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Sami Kormi

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“Movement is life, and life is movement. Our job as surgeons is to give back what disease or injury has taken away.”
Sir John Charnley

To my ever-beloved family

UNIVERSITY OF TURKU
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ABSTRACT

Total ankle replacement (TAR) outcomes have improved in treating ankle osteoarthritis, although complication rates are higher than for hip and knee arthroplasties. Modern implant designs are typically categorized into two groups based on the mobility of the polyethylene component: mobile bearing implants (MBI) and fixed bearing implants (FBI). The most common surgical approach is anterior, but a lateral approach is also used.

The aims of this doctoral thesis were to evaluate the functional and radiological outcomes, patient satisfaction, and implant survival of TAR using a trabecular-coated FBI model with a lateral approach (Zimmer Trabecular Total Ankle, Zimmer, TMTA, Warsaw, IN) and an older MBI model (Ceramic Coated Implant; Wright Medical Technology, CCI, Arlington, TN, USA) with the traditional anterior approach. We also investigated the motion of the polyethylene insert relative to the tibial component in the MBI implants using cone-beam computed tomography (CBCT). Lastly, we evaluated the incidence of peri-implant osteolysis associated with a new surgical technique and implant model, TMTA.

Based on the results of our studies, we conclude that using the FBI model achieved better outcomes in terms of patient satisfaction, pain management and implant survival. Additionally, the lateral approach combined with an external frame allowed for correction of more complex deformities and enabled more precise alignment. We also demonstrated that the incidence of periprosthetic osteolysis is significantly lower when using the new trabecular-coated FBI. Consequently, the need for additional procedures due to osteolysis was reduced.

Based on our findings, we recommend centralizing TAR operations in experienced centres, shifting to modern implant designs and adopting advanced surgical techniques to achieve better treatment outcomes.

KEYWORDS: ankle osteoarthritis, total ankle replacement, lateral approach, osteolysis

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Lääketieteellinen tiedekunta
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TIIVISTELMÄ

Nilkan tekonivelleikkauksen (TAR) tulokset ylemmän nilkkanivelen nivelrikon hoidossa ovat parantuneet merkittävästi, vaikka uusintaleikkausten määrä on korkeampi verrattaessa suurten nivelten tekonivelhoitomuotoihin. Nykyaikaiset tekonivelmallit jaotellaan tyypillisesti kahteen kategoriaan muovikomponentin liikkuvuuden perusteella; liikkuviin (mobile bearing, MBI) ja kiinteisiin muoveihin (fixed bearing, FBI). Toimenpidetekniikka on edestä tai ulkosivulta pohjeluun läpi.

Tämän väitöskirjan tarkoituksena oli: 1) selvittää nilkan tekonivelleikkauksen toiminnallisia ja kuvantamistuloksia, potilastyytyväisyyttä sekä tekonivelten pysyvyyttä käytettäessä trabekulaaripinnoitteista FBI-mallia uudemmasta lateraalisesta avauksesta (Zimmer Trabecular Total Ankle, Zimmer, TMTA, Warsaw, IN) sekä MBI-mallia (Ceramic Coated Implant; Wright Medical Technology, CCI, Arlington, TN, USA) perinteisestä etuavauksesta. 2) Selvittää kartiokeilatietokonetomografian avulla MBI proteesin muovin liikettä suhteessa sääriluun komponenttiin. 3) Selvittää periproteettisen osteolyysin ilmaantuvuutta käytettäessä uutta leikkaustekniikkaa sekä proteesimallia.

Osatöiden tulosten perusteella voimme todeta, että FBI mallilla saavutettiin paremmat tulokset potilastyytyväisyydessä, kivunhoidossa sekä proteesien pysyvyydessä. Lisäksi lateraalisen avauksen sekä ulkoisen kehikon avulla pystyttiin korjaamaan vaativampia virheasentoja sekä saavuttamaan tarkempi komponenttien asemointi. Osoitimme myös, että proteesikomponenttien ympärillä esiintyvän osteolyysin määrä on huomattavasti vähäisempi käytettäessä uutta trabekulaaripinnoitettua FBI proteesimallia. Näin ollen myös osteolyysistä aiheutuvien uusintaleikkausten määrä väheni.

Suosittelemme keskittämään toimenpiteet kokeneisiin yksiköihin, siirtymään moderneihin tekonivelmalleihin sekä nykyaikaisiin leikkaustekniikoihin.

AVAINSANAT: nilkan nivelrikko, nilkan tekonivel, lateraalinen avaus, osteolyysi

Table of Contents

Abbreviations

AAD	Ankle arthrodesis
AOA	Ankle osteoarthritis
AOFAS	American Orthopaedic Foot and Ankle Society
AP	Anteroposterior
ATFL	Anterior talofibular ligament
CBCT	Cone-beam computed tomography
CCI	Ceramic Coated Implant
CT	Computed tomography
FBI	Fixed bearing implant
MBI	Mobile-bearing implant
MRI	Magnetic resonance imaging
OA	Osteoarthritis
PI	Polyethylene insert
PROM	Patient-reported outcome measure
PSI	Patient-specific instrumentation
RA	Rheumatoid arthritis
RCT	randomized controlled trial
ROM	Range of motion
SD	Standard deviation
TAR	Total ankle replacement
TARVA	The total ankle replacement versus ankle arthrodesis -trial
TMTA	Trabecular Metal Total Ankle
VAS	Visual analogue scale
WBCT	Weight bearing computed tomography

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

I Tiusanen H, Kormi S, Kohonen I, Saltychev M. Results of trabecular-metal total ankle arthroplasties with transfibular approach. Foot Ankle Int. 2020 Apr;41(4):411–418

II Koivu H, Kormi S, Kohonen I, Tiusanen H. The motion between components in a mobile-bearing total ankle replacement measured by cone-beam CT scanning. Foot Ankle Surg. 2022 Apr;28(3):324–330.

III Kormi S, Kohonen I, Koivu H, Tiusanen H. Low rate of peri-implant osteolysis in trabecular metal total ankle replacement on short- to midterm follow-up. Foot Ankle Int. 2021 Nov;42(11):1431–1438

IV Kormi S, Koivu H, Kohonen I, Mäkelä K, Tiusanen H, Saltychev M. The ceramic coated implant (CCI). Evolution total ankle replacements: a retrospective analysis of 40 ankles with 8 years follow-up. Acta Orthop Belg. 2023 Sep;89(3):515–524.

1 Introduction

Osteoarthritis is one of the most common joint diseases globally and a leading cause of disability. Total ankle replacement (TAR), or total ankle arthroplasty, is a surgical procedure used to treat end-stage ankle arthritis by replacing the damaged articular surfaces of the ankle joint with artificial components. The method requires an experienced orthopaedic surgeon to make a well-considered operative decision. The primary goals are to relieve the patient's pain and preserve ankle motion. However, the operation is demanding and carries a relatively high risk of complications, such as peri-implant osteolysis. Recent advances in implant design and surgical techniques have shown promising improvements in clinical outcomes.

The first total ankle implant was introduced in 1970. TAR was developed as an alternative to ankle joint fusion. However, the unique anatomical and biomechanical characteristics of the ankle, combined with the multifactorial changes caused by end-stage ankle arthritis, initially led to unacceptably high failure and complication rates. For decades, arthrodesis has remained the gold standard. Nevertheless, research continued to improve ankle replacement techniques and implants. Today's modern third, fourth, and even fifth-generation TAR implants can be divided into two main categories: mobile-bearing implants (MBI), where the polyethylene insert (PI) can move freely, and fixed-bearing implants (FBI), where the PI is attached to the tibial component. Both types of implants are currently in use, and manufacturers are under pressure to develop better prosthesis designs. However, concerns about TAR performance persist.

This thesis aimed to evaluate the clinical, radiological, and functional outcomes of patients who underwent primary TAR with two different types of implants. Another goal was to explore the use of cone-beam computed tomography (CBCT) during follow-up for TAR to demonstrate the potential motion of the mobile-bearing PI. Lastly, we sought to determine the rate of peri-implant osteolysis in trabecular-metal TAR.

2 Review of the Literature

2.1 Ankle anatomy

A solid understanding of anatomy is essential for working with TAR. The ankle is an imprecise region between the leg and the foot. The ankle joint, also known as talocrural articulation, is generally considered a hinged synovial joint, formed by the talus, tibia and fibula articulation (Gray et al., 2022). More precisely, it can be defined as a multiaxial joint system that facilitates three-dimensional motion. The structures of the ankle and the foot form a substantial entity. The movement of the foot consists of multi-joint functions. Any anatomical reformation or change in these characteristics changes the entire function of the lower limb. The axis of the joint partly depends on the anatomy and the stability of the ligamentous structures (Gomes et al., 2023). In this thesis, "ankle joint" refers explicitly to the talocrural joint. However, acknowledging the broader ankle joint complex is crucial for comprehending the disorders resulting from ankle trauma or osteoarthritis. It also clarifies the requirements for the properties of TAR.

2.1.1 Bony and ligamentous structures

The foot and ankle region has 28 bones, 33 joints, 112 ligaments, 13 extrinsic and 21 intrinsic muscles. The hind foot has three main joints: the ankle joint, the talocalcaneal joint (the subtalar joint) and the midtarsal joints (the Chopart joint).

The ankle joint is formed by three bones: the tibia on the medial side, the fibula on the lateral side and the talus. There are two bony enlargements on either side of the ankle, the malleoli. The medial malleolus is the distal part of the tibia, and it forms the V-shaped tibial plafond (the tibia´s articular surface). The lateral malleolus is the distal part of the fibula. Together, these structures create an arch known as the ankle mortise, which articulates with the talus (Gomes et al., 2023).

The talus is an irregularly shaped bone with no muscular attachments. It is divided into the head, neck and body. Approximately 60% of the surface of the talus is covered with articular cartilage. The talus is in the centre of a vast but fragile vascular network, but there is only a small area to be perforated by blood vessels. Its arterial supply comes from the three main arteries of the lower

extremity: the posterior tibialis, the anterior tibialis, and the peroneal artery (Peterson et al., 1974).

The subtalar joint is located directly below the ankle joint, between the talus and the calcaneus. It is a multi-articular joint consisting of three articulated facets: the anterior subtalar joint, the medial subtalar joint, and the posterior subtalar joint. The subtalar joint structure enables the inversion and eversion movements of the ankle. The primary connective tissue between these bones is the interosseus talocalcaneal ligament (Gray et al., 2022).

The midtarsal joints separate the rearfoot from the midfoot and consist of the talonavicular and calcaneocuboid joints. The talonavicular joint, located between the talus and navicular bones, is stabilized by the anterior talocalcaneal joint capsule. It allows for ankle pronation and supination. The concavoconvex calcaneocuboid joint is located between the calcaneus and the cuboid bone, with corresponding articular surfaces that are relatively flat but exhibit some irregular contours. The cuboid bone can rotate and pivot around the calcaneal process of the calcaneus. Mobility varies, but it can be up to 25°. The joint also permits some degree of gliding movement along the edges of the joint (Greiner & Ball, 2008). The critical anatomy of the ankle is illustrated in Figures 1 and 2.

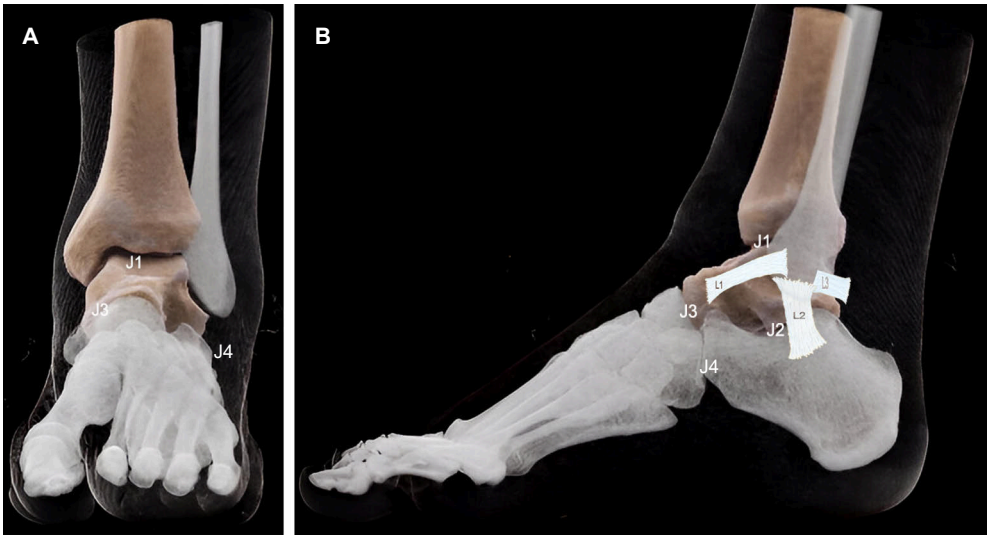

Figure 1. (**A**) anterior view and (**B**) lateral view of the ankle. J1: ankle joint, J2: talocalcaneal joint, J3: talonavicular joint, J4: calcaneocuboid joint, L1: anterior talofibular ligament, L2: calcaneofibular ligament, L3: posterior talofibular ligament. © Sami Kormi

The stability of the ankle joint is formed by the bones, the joint capsule and the ligamentous support. The static stabilizers of the ankle are the anterior talofibular

ligament (ATFL), calcaneofibular and posterior talofibular ligaments. On the lateral side, the tibia and fibula are firmly interconnected by the interosseus membrane, anterior inferior tibiofibular ligament (AITFL) and posterior inferior tibiofibular ligament (PITFL). The AITFL, PITFL, interosseus ligament and transverse tibiofibular ligament form the anterior and posterior syndesmosis (Burks & Morgan, 1994). The lateral ligament complex resists inversion, external tibial rotation, and anterior draw of the talus while the ankle is plantarflexed. It also guides calcaneal inversion. The main medial stabilizers are the deltoid and spring ligaments and the medial malleolus, which resist lateral talar translation, rotation and valgus. The deltoid ligament is a complex structure, consisting of up to six individual ligamentous bands (Cain & Dalmau-Pastor, 2021). The two primary components are the superficial and deep deltoid ligaments. The superficial component is a multi-part structure that originates from the medial malleolus and inserts into the plantar

Figure 2. Medial collateral (deltoid) ligament and spring (Sp1). M1: anterior tibiotalar ligament, M2: tibionavicular ligament, M3: tibiospring ligament, M4: tibiocalcaneal ligament, M5: posterior tibiotalar ligament. © Sami Kormi

calcaneonavicular ligament, including the spring ligament (Campbell et al., 2014). There is a close relationship between the deltoid and spring ligaments, the latter being particularly important when discussing hindfoot alignment (Krautmann & Kadakia, 2021). The presence of individual ligamentous bands varies between individuals, with no consensus on which bands are constant or variable. Additionally, there is no agreement on the size, orientation, spatial relationships between the bands, or their distance from bony landmarks (Campbell et al., 2014).

2.1.2 Tendons and neurovascular structures

Three sets of tendons cross the ankle joint, excluding the Achilles and plantaris tendons. On the medial side, passing behind the medial malleolus, are the flexor tendons: the tibialis posterior, flexor digitorum longus and flexor hallucis longus. The tibial nerve innervates muscles that attach to these tendons. Anteriorly, the extensor tendons include the tibialis anterior, extensor digitorum longus, extensor hallucis longus, and peroneus tertius. The deep peroneal nerve innervates these tendons. On the lateral side, passing behind the lateral malleolus, are the evertor tendons: the peroneus longus and peroneus brevis. The superficial peroneal nerve innervates muscles that attach to these tendons.

