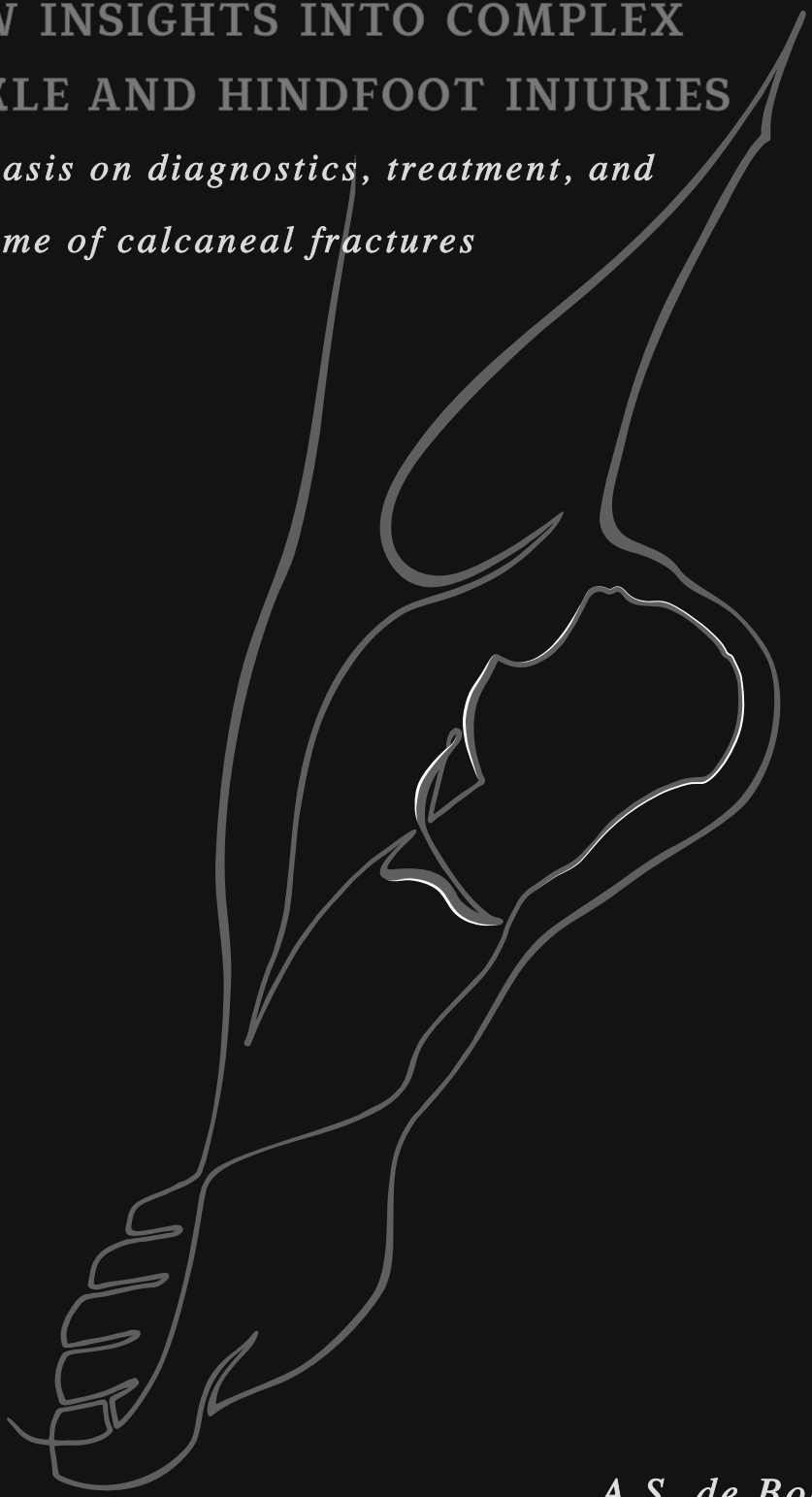
NEW INSIGHTS INTO COMPLEX ANKLE AND HINDFOOT INJURIES

Emphasis on diagnostics, treatment, and outcome of calcaneal fractures



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ISBN: 978-94-6295-848-7

Cover design: L.J. van Oijen, A.S. de Boer
Layout and printing: ProefschriftMaken || www.proefschriftmaken.nl

Printing and distribution of this thesis has been financially supported by:

Blaak & Partners
Centrum Orthopedie Rotterdam
Erasmus MC Afdeling Heelkunde
Erasmus Universiteit Rotterdam
Flen Health
GDM
Nederlandse Vereniging voor Traumachirurgie
Oldekamp Medisch
Raadsheeren
Rabobank Medicidesk
Smith & Nephew
Traumacentrum Zuid West Nederland

New Insights into Complex Ankle and Hindfoot Injuries

Emphasis on diagnostics, treatment, and outcome of calcaneal fractures

Nieuwe inzichten in complexe enkel- en achtervoetletsels

Nadruk op diagnostiek, behandeling en uitkomsten van calcaneusfracturen

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
rector magnificus

Prof.dr. H.A.P. Pols

en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
woensdag 4 april 2018 om 9.30 uur

door

Auke Siebren de Boer
geboren te Utrecht

Erasmus University Rotterdam

Promotiecommissie

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Chapter 1

General introduction and outline of this thesis

EPIDEMIOLOGY, BURDEN ON HEALTH CARE, AND HEALTH CARE COSTS

The calcaneus is the most commonly fractured tarsal bone, representing 60% of all tarsal fractures in adults (1). The incidence rate of calcaneal fractures is 11.5 per 100,000 person years and these fractures occur 2.4 times more frequently in males than females (2). In males, the incidence rate was 16.5 per 100,000 per year, with a peak in the age range 20-29 (2, 3). In females the distribution is more equally spread throughout the age cohorts and shows a gradual increase towards the post-menopausal years (2).

Calcaneal fractures lead to long-term disability and most patients are in their wage-earning age. Although they are relatively uncommon (1-2% of all fractures), the socio-economic burden is high. In the Netherlands the overall emergency attendance for foot and ankle injuries was 640 per 100,000 person years in 2010 (4). It is estimated that more than 25,000 people suffer from an ankle fracture each year in the Netherlands and the incidence is rising worldwide (4, 5). The overall costs for all patients with ankle and foot injuries amounted 161.9 million euro in 2010 in the Netherlands (4). An overall increase of 1.2% was noted in the period 2001 to 2010. Attendance rates and health care costs were gender- and age-related.

CLINICAL ASSESSMENT AND DIAGNOSTICS

Most calcaneal fractures are occupational, and are sustained by axial loading in falls from height (71.5%) (3). Calcaneal fractures can be divided into extra-articular and intra-articular types. Extra-articular fractures are in general less invalidating and mostly managed non-operatively. The majority (60-75%) however are displaced intra-articular fractures (3).

Patients with calcaneal fractures often have multiple concomitant injuries, the most commonly seen concomitant injuries were spinal injuries (6.3%) and lower limb injuries (13.2%) such as femoral and tibial shaft fractures, ankle fractures, hindfoot (*i.e.,* talus fracture), midfoot fractures, and metatarsal fractures. A substantial number of the patients who suffered a high energy trauma (*e.g.,* fall from height) have, beside hindfoot injuries, severe concomitant injuries. Hindfoot injuries are therefore often missed in initial assessment, since these concomitant injuries often have priority in acute trauma life support. It is important to consider the presence of these associated injuries during clinical evaluation.

At hospital presentation, features of patients with calcaneal fractures are swelling, hematoma, and pain at the ankle and hindfoot region. Patients are often not able to bear weight on the affected foot, have functio laesa (*i.e.,* reduced ability to pro-and supinate the foot), valgus hindfoot deformity, and palpation of the hindfoot is often painful.

The continuous assessment of soft tissue status is of imminent importance. It is hypothesized that swelling and hematoma in combination with pressure from the inside (due to fracture displacement, haematoma, and edema) may result in lack of adequate blood supply and may develop in blisters and ischemia. The results of these features, skin necrosis with disastrous (infectious) sequelae, must be avoided, this hypothesis of soft tissue deterioration is tested in this thesis. The soft tissue condition often determines when surgical intervention is allowed. In the meantime, several swelling reduction methods (*e.g.,* pressure bandage, plaster cast, or pneumatic compression) and elevation of the leg can be applied to accelerate surgical treatment and thus functional recovery. In this thesis a relative new approach to reduce swelling, static compression with cryotherapy, is evaluated.

RADIOLOGICAL ASSESSMENT AND RADIOGRAPHIC MEASUREMENTS

The diagnosis and management of calcaneal fractures is based on radiological examinations, which initially consist of lateral and axial radiographs of the foot. Böhler's angle and the angle of Gissane indicate the degree of depression and displacement of the subtalar joint. It is unclear what the influence of foot position during radiography on these angles is, therefore it is studied in this thesis. In particular Böhler's angle is frequently used as a measure for the quality of restoration of the anatomical shape after calcaneal fractures during follow-up.

Böhler's angle

Böhler's angle is determined in the lateral view by drawing lines from three anatomical landmarks; the tip of the anterior process to the highest point of the posterior calcaneal facet and the line from the top of the calcaneal tuberosity to the highest point of the joint. Normally, this angle is between 25° and 40° (6). The extent to which foot position attributes to this variation is unclear.

Angle of Gissane

The angle of Gissane runs along the posterior side of the anterior process of the calcaneus and the anterior side of the subtalar joint and can be drawn in the lateral radiographic projection Normally, this angle is between 120° and 145° (7).

Findings on conventional lateral and axial radiographs indicate the need for supplementary Computed Tomography (CT) scan. Both plain radiographs as CT scans are commonly used in order to decide whether a calcaneal fracture should be treated (non)-operatively. A CT scan accurately shows the extent of the fracture, the number of fragments, the degree of comminution and dislocation of the various fragments, broad-

ening, and the congruence of the subtalar joint; factors that have to be taken into account in treatment decision making (6, 7).

ANATOMY

This thesis outlines the clinical aspects on management of ankle and hindfoot fractures. In particular for calcaneal fractures, it is essential to have a profound knowledge of the complex anatomy of the calcaneus, the multiple articular surfaces, surrounding soft tissue envelope, neurovascular bundle, and tendons.

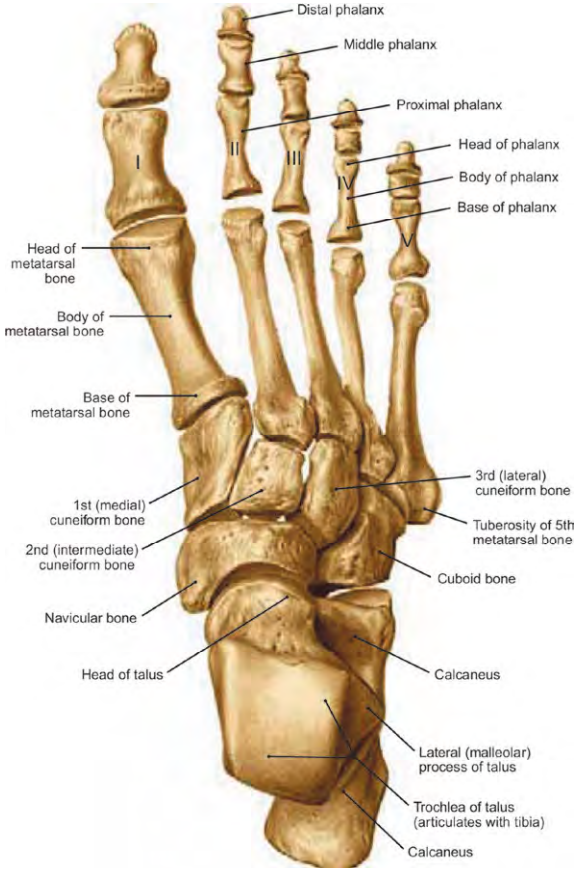

Figure 1. Superior aspect of the right foot
(Ref: Paulsen, Waschke, Sobotta Atlas der Anatomie, 24th Edition 2017©Elsevier GmbH, Urban & Fischer, Munich)

Bones and ligamentous structures

The hind- and midfoot are composed of seven articulating bones, the tarsus. The hindfoot consists of two of these tarsus, the talus (ankle bone) and calcaneus (heel bone), Figure 1. The calcaneus is the largest of the tarsal bones and plays a crucial role in weightbearing, standing and walking through the Achilles tendon, the plantar fascia and intrinsic foot musculature.

The axial compression forces caused by the body weight on the calcaneus result in a cortex of varying thickness and a trabecular pattern of the cancellous bone. The cortical bone is especially thin at the lateral wall of the calcaneus, which frequently leads to 'blow-out' of the lateral wall in calcaneal fractures. The calcaneus is exposed to different tensile forces generated by tendinous and fascial contractions (Figure 2). Another anatomical region in the calcaneus is the neutral triangle, a fictitious triangle with a low density of trabeculae and therefore prone to collapse with excessive axial forces.
Specifically beneath the posterior facet of the subtalar joint these trabeculae are concentrated and form the thalamic portion.

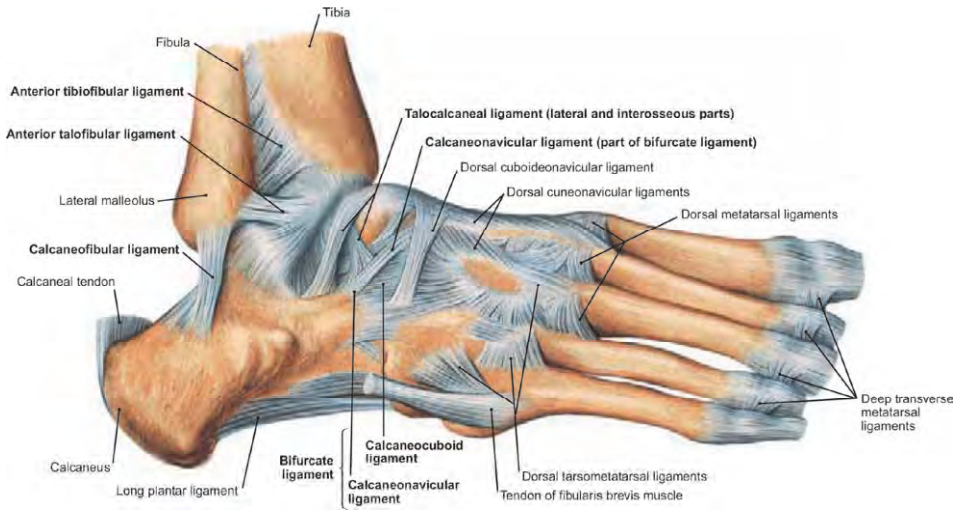

Figure 2. Lateral ligaments of the ankle joint and of the dorsolateral right foot
(Ref: Paulsen, Waschke, Sobotta Atlas der Anatomie, 24th Edition 2017©Elsevier GmbH, Urban & Fischer, Munich)

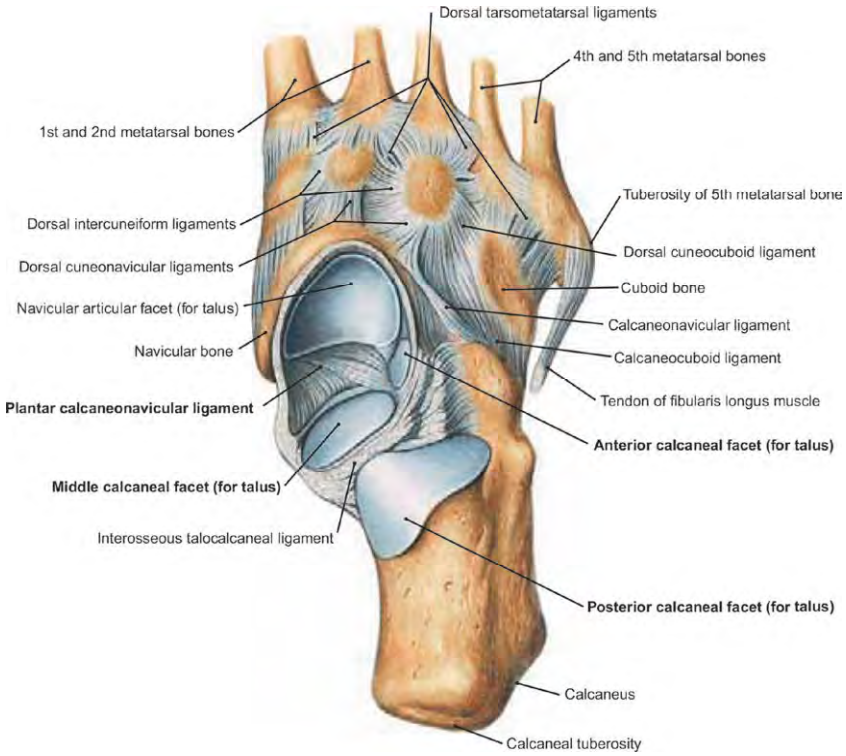

Figure 3. Superior aspect of the right talocalcaneonavicular joint
(Ref: Paulsen, Waschke, Sobotta Atlas der Anatomie, 24th Edition 2017©Elsevier GmbH, Urban & Fischer, Munich)

Articular surfaces

The subtalar surface attributes to inversion and eversion of the hindfoot and is essential for shock absorption and adaptation of the foot to (irregular) surfaces.

The subtalar joint consists of three joint facets and provides articulation between the superior aspect of the calcaneus and the talus (Figure 3). The convex-shaped posterior facet is the largest, most weightbearing and therefore most important facet. The (concave-shaped) middle facet and the anterior facet are merged in approximately 20% of the calcanei (8). The calcaneal sulcus separates the posterior facet from the middle and anterior facets. The area medial and superior of this sulcus is called the tarsal canal and at the lateral side the sinus tarsi.

The talocalcaneal interosseous ligament is located within the sinus tarsi, this ligament plays an important role in subtalar stability (9).

The anterior process of the calcaneus is connected to the cuboid bone by the calcaneocuboid ligaments via a concave, saddle-shaped facet. This anterior facet is part of the Chopart's, mid-tarsal, joint (8).

On the medial side of the calcaneus the sustentaculum tali is located (Figure 4). The sustentaculum tali is important in calcaneal fracture management since this part of the calcaneus is rarely dislocated, a vital weightbearing structure, and therefore a decent anatomical structure to fixate fractured bone fragments (10). At the medial and lateral portion it is connected to the talus via talocalcaneal ligaments.

Screw fixation with the sustentaculum tali as landing zone is challenging since the flexor hallucis longus tendon, flexor digitorum longus tendon, and the tendon of the tibialis posterior run dorsally beneath the inferior border of the small sustentaculum tali. On the lateral side of the calcaneus, underneath the peroneal retinaculum, the peroneal longus tendon is running inferiorly of the peroneal tubercle and the peroneal brevis tendon superiorly.

