

THE **CLINICAL**
AND **BIOMECHANICAL**
IMPLICATIONS OF
HALLUX RIGIDUS
AND RELATED
SURGICAL
INTERVENTIONS
ON **GAIT**

ROBIN DE BOT

The clinical and biomechanical implications of hallux rigidus and related surgical interventions on gait

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The clinical and biomechanical implications of hallux rigidus and related surgical interventions on gait

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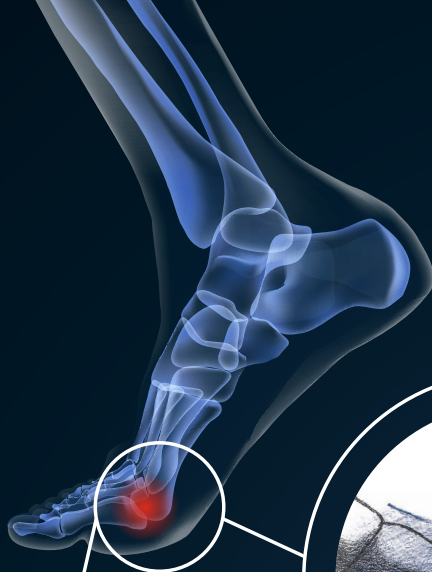
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Table of contents

Chapter 1	Introduction	7
Chapter 2	Gait analysis of foot compensation in symptomatic hallux rigidus patients	25
Chapter 3	A prospective study evaluating gait and clinical outcome following first metatarsophalangeal arthrodesis for hallux rigidus	43
Chapter 4	Long-term effects of cheilectomy, Keller's arthroplasty, and arthrodesis for symptomatic hallux rigidus on patient-reported and radiological outcome	63
Chapter 5	Gait and dynamic pedobarographic analyses in hallux rigidus patients treated with Keller's arthroplasty, arthrodesis or cheilectomy 22-years after surgery	87
Chapter 6	Metallic hemiarthroplasty or arthrodesis of the first metatarsophalangeal joint as treatment for hallux rigidus: a systematic review and meta-analysis	105
Chapter 7	Comparing kinematics and assessing repeatability of the Oxford Foot Model in 3D gait analysis of healthy individuals	141
Chapter 8	General discussion	163
Chapter 9	Impact	179
Chapter 10	Summary	184
	Nederlandse samenvatting	188
	Curriculum Vitae	193
	List of publications	194
	Dankwoord	195



CHAPTER 1

Introduction

Osteoarthritis

Osteoarthritis (OA) is the most common joint disorder and leading cause of pain and disability worldwide [1]. It is characterized by degeneration of articular cartilage, intra-articular inflammation with synovitis, and changes in periarticular and subchondral bone [2]. This leads to joint destruction, resulting in pain, swelling, joint motion limitation, and finally disability, and significant reductions in health related-quality of life. It is typically a progressive disease, and symptoms become more severe, more frequent, and more debilitating over time. Multiple factors are involved in OA development, including mechanical influences, aging effects, and genetic factors [3]. There is no cure for OA, and all currently available treatments are directed toward reducing symptoms [4]. In the Netherlands, it is expected that the number of patients suffering from OA will increase by 92% from 1.2 million patients in 2015 to 2.3 million patients in 2040 due to aging [5]. It is estimated that OA accounts for 15% of all musculoskeletal consultations in primary care among those aged 45 years and older [6]. This rapidly increasing prevalence of this already common disease suggests that OA will continue to have a growing impact on health care and public health systems in the future [3]. Conducting OA research is essential to further increase knowledge of OA prevention and to ensure optimal treatment strategies for patients affected by this debilitating condition.

Hallux rigidus

Hallux rigidus (HR), Latin for “stiff toe,” is a condition that refers to degenerative OA of the first metatarsophalangeal (MTP1) joint (Figure 1) [7]. The condition was first described by Davies Colley in 1887 [8,9]. Osteoarthritis of the MTP1 joint is the most common degenerative joint disease in the foot [10]. Of all patients aged over 50 years, 2.5% report degenerative arthritis of the MTP1 joint [11]. Females are twice as likely as men to suffer from HR [11]. MTP1 osteoarthritis is characterized by degeneration of the cartilage, especially dorsally in early stages of the disease and progresses during aging to involve the entire joint (Figure 2) [7,12]. Furthermore, osteophytes develop around the joint margins, especially on the dorsal aspect, and increase throughout disease progression, which further restricts joint motion and results in an increased bulk of the joint (Figure 2) [12]. Weight-bearing antero-posterior and lateral radiographs can be used to observe these bony deformations. Several classification systems describe HR severity, including the Regnault classification [13] and the Coughlin and Shurnas classification [14] (Table 1).

HR development seems to be a multifactorial process. Several factors can influence the development of degenerative changes. Trauma is one of the most frequently cited factors in literature and may occur as single isolated injury, such as a fracture [8,15]. However, it could also be due to a secondary process of repetitive stress, resulting

in microtraumas or inflammatory conditions, such as gout and rheumatoid arthritis [7-9]. Biomechanical factors, including a long first metatarsal, metatarsus elevatus, and metatarsus adductus can lead to an increased risk of HR [7,9]. Furthermore, a positive family history and female gender are risk factors for the development of this disease [8].

The MTP1 joint has an important functional role in the gait cycle since it carries approximately 119% of an individual's body weight with each step [7]. Forces on the first ray of the foot are increased during sporting activities: forces can increase by approximately two to three times the body weight during running and up to eight times during running jumps [16]. The MTP1 joint has important functions in balance and stability, weight distribution, and efficient movement during various activities that involve the feet. Patients suffering from HR experience joint pain, swelling, stiffness, and dorsiflexion restriction, especially during activities (Figure 1). This leads to altered gait mechanics and results in a significant reduction in activity, social participation, and economic productivity, which could have a significant impact on health-related quality of life [10,17]. In conclusion, the MTP1 joint is indispensable due to its important function during gait, which can be significantly influenced by OA. HR research is necessary to assist people in managing the condition, to expand the understanding of prevention, and to provide more effective treatments for those living with the disease.

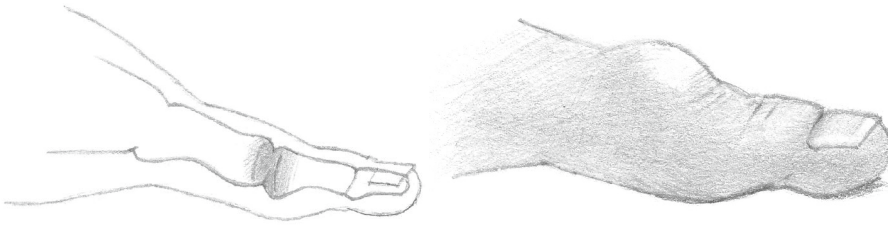


Figure 1: Hallux rigidus: The images on the left show the affected first metatarsophalangeal (MTP1) joint in a case of hallux rigidus, while the images on the right illustrate the clinical appearance of the MTP1 joint associated with the condition.

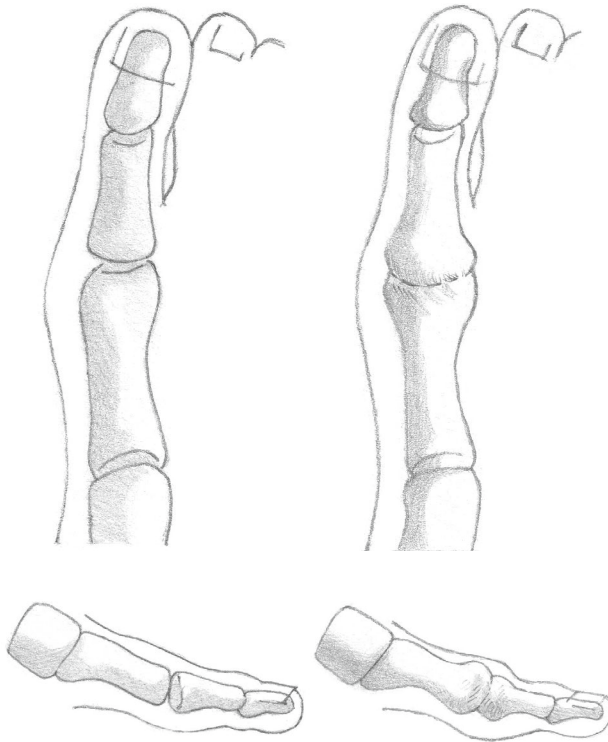


Figure 2: The left image shows a normal foot, whereas the right image displays a foot with an affected first metatarsophalangeal (MTP1) joint due to hallux rigidus, with the signs of joint space narrowing and osteophyte formation on the margins of the joint.

Table 1: Coughlin and Shurnas and Regnault HR classification system, based on clinical and radiographic findings.

Coughlin and Shurnas classification			
HR grade	Clinical findings	Radiographic signs	MTP1 dorsiflexion
0	No pain, only moderate stiffness	Normal	40°-60°
1	Mild pain at extremes of motion	Mild dorsal osteophyte Normal joint space	30°-40°
2	Moderate pain at extremes of motion, increasingly more constant	Moderate dorsal osteophyte < 50% joint space narrowing	10°-30°
3	Nearly constant pain and significant stiffness, pain at extreme joint motion of MTP1, no pain at mid-range	Severe dorsal osteophyte > 50% joint space narrowing	< 10°
4	Significant stiffness, pain at mid-range, and extreme range of motion	Same as grade 3	< 10°
Regnault classification			
HR grade	Clinical and radiographic signs		
1	Slight narrowing of the joint space, functional hallux limitus		
2	Joint adaptation with moderate osteophytes, narrowing of joint space, subchondral sclerosis or cysts, and pain at the end range of motion of MTP1		
3	Arthrosis with severe osteophytes, complete disappearance of joint space, and erosions plus continuous pain		

Treatments for hallux rigidus

HR is initially nonoperatively managed; surgical interventions are indicated when conservative treatments fail [7,12]. Conservative treatments include shoe modifications, such as insoles and foot orthoses, with the aim to support the first row and reduce MTP1 motion, limit irritation from the dorsal osteophyte, and reduce mechanical stress on the joint to alleviate pain (Figure 3A) [9,11,18]. Furthermore, in an acute episode, nonsteroidal anti-inflammatory drugs and intra-articular steroid injections can provide temporary relief but have not shown long-term benefits [11,12,18]. However, if nonoperative management fails, then surgical interventions are indicated. A variety of surgical options are available for HR; they are classified in joint-preserving and joint-sacrificing procedures. In joint-preserving surgical techniques, the deteriorating joint is spared, and function is restored to delay or avoid joint replacement surgery [19]. In joint-sacrificing techniques, the joint is removed or replaced by implants. Joint-preserving procedures are generally preferred in early HR stages, while in cases of severe OA, joint-sacrificing procedures are indicated [19]. Furthermore, a patient's age, activity level, and expectations are important factors in selection of the preferred surgery. Several techniques have been proposed, while the optimal operative technique has yet to be defined [7].

Joint-preserving surgical procedures

Cheilectomy is a joint-preserving technique that is indicated in mild-to-moderate HR (Grades 1 or 2) (Figure 3B). The procedure commonly includes the resection of dorsal osteophytes from the metatarsal head and proximal phalanx, the removal of loose bodies, a synovectomy, and release of the medial and lateral capsule and ligaments [7,11,19]. Advantages of a cheilectomy include improved MTP1 motion, low morbidity, and allowable secondary future procedures [9]. However, cheilectomy does not prevent disease progression, and therefore, a recurrence of complaints could occur [19]. Additional joint-preserving procedures are known, including phalangeal or metatarsal component osteotomies [9,11,17,19].

Joint-sacrificing techniques

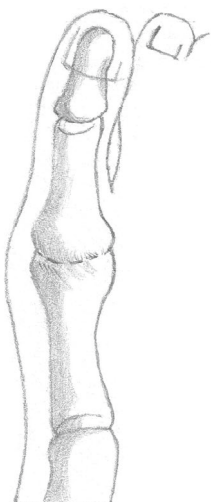
Keller's arthroplasty is a joint-sacrificing technique. It consists of removal of the base of the proximal phalanx to decompress the joint and increase movement (Figure 3C) [9]. It results in pain reduction and improvements in range of motion after surgery. It is typically performed in mild-to-moderate HR and is a relatively easy-to-perform technique. Patients frequently report satisfaction after surgery. However, the procedure may destabilize the MTP1 joint and could lead to weakness with toe-off, transfer metatarsalgia, and cock-up deformity of the big toe [7,11].

Arthrodesis, another joint-sacrificing technique, is currently considered the gold standard treatment for patients with end-stage OA (Grades 3 or 4) [11]. In arthrodesis, the MTP1 joint is sacrificed and is fused to the proximal phalanx (Figure 3G, 3H). This results in a stiff and motionless MTP1 joint. There are multiple techniques for arthrodesis to achieve fusion between the bones, including plates (Figure 3G), screws (Figure 3H), wires, and staples. After arthrodesis, a majority of patients report pain reduction and satisfaction with the procedure. However, disadvantages include loss of joint motion, nonunion, pain from implanted hardware, and metatarsalgia [20-22]. Loss of motion can especially be an issue for those who are young or have an active lifestyle, since limitations are reported in recreational activities, such as playing sports (e.g., running), wearing high-heeled shoes, and performing occupations that require, for instance, kneeling or squatting [20,23]. Therefore, interest remains in alternative treatment options.

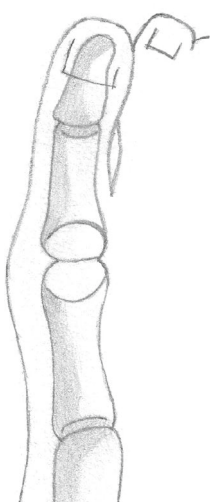
A more novel technique is implant arthroplasty, which is already often performed for hip and knee OA. For the MTP1 joint, several implants have been developed, including hemiarthroplasty and total joint arthroplasty (TJR), both of which have the primary advantage of restoring MTP1 joint motion [23]. In TJR, the metatarsal head and proximal phalanx are replaced by an implant (Figure 3D) [7,11,19]. In metallic hemiarthroplasty, only the metatarsal head or phalangeal head is resurfaced (instead of both sides of the joint, as occurs in TJR) (Figure 3E and 3F) [7,11,19]. These options demonstrate favorable results with high patient satisfaction and preserved range of motion; they could primarily be appropriate for patients with an active lifestyle where loss of motion of the MTP1 joint may not be acceptable. Despite the advantages, challenges remain, such as intervention-related complications and revisions, including postoperative infections, implant migration, metatarsalgia, and persistent pain [24].

As stated, several surgical interventions for HR exist [7,9,11,19]. Most results are based on short- to mid-term follow-up studies in which researchers performed clinical evaluations and reported patient satisfaction. However, long-term follow-up results, including the changed biomechanics in foot function during walking and running after surgery, are currently not clarified in clinical studies and need to be examined.

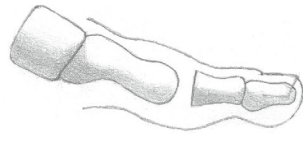
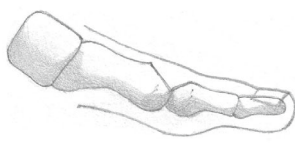
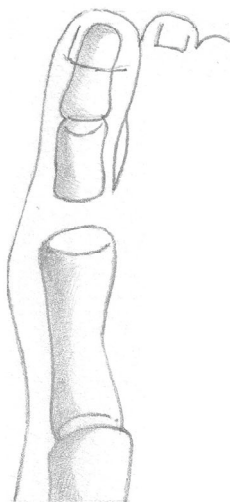
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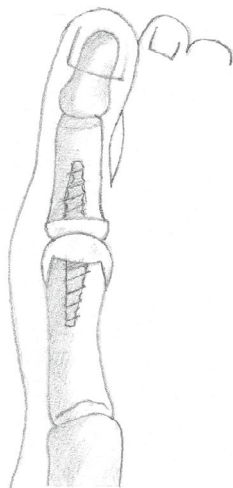
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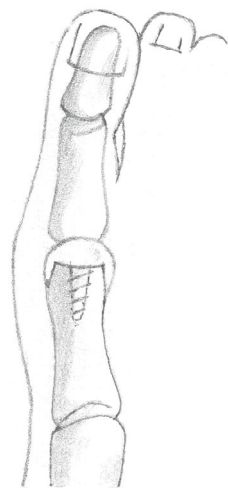
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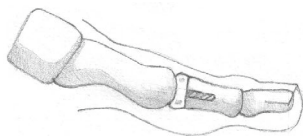
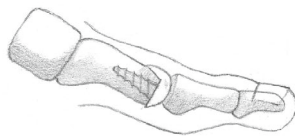
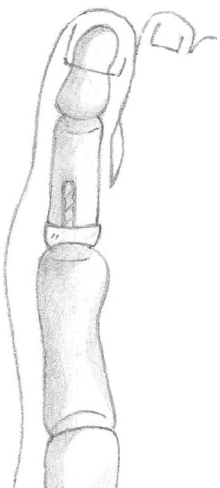
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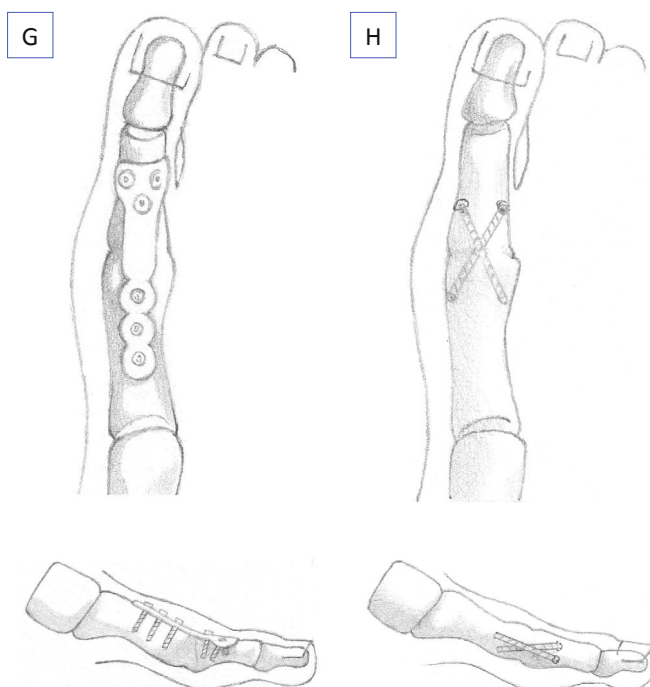


Figure 3: Surgical interventions for hallux rigidus. A: hallux Rigidus, B: cheilectomy, C: Keller's arthroplasty, D: total joint replacement, E: metallic hemiarthroplasty of the metatarsal component, F: metallic hemiarthroplasty of the phalanx component G: arthrodesis with a plate H: arthrodesis with screws.

Gait analysis

As mentioned, the MTP1 joint has an indispensable function during gait. OA and related HR surgeries influence joint and foot function, resulting in a different gait pattern during walking and running. To observe these effects, a gait analysis needs to be performed, which can assist in identifying specific gait deviations and compensatory strategies as well as the causes of abnormalities in diseases such as MTP1 OA [25]. In these analyses, gait is described based on the gait cycle, which refers to the sequence of movements involved in walking or running. It encompasses a series of events that occur from the moment one foot touches the ground to the moment that the same foot makes contact again. The gait cycle is typically divided into two phases: stance and swing. Both can be further subdivided in specific parts (Figure 4) [26].

Various techniques are used to study the gait cycle, such as instrumented treadmills and 3D motion capture systems [27,28]. Instrumented treadmills have embedded force-sensitive platforms that provide information about the timing, magnitude, and distribution of forces in the foot during each step [27]. A 3D motion capture system is a sophisticated and comprehensive system for gait analysis that uses reflective markers or inertial sensors placed on specific bony landmarks (Figure 5). Multiple cameras are used to track the markers' 3D movement. This method provides precise kinematic data that allows for detailed analysis of joint angles, segmental movements, and spatiotemporal parameters during gait in walking and running [28].

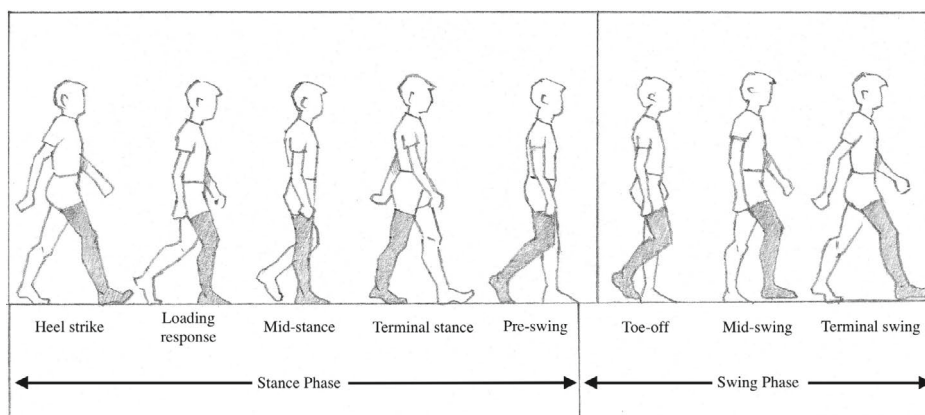


Figure 4: The gait cycle subdivided in the several phases during gait.

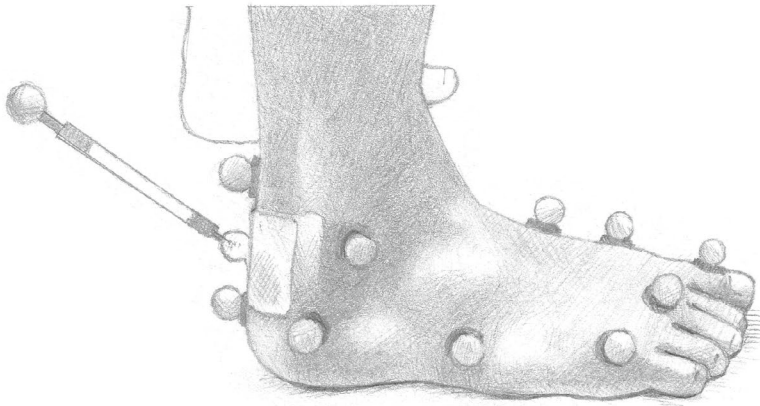


Figure 5: Reflective markers placed on specific bony landmarks of the foot according to the Oxford Foot Model, used to detect motion during gait analysis. Note that the Oxford Foot Model is partly illustrated.

Gait analysis in hallux rigidus and related interventions

As previously described, the big toe has an important function during walking and running. If the big toe is affected by OA, then this could lead to clinical symptoms as well as gait deviations and an antalgic gait pattern. Surgical interventions may also affect foot anatomy and could therefore change the kinematics of the lower extremity, resulting in a different gait pattern. Most studies of HR and related surgical interventions are focused on clinical outcomes and patient satisfaction, while fewer studies are focused on one of the most important functions performed with the foot: normal walking.

Patients suffering from HR tend to have a different foot loading pattern compared to healthy individuals since HR reduces motion in the hallux and the patient typically avoids loading on the hallux due to pain [29-33]. Previous pedobarographic studies have elucidated reduced loading of the MTP1 joint and increased loading of the lateral plantar foot zones and lesser metatarsal heads (i.e., fourth and fifth) in HR patients, who are also described as lateral loaders [31,34-36]. Increased loading of the lateral plantar zones in HR suggest a compensatory foot and ankle movement to facilitate motion while avoiding the painful and degenerative hallux. Two studies have used 3D motion capturing cameras and have observed diminished forefoot plantar flexion during pre-swing, while decreased ankle motion was observed during the whole gait cycle [37,38]. However, how the foot compensates for the loss of MTP1 motion and which foot segments are responsible for it remains unknown.

Furthermore, studies regarding the effects of HR surgical interventions on foot and ankle motion are limited. Findings from some studies that have a certain degree of heterogeneity have reported gait changes after MTP1 arthrodesis [29-32,39,40]. Some

studies have demonstrated altered spatiotemporal parameters, such as a decreased step length [30] and step width [29,31], while other studies have not been able to observe these effects [39,40]. No changes in hip, knee, and especially ankle kinematics have been observed after a MTP1 arthrodesis [29-32]. However, only two cross-sectional studies have analyzed foot and ankle kinematics after MTP1 arthrodesis using a multi-segment foot model (MFM) [31,40]. A decreased eversion of the hindfoot during midstance was seen, which was followed by increased supination of the forefoot during pre-swing [31]. Further studies are necessary to examine these effects and explore the existence of a compensation mechanism in the foot and ankle.

Selection of an appropriate multi-segment foot model

To study compensation mechanisms in HR patients' feet and the related surgery, a 3D motion capture system and an MFM are necessary to identify differences. In 3D gait analysis, reflective markers are placed on specific bony landmarks while motion is traced using cameras. Thereafter, joint motion can be explored using an MFM. Several different MFMs exist and vary in the number of foot segments, which represent foot bones and joints, to describe foot motion. One commonly used MFM to evaluate foot pathology in research and clinical settings is the Oxford Foot Model (OFM), a validated and repeatable MFM that allows scientists to describe and investigate foot biomechanics during gait [31,41-52]. This four-segment foot model divides the foot into tibial (tibia and fibula), hindfoot (calcaneus and talus), forefoot (five metatarsals), and hallux (hallux/proximal phalanx) and can be used to analyze motion between the segments during gait [41,53]. This foot model enables the study of motion patterns in foot and ankle joints, which is relevant for HR since it is supposed that the foot compensates for kinematic changes imposed by HR. Furthermore, the OFM is one of the few foot models that can trace hallux motion.

However, kinematic models (including OFM) that rely on skin-mounted markers to define and track segments are particularly sensitive to measurement variability, such as soft tissue artifacts and marker misplacement, which affects the segment coordinate systems and consequently the interpretation of kinematic data [54,55]. Therefore, repeatability studies are essential to acquire a thorough understanding of kinematic measurement errors to avoid over- and under-interpretation of clinical data. Although several studies have investigated the OFM's repeatability, a minority of these studies have evaluated the repeatability of the hallux-forefoot segment [56,57]. Insights regarding the repeatability of the hallux-forefoot segment are essential, since the OFM is frequently used for clinical evaluation in hallux pathologies [31,48,49,58-60].

Thesis objectives

Hallux rigidus is a disabling disease that leads to pain and walking difficulties, resulting in a reduction in activity, social participation, economic productivity, and quality of life. More knowledge is needed regarding outcomes after long-term follow-up and gait deviations after surgical interventions to ensure optimal interventions for each patient and to facilitate clinical decision-making. The following research questions are examined in the present thesis:

1. What are the effects of HR on gait, and what are the biomechanical consequences? Which joints compensate for the loss of MTP1 motion? **(Chapter 2)**
2. How does MTP1 arthrodesis as an HR treatment affect gait? Is gait restored to a pattern similar to healthy subjects? **(Chapter 3)**
3. What are the clinical and patient-reported outcomes as well as gait effects of a surgical intervention for HR at long-term follow-up? Which intervention yields the best outcomes at long-term follow-up? **(Chapters 4, 5)**
4. Are metallic implant interventions challenging regarding clinical outcome, pain, and the number of complications and revisions compared to the widely used MTP1 arthrodesis for patients suffering from HR? Which could be the new preferred surgical intervention for HR? **(Chapter 6)**
5. What is the repeatability of the OFM, which is one of the most used MFMs for HR gait evaluation and related surgical treatments? **(Chapter 7)**

Thesis outline

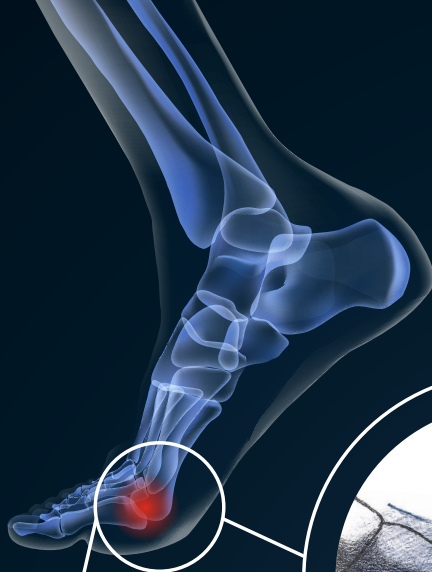
The present thesis aims to acquire further insights on the impact of HR and accompanying surgical interventions on gait and patient-reported outcomes. **Chapter 2** presents a characterization of foot and ankle kinematics in patients suffering from HR using a case-control design. The OFM is used to identify the biomechanics and clarify which foot joints are responsible for compensating for the loss of the MTP1 joint. **Chapter 3** offers an exploration of the effects of MTP1 arthrodesis on foot and ankle kinematics and patient-reported outcomes compared to their preoperative state (as described in Chapter 2) and healthy individuals. **Chapter 4** details a comparative study after long-term follow-up to assess the clinical and radiographic outcomes after cheilectomy, Keller's arthroplasty, and arthrodesis of the MTP1 joint, which are frequently performed interventions in patients treated for HR. **Chapter 5** presents an evaluation of the results and impact on gait and plantar pressure distribution among these patient groups. **Chapter 6** offers a systematic review and meta-analysis to compare MTP1 metallic hemiarthroplasty to MTP1 arthrodesis regarding clinical outcomes, pain reduction, and the number of complications and revisions in the treatment of patients with HR. **Chapter 7** details the repeatability of the OFM as an often-used MFM. The hallux and forefoot are critically assessed regarding repeatability for analyzing foot pathologies. **Chapter 8** of this thesis provides a general discussion of the study results as well as the impact and summary of this thesis.

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CHAPTER 2

Gait analysis of foot compensation in symptomatic hallux rigidus patients

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Abstract

Background

Compensatory motion of foot joints in hallux rigidus (HR) are not fully known. This study aimed to clarify the kinematic compensation within the foot and to detect whether this affects plantar pressure distribution.

Methods

Gait characteristics were assessed in 16 patients (16 feet) with HR and compared with 15 healthy controls (30 feet) with three-dimensional gait analysis by using the multi-segment Oxford Foot Model, measuring spatio-temporal parameters, joint kinematics and plantar pressure.

Results

HR subjects showed less hallux plantar flexion during midstance and less hallux dorsiflexion during push-off, while increased forefoot supination was detected during push-off. No significant differences in plantar pressure were detected. Step length was significantly smaller in HR subjects, while gait velocity was comparable between groups.

Conclusion

HR significantly affects sagittal hallux motion, and the forefoot compensates by an increased supination during push-off. Despite this kinematic compensatory mechanism, no significant differences in plantar loading were detected.

Introduction

Hallux Rigidus (HR) is a degenerative condition of the first metatarsophalangeal (MTP1) joint and characterized by pain while walking, joint swelling and difficulties in wearing shoes. Restricted joint motion and gait alterations were observed during physical examination [1]. The etiology seems to be multifactorial, with female gender, aging, interphalangeal hallux valgus, trauma history and a positive family history being predisposing factors [1,2]. HR negatively affects quality of life, since patients experience more difficulties with performing daily tasks and recreational activities [3,4].

When conservative treatment failed, surgical treatment is often necessary. MTP1 joint arthrodesis, hemiarthroplasty, resection arthroplasty and total joint arthroplasty have been utilized for HR. Arthrodesis seems to be superior in terms of patient reported outcome and treatment longevity of these options [5-7]. However hallux motion is eliminated after an arthrodesis, which subsequently affects spatiotemporal gait parameters [8,9] and causes aberrations in foot and ankle kinematics [10]. It is not fully known which joints compensate for the altered MTP1 motion after these interventions, which seems to be important in preoperative planning. It is likely that surgery, after which motion of these joints is necessary, results in poorer postoperative outcomes when these joints are osteoarthritic as well. Therefore, it is essential to know how HR affects foot kinematics before investigating this hypothesis, since it is reasonable to assume that most compensatory motion will take place in the foot.

Previous pedobarographic studies showed an increased loading of the lateral plantar zones and the lesser metatarsal heads in patients with HR (i.e., “lateral loaders”), most likely to avoid the painful hallux [11-13]. Although a decrease in lateral loading was expected after surgery, this effect was not observed after cheilectomy [14], and MTP1 arthrodesis [8,15]. In contrast, even increased loading of the lateral metatarsal heads was observed after MTP1 total joint arthroplasty in some [15,16], but not all studies [17,18]. Increased loading of the lateral plantar zones in HR suggests a compensatory motion in the foot and ankle in order to facilitate motion while avoiding the painful and degenerative hallux during push-off. Three-dimensional motion capturing provides a possibility to elucidate which joints facilitate this compensatory mechanism. A decreased sagittal hallux ROM was observed in two kinematic studies comparing HR patients with healthy controls [19,20]. In addition, diminished forefoot plantar flexion was detected in pre-swing, while decreased ankle motion during the whole gait cycle was observed [19,20]. Although two studies addressed multi-segment foot motion in HR subjects [19,20], no former study evaluated segmental foot and ankle kinematics together with plantar pressures.

It is assumed that surgeons may benefit from further knowledge which joints compensate for the loss of hallux motion in HR subjects. Joint preserving or replacing

surgery should be advised to a subject with a less functioning compensatory mechanism, while an arthrodesis can be advised in subjects with a proper functioning compensatory mechanism. To investigate whether this is true, the compensatory mechanism should be elucidated first. Therefore, the aim of this study was to characterize multi-segmental foot and ankle kinematics in HR subjects by using the 4-segment Oxford Foot Model (OFM), and combine segmental kinematics with plantar pressure distributions in order to identify which foot joints are responsible to compensate for the loss of motion of the MTP1 joint in HR.

It was hypothesized that patients with HR have an increased forefoot supination or hindfoot inversion resulting in increased plantar pressures beneath the lesser metatarsals, due to the decreased motion in the MTP1 joint.

Methods

Study population

Patient files of the Departments of Orthopedic surgery were screened for eligible patients. Inclusion criteria were a symptomatic, radiologically confirmed HR, in which conservative therapy failed and surgery was planned. Patients with medical conditions affecting foot and ankle kinematics (e.g., inflammatory joint diseases or arthrodesis of foot joints) were not eligible for inclusion. Additional exclusion criteria were the inability to walk more than 100m barefoot without assistance. Patients were compared to healthy controls without a medical history of foot complaints or resulting in an abnormal gait pattern. Sixteen HR subjects (16 feet) were included and compared to 15 healthy controls (30 feet). This study was approved by the local ethics committee and patients provided their written informed consent.

Motion analysis

Motion capture was conducted using a Vicon system (Vicon Motion Systems, Oxford, UK), consisting of 8 infrared cameras (six MX3 and two T20 running at 200Hz). Subjects were asked to walk on a ten-meter platform equipped with a forceplate (AMTI OR6 Series, Advanced Mechanical Technology Inc., Watertown, NY, USA). Dynamic plantar pressures were measured using a pressure plate (High Speed Advanced Footscan® System, RSscan International, Paal, Belgium), which was mounted on top of the forceplate.

Subject height, weight, knee and ankle width and leg length were measured and markers were placed by two trained researchers at specific bony landmarks according to the OFM guidelines [21-23]. One static trial was performed in which the markers were calibrated and subject-specific axes were calculated. Next, subjects were asked to walk at a comfortable speed and 15 recordings with the subject cleanly striking the pressure plate were obtained.

Data processing

Marker tracking and labelling were performed by using Vicon Nexus 1.8.5 and further processed with MATLAB (version R2012A, The MathWorks Inc, Natick, MA, USA). Gait velocity, stance time, step length and step width were calculated as previously reported [10]. Kinematic waveforms and ROM in push-off were gained for the hallux-forefoot, forefoot-hindfoot and hindfoot-tibia segment in the sagittal plane and for the forefoot-hindfoot and hindfoot-tibia segment in the frontal plane after time normalisation of a stride (i.e., 0-100%). Gait cycle was divided in stance (i.e., 0-62% of the gait cycle), consisting of loading response (0-12%), midstance (13-31%), terminal stance (32-50%) and pre-swing (51-62%) and swing phase (i.e., 63-100% of the gait cycle) consisted of initial swing (63-75%), midswing (76-87%) and terminal swing (88-100%) [24]. ROM in push-off was identified as the difference between maximal and minimal intersegmental angle in time interval 45-75% of the gait cycle. Intersegmental ROM was averaged for at least 6 trials per subject, which has proven to be a sufficient number of trials to achieve high intraclass correlation coefficients for the OFM [25].

The force plate was used to identify initial contact and toe-off (i.e., onset of a vertical ground reaction force exceeding and below 20 Newton respectively). Off-set correction was performed for the intersegmental kinematic waveforms, by summing the intersegmental angles at timepoint 0-100 and subsequently divided by 100 to gain the value of off-set correction.

The foot was automatically divided in 10 anatomical zones by Footscan® 7.0 Gait 2nd generation software to investigate plantar pressure. Inconsistencies in the automatic masking procedure were manually adjusted. The pressure-time integral (PTI) was calculated as previously described [26], by using the obtained force-time integrals and contacts areas. The PTI is the cumulative effect of pressure on a plantar area over time (i.e., area under the peak pressure-time curve) instead of summing the peak pressure per timeframe for an entire trial, and provides a representative value of the total load exposure of a plantar area during stance.

Statistical analysis

Graphpad Prism 8.3 (Graphpad Software Inc., San Diego, USA) was used for statistical analysis. Differences in patients demographics, temporal-spatial parameters, intersegmental ROM and PTI between groups were compared by using the non-parametric Mann-Whitney U test. Statistical Parametric Mapping (SPM; version M.0.4.5), a statistical approach which allows hypothesis testing on kinematic waveforms without the need of a priori data reduction, was performed to test for differences in intersegmental motion between groups. A SPM unpaired t-test was used. A *p*-value of less than 0.05 was considered as statistically significant.

Results

Subject characteristics

Baseline subject characteristics showed that the HR group had a significant lower height ($P=0.015$) and contained more female patients, as compared to healthy controls (Table 1). No significant differences in age, weight, foot side analyzed and body mass index were detected between groups.

Temporal-spatial parameters

No significant differences in gait velocity, stance time and step width were detected between HR subjects and healthy controls (Table 2). Step length ($P=0.002$) was significant shorter in HR subjects.

Table 1: Subject characteristics.^a

	Hallux Rigidus	Healthy Controls	P-value
No. of subjects (no. of feet)	16 (16)	15 (30)	-
Age (years)	63.7 ± 10.5 (40-79)	59.1 ± 5.0 (53-70)	0.137
No. (% of subjects) male	5 (31.3)	9 (60)	-
No. (% of feet) right side	8 (50)	15 (50)	-
Height (m)	1.68 ± 0.09 (1.55-1.85)	1.74 ± 0.09 (1.62-1.88)	0.015 ^b
Weight (kg)	75.5 ± 18.5 (50.5-122.0)	83.0 ± 11.9 (56.5-98.2)	0.187
Body Mass Index (kg/m ²)	26.7 ± 5.9 (20.4-43.2)	27.4 ± 3.9 (20.2-33.3)	0.811

^a Mean values and standard deviations with range in parentheses are presented.

^b Significant difference between hallux rigidus and healthy controls $P<0.05$.

Table 2: Temporal-spatial parameters of gait for the hallux rigidus group and healthy controls.^a

	Hallux Rigidus	Healthy Controls	P-value
Gait velocity (m/s)	1.05 ± 0.20 (0.64-1.44)	1.14 ± 0.19 (0.73-1.46)	0.160
Stance time (s)	0.71 ± 0.09 (0.59-0.91)	0.71 ± 0.11 (0.52-0.96)	0.980
Step length (m)	0.57 ± 0.06 (0.48-0.78)	0.64 ± 0.07 (0.49-0.76)	0.002 ^b
Step width (m)	0.12 ± 0.05 (0.05-0.20)	0.13 ± 0.04 (0.07-0.20)	0.750

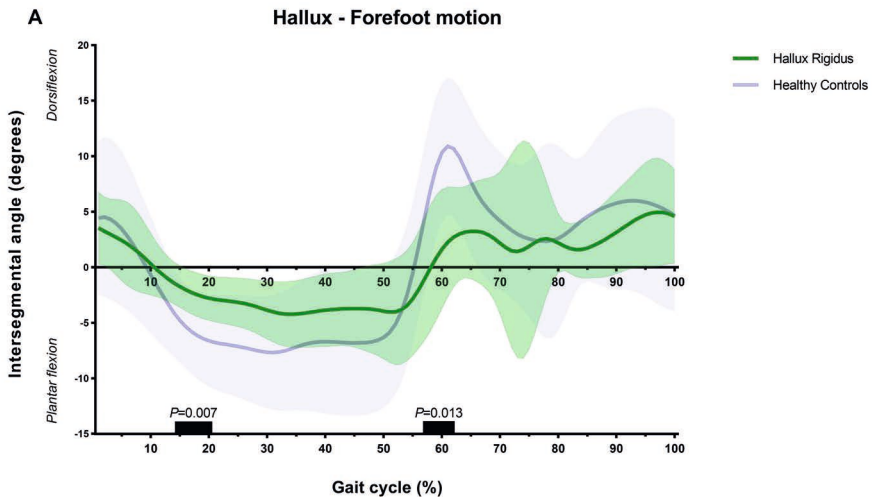
^a Mean values and standard deviations with range in parentheses are presented.

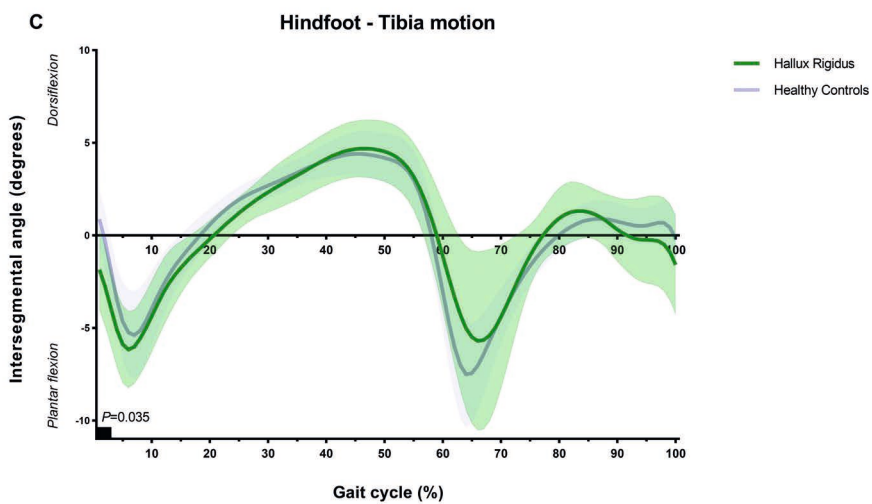
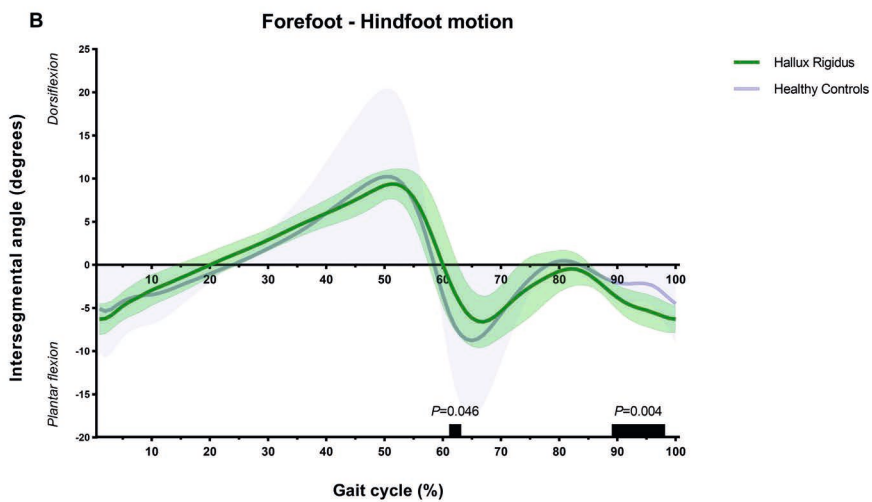
^b Significant difference between hallux rigidus and healthy control $P<0.05$.