Two principal neurovascular bundles crossing the ankle joint must be considered when performing surgery in the ankle region. The anterior neurovascular bundle, consisting of the deep peroneal nerve and the anterior tibial artery, runs along the front of the ankle between the tibialis anterior and extensor hallucis longus, proximal to the ankle joint. At the level of the ankle joint, the extensor hallucis longus tendon crosses this bundle. The posterior neurovascular bundle comprises the posterior tibial artery and the tibial nerve. Additionally, two sensory nerves crossing the ankle joint: the nervus saphenus on the medial side and the nervus suralis on the lateral side (Gray et al., 2022).

2.1.3 Cartilage

Unlike other large load-bearing joints, the ankle rarely develops osteoarthritis, likely due to the cartilage quality in the ankle joint. The reasons for this lower incidence are not comprehensively understood. Anatomical, evolutionary, metabolic, biomechanical, and biochemical differences exist between these joints (Kraeutler et al., 2017). Ankle osteoarthritis (AOA) affects approximately 1% of the global adult population (Jaleel et al., 2021). Primary osteoarthritis of the ankle accounts for only 9% of ankle arthritis cases. However, the ankle joint is often exposed to trauma, which is hypothesized to lead to secondary osteoarthritis, as 78% of ankle

osteoarthritis is attributed to trauma (Saltzman et al., 2005; Valderrabano et al., 2009).

Variations among joints in the initiation and progression of degeneration have been attributed to multiple factors. The articular cartilage in the ankle is thinner than in the knee or hip, with tibial cartilage thickness ranging from 1.06 to 1.63mm and talar cartilage thickness from 0.94 to 1.62mm (Shepherd & Seedhom, 1999). The cartilage surface is also more uniform, preserving its elastic yet stiff form. The superficial zone of hyaline articular cartilage is tangential. In this layer, the chondrocytes are aligned horizontally, and most are paired, but in the knee joint, more than half are arranged in strings and clusters (Rolauffs et al., 2008). Research has shown that ankle joint cartilage has a better capability of repairing itself and has increased stiffness and decreased permeability because of increased proteoglycans and water (Kuettner & Cole, 2005). Additionally, the high density of the extracellular matrix in ankle cartilage is believed to provide better protection against mechanical stress (Treppo et al., 2000).

Individual differences in cartilage composition, as well as variations in the cartilage cells and matrix morphologies of the ankle joint, likely contribute to osteoarthritis (Quinn et al., 2013).

The only cell type present in articular cartilage is chondrocytes. When comparing the ankle to the knee and hip, the chondrocytes in the ankle synthesize more proteoglycans and are more responsive to anabolic factors, such as osteogenic protein-1 (Cole & Kuettner, 2002). Additionally, ankle chondrocytes are less responsive to proteoglycan synthesis inhibitors, such as fibronectin fragments and interleukin-1β (Dang et al., 2003). Matrix metalloproteinases (MMPs) are enzymes that cause degeneration of extracellular matrix proteins. It has been shown that in ankle cartilage, there is less mRNA expression of matrix metalloproteinase-8, which may offer protective advantages to the ankle joint compared to the knee joint (Eger et al., 2002).

2.2 Ankle biomechanics

To identify and describe the movements of the ankle joint, one must use precise definitions of the positions, motions, and planes that divide the body into two halves. The standard anatomical body position is defined as standing erect, with the head facing forward, arms relaxed at the sides, palms facing forward, and feet parallel and slightly separated. This position is the reference position in the definition of body movement terms.

2.2.1 Anatomical reference planes and axes

Three hypothetical anatomical reference planes transect the body to describe anatomical motion. Three reference axes, which are straight lines around which objects rotate, also exist. Movement at the ankle takes place in a plane around a rotational axis. Figure 3 illustrates these features.

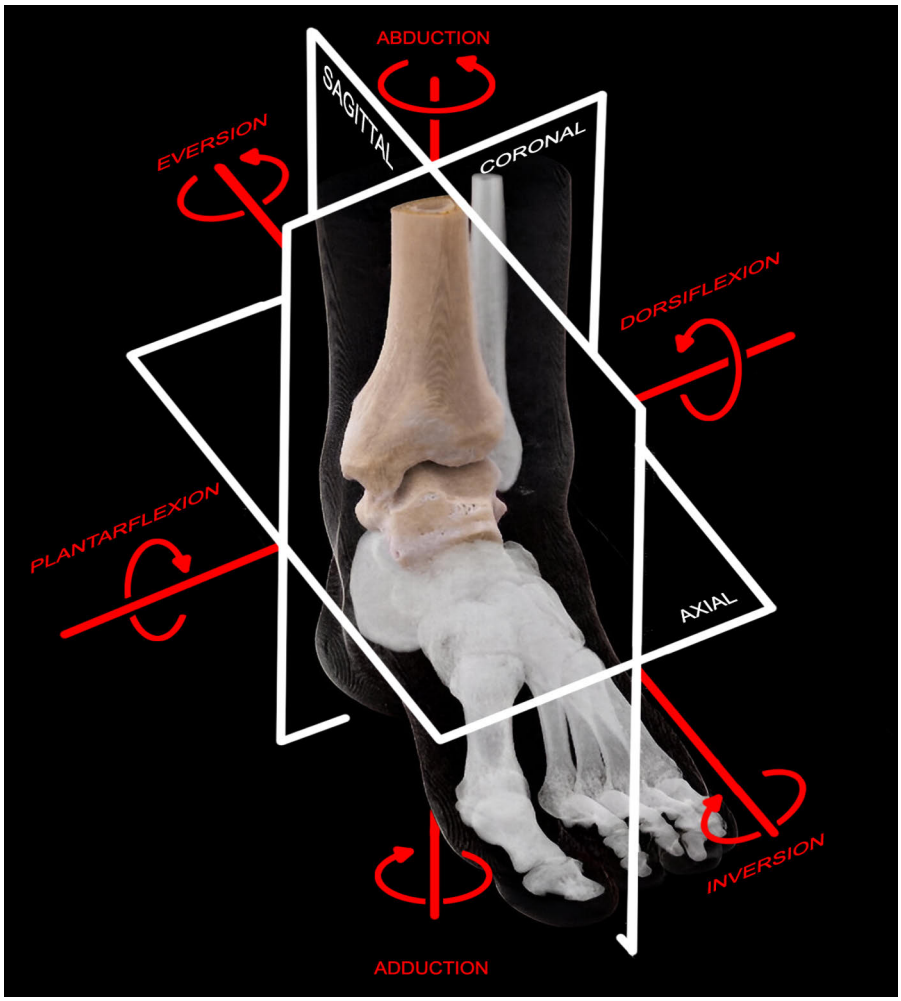

Figure 3. Anatomical reference planes and axis. Eversion leads to valgus alignment, whereas inversion results in varus alignment. © Sami Kormi

2.2.2 Joint motion and position

Movements in the ankle are combinations of linear and rotational factors, with anatomical motions occurring along these anatomical reference planes. When

evaluating the biomechanical characteristics of the ankle, it is essential to compare measurements to a theoretically conceived reference position. In the standard anatomical position, the ankle is positioned at zero degrees and the gold standard is a weight-bearing posture.

The joints in the ankle have a simultaneous triplane motion, occurring across the three anatomic planes. Any rotation of the ankle joint that deviates from the anatomical position is named according to the direction of the movement. The extent of the rotation can be calculated by measuring the angle between the resulting position and the standard anatomical position. The ankle joint mainly allows plantar flexion and dorsiflexion on the transverse axis. This rotation is usually in conjunction with other joints. When the subtalar and midtarsal joints are associated with movement, adduction, abduction, supination and eversion can occur (Gray et al., 2022).

Two other important terms are valgus and varus, which refer to the angulation in the coronal plane between two limb parts. The proximal part is the reference point, while the distal part defines the malalignment if present. When the distal part is more lateral, it is termed valgus; when it is more medial, it is termed varus.

Range of motion (ROM) refers to the degrees a joint can move within its full potential. Historically, dorsiflexion and plantarflexion were solely attributed to the tibiotalar joint, while inversion and eversion were seen exclusively as functions of the subtalar joint. This perspective neglected the minor contributions of the subtalar joint to plantarflexion and dorsiflexion and overlooked the fact that inversion, eversion, and rotational movements occur across both joints. Although gait analysis objectively quantifies lower limb joint motion, it cannot distinctly separate subtalar, tibiotalar, and transverse tarsal joints due to limitations in accurately tracking the talus. Therefore, the clinical ROM is the combined effect of all joints (Brockett & Chapman, 2016).

The ankle's ROM can be measured under two conditions: a non-weight-bearing passive condition, where the ankle moves freely, and weight-bearing active condition, where the muscles maintain and stabilize the joints. In practice, measurements primarily rely on passive methods, while reliable active or even weight-bearing ROM assessments remain lafgely theoretical. There is a significant difference between the ROMs obtained through active and passive methods, with a poor correlation between the two. The responsiveness of ankle joint range-of-motion measurements is uncertain (R. R. L. Martin & McPoil, 2005). This raises questions about the clinical relevance of non-weight-bearing measurements (Baggett & Young, 1993). Normal values for ROM in the ankle joint appear to range from 13 to 33 degrees for dorsiflexion and from 23 to 56 degrees for plantarflexion (Roaas & Andersson, 1982). Ankle ROM varies considerably among individuals. Simple factors such as age, gender, cultural differences in daily activities, or calf muscle

tightness can significantly influence ankle biomechanics (Brockett & Chapman, 2016; Grimston et al., 1993; Nigg et al., 1994).

It is important to note that total dorsiflexion and plantarflexion comprise the entire foot and ankle interaction. A required ROM of 30 degrees has been identified to walk normally, with 37 degrees needed for ascending stairs and 56 degrees for descending stairs (Michael et al., 2008). The ROM of the ankle joint tends to decrease with age (Boone & Azen, 1979). It is essential to maintain ankle mobility, as it plays a central role in balance control and maintaining a normal gait (Singer et al., 2013; Spink et al., 2011). The minimum required ROM for ankle arthroplasty is 10 degrees dorsiflexion and 20 degrees plantarflexion. This ROM is essential for preserving the ability to perform daily activities (Lundberg et al., 1989).

2.2.3 Gait cycle and force generation

Gait and mobility are distinct concepts, and good enough joint mobility is essential for normal gait. Gait is a complex and cyclical process requiring sufficient musculoskeletal functions controlled by a nervous system (Saunders et al., 1953). The gait cycle is the time interval between the repetitive event of walking. It can be divided into phases: the stance phase, where the foot is in contact with the surface, and the swing phase, where the foot moves forward. For walking to be successful, the ankle must perform a complex series of movements, including maximal eversion, internal rotation of the tibia, pronation of the foot, maximal inversion, and external rotation of the tibia. These movements are usually simplified as dorsiflexion and plantarflexion.

In biomechanical models evaluating ankle dynamics, the foot is commonly represented as a single rigid segment. However, this approach can lead to significant inaccuracies in understanding ankle joint function (Pothrat et al., 2015). Brodsky et al. compared the operative and unaffected sides after the TAR. Gait analysis was done using a multi-segment foot model, and the ROM for the operated side was significantly lower, suggesting that the gait was impaired. However, the study does not describe whether the limitation existed before the surgery (Brodsky et al., 2013). It has been reported that patients with degenerative joint disease experience significant decreases in walking speed, cadence, altered kinematics, and reduced ankle ROM before surgical intervention compared to a control population (Canseco et al., 2018). A randomized study reported no clinically significant differences between FBI and MBI models in postoperative gait mechanics (Queen et al., 2017).

The ankle joint and the whole foot lacked investigation regarding acting forces (Kitaoka et al., 2006). However, interest in the foot and ankle has increased significantly in recent years. An elaborate foot model was recently introduced to predict joint reaction forces at the tibiotalar joint during walking. Maximal ankle

joint forces were about 2.6 to more than eight times the body weight during walking (Kim et al., 2018; Prinold et al., 2016). In comparison, the peak axial forces when walking are 2.2 to 2.5 times the body weight in the distal femur and the knee (Taylor et al., 1998).

2.3 Osteoarthritis

An estimated 300 million individuals worldwide suffer from osteoarthritis (OA), which makes it one of the most common joint diseases in the world and a leading cause of disability. AOA is significantly less common; knee OA is 10 times more prevalent than ankle OA (Huch et al., 1997). Approximately 1% of the world's adult population is affected by AOA (GBD 2017 Disease and Injury Incidence and Prevalence Collaborators., 2018; Glazebrook et al., 2008; Murray et al., 2012). The prevalence of OA is expected to rise in the coming decades as the population ages and obesity rates increase (Cross et al., 2014). Without proper treatment, OA leads to pain, stiffness, loss of function and decreased health-related quality of life (Hunter et al., 2014). Symptomatic ankle OA similarly impacts the health related quality of life as end-stage hip arthritis (Glazebrook et al., 2008).

Previously, overload and impaired biomechanics were believed to be the primary causes of articular cartilage destruction. However, current understanding suggests that OA is a much more complex process than previously thought. The disease involves inflammatory and metabolic factors that affect the entire joint, including the synovium, subchondral bone, and joint ligaments (Mobasheri & Batt, 2016).

The reasons behind synovial inflammation in OA remain controversial. Worn cartilage may induce a foreign body reaction within synovial cells, producing inflammatory cytokines and synovial angiogenesis, which further contributes to cartilage destruction. It is also presented that the synovial macrophages activate, and the innate immune system has a role in the progression of OA. In recent years, many different topics have been studied that can contribute to the development of OA; for example, obesity is causing it beyond body weight and joint mechanics but through systemic factors such as leptin and other adipokines (Yusuf et al., 2010). The role of the endocrine system, particularly oestrogen, in joint health and the effects of aging on cartilage are also areas of ongoing investigation (Berenbaum, 2013). Despite these advancements, evidence-based information, especially concerning the foot and ankle, still needs to be improved.

2.3.1 Types of arthritis

The scientific literature on the aetiology of ankle osteoarthritis is limited. OA can be divided into two broad types: primary and secondary. There is no known cause of

primary OA, and its incidence in the ankle joint is low, accounting for approximately 9% of all arthritis cases, unlike in the hip, where post-traumatic OA accounts for only around 2% of all cases of hip OA (Brown et al., 2006a). Secondary OA, on the other hand, has a known cause and constitutes about 13% of OA cases (e.g. rheumatoid arthritis, diabetes mellitus, Charcot's disease, haemochromatosis, haemophilia or osteonecrosis) (Saltzman et al., 2005). In rare cases, abnormalities of adjacent joints, lower limb torsional deformities or flat foot deformity may also contribute to secondary osteoarthritis of the ankle, although direct evidence remains somewhat limited (Al-Hourani et al., 2020). Trauma is the most common cause of AOA, responsible for 70% to 90% of all cases (Brown et al., 2006b; Saltzman et al., 2005; Valderrabano et al., 2009). Any event that compromises the articular surface of the ankle joint can lead to posttraumatic AOA due to irreversible cartilage damage. Ankle fractures are the cause of approximately 80% of posttraumatic AOA cases (Valderrabano et al., 2009). Additionally, inaccurate reduction of intra-articular fractures results in post-traumatic AOA (Marsh et al., 2002). Severe sprains can result in ankle instability and chronic pain without adequate treatment and rehabilitation. This can indirectly alter ankle biomechanics, causing changes in the mechanical loading of the joint. Some researchers believe this cascade initiates a mechanically driven degenerative remodelling process (J. A. Martin et al., 2017). It has been reported that ankle strains cause 19% of post-traumatic AOA (Valderrabano et al., 2006).

When comparing patients with end-stage AOA to those with hip OA, it has been observed that AOA patients tend to have worse scores in the mental component summary, role-physical, and general health categories, as assessed by the Short Form-36 (SF-36) outcome instrument. This suggests that patients with AOA experience mental and physical disabilities at least as severely as those with hip OA (Glazebrook et al., 2008).

