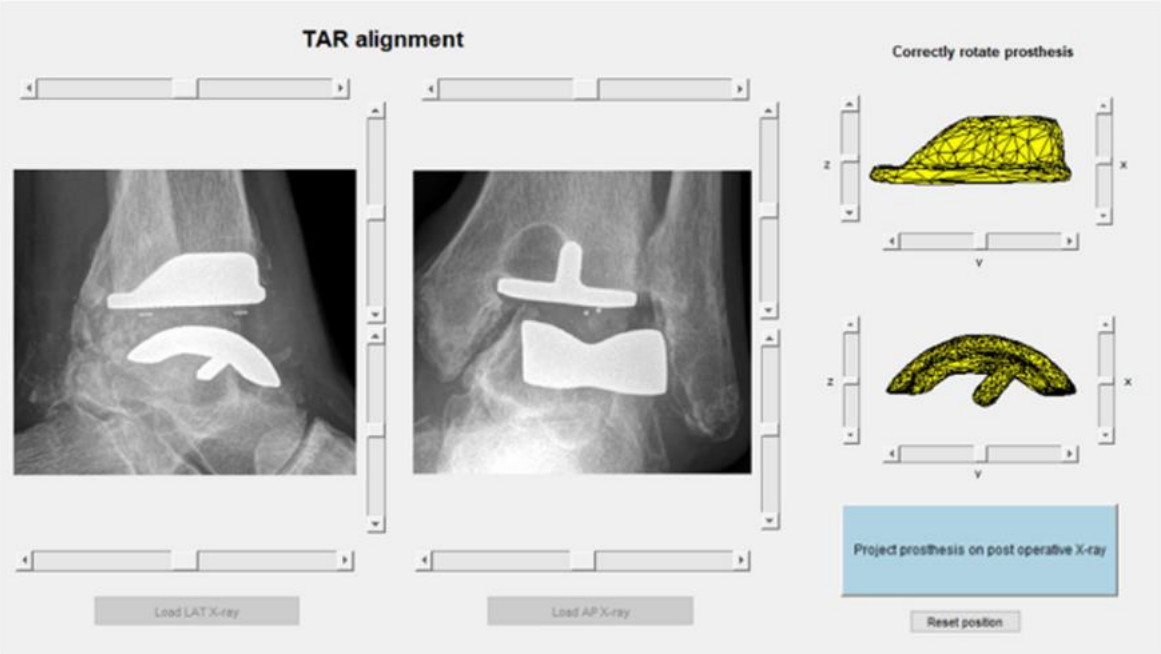

Fig. 2 The graphical user interface of the tool displaying the lateral and anteroposterior radiographs (on the left) and 3D reconstructions of the tibial and talar CCI Evolution TAR component (on the right). Sliders around the radiographs to translate the contours of the 3D CCI parts, sliders around the 3D reconstructions to rotate the contours of the 3D CCI parts

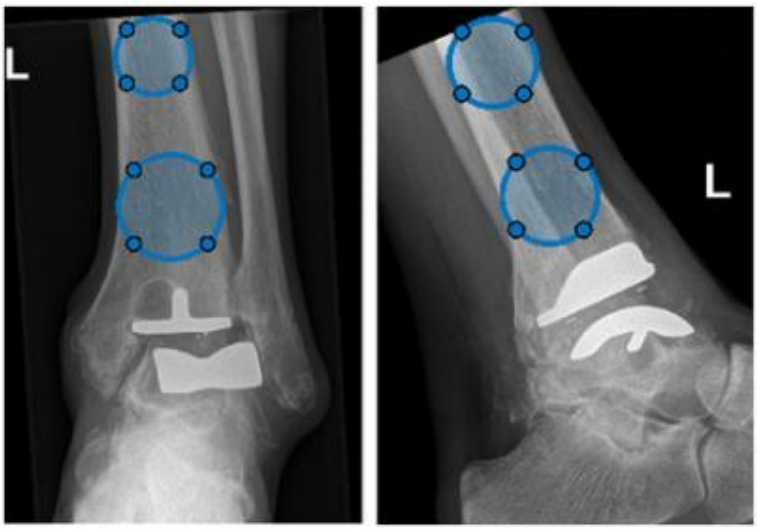

Fig. 3 Circles fitted on the tibial shaft of the tibia to measure the anatomical tibia axis

After selecting the tibial axis, the contours of the 3D-scanned TAR components are plotted on top of the radiographs. The user can translate and rotate the contours of

the 3D TAR components, using the sliders next to respectively the radiographs and 3D TAR components (Fig. 2), until the contours of the 3D components match the contours of the TAR on the radiographs. The radiographs depicted in Fig. 2 are cropped around the TAR for better visualization, but the tibial axis measured before cropping is saved. When rotating the 3D components, contours on both radiographs rotate simultaneously due to the perpendicular relationship of the anteroposterior and lateral radiographs. This way, only one configuration of the 3D scanned TAR components can be found to fit the contours on both radiographs simultaneously (Fig. 4).

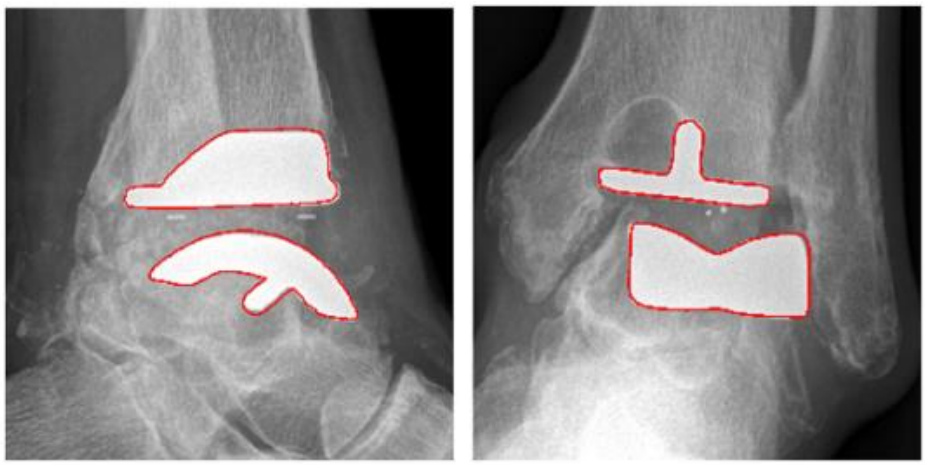

Fig. 4 Contour mapping of the 3D TAR component contours on the lateral and anteroposterior radiographs

Radiological analysis

Once the 3D components are rotated such that the contours fit the TAR contours on both radiographs (Fig. 4), TAR alignment parameters are obtained. TAR component rotation along the x, y, and z-axis and distance between the TAR components along the x- and y-axis is calculated from the corresponding slider values. The x-axis is equal to the tibial axis, used as a reference line to map the TAR contours on the radiographs to find the relative TAR component position. A MATLAB script was developed to save all measured data automatically in a database, together with clinical patient data. Differences in TAR alignment are automatically detected when new data of the same patient is saved to the database.

Reliability and statistics

To determine the inter-observer reliability of the tool, two observers measured TAR alignment on the radiographs of the selected patients using the developed tool.

One observer performed a second measurement on the same radiograph six weeks after the first measurement, to determine the intra-observer reliability. The means of the measured outcomes were used in further statistical analysis. Using IBM SPSS 22.0,

Intra-class Correlation Coefficients (ICC) were calculated to determine inter-and intra-observer reliability [25].

TAR rotation along the x, y, and z-axis was included in the results, as well as the distance between the centers of the contours of the 3D components in the lateral-medial and anterior–posterior direction. The outcome measures of the manual method used in clinical practice were compared to the outcomes obtained with the semi-automatic tool, using paired t-tests with a significance level of $p < 0.05$.

Accuracy

The available postoperative CT scans of the ten selected patients in this study were used to test the accuracy of the tool. Coronal and sagittal alignment—corresponding to rotation along the x- and y-axis in the tool, respectively – were calculated in a 3D reconstruction of the tibias with tibial TAR components. The 3D reconstructions were created by segmenting CT scans in Mimics (Research 22.0; Materialise NV, Leuven, Belgium). TAR alignment was measured by obtaining the angle between the tibial axis and the plateau of the tibial TAR component. The tibial axis was obtained by finding the centroids along the tibial shaft and fitting a line through these centroids (Fig. 5) [26].

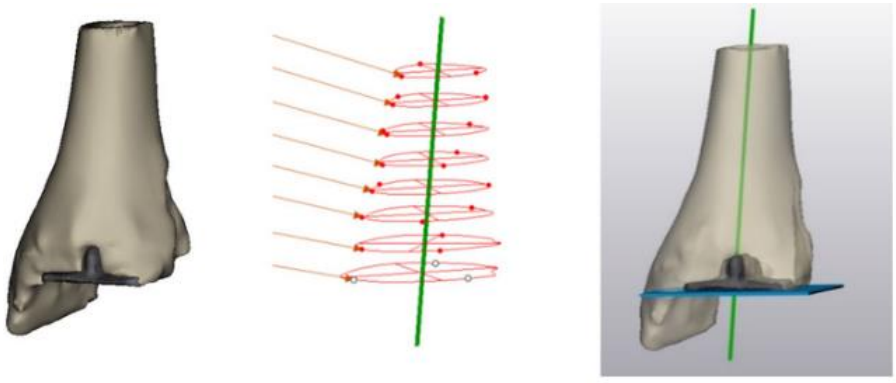

Fig. 5 Tibial axis measurement in a 3D reconstruction, by fitting a line through centroids of the tibial shaft

The tibial plateau was obtained by fitting a line along the bottom plateau of the tibial TAR component. The angle between the tibial axis and tibial TAR in the coronal and sagittal plane is regarded as the true TAR alignment. The percentage of accuracy was calculated using % accuracy = (1 − abs ((V_A−V_O) / V_A)) ∗ 100% with V_A being the accepted value obtained from the 3D reconstruction, and V O being the outcome obtained from the semi-automatic tool.

As the database of the manual TAR alignment measurements obtained during the follow-up of the ten patients was present as well, the accuracy of this manual method was calculated and compared to that of the newly developed semi-automatic approach.

Results

Reliability

Results for the rotation and component distance measurements are given in respectively Tables 2 and 3. The average differences of the measured angles and distances between the two observers were less than 1 degree and 0.4 mm, respectively. No significant differences were found. Two patients were excluded due to a mismatch in foot position between the anteroposterior and lateral radiograph, of which the effect will be discussed later.

For both the rotation and component distance measurement results, high correlation coefficients between the two observers were found with an ICC ≥ 0.80. Also, high intra-observer correlation coefficients were found for all measurements with an ICC ≥ 0.95 (Tables 2 and 3).

Observer	Tibial alignment (°)		Talar alignment (°)	
	Coronal Mean ± 2D	Sagittal Mean ± 2D	Coronal Mean ± 2D	Sagittal Mean ± 2D
1	2.8 ± 3.6	4.1 ± 5.8	4.8 ± 3.2	4.6 ± 5.7
2	6.4 ± 3.5	3.6 ± 3.1	4.0 ± 3.5	2.4 ± 5.8
Δ	0.6	0.5	0.8	0.8
ICC (p-value)				
Mean 1–2	0.98 (p < 0.01)	0.98 (p < 0.01)	0.80 (p < 0.01)	0.95 (p < 0.01)
Mean 1a-1b	0.98 (p < 0.01)	0.98 (p < 0.01)	0.98 (p < 0.01)	0.96 (p < 0.01)

Table 2 Tibial and talar rotation in the coronal and sagittal plane per observer (in degrees), given as mean with standard deviation (SD) with absolute difference between observers (Δ), and inter-observer results with intraclass correlation coefficient and p-value between both observers (n = 8)

Observer	Distance between the tibial and talar component along the x-axis (mm)		Distance between the tibial and talar component along the y-axis (mm)	
	Medial–lateral Mean ± SD	Anterior–posterior Mean ± SD	Medial–lateral Mean ± SD	Anterior–posterior Mean ± SD
1	2.4 ± 1.5	5.9 ± 2.2	18.1 ± 2.2	19.0 ± 1.2
2	2.3 ± 1.7	6.1 ± 2.4	18.5 ± 1.7	18.9 ± 1.6
Δ	0.1	0.2	0.4	0.1
ICC (*p*-value)				
Means 1–2	0.95 ($p < 0.01$)	0.98 ($p < 0.01$)	0.90 ($p < 0.01$)	0.93 ($p < 0.01$)
Means 1a-1b	0.92 ($p < 0.01$)	0.96 ($p < 0.01$)	0.92 ($p < 0.01$)	0.93 ($p < 0.01$)

Table 3 The distance between the tibial and talar component (in mm) over the x- and y-axis, given as mean with standard deviation (SD) with absolute difference between observers (Δ), and inter-observer results with intraclass correlation coefficient and p-value between both observers (n = 8)

Manual measurement method vs. semi-automatic tool

Mean outcome parameters obtained by the manual measurement method and the semi-automatic tool are reported in Table 4. Results from the paired t-tests show no significant differences between the two measurement methods, probably due to the small sample size.

	Tibial alignment (°)		Talar alignment (°)
	Coronal Mean ± SD	Sagittal Mean ± SD	Coronal Mean ± SD
Manual	4.6 ± 3.4	3.5 ± 2.7	4.3 ± 3.7
Semi-automatic	6.1 ± 3.4	4.0 ± 2.8	4.4 ± 3.3
Δ	1.5	0.5	0.1
p-value	$p > 0.05$	$p > 0.05$	$p > 0.05$

Table 4 Mean results for tibial and talar rotation (in degrees) in the coronal and sagittal plane, given as mean value per measurement with absolute difference between methods (Δ), including the p-value to compare means of both measurement methods (n = 8)

Accuracy

For the eight patients included in the results, 3D reconstructions of the tibia with tibial components were made and alignment of the tibial component was measured.

The accuracy of both the presented tool and the manual measurement method was calculated. The average accuracy was 77% and 70% for the semi-automatic and manual methods, respectively (Table 5).