Foot and ankle kinematics

Significant less hallux plantarflexion in midstance ($P=0.007$) and dorsiflexion in pre-swing ($P=0.013$) was observed in HR subjects (Figure 1A). Less forefoot plantarflexion in initial swing ($P=0.046$) and increased plantarflexion ($P=0.004$) in terminal swing (Figure 1B), and significant less hindfoot plantarflexion ($P=0.035$) in loading response were observed in HR subjects (Figure 1C).

Increased forefoot pronation during midstance ($P=0.012$) and increased forefoot supination during pre-swing ($P=0.012$) were detected in HR subjects (Figure 1D). No statistically significant differences in frontal plane motion were observed between groups in the hindfoot-tibia segment (Figure 1E).





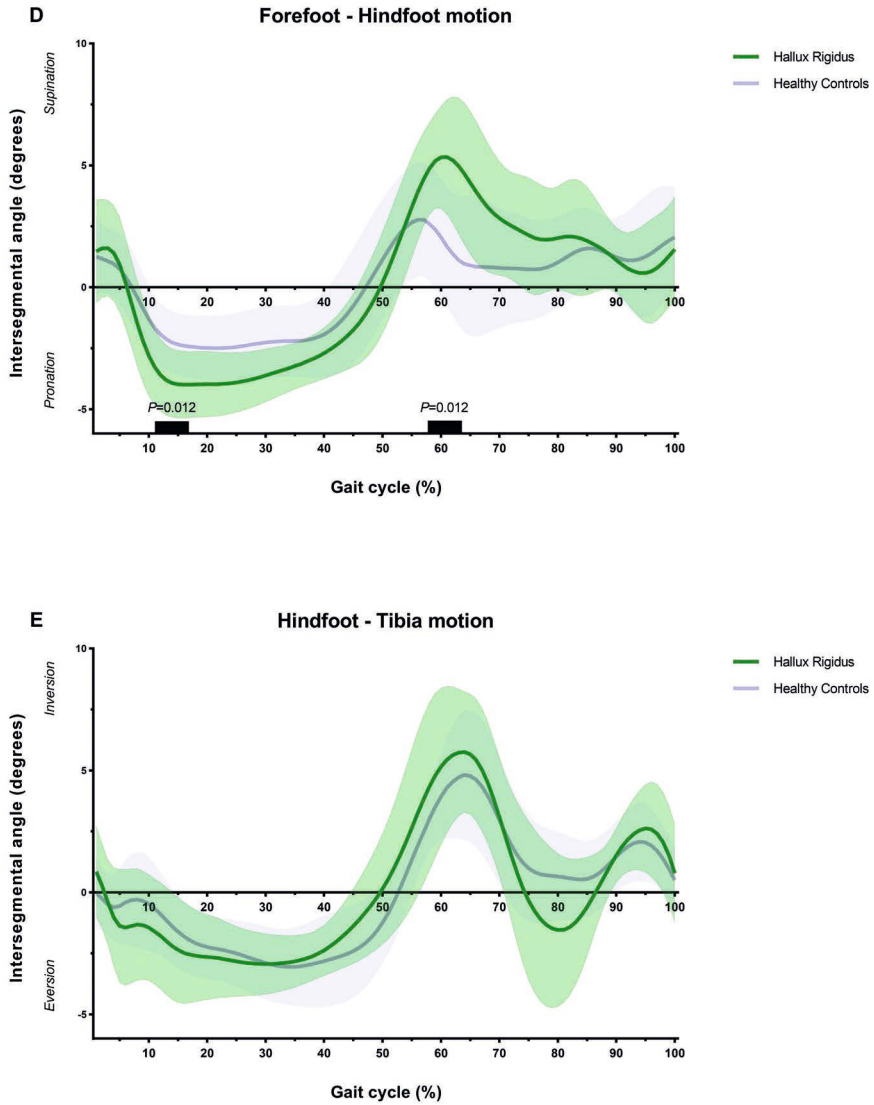


Figure 1: Averaged absolute joint angles in sagittal plane after off-set correction in the hallux-forefoot, forefoot-hindfoot and hindfoot-tibia segment (1A, 1B and 1C respectively) and in the frontal plane for the forefoot-hindfoot and hindfoot-tibia segment (1D and 1E respectively) during gait for the hallux rigidus group and healthy controls.

Intersegmental ROM during push-off

Hallux ROM (i.e., plantar/dorsiflexion) was significantly lower in HR subjects during push-off ($P=.003$, Figure 2A). No significant differences in sagittal ROM were detected in the forefoot-hindfoot and hindfoot-tibia segment (Figure 2B and 2C respectively). An increased ROM (i.e., supination/pronation) was present in the forefoot-hindfoot segment in HR subjects ($P=.006$, Figure 2D), while no difference in frontal plane hindfoot-tibia intersegmental ROM (i.e., inversion/eversion) was detected between groups (Figure 2E).

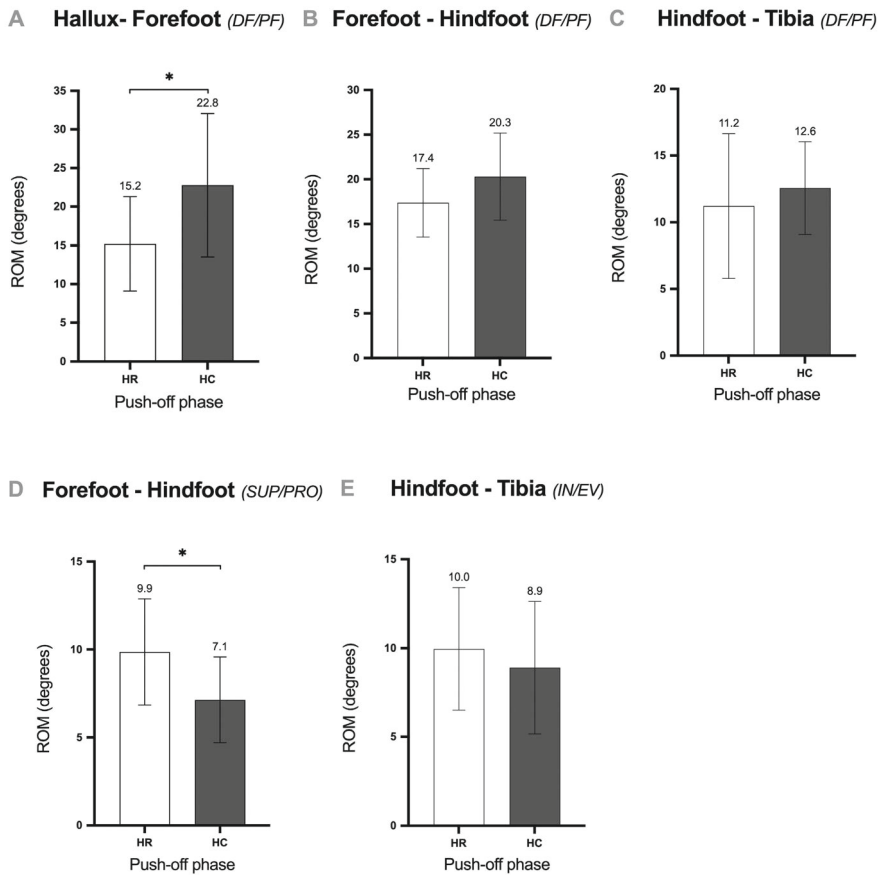


Figure 2: Intersegmental range of motion in the sagittal plane (A-C) and frontal plane (D-E) during gait for the hallux rigidus group and healthy controls.

*Indicates a significant difference in range of motion ($P<0.05$).

Abbreviations: ROM, range of motion; DF, dorsiflexion; PF, plantar flexion; SUP, supination; PRO, pronation; IN, inversion; EV, eversion; HR, hallux rigidus; HC, healthy controls.

Plantar pressure

No significant differences in PTI were detected between HR subject and healthy controls in the 10 plantar zones of interest (Figure 3).

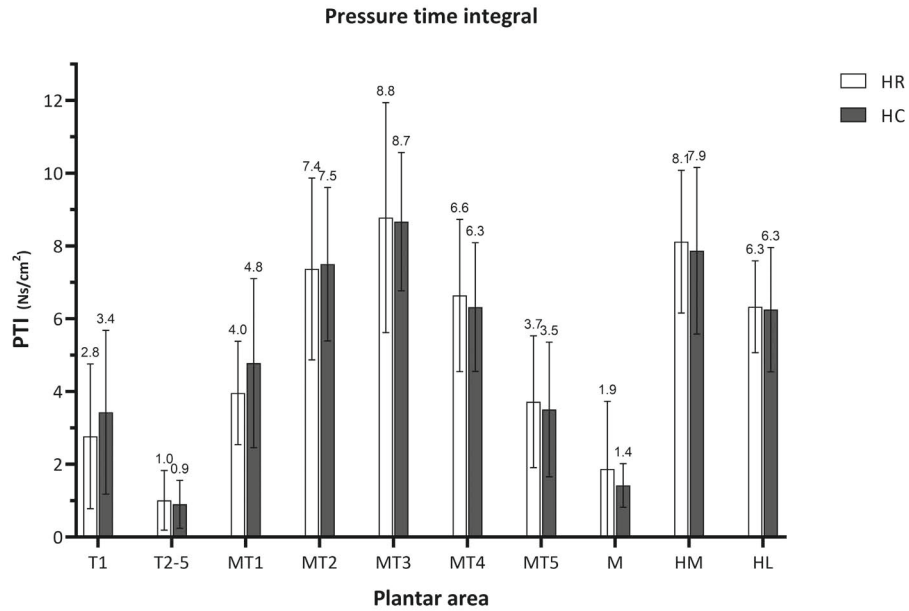


Figure 3: Pressure time integrals for the 10 anatomical areas of the foot for the first metatarsophalangeal joint arthrodesis group and healthy controls.

Abbreviations: *PTI*, pressure time integral; *T1*, hallux; *T2–5*, lesser toes; *MT1–5*, metatarsal heads 1–5; *M*, midfoot; *HM*, medial heel; *HL*, lateral heel; *HR*, hallux rigidus; *HC*, healthy controls.

Discussion

This study aimed to determine how the foot compensates for the loss of sagittal hallux motion in HR and how this subsequently affects plantar pressure. It was hypothesized that an increased forefoot supination or hindfoot inversion will compensate for the limited MTP1 motion in HR. As a consequence, increased plantar loading of the lesser metatarsals was expected.

As expected, HR significantly affects hallux sagittal plane motion. Less plantar flexion of the hallux in midstance and less hallux dorsiflexion in pre-swing were detected, where intersegmental ROM analysis confirmed this decreased hallux ROM during push-off. Additionally, the expected compensatory motion was found in the forefoot-hindfoot segment, where an increased forefoot supination was seen in HR during pre-swing. This result was confirmed with the intersegmental ROM analysis where a greater frontal ROM (i.e., increased supination/pronation) in the forefoot-hindfoot segment was present in the HR group. Additionally, some significant differences in sagittal motion in the forefoot-hindfoot in swing and hindfoot-tibia segment during stance were detected. However, since these differences were small, it was concluded that these differences were not clinically relevant.

These results confirmed the hypothesis that the forefoot compensates for the loss of motion in MTP1 joint motion in HR. Canseco et al. also showed a significantly reduced hallux motion in HR subjects from pre-swing till midswing by using the 4-segment Milwaukee Foot Model. However, an increased forefoot supination during push-off was not seen in this study [20]. Kuni et al. also showed a significantly lower hallux ROM in HR subjects with the Heidelberg foot measurement measure when analyzing a whole stride [19]. Contrary to our results, HR subjects showed less forefoot frontal motion (i.e., supination/pronation) as compared to healthy controls in this study. Nawoczinski et al. showed a significant increase in dynamic MTP1 joint motion in HR subjects which underwent cheilectomy, but no healthy control group was reported in these studies [14]. A study in which arthrodesis was performed for HR showed that both the forefoot and hindfoot were responsible to compensate for the loss of MTP1 joint motion, due to a decreased hindfoot eversion during midstance followed by an increased forefoot supination during pre-swing [10]. Based on presented results and previous studies, it can be concluded that the forefoot is particularly important to compensate for a loss of motion in the MTP1 joint.

Based on the reduced hallux dorsiflexion and increased forefoot supination during stance an increased loading of the lateral plantar zones of the foot was expected. This hypothesis was based on previously reported studies where reduced MTP1 joint motion due to fusion resulted in unloading of the hallux and an increased lateral loading of the foot [10]. However, PTI values in this study showed no differences in plantar

loading between HR subjects and controls and thereby did not support the stated hypothesis. Nawoczenski et al. evenly presented no significant differences in plantar loading between HR subjects and controls, although a (non-significant) decreased loading of the medial metatarsal heads was detected in symptomatic feet as compared to asymptomatic feet [14]. Zammit et al. reported increased peak pressures beneath the hallux and lesser toes in HR subjects, while no differences beneath the metatarsals. Peak pressures were in our opinion less informative as compared to PTI values, since peak pressures represents the maximal load in an area under the foot during one step while PTI describes the cumulative effect of pressure over time in a certain area of the foot, and thus provides a value for the total load exposure of a foot sole area during one step [27].

A possible explanation for the absence of differences in plantar pressure distribution is that there is, although limited and painful, still enough motion in the MTP1 joint left and therefore plantar loading is not affected.

Regarding temporal-spatial parameters, a significant shorter step length in HR subjects was detected, while no significant differences in stance time and gait velocity were detected between groups. Canseco et al. evaluated stride length and reported a non-statistically significant but potentially clinically relevant difference in stride length between groups (i.e., HR 1.20 ± 0.19 vs. healthy control 1.29 ± 0.10 ; $P=0.053$). The significant lower height of HR subjects in this study, and consequent shorter leg length, is the most plausible explanation for this difference in step length, although pain while walking might also result in a shorter step length. Gait velocities between subjects and controls were comparable with values reported by Canseco et al. [28].

We acknowledge that this study had some limitations. Selection of an age- and gender-matched control group would have been more appropriate, since the healthy control group contained significantly more male subjects, and there was a non-significant mean difference in age of 4.6 years. As a result, the healthy control group had a significantly greater height, and it is known that age and height affect gait velocity, which subsequently strongly influences gait kinematics [29,30]. Since no statistically difference in gait velocity was detected, it was though that the difference in height did not significantly influence our results. However, although not statistically significant, it cannot be ruled out whether a difference in gait velocity of 0.09 m/s between groups was clinically relevant. In addition, some studies show a true age effect [31,32] and gender-specific differences [30,33] independent of gait velocity, so the non-significant difference in age and significant differences in sex distribution between groups might have influenced the presented results, although this true age-effect was not seen in other studies [34]. The relative small sample size might be a potential weakness of this study since no sample size was calculated before the start of the study, although

these group sizes are common in this research area due to the relative extensiveness of measurements.

Despite these limitations, this study revealed important information regarding the compensatory mechanism of the foot for the loss of MTP1 motion in HR subject. Knowledge of this compensatory mechanism seems to be highly relevant for planning of surgical intervention. For example, it is reasonable to assume that an arthrodesis is a less suitable option for a subject with less frontal forefoot motion (i.e., less compensatory reserve), since a well-functioning compensatory mechanism is mandatory to restore gait for the complete loss of MTP1 joint motion in this intervention. In this situation, a MTP1 joint preserving (cheilectomy) or replacing method (prosthesis or hemiprosthesis), in which less compensatory motion is required, might be more suitable.

Conclusion

The forefoot compensates for the loss of motion MTP1 joint motion by an increase in supination. Although forefoot kinematics changed, no significant differences in plantar loading were detected. These results proved that the foot has the intrinsic capacity to compensate for the loss of MTP1 joint motion in HR and knowledge of this compensatory mechanism should be used in further research. These studies should focus on the hypothesis if patients with less compensatory capacity would benefit more from joint replacing interventions (i.e., in which it is thought that less compensatory motion is necessary), than from an arthrodesis (i.e., more compensatory motion is expected to be mandatory). Subsequently it would be interesting to investigate whether this 'foot-specific treatment' will improve patient satisfaction.

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CHAPTER 3

A prospective study evaluating gait and clinical outcome following first metatarsophalangeal arthrodesis for hallux rigidus

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Abstract

Background

Arthrodesis of the first metatarsophalangeal joint (MTP1) is a common intervention for hallux rigidus (HR). The procedure eliminates MTP1 motion but results in significant pain relief and high satisfaction rates, although MTP1 is eliminated. Less evidence is available regarding the effects on gait and the presence of compensatory mechanisms. The aim of this study is to investigate the effects of MTP1 arthrodesis on gait and patient-reported outcome measures (PROMs) compared with preoperative functioning and healthy individuals.

Methods

In this prospective study, 10 patients (10 feet) with HR who underwent MTP1 arthrodesis were evaluated before and after surgery and compared with 15 healthy controls (30 feet). Gait analysis was performed with a motion capturing system using the multi-segment Oxford Foot Model. Spatiotemporal parameters and kinematics were quantitatively analyzed. PROMs were evaluated using validated questionnaires including the American Orthopedic Foot and Ankle Society Hallux Metatarsophalangeal-Interphalangeal (AOFAS-HMI) scale, the Numeric Pain Rating Scale (NPRS), and the Manchester–Oxford Foot Questionnaire (MOXFQ).

Results

MTP1 joint motion was reduced in HR and further reduced after MTP1 arthrodesis compared with healthy controls. Furthermore, intersegmental ROM analysis revealed increased forefoot frontal plane motion (pronation and supination) in HR compared with healthy controls. This was also observed after MTP1 arthrodesis, while additionally increased frontal plane motion in the hindfoot (inversion and eversion) was observed compared with HR and healthy controls. PROM evaluation revealed improved AOFAS-HMI (from 55.7 to 79.1 points, $P=0.002$) and NPRS (from 5.7 to 1.5 points, $P=0.004$) scores after surgery. Additionally, improvements in the MOXFQ score (from 51.0 to 20.0 points, $P=0.002$) were observed.

Conclusion

Due to the loss of sagittal hallux motion, foot and ankle kinematics are changed in HR patients and after MTP1 arthrodesis compared with healthy controls. Loss of MTP1 motion results in increased frontal plane motion of the forefoot in HR, and increased frontal plane motion of the fore- and hindfoot after MTP1 arthrodesis. Additionally, substantial improvements in PROMs were recorded after surgery.

Introduction

Hallux rigidus (HR) is a degenerative condition of the first metatarsophalangeal joint (MTP1). It is the most common foot joint to be affected by osteoarthritis (OA), which progresses during aging [1,2]. Surgical interventions are indicated when conservative treatments fail [2,3]. Arthrodesis is currently the gold standard treatment for moderate to severe HR [1,3-5]. It sacrifices motion but results in significant pain relief and high satisfaction rates at short-, mid-, and long-term follow-up [1,3,6,7]. Due to rigid fixation of MTP1, hallux motion is absent, leading to gait alterations and a different pattern of foot loading [3,8-11].

Pedobarographic studies on subjects with HR have elucidated reduced loading of the hallux and increased loading of the lateral plantar foot zones and lesser metatarsal heads (i.e., fourth and fifth) in patients with HR, who are also described as 'lateral loaders' [10,12-14]. Evaluation of foot and ankle kinematics exposed reduced dorsiflexion and plantar flexion in the hallux range of motion (ROM), which is compensated via frontal plane motion through increased forefoot pronation and supination [15,16]. This altered gait pattern and weight shift to the lateral side of the foot is considered a compensatory mechanism for the limited ROM and avoidance of engaging the painful MTP1 during gait.

Limited knowledge exists regarding foot compensation after surgical interventions for HR. Some studies, with a certain degree of heterogeneity, have addressed gait changes after MTP1 arthrodesis [3,8-10,17]. These studies have reported altered spatiotemporal parameters, such as a decreased step length [9] and step width [8,10], while others have been unable to observe these effects [17,18]. No changes in hip, knee, and especially ankle kinematics have been observed after MTP1 arthrodesis [3,8-10]. However, only two cross-sectional studies have analyzed foot and ankle kinematics after MTP1 arthrodesis by using a multi-segment foot model [10,18]; they reported a decreased hindfoot eversion during midstance followed by increased forefoot supination during pre-swing [10,18]. The use of multi-segment foot models is encouraged due to the potential to study motion patterns in multiple foot and ankle joints, which is especially relevant for HR, since it is supposed that kinematic changes imposed by HR are compensated in the foot. A better insight into this compensatory mechanism is relevant in preoperative planning and selecting the optimal intervention for a patient.

The aim of this study is to explore the effects of HR and subsequent treatment with MTP1 arthrodesis on foot and ankle kinematics. Pre- and postoperative kinematics are compared with healthy individuals. It is hypothesized that the forefoot compensates (more pronation and supination) for the loss of hallux motion in subjects with HR and after MTP1 arthrodesis. Additionally, it is expected that patient satisfaction will increase after MTP1 arthrodesis, as well as pain and daily activity limitations declining,

compared with the preoperative state, which is studied by using patient-reported outcome measures (PROMs).

Methods

Study population

This prospective longitudinal study was conducted at the human movement sciences laboratory of our institution. Eligible patients were diagnosed with unilateral symptomatic and radiologically confirmed MTP1 OA, who did not respond to conservative interventions and were willing to undergo MTP1 arthrodesis. Patients with inflammatory joint diseases, bilateral HR, neurological disorders that influence gait, or previously performed surgical interventions to the lower extremities (e.g., hip, knee, or foot) were excluded. Exclusion criteria were identical for healthy controls, although this group was free of lower extremity pathologies. Patients were invited to our laboratory before surgery and at least 9 months after surgery. This study was performed according to the Declaration of Helsinki (2013), and the local medical ethical committee approved this study. All study subjects provided their written informed consent.

Operative technique

All surgical procedures were performed by two experienced surgeons. A Hallu-FIX Integra plate (Integra Life Sciences, Plainsboro, NJ, USA) was used to achieve fixation between the first metatarsal and the proximal phalanx. Patients were restricted from weight-bearing activities on the affected foot for the first month after surgery and wore a stiff-soled shoe postoperatively for two months. One patient underwent revision surgery due to nonunion.

Motion analysis

A VICON motion capture setup (Vicon Motion Systems, Oxford, England, UK) consisting of 12 infrared cameras (eight MX3 and four T20 cameras with sampling at 200 Hz) were placed beside a 10 m runway equipped with a force plate (AMTI OR6 Series, Advanced Mechanical Technology Inc., Watertown, NY, USA). According to the Oxford Foot Model (OFM) guidelines, markers were placed on bony landmarks on both lower extremities [19,20]. Before gait analysis, height, weight, leg length (distance between the anterior iliac spine and medial malleolus), and knee and ankle width (distance between lateral and medial condyles of the knee, and distance between lateral and medial malleoli of the ankle) were measured and used for running the OFM. Thereafter, a static trial in a standing neutral anatomical position was performed. Markers were calibrated and subject-specific joint axes were calculated with this static trial. Subsequently, six markers were removed and dynamic measurements were gained. Subjects were asked to walk barefoot at a self-selected speed. After some practice trials, subjects were asked to walk until at least 15 proper recordings were obtained.

Data analysis

VICON Nexus 2.8.1 software was used to trace and label the markers. Subsequently, kinematic data was processed with MATLAB version R2012A (The Mathworks Inc., Natick, MA, USA). Spatiotemporal parameters including gait speed, step width, step length, and stance time were determined. Kinematic waveforms were produced from sagittal plane motions (flexion and extension) of the hallux/forefoot, forefoot/hindfoot, and hindfoot/tibia, as well as frontal plane motions of the forefoot/hindfoot (pronation and supination) and hindfoot/tibia (inversion and eversion). Data was analyzed as one stride (i.e., heel strike to heel strike of the same foot, traced using the force plate forces). For description in this paper of events occurring during the gait cycle, the gait cycle was divided into stance (0–62%) and swing phases (63–100%). Stance was divided into the following phases: loading response (0–12%), midstance (13–31%), terminal stance (32–50%), and pre-swing (51–62%). Swing was divided into initial swing (63–75%), mid-swing (76–87%), and terminal swing (88–100%) [21]. Offset correction was performed for the intersegmental kinematic waveforms by summing the intersegmental angles at each time point (0–100%) and subsequently dividing the sum by 100. ROM during the push-off phase was calculated in each of the planes and was defined as the difference between maximal and minimal intersegmental angles in the 45–65% time interval of the gait cycle.

Clinical assessment

PROMs were recorded before and after surgery by using the American Orthopedic Foot and Ankle Society Hallux Metatarsophalangeal-Interphalangeal (AOFAS-HMI) scale, the Manchester–Oxford Foot Questionnaire (MOXFQ) score, and the Numeric Pain Rating Scale (NPRS). The AOFAS-HMI offers scores for pain, function, and alignment. Scores range between 0 and 100 points, with higher scores indicating better outcomes [22]. After arthrodesis, the maximum achievable score is 90, since 10 points are awarded to MTP1 motion, which is eliminated during surgery [23]. The MOXFQ is divided into three subscales: walking and standing problems, foot pain, and issues related to social interactions. Scores range from 0 to 100, where 100 represents the poorest outcome [24–26]. The pain experience was assessed with the NPRS, which ranges from 0 to 10, where 10 reflects severest pain [27].

Radiographic evaluation

Radiological assessments were performed, and Regnault's radiographic classification was used to grade degenerative MTP1 changes preoperatively [28]. The dorsiflexion fusion angle (DFA) was measured with the postoperative radiographs [29].

Statistical analysis

Statistical analyses were conducted in GraphPad Prism 8.3 (GraphPad Software, Inc., San Diego, CA, USA). Patient characteristics were compared by using the Mann–Whitney U test. Spatiotemporal parameters and intersegmental ROM in the push-off phase

were statistically tested with the Wilcoxon signed rank test (pre- vs. postoperative) and Mann–Whitney U test (HR vs. healthy controls). Pre- and postoperative PROMs were compared with the Wilcoxon signed rank test. Kinematic data was tested using statistical parametric mapping (SPM; version M.0.4.5), which can detect differences at any time point of the gait cycle (0–100%) [30]. An SPM paired *t*-test was used to compare pre- and postoperative measurements in HR subjects, and an SPM unpaired *t*-test was used to compare subjects with HR and healthy controls and to compare subjects treated with MTP1 arthrodesis to healthy controls. A *p*-value ≤ 0.05 was considered statistically significant.

Results

Patient demographics

In total, 10 patients with HR (10 feet) and 15 healthy controls (30 feet) were available for evaluation. Patients with HR were evaluated prior to surgery and after a mean follow-up duration of 20 months post-MTP1 arthrodesis (range: 10–29 months). Baseline patient demographics demonstrated a significant lower height ($P=0.04$) and a higher number of females in the HR group (Table 1). Before surgery, seven patients suffered from HR Grade II and three patients from HR Grade III according to the Regnauld grading system (Table 2). MTP1 arthrodesis resulted in a mean DFA of 25.0°, and MTP1 consolidation was observed in all patients.

Table 1: Patient demographics.^a

	HR	Healthy Controls	P-value
Number of participants (number of feet)	10 (10)	15 (30)	-
Male/Female	3:7	9:6	-
Left/Right feet	3:7	15:15	-
Age (y)	65 ± 9.5 (52-79)	59 ± 5.0 (53-70)	0.16
Height (m)	1.66 ± 0.09	1.74 ± 0.09	0.04
Weight (kg)	72.8 ± 14.7	83.0 ± 11.9	0.06
BMI	26.2 ± 4.3 (20.4-33.2)	27.4 ± 3.9 (20.2-33.3)	0.37
Leg length (cm)	89.0 ± 5.0 (82-98)	91.6 ± 4.9 (84-104)	0.21
Preoperative HR grade	II = 7, III = 3		
Postoperative DFA	25.0 ± 5.66 (19.0-38.0)		

^a Means and standard deviations (with the range in parentheses) are presented.

^b A p -value ≤ 0.05 is considered a statistically significant difference and marked in bold.

^c HR was graded based on the Regnaud grading system [28].

Table 2: Spatiotemporal parameters.^a

	HR (1)	MTP1 Arthrodesis (2)	Healthy Controls (3)	P-value 1-2	P-value ^b 1-3	P-value ^b 2-3
Gait speed (m/s)	1.01 ± 0.19	1.07 ± 0.29	1.14 ± 0.19	0.30	0.09	0.65
Step width (m)	0.12 ± 0.05	0.10 ± 0.04	0.13 ± 0.04	0.27	0.64	0.05
Step length (m)	0.56 ± 0.02	0.60 ± 0.09	0.64 ± 0.07	0.21	0.002	0.33
Stance time (s)	0.71 ± 0.10	0.75 ± 0.13	0.71 ± 0.11	0.11	0.85	0.71

^a Data are presented as means with standard deviations.

^b A p -value ≤ 0.05 was considered a statistically significant difference and marked in bold.

Spatiotemporal parameters

No statistically significant differences were observed in spatiotemporal parameters before and after surgery (Table 2). HR step length was significantly shorter preoperatively compared with healthy controls (0.56 m vs. 0.64 m, respectively; $P < 0.002$), while HR step width was significantly smaller postoperatively compared with healthy controls (0.10 m vs. 0.13 m, respectively; $P = 0.05$) (Table 2).

Foot and ankle kinematics

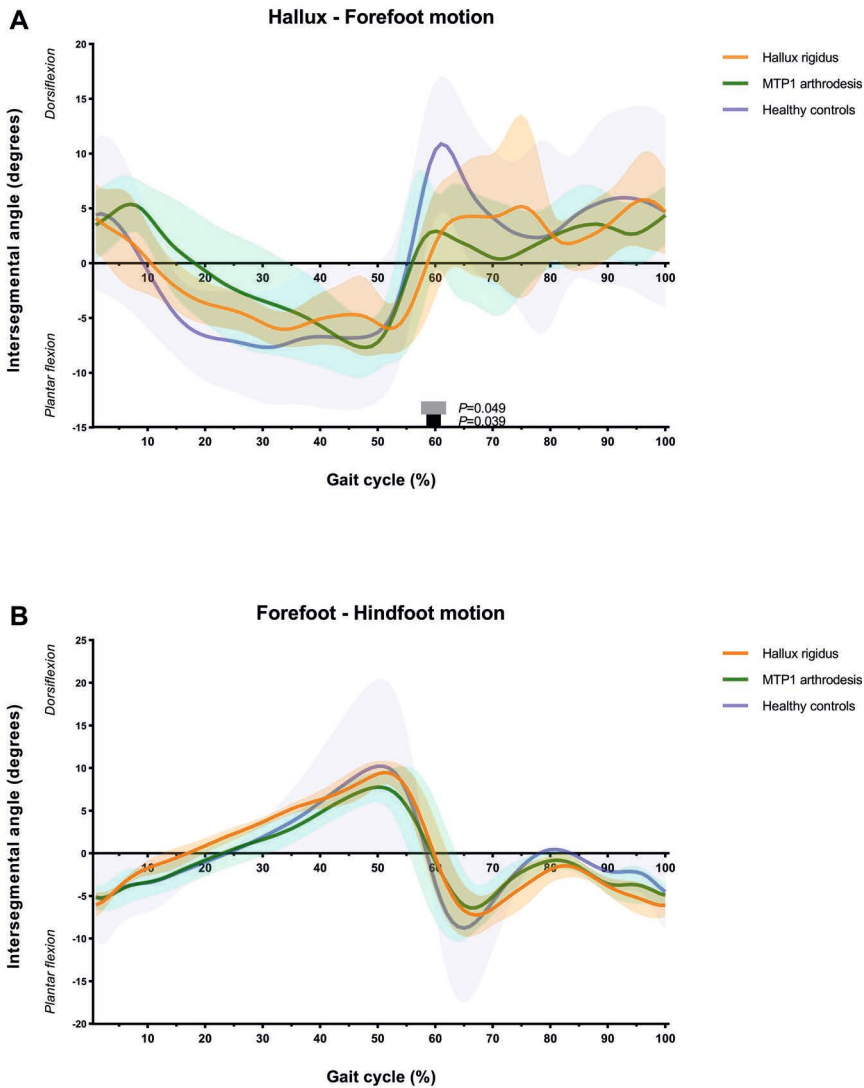
Reduced dorsiflexion in the hallux/forefoot segment was observed in subjects with HR during pre-swing before ($P = 0.039$) and after surgery ($P = 0.049$) compared with healthy controls (Figure 1A). Sagittal ROM (dorsiflexion and plantar flexion) during push-off in

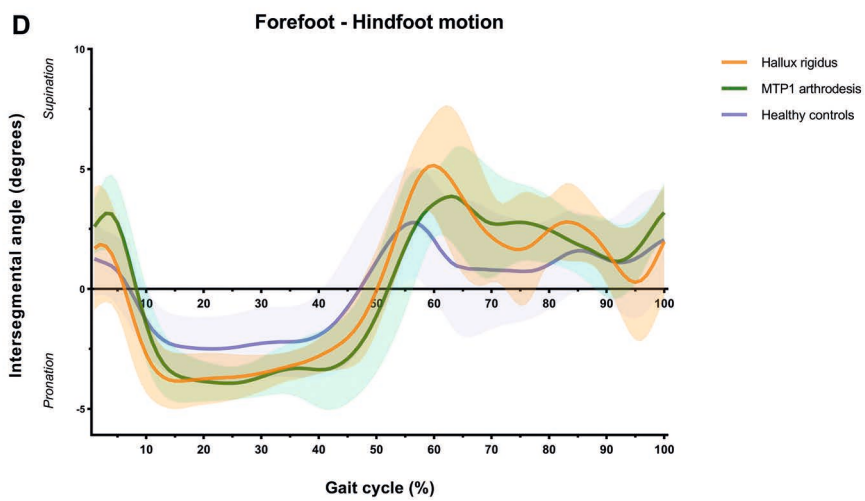
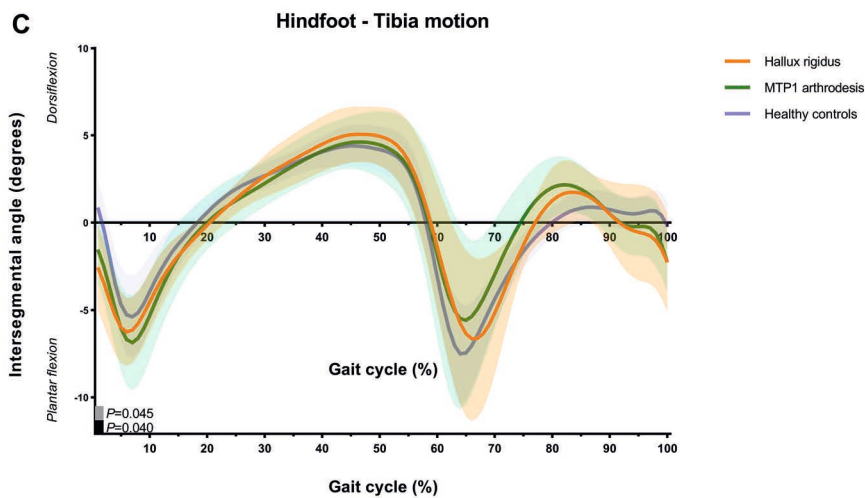
the hallux/forefoot segment was significantly lower prior to surgery (15.9° vs. 22.8°, respectively; $P=0.02$) and after MTP1 arthrodesis (14.4° vs. 22.8°, respectively; $P=0.02$) compared with healthy controls (Figure 2A). No difference was detected in sagittal ROM during push-off in the hallux/forefoot segment before and after MTP1 arthrodesis ($P=0.91$, Figure 2A).

Sagittal forefoot and hindfoot motion (dorsiflexion and plantar flexion) were comparable in the three studied groups (Figure 1B,C). Only increased plantar flexion was observed in subjects with HR and MTP1 compared with healthy controls ($P=0.045$ and $P=0.04$, respectively; Figure 1C) during loading response in the hindfoot/tibia segment. Furthermore, no differences in sagittal ROM (dorsiflexion and plantar flexion) during push-off in the forefoot and hindfoot were seen between the studied groups (Figures 2B, 2C).

In the frontal plane, increased forefoot motion (pronation and supination) was seen during push-off in the HR group compared with healthy controls (9.8° vs. 7.1°, respectively; $P=0.04$, Figure 2D) and in the MTP1 arthrodesis group compared with healthy controls (9.7° vs. 7.1°, respectively; $P=0.02$, Figure 2D). These differences in frontal plane forefoot motion were not seen after analyzing the kinematic data with SPM (Figure 1D).

Furthermore, increased frontal plane hindfoot motion (inversion and eversion) was seen during push-off after MTP1 arthrodesis compared with healthy controls (13.8° vs. 8.9°, respectively; $P=0.009$, Figure 2E). This finding was not seen after analyzing the data with SPM (Figure 1E), although increased inversion of the hindfoot was seen after MTP1 arthrodesis compared with healthy controls in loading response ($P=0.041$, Figure 1E).





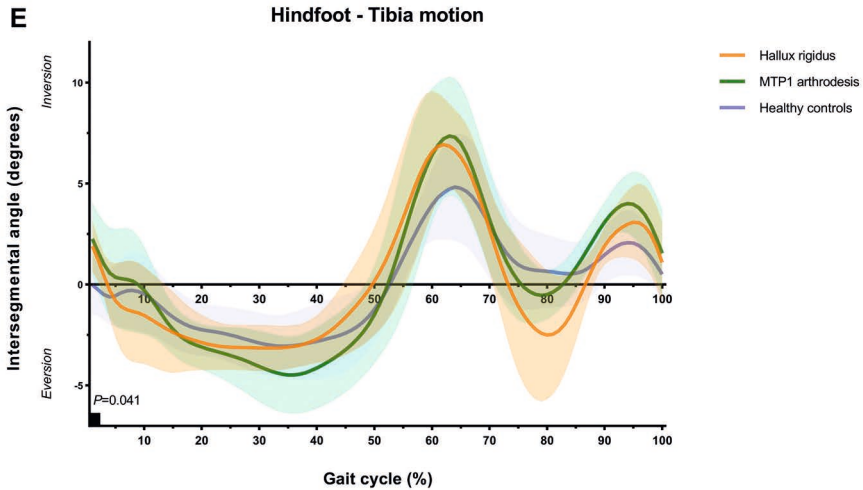


Figure 1: This collection of figures presents average absolute joint angles of one stride during gait in the HR group, the MTP1 arthrodesis group, and healthy controls. Motion in the sagittal plane for the hallux/forefoot, forefoot/hindfoot, and hindfoot/tibia ((A), (B), (C), respectively) and in the frontal plane for the forefoot/hindfoot and hindfoot/tibia ((D), (E), respectively).^a

^a Mean values (dark lines) are accompanied by their standard deviations (transparent areas).

^b Results of the SPM analyses are displayed on the x-axis. Statistically significant differences ($P \leq 0.05$) are indicated in black (HR vs. healthy controls) or gray (MTP1 arthrodesis vs. healthy controls). No statistically significant differences were detected between the HR and MTP1 arthrodesis groups.

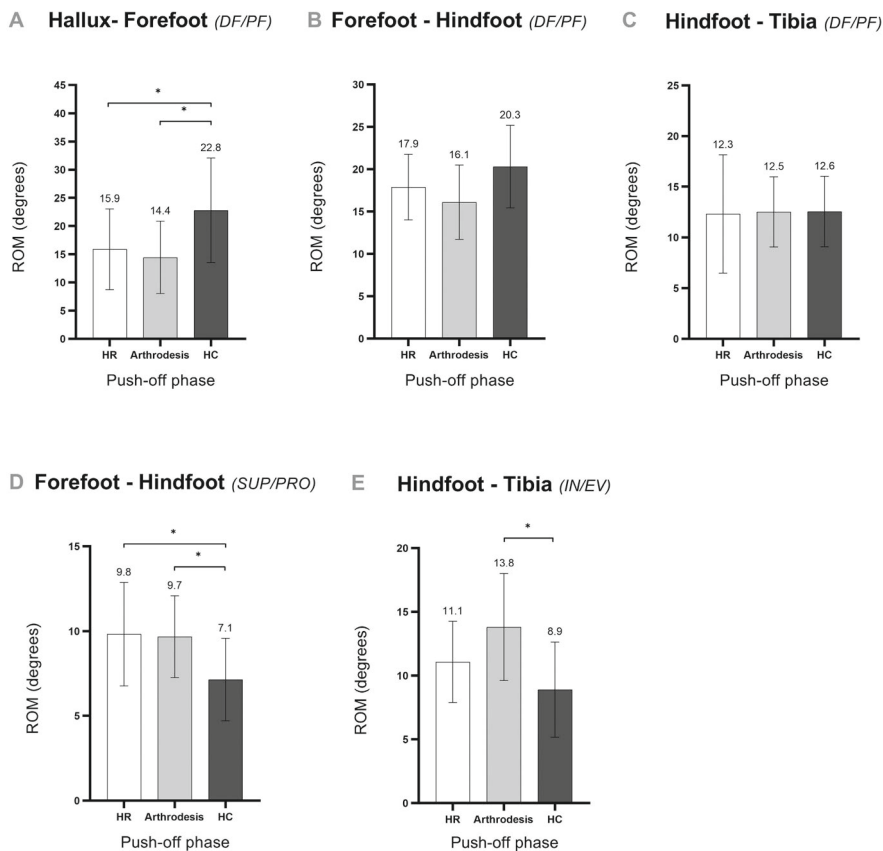


Figure 2: These five figures present intersegmental ROM during push-off in the sagittal plane (A–C) and frontal plane (D,E) in the different foot segments. Results are before surgery (HR), after MTP1 arthrodesis (arthrodesis), and healthy controls (HC).^a

^a Data are presented as means with standard deviations.

* A p -value ≤ 0.05 is considered a statistically significant difference.

Abbreviations: *DF*, dorsiflexion; *PF*, plantar flexion; *SUP*, supination; *PRO*, pronation; *IN*, inversion; *EV*, eversion.

PROMs

AOFAS-HMI scores increased significantly from 55.7 points prior to surgery to 79.1 points after surgery ($P=0.002$). Additionally, NPRS scores significantly decreased from 5.7 points prior to surgery to 1.5 points after surgery ($P=0.004$). MOXFQ index scores improved from 51.0 points before surgery to 20.0 points after surgery ($P=0.002$). Furthermore, significant improvements in all subdomains of the MOXFQ were observed (Table 3).

Table 3: Clinical outcome measures and PROMs prior to surgery (HR) and after surgery (MTP1 arthrodesis).^a

	HR	MTP1 Arthrodesis	P-value ^b
AOFAS-HMI score^c	55.7 ± 8.7 (42 - 70)	79.1 ± 15.5 (52.2 - 100)	0.002
NPRS	5.7 ± 2.5 (1 - 8)	1.5 ± 1.8 (0 - 5)	0.004
MOXFQ	51.0 ± 15.6 (22.5 - 78.8)	20.0 ± 13.5 (0 - 43)	0.002
Standing or walking (%)	43.1 ± 23.9 (5.7 - 80)	19.1 ± 15.5 (0 - 45.6)	0.027
Pain (%)	53.2 ± 14.9 (20 - 76)	25.6 ± 18.8 (0 - 64)	0.004
Social interactions (%)	50.8 ± 8.2 (40 - 64)	28.0 ± 17.0 (0 - 44)	0.008

^a Data are presented as means with standard deviations and ranges in parentheses.

^b A *p*-value ≤0.05 is considered a statistically significant difference.