Rheumatoid arthritis (RA) is the most common systemic inflammatory arthritis and accounts for a large part of AOA. RA is an autoimmune disease and, like many autoimmune diseases, its aetiology is multifactorial and partly unclear. Genetic susceptibility has been well documented, with heritability estimates ranging from 53% to 65% (Macgregor et al., 2000). Especially smoking can trigger RA in those with a genetic predisposition (Bang et al., 2010). Other known risk factors are older age and female sex.

The Larsen score can be used to assess joint changes caused by osteoarthritis in radiographic images. It was initially developed to evaluate joint damage in rheumatic diseases but can also be used to classify the severity of other forms of osteoarthritis. The score is illustrated in Table 1 (Larsen et al., 1977).

Table 1. Larsen score.

Larsen score	Radiographic status
0	**No changes**: normal joint
1	**Slight changes**: erosions <1mm, slight joint space narrowing
2	**Definite early changes**: erosin >1mm, distinct joint space narrowing
3	**Medium destructive changes**: marked erosions, distinct joint space narrowing
4	**Severe destructive changes**: severe erosions, preserved bony outlines
5	**Mutilating changes**: original articular surfaces have dissapeared, gross bone deformation

2.3.2 Symptoms

RA can lead to inflammation and stiffness in the ankle joints, as well as in other joints. Prolonged inflammation results in permanent alterations to the structures of the ankle and the shape of the joint. Focal bone erosions are common, and the severity of these erosions frequently correlates with the overall severity of the disease. Changes in the forefoot typically manifest first, while alterations in the hindfoot involving the ankle joint are more prevalent later in the disease progression. However, these radiographic changes do not always align with patient-reported pain. For example, Vidigal et al. found radiographic changes in the subtalar joint in 32% of the feet they examined, yet only 21% of the patients reported any clinical symptoms. Likewise, tarsometatarsal joint changes were identified in 62% of cases, but only 27% of the patients reported experiencing pain (Vidigal et al., 1975). In contrast, it has been reported that 69% of individuals with symptomatic radiographic foot OA face disabling foot pain (Roddy et al., 2015).

Progressive joint pain is the most common reason patients with AOA seek treatment. In the early stage of AOA, pain is typically associated with daily or athletic activities and may persist during the day. The pain may even be present at rest in the later stages of AOA (Buckwalter & Martin, 2006). Other clinical signs are changes of alignment, as seen in weight-bearing radiographs. However, visual observation of the patient while standing is often inadequate, as it accurately predicts alignment in less than half of clinical cases (Frigg et al., 2010). Stiffness and a substantial decrease in ROM can result from various causes, such as extracts from the articular cartilage, contractures of periarticular ligaments, osteocytes, intra-articular fragments (loose bodies) of cartilage or muscle spasms (Buckwalter & Martin, 2006).

2.3.3 Imaging tests

Conventional weight-bearing anterior-posterior and lateral radiographs of the ankle are the first-line imaging modality, where joint space narrowing indicating loss of cartilage, osteophytosis, subchondral cysts and subtle arch collapse may be observed. This is illustrated in Figure 4. Further imaging may be required for a more precise evaluation, as angle measurements from standard radiographs can be unreliable due to projection inaccuracies (central beam orientation) and/or improper foot positioning (Johnson et al., 1999). Assessing the three-dimensional relationships of the bones in the foot is challenging with standard radiographs because of the superimposition of the different bones (Ferri et al., 2008). Selection of the most appropriate imaging modality typically depends on several factors, including diagnostic reliability, local availability, contrast sensitivity, and patient considerations such as cost.

Figure 4. In plain weight-bearing radiographs of an ankle end-stage osteoarthritis is seen. In image **A**, the lateral cartilage (1) of the ankle joint is completely lost, and the joint exhibits a 10-degree valgus malalignment. In image **B**, joint space narrowing (2) is observed, particularly anteriorly, along with an anterior osteophyte (3). Own collection.

CT technology is frequently utilized to assess skeletal pathology because it provides high-resolution, thin-slice images in any plane, offering excellent visualization of degenerative changes. However, since CT scans are performed

without weight bearing, the true alignments of the joints and impingements cannot be reliably captured (Greisberg et al., 2003).

Cone-beam computed tomography (CBCT) was introduced in 2012 for foot and ankle use and allows weight-bearing imaging. These images offer excellent image quality, fast image acquisition, reduced radiation exposure, and a detailed view of the foot's current alignment (Carrino et al., 2014; Tuominen et al., 2013). Accurate assessment of the foot alignment and position of the fibula in relation to the tibia and joint space analysis are useful for evaluating AOA and planning appropriate treatment (Richter et al., 2022).

In addition to detecting osteophytes, joint space narrowing, subchondral sclerosis, subchondral cysts, and lesions, magnetic resonance imaging (MRI) can also identify joint effusion, synovitis, and bone marrow oedema, which may contribute to pain. MRI is also valuable for uncovering underlying aetiologies such as ligament and tendon injuries, osteochondral lesions, or ankle impingement syndromes (Weber et al., 2017).

2.4 Generations of total ankle replacement

Previously, fusion was the only treatment available for end-stage AOA. In 1913, a significant attempt was made to avoid fusion when Eloesser performed the first ankle cartilage allograft transplantation (Eloesser, 1913). Later, in 1962, Lord and Marotte performed the first ankle hemiarthroplasty using a custom Vitallium talar dome resurfacing implant through a lateral approach (Figure 5) (Muir et al., 2002). Insertion of this 'reverse hip prosthesis' involved attaching a long-stem metallic component implant to the tibia and cementing an acetabular cup into the calcaneus. During this procedure, the talus was removed entirely. However, this model was discontinued after it was performed on 25 patients due to poor outcomes.

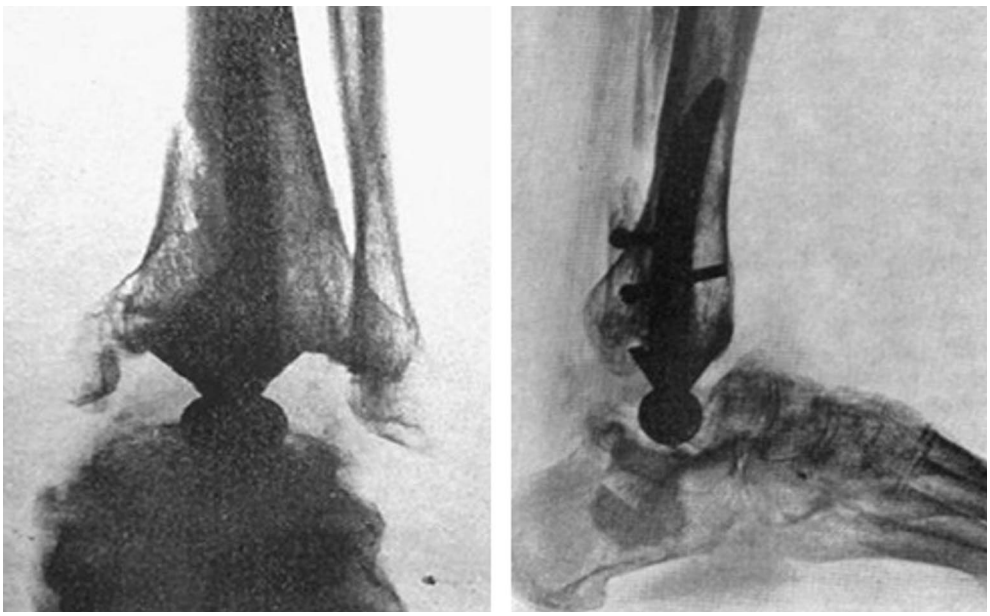

Figure 5. Radiographs of Lord and Marotte's total ankle replacement. Reprinted with permission from Muir et al, (2002) via Copyright Clearance Center.

The development of ankle prostheses has been challenging, and early designs of TAR had unacceptably high failure and complication rates. Most first-generation implants were constrained; the prosthesis consisted of two parts and the implants were cemented to the bone. The prostheses became cementless with three components and less constrained mobile-bearing designs with development. Promising results have been reported with new designs and methods. In addition, research and development continue, and interest in ankle prostheses has increased in recent years.

Ankle prostheses can be classified in many ways, such as fixation type (cemented or uncemented), bearing type (fixed or mobile), number of components (two or three), and constraint type (constrained, semi-constrained or unconstrained). The classic way is to divide the prostheses into different generations. Figure 6 shows the evolution of TAR implants from the first generation, which were non-anatomical, constrained, or non-constrained, through the second and third generations, which mainly were mobile-bearing implants, to the modern fourth—to fifth-generation implants, most of which are fixed-bearing designs.

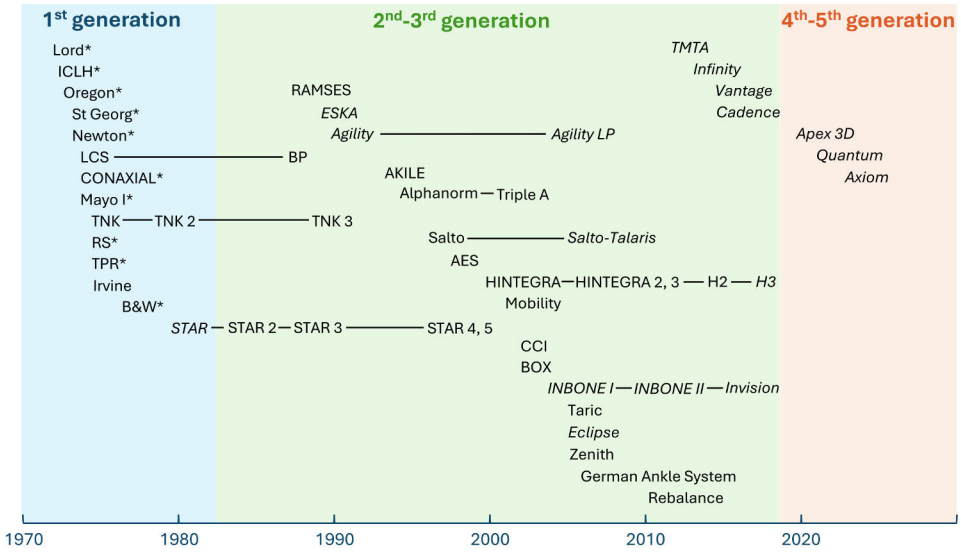

Figure 6. Different TAR implants through the years. Fixed-bearing (FB) implants are shown in italics. First-generation two-component designs are marked with an asterisk. AES=Ankle Evolutive System (Biomet, Warsaw, IN, USA), Agility (DePuy, Warsaw, IN, USA), AKILE (Lavender Medical Limited, UK), Alphanorm, Apex 3D (Paragon28, Inc., Englewood, CO, USA), Axiom (restor3d, Durham, NC, USA), B&W=Bath & Wessex (Howmedica, Rutherford, NJ, USA), BOX=Bologna-Oxford (Finsbury Orthopaedics Ltd, Leatherhead, UK), BP=Buechel-Pappas (Endotec, Orange, NJ, USA), Cadence (Smith & Nephew, London, UK), CCI=Ceramic Coated Implant (Wright Medical Technology, Arlington, TN, USA), CONAXIAL Beck-Steffee (DePuy, Warsaw, IN, USA), Eclipse (Kinetikos Medical Inc., CA, USA), ESKA (ESKA Orthodynamics, Lübeck, Germany), German Ankle System (R-Innovation, Coburg, Germany), HINTEGRA (Integra, Plainsboro, NJ, USA), ICLH=Imperial College of London Hospital (Howmedica), INBONE I (Stryker, Mahwah, NJ, USA), INBONE II (Stryker, Mahwah, NJ, USA), Infinity (Stryker, Mahwah, NJ, USA), Invision (Stryker, Mahwah, NJ, USA), Irvine (Howmedica, Rutherford, NJ, USA), LCS=Low Contact Stress/New Jersey (DePuy, Warsaw, IN, USA), Lord, Mayo I=Mayo Total Ankle Replacement , Mobility (DePuy Synthes, Warsaw, IN, USA), Newton=Newton Ankle Implant (Howmedica, Rutherford, NJ, USA), Oregon, Quantum (Conmed, Largo, FL, USA), RAMSES (Fournitures Hospitaliers, Mulhouse, France), Rebalance (Zimmer-Biomet, Warsaw, IN, USA), RS=Richard Smith (Dow Corning, Arlington, TN, USA), Salto (Tornier, Edina, MN, USA), Salto-Talaris (Tornier, Edina, MN, USA), STAR=Scandinavian Total Ankle Replacement (Stryker Corporation, MI, USA), St Georg, Taric (Implantcast GmBH, Buxtehude, Germany), TMTA=Trabecular Metal Total Ankle (Zimmer-Biomet, Warsaw, IN, USA), TNK (Kyocera Medical, Kyoto, Japan), TPR=Thompson Parkridge Richards (Smith & Nephew, Memphis, TN, USA), Triple A=Alpha Ankle Arthroplasty (Implantcast GmBH, Buxtehude, Germany), Vantage (Exactech Gainesville, FL, USA), Zenith (Corin Group, Cirencester, UK). Some of the manufacturing information is missing or might have changed.

2.4.1 First generation

Several models belong to this group, almost all of which were two-component designs. The low contact stress (LCS) TAR was the first three-component TAR. Most of these designs had polyethylene concave tibial and metallic convex talar

components, except for the Imperial College of London Hospital, where the materials were inverted. These prostheses included constrained and non-constrained designs, but all were cemented to the bone. In the constrained designs the mobility of the prosthesis is restricted, which leads to high forces at the bone-prosthesis interface. The advantage of these prostheses is good wear resistance. On the other hand, a non-constrained design relies on the ligaments to provide stability, which, when deficient, causes instability. The contact surface in these designs is smaller, which leads to wear. The only method of attaching the implants to the bone was by cementing. However, this required extensive bone resections to fit the implant and cement. This rapidly decreased bony strength in the tibia and the talus and had inferior survival. There were also no specific instruments available for performing TAR. The surgeries were associated with a significant number of fractures as well as skin damage during the surgery. Infections, wound healing problems and severe osteolysis were common (Kofoed, 2004; Vickerstaff et al., 2007).

The results were poor, and the use of every first-generation TAR was discontinued (Kitaoka & Patzer, 1996). Ankle arthrodesis was the treatment of choice until the 1980s, when development of the ankle prosthesis began to attract renewed interest (Vickerstaff et al., 2007).

2.4.2 Second generation

One of the most critical developmental milestones was the press-fit fixation. The implant surface often consisted of hydroxyapatite porous beads, designed to allow ossification directly onto the prosthetic surface and achieving a strong connection (Jackson & Singh, 2003). New cementless designs allowed for minor bone resections, and the shape of the new designs tended to replicate the natural anatomy of the ankle. In addition, the heat caused by curing the cement no longer caused problems with the soft tissue.

The problems that arose with either constrained or non-constrained prostheses were solved by developing semi-constrained designs (Buechel et al., 1988). The force transfer from the tibia to the foot became more administrative and the designs allowed for more natural ankle movement (Komistek et al., 2000). Over time, the instrumentation also developed better. In addition, the material of the intermediate component was replaced with polyethylene, which is biocompatible and has low friction. This insert could move freely, as it does in three-component mobile-bearing designs. Free movement is intended to reduce strain at the bone-prosthesis interface to avoid loosening and preserve natural kinematics. Unfortunately, there is a risk of subluxation or dislocation with these designs (Kofoed, 2004). As in the fixed-bearing designs, the insert could also be fixed to the tibial component. These designs acted as two-component prostheses but still had three components.