Measurement method	Accuracy of coronal tibial alignment measurements	Accuracy of sagittal tibial alignment measurements
Semi-automatic	81%	73%
Manual	68%	71%

Table 5 Accuracy of the semi-automatic and manual measurement methods. Mean accuracy of the coronal and sagittal alignment of the tibia component of all patients is reported

Discussion

The purpose of this study was to develop and validate a semi-automatic clinical tool to measure TAR alignment on plain radiographs. TAR alignment of eight patients from the CCI Evolution cohort was measured using the tool, and accuracy and reliability were calculated. By providing this semi-automatic tool, which standardizes TAR alignment measurements and expands the set of measurable parameters using radiographs, research on the correlation between TAR alignment, migration, and clinical outcome will be improved and facilitated. With this technique, this can be reached without additional radiation doses or costs as no CT scan is necessary to find the 3D alignment of the TAR components. Relative migration of the TAR components can be detected by applying this tool on radiographs of the same patients at different time points during follow-up. High inter-and intra-observer reliability was found (ICC ≥ 0.94), so the tool is a reproducible and reliable method for measuring TAR alignment. On average, the accuracy of the coronal alignment measurements increased by 13% and the accuracy of the sagittal alignment measurement showed a small increase of 2% when using the tool compared to the manual method. Now that the tool is validated, future studies must be performed to apply the tool to the CCI cohort in order to gain insight into the relationship between TAR malalignment and the clinical outcome.

The tool presented in this study is applicable to any TAR design as long as one asymmetric plane is present in the TAR components, which for most TAR designs is true.

When implemented in the clinic, the tool also standardizes the tibial axis measurements. The tibial axis measurement method that was implemented resulted from descriptions found in the literature [27–32] and was based on a previous study investigating the most accurate method to measure the longitudinal tibial axis [21]. In this study, the anatomical axis was selected, but the tool allows the user to choose the mechanical axis, or any other axis if preferred, as long as the user is consistent in

using the same axes during the follow-up of a patient. With the manual TAR alignment measurement method, the tibial axis is drawn by hand. Although it must be confirmed by future studies, it is expected that the accuracy and reliability of the anatomical tibial axis measurements will increase upon implementation of the tool. What must also be pointed out regarding the tibial axis measurements, is that it is essential to obtain lower-leg radiographs during clinical follow-up, as too distally tibial radiographs can give inaccurate results when measuring the tibial axis [27]. In the current study, some radiographs only showed a distal part of the tibia. Still, the tool showed higher accuracy than the manual measurement method, when compared to CT data. This shows that upon the usage of full-leg images, the tool will show even higher accuracy when compared to the CT data.

With future use of the developed tool, it is recommended that at least lower-leg radiographs are used. However, it must be stated that in clinical practice optimal radiograph quality cannot always be guaranteed. Even in a suboptimal situation, this tool shows that more accurate TAR alignment measurements can be obtained.

Other methods to assess TAR position and kinematics have been frequently applied in TAR research, such as in vivo 3D fluoroscopy and radiostereometric analysis (RSA). These methods give detailed insight into the kinematic behavior of TAR components [33–39]. However, these techniques require a prospective study design, whereas the presented tool in this research can be applied retrospectively to study TAR component position, using radiographs obtained during routine follow-up consults. This shows the main strength of the presented tool, as it serves as an alternative measurement method, standardizing and improving the accuracy of TAR measurements, which can be used to study TAR failure in a retrospective manner. Compared to 3D fluoroscopy and RSA, this makes the presented method a valuable tool in TAR research without additional impact on the patient or increase in healthcare costs.

Some limitations of the current study must be discussed. Firstly, we assumed that the lateral and anteroposterior radiographs were perpendicular. However, since radiographs were obtained during regular patient care without a reference line or bilateral imaging, it is possible that the anteroposterior and lateral radiographs were not exactly perpendicular. Large discrepancies, however, would have been detected as it would make it impossible to find the configuration of the 3D TAR components. However, the presence of perpendicular radiographs is crucial for the tool to add value in the clinic. A problem regarding radiograph quality was encountered during

measurements of two of the ten selected patients, which showed a moving artifact in between obtaining the anteroposterior and lateral radiograph. Since the tool relies on the perpendicularity and coupling of these two radiographs, foot movement leads to the fact that it is impossible to find a matching configuration of the TAR components. This major problem, however, can be resolved in the clinic by easy fixation of the foot using a brace or holder for example. More importantly, when foot fixation is guaranteed using a brace, the tool presents a method to measure sagittal talar alignment, which currently does not exist yet, and also for this output parameter high accuracy and reliability are expected. Furthermore, this would allow the addition of a landmark on both the lateral and anteroposterior radiograph, expanding the TAR position measurements to absolute values as well. Weight-bearing CT imaging would be a valuable addition for the validation of our tool and using WBCT will take away problems regarding foot movement in plain radiography [40, 41]. Unfortunately, WBCT was not available at the moment in our clinical center. Another limitation is that only inter and intra-observer reproducibility was tested. A more thorough reproducibility would require making multiple radiographs of the same patient with more observers. Furthermore, the sample size of this study was small, and validating the tool with a larger sample size will increase the robustness of the validation.

However, regarding the convincing ICC values and the fact that validity was determined comparing to CT data as the golden standard, the small sample size and the fact that intra-observer reliability was only obtained for one observer study were not considered as major limitations. However, a larger scale study is expected to show convincing results on the accuracy and reliability of the presented tool. Also, statistical analysis was limited due to the small sample size and the continuous outcome parameters. Besides, the selection criteria that were applied to the cohort that led to the small sample size, were chosen for validation purposes as the presence of CT data was required. Furthermore, the 3D reconstructions to calculate accuracy were developed according to a method presented in the literature showing high intra-class agreement [26]. However, the accuracy of the talar component alignment measurements was not calculated, since the foot is positioned differently during a CT scan compared to weight-bearing radiographs and the tibial axis cannot be used as a reference line. After validation, the tool can be broadly applied to patients with a TAR as CT data will not be necessary for application of the tool.

Applying the tool to a larger dataset to gain clinical information was, however, outside of the scope of this study.

Also, the current tool is not fully automated but in future development, this could be reached by using automatic edge-detection algorithms [42–45]. This will result in a very efficient method to measure TAR alignment, which will greatly enhance insight into the relationship between TAR alignment and clinical outcomes. The accuracy values found when comparing the radiographic TAR measurement methods to measurements using a CT scan, show the importance of improving these radiographic TAR alignment measurements. Lastly, in this study, the tool was used to measure TAR alignment during follow-up, but upon further development the tool has potential as a pre-operative mapping tool, finding the optimal TAR alignment per patient.

Conclusions

Concluding, a reproducible tool was developed to semi-automatically measure TAR alignment on anteroposterior and lateral radiographs. Only tibial alignment measurements were included to validate the tool, as the talar component shifts relative to the tibial component from weight-bearing radiographs to non-weight-bearing CT scans. Future research should be dedicated to the automation and application of the tool on a larger dataset. The developed tool increases accuracy from the current measurement method but more importantly allows measurement of 3D alignment parameters on 2D radiographs, increasing insight into TAR position. The tool facilitates research on the relationship between TAR alignment, migration, and clinical outcome, by standardizing and expanding TAR alignment measurements.

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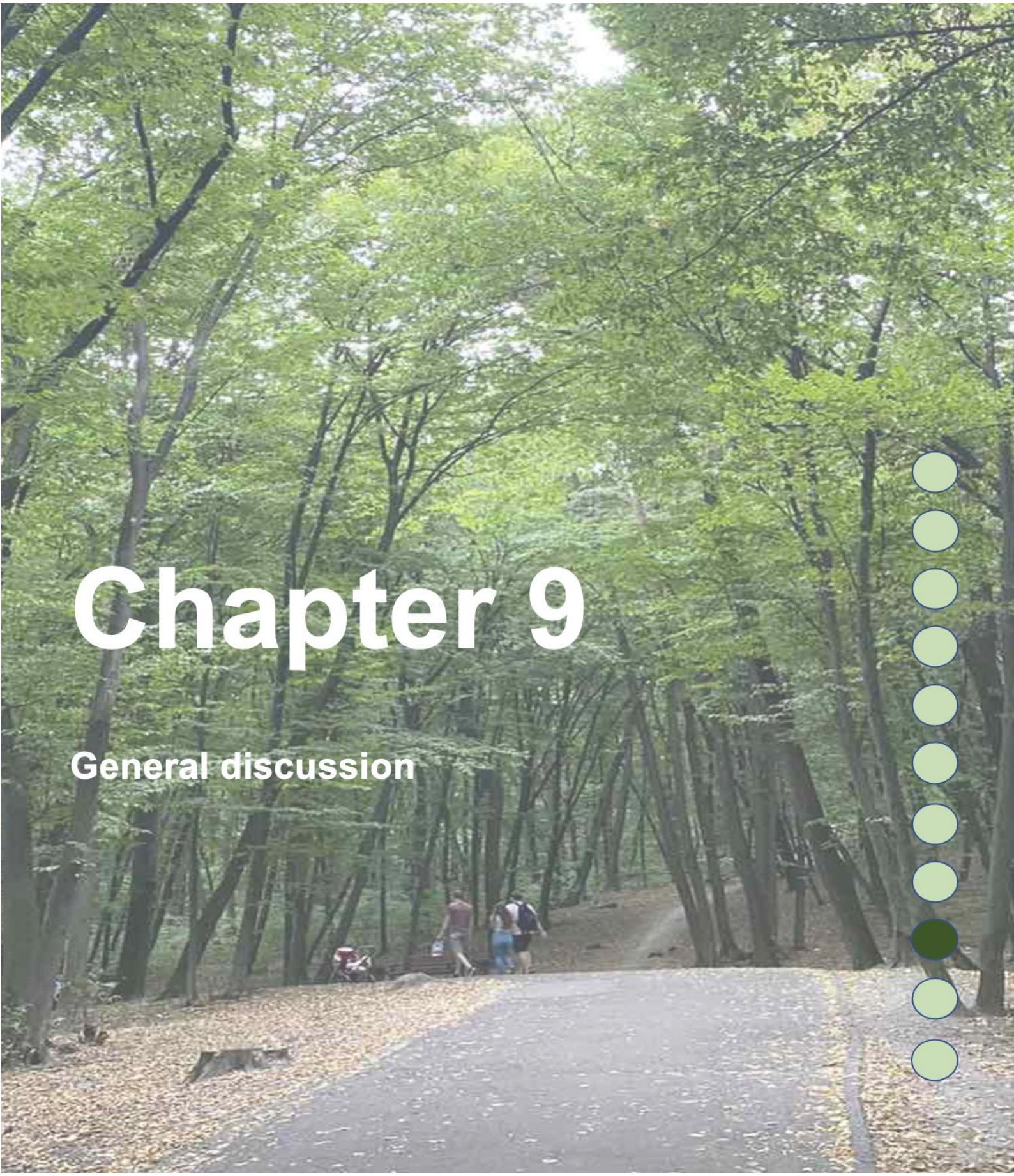
Chapter 9
General discussion

This research aims to refine surgical techniques and improve patient outcomes by addressing complications and failures, supporting the development of better total ankle replacement technologies, and investigating biomechanical and alignment factors that are essential for implant success, thereby contributing to advancements in total ankle replacement (TAR) surgery.

The research places a strong emphasis on the evaluation of clinical outcomes, delving into the effectiveness, functionality and long-term durability of total ankle replacement in light of advancements in implant design and surgical technique. This involves a detailed analysis of how implants function in everyday clinical practice, aiming to offer patients improved mobility and an enhanced quality of life.

Equally important is the focus on complications and failures associated with total ankle replacement surgery. By examining the frequency, underlying causes and management strategies for these issues, the study seeks to not only minimize the occurrence of complications but also optimize their resolution. This proactive approach aims that patients benefit from safer and more reliable surgical interventions.

Additionally, the investigation extends to the intricate dynamics of alignment and biomechanics, emphasizing their critical role in implant longevity and functionality. By leveraging innovative technological solutions, such as semi-automated three-dimensional alignment measurement tools and finite element modeling, the research seeks to provide new insights into how these factors can be optimized to support better surgical outcomes.

Through these pursuits, the research aspires to refine surgical techniques, enhance patient satisfaction and pave the way for the development of superior ankle replacement technologies. By integrating state-of-the-art methodologies with a focus on personalized patient care, this study aims to make a valuable contribution to the advancement of the field while thoughtfully addressing the persistent challenges associated with total ankle replacement surgery.

Comparative Analysis of Cohorts

This thesis evaluates outcomes from two distinct cohorts—the CCI Evolution Total Ankle System (**Chapter 2**) and the Infinity Ankle Replacement System (**Chapter 4**)—to assess failures, patient-reported outcome measures (PROMs) and complications. The CCI cohort experienced a higher complication rate, particularly during the early learning curve. Intraoperative issues, such as medial malleolar fractures, occurred in 15.4% of cases, while 35.4% faced post-operative complications. These findings could suggest that some issues may derive more from procedural challenges than from inherent implant design flaws, making it important to differentiate between surgeon-related factors and implant-specific factors when interpreting these outcomes.

Conversely, the Infinity cohort exhibited fewer complications, benefiting from the implementation of stringent patient selection criteria—such as excluding individuals with high BMI, significant malalignment or prior osteochondral defect treatments—and the adoption of advanced surgical techniques that emphasized precise alignment and adherence to best practices. Additionally, early patient stratification and adherence to updated surgical protocols significantly impacted outcomes in the Infinity cohort. However, this raises a significant question: Are the better results primarily due to the implant design, or do they result from rigorous patient selection and protocol improvements? This distinction is crucial for understanding the true performance of the Infinity system and underscores the importance of controlled studies to isolate these variables. In our Maastricht UMC Infinity and CCI cohorts, a DAIR procedure was not considered a failure of the total ankle replacement system as defined by Henricson [1,2, Chapter 4]. While no failures were recorded in our Infinity cohort (excluding the deep infection requiring revision), the CCI cohort showed a failure rate of 12.3%. This failure rate was significantly higher compared to the 4.7% reported in the Dutch Arthroplasty Register, which had a median follow-up of 3.2 years. This may suggest potential underreporting of revision procedures in the national register, a concern highlighted not only in Dutch literature but also in international literature.

[3-11]. Skyttä suggests that underreporting of failures can be caused by not reporting the implants of the conversions of a failed TAA to an arthrodesis [12]. Failures are considered clear events where implant components need to be revised or removed due to issues such as mechanical loosening, subsidence, or infection. However, what exactly qualifies as a failure is open to debate. For example, some studies argue that exchanging a polyethylene insert due to infection or impingement should not count as

a failure, while others insist that any unintended outcome requiring reoperation inherently constitutes failure [13,14]. This lack of consensus and reporting complicates the comparison of results across studies and registries.