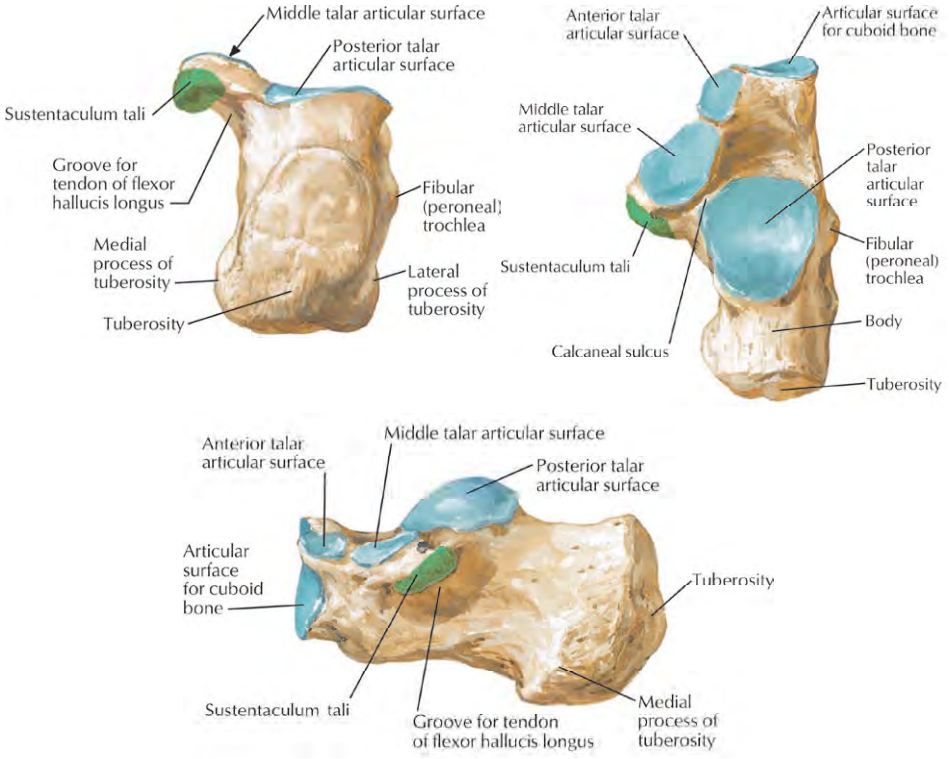

Figure 4. Dorsal, superior and medial aspect of the foot, sustentaculum tali marked in green (Ref: Modified (green highlighted) from Atlas of Human Anatomy, 5th edition, Frank H. Netter).

Arterial and venous structures

Arterial blood supply on the medial side of the foot in most patients is provided by the medial calcaneal branches of the posterior tibial artery. The posterior tibial artery bifurcates inferior of the sustentaculum tali into the medial and lateral plantar artery. In turn the lateral plantar artery continues in the medial calcaneal branches which provide the major vascular supply to the heel, furthermore into branches to the adductor digiti minimi, digital branch of the fifth phalanx and into a plantar branch (Figure 5). A variable number of medial calcaneus branches occur, and possibly communicate superficially with the tarsal artery or the metatarsal artery (both originating from the dorsalis pedis artery).

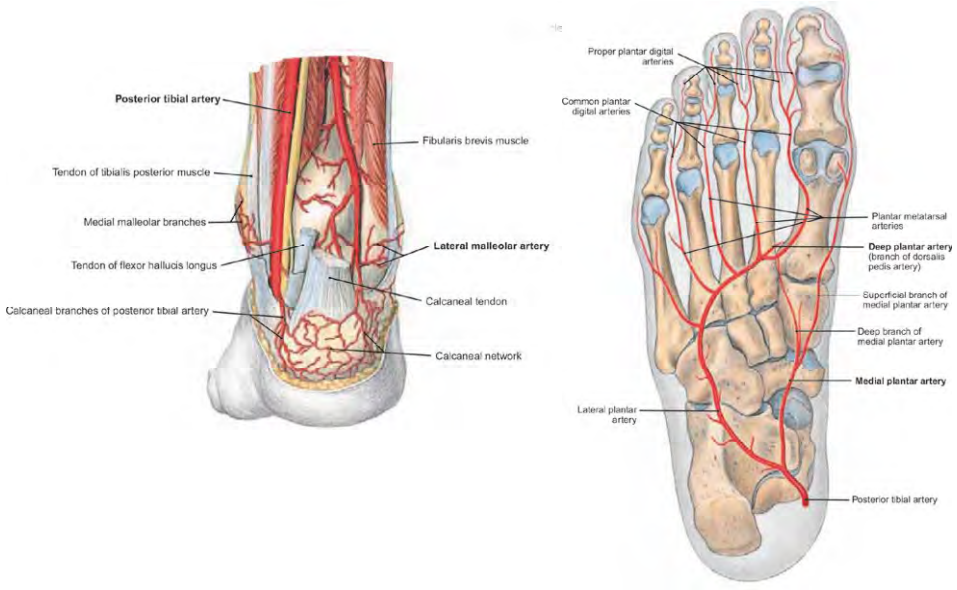

Figure 5. Dorsal and plantar aspect of the foot: Diagram of arteries and bones
(Ref: Paulsen, Waschke, Sobotta Atlas der Anatomie, 24th Edition 2017©Elsevier GmbH, Urban & Fischer, Munich)

The dorsalis pedis artery originates from the anterior tibial artery and is palpable over the dorsum of the foot, lateral to the extensor hallucis longus. The branches of the anterior tibial artery supply the dorso-lateral side of the foot. The dorsalis pedis artery terminates into the dorsal metatarsal arteries at the first intermetatarsal space.

More proximally, the peroneal artery originates from the posterior tibial artery and communicates to the lateral malleolar artery, lateral tarsal artery, and anterior tibial artery. The peroneal artery supplies the soleus, tibialis posterior, flexor hallucis longus, and peroneal muscles along its course. The lateral calcaneal branches continue from the peroneal artery, thus providing perfusion on the lateral aspect of the hindfoot.

Concerning the venous system the dorsal venous arch of the foot is a superficial vein that drains into the small and great saphenous vein (Figure 6).

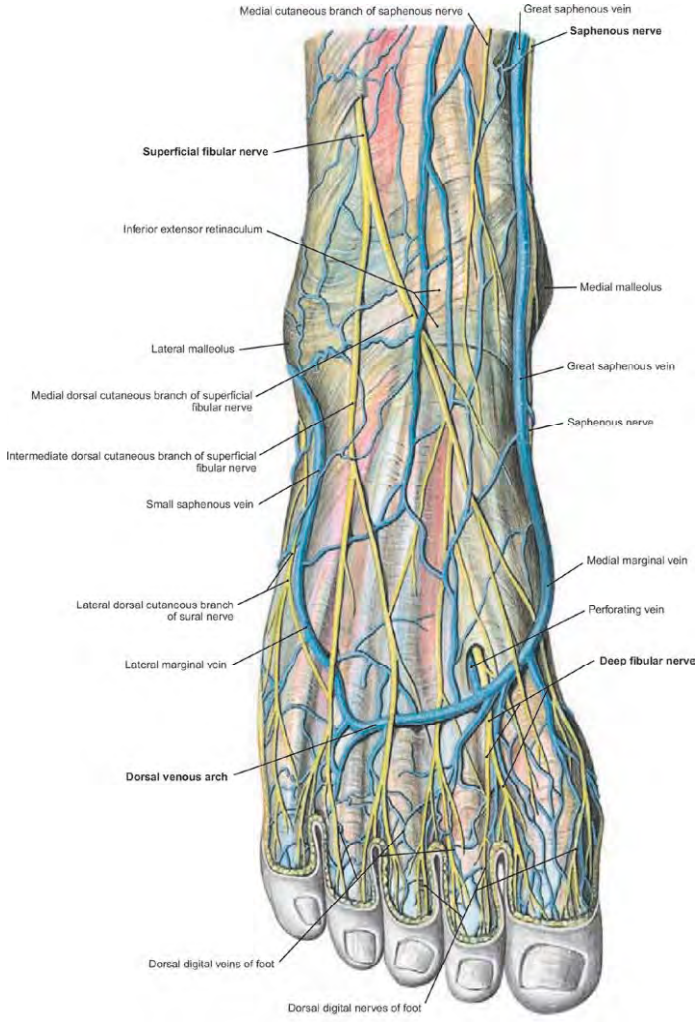

Figure 6. Superficial nerves and veins of the dorsal aspect of the right foot
(Ref: Paulsen, Waschke, Sobotta Atlas der Anatomie, 24th Edition 2017©Elsevier GmbH, Urban & Fischer, Munich)

Nerves

The sural nerve is a sensory nerve in the lower leg and the foot and innervates the lateral part of the foot and fifth phalanx. The medial cutaneous branch arises from the tibial nerve, and the lateral branch of the sural nerve is originating from the common

peroneal nerve. In turn, the tibial nerve and common peroneal nerve originate at the height of the popliteal fossa from the ischiadic nerve.

Inferior of the medial malleolus the posterior tibial nerve divides first into the medial calcaneal branches (responsible for the innervation of the posterior plantar aspect of the foot) and more distally into the medial and lateral plantar nerves. The lateral plantar nerve innervates the quadratus plantae, adductor hallucis, interossei, second to fourth lumbricals, and lateral phalanx. The medial plantar nerve innervates the abductor hallucis, flexor digitorum brevis, flexor hallucis brevis, and first lumbrical. The saphenous nerve is the largest cutaneous branch of the femoral nerve and has a sensory function in the medial aspect of the foot.

The peroneal nerve is a sensory and motor nerve in parts of the lower leg. It descends obliquely along the lateral side of the popliteal fossa and is palpable at the height of the head of the fibula. A laesion of this nerve can cause foot drop. It divides in a superficial and deep peroneal branch. The superficial peroneal nerve innervates the muscles of the lateral compartment of the leg (*i.e.,* peroneus longus and peroneus brevis, which are responsible for eversion and plantar flexion). The deep peroneal nerve innervates the muscles of the anterior compartment of the leg (*i.e.,* tibialis anterior, extensor hallucis longus, extensor digitorum longus, and the peroneus tertius, which have a dorsiflexion of the foot and extension of the toes function).

CLASSIFICATION SYSTEMS

In calcaneal fracture management multiple classification systems have been developed based on conventional radiographs (*e.g.,* AO/OTA classification system (11, 12), Böhler (6), McReynolds (13), Palmer (14), Essex-Lopresti (7), Ross and Sowerby (15), Rowe (16), Soeur and Remy (17), Warrick and Bremner (18), Watson-Jones (19), and Wondrák (20)) and based on computed tomography scanning (*e.g.*, Crosby and Fitzgibbons (21), Eastwood (22), Sanders classification (23), Zwipp (24)). The Essex-Lopresti and Sanders classifications are nowadays most frequently used in clinical practice.

Essex-Lopresti

The most used classification system based on radiographs is the one developed in 1952 by Palmer and, most notably, Essex-Lopresti. In those days only radiographs were available. Palmer and Essec-Lopresti based their fracture classification on the location of the secondary fracture lines in displaced, intra-articular calcaneal fractures: Joint depression and tongue-type calcaneal fractures (Figure 7) (7).

In joint depression type fractures the secondary fracture line runs downward posterior to the impacted posterior facet, only marginally involving the tuberosity. The posterior facet is compressed as a separate entity with regard to the posterior tuberosity.

In tongue-type fractures the secondary fracture line disperses longitudinally from the articular surface posteriorly into the tuberosity, resulting in a complex deformity of the hindfoot with the Achilles tendon attached to the displaced fragment (25). The posterior facet is impacted into the neutral triangle and the posterior tuberosity fragment is displaced superiorly and dorsally. The articular surface of the posterior facet is often partially or completely in continuity with the posterior tuberosity fracture fragment.

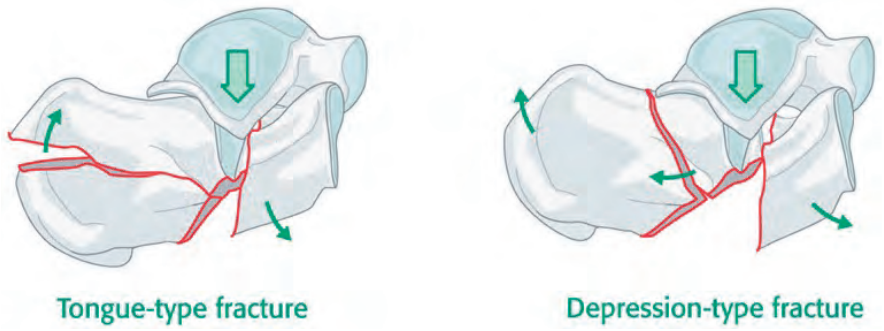

Figure 7. Essex-Lopresti classification. Left: tongue-type fracture, right: joint depression type fracture. (Ref: www.aofoundation.org)

Sanders

Later, when CT-imaging became available also visualization of fracture configuration improved. The most widely used classification is that developed in 1993 by Sanders *et al.* (23), which is based purely on the amount and location of fracture lines in the coronal CT scans at the level of the posterior calcaneal facet (Figure 8).

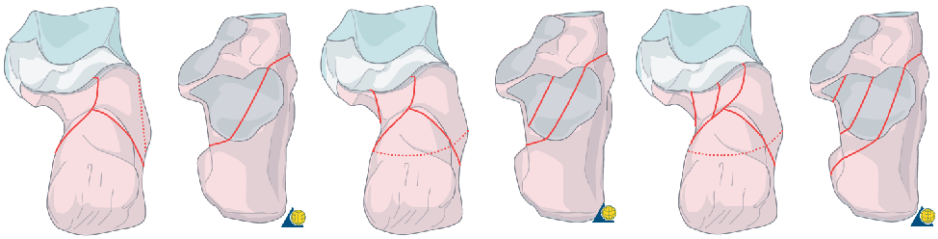

Figure 8. Sanders classification (Ref: www.aofoundation.org).

MANAGEMENT OF CALCANEAL FRACTURES

Since calcaneal fractures are devastating and have long-term impact on a patient's life, it is important to inform patients about the significance of these fractures. Management of expectations include limb elevation, early mobilization, and smoking cessation. Controversy exists on the best treatment for displaced intra-articular calcaneal fractures, this thesis adds information intended to elucidate the controversy on this topic.

Non-operative treatment of calcaneal fractures may be indicated in patients with adequate maintenance of anatomy, minimal articular involvement (less than 2 mm displacement of articular surface), no gross varus or valgus malalignment, or medical contraindications to operative care. Non-operative treatment consist of limb elevation, posterior splint plaster cast, or pressure bandage that allows early range of motion exercises to prevent pes equinus.

Operative treatment is generally indicated for open fractures, anterior process fractures with more than 35% involvement of calcaneocuboid joint, tongue-type 'beak' fractures with high risk of posterior soft tissue complications, displaced (more than 2 mm) intra-articular calcaneal fractures in the posterior talocalcaneal facet, > 30 degrees varus or 40 degrees valgus deformities, lateral or medial process fractures with > 1.5 cm displacement.

The timing of surgery is considered an important factor in preventing soft tissue complications. When performing surgery too early, wound edge necrosis is lurking. But delaying surgery is not only uncomfortable for the patient but also complicates fracture fragment reduction.

When a calcaneal fracture is minimally displaced, tongue-type, or of a simpler classification, fractures can be treated via a closed reduction and internal fixation (CRIF) or minimally invasive osteosynthesis. For the more severe fractures open reduction and internal fixation (ORIF) is indicated. Rarely, non-resorbable bone void fillers are injected in the subtalar defect during ORIF, which are assumed to allow direct full weightbearing. The three most widely used approaches are described below.

Extended Lateral Approach

Several surgical approaches for open reduction have been developed over the years. The oldest approach is the Extend Lateral Approach (24, 26, 27). The vertical arm of the incision is placed at one third the distance between the posterior aspect of the fibula and the anterior margin of the Achilles tendon. The straight horizontal arm of the incision was placed at the level at which the smooth skin of the lateral aspect transformed to the hyperkeratotic skin of the plantar aspect of the foot (glabrous junction) aimed just below the tip of the fifth metatarsal (28). The two incisions connect at a corner where the skin must be handled with infinite care. The extensive exposure makes this approach suitable for the majority of the displaced calcaneal fractures configurations.

Since the soft tissue of the foot is often bruised and fragile after high energy trauma, it is paramount to limit iatrogenic arterial damage as much as possible to prevent skin necrosis. The 'L' shaped flap is therefore intentionally located in the watershed area. Despite these measures up to 25% superficial necrosis is reported in literature (29-31). The risk of sural nerve damage is limited by this incision location, but partly because of the full thickness flap nevertheless 10% nerve damage is described (32).

Sinus Tarsi Approach

The Sinus Tarsi Approach has recently gained recognition as it is thought to facilitate a similar anatomical reduction, lower soft tissue complication rates and herewith better functional outcome (33, 34). The incision starts at the inferior tip of the lateral malleolus and runs towards a point approximately 15mm cranial to the tuberosity of the fifth metatarsal bone, therefore the sural nerve is mostly protected inferiorly.

The neurovascular anatomy of the lateral hindfoot is relatively predictable. With an anatomy mapping tool, Computer-Assisted Surgical Anatomy Mapping (CASAM), the variation of the neurovascular structures can be mapped pre-operatively (35). With this knowledge more 'tailor-made' incisions can be made and herewith iatrogenic neurovascular damage might be further minimized (35).

Medial Approach

The medial approach is most used for fractures of the sustentaculum tali (13, 36). This approach is also used for debriding open fractures, as almost all open fractures occur over the sustentacular fragment on the medial side. The ideal incision line runs from 2 cm inferior of the medial malleolus to 2 cm proximal of the navicular bone, and is approximately 5 cm in length following the neurovascular structures. However, in case of an open fracture the traumatic wound should be incorporated to avoid soft tissue necrosis. Dissection deep to the flexor hallucis reveals the sustentaculum and the medial wall of the calcaneus.

POST-OPERATIVE MANAGEMENT

To avoid wound infections after ORIF, a percutaneous closed suction drain is often applied (37), sometimes followed by a computer controlled-cooling device. Since fracture healing normally is assured at six weeks, weightbearing is usually not allowed for at least six weeks, after which progressive weightbearing is allowed until full weightbearing is reached. Nevertheless, more conservative post-operative weightbearing regimes are common, which is a burden for patient and can be accompanied with high socio-economic costs. In this thesis it is aimed to answer the question whether earlier weightbearing can be recommended in the future to reduce the burden for patients.

LONG-TERM OUTCOMES

In general, patients should refrain from high risk active sports and heavy axial loading of the fractured foot for at least three months post-operatively. Special rehabilitation programs are normally not required. When patients have osteosynthesis material-related complaints, the implants can be removed approximately one year after surgery if consolidation is reached. Local hospital guidelines may vary on this topic. This implant removal could be combined with subtalar arthrolysis in case of stiffness of the subtalar joint (38).

A review on the long-term outcomes of 1,730 calcaneal fractures showed that hardware was removed, mostly because of pain, in 11.4% of the patients (39). The average American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot score was 73.7 of 100 (range 63-92), the Maryland Foot Score 77.5 of 100 (range 63.5 to 90), and the Creighton-Nebraska Health Foundation Assessment score 82.6 of 100 (range 76 to 86.7) (40-42). Another study with a follow-up of at least twenty years, described only 55% good or very good clinical overall results.

Wound infections were described in 20% of the patients, 23% of the patients were unable to return to work and 17.5% were unable to wear normal shoes. Persisting heel pain occurred in 14.8% and persisting complaints and/or the development of subtalar osteoarthritis leading to subtalar arthrodesis was described in 44 of 618 (7.1%) patients (39).

OUTLINE OF THIS THESIS

This thesis explores the variety of clinical perspectives on complex ankle and hindfoot injuries in a more or less chronological order. A general introduction to the topic and an overview of literature on ankle and hindfoot, in particular calcaneal fractures, are presented in this chapter, Chapter 1. The epidemiology and burden on health care is described. Clinical assessment of patients with ankle or hindfoot injuries and the necessary (radiological) diagnostics are discussed. Followed by an elaboration on the fundamental anatomy and fracture classification systems. Furthermore, the management of calcaneal fractures with different treatment modalities is presented. Finally, long-term outcomes after displaced intra-articular fractures are described.

First the epidemiology and health care costs of these injuries are considered. Foot and ankle injuries account for a large proportion of Emergency Department attendance. Chapter 2 presents population-based trends in attendance due to foot and ankle injuries in the Netherlands from 1986 to 2010. Also a detailed analysis in health care costs in these patients is provided.