Second-generation prostheses also faced a considerable number of challenges. Still, three designs did report reasonable results: the Agility Total Ankle System (DePuy, Warsaw, IN, USA), the Buechel-Pappas Total Ankle Replacement (Endotec, Orange, NJ) and the Scandinavian Total Ankle Replacement (STAR; first generation) (Rippstein, 2002). Later, the Buechel-Pappas was withdrawn from the market. STAR has fallen into worldwide disuse due to high revision rates, which can be observed in the registries of several countries (Bartel & Roukis, 2015).

2.4.3 Third to fifth generation

There are several third-generation designs, for example, the HINTEGRA ankle (New deal, Lyon, France/Integra, Plainsboro, NJ, USA), the Infinity Total Ankle Arthroplasty (Stryker, Mahwah, NJ), the INBONE TAR implant (Wright Medical Technology, Arlington, TN, USA), the STAR prosthesis (Scandinavian TAR), the Mobility prosthesis (DePuy, Leeds, United Kingdom), the Salto Talaris (Tornier, Edina, MN, USA), the Ankle Evolutive System (AES; Biomet, Warsaw, Indiana, USA) and especially relevant to this thesis, the CCI (Ceramic Coated Implant; Wright Medical Technology, Arlington, TN, USA) and TMTA (Trabecular Metal Total Ankle, Zimmer, Warsaw, IN, USA).

Ankle prostheses have progressed considerably in recent years, contributing to increased interest in them. It is widely accepted that first-generation TAR prostheses were significantly inferior to second-generation models, which in turn were outperformed by the current third-generation prostheses (Gougoulias & Maffulli, 2013). Most prosthesis models currently in use belong to the third or newer generations. They are semi-constrained and have either mobile or fixed polyethylene bearings. The stability of these designs is ensured by the ligaments. The bony resections are smaller than in the designs requiring cementation, and these designs conform more to the characteristics of ankle biomechanics.

Advanced instrumentations for prosthetic component implantation include intra- and extramedullary referencing, computer-assisted bone preparation, patient-specific instrumentation (PSI) and guides derived from computed tomography (CT) scans. However, the benefits of PSI in clinical outcomes or cost-effectiveness remain theoretical, and there is no consensus on its indications in TAR (Mazzotti et al., 2022; Park & Mroczek, 2018).

On the other hand, according to the Swedish Ankle Registry or the Norwegian arthroplasty register, modern prosthetic designs are reported to have better survival rates than older designs (Sundet et al., 2023; Undén et al., 2020). This thesis focuses on patients operated with CCI or TMTA.

2.4.3.1 Ceramic Coated Implant

The CCI Evolution TAR is a mobile-bearing three-component design allowing for ligament-guided motion. The tibial and talar components have titanium plasma spray surface structures at the implant-bone interface, which is theorized to allow strong osteointegration without cement. The articulating surface has a hard and smooth titanium nitride coating designed to prevent the release of metal ions and protect the polyethylene bearing. The insert has a flat surface on the tibial side and a concave V-shaped surface on the talar side.

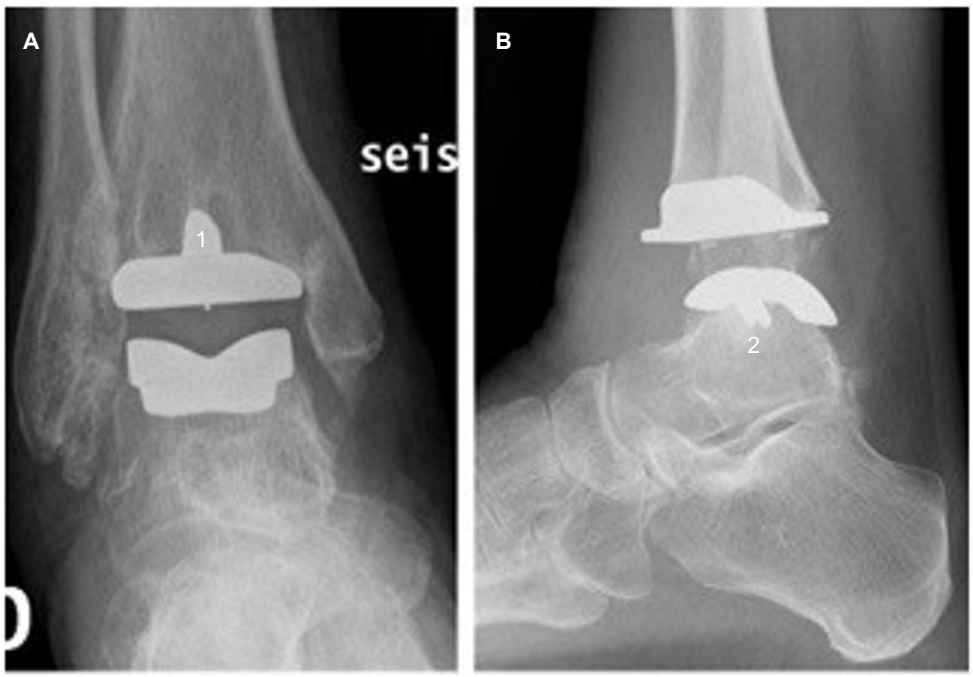

Figure 7. Radiographs of a CCI implant from a patient in Study IV. In image **A**, the implant is seen in the anteroposterior view, with the keel-type fixation fin (1) also well visualized. The talar component's V-shaped design is also clearly visible in the image. In image **B**, the curved shape of the talar component and the fixation pegs (2) are visible. Own collection.

The surgical approach for this design is anterior; a straight anterior midline incision is made on the ankle joint. The anterior tibial tendon and the tibialis anterior vascular bundle must be identified and protected. High rates of wound healing complications ranging from 8% to 25% have been reported, resulting in poorer patient outcomes (Glazebrook et al., 2009; Raikin et al., 2010). An extensile anteromedial approach has also been described. This surgical approach focuses on preserving the anteromedial blood supply from the posterior tibial artery, as well as

the anterior and lateral blood supply from the dorsalis pedis artery. This may help reduce the risk of developing wound complications (Amin et al., 2012; Halai et al., 2020). The implant design requires minimal bone resection: a tibial resection aiming for a 0-degree slope and then a V-shaped resection of the talus. The overhang must be avoided to prevent impingement. After the components are inserted, the extensor retinaculum and skin are sutured.

Voesenek et al. presented their results of 58 CCI implants in short-term (mean 21.6 months) follow-up at the European Orthopaedic Research Society (EORS) Annual Meeting in 2016 as an abstract (Voesenek et al., 2017). Nieuwe Weme et al. reported the medium-term results of mobile-bearing TAR for two subgroups of post-traumatic arthritis: postfracture arthritis and instability arthritis including 15 Buechel-Pappas (Endotec, South Orange, NJ) and 75 CCI implants, but the results were not specified between the implants (Weme et al., 2015). The latest study of 254 CCI implants was published with long-term follow-up. They reported a 10-year survival rate of 67.5% (van Es et al., 2022).

2.4.3.2 Trabecular Metal Total Ankle

The Zimmer Biomet Trabecular Metal Total Ankle is a semi-constrained design consisting of three implant components: talar component, tibial base component and crosslinked polyethylene insert attached to the tibial component. The tibial and talar components have a trabecular metal surface structure at the implant-bone interface. Trabecular metal has been used in clinical practice since 1997, and there are over 300 positive reports of its use in hip and knee arthroplasties and spinal surgery. Tantalum is heated in chlorine gas with vitreous carbon, resulting in 80% porosity and high friction for osteointegration (Bobyn et al., 1999).

A lateral approach is used and the ankle is aligned with an external frame. An incision is made along the posterior aspect of the fibula. The ATFL is sectioned. The fibula is exposed and an oblique osteotomy is made to reveal and release the capsule. The external frame is used to align the ankle. The bone resections are done, and implants placed according to protocol. Subsequwntly, the fibular osteotomy must be reduced, the ATFL repaired and the wound closed (ZimmerBiomet, 2017).

The lateral approach seeks to preserve the blood supply to the ankle as well as possible, especially to the skin, to reduce wound healing issues (Femino & Vaseenon, 2009). This approach also provides better visibility to the center of rotation. In theory, bone resection can be performed in greater detail to preserve bone stock and achieve better joint alignment and kinematics (La Mothe et al., 2015). The fastener fins of the implants are oriented transversely to the tibia and calf, allowing the implant to receive force more firmly. Early results of the lateral approach have been promising (Tan et al., 2016; F. Usuelli et al., 2019; Usuelli et al., 2019).

Fibular non-union may occur or the osteotomy fixation material may cause problems, increasing the risk of reoperation. Implant revision can be challenging, requiring an anterior approach. The lateral approach technique also prolongs the total operative time, although the procedure can be performed without a tourniquet (Clement et al., 2012; Usuelli et al., 2019; Willis-Owen et al., 2010).

The long-term effectiveness and complication rates of this design and the lateral approach have yet to be reported (Bagheri et al., 2024). Considering that the model was introduced to the market in 2012, the longest follow-up results have been reported at the 5-year mark, showing a survival rate of 97.7% (Maccario et al., 2022).

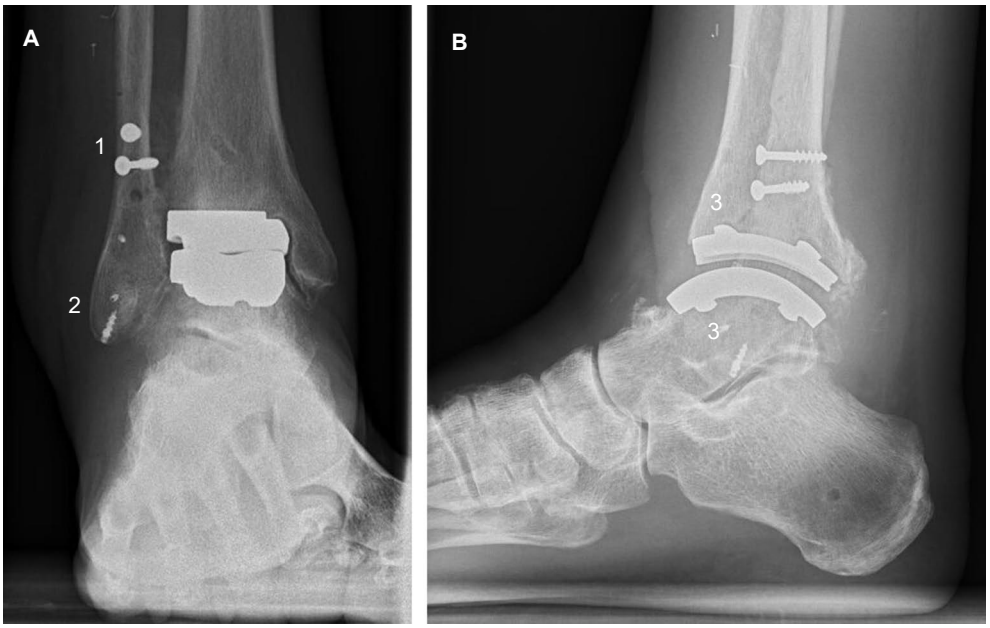

Figure 8. Radiographs of a TMTA implant from a patient in Study I. In image **A**, the fibular osteotomy is fixed with two screws (1), and the anterior inferior tibiofibular ligament is secured with an anchor (2). In image **B**, the transversely oriented fastener fins (3) of the implants are visible. Own collection.

2.5 Total ankle replacement complications, outcomes and survivorship

Although the results of the first-generation prostheses were unacceptable, studies evaluating outcomes after TAR have shown great improvements in patient satisfaction, pain relief and functional outcome metrics (Hermus et al., 2022). Complications occur consistently, but not all complications carry the same significance. The literature identifies nine main complications: intraoperative fractures, postoperative fractures, wound healing issues, deep infections, aseptic

loosening, nonunion, implant failure, subsidence and technical errors (Glazebrook et al., 2009). According to Glazebrook et al., intraoperative bone fractures and wound healing issues are classified as low-grade complications and are unlikely to cause failure. Medium-grade complications, such as technical errors, subsidence and postoperative bone fractures result in failure less than 50% of the time. High-grade complications, including deep infection, aseptic loosening and implant failure, lead to TAR failure in more than 50% of cases (Glazebrook et al., 2009). In TAR surgery, revision is generally defined as the adjustment or replacement of the metal component, but alternative interpretations are also used, which complicates the standardization of research data (Henricson et al., 2011).

Despite the progress, the complication rate remains somewhat high; according to a recent systematic review, up to 23.7% of TAR operations had some form of complication, of which 35.6% were classified as high grade (Vale et al., 2023). According to a recent and only meta-analysis with a follow-up time of at least 10 years regarding TAR, the revision rate was 20.5% (Bagheri et al., 2024). When compared to hip and knee replacement surgeries, the 10-year revision rate is reported to be less than 5% for hip replacements and, according to global arthroplasty registries, the revision rate for knee replacements after 10 years is 6.2% for total knee arthroplasty and up to 16.5% for unicondylar knee arthroplasty (Pabinger et al., 2013). However, caution must be exercised when comparing TAR to other joints, as implants and methods continuously evole significantly. Several factors beyond the TAR, such as improved patient selection, implant type, surgical volume, and surgeon expertise, will likely influence revision rates and implant survival (Bayliss et al., 2017; Liddle et al., 2016).

One highly significant factor is the surgeon's experience, as time-to-proficiency analyses have reported a demanding learning curve for TAR, with surgeons achieving better results in higher-volume TAR centres after operating 28–39 patients (Maccario et al., 2021; Usuelli et al., 2017). According to the Swedish Joint Arthroplasty Registry analysis, the 5-year survival rate after TAR increased from 70% to 86% after as many as 90 surgeries. Therefore, results may improve as surgeons worldwide gain more experience with TAR (Gougoulias et al., 2009).

Bagheri et al. could not assess the survivability of TAR in a systematic review and meta-analysis due to insufficient data reported in the publications. Outcomes following TAR are generally favourable, with improved patient-reported outcomes observed over long-term follow-up (Bagheri et al., 2024).

The number of publications reporting positive outcomes after TAR is growing significantly, but the number of studies reporting high-quality long-term results is relatively small. According to Bagheri et al., there was no single patient-reported outcome measure (PROM) across all studies. Although American Orthopaedic Foot and Ankle Society (AOFAS) and visual analogue scale (VAS) scores improved

significantly during the follow-up in their study, the use of several different PROMs creates a significant issue. Therefore, it is crucial to standardize TAR research and start using consistent measures. This will enable a better combination of future studies and lead to more comprehensive meta-analyses (Bagheri et al., 2024). To be precise, AOFAS is not technically a PROM but rather an outcome measure that requires scoring from both the patient and the physician. A new version that meets the PROM criteria has been developed, called PR-AOFAS (Paget et al., 2023).

Obtaining accurate data regarding TAR is challenging. Currently, only six countries collect data on TAR in national arthroplasty registers, Finland, Sweden, Norway, New Zealand, Australia, and the United Kingdom. According to a recent study, local experts consider Finland's data incomplete, and the United Kingdom's registry could not provide the requested survival analysis (Perry et al., 2022). Additionally, underreporting revisions to arthrodesis is a significant concern (Ben-Shlomo et al., 2021). According to estimates from the Norwegian register, only 2/3 of revisions were reported to the registry in 2019/2020. Table 2 illustrates survival data from different registers over various periods. There may be under-reporting of both primary surgeries and revisions in these registers. A revision could be recorded for a prosthesis without a corresponding primary procedure in the registry and vice versa (Perry et al., 2022). There are several reasons for under-reporting. One could be doctors' or hospitals' reluctance or failure to report adverse outcomes. Strong disincentives include feelings of shame, fear of legal consequences, concerns about reputation, and the risk of peer disapproval. Additionally, the number of TAR procedures is relatively low compared to knee and hip surgeries. Established practices are not widely implemented, and ankle registries have received less attention and funding (Leape, 2002; Ubbink et al., 2012). On a broad scale, TAR survivorship appears to be poor. However, more detailed analyses from registries reveal some apparent emerging factors.