McKenna et al. defined failure as the removal of either the tibial or talar component—or both—followed by the use of an antibiotic spacer, reimplantation of metal components, conversion to arthrodesis, or amputation [15]. Henricson et al., on the other hand, described revision as the removal or exchange of one or more prosthetic components, excluding incidental polyethylene insert exchanges (e.g., those due to infection) [2]. In contrast, both the LROI and the national joint registry of the UK define revision as the exchange or removal of any component [Chapter 3, 16,17]. Liebs et al. noted that the lack of clarity around the definition of failure also applies to knee and hip arthroplasty [18]. The annual report of the Swedish Knee Arthroplasty Register pointed out that a surgeon's decision not to replace a fixed liner could make the implant appear more successful in registry data [19,20]. Other registries followed this advice [18,21,22]. From a patient's perspective, however, any additional surgery—whether classified as a revision or not—is a burden [13]. It is crucial to distinguish between revision and reoperation: while all revisions are reoperations, not every reoperation is a revision. I would suggest defining implant failure as any situation where a component is revised or removed due to mechanical failure or loosening. Under this definition, an insert exchange for issues like DAIR or impingement should be classified as a reoperation rather than a failure, reducing the likelihood of underreporting failures. Nonetheless, future studies should report all types of reoperations, as these distinctions are vital for clarity and consistency in data interpretation. Reaching consensus among clinicians and researchers is essential. Without a universally agreed-upon framework, differences in the way complications are reported and interpreted will continue to make it difficult to compare outcomes effectively.

Complications in ankle replacement can sometimes necessitate reoperations, which may increase the risk of further challenges or even failure [25]. A clear definition and classification of complications are essential to accurately identify and categorize them in the correct order [2,13,14,23,24]. According to the Glazebrook classification, complications are events that may not immediately result in failure, but can potentially lead to implant issues over time. These are categorized into low-grade (unlikely to

cause failure), medium-grade (17–45% likelihood of failure), and high-grade (69–81% likelihood of failure) [26]. In our Maastricht UMC Infinity cohort, we observed three intra-operative complications (12%) and three postoperative complications (12%), one of which required a polyethylene liner exchange as a DAIR procedure for infection [Chapter 4, 1]. A systematic review reported the results of six studies including 432 prostheses with a mean follow-up of 24.5 months. Complications occurred in 10% of cases, comprising 9 low-grade, 16 medium-grade, and 18 high-grade events. Revision surgeries were performed in 6% of cases, primarily due to deep infection, aseptic loosening, and subsidence. Implant survivorship was 94% and 96% excluding infections [26–33]. A meta-analysis by Vale et al. reported 1,047 complications out of 4,412 total ankle arthroplasties, resulting in an adjusted mean complication rate of 23.7%, with a range between 2.4% and 52%. They also concluded that chronic pain and/or gutter impingement should be considered minor complications according to Glazebrook's classification, as they are significant causes for re-intervention after long-term follow-up [26,34].

It could be concluded that TAA may be more susceptible to complications, failure, and subsequent reoperation as compared to other surgical interventions of the ankle, especially compared to ankle arthrodesis [35]. In comparison, ankle arthrodesis showed perioperative major complications occurring 1.8 times more frequently than in total ankle replacement. However, after adjusting for patient and hospital factors such as gender, age, and health status, it had a 29% lower risk of minor complications [36]. Registration of complications in ankle replacement reflects the learning curve, showing the process of gaining experience and achieving better outcomes [37,38].

Patient-reported outcome measures (PROMs) are essential tools for evaluating the outcomes of ankle replacement surgery [39]. They provide a comprehensive view of outcomes by focusing on pain relief, mobility, and quality of life while enabling early detection of complications and monitoring long-term success [40]. By aligning treatments with individual patient needs, PROMs enhance decision-making, improve patient care, and support advancements in surgical techniques and evidence-based practices.

Our Maastricht UMC Infinity cohort demonstrated improved patient-reported outcomes (PROMs), better post-operative range of motion (ROM), and fewer complications

compared to the CCI cohort [Chapters 2&4,41]. These findings highlight the importance of adequate patient stratification, optimized treatment protocols and the influence of implant design [42–44]. The fixed-bearing design and alignment tools of the Infinity system played a key role in significantly reducing complications such as impingement and fractures [45]. However, it remains unclear whether comparable outcomes could be achieved with other implant designs or if these advantages rely on surgical techniques and patient selection. Yau et al. reported similar improvement in MOxFQ scores but no significant differences in PROMs between standard and patient-specific instrumentation for the Infinity system [46]. In comparison, the Hintegra system produced similar MOxFQ scores, whereas the BOX system showed less improvement [47,48].

These contrasting results between the CCI and Infinity cohorts highlight the roles of patient iteration, through continuous refinement of surgical techniques and treatment strategies, and patient stratification in achieving improved outcomes [**Chapters 2&4**]. After analyzing the results of the Maastricht UMC CCI cohort, we observed that impingement and intra-operative fractures were the most common complications, with an average improvement in range of motion of only 5.8 degrees. To address these issues, we increased the use of Achilles tendon lengthening procedures, achieving an average gain of 9.2 degrees in range of motion. Additionally, the introduction of the resection guide for the Infinity ankle replacement led to a significant reduction in intra-operative fractures. The surgical technique for the Infinity total ankle replacement also focused on optimizing implant rotation, which significantly reduced the incidence of impingement. By learning from patient-reported outcomes and complication data, clinicians can drive progress, enhance care, and achieve greater surgical success.

Strategies to Improve Outcomes

1. Learning from Past Complications

The CCI cohort's steep learning curve, evidenced by perioperative issues during the first 30 surgeries, highlights the critical importance of structured training and supervision during the early phases of system adoption [7,10,49-59]. In this cohort the

most common complications identified, such as intraoperative fractures and postoperative impingement, underscore areas where technical refinement is essential [**Chapter 5&6**,58-61]. Schimmel and colleagues advised a stricter patient selection for total ankle replacement, especially during the first 50 total ankle replacements [7]. During the learning curve period, careful surgical indications and surgeries are desired. A meta-analysis of 25 articles by Simonson and colleagues reports the risk of complications during the learning curve of a total ankle replacement. A total of 1085 complications occurred during their learning curve in 2453 total ankle replacements, yielding an overall incidence of complications of 44.2% [38]. Our findings align with those of other studies, which have shown that stricter patient selection and attention to the learning curve are crucial to reducing complications and improving outcomes during the early phases of adopting total ankle replacement procedures [**Chapter 5,6]**. In addition, Kurokawa and colleagues advised that involving experienced surgeons as assistants can lead to favorable results, even when the primary surgeon lacks experience [62]. This further supports the notion that the involvement of experienced surgeons during the learning curve can help mitigate complications and improve outcomes.

The results of Vink et al. are also anticipated, as their study examines the relationship between the learning curve and failure rates of total ankle replacements using data from the Dutch Arthroplasty Register. This research is expected to contribute valuable scientific insights into this critical aspect of surgical performance [63].

The volume-outcome relationship in total ankle replacement remains a complex topic, with the ongoing debate about whether center volume or surgeon volume plays a more critical role in determining outcomes. High-volume centers are often associated with better results, but inconsistencies in how volume is defined, as well as confounding factors, such as patient populations and prosthesis types, complicate meaningful comparisons [10,64]. Zaidi et al. found in the NJR database that early revision rates are statistically significantly higher in low-volume centers [65]. They identified a cut-off of 20 total ankle replacements (TAR) per year, finding that 19 units performing more than 20 TAR annually accounted for half of all procedures, while 163 units performing fewer than 20 TAR per year accounted for the other half in the UK.

Surgeon-specific experience appears to have a particularly strong influence. Studies have shown that as surgeons gain experience, complication rates decrease,

highlighting the importance of the learning curve in total ankle replacement. This suggests that surgeon volume may, in some cases, outweigh the impact of center volume [66]. Future research should aim to standardize definitions of volume, analyze surgeon-specific metrics, and explore the interplay between surgeon and center volume to gain a clearer understanding of their respective roles in optimizing total ankle replacement outcomes and reducing complications. As a clinician, I would propose to centralize total ankle replacements to higher-volume centers within a specific region, ensuring that expertise is both enhanced and consistently maintained, ultimately leading to better patient outcomes and reduced complication rates.

2. Stricter Indications and Patient Stratification

Risk assessments, including our own data from the LROI, have identified several key factors that increase the likelihood of complications, such as high BMI, advanced age and previous OCD treatment [**Chapter 3,** 67-71]. The National Joint Registry Data and National Health Service Digital data combined specified age as a risk factor of failure: 65-74 years (HR 0.61) and those aged ≥75 years (HR 0.25) compared to those aged <65 years. Rheumatoid arthritis had a significantly lower risk of failure than patients with osteoarthritis with a HR of 0.37. A higher risk of failure is also associated with an overweight BMI (HR 1.65) and obesity (HR 1.76) compared to a healthy BMI [67].
Using risk assessment, particularly for complications, failures, and prolonged hospitalization, it becomes possible to achieve effective patient stratification [68-72].

Implementing stricter patient selection criteria has demonstrated to effectively minimize risks, particularly during the learning phase. Excluding cases with severe deformities and prioritizing straightforward cases allows surgeons to build experience and confidence while reducing the likelihood of adverse outcomes. During the learning curve of the Infinity Total Ankle System, we implemented a stricter patient selection process, prioritizing patients with minimal varus deformities and no need for additional corrective surgeries. This approach was integral to optimizing outcomes and minimizing complications during the early phase of system adoption.

Preoperative psychological counseling and education are important elements for improving patient outcomes [73]. These interventions support patients in setting realistic expectations for their recovery and address mental health concerns, such as anxiety or depression, which can negatively affect pain perception and overall recovery [74]. In our Maastricht UMC Infinity cohort, anxiety negatively impacted the postoperative patient-reported outcome measures (EQ-5D-5L and MOxFQ), although this effect diminished over time [**Chapter 4**].

A 2014 Cochrane review concluded that traditional preoperative education often fails to significantly enhance postoperative outcomes. The review advised the implementation of a stratified biopsychosocial model, which considers each patient's unique physical, psychological and social needs, allowing preoperative education to be tailored accordingly [75]. In 2022, Ho et al. were the first to demonstrate the effectiveness of a personalized integrated education program for patients undergoing total knee replacement. Their study showed notable improvements, including reduced postoperative pain, lower perioperative anxiety and better functional recovery [76]. In total knee replacement, prehabilitation demonstrated significant improvements in the Knee Score preoperatively and at 6 months postoperatively, but this effect diminished by 12 months [77,78]. By combining insights from past complications, integrating advanced analytics and technology, and employing rigorous patient selection and stratification strategies, health systems can significantly improve patient outcomes while reducing adverse effects [79-81, 68,82].

3. Implant Choice

The comparison between mobile and fixed-bearing systems revealed distinct outcomes, supported by registry data and meta-analyses. Fixed-bearing systems, such as the Infinity implant, have shown significant advantages in terms of stability and reduced complication rates. According to a study from the Dutch Arthroplasty Register (LROI), fixed-bearing systems demonstrated a lower risk of revision compared to mobile-bearing systems, with 7-year revision rates of 5.4% versus 11.3% for mobile bearings [83,84]. Fixed-bearing designs reduce the risk of complications,

such as instability, malalignment and arthrofibrosis. Mobile-bearing systems, although theoretically allowing for greater range of motion and load distribution, are more prone to developing complications, such as subluxation and polyethylene insert dislocation [83,84].

Moreover, fixed-bearing implants have benefited from advancements in material technologies, such as highly cross-linked polyethylene (HXPLE), which significantly reduces wear and loosening risks compared to conventional polyethylene [84,85]. While mobile bearings offer some biomechanical benefits, including potentially lower stress at the bone-implant interface, their long-term survival is inversely correlated with follow-up duration, as demonstrated in a meta-analysis where survivorship decreased significantly over time [84]. This highlights the need for improved designs in mobile-bearing systems to address these limitations.

Periprosthetic cyst formation tends to occur less frequently with fixed-bearing implants, which may be attributed to their reduced shear forces and improved stability [84,85]. Despite these benefits, the higher costs associated with fixed-bearing TAR systems compared to mobile designs remain a challenge. This is especially important when looking at the cost in relation to the relatively lower number of ankle replacements compared to more common procedures, like total hip or knee replacements [86]. Future innovations must balance cost-effectiveness with performance and durability [87]. Although advanced implant designs show promising results in reducing complications, managing costs remains essential to ensure accessibility across different healthcare systems and patient populations [88]. Given the differences in revision rates, complication profiles and costs, fixed-bearing systems appear to offer superior outcomes for most patient populations [83,84,88-90].

Should the selection of implants for ankle replacements remain individualized, taking into account patient-specific factors such as age, activity level, and alignment deformities, particularly given the challenges of the learning curve? From a clinician’s perspective, improving patient outcomes and reducing complications are always priorities; however, the significantly higher costs of ankle replacements present a considerable challenge [91]. For researchers, this creates an interesting opportunity

to focus on the unique needs of ankle replacement patients and identify specific areas for improvement.

4. Operative Techniques and Skills

Precision in implant placement is essential to reducing complications, such as malalignment and subsidence. Proper positioning of a Total Ankle Replacement involves aligning the implant components to the anatomical axis of the tibia and talus while ensuring neutral alignment to avoid excessive stress distribution. Malalignment—whether varus, valgus, anterior, or posterior—can significantly increase peak contact stresses and shear forces at the bone-implant interface, as demonstrated in finite element analysis studies [**Chapter 7**, 92]. For example, valgus malalignment of 10° can elevate peak stresses by up to 158%, increasing the risk of bone damage, implant loosening and eventual failure [**Chapter 7]**.

Optimal implant placement requires careful attention to several factors:

1. **Bone Resection Depth:** Resection depth should be minimized to preserve the subchondral bone, which provides essential support and stability for the implant. For instance, a depth of 6 mm above the tibial roof is recommended to maintain implant fixation and avoid increased micromotion. Excessive resection can compromise implant stability, lead to stress shielding and increase the risk of aseptic loosening [93,94].
2. **Implant Design:** The design of an implant has a direct effect on the mechanics of fixation. Keel designs have shown greater stability and less micromotion when compared to stem or peg designs. While stem designs can be effective in certain cases, they often exhibit more rotational micromotion due to their symmetrical fixation structure. [95,96]. A meta-analysis found that non-anatomic, mobile-bearing, hydroxyapatite-coated, and non-tibial-stemmed total ankle replacements are linked to a higher incidence of periprosthetic bone cysts [97].
3. **Alignment Tools:** Achieving precise alignment is critical for successful outcomes [**Chapter 2,4,7,8**]. Patient-Specific Instrumentation (PSI) and intraoperative imaging tools facilitate accurate positioning, particularly in complex cases involving

deformities. In fixed-bearing systems, additional tools have proven effective in reducing complications, in particular impingement and improving implant alignment [46,98]. Some surgeons may wonder if the additional costs and time involved with PSI truly lead to significantly better outcomes compared to traditional methods. For example, in total knee replacements, two meta-analyses showed no clinically significant differences in efficacy and safety between patients treated with PSI total knee replacements and those treated with non-PSI total knee replacements [99,100].