^c Postoperatively, the maximum obtainable AOFAS-HMI score is 90 points, since 10 points are devoted to MTP1 ROM. The reported scores were therefore calculated by dividing the subtotal by 90 instead of 100 [23].

Discussion

The aim of this prospective study is to determine the effects of MTP1 arthrodesis on foot and ankle kinematics, as well as on PROMs, compared with patients' preoperative state and healthy controls. As hypothesized, after MTP1 arthrodesis, dorsiflexion in the hallux/forefoot segment was reduced during pre-swing; accordingly, intersegmental ROM analysis confirmed the decreased ROM during push-off in the hallux/forefoot segment compared with healthy controls. Loss of MTP1 motion after MTP1 arthrodesis is compensated in the forefoot and hindfoot via increased frontal plane motion during push-off compared with healthy controls. Increased frontal plane motion (pronation and supination) in the forefoot during push-off was also seen in subjects with HR, although hindfoot motion (inversion and eversion) was not affected. Subjects reported significant pain reduction and fewer limitations in standing and walking after MTP1 arthrodesis. Additionally, improvements in participating in daily and social activities were seen.

This prospective comparative study is one of the first studies evaluating effects of MTP1 arthrodesis on foot and ankle kinematics and PROMs before and after surgery. The number of quantitative kinematic studies in which studies evaluate gait after MTP1 arthrodesis is limited [3,8-10,17]. Previous studies used a foot model where the foot was analyzed as single rigid body, wherein sagittal ankle kinematics was analyzed [3,8,9]. In the present study, no significant changes in ankle ROM during gait before and after MTP1 arthrodesis were observed, which was in accordance with the literature [3,8,9]. Two cross-sectional studies have used multi-segment foot models and have observed similar foot compensation after MTP1 arthrodesis [10,18]. In the present study, reduced dorsiflexion in the hallux/forefoot segment during stance (0–62% of the gait cycle) and increased frontal plane motions (pronation and supination) in the forefoot after

MTP1 arthrodesis compared with healthy controls was observed. This has also been observed in the previous studies [10,18]. Increased hindfoot inversion and eversion during stance has not been observed by previous studies [10,18]. However, the present study determined that this compensation occurred during push-off. This part of the gait cycle has not been analyzed by previous studies [10,18]. Additionally, some significant differences during loading response were observed in the sagittal plane of the hindfoot/tibia and in the frontal plane of the hindfoot/tibia. However, since these differences were small, it was concluded that they were not clinically relevant.

Previous gait studies have reported differences in spatiotemporal parameters after MTP1 arthrodesis. One study has reported decreased step length [9], and two studies have reported a decreased step width [8,10]; others have not observed these effects [17,18]. In the presented study, a decreased step width was also observed after MTP1 arthrodesis, which is in accordance with previous published studies [8,10]. Brodsky et al. suggested that a decrease in step width indicates a narrower base of support during gait, which is interpreted as increased stability during this activity [8]. Stevens et al. suggested that the decrease in step width was an effect of the inclusion of more women in their MTP1 arthrodesis group, since it is known that step width is smaller in women [10]. We agree with both suggestions; also, in our study, more women were included in our intervention group. Based on the present results, it is additionally suggested that step width narrows after MTP1 arthrodesis due to the observed compensation mechanism of increased frontal plane motion in the forefoot (pronation and supination) and hindfoot (inversion and eversion). It is suggested that these foot motions could be easier to perform and require less effort when feet are positioned in a narrower base. Furthermore, step length was significantly shorter in HR compared with healthy controls. This was also observed in one previous study, while it was not further discussed [9]. It is suggested that this will be an effect of the lower gait speed, since step length is directly related to gait speed [31,32]. This trend was also observed in the present study; step length will be greater when gait speed increases (Table 2). Finally, in the present study, healthy controls were taller than patients of the intervention groups, which could also lead to an increased step length [31].

This study demonstrates that foot motion is changed in HR and after MTP1 arthrodesis compared with healthy controls. Intersegmental foot motion is partly comparable in HR and after subsequent MTP1 arthrodesis. In HR, frontal plane motion (pronation and supination) in the forefoot increases due to reduced MTP1 motion. After MTP1 arthrodesis, increased frontal plane motion in the forefoot is also observed, while increased hindfoot motion in the frontal plane (inversion and eversion) is detected, which is not seen in HR. It is suggested that frontal plane motion in the forefoot increases due to the severely affected MTP1 joint in subjects with HR, causing pain and mechanical impingement, which limits MTP1 joint motion. These factors lead to the avoidance of loading and toeing-off over the MTP1 joint during push-off, which is

compensated by an increased frontal plane motion of the forefoot [33]. After surgery, MTP1 joint motion is further lost due to fusion of the MTP1 joint. Therefore, toeing-off over the MTP1 joint is further reduced and other joints need to compensate for the loss of hallux motion. Due to further loss of MTP1 joint motion after MTP1 arthrodesis, the hindfoot is also compensating in frontal plane motions besides the forefoot. Therefore, frontal plane motions in the forefoot and hindfoot seem to be essential to compensate for the loss of motion of the MTP1 joint.

The long-term effects of this compensatory mechanism, as well as the development of additional foot and ankle complaints or pathologies in other foot joints, remain unclear and need further investigation through future long-term follow-up studies. Nevertheless, a significant impact on the emergence of new foot and ankle complaints is not expected, as existing long-term clinical follow-up data after MTP1 arthrodesis demonstrate minimal pain (VAS 0.66) and high levels of patient satisfaction (AOFAS 91 points, MOXFQ 19.6 points) after 22 years of follow-up [7]. These findings suggest that the compensatory mechanism is unlikely to contribute to the development of new foot and ankle issues. However, based on the current study results and the available evidence, no definitive recommendations can yet be made regarding revalidation and rehabilitation protocols following MTP1 arthrodesis. Further studies are needed to confirm these findings and to specifically assess the long-term effects and potential emergence of new foot and ankle complaints resulting from this compensatory mechanism.

Surgery results in a significant reduction in patient-reported complaints and improvements in patient-reported satisfaction. The use of several PROMs (AOFAS-HMI, NPRS, and MOXFQ) indicate that, after MTP1 arthrodesis, pain is significantly reduced and patients report fewer limitations in standing and walking; additionally, participation is improved in daily and social activities. The observed clinical improvements align with findings from previously published studies, which evaluated PROMs postoperatively or at midterm follow-up after MTP1 arthrodesis [7,34-38]. Furthermore, the following clinically relevant improvements based on the MOXFQ are observed after surgery: scores in the MOXFQ domains are comparable to or greater than the minimal clinically important differences of 12, 16, and 24 in the MOXFQ domains of pain, walking or standing, and social interaction, respectively [25]. Comparing the AOFAS-HMI scores with healthy individuals' values, which range between 87.4 and 84 points for people between 50 and 79 years of age, allows to conclude that a mean AOFAS-HMI score of 79.1 after surgery in the present study is approaching the normal reference values of individuals without any foot pathology [39].

Moreover, the present study demonstrates that following MTP1 arthrodesis, patients experience a substantial reduction in complaints and an increase in satisfaction, while the foot compensates for the loss of MTP1 joint motion after surgery. Therefore,

improvements in PROMs do not necessarily indicate normalized foot function to the level observed in healthy individuals without foot pathology. In addition to the altered foot biomechanics following MTP1 arthrodesis, the observed improvements in clinical outcomes and reduction in pain may, from the patient's perspective, be the most meaningful and valuable results.

This is the first prospective study evaluating the effects of MTP1 arthrodesis on foot and ankle kinematics and on PROMs in patients with HR before and after surgery compared with healthy individuals. Most prior studies have been limited to describing one of these outcomes or have used a cross-sectional study design [3,8,10,33].

Another strength of this study is the use of the OFM, a widely adopted multi-segment model for assessing foot and ankle kinematics that enables motion detection in the first ray [19,20,40,41]. However, it is important to note that the OFM measures relative motion between foot segments rather than at isolated joints in the traditional anatomical sense. Consequently, motion detected in the hallux/forefoot segment following MTP1 arthrodesis still represents movement of the forefoot and the interphalangeal joint of the first ray. The identification of joint motion using dynamic imaging techniques and markers remains challenging. Research and development of multi-segment foot models is ongoing to improve the reliability of detecting foot and ankle motion during gait [41,42]. Despite the described findings, the present study has some limitations. The relatively small sample size could be a potential weakness, as it could result in underpowering. Therefore, absolute data is reported to present the magnitude of the observed differences and to facilitate the decision regarding whether a clinically relevant effect has been found [43,44]. Secondly, ROM during the push-off phase is calculated based on percentages of the gait cycle, although determination based on ground reaction force (GRF) data is considered the most accurate approach. This method is recommended in future gait studies. Finally, one surgical revision is performed due to nonunion. The literature reports of nonunion or delayed union rates are approximately 6.6% [6]. Despite the complication in this study, no specific gait deviations are noted compared with the other patients with arthrodesis.

Long-term studies are recommended to investigate functional foot and ankle problems after long-term follow-up due to the altered gait pattern in patients with MTP1 arthrodesis compared with healthy subjects. Moreover, comparison with different surgical interventions could be innovative, as an increase in hallux motion during walking is expected after total joint replacement. Therefore, the foot is likely to compensate less and present gait patterns comparable to healthy individuals. Perhaps this is a more suitable option for patients with less compensatory reserve (i.e., less frontal forefoot and hindfoot motion). Upcoming studies must also elucidate which patient would have, for example, an advantage from a restoration of hallux motion (i.e., a total joint prosthesis) instead of an MTP1 fixation with arthrodesis. If known, kinematic analysis

could contribute to surgical planning, resulting in an optimal selection of a patient's intervention.

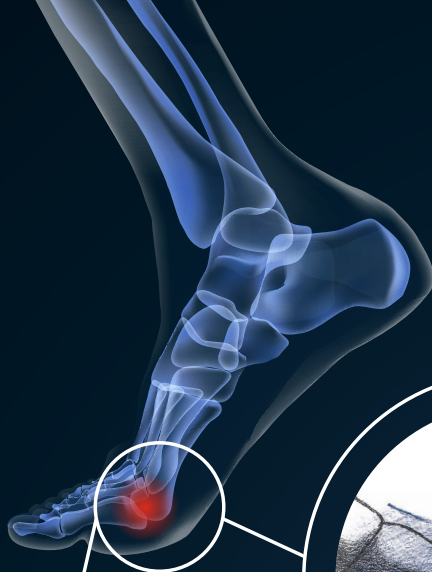
Conclusion

The present study demonstrates that the loss of hallux motion after MTP1 arthrodesis is compensated by increased frontal plane motion in the forefoot and hindfoot. Prior to surgery, in which patients suffer from painful HR, a comparable motion pattern in the forefoot by increased frontal plane motion is observed, while hindfoot motion in the frontal plane does not change. Therefore, it is proved that the foot has the intrinsic capacity to compensate for the loss of MTP1 motion in HR and after MTP1 arthrodesis. Proper functioning of the forefoot and hindfoot is a considerable component of preoperative planning to select subjects suitable for MTP1 arthrodesis. Furthermore, improvements in PROMs, which reflect a significant reduction in pain and increased satisfaction in functioning in daily and social activities, are seen after surgery.

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CHAPTER 4

Long-term effects of cheilectomy, Keller's arthroplasty, and arthrodesis for symptomatic hallux rigidus on patient-reported and radiological outcome

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Keywords: Hallux Rigidus, Cheilectomy, Keller's arthroplasty, Arthrodesis, Patient-reported outcome measure

Abstract

Background

Several surgical interventions are available to alleviate pain in hallux rigidus, and the optimal operative technique is still a topic of debate among surgeons. Three of these are arthrodesis, cheilectomy, and Keller's arthroplasty. Currently, it is unclear which intervention yields the best long-term result. The aim of this study was to assess which of these interventions performed best in terms of patient-reported outcome, pain scores and disease recurrence at long-term follow-up.

Methods

These data are the follow-up to the initial study published in 2006. In the original study, 73 patients (n=89 toes) with symptomatic hallux rigidus were recruited and underwent first metatarsophalangeal joint arthrodesis (n=33 toes), cheilectomy (n=28 toes) or Keller's arthroplasty (n=28 toes). Outcome measures were AOFAS hallux metatarsophalangeal-interphalangeal (HMI) score, and pain was assessed with a visual analogue scale (VAS) at a mean follow-up period of 7-years. Patients of the original study were identified and invited to participate in the current study. Data were collected in the form of AOFAS-HMI score, VAS pain score, Manchester-Oxford Foot Questionnaire (MOXFQ), and Forgotten Joint Score (FJS-12). In addition, a clinical examination was performed and radiographs were gained. Data were available for 37 patients (n=45 toes), with a mean follow-up period over 22-years.

Results

AOFAS-HMI and VAS pain score improved during follow-up only in arthrodesis patients. Furthermore, no statistically significant differences in clinical and patient-reported outcome were detected between groups based on AOFAS-HMI, VAS pain, MOXFQ or FJS-12. However, clinically important differences in patient-reported outcomes and pain scores were detected, favouring arthrodesis. Radiographic disease progression was more evident after cheilectomy compared with Keller's arthroplasty.

Conclusion

Arthrodesis, cheilectomy, and Keller's arthroplasty are 3 successful operative interventions to treat symptomatic hallux rigidus. Because clinically important differences were detected and symptoms still diminish many years after surgery, a slight preference was awarded for arthrodesis.

Introduction

Osteoarthritis (OA) of the first metatarsophalangeal (MTP1) joint, also known as hallux rigidus (HR), is a common disorder of the musculoskeletal system in middle-aged people and progresses with age. The exact etiology of HR is believed to be multifactorial because anatomic variation, trauma, surgery, deformations (e.g., hallux valgus) and the length of the first metatarsal seem to be involved in the development of HR [1,2]. The prevalence is estimated at approximately 30% at an age of 50 years, and increases toward 40% for men and 55% for women at an age of 65 years [3]. HR is a major cause of chronic pain and disability and severely affects the experienced quality of life [4,5]. The osteoarthritic process results in loss of range of motion of the MTP1 joint and can be observed on conventional radiographs, although the grade of OA seen on radiographs poorly correlates with the experienced functional impairment [4-7].

Three widely used operative techniques for HR are cheilectomy, Keller's arthroplasty, and arthrodesis of the MTP1 joint [8]. Of these interventions, Keller's arthroplasty was originally reserved for low-demand, older patients, since it may result in a nonfunctional, unstable hallux and high incidence of metatarsalgia [8]. Cheilectomy is predominantly recommended for patients with mild to moderate HR resulting in high satisfaction rates at short term [8,9]. Arthrodesis is mainly performed in patients with severe HR and as a salvage procedure after prior HR surgery, resulting in high satisfaction rates but a stiff, motionless MTP1 joint [9].

In 2006, Beertema et al. published a study in which the outcome after these 3 interventions was assessed by using the AOFAS-HMI score and VAS pain score in HR patients. Cheilectomy and Keller's arthroplasty showed better outcome in low-grade HR (i.e., Regnault classification grade I or II), whereas the best outcome was after Keller's arthroplasty in grade III HR. Furthermore, pain scores were higher after arthrodesis in low-grade HR (i.e., grade I HR). Therefore, it was concluded that cheilectomy should be considered in low-grade HR (i.e., grade I or II) and Keller's arthroplasty in patients with any grade of HR (i.e., grade I to III) [10].

Despite these valuable findings at 7 years of follow-up, no long-term comparative studies are available describing outcome of these operative interventions. In the literature, several studies described outcome after MTP1 arthrodesis or cheilectomy for HR, where only a few studies evaluated outcome after Keller's arthroplasty [10-14]. At the moment, only 2 studies have investigated the outcome after one of these interventions with a follow-up duration longer than 10 years [14,15].

The aim of this comparative follow-up study was to assess clinical and radiographic outcome after cheilectomy, Keller's arthroplasty, and arthrodesis in patients treated for HR after a very long follow-up period. We hypothesized that arthrodesis would

perform better compared with cheilectomy due to disease progression in the latter group. Comparable outcomes for Keller's arthroplasty and the arthrodesis group were expected. In addition, an overview of the literature was provided.

Methods

Study population

The present retrospective comparative cohort study was performed at the department of orthopedics of our institution and was a follow-up study to one by Beertema et al. [10]. Patients were eligible for inclusion in the original study when they were treated for symptomatic hallux rigidus or hallux valgus/rigidus. All patients had pain and loss of motion of the MTP1 joint. Ninety-four feet ($n=77$ patients) were included and treated with cheilectomy ($n=32$), Keller's arthroplasty ($n=28$), or arthrodesis ($n=34$). Type of surgery was based on surgeon preference. Eventually, 89 feet ($n=73$ patients) were included in the outcome analysis in the original study [10]. These subjects were eligible for inclusion in this follow-up study. Patients were invited to visit our outpatient clinic for a clinical examination (i.e., patient anthropometrics, MTP1 joint and interphalangeal (IP) motion) and were independently examined by 2 investigators who were not involved in the primary operative procedure. Approval for this study was obtained from the local ethics committee, and all patients provided written informed consent.

Twenty-eight cheilectomy toes together with 33 arthrodesis toes and 28 Keller's arthroplasty toes were included in the original study (Figure 1) [10]. Of the cheilectomy group, 5 patients (6 toes) were deceased, 2 patients (2 toes) were lost to follow-up, and 7 patients (9 toes) were not able or not willing to participate, resulting in a total of 10 cheilectomy patients (11 toes) in this study. Regarding the arthrodesis group, 5 patients died (7 toes), 3 patients (3 toes) were untraceable at the time of this study, and 5 patients (7 toes) were not able or willing to participate, yielding a total of 12 arthrodesis patients (16 toes). In the Keller's arthroplasty group, 6 patients (7 toes) died, 1 patient was lost to follow-up (1 toe), and 2 patients (2 toes) were not willing or able to participate. As a result, 15 patients (18 toes) treated with a Keller's arthroplasty were included.

Demographic data of included subjects are shown in Table 1. No statistically significant differences between groups were observed for age at surgery, age at follow-up, follow-up duration, weight, length and BMI.

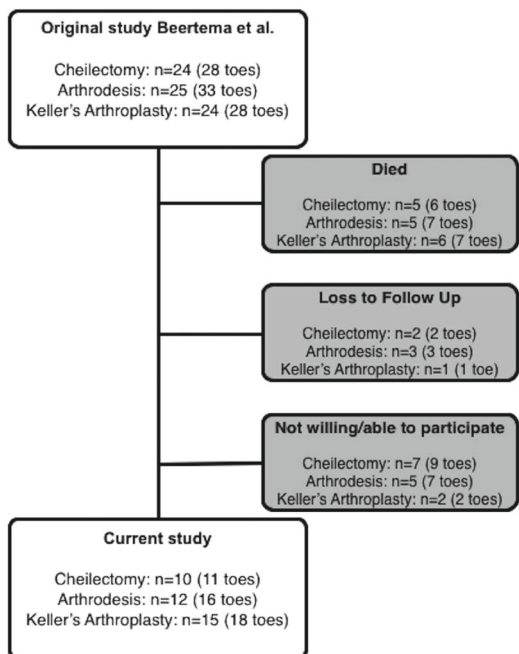


Figure 4: Study population.

Table 1: Patient characteristics.^a

	Keller's Arthroplasty (1)	Arthrodesis (2)	Cheilectomy (3)	P-value 1-2	P-value 1-3	P-value 2-3
Patients (toes)	15 (18)	12 (16)	10 (11)	-	-	-
Man/female	9:6	4:8	6:4	-	-	-
Age Surgery, y	53.4 ± 7.5 (31-63)	49.5 ± 9.9 (34-68)	51.4 ± 7.0 (39-62)	0.433	0.882	0.918
Age follow-up, y	75.1 ± 7.2 (57-87)	73.0 ± 8.2 (61-89)	74.1 ± 7.8 (62-86)	0.865	0.985	0.982
Follow-up, y	22.4 ± 2.7 (19-27)	23.0 ± 3.8 (18-29)	22.6 ± 3.1 (19-28)	0.926	0.999	0.977
Weight, kg	79.6 ± 12.1 (58-94)	79.4 ± 13.9 (58-94)	81.3 ± 7.4 (73-92)	0.999	0.985	0.985
Length, m	1.69 ± 0.08 (1.50-1.77)	1.64 ± 0.13 (1.47-1.82)	1.72 ± 0.09 (1.63-1.86)	0.634	0.887	0.350
BMI	27.9 ± 3.7 (22.1-34.8)	30.1 ± 7.6 (17.5-41.2)	27.6 ± 2.2 (23.1-29.6)	0.700	0.999	0.710
MTP1 ROM, degrees	60.0 ± 13.3 (40-90)	0 ± 0 (0-0)	43.1 ± 18.7 (25-65)	-	0.046 ^b	-
Dorsiflexion, degrees	43.2 ± 14.4 (15-65)	0 ± 0 (0-0)	24.6 ± 19.0 (10-55)	-	0.017 ^b	-
IP motion, degrees	29.6 ± 21.5 (5-75)	23.2 ± 12.8 (5-50)	36.9 ± 14.6 (15-60)	0.758	0.727	0.294

^a Data are presented as mean with standard deviation and the range in parentheses.^b Statistically significant difference between groups in which a *p*-value ≤ 0.05 was considered as statistically significant. Abbreviations: BMI, body mass index; IP, interphalangeal; MTP1, first metatarsophalangeal joint; ROM, range of motion.

Patient-reported outcomes

Patient-reported outcomes (PROs) were assessed by using the validated Manchester-Oxford Foot Questionnaire (MOXFQ) and Forgotten Joint Score (FJS) [16,17]. The MOXFQ is a 16-item instrument answered on a 5-point scale concerning walking/standing problems (7 items), foot pain (5 items), and issues related to social interaction (4 items) [16,18]. MOXFQ scores were presented on a 100-point scale, with 0 representing the best outcome and 100 the poorest outcome. The FJS is a 12-item questionnaire answered on a 5-point scale, which focuses on the awareness of having an affected joint during daily life and daily activities, and higher scores correspond with lower awareness (i.e., 0 represents poorest outcome and awareness during all daily activities and 100 represents the best outcome and no awareness) [17].

Clinical outcome was assessed with the American Orthopaedic Foot & Ankle Society (AOFAS) rating system for the hallux metatarsophalangeal-interphalangeal (AOFAS-HMI) modified by Roukis et al. [19,20]. This modified AOFAS-HMI allows 40 possible points for pain, 40 points for function, and 20 points for alignment, with higher scores corresponding with better outcomes. The AOFAS scores for the arthrodesis group were adjusted to eliminate 10 points devoted to range of motion, and scores were therefore calculated by dividing the subtotal by 90.

Current pain perception was assessed by using the visual analogue scale (VAS), where 0 corresponds with no pain and 10 with the most intense pain [21,22].

Radiographic evaluation

Weightbearing anterior-posterior and lateral radiographs were evaluated by 2 independent observers, who were blinded to clinical outcomes. The following parameters were evaluated on radiographs: intermetatarsal angle (IMA), hallux valgus angle (HVA), and dorsiflexion fusion angle (DFA) for the arthrodesis group [23]. The DFA was measured as described by Coughlin [24]. Mean angles of both measurements were calculated. Differences between observers greater than 5 degrees were resolved by consensus. As in the original study, Regnauld radiographic classification of HR was used to grade degenerative changes of the MTP1 joint in the cheilectomy and Keller's arthroplasty group [25].

Statistical analysis

Statistical analyses were performed with SPSS software (version 26; IBM, Armonk, NY). Analysis of variances (ANOVA), with post-hoc Gabriel correction, was used to detect differences in patient characteristics, outcomes of clinical questionnaires, IP ROM and radiographic angles between the 3 groups. Welch's *F* test was used to test for homogeneity of variance. The unpaired Student *t* test was used to test differences in MTP1 ROM and MTP1 dorsiflexion between the Keller's arthroplasty and cheilectomy group. Differences in AOFAS-HMI score between the original study and the present

study were tested with the paired Student *t* test. A *p*-value comparable to or less than 0.05 was considered to be statistically significant.

To evaluate the power of the study, effect sizes (Cohen *d*) were calculated for the patient-reported outcome measures (PROMs) as the standardized difference between 2 means divided by the standard deviation of either group. An effect size of 1.0 is equivalent to a change of 1 SD in the sample, which is considered to be a very large change, and an effect size of 0.8 is considered to be large, 0.5 is moderate, and 0.3 is small [26]. A large effect size subsequently corresponds with a high power, a small effect size with a low power.

Results

Patient-reported outcome measures

After 22 years of follow-up, no statistically significant differences between groups in AOFAS-HMI score were detected (Table 2). However, AOFAS-HMI scores significantly improved during follow-up in the arthrodesis group (i.e., 82.2 to 91.0; *P*=0.022, Figure 2B). This improvement in outcome was not detected in the Keller's arthroplasty (i.e., 86.1 to 83.9; *P*=0.657) and cheilectomy group (i.e., 79.8 to 77.1; *P*=0.703). Although higher pain scores were reported in the cheilectomy group at long-term follow-up (i.e., VAS 1.8 vs. 0.7 and 0.7 in the arthrodesis and Keller's arthroplasty group, respectively), no statistically significant differences were detected between groups. VAS pain score significantly decreased in the arthrodesis group (i.e., 1.9 to 0.7; *P*=0.026, Figure 2A) during follow-up. This change in VAS pain score over time was not seen in the Keller's arthroplasty (i.e., 1.2 to 0.7; *P*=0.311) and cheilectomy group (i.e., 2.0 to 1.8; *P*=0.823). Comparable results in MOXFQ index score and 3 MOXFQ domain scores were seen at follow-up in the 3 groups. No statistically significant differences between groups were observed in terms of awareness of the operated joint, as assessed with the FJS, although lowest score (i.e., highest awareness) was present in the cheilectomy group. Calculated effect sizes were small (≤ 0.3) for all the PROMs.

Table 2: Clinical outcome assessed with patient-reported outcome measures.^a

	Keller's Arthroplasty (1)	Arthrodesis (2)	Cheilectomy (3)	P-value 1-2	P-value 1-3	P-value 2-3
AOFAS-HMI^b	83.9 ± 16.7 (54-100)	91.0 ± 6.8 (78-100)	77.1 ± 27.2 (24-100)	0.704	0.774	0.335
VAS Pain	0.72 ± 1.23 (0-4.6)	0.66 ± 1.02 (0-3.9)	1.81 ± 2.28 (0-7.1)	0.999	0.171	0.151
FJS-12 (in %)	82.6 ± 24.8 (8-100)	83.1 ± 22.1 (40-100)	71.8 ± 30.7 (25-100)	0.999	0.606	0.590
MOXFQ index score	27.9 ± 33.6 (0-90.6)	19.6 ± 21.5 (0-62.5)	26 ± 24.9 (0-70.3)	0.764	0.997	0.907
Standing/ Walking	27.8 ± 37.9 (0-96.4)	20.8 ± 27.7 (0-71.4)	24.4 ± 26.5 (0-64.3)	0.888	0.989	0.988
Pain	23.3 ± 28.1 (0-75)	14.4 ± 17.1 (0-50)	20.9 ± 21.5 (0-65)	0.586	0.989	0.845
Social Interaction	33.7 ± 36.1 (0-100)	23.9 ± 22 (0-68.8)	35.2 ± 31.9 (0-100)	0.722	0.999	0.706

^a Data are presented as mean with standard deviation and the range in parentheses. $P \leq 0.05$ was considered as statistically significant.

^b The adapted AOFAS-HMI score was used with a maximum achievable amount of points of 100.

Abbreviations: *AOFAS-HMI*, American Orthopaedic Foot & Ankle Society (AOFAS) rating system for the Hallux Metatarsophalangeal-Interphalangeal (HMI); *VAS*, visual analogue scale; *FJS*, forgotten joint score; *MOXFQ*, Manchester-Oxford Foot Questionnaire.

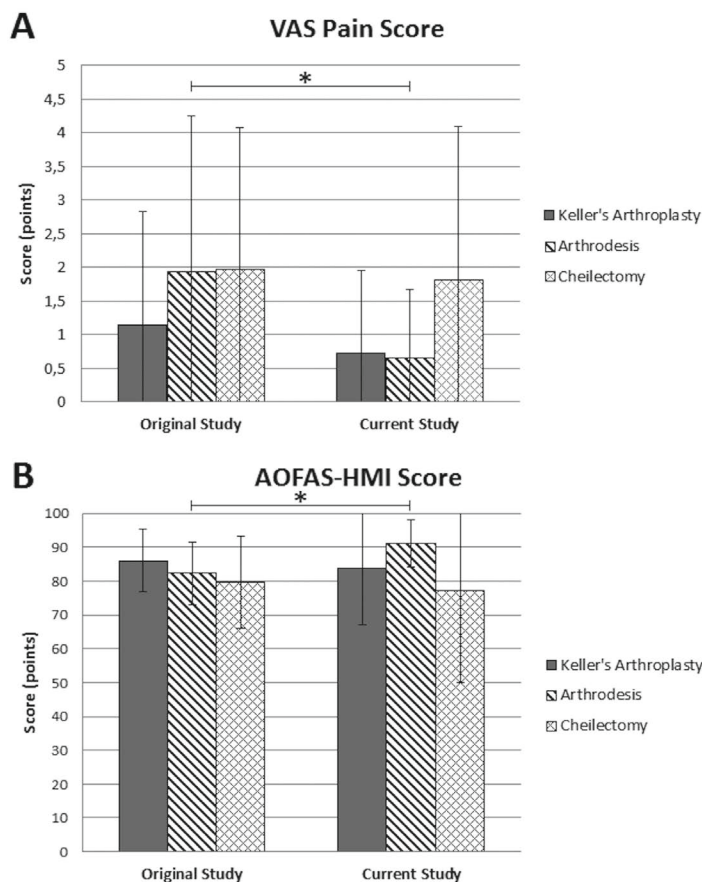


Figure 5: (A) VAS pain scores and (B) AOFAS-HMI scores for the Keller's arthroplasty, arthrodesis, and cheilectomy groups of patients included in the original study and current study.

* P -value ≤ 0.05 was considered as a statistically significant difference.

Radiographic evaluation and MTP1 joint motion

No statistically significant differences in IMA and HVA were detected between groups (Table 3). The highest degree of OA, assessed with Regnault classification system, was seen in the Keller's arthroplasty groups as compared to the cheilectomy group (i.e., 2.15 and 1.75, respectively). However the progression of OA over time was higher in the cheilectomy group (i.e., 0.5 vs. 0.15 degree in the Keller's arthroplasty group).

A statistically significant larger MTP1 ROM and MTP1 dorsiflexion was observed in the Keller's arthroplasty group as compared to the cheilectomy group (i.e., 60.0 vs. 43.1 degrees; $P=0.046$ and 43.2 vs. 24.6 degrees; $P=0.17$, respectively). As expected, no motion in the MTP1 joint was detected after arthrodesis. No significant differences in IP ROM were observed between groups.

Table 3: Radiographic evaluation of Keller's arthroplasty, arthrodesis and cheilectomy at follow-up.^a

	Keller's Arthroplasty (1)	Arthrodesis (2)	Cheilectomy (3)	P-value 1-2	P-value 1-3	P-value 2-3
Patients (toes)	12 (14)	8 (10)	7 (8)	-	-	-
IMA, degrees	8.9 ± 3.0 (5.3-13.8)	10.4 ± 4.5 (6.4-19.5)	9.5 ± 2.5 (5.1-13.4)	0.665	0.969	0.935
HVA, degrees	9.8 ± 8.0 (-3.4-24.8)	13.6 ± 10.0 (3.1-29.9)	15.9 ± 6.3 (7.1-26.9)	0.617	0.911	0.278
DFA, degrees	NA	26.2 ± 8.0 (11.3-39.6)	NA	-	-	-
HR grade^b	Gr I n=2, Gr II n=8, Gr III n=4 Initial study: Gr 2 Current study: 2.15	NA	Gr I n=3, Gr II n=4, Gr III n=1 Initial study: Gr 1.25 Current study: Gr 1.75	-	-	-

^a Data are presented as mean with standard deviation and the range in parentheses.

^b Grading system based on Regnauld [25].

Abbreviations: DFA, dorsiflexion fusion angle; HR, hallux rigidus; HVA, hallux valgus angle; IMA, intermetatarsal angle; NA, not applicable.

Overview of literature

An overview of the studies which assessed clinical outcome, patient-reported outcome or pain with the VAS or numeric rating scale (NRS) after cheilectomy (Supplemental Table S1), Keller's arthroplasty (Supplemental Table S2) and arthrodesis (Supplemental Table S3) for symptomatic OA of the MTP1 joint were provided.

Discussion

This study aimed to evaluate long-term patient-reported and radiographic outcome in patients who were treated with Keller's arthroplasty, arthrodesis or cheilectomy for HR [10]. Best outcomes were reported after cheilectomy and Keller's arthroplasty in low-grade HR and after Keller's arthroplasty in high-grade HR by using VAS pain and AOFAS-HMI score in the initial study, where patients had a mean follow-up duration of 7-years. In the present study, we hypothesized that the arthrodesis group and Keller's arthroplasty group would perform better as compared to cheilectomy, because of disease progression in the latter group.

As hypothesized, no significant differences between arthrodesis and Keller's arthroplasty were detected based on AOFAS-HMI score. Surprisingly, cheilectomy showed a comparable outcome, despite the disease progression that was detected on radiographs. Although differences in AOFAS-HMI scores between groups were not statistically significant, there was a clinically relevant difference between groups. In hallux surgery, a difference larger than 7.9 points in AOFAS score is considered as a minimal clinical important difference (MCID), that is, the smallest difference that is important for a patient or the smallest improvement considered worthwhile by a patient [27]. As a result, arthrodesis had a better outcome as compared to cheilectomy 22 years postoperatively.

Most arthrodesis studies published in the literature showed AOFAS-HMI scores ranging between 72 and 83 points [28-35], except for 3 other studies showing higher AOFAS-HMI scores (i.e., 90 points) [9,32,36], and 1 study reporting a lower outcome (i.e., 53 points) [37]. These studies had a mean follow-up period ranging between 28 months and 8.6 years. The results presented in this study showed that the AOFAS-HMI at long term was comparable with these studies, but also significantly improved over time. Based on our results and the literature, it can be concluded that an arthrodesis is an excellent intervention at very long term, with a positive time effect and longevity [15,28].

In cheilectomy studies, AOFAS-HMI scores ranged between 76 and 85 points after 1.1 to 5.4 years of follow-up [8,38-44]. Only Coughlin and Shurnas showed a better outcome after a longer follow-up period (i.e., 90 points at 9.6 years post-surgery) [9]. The present results are consistent with the initial study at the 7-year follow-up and the

outcome remained stable over years. Thus, the deterioration of the MTP-1 joint seen on radiographs did not significantly affect clinical outcome. This finding, that radiographic severity of OA is not necessarily inversely correlated with PROM, is more frequently observed in orthopedic surgery [45]. Keller's arthroplasty for HR is less well described in literature. Only 3 studies reported AOFAS-HMI scores ranging between 83 to 89 points with a wide spread in follow-up period from 14-months to 23-years [11-14]. Our results are consistent with these studies, which showed that the good mid-term results of a Keller's arthroplasty remain stable over a long time. In addition, the fear of having a nonfunctional first ray resulting in limitations and/or pain was not proved with these results.

In terms of pain, no significant differences between groups were detected in VAS-pain score. However, VAS-pain score significantly improved in the arthrodesis patients during follow-up. Unsurprisingly, results for the VAS-pain score were consistent with the AOFAS-HMI score, because a major part of the points in the AOFAS-HMI score were allocated for pain [19,20]. Arthrodesis is a highly effective intervention to reduce pain in HR, because fusion of the first metatarsal and proximal phalanx eliminates the motion between the osteoarthritic surfaces of these bones which causes pain. Previous studies showed a significant decrease in VAS-pain scores from values ranging between 6.2 and 8.7 preoperatively to 0.4 and 2.7 postoperatively, with in general lower VAS-pain scores in studies with a longer follow-up period [9,10,15,28,31,34,37,46-49]. The results presented in this study were in line with the literature and also demonstrate a further improvement in pain relief over time after arthrodesis of the MTP1 joint. This pain-reducing effect in HR is also reported for cheilectomy, reducing pain scores from values between 7.1 and 8.1 preoperatively to values 1.1 and 2.2 postoperatively [9,10,41,50-53]; no other study except the study of Beertema et al. previously reported VAS-pain scores after Keller's arthroplasty [10]. Contrary to arthrodesis, no further decreases in VAS-pain scores were detected in these 2 groups. This might be due to disease recurrence and/or progression detected in follow-up radiographs. Although not statistically significant, a difference larger than 1.0, which is considered as an MCID for VAS pain scores, was present between the arthrodesis and Keller's arthroplasty group (i.e., 1.2 points and 1.1, respectively) as compared to cheilectomy group [54]. Therefore, our results indicate that both arthrodesis and Keller's arthroplasty perform better as a pain-reducing intervention as compared to cheilectomy after very long follow-up.

No statistically significant differences between groups were identified by using the foot specific PROM MOXFQ, which is often used to assess outcome in hallux surgery [12,55,56]. Significant lower MOXFQ scores were expected in the arthrodesis group as compared to the cheilectomy group, especially in the pain domain due to disease progression in the cheilectomy group, and the Keller's arthroplasty group, because of biomechanical limitations due to the nature of the latter intervention. Also, there were no statistically significant differences; neither clinically important differences were

identified because differences between groups were below the MCID values of 16, 12 and 24 for the walking/standing, pain and social interaction domain of MOXFQ [18]. The absence of statistically significant and clinically relevant differences might indicate that there were no true differences between groups. Other explanations were the lack of sensitivity to capture change of these scores, or the lack of power to detect changes due to the design of this study. The former explanation seems unlikely since the MOXFQ is an extensively tested PROM that is highly responsive for hallux surgery [18], whereas the latter could be present because of the relatively high number of dropouts due to the long period of follow-up.

In the literature, only 4 studies previously investigated the 3 studied interventions at 6 to 50 months by using the MOXFQ, and compared to our results showed better outcomes in MOXFQ for Keller's arthroplasty at short-term [12], comparable to cheilectomy studies [53,56], whereas better outcomes were presented in this study with respect to a previous arthrodesis study [55]. This is consistent with the results seen in the original article, in which it was stated that cheilectomy and Keller's arthroplasty yields best outcomes in the short term [10], but arthrodesis improves over time as shown in our results.

To our knowledge, this was the first study reporting the FJS-12 in HR surgery in order to evaluate joint awareness after HR surgery during normal daily activities. Although the FJS-12 is not validated for hallux surgery [17], it was thought that it had an added value on evaluating long-term outcome after hallux surgery, because it assesses how joint surgery affects normal daily activities and/or tasks and is therefore more specific than questionnaires assessing general quality of life, which were expected to be more influenced by major comorbidities. It was expected that disease progression after cheilectomy, which was expected and observed in radiographs, would have resulted in more joint awareness in daily living. However, no statistically significant differences in FJS-12 scores were detected between groups, which implies that radiographic disease progression does not necessarily corresponds with poorer patient-reported functioning during daily life. Nevertheless, a difference greater than 10 points was detected between the cheilectomy group and both the Keller's arthroplasty and arthrodesis groups. It is unclear if this relatively large difference is clinically relevant, since MCID values of FJS-12 are not known yet in foot surgery and are not available for evaluating the outcome of hip or knee surgery in which the FJS-12 is often applied.

The biggest strength of this study was the very long follow-up period of more than 22-years, evaluating 3 of the most commonly used interventions for symptomatic HR, that is, cheilectomy, Keller's arthroplasty, and arthrodesis.

Despite the very long follow-up period, the use of several clinical and patient-reported outcomes, radiological evaluation, and the comparison of the presented results with the

results gained in the initial study, we acknowledge that this study had some limitations. There was a high dropout rate, since only 37 of the 73 subjects who participated in the initial study were able to participate in this study. This was inherent to the studied pathology that in general develops during aging, and the study design with a long follow-up duration. This study was therefore limited because of the number of patients. As a result, relatively large differences in PROMs detected in this study (e.g., FJS-12 between arthrodesis and cheilectomy group) that were not statistically significant would probably be statistically significant with higher numbers of subjects, that is, the relative large dropout of patients in this study may have resulted in non-significant results because of chance. In addition, calculated effect sizes showed that this study was underpowered.

Lastly, randomization of patients in the original study would have been more appropriate. For example, cheilectomy was only performed in low-grade HR and arthrodesis predominantly in high-grade HR, which may have caused significant differences in clinical and patient-reported outcomes between groups before surgery. Assuming that the latter subjects had worse preoperative scores, greater improvements after surgery would be expected in this group. As a result, arthrodesis would be favored, although this difference might be based on baseline difference in groups (i.e., selection base). In our opinion, the lack of preoperative scores did not influence our results, because the original study already showed better outcomes after Keller's arthroplasty and cheilectomy for low-grade and high-grade HR respectively, as compared to arthrodesis. That arthrodesis yields better PROMs in the long term as compared to cheilectomy therefore seems to be a real effect.

Conclusion

The present study showed clinical, patient-reported, and radiological outcome at a follow-up of more than 22-years after arthrodesis, cheilectomy and Keller's arthroplasty for symptomatic HR. A significant further improvement in clinical outcome and pain reduction was seen after follow-up in the arthrodesis group, but not in the Keller's arthroplasty and cheilectomy group, indicating that symptoms can still diminish many years after surgery. Clinically important differences in outcome between arthrodesis and cheilectomy group were detected in the AOFAS-HMI and VAS-pain score, favoring arthrodesis. In addition, a clinically relevant lower pain score was also seen after Keller's arthroplasty as compared to cheilectomy 22 years after surgery. In addition, the greatest radiologic disease progression was observed in the cheilectomy group. The findings in this study, together with the presented previously performed studies, show that arthrodesis, cheilectomy and Keller's arthroplasty are 3 proper methods to treat symptomatic HR with good to excellent clinical and patient-reported outcome after a very long period after surgery. We did find a slightly better outcome for arthrodesis for treatment of HR base on clinical and patient-reported outcome.