When comparing early models to current ones, the current models performed significantly better in both the Norwegian and Swedish registers (Sundet et al., 2023; Undén et al., 2020). This analysis has many possible biases, and these results should not automatically be interpreted as proof that newer prostheses are better. However, this is one of the explanatory factors. Several single-centre series have also been published, where certain modern prostheses have performed exceptionally well. The survival rates reported in registers appear lower than those reported in many single-centre publications. On the other hand, the survival rates in the UK and New Zealand are very high, as illustrated in Table 2.

The impact of patients' age on the revision rate has been considered controversial. However, in all the registers mentioned in the table below, older age was associated with a lower risk of revision. In the Norwegian register, the risk of revision within 10 years of surgery for patients operated on under the age of 45 was

more than three times higher compared to those operated on over the age of 75 (45% vs 13%). The risk was also almost double compared to those aged 60–74 (45% vs 23% (Sundet et al., 2023).

When comparing the results of fixed-bearing models to mobile-bearing models, fixed-bearing seems to perform better (Sundet et al., 2023). Similar results have been observed in the US, where almost all revisions due to insert wear were associated with mobile-bearing prostheses (Jiang et al., 2023). According to the Norwegian register, insert wear was the most common reason for revision, but no revisions due to polyethylene wear were recorded for fixed-bearing prostheses. Additionally, aseptic loosening appears to be very rare with fixed-bearing prostheses. The total ankle replacement versus ankle arthrodesis (TARVA) trial results also showed that current fixed-bearing models performed better than mobile-bearing models (Goldberg et al., 2023).

Table 2. Survival of TAR implants based on registry data.

First author (year)	Time period	Register	Cases	5 year survival (%)	10 year survival (%)
Fevang (2007)	1994–2005	Norwegian Arthroplasty Register (NAR)	257	89	76
Skyttä (2010)	1982–2006	Nationwide Arthroplasty Registry in Finland	515	83*	
Undén (2020)	–2006	Swedish Ankle Registry (SwedAnkle)	1226	85	74
Ben-Shlomo (2020)	2003–2019	National Joint Registry (NJR, UK)	6589	93.6**	N/A
Mckie (2020)	2000–2019	New Zealand Joint Registry	1737	91.3	84.2
Sundet (2024)	1994–2021	Norwegian Arthroplasty Register (NAR)	1368	81	69.3

* The Data is considered notably incomplete by local experts. ** The authors assume that the data is insufficient due to presumed under reporting. N/A = Not available.

2.6 Total ankle replacement vs fusion

TAR and ankle arthrodesis (AAD) are the two main surgical treatments for end-stage ankle arthritis. Short- and medium-term results of ankle fusion are good, but in the long term, the incidence of nearby joint arthritis is over 80% due to the increased stress and motion of the other foot joints (Fuchs et al., 2003). Within 10 years after an ankle fusion surgery, up to 84% of patients report pain in adjacent joints and osteoarthritis is reported to develop in 24–100% of subtalar joints and 18–77% of Chopart joints (Ebalard et al., 2014; Ling et al., 2015). Also, non-union,

malalignment, pain and dysfunction are known complications of ankle fusion (Cooper, 2001). According to Coester et al., with an average follow-up of 23 years, 96% of patients after post-traumatic ankle arthrodesis had a slight-to-moderate limp (Coester et al., 2001).

There is no long-term, high-quality study comparing the two treatments, and no apparent difference between the treatment methods exists in the literature, as noted in at least three systematic reviews and meta-analyses. The primary challenge in conducting meta-analyses regarding TAR is the large variety of clinical outcome measures used. Furthermore, patient satisfaction, complications, and survival rates are reported quite variably across studies (Glazebrook et al., 2024; Haddad et al., 2007; Li et al., 2020).

Haddad et al. conducted the first systematic review in 2009, examining the intermediate and long-term outcomes of total ankle arthroplasty compared to ankle arthrodesis. They demonstrated that both procedures provide satisfactory outcomes, with data suggesting that they are comparable. This challenges the negative perceptions of ankle arthroplasty stemming from the failures of first-generation implants. TAR should be considered a viable treatment option for those with ankle arthritis, allowing the clinician to determine the appropriate indications (Haddad et al., 2007). Li et al. found no statistically significant differences in their meta-analysis between TAR and AAD regarding clinical outcomes, patient satisfaction, complications or survival. The findings suggest that TAR and AAD may yield similar results in these areas. Consequently, the current evidence is insufficient to determine which method is superior definitely (Li et al., 2020). Glazebrook et al. concluded that both TAR and fusion are suitable for treating ankle osteoarthritis. TAR outperformed in pain relief, activity levels and hospital readmission rates, whereas fusion exhibited lower revision rates. Complication rates showed conflicting results, although higher-quality studies indicated that TAR had a lower revision rate. However, the overall assessment was inconsistent, and the groups had no significant difference (Glazebrook et al., 2024).

More high-quality literature is needed to determine which procedure is most appropriate for individual patients. However, several individual reports show promising results in favour of ankle replacement compared to ankle fusion in treating end-stage ankle osteoarthritis (Glazebrook et al., 2021; Karzon et al., 2022; Pedowitz et al., 2016; Saltzman et al., 2009, 2010; Veljkovic et al., 2019).

The first randomized controlled trial (RCT) was conducted by Glazebrook et al., a pilot study that included 39 ankles from 39 subjects across three centres. The results showed statistically significant improvements in all AOS for both ankle replacement and arthrodesis independently, slightly favouring fusion surgery. However, the difference between the groups was not statistically significant (Glazebrook et al., 2021).

The TARVA trial is the first and, so far, the only high-quality randomized study comparing TAR with AAD. In the study, 303 patients, with a mean age 68 years and 71% men, were randomized into two groups: 152 underwent TAR and 151 underwent AAD. At 1 and 2 years, the Manchester-Oxford Foot Questionnaire walking/standing domain score showed greater improvement in the TAR group, but the difference was not considered clinically or statistically significant. The number of adverse events was comparable between the groups (109 vs. 104). However, the TAR group experienced more wound healing issues, while the AF group had a higher incidence of thromboembolic events and nonunion. A post-hoc analysis comparing FBI (with out MBI) with AAD showed a statistically significant improvement of TAR over AAD (−11.1 [CI, −19.3 to −2.9]) (Goldberg et al., 2023). The long-term follow-up for the TARVA study continues.

2.7 Peri-implant osteolysis and cysts

Peri-implant osteolysis has been a significant problem, leading to complications in many TAR implants (Espinosa et al., 2017; Hanna et al., 2007; Koivu et al., 2009). Bone loss, component loosening and osteolytic cysts continue to cause challenges (Kohonen et al., 2017; Yang et al., 2019). The rates of osteolysis are higher in TAR than in hip or knee replacements. Osteolysis can lead to massive bone loss and loosening, and treating progressive osteolytic cysts is contradictory (Besse et al., 2013; Gross et al., 2015; Kohonen et al., 2017). The causes of osteolysis are still somewhat unclear. A pathological immunological process in response to wear debris may cause osteolysis. The aetiology is multifactorial, the principal reason being the local immune response of the host tissue cells initiated by biological or mechanical factors. Factors such as wear particles from the implant or its coating materials, joint fluid pressure and flow, local damage to the blood supply, and various anatomical, physiological and mechanical factors likely influence the process (Gallo et al., 2013; Mehta et al., 2021). TAR revision cases often involve relatively extensive necrosis of soft and bone tissues. The local toxic or allergic effects of metal particles or ions released from the implant do not fully explain the necrosis of peri-implant tissues, which triggers chronic foreign body reactions. This reaction may be mediated by the receptor activator of nuclear factor kappa B ligand (RANKL) (Koivu et al., 2012).

In a systematic review, the presence of cysts was higher in non-anatomical designs, hydroxyapatite(HA)-coated, mobile-bearing and nontibial-stemmed implants (Arcângelo et al., 2019). Additionally, coronal malalignment has been hypothesized and shown to correlate with the volume and location of periprosthetic cysts: patients with residual valgus malalignment presented cysts positioned in a more lateral and those with varus malalignment in a more medial location (Lintz et al., 2019). The implant design, coating, alignment, incomplete seating, and geometry

of the components may influence the amount of micromotion at the bone-implant interface and the initial stability (Dunbar et al., 2012; Mehta et al., 2021; Sopher et al., 2017; Yu et al., 2020). The highest micromotion was found in stem-type implants, followed by keel-type and bar-type, and the lowest in peg-type geometries, and the initial stability of an ankle implant was proposed to be optimized by decreasing fixation size (Yu et al., 2020)

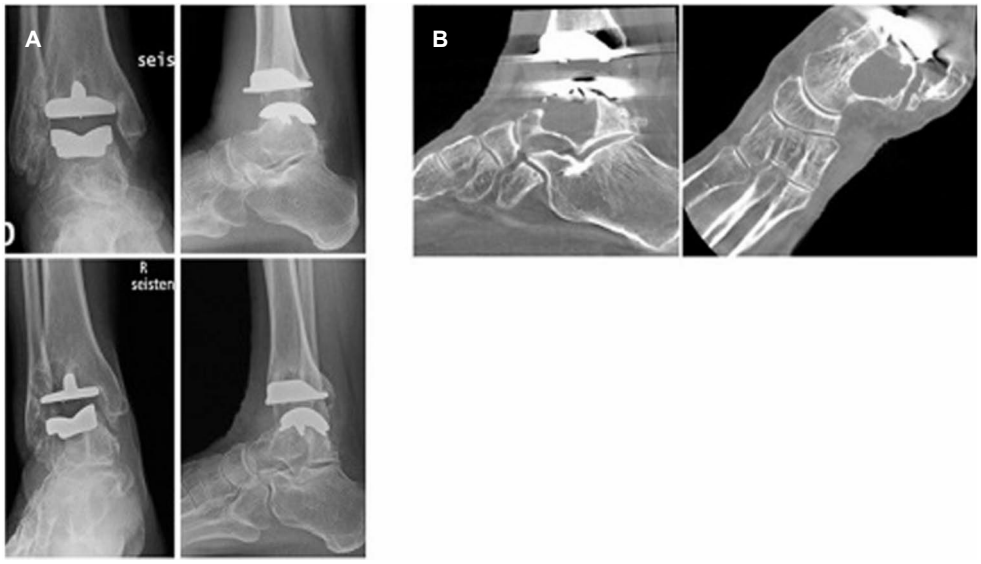

Figure 9. Example of osteolysis. (**A**) Radiographs of CCI implant at 4 years after implantation and (**B**) CT scan 2 years after the operation with large a osteolytic cyst under the talar component. Own collection.

3 Aims of the Present Study

To investigate the patient safety and clinical and radiographic outcomes of the trabecular metal ankle prosthetic system using a lateral approach and external frame. (I)

To measure the motion of the polyethylene insert and implant components in a MBI TAR using CBCT scanning as the imaging method. (II)

To investigate the short- to midterm incidence of peri-implant osteolysis in a FBI (TMTA) implant using CT as the imaging method. (III)

To investigate the medium-term functional and radiological outcome and implant survival of the CCI Evolution implant. (IV)

4 Patients, Materials and Methods

4.1 Patients

4.1.1 Retrospective analysis of TMTA (Studies I and III)

In Studies I and III, data were collected from a consecutive series of 104 patients who underwent primary TAR using the Zimmer Trabecular Total Ankle (Zimmer, Warsaw, IN). All ankles were operated between May 2013 and June 2017. The indications for surgery were post-traumatic and idiopathic osteoarthritis in 69 (66%) and rheumatoid arthritis in 35 (34%) patients. The median age of patients was 61 (SD 14); years, 51 (49%) were males and 53 (51%) females. The severity of rheumatic and osteoarthritic changes on radiographic images was defined according to the Larsen scale. Prospective clinical and radiographic data were collected. Demographic data in presented in Table 4.

4.1.2 Motion analysis of CCI (Study II)

For Study II, we identified 10 patients from the Study IV sample with the highest clinical ROM at 1 year postoperatively. The group included five females and five males, with an average age of 64 years at the time of surgery (range 47–84). The average clinical total ROM was 42 degrees (range 40–55). The average time interval between operation and CBCT scanning was 45 (range 33–57) months. Demographic data in presented in Table 3

Table 3. Demographic data for Study II.

Demographic	Study II
Patients	10
Implant	CCI
Implanting period	2010–2013
Age, mean in years (Range)	64 (47–84)
Sex	
Male	5 (40%)
Female	5 (50%)
Average clinical ROM, degrees (Range)	42 (40–55)
The average time-interval between operation and CBCT, mean in months	45 (33–57)
Diagnosis	
Rheumatoid arthritis	1 (10%)
Osteoosteoarthritis	8 (80%)
Other	1 (10%)

ROM = Range of motion, CCI = Ceramic Coated Implant, CBCT = Cone-beam computed tomography

4.1.3 Retrospective analysis of CCI (Study IV)

Data were collected from a consecutive series of 40 ankles of 39 patients who underwent primary TAR using the CCI Evolution Implant (Ceramic Coated Implant; Wright Medical Technology, Arlington, TN, USA). All operations were performed from an anterior midline incision and all ankles were operated on between November 2010 and March 2013. Indications for surgery were post-traumatic and idiopathic osteoarthritis in 27 (69%) and rheumatoid arthritis in 13 (31%) patients. The severity of rheumatic and osteoarthritic changes on radiographic images was defined according to the Larsen scale (Larsen et al., 1977b). The average age of patients was 65 (SD 12, range 40–84) years; there were 18 (46%) males and 21 (54%) females. Prospective clinical and radiographic data were collected. The demographic data are shown in Table 4.

Table 4. Demographic data for Studies IV and I.

Demographic	Study IV	Study I
Patients	40	104
Implant	CCI	TMTA
Implanting period	2010–2013	2013–2017
Age, mean in years (SD)	65 (12)	61(14)
Sex		
Male	18 (46%)	51 (49%)
Female	21 (54%)	53 (51%)
Larsen		
2	10 (26%)	6(6%)
3	10 (26%)	13 (13%)
4	9 (23%)	70 (67%)
5	10 (26%)	15 (14%)
Diagnosis		
Rheumatoid arthritis	13 (33%)	35 (34%)
Posttraumatic osteoarthritis	26 (65%)	67 (64%)
Idiopathic	1 (2%)	2 (2%)
Follow-up (months)		
Mean (SD)	70	44 (14,6)
Mini	6	17
Max	108	72

CCI = Ceramic Coated Implant, TMTA = Trabecular Metal Total Ankle, SD = standard deviation

4.2 Methods and statistical analyses

4.2.1 Clinical and radiological assessment

4.2.1.1 Retrospective analysis of TMTA outcome (Study I) and CC outcome (Study IV)

Clinical evaluations were performed preoperatively and postoperatively at regular intervals. In Study I, assessments were conducted every 12 months, whereas in Study II, evaluations took place at 3 and 6 months, at 1 year, and biennially thereafter. Clinical outcomes were measured using the Kofoed scale (Table 5) which evaluates pain severity, function, and ankle deformities. The points for pain were analyzed separately. Additionally, subjective outcomes, including perceived functional improvement and overall satisfaction with surgery, were assessed using an in-house

questionnaire (Table 6). Ankle ROM was measured with 1-degree precision as the difference between maximal active plantarflexion and dorsiflexion in a non-weight-bearing position. Follow-up duration was defined in full months, and perioperative complications, and the need for additional surgery or interventions were documented.