Incorrect placement often involves [92,93,98]:

- Malrotation of components, which exacerbates shear stresses or can cause impingement.
- Over-resection of bone, leading to implant subsidence.
- Misalignment that creates uneven stress distribution and increases wear on polyethylene liners.

Finite Element Analysis (FEA) has advanced understanding of these biomechanical factors, emphasizing the importance of neutral alignment and controlled resection depths. By simulating different scenarios, FEA provides insights into optimizing surgical techniques and implant designs [**Chapter 7**,92,93]. However, its practical translation into everyday surgical practice could be debated Finite Element Analysis (FEA) has difficulties with accurately estimating forces and modeling dynamic activities such as gait cycles. Musculoskeletal (MSK) modeling can offer important input for FEA, allowing for more accurate simulations of biomechanical environments. Nevertheless, challenges persist in capturing the complexities of dynamic activities, which demand advanced computational techniques [101].

Enhanced surgical skills, developed through experience and specialized training, are integral to achieving better outcomes. Early data suggest that performing Achilles tendon lengthening in cases of stiffness significantly improves post-operative ROM and alignment [**Chapter 4**]. Improved surgical techniques, such as the use of medial malleolus osteotomy in varus deformities, could also contribute to reducing complication rates [102,103].

Could the incorporation of innovative surgical tools further enhance precision and minimize the margin for human error, particularly in complex cases requiring advanced alignment strategies? While some might argue that such innovations can indeed reduce human error and improve precision, they also bring challenges, such as the need for additional training and increased costs. Should these tools, therefore, be reserved exclusively for complex cases [79-81,87].

5. Continuous Monitoring

The Glazebrook classification system has proven effective in categorizing complications and guiding post-operative management [26,34]. Long-term follow-up studies, such as TARVA, highlight the importance of ongoing monitoring to detect late-stage failures [105].

National registries, such as the Dutch Arthroplasty Register (LROI), have been pivotal in providing comprehensive data on survival rates, risk factors for failure and patient outcomes [**Chapter 3**]. These registries collect detailed information on implant designs, surgical techniques and patient demographics, offering a rich resource for evaluating TAR practices [4,21,83,105]. For instance, the LROI demonstrated excellent short-term survival rates of 95.3% at three years while identifying significant risk factors, such as lower patient age, higher BMI and prior OCD treatment as predictors of early failure [**Chapter 3**]

Despite their utility, national registries various challenges, particularly incomplete follow-up data, inconsistencies in complication reporting, and the need for standardized definitions of failure and complications [**Chapter 3**,106]. Another concern, highlighted by Skyttä, is the potential underreporting of failures, which may occur when the implants used in conversions of failed total ankle replacement to arthrodesis are not documented [12]. Addressing these gaps will enhance the utility of registry data for improving TAR outcomes.

The prevention of complications is crucial for improving outcomes in total ankle replacement (TAR), ensuring patient safety and minimizing adverse events. TAR presents unique challenges, with higher rates of complications, failures and reoperations compared to ankle arthrodesis [35]. However, a meta-analysis found no statistically significant differences between TAR and ankle arthrodesis in clinical outcomes, patient satisfaction, complications or survival [107]. Spirit et al. indicated that up to 28% of TAR patients require additional surgeries due to complications [25]. Unlike hip or knee replacements, TAR outcomes are not directly comparable, highlighting the importance of tailored strategies to address its specific challenges [108,109].

Thorough documentation of complications is essential for identifying areas of improvement and refining surgical practices. Lamothe et al. observed that TAR failures requiring reoperation often occur around 16.4 months postoperatively, largely due to early surgical complications rather than mechanical implant failures [104]. These findings highlight the importance of optimizing surgical techniques, minimizing intraoperative risks and providing comprehensive perioperative care. Clear patient selection criteria, along with realistic patient education and expectations, are crucial for balancing functional improvements with reduced complication and revision rates [42,,67-72].

How long do ankle replacements last?

A data linkage study combining National Joint Registry (NJR) data and NHS Digital data reported a five-year survival rate of 90.2% for ankle arthroplasties [110]. In our CCI cohort, we observed a survival rate of 87.7% over a follow-up period of 7.1 years, which aligns with findings by Kormi et al., who reported a similar survival rate of 87% for the same CCI total ankle replacement system [**Chapter 2**,111]. Van Es et al. documented a 10-year survival rate of 67.5%, with an average time to revision of 4.5 years [112]. Furthermore, a meta-analysis of 28 studies involving 3,902 ankles reported an overall survival rate of 94% [84]. These findings highlight variability in survival rates depending on the follow-up duration and study context, emphasizing the need for standardized reporting and longer-term evaluations [113].

Achieving Long-Term Follow-Up

Current cohort studies often provide low levels of evidence due to limited sample sizes and follow-up periods. While long- and mid-term follow-up data from other cohorts provide valuable insights, the inclusion of short-term follow-up from our cohort is essential to identify early trends and outcomes specific to our patient population [113,114]. Moreover, there is an urgent need to prioritize randomized controlled trial (RCT) follow-up studies over observational cohort studies to establish stronger causal relationships and enhance the robustness of findings. RCTs offer the advantage of minimizing bias and confounding, thereby addressing the inherent limitations of observational designs [**Chapter 5**, 104,115]. This shift will not only strengthen evidence quality but also guide the optimization of patient-specific strategies [116].

By combining insights from past complications, integrating advanced analytics and technology, and employing rigorous patient selection and stratification strategies, health systems can significantly improve patient outcomes while reducing the adverse effects of steep learning curves in surgical and medical practices [81,116].

A dilemma arises as the medical industry faces the need to provide follow-up data beyond 10 years to comply with MDR regulations, while Dutch insurance companies aim to reduce medical costs [117]. This challenge continues to affect healthcare providers nationwide. Establishing long-term follow-up registries for total ankle replacements could be considered the responsibility of the medical industry, including funding their implementation.

Limitations of Research Approaches

The limitations of this thesis are apparent in its examination of total ankle replacement surgery, particularly in efforts to optimize clinical outcomes, address inherent complications, and improve both short-term follow-up practices.

a. Short Cohort Duration

Cohort studies often fail to capture long-term complications, such as implant loosening or osteolysis due to their relatively short durations. This limitation can obscure the true

survivorship of TAR implants, necessitating the establishment of registries with mandated long-term follow-ups [113].

b. Variation in Prosthesis Design

The steep learning curve associated with newer prosthesis designs complicates early outcome assessments [96]. For example, the CCI cohort experienced higher complication rates during the initial adoption phase, highlighting the need for comprehensive surgeon training and standardized protocols [66,118].

c. Outcome Limitations

The placement of outcome limitations, such as relying heavily on clinician-reported measures, particularly the AOFAS score, introduces bias [119]. Combining these measures with robust patient-reported outcome measures (PROMs) ensures a more holistic assessment of TAR success [46].

Strategies for Improvement

1. Enhanced Patient Stratification: Incorporating advanced machine learning models into patient selection can predict complication risks based on demographic, clinical and psychosocial variables. Stricter stratification criteria during early adoption phases of new implants can mitigate risks associated with the learning curve [Chapter 27,67-71,120].

2. Standardization of Definitions: The absence of consensus on defining TAR complications and failures hampers comparative analyses. Standardizing these definitions, such as distinguishing between low-grade complications and definitive failures, would facilitate more meaningful cross-study comparisons [13,14,15- 24].

3. Integration of Technology: Emerging technologies, such as AI-assisted surgical tools and wearable health monitors, can provide continuous feedback on implant performance and patient recovery. These tools enable proactive interventions, potentially reducing complication rates and improving long-term outcomes [53,81,121-123].

Conclusion

This thesis highlights the necessity of a multi-faceted approach to optimize TAR outcomes. By leveraging cohort registries and meta-analyses while addressing their limitations, the pathway to long-term success in TAR can be illuminated. Achieving this requires standardized definitions, enhanced patient stratification and the integration of advanced technologies. Ultimately, a collaborative effort to establish robust long-term follow-up mechanisms and incorporate innovative research methodologies will drive the evolution of TAR practices toward optimal patient care.

Future Research Directions

As a clinician who has reviewed numerous complications and witnessed the evolution of ankle replacement technologies, I have seen firsthand the critical importance of matching the correct prosthesis to the patient. Despite advancements such as the implant design and improved patient stratification, challenges remain in achieving unrestricted functionality and lifetime durability for all patients [66].

Future studies face the challenge of identifying the ideal prosthesis-patient pairing, aiming to create prostheses that offer unrestricted functionality and lifetime durability. Achieving this goal depends on several critical factors, including precise patient selection, minimizing complications, fostering shared decision-making, and effectively managing patient expectations.

These elements—patient selection, shared decision-making, expectation management, and meticulous surgical technique—do not exist in isolation. Instead, they intersect to form a comprehensive, patient-centered framework that drives advances in total ankle replacement surgery. For instance, shared decision-making is enriched by technological innovations such as advanced imaging and predictive modeling, which help clinicians better communicate surgical risks and benefits to patients [82,87,124]. Similarly, precise patient selection relies on clinical expertise and tools like real-time analytics, which can integrate patient-specific factors to refine treatment plans [42]. Together, these interconnected elements ensure that surgical interventions are not only technically successful but also tailored to meet patients' individual needs and expectations.

To address the challenges associated with the learning curve, real-time analytics and advanced technology present valuable opportunities for improvement. For instance, robotic-assisted surgery in total knee replacement has demonstrated improved accuracy in component positioning and enhanced patient-reported outcomes. Similarly, total ankle replacement surgery could benefit from such technological advancements. Evidence from robotic-assisted total knee and hip arthroplasty shows promising clinical outcomes, suggesting potential applications for total ankle replacement surgery [79-81,125]. However, the diverse range of foot and ankle procedures, combined with lower surgical volumes compared to arthroplasty, creates significant cost barriers that currently hinder the widespread implementation of these technologies in total ankle replacement [87].

National registry studies, such as those conducted by Vink et al., can provide valuable insights into the factors influencing the learning curve and how these factors vary across countries [83]. These findings are essential in understanding differences in outcomes and identifying areas for improvement [36,37]. By integrating data from such studies with emerging technologies, foot and ankle surgeons can create a feedback loop that drives continuous improvement and enhances the integrated approach to care, aligning with the focus on combining data, technologies and advancements into a unified care model.

In my role as an executive officer and faculty member of the European Foot and Ankle Society, I mentor the next generation of orthopedic surgeons to emphasize the importance of listening to patients' needs and tailoring treatments to their specific circumstances. This approach not only improves patient outcomes but also enhances the surgeons' professional growth and success. By integrating operational excellence, patient-centered care, and cutting-edge technology, we can continue to advance total ankle replacement surgery, ensuring better outcomes and improved quality of life for patients worldwide [87].

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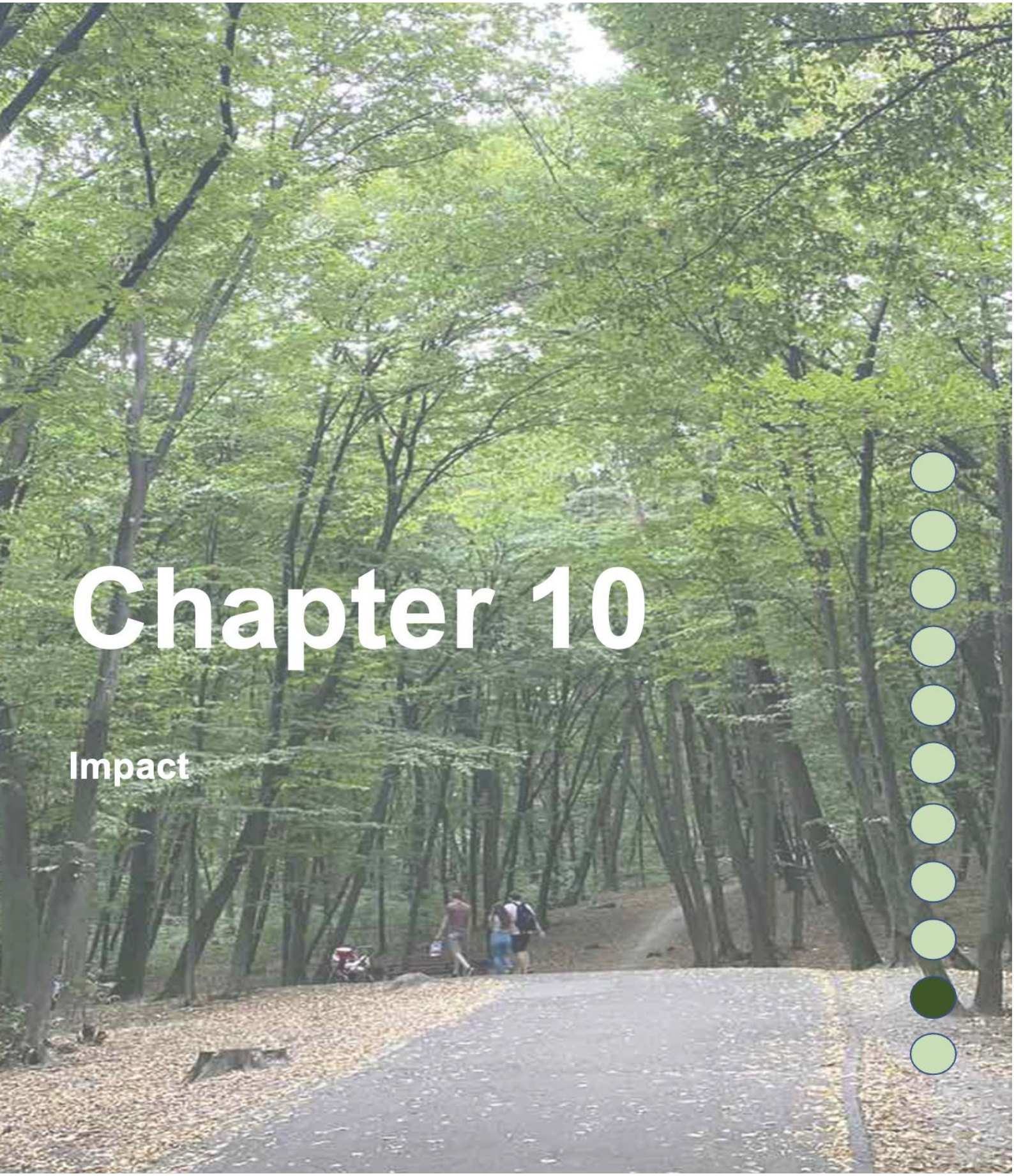
Chapter 10
Impact

Introduction

Over the past two decades, total ankle replacement (TAR) has gained increasing popularity as an alternative to ankle arthrodesis for treating severe ankle arthritis [1]. It has proven effective in alleviating pain, improving mobility, and enhancing patient satisfaction. Nonetheless, concerns persist regarding limited improvements in joint movement, potential complications, and the necessity for additional surgeries [2]. Although gait analysis, Deleu et al. demonstrated that total ankle replacement improves ankle mechanics and reduces compensatory mechanisms in the Chopart and hip joints, it may also minimize adjacent joint disease and alter walking patterns [3].