The epidemiology is followed by a diagnostic study on the influence of malposition of the foot during radiographic diagnostics. Böhler's angle and angle of Gissane are considered important parameters to guide treatment strategy in calcaneal fractures,

and also provide prognostic information during follow up. Unfortunately, inadequate lateral radiographs are often obtained which makes it difficult to interpret these radiographic measurements adequately. In Chapter 3 the effect of lower leg malposition on these radiographic measurements is evaluated by simulating malposition with craniocaudal and posteroanterior angular variations from the true lateral radiograph.

After a calcaneal fracture is diagnosed, screw fixation with and without the use of a Screw Targeting Clamp is performed and the additional value of 3D compared to 2D radiographs is assessed. Precise placement of sustentaculum tali screws is essential for restoring biomechanical stability of the calcaneus. This can be challenging due to the small target area and the presence of neurovascular structures on the medial side of the calcaneus. In a pre-clinical study described in Chapter 4 a Screw Targeting Clamp, which should facilitate surgeons in the right screw positioning is investigated. This study was aimed to evaluate the quality of sustentaculum tali and processus anterior screw positioning with or without this Screw Targeting Clamp. Also, the added value of peroperative 3D imaging over 2D radiographs alone was described.

Subsequently, it is important to know what the most optimal choice of treatment is, the three most used treatments are compared. Controversy exists about the optimal treatment for displaced intra-articular calcaneal fractures. In Chapter 5 the outcome of patients with these fractures treated by open reduction and internal fixation (ORIF), percutaneous treatment, or non-operative methods is studied. Also insight is gained in the effect of treatment on health-related quality of life, overall patient satisfaction, time to work resumption, and the rate of complications and late interventions.

Before and after surgery cryotherapy can be used, the influence of a computer-controlled cooling device on soft tissue complications, pain and analgesics is evaluated in this thesis. Ankle and hindfoot fractures are often accompanied by a considerable amount of pain and herewith the need for systemic analgesics. Cooling devices have been developed in order to reduce swelling to make early surgery possible, reduce pain and the need for analgesics, wound complications, length of hospital stay, and the risk of adverse events. In Chapter 6 the effect of pre-and postoperative cooling on the pain level and analgesics use in adult patients who sustained an ankle or hindfoot fracture were presented. Also questions about patient satisfaction with the approach to reduce swelling, hospital length of stay, complication rate, and rate of secondary interventions were answered.

Soft tissue is of indescribable importance in the treatment of calcaneal fractures, therefore the risk by the specific fracture displacement of tongue-type calcaneal fractures on the posterior soft tissue heel envelope is investigated in an international study. Chapter 7 focuses on soft tissue complications in tongue-type displaced intra-articular calcaneal fractures. The specific pattern of fracture displacement in this fracture type can result in tension of soft tissue in the posterior part of the heel. Too much or prolonged tension may aggravate trauma-induced soft tissue injury. This international, retrospective cohort studied whether patients with tongue-type fractures exert a higher

risk of posterior soft tissue compromise, other complications, and late interventions than patients with non-tongue-type fractures. Furthermore, the effect of timing of surgery on the complication rate was assessed.

After the (non)operative treatment, patients start their long-term rehabilitation period. The most important factor in the post-operative treatment of displaced intra-articular calcaneal fractures is to avoid fracture displacement or implant failure. Mostly, non-weightbearing is recommended for six to nine weeks, followed by physical therapy and progressive weightbearing as tolerated for the surgically managed fractures. During the period of recovery and rehabilitation most patients cannot return to their normal daily activity. High socio-economic and psychological cost are associated with this long-term rehabilitation period. Chapter 8 provides a review and pooled-analysis of results after early weightbearing in operatively treated patients with closed displaced intra-articular calcaneal fractures. It is reviewed whether the current weightbearing regimes are too conservative and more progressive early weightbearing regimes could be recommended in the future.

Finally, in order to determine the functional outcome in patients with an ankle or hindfoot fracture, the American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot scale is a widely used instruments in daily clinical practice. Chapter 9 describes a study protocol for translating and validating the AOFAS Ankle-Hindfoot scale. Although the AOFAS Ankle-Hindfoot scale is commonly used, a validated, Dutch version of this instrument is currently not available. Such a translated and validated instrument would allow objective comparison across hospitals or between patient groups, and with shown validity and reliability it may become a quality of care indicator in future. In Chapter 10 the AOFAS Ankle-Hindfoot scale is translated, cultural adapted, and the measurement properties of the questionnaire are evaluated for patients with unilateral hindfoot fractures. Chapter 11 reports the validation of the Dutch language version of the AOFAS Ankle Hindfoot scale for patients with unilateral ankle fractures. Chapter 12 presents a general discussion and a vision for future research options. Chapter 13 summarizes the main findings presented in this thesis in English and Dutch.

GENERAL AIM

The aim of this thesis was to deduct lacunas in specific elements of epidemiology, diagnostics, treatment, outcome measurements, and post-operative recommendations in the management of patients with complex ankle and hindfoot injuries. These lacunas are discussed chronologically, from various clinical perspectives.

REFERENCES

1. Eiff MP HR. Fracture Management for Primary Care. Elsevier Saunders, Philiadelphia. 2012; 3rd.
2. Mitchell MJ, McKinley JC, Robinson CM. The epidemiology of calcaneal fractures. Foot (Edinb). 2009;19(4):197-200.
3. Sanders RW CM, Bucholz, RW, Heckman JD, et al. (Eds). Calcaneous fractures Rockwood and Green's Fractures in Adults. 2010;Lippincott Williams & Wilkins, Philadelphia (7th):2064.
4. De Boer AS, Schepers T, Panneman MJ, Van Beeck EF, Van Lieshout EMM. Health care consumption and costs due to foot and ankle injuries in the Netherlands, 1986-2010. BMC Musculoskelet Disord. 2014;15:128.
5. Bugler KE, Watson CD, Hardie AR, Appleton P, McQueen MM, Court-Brown CM, et al. The treatment of unstable fractures of the ankle using the Acumed fibular nail: development of a technique. J Bone Joint Surg Br. 2012;94(8):1107-12.
6. Böhler L. Diagnosis, pathology and treatment of fractures of the os calcis. J Bone Joint Surg. 1931(13):75–89.
7. Essex-Lopresti P. The mechanism, reduction technique, and results in fractures of the os calcis. Br J Surg. 1952;39(157):395-419.
8. Sarrafian SK. Anatomy of the foot and ankle. Philadelphia Lippincott. 1993.
9. Tochigi Y, Amendola A, Rudert MJ, Baer TE, Brown TD, Hillis SL, et al. The role of the interosseous talocalcaneal ligament in subtalar joint stability. Foot Ankle Int. 2004;25(8):588-96.
10. Della Rocca GJ, Nork SE, Barei DP, Taitsman LA, Benirschke SK. Fractures of the sustentaculum tali: injury characteristics and surgical technique for reduction. Foot Ankle Int. 2009;30(11):1037-41.
11. Marsh JL, Slongo TF, Agel J, Broderick JS, Creevey W, DeCoster TA, et al. Fracture and dislocation classification compendium - 2007: Orthopaedic Trauma Association classification, database and outcomes committee. J Orthop Trauma. 2007;21(10 Suppl):S1-133.
12. Fracture and dislocation compendium. Orthopaedic Trauma Association Committee for Coding and Classification. J Orthop Trauma. 1996;10(Suppl : v-ix):1-154.
13. Burdeaux BD. Reduction of calcaneal fractures by the McReynolds medial approach technique and its experimental basis. Clin Orthop Relat Res. 1983(177):87-103.
14. Palmer I. The mechanism and treatment of fractures of the calcaneus; open reduction with the use of cancellous grafts. J Bone Joint Surg Am. 1948;30A(1):2-8.
15. Ross SD, Sowerby MR. The operative treatment of fractures of the os calcis. Clin Orthop Relat Res. 1985(199):132-43.
16. O'Connell F, Mital MA, Rowe CR. Evaluation of modern management of fractures of the os calcis. Clin Orthop Relat Res. 1972;83:214-23.
17. Soeur R, Remy R. Fractures of the calcaneus with displacement of the thalamic portion. J Bone Joint Surg Br. 1975;57(4):413-21.
18. Warrick CK, Bremner AE. Fractures of the calcaneum, with an atlas illustrating the various types of fracture. J Bone Joint Surg Br. 1953;35-B(1):33-45.
19. Watson-Jones R. The classic: "Fractures and Joint Injuries" by Sir Reginald Watson-Jones, taken from "Fractures and Joint Injuries," by R. Watson-Jones, Vol. II, 4th ed., Baltimore, Williams and Wilkins Company, 1955. Clin Orthop Relat Res. 1974(105):4-10.
20. Wondrak E. [Treatment of petrous bone fractures by internal fixation]
Die Behandlung von Fersenbeinbruchen durch innere Fixation. Zentralbl Chir. 1959;84(7):260-6.
21. Crosby LA, Fitzgibbons T. Computerized tomography scanning of acute intra-articular fractures of the calcaneus. A new classification system. J Bone Joint Surg Am. 1990;72(6):852-9.
22. Eastwood DM, Gregg PJ, Atkins RM. Intra-articular fractures of the calcaneum. Part I: Pathological anatomy and classification. J Bone Joint Surg Br. 1993;75(2):183-8.

23. Sanders R, Fortin P, DiPasquale T, Walling A. Operative treatment in 120 displaced intraarticular calcaneal fractures. Results using a prognostic computed tomography scan classification. Clin Orthop Relat Res. 1993(290):87-95.
24. Zwipp H, Tscherne H, Thermann H, Weber T. Osteosynthesis of displaced intraarticular fractures of the calcaneus. Results in 123 cases. Clin Orthop Relat Res. 1993(290):76-86.
25. Wülker N. SM, Cracchiolo A.C. An Atlas Foot and Ankle Surgery. 2005;Second Edition.
26. Benirschke SK, Sangeorzan BJ. Extensive intraarticular fractures of the foot. Surgical management of calcaneal fractures. Clin Orthop Relat Res. 1993(292):128-34.
27. Sanders RW. Displaced intra-articular fractures of the calcaneus. J Bone Joint Surg Am. 2000;82(2):225-50.
28. Freeman BJ, Duff S, Allen PE, Nicholson HD, Atkins RM. The extended lateral approach to the hindfoot. Anatomical basis and surgical implications. J Bone Joint Surg Br. 1998;80(1):139-42.
29. Zwipp H, Rammelt S, Barthel S. Calcaneal fractures--open reduction and internal fixation (ORIF). Injury. 2004;35 Suppl 2:SB46-54.
30. Rammelt S, Amlang M, Barthel S, Zwipp H. Minimally-invasive treatment of calcaneal fractures. Injury. 2004;35 Suppl 2:SB55-63.
31. Folk JW, Starr AJ, Early JS. Early wound complications of operative treatment of calcaneus fractures: analysis of 190 fractures. J Orthop Trauma. 1999;13(5):369-72.
32. Harvey EJ, Grujic L, Early JS, Benirschke SK, Sangeorzan BJ. Morbidity associated with ORIF of intra-articular calcaneus fractures using a lateral approach. Foot Ankle Int. 2001;22(11):868-73.
33. Schepers T. The sinus tarsi approach in displaced intra-articular calcaneal fractures: a systematic review. Int Orthop. 2011;35(5):697-703.
34. Schepers T, Backes M, Dingemans SA, de Jong VM, Luitse JSK. Similar Anatomical Reduction and Lower Complication Rates With the Sinus Tarsi Approach Compared With the Extended Lateral Approach in Displaced Intra-Articular Calcaneal Fractures. J Orthop Trauma. 2017;31(6):293-8.
35. Kerver A. Computer assisted surgical anatomy mapping : applications in surgical anatomy research, tailor-made surgery and presonalized teaching [Ph.D. thesis]: Erasmus University Rotterdam; 2017.
36. McReynolds IS. Trauma to the os calcis and heel cord. Disorders of the Foot W B Saunders, Philadelphia. 1982;Vol. 2:1497.
37. Backes M, Schepers T, Beerekamp MS, Luitse JS, Goslings JC, Schep NW. Wound infections following open reduction and internal fixation of calcaneal fractures with an extended lateral approach. Int Orthop. 2014;38(4):767-73.
38. Rammelt S, Gavlik JM, Barthel S, Zwipp H. The value of subtalar arthroscopy in the management of intra-articular calcaneus fractures. Foot Ankle Int. 2002;23(10):906-16.
39. Veltman ES, Doornberg JN, Stufkens SA, Luitse JS, van den Bekerom MP. Long-term outcomes of 1,730 calcaneal fractures: systematic review of the literature. J Foot Ankle Surg. 2013;52(4):486-90.
40. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int. 1994;15(7):349-53.
41. Myerson MS, Fisher RT, Burgess AR, Kenzora JE. Fracture dislocations of the tarsometatarsal joints: end results correlated with pathology and treatment. Foot Ankle. 1986;6(5):225-42.
42. Crosby LA, Fitzgibbons TC. Open reduction and internal fixation of type II intra-articular calcaneus fractures. Foot Ankle Int. 1996;17(5):253-8.

Chapter 2

Health care consumption and costs due to foot and ankle injuries in the Netherlands, 1986-2010

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ABSTRACT

Background: Foot and ankle injuries account for a large proportion of Emergency Department attendance. The aim of this study was to assess population-based trends in attendances due to foot and ankle injuries in the Netherlands since 1986. A secondary aim was to provide a detailed analysis in health care costs in these patients.

Methods: Age- and gender-standardized emergency attendance rates and incidence rates of admitted patients were calculated for each year of the study. Injury cases and hospital length of stay were extracted from the National Injury Surveillance System (non-hospitalized patients) and the National Medical Registration (hospitalized patients). Data were grouped into osseous and ligamentous injuries for foot and ankle separately. An incidence-based cost model was applied in order to calculate associated direct health care costs in the period 2006-2010.

Results: Since 1986 the overall emergency attendance rate decreased from 858 to 640 per 100,000 person years. In the non-admitted patients, representing 90% of cases, attendance rates of ligamentous injuries approximately halved, whereas osseous injuries increased by 28% and 25% in the foot and ankle, respectively. The incidence rate of admitted patients increased by 35%, mainly due to an almost doubling of osseous foot and ankle injuries. Attendance rates showed a peak in adolescents and adults until ~45 years of age in males and (less pronounced) in females. The total number of hospital days decreased to 58,708 days in 2010. Hospital length of stay (HLOS) increased with age and was highest for osseous injuries. HLOS was unaffected by gender, apart for longer stay in elderly females with an osseous ankle injury. The health care costs per case were highest for osseous injuries of the ankle (€ 3,461). Costs were higher for females and increased with age to € 6,023 in elderly males and € 10,949 in elderly females. The main cost determinants were in-hospital care (56% of total costs), rehabilitation/nursing care (15%), and physical therapy (12%).

Conclusions: Since 1986, the overall emergency attendance rate of foot and ankle injuries in the Netherlands seems to have decreased by 25%. Throughout the years, the attendance rate of (relatively simple) ligamentous injuries strongly reduced, whereas the rate of osseous injuries nearly doubled. Attendance rates and health care costs were gender- and age-related. The main cost determinants were in-hospital care, rehabilitation/nursing care, and physical therapy.

BACKGROUND

During the last decades, quality of trauma care (both prehospital and hospital care) has improved and complication rates have decreased (1, 2). Lower extremities are among the most frequently injured body regions in trauma patients (2-5). The majority of foot and ankle injuries occur during sports or work; they form a leading cause of trauma hospitalizations (3-7). As foot and ankle injuries account for over 20% of all injury patients visiting an Emergency Department (ED), research on trends in emergency attendance and health care use in this group is needed (8).

Population-based knowledge on emergency attendance rates, health care use and economic burden of foot and ankle injuries is essential for the allocation of health care services, optimization of preventive measures and research purposes, but it also provides a forecast for the future. Most epidemiologic studies on foot and ankle injuries focused on one distinct subgroup such as a specific type of injury, anatomical region, or age group (8-20). Most studies used data from a single hospital or a regional database (8, 9, 12, 15, 16, 18, 19, 21-23). Some papers used a national injury database (10, 11, 17, 20, 24-26). No papers summarize long-term population trends in emergency attendance rates, health care used and costs of all foot and ankle injuries presented to the emergency department at a national level. Detailed evaluations of costs, gaining insight in the parameters that contribute most to the overall costs, such as cost for hospital stay, physical therapy and rehabilitation are not available. Due to budgetary restraints and increasing health care costs, such economic analyses are gaining importance.

Therefore, the aim of the current study was to examine long-term population-based trends in the emergency attendance and associated hospitalization and health care costs of foot and ankle injuries in the Netherlands from 1986 to 2010.

METHODS

Data sources

For this retrospective study data were collected for patients with foot and ankle injuries in the Netherlands in the period 1986-2010. Injury cases were extracted from the National Injury Surveillance System (LIS) (27) and National Medical Registration (LMR) (28), to include non-hospitalized and hospitalized patients, respectively. LIS is a continuous monitoring system that records unintentional and intentional injuries. It has been implemented in 17 hospital EDs, resulting in a representative 12% sample of all injury-related ED visits in the Netherlands (27). These hospitals are geographically distributed across the country with their adherence population being representative for the Dutch population in age and gender structure (29). LMR collects data regarding hospital ad-

missions, admission diagnosis, gender, age, and length of hospital stay. LMR is centrally evaluated for plausibility and completeness before entry into the LIS database (27). LMR has almost complete national coverage (<5% missing except 12% for 2007) and figures are extrapolated to full national coverage for each year. An extrapolation factor was determined by comparing the adherence population of the participating hospitals with the total Dutch population in each year (28). Patients are included in LIS and LMR according to their main diagnosis at discharge, which is generally the most severe injury. Coding of patients was consistently based upon full patient chart review including routine radiological assessment as available in the patient files.

Injuries in hospitalized patients (LMR) were defined using the International Classification of Diseases, 10th revision (ICD-10, including codes for injuries to the lower leg (S82), foot (S92-93, S79), and ankle (S82, S93, S97) (30). During the study period the ICD-version changed from the 9th to the 10th revision version in the year 2010. Data encoded using ICD-9 were extracted using a conversion table developed by the World Health Organization Collaborating Center for the Family of International Classifications (WHO FIC). Injuries in non-hospitalized patients (LIS) were defined using injury type descriptions. In order to report data on both databases combined (which is also the most clinically relevant grouping), patients were grouped into four injury categories; 1) Osseous ankle injuries; 2) Ligamentous ankle injuries; 3) Osseous foot injuries; 4) Ligamentous foot injuries (Table 1). Since the LIS database contains a limited number of injury classes, a more detailed analysis was not possible.

Table 1. Subdivision of the ICD-codes from the LMR database and the injury types from the LIS database in the four main injury groups

	LMR database	LIS database
Foot injuries		
Osseous	Fracture of calcaneus (S920) Fracture of talus (S921) Fracture of other tarsal bone(s) (S922) Fracture of metatarsal bone (S923) Fracture of other toe (S925) Fracture of foot, unspecified (S929) Dislocation of toe(s) (S931) Dislocation of other and unspecified parts of foot (S933)	Fracture of foot/toe Dislocation of foot/toe
Ligamentous	Sprain and strain of toe(s) (S935) Sprain and strain of other and unspecified parts of foot (S936)	Sprain and strain foot/toe Muscle-/tendon injury foot/toe
Ankle injuries		
Osseous	Fracture of fibula alone (S824) Fracture of medial malleolus (S825) Fracture of lateral malleolus (S826) Fractures of other parts of lower leg (S828) Dislocation of ankle joint (S930)	Fracture of ankle Dislocation of ankle
Ligamentous	Sprain and strain of ankle (incl. Achilles tendon rupture) (S934)	Muscle-/tendon injury of ankle Sprain and strain of ankle Achilles tendon injury

Data regarding hospital length of stay (HLOS) were extracted from the LMR database for 10-year age categories. In order to assess trends in HLOS over time, the mean HLOS was averaged over 5-year intervals from 1991-2010.