Radiographic assessments included weight-bearing anteroposterior (AP) and lateral views at baseline and postoperative intervals. In Study I, radiographs were analyzed at 3, 6, and every 12 months postoperatively. In Study VI, radiographs were analyzed on the first postoperative day and at the latest clinical follow-up. Angular measurements followed the same methodology in both Studies. The tibiotalar angle was recorded as the angle between the longitudinal axis of the tibia and a parallel line to the superior articular surface of the talus. Malposition was noted when tibial and talar components were incongruent.

Subsidence was defined as a vertical shift of ≥5 mm in prosthesis components. Radiolucency, characterized by a complete radiolucent line <2 mm in width, and osteolysis, identified as well-circumscribed lucent areas ≥2 mm in width, were recorded and categorized into zones on AP and lateral radiographs. CT imaging was conducted biennially in Study I and selectively in Study VI when osteolysis or loosening was suspected. The imaging assessments were carried out by an experienced musculoskeletal radiologist (Ia Kohonen).

Table 5. Kofoed ankle score.

Kofoed scale					
Pain (max. 50 points)					
No pain **50**	Starting pain **40**	Pain walking levels **35**	Loading pain occasionally **30**	Loading pain always **15**	Pain during test or spontaneously **0**
Function (max. 30 points)					
Toe walking **3**	Heal walking **3**	Normal cadence walking stairs **6**	One-leg standing **6**	No walking aids **6**	No orthopedic foot wear **6**
Mobility (max. 20 points)					
Extension	> 10 degrees **5**		5-9 degrees **3**		< 5 degrees **1**
Flexion	> 30 degrees **5**		15-29 degrees **3**		< 15 degrees **1**
Supinaion	> 30 degrees **3**		15-29 degrees **2**		< 15 degrees **1**
Pronation	> 20 degrees **3**		10-19 degrees **2**		< 10 degrees **1**
Valgus	< 5 degrees **2**		5-10 degrees **1**		> 10 degrees **0**
Varus	< 3 degrees **2**		4-7 degrees **1**		> 7 degrees **0**
85-100 Excellent; 75-84 Good; 70-74 Fair; < 70 Not acceptable.					

Table 6. Inhouse questionnaire.

	1	2	3	4
Improvement in function	Worse	No change	Better	Markedly better
Satisfaction	Worse	Cannot say	Satisfied	Very satisfied

4.2.1.2 Motion of the CCI (Study II)

The patients underwent radiological and clinical follow-ups at 6 weeks, 3 months, 6 months, 1 year postoperatively, and biennially thereafter. Clinical range of motion (ROM) was measured by an experienced physiotherapist, assessing maximum ankle dorsiflexion and plantarflexion.

Weight-bearing cone-beam computed tomography (CBCT; Planmed Verity, Helsinki, Finland) was performed with patients positioned to mimic various ankle motions: neutral 90-degree position (non-weightbearing and weightbearing), plantarflexion (with a 6.5 cm block under the heel), and dorsiflexion (with a 4 cm block under the forefoot). Original data were reformatted into coronal, sagittal, and axial images aligned with the tibial component.

Radiological ROM was determined by measuring the angle between metallic components on midsagittal images during dorsiflexion and plantarflexion, using lines along the inferior edges of the components. Polyethylene insert motion relative to the tibial component was evaluated on midcoronal and midsagittal slices. Specifically, the anterior displacement (in mm) between the tibial plate and polyethylene insert was measured midsagittally.

Axial rotation between the tibial and talar components was assessed by measuring angles between their medial margins, as well as the angle between the medial borders of the tibial plate and polyethylene insert, on axial reformatted slices. Image analysis was conducted by an experienced musculoskeletal radiologist (Ia Kohonen).

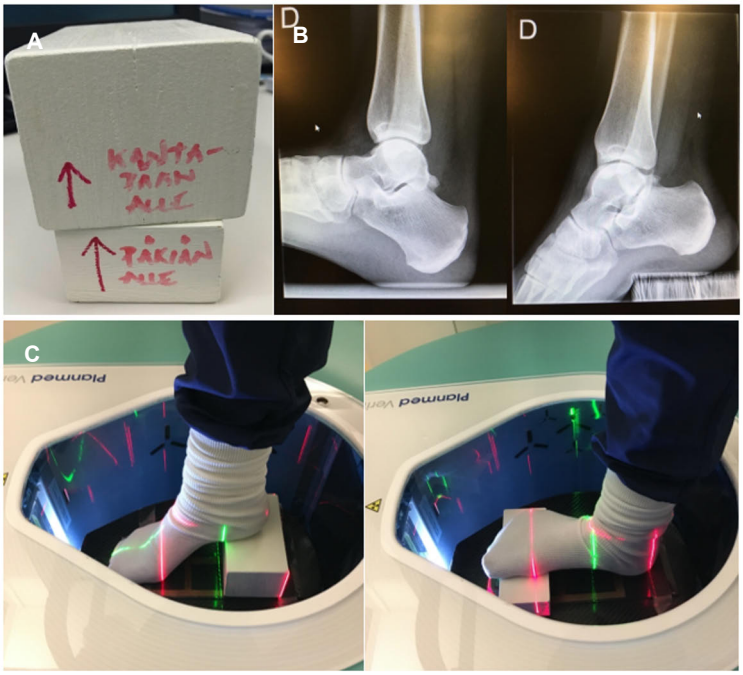

Figure 10. In Image **A**, the blocks placed under the foot are shown. In Image **B**, example images of the foot are presented. In Image **C**, an example of the imaging process is displayed. Reprinted with permission from Foot and Ankle Surgery.

4.2.1.3 TMTA osteolysis (Study III)

The radiographic evaluation protocol included weightbearing AP and lateral views at baseline and at 3, 6, and every 12 months postoperatively. The latest follow-up radiograph was used for the final analysis. Radiolucency was defined as a complete radiolucent line <2 mm in width and osteolysis as discrete, well-circumscribed areas of lucency ≥2 mm in width in the periprosthetic bone. Radiolucency or osteolysis around the tibial and talar components was recorded by zones as illustrated in Figure 11.

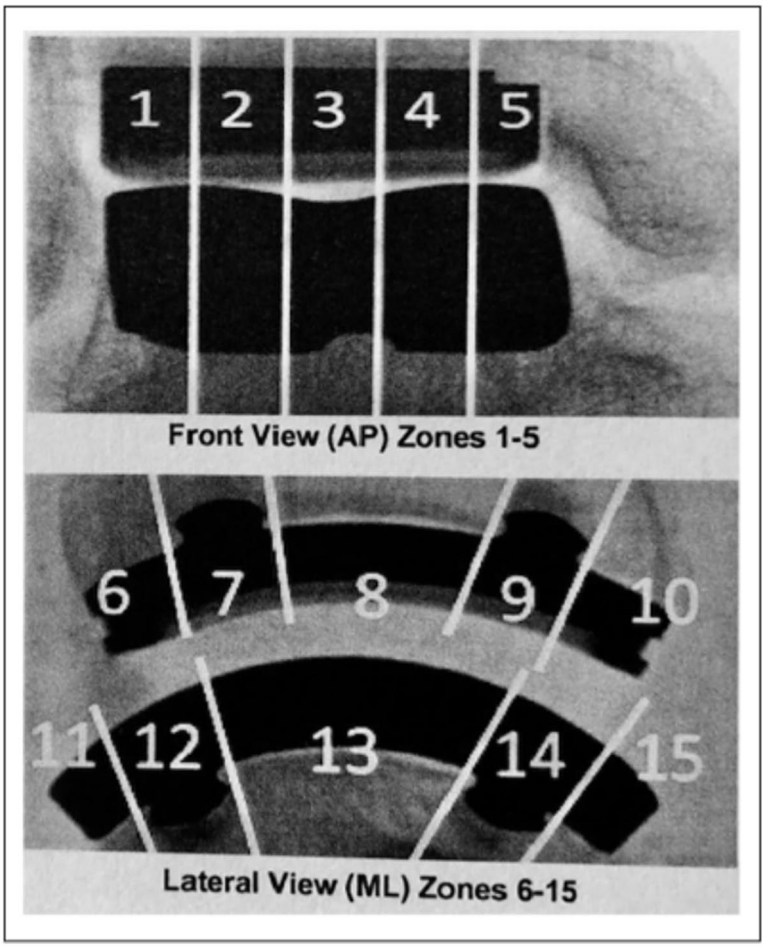

Figure 11. Zones 1–5 in AP-view; zones 6–15 in lateral view. Reprinted with the permission from Foot & Ankle International.

In addition to conventional radiographs, helical CT was performed preoperatively for every patient except those who already had a preoperative MRI, and for patients available for follow-up at 1 year and every 2 years thereafter. Five patients died during follow-up due to causes unrelated to ankle replacement, and 15 patients were lost to follow-up, yielding a total of 84 patients available for CT scanning. The latest CT scan was conducted at least 12 months postoperatively in 80 of these patients. The most recent CT scan available was utilized for the final analysis. The scanned area encompassed the entire implant and the peri-implant region. During scanning, patients lay supine on the table. Coronal, sagittal, and axial images (based on the tibial implant) were reformatted from the original data. Osteolytic lesions were characterized as well-demarcated, periprosthetic lucencies

containing no osseous trabeculae. The location of the osteolytic lesion around the tibial and talar components observed on CT was documented by zones, as illustrated in Figure 9, and the largest dimension and volume of the lesion were recorded. The vertical (v), transverse (t), and anteroposterior diameters of the lesions were measured. The volume was calculated using the formula $(v \times t \times ap \times \pi)/6$, which approximates the volume of the closest ellipsoid derived from the nearest circumscribing rectangular cuboid (Lintz et al., 2019). The radiological measurements were conducted by an experienced musculoskeletal radiologist (Ia Kohonen).

4.2.2 Statistics

Descriptive statistics were reported as absolute numbers and percentages or as means with SDs for normally distributed data. Medians, ranges, and interquartile ranges were used for non-normally distributed data.

To assess differences between baseline and follow-up in total Kofoed scores, degrees of deformities, and degrees of motion, a paired Student's t-test was applied. The χ^2 test was used to evaluate differences in proportions within individual Kofoed score items. A two-tailed p-value ≤ 0.05 was considered statistically significant.

Due to the abnormal distribution of Kofoed scores, they were log-transformed, and multinomial (quadratic) regression analysis was conducted on a lognormal scale. A cubic regression model was tested as a sensitivity analysis but did not improve the model. Regression results were evaluated graphically.

Because of small sample sizes at later follow-ups in study IV, data collected beyond 5 years (ranging from 6 to 9 years) were combined as ">6 years."

All statistical analyses were performed using Stata/IC Statistical Software: Release 15 and Release 16 (StataCorp LP, College Station, TX, USA).

The implant survival data were calculated using the Kaplan-Meier estimator, with a 95% confidence interval. Failures were defined as a need for revision by exchanging metal components or conversion to arthrodesis (Henricson et al., 2011). All complications were listed and the overall revision rate was calculated.

4.2.3 Ethical considerations

All studies were conducted following the ethical principles outlined in the Declaration of Helsinki. Institutional approval was obtained from University Hospital Turku, and local ethical committee approval was granted where required. In Study 2, informed consent was obtained from all participants.

5 Results

5.1 Study I

5.1.1 Function, satisfaction, alignment, radiolucency, and survival of TMTA

The average follow-up time was 43.6 months. The mean Kofoed score increased from a preoperative value of 37.6 (SD 17.4) to 75.8 (SD 22.6). At the follow-up, the mean total ankle motion was 30 degrees (SD 12.7; range 5–60) preoperatively and 33 degrees (SD 12.8; range 5–70) postoperatively (Table 7).

At the end of follow-up, 11 patients had fair, 32 patients good and 35 patients excellent results, but in 26 patients (25%) the score was not acceptable according to Kofoed score. Fifty-one patients (50%) reported no pain, and only 18 (18%) experienced pain at rest or always when walking. In subjective questioning, 88 patients (89%) reported improved ankle function, 65 (70%) were very satisfied and 17 (18%) were satisfied with the ankle.

Before the surgery, 36 patients (35%) had a varus deformity of 14 degrees on average. The mean varus angle at the end of follow-up was 2.1 degrees (SD 5.0). Respectively, 37 patients (36%) had a valgus deformity of 11 degrees on average. The mean valgus angle at the end of follow-up was 2 degrees.

Four (4%) patients had more than 5 mm subsidence on the tibial side, and three (3%) had it on the talar side.

Table 7. Results for Studies IV and I.

Results	Study IV	Study I
Patients	40	104
Implant	CCI	TMTA
Implanting period	2010–2013	2013–2017
Follow-up, months	70	43
Kofoed score, mean		
baseline	40.6 (SD 12.6)	37.6 (SD 17.4)
latest follow-up	67.2 (SD 21.1)	75.8 (SD 20.6)
Kofoed score, results		
Not acceptable	19 (49%)	26 (25%)
Fair	6 (15%)	11 (11%)
Good	6 (15%)	32 (31%)
Excellent	8 (21%)	35 (34%)
Pain		
No	15 (38%)	51 (50%)
At rest or when walking	7 (18%)	18 (18%)
Deformity varus		
Varus		
before	7.4	14.3
after	4.7	2.2
Valgus		
before	6.3	11.0
after	2.2	2
Total ankle motion, degrees		
before	35	30
after	35	33
Subjective questioning		
Improved ankle function	32 (82%)	88 (89%)
Satisfaction with surgery		
Very much	24 (62%)	65 (70%)
Little	12 (31%)	17 (18%)
None		1 (1%)
Worse		10 (11%)
Implant survival		
5 years	97%	N/A
8 years	81%	N/A

CCI = Ceramic Coated Implant, TMTA = Trabecular Metal Total Ankle, SD = standard deviation, N/A = Not available

5.1.2 Complications and additional procedures of TMTA

Thirty-one (30%) needed additional surgery, resulting in 38 additional procedures. Based on the postoperative evaluation, postoperative procedures were performed if needed and are indicated in Table 8.

Table 8. Additional operative procedures.

Surgical Procedure	TMTA	CCI
Number of patients	104	40
Plate removal	12	*
Rod removal	1	*
Screw removal	1	*
Syndesmosis screw removal	3	*
Muscular flaps	3	
Free skin transfer	1	1
Syndesmosis fusion	1	
Reoperation of fibular osteotomy	1	
Delta ligament reconstruction	1	
Lateral ligament reconstruction	1	
Flexor hallucis longus suturation		1
Calcaneal osteotomy	1	2
Subtalar fusion	3	1
Medial malleolus osteotomy	2	2
Nerve reconstruction	2	
Prosthesis removal	3	
Component revision		1
Osteolytic cyst bone grafting		1
Osteolytic cyst cement grafting		2
Converted to arthrodesis		4

* In the anterior approach, these are not routinely required, so the need for removal typically does not arise.

5.2 Study II

5.2.1 Motion between the mobile bearing insert and the tibial component

We found measurable motion between the CCI mobile-bearing insert and the tibial component in all three planes: coronal, sagittal and axial. The measurement results

are shown in Table 9. The rotational motion between the components was also calculated; the resulting scatterplot is shown in Figure 12.

Table 9. Radiological measurements of ROM (range of motion).