According to data collected in the TARVA trial, the economic evaluation of total ankle replacement indicates that it is cost-effective regarding quality-adjusted life years (QALYs) gained over the patient's lifetime. A QALY quantifies the value of medical interventions by considering the quality and quantity of life they provide, helping assess cost-effectiveness. When considering societal costs like lost earnings and dependence on family support, total ankle replacement was demonstrated to impose a lower economic burden than arthrodesis [4,5]. These findings, derived from external research, offer valuable insights into the clinical and socioeconomic benefits of total ankle replacement. In our Maastricht UMC Infinity cohort, we observed that patients experienced an improved quality of life postoperatively following total ankle replacement [**Chapter 4**].

Socioeconomic Impact

Improved classification in total ankle replacement surgery is essential for understanding the risk factors associated with failure and complications [**Chapter 3**]. This insight enables healthcare providers to stratify patients more effectively and tailor surgical and postoperative plans to individual needs. By identifying variables such as biomechanical characteristics, prior surgeries, or underlying health conditions, surgeons can make better-informed decisions about whether a patient is a suitable candidate for surgery or if alternative approaches are more appropriate [6].

Recognizing that patients with prior OCD surgery, higher BMI, or younger age are at greater risk for implant failure allows for more thorough patient selection processes [**Chapter 3**]. Emphasizing these risk factors during preoperative evaluations can reduce complication rates and improve the survivorship of total ankle replacement implants. Patients with these risk factors may benefit from targeted interventions, such as psychological support to address anxiety, which can adversely affect outcomes, particularly in the first year after surgery [**Chapter 4**]. Additionally, understanding the prevalence of complications like impingement highlights the importance of precise surgical techniques and advanced alignment tools to reduce these risks during operations [**Chapter 1 & 4-6**].

A comprehensive understanding of complications informs surgical decisions and guides the development of strategies to mitigate risks. For example, complications like implant migration or malalignment can be addressed using advanced imaging techniques or finite element analyses during preoperative planning [**Chapter 7 & 8**]. Ensuring proper ligament balance and minimizing bone resection during surgery is critical for reducing postoperative complications and enhancing implant longevity. Providing patients with clear information about their individual risks and expected outcomes helps manage their expectations, leading to greater satisfaction and adherence to postoperative care plans [7,8].

Incorporating improved classification systems creates a foundation for more effective treatment strategies. Understanding patient-specific factors and complications enables a more personalized approach, enhancing the surgical process and recovery outcomes [9].

The learning curve for total ankle replacement surgery is crucial for achieving optimal results [**Chapter 2, 3 & 5**]. Surgeons who are new to the procedure benefit from starting with simpler cases, such as those involving patients with less severe deformities, good bone quality, and minimal comorbidities. During the initial adoption phase of the Infinity Total Ankle System, focusing on minimal varus deformities and avoiding additional corrective surgeries helped optimize outcomes and reduce complications [**Chapter 4**]. This approach enables surgeons to refine their skills and build confidence before progressing to more complex cases.

The ongoing debate revolves around lowering the threshold for TAR to allow the procedure to be performed more frequently versus focusing on stricter patient selection to achieve better outcomes. Centralizing TAR procedures is increasingly important, as data from the LROI shows that 15 hospitals collectively performed 190 total ankle replacements [10]. Zaidi et al. highlighted in the NJR database that early revision rates are significantly higher in low-volume centers [11]. Given the demonstrated impact of surgical volume on outcomes, as noted in the NJR database, centralization offers a viable approach to standardize care and reduce complications. Their analysis in the UK established a threshold of 20 TARs per year, revealing that 19 centers performing over 20 TARs annually accounted for half of all procedures, while 163 centers performing fewer than 20 accounted for the other half. If a similar centralization strategy were implemented in our setting, it would raise important considerations. Assuming the three leading hospitals in the Netherlands maintain their current contributions in TAR, only four additional hospitals would meet the threshold of 20 procedures per year. This would reduce the number of hospitals performing TAR from the current 15 to merely 7. This is crucial because higher surgical volumes have been linked to better outcomes. Implementing centralization strategies could help mitigate complications and enhance the overall quality of care. By centralizing treatment in regional centers, patients can benefit from being treated by experienced surgeons, potentially leading to better outcomes and lower healthcare costs [12].

Scientific Impact

Despite their value, national registries face challenges, including incomplete follow-up data, inconsistencies in complication reporting, and the lack of standardized definitions for failures and complications. Additionally, underreporting of failures may occur when conversions to arthrodesis are not fully documented [**Chapter 3**]. Expanding and integrating registries such as the National Joint Register, Swedish Ankle Register, and Dutch Arthroplasty Register could enhance the reliability of data and support better decision-making. Comprehensive data collection also creates opportunities for incorporating advanced technologies such as artificial intelligence (AI). AI can analyze large datasets to identify patterns, enhance patient selection, and enable risk

stratification, leading to more precise and personalized treatment decisions. Robotic surgery and patient-specific instrumentation are additional promising advancements that can improve surgical precision and alignment in TAR [13,14]. However, their successful implementation relies on effective integration into clinical practice and the willingness of healthcare providers to adopt these innovations.

Conclusion

Total ankle replacement has become a transformative option for individuals with severe ankle arthritis, providing significant pain relief and improved mobility. While challenges remain, advancements in technology and patient care are addressing these issues. Integrating comprehensive data collection, artificial intelligence, robotic surgery, and patient-specific instrumentation can further refine treatment strategies and improve outcomes. The impact of my thesis lies in advancing knowledge regarding complications and failures, enabling enhanced risk stratification and improved patient selection to optimize outcomes, ensuring that total ankle replacement is offered to those most likely to benefit.

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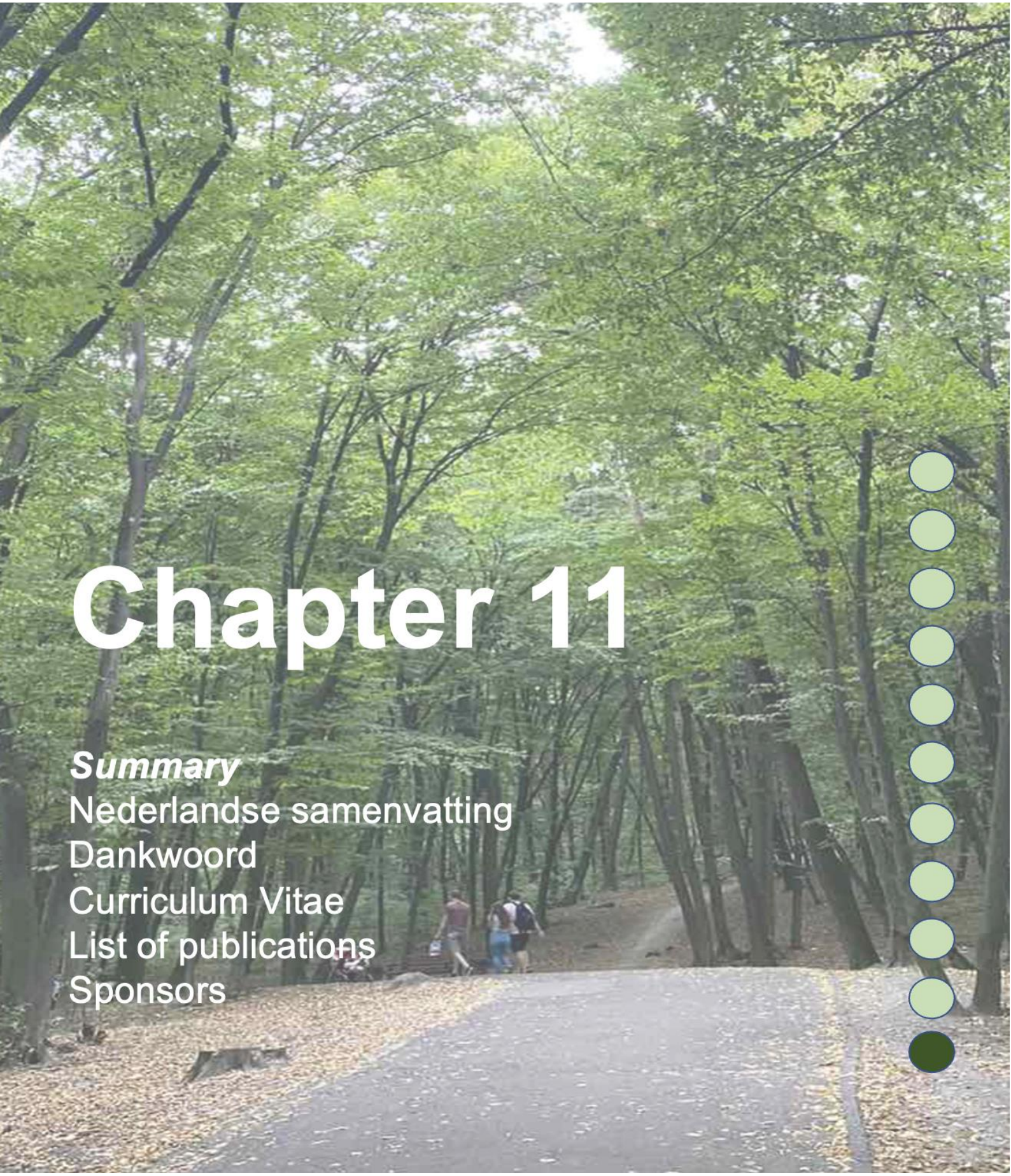


Chapter 11

Summary
Nederlandse samenvatting
Dankwoord
Curriculum Vitae
List of publications
Sponsors

Chapter 1: Introduction

This thesis explores the impact of total ankle replacement (TAR) as a treatment for end-stage ankle osteoarthritis, offering an alternative to arthrodesis by preserving joint mobility. Unlike hip and knee osteoarthritis, ankle osteoarthritis is often post-traumatic, leading to pain, stiffness, and functional limitations. While TAR provides significant benefits, it also presents challenges, including high failure rates, malalignment, and complications. This chapter outlines the study's objectives, including evaluating clinical outcomes, understanding complications, analyzing the role of alignment and biomechanics, developing tools to enhance surgical accuracy, and identifying the psychosocial factors that affect the patient's outcome. The chapter underscores the need for a multidisciplinary approach to optimize TAR outcomes.

Chapter 2: Alignment of CCI Total Ankle Replacements

This chapter explores the mid-term outcomes of Ceramic Coated Implant (CCI) total ankle replacements, focusing on clinical function, survival rates, and complications. Among 61 patients with 65 implants followed for a median of 85.2 months, survival was 87.7%, but 12.3% of cases failed, mainly due to migration or fractures. Complications occurred in 35.4% of cases, particularly impingement (12.3%) and deep infections (10.8%). All perioperative complications were reported within the first thirty ankle replacements, suggesting a potential learning curve in surgical technique. Radiographic analysis highlighted varus malalignment in 11.3% of cases and progressive radiolucency, particularly in zone 3, which correlated with failure risk. Despite these challenges, CCI TAR demonstrated comparable survival rates to other TAR designs, reinforcing the need for continued refinement of surgical techniques.

Chapter 3: Risk Factors for Failure in Total Ankle Arthroplasty

This chapter examines the risk factors for failure in total ankle replacement (TAR) based on data from the Dutch Arthroplasty Register (LROI). The study included 807 patients with 836 ankle replacements between 2014 and 2020, with a median follow-up of 38 months. The overall survival rate was 95.3%, while 4.7% of implants failed, necessitating revision or arthrodesis. Factors associated with a higher risk of failure included prior osteochondral defect (OCD) treatment, elevated BMI, and younger age.

The findings underscore the importance of careful patient selection, especially for those with a history of prior surgeries or elevated BMI. The study confirms that national arthroplasty registries provide reliable long-term survival data and highlight key risk factors that could impact future TAA outcomes. The study highlights also the challenges of data accuracy in national registries, where underreporting of TAR failures remains an issue, as conversions of failed TAAs to arthrodesis are not consistently documented.

Chapter 4: Does Anxiety Influence Outcome Measurements?

This chapter examines the impact of anxiety on outcomes in total ankle replacement (TAR). The study followed 25 patients with Infinity TAR implants over an average period of 34.18 months, assessing their functional, clinical, and radiographic results. Total ankle replacement (TAR) has been shown to significantly improve postoperative range of motion (ROM) and patient-reported outcome measures (PROMs). However, patients with higher anxiety levels, as measured by the Hospital Anxiety and Depression Scale (HADS), reported significantly worse outcomes in terms of pain perception, quality of life, and functional recovery. Linear regression analysis confirmed a strong negative correlation between anxiety and postoperative scores on the EQ-5D-5L, VAS, and MOxFQ. This chapter also highlights the need to shift the paradigm of TAR by integrating the psychological aspects of patient management into the treatment plan.

Chapter 5: Complications Following Total Ankle Arthroplasty: meta-analysis

This chapter provides a systematic review and meta-analysis of complications in total ankle replacement (TAR) based on 127 studies covering 16,964 procedures with an average follow-up of 48 months. The most frequent complications were intraoperative fractures and impingement, both occurring in 6% of cases, followed by aseptic loosening, wound healing issues, and component subsidence. The analysis revealed considerable variation in complication rates, which may be attributed to differences in patient selection, implant design, and surgical expertise. The overall quality of evidence was rated as low to very low according to the GRADE methodology. Awareness of these complications in TAR is essential for reducing their occurrence

and improving surgical outcomes. This study highlights the need for stringent patient selection criteria and precise surgical techniques to mitigate these risks. It also emphasizes the importance of effective complication management to ensure the longevity of the implant.