The time periods for the different analyses (1986-2010 for incidence rates, 1991-2010 for HLOS, and 2010 for health care consumption and associated costs) was based on data availability.

The study was exempted by the local Medical Research Ethics Committee Erasmus MC (No. MEC-2014-006).

Calculation of emergency attendance and clinical incidence rates

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 16.0 for Windows.

Age-specific emergence attendance rates (for all patients presented to the ED) and incidence rates of admitted patients (*i.e.*, clinical incidence rates) were calculated in 5-year age groups. This was done for the total population and for males and females separately. For each age group the absolute numbers of hospitalized and non-hospitalized cases with foot and ankle injuries were extracted from the LMR and LIS database, respectively. Since patient numbers in the LIS database were obtained from a sample, they were weighted in order to create national estimates. An extrapolation factor was determined by comparing the number of admitted injury patients in the LIS database with the total number of admitted injury patients in the LMR database. In order to adjust for differences in the demographic composition over time, emergency attendance and clinical incidence rates were standardized for age (in 5-year age groups) and gender using a direct standardization method. The age- and gender-specific emergency attendance and clinical incidence rates per 100,000 person years were calculated based upon the Dutch mid-year standard population. Mid-year population sizes for all age groups were obtained from Statistics Netherlands (31). Age-adjusted emergency attendance and clinical incidence rates were calculated using 'direct standardization' (32). The average number of persons in each 5-year age class for each year of the study (1986-2010) was calculated. This number was used as the standard (reference) population, as described previously (33, 34). Overall increase in hospital admissions was calculated for 2010 in per cents relative to 1986.

Calculation of costs

The incidence-based Dutch Burden of Injury Model, which has been used in ten European countries, was used in order to measure and describe the health care costs for the year 2010 (24, 33, 35-38). Patient numbers, health care consumption, and related costs were calculated for the four injury groups using the LIS database, the National Hospital Discharge Registry, and a patient follow-up survey to calculate associated direct health care costs in 2010. The patient follow-up survey collected data on in-hospital care, out-

patient visits, general practitioner (G.P.) visits, outpatient physical therapy, home care, medication, and aids and appliances (29). Costs and health care consumption are injury, gender- and age-dependent. In our model, the age- and injury-specific costs were based upon the estimated health care supplied to the individual patients. Costs were determined for the following categories: 1) ambulance care; 2) G.P. visits; 3) in-hospital care; 4) home care; 5) rehabilitation and nursing home care; and 6) physical therapy. Health care costs of injuries were calculated by multiplying incidence, health care volumes (*e.g.,* length of stay in hospital or institution, the number of outpatient visits, G.P. visits, home care hours, and physical therapy treatments) with unit costs (*e.g.*, costs per day in hospital). Unit costs were estimated according to national guidelines for health care costing (38). Age-specific costs are presented in 10-year age groups for men and women separately.

RESULTS

Emergency attendances and hospital admissions

During the study period, the absolute number of patients reporting to an ED with a foot or ankle injury decreased from 124,595 in 1986 to 106,157 in 2010. The emergency attendance rate of all injuries combined decreased from 858 to 640 per 100,000 persons (-25.4%). Whereas ligamentous injuries approximately halved, osseous injuries nearly doubled.

In non-admitted patients, representing 90% of patients, the overall emergency attendance rate decreased by 30.2% (Figure 1A). This was mainly due to a decrease in ligamentous injuries of the ankle (504/100,000 in 1986 versus 228/100,000 in 2010; -54.8%) and foot (26/100,000 in 2010; -50.9%). Osseous injuries in the foot and ankle, however, increased by 28.3% (152/100,000 in 2010) and 25.3% (104/100,000 in 2010), respectively.

The admission rate increased from 7.6% in 1986 to 13.8% in 2010 (Figure 1B). This was mainly due to a 31.8% admission rate of patients with osseous ankle injuries. Admission of patients with osseous foot injuries (4.0% admitted) or ligamentous injuries in the ankle (3.8%) or foot (<0.1%) was low. Since 1986, the incidence rate of patients admitted for foot and ankle injuries increased by 35.4%. This was mostly due to increased incidences of osseous ankle injuries (33/100,000 in 1986 versus 62/100,000 in 2010; +87.9%). The incidence rate of patients admitted for a ligamentous ankle injuries diminished with 42.3% (26 to 15/100,000).

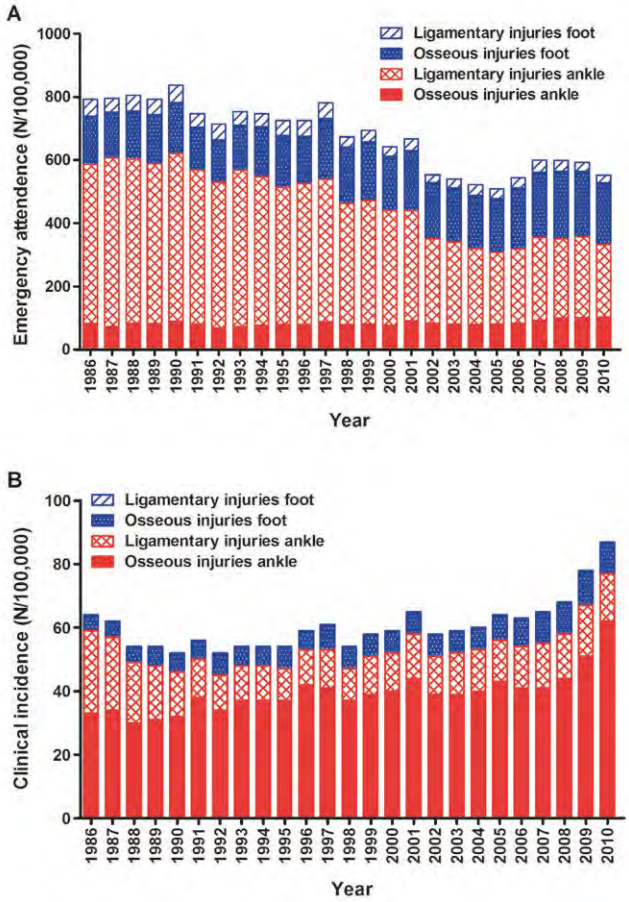

Figure 1. Trends in age- and gender adjusted emergency attendance and clinical incidence (per 100,000 person years) of foot and ankle injuries in the period 1986-2010 for non-admitted (**A**) and admitted (**B**) patients. Emergency attendance refers to all patients presented to the Emergency Department, and clinical attendance refers to all patients admitted to hospital.

The emergency attendance rates of foot and ankle injuries varied with age in males and, less pronounced, also in females (Figures 2A and 2B). Attendance rates showed a peak in adolescents and adults until ~45 years of age. Until this age the attendance rate in males was higher than in females. Since 1986 this peak in attendance has decreased in both genders. The decrease in incidence peaks at younger ages over time suggest a shift towards a higher mean age. Indeed, the mean age of patients increased throughout the study period by 8.3 years for osseous ankle injuries (from 32.1±19.7 (SD) years in 1986 to 40.4±22.7 in 2010) and by 4.0 years for osseous foot injuries (from 31.6±18.5 in 1986 to 35.5±20.9 in 2010), Mean ages were much more stable for ligamentous injuries (age increased from 25.4±15.7 to 26.7±17.9 years for the foot and from 27.0±13.4 to 29.6±16.7 years for the ankle).

Figures 2C and 2D show age-trends of the four main injury types in 2010. Again, a peak in adolescents was seen, especially in males. Whereas the incidence in all injury types reduced with age in males, the incidence of osseous injuries in elderly women remained more stable.

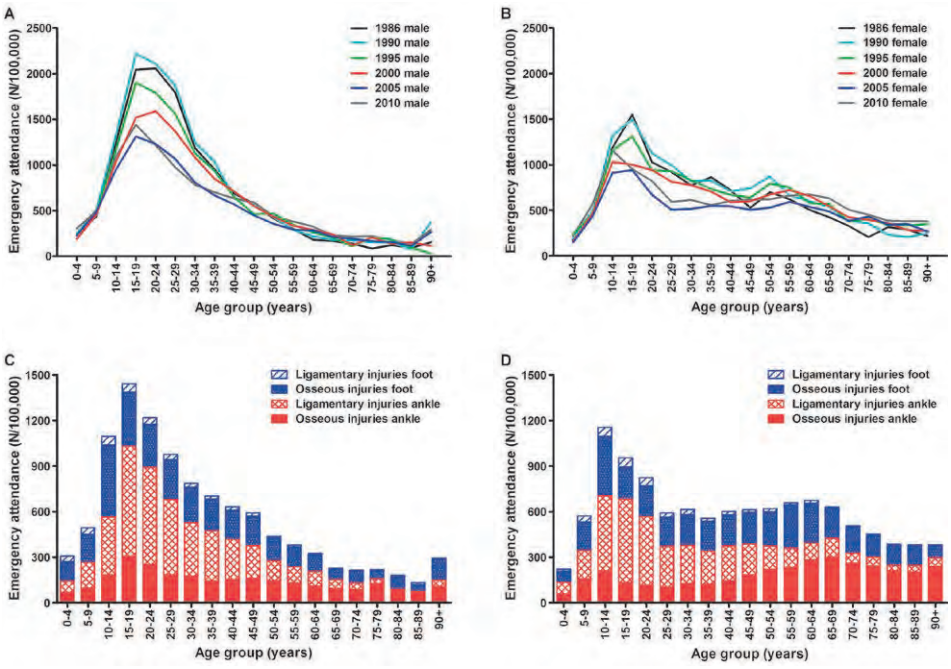

Figure 2. Trends in emergency attendance (per 100,000 person years) of foot and ankle injuries by age
The upper panels show data for six different years for males (**A**) and females (**B**). In the lower panels, data are separated into osseous and ligamentous injuries of the foot and ankle. Data are shown for males (**C**) and females (**D**) in 2010.

Hospital Length of Stay

Hospital length of stay (HLOS) in four consecutive five-year periods is shown in Figures 3A and 3B. Each period showed a gradual increase with age, yet over time the HLOS decreased for all age groups. The HLOS per case more than halved both in males (7.8 days in 1991 versus 3.3 in 2010) and females (11.5 days versus 4.9). The total number of hospital days for men and women of all ages combined decreased from 78,951 days in 1991 to 58,708 days in 2010. Patients aged 20-65 year accounted for 51% of all hospital days.

The HLOS for different types of injuries is shown in Figures 3C and 3D (for males and females, respectively). Osseous injuries caused the longest hospital stay per case in almost every age group, with limited differences between foot and ankle injuries. HLOS in males and females was similar for all injury types; in every age group the difference

was restricted to one day at most. Exceptions to this were noted in elderly (70+) with an ankle injury; HLOS for osseous ankle injuries was 11.0 days in females versus 8.2 days in males. HLOS for ligamentous ankle injuries was 5.3 and 3.4 days, respectively.

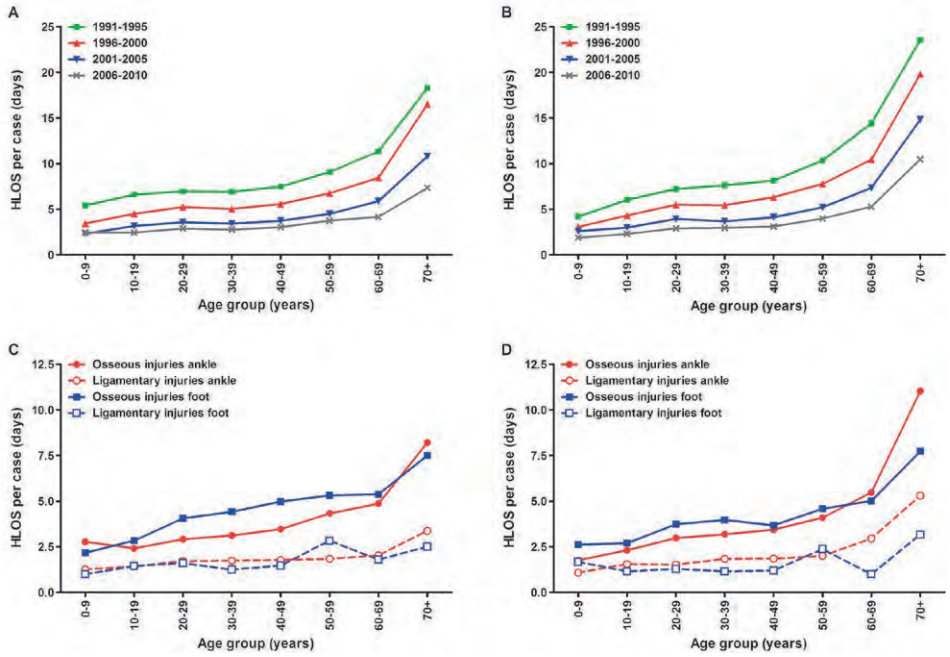

Figure 3. Age-related trends in hospital length of stay due to foot and ankle injuries
The upper panels show data for four different time periods for males (**A**) and females (**B**). The lower panels show data for the four main categories of injuries in males (**C**) and females (**D**) in 2010.

Costs for health care consumption

The overall costs for all patients amounted 161.9 million euro in 2010. Between 2001 and 2010, costs remained fairly stable; an overall increase of 1.2% was noted (data not shown).

Costs per case for all injuries and age groups combined were € 1,802 for females and € 1,204 for males (Table 2). For all four injury groups, the costs per case were higher in females than in males; they were highest for osseous injuries of the ankle (€ 4,294 and € 2,549 in females and males, respectively) and the foot (€ 1,229 and € 898), and were lowest for ligamentous foot injuries (€ 740 and € 653).

Table 2. Total and mean cost of all injuries of the foot and ankle for admitted and non-admitted patients (2006-2010)

	Overall		Males		Females	
	N cases	Cost / case (€)	N cases	Cost / case (€)	N cases	Cost / case (€)
Admitted patients						
Osseous injuries foot	1,527	6,088 (1,469)	969	4,475 (961)	558	8,887 (2,349)
Ligamentous injuries foot	36	2,582 (199)	22	2,746 (244)	14	2,322 (129)
Osseous injuries ankle	8,737	7,383 (1,620)	3,931	5,415 (998)	4,806	8,993 (2,128)
Ligamentous injuries ankle	2,869	2,780 (281)	2,153	2,586 (251)	716	3,364 (373)
Subtotal	**13,169**	**6,217 (1,307)**	**7,075**	**4,417 (764)**	**6,094**	**8,306 (1,937)**
Non-admitted patients						
Osseous injuries foot	33,511	836 (126)	16,418	687 (93)	17,092	979 (157)
Ligamentous injuries foot	5,203	685 (96)	2,502	634 (85)	2,701	732 (106)
Osseous injuries ankle	15,916	1,308 (154)	7,832	1,110 (129)	8,084	1,500 (177)
Ligamentous injuries ankle	40,368	684 (82)	21,460	642 (69)	18,908	731 (97)
Subtotal	**94,998**	**842 (110)**	**48,213**	**733 (88)**	**46,785**	**955 (133)**
All patients						
Osseous injuries foot	35,038	1,065 (184)	17,387	898 (141)	17,650	1,229 (226)
Ligamentous injuries foot	5,240	698 (97)	2,525	653 (87)	2,715	740 (106)
Osseous injuries ankle	24,653	3,461 (673)	11,763	2,549 (420)	12,890	4,294 (904)
Ligamentous injuries ankle	43,237	823 (92)	23,613	819 (86)	19,624	827 (107)
Total	**108,167**	**1,496 (255)**	**55,288**	**1,204 (174)**	**52,879**	**1,802 (338)**

Mean costs per case are given, with the standard deviation between brackets.

Figure 4 shows the costs per case for the four main injury groups, separated into costs for different types of health care use. In addition to costs per case being higher in females than in males, costs consistently increased with age for all four injury categories; from 0 to 70+ years, costs for all injuries combined increased 9.2-fold in females and 5.7-fold in males. The largest increase with age was seen for osseous injuries of the ankle (from € 996 to € 6,023 in males and from € 1,127 to € 10,949 in females; Figures 4E and F) and foot (from € 571 to € 1,716 in males and from € 642 to € 3,626 in females; Figures 4A and B). Ligamentous foot injuries showed only a 1.7-fold and 2.0-fold increase across the age groups in males and females, respectively (Figures 4C and D). Costs for ligamentous injuries were independent of gender. For osseous injuries, the costs per case were similar in males and females until 60 years of age, but a clear gender-dependency was noted for the 70+ group.

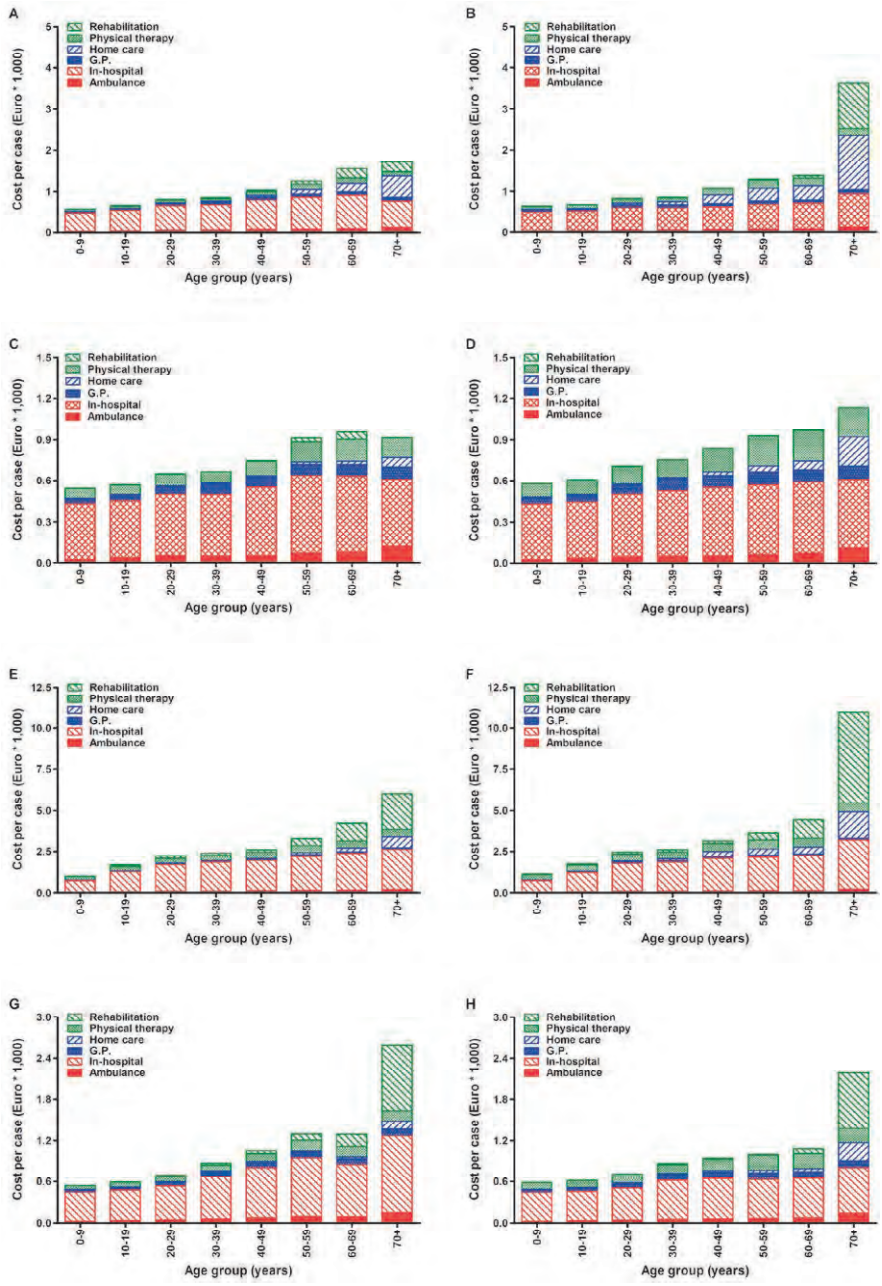

Figure 4. Age- and injury-related costs per case for the treatment of foot and ankle injuries in males (**A**, **C**, **E**, and **G**) and females (**B**, **D**, **F**, and **H**), separated into different cost determinants

Costs per case are given for osseous foot injuries (**A** and **B**), ligamentous foot injuries (**C** and **D**), osseous ankle injuries (**E** and **F**) and ligamentous ankle injuries (**G** and **H**). Costs are shown separately for ambulance care, in-hospital care, general practitioner visits, home care, physical therapy, and rehabilitation/nursing home care. Data for 2010 are shown for admitted and non-admitted patients combined.