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Supplementary files

Supplemental table S1: Previous studies evaluating clinical outcome with questionnaires, visual analogue scale for pain, and first metatarsophalangeal joint motion after cheilectomy in hallux rigidus.[†]

Author (y)	Study Design	Patients (Toes)	Age (y) [†]	Follow-up [†]	Stage of Disease	Clinical Outcomes	First Metatarsophalangeal Joint Motion
Easley et al. (1999) [38]	Retrospective case serie	57 (75) ^a	51 (36-70)	63 (37-92) months	Gr I n=2, Gr II n=24, Gr III n=42 ^c	AOFAS 45 ± 13 to 85 ± 14*	Dorsiflexion 20° ± 7 to 39° ± 14* ROM 34° ± 9 to 64° ± 18*
Lau et al. (2001) [41]	Retrospective cohort study	19 (24) ^b	51.9 ± 7.9	2.0 ± 1.0 years	Gr II n=20, Gr III n=4 ^c	AOFAS post: 78 ± 13.0, FFI post: 21.0 ± 24.5 VAS 8.1 ± 1.6 to 2.9 ± 2.2*	Dorsiflexion 14.1° ± 7.4 to 30.9° ± 7.7*
Feltham et al. (2001) [39]	Retrospective cohort study	67 (67) ^a	54.5 (23-80)	65 (28-117) months	Gr I n=4, Gr II n=37, Gr III n=16 ^d	AOFAS post: 79.9	ROM 13° to 59**
Coughlin and Shurnas (2003) [9]	Retrospective cohort study	80 (93) ^a	50 (16-76)	9.6 (2.3-20.3) years	Gr I n=6, Gr II n=32, Gr III n=34, Gr IV n=8 ^e	AOFAS 45 (24-70) to 90 (67-100)* VAS 8 (6-10) to 1.5 (0-8)*	Dorsiflexion 14.5° (0-45) to 39° (10-65)* ROM 39° (5-80°) to 64° (15-110°)*
Keiserman (2005) [8]	Retrospective case serie	17 (8°, 9°)	55.5	34.2 (12-83) months	Gr II n=12, Gr III n=2 ^c	AOFAS 61.2 to 85.5*	NA
Beertema et al. (2006) [10]	Retrospective cohort study	24 (28)	49 (22-72)	8 (2-12) years	Gr I n=16, Gr II n=7, NA n=5 ^a	AOFAS post: 79.8 ± 13.6 (65-100) VAS post: 1.98 ± 2.09 (0-6.8)	Dorsiflexion 44° ± 16.0 (0-80) ROM 54.6° ± 20.3 (0-100)
Nawoczinski et al. (2008) [50]	Prospective case serie	20 (20) ^a	49 (34-63)	6.2 (4.6-8.9) years	NA	VAS 7.1 (2-10) to 1.7 (0-5)*	ROM 13.3° ± 12.7 to 21.7° ± 14.7*
Canseco et al. (2009) [44]	Prospective case serie	19 (19) ^a	50.5 (34-75)	1.5 years	NA	AOFAS significant increase (no values)	ROM significant increase (no values reported)
Lin and Murphy (2009) [42]	Retrospective case serie	20 (20) ^a	53.8 (29-69)	2.8 years	Gr I n=1, Gr II n=9, Gr III n=4 ^d	AOFAS 53.5 to 84*	ROM 44.8° to 57.5*

Supplemental table S1: (continued)

Author (y)	Study Design	Patients (Toes)	Age (y) [†]	Follow-up [†]	Stage of Disease	Clinical Outcomes	First Metatarsophalangeal Joint Motion
Harrison et al. (2010) [56]	Prospective case serie	25 (25) ^a	62 (39-80)	17 (9-27) months	NA	MOXFQ index 33/64 to 9.6/64* ^f Walking/Standing ↓ 41.1 Pain ↓ 31.6 Social interaction ↓ 34.4	NA
Smith et al. (2012) [43]	Prospective cohort study	17 (17) ^a	47.4 (37-64)	1.8 (1.0-3.6) years	NA	AOFAS 62 ± 7.7 to 81 ± 6.4*	ROM 33.9° ± 11.1 to 50.6° ± 11.3*
Kuni et al. (2014) [40]	Prospective case serie	8 (8) ^a	59.1 ± 6.4	1.1 ± 0.3 years	NA	AOFAS 56.9 ± 19.9 to 75.9 ± 13.9*	ROM 37.4° ± 8.3 to 34.8° ± 9.7
Nicolosi et al. (2015) [51]	Retrospective case serie	58 (58) ^a	55.7 ± 9.5	7.1 (0.8-14.9) years	NA	VAS post: 1.1 ± 1.6	NA
Ruff et al. (2018) [52]	Retrospective case serie	57 (57) ^a	56.7 (29-74)	49.2 (24-96) weeks	NA	VAS 6.5 (3-10) to 1.3 (0-6)*	Dorsiflexion 5.8° (0-10°) to 50.9° (32-72)*
Teoh et al. (2019) [53]	Prospective case serie	89 (98) ^a	54 (29-71)	50 (12-84) months	Gr I n=33, Gr II n=54, Gr III n=11 ^e	VAS 8.0 (6-10) to 3 (0-10)* MOXFQ index 58.6 (30-94) to 30.5 (0-92) ^g Walking/Standing ↓ 32.4 Pain ↓ 31.5 Social interaction ↓ 26.1	

[†] Data are presented as mean with standard deviation and the range in parentheses.

* Significant difference in outcome after surgery; NA, not available.

^a Cheilectomy.

^b Cheilectomy plus Kessel Bone Osteotomy.

^c Grading system based on Hattrup and Johnson.

^d Grading system based on Regnault.

^e Grading system based on Coughlin and Shurnas.

^f A total of 64 was the maximum score in MOXFQ score.

^g A total of 100 was the maximum score in MOXFQ score.

Supplemental table S2: Previous studies evaluating clinical outcome with questionnaires, visual analogue scale for pain and first metatarsophalangeal joint motion after Keller's arthroplasty in hallux rigidus.[†]

Author (y)	Study Design	Patients (Toes)	Age (y) [†]	Follow-up [†]	Stage of Disease	Clinical Outcome	First Metatarsophalangeal Joint Motion
Beertema et al. (2006) [10]	Retrospective cohort study	24 (28)	58 (31-77)	6 (2-12) years	Gr I n=6, Gr II n=14, Gr III n=4, NA n=4 ^a	AOFAS post: 86.1 ± 9.2 (72-100) VAS post: 1.15 ± 1.68 (0-5.7)	Dorsiflexion post: 44.6°±11.1 (30-65) ROM post: 59.4°±16.1 (20-85) ROM 28.2°±15.2 to 52.2°±15.7*
Schenk et al. (2009) [13]	Retrospective cohort study	22 (30)	57.8 (43.5-75.6)	14.1 (6-27) months	NA	AOFAS 50 to 88 ± 21.6*	
Schneider et al. (2011) [14]	Retrospective case serie	78 (87)	50	23 (20-33) years	Mean Gr1.7 ^a	AOFAS post: 83 (15-100)	Dorsiflexion post: 15°±16 ROM post: 30°±14
Coutts et al. (2012) [11]	Retrospective case serie	32 (42)	NA (42-78)	92 (36-154) months	Gr II n=42 ^a	AOFAS 38 to 89*	ROM post: 59.5°
Maher et al. (2017) [12]	Retrospective cohort study	48 (53)	NA (45-89)	6 months	NA	MOXFQ domain ^b Walking/Standing 59.5 ± 25.4 to 21.8 ± 25.8* Pain 58.4 ± 16.6 to 23.1 ± 22.8* Social interaction 48.8 ± 23.6 to 14.6 ± 19.8*	NA

[†] Data are presented as mean with standard deviation and the range in parentheses.

* Significant increase in outcome after surgery; NA, not available.

^a Grading system based on Regnauld.^b A total of 100 was the maximum score in MOXFQ score.

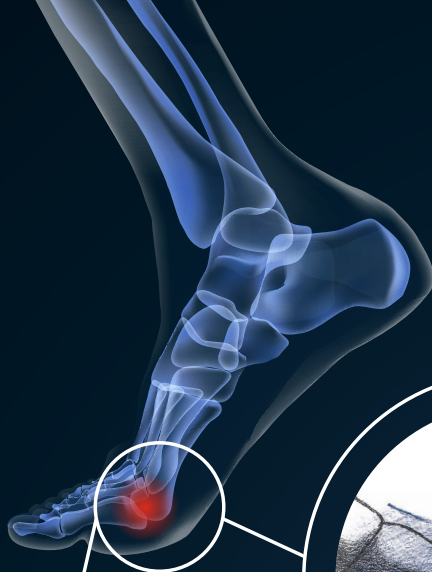
Supplemental table S3: Previous studies evaluating clinical outcome with questionnaires, visual analogue scale for pain and first metatarsophalangeal joint motion after arthrodesis in hallux rigidus. †

Author (y)	Study Design	Patients (Toes)	Age (y)†	Follow-up†	Stage of Disease	Clinical Outcome
Lombardi et al. (2001) [33]	Retrospective case series	17 (21)	53.2 (36-77)	28.1 (10-66) months	Gr II n=9, Gr III n=5, Gr IV n=4 ^a	AOFAS 39.1 (10-70) to 75.6 (22-90)*
DeFrino et al. (2002) [36]	Prospective case series	9 (10)	56 (38-72)	34 (26-44) months	NA	AOFAS 38 (20-62) to 90 (74-100)*
ETI et al. (2003) [37]	Retrospective case series	34 (38)	52 (24-71)	54 (18-116) months	Gr III n=38 ^a	AOFAS post: 53 (5-84) VAS 8.0 to 2.7*
Coughlin and Shurnas (2003) [9]	Retrospective cohort study	30 (34)	50 (16-76)	6.7 (2.1-12.2) years	Gr III n=10, Gr IV n=20 ^b	AOFAS 38 (24-60) to 89 (72-90)* VAS 8.7 (6.0-10) to 0.4 (0-5.0)*
Gibson et al. (2005) [47]	Randomized controlled trial	22 (38)	55 (34-77)	24 months	Gr I n=3, Gr II n=10, Gr III n=10, Gr IV n=15 ^b	VAS 6.2 ± 1.8 to 1.1 ± 1.6*
Beertema et al. (2006) [10]	Retrospective cohort study	25 (34)	54 (31-68)	7 (2-13) years	Gr I n=4, Gr II n=18, Gr III n=7, NA n=5 ^a	AOFAS post: 82.2 ± 9.2 (67-100) VAS post: 1.93 ± 2.32 (0-8)
Raikin et al. (2007) [34]	Retrospective cohort study	26 (27)	54.1 (32-73)	30 (13-67) months	NA	AOFAS 36.1 (19-62) to 83.8* VAS post: 0.7
Aas et al. (2008) [28]	Retrospective case series	35 (39)	52 (34-69)	8 (2-15) years	NA	AOFAS post: 74 ± 15 (23-90) VAS post: 1.0 ± 2.3 (0-8.4)
Wassink and van den Oever (2009) [57]	Retrospective case series	89 (109)	59 ± 10 (41-82)	69 (7-114) months	NA	AOFAS post: 50 ± 12 (10-60) ^d
van Doeselaar et al. (2010) [49]	Prospective case series	27 (27)	58 (42-72)	37 (14-54) months	NA	VAS post: 0.5 (0-7.9)
Kim et al. (2012) [32]	Retrospective cohort study	51 (51)	60.5 ± 9.7 (36-84)	194 weeks	NA	AOFAS post: 90
Erdil et al. (2013) [31]	Retrospective cohort study	12 (12)	58.2 ± 8.5	35.33 (24-66) months	Gr III n=1, Gr IV n=11 ^b	AOFAS 33.6 ± 3.8 to 76.1 ± 5.7* VAS 8.0 ± 0.7 to 0.5 ± 0.7*

Supplemental table S3: (continued)

Author (y)	Study Design	Patients (Toes)	Age (y) [†]	Follow-up [†]	Stage of Disease	Clinical Outcome
Fanous et al. (2014) [55]	Prospective case serie	25 (26)	59 (38-75)	10 (4-10) months	Gr IV n=26 ^b	MOXFQ 42/64 (21-54) to 18/64 (8-40) ^c
Simons et al. (2015) [48]	Retrospective cohort study	132 (132)	59.6 ± 9.5	39.5 (12-96) months	NA	VAS post: 1 (0-10)
Voskuilj (2015) [35]	Retrospective cohort study	50 (58)	63 ± 7.1 (47-78)	4.4 (1.3-7.0) years	NA	AOFAS post: 77 ± 18
Baumhauer et al. (2016) [46]	Randomized controlled trial	50 (50)	54.9 ± 10.5 (32.4-78.2)	24 months	Gr II n=18, Gr III n=23, Gr IV n=19 ^b	VAS 6.9 ± 1.4 (3.8-9.8) to 0.6 ± 1.2 (0-7.0) [*]
Chraim et al. (2016) [30]	Retrospective case series	60 (61)	68.5 (55-81)	47.3 (39-56) months	NA	AOFAS 40.9 ± 18.8 to 79.3 ± 11.2 [*]
Stone et al. (2017) [15] i.e. follow-up study Gibson et al. (2005) [47]	Randomized controlled trial	30 (30)	NA	15.2 (13.8-17.2) years	NA	VAS 6.2 ± 1.8 to 0.5 (0-40)
Beekhuizen et al. (2018) [29] i.e. follow-up study Voskuilj et al. (2015) [35]	Retrospective cohort study	39 (47)	62.3 ± 7.7 (47-78)	103.2 ± 25.9 (61-141) months	NA	AOFAS post: 72.8 ± 14.5

[†] Data are presented as mean with standard deviation and the range in parentheses.
^{*} Significant increase in outcome after surgery; NA, not available.
^a Grading system based on Regnauld.
^b Grading system based on Coughlin and Shurnas.
^c A total of 100 was the maximum score in MOXFQ score.
^d Maximum achievable amount of points of 60.



CHAPTER 5

Gait and dynamic pedobarographic analyses in hallux rigidus patients treated with Keller's arthroplasty, arthrodesis or cheilectomy 22-years after surgery

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Abstract

Background

Keller's arthroplasty, arthrodesis and cheilectomy are well-known surgical interventions for hallux rigidus. This study aimed to evaluate the effects of these surgical interventions on gait, plantar pressure distribution and clinical outcome in patients treated for hallux rigidus 22-years after surgery.

Methods

Spatio-temporal gait parameters and plantar pressure distribution, determined as pressure time integrals (PTIs) and peak pressures (PPs), were analyzed using a 7-foot tone analysis model. Patient-reported outcome was assessed using the Manchester-Oxford Foot Questionnaire (MOXFQ). Of the 73 patients (89 feet) from the original study, 27 patients (33 feet) and 13 healthy controls (26 feet) were available for evaluation 22-years after hallux rigidus surgery.

Results

Spatio-temporal gait parameters were comparable between all groups and were in line with healthy controls ($P \geq 0.05$). No differences ($P \geq 0.05$) in PTIs and PPs were found in the 7 plantar zones between groups and as compared to healthy controls. MOXFQ scores in all domains (walking/standing, range 21.4–24.1; pain, range 16.5–22.2 and social interaction, range 23.8–35.4) were not clinically and statistically different ($P \geq 0.05$) between the three different surgical interventions.

Conclusion

These results suggest no long-term functional and biomechanical differences after these surgical interventions for hallux rigidus correction. The interventions seem to be appropriate treatment options for a selective group of patients with symptomatic hallux rigidus.

Introduction

Hallux rigidus (HR) defined as osteoarthritis of the first metatarsophalangeal (MTP1) is the most commonly affected joint in patients with osteoarthritis of the foot [1]. Most reported symptoms are pain, swelling and a restriction of range of motion (ROM) of the MTP1 joint leading to difficulties while walking [2,3]. These symptoms progress over time resulting in a significantly decreased experienced health-related quality of life [4].

Surgical interventions are indicated when conservative treatments failed [2]. Keller's arthroplasty, arthrodesis and cheilectomy are surgical interventions for HR [2,5]. In Keller's arthroplasty, the base of the proximal phalanx is resected leading to MTP1 joint decompression and increased dorsiflexion. In this procedure, joint stability is sacrificed, which results in an unstable and non-supporting hallux [2,6]. An arthrodesis, in which the first metatarsal bone and proximal phalanx are fused, leads to a stiff and motionless MTP1 joint [2,3,6-8]. In cheilectomy, the dorsal osteophyte at the first metatarsal head is removed, leading to a reduction in pain and improvement in ROM after surgery [2,6]. Cheilectomy is predominantly recommended for patients with mild to moderate HR, while Keller's arthroplasty and arthrodesis is performed in patients with a more progressed stage of HR (stage 2 and 3) [2,5,6]. Improvements in clinical outcome and patient satisfaction are reported after all three surgical techniques [8-11].

Several studies have been performed to evaluate clinical outcomes after these surgical interventions. Only a few studies have evaluated gait and plantar pressures distribution after Keller's arthroplasty [10], arthrodesis [7,12-15] and cheilectomy [16,17] for HR. None of these studies directly compared these techniques. Previous mentioned studies observed reduced peak pressures under the hallux whereas increased peak pressures were observed beneath the first to the fourth metatarsal head after surgery when compared to unaffected feet [10,15,16]. However, a high methodological heterogeneity is present between these studies with respect to: (i) measurements systems, (ii) used pressure distribution models and subdivision in foot areas, (iii) used control groups (iv) variety in outcomes and (v) differences in follow-up period [7,10,12-17]. Currently, no long-term evaluation studies are available that evaluated long-term effects of these interventions for HR on biomechanical outcomes.

The aim of this comparative long-term evaluation study was to evaluate the effects of Keller's arthroplasty, arthrodesis and cheilectomy on gait, plantar pressure distribution and clinical outcome of patients treated for HR 22-years after surgery. Results were compared to each other and compared to healthy controls without foot complains. Correlation analysis was performed between gait and clinical outcomes to observe if certain associations could be detected. It was hypothesized that after long-term follow-up, a high satisfaction and normalized plantar pressures beneath the 1th and 2nd metatarsal head will be observed in subjects with an arthrodesis compared to

healthy controls. Since, the MTP-joint is sacrificed and metatarsal bones are fused, which creates stability and convert soft tissue and intrinsic foot musculature into stabilizing forces resulting in reestablishment of weightbearing distribution of the foot. Keller's arthroplasty will follow this distribution, since motion and some rolling of is still possible within the unstable and non-supporting hallux. Finally, the lowest pressures are expected for the cheilectomy group since, they will avoid the medial side of the forefoot as a result of the expected disease progression, and accompanying pain.

Methods

Study participants

Eligible study participants were derived from a cohort previously evaluated after a follow-up period of 7-years after surgery [11]. Patients underwent Keller's arthroplasty, arthrodesis or cheilectomy operations between 1990 and 2000 for a symptomatic HR. All patients had pain and loss of motion of the MTP1 joint [11]. The operations were performed by 4 experienced surgeons, who used a consistent operative technique and standardized postoperative regimen for each procedure. Participants who were able to walk barefoot and participated in the previous study were eligible for inclusion [11]. Furthermore, results of the interventions groups were compared to healthy controls with a comparable median age, sex and body mass index (BMI). The same inclusion criteria were eligible for the healthy controls. Healthy controls were free of any clinical signs or symptoms of hallux rigidus or other pathological conditions of the lower extremities.

Study design

This study was performed at our department of Orthopaedic Surgery and Traumatology. Long-term clinical outcome of these patients were recently evaluated [18]. A clinical examination (i.e., anthropometrics), gait analysis (i.e., spatio-temporal gait characteristics and pedobarographic assessment) and patient-reported outcome measures (PROMs) was performed at follow-up. Results of the present study were not compared to the previous study since the outcomes of the present study were not evaluated in the initial study [11]. The study was performed according to the Declaration of Helsinki (2013) and the Medical Ethical Committee Zuyderland (number 17-T-09) gave approval for this study. All patients provided written informed consent.

Gait and pedobarographic analysis

The Zebris FDM-TLR instrumented treadmill (Zebris Medical GmbH, Isny, Germany) was used for gait and pedobarographic analysis. This treadmill is equipped with a 123 cm x 44 cm electronic mat sensor (Zebris Medical GmbH, Isny, Germany) embedded beneath the belt. It contains 5376 miniature capacitive pressure sensors, registering the exerted force at a rate of 100 Hz ranging from 1 to 120 N/cm². The speed of the

treadmill can be adjusted from 0.8 up to 14 km/h with intervals of 0.1 km/h. Patients started with walking at the treadmill for four minutes to become familiarized with it. After this period of acclimatization to the treadmill, subjects were asked to walk at a self-selected comfortable speed, which is essential to obtain comparable data to overground walking [19]. To determine comfortable walking speed, participants started walking at a fixed speed of 0.5 km/h. Subsequently, belt speed was increased in a stepwise manner with steps varying from 0.1 to 0.3 km/h until the comfortable walking speed was reached. Thereafter, two measurements were performed, resulting in 30 to 40 steps per measurement. One of these two measurements were randomly chosen and used for further analysis.

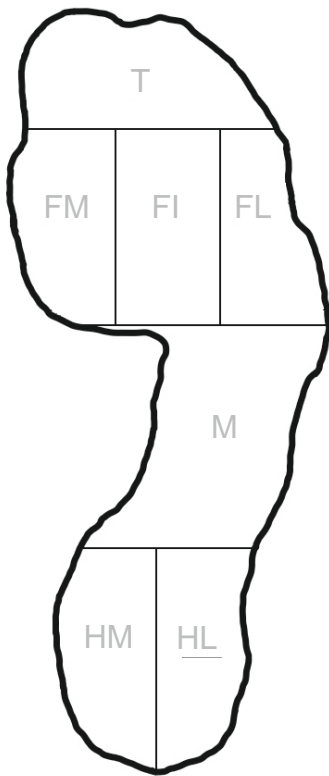


Figure 1: Seven plantar areas' according to the Zebris 7-foot tone model. The foot was divided into Toes (T), Forefoot medial (FM), Forefoot inner (FI), Forefoot lateral (FL), Midfoot (M), Heel medial (HM) and Heel lateral (HL).

The integrated 7-foot tone analysis model WinFDM-T software version 2.0.39 (Zebris medical GmbH, Isny, Germany) was used to assess gait and pedobarographic data. This software divides the foot in 7 zones i.e., heel lateral, heel medial, midfoot, forefoot lateral, forefoot inner, forefoot medial and toes (Figure 1). In this model, it was suggested that the forefoot medial represents the 1th and 2th metatarsal head, forefoot inner the 3th and 4th metatarsal head and forefoot lateral the 5th metatarsal head. All toes (i.e., 1 to 5) were included in the toe zone. Spatio-temporal parameters of interest were gait velocity (km/h), step length (cm), step width (cm), step time (s), stance phase (%; subdivided in load response, single support and pre-swing), swing phase (%) and double stance phase(%). For plantar pressure analysis, the pressure time integral (PTI; Ns/cm²) and peak pressures (PP; N/cm²) of the pressure curves were determined using a software tool developed by using MATLAB (MathWorks, version 9.7, Natick, MA, USA) [20,21]. Both outcomes are mainly used in pedobarographic studies [20-22]. The PTI described the cumulative effect of pressure over time in a certain area of the foot and therefore provided a value for the total load exposure of a planter area during stance [20,21]. The peak pressure was the maximum peak pressure measured in one zone during the stance phase [20-22].

The foot specific PROMs, the Manchester-Oxford Foot Questionnaire (MOXFQ), which is often used to assess clinical outcome in hallux surgery, was used [23,24]. The MOXFQ is used since it gave insights in the experience and satisfaction of patients and evaluates three domains, i.e., walking/standing problems (seven items), foot pain (five items) and issues related to social interaction (four items). A score of 0 represents the best outcome and 100 as the poorest outcome [23].

Statistical analysis

Statistical analysis was conducted with GraphPad Prism 8.3 (Graphpad Software, Inc., version 9.1.1., San Diego, CA, USA) and SPSS (IBM Statistics, version 25, Armonk, NY, USA). Descriptive statistics were calculated for patient demographics, spatio-temporal parameters, plantar pressure measurement, and PROMs. Normality of distributions was tested using the D'Agostino-Pearson normality test and revealed that spatio-temporal parameters and plantar pressure data need to be analyzed using non-parametric statistics. The Kruskal-Wallis test was conducted to test for significant differences between the three intervention groups and control group. Dunn's multiple comparison test was performed for pairwise comparisons [25]. Effect sizes were calculated using the Hodges-Lehmann estimator of location shift, calculated as the median of differences. According to the D'Agostino-Pearson normality test, there was no significant departure of normality of the MOXFQ data. Therefore, an analysis of variance (ANOVA) was performed to test for differences between groups. Finally, spearman rho correlation analysis was used to detect associations between plantar pressure in the forefoot and MOXFQ. A *p*-value ≤ 0.05 was considered as statistically significant.

Results

The initial study (2006) included 73 patients (89 feet) and after a median follow-up period of 22-years (range 19.0 up to 26.3 years) 27 patients (33 feet) were available for assessment. Results were compared to 13 (26 feet) healthy controls (Table 1). Of the 73 patients (89 feet), 17 patients (23%; 20 feet) died, 6 patients (8%; 6 feet) were lost to follow-up and 23 patients (32%; 30 feet) were not able or willing to participate in the present study resulting in 27 patients (37%; 33 feet) available for gait evaluation [11]. Of these patients, twelve subjects were treated with a Keller's arthroplasty (14 feet), 8 with an arthrodesis (10 feet) and 7 with a cheilectomy (9 feet). In each group, two patients underwent bilateral surgery. Based on preoperative radiographs, cheilectomy was performed in grade 1 and 2 HR and Keller's arthroplasty and arthrodesis predominantly in grade 2 and 3 HR, according to the Regnault's classification (Table 1) [26]. No statistically significant differences in demographical parameters were observed between the groups (Table 1).

Gait analysis

No differences in gait velocity and spatio-temporal parameters were detected between intervention groups and healthy controls ($P>0.05$) (Table 2).

PTIs and PPs in foot zones

Analyses of the PTIs showed no statistically significant differences between the Keller's arthroplasty (KA), arthrodesis (A), cheilectomy (C), and control group (CG) in each of the 7 analyzed foot zones (Figure 2). Effect sizes calculated as Hodges-Lehmann median of differences ranged in the forefoot medial from 0.46 (CG vs. C, $P>0.99$) to 2.75 Ns/cm² (A vs. C, $P=0.54$), in forefoot inner from 0.21 (CG vs. C, $P>0.99$) to 1.27 Ns/cm² (A vs. C, $P>0.99$), forefoot lateral from 0.08 (CG vs. KA, $P>0.99$) to 1.50 Ns/cm² (C vs. KA, $P=0.77$), and toes from 0.48 (CG vs. C, $P>0.99$) to 1.19 Ns/cm² (KA vs. C, $P>0.99$).

Also, for PPs, no statistically significant differences were detected between the surgical and control groups in each of the foot zones of interest (Figure 3). The largest differences were observed in the forefoot medial and forefoot inner. Effect sizes calculated as Hodges-Lehmann median of differences ranged in the forefoot medial from 1.14 (CG vs. C, $P>0.99$) to 10.33 N/cm² (A vs. C, $P=0.22$) and forefoot inner from 0.65 (CG vs. C, $P>0.99$) to 12.63 N/cm² (A vs. C, $P=0.46$).

Table 1: Patient demographics.^a

	Keller's arthroplasty	Arthrodesis	Cheilectomy	Healthy controls
Number of participants (number of feet)	12 (14)	8 (10)	7 (9)	13 (26)
Male / Female	9 / 3	3 / 5	4 / 3	6 / 7
Left feet / Right feet	8 / 6	4 / 6	5 / 4	13 / 13
Age at surgery (years)	54.0 (48.5-58.3)	48.5 (43.5-54.0)	53.0 (50.0-56.0)	-
Age at follow-up (years)	75 (71-78)	71 (65-74)	70 (68-84)	68 (62-73)
Follow-up (years)	22 (20-22.8)	22 (19.5-26.3)	22 (19-25)	-
Height (m)	1.72 (1.64-1.73)	1.67 (1.51-1.74)	1.72 (1.64-1.79)	1.75 (1.72-1.79)
Body mass (kg)	83.0 (67.0-86.0)	81.5 (65.0-93.0)	80.0 (74.0-87.0)	76.0 (70.0-89.5)
BMI (kg/m²)	27.8 (24.4-30.7)	28.7 (26.8-37.8)	28.4 (26.5-29.1)	25.6 (23.2-27.5)
HR grade before surgery	Gr I: 2 Gr II: 8 Gr III: 3 N/A: 1	Gr I: 1 Gr II: 5 Gr III: 3 N/A: 1	Gr I: 5 Gr II: 2 Gr III: 0 N/A: 2	-

^a Median and interquartile range are presented in parentheses.

* No statistically significant differences were detected between the groups $P>0.05$.

Abbreviations: *BMI*, Body mass index; *N/A*, no preoperative radiographic results were available.

Table 2: Gait analysis results.^a

	Keller's arthroplasty	Arthrodesis	Cheilectomy	Healthy controls
Gait velocity (km/h)	2.5 (1.9-3.4)	3.1 (1.1-4.5)	2.8 (1.5-4.2)	2.9 (2.6-3.9)
Step length (cm)	41.6 (29.6-50.9)	47.4 (37.7-58.2)	47.9 (35.2-58.6)	47.1 (43.5-51.4)
Step width (cm)	10.2 (6.6-13.8)	8.3 (6.0-14.5)	7.7 (4.2-10.3)	9.9 (6.4-14.2)
Step time (s)	0.57 (0.51-0.76)	0.55 (0.50-0.60)	0.63 (0.55-0.76)	0.55 (0.53-0.60)
Stance phase (%)	65.7 (64.8-70.5)	63.4 (62.7-65.7)	65.5 (62.2-68.4)	65.2 (62.8-66.5)
Load response (%)	16.0 (14.5-21.4)	13.4 (12.5-17.2)	16.4 (12.1-17.4)	15.0 (13.1-16.7)
Mid stance (%)	33.8 (29.7-36.0)	35.1 (33.2-37.3)	34.2 (31.3-38.1)	34.8 (33.4-37.3)
Pre-swing (%)	16.0 (14.5-20.3)	13.9 (12.5-18.1)	16.8 (12.1-18.6)	15.0 (13.0-16.8)
Swing phase (%)	34.3 (29.5-35.2)	36.6 (34.3-37.3)	34.5 (31.6-37.8)	34.8 (33.5-37.2)
Double stance phase (%)	32.0 (30.0-36.3)	29.2 (25.2-47.4)	33.4 (24.1-38.2)	30.4 (25.5-33.8)

^a Median and 95% CI presented in parentheses.* No statistically significant differences were detected between the groups $P>0.05$.

PROMs

The lowest MOXFQ scores in all domains were reported in the arthrodesis group (walking/standing 21.4; pain 16.5 and social interaction 23.8), without statistically significant differences between the surgical groups ($P>0.05$) (Table 3).

Correlation analysis

Spearman rho correlation analysis showed no significant associations in the arthrodesis and Keller's arthroplasty group between the PTI in the medial forefoot and MOXFQ pain domain (A $r=-0.20$, $P=0.58$; KA $r=-0.26$, $P=0.42$) and MOXFQ walking/standing domain (A $r=-0.29$, $P=0.42$; KA $r=-0.358$, $P=0.25$). Only negative associations were observed after cheilectomy (PTI medial forefoot and MOXFQ pain $r=-0.78$ $P=0.01$; PTI medial forefoot and MOXFQ walking/standing $r=-0.69$, $P=0.04$). No associations were observed after comparing PTI in the inner forefoot and PTI in the lateral forefoot to both MOXFQ domains in all three intervention groups.

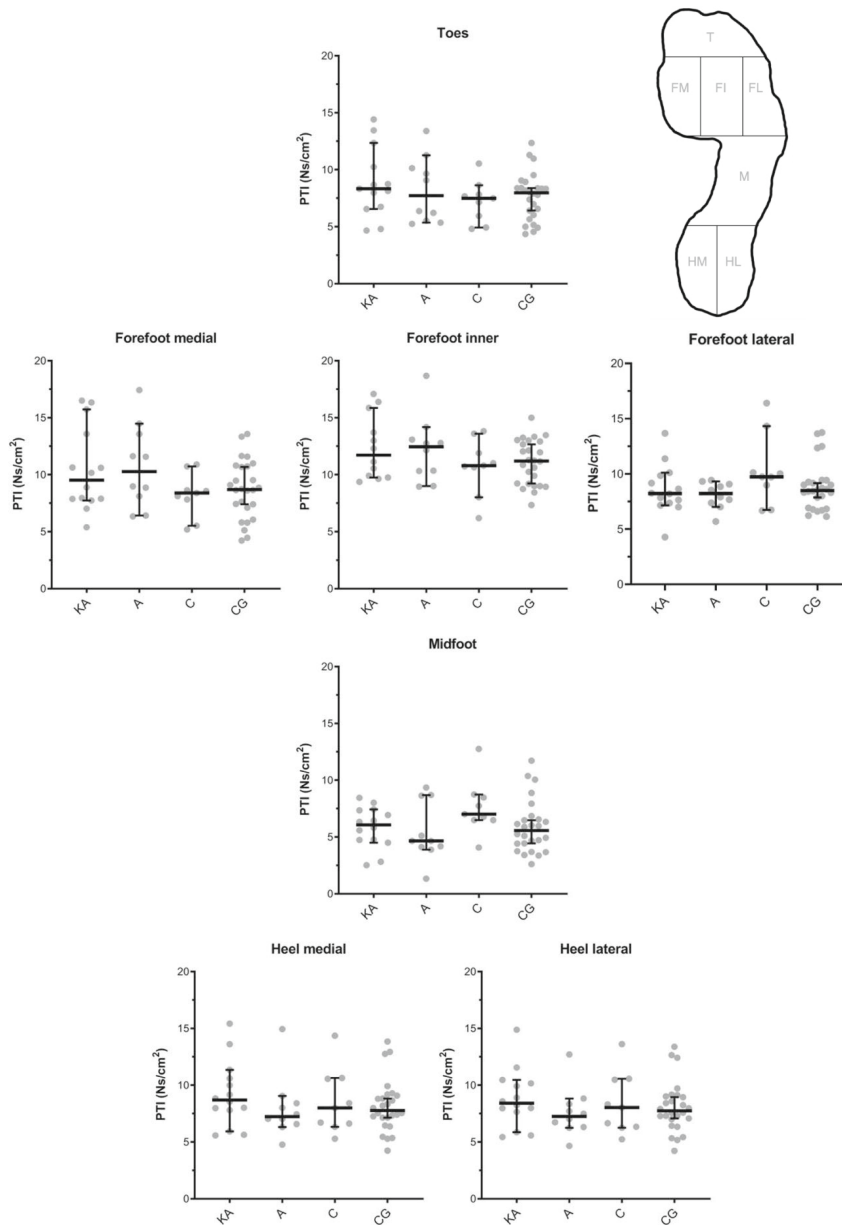


Figure 2: Pressure time integrals (PTIs) of the Keller's arthroplasty (KA), Arthrodesis (A), Cheilectomy (C) and Control group (CG) in 7 foot zones as shown in Figure 1. Results were presented as median and 95% confidence interval, with individual values.

* All interventions were within each foot zone statistically compared to each other (i.e., KA vs. A, KA vs. C, KA vs. CG, A vs. C, A vs. CG, C vs. CG) and no significant differences were detected ($P > 0.05$).

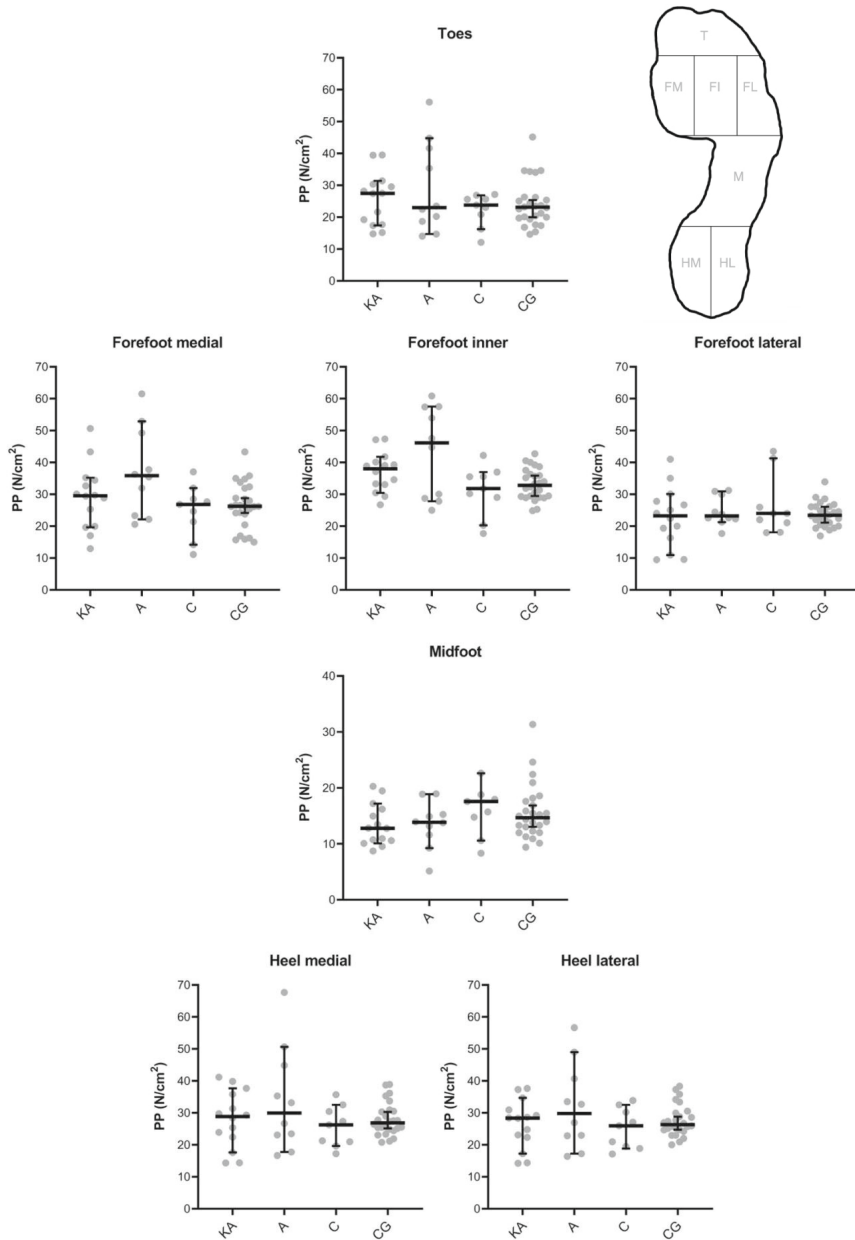


Figure 3: Peak Pressures (PPs) of the Keller's arthroplasty (KA), Arthrodesis (A), Cheilectomy (C) and Control group (CG) in 7 foot zones as shown in Figure 1. Results were presented as median and 95% confidence interval, with individual values.

* All interventions were within each foot zone statistically compared to each other (i.e., KA vs. A, KA vs. C, KA vs. CG, A vs. C, A vs. CG, C vs. CG) and no significant differences were detected ($P > 0.05$).

Table 3: Manchester-Oxford Foot Questionnaire (MOXFQ) results of the different surgical interventions.^{a,b}

	Keller's arthroplasty	Arthrodesis	Cheilectomy
Walking/standing	24.1 ± 33.7 (0-89.3)	21.4 ± 33.0 (0-71.4)	21.4 ± 24.0 (0-57.1)
Pain	21.3 ± 24.0 (0-70.0)	16.5 ± 20.3 (0-50.0)	22.2 ± 22.7 (0-65.0)
Social interaction	31.3 ± 29.9 (0-100.0)	23.8 ± 27.0 (0-68.8)	35.4 ± 31.7 (0-100.0)
Index score	25.0 ± 28.4 (0-81.3)	20.5 ± 26.0 (0-62.5)	25.2 ± 24.5 (0-70.3)

^a Mean ± standard deviation presented and range in parentheses.

^b Table represents the scores on each domain and the overall index score, whereas a score of 0 represents the best outcome and 100 the poorest outcome.

* All groups were statistically compared to each other and no statistically significant differences were detected ($P>0.05$).

Discussion

The aim of this comparative study was to evaluate the long-term effects of Keller's arthroplasty, arthrodesis and cheilectomy on gait, plantar pressure distribution and clinical outcome of patients treated for hallux rigidus. The present study did not find differences based on effect-sizes and statistical analysis in spatio-temporal parameters nor for the plantar pressure analysis (PTIs and PPs) in foot zones and PROMs in patients treated for HR 22-years after surgery.

This is the first comparative pedobarographic study that evaluates Keller's arthroplasty, arthrodesis and cheilectomy as frequently performed surgical interventions for HR. Multiple studies have reported improvements in clinical outcome and patient satisfaction after all three surgical techniques [8-11]. For this reason, gait studies, such as pedobarographic studies are in particular relevant, since they can elaborate if satisfaction or complains after follow-up can be explained by locomotor alternations or inefficiencies [22,27]. Pressure time integral and peak pressure are the most widely used variables for assessment of plantar loading in pedobarographic studies [20-22].

A limited number of studies are available evaluating plantar pressure of one of the three interventions (Keller's arthroplasty, arthrodesis, cheilectomy), while no study comparing all three interventions, is currently available [12-17]. Four studies reported previously pedobarographic results after MTP1 arthrodesis [12-15]. Two of them compared pre- to postoperative differences and reported a statistically non-significant increase of PPs under the metatarsal heads [12,13]. Two other studies evaluating plantar pressure postoperatively, reported a statistically significant increase in PP beneath the first metatarsal head compared to the contralateral foot after 47-months of follow-up [14], while the other only detected a statistically significant increase in PP beneath the second to fifth metatarsal head compared to healthy controls after 27-months of

follow-up [15]. These studies show heterogeneity in methodological design, including the comparator groups and follow-up periods. Compared to the presented study are beneath the metatarsal heads (i.e., medial and inner forefoot zone) higher pressures observed after MTP1 arthrodesis compared to healthy controls. However, the effects sizes of PTI are small and not significant different, indicating that total load exposure of a plantar area during stance was comparable. Therefore, total load exposure during stance in a plantar foot zone seems to be similar to healthy controls.

Pedobarographic results after cheilectomy were reported by two studies previously and showed a slight but not significant increased pressures beneath the first and second metatarsal head and decreased pressure beneath the phalanx [16,17]. Besides, comparable results of both studies, differences in methodology remain, since one study compared the affected foot to the unaffected foot at 2-years follow-up [16], while the other compared pre- to postoperative hallux rigidus results after 2-years follow-up [17]. Therefore, study design (i.e., longitudinal vs. cross-sectional) and comparator group remains different between both studies. Compared to the present study, also no differences in effect sizes nor significant differences in PTIs and PPs between cheilectomy subjects and healthy controls were observed.

Only one study evaluated pedobarographic results after Keller's arthroplasty after 20-years of follow-up [10]. Solely plantar pressure data of the hallux and toes 2 to 5 were reported and results showed a decreased PP beneath the hallux and increased PP in toes 2 to 5, compared to healthy controls [10]. No statistical analyses were performed and plantar pressure data of the other zones were not reported. In the present study effect sizes were small and no statistically significant differences in PP and PTI beneath the toes were observed compared to healthy controls 22-years after surgery. Based on the present study results and results of previous published studies, it is suggested that after Keller's arthroplasty, arthrodesis and cheilectomy as surgical interventions for HR does not have a major impact on plantar pressure distribution in the foot. After surgery, the biomechanics related to foot loading are not sufficiently influenced. While plantar pressure distribution is not sufficiently influenced, differences in compensation in kinematics and kinetics could still exist [8,12,17]. Future studies are recommended to elucidated these effects and observe the impact on gait.

In the present study, no differences were observed in the foot-specific PROMs (MOXFQ) between the surgical interventions after 22-years of follow-up. Clinically important differences between the groups were below the minimally clinically important difference (MCID) values of: 16 for walking/ standing, 12 for pain and 24 for social interaction domain [24]. Four studies have previously investigated the MOXFQ after HR surgery. Compared to the present study, Keller's arthroplasty showed better outcomes after 6-months follow-up [28], whereas comparable results were observed after cheilectomy (17 and 50-months) [29,30], while better results were observed in the present study for

arthrodesis compared to a previous arthrodesis study with 10-months follow-up [31]. The results suggest that cheilectomy and Keller's arthroplasty showed better outcomes at short term, while improved outcomes after arthrodesis are observed at long-term follow-up. A comparable trend was observed within the original study performed after 7-years of follow-up [11]. The results of the present study indicate that patient's function is similar 22-years after surgery, irrespective to the performed surgery. This supports the finding that also no difference in spatio-temporal gait parameters and pedobarographic assessment were observed. This is an interesting observation, as for the last few decades there has been an increasing preference to perform cheilectomies and arthrodesis over Keller's arthroplasty in HR patients. The preferences raised due to the fact that Keller's arthroplasty results in a nonfunctional first ray, which is basically the cause of several complications such as, cock-up deformity, limitation of active flexion and a floppy toe [32]. Therefore, Keller's arthroplasty was less favorable for the fear of having a nonfunctional first ray, which could result in pain and functional limitations [12,13].