Chapter 6: Complications in Total Ankle Replacement

This chapter provides a comprehensive analysis of complications and discusses strategies for prevention and management. Common complications include deep infections, impingement, and intraoperative fractures. The chapter highlights that many of these issues arise in the early stages of a surgeon's learning curve, underscoring the necessity for robust training programs. It also addresses advancements in implant design, such as mobile-bearing systems, which have mitigated certain risks but have not completely eliminated them. The chapter advocates for continuous innovation and education to reduce complications and enhance patient outcomes.

Chapter 7: Malalignment and Biomechanical Stress

This chapter explores the biomechanical consequences of malalignment in ankle prostheses using finite element analysis. Malalignment significantly increases peak contact pressures, with valgus and posterior misalignments generating the highest stress levels. These elevated stresses are concentrated around the implant edges and fixation pegs, potentially leading to bone damage, micromotion, and implant loosening. Proper alignment is essential for reducing stress concentrations and ensuring implant longevity. While this study does not provide direct clinical recommendations, it highlights the biomechanical risks associated with misalignment and underscores the importance of precise surgical technique. Future research should focus on validating these findings with clinical data and developing strategies to minimize stress-induced implant failure.

Chapter 8: Development of a Tool for Measuring TAR Alignment

This chapter focuses on the development and validation of a semi-automatic clinical tool for measuring three-dimensional total ankle replacement (TAR) alignment using two-dimensional radiographs. Malalignment is a key factor in TAR failure, yet standard measurement methods are inconsistent and limited. The tool, implemented in MATLAB, uses edge contouring and perpendicular radiograph relationships to determine component positioning. Validation was conducted with ten patients, comparing tool accuracy to manual clinical measurements and CT data. By standardizing and improving TAR alignment measurements without requiring additional CT scans, the tool offers a cost-effective and radiation-free alternative for clinical and research applications. Future studies should focus on automating the tool further and applying it to larger datasets to refine TAR alignment assessment and its correlation with clinical outcomes.

Chapter 9: General Discussion

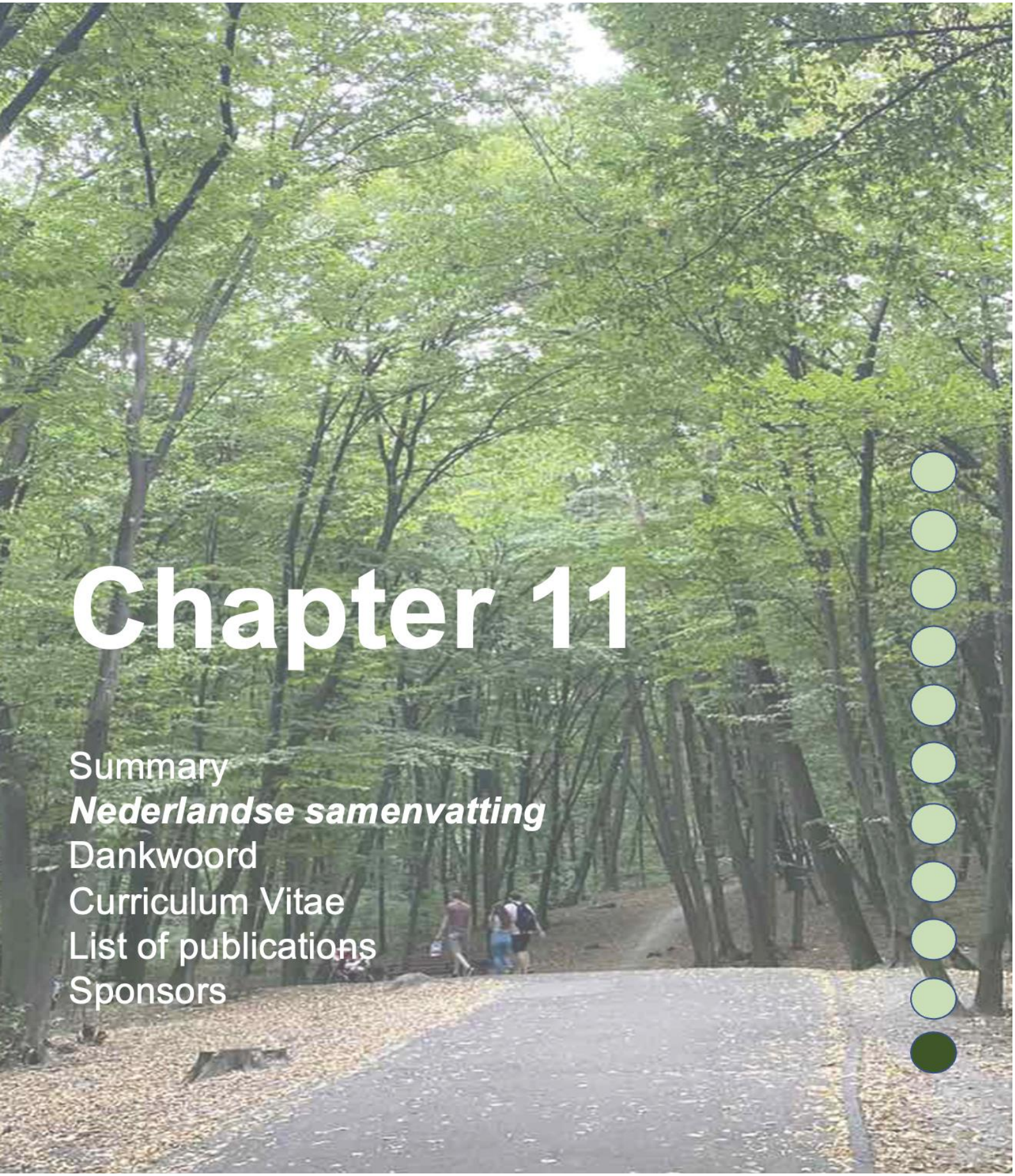
This research aims to refine surgical techniques and improve patient outcomes by addressing complications and failures in total ankle replacement (TAR). The study evaluates clinical outcomes, functionality, and long-term durability in light of advancements in implant design and surgical techniques. A key aspect is the analysis of complications and failures, examining their frequency, causes, and management strategies to enhance patient safety and surgical success. The investigation also highlights the role of biomechanics and alignment in implant longevity, integrating innovative tools such as semi-automated three-dimensional alignment measurements and finite element modeling to improve precision. Additionally, the thesis explores inconsistencies in defining implant failure across registries, emphasizing the importance of standardized reporting for better data interpretation. Findings indicate that strict patient selection, refined surgical techniques, and advanced implant designs significantly reduce complications. While ankle replacement remains a viable alternative to arthrodesis, the research underscores the need for continued technological and procedural refinements. Future studies should focus on incorporating real-time analytics, robotic-assisted surgery, and long-term follow-up

data to further optimize TAR outcomes.

Chapter 10: Impact

This chapter explores the impact of this thesis on advancing total ankle replacement (TAR), focusing on its influence on clinical outcomes, complication management, and implant longevity. While TAR has proven effective in alleviating pain and restoring mobility, challenges remain regarding implant survival, complication rates, and revision surgeries. Identifying key risk factors—such as high BMI, prior osteochondral defect surgery, and younger age—underscores the need for precise patient selection to improve long-term success. Evidence suggests that higher surgical volumes lead to better outcomes, reinforcing the importance of centralizing TAR procedures in experienced centers. National registries provide valuable data on TAR performance, yet inconsistencies in complication reporting and underreporting of failures highlight the need for standardized definitions. Emerging technologies, including artificial intelligence, robotic-assisted surgery, and patient-specific instrumentation, offer promising advancements in surgical precision and implant alignment. Moving forward, refining risk stratification, optimizing surgical techniques, and integrating cutting-edge technologies will be essential to enhancing TAR outcomes and ensuring greater implant longevity.

The TAR is associated with many advantages for patients with end-stage ankle OA, but at the same time has several drawbacks, which include high complication rates and the need for accurate alignment. This paper also highlights the importance of surgical techniques, the experience of the surgeon, and the use of patient-specific techniques in achieving positive outcomes. The thesis also emphasizes the psychosocial factors, such as anxiety, that affect patient satisfaction and recovery. New technologies, including innovative tools and implant designs, have the potential to minimize complications and improve the longevity of TAR implants. Therefore, the thesis concludes with a recommendation for a holistic approach to TAR that integrates technical, clinical, and psychological aspects to enhance patient care and outcomes.



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Hoofdstuk 1: Inleiding

Dit proefschrift onderzoekt de impact van totale enkelprothese (TEP) als behandeling voor eindstadium enkelartrose, waarbij een alternatief voor artrodese wordt geboden door het behoud van de gewrichtsmobiliteit. In tegenstelling tot heup- en knieartrose is enkelartrose vaak posttraumatisch, wat leidt tot pijn, stijfheid en functionele beperkingen. Hoewel TEP aanzienlijke voordelen biedt, zijn er ook uitdagingen, waaronder hoge faalpercentages, malalignement en complicaties. Dit hoofdstuk schetst de doelstellingen van het onderzoek, waaronder het evalueren van klinische uitkomsten, het begrijpen van complicaties, het analyseren van de rol van uitlijning en biomechanica, het ontwikkelen van hulpmiddelen om de chirurgische nauwkeurigheid te verbeteren en het identificeren van psychosociale factoren die de uitkomst voor de patiënt beïnvloeden. Het hoofdstuk benadrukt de noodzaak van een multidisciplinaire benadering om de resultaten van TEP te optimaliseren.

Hoofdstuk 2: Uitlijning van CCI-totale enkelprothesen

Dit hoofdstuk onderzoekt de middellangetermijnresultaten van Ceramic Coated Implant (CCI) enkelprothesen, met de nadruk op klinische functie, overlevingspercentages en complicaties. Onze studie van 65 CCI enkelprothesen met een mediane follow-up van 85,2 maanden toont een overleving van 87,7%, maar in 12,3% van de gevallen trad falen op, voornamelijk door migratie of fracturen. Complicaties kwamen voor in 35,4% van de gevallen, met name inklemming (12,3%) en diepe infecties (10,8%). Alle perioperatieve complicaties traden op bij de eerste dertig enkelprthesen, wat wijst op een mogelijke leercurve in de chirurgische techniek. Radiografische analyse toonde varus-misalignment in 11,3% van de gevallen en progressieve radiolucentie, vooral in zone 3, wat correleerde met een verhoogd risico op falen. Ondanks deze uitdagingen toonde de CCI enkelprothese vergelijkbare overlevingspercentages met andere enkelprothese-ontwerpen, wat de noodzaak benadrukt voor voortdurende verfijning van chirurgische technieken.

Hoofdstuk 3: Risicofactoren voor falen bij totale enkelprothesen

Dit hoofdstuk onderzoekt de risicofactoren voor falen bij totale enkelprothesen (TEP) op basis van gegevens uit het Nederlandse Enkelprothese Register (LROI). De studie omvatte 807 patiënten met 836 enkelprothesen tussen 2014 en 2020, met een mediane follow-up van 38 maanden. De algehele overlevingskans was 95,3%, terwijl 4,7% van de implantaten faalde, wat revisie of artrodese noodzakelijk maakte. Factoren die geassocieerd werden met een hoger risico op falen waren eerdere behandeling van osteochondrale defecten (OCD), een verhoogde BMI en een jongere leeftijd. Deze bevindingen onderstrepen het belang van zorgvuldige patiëntselectie. De studie bevestigt dat nationale enkelprothese registers betrouwbare langetermijngegevens over overleving bieden en belangrijke risicofactoren identificeren die de toekomstige resultaten van totale enkelprothese kunnen beïnvloeden. Daarnaast benadrukt de studie de uitdagingen rondom de nauwkeurigheid van gegevens in nationale registers, waarbij onderrapportage van totale enkelprothese -falen een probleem blijft, aangezien conversies van mislukte totale enkelprothesen naar een artrodese niet altijd consistent worden gedocumenteerd.

Hoofdstuk 4: Heeft angst invloed op uitkomstmetingen?

Dit hoofdstuk onderzoekt de invloed van angst op de uitkomsten van totale enkelprothesen (TEP). In onze studie met 25 patiënten die een Infinity enkelprothese kregen werden gemiddeld 34,18 maanden gevolgd. De functionele, klinische en radiografische resultaten werden poliklinisch beoordeeld. Hoewel de postoperatieve bewegingsuitslag (ROM) en door patiënten gerapporteerde uitkomstmaten (PROMs) bij een enkelprothese aanzienlijk verbetert, rapporteerden patiënten met een hogere angstniveau, gemeten met de Hospital Anxiety and Depression Scale (HADS), significant slechtere uitkomsten op het gebied van pijnbeleving, kwaliteit van leven en functioneel herstel postoperatief. Lineaire regressieanalyse bevestigde een sterke negatieve correlatie tussen angst en postoperatieve scores op de EQ-5D-5L, VAS en MOxFQ. Dit hoofdstuk adviseert de psychologische aspecten van patiëntenzorg te laten integreren in het behandelplan van een enkelprothese.

Hoofdstuk 5: Complicaties bij totale enkelprothesen: meta-analyse

Dit hoofdstuk biedt een systematische review en meta-analyse van complicaties bij totale enkelprothese (TAR), gebaseerd op 127 studies die 16.964 procedures beslaan met een gemiddelde follow-up van 48 maanden. De meest voorkomende complicaties waren intraoperatieve fracturen en impingement, beide voorkomend in 6% van de gevallen, gevolgd door aseptische loslating, wondgenezingsproblemen en verzakking van componenten.

De analyse toonde aanzienlijke variatie in complicatiepercentages, wat mogelijk te wijten is aan verschillen in patiëntselectie, implantaatontwerp en chirurgische expertise. De algehele bewijskwaliteit werd volgens de GRADE-methodologie beoordeeld als laag tot zeer laag. Bewustwording van deze complicaties bij TAR is essentieel om het optreden ervan te verminderen en chirurgische resultaten te verbeteren.

Deze studie benadrukt de noodzaak van strikte patiëntselectiecriteria en nauwkeurige chirurgische technieken om deze risico’s te beperken. Daarnaast wordt het belang onderstreept van een effectieve complicatiemanagementstrategie om de levensduur van het implantaat te waarborgen.