Patient	Radio-logical PF (degrees)	Radio-logical DF (degrees)	Radio-logical total ROM (degrees)	Clinical total ROM at 1 y (degrees)	Radio-logical/ clinical ROM (%)	Coronal total motion (mm)	Sagittal total motion (mm)
1	3	14	17	35	49	0	2
2	21	8	29	45	64	0	2
3	1	20	21	35	60	1	4
4	5	15	20	50	40	1	1
5	10	-1	9	40	23	2	5
6	9	10	19	45	42	1	2
7	16	13	29	55	53	2	6
8	4	14	18	40	45	0	1
9	13	17	30	35	86	0	2
10	12	18	30	40	75	1	4
Average (range)	9.4 (1–21)	12.8 (–1 to 20)	22.2 (9–30)	42 (35–55)	54 (23–86)	0.8 (0–2)	2.9 (1–6)

PF = plantarflexion, DF = dorsiflexion, ROM = Range of motion, mm = millimeter

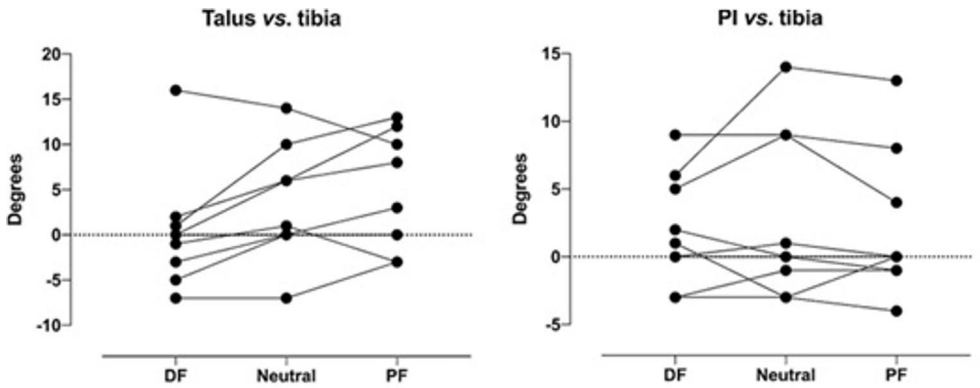

Figure 12. Connected scatterplot of individual patient data on rotational motion between CCI components. External rotation is shown as negative and internal rotation as positive. PI = polyethylene insert, DF = dorsiflexion, PF = plantarflexion, Neutral = neutral weightbearing. Reprinted with permission from Foot and Ankle Surgery.

5.3 Study III

5.3.1 Peri-implant osteolysis in TMTA replacement

Eight of 80 patients had osteolytic lesions around the TMTA components on CT images. The average follow-up was 39 (range 12–85) months, and the lesions were initially detected at an average of 42 months postoperatively. The findings are presented in Table 10.

Conventional radiographs were also taken and analysed. Fourteen patients had radiolucent lines <2mm wide along the prosthesis components. Four of the 14 patients underwent CT scans with no osteolysis.

Table 10. Locations, time of detection, and sizes of osteolytic cysts on CT scan.

Patient	Location (coronal and sagittal view)	Time at detection (months postoperatively)	Maximum diameter	Volume, mm^3
1	2, 9	49	7	110
2	3, 12 5, 6	32 42	11 9	176 254
3	5 (MM)	66	13	1389
4	5 (MM) 2, 8	64 64	12 8	415 165
5	LM	49	20	2350
6	5 (MM)	24	19	1709
7	5 (MM)	24	13	691
8	1, 13 5, 12	25 25	10 8	209 113
Average (range)		42 (24–66)	12 (7–20)	689 (110–2350)

MM = medial malleolus, LM = lateral malleolus

5.4 Study IV

5.4.1 Function, satisfaction, alignment, radiolucency and survival of CCI

The average follow-up time was 70 months (5.8 years). The mean Kofoed score inproved from a preoperative value of 40.6 (SD 12.6) to 67.2 (SD 21.1). At the latest follow-up, the mean total ankle motion was 35 degrees (SD 6.4; range 5–40) preoperatively and 35 degrees (SD 5.3; range 15–40) postoperatively (Table 7, Figure 13).

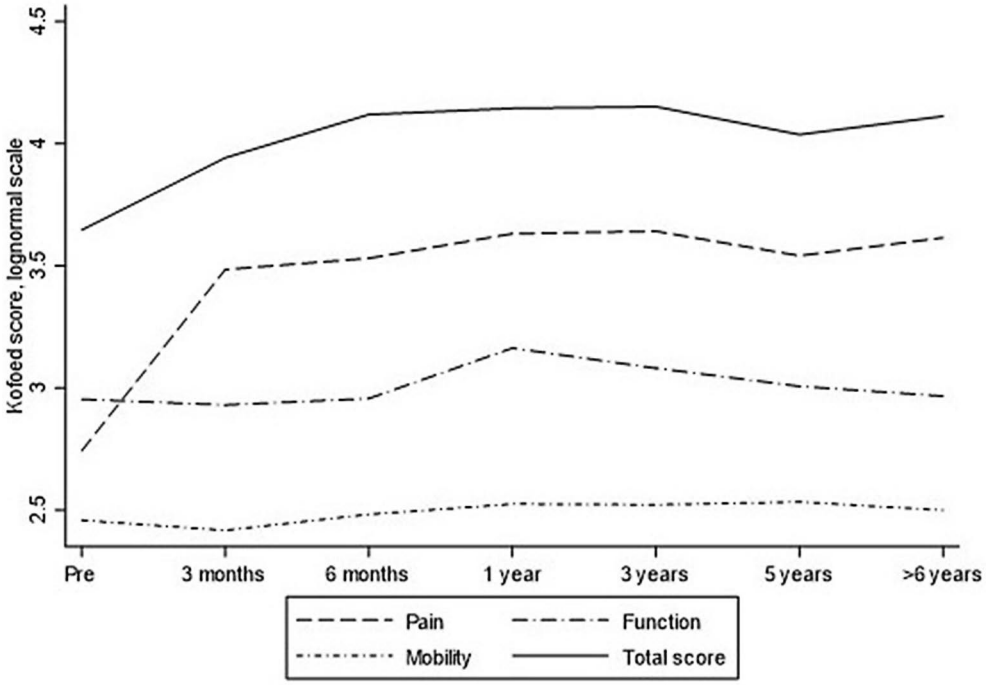

Figure 13. Development of the Kofoed score over the follow-up time (log-normal scale). Reprinted with permission from Foot and Ankle Surgery.

At the end of the follow-up, six patients had fair, six good, and eight excellent results, but the score was not acceptable in 19 patients (49%). Fifteen patients (38%) reported no pain, and only seven (18%) experienced pain at rest or always when walking. In subjective questioning, 32 patients (82%) reported improved ankle function, 24 (62%) were very satisfied, and 12 (31%) were satisfied with the ankle.

Malposition of prosthetic components was seen in 12 (31%) ankles. During follow-up, talar component migration was found in 10 (26%) and tibial component migration in three (8%) ankles.

The average preoperative varus alignment was 7.4 degrees in 19 ankles, and valgus alignment 6.3 degrees in 20 ankles. The average varus alignment at the end of the follow-up was 5 degrees in 23 ankles, and valgus alignment was 2 degrees in 16 ankles. The results are summarized in Table 7.

Radiolucent lines or osteolytic lesions were observed on radiographs one year postoperatively in six (15%) ankles and at the end of the follow-up period in 22 (56%) ankles. The distribution of radiolucency is illustrated in Figure 12. Postoperative CT scans were obtained for 29 ankles within 2 to 7 years postoperatively, of which 20 showed signs of osteolysis. The implant survival rate was 97% (95% confidence interval (CI): 81–100%) at 5 years and 81% (95% CI: 60–92%) at 8 years. The Kaplan-

Meier analysis was performed (Figure 12). There were five (13%) failures, defined as the need for revision involving the exchange of metal components or conversion to arthrodesis. In addition to the cases of failure, there were 20 (51%) complications, including perioperative fractures. The overall revision rate was 28% (11/39), encompassing all postoperative revisions due to wound healing issues, malalignments, osteolysis, component exchanges, and conversions to arthrodesis.

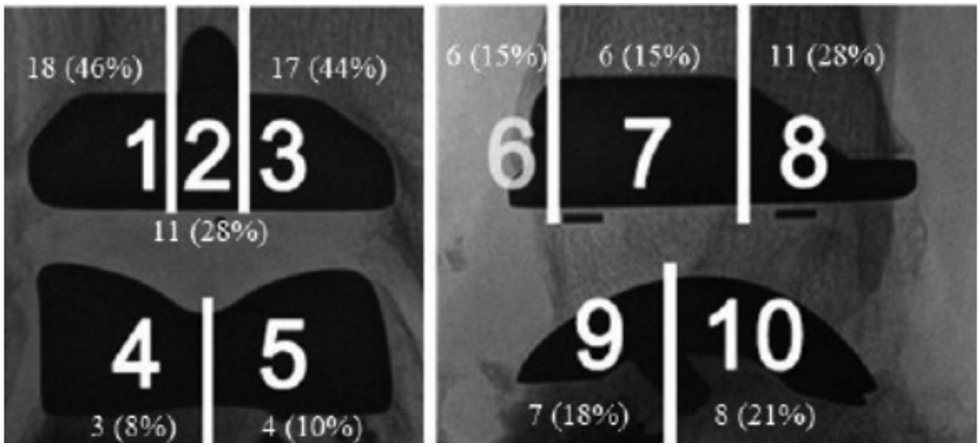

Figure 14. Number of patients with radiolucent lines (%): Zones 1–5 in AP view and Zones 6–10 in lateral view. Reprinted with permission from Foot and Ankle Surgery.

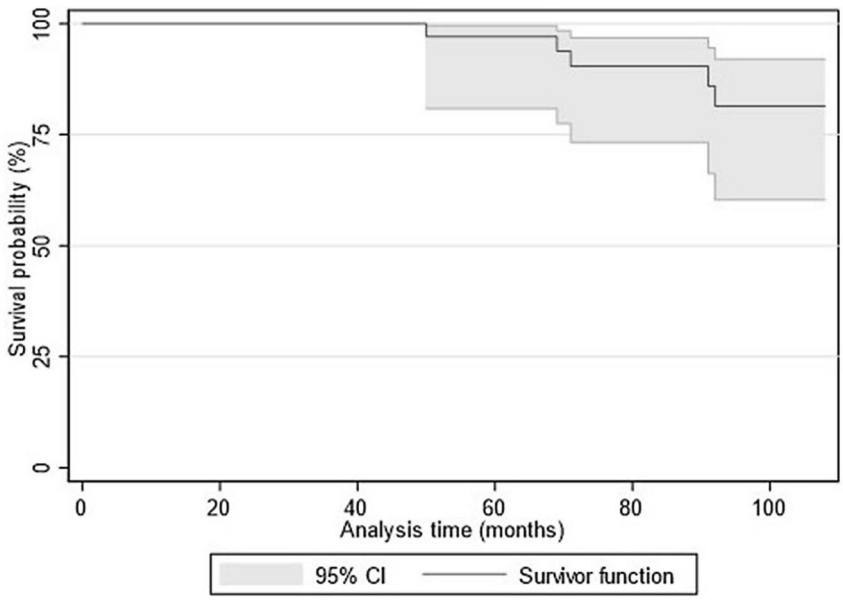

Figure 15. Kaplan-Meier survival chart for CCI implants. The 95% confidence interval is shown in grey. CI = Confidence interval. Reprinted with permission from Foot and Ankle Surgery.

5.4.2 Complications and additional procedures of CCI

The most common additional procedure was conversion to arthrodesis, performed on four patients. All additional surgeries are listed above in Table 8. Malposition of prosthetic components was observed in 31% of cases, with osteolysis present in 31% at the final follow-up. Perioperative fractures occurred in six cases, all of which healed without complications. Complications, including all reoperations, were noted in 64% of ankles (Table 11). The reoperation rate was 28%. The complications are detailed in Table 10.

Table 11. If there were several operations on one ankle, it appears only in the column of the last operation, but the same case may appear on several rows.

	No further surgery	Intraoperative corrective surgery	Further corrective surgery	Revised by fusion	Revised by exchange	Revised with debridement and filling
Major delay of wound healing			1			
Deep infection				1		
Intraoperative fracture of medial malleolus		3				
Intraoperative fracture of lateral malleolus		2				
Stress fracture of medial malleolus	5					
Osteolysis	12		6	2	1	3
Aseptic loosening	1					
Component migration	13			1	1	
Varus malalignment (>10º)	3		2			
Valgus malalignment (>10º)	1					

6 Discussion

6.1 Introduction

General opinion on TAR has evolved significantly over the years. The poor outcomes of first-generation prostheses initially led to skepticism, but modern implants and improved surgical techniques have increased interest and confidence in TAR. Although complication and revision rates remain a concern, contemporary implants and surgical advancements have improved outcomes.

According to our results, even with an older MBI model (CCI), good pain relief was achieved—so much so that patients whose radiological or functional condition met the definition of failure did not wish to undergo revision. However, the incidence of osteolysis was high. We also confirmed the mobility of the polyethylene insert in MBI design. To our knowledge, we were the first in the world to do so. The clinical significance of insert mobility remains unclear.

With the new FBI model (TMTA), using a lateral approach, we achieved better clinical outcomes, with 89% of patients reporting improved function and 66% being very satisfied with the surgery. The new technique demonstrated a lower risk of peri-implant osteolysis in the short to midterm, likely due to its anatomic configuration, unique material properties, and more precise surgical technique.

6.2 Implications of the approach and bearing

Our studies used two surgical approaches: the traditional anterior and the rarely used lateral approaches. In Study IV, where the anterior approach was used, and the implant was an older MBI (CCI), the re-operation rate was 37 %, and complications, including all reoperations, were documented in up to 64% of ankles. Although only one-fifth of the complications in the study were high-grade in terms of risk of implant failure (Glazebrook et al., 2009), the problems associated with the CCI implant led us to discontinue its use only after a few years. We discontinued using the implants that required an anterior approach and changed to the lateral approach and trabecular metal implant in 2013 to achieve better results. For example, when using an anterior approach, wound healing problems might occur even in as many as 40% of cases (Myerson & Mroczek, 2003)

Initially, the number of infections was relatively high, with three deep infections and nine superficial ones across 104 ankles. However, eleven of these twelve infections occurred with plate fixation (n = 78), while one deep infection was associated with intramedullary rod fixation (n = 8). After observing a trend of numerous complications associated with both plate and intramedullary rod fixation, we transitioned to using screws in our clinic. By performing fibular osteotomy fixation with two or three screws instead of plates, we significantly reduced the rates of infection and wound complications, noting only one case of delayed wound healing in this group (n = 18). Many patients with post-traumatic ankle osteoarthritis have previously undergone ankle surgery, such as plate fixation of the lateral malleolus, followed by subsequent plate removal. This often results in the lateral approach being made through scar tissue, which can potentially increase infection risks. In Study I, 64% of patients had a history of prior ankle surgery. As our clinic's expertise grew and the technique became more established, wound complications decreased. Overall, the complication rate in Study I with total ankle replacement using lateral malleolar osteotomy was 20%, consistent with a prior report from DeVries et al., who documented a 25% incidence of complications (DeVries et al., 2017). Substantially better outcomes have also been reported from individual centers (Usuelli et al., 2019).