Correlation analysis was performed between pedobarographic results and clinical outcome. With the numbers available, no substantial associations were observed comparing PTI forefoot and the MOXFQ domains in each intervention group. Therefore, no relation between PROMs and pedobarographic results was observed. Predicting plantar pressure in the forefoot based on PROMs and vice versa is currently not reliable for clinical practice based on the present study results.

Besides the assessment after long-term follow-up evaluation, pedobarographically and clinically of the three most commonly used interventions for HR, we acknowledge that this study has some limitations. A limited number of subjects per intervention were available for follow-up resulting in a small sample size. All available participants at follow-up were included, however a substantial part of the initial cohort was not available for follow-up. As already mentioned, 23% of patients was deceased, 8% was loss to follow-up and 32% was not able or willing to participate. The high drop-out rate is a commonly reported problem in HR follow-up studies, since HR mainly affects middle-aged to elderly individuals, therefore a substantial part of the patients may be deceased at long-term follow-up [3,5,8]. Furthermore, subjects should be able to walk individually barefooted in gait studies, which is an additional demand for elderly individuals participating in this kind of studies. This was also the case in the present study, since a major part (32% of patients), was not willing or able to participated since they did not walk or could not walk individually due to their progressed age. Based on the limited number of subjects in the present long-term follow-up study, underpowering cannot be ruled out. Therefore, effect sizes were reported to present the magnitude of observed differences between the groups and to facilitated the decision whether a clinically relevant effect was found [33,34]. To accompany the effect sizes, statistical analyses was additionally performed. Furthermore, no major

foot deviations or additional foot surgery was performed until follow-up evaluation. This study was limited in the evaluation of other comorbidities at the musculoskeletal system, which are not uncommon in this elderly population evaluated after long-term follow-up. Despite the limitations, this study is of additive value since it evaluates gait, plantar pressure and PROMs of the three most performed surgical interventions for HR after a very long-term after surgery.

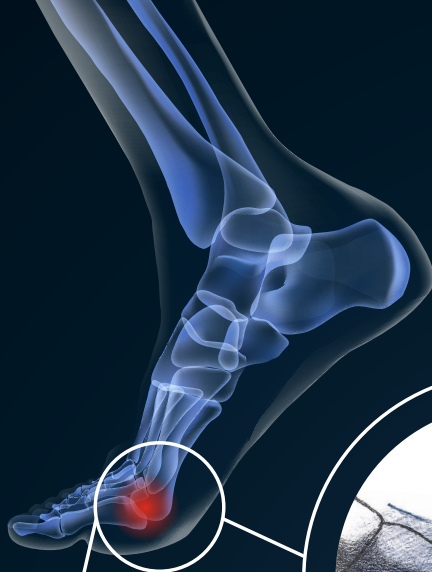
Conclusion

The present study, showed trends of comparable effect sizes, without clinically relevant differences on spatio-temporal parameters, plantar pressure analysis and PROMs after Keller's arthroplasty, arthrodesis and cheilectomy 22-years after surgery. Proper preoperative staging of HR is essential since cheilectomy is predominantly recommended for patients with mild to moderate HR (grade 1 and 2) and Keller's arthroplasty and arthrodesis is predominately used in more progressed HR (grade 2 and 3). The present study results suggest that Keller's arthroplasty, arthrodesis and cheilectomy are appropriate surgical treatments for a selective group of patients suffering from a symptomatic hallux rigidus and patients function to a comparable level after long-term follow-up. Further research is recommended to approve the observation in the present study after such long-term follow-up.

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CHAPTER 6

Metallic hemiarthroplasty or arthrodesis of the first metatarsophalangeal joint as treatment for hallux rigidus: a systematic review and meta-analysis

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Abstract

Background

Arthrodesis and metallic hemiarthroplasty are two surgical options for the treatment of end-stage osteoarthritis of the first metatarsophalangeal (MTP1) joint. This systematic review and meta-analysis aim to compare the two operations with regards to patient-reported outcomes, pain reduction, complications and revision rates.

Methods

A systematic literature search identified all relevant studies. The methodological quality was assessed using two validated tools. Data of interest were derived and presented. For non-comparative studies, data was assessed for trends, while for comparative studies pooling statistics were performed.

Results

A total of 33 studies were included for analysis. The majority of studies (>75%) reported an AOFAS-HMI score greater than 80 points after both metallic hemiarthroplasty and arthrodesis. The lowest VAS pain score was observed after arthrodesis (weighted mean difference -1.58, 95% confidence interval (CI) -2.16 to -1.00 $P<0.00001$). Comparable numbers of complications (odds ratio 1.48, 95% CI 0.81 to 2.73, $P=0.21$, favoring: hemiarthroplasty) and revisions (odds ratio 1.16, 95% CI 0.62 to 2.15 $P=0.64$, favoring: hemiarthroplasty) were observed after both interventions.

Conclusion

Metallic hemiarthroplasty and arthrodesis have excellent clinical outcomes and acceptable complication- and revision rates. Arthrodesis seems to be superior in pain reduction, while metallic hemiarthroplasty is a suitable alternative for patients performing activities that requires motion in the first metatarsophalangeal joint.

Introduction

The first metatarsophalangeal (MTP1) joint is the most common joint in the foot affected by degenerative osteoarthritis (OA), which is referred to as hallux rigidus (HR) [1,2]. Operative treatments are inevitable when nonoperative treatments are not sufficient. Several surgical procedures have been proven to be successful; however, the optimal procedure for an individual patient depends on disease severity, patient's age and physical demands of the patient [3,4]. Arthrodesis and arthroplasties are generally reserved for a more severe degree of MTP1 osteoarthritis [5]. Currently, MTP1 arthrodesis is considered to be the golden standard for treatment of an end-stage osteoarthritis of MTP1 [1,4,6]. Although patient satisfaction with arthrodesis is high, there are some disadvantages to the procedure such as loss of joint motion, metatarsalgia, painful hardware and the risk of nonunion [5,7,8]. In particular, loss of motion is a potential issue for those who are young and live an active lifestyle. Limited MTP1 joint motion limits subjects in recreational activities such as playing sports (e.g., running), wearing high-heeled shoes and performing occupations, that require activities such as kneeling or squatting [5,9]. Therefore, there is still interest towards surgical options as an alternative for arthrodesis. Total joint arthroplasty and (metallic) hemiarthroplasty are well-known alternatives, which have the advantage of restoring MTP1 joint motion [9].

Recent short- to mid-term follow-up studies reported comparable or superior results after metallic hemiarthroplasty compared to arthrodesis in terms of clinical outcome, and complications and revisions [7,10,11]. Currently, no systematic review with a quantitative overview on the comparison between MTP1 metallic hemiarthroplasty and MTP1 arthrodesis is available for the treatment of HR. Therefore, this systematic review and meta-analysis aims to compare MTP1 metallic hemiarthroplasty to MTP1 arthrodesis with regards to the clinical outcome, reduction of pain and number of complications and revisions in the treatment of patients with HR.

Methods

The present systematic review and meta-analysis was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement [12]. The search was conducted in PubMed/Medline, Embase, Web of Science and Cochrane library. The search consisted of terms related to disorder ('Hallux Rigidus', 'Hallux Limitus' or 'First metatarsophalangeal joint') and the interventions ('Hemiarthroplasty', 'Arthroplasty', 'Arthroplasty replacement', 'Replacement prosthesis', 'Prosthesis', 'Joint implant', 'Arthrodesis' or 'Joint fusion'). An additional filter was applied, which enabled us to directly filter out all hallux valgus studies investigating the interventions of interest. This was done in order to specify the search

towards interventions only performed for hallux rigidus. No restrictions on publication date were applied to the search strategy. The final search was performed at September 11th 2020.

Inclusion and exclusion criteria were developed using the participants, interventions, comparators, outcomes timing and study design (PICOTS) framework. Participants must have been treated for symptomatic hallux rigidus, and studies of participants treated for hallux valgus or inflammatory arthropathy were excluded. Furthermore, the participants in the eligible studies were treated with a metallic MTP1 hemiarthroplasty or MTP1 arthrodesis. Studies describing non-metallic MTP1 arthroplasty implants, silicone implants, total joint implants, interpositional arthroplasty or other operative treatments for HR (e.g., Keller's arthroplasty, cheilectomy) were excluded. A comparative group in an original article was not mandatory. Studies that evaluated only MTP1 arthrodesis or metallic MTP1 hemiarthroplasty were also considered eligible. The most frequent reported outcomes including American Orthopaedic Foot & Ankle Society Hallux Metatarsophalangeal-Interphalangeal (AOFAS-HMI) score, Visual Analogue Scale (VAS) for pain, Foot Function Index (FFI), Manchester-Oxford Foot Questionnaire (MOXFQ) and Short Form-36 (SF-36) were considered as primary outcomes. Secondary outcomes included: the number and nature of the occurred complications and revisions, as well as the results of radiological evaluation and clinical examination of the range of motion (ROM). Solely studies investigating at least 10 feet with a minimum mean follow-up duration of 12 months were considered eligible. No restrictions regarding study design were applied. Finally, only original scientific papers were included. Relevant studies retrieved using the initial search were screened based on titles and abstracts for eligibility. Subsequently, full-text article screening was performed on the potentially eligible studies. When it was evident that a follow-up study was published, only the study with the longest follow-up was included. Two reviewers (RdB and RE) conducted the initial search and study selection process independently and discrepancies were resolved by discussion and consultation of a third reviewer (HV).

Data of interest, including study characteristics (i.e., author, year of publication, journal, study design, setting, indication, intervention comparison, type of hemiprosthesis or arthrodesis fixation technique, duration of follow-up, enrolment period) and characteristics of the patients (i.e., number of participants, number of feet and age), as well as the outcomes of interest, were extracted.

The methodological quality of the included studies was assessed. Case series or cohort studies evaluating one of the interventions, or comparing one of the interventions to an intervention outside the scope of this study were assessed using the Methodological Index for Non-Randomized Studies (MINORS) tool [13]. The 8 items of the MINORS were scored with 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The score ranges between 0 points (lowest quality) and 16 (highest quality).

Furthermore, the studies were qualified according to the following quartiles: very low quality (0-4), low quality (5-8), moderate quality (9-12) and high quality (13-16) according to previous studies [14,15]. Comparative studies, comparing metallic hemiarthroplasty to arthrodesis, were assessed using the Risk of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool [16,17]. ROBINS-I is the preferred tool for assessing methodological quality in comparative non-randomized studies according to the Cochrane methods for systematic reviews [16,17]. The 7 items were scored according to low, moderate, serious or critical risk of bias if reported. Thereafter an overall judgement was made [16]. The data extraction and quality assessment process were performed independently by two reviewers (RdB and RE). Inconsistencies in the data extraction process and critical appraisal were resolved by discussion and consultation of a third reviewer (HV) until consensus was reached.

The characteristics and reported mean outcomes of each included study were presented as an overview.

In case an individual study reported the median instead of the mean, the median value was presented and considered to be an estimator of the mean in normally distributed data, which is mostly the case for clinical outcomes [18].

Synthesis of results for non-comparative studies was done by assessing potential trends along the reported outcomes of individual studies. For comparative studies, data pooling was performed of the reported outcomes. If a comparative study did not report values for standard deviation (SD), the mean SD of all other studies in the meta-analysis was applied for this study. This was done for enabling pooling with the particular study and for preventing loss of valuable data. In the pooling process, weighted mean differences (WMDs) were calculated for continuous variables and odds ratios (ORs) for dichotomous outcome measures. The 95% confidence intervals (CIs) were calculated for each outcome as well. A chi-squared test was used to measure heterogeneity quantified by I^2 . Synthesis of results was done by pooling according to the fixed-effects model for analyses with a low level heterogeneity ($I^2 < 50\%$), otherwise pooling was performed according to the random-effects model ($I^2 \geq 50\%$) [19]. The level of statistical significance was set at $P < 0.05$. Finally, the occurrence of publication bias along studies was evaluated by visual assessment of a funnel plot. All statistical analyses of this study were performed in Revman Review Manager (Revman 5.3; The Nordic Cochrane Centre, Cochrane Collaboration, Copenhagen, Denmark, 2014).

Results

Study selection

The initial search, reasons for exclusion and final selection of studies are presented in Figure 1. A total of 33 articles were considered eligible for inclusion in this systematic review.

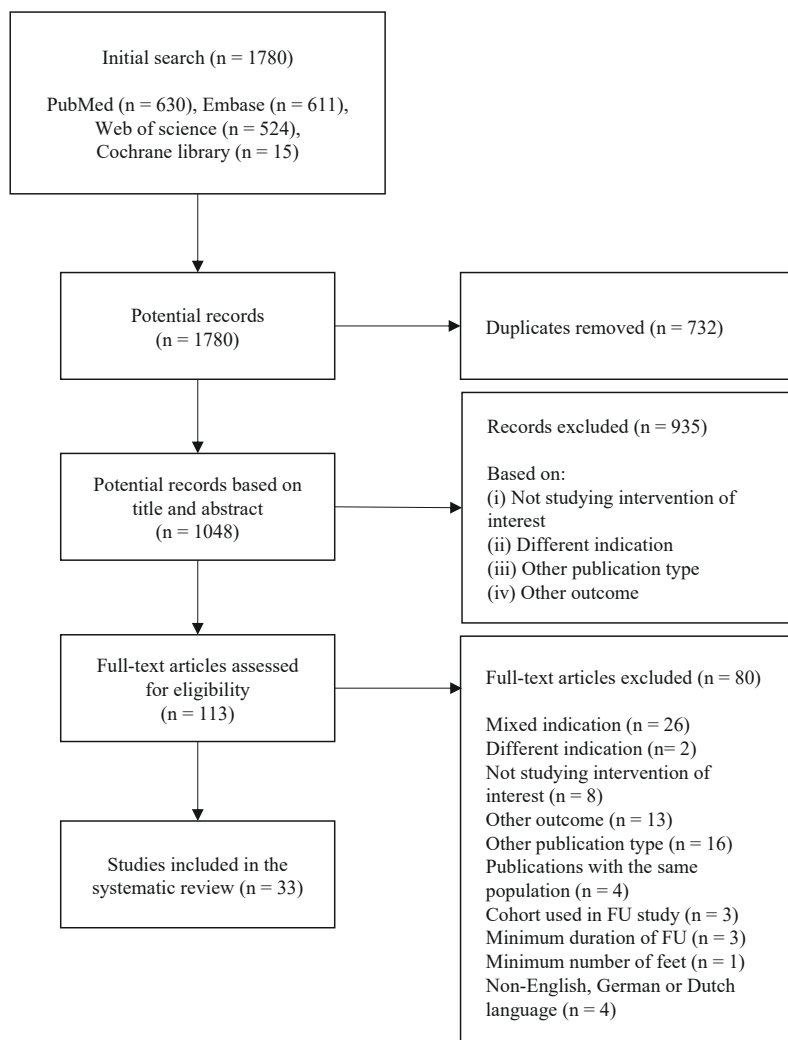


Figure 1: Flowchart of the study selection process.

Study characteristics

From the 33 included studies, 16 studies solely studied MTP1 metallic hemiarthroplasties [5,9,20-33], 11 investigated MTP1 arthrodesis [34-44] and 6 compared both interventions [7,8,10,11,45,46]. An overview of the characteristics of the included non-comparative and comparative studies are presented in Table 1 and Table 2 respectively. Although symptomatic HR was the indication for all surgical interventions, several studies (22/33) reported the severity of HR according to several grading systems [23,37,47-49]. A female predominance was observed in nearly all studies on both metallic hemiarthroplasty and arthrodesis. The mean age at time of surgery ranged between 49.5 years to 63 years [5,7-11,20-46]. Of the studies describing one intervention, 15 had a mean follow-up between 1 to 5 years [9,20,21,23,24,26,29,30,33,36,38-40,43,50] and 12 studies reported a longer mean follow-up [5,22,25,27,28,31,32,34,37,41,42,44]. A follow-up of more than 5 years for both interventions was only performed for one comparative study [10], while in another comparative study solely the metallic hemiarthroplasty group had a longer follow-up period of 5 years [8]. Eleven studies used a metallic hemiprosthesis wherein the first metatarsal head was resurfaced (i.e., HemiCAP®, Arthrosurface Inc. Franklin, MA) [5,20,21,23-26,29-31,33], while five studies used a hemiprosthesis wherein the base of the proximal phalanx was resurfaced including BioPro® (Biopro Corporation, Port Huron, MI), Swanson® (Wright medical technologies, Arlington, TN), Futura® (Tournier Inc., Edina, MN) and Trihedron® (Small bone innovations, New York, NY) [9,22,27,28,32]. Four of the six comparative cohort studies [7,8,10,11] reported the use of the proximal phalanx implant (i.e., BioPro). For the arthrodesis, several techniques were used for fusion of MTP1 including: plate fixation [7,36,37], screw fixation [8,38,40,41,43-45], cerclage fixation with Kirschner wires [42], or a combination of these techniques [10,11,34,35,39,46].

Table 1: Study characteristics of the included studies solely describing hemiarthroplasty or arthrodesis as an intervention in the treatment of hallux rigidus.

Author and publication year	Journal	Study design (level of evidence)	Setting	Indication	Intervention comparison	Type of Hemiprosthesis or Arthrodesis	No. of participants (M/F)	No. of feet (L/R/Both)	Age [years]	Duration of FU [months]	Enrolment period
Hemiarthroplasty studies	Konkel 2006 [27]	Foot Ankle Int	Retrospective case series (IV)	NR	Symptomatic HR grade II-III†	HA	Swanson Hemi-great toe implant	13	53.0 (42-60)	66.0 (37-105)	February 1995 - July 1998
	Sorbie 2008 [32]	Foot Ankle Int	Prospective case series (IV)	NR	Symptomatic HR	HA	Trihedron implants	19 (9/10)	M: 51.6 (41-61) F: 53.0 (35-70)	68.0 (34-72)	June 2000 - October 2001
	Konkel 2009 [28]	Foot Ankle Int	Retrospective case series (IV)	NR	Symptomatic HR grade III-IV†	HA	Futura hemi-great toe implant	23 (6/17)	62.0	72.0 (54-95)	April 2000 - August 2003
	Giza 2010 [9]	Int Orthop	Prospective case series (IV)	NR	Symptomatic HR grade III-IV§	HA	BioPro® First MPJ	20 (7/13)	61.0 (46-80)	24.0	NR
	Aslan 2012 [20]	Acta Orthop Traumatol Turc	Prospective case series (IV)	NR	Symptomatic HR grade III-IV§	HA	HemiCAP®	25 (6/19)	58.0 (40-71)	37.6 (30-43)	March 2007 - April 2008
Arthrodesis studies	Dos Santos 2013 [23]	Acta Orthop Bras	Prospective case series (IV)	NR	Symptomatic HR II-III*	HA	HemiCAP®	11 (5/6)	51.9 ± 1.1 (46-58)	44.8 ± 1.7 (36-48)	June 2008 - May 2009
	Kline 2013 [26]	Foot Ankle Int	Prospective case series (IV)	NR	Symptomatic HR grade II-III†	HA	HemiCAP®	26	51.0 (35-74)	27.0 (17-38)	2005 - 2006
	Gheorghiu 2015 [24]	J Foot Ankle Surg	Retrospective case series (IV)	NR	Symptomatic HR grade II§	HA	HemiCAP®	11 (4/7)	NR	47.0 (36-48)	March 2007 - March 2008
	Meric 2015 [29]	J Foot Ankle Surg	Prospective case series (IV)	Single center	Symptomatic HR grade III-IV§	HA	HemiCAP®	14 (5/9)	58.7 ± 7.4 (52-75)	24.2 ± 7.2 (12-36)	March 2010 - September 2012
	Circi 2016 [21]	Musculoskelet Surg	Retrospective case series (IV)	NR	Symptomatic HR grade III-IV§	HA	HemiCAP®	12 (5/7)	62.3 ± 6.1 (48-72)	22.3 ± 12.9 (12-54)	March 2010 - October 2013

Table 1: (continued)

Author and publication year	Journal	Study design (level of evidence)	Setting	Indication	Intervention comparison	Type of Hemiprostheses or Arthrodesis	No. of participants (M/F)	No. of feet (L/R/Both)	Age [years]	Duration of FU [months]	Enrolment period
Clement 2016 [22]	Bone Joint J	Retrospective case series (IV)	NR	Symptomatic HR II-III**	HA	BioPro® First MPJ	80 (19/61)	97	M: 54.4 ± 11.2 F: 55.7 ± 9.7	64.8 (56-98)#	2008 - 2010
Hemiarthroplasty studies											
Mermerkaya 2016 [30]	Clin Interv Aging	Retrospective comparative cohort study (III)	Two centers	Symptomatic HR grade II-III†	HA vs. TJR	HemiCAP®	26 (12/14)	28 (12/12/2)	56.3 ± 4.5 (47-63)	29.9 ± 5.2	2012 - 2014
Hilario 2017 [5]	J Foot Ankle Surg	Retrospective case series (IV)	Multi center	Symptomatic HR grade II-III†	HA	HemiCAP®	42	45	57.4 (33-86)	117.7 ± 14.3 (96-143)	January 2005 - December 2009
Mermerkaya 2018 [31]	Foot Ankle Spec	Retrospective case series (IV)	Single center	Symptomatic HR grade II-III†	HA	HemiCAP®	57 (25/32)	65 (27/22/8)	61.0 ± 6.4 (44-78)	81.0 (8-98)#	August 2007 - September 2010
Uzer 2018 [33]	Bezmialem Science	Retrospective case series (IV)	Single center	Symptomatic HR	HA	HemiCAP®	19 (4/15)	21 (9/12)	56.0 (47-73)	24.0 (12-66)	January 2013-December 2015
Jorsboe 2019 [25]	Foot Ankle Surg	Retrospective comparative cohort study (III)	Multi center	Symptomatic HR	HA vs. HC	HemiCAP®	41 (10/31)	45	61.0 (47-78)#	60.0 (12-84)	2007 - 2014

Table 1: (continued)

Author and publication year	Journal	Study design (level of evidence)	Setting	Indication	Intervention comparison	Type of Hemiprosthesi or Arthrodesis	No. of participants (M/F)	No. of feet (L/R/Both)	Age [years]	Duration of FU [months]	Enrolment period
Lombardi 2001 [40]	J Foot Ankle Surg	Retrospective case series (IV)	NR	Symptomatic HR grade II-IV‡	A	2 crossed screws	17 (7/10)	21	53.2 (36-77)	28.1 (10-66)	1994 - 1999
Defrino 2002 [38]	Foot Ankle Int	Prospective case series (IV)	NR	Symptomatic HR	A	2 parallel cortical screws	9 (4/5)	10	56.0 (38-72)	34.0 (26-44)	NR
Coughlin 2003 [37]	Bone Joint J	Retrospective comparative cohort study (III)	NR	Symptomatic HR grade III-IV§	A vs. C	Vitalium 6-hole mini-compression plate fixed and lag screw	30	34	50.0 (16-76)	80.4 (25-146)	November 1981 - November 1999
Arthrodesis studies											
Etti 2003 [39]	Int Orthop	Retrospective case series (IV)	NR	Symptomatic HR grade III§	A	2 crossed screws or Kirschner wires with wire sutures	34 (7/27)	38	52.0 (24-71)	54.0 (18-116)	1989 - 1999
Aas 2008 [34]	The Foot	Retrospective case series (IV)	NR	Symptomatic HR	A	Various techniques	35 (14/21)	39	52.0 (34-69)	96.0 (24-180)	1990 - 2002
Wassink 2009 [44]	J Foot Ankle Surg	Retrospective case series (IV)	Single center	Symptomatic HR	A	Single lag compression screw	89 (19/70)	109 (47/62)	59.0 ± 10.0 (41-82)	69.0 (7-114)	1996 - 2005
van Doeselaar 2010 [43]	Foot Ankle Int	Prospective case series (IV)	NR	Symptomatic HR	A	2 crossed screws	27 (9/18)	27	58.0 (42-72)#	37.0 (14-54)#	January 2002 - December 2005
Baumhauer 2016 [35]	Foot Ankle Int	Prospective RCT (I)	Multi center	Symptomatic HR grade II-IV§	A vs. SCI	2 crossed screws or plate-screw fixation	50 (12/38)	50	54.9 ± 10.5 (32.4-78.2)	24.0	October 2009 - July 2012

Table 1: (continued)

Author and publication year	Journal	Study design (level of evidence)	Setting	Indication	Intervention comparison	Type of Hemiprostheses or Arthrodesis	No. of participants (M/F)	No. of feet (L/R/Both)	Age [years] (55-81)	Duration of FU [months]	Enrolment period
Arthrodesis studies	Chraim 2016 [36]	Int Orthop	Retrospective case series (IV)	NR	Symptomatic HR grade III†	A	60 (6/54)	61	68.5 (55-81)	47.3 (39-56)	December 2006 - April 2009
	Stone 2017 [42]	Foot Ankle Int	RCT (I)	Single center	Symptomatic HR	A vs. TJR	30	30	54.2 ± 10.6 (34-77)	182.4 (166- 206)	November 1998 - January 2001
	Stevens 2020 [41]	Foot Ankle Int	Retrospective comparative cohort study (IV)	Single center	Symptomatic HR	A vs. C vs. KA	12 (4/8)	16	49.5 ± 9.9 (34-68)	276.0 ± 45.6 (228-348)	1990 - 2000

Unless otherwise stated, the values are given as mean with or without standard deviation and/or range in parentheses.
The values are given as median, with or without range in parentheses.

HR grading system according to: § Coughlin and Shurnas [37]; †Hattrup and Johnson [47]; ‡ Regnaud [48]; * Kravitz [23]; ** Menz [49].

Abbreviations: HR, hallux rigidus; HC, healthy controls; A, arthrodesis; HA, hemiarthroplasty; KA, Keller's arthroplasty; C, cheilectomy; TJR, total joint replacement; SCI, synthetic cartilage implant; M, male; F, female; L, left; R, right; FU, follow-up; RCT, randomized control trial; vs., versus; NR, not reported.

Table 2: Study characteristics of the included studies comparing hemiarthroplasty versus arthrodesis in the treatment of hallux rigidus.

Author and publication year	Journal	Study design (level of evidence)	Setting	Indication	Intervention comparison	Fixation technique A	Type of HA	No. of participants			No. of feet (L/R)			Age [years]			Duration of FU [months]			Enrolment period
								A (M/F)	HA (M/F)	Total	A (L/R)	HA (L/R)	A	HA	A	HA	A	HA		
Raikin 2007 [8]	J Bone Joint Surg Am	Retrospective comparative cohort study (III)	NR	Symptomatic HR grade III-IV§	A vs. HA	2 crossed screws	BioPro® First MPJ	26 (10/16)	20 (6/14)	46	27 (14/13)	21 (10/11)	54.1 (32-73)	59.7 (39-70)	79.2 (68.0-85.7)	30.0 (13-67)	30.0 (13-67)	79.2 (68.0-85.7)	January 1999 - April 2005	
Kim 2012 [46]	J Foot Ankle Surg	Retrospective comparative cohort study (III)	Multi center	Symptomatic HR grade III-IV§	A vs. HA vs. RA	Various techniques	Various brands	51 (20/31)	52 (20/32)	103	51	52	60.5 ± 9.7 (36-84)	61.4 ± 7.5 (45-85)	43.4#	44.8#	43.4#	NR	NR	
Erdli 2013 [45]	J Foot Ankle Surg	Retrospective comparative cohort study (III)	Two centers	Symptomatic HR grade III-IV§	A vs. HA vs. TJR	2 compression screws	HemiCAP®	12 (4/8)	14 (5/9)	26	12 (7/5)	14 (7/7)	58.2 ± 8.5	58.2 ± 6.1	30.2 (24-42)	35.3 (24-66)	30.2 (24-42)	2006 - 2010	2006 - 2010	
Simons 2015 [7]	J Foot Ankle Surg	Retrospective comparative cohort study (III)	Two centers	Symptomatic HR	A vs. HA	Hallux plate	BioPro® First MPJ	132	46	178	135	49	59.6 ± 9.5	61.9 ± 8.4	38.4 (13-94)#	41.5 (13-98)#	38.4 (12-94)#	January 2005 - March 2012	January 2005 - March 2012	
Voskuil 2015 [11]	J Foot Ankle Surg	Retrospective comparative cohort study (III)	Single center	Symptomatic HR	A vs. HA	Various techniques	BioPro® First MPJ	50 (8/42)	33 (8/25)	83	58 (26/32)	36 (15/21)	63.0 ± 7.1 (47-78)	60.0 ± 6.6 (42-74)	42.0 (16.8-80.4)#	52.8 (16-84)#	42.0 (16.8-80.4)#	January 2005 - December 2010	January 2005 - December 2010	
Beekhuizen 2018 [10]	J Foot Ankle Surg	Retrospective comparative cohort study (III)	NR	Symptomatic HR grade III-IV§	A vs. HA	Various techniques	BioPro® First MPJ	39 (8/31)	27 (10/17)	66	47	31	62.3 ± 7.7 (47-78)	58.3 ± 6.9 (36-67)	92.9 ± 19.9 (61-141)	103.2 ± 25.9 (61-141)	92.9 ± 19.9 (62-136)	January 2005 - December 2011	January 2005 - December 2011	

Unless otherwise stated, the values are given as mean with or without standard deviation and/or range in parentheses.

The values are given as median, with or without range in parentheses.

§ HR grading system developed by Coughlin and Shurnas [37], all other studies did not grade HR.

Abbreviations: HR, hallux rigidus; A, arthrodesis; HA, hemiarthroplasty; TJR, total joint replacement; RA, resectional arthroplasty; M, male; F, female; L, left; R, right; FU, follow-up; vs., versus; NR, not reported.

Table 3: Primary and secondary clinical outcomes of the individual hemiarthroplasty and arthrodesis studies.

	Clinical outcome	Pre	FU	Δ	Reported complications	Revisions
Hemiarthroplasty	Konkel 2006 [27]	AOFAS-HMI	86.5 (70-95)		10.0% (1/10) transfer metatarsalgia to second toe, 10.0% (1/10) hyperextension of the great toe	10.0% (1/10) transfer metatarsalgia to second toe treated with Weil osteotomy, 10.0% (1/10) developed a scar contracture with hyperextension of the great toe treated with Z arthroplasty
	Sorlie 2008 [32]	AOFAS-HMI	56.8 ± 14.4	+31.4	Hematoma (results not reported)	4.3% (1/23) revision performed (operation NR) due to worsening of a tendency to HV
	Konkel 2009 [28]	AOFAS-HMI	19.0 (17-50)	+70.0	8.0% (2/25) transfer metatarsalgia postoperative, 8.0% (2/25) mild clawing of great toe postoperative, 16.0% (4/25) reported pain complaints at FU, 68.0% (17/25) a recurrence of dorsal osteophytes was observed at FU	None
	Giza 2010 [9]	AOFAS-HMI	61.1 ± 12.7 (35-80)	+25.0	4.5% (1/22) superficial infection postoperative, 13.6% (3/22) postoperative stiffness requiring manipulation under anesthesia	9.1% (2/22) revisions to arthrodesis
	Asian 2012 [20]	AOFAS-HMI	40.9 (25-63)	+44.2	4.0% (1/25) superficial infection postoperative	NR
		VAS	8.3	-6.2		
	Dos Santos 2012 [23]	AOFAS-HMI	32.0 ± 0.0 (32-32)	+45.3	NR	NR
		VAS	6.6 ± 0.2 (6-7)	-5.9		
	Kline 2013 [26]	AOFAS-HMI	51.5 ± 12.6 (35-74)	+42.6	3.3% (1/30) postoperative infection	10.0% (3/30) silastic implants placed, 3.3% (1/30) arthrodesis. Both interventions performed due to phalangeal pathology
		VAS	6.8	-5.4		
		SF-36	MHC: 75.8 (57-91) PHC: 66.7 (40-87)	MHC: +10 PHC: +23.9		
	Gheorghiu 2015 [24]	AOFAS-HMI	66.5 (22-92)		NR	8.3% (1/12) revision to arthrodesis
Arthrodesis	Meric 2015 [29]	AOFAS-HMI	33.9 ± 9.8 (22-59)		None	7.1% (1/14) revision to arthrodesis due to persistent pain and immobility
	Circi 2016 [21]	AOFAS-HMI	49.2 ± 13.1 (30-70)	+31.6	None	25.0% (3/12) required revision surgery due to persistent pain (2 arthrodesis, 1 interposition arthroplasty)

Table 3: (continued)

	Clinical outcome	Pre	FU	Δ	Reported complications	Revisions
Clement 2016 [22]	MOXFQ	53.2 ± 16.5	33.2 ± 16.1	-20.0	NR	15.5% (15/97) revisions (8 arthrodesis, 7 excision arthroplasty), 1.0% (1/97) deep infection treated with excision arthroplasty, 2.1% (2/97) osteolysis treated with arthrodesis, 12.4% (12/97) persistent pain (6 arthrodesis, 6 excision arthroplasty)
Mermerkaya 2016 [30]	AOFAS-HMI VAS	33.0 (22-48) 8.5 (7-10)	87.7 (72-96) 2.0 (1-3)	+54.7 -6.5	3.6% (1/28) superficial infection postoperative	NR
Hilario 2017 [5]	AOFAS-HMI	36.6 ± 12.0	90.6 ± 7.6	+54.0	None	2.4% (1/42) revision to arthrodesis due to persistent pain (a second hardware removal of arthrodesis was also performed due to persistent pain), 2.4% (1/42) underwent cheilectomy for dorsal spurring without removal of the implant
Mermerkaya 2018 [31]	AOFAS-HMI	34.0 (22-59)#	83.0 (26-97)#	+49.0	NR	12.3% (7/57) revisions to arthrodesis due to persistent pain (1.8% (1/57) painless nonunion, no revision performed)
Uzer 2018 [33]	AOFAS-HMI	72.0 (82-92)	96.0 (79-100)	+24.0	NR	9.5% (2/21) revision to arthrodesis, due to persistent pain and joint stiffness
Jorsboe 2019 [25]	VAS	39.1 (10-70)‡	1.81		None	None (these were not included in the study)
Lombardi 2001 [40]	AOFAS-HMI	75.6 (22-90)\$	75.6 (22-90)\$	+36.5	9.5% (2/21) screw irritation/pain (required screw removal)	NR
DeRino 2002 [38]	AOFAS-HMI	38.0 (20-62)	90.0 (74-100)\$	+52.0	14.3% (3/21) nonunion (2 painful, 1 not painful)	NR
Coughlin 2003 [37]	AOFAS-HMI	38.0 (24-60)	89.0 (72-90)	+51.0	10% (1/10) patient with deep-vein thrombosis requiring anti-coagulation therapy	NR
	VAS	8.7 (6-10)	0.4 (0-5)	-8.3	11.8% (4/34) callus interphalangeal joint	None
	AOFAS-HMI	53.0 (5-84)\$	53.0 (5-84)\$		6.7% (2/30) mild postoperative cellulitis requiring antibiotics	None
Etti 2003 [39]	VAS	8.0	2.7 (F)	-5.3	5.9% (2/34) hardware pain (requiring plate removal)	None
					15.8% (6/38) superficial infection postoperative	None
					7.9% (3/38) numbness on dorsum of hallux	None
					21.1% (8/38) persistent mild swelling	None
Aas 2008 [34]	AOFAS-HMI	74.0 ± 15.0	74.0 ± 15.0		10.3% (4/39) nonunion, (3 painful, 1 not painful)	7.7% (3/39) arthrodesis reoperation due to painful nonunion
	VAS	(23-90)#	(23-90)#		12.8% (5/39) hardware removal	
		1.0 ± 2.3 (0-8.4)	1.0 ± 2.3 (0-8.4)			
Wassink 2009 [44]	AOFAS-HMI	50.0 ± 12.0	50.0 ± 12.0		3.7% (4/109) nonunion	4.6% (5/109) required revision surgery (1 malunion, 4 nonunion)
		(10-60)†	(10-60)†		0.9% (1/109) malunion	
van Doeselaar 2010 [43]	VAS	0.5 (0-7.9)#	0.5 (0-7.9)#		78.0% (85/109) screw removal due to pain	None
	FFI	34.0 (0-80)#	34.0 (0-80)#	-29.0	NR	

Table 3: (continued)

	Clinical outcome	Pre	FU	Δ	Reported complications	Revisions
Baumhauer 2016 [35]	VAS	6.9 ± 1.4 (4-10)	0.6 ± 1.2 (0-7)	-6.3	10.0% (5/50) nonunion	
	SF-36	49.8 ± 23.6 (15-100)	85.1 ± 19.5 (5-100)	+35.3	2.0% (1/50) broken screw 14.0% (7/50) isolated screws or plate or screw removal, due to persistent pain	4.0% (2/50) required revisions due to nonunion
	AOFAS-HMI	40.9 ± 18.8	79.3 ± 11.2	+38.4	6.7% (4/60) painless nonunion (no revision operation necessary) 3.3% (2/60) persistent pain requiring implant removal 3.3% (2/60) superficial wound healing disturbances treated with oral antibiotics	
Chralim 2016 [36]	FFI	38.0 (0-80)†	8.0 (0-59)‡	-30.0		Patients were not included in the study
Stone 2017 [42]	VAS		0.5 (0-4)			
	AOFAS-HMI		91.0 ± 6.8 (78-100)§			
Stevens 2020 [41]	VAS		0.7 ± 1.0 (0-3.9)		NR	NR
	MOXFQ		19.6 ± 21.5 (0-63)			3.3% (1/30) revision due to angular malunion

Unless otherwise stated, the values of the clinical outcomes are given as mean with or without standard deviation and/or range in parentheses. Reported complications and revisions are given as percentage and absolute values of the affected toes are described in parentheses. Values in **bold** indicate a statistically significant increase or decrease postoperatively compared to preoperatively $P < 0.05$ as reported by the individual studies.

The values are given as median, with or without range in parentheses.

§ The modified AOFAS-HMI was used in this study. The maximum achievable score was 90 points instead of 100 points, since the ten points which are normally devoted to the range of motion of the first metatarsophalangeal joint were eliminated. Range of motion is sacrificed after MTP1 arthrodesis.

† A modified AOFAS score with a maximum of 60 points were used since, questions regarding first metatarsophalangeal joint and interphalangeal joint motion and stability, callosity formation and alignment of the hallux from the original AOFAS-HMI score was removed.

‡ Retrospective assessment of preoperative values.

Abbreviations: Pre, preoperative; FU, follow-up; Δ, difference; NR, not reported; HV, hallux valgus; MHC, Mental Health Component; PHC, Physical Health Component; AOFAS-HMI, American Orthopaedic Foot & Ankle Society (AOFAS) rating system for the Hallux Metatarsophalangeal-Interphalangeal (HMI); FFI, Foot Function index; MOXFQ, Manchester-Oxford Foot Questionnaire; SF-36, Short Form Health Survey; VAS, Visual Analogue Scale.

Table 4: Primary and secondary clinical outcomes of the individual comparative studies.

	Clinical outcome	Pre	FU	Δ	Reported complications	Revisions
Raikin 2007 [8]	AOFAS-HMI	36.1 (19-62)	93.1\$	+57.0	7.4% (2/27) screw removal due to prominent screw head over the medial aspect of the proximal phalanx	
	A VAS		0.7 ^c		7.4% (2/27) painful plantar callosity under second metatarsal head and instability of the second MTP-joint	None
	HA AOFAS-HMI	35.6	71.8	+36.2	61.5% (8/13) radiological evidence for plantar cut out of the prosthetic stem, 31.3% (5/16) plantar callosities	19.0% (4/21) converted to arthrodesis due to pain and aseptic loosening 4.8% (1/21) revision to hemiarthroplasty due to pain and aseptic loosening
	VAS		2.4			
Kim 2012 [46]	A AOFAS-HMI		90##		9.8% (5/51) metatarsalgia, 7.8% (4/51) nonunion, 7.8% (4/51) malalignment, 3.9% (2/51) interphalangeal joint pain, 2.0% (1/51) delayed union	3.9% (2/51) revision with fusions with bone graft, 2.0% (1/51) without bone graft
	HA AOFAS-HMI		80## ^a		28.8% (15/52) bony overgrowth into the joint, 19.2% (10/52) radiolucency around the implant, 15.4% (8/52) migration of the implant, 11.5% (6/52) dorsal drift of the hallux, 7.7% (4/52) cystic changes around the implant	3.8% (2/52) revision performed Keller's arthroplasty
	AOFAS-HMI	33.6 ± 3.8	76.1 ± 5.7 ^d	+42.5	7.7% (4/52) metatarsalgia, 5.8% (3/52) elevation of the first ray, 1.9% (1/52) subsidence of the implant, 1.9% (1/52) sub-first metatarsal pain	
	A VAS	8.0 ± 0.7	0.5 ± 0.6 ^c	-7.5	25.0% (3/12) mild metatarsalgia	None
Erdil 2013 [45]	HA AOFAS-HMI	38.4 ± 6.7	86.1 ± 6.9 ^d	+47.7	8.3% (1/12) delayed union, union achieved without additional surgery	None
	VAS	7.9 ± 0.7	1.4 ± 0.9	-6.5	14.3% (2/14) mild metatarsalgia	None
	VAS		1.0 (0-10)##			
Simons 2015 [7]	A FFI		13.8 (0-81)##		NR	3.8% (5/132) revision arthrodesis due to nonunion
	VAS		3.0 (0-7)## ^a		NR	11.4% (15/132) hardware removal due to pain complaints or infection
	HA FFI		17.9 (0-62)##			4.3% (2/46) revision to arthrodesis due to persistent pain

Table 4: (continued)

	Clinical outcome	Pre	FU	Δ	Reported complications	Revisions
Voskuil 2015 [11]	A AOFAS-HMI		77.5 ± 18.5§		8.6% (5/58) metatarsalgia, 5.2% (3/58) posture of first MTP-joint, 10.3% (6/58) posture of second digit	13.8% (8/58) nonunion repair after arthrodesis 1.7% (1/58) position correction
	HA AOFAS-HMI		77.8 ± 12.0 ^a		8.3% (3/36) metatarsalgia, 8.3% (3/36) restriction of motion 5.6% (2/36) persisting pain in first MTP-joint	8.3% (3/36) capsular release 5.6% (2/36) conversion to arthrodesis
Beek huizen 2018 [10]	A AOFAS-HMI		72.8 ± 14.5§		NR	10.3% (4/39) revision arthrodesis due to nonunion
	HA AOFAS-HMI		89.7 ± 6.6 ^b		NR	3.7% (1/27) revision for loosening of the prosthesis 7.4% (2/27) revision due to limited range of motion

Unless otherwise stated, the values of the clinical outcomes are given as mean with or without standard deviation and/or range in parentheses. Reported complications and revisions are given as percentage and absolute values of the affected toes are described in parentheses.

Values in **bold** indicate a statistically significant increase or decrease postoperatively compared to preoperatively $P < 0.05$ as reported by the individual studies. The values are given as median, with or without range in parentheses.

§ The modified AOFAS-HMI was used in this study. The maximum achievable score was 90 points instead of 100 points, since the ten points which are normally devoted to the range of motion of the first metatarsophalangeal joint were eliminated. Range of motion is sacrificed after MTP1 arthrodesis.

‡ A modified AOFAS-HMI according to Roukis et al. [46] was used in this study.

^a The study reported no significant difference between hemiarthroplasty and arthrodesis.

^b The study reported a significant higher score after hemiarthroplasty compared to arthrodesis.

^c The study reported a significant lower score after arthrodesis compared to hemiarthroplasty.

^d The study reported a significant higher score after hemiarthroplasty compared arthrodesis. However, this was due to the loss of motion after MTP1 arthrodesis. The AOFAS score was not modified to the maximum achievable score of 90 points as described above.