Hoofdstuk 6: Complicaties bij totale enkelprothesen

Dit hoofdstuk biedt een uitgebreide analyse van complicaties en bespreekt strategieën voor preventie en beheer. Veelvoorkomende complicaties zijn onder meer diepe infecties, impingement en intraoperatieve fracturen. Het hoofdstuk benadrukt dat veel van deze problemen zich voordoen in de vroege stadia van de leercurve van een chirurg, wat de noodzaak van robuuste trainingsprogramma's onderstreept. Het bespreekt ook de vooruitgang in implantaatontwerp, zoals systemen met een mobiele lagers, die sommige risico's hebben verminderd, maar ze niet volledig hebben geëlimineerd. Het hoofdstuk pleit voor voortdurende innovatie en educatie om complicaties te minimaliseren en de resultaten te verbeteren.

Hoofdstuk 7: Malalignement en biomechanische stress

Dit hoofdstuk onderzoekt de biomechanische gevolgen van malalignment in enkelprothesen met behulp van eindige-elementenanalyse. Malalignment verhoogt significant de piekcontactdrukken, waarbij valgus- en posterieure malalignments de hoogste stressniveaus genereren. Deze verhoogde spanningen concentreren zich rond de randen van het implantaat en de fixatiepennen, wat mogelijk kan leiden tot botschade, micromotie en loslating van het implantaat. Een correcte uitlijning is essentieel om stressconcentraties te verminderen en de levensduur van het implantaat te waarborgen. Hoewel deze studie geen directe klinische aanbevelingen geeft, benadrukt zij de biomechanische risico's die gepaard gaan met malalignment en onderstreept zij het belang van een nauwkeurige chirurgische techniek. Toekomstig onderzoek zou zich moeten richten op het valideren van deze bevindingen met klinische gegevens en het ontwikkelen van strategieën om stress-geïnduceerd falen van implantaten te minimaliseren.

Hoofdstuk 8: Ontwikkeling van een hulpmiddel om de uitlijning te meten van de enkelprothese

Dit hoofdstuk richt zich op de ontwikkeling en validatie van een semiautomatisch klinisch hulpmiddel voor het meten van de driedimensionale uitlijning van totale enkelprothesen met behulp van tweedimensionale röntgenbeelden. Malalignment is een belangrijke factor bij het falen van TAR, maar standaard meetmethoden zijn inconsistent en beperkt. Het hulpmiddel, geïmplementeerd in MATLAB, maakt gebruik van contourdetectie en loodrechte radiografische relaties om de positionering van componenten te bepalen. De validatie werd uitgevoerd bij tien patiënten, waarbij de nauwkeurigheid van het hulpmiddel werd vergeleken met handmatige klinische metingen en CT-gegevens. Door TAR-alignmentmetingen te standaardiseren en te verbeteren zonder extra CT-scans, biedt het hulpmiddel een kosteneffectief en stralingsvrij alternatief voor klinische en onderzoeksdoeleinden. Toekomstig onderzoek zou zich moeten richten op verdere automatisering van het hulpmiddel en de toepassing ervan op grotere datasets om de evaluatie van TAR-alignment en de correlatie met klinische uitkomsten te verfijnen.

Hoofdstuk 9: Algemene discussie

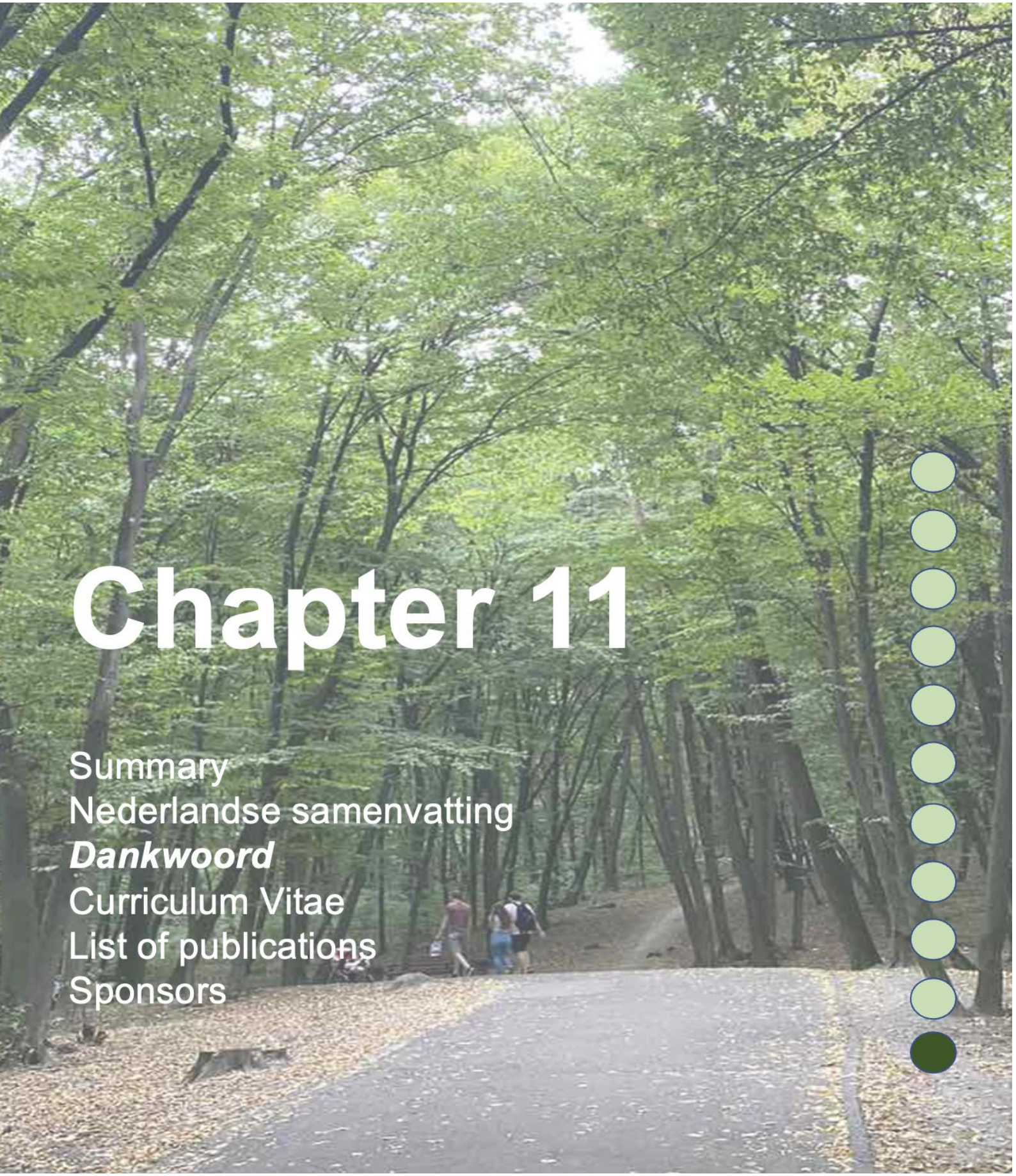
Dit onderzoek heeft als doel chirurgische technieken te verfijnen en patiëntuitkomsten te verbeteren door complicaties en falen bij totale enkelprothese aan te pakken. De studie evalueert klinische uitkomsten, functionaliteit en langdurige duurzaamheid in het licht van vooruitgang in implantaatontwerpen en chirurgische technieken. Een belangrijk aspect is de analyse van complicaties en falen, waarbij de frequentie, oorzaken en beheersstrategieën worden onderzocht om de patiëntveiligheid en chirurgisch succes te vergroten. Het onderzoek benadrukt ook de rol van biomechanica en alignment bij de levensduur van implantaten, waarbij innovatieve hulpmiddelen zoals semiautomatische driedimensionale alignmentmetingen en eindige-elementenanalyse worden geïntegreerd om de precisie te verbeteren. Daarnaast wordt in de thesis gewezen op inconsistenties in de definitie van implantaatfalen in verschillende registers, wat het belang onderstreept van gestandaardiseerde rapportage voor een betere interpretatie van gegevens. De bevindingen tonen aan dat strikte patiëntselectie, verfijnde chirurgische technieken en geavanceerde implantaatontwerpen complicaties aanzienlijk verminderen. Hoewel enkelprothese een levensvatbaar alternatief blijft voor arthrodese, benadrukt het onderzoek de noodzaak van voortdurende technologische en procedurele verfijningen. Toekomstige studies zouden zich moeten richten op de integratie van realtime analyses, robot-geassisteerde chirurgie en langetermijn-follow-up gegevens om enkelprothese-uitkomsten verder te optimaliseren.

Hoofdstuk 10: Impact

Dit hoofdstuk onderzoekt de impact van deze thesis op de vooruitgang van totale enkelprothese, met een focus op de invloed op klinische uitkomsten, complicatiebeheer en de levensduur van het implantaat. Hoewel de enkelprothese effectief is gebleken in het verlichten van pijn en het herstellen van mobiliteit, blijven er uitdagingen bestaan met betrekking tot implantaatoverleving, complicatiepercentages en revisieoperaties. Het identificeren van belangrijke risicofactoren—zoals een hoge BMI, eerdere osteochondraal defectchirurgie en jongere leeftijd—onderstreept de noodzaak van nauwkeurige patiëntselectie om het langdurig succes te verbeteren. Bewijs suggereert dat een hoger chirurgisch volume leidt tot betere uitkomsten, wat het belang benadrukt van centralisatie van

enkelprothese-procedures in ervaren centra. Nationale registers bieden waardevolle gegevens over enkelprothese-prestaties, maar inconsistenties in het rapporteren van complicaties en onderrapportage van falen onderstrepen de noodzaak van gestandaardiseerde definities. Opkomende technologieën, waaronder kunstmatige intelligentie, robot-geassisteerde chirurgie en patiëntspecifieke instrumentatie, bieden veelbelovende vooruitgangen op het gebied van chirurgische precisie en implantaatuitlijning. Vooruitkijkend zullen het verfijnen van risicostratificatie, het optimaliseren van chirurgische technieken en de integratie van geavanceerde technologieën essentieel zijn om enkelprothese-uitkomsten te verbeteren en een langere levensduur van het implantaat te waarborgen.

De enkelprothese biedt aanzienlijke voordelen voor patiënten met vergevorderde enkelartrose, maar brengt unieke uitdagingen met zich mee, waaronder hoge complicatiepercentages en de noodzaak van nauwkeurige uitlijning. Correcte chirurgische technieken, ervaren chirurgen en patiëntspecifieke benaderingen zijn cruciaal om optimale resultaten te behalen. De thesis benadrukt ook de rol van psychosociale factoren, zoals angst, bij het vormgeven van patiënttevredenheid en herstel. Innovaties in hulpmiddelen en implantaatontwerpen bieden hoop om complicaties te verminderen en de duurzaamheid van enkelprothese-implantaten te verbeteren. De thesis roept op tot een multidisciplinaire aanpak van de enkelprothese, waarbij technische, klinische en psychologische expertise wordt gecombineerd om de zorg en resultaten van de enkelprothese te verbeteren.



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Beste Lodewijk, Martijn en Chris,

Wat een reis is het geweest! Ik had het niet zonder jullie kunnen doen. Elk van jullie heeft een unieke rol gespeeld in dit traject, en ik wil graag even stilstaan bij wat jullie voor mij hebben betekend.

Lodewijk, jouw begeleiding was een baken van rust en wijsheid. Jij wist altijd de juiste vragen te stellen, zonder dat ik het gevoel kreeg dat ik constant getest werd – al zat ik soms stiekem wel even te zweten bij je scherpe blik. Dankzij jouw geduld en vertrouwen kon ik groeien en mijn eigen weg vinden, en daar ben ik je ontzettend dankbaar voor.

Martijn, mijn trouwe partner in crime op het gebied van enkelprotheses. Je was niet alleen een geweldige collega met wie ik klinische kennis kon delen, maar ook een bron van praktische inzichten en humor. Geen uitdaging was te groot, geen casus te ingewikkeld – al vraag ik me soms nog af hoe jij altijd wist wanneer ik koffie (dr. de Bruin) nodig had. Bedankt voor het zijn van een fantastische collega en vriend.

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Beste collega's (Adhiambo Witlox , Tim Boymans, Heleen Staal, Paul Willems, Mark van de Boogaart, Eva Jacobs, Jan Geurts, Erwin Peters, Loek Verlaan, Sharmila Venkatesan, Tom van Vugt, Peter Feczko, Pieter Emans, Chris Arts en Tim Welting)

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vergaderingen—het zijn deze momenten samen die ons team sterk maken en ons werk nog leuker maken.
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Beste dames van het secretariaat
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Beste A(N)IOS

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tijden was jij daar ook. Je steun en luisterend oor waren van onschatbare waarde, en dat vergeet ik niet.
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straks het verschil gaat maken in het MUMC+, vervult me met een trots die met geen pen te beschrijven is.

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Jullie drieën zijn mijn grootste trots en het mooiste cadeau dat ik me kan voorstellen. Jullie liefde, steun en humor hebben me door dit traject heen geholpen, en ik ben zó dankbaar om te kunnen zeggen dat ik jullie vader mag zijn. Bedankt dat jullie er altijd voor me zijn en dat jullie mij zo veel geluk brengen.