In Study I, marked varus-valgus malalignments of up to 28 to 32 degrees of varus or valgus could be corrected to neutral alignment. Even with such severe malalignment, the components remained congruent. The increased surface area at the bone-implant interface and the ability to orient the rails in the coronal plane also enhance initial stability and reduce the risk of complications. Historically, TAR has not been recommended for patients with preoperative varus or valgus deformities exceeding 15 degrees, as these have been considered relative contraindications. Deformities surpassing 20 degrees were deemed an absolute contraindication for the procedure (Hintermann & Ruiz, 2019; Hobson et al., 2009b; Wood & Deakin, 2003). However, with modern implant designs, improved surgical techniques, and better instrumentation, encouraging results have been achieved even in complex deformities, as demonstrated in Study I (Hobson et al., 2009b; Queen et al., 2013) With the lateral approach, the operation uses a frame with a more anatomical placement, resulting in greater reproducibility (Usuelli et al., 2017)

Correct implant positioning is essential, as malalignment is a major cause of failure and is strongly linked to functional outcomes (Espinosa et al., 2010; Johnson-Lynn & Siddique, 2019). The anterior approach has certain limitations, especially when managing sagittal malalignment deformities. A study by Najefi et al. identified significant variability in tibial torsion among TAR patients, complicating alignment correction, particularly when using the medial gutter line and trans-malleolar axis as reference points (Najefi et al., 2019). Moreover, recent implant designs prioritize

bone preservation and low-volume components, particularly for the talar component. Utilizing an anterior approach may require a more proximal tibial cut to facilitate joint preparation and implant placement (Yu et al., 2020). From the anterior approach, it is challenging to accurately determine the ideal positioning and standardize the rotation of the implants due to a wide variation of tibial torsion among patients, especially when using the tibial tuberosity for reference (Najefi et al., 2019). Coronal-plane malalignment of the tibiotalar joint is commonly observed in end-stage ankle arthritis. Restoring neutral coronal alignment is critical for successful TAR outcomes (Greisberg & Hansen, 2002). Improperly balanced ankle prostheses can lead to edge-loading, increased contact stresses on the polyethylene insert, accelerated wear, and premature implant failure. The lateral approach enables direct visualization of the anatomical center of rotation of the ankle, improves implant placement, preserves native deltoid ligament stability, and reduces the need for bone resection. Compared to traditional flat cuts, the curved bone preparation preserves more bone; bone can be preserved as much as the anatomy allows. Preserving the dense subchondral bone also makes it easier to perform revisions.

Study I encompasses all ankles with TMTA implants from the beginning, highlighting the learning curve associated with this new approach. A larger portion of complications arose in ankles at the start of this series. This occurred despite our institute's extensive experience and history in the surgical management of total ankle replacements. At our institute, 160 TARs using the anterior approach were carried out before the CCI implant, and over 250 TARs were performed before the transition to the TMTA implant. It has been noted that the learning curve for TAR surgery is rigorous, and complication rates tend to be higher during a surgeon’s early procedures. Despite this evident learning curve, the FBI utilized in the study outperformed the older MBI in nearly all aspects.

An accurate, generalizable comparison between the FBI and MBI models cannot be made, as this study only examined the outcomes of the two different models independently, with patient treatment occurring during various timeframes and with two entirely different surgical techniques. Therefore, based on these studies, we cannot determine whether the MBI or FBI is superior. However, the procedures were performed in the same hospital, primarily by the same surgeons, suggesting that these results can inform implementation decisions and evaluations of current designs. In our studies, the FBI combined with the lateral approach resulted in better outcomes (Kofoed scores 75.8 vs. 67.2) than the MBI with the anterior approach despite a lower baseline score. A larger number of patients in the FBI group reported good to excellent results, experienced no pain, and showed higher satisfaction levels. Conversely, the MBI group demonstrated a higher proportion of unacceptable outcomes, lower satisfaction rates, and more cases of persistent pain. This aligns with the initial results of the TARVA study replacement (Goldberg et al., 2022).

Both implants maintained but did not significantly improve preoperative range of motion. Better deformity correction was achieved with the FBI implant, and revision rates were lower compared to the MBI.

6.3 Motion of the mobile-bearing insert

We observed measurable motion between the mobile-bearing insert and the tibial component across the coronal, sagittal, and axial planes. WBCT proved useful in detecting the movement between these components. In Study II, the axial rotation between the metallic components in a neutral weight-bearing position varied from 14 degrees of internal rotation to 7 degrees of external rotation, with an average of 3 degrees of internal rotation. The average axial rotation between the metallic components in different ankle positions did not significantly differ from the neutral weight-bearing situation. The variation in axial rotation was broad among patients but somewhat consistent within the measurements of a single patient. In most patients, the rotation between metallic components shifted from external to internal rotation as the ankle moved from dorsiflexion to plantarflexion, which is expected in a natural ankle. Considered more complex than a simple hinge, the ankle exhibits motion in the transverse plane, with rotation estimated to range from 6 to 12 degrees. Thus, the mobile-bearing insert type may better mimic the ankle's natural movement by accommodating translational and rotational movements (Sammarco et al., 1973).

The importance of motion in TAR was demonstrated in a study by Dekker et al., where radiographic sagittal plane motion positively correlated with multiple PROMs. The overall ankle ROM showed a significant correlation, with dorsiflexion positively associated with postoperative PROMs, while plantarflexion did not similarly affect outcomes (Dekker et al., 2018). However, clinical ROM encompasses motion at both the tibiotalar and hindfoot joints, and no differences have been observed between fixed- and mobile-bearing implants regarding radiological motion assessed through radiographs (Dekker et al., 2017). Moreover, neither randomized nor retrospective studies analyzing the impact of bearing type on gait mechanics and pain detected statistically or clinically significant differences (Lullini et al., 2020; F. G. Usuelli et al., 2020). A recent review comparing ankle arthrodesis and TAR, which included mobile-bearing implants (MBI) and fixed-bearing implants (FBI), found no substantial differences in gait biomechanics (Deleu et al., 2020). Therefore, based on our studies, we cannot confirm that the mobility of the insert has either positive or negative effects.

6.4 Osteolysis

In Study IV, which investigated the MBI CCI with an anterior approach, the incidence of osteolysis was high, 31% on radiographs and 69% for those ankles imaged by CT scanning. The CCI implant was a third-generation implant, and the incidence of osteolysis has been notably high in many similar third-generation implants, reaching up to 70% (Di Iorio et al., 2017; Koivu et al., 2017). The tibial component features a keel-type design, while most recent TAR tibial components utilize peg- or bar-type designs. The dual coating of titanium and calcium phosphate found in the CCI implant resembled many other designs of that era, which may have contributed to the observed complications. In Study IV, over half of the revisions were attributed to osteolysis (3/5). This aligns with previous findings regarding the CCI implant (Voesenek et al., 2017). The latest analysis from the Swedish Ankle Register included 151 CCI implants, with 28 revisions (19%) noted over approximately 8 years of follow-up. The most prevalent reason for revision was loosening, followed by pain (Undén et al., 2020). Van Es et al. published a 10-year follow-up on 254 CCI implants, reporting long-term results. The 10-year survival rate for aseptic loosening was 70.0% (95% CI: 61.0-78.6). They indicated a 67.5% 10-year survival rate for all-cause revision, with a median follow-up of 6.9 years (range 0.04–13.9 years) and a mean time to revision of 4.5 years (range 0.04–12.2 years) (van Es et al., 2022). Although the survival rates are not directly comparable to our study due to differences in how revisions are reported, the survival rate in our series is likely to decline over time, considering the significant number of issues already encountered in our series.

In Study III, which investigated the FBI TMTA using a lateral approach, we concluded that the risk of peri-implant osteolysis was low in the short to midterm. Only eight out of 80 patients (10%) exhibited postoperative osteolytic lesions on CT images. Although the average follow-up time was somewhat short at 39 months, the incidence of osteolysis is considered very low compared to the study by Lintz et al., which examined 48 different TAR implants, including Salto Talaris (Integra), Salto (Tornier), Hintegra (Integra), Cadence (Integra), and Zenith (Corin) implants. In that study, the authors found at least one cyst in 81% of the ankles over a mean follow-up of 48 months (Lintz et al., 2019).

Regarding the bony ingrowth providing better initial stability of the TAR implant, tantalum metal could be a beneficial material to reduce the risk of osteolysis. Additionally, the kinematics of the TMTA ankle differ from those of conventional TAR implants, which may also enhance the implant's initial stability. In the previously mentioned study by Lintz et al., the magnitude of residual varus or valgus alignment positively correlated with cyst volume. Moreover, patients with residual varus and valgus had more cysts (Lintz et al., 2019). Different imaging methods partly account for the discrepancies between the findings, as 3-dimensional imaging

enables a more reliable assessment of the hindfoot alignment compared to plain radiographs. In Study III, determining the associations between alignment and the presence of cysts was not possible due to neutral alignment and the low incidence of cysts.

A key concern has been whether peri-implant osteolytic cysts are already present before surgery since bone cysts are a common feature of osteoarthritis. Additionally, pre-existing osteoarthritic bone cysts could expand after surgery. In a series of 120 consecutive patients with end-stage ankle osteoarthritis who were imaged by CT before TAR, 78% of patients had bone cysts in areas that would not have been removed during surgery, primarily located in the medial and lateral malleoli (Najefi et al., 2021). Our findings did not support this concern, as all the osteolytic lesions in the ankles with TMTA detected on CT images developed after surgery, with none observed on preoperative CT or MRI images. Eight of 80 patients (10%) had postoperative osteolytic lesions around the components on CT images; three had two different lesions. Among the lesions found on CT images, seven were located in the tibia, three in the talus, and one in the distal fibula. Five lesions were not in immediate contact with the prosthesis components; four tibial lesions were positioned in the medial malleolus, and one lesion was in the lateral malleolus. However, these lesions also developed postoperatively, and we interpreted them as true osteolytic lesions rather than preoperative cysts. The cyst found in the lateral malleolus may have developed due to a superficial infection and plate removal; otherwise, the etiology of these separate lesions remains unclear.

Along with the advancements in material technology, implant design, and surgical techniques for modern ankle implants, the incidence of cysts and especially the complications they cause are decreasing.

6.5 CT for detecting osteolytic changes

The primary imaging technique for TAR patients is weight-bearing radiographs. However, in Study III, we observed that this method is ineffective for identifying osteolytic changes. Only eight out of 80 patients (10%) showed postoperative osteolytic lesions surrounding the components in CT images, and only one of these changes was also visible in the radiographs. A total of 14 patients exhibited partial radiolucent lines less than 2 mm wide around the prosthesis components as seen in the radiographs. Of these 14 patients, four had CT scans available, and the findings from the radiographs were not confirmed by the CT images. The partial, non-circumferential radiolucent lines along the components noted in the plain radiographs are unlikely to indicate loosening. Based on our experience, these do not progress into balloon-like osteolytic cysts.

It has been shown that CT significantly outperforms radiographs in detecting osteolytic lesions around the TAR, particularly on the talar side (Hanna et al., 2007; Kohonen et al., 2013). In the study by Najefi et al., preoperative cysts were not visible on plain radiographs in 60% of cases (A. A. Najefi et al., 2019). Radiation exposure is not a major concern, as the ankle is located peripherally, and the mean effective dose for an ankle CT scan is only 0.07 mSv. The dose for ankle CBCT is even lower, ranging from 0.01 to 0.03 mSv (Alexander et al., 2023). Recent studies indicate that WBCT scanners provide cost-effectiveness and faster image acquisition times compared to conventional CT imaging, along with the added advantage of portability offered by CBCT devices (Alexander et al., 2023; Richter et al., 2020).

Although the clinical significance of minor peri-implant osteolytic changes remains unclear, CT during follow-up simplifies decision-making in cases with such findings.

6.6 Strength and weaknesses

6.6.1 Study I

The study I was retrospective and subject to bias, similar to most studies on TAR. The number of patients in TAR studies is typically small, and follow-up times are somewhat short. However, this study included 104 consecutive patients, which can be seen as a strength. The mean follow-up time was 43.6 months, considered a mid-term follow-up period.

6.6.2 Study II

We also recognize several limitations in Study II, which concentrated on PI motion. One limitation is the small and selective group of patients, as the study aimed to evaluate the imaging method. Patients were selected solely based on their ROM and not on other demographic factors. Additionally, potential malalignment or improper positioning of the components, which could have influenced the measurements, was not investigated. Furthermore, the ankle motion during scanning was only generated in the sagittal plane, and the positions created by the standard blocks to simulate motion may not accurately reflect the true ROM of the ankles.

On the other hand, Study II was the first study using WBCT to measure PI motion. Using WBCT allowed for more accurate measurements with a three-dimensional perspective than with plain radiographs.

6.6.3 Study III

There were 104 patients, which represents a relatively large sample size. However, the incidence of osteolysis was low, at only 10%. One limitation of Study III is the variation in the time between the operation and the CT scan, despite a planned follow-up protocol. The patients, coming from a wide geographical area and often traveling long distances, routinely have clinical follow-ups at the hospital but are seen by different physicians as outpatients. As a result, the scheduled follow-up time points are not always followed as intended. Consequently, the exact timing of when lesions emerged during the postoperative period remains undetermined. Another limitation is the relatively short interval between the TAR operation and the CT scan, as more time may have been necessary for all potential cysts to develop.

6.6.4 Study IV

The study IV was retrospective and prone to bias, similar to most studies on TAR. Furthermore, it was impossible to evaluate associations between patient-related factors or ankle alignment and clinical outcomes. Since CT scans were conducted only when osteolysis or loosening was suspected, rather than as part of routine follow-up, the timing of the scans varied among patients. Despite these limitations, we believe that a consecutive series with structured follow-up of previously widely used implants offers valuable insights for future implant development and TAR surgeons and patients with these implants.

6.7 Future focus

Achieving success in TAR requires careful consideration. Orthopaedic surgeons must optimize every aspect of surgical treatment to minimize revision rates. This entails thorough patient selection, considering the unique advantages and disadvantages of various prosthetic models and the technical demands of the surgical procedure. Additionally, we should assess whether TAR procedures should be centralized in facilities with higher procedure volumes to improve outcomes. For example, in Norway, seven hospitals performed TAR procedures in 2015, but by 2019–2021, that number had decreased to two. The findings regarding new prostheses in Norwegian studies indicate improvement (Sundet et al., 2023).

Several long-term outcome studies have been published on some still in use of third-generation prostheses. These earlier designs and surgical techniques have established the groundwork for today's development efforts, modern models, and methods, which are anticipated to further enhance outcomes. However, the number of articles addressing the long-term results of the latest fourth- and even fifth-

generation prostheses still needs to increase. Thus, future research should focus on comparing these newer models with the long-term outcomes of older designs.

The ankle registry is significantly lower in quality compared to hip and knee arthroplasty registries in Finland and worldwide. Moving forward, we need to critically evaluate our practices and ensure that all accurate arthroplasty data are transferred to the registries, which were once among the best in the world. The repeated rejection of funding for a new foot and ankle registry is frustrating and greatly hinders the critical evaluation and development of this method. First, the TAR registry must become a nationwide standard in Finland.Success in TAR requires extensive consideration. To minimize revision rates, orthopaedic surgeons must optimize all aspects of the surgical treatment. This involves careful patient selection, considering the specific advantages and disadvantages of different prosthetic models, as well as the technical requirements of the surgical procedure.

7 Conclusions

Study I

The Trabecular-metal TAR implant demonstrated good pain relief and promising functional outcomes, with infrequent osteolysis and component loosening at 5 years. However, the lateral approach had a nearly 20% complication rate and a 38% rate of additional procedures, partly attributed to the learning curve.

Study II

The CCI MBI exhibits measurable motion between the insert and tibial component across all three planes, with CBCT proving effective for evaluation. While sagittal and coronal plane motion is likely of minor importance, the wide variation in axial rotation suggests that the mobile-bearing design may better adapt to component misalignment. However, mobile inserts may cause undesired contact with adjacent bones and become dislocated, contributing to wear, osteolysis and loosening.

Study III

The risk of peri-implant osteolysis with the TMTA FBI is low in the short- to midterm, likely due to its anatomical design, specialized materials and precise surgical technique. By reducing the incidence of osteolysis, the longevity of TAR is significantly improved.

Study IV

The CCI MBI outcome was unacceptable, as malposition, subsidence, and peri-implant osteolysis were often recorded. Patients with these implants should be monitored carefully, and additional research is necessary to explore why implants fail. Such poor results highlight the importance of well-functioning registries in evaluating current and potentially discontinued treatment methods.

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