Abbreviations: A, arthrodesis; HA, hemiarthroplasty; Pre, preoperative; FU, follow-up; Δ, difference; NR, not reported; MTP, metatarsophalangeal joint; AOFAS-HMI, American Orthopaedic Foot & Ankle Society (AOFAS) rating system for the Hallux Metatarsophalangeal-Interphalangeal (HMI); FFI, Foot Function index; VAS, Visual Analogue Scale.

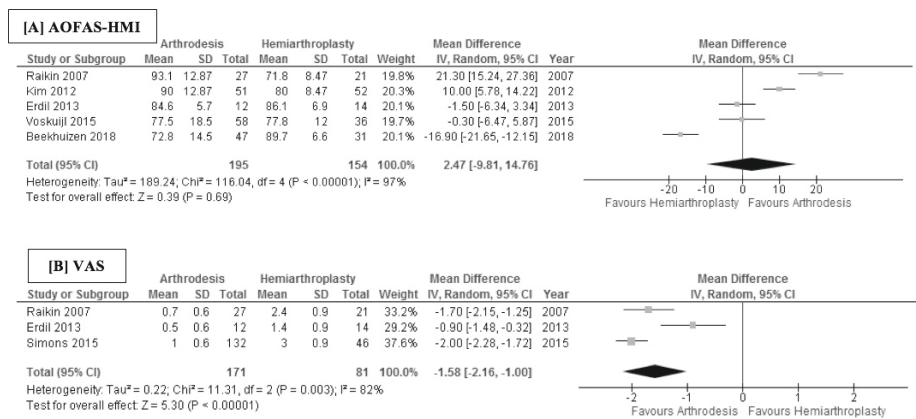


Figure 2: Forest plot of (A) AOFAS-HMI and (B) VAS at follow-up after hemiarthroplasty versus arthrodesis.

Abbreviations: *CI*, confidence interval; *IV*, inverse variance; *df*, degrees of freedom; *SD*, standard deviation.

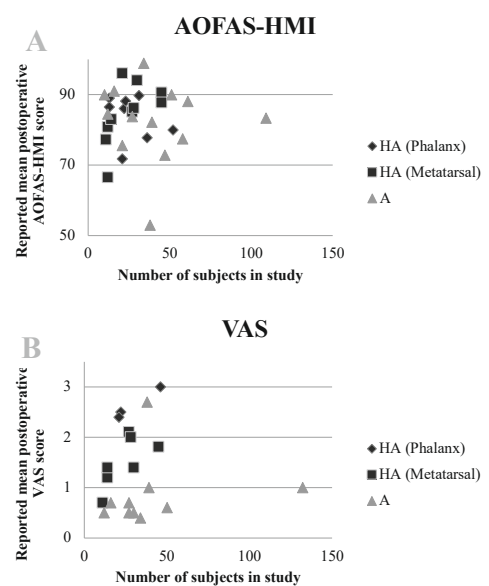


Figure 3: The reported (A) mean postoperative AOFAS-HMI score and (B) the mean postoperative VAS score per study plotted against the number of subjects in the particular study.

A, arthrodesis; *HA (Phalanx)*, hemiarthroplasty of the phalanx; *HA (Metatarsal)*, hemiarthroplasty of the metatarsal head; *AOFAS-HMI*, American Orthopaedic Foot & Ankle Society (AOFAS) rating system for the Hallux Metatarsophalangeal-Interphalangeal (HMI); *VAS*, Visual Analogue Scale.

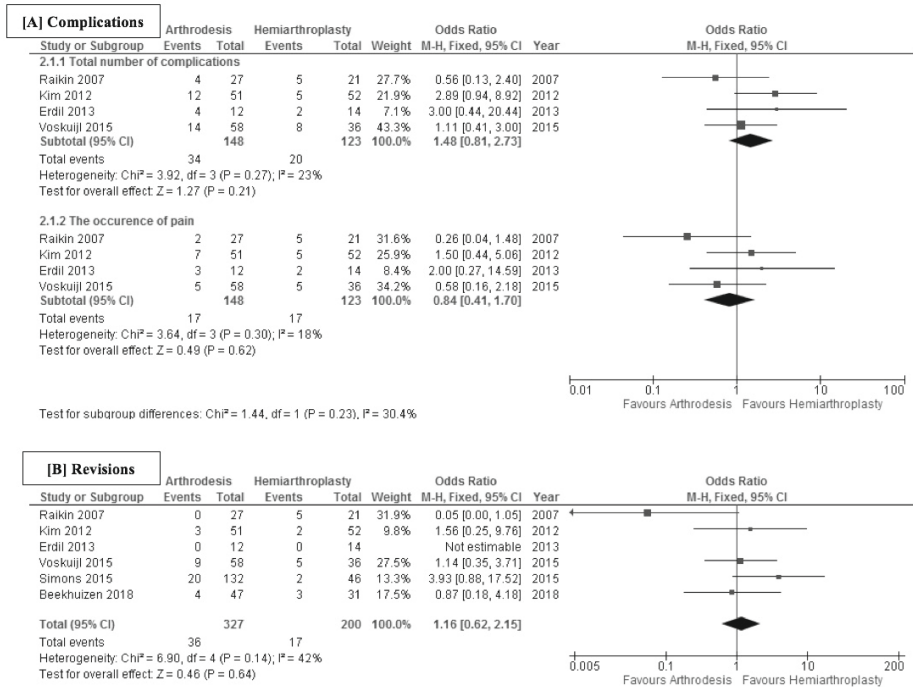


Figure 4: Forest plot of (A) complications and (B) revisions after hemiarthroplasty versus arthrodesis.

Abbreviations: *CI*, confidence interval; *M-H*, Mantel-Haenszel; *df*, degrees of freedom.

Risk of bias

The risk of bias of the 27 non-comparative studies evaluating metallic hemiarthroplasty or arthrodesis were assessed with the MINORS tool and revealed that the majority studies (16/27 studies) [5,20-23,25,30,31,34,36-38,40-43] were of moderate methodological quality, while 4 studies [9,26,29,35] were of high quality and 7 studies [24,27,28,32,33,39,44] of low quality (supplementary data Table 1). The ROBINS-I tool was used for risk of bias analysis in the 6 comparative studies and revealed that 5 studies [7,10,11,45,46] were of moderate risk of bias (supplementary data Table 2). A moderate risk indicates that the study provides sound evidence for a non-randomized study [16,17]. The last comparative study was shown to have some serious issues regarding methodological quality and was therefore classified as having a serious risk of bias [8]. Risk of publication bias across studies was assessed of the 6 comparative studies which were included in the meta-analysis. All comparative studies included the number of revisions as an outcome. Therefore, a funnel plot was created based on number of revisions for the assessment of publication bias in the comparative studies. Visual assessment of the created funnel plot did not suggest evident asymmetry. However,

due to the low number of data points, this statement on the occurrence of publication bias is not solid.

Postoperative results

Multiple studies on metallic hemiarthroplasty assessed range of motion (ROM) and all found an increase in ROM due to the intervention, which confirmed the rationale behind the intervention (supplementary data Table 3) [8-10,20,21,23,25-31,45]. Furthermore, anatomical alignment was assessed in several studies evaluating metallic hemiarthroplasty or arthrodesis. It was shown that anatomical alignment was achieved postoperatively after both interventions (supplementary data Table 4) [21,33,34,36-40,43].

AOFAS-HMI

AOFAS-HMI was reported by 27 of the total 33 studies, which was the most reported clinical outcome (Table 3 and Table 4). All individual studies reported a significant increase in AOFAS-HMI score due to surgery. AOFAS-HMI scores above 70.0 were reported at follow-up for metallic hemiarthroplasty and arthrodesis (range of reported mean scores of included studies: 77.3 to 94.1 and 72.8 to 91.0 respectively). There was one outlier study that reported a mean of 53.0 at follow-up after metallic hemiarthroplasty [39].

Five of the six comparative studies reported AOFAS-HMI at follow-up as a clinical outcome, which enabled pooling of results (Figure 2A). The SDs of Raikin et al. [8] and Kim et al. [46] were not reported and were constructed by calculation of the mean SD of the other three studies [10,11,45]. Furthermore, the postoperative AOFAS-HMI of the arthrodesis group of Erdil et al. was corrected to a maximum achievable score of 90, which was already done by the other individual studies [8,10,11,46]. Data was pooled according to the random effects model because of high heterogeneity ($I^2=97\%$, $P<0.00001$). After pooling, a non-significant higher AOFAS-HMI score was observed after arthrodesis compared to metallic hemiarthroplasty (weighted mean differences: 2.47, 95% CI -9.81 to 14.76 $P=0.69$) (Figure 2A).

In order to assess trends along the 27 studies, which reported the AOFAS-HMI score, a scatter plot was constructed. For each study the reported mean AOFAS-HMMI score at follow-up was plotted against the number of subjects in the particular study (Figure 3A). A sufficient level of variance was seen, but no specific trends could be visually observed. A mean AOFAS-HMI score greater than 80 was reported in the majority of studies (i.e., metatarsal head hemiarthroplasty 80% (8/10 studies), arthrodesis 77% (10/13 studies) and phalanx hemiarthroplasty 75% (6/8 studies)).

VAS

VAS score was the second most reported clinical outcome, as it was reported in 17 of the 33 included studies (Table 3 and Table 4). All studies reported a low postoperative VAS score after arthrodesis (range 0.4 to 1.0) and metallic hemiarthroplasty (range 0.7 to 3.0). Each study that compared the preoperative and postoperative score, observed a significant decrease in pain according to the VAS (Table 3 and Table 4).

Three of the six comparative studies included VAS pain scores as an outcome and were used for data pooling [7,8,45]. Raikin et al. and Simons et al. did not report a SD, therefore the SD was approached by the use of the SD of Erdil et al. After pooling, a significant lower VAS pain score was reported after arthrodesis compared to metallic hemiarthroplasty (weighted mean difference: -1.58, 95% CI -2.16 to -1.00 $P<0.00001$) (Figure 2B). Data was pooled according to the random effects model because of high heterogeneity ($I^2=82\%$, $P<0.001$).

In order to assess trends along the 17 studies reporting VAS scores at follow-up, a scatter plot was constructed. In this scatter, the mean reported VAS at follow-up of a particular study was plotted against the number of subjects in that study (Figure 3B). It was observed that the lowest postoperative mean VAS scores were reported in arthrodesis patients (VAS 0.4 to 1, except for one study reporting a score of 2.7), followed by metallic hemiarthroplasty of the first metatarsal head (VAS 0.7 to 2), while the highest mean VAS scores at follow up were reported after metallic hemiarthroplasty of the proximal phalanx (VAS 2.4 to 3).

Other clinical outcomes

FFI, MOXFQ and SF-36 were reported by a minority of studies [7,22,26,35,41,43]. Therefore, these parameters were not suitable for data-pooling, nor were we able to assess trends along the reported values. The scores of the individual studies that did report these outcomes are presented in Table 3 and Table 4.

Complications

Complications were reported by 11 of the 22 metallic hemiarthroplasty studies (comparative and non-comparative) and by 12 of the 17 arthrodesis studies in the individual and comparative studies (Table 3 and Table 4). The most frequently reported complications of metallic hemiarthroplasty include metatarsalgia (5/11 studies, range 7.7%-14.3%), postoperative infections (4/11 studies, range 3.3%-4.5%) and persistent pain (3/11 studies, range 1.9%-16.0%). Furthermore, anatomical issues of MTP1 were observed including hyperextension, clawing toe, stiffness, restriction of motion and implant migration (5/11 studies, range 8.0%-13.6%).

The most frequently reported serious complications of arthrodesis included persistent pain due to hardware in situ, which required removal (5/12 studies, range 3.3%-14%,

while one study reported 78.0% [44]), delayed or nonunion (7/12 studies, range 3.7%-14.3%), superficial infections postoperative (3/12 studies, range 3.3%-15.8%) and metatarsalgia (3/12 studies, range 9.8%-25.0%).

Pooling of complications was performed on the 4 comparative studies (Figure 4A) [8,11,45,46]. Since there was high variability along the comparative studies on which was considered a complication, it was chosen to only include the following reported complications in pooling of results: (i) the occurrence of pain (e.g., metatarsalgia, pain due to hardware), (ii) the removal of hardware and (iii) delayed-, mal- or nonunion. Overall, no significant lower number of complications was observed after metallic hemiarthroplasty compared to arthrodesis (OR 1.48, 95% CI 0.81 to 2.73, $P=0.21$). Heterogeneity was small ($I^2=23\%$, $P=0.27$) for this comparison. Sub-analyzing the frequently reported complication 'occurrence of pain' revealed that a comparable number of patients presented with the complication pain after metallic hemiarthroplasty compared to arthrodesis (OR 0.84, 95% CI 0.41 to 1.70, $P=0.62$). Heterogeneity was small ($I^2=18\%$, $P=0.30$).

Revisions

The majority of the studies reporting complications additionally described related revision (Table 3 and Table 4). Only four studies describing complications did not report revisions [20,30,38,40]. Seven metallic hemiarthroplasty studies [5,21,22,24,29,31,33], two arthrodesis studies [42,43] and two comparative studies [7,10] did not report complications but solely reported revisions. Revision surgery after metallic hemiarthroplasty was mainly performed due to pain or anatomical issues including nonunion, malalignment or prosthesis loosening. Several studies reported conversion of metallic hemiarthroplasty to MTP1 arthrodesis [5,7,9,11,21,22,24,29,31,33]. After arthrodesis, revision surgery was most frequently performed due to malunion or nonunion.

The revisions described in the 6 comparative studies were pooled and did not show a statistically significant higher revision rate after metallic hemiarthroplasty compared to arthrodesis (OR 1.16, 95% CI 0.62 to 2.15 $P=0.64$) (Figure 4B) [7,8,10,11,45,46]. Small heterogeneity was observed ($I^2=42\%$, $P=0.64$).

Discussion

This study aimed to compare the results of MTP1 metallic hemiarthroplasty to MTP1 arthrodesis and to investigate which of the interventions is superior with regards to the improvement in clinical outcome, the reduction of pain and which intervention results in the lowest number of complications and revisions in patients with HR. The present

study showed that metallic hemiarthroplasty yielded a comparable clinical outcome and comparable rates of complications and revisions when compared to arthrodesis.

Clinical outcome was comparable after both interventions. The majority of studies (>75%) reported a mean AOFAS-HMI of greater as 80 points, which is an excellent score compared to the norm values of the AOFAS-HMI of healthy elderly without foot pathology [51]. The norm values decrease with aging, and AOFAS-HMI reference scores are described to range between 84 and 87.4 at an age interval between 50-79 years [51]. This indicates that most patients treated with metallic hemiarthroplasty or arthrodesis achieve AOFAS-HMI scores at follow-up comparable to healthy subjects of the same age. Additionally, the minimal clinical important difference (MCID) of the AOFAS-HMI is described to range between 7.9 to 30.2 points in literature [52]. Included studies that reported pre- and postoperative values for the AOFAS-HMI reported mostly an increase in AOFAS-HMI greater than 30.2 points due to arthrodesis (range 36.5 to 57) or metallic hemiarthroplasty (range 31.4 to 70.0) (Table 3 and 4) [5,8,20,23,26,28,30,31,36-38,40,45]. Solely two metallic hemiarthroplasty studies reported an increase of 24.0 [33] and 25.0 [9] in AOFAS-HMI score. Furthermore, it was found that, patients reported less pain, based on VAS pain score, after arthrodesis when compared to metallic hemiarthroplasty. However, no difference was observed after both interventions in the occurrence of pain as being a reported complication. Generally, the number and nature of complications is comparable after metallic hemiarthroplasty and arthrodesis. The most reported complications after both interventions were superficial postoperative infections, metatarsalgia, pain in general or due to hardware and anatomical issues. Implant related issues after metallic hemiarthroplasty were stiffness, restriction of motion or implant migrations, while complications after arthrodesis were mostly related to suboptimal joint fusion, resulting in delayed or nonunion. Anatomical issues or pain were also the most frequently reported reasons for revision surgery. No differences were observed between the rates of revision. Therefore, metallic hemiarthroplasty seems to be a good alternative for arthrodesis for patients performing activities that require motion in the first MTP joint.

In the present systematic review, only hemiarthroplasty implants made from metal were included. Implants wherein the first metatarsal head was resurfaced e.g., HemiCAP) and implants resurfacing the proximal phalanx (e.g., BioPro) were included. In the comparative studies, the BioPro was predominantly used, while non-comparative studies mostly used the HemiCAP or a comparable implant. An implant specific sub-analysis was not possible. However, a quantitative review using scatter plots showed trends of lower VAS pain scores after metatarsal head resurfacing compared to phalanx resurfacing. A feasible explanation is that the pathologic features of HR are believed to be the most present at the metatarsal side of the joint, since this is resurfaced by metatarsal head prosthesis, this could explain the superior success with regards to the lower pain scores [5,53]. No other specific trends were observed after comparing

complications and revisions. Currently, no comparative studies comparing both implants are available. However, since our findings suggest differences in outcome based on implant rationale, future studies comparing specific implants seem desirable.

Arthrodesis of the MTP1 joint is currently considered as the golden standard for treatment of an end-stage HR [1,4,6]. Other surgical options are still considered and the optimal surgical treatment for HR is a topic of debate [35,54,55]. Assessment of the results of previously published systematic reviews or RCTs on these alternative surgical interventions suggest trends of comparable clinical outcome after interpositional arthroplasty, total joint arthroplasty and synthetic cartilage implant compared to metallic hemiarthroplasty and arthrodesis [35,54,55]. However, arthrodesis seems to be the optimal intervention for reducing pain. Implant related complications (e.g., prosthesis loosening) seem to be more of an issue in total joint replacement, since it is to a lesser extent observed after metallic hemiarthroplasty, interpositional arthroplasty and synthetic cartilage implantation based on the current evidence [35,54,55]. Nevertheless, long-term studies evaluating implant survival are recommended to observe the effects after a sufficient follow-up for all interventions.

Previous reviews describing surgical treatments for HR have been published [54-60]. However, this is the first study that compares metallic hemiarthroplasty to the current golden standard arthrodesis and includes all available studies on metallic hemiarthroplasty and/or arthrodesis, and analyzed in a systematic and methodologically sound fashion. Previously published overviews evaluated solely one HR intervention [54,56,57,59], compared other interventions [60], or assessed implant arthroplasty as a whole which is a rather general comparison [58]. Furthermore, individual quality assessment of the studies was not routinely performed. Finally, this study provides overall effects based on methodologically sound pooling and the visual assessment of trends. Several previous reviews aimed to pool results of individual studies in order to present an overall effect as well. However, this was frequently done in an incorrect matter [54-56,60]. These studies calculated an overall mean for a certain parameter by adding all means reported by individual studies. They aimed to add weight by multiply the means by the number of subjects. This process of calculating weighted means is not statistically sound.

Although we believe this is the most complete and methodologically correct overview possible on metallic hemiarthroplasty versus arthrodesis as treatment for HR, some issues should be considered. Firstly, besides the valuable findings, nearly all studies included in the present systematic review were evaluation studies describing metallic hemiarthroplasty or arthrodesis (i.e., level 3 and 4 evidence), while the comparative studies were retrospective cohort studies (i.e., level 3 evidence). No randomized controlled trials (RCTs) were available comparing both interventions. The absence of high quality RCTs and the moderate or low-level evidence that was included, impacts

the solidness of our conclusions negatively. However, the performed risk of bias analysis, revealed that most studies still had a moderate quality. Secondly, the majority of studies were short- to mid-term follow-up studies, while a minority of studies reported outcomes at follow-up longer than 5 years. A higher number of studies with long-term follow-up would enable us to gain more insight in the successfulness of both interventions on the longer term. Furthermore, selection bias is in particular relevant in comparing both interventions. Results showed comparability in surgical indication and the age of performing a surgical intervention. However, there were still a couple of studies where selection bias could not be ruled out. Selection bias seems to be a point of attention by analyzing and comparing interventions. Thirdly, only six studies were eligible for performing a meta-analysis because of their comparative nature. Unfortunately, not all 6 studies reported the same outcomes of interest, therefore not all of them could be used in each of the performed parts of the meta-analysis. Fourthly, AOFAS score is the most used clinical outcome instrument in evaluating foot and ankle pathology [61,62]. In the present studies, AOFAS-HMI was the most reported outcome. However, after arthrodesis a modified AOFAS-HMI should be used, since 10 points are allocated in this tool based on the ROM of the first metatarsophalangeal joint, while obviously no MTP1 motion is possible after arthrodesis. Therefore, a maximum score of 90 points is achievable instead of 100. During quantitative review, a number of studies in these studies, did not use a modified score. These studies were corrected for exploration of the study results. Finally, it was observed that complications and revisions were not systematically and separately reported by the included studies. Considerable heterogeneity was observed along studies in which was considered a complication of the intervention. Some studies reported conditions such as radiological changes as bony overgrowth into the joint as a complication [46], while others solely reported revisions or considered a revision a complication [7,10]. Revisions may be considered the most reliable, because the outcome is not much open for interpretation or opinion as defining complications [63].

The present study reported good results after metallic hemiarthroplasty and arthrodesis based on AOFAS-HMI and VAS. However, one unique difference between both interventions is that MTP1 motion is restored after metallic hemiarthroplasty, while it is sacrificed after arthrodesis. Loss of motion can be an issue in patients with an active lifestyle, performing occupations that requires for instance kneeling or squatting or during recreational activities such as playing sports [5,9]. These activities or domains were not analyzed in the AOFAS-HMI and VAS pain score, but are evaluated in the MOXFQ and FFI [64,65]. Unfortunately, evaluation of these questionnaires was not possible since these outcome measures was nearly never reported in the included studies. The use of such questionnaires could be interesting in further studies investigating hemiarthroplasty, in order to see whether scores were higher in these domains after hemiarthroplasty as compared to arthrodesis. In addition, long-

term studies are recommended to gain more insight in the implant survival time of hemiarthroplasty.

Conclusion

In conclusion, MTP1 metallic hemiarthroplasty as well as MTP1 arthrodesis are appropriate interventions for HR patients. Excellent clinical outcomes as well as an acceptable number of complications and revisions are observed after both interventions. Arthrodesis seems to be superior in pain reduction, while MTP1 motion was regained after metallic hemiarthroplasty. Therefore, metallic hemiarthroplasty is a suitable alternative for patients performing activities that require motion in the first MTP joint.

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Supplementary files

Supplemental table 1: Risk of bias results of the studies evaluating hemiarthroplasty or arthrodesis of the MTP1 joint. Risk of bias assessed by using MINORS tool [13].

Study	Clearly stated aim	Inclusion of consecutive patients	Prospective collection of data	Endpoints appropriate to the aim of the study	Unbiased assessment of the study endpoint	Follow-up period appropriate to the aim of the study	Loss to follow up less than 5%	Prospective calculation of the study size	Total score	Overall judgment
Konkel 2006 [27]	2	0	0	1	0	1	1	0	5	Low
Sorbie 2008 [32]	0	0	1	1	0	2	0	1	5	Low
Konkel 2009 [28]	2	1	0	1	0	1	1	0	6	Low
Giza 2010 [9]	2	2	2	2	0	2	2	2	14	High
Aslan 2012 [20]	2	1	2	2	0	2	0	2	11	Moderate
Dos Santos 2012 [23]	2	2	1	2	0	2	0	1	10	Moderate
Kline 2013 [26]	1	2	2	2	2	2	0	2	13	High
Gheorghiu 2015 [24]	2	0	0	2	1	2	0	0	7	Low
Meric 2015 [29]	2	2	2	2	2	2	0	2	14	High
Circi 2016 [21]	2	2	0	2	0	1	0	2	9	Moderate
Clement 2016 [22]	2	0	0	2	0	2	2	2	10	Moderate
Mermerkaya 2016 [30]	2	2	0	2	1	2	1	2	12	Moderate
Hilario 2017 [5]	2	1	0	2	1	2	1	2	11	Moderate
Mermerkaya 2018 [31]	2	2	0	2	1	2	0	2	11	Moderate
Uzer 2018 [33]	2	1	0	2	0	2	0	1	8	Low
Jorsboe 2019 [25]	2	1	2	1	0	2	1	1	10	Moderate

Supplemental table 1: (continued)

Study	Clearly stated aim	Inclusion of consecutive patients	Prospective collection of data	Endpoints appropriate to the aim of the study	Unbiased assessment of the study endpoint	Follow-up period appropriate to the aim of the study	Loss to follow up less than 5%	Prospective calculation of the study size	Total score	Overall judgment
Lombardi 2001 [40]	2	1	0	2	0	2	0	2	9	Moderate
DeFrino 2002 [38]	2	2	1	2	0	2	0	0	9	Moderate
Coughlin 2003 [37]	2	1	0	2	1	2	2	2	12	Moderate
Etti 2003 [39]	0	1	0	2	1	2	0	2	8	Low
Aas 2008 [34]	2	1	0	2	0	2	1	2	10	Moderate
Wassink 2009 [44]	2	2	0	1	0	2	1	0	8	Low
van Doeselaar 2010 [43]	2	2	1	2	0	2	1	2	12	Moderate
Baumhauer 2016 [35]	2	2	2	2	0	2	2	2	14	High
Chraim 2016 [36]	2	2	0	2	1	2	0	1	10	Moderate
Stone 2017 [42]	2	1	2	1	0	2	1	2	11	Moderate
Stevens 2020 [41]	2	2	1	2	1	2	0	2	12	Moderate

* The studies were grouped according to the following quartiles: very low quality (0-4), low quality (5-8), moderate quality (9-12) and high quality (13-16) according to previous studies [14,15].

Supplemental table 2: Risk of bias of the comparative studies assessed using the ROBINS-I tool [16].

Study	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcome	Bias in selection of the reported results	Overall judgement
Raikin 2007 [8]	Serious	Serious	Low	Moderate	Low	Serious	Serious	Serious
Kim 2012 [46]	Moderate	Moderate	Low	Low	Moderate	Moderate	Moderate	Moderate
Erdil 2013 [45]	Moderate	Moderate	Low	Low	Low	Moderate	Moderate	Moderate
Simons 2015 [7]	Moderate	Moderate	Low	Low	Moderate	Moderate	Moderate	Moderate
Voskuyl 2015 [11]	Moderate	Moderate	Low	Low	Moderate	Moderate	Low	Moderate
Beekhuizen 2018 [10]	Moderate	Moderate	Low	Low	Moderate	Moderate	Low	Moderate

Supplemental table 3: Passive range of motion of the hemiarthroplasty studies measured preoperative and postoperative.

	Konkel 2006 [27]	Raikin 2007 [8]	Konkel 2009 [28]	Giza 2010 [9]	Aslan 2012 [20]	Dos Santos 2012 [23]	Erdil 2013 [45]	Kline 2013 [26]	Meric 2015 [29]	Circi 2016 [21]	Mermerkaya 2016 [30]	Beekhuizen 2018 [10]	Mermerkaya 2018 [31]	Jorsboe 2019 [25]
Pre	NR	NR	17.0 (10-55)	32.7 ± 10.7 (3-49)	14.4	4.6 ± 1.6 (0-10)	20.5 ± 9.10	28.0 ± 12.6 (10-60)	22.8 ± 7.7 (15-45)	16.3 ± 4.8 (10-25)	27.5 (15-40)	< 20.0	25.0 (15-40) ^a	NR
FU	60.2	10.0 (0-30)	72.0 (15-115)	48.1 ± 10.6 (25-62)	54.4	21.8 ± 2.6 (0-30)	47.9 ± 11.72	66.3 ± 13.4 (40-90)	69.6 ± 11.8 (50-90)	45.4 ± 13.2 (25-65)	75.0 (35-85)	30.0-74.0 ^b	75.0 (30-85) ^a	45.0 (10-75) ^{b,c}
Δ	-	-	55	15.4	40.0	17.2	27.4	38.3	46.8	29.1	47.5	-	50.0	-

Unless otherwise stated, the values represented passive range of motion and are given as mean with or without standard deviation and/ or range in parentheses. Values in **bold** indicate a statistically significant increase postoperatively compared to preoperatively $P < 0.05$ as reported by the individual studies.

^a The values are given as median, with or without range in parentheses.

^b ROM presented as range.

^c Solely dorsiflexion is presented.

Abbreviations: Pre, preoperative; FU, follow-up; Δ, difference; NR, not reported.

Supplemental table 4: Radiological results preoperative to postoperative of the individual studies.

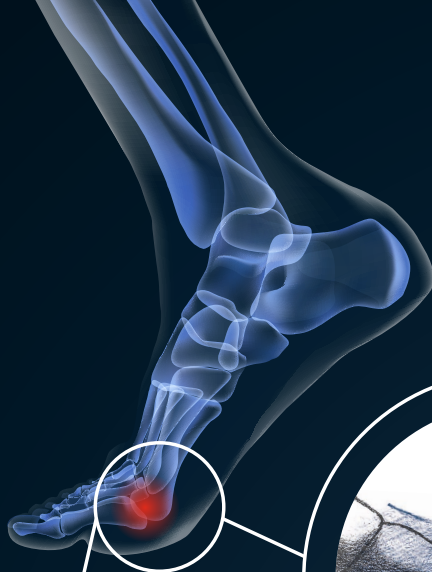
Study	Hemiarthroplasty			Arthrodesis					
	Circi 2016 [21]	Uzer 2018 [33]	Lombardi 2001 [40]	DeFrino 2002 [38]	Coughlin 2003 [37]	Etti 2003 [39]	Aas 2008 [34]	van Doeselaar 2010 [43]	Chraim 2016 [36]
Pre	HVA: 13.9 ± 4.1 (9-21) IMA: 9.1 ± 2.2 (6-13)	HVA: 18.0 (7-30) IMA: 9.0 (4-16)	IMA 10.6	HVA: 11.0 ± 3.5 (7-16) IMA 10.0 ± 0.6 (9-11)	HVA: 12.2 (0-20) IMA: 8.1 (4-14)	NR	NR	HVA: 11.0 (4-15) ^a	NR
FU	HVA: 12.8 ± 3.6 (9-20) IMA: 8.7 ± 2.0 (6-12)	HVA: 13.0 (7-22) IMA: 11.0 (6-16)	IMA 8.5 ^b	HVA 6.0 ± 4.4 (0-10) ^b IMA 10.0 ± 1.3 (9-12)	HVA: 11.7 (5-19) IMA: 20.0 (15-26)	HVA: 14.0 (2-32)	HVA: 11.0 ± 8.0 (-7-26) DFA: 27.0 ± 7.0 (12-24)	HVA 10.0 (-2-20) ^a DFA: 23.0 (7-37) ^a	HVA: 13.7 ± 5.5 IMA: 11.8 ± 3.6 DFA: 21.0 ± 4.0
Δ	HVA: -1.1 IMA: +0.4	HVA: -5.0 IMA: +2.0	IMA: -2.1	HVA: -5.0 IMA: 0	HVA: -0.5 IMA: +11.9	-	-	HVA: -1.0	-

Unless otherwise stated, the values are given as mean with or without standard deviation and/ or range in parentheses. Values in **bold** indicate a statistically significant decrease postoperatively compared to preoperatively $P<0.05$ as reported by the individual studies.

^a The values are given as median, with or without range in parentheses.

^b Statistically significant decrease postoperative compared to preoperative ($P<0.05$).

Abbreviations: Pre, preoperative; FU, follow-up; Δ, difference; NR, not reported; HVA, hallux valgus angle; IMA, intermetatarsal angle; DFA, dorsifusion angle.



CHAPTER 7

Comparing kinematics and assessing repeatability of the Oxford Foot Model in 3D gait analysis of healthy individuals

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Keywords: Repeatability, Oxford Foot Model, Foot kinematics, Biomechanics, Statistical parametric mapping

Abstract

Background

The Oxford Foot Model (OFM) is a multi-segment foot model that is widely used for assessing hallux, forefoot, and hindfoot motion. The purpose of this study is to compare the kinematics within and between assessors and to evaluate the intra- and inter-assessor repeatability of the OFM with special attention to the repeatability of motion in the hallux segment and swing phase of gait, which has not been evaluated in previous studies.

Methods

Ten healthy adults without a history of musculoskeletal disorders were tested on two days by two assessors. Gait was traced using the Vicon motion capturing system and analyzed using the OFM. Dynamic joint angles were acquired and analyzed by using statistical parameter mapping *t*-tests. Furthermore, the intersegmental range of motion of the total gait cycle was calculated, and the standard error of measurement (SEM) was determined.

Results

Comparable kinematics were detected in the hallux-forefoot segment and other foot segments by evaluating dynamic joint angles ($P>0.05$) within and between the assessors. Differences in intersegmental motion were seen in the terminal stance and pre-swing phase in the forefoot-hindfoot's transverse plane as well as in the initial and mid-swing phases in the hindfoot-tibia's transverse plane when comparing both assessors. Focusing on repeatability, the SEM was relatively high in the sagittal plane of the hallux-forefoot segment (intra-SEM 7.9°, inter-SEM 8.4°) and the transverse plane of the hindfoot-tibia (intra-SEM 8.7°, inter-SEM 7.7°). SEM values in the other foot segments and planes were all below 5°.

Conclusion

Based on intra- and inter-tester repeatability, the OFM is a largely repeatable multi-segment foot model. The results of this study indicate lower intra- and inter-assessor repeatability for the hallux-forefoot segment compared to the forefoot and hindfoot segments. Caution by interpreting results of hallux joint angles is recommended. Repeatability of the swing phase is comparable to that of the entire gait cycle. Consequently, OFM demonstrates reasonable repeatability for use in 3D gait analysis and clinical practice.

Introduction

The foot is a complex body part consisting of 26 bones, multiple muscles, tendons, and ligaments. Many health conditions impair foot functioning, such as cerebral palsy, clubfoot, fractures, osteoarthritis, posterior tibial tendon dysfunction, and hallux deformities [1-3]. Gait analysis provides a measure to evaluate foot and ankle kinematics during walking and is used to evaluate treatments with the aim of improving clinical decision-making [4,5]. Traditional foot models in gait analysis present the foot as a single rigid segment of the human body. Although these models are easy to use, this modeling method does not provide any information regarding internal foot and ankle motion during gait [6]. Recently, numerous multi-segment foot models have been developed; these vary in the number of segments, marker sets, anatomic segment definition, modeling, repeatability, and necessary equipment, resulting in a complex array of models suited for evaluation of different clinical and biomechanical issues [4,7].

One of the most commonly used multi-segment foot models to evaluate foot pathology in research and clinical setting is the Oxford Foot Model (OFM), [8-19] which was developed to assess intersegmental motion between the tibia, hindfoot (calcaneus) and forefoot (five metatarsal bones), and hallux (proximal phalanx) [9,12]. Multi-segment foot models rely on skin-mounted markers to define and track segments and are sensitive to measurement variability induced by, for example, soft tissue artifacts and marker misplacement. Soft tissue artifacts are tracking marker movements in relation to their corresponding bony landmarks, which can induce measurement errors. Furthermore, precise identification of anatomic landmarks that guide skin marker placement can be difficult and may result in marker misplacement. These factors are known to produce relevant measurement errors and affect the repeatability of the model used [5,20]. Therefore, repeatability studies are essential for a careful interpretation of clinical data gained with a particular foot model.

In several studies the repeatability of OFM was studied during barefoot walking in children and, to a lesser extent, in adults [9,11,12,19,21-23]. Generally, the findings from most of these studies suggest satisfactory repeatability of the OFM, wherein the highest repeatability is observed in the sagittal plane, which is followed by the frontal plane; the lowest repeatability is in the transverse plane [9,11,12,19,24]. Most studies have used reliability indexes (e.g., intraclass correlation coefficient (ICC)) to evaluate reliability, although it is recommended to use absolute measures for measurements errors, such as the standard deviation (SD) or standard error of measurement (SEM), to report reliability in 3D gait analysis studies [25]. Although several studies have investigated the repeatability of the OFM, only two have evaluated the repeatability in the hallux-forefoot segment [26,27]. This knowledge is essential, since the OFM has been used for clinical evaluation in hallux pathologies in several studies [2,13,15,16,28,29]. Furthermore, repeatability in the swing phase must be evaluated since most studies

have analyzed the repeatability of the stance phase, while current gait studies of the foot and ankle use the OFM for analyzing motion during the total gait cycle, including stance and swing phase [21]. The swing phase is an important part of the gait cycle since it contributes to proper positioning of the foot in preparation for the next heel strike and following stance phase [30,31]. Improper foot placement can lead to instability or inefficient force distribution during the next step. Disorders that affect the swing phase (e.g., foot drop, spasticity of weak hip flexors) can lead to compensatory gait patterns that increase the risk of falling. Evaluating the repeatability in this phase of the gait cycle is essential to determining whether the OFM can reliably analyze it.

The aim behind this study is to compare the kinematics within and between assessors and to evaluate the intra- and inter-assessor repeatability of the OFM. Special attention was given to the hallux-forefoot segment and the swing phase of gait during barefoot walking, as the reliability of these aspects remains insufficiently established. It was hypothesized that the OFM would demonstrate satisfactory repeatability throughout the gait cycle, with the lowest repeatability expected in the transverse plane, which is consistent with previous studies. Additionally, it was expected that the repeatability of the hallux-forefoot segment would be comparable to the sagittal plane motions of other foot segments. Furthermore, repeatability of the swing phase was expected to be similar to the repeatability during the stance phase.

Methods

Subject characteristics

Ten healthy subjects (20 feet) with no history of foot or ankle complaints that influence gait were recruited for gait analysis. The sample size was chosen to replicate previous repeatability studies [11,21,23,26,32,33]. The study was performed according to the Declaration of Helsinki (2013), and the local medical ethical committee approved the study. All subjects provided their written informed consent.

Data collection

All subjects underwent 3D gait analysis using a Vicon motion capturing system (Vicon Motion Systems Ltd., Oxford, UK) consisting of eight infrared cameras. A 10-meter walkway was used and equipped with two force plates (AMTI OR6 Series, Watertown, USA) that identified initial contact and toe off. Patients were measured on two days (the interval between measurements ranged from one to 14 days with a median of seven days). On the first day, all subjects were measured by both assessors; on the second day, all subjects were measured by one assessor. After the first session on the first test day, markers were removed by the first assessor. The second assessor, who was blinded for the first session, repeated the protocol after an interval of at least 30 minutes between the sessions. Measurements were performed by two assessors who were experienced

with using the OFM. Age, height, weight, body mass index, leg length (i.e., distance between the anterior superior iliac spines and the malleoli), knee width (i.e., distance between both femur condyles), and ankle width (i.e., distance between both malleoli) were registered. After careful identification of marker location according to the OFM protocol (Table 1), 43 passive markers were placed on each subject using double-sided tape on both legs [9,12,19]. After marker placement, at least one static calibration trial was performed with the subject standing in a neutral position. Six markers (i.e., LMMA/RMMA, LPCA/RPCA, LD1M/RD1M; Table 1) necessary for the static calibration trial were subsequently removed. Next, dynamic trials were conducted, with the subjects walking at their normal comfortable walking speed. After some practice trials, at least 10 trials were recorded.

Table 2: Marker positioning according to the OFM.

Marker name	Marker position
LASI/RASI	Anterior superior iliac spine
LPSI/RPSI	Posterior superior iliac spine
SACR	Sacral marker – Midway between LPSI and RPSI
LTHI/RTHI	Thigh marker – Half of a straight line between trochanter major and LKNE/RKNE
LKNE/RKNE	Knee – Lateral joint space of the knee
LHFB/RHFB	Head fibula – Proximal head of the fibula
LTUB/RTUB	Tibial tuberosity – Tuberosity of the tibia
LTIB/RTIB	Tibial marker – On the lateral tibia; half of a straight line between LKNE/RKNE and LANK/RANK
LSHN/RSHN	Shin – Anterior aspect on shin; the middle of the tibia
LANK/RANK	Ankle – Lateral malleoli
LMMA/RMMA*	Ankle – Medial malleoli
LCGP/RCGP	Wand marker on the heel pointing cranially in line with the varus or valgus alignment of the heel
LHEE/RHEE	Heel – Most distal aspect of the heel
LPCA/RPCA*	Posterior calcaneus – above the base of LCGP/RCGP marker
LLCA/RLCA	Lateral calcaneus – Lateral aspect of the calcaneus
LSTL/RSTL	Sustentaculum tali – Medial aspect of the calcaneus
LP1M/RP1M	Base of the first metatarsal
LD1M/RD1M*	Head of the first metatarsal
LP5M/RP5M	Base of the fifth metatarsal
LD5M/RD5M	Head of the fifth metatarsal
LTOE/RTOE	Toe – On the dorsum of the foot between the second and third phalanges
LHLX/RHLX	Hallux – Proximal end of the distal phalanx

* These markers were removed after the static trials.

Data processing

Vicon Nexus 1.8.5 was used to visualize and process marker motions. Joint kinematics were processed using Matlab (R2012A, MathWorks, USA), and the following joint kinematics were produced: sagittal plane motions in the hallux-forefoot (dorsiflexion and plantar flexion), forefoot-hindfoot (flexion and extension), and hindfoot-tibia (flexion and extension); frontal plane motions of the forefoot-hindfoot (pronation and supination) and hindfoot-tibia (inversion and eversion); and transverse plane motions of the forefoot-hindfoot (abduction and adduction) and hindfoot-tibia (internal and external rotation).

The gait cycle (one stride from 0%-100%) was divided into stance and swing phases. For description of the results, both were further subdivided into loading response (0%-12%), midstance (13%-31%), terminal stance (32%-50%) and pre-swing (51%-62%) for the stance phase (total 0%-62%), and initial swing (63%-75%), mid-swing (76%-87%) and terminal swing (88%-100%) for the swing phase (total 63%-100%) as defined by Perry et al. [34]. Off-set correction was performed to the intersegmental kinematic waveforms by summing the intersegmental angles at time points from 0%-100% of the cycle and subsequently dividing by 100 to acquire the value of the off-set correction. The intersegmental range of motion (ROM) in all planes of the foot segments were calculated. ROM was defined as the difference between the maximal and minimal intersegmental angle in the time intervals of 0%-100% of the gait cycle. Additionally, the ROM during the stance and swing phases was also calculated.

Statistical analysis

Statistical analyses were performed using SPSS (version 28, IBM Statistics, Chicago, USA). At least six trials were used in the final analysis for every subject. The mean dynamic joint angle over time was tested using statistical parametric mapping (SPM; version M.0.4.5) in Matlab. SPM detects differences at any point of the gait cycle [35]. An SPM paired-sample t-test was used to compare the kinematic data of Assessor 1 on Days 1 and 2 (intra-assessor) and of Assessors 1 and 2 (inter-assessor) on Day 1. The significance level was set at $\alpha = 0.05$. Furthermore, intra- and inter-assessor repeatability was also analyzed using calculations of the ROM's mean difference and SEM; SEM was chosen since it is recommended for reporting reliability in 3D gait analysis studies [5,21,23,25,27,33]. SEM is an absolute measure of error and is reported in degrees ($^{\circ}$). SEM was calculated as $SD \cdot \sqrt{1-rxx}$ where rxx refers to ICC (3, k) [36,37]. The highest calculated SD, which indicates the most variability, was used to calculate the SEM. The ICC's reliability indexes are not reported since they are not recommended or clinically meaningful in 3D gait analysis studies [25]. To interpret the SEM, recommendations of McGinley et al. were followed, who consider errors smaller than 5° to be clinically acceptable and errors exceeding 5° to potentially cause clinical misinterpretation [25].

Results

Subject characteristics

Subject characteristics are presented in Table 2. Ten healthy subjects (20 feet) consisting of five males and five females were included; their mean age was 25.3 ± 2.4 years (range: 22-29 years). Baseline subject demographics are also reported in Table 2. The average walking speed was 1.21 ± 0.09 m/s (range: 1.03-1.45 m/s).