Costs for in-hospital care consistently contributed most to the total cost per case (64-69% of total costs in males and 45-62% in females; Figure 4). Physical therapy was the second largest determinant (8-19% of total costs). Ambulance care and G.P. visits each contributed less than 10% to the overall cost per case; they doubled or tripled over the age groups, but were unrelated to injury type and gender. For osseous foot and ankle injuries, the increase in costs over the age groups was mainly due to increased use of rehabilitation/nursing care and home care in the elderly. This effect was more pronounced in females than in males. The age-effect on costs in ligamentous foot injuries was mainly attributable to increased costs for physical therapy, G.P. visits, and home care. Higher use of home care also explained the larger cost increase in females. For ligamentous ankle injuries, in-hospital costs increased more with age in males, whereas costs for home care and physical therapy increased more in females.

DISCUSSION

Since 1986 the emergency attendance rate of ligamentous foot and ankle injuries consistently decreased, yet osseous injuries increased over time. Osseous injuries were the most expensive type of injury. The main cost determinants were in-hospital care and physical therapy.

This study shows the reduction in emergency attendance over time is mainly attributable to a decrease in clinically observed ligamentous ankle injuries. During the study period new guidelines and After Hours Medical Clinics were established (39, 40), so patients with minor injuries can nowadays get G.P. consultations and treatment 24/7. The annual number of patients visiting a G.P. with distal lower extremity problems increased from 300,000 in 2000 to 600,000 in 2005 (39). LIS and LMR do not record patients visiting only a G.P., so they were not included in our study.

The incidence rate of patients with osseous injuries strongly increased since 1986, especially in admitted patients. This may indicate a shift towards more complex injuries over time or an increase in the number of surgically treated fractures which is especially seen in ankle fractures (20, 41, 42). Similar trends towards increased operative treatment have also been reported for other injuries (43-45).

Several studies have shown increased incidence rates of foot and ankle injuries in the last decades (2, 8, 41). This is in line with an increase in fractures found in the current study, although we noted a decrease in emergency attendance overall. The profile and presentation of emergency department injuries have altered and the increase in osseous injuries may be proportional to the increase seen in all lower limb injuries.

Over the years, the HLOS per case decreased. Our data do not allow us to conclude whether that was due to improved health care programs, operative procedures and implants, or changes in admission and discharge guidelines. Introduction of evaluation guidelines like the Ottawa Ankle Rules (40) may also have resulted in earlier diagnosis

and subsequent earlier treatment and lower complication rates. The increase in HLOS in elderly women with osseous injuries suggests a role for osteoporosis, as also noted before (8). Osteoporotic fractures are often more complicated to treat, resulting in prolonged hospital stay.

One study reported on costs of foot and ankle fractures in the Netherlands in 1999, using the same cost model (24). After correction for inflation, the corresponding costs in 2010 would be € 25.7 million (€ 861/case) for foot/toe fractures and € 54.5 million (€ 2,870/case) for ankle fractures. The higher costs observed in the current study may be attributable, at least partly, to more fractures treated operatively and higher costs for novel implants. Also, improvement in data sources on home and nursing care and on operative interventions may have resulted in more accurate, most likely higher, estimates of costs in the current study.

As expected, in-hospital care (especially admission days), rehabilitation/nursing care, and physical therapy were the main cost drivers. Similar results have been reported for ankle fractures (46). In-hospital cost for osseous ankle fractures cost €4,000/case in our study, which was in line with data from Murray *et al.* reported £4730 (*i.e.*, €4230) (47). The fact that the age effect was larger in females than in males may reflect that females tend to outlive their partners; elderly are more prone to losing their independence after sustaining a foot or ankle injury. Higher costs for osseous injuries were mainly attributable to longer HLOS.

This study is unique as it is a population-based study showing national and long-term trends in emergency attendance and hospitalization of patients with all foot and ankle injuries. Detailed data on health care costs is also novel. Most studies on lower leg injuries were restricted to one distinct injury or age group (8-19), focused on few hospitals, or were limited to (non-)hospitalized patients. Some studies used national injury databases (10, 11, 17, 20, 24-26). National registry data more reliably represent the true health care problem than extrapolating data from one trial or hospital (27). Although LIS-data covers 12% of the Dutch population, international validation studies have shown that the mathematical model underlying the extrapolation has a high level of completeness and validity (27). Agreement of LIS recordings with hospital discharge systems and actual incidence of hospital admissions is high (27, 48). Both rural and urban areas and all levels of trauma care are included, supporting validity and generalizability of our findings.

We also acknowledge limitations, the most obvious being that patients who only visited a G.P./sports physician were not included. Although this indicates an underestimation of the problem at large, it can be expected that the excluded patients had minor injuries not requiring substantial treatment. Furthermore, there may be some statistical uncertainty due to underreporting of combined injuries, as patients are recorded based upon their main injury at discharge. A related limitation is that despite the introduction of evaluation guidelines like the Ottawa Ankle Rules (40), 8-18% of all foot fractures and 3-22% of ankle fractures are still missed at initial evaluation (49). This likely caused a

bias towards a lower emergency attendance rate, but this applies to all studies. A final limitation is that indirect health care costs like absenteeism and work disability were not taken into account in the cost model. Since the majority of patients with foot or ankle injuries are 20-60 years, the total societal burden will be higher than our data indicate. For calcaneal fractures, the work absenteeism costs exceeded the direct medical costs (50).

CONCLUSIONS

The overall emergency attendance rate of foot or ankle injuries in the Netherlands seems to have decreased by 25% since 1986. The highest attendance was noted in patients aged 20-50 years. Whereas an approximately 50% reduction in ligamentous injuries was noted, the osseous injuries increased over time (25-28% in non-admitted patients, 87-100% in admitted patients), which might indicate a shift towards more substantial injuries. Attendance rates and health care costs were gender- and age-related. The main cost determinants were in-hospital care, rehabilitation/nursing care, and physical therapy.

REFERENCES

1. Probst C, Richter M, Lefering R, Frink M, Gaulke R, Krettek C, et al. Incidence and significance of injuries to the foot and ankle in polytrauma patients--an analysis of the Trauma Registry of DGU. Injury. 2010;41(2):210-5.
2. Regel G, Lobenhoffer P, Grotz M, Pape HC, Lehmann U, Tscherne H. Treatment results of patients with multiple trauma: an analysis of 3406 cases treated between 1972 and 1991 at a German Level I Trauma Center. J Trauma. 1995;38(1):70-8.
3. Holbrook TL, Hoyt DB, Anderson JP. The importance of gender on outcome after major trauma: functional and psychologic outcomes in women versus men. J Trauma. 2001;50(2):270-3.
4. Holbrook TL, Anderson JP, Sieber WJ, Browner D, Hoyt DB. Outcome after major trauma: 12-month and 18-month follow-up results from the Trauma Recovery Project. J Trauma. 1999;46(5):765-71; discussion 71-3.
5. Holbrook TL, Hoyt DB, Anderson JP. The impact of major in-hospital complications on functional outcome and quality of life after trauma. J Trauma. 2001;50(1):91-5.
6. Zelle BA, Brown SR, Panzica M, Lohse R, Sittaro NA, Krettek C, et al. The impact of injuries below the knee joint on the long-term functional outcome following polytrauma. Injury. 2005;36(1):169-77.
7. Rhodes M, Aronson J, Moerkirk G, Petrash E. Quality of life after the trauma center. J Trauma. 1988;28(7):931-8.
8. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. Injury. 2006;37(8):691-7.
9. Wood AM, Robertson GA, Rennie L, Caesar BC, Court-Brown CM. The epidemiology of sports-related fractures in adolescents. Injury. 2010;41(8):834-8.
10. Waterman BR, Owens BD, Davey S, Zacchilli MA, Belmont PJ, Jr. The epidemiology of ankle sprains in the United States. J Bone Joint Surg Am. 2010;92(13):2279-84.
11. Parenteau CS, Viano DC, Lovsund P, Tingvall C. Foot-ankle injuries: influence of crash location, seating position and age. Accid Anal Prev. 1996;28(5):607-17.
12. Fong DT, Man CY, Yung PS, Cheung SY, Chan KM. Sport-related ankle injuries attending an accident and emergency department. Injury. 2008;39(10):1222-7.
13. Fong DT, Hong Y, Chan LK, Yung PS, Chan KM. A systematic review on ankle injury and ankle sprain in sports. Sports Med. 2007;37(1):73-94.
14. Cummings SR, Melton LJ. Epidemiology and outcomes of osteoporotic fractures. Lancet. 2002;359(9319):1761-7.
15. Court-Brown CM, McBirnie J. The epidemiology of tibial fractures. J Bone Joint Surg Br. 1995;77(3):417-21.
16. Bridgman SA, Clement D, Downing A, Walley G, Phair I, Maffulli N. Population based epidemiology of ankle sprains attending accident and emergency units in the West Midlands of England, and a survey of UK practice for severe ankle sprains. Emerg Med J. 2003;20(6):508-10.
17. Thur CK, Edgren G, Jansson KA, Wretenberg P. Epidemiology of adult ankle fractures in Sweden between 1987 and 2004. Acta Orthop. 2012;83(3):276-81.
18. Hasselman CT, Vogt MT, Stone KL, Cauley JA, Conti SF. Foot and ankle fractures in elderly white women. Incidence and risk factors. J Bone Joint Surg Am. 2003;85-A(5):820-4.
19. Court-Brown CM, Clement N. Four score years and ten: an analysis of the epidemiology of fractures in the very elderly. Injury. 2009;40(10):1111-4.
20. Kannus P, Palvanen M, Niemi S, Parkkari J, Jarvinen M. Increasing number and incidence of low-trauma ankle fractures in elderly people: Finnish statistics during 1970-2000 and projections for the future. Bone. 2002;31(3):430-3.
21. Tadros AM, Eid HO, Abu-Zidan FM. Epidemiology of foot injury in a high-income developing country. Injury. 2010;41(2):137-40.
22. Rennie L, Court-Brown CM, Mok JY, Beattie TF. The epidemiology of fractures in children. Injury. 2007;38(8):913-22.

23. Fernandez WG, Yard EE, Comstock RD. Epidemiology of lower extremity injuries among U.S. high school athletes. Acad Emerg Med. 2007;14(7):641-5.
24. Meerding WJ, Mulder S, van Beeck EF. Incidence and costs of injuries in The Netherlands. Eur J Public Health. 2006;16(3):272-8.
25. van Staa TP, Dennison EM, Leufkens HG, Cooper C. Epidemiology of fractures in England and Wales. Bone. 2001;29(6):517-22.
26. Lambers K, Ootes D, Ring D. Incidence of patients with lower extremity injuries presenting to US emergency departments by anatomic region, disease category, and age. Clin Orthop Relat Res. 2011;470(1):284-90.
27. Meerding WJ, Polinder S, Lyons RA, Petridou ET, Toet H, van Beeck F, et al. How adequate are emergency department home and leisure injury surveillance systems for cross-country comparisons in Europe? Int J Inj Contr Saf Promot. 2010;17(1):13-22.
28. Van der Stegen R, Ploemacher J. Discription of methods for statistics by diagnoses in time by using the LMR (1981-2005). The Hague: Statistics Netherlands (CBS), 2009.
29. Polinder S, van Beeck EF, Essink-Bot ML, Toet H, Looman CW, Mulder S, et al. Functional outcome at 2.5, 5, 9, and 24 months after injury in the Netherlands. J Trauma. 2007;62(1):133-41.
30. www.who.int/classifications/icd.
31. Eiff MP HR. Fracture Management for Primary Care. Elsevier Saunders, Philiadelphia. 2012; 3rd.
32. Curtin LR, Klein RJ. Direct standardization (age-adjusted death rates). Healthy People 2000 Stat Notes. 1995(6):1-10.
33. Hartholt KA, Van Lieshout EM, Polinder S, Panneman MJ, Van der Cammen TJ, Patka P. Rapid increase in hospitalizations resulting from fall-related traumatic head injury in older adults in The Netherlands 1986-2008. J Neurotrauma. 2011;28(5):739-44.
34. Polinder S, Iordens GI, Panneman MJ, Eygendaal D, Patka P, Den Hartog D, et al. Trends in incidence and costs of injuries to the shoulder, arm and wrist in The Netherlands between 1986 and 2008. BMC Public Health. 2013;13(1):531.
35. Polinder S, Meerding WJ, van Baar ME, Toet H, Mulder S, van Beeck EF. Cost estimation of injury-related hospital admissions in 10 European countries. J Trauma. 2005;59(6):1283-90; discussion 90-1.
36. Mulder S, Meerding WJ, Van Beeck EF. Setting priorities in injury prevention: the application of an incidence based cost model. Inj Prev. 2002;8(1):74-8.
37. de Putter CE, Selles RW, Polinder S, Panneman MJ, Hovius SE, van Beeck EF. Economic impact of hand and wrist injuries: health-care costs and productivity costs in a population-based study. J Bone Joint Surg Am. 2012;94(9):e56.
38. Sanders RW CM, Bucholz, RW, Heckman JD, et al. (Eds). Calcaneous fractures Rockwood and Green's Fractures in Adults. 2010;Lippincott Williams & Wilkins, Philadelphia (7th):2064.
39. CBO. Dutch guideline "Acute lateral ankle ligament injuries [Acuut lateraal enkelbandletsel]; http://www.cbo.nl/Downloads/1157/conc_rl_enkelletsel.pdf (last accessed on July 9, 2013.
40. Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Worthington JR. A study to develop clinical decision rules for the use of radiography in acute ankle injuries. Ann Emerg Med. 1992;21(4):384-90.
41. Richter M, Thermann H, Wippermann B, Otte D, Schratt HE, Tscherne H. Foot fractures in restrained front seat car occupants: a long-term study over twenty-three years. J Orthop Trauma. 2001;15(4):287-93.
42. Richter M, Thermann H, von Rheinbaben H, Schratt E, Otte D, Zwipp H, et al. [Fractures of the foot region of car drivers and passengers. Occurrence, causes and long-term results]. Unfallchirurg. 1999;102(6):429-33.
43. Bell JE, Leung BC, Spratt KF, Koval KJ, Weinstein JD, Goodman DC, et al. Trends and variation in incidence, surgical treatment, and repeat surgery of proximal humeral fractures in the elderly. J Bone Joint Surg Am. 2011;93(2):121-31.
44. Huttunen TT, Kannus P, Lepola V, Pihlajamaki H, Mattila VM. Surgical treatment of humeral-shaft fractures: A register-based study in Finland between 1987 and 2009. Injury. 2012;43(10):1704-8.

45. Mattila VM, Huttunen TT, Sillanpaa P, Niemi S, Pihlajamaki H, Kannus P. Significant change in the surgical treatment of distal radius fractures: a nationwide study between 1998 and 2008 in Finland. J Trauma. 2011;71(4):939-42; discussion 42-3.
46. Lin CW, Haas M, Moseley AM, Herbert RD, Refshauge KM. Cost and utilisation of healthcare resources during rehabilitation after ankle fracture are not linked to health insurance, income, gender, or pain: an observational study. Aust J Physiother. 2008;54(3):201-8.
47. Murray AM, McDonald SE, Archbold P, Crealey GE. Cost description of inpatient treatment for ankle fracture. Injury. 2011;42(11):1226-9.
48. Lyons RA, Polinder S, Larsen CF, Mulder S, Meerding WJ, Toet H, et al. Methodological issues in comparing injury incidence across countries. Int J Inj Contr Saf Promot. 2006;13(2):63-70.
49. Schepers T, van Schie-van der Weert EM, de Vries MR, van der Elst M. Foot and ankle fractures at the supination line. Foot (Edinb). 2011;21(3):124-8.
50. Brauer CA, Manns BJ, Ko M, Donaldson C, Buckley R. An economic evaluation of operative compared with nonoperative management of displaced intra-articular calcaneal fractures. J Bone Joint Surg Am. 2005;87(12):2741-9.

Chapter 3

The influence of radiograph obliquity on Böhler's and Gissane's angle in calcanei

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ABSTRACT

Introduction: In calcaneal fractures, Böhler's and Gissane's angles are considered important parameters to guide treatment strategy (fracture reduction and internal fixation versus nonoperative) and provide prognostic information during follow up. Therefore, lateral radiographs have to be accurate. However, inadequate radiographs are often obtained. The aim of this study was to evaluate the effect of craniocaudal and posteroanterior angular variations (*i.e.,* simulate lower leg malposition) from the true lateral radiograph on Böhler's and Gissane's angle.

Methods: In this radio-anatomical study, 15 embalmed, skeletally mature, human anatomic lower limb specimens were used. Using predefined criteria, a true lateral radiograph (*i.e.,* 0° angular variation) was obtained. Angular variations from this true lateral radiograph were made from -30° to +30° deviation in the craniocaudal and posteroanterior direction at 5° intervals. In each of the 420 radiographs, Böhler's and Gissane angles were independently assessed by two experienced trauma surgeons.

Results: The mean age of the specimens was 87 years (SD 9.2). Böhler's angle decreased with increasing caudal angular variations (max. -4.3° deviation at -30°). With increasing the posterior angular variations, Böhler's angle increased (max. 5.0° deviation at +30°) from the true lateral radiograph, but all deviations were within the measurement error. The deviation of the angle of Gissane was most pronounced in the cranial direction, with the mean angle decreasing by -8.8° at +30° angular variation. Varying angular obliquity in the caudal and posteroanterior direction hardly affected Gissane's angle.

Conclusion: Foot malpositioning during the making of a lateral radiograph has little influence on Böhler's and Gissane's angle. If used for clinical decision making in initial treatment and during follow up of calcaneal fractures, these parameters can reliably be taken from any lateral radiograph.

INTRODUCTION

The presence of a calcaneal fracture is based on radiological examinations, which initially consist of a lateral and an axial radiograph of the foot (1). In case of a fracture, management can be surgical or nonoperative. The decision to perform an open reduction and internal fixation is merely based on the amount of dislocation. Although a Computed Tomography (CT) scan provides a better visualization of the extent of the fracture, the number of fragments and their displacement, the amount of height loss, broadening of the calcaneus and the subtalar joint congruency (2, 3), the decision to operate or not is still predominantly based on plain radiographs. Loucks *et al.* and Shuler *et al.* showed that the initial Böhler's angle at the time of trauma still guides this treatment decision (4, 5).