Lieve Tanya,

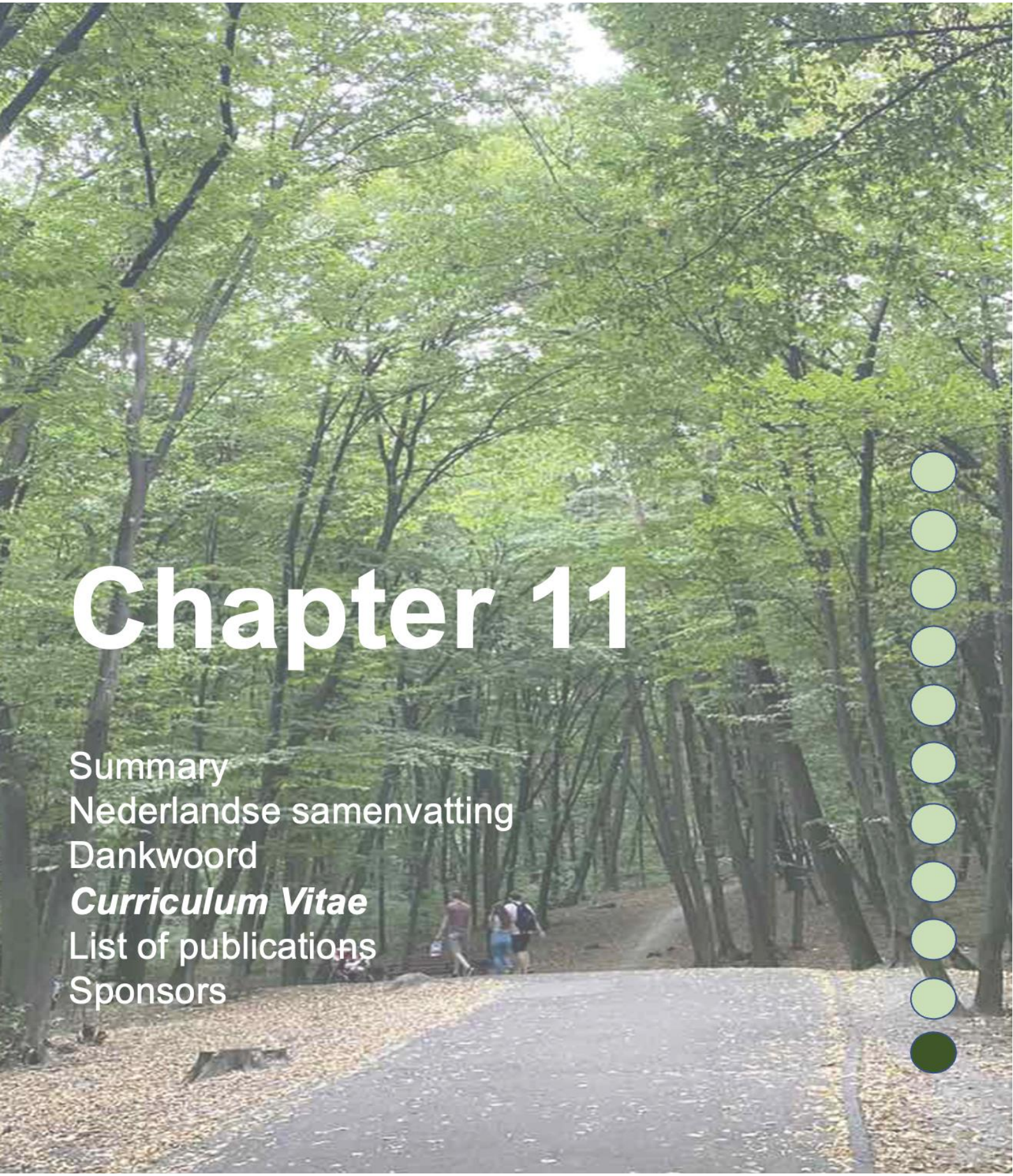
Wat ben ik een gelukkig man om jou aan mijn zijde te hebben. Jij bent, zonder twijfel, mijn supervrouw. Vanaf het moment dat we samen besloten om onze levens te verbinden, heb je niets anders gedaan dan je volledig inzetten voor ons, en ik kan niet genoeg woorden vinden om uit te drukken hoe dankbaar ik daarvoor ben.

Binnen een paar jaar heb jij de Nederlandse taal onder de knie gekregen – iets wat al bewonderenswaardig is – maar daar bleef het niet bij. Je behaalde, met vlag en wimpel, alle examens die nodig waren om ervoor te zorgen dat we samen konden blijven en hier een leven konden opbouwen. Jouw vastberadenheid en doorzettingsvermogen zijn niets minder dan inspirerend.

Thuis ben jij mijn rots en mijn warmte. Iedere keer als ik thuiskom, word ik met liefde verwelkomd door jouw glimlach en jouw ongelofelijke Oekraïense lekkernijen. Jouw zorgzaamheid en toewijding maken ons huis niet alleen een plek om te wonen, maar echt een thuis.

Daarnaast ben je ook mijn steunpilaar geweest tijdens het schrijven van dit proefschrift. Als lerares Engels bij United World College wist je precies hoe je mijn teksten naar een hoger niveau kon tillen. Jouw scherpe blik en taalgevoel hebben ervoor gezorgd dat ik mijn werk met trots kon presenteren.

Lieve Tanya, zonder jou had ik dit nooit kunnen bereiken. Jij bent mijn kracht, mijn steun, en mijn grote liefde. Dank je wel voor alles wat je doet en bent. Ik ben ongelooflijk dankbaar dat jij mijn vrouw bent en dat we samen dit mooie leven mogen delen.



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Curriculum Vitae: Joris Hermus

Joris Hermus was born on June 16, 1973, in Nijmegen, Netherlands. He completed his secondary education in Steenbergen and attended college in Bergen op Zoom. In 1991, he began his medical studies at Erasmus University Medical Center in Rotterdam, graduating in 1998.

After earning his medical degree, Joris Hermus started his surgical residency at Hospital De Lichtenberg in Amersfoort and continued his training at the Zuiderziekenhuis in Rotterdam. He pursued his orthopedic surgery residency at various institutions, including Erasmus Medical Center, the Red Cross Hospital, and Juliana Children's Hospital in The Hague. In 2005, he joined Maastricht University Medical Center+ (MUMC+) to complete his orthopedic training, becoming a certified orthopedic surgeon by the end of 2008.

In 2009, Joris Hermus began his career as an orthopedic surgeon at Maastricht University Medical Center+. To further specialize in foot and ankle surgery, he completed a fellowship at the University Hospital Antwerp under the mentorship of Professor Greta Dereymaeker. That same year, he was appointed as the education coordinator for the Department of Orthopedic Surgery at the Faculty of Health, Medicine, and Life Sciences, Maastricht University, where he has been instrumental in training students, residents, and surgeons.

Joris Hermus became a certified foot and ankle surgeon in 2014 after passing the European Foot and Ankle Society (EFAS) certification exam, being one of the first surgeons in Europe to achieve this distinction. He has served as the orthopedic consultant for MVV Maastricht, a professional soccer team, and completed training as a level 1 trauma orthopedic trauma surgeon in 2015.

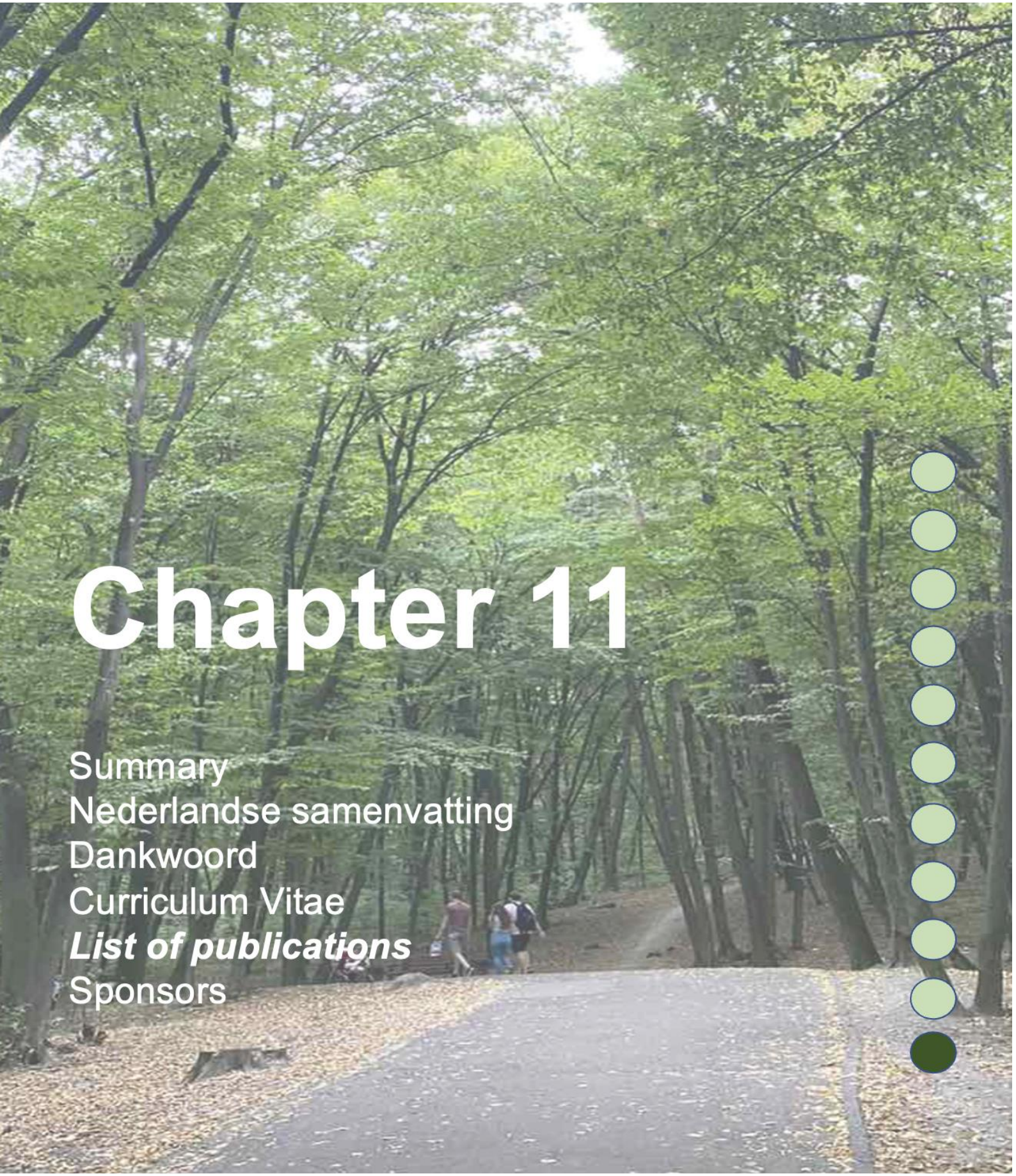
In addition to his clinical practice, Joris Hermus is deeply involved in research, focusing on topics such as ankle prostheses, joint-preserving techniques, and innovative solutions. His work is guided by collaborations with renowned professors Chris Arts, Martijn Poeze, and Lodewijk van Rhijn.

In 2017 Joris Hermus passed the BKO Basic qualification skill for pedagogical competencies. From the start of his career as an orthopedic surgeon at MUMC+, Joris Hermus has been deeply committed to training medical students and actively engaging them in the field of orthopedics. He was a coach for the third year Medical

students, AKO BBG II, educational coordicator of Orthopedic surgery and Coordinator of the Orthopedic surgery medical internship.

Joris Hermus is an active member of the European Foot and Ankle Society, where he has served as a council member since 2019. He currently holds the position of honorary secretary and chairs the society's media committee. Additionally, he participates in Dutch Foot and Ankle Society activities as an education commissioner.

On a personal note, Joris Hermus shares his life with his partner, Tanya Kryvoruchko, who has been a constant source of support throughout his career and academic pursuits. He has three children: Koen, Stijn, and Eline. Joris Hermus remains committed to advancing orthopedic surgery through his practice, education, and research.



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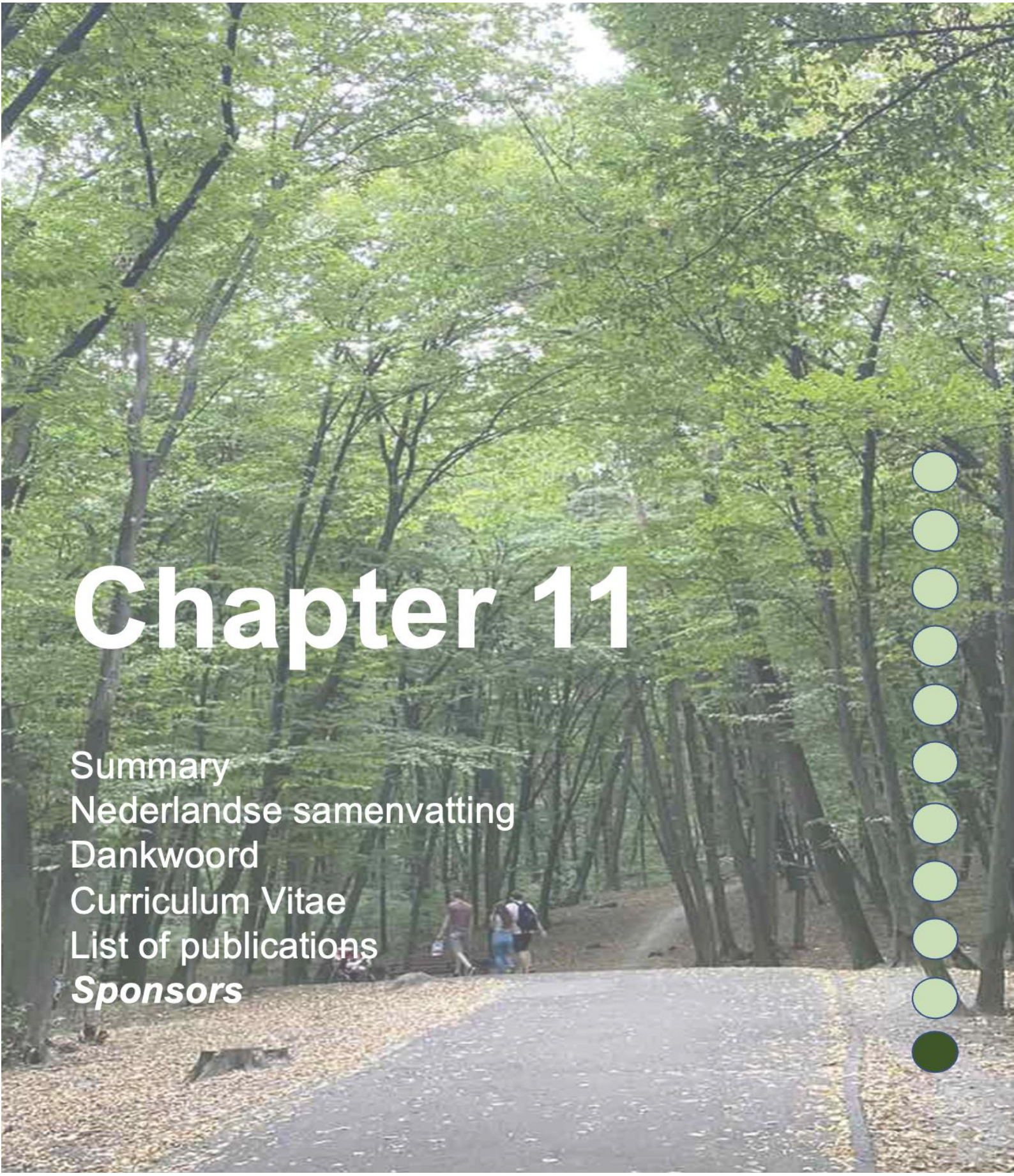

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