Table 2: Subject characteristics.^a

	Subject characteristics
No. of subjects (No. of feet)	10 (20)
Age (years)	25.3 ± 2.4 (22-29)
No. Male/Female	5/5
Height (cm)	176.2 ± 6.6 (166.5-186.0)
Weight (kg)	75.6 ± 14.4 (56.7-103.1)
Body Mass Index (kg/m ²)	24.2 ± 3.3 (20.3-30.1)
Walking Speed (m/s)	1.21 ± 0.09 (1.03-1.45)

^a Data are presented as means with standard deviations and ranges in parentheses.

Intra-assessor analyses

Intra-assessor kinematic analysis (i.e., Day 1 versus Day 2 by Assessor 1) showed comparable kinematic waveforms during the gait cycle (Figure 1). No statistically significant differences were observed (Figure 1). Sagittal intersegmental ROM in the hallux-forefoot segment showed small mean differences in total ROM (0.03°; Table 3), ROM during stance (0.2°), and ROM during the swing phase (1.1°). SEM was relatively high for total ROM (SEM 7.9°), ROM during stance (7.3°), and ROM during the swing phase (SEM 5.7°).

For the forefoot-hindfoot segment, mean differences in intersegmental ROM were small in all planes and were all below 1.1°. SEM values in all segments were below 3.5°.

For the hindfoot-tibia segment, all values except 2 had a mean difference in intersegmental ROM below 1.5° (i.e., in the transverse plane, the ROM total was 2.7° and the ROM stance was 2.2°). SEM values in the sagittal and frontal planes were below 3.7°, while higher SEM values were measured in the transverse plane (i.e., 8.7° for ROM total, 4.5° for ROM stance, and 6.3° for ROM swing).

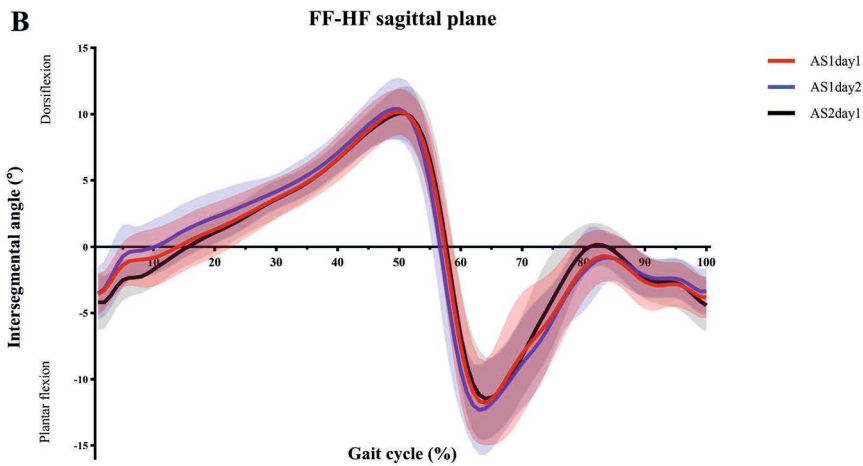
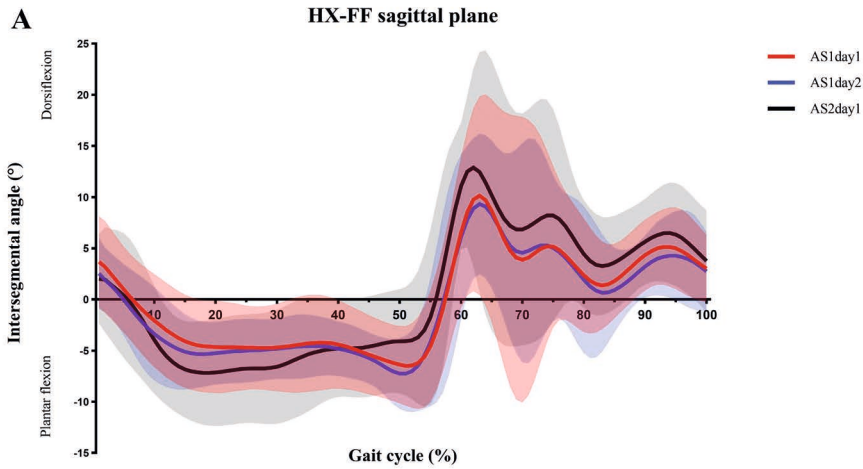
Inter-assessor analyses

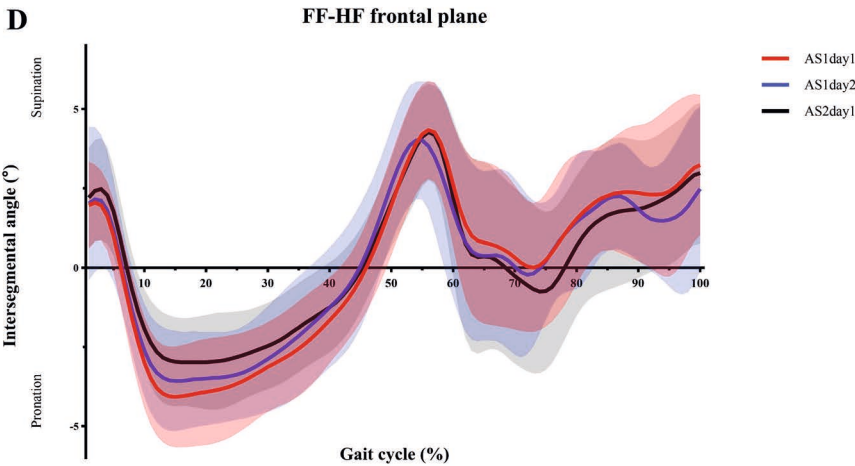
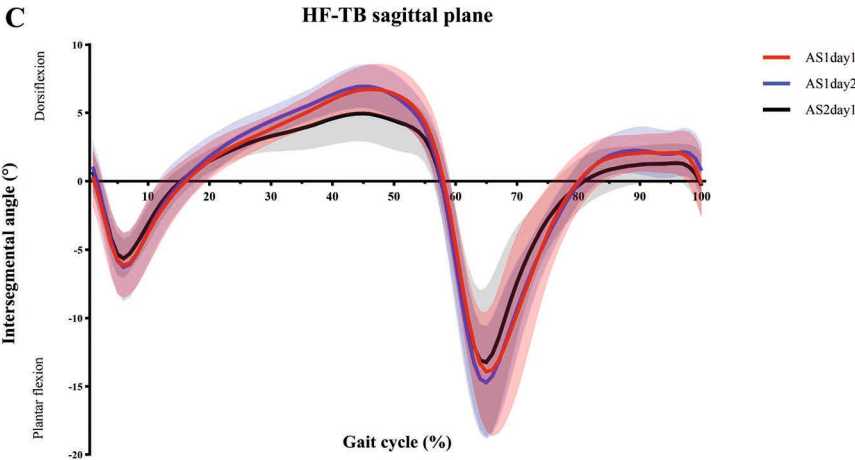
Kinematic analysis of inter-assessor repeatability (i.e., Assessor 1 versus Assessor 2) showed comparable kinematic waveforms for the hallux-forefoot, forefoot-hindfoot, and hindfoot-tibia in the sagittal and frontal plane motions (Figures 1A-1G). Different motion patterns were seen in the forefoot-hindfoot and hindfoot-tibia segments in the transverse plane in the stance phase (Figure 1F) and swing phase (Figure 1G), respectively.

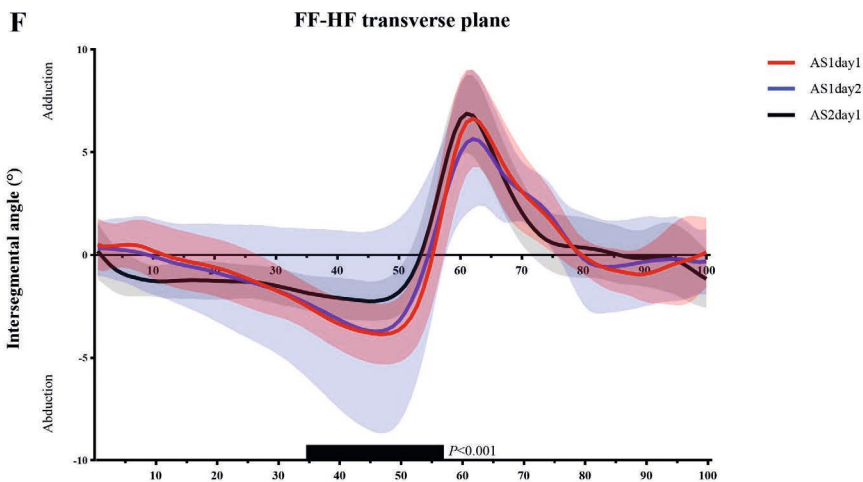
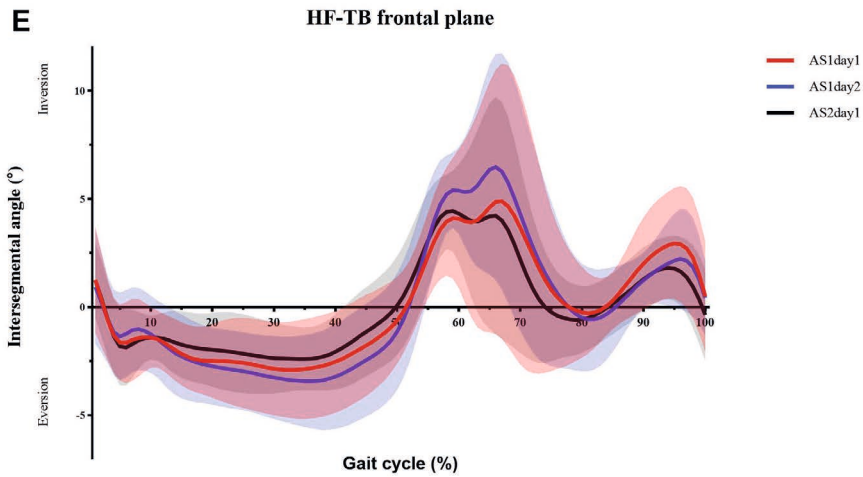
Sagittal intersegmental ROM analysis of the hallux-forefoot showed a mean difference in total ROM of 5.9°, during the stance phase of 5.8°, and during the swing phase of 3.5° (Table 4). A relatively high SEM in total ROM (8.4°), stance (7.6°), and swing (6.7°) was seen.

For the forefoot-hindfoot segment, all values except 2 had a mean difference in intersegmental ROM below 1.0° (i.e., in the transverse plane, the ROM total was 1.2°, and the ROM during the stance phase was 1.1°). Furthermore, SEM values in all segments were below 2.2°.

In the hindfoot-tibia segment, all values except the results of the transverse plane had a mean difference in intersegmental ROM below 3.0° (i.e., the transverse plane total ROM was 8.9°, the stance phase ROM was 3.6°, and the swing phase ROM was 9.1°). Additionally, SEM values in the frontal and sagittal planes were all below 3.6°. Higher SEM values were seen in the transverse plane (i.e., total ROM was 7.7°, ROM during stance phase was 3.8°, and ROM during swing phase was 7.0°).







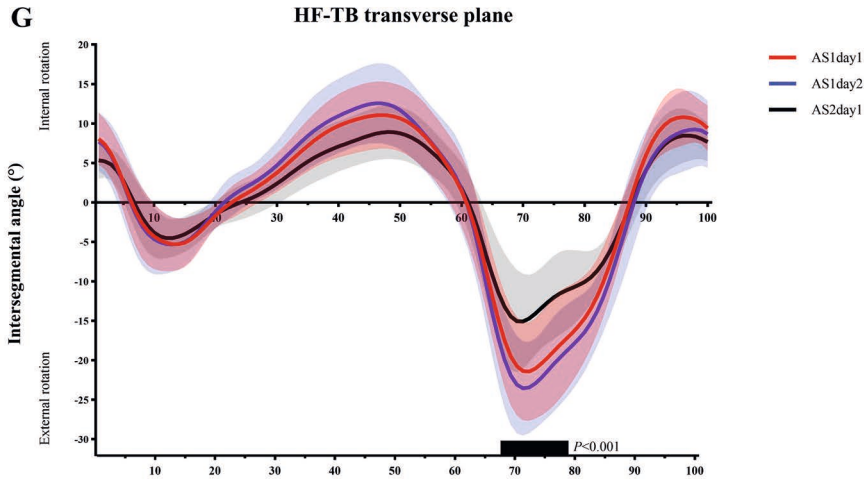


Figure 1: Average absolute joint angles during gait. Figures 1A, 1B, and 1C present motion in the sagittal plane for the hallux-forefoot (HF-XX), forefoot-hindfoot (FF-HF), and hindfoot-tibia (HF-TB); Figures 1D and 1E present motion in the frontal plane for the forefoot-hindfoot (FF-HF) and hindfoot-tibia (HF-TB); and Figures 1F and 1G present motion in the transverse plane for the forefoot-hindfoot (FF-HF) and hindfoot-tibia (HF-TB).^a

^a Mean values (dark lines) are accompanied by corresponding standard deviations (transparent areas).

^b Hallux-forefoot (HX-FF), forefoot-hindfoot (FF-HF), hindfoot-tibia (HF-TB), assessor (AS)

^c Results of the SPM analyses are displayed on the x-axis. The results in black indicate statistically significant differences between Assessors 1 and 2 (inter-assessor) ($P \leq 0.05$), while no statistically significant differences were observed between Assessor 1's measurements on Days 1 and 2 (intra-assessor).

Table 3: Intra-assessor repeatability and intersegmental ROM of the OFM's Hallux-Forefoot, Forefoot-Hindfoot, and Hindfoot-Tibia segments.^a

		Day 1 (°)	Day 2 (°)	Mean difference (Day 1 versus Day 2) (°)	SEM (°)
Hallux-Forefoot					
Sagittal plane	ROM total	23.6 ± 11.1	23.6 ± 9.6	0.03 ± 12.0	7.9
	ROM stance	19.9 ± 10.8	20.2 ± 9.2	0.2 ± 11.3	7.3
	ROM swing	16.2 ± 9.5	15.1 ± 7.8	1.1 ± 8.9	5.7
Forefoot-Hindfoot					
Sagittal plane	ROM total	23.2 ± 3.6	23.4 ± 4.7	0.2 ± 3.8	2.4
	ROM stance	21.6 ± 3.9	22.6 ± 4.3	1.1 ± 4.1	2.5
Frontal plane	ROM swing	12.4 ± 3.6	12.4 ± 4.6	0.03 ± 4.7	3.2
	ROM total	10.2 ± 2.4	10.0 ± 2.6	0.2 ± 2.7	1.7
	ROM stance	9.1 ± 2.1	9.5 ± 2.5	0.5 ± 2.6	1.7
Transverse plane	ROM swing	6.1 ± 1.6	5.4 ± 3.0	0.8 ± 3.0	2.4
	ROM total	11.3 ± 2.9	12.1 ± 4.2	0.7 ± 4.6	3.5
	ROM stance	11.1 ± 3.0	11.8 ± 4.1	0.8 ± 4.6	3.4
	ROM swing	8.2 ± 2.9	8.3 ± 2.7	0.1 ± 3.4	2.2
Hindfoot-Tibia					
Sagittal plane	ROM total	22.1 ± 5.8	22.4 ± 4.5	0.3 ± 4.9	3.1
	ROM stance	17.5 ± 2.8	18.6 ± 4.1	1.1 ± 4.2	3.1
	ROM swing	17.9 ± 6.0	18.2 ± 5.4	0.3 ± 4.4	2.5
Frontal plane	ROM total	12.5 ± 5.6	13.9 ± 3.4	1.4 ± 5.1	3.7
	ROM stance	10.3 ± 3.4	11.8 ± 2.4	1.5 ± 3.8	2.9
	ROM swing	9.9 ± 5.1	10.3 ± 2.7	0.4 ± 4.7	3.6
Transverse plane	ROM total	36.6 ± 9.3	39.3 ± 7.0	2.7 ± 11.3	8.7
	ROM stance	19.7 ± 5.5	21.9 ± 5.9	2.2 ± 6.9	4.5
	ROM swing	34.8 ± 8.7	35.1 ± 8.0	0.3 ± 12.9	6.3

^a Mean values in degrees and standard deviations.
ROM total comprises 0%-100% of gait cycle, ROM stance comprises the stance phase (0%-62%), and ROM swing comprises the swing phase (63-100%).

Table 4: Inter-assessor repeatability and intersegmental ROM of the OFM's Hallux-Forefoot, Forefoot-Hindfoot, and Hindfoot-Tibia segments.^a

		Assessor 1 (°)	Assessor 2 (°)	Mean difference (Assessor 1 versus Assessor 2) (°)	SEM (°)
Hallux-Forefoot					
Sagittal plane	ROM total	23.6 ± 11.1	29.5 ± 8.1	5.9 ± 11.7	8.4
	ROM stance	19.9 ± 10.8	25.8 ± 8.8	5.8 ± 11.3	7.6
	ROM swing	16.2 ± 9.5	19.7 ± 8.8	3.5 ± 10.6	6.7
Forefoot-Hindfoot					
Sagittal plane	ROM total	23.2 ± 3.6	22.5 ± 3.8	0.7 ± 2.7	1.5
	ROM stance	21.6 ± 3.9	20.9 ± 3.7	0.7 ± 3.8	2.2
	ROM swing	12.4 ± 3.6	12.8 ± 3.5	0.4 ± 3.2	1.8
Frontal plane	ROM total	10.2 ± 2.4	9.9 ± 1.7	0.3 ± 1.9	1.2
	ROM stance	9.1 ± 2.1	8.9 ± 1.8	0.2 ± 1.9	1.2
	ROM swing	6.1 ± 1.6	6.1 ± 2.5	0.04 ± 2.1	1.5
Transverse plane	ROM total	11.3 ± 2.9	10.2 ± 2.3	1.2 ± 2.0	1.2
	ROM stance	11.1 ± 3.0	10.0 ± 2.3	1.1 ± 2.0	1.2
	ROM swing	8.2 ± 2.9	8.1 ± 2.9	0.04 ± 2.1	1.1
Hindfoot-Tibia					
Sagittal plane	ROM total	22.0 ± 5.8	19.0 ± 5.6	3.0 ± 5.8	3.4
	ROM stance	17.5 ± 2.8	15.7 ± 4.5	1.8 ± 1.0	3.6
	ROM swing	17.9 ± 6.0	15.8 ± 5.7	2.0 ± 4.7	2.6
Frontal plane	ROM total	12.5 ± 5.6	11.1 ± 4.1	1.4 ± 4.2	2.6
	ROM stance	10.3 ± 3.4	9.6 ± 2.8	0.7 ± 2.7	1.6
	ROM swing	9.9 ± 5.1	8.5 ± 4.1	1.4 ± 3.9	2.4
Transverse plane	ROM total	36.6 ± 9.3	27.7 ± 7.3	8.9 ± 10.7	7.7
	ROM stance	19.7 ± 5.5	16.1 ± 4.5	3.6 ± 5.7	3.8
	ROM swing	34.8 ± 8.7	25.8 ± 7.9	9.1 ± 10.4	7.0

^a Mean values in degrees and standard deviations.
ROM total comprises 0%-100% of gait cycle, ROM stance comprises the stance phase (0%-62%), and ROM swing comprises the swing phase (63%-100%).

Discussion

This study aimed to compare the kinematic output within and between assessors and to evaluate the intra- and inter-assessor repeatability of the OFM with a focus on the hallux-forefoot segment and the swing phase of gait. As hypothesized, the OFM demonstrated comparable kinematic output and sufficient repeatability in the forefoot and hindfoot within the sagittal and frontal planes. However, motion in the transverse plane of the hindfoot exhibited lower intra- and inter-assessor repeatability, as indicated by the SEM values. Additionally, differences in kinematic output were observed, particularly during the terminal stance and pre-swing phases in inter-assessor measurements of the forefoot and during the initial swing and mid-swing phases in inter-assessor measurements of the hindfoot in the transverse plane. The hallux-forefoot segment showed reasonable agreement based on kinematic analysis, while higher SEM values were observed as compared to the forefoot and hindfoot segments. Furthermore, repeatability analyses of the total gait cycle and swing phase revealed comparable intra- and inter-assessor repeatability for the forefoot and hindfoot segments. Finally, repeatability was equal in the swing and stance phases.

Results showed comparable kinematics in the hallux-forefoot segment based on intra- and inter-assessor analyses. Comparison of dynamic joint angles over time showed no differences in the hallux-forefoot segment when data was derived from both assessors (i.e., inter-assessor) or from one assessor at two time points (i.e., intra-assessor). However, the calculated SEM value for the hallux-forefoot was higher than 5° (i.e., intra-assessor SEM was 7.9° ; inter-assessor SEM was 8.4°). McGinley et al. describe SEM reference values and consider errors smaller than 5° to be clinically acceptable, whereas errors exceeding 5° are sufficient to result in clinically relevant errors [25]. The OFM repeatability in the hallux-forefoot segment has been described in two previous studies [26,27]. Mahaffey et al. evaluate repeatability based on kinematic peaks during the gait cycle and report mean ICCs of 0.31° - 0.40° and mean SEM values of 6.09° - 7.52° for the OFM, which aligns with the SEM values calculated in this study [27]. They suggest that lower repeatability in the hallux segment is likely to be affected by the close proximity of other forefoot markers, which leads to marker trajectory cross-over and drop-out [27]. Moreover, it is hypothesized that using only one hallux marker as a segment definition in OFM has a negative impact on repeatability. In OFM, the hallux is modeled as a vector relative to the forefoot to describe hallux motion (dorsiflexion or plantar flexion). Determining the direction of an axis becomes more robust for marker misplacement when more than one marker is used for segment definition [5]. Since the hallux segment and motion are currently defined by one marker in OFM, inconsistent marker placement has a more prominent role and probably results in decreased repeatability. Further work is necessary to examine the effects when more markers or different placement are used for segment definition of the hallux-forefoot segment, which may increase repeatability in this segment. Based on the

moderate repeatability demonstrated and the results offered in the literature, it is recommended to handle the results of the hallux segment of the OFM with caution due to the moderate repeatability.

Results in this study showed satisfactory intra- and inter-assessor repeatability in the forefoot-hindfoot segment, with SEM values below 3.5° in all planes. SEM values in the hindfoot-tibia segment were below 3.7° in the sagittal and frontal plane but exceeded 5° in the transverse plane, which is considered sufficient to potentially introduce clinically relevant errors [25]. A comparison to previous studies is difficult due to methodological variations in the study population, the part or time points of the gait cycle chosen for analysis, and the performed statistical tests for evaluating repeatability. However, findings from previous studies have generally reported SEM values below 5° for the sagittal and frontal planes of the forefoot and hindfoot for intra-assessor repeatability in children [27] and adults [19,21,23] and inter-assessor repeatability in adults [21,23]. Findings have also demonstrated higher errors in the transverse plane of the forefoot and hindfoot segments [11,12,19,21,23]. The present study also showed lower repeatability in the transverse plane of the hindfoot compared to other planes. In the hindfoot-tibia, high SEM values (above 5°) were observed, indicating that attention is required in interpreting the data [25,38]. These results align with findings presented in previous OFM repeatability studies, which have reported the lowest repeatability and higher errors across repeated test sessions in the transverse plane [11,12,39]. McCahill et al. explain that this could be caused by misplacement of the four calcaneal markers [40]. Variations in marker placement occur when issues arise during identification and definition of the hindfoot's neutral position and the related placement of the heel marker [11]. Such misplacement could cause a different segment axis orientation and consequently a difference in detected motion. Therefore, lower repeatability in this segment is found in repeatability analyses. Alignment of the posterior calcaneal marker with the transverse plane marker also influences segment axis orientation. Insufficient alignment could result in lower reliability and higher errors between sessions [12,27]. One study studied whether an anatomical alignment device could reduce intra-tester variability by comparing its results to results when marker placement occurred without an alignment device. They note an improvement in intra-tester variability but not in inter-tester variability. Consequently, the use of such devices was not encouraged [40]. The present study results suggest satisfactory repeatability in the OFM's forefoot-hindfoot and hindfoot-tibia segments in the sagittal and frontal planes for total gait cycle and the swing phase. Repeatability in the hindfoot transverse plane was poorer. Therefore, the hindfoot transverse plane motion results should be interpreted with caution.

As recommended by previous studies, reliability indexes, such as ICCs, are often used but are not suitable for evaluating reliability in 3D gait analysis [23,25,27]. Therefore, findings from the present study suggest reliability based on absolute measures of

measurement errors. However, there are some limitations in the present study that must be considered. Adults aged between 22 and 29 years were analyzed in this study. Results of other studies show differences in foot kinematics between young and older adults, [41] although this effect is not confirmed in all studies [42]. Changes in foot kinematics due to a progressed age could influence the model's repeatability. Therefore, results described herein are primarily applicable to healthy adults and may differ for older subjects. Another limitation regards the inter-assessor analysis, as subjects were measured on the same day. Double-sided tape was used to attach markers and was removed after the first measurement. After at least 30 minutes, the second assessor attached the markers. Total blinding of the assessors cannot be guaranteed since the double-sided tape that was used to attach the initial markers could have left some skin signs after removal, although the second measurement began at least 30 minutes after removal of the initial markers so the skin signs would have time to disappear. Finally, marker misplacement and soft tissue artifacts can introduce measurements errors in 3D gait analysis [25,43-45]. In this study, measurements were conducted by two assessors with experience using the OFM. The present study enhances understanding of the OFM's repeatability and highlights key considerations for future researchers who utilize this multi-segment foot model in kinematic studies.

Conclusion

This study presented an examination of the OFM's repeatability, with a particular focus on the hallux-forefoot segment and the swing phase of gait in healthy adults. Based on intra- and inter-tester repeatability, the OFM is a largely repeatable multi-segment foot model. However, the hallux-forefoot segment exhibits lower intra- and inter-assessor repeatability compared to the forefoot and hindfoot segments. Therefore, careful interpretation of hallux-related results is recommended to ensure that conclusions are appropriately drawn based on individual study data. Furthermore, the swing phase demonstrates repeatability comparable to that of the entire gait cycle, making it a reliable component for analysis. Overall, all OFM segments offer reasonable repeatability for clinical use with minimal errors. However, special caution is advised when interpreting results from the hindfoot's transverse plane motion, as it presents greater variability in 3D gait analysis.

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CHAPTER 8

General discussion

General discussion

Hallux rigidus is a disabling disease with rising prevalence. It can impact a person's quality of life by causing pain and limiting the ability to move normally, resulting in a reduction in activity, social participation, and economic productivity. The present thesis presents an exploration of the effects of HR on normal walking and the related lower-limb compensation for the loss of hallux motion; additionally, the effects on gait pattern of MTP1 arthrodesis as an HR surgical intervention and the related lower-limb compensation mechanism are examined. Furthermore, the thesis offers an evaluation of the effects of surgery on clinical outcome and gait after long-term follow-up to observe which surgical interventions produce the best outcomes. Implant arthroplasty is also receiving increased attention; therefore, a systematic analysis provides the results of MTP1 metallic hemiarthroplasty as a treatment for HR. Finally, a methodological study was performed to increase the knowledge regarding the repeatability of the OFM's foot segments, as the OFM is one of the most used MFMs for gait evaluation.

Overview of findings

The present thesis demonstrates that patients suffering from HR have a different gait pattern compared to healthy individuals. Patients compensate for the painful hallux and reduced hallux motion in the forefoot by using increased forefoot supination and pronation (**Chapter 2**). MTP1 arthrodesis is a successful treatment for HR, as patients report pain reduction and high satisfaction rates after surgery. The fixation of the first metatarsal to the proximal phalanx results in a rigid MTP1 joint without the ability to move. The resulting loss of motion in the MTP1 joint is compensated in the forefoot through increased supination and pronation as well as in the hindfoot through increased inversion and eversion (**Chapter 3**). A well-functioning forefoot and hindfoot is desirable if a patient chooses for an MTP1 arthrodesis. Furthermore, at long-term follow-up, it was observed that arthrodesis, cheilectomy, and Keller's arthroplasty yield comparable patient satisfaction after more than 22 years of follow-up. The highest scores in patient satisfaction and pain reduction were observed after arthrodesis; therefore, there is a slight preference toward arthrodesis for HR patients. Pedobarographic analysis of these patients revealed no differences in plantar pressure distribution during walking after 22 years of follow-up (**Chapters 4 and 5**). A systematic review of the literature highlighted that metallic MTP1 hemiarthroplasty yields excellent and comparable clinical outcomes to MTP1 arthrodesis as well as comparable rates of complications and revisions. Arthrodesis seems to be superior in pain reduction, while MTP1 motion was regained after hemiarthroplasty. Therefore, metallic hemiarthroplasty is a suitable alternative for patients who perform activities that require motion in the MTP1 joint (**Chapter 6**). Furthermore, the OFM is a repeatable MFM and useful in 3D gait analysis. The hallux segment offers moderate intra- and inter-assessor repeatability; additionally, the swing phase demonstrates comparable repeatability to the total gait cycle and is a legitimate portion of analysis (**Chapter 7**). The results in the present thesis contribute

to increasing the insights regarding the effects of HR and related treatments and can accompany clinical decision-making to determine the most suitable treatment for a patient.

Gait deviations observed in HR and after MTP1 arthrodesis

The present thesis offers a study of the foot compensation mechanism in HR and after MTP1 arthrodesis; 3D gait analysis demonstrated that HR significantly reduced hallux motion. Foot and ankle kinematics exposed reduced plantar flexion of the hallux in midstance and reduced hallux dorsiflexion in pre-swing (**Chapter 2**). The expected compensation for loss of hallux motion was found in the forefoot with increased forefoot supination during pre-swing. This altered gait pattern is considered a compensatory mechanism for the limited range of motion and avoidance of the painful MTP1 joint during gait and has not been previously described in literature. Furthermore, foot loading was studied, since some studies have suggested that HR patients reduce loading of the MTP1 joint and increase loading of the lateral plantar foot zones (lateral loaders) [1,2], while others have not observed this effect [3]. The findings in the present study do not reveal differences in plantar loading. The lack of differences in plantar pressure distribution could be explained by the fact that, although limited and painful, there is still enough motion remaining in the MTP1 joint, and consequently, plantar loading is not affected. Furthermore, the present study used pressure time integral (PTI) values instead of peak pressures (PPs) to study foot loading because PTIs are more informative than PPs since PTIs describe the cumulative effect of pressure over time in a certain area of the foot and thus provide a value for total load exposure of a foot sole during one step, whereas PPs represent the maximal load in an area under the foot during one step [4]. Therefore, it could be that higher PPs are observed in the lateral sides of the foot, while total load exposure of the foot during one step is not affected.

Furthermore, in addition to HR patients' compensatory mechanisms, there is less evidence regarding foot compensation after MTP1 arthrodesis as an HR surgical intervention [5-8]. As expected, loss of motion of MTP1 after arthrodesis due to rigid MTP1 fixation is compensated by increased forefoot pronation and supination as well as increased hindfoot inversion and eversion motion (**Chapter 3**). Based on the study results of **Chapters 2 and 3** it is demonstrated that patients compensate in a comparable way by increased frontal plane motions in the forefoot and hindfoot in HR and after MTP1 arthrodesis. It is suggested that this is because the MTP1 joint is substantially affected preoperatively in HR patients', resulting in pain and mechanical impingement, which limits MTP1 joint motion. These factors lead to avoidance of loading and toeing-off over the MTP1 joint during push-off, which is compensated by increasing pronation and supination of the forefoot [9]. After surgery, MTP1 joint motion is lost due to fusion of the proximal phalanx to MTP1. Therefore, toeing-off over the MTP1 joint is further reduced and remains limited. More compensation is necessary and the forefoot (pronation and supination) and hindfoot (inversion and eversion) compensate in the

frontal plane for the loss of motion. Altogether, this suggests that MTP1 joint motion preoperatively and postoperatively is not significantly changed, and in both scenarios, MTP1 joint motion is significantly limited or impossible. A well-functioning forefoot and hindfoot to fulfill frontal plane motions is necessary for a MTP1 arthrodesis to compensate for the loss of motion in MTP1 after arthrodesis.

Sufficient improvements after surgical interventions for HR in patients' satisfaction and clinical outcomes

Surgical interventions are indicated when conservative treatments fail [10,11]. As described in **Chapter 1**, a variety of surgical techniques are available, all of which have the same goal: to relieve pain, enhance function, and improve quality of life [5,6]. Clinical and patient-reported outcome measures (PROMs) are evaluated in HR patients before and after MTP1 arthrodesis in **Chapter 3** and demonstrate that surgery results in a clinically significant reduction in patient complaints and increased patient satisfaction. Pain was significantly reduced and patients reported fewer limitations in standing and walking in addition to improvements in participating in daily and social activities. Results of the AOFAS-HMI (American Orthopaedic Foot & Ankle Society Hallux Metatarsophalangeal-Interphalangeal) questionnaire revealed that after MTP1 arthrodesis, patients approached the normal reference values (AOFAS-HMI scores) of individuals without any foot pathology, thereby indicating that patient functioning after MTP1 arthrodesis is comparable to patients without foot complaints [12]. The observed clinical improvements in the present chapter were in accordance with findings from previously published studies in which PROMs were evaluated postoperatively or at midterm follow-up after MTP1 arthrodesis [13-18].

The results in the present chapter confirm that MTP1 arthrodesis is a sufficient treatment for patients suffering from HR. After this surgical intervention, pain and related complaints are sufficiently reduced and patient function returns to a similar level as patients without foot pathology.

In addition to MTP1 arthrodesis, cheilectomy and Keller's arthroplasty are often performed as surgical interventions for HR (**Chapter 1**) [19]. The thesis offers an evaluation of the long-term follow-up results and a comparative study after 22 years of follow-up, since this was not previously available. **Chapter 4** reports that arthrodesis, cheilectomy, and Keller's arthroplasty yield comparable patient satisfaction based on several PROMs (AOFAS-HMI, Visual Analog Scale (VAS), Forgotten Joint Score (FJS-12), and Manchester Oxford Foot Questionnaire (MOXFQ)) after more than 22 years of follow-up. Although no statistically significant differences were detected between groups at follow-up, minimally clinically important differences (MCIDs) in outcome between arthrodesis and cheilectomy patients were detected with the AOFAS-HMI and VAS pain scores, in favor of arthrodesis. Furthermore, a clinically relevant lower pain score was also seen after Keller's arthroplasty as compared to cheilectomy. Results

were also compared to the study after seven years of follow-up; here, a significant improvement in clinical outcome and pain reduction during follow-up was seen only in the arthrodesis group [13]. The results of these long-term follow-up studies (**Chapter 4**) suggest that arthrodesis, cheilectomy, and Keller's arthroplasty are proper methods to treat symptomatic HR with good-to-excellent PROMs after a long postsurgical period. All three methods can be recommended as surgical interventions for HR, although proper preoperative staging remains essential since cheilectomy is predominantly recommended for patients with mild-to-moderate HR whereas Keller's arthroplasty and arthrodesis are predominantly used for more progressed patients. Furthermore, based on these studies, there could be a slight preference toward performing arthrodesis based on improvements in clinical and patient-reported outcomes as well as pain reduction at long-term follow-up.

In addition to the success of different surgical techniques presented in this study, there is increasing interest for novel surgical techniques including implant arthroplasty. A systematic review and meta-analysis of literature was performed to compare the results of MTP1 metallic hemiarthroplasty to MTP1 arthrodesis (**Chapter 6**). The results presented in this chapter offer a comparable and excellent clinical outcome as well as an acceptable number of complications and revisions after both interventions. Arthrodesis was superior in pain reduction, while MTP motion was regained after MTP1 hemiarthroplasty. However, a unique difference between these interventions is that MTP1 motion is restored after hemiarthroplasty, while it is sacrificed after arthrodesis. Loss of motion can be an issue for younger patients with an active lifestyle; for those whose occupations require, for instance, kneeling or squatting; or for those who enjoy recreational activities such as playing sports [20,21]. These activities or domains were not analyzed in most used questionnaires of the AOFAS-HMI and VAS pain score of the individual studies. Evaluation could be performed using the MOXFQ and foot function index (FFI); however, this was not possible in the present study since these outcomes are rarely reported in the included studies [22,23]. The use of such questionnaires could be profitable in further hemiarthroplasty studies to see whether higher scores are observed in these domains after hemiarthroplasty as compared to arthrodesis.

Furthermore, **Chapter 6** offers a systematic review and meta-analysis in which metallic hemiarthroplasty implants were evaluated. A sub-analysis exposed lower pain scores after metatarsal head resurfacing compared to phalanx resurfacing. A feasible explanation for this difference is that the pathologic features of HR are believed to be most present on the metatarsal side of the joint; since this is resurfaced during metatarsal head prosthesis, this could explain decreased pain scores [20,24]. However, no comparative studies of specific implants were available; future studies should test the hypothesis to explain the differences between implants based on the implant rationale.

Gait and biomechanical outcomes do not influence the long-term follow-up results

As previously described and studied, a surgical intervention could result in gait deviations. Limited gait and biomechanical evaluation studies after surgical treatments in HR are available [3,17,25-30]. Few studies have evaluated gait and plantar pressure distribution after Keller's arthroplasty [25], arthrodesis [17,26-29], and cheilectomy [3,30] for HR as frequently performed interventions for HR. Comparing these study results is difficult due to the methodological heterogeneity that is present between these studies in (i) measurement systems, (ii) pressure distribution models used and subdivision in foot areas, (iii) control groups used, (iv) variety in outcomes, and (v) differences in follow-up periods [3,17,25-30]. Therefore, we decided to perform a comparative study and invited Keller's arthroplasty, arthrodesis, and cheilectomy patients after 22 years of follow-up for gait analysis and an investigation of clinical and patient-reported outcomes (**Chapters 4 and 5**).

The findings do not reveal differences between the interventions or compared to healthy controls based on foot pressure analysis. Effect sizes were small and no statistically significant differences were observed in plantar pressure analysis (PTIs and PPs) in the analyzed foot zones (**Chapter 5**). The results of the present biomechanical study and the clinical evaluation study in Chapter 4 indicate that patient function is similar after 22 years of follow-up, irrespective of the performed surgery. This is a notable observation, as the past few decades have witnessed an increasing preference to perform cheilectomies and arthrodesis over Keller's arthroplasty in HR patients. The preferences grew because Keller's arthroplasty results in a nonfunctional first ray, which can cause several complications, including cock-up deformity, active flexion limitation, and a floppy toe [31]. Therefore, Keller's arthroplasty was less favorable because of the fear of having a nonfunctional first ray that could result in pain and functional limitations [26,27]. Additionally, proper preoperative staging of HR is essential since cheilectomy is generally performed in low-grade HR, whereas Keller's arthroplasty and arthrodesis is predominantly used in more progressed HR (and in the performed study). The present study results suggest that Keller's arthroplasty, arthrodesis, and cheilectomy are appropriate surgical treatments for a selective group of patients suffering from symptomatic HR as they return patients' function to a level comparable to healthy controls after long-term follow-up.

Use and repeatability of MFMs in analyzing hallux and forefoot pathologies

Based on the available evidence at the start of this study, the OFM was chosen to perform gait analysis studies in HR patients before and after surgery since it is one of the most frequently used MFMs in 3D gait analysis, offers satisfactory repeatability in several foot segments, and includes a hallux segment [41,42,45,53,57]. However, repeatability of the hallux segment and the swing phase of gait have not been previously examined. The results demonstrate moderate intra- and inter-assessor repeatability of

the hallux segment, although it is lower than sagittal plane motion in the forefoot and hindfoot (**Chapter 7**). Therefore, caution is recommended when interpreting results of the hallux segment and reporting appropriate conclusions based on the individual study data. Furthermore, the swing phase demonstrates comparable repeatability compared to the total gait cycle and is a legitimate part of analysis. All OFM segments demonstrate reasonable repeatability for use in clinical practice with small errors. Only motion in the transverse plane of the hindfoot receives special attention for data interpretation in 3D gait analysis due to the low repeatability and high errors across repeated test sessions.

Based on these results, the OFM remains a valuable MFM. However, the results indicate some room for improvement. Research and development in MFMs is growing; while the OFM belongs with Milwaukee and Rizzoli Foot Model (RFM) models as the most widely applied foot models, there are 39 other known MFMs [37]. More recently, the innovative Amsterdam foot model (AFM) was published, which is based on the OFM and RFM and incorporates the advantages of both models [38]. Based on the repeatability study in **Chapter 7**, it is recommended to critically analyze hallux segment markers and aim to increase the repeatability of this segment if new MFMs are developed.

Furthermore, the models vary in number of segments, marker sets, anatomic segment definition, modeling, repeatability, and equipment, resulting in a complex array of models suited for the evaluation of different clinical and biomechanical situations [37,39]. Future studies should use a universally accepted foot model in 3D gait analysis since several available foot models could introduce diversity of results due to model-specific characteristics of measurement and analysis. This hampers comparison of study results and observation of effects of a specific intervention.

Limitations

Despite the described findings in the present thesis, some limitations must be acknowledged. Comparing biomechanical study results was challenging since a wide variety is present in the literature, which originates from the heterogeneity in study design and methodological set-up. First, different study designs were used in the previous biomechanical studies, including longitudinal (i.e., preoperative to postoperative analysis) and cross-sectional study designs (i.e., evaluating postoperatively or at follow-up). Both types of designs lead to different comparisons, which could explain the differences in study results [17,26,27,29]. Second, biomechanical evaluations were performed at varying follow-up times from postoperative to short- and mid-term follow-up (ranging from 20 to 47 months) [3,17]. Evaluation at different follow-up times could also affect study results. Third, a variety of comparator groups (i.e., another surgical intervention, the contralateral foot, or healthy controls) were used in previous biomechanical studies. The contralateral foot is often used as the healthy standard [3,17,30]. It remains debatable whether the contralateral foot should be used as a healthy comparator, since it is largely unclear if the contralateral foot

is free of any pathology and therefore is unknown if it functions as a healthy foot [40,41]. Healthy controls without any symptoms are possibly a more appropriate and representative control group [42,43]. It is assumed that in every study a certain degree of heterogeneity exists, although it is probably more pronounced in gait studies due to the diversity in measurement methods. Therefore, it is important to remember these points when interpreting study results. In the present thesis, we attempted to manage these methodological issues to incorporate these findings, describe detailed information, and pursue a contemporary methodology.

The limitations of MFMs

Dynamic evaluations of clinical foot and ankle disorders are regularly performed with 3D gait analysis using marker-based MFMs. Currently, 39 MFMs are known [37]. However, using MFMs to evaluate foot motion has limitations. MFMs that rely on skin-mounted markers to define and track segments are particularly sensitive to measurement variability, such as soft tissue artifacts and marker misplacement, which affect the segment coordinate systems and consequently the joint kinematics [38,44]. Soft tissue artifacts are tracking marker movements on their corresponding bony landmarks, which can induce measurement errors. Furthermore, precise identification of anatomic landmarks that guide skin marker placement can be difficult and may introduce marker misplacement, which could lead to measurement errors and affect the repeatability and interpretation of kinematic data [38,44]. Inconsistent marker placement could be caused by the use of different examiners or different sessions. Therefore, repeatability studies are essential to acquire a thorough understanding of kinematic measurement errors to avoid over- and under-interpretation of clinical data.

Chapter 7 of this thesis reports that OFMs demonstrate an overall reasonable repeatability for use in clinical practice with small measurement errors. Therefore, the OFM remains an accurate and valuable model for 3D gait analysis. However, the described limitations of foot models must be remembered when analyzing results. Furthermore, research and development of kinematic foot models is ongoing. The innovative AFM was recently published and is based on the OFM and RFM but incorporates the advantages of both models; the AFM offers smaller measurement errors compared to OFM and RFM [38]. Future studies are recommended to evaluate the AFM's repeatability and clinical applicability.