From the lateral radiograph two angles are used to estimate the degree of depression and displacement of the subtalar joint. Böhler's angle is determined by drawing lines from the tip of the processus anterior calcanei to the most cranial point of the posterior facet and from the top of the tuber calcanei to the most cranial point of the subtalar joint. Normally, this angle is between 25° and 40° (6) (Figure 1A). Those with a decreased Böhler's angle are more likely to undergo fracture reduction and internal fixation to restore congruity of the posterior facet (4, 7). Furthermore, the angle of Gissane is used. It runs along the posterior side of the processus anterior calcanei and the anterior side of the subtalar joint (Figure 1B). Normally, this angle is between 120° and 145° (8).

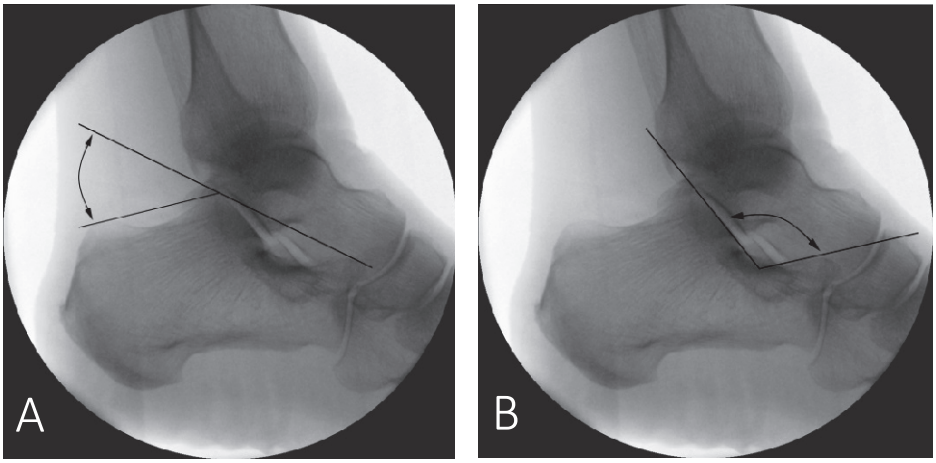


Figure 1. A. Böhler's angle, **B**. Angle of Gissane

Research has shown that the standard lateral and axial views often depict the main joint - the posterior facet - only partially (9). In clinical practice these views can be difficult to assess, especially due to positioning the patient's foot with discomfort, pain, soft tissue

swelling, and associated injuries. Also the expertise of the radiologic technologist also influences the diagnostic value of the lateral and axial radiographs. In the course of years several additional radiographs (according Brodèn, Isherwood, Anthonson and Harris Beath) were developed to fully identify the subtalar joint (2, 3). However, these radiographs are nowadays rarely used. If both therapeutic decisions and prognostic information rely on Böhler's and Gissane angle the radiographic measurements should be accurate (10-13). Inaccurate measurements could lead to inadequate treatment decisions and consequently to suboptimal outcomes and disability. Moreover, reliable radiographic measurements are required to be able to adequately compare research results. To what extent malposition of the foot influences these quantitative radiographic parameters is unknown.

The aims of this study were to evaluate the effect of craniocaudal and posteroanterior angular variation in 2D, lateral radiographs on both Böhler's and Gissane's angle.

METHODS

Fifteen AnubiFiX™ embalmed, human anatomic specimens of the leg (including at least 10 cm proximal from the knee) were used. All specimens were from persons with a known age of 18 years or older (mean 87 ± 9 years). Specimens were excluded if an osseous anomaly or deformity affecting anatomy of the hindfoot, was present. Specimens with visible scarring suggesting previous injury, with visible or known previous fractures in the hindfoot or midfoot or with prosthetic or fixation material in situ in the ankle, hindfoot, or midfoot were excluded as well. Radiographs of the foot were made in order to exclude any osseous pathology of pre-existing disease or trauma. Age, gender, side, and presence of evident pre-existent (traumatic) injuries in the foot and/or ankle region were noted as demographic characteristics.

The embalming method AnubiFiX™ combines long-term high-quality embalming of human bodies with almost normal flexibility and plasticity. The body can be kept operational as long as conventionally embalmed human specimens (14). All measurements were performed at the anatomical dissection room at Erasmus MC (Department of Anatomy and Neurosciences).

Lateral radiographs

The anatomic specimens were positioned on a radiolucent table resting on the lateral femur condyle, the lateral malleolus, and the lateral foot edge (metatarsal-phalangeal fifth articulation) and with the tibiotalar joint in plantigrade position. All radiographs were made using a C-arm (SIEMENS Arcadis Orbic 3D®, SIEMENS, Munich, Germany, Manufactured November 2013, Model No. 08079233, Serial No. 7140) in order to obtain radiographs. The C-arm was positioned exactly perpendicular to the axis of the

tibia. Radiographs were made in automatic mode using 56kV and 0.4mA as exposure values. A series of freehand, lateral 2D radiographs were made by an experienced radiologic technologist (LV). The mediolateral projection was centered on the middle of the calcaneus, three centimeters caudal and one centimeter posterior of the medial malleolus. The true lateral radiograph or neutral position (*i.e.,* 0° angular variation) had to meet the following criteria; 1) 90° dorsiflexion of the foot, 2) calcaneus depicted in its entirety, 3) lateral malleolus projected posteriorly of the medial malleolus, 4) an open projected subtalar joint, 5) no double contours in the posterior talocalcaneal facet, 6) base of the fifth metatarsal depicted in profile. The position of the leg and/or C-arm were adapted until a perfect lateral view was available.

With this image as a starting point, angular variations with 5° intervals were made from + 30° to - 30° deviation in a craniocaudal and posteroanterior direction; Figure 2. Cranial and caudal angular variation representing respectively valgus and varus malposition of the foot. Variation in the anterior direction represents internal rotation and posterior stands for external rotation. Angular variations towards a posterior or cranial direction were given a connotation '+', variations towards in the anterior and caudal direction were considered '-'.

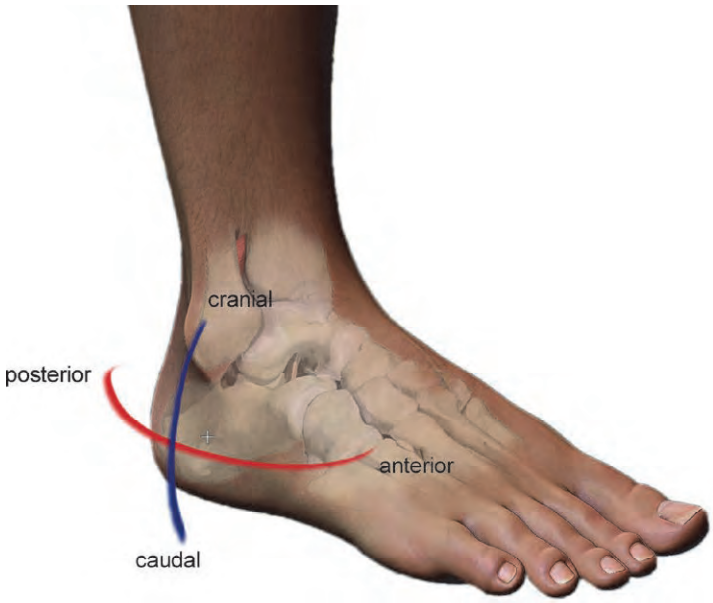


Figure 2.
Red line: posteroanterior angular variation in radiographic projections (Anterior and posterior angular variation representing respectively internal and external rotation of the foot).
Blue line: craniocaudal angular variation in radiographic projections (Cranial and caudal angular variation representing respectively valgus and varus malposition of the foot).

Böhler's angle and the angle of Gissane were measured in all radiographs independently by two trauma surgeons, experienced in the surgical and nonoperative treatment of calcaneal fractures, (DDH and MHJV) with an open-source Digital Imaging and Communications in Medicine (DICOM) compliant viewer (RadiAnt DICOM Viewer 1.9.14, Medixant, Poznan, Poland). Angles were averaged between the observers and the angular deviation from the neutral position (0°) was calculated for each radiograph, by dividing the observed measurement by the true lateral (neutral) radiograph. A negative deviation means a smaller observed angle pertaining to the true lateral, a positive deviation is a greater observed angle.

Analysis

Descriptive analysis was performed for each 5° angular variation radiograph. The mean Böhler's angle and angle of Gissane (as well as the calculated deviation) were determined with standard deviation (SD), since all data were normally distributed (tested with a Shapiro-Wilk test). Figures were composed in GraphPad Prism 5 Software Inc. (California, USA).

RESULTS

Twelve of the 15 specimens were of male origin. Eleven right feet and four left feet were used. In the appendix an example of some radiographs with angular variations in the posteroanterior and craniocaudal direction are shown (Supplemental Figure 1).

Böhler's angle deviated from the true lateral radiograph in both cranial and, most explicit, in the caudal direction (Figure 3A). At increasing angular variation in the caudal direction, Böhler's angle decreased by a maximum of 4.3° at -30° deviation. From -15° onwards, the 95% confidence interval did not include 0°. With 95% confidence intervals consistently spanning 0°, indicating no significant difference. Böhler's angle was only marginally affected by angular variation in the cranial direction (maximum 2.0°).

At + 30° angular variation in the posterior direction Böhler's angle increased from 0.3 degrees at +10° to a maximum 5° degrees increase (Figure 3B). However, in the anterior direction (towards -30°), the maximum deviation was only marginal, 1.3°, and the 95% confidence interval consistently contained 0°.

In the craniocaudal direction, the deviation of the angle of Gissane is most pronounced in the cranial direction (towards +30°), with the mean angle decreasing to -8.8° at +30° angular variation (Figure 3C). The angle of Gissane was hardly affected by deviation in the caudal direction (towards -30°); all 95% confidence intervals spanned 0°.

Varying angular obliquity in the posteroanterior direction (Figure 3D) did not evidently affect the angle of Gissane, with a maximum decrease in the angle of Gissane of 3.3° in the anterior direction and 2.9° in the posterior direction.

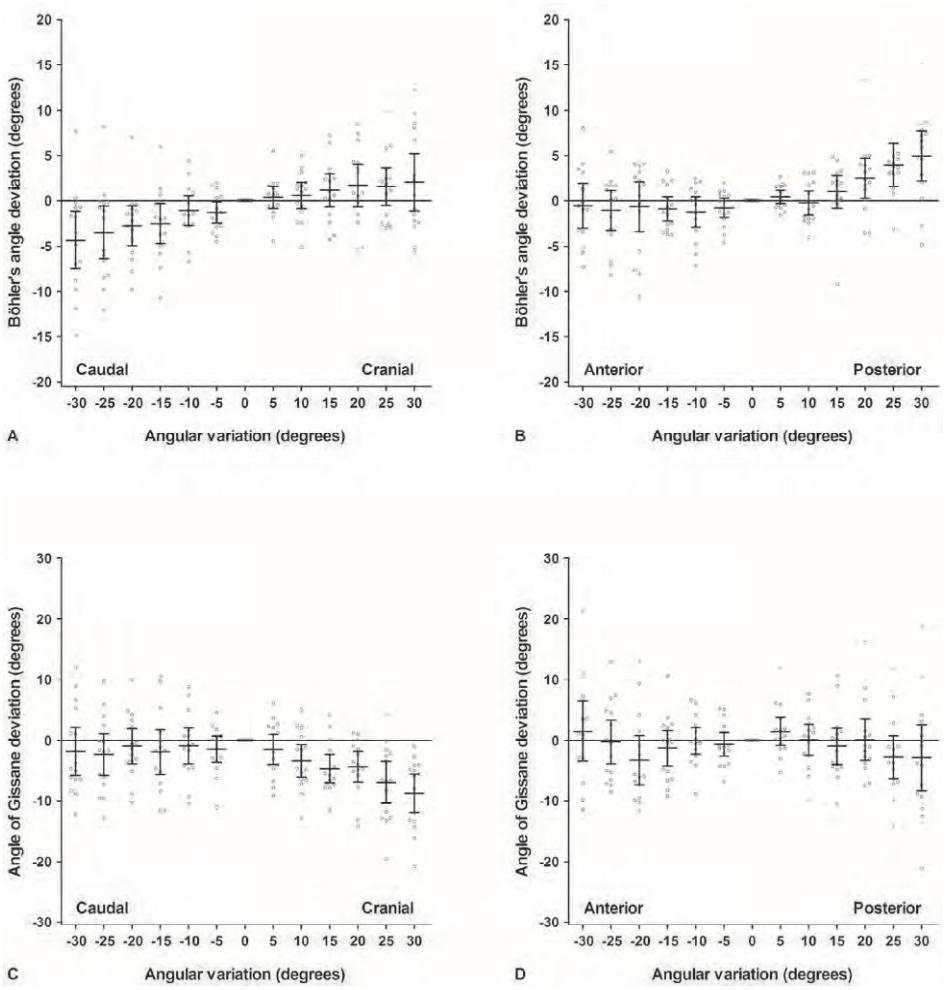


Figure 3. Scatter dot plot and box-whiskers plot with mean and 95% CI depicted. Averaged radiographic parameters with angular variation in the craniocaudal direction and posteroanterior direction. **A**, **B**: Böhler's angles. **C**, **D**: Angle of Gissane.

DISCUSSION

Radiographic parameters (*i.e.,* Böhler's angle and the angle of Gissane) are of both therapeutic as prognostic value in the pre- and postoperative assessment. Surgeons should be aware that the accuracy of radiographs, and hence radiographic measurements, can be influenced by multiple factors. The aim of this study was to evaluate the effect of craniocaudal and posteroanterior angular variations from lateral radiographs on Böhler's angle and the angle of Gissane. The data showed that Böhler's angle most explicitly decreased with increasing caudal angular variations and increased with increasing posterior angular variations. The angle of Gissane decreased most pronounced with increasing cranial angular variation.

To our knowledge, only one study described the influence of obliquity on accuracy (15). The observed Böhler's angle reported by Gonzalez *et al.* (2016) deviated with a maximum of 7° (in the anterior direction; at 10° and 15° angular variation) of the perfect lateral image. This study showed similar results concerning observed Böhler's angles; Böhler's angle deviated maximum 5° from the true lateral radiograph. Gonzalez *et al.* reported a measurement error for Böhler's angle of 6° (15).

Furthermore, in their study the orthopedic surgeons' ability to accurately measure Böhler's angle significantly decreased with increasing obliquity of the lateral radiograph (15). Both observers in this study also experienced more difficulty in finding anatomical landmarks, in particular for the angle of Gissane, with increasing angular variations (mostly from 20° deviation onwards), often due to double contours in the posterior talocalcaneal facet and over projection of different osseous structures (*e.g.,* sustentaculum tali). For example, visualization of the processus anterior calcanei is crucial to determine Böhler's angle, which could be difficult after increasing angular variation.

Despite the difference in angles after angular variations, all mean Böhler's angles were within Gonzalez's measurement error of 6° (95% CI: -4° to 15°) (15). To our knowledge, the measurement error of the angle of Gissane has not been established in the literature.

In contrast to Gonzalez *et al.* (15), we did not use metallic markers to mark the relevant anatomical structures. We tried to mimic the normal clinical situation as much as possible and such markers are not used in common clinical practice.

In daily practice at an emergency department, radiographs are produced with a conventional tube with a diverging radiation beam. This differs from a three dimensional C-arm based imaging device, as used in this study, which produces an exact parallel radiation beam. Although a parallel beam produces more reliable images, it is unlikely that this difference influences the deviation in Böhler's and Gissane angle with increasing angular obliquity from the true lateral radiograph.

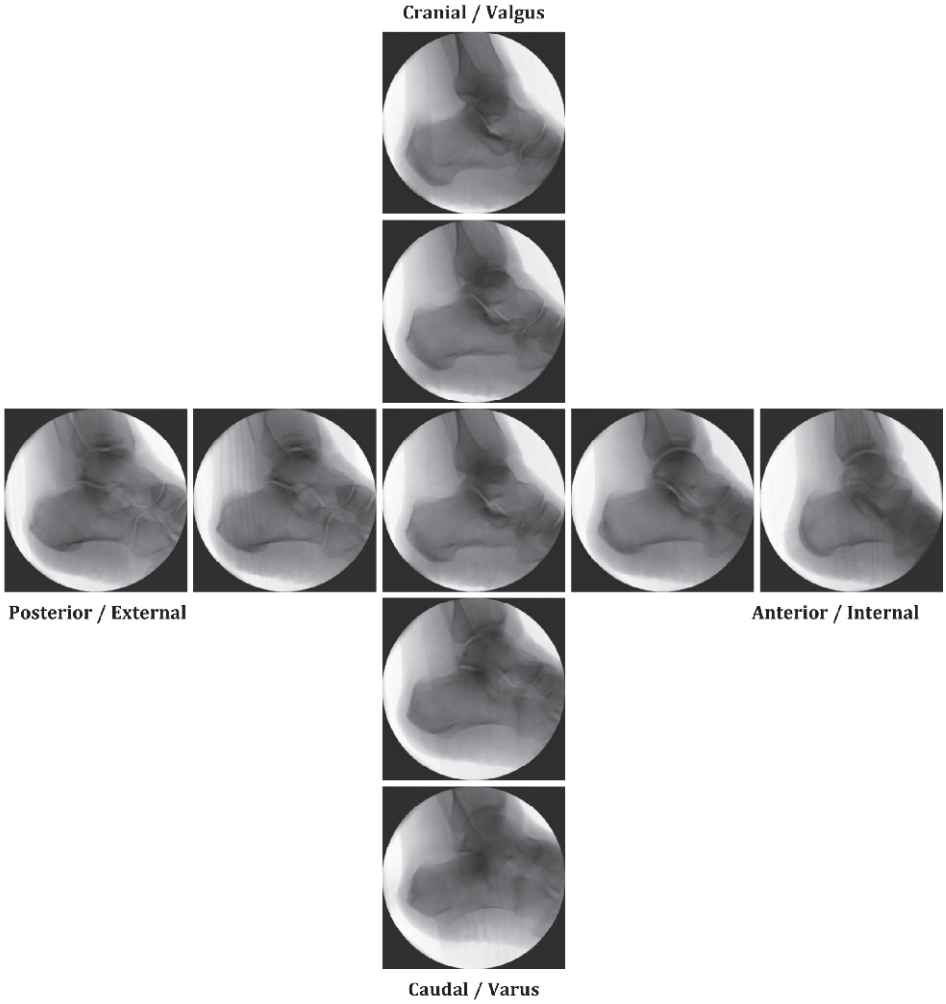
A methodological strength of the current study is the use of 15 anatomic specimen to rule out anatomic variation as much as possible, whereas Gonzalez *et al.* only used one anatomic specimen (15). A total of 1,680 radiographic measurements were ob-

tained in all specimens by the two observers, more than double the amount of measurements that Gonzalez *et al.* reported (15).

CONCLUSION

In this study, inaccurate radiographs are simulated using standardized angular variations up to 30° from the true lateral radiograph. Böhler's angle decreased with increasing caudal, and increased with increasing posterior angular variations. The angle of Gissane decreased with increasing cranial angular variation. But the error due to inaccuracy in clinical practice does not seem to be enough to influence reliable decision making.