The limitations of foot-specific questionnaires

In the present thesis, several foot-specific questionnaires were used (**Chapters 3 to 6**). The AOFAS-HMI score is the most frequently used clinical outcome instrument in evaluating foot and ankle pathology (**Chapter 6**) [45,46]. This reliable and responsive instrument provides insights into foot function and pain, although some parts seem to be invalid after surgery for HR [47,48]. For instance, the MTP1 joint's range of motion is evaluated, but no MTP1 motion is possible after arthrodesis. To overcome

this problem, a modified AOFAS-HMI score was developed and used in the studies (**Chapters 3, 4 and 6**) in this thesis [49]. The limitations of questionnaires were recalled when performing the systematic review and meta-analysis in the present thesis, and methodology adjustments were made before comparisons were performed (**Chapter 6**). Furthermore, the AOFAS-HMI is not a patient-reported outcome measure, since a foot clinician's experience and evaluation is necessary [50]. Therefore, the use of other patient-reported instruments, including the MOXFQ and FFI, is encouraged. These foot-specific questionnaires are validated and reliable to assess foot and ankle complaints [23,51]. Additionally, these foot scores were included in the performed studies (**Chapters 3, 4 and 6**). As observed in **Chapter 6**, the use of these questionnaires is encouraged since they evaluate helpful domains when comparing surgical techniques, such as implant arthroplasty and arthrodesis (in implant arthroplasty, MTP1 motion is restored while it is sacrificed after arthrodesis). Perhaps this could assist in future clinical decisions regarding which technique is preferred by a specific patient.

Future directions for research and clinical care

The present thesis provides quantitative information on multi-segment changes in foot kinematics and the related compensatory mechanism in patients suffering from HR before and after MTP1 arthrodesis. A well-functioning forefoot and hindfoot that can perform frontal plane motions (pronation and supination as well as inversion and eversion) is desirable if a patient is to undergo MTP1 arthrodesis. Obtaining further knowledge regarding foot and ankle kinematics after surgical interventions, such as implant arthroplasty, could be innovative. For instance, it is expected that after implant arthroplasty, an increase in hallux motion during walking will be observed. Therefore, the foot will probably compensate less, and the gait pattern after such an intervention will be comparable to the gait pattern of healthy individuals. Perhaps this is a more suitable option for patients with less compensatory reserve (i.e., less frontal forefoot and hindfoot motion). Future studies must elucidate which patients experience advantages from a restoration of hallux motion and which patients benefit from a compensation in other foot segments. If known, kinematic analysis could contribute to surgical planning, resulting in an optimal intervention selection.

In the present thesis, no differences were observed in pedobarographic analysis in HR patients (**Chapter 2**) or after 22 years of follow-up after arthrodesis, cheilectomy, and Keller's arthroplasty (**Chapter 5**). However, in-depth analysis of the foot and ankle kinematics in HR and after MTP1 arthrodesis revealed differences as compared to healthy controls (**Chapters 2 and 3**). This could indicate that foot pressure distribution is not sufficiently affected by HR and related surgeries, while extensive study of the effects on joint angles and foot segment motions (kinematics) may reveal that the differences are still there. Combining both methods can provide a more comprehensive understanding of gait and foot functioning. However, based on the findings presented in

this thesis, future researchers should perform kinematic analysis over pedobarographic analysis to study the effects of HR and accompanying surgical interventions.

Instrumented gait analysis (3D gait analysis) in traditional gait laboratories is a well-established tool for quantitative gait assessment, which could be used for functional diagnosis, treatment planning, rehabilitation, and progress monitoring for a wide spectrum of diseases including foot and ankle pathologies. However, performing this process and analyzing the results for use in clinical practice is extensive, time-consuming, and costly. Future researchers must focus on optimizing this process using, for instance, wearable technology and computationally advanced data analytics; including artificial intelligence; allowing gait analysis in less costly, portable, and relatively simple gait testing protocols in clinical settings; and implementing user-friendly data management, analysis, and interpretation.

Surgical techniques for HR—arthrodesis, Keller’s arthroplasty, and cheilectomy—offer satisfactory results after long-term follow-up, as presented in **Chapters 4 and 5**. In recent decades, there has been an increasing interest in MTP1 implant arthroplasties including hemiarthroplasty and TJR. As described in **Chapter 6**, such interventions have advantages and disadvantages compared to more traditional surgical techniques. However, more comparative studies are necessary to explore which implant produces ideal patient-reported outcomes as well as complications and revisions. Furthermore, few results regarding implant functioning after long-term follow-up are available; therefore, long-term follow-up studies are recommended to evaluate implant survival time. The use of foot-specific patient-reported outcome questionnaires is also recommended to acquire more insights into the advantages of implants over the current techniques.

Besides, biomechanical and clinical outcomes of interventions, there is raising interest in cost-effectiveness evaluations. In recent decades, health care costs have risen due to the aging population, chronic disease prevalence, and lifestyle changes. Therefore, there is more pressure on the health care system to perform cost-effective interventions. In cost-effectiveness analyses, economic costs and clinical effects are combined. Only a few cost-effectiveness analyses are available for HR and the related surgery [52-54]. However, such analyses could be of additive value and could assist clinical and health care-related decision-making.

These analyses are necessary due to the expected increasing prevalence of HR and the accompanying impact on health care and public health systems.

Conclusion

The present thesis adds to the insights regarding the effects of HR and the related treatments, which can accompany clinical decision-making in determining the most suitable treatment for a patient. This thesis highlights the significant gait deviations observed in HR and after MTP1 arthrodesis, particularly in reduced hallux motion and compensatory mechanisms in the forefoot and hindfoot. The findings confirm that MTP1 joint motion remains substantially limited preoperatively as well as postoperatively and that a well-functioning forefoot and hindfoot are essential to compensate for the loss of motion in the MTP1 joint. Additionally, the method of analysis proves to be important: kinematic analysis revealed gait deviations in HR and after MTP1 arthrodesis, whereas no differences were found in foot pressure analyses. This suggests that while plantar pressure does not change, joint motion is influenced. Therefore, it is recommended to conduct foot and ankle research using kinematic analysis methods. Further opportunities for study are gait pattern analyses after other surgical interventions for HR and exploring the existence of compensation mechanisms in the foot during gait as well as identifying which patient profile would benefit the most from a specific intervention. This could be used in addition to the existing selection criteria for specific treatments to determine the ideal intervention for each patient. Additionally, challenges remain in the measurement methods for joint kinematics. While current measurement and analysis methods are comprehensive, costly, and time-consuming, simpler and quicker methods could improve clinical applicability. The current study also demonstrates that existing surgical interventions (Keller's arthroplasty, cheilectomy, and arthrodesis) for HR yield appropriate long-term results based on clinical and patient-reported outcomes, which leads to the conclusion that the performed surgeries are valued by HR patients after long-term follow-up. All techniques offer adequate results, with the least pain observed in the long-term following arthrodesis. Additionally, newer and innovative methods involving prostheses have provided satisfactory clinical outcomes with acceptable numbers of complications and revisions. However, long-term studies are needed to determine whether these newer methods ultimately perform as well as the current techniques.

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CHAPTER 9

Impact

Impact

The hallux or big toe fulfills an indispensable function in daily life. It distributes weight across the foot, aiding propulsion during toeing-off and providing stability and balance during standing, walking, and running. Pathologies affecting the hallux can negatively influence the core functions of the hallux and could result in severe limitations during daily activities. OA of the MTP1 joint is the most common form of degenerative joint disease in the foot. Of all patients aged 50 years, 2.5% report degenerative arthritis of the MTP1 joint. HR could have a significant social impact on individuals, particularly for those who are physically active or have occupations that require standing, walking, or kneeling for extended periods. The related pain and the restricted mobility could affect many domains, including regular daily activities, occupations and job performance, participation in social interactions and events, and emotional well-being, as feelings of sadness, isolation, or exclusion may occur.

Recognition and sufficient treatment of HR is necessary to treat patients using the optimal intervention to avoid the negative social and socioeconomic impacts of HR. As mentioned, the hallux has an important function during standing, walking, and running. Less knowledge is available in these domains; therefore, the present thesis provides an examination of functional and clinical outcomes and offers results from gait studies to supply insights into the impact of HR on gait. It was revealed that HR patients compensate in the forefoot for the painful and reduced motion in the hallux. After a surgical intervention using MTP1 arthrodesis, this compensation is maintained. Since hallux motion is further reduced due to surgical characteristics wherein a rigid fixation is created in the MTP1 joint, the hindfoot works with the forefoot to compensate for the reduced hallux motion, which is a sufficient mechanism since patients report pain reduction and increased participation in daily and social activities after MTP1 arthrodesis. This is a first step into clarifying the intrinsic foot compensation mechanism after MTP1 arthrodesis; however, the effects after long-term follow-up need to be examined even as the effects and possible development of other foot problems which could be related to this compensation mechanism.

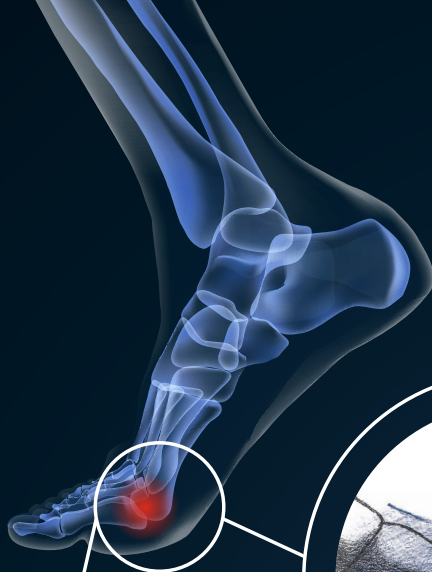
Less evidence is available regarding the impact to patient functioning in daily activities after surgical interventions for HR or at long-term follow-up. To acquire further insights into the long-term effects, the present thesis offers an evaluation of three well-known surgical techniques: Keller's arthroplasty, arthrodesis, and cheilectomy. Based on the disease state, patient's age, and activity level evaluated by a health care provider, a technique can be chosen for a patient: cheilectomy is recommended for patients with mild-to-moderate HR, whereas Keller's arthroplasty and arthrodesis are preferred for a more progressed stage of HR. Based on patient-reported outcomes, patients remain satisfied, experience fewer limitations in daily life, and function comparably to patients without foot pathologies at long-term follow-up. No major

differences were observed after undergoing one of the three techniques, while the greatest improvements were observed after arthrodesis. Furthermore, functional evaluations of gait using a pedobarographic analysis method revealed no differences in plantar pressure distribution between the three techniques and compared to healthy subjects. Additionally, this thesis demonstrates that patients who underwent a surgical intervention for a painful hallux remain satisfied and function at a comparable level to healthy subjects after long-term follow-up. The reported results are useful for health care providers, including orthopedic surgeons, general practitioners, and physical therapists, in advising and describing the expected clinical and functional outcomes after treatment and can therefore assist in clinical decision-making. Using shared decision-making, patients can, with their health care provider, make a well-considered decision regarding the most appropriate treatment.

This thesis also indicates that implant arthroplasty for HR has promising results and could impact certain patients: metallic hemiarthroplasty offers comparable outcomes to arthrodesis, which is currently the gold standard treatment for HR. While hallux motion is sacrificed after arthrodesis, it is restored after hemiarthroplasty, which is attractive for younger patients who live an active lifestyle, for those with occupations that require kneeling or squatting, for those who play sports that require prolonged running, or for those who enjoy wearing fashionable shoes, such as high heels. Hemiarthroplasty's long-term effects and functional outcomes in foot and ankle kinematics are currently unclear and must be examined in upcoming studies.

This thesis impacts the scientific research community, since several methods are used for quantitative gait assessment. In 3D gait analysis, the OFM is a repeatable MFM that can therefore be recommended for further research purposes and use in clinical settings to observe the foot and ankle kinematics in a broad range of foot and ankle pathologies. Furthermore, the findings in this thesis verify that kinematic analysis is recommended over pedobarographic analysis in HR studies and related surgeries, as differences can be observed in foot and ankle kinematics that cannot be traced using pedobarographic analysis.

Finally, this thesis highlights several new aspects of HR and the related surgical interventions regarding clinical and functional outcomes. In addition to offering further knowledge, more questions were developed as part of the process of clinical scientific research; these can be clarified in future studies. The results of the thesis impact patients, health care providers, and the scientific community: all can gain more knowledge and ultimately optimize clinical decision-making. The findings in this thesis can be incorporated in the development of guidelines for clinicians who treat patients with HR.



CHAPTER 10

Summary

Nederlandse samenvatting

Curriculum Vitae

List of publications

Dankwoord

Summary

Osteoarthritis (OA) is the most common joint disorder and a leading cause of pain and disability worldwide. It is typically a progressive disease, and symptoms become more severe, more frequent, and more debilitating over time. The prevalence is rapidly rising, which suggests that OA will have a growing impact on health care and public health systems in the future. OA predominantly affects hips, knees, hands, and feet. MTP1 OA, also named HR, is the most common form of degenerative joint disease in the foot. It is characterized by cartilage degeneration, especially dorsally in early stages of the disease and progressing during aging to involve the entire joint. The development is a multifactorial process including trauma, positive family history, and female gender. The MTP1 joint has important functions in balance and stability, weight distribution, and efficient movement during various activities involving the feet. Since the joint is affected by the process of OA, patients experience joint pain, swelling, stiffness, and restriction in dorsiflexion, especially during activities. This results in altered gait mechanics and walking difficulties that influence daily activities, social participation, economic productivity, and health-related quality of life. Initially, HR is managed nonoperatively, while surgical interventions are inevitable when conservative treatments fail.

Several techniques, including joint-preserving and joint-sacrificing procedures, are available, while the optimal operative technique has yet to be defined since each treatment has advantages and disadvantages. The choice of an operative intervention is based on the degree of HR, patient's age, activity level, and expectations. Each technique influences gait, especially foot and ankle motion, as each surgical technique has its own characteristics that either restore or sacrifice MTP1 joint motion. The reduction in or complete loss of motion must be compensated through other joints of the foot and ankle. Knowledge about the compensation mechanism as well as which foot and ankle joints are involved is necessary to select the optimal treatment for a patient since an intervention that needs compensatory motion in an adjacent foot joint is not suitable for subjects who already have arthritic changes in these other joints. Before suggestions and tailor-made advice can be offered to patients, knowledge regarding the compensation mechanisms in the foot and ankle in HR and after surgery must be known.

The present thesis offers an exploration of the compensation mechanisms in the foot and ankle in patients suffering from HR and after surgical interventions (**Chapters 2 and 3**). Furthermore, the thesis provides an evaluation of long-term clinical and biomechanical outcomes after surgical interventions for HR (**Chapters 4 and 5**) and more novel methods, including implant arthroplasty for HR (**Chapter 6**). Finally, the thesis supplies an analysis of the repeatability of the OFM, which is used in 3D gait analysis to evaluate foot and ankle disorders (**Chapter 7**).

The gait patterns of patients suffering from HR are explored in **Chapter 2** and compared to healthy controls through 3D gait analysis using a VICON motion capturing system. It was observed that hallux motion was significantly reduced in patients suffering from HR during walking. Dorsal and plantar flexion of the hallux during push-off was significantly reduced. A compensatory motion was observed in the forefoot, where increased forefoot supination and pronation was observed during gait. Based on these altered foot kinematics, increased loading of the lateral plantar foot zones were expected. However, these effects were not observed during plantar pressure measurements during walking. The findings from this study reveal that the foot compensates in other foot segments for the painful and reduced MTP1 motion during walking in patients suffering from HR.

Furthermore, the thesis furnishes an examination of the effects of surgery on the gait pattern to observe whether postsurgical gait would be restored to that of healthy individuals. **Chapter 3** presents a study where patients with HR were treated with MTP1 arthrodesis, which is considered the gold standard treatment for HR. The results were compared to the walking pattern before surgery and in healthy controls; the results demonstrate that the loss of motion in MTP1 after arthrodesis due to plantar and dorsiflexion inability in MTP1 is compensated by increasing forefoot pronation and supination as well as increasing hindfoot inversion and eversion. Furthermore, the forefoot and hindfoot compensate for the loss of motion in MTP1 after MTP1 arthrodesis. The foot and ankle kinematics are not restored to the gait pattern of healthy individuals. Additionally, clinical outcomes and patient-reported outcomes were evaluated and demonstrated that pain is significantly reduced after surgery. Patients reported fewer limitations in standing and walking, while participation in daily and social activities was improved. Patient functioning was comparable to subjects without foot pathologies. Additionally, foot kinematics are different after MTP1 arthrodesis compared to healthy controls, while pain complaints are reduced and substantial improvements in daily and social activities are observed.

Additionally, the thesis provides additional knowledge on the long-term effects of surgery for HR. Since few studies are available that evaluate the long-term effects, it was decided to perform an evaluation study (**Chapters 4 and 5**) after long-term follow-up. Three widely used surgical techniques—Keller’s arthroplasty, arthrodesis, and cheilectomy—were evaluated. Patients were initially evaluated after seven years of follow-up and were invited for follow-up evaluation. After 22 years of follow-up, no statistically significant differences in clinical outcomes and patient-reported outcomes, as assessed using AOFAS-HMI, VAS pain score, FJS-12, and MOXFQ, were observed between the groups. However, MCIDs were observed between the groups. A clinically relevant difference in higher AOFAS-HMI score was observed after arthrodesis as compared to cheilectomy. Furthermore, clinically relevant lower pain scores were observed after arthrodesis and Keller’s arthroplasty as compared to cheilectomy. Comparing the results after 22 years of follow-up to the initial study after seven years

of follow-up, patients with an MTP1 arthrodesis reported improved AOFAS-HMI scores and less pain based on the VAS pain score at follow-up. No differences over time were observed after Keller's arthroplasty and cheilectomy. The findings in this study suggest that arthrodesis, Keller's arthroplasty, and cheilectomy are all proper methods to treat symptomatic HR patients with good-to-excellent clinical and patient-reported outcomes after a long postsurgical period. The results of the present study indicate a slightly better clinical outcome after arthrodesis.

The thesis also supplies a gait evaluation at long-term follow-up (**Chapter 5**). A Zebris instrumented treadmill was used for gait and pedobarographic analysis, and results from the three intervention groups were compared to the gait of healthy subjects without foot pathologies. The results revealed comparable spatiotemporal parameters between all groups during walking. No differences were observed between the groups in plantar PPs and PTIs as pressure distribution outcomes during walking. MOXFQ questionnaires results are also evaluated in **Chapter 4** and used for correlation analysis. No clinical or statistical differences were observed between the groups based on MOXFQ results. Correlation analysis exposed no substantial associations between plantar pressure results of the forefoot and the MOXFQ results. Predicting plantar pressure in the forefoot based on PROMs and vice versa is currently not reliable for clinical practice based on the present study's results, and the results of the present study suggest no long-term functional or biomechanical differences after these surgical interventions for HR. The surgical interventions are appropriate treatment options for a selective group of patients with symptomatic HR.

Implant arthroplasty is becoming increasingly popular in HR, and several papers have been published. **Chapter 6** details a systematic review with a meta-analysis to assess whether MTP1 arthrodesis or metallic hemiarthroplasty is superior in the treatment of HR in clinical outcomes, pain reduction, and complication and revision rates. Comparable clinical outcomes were observed after both interventions, which aligns with the majority of studies that have reported scores comparable to the typical values of healthy elderly people without foot pathology. Patients reported less pain, based on VAS pain score, after arthrodesis as compared to metallic hemiarthroplasty. Furthermore, the number and nature of complications and rates of revision were comparable after hemiarthroplasty and arthrodesis. Further in-depth analysis exposed trends of lower pain scores in hemiarthroplasty implants wherein the metatarsal head is resurfaced comparable to when the phalanx component is resurfaced. Results in the present study suggest that arthrodesis is superior in pain reduction, while hemiarthroplasty is a suitable alternative for patients who perform activities that require motion in the MTP1 joint.

In 3D gait analysis for determination of foot and ankle motion during walking, an MFM is necessary to visualize motion. One of the most commonly used MFMs to evaluate foot

pathology in research and clinical settings is the OFM. This model is used in **Chapters 2 and 3** to visualize foot and ankle motion in HR patients before and after a surgical intervention. In **Chapter 7**, the intra- and inter-repeatability of the OFM is assessed, with special attention on the hallux-forefoot segment and swing phase of gait during walking. The hallux-forefoot segment demonstrated moderate intra- and inter-assessor repeatability, while a lower repeatability was observed as compared to sagittal plane motions in the forefoot and hindfoot. Based on the present results, the total gait cycle (especially the swing phase in the sagittal plane and frontal plane of the forefoot and hindfoot) is legitimate for analysis, while the transverse plane of the hindfoot requires some attention when interpreting data. In conclusion, the OFM offers reasonable repeatability in foot segments for use in clinical practice with overall small errors.

In summary, this thesis provides new insights in gait and clinical outcomes at short- and long-term follow-up of patients suffering from HR after related surgical treatments. It demonstrates insights in gait changes in HR patients and after surgery. Changes in gait patterns have to be observed before it can be determined whether gait analysis can be applied as a diagnostic tool. This thesis proves that kinematic analysis using 3D motion capturing systems are useful to determine gait alterations before and after surgery for HR. However, plantar pressure is not influenced by surgery and is therefore not useful in studying HR. Future researchers should focus on gait changes using 3D gait analysis after other treatments to observe whether alternating gait patterns exist between treatments and whether this can be used as a diagnostic tool for selecting the optimal treatment for a patient suffering from HR. Moreover, the present thesis demonstrates that the current treatments including arthrodesis, Keller's arthroplasty, and cheilectomy are all proper treatments for HR and that patients are still satisfied after long-term follow-up. Additionally, novel treatments using metallic hemiarthroplasty provide promising results as treatments for HR. Long-term patient satisfaction and implant survival time have to be evaluated in future studies to observe whether these interventions are comparable or superior to the current treatments for HR.

Nederlandse samenvatting

Artrose is de meest voorkomende gewrichtsaandoening en de belangrijkste oorzaak van pijn en invaliditeit wereldwijd. Het is een progressieve ziekte, waarbij de symptomen in de loop van de tijd ernstiger, frequenter en meer invaliderend worden. De prevalentie stijgt snel, wat suggereert dat artrose in de toekomst een toenemende impact zal hebben op het gezondheidszorgsysteem. Artrose, ook wel osteoarthritis, treft vooral de heupen, knieën, handen en voeten. MTP1-artrose, ook wel hallux rigidus of in de volksmond grote-teen artrose genoemd, is de meest voorkomende vorm van degeneratieve gewrichtsaandoeningen in de voet. Het wordt gekarakteriseerd door degeneratie van het kraakbeen op vooral het dorsale deel van het MTP1-gewricht in het vroege stadium van de ziekte. Naarmate de ziekte vordert, zal dit uitbreiden, zodat het gehele gewricht zal worden aangedaan. De ontwikkeling van de aandoening is een multifactorieel proces, waarbij trauma, een positieve familiegeschiedenis en het vrouwelijke geslacht risicofactoren zijn. Het MTP1-gewricht heeft een belangrijke functie bij evenwicht en stabiliteit en bij de afwikkeling van de voet tijdens het lopen. Indien het gewricht wordt aangetast door het proces van artrose, ervaren patiënten gewrichtspijn, zwelling, stijfheid en een beperking in het buigen (dorsale flexie) van de grote teen, vooral tijdens bewegingsactiviteiten. Dit resulteert in een veranderd looppatroon en loopproblemen, wat invloed heeft op dagelijkse activiteiten, zoals deelname aan werk en sociale activiteiten. Hierdoor zal hallux rigidus uiteindelijk een impact hebben op de kwaliteit van leven van de betreffende persoon. In eerste instantie wordt hallux rigidus altijd niet-operatief behandeld. Wanneer conservatieve behandelingen falen, zijn chirurgische interventies onvermijdelijk.

Er zijn verschillende operatieve technieken beschikbaar, waaronder gewrichtssparende en gewrichtsvervangende operaties. De optimale operatieve techniek is nog niet beschreven, aangezien elke behandeling voor- en nadelen heeft. De keuze voor een operatieve interventie is onder andere gebaseerd op de mate van artrose, en op de leeftijd, het activiteitsniveau en de verwachtingen van de patiënt. Elke ingreep zal invloed hebben op het looppatroon en met name de voet- en enkelbewegingen. Aangezien elke chirurgische operatie zijn eigen kenmerken heeft, zoals het herstellen of opgeven van de beweging in het MTP1-gewricht, moet de verminderde of verloren beweging in dit gewricht worden gecompenseerd door andere gewrichten in de voet en enkel. Bepaalde interventies zijn mogelijk minder geschikt als er al artrotische veranderingen aanwezig zijn in deze gewrichten waaruit de compensatie moet plaatsvinden. Daarom is eerst meer kennis nodig van het compensatiemechanisme na een chirurgische ingreep en in welk gedeelte van het betrokken voet- en enkelgewricht compensatie plaatsvindt. Pas daarna kan worden bepaald welke interventie het meest geschikt is voor een bepaalde patiënt. Voordat op maat gemaakte adviezen voor een patiënt kunnen worden geformuleerd, is eerst meer kennis nodig over het compensatiemechanisme in de voet en enkel bij hallux rigidus en na de operatieve ingrepen.

In dit proefschrift zijn de compensatiemechanismen in de voet en enkel van patiënten met hallux rigidus onderzocht vóór en na chirurgische ingrepen (**hoofdstuk 2 en 3**). Verder is gekeken naar de klinische en biomechanische effecten op langere termijn na veel uitgevoerde operatieve ingrepen voor hallux rigidus (**hoofdstuk 4 en 5**). Ook de nieuwere operatieve ingrepen, middels prothesiologie van het MTP1-gewricht, zijn nader bestudeerd (**hoofdstuk 6**). Tot slot is de herhaalbaarheid van het Oxford Foot Model kritisch geanalyseerd. Dit is een veelgebruikt multisegment-voetmodel in driedimensionale gangbeeldanalyses voor de evaluatie van voet- en enkelafwijkingen (**hoofdstuk 7**).

Het looppatroon van hallux rigidus patiënten is onderzocht (**hoofdstuk 2**) en vergeleken met dat van gezonde personen. Hiervoor werden 3D-gangbeeldanalyses gemaakt met behulp van het VICON-bewegingsanalysesysteem. Bij patiënten met hallux rigidus werd een significante vermindering van de bewegingen in het MTP1-gewricht tijdens het lopen vastgesteld. Met name het buigen (dorsaal- en plantairflexie) in het MTP1-gewricht tijdens de afzettefase van het lopen bleek significant verminderd. Waargenomen werd dat de voet hiervoor compenseert door een toegenomen pronatie- en supinatiebeweging in de voorvoet tijdens het lopen. Op basis van deze veranderde voetkinematica werd een verhoogde belasting van de laterale plantaire voetzones verwacht. Deze effecten werden echter niet gezien tijdens de plantaire drukmetingen gedurende het lopen. De resultaten van deze studie tonen aan dat de voet bij patiënten met hallux rigidus compenseert in andere voetsegmenten voor de pijnlijke en verminderde MTP1-beweging tijdens het lopen.

In de vervolgstudie (**hoofdstuk 3**) werd het effect van operatieve behandelingen op het looppatroon onderzocht. Tevens werd bekeken of het looppatroon na de operatie terugkeert naar het looppatroon van gezonde individuen. Hiervoor werd een studie uitgevoerd waarbij patiënten met hallux rigidus werden behandeld met MTP1-artrodesis, wat momenteel wordt beschouwd als de beste operatieve behandeling voor hallux rigidus. De resultaten werden vergeleken met het looppatroon vóór de operatie, na de operatie en met dat van gezonde personen. In deze studie werd waargenomen dat MTP1-artrodesis, die leidt tot onvermogen tot het maken van dorsaal- en plantair flexie in het MTP1-gewricht, werd gecompenseerd door een toename van voorvoetpronatie en -supinatie en een toename van achtervoetinversie en -eversie. Het verlies van bewegingen in het MTP1-gewricht wordt dus gecompenseerd in zowel de voor- als de achtervoet. Daarbij wordt de voet- en enkelkinematica niet hersteld tot die van gezonde individuen. Klinische en patiëntgerapporteerde uitkomsten lieten zien dat patiënten na de operatie een sterke afname van pijn ervaarden, minder beperkingen ondervonden tijdens het staan en lopen, en dat hun deelname aan dagelijkse en sociale activiteiten was verbeterd. Patiënten functioneerden op hetzelfde niveau als patiënten zonder voetaandoeningen. Resumerend wijkt de voetkinematica na MTP1-artrodesis af van die

van gezonde controles, zijn de pijnklachten sterk verminderd en worden er aanzienlijke verbeteringen in dagelijkse en sociale activiteiten waargenomen.

Naast de postoperatieve effecten van MTP1-artrodesis op het looppatroon en de klinische uitkomst, werden ook de langetermijneffecten van operatieve behandelingen voor hallux rigidus onderzocht. Aangezien er weinig studies beschikbaar zijn die de langetermijneffecten evalueren, werd een vergelijkende langetermijn-evaluatiestudie uitgevoerd (**hoofdstuk 4 en 5**). Drie veelgebruikte chirurgische technieken voor de behandeling van hallux rigidus – Keller's arthroplastiek, artrodesis en cheilectomie – werden nader geanalyseerd. Patiënten die initieel geëvalueerd zijn na 7 jaar follow-up, werden opnieuw uitgenodigd voor een evaluatie. Na 22 jaar follow-up werden geen statistisch significante verschillen waargenomen in klinische en patiëntgerapporteerde uitkomsten tussen de groepen, zoals geëvalueerd met behulp van de AOFAS-HMI, VAS-pijnscore, FJS-12 en MOXFQ. Er werden echter wel klinisch relevante verschillen waargenomen tussen de groepen op basis van de 'minimal clinically important difference' (MCID). Ten opzichte van cheilectomie werd na artrodesis een klinisch relevante verbetering in de AOFAS-HMI-score waargenomen. Daarnaast werden klinisch relevante lagere pijnscores vastgesteld bij zowel artrodesis als Keller's arthroplastiek in vergelijking met cheilectomie. Na vergelijking van de resultaten na 22 jaar follow-up met die van de initiële studie na 7 jaar follow-up, bleken patiënten na een MTP1-artrodesis betere AOFAS-HMI-scores te hebben en minder pijn te rapporteren op basis van de VAS-pijnscore. Bij Keller's arthroplastiek en cheilectomie werden over de tijd geen veranderingen waargenomen. De bevindingen van deze studie laten zien dat artrodesis, Keller's arthroplastiek en cheilectomie alle drie geschikte behandelmethoden zijn voor symptomatische patiënten met hallux rigidus, met goede tot uitstekende klinische en patiëntgerapporteerde uitkomsten na een zeer lange periode na de operatie. De resultaten tonen aan dat artrodesis de gunstigste uitkomsten heeft.

Naast de klinische evaluatie, werd ook geprobeerd het looppatroon na een lange termijn van follow-up te evalueren (**hoofdstuk 5**). Een loopband van Zebris werd gebruikt voor loop- en pedobarografische analyse. De resultaten van de drie interventiegroepen werden vergeleken met het looppatroon van gezonde personen zonder voetaandoeningen. De resultaten toonden vergelijkbare spatiotemporele parameters tussen alle groepen tijdens het lopen. Er werden geen verschillen tussen de groepen waargenomen in piekdrukken en totale drukken in de voet als uitkomst van de drukverdeling in de voet tijdens het lopen. De resultaten van de MOXFQ-vragenlijsten werden ook beschreven en gebruikt voor correlatieanalyse. Er werden geen klinisch en statistisch significante verschillen waargenomen tussen de groepen op basis van de MOXFQ-resultaten. Correlatieanalyse toonde geen substantiële associaties tussen de plantaire drukresultaten van de voorvoet en de MOXFQ-resultaten. Op basis van de huidige studie is het voor de klinische praktijk niet betrouwbaar om plantaire druk in de voorvoet te voorspellen op basis van PROM's en vice versa. Bovendien

suggereren de resultaten van deze studie dat er op de lange termijn geen functionele en biomechanische verschillen zijn tussen de patiënten na deze chirurgische interventies voor hallux rigidus. De interventies zijn daarmee geschikte behandelingen voor patiënten met een symptomatische hallux rigidus.

Naast de genoemde chirurgische interventies is er een toename in de populariteit van prothesiologie (arthroplastiek) bij patiënten met een hallux rigidus. Hierover zijn reeds verschillende publicaties verschenen. In **hoofdstuk 6** werd een systematische review met meta-analyse uitgevoerd om te beoordelen welke van de twee behandelingen, MTP1-artrodesis of hemiarthroplastiek, superieur is in de behandeling van hallux rigidus wat betreft klinische uitkomsten, pijnreductie en complicatie- en revisiepercentages. De resultaten lieten vergelijkbare klinische uitkomsten zien na beide ingrepen, waarbij de meeste studies scores rapporteerden die vergelijkbaar waren met de referentiewaarden van gezonde personen zonder voetaandoeningen. Patiënten rapporteerden minder pijn na MTP1-artrodesis in vergelijking met MTP1-hemiarthroplastiek. Bovendien waren het aantal complicaties, de aard van de complicaties en de revisiepercentages vergelijkbaar na beide ingrepen. Een nadere analyse van de resultaten van de hemiarthroplastiek toonde een trend van lagere pijnscores bij hemiarthroplastiek-implantaten waarbij het metatarsale deel werd vervangen, in vergelijking met wanneer het falanxdeel werd vervangen. De resultaten van de huidige studie tonen aan dat MTP1-artrodesis superieur lijkt wat betreft pijnvermindering, terwijl MTP1-hemiarthroplastiek een geschikte alternatieve optie is voor patiënten die activiteiten uitvoeren waarbij beweging in het eerste metatarsophalangeale gewricht noodzakelijk is.

Vervolgens werd een kritische evaluatie gedaan van de uitvoering van 3D-gangbeeldanalyses. Om met behulp van 3D-loopanalyse voet- en enkelbewegingen tijdens het lopen in kaart te brengen, is een multisegment-voetmodel noodzakelijk. Een van de meest gebruikte multisegment-voetmodellen voor het evalueren van voetaandoeningen in klinische en onderzoekssettingen is het Oxford Foot Model. Dit model werd ook gebruikt om voet- en enkelbeweging te analyseren bij hallux rigidus-patiënten voor en na een operatieve ingreep, zoals beschreven in hoofdstuk 2 en 3. In **hoofdstuk 7** was het doel om de herhaalbaarheid van het Oxford Foot Model te beoordelen, met speciale aandacht voor het hallux-voorvoetsegment en de swingfase tijdens het lopen. Het hallux-voorvoetsegment vertoonde matige herhaalbaarheid, zowel intra- als inter-assessor, en had een lagere herhaalbaarheid in vergelijking met andere sagittale voetbewegingen in de voor- en achtervoet. Daarnaast lijkt op basis van de huidige resultaten de totale loopcyclus, dus zowel de standfase als de swingfase, in het sagittale en het frontale vlak van de voor- en achtervoet een legitiem onderdeel te zijn voor analyse. Het transversale vlak van de achtervoet toont lagere herhaalbaarheid en vergt speciale aandacht bij de interpretatie van de gegevens. Concluderend toont het Oxford Foot Model acceptabele herhaalbaarheid in voetsegmenten voor gebruik in de klinische praktijk.

Samenvattend biedt dit proefschrift nieuwe inzichten in het looppatroon en de klinische uitkomsten op korte en lange termijn bij patiënten met hallux rigidus en gerelateerde chirurgische behandelingen. Voordat kan worden bepaald of loopanalyse als diagnostisch hulpmiddel kan worden toegepast, moeten eerst veranderingen in looppatronen worden waargenomen. Dit proefschrift toont aan dat kinematische analyse met behulp van 3D-gangbeeldanalyses zinvol is voor het bepalen van looppatroonveranderingen voor en na operatieve ingrepen voor hallux rigidus. Plantaire voetdrukken lijken echter niet te worden beïnvloed door een operatieve ingreep en zijn daarom niet geschikt voor het bestuderen van patiënten met hallux rigidus. Toekomstige studies moeten zich richten op 3D-looppatroonanalyses voor en na behandelingen voor hallux rigidus en onderzoeken of deze analyses gebruikt kunnen worden als diagnostisch hulpmiddel voor de selectie van de meest optimale behandeling voor een patiënt met hallux rigidus. Daarnaast laat dit proefschrift zien dat de huidige behandelingen, waaronder artrodesis, Keller's arthroplastiek en cheilectomie, alledrie geschikte behandelingen zijn voor hallux rigidus, en dat patiënten nog steeds tevreden zijn na lange termijn follow-up. Naast deze behandelingen blijkt dat ook prothesiologie middels MTP1-hemiarthroplastiek veelbelovende resultaten laat zien als behandeling voor hallux rigidus. Toekomstige studies zouden de patiënttevredenheid op lange termijn en de levensduur van de prothesen moeten evalueren om te bepalen of deze interventies net zo effectief zijn als de huidige behandelingen voor hallux rigidus.

Curriculum Vitae

Robin de Bot werd geboren op 16 mei 1991 te Roermond en groeide op in Maasbracht. Hij voltooide zijn voortgezet onderwijs aan het Connect College in Echt en het Luzac College in Roermond (2010). Vervolgens startte hij de bacheloropleiding Biomedische Wetenschappen aan de Universiteit van Maastricht, welke hij in 2013 succesvol afrondde.

Aansluitend werd hij toegelaten tot de masteropleiding Arts-Klinisch Onderzoeker (A-KO) aan dezelfde Universiteit van Maastricht, waarmee hij zijn medische carrière verder kon ontwikkelen. Na het behalen van deze master in 2018 volgde hij een aanvullende masteropleiding in Healthcare Policy, Innovation and Management (HPIM) aan eveneens de Universiteit van Maastricht, om zijn kennis van zorgmanagement, organisatie en innovatie uit te breiden. Deze opleiding rondde hij in 2019 cum laude af.

Gelijktijdig met de HPIM-master startte hij een promotietraject onder supervisie van dr. M.A. Witlox, prof. dr. K. Meijer en dr. H. Staal waarvan het huidige proefschrift het resultaat is. Na afronding van de HPIM-master werd hij werkzaam bij de afdeling Orthopedie van het Maastricht Universitair Medisch Centrum (MUMC+), waar hij samen met diverse stafleden van de Orthopedie waaronder prof. dr. L. van Rhijn, betrokken was bij de oprichting van het “Beweeghuis”. Naast deze werkzaamheden zette hij zijn promotieonderzoek voort.

Zijn klinische carrière vervolgde hij eveneens binnen de afdeling Orthopedie van het MUMC+, waarna hij in 2021 besloot zich verder te specialiseren in de huisartsgeneeskunde. In datzelfde jaar startte hij de opleiding tot huisarts aan de Universiteit van Maastricht. Gedurende het eerste opleidingsjaar werkte hij bij huisartsenpraktijk Mosae Forum in Maastricht onder supervisie van drs. T. Berghmans. Daarna volgde klinische stages op de Spoedeisende Hulp van het Zuyderland ziekenhuis in Heerlen en Sittard, een verpleeghuisstage in Meander Hambos te Kerkrade en een stage Spoedeisende Psychiatrie bij Mondriaan te Maastricht. Het laatste opleidingsjaar voltooide hij bij huisartsenpraktijk De Hofhoek in Maastricht onder supervisie van drs. L. Jansen. In 2024 rondde hij de huisartsopleiding af en is sindsdien werkzaam als waarnemend huisarts in de regio Zuid-Limburg.

Sinds 2020 woont hij samen met zijn partner Vivian Oostwegel en zijn ze de trotse ouders van hun zoon Thomas. In de vrije tijd geniet hij van watersport en wintersport en brengt hij graag tijd door met zijn gezin. Zijn levensmotto is: ‘geniet van het leven’.

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Hidde, ook wij hebben vele momenten waarop we terug kunnen kijken. Naast dat we een hele goede vriendschap hebben welke begon tijdens onze A-KO master reikte onze samenwerking veel verder als dat. Wij allebei hadden een bijzondere affiniteit met de Orthopedie en wetenschappelijk onderzoek hierin en beiden zijn we een promotietraject aangegaan binnen het Orthopedische vakgebied. Gedurende onze trajecten hebben we veel aan elkaar gehad. We hadden vaak inhoudelijk discussies rondom ieders werk en keken kritisch ernaar, bediscussieerden het en herschreven elkaars wetenschappelijke stukken. Dit bracht onze wetenschappelijke werken naar een hoger niveau. Buiten dit ging onze wetenschappelijke samenwerking verder en hebben we ook samen mooi wetenschappelijk werk uitgevoerd en opgeschreven zowel in dit proefschrift, als in jouw eigen proefschrift. Naast deze fijne, leerzame en succesvolle samenwerking ben je bovenal een heel goede en betrouwbare vriend. Naast het promotietraject ben jij verdergegaan binnen de Orthopedie, en doorloop je momenteel de opleiding tot orthopedisch chirurg. Ik ben ervan overtuigd dat je een gepassioneerde vakbekwame orthopedisch chirurg zal worden.

Koen en Armand, samen met Hidde hebben wij een goede vriendschappelijke band opgebouwd tijdens de A-KO master, als 4 handen op een buik hebben we de opleiding doorlopen. Vele avonden hebben we samen doorgebracht waarbij de basisvaardigheden als artsen in spé eigen hebben gemaakt. Armand, met jou onderhouden we een lange afstand relatie in Leiden, waar jij na afronding van jou PhD heen verhuisd bent voor je partner. Aldaar doorloop jij momenteel de huisartsopleiding, waarbij ik ervan overtuigd ben dat straks in jouw regio ze een vriendelijke, adequate en doortastende huisarts rijker zijn. Koen, na de opleiding hebben wij ons goede contact gecontinueerd binnen de huisartsgeneeskunde, momenteel beiden werkzaam in dezelfde regio en hebben we al een aantal samenwerkingen op de huisartsenpost erop zitten! Wie weet wat de toekomst ons allemaal nog brengt binnen en buiten dit vakgebied. Dat nog vele mooie samenwerkingen en momenten met gezelligheid mogen volgen!

Daarnaast wil ik graag Tim Berghmans en team huisartsenpraktijk Mosae Forum bedanken. Tim, bij jou heb ik mijn eerste vaardigheden als huisarts ontwikkeld. Ik kijk terug op een leerzame en innoverende tijd.

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Quincy, Daan, Nick, Regilio, Louk, Tim, Gerald, Guus, Gydo, Jeroen, Joris en Stef we onderhouden een mooi contact als vriendengroep, naast de drukke carrières, werk en ondernemingen en gezinslevens weten we erin te houden dat we elkaar geregeld als groep treffen, met veel gezelligheid tot gevolg. Onze jaarlijks ski-reis is een van de hoogtepunten hierin, waarin ski met vooral après-ski centraal staat. Deze trip zorgt voor vele mooie momenten waar we het hele jaar over spreken. Als een van de kar-trekkers zal ik ervoor zorgen dat deze ski-trip er altijd in blijft!

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We hebben vele overeenkomsten waarbij doorzettingsvermogen en leergierigheid twee punten zijn die in het bijzonder naar voren komen. Naast mijn traject dat ik binnen de geneeskunde heb doorlopen, heb jij deze binnen de tandheelkunde doorlopen waar ik erg trots op ben. Momenteel ben jij aan het werk als een gepassioneerde, enthousiaste vakbekwame tandarts die ik graag zorg laat dragen voor mijn gebit! Buiten onze werkzaamheden hoop ik dat we samen met onze gezinnen nog vele mooie momenten gaan beleven.

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