APPENDIX



Supplemental Figure 1: Angular variations
Left to right: posterior (external) +30°, +15°, 0° and anterior (internal) -15°, -30°
Top to bottom: cranial (valgus) +30°, +15°, 0° and caudal (varus) -15°, -30°

REFERENCES

1. Rammelt S, Zwipp H. Calcaneus fractures: facts, controversies and recent developments. Injury. 2004;35(5):443-61.
2. Giachino AA, Uhthoff HK. Intra-articular fractures of the calcaneus. J Bone Joint Surg Am. 1989;71(5):784-7.
3. Schepers T, Ginai AZ, Mulder PG, Patka P. Radiographic evaluation of calcaneal fractures: to measure or not to measure. Skeletal Radiol. 2007;36(9):847-52.
4. Loucks C, Buckley R. Bohler's angle: correlation with outcome in displaced intra-articular calcaneal fractures. J Orthop Trauma. 1999;13(8):554-8.
5. Shuler FD, Conti SF, Gruen GS, Abidi NA. Wound-healing risk factors after open reduction and internal fixation of calcaneal fractures: does correction of Bohler's angle alter outcomes? Orthop Clin North Am. 2001;32(1):187-92, x.
6. Böhler L. Diagnosis, pathology and treatment of fractures of the os calcis. J Bone Joint Surg. 1931(13):75–89.
7. Knight JR, Gross EA, Bradley GH, Bay C, LoVecchio F. Boehler's angle and the critical angle of Gissane are of limited use in diagnosing calcaneus fractures in the ED. Am J Emerg Med. 2006;24(4):423-7.
8. Essex-Lopresti P. The mechanism, reduction technique, and results in fractures of the os calcis. Br J Surg. 1952;39(157):395-419.
9. Shereff MJ, Johnson KA. Radiographic anatomy of the hindfoot. Clin Orthop Relat Res. 1983(177):16-22.
10. Bakker B, Halm JA, Van Lieshout EM, Schepers T. The fate of Bohler's angle in conservatively-treated displaced intra-articular calcaneal fractures. Int Orthop. 2012;36(12):2495-9.
11. Barla J, Buckley R, McCormack R, Pate G, Leighton R, Petrie D, et al. Displaced intraarticular calcaneal fractures: long-term outcome in women. Foot Ankle Int. 2004;25(12):853-6.
12. Buckley RE. Evidence for the best treatment for displaced intra-articular calcaneal fractures. Acta Chir Orthop Traumatol Cech. 2010;77(3):179-85.
13. Su Y, Chen W, Zhang T, Wu X, Wu Z, Zhang Y. Bohler's angle's role in assessing the injury severity and functional outcome of internal fixation for displaced intra-articular calcaneal fractures: a retrospective study. BMC Surg. 2013;13:40.
14. Slieker JC, Theeuwes HP, van Rooijen GL, Lange JF, Kleinrensink GJ. Training in laparoscopic colorectal surgery: a new educational model using specially embalmed human anatomical specimen. Surg Endosc. 2012;26(8):2189-94.
15. Gonzalez TA, Ehrlichman LK, Macaulay AA, Gitajn IL, Toussaint RJ, Zurakowski D, et al. Determining Measurement Error for Bohler's Angle and the Effect of X-Ray Obliquity on Accuracy. Foot Ankle Spec. 2016;9(5):409-16.

Chapter 4

2D and 3D assessment of sustentaculum tali screw fixation with or without Screw Targeting Clamp

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ABSTRACT

Introduction: Precise placement of sustentaculum tali screw(s) is essential for restoring anatomy and biomechanical stability of the calcaneus. This can be challenging due to the small target area and the presence of neurovascular structures on the medial side of the calcaneus. A Screw Targeting Clamp recently became available to facilitate surgeons in screw positioning. The aim of this study was to evaluate the precision of positioning of the subchondral posterior facet screw and processus anterior calcanei screw with or without a Screw Targeting Clamp. The secondary aim was to evaluate the added value of peroperative 3D imaging over 2D radiographs alone.

Methods: Twenty Anubifix™ embalmed, skeletally mature, human anatomic lower limb specimens were used. A subchondral posterior facet screw and a processus anterior calcanei screw were placed using an extended lateral approach. A senior orthopedic trauma surgeon experienced in calcaneal fracture surgery and a senior resident with limited experience in calcaneal surgery performed screw fixation in five specimens with and in five specimens without the clamp. 2D lateral and axial radiographs and a 3D recording were obtained postoperatively. Anatomical dissection was performed postoperatively as a diagnostic golden standard in order to obtain the factual screw positions. Blinded assessment of quality of fixation was performed by two surgeons.

Results: In 2D, eight screws were considered malpositioned when placed with the targeting device versus nine placed freehand. In 3D recordings, two additional screws were malpositioned in each group as compared to the golden standard. As opposed to the senior surgeon, the senior resident seemed to get the best results using the Screw Targeting Clamp (number of malpositioned screws using freehand was eight, and using the targeting clamp five). In nine out of 20 specimens 3D images provided additional information concerning target area and intra-articular placement. Based on the 3D assessment, five additional screws would have required repositioning. Except for one, all screw positions were rated equally after dissection when compared with 3D examinations.

Conclusion: This study does not show a substantial benefit between the Screw Targeting Clamp and the freehand technique as well between experienced and inexperienced surgeons. Data suggest that the clamp might help positioning sustentaculum tali screws, especially for inexperienced surgeons. Perioperative 3D recordings facilitate identification of malpositioned screws.

INTRODUCTION

The results of Open Reduction and Internal Fixation (ORIF) of displaced intra-articular calcaneal fractures are controversial, presumably because surgery is difficult and prone for suboptimal positioning of screws. Nevertheless, ORIF is assumed to provide better long-term results than non-operative treatment (1, 2). To what extent the surgeon is able to restore the anatomic contour of the subtalar joint, especially of the posterior facet, is critical to the success of the treatment (1). The displaced posterior facet fragments are reduced and fixated to the sustentaculum tali (ST). The screws in the sustentaculum tali are meant to ensure sufficient reinforcement to support the talus.

Furthermore they serve to apply sufficient compression of the posterior facet in order to create joint congruency with absolute stability. For this fixation, a posterior facet (PF) screw typically is placed in the most cranial part of the posterior facet and runs subchondral, ideally into the medial end of the sustentaculum tali. Additionally, a processus anterior (PA) screw can be drilled from the processus anterior calcanei into the sustentaculum tali. The necessity of sustentaculum tali screw fixation has recently been examined. Treatment of Sanders type II or III calcaneal fractures with a calcaneal locking plate and fixation of the sustentaculum tali resulted in high biomechanical stability (3, 4), less postoperative pain, rapid functional recovery (5). After axial loading, the stress distribution on the sustentaculum tali was more dispersed and the fracture line displacement was smaller with additional sustentaculum screw fixation (4).

Because the target area in the sustentaculum tali is small, precise placement of ST screws can be challenging. Penetration of the subtalar joint as well as the flexor tendons or neurovascular bundle should be avoided. Besides the complex anatomic configuration, the fixation procedure is demanding due to the limited visualization with intraoperative two-dimensional (2D) fluoroscopy. Therefore, malpositioned and intra-articular screws frequently remain undiscovered during surgery, and are only recognized on postoperative Computed Tomography (CT) scans (6, 7). Literature reports a 24% rate of intra-articular screw placement on CT (6). These screws may cause severe subtalar joint osteoarthritis and poor clinical outcome (1). Three-dimensional (3D) imaging can detect up to 30% malpositioned implants and therewith lead to repositioning (1). This suggests that surgical re-interventions could be avoided when using intraoperative 3D imaging.

A Screw Targeting Clamp (DePuy Synthes Trauma, Johnson & Johnson; Figure 1) has been developed in order to decrease the risk of screw malpositioning. There are no data yet to confirm whether this clamp facilitates screw placement and decreases the rate of malpositioned screws.

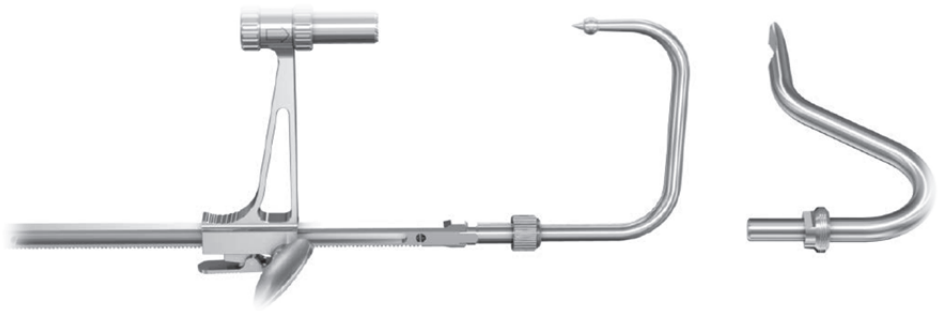

Figure 1. Sustentaculum tali Screw Targeting Clamp
Attached to the clamp the ball-spike arm, on the right the (disconnected) Hohmann arm.
Image from DePuy Synthes Trauma, Screw Targeting Clamp, Reference Guide.

The aim of this study was to evaluate the precision of positioning of the subchondral posterior facet screw and processus anterior calcanei screw in the sustentaculum tali, with or without a Screw Targeting Clamp. The secondary aims were to compare the rate of screw malposition using both methods when used by a senior trauma surgeon versus a senior resident, and to evaluate the added value of peroperative 3D imaging over 2D radiographs alone.

METHODS

This radio-anatomical study used 20 (10 bilateral) Anubifix™ embalmed, human anatomic specimens of the lower leg (ex-articulated in the knee). Specimens were skeletally mature or had a known adult age. None had a visual or known deformity, malalignment, or scarring of the foot or ankle region. Radiographs of the foot were made in order to exclude any osseous pathology of pre-existing disease or trauma. The mean age was 85 years (SD 7), six specimens (60%) were male.

Osteosynthesis

The anatomic specimens were not fractured, to simulate an anatomical reduction of the posterior talocalcaneal facet in standard surgical treatment. In all specimens a subchondral posterior facet (PF) screw and a processus anterior (PA) screw were placed with the intention to penetrate the medial end of the sustentaculum tali.

One senior orthopedic trauma surgeon (MHJV) experienced in calcaneal fracture surgery and a senior resident (SPK) with limited experience in calcaneal surgery performed osteosynthesis via an extended lateral approach without additional aids, such as fluoroscopy. Each surgeon placed a subchondral posterior facet and a processus anterior screw in each of 10 (five pairs) anatomic specimens. The freehand and targeting clamp procedures were performed in an alternating order for bilateral feet per specimen.

In both groups a non-oscillating 2.5 mm drill without fluoroscopy in a single shot attempt (*i.e.,* no repositioning) was used in order to create a drill hole. In the freehand group, the drill was directed while the surgeon palpated the sustentaculum tali with a fingertip. After positioning of a subchondral lag screw a similar procedure was performed for the processus anterior screw. In the Screw Targeting Clamp group, the ball-spike arm attached to the Screw Targeting Clamp (Figure 1) was manually applied on the medial side of foot at the bony prominence of the sustentaculum tali by finger palpation as well (Figure 2A). After applying the clamp to an appropriate part of the lateral calcaneal wall, a hole inferior to the subchondral posterior talocalcaneal facet (PTC) was drilled (Figures 2B and C). This way, the Screw Targeting Clamp determined the course of the subchondral screw towards the sustentaculum tali. This procedure was repeated for the processus anterior screw (Figure 2D). In all cases stainless steel, non-cannulated cortical 3.5 mm self-tapping screws (DePuy Synthes GmbH, Oberdorf, Switzerland) were introduced until the screw head touched the lateral cortical wall of the calcaneus. The lengths of available screws varied, when the exact screw length was not available, the most appropriate (longer) available screw was chosen. Since none of these too long screws had potential clinical impact on soft tissue, all screws were rated as 'moderate' or 'good'.

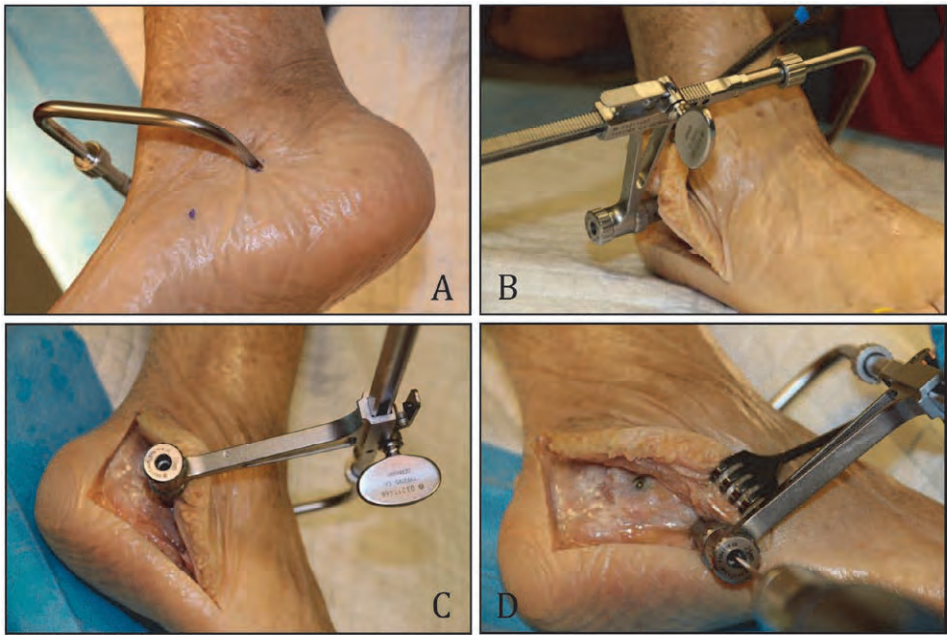

Figure 2. Screw Targeting Clamp position
A. Medial side of the foot with the ball-spike placed on the sustentaculum tali, **B**. After extended lateral approach, **C**. Before drilling for the posterior facet screw, **D**. Drilling for the processus anterior screw (subchondral posterior facet screw already placed).

2D and 3D evaluation

A C-arm based three dimensional imaging device (SIEMENS Arcadis Orbic 3D®, SIEMENS, Munich, Germany, Manufactured November 2013, Model No. 08079233, Serial No. 7140) was used in order to produce radiographs and 3D reconstructions as used during surgery in daily clinical practice. Radiographs were made in automatic mode using 56kV and 0.4mA as exposure values. All measurements were performed at the anatomical dissection room at the Erasmus MC (Department of Anatomy and Neurosciences).

After osteosynthesis, the definitive screw position was evaluated from 2D radiographs (lateral radiograph, axial radiograph and when indicated fluoroscopy) and from a 3D recording. For axial radiographs, the anatomic specimens were positioned on a radiolucent carbon table with the toes pointing upwards and the ankle in neutral position (foot - lower leg angle is 90°). The projections were centered 45° caudal-cranial, with the calcaneus as center point. For the lateral radiograph, the anatomic specimens were positioned, resting on the lateral femur condyle (if present), the lateral malleolus and the lateral foot edge (metatarsal-phalangeal fifth articulation). The lateral projection was centered on the middle of the calcaneus, three centimeters caudal and one centimeter posterior of the medial malleolus. The radiograph that showed the calcaneus in its entirety with an open projected subtalar joint was considered a true lateral projection.

Evaluation of screw positioning

Screw positioning was assessed first on 2D radiographs followed by the 3D recordings by a consultant surgeon (MHJV) and a senior resident (SPK). Postoperatively, all calcanei were dissected and the factual screw positions were obtained. Correct placement of screws depends mainly on three factors, 1) entry point; the position at which a screw is introduced on the lateral wall, 2) trajectory; the course of the screw between the entry point and the target area, and 3) target area; the area around the sustentaculum tali in which the screw ideally ends. In this study the entry point and target area were rated. The screw positioning was assessed following predefined quality criteria as shown in Table 1. A screw was considered malpositioned if ‘Good’ or ‘Moderate’ quality criteria (entry point or target area) were not met, and thus replacement of these ‘Poor’ screws would be necessary. Entry point and target area criteria are shown in Figures 3, 4, and 5. Discrepancies were resolved by consensus.

Table 1: Quality criteria for subchondral posterior facet (PF) and processus anterior (PA) screw positioning

	Entry-point	Target area
Good (green)	PF: Subchondral, cranial part PA: Inferior half of calcaneus height	In the center of sustentaculum tali (ST)
Moderate (orange)	PF: Superior middle part PA: Inferior half of cranial part / just dorsal of lowest point PTC	At the dorsal border of sustentaculum tali
Poor (red)	PF: Inferior middle and caudal part PA: Superior half of cranial part	Anterior outside ST, fully intra-articular (penetrating osseous structure other than the calcaneus)
	PF: Too close or within PTC PA: -	Borderline anterior of ST, partially intra-articular (not penetrating other osseous structures)
	PF: Too dorsal PA: Too dorsal	Dorsal outside sustentaculum tali (potential neurovascular and tendon damage)
	PF: Too anterior PA: Too anterior, intra-articular	Too short (not sufficiently supporting the ST)
		Extra-osseous (more than 2 mm too long and with potential clinical impact on soft tissue)

Screw placement was rated as good (correct), moderate (correct), or poor (malpositioned). Poorly rated screws can be defined as a not acceptable position and/or reposition would be required. Moderate rated screws are screws that are not placed perfect but acceptable, reposition is not required. Quality criteria for entry-point differ between the subchondral posterior facet (PF) screw and processus anterior (PA) screw. Target area criteria are similar for both screws.

The colors described match with the colors depicted in Figure 3 to 5. The height of the calcaneus (measured from the most inferior to the most superior point of the calcaneus) is divided in three parts: the cranial, middle, and caudal 1/3rd part.

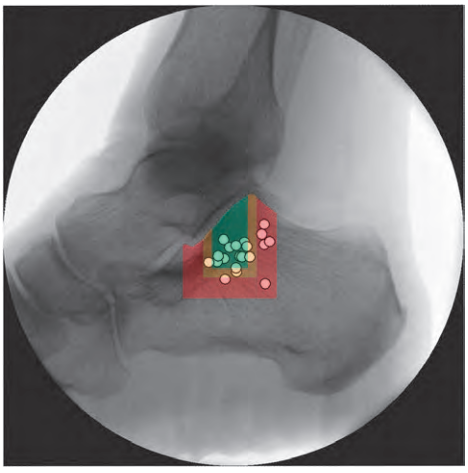

Figure 3. Entry-point quality area's for all subchondral posterior facet screw positions.
A white dot represents an entry-point of one screw. Area's in colors are related to the criteria in Table 1. Green = Good; Orange = Moderate, Red = Poor.

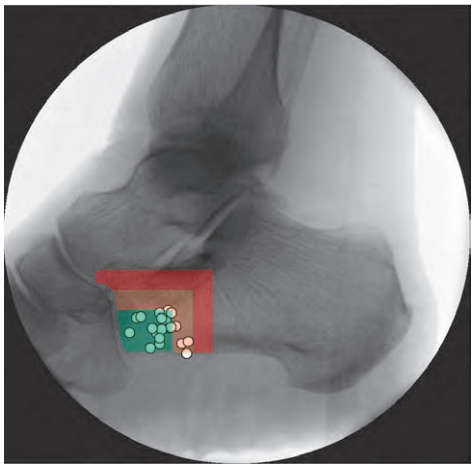

Figure 4. Entry-point quality area's for all processus anterior screw positions.
A white dot represents an entry-point of one screw. Area's in colors are related to the criteria in Table 1. Green = Good; Orange = Moderate, Red = Poor.

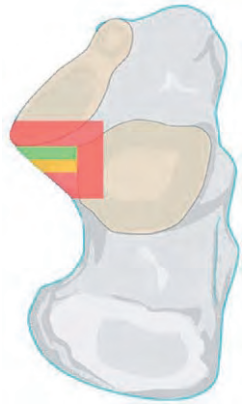

Figure 5. Sustentaculum tali quality area's (target area) in colors for all screw positions.
Schematic axial view of the calcaneus. Areas are related to the criteria in Table 1.
Green = Good; Orange = Moderate, Red = Poor.

Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.0 (SPSS, Chicago, Ill., USA). The crude number of malpositioned screws in both groups (freehand and using a Screw Targeting Clamp) were reported and compared using a Chi-squared analysis or Fisher's Exact test, as applicable. Concerning the diagnostic accuracy of 2D and 3D images, 2x2 tables were made for correct versus malpositioned screws as judged on 2D versus 3D imaging. Data were compared using a McNemar test.

RESULTS

Crude data per specimen are shown in Supplemental Table 1. Table 2 provides a summary of the screw positioning of the freehand method versus the Screw Targeting Clamp method. With the freehand method, positioning of four PF screws and five PA screws was considered malpositioned when judged on 2D. In two PF screws the target area was incorrect and in two PF screws both the entry-point as the target area were incorrect. In 3D, one additional PF (No. 3, target area) and one additional PA screw (No. 9, target area) were considered malpositioned. Although not statistically different from freehand, in the Screw Targeting Clamp group more PF screws (N=6 on 2D and N=7 on 3D) but fewer PA screws (N=2 on 2D and N=3 on 3D) were judged as malpositioned. See Table 2 and Supplemental Table 1 for more detailed information on which of the quality criteria were not met.

Table 2: Screw positioning, when placed freehand or with a Screw Targeting Clamp

	Freehand (N=20)	Screw Targeting Clamp (N=20)	p-value
2D			
PF malpositioned	4	6	0.656
PA malpositioned	5	2	0.350
3D			
PF malpositioned	5	7	0.650
PA malpositioned	6	3	0.370

Data are shown as number of screws. Fisher's Exact test was used for statistical testing.
PF, subchondral posterior facet screw; PA, processus anterior screw. Data are shown as number of screws.

The screw positioning, depending on the level of experience of the physician, is shown in Table 3. Overall, the surgeon malpositioned seven (judged on 2D) and eight (judged on 3D) out of twenty screws. The resident seemed to perform worse; he malpositioned ten (2D) and thirteen (3D) out of twenty screws.

The senior surgeon malpositioned more PF screws with the targeting clamp (N=3 in both 2D and 3D) than with the freehand method (N=1 in both 2D and 3D; $p > 0.05$). Also, the total number of malpositioned screws was higher when the senior surgeon used the targeting clamp, than freehanded.

The resident, on the other hand, seemed to benefit from the targeting clamp; he malpositioned fewer PA screws with the targeting clamp (N=1 in both 2D and 3D) than with the freehand method (N=3 in 2D and N=4 in 3D; $p > 0.05$). There was an overall improvement, most pronounced for the PA screws.

Results for the secondary aim, the added value of 3D over 2D, is shown in Table 4. In four out of twenty specimens, 3D provided additional information. In two specimens, malpositioning (inadequate target area) of a PF screw was missed in the 2D evaluation (No 3 and 13; See Supplemental Table 1), in the other two specimens, the PA screw malpositioning (inadequate target area) was missed (No. 9 and 12).

Table 3: Screw positioning, depending on the level of experience of the physician

	Senior surgeon	Senior resident	p-value
2D	**(N=20)**	**(N=20)**	
PF malpositioned	4	6	0.656
PA malpositioned	3	4	1.000
3D			
PF malpositioned	4	8	0.170
PA malpositioned	4	5	1.000
2D - freehand	**(N=10)**	**(N=10)**	
PF malpositioned	1	3	0.524
PA malpositioned	2	3	1.000
3D - freehand			
PF malpositioned	1	4	0.206
PA malpositioned	2	4	0.524
2D – Screw Targeting Clamp	**(N=10)**	**(N=10)**	
PF malpositioned	3	3	1.000
PA malpositioned	1	1	1.000
3D – Screw Targeting Clamp			
PF malpositioned	3	4	1.000
PA malpositioned	2	1	1.000

Data are shown as number of screws. Fisher's Exact test was used for statistical testing.
PF, subchondral posterior facet screw; PA, processus anterior screw. Data are shown as number of screws.

Table 4: 2D versus 3D malpositioning of the subchondral posterior facet (PF) and processus anterior (PA) screw

PF malpositioned		3D		p-value
		Yes	No	
2D	Yes	10	0	0.500
	No	2	8	

PA malpositioned		3D		p-value
		Yes	No	
2D	Yes	7	0	0.500
	No	2	11	

Data are shown as number of screws. McNemar test was used for statistical testing.
PF, subchondral posterior facet screw; PA, processus anterior screw.
Identical 2D and 3D ratings are shaded in grey, discrepancies are outlined in black.

In nine out of twenty specimens, 3D recording provided new information and caused a different rating concerning the target area, but no new information on the entry point (Supplemental Table 1 and Table 5). 3D recordings provided new information on PF screw positioning concerning target area in four specimens. Out of five PF screw target areas that were rated 'moderate' in 2D, one was rated 'poor' in 3D (No. 5). Out of eight PF screw target areas that were judged 'good' in 2D, one was judged 'moderate' in 3D (specimen No. 17), and two other even as 'poor'. Partial intra-articular placement was diagnosed in 3D but not (specimens No. 3; Figure 6) or uncertain (No. 13) in 2D.

Table 5: 2D versus 3D evaluation of the entry point and target area of the subchondral posterior facet (PF) and processus anterior (PA) screw

Entry Point		3D		
PF		Poor	Moderate	Good
2D	Poor	6	0	0
	Moderate	0	3	0
	Good	0	0	11

Entry Point		3D		
PA		Poor	Moderate	Good
2D	Poor	0	0	0
	Moderate	0	6	0
	Good	0	0	14

Target Area		3D		
PF		Poor	Moderate	Good
2D	Poor	7	0	0
	Moderate	1	4	0
	Good	2	1	5

Entry Point		3D		
PA		Poor	Moderate	Good
2D	Poor	7	0	0
	Moderate	0	2	1
	Good	2	0	8

Data are shown as number of screws.
PF, subchondral posterior facet screw; PA, processus anterior screw.
Identical 2D and 3D ratings are shaded in grey, discrepancies are outlined in black.

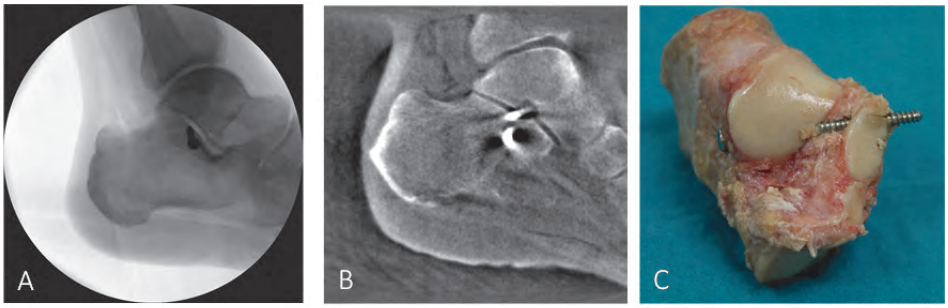

Figure 6. Missed partial intra-articular screw with 2D evaluation
Specimen No. 3. **A**. The subchondral posterior facet (PF) screw was rated as 'correct' on the 2D lateral radiograph, **B**. The PF screw (white arrow) was rated as 'partial intra-articular' with 3D evaluation, and thus malpositioned. The other white dot is the processus anterior (PA) screw, **C**. After dissection the ST screw is confirmed to be placed partial intra-articular.

Out of ten PA screw target areas that were judged 'good' in 2D, two were judged 'poor' in 3D due to full intra-articular placement (specimens No. 9 and 12). Out of three PA screw target areas that were rated 'moderate' in 2D, one was rated 'good' in 3D (No. 7).

In addition, two PA screws with a target area rated as 'poor', intra-articular placement was scored 'partial' in 2D but 'full' in 3D (specimens No. 6 and 11, Supplemental Table 1). A final specimen where 3D imaging provided new information is No. 5; the doubtful intra-articular placement seen in 2D was proven otherwise in 3D.

Dissection of the calcanei confirmed the 3D ratings of screw positions. Only in one specimen (No. 8) the PF screw was judged as 'moderate' after dissection instead of 'good' with 2D and 3D assessment (Supplemental Table 1).

DISCUSSION

This study aimed to determine the screw malpositioning using a freehand method versus a Screw Targeting Clamp, placed by both a senior trauma surgeon and a senior resident without additional aids, such as fluoroscopy. The senior resident, inexperienced concerning calcaneal surgery seemed to benefit of the Screw Targeting Clamp. With the use of the targeting device similar results between both physicians were found, this in contrast with the freehand method where the senior surgeon performed better.

Secondly, the sensitivity of diagnosing screw malposition using conventional 2D radiographs and 3D recordings was determined. For this part a C-arm based (3D) imaging device was used as in clinical perioperative practice. Entry point ratings on 2D and 3D images were similar. However, when more detail was required to rate target area screw positioning, 3D recordings helped modify ratings for seven out of twenty screws. For daily clinical practice it is important to know whether 3D recordings would lead to a policy change, *i.e.* on 2D 'correctly' assessed screws that were diagnosed as 'malpositioned' with 3D evaluation. Yet two additional malpositioned PA screws and three PF screws were identified with 3D imaging. Thus, in five of the twenty specimens (25%) at least one of the screws required repositioning. This is in line with the 30% implant repositioning described by Geerling *et al.* (1). They concluded that intra-operative 3D visualization provides important information in the operative treatment of calcaneal fractures which cannot always be obtained from plain radiographs or standard fluoroscopy alone (1). More recent studies have shown that 3D evaluation is useful and identifies intra-articular incongruence and screw misplacement that are not detected by fluoroscopy in 20% of the cases (8-10). Due to the options for better joint surface reconstruction, clinical outcomes may be improved.

The current data suggests that if a screw is assessed as malpositioned with 2D evaluation, no further 3D radiological examinations are required. 3D would only confirm the malposition and reposition would be needed anyway. The opposite (screws that are placed correctly in 2D) is not the case. Also when there is doubt about screw positioning with 2D evaluation, an additional 3D recording is advisable for determining the screw positioning.

In this study stainless steel screws were used in order to investigate a worst case scenario. They produce more scattering in 3D imaging than titanium or vanadium alloys. Whereas these alloys were very popular, at least in Europe, their use is decreasing. Since these alloys are more expensive than stainless steel and similar infection rates have been described recently, more physicians started to use stainless steel screws again (11). However, it remains evident that stainless steel produces more scattering on 3D imaging, which is especially problematic for screws near the subchondral surfaces (12). This means that reliability of 3D evaluation would benefit from the use of titanium or vanadium alloys.

The Screw Targeting Clamp has been designed to improve screw positioning. However, neither the experienced nor the inexperienced surgeon performed flawless with the clamp. Two issues were encountered with the current device. In one specimen (specimen No. 7), the drill hole for the PA screw missed the ball-spike which was placed on the sustentaculum tali because of a minimal mobility between carriage and rail of the Screw Targeting Clamp (Figure 7). This problem can be prevented by making a minimal incision on the medial side of foot, at the point where the sustentaculum tali can be palpated. Subsequently, a Kirschner-wire has to be drilled superficially in the top of the sustentaculum tali. The Screw Targeting Clamp with a Hohmann arm (Figure 1) attached to the clamp can be manually applied over this Kirschner-wire, in this manner the Hohmann arm will not dislocate during the procedure.

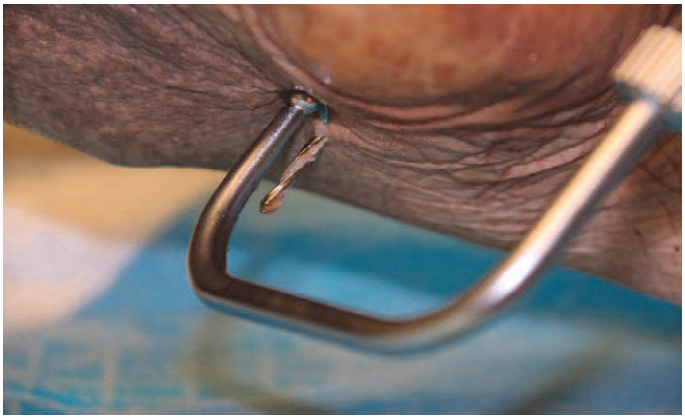

Figure 7. The drill hole for the processus anterior screw missed the ball-spike

It is currently not possible to measure the depth of the drill hole while using the Screw Targeting Clamp. Hereby, one has to remove the targeting device to measure the desired screw length. The above mentioned modifications would improve the use of the targeting clamp and potentially result in better restoration and functional recovery of patients.

The authors acknowledge limitations of this study. Since the study sample was very small, no definite conclusion can be made. Partly because of the low number of specimens used, no statistically significant differences could be found between physicians, method of screw placement, and examination of 2D and 3D images. A power analysis a priori was not possible. Therefore, a post hoc analysis was performed. A much larger number of anatomic specimens should be required to prove a statistical significant difference. For medical ethical reasons we used a limited number of 20 specimens. Findings of this study should be interpreted with care, but they at least provide information for future developments.

CONCLUSION

The results of this study do not show a substantial benefit between the Screw Targeting Clamp and the freehand technique as well between experienced and inexperienced surgeons. Data suggest that the Screw Targeting Clamp might be of additional value to place subchondral posterior facet and processus anterior screws, in particular for surgeons with limited experience in calcaneal surgery. Furthermore, 3D evaluation of screw positioning provides extra information when uncertainty exists about positioning of the screws with 2D evaluation. In particular to determine screw positioning in the target area, 3D imaging is of additional value. Larger clinical studies are needed to demonstrate the exact value of the Screw Targeting Clamp and the added value of a C-arm based 3D imaging device to judge screw positioning during surgery.

Supplemental Table 1: Individual data for screw positioning, separated by level of experience of physician and evaluated on 2D radiographs and 3D recordings

Sample	Insertion		PF screw								PA screw							
	Method		Entry point		Target area			Intra-articular			Entry point			Target area			Intra-articular	
			2D	3D	2D	3D	Vue	2D	3D	Vue	2D	3D	Vue	2D	3D	Vue	2D	3D	Vue
Senior surgeon																			
1	Freehand		(+/-)	(+/-)	(-)	(-)	-	(full)	(full)	full	(+)	(+)	(-)	(-)	-				
8	Freehand		+/-	+/-	+	+	+/-				+	+	+/-	+/-	+/-				
11	Freehand		+	+	+	+	+				(+)	(+)	(-)	(-)	-		(part)	(full)	full
16	Freehand		+	+	+	+	+				+	+	+	+	+				
19	Freehand		+/-	+/-	+	+	+				+/-	+/-	+/-	+/-	+/-				
2	Clamp		+	+	+/-	+/-	+/-				+/-	+/-	+	+	+				
7	Clamp		(-)	(-)	(+/-)	(+/-)	+/-				+	+	+/-	+	+				
12	Clamp		+	+	+/-	+/-	+/-				+	(+)	+	(-)	-			(full)	full
15	Clamp		(+)	(+)	(-)	(-)	-				(+)	(+)	(-)	(-)	-		(full)	(full)	full
20	Clamp		(+)	(+)	(-)	(-)	-				+/-	+/-		+	+				
Correct	Good		4	4	4	4					4	3	4	4					
	Moderate		2	2	2	2					3	3	3	2					
	Poor		0	0	0	0					0	0	0	0					
Mal-	Good		2	2	0	0					3	4	0	0					
position	Moderate		1	1	1	1					0	0	0	0					
	Poor		1	1	3	3		1 full	1 full		0	0	3	4			1 part, 1 full	3 full	
Senior resident																			
3	Freehand		+	(+)	+	(-)	-		(part)	part	(+)	(+)	(-)	(-)	-				
6	Freehand		(-)	(-)	(-)	(-)	-	(part)	(part)	part	(+)	(+)	(-)	(-)	-		(part)	(full)	full
9	Freehand		(-)	(-)	(-)	(-)	-				+	(+)	+	(-)	-			(full)	full
14	Freehand		(+)	(+)	(-)	(-)	-				(+/-)	(+/-)	(-)	(-)	-				
17	Freehand		+	+	+	+/-	+/-				+	+	+	+	+				
4	Clamp		(-)	(-)	(+/-)	(+/-)	+/-				+	+	+	+	+				
5	Clamp		(-)	(-)	(+/-)	(-)	-				+	+	+	+	+		doubt	not	not
10	Clamp		(-)	(-)	(-)	(-)	-				(+/-)	(+/-)	(-)	(-)	-				
13	Clamp		+	(+)	+	(-)	-	doubt	(part)	part	+	+	+	+	+				
18	Clamp		+	+	+	+	+				+/-	+/-	+	+	+				
Correct	Good		4	2	4	1		1 doubt			5	4	6	5			1 doubt		
	Moderate		0	0	0	1					1	1	0	0					
	Poor		0	0	0	0					0	0	0	0					
Mal-	Good		1	3	0	0					2	3	0	0					
position	Moderate		0	0	2	1					2	2	0	0					
	Poor		5	5	4	7		1 part	3 part		0	0	4	5			1 part	2 full	

+ = Good; +/- = Moderate; - = Poor, PF = subchondral posterior facet screw; PA = processus anterior screw; full = fully intra-articular; part = partially intra-articular; doubt = doubtful if intra-articular or not, 2D = Two dimensional, 3D = Three dimensional, Vue = After dissection. Data for screws that are rated as malpositioned (*i.e.,* entry point or target area with poor position) are shown in parenthesis. Screws for which data are not in parenthesis were rated as correctly positioned. The numbers are a summary of correct and malpostioned rated screws. Grey shading indicates that 3D evaluation provided extra information relative to 2D ratings. In specimen No. 8 (black borders) new information was found after the dissection, 'a vue' the ST screw was assessed as 'moderate' instead of 'good' with 2D and 3D evaluation.

REFERENCES

1. Geerling J, Kendoff D, Citak M, Zech S, Gardner MJ, Hufner T, et al. Intraoperative 3D imaging in calcaneal fracture care-clinical implications and decision making. J Trauma. 2009;66(3):768-73.
2. De Boer AS, Van Lieshout EMM, Den Hartog D, Weerts B, Verhofstad MHJ, Schepers T. Functional outcome and patient satisfaction after displaced intra-articular calcaneal fractures: a comparison among open, percutaneous, and nonoperative treatment. J Foot Ankle Surg. 2015;54(3):298-305.
3. Lin PP, Roe S, Kay M, Abrams CF, Jones A. Placement of screws in the sustentaculum tali. A calcaneal fracture model. Clin Orthop Relat Res. 1998(352):194-201.
4. Pang QJ, Yu X, Guo ZH. The sustentaculum tali screw fixation for the treatment of Sanders type II calcaneal fracture: A finite element analysis. Pak J Med Sci. 2014;30(5):1099-103.
5. Gu ZQ, Pang QJ, Yu X, Chen L, Guo ZH. [Sustentaculum tali screw fixation for the treatment of Sanders type II and III calcaneal fractures]. Zhongguo Gu Shang. 2015;28(1):31-5.
6. Phisitkul P, Sullivan JP, Goetz JE, Marsh JL. Maximizing safety in screw placement for posterior facet fixation in calcaneus fractures: a cadaveric radio-anatomical study. Foot Ankle Int. 2013;34(9):1279-85.
7. Euler E, Wirth S, Linsenmaier U, Mutschler W, Pfeifer KJ, Hebecker A. [Comparative study of the quality of C-arm based 3D imaging of the talus] Vergleichende Untersuchung zur Qualitat der C-Bogenbasierten 3D-Bildgebung am Talus. Unfallchirurg. 2001;104(9):839-46.
8. Franke J, Wendl K, Suda AJ, Giese T, Grutzner PA, von Recum J. Intraoperative three-dimensional imaging in the treatment of calcaneal fractures. J Bone Joint Surg Am. 2014;96(9):e72.
9. Gwak HC, Kim JG, Kim JH, Roh SM. Intraoperative Three-Dimensional Imaging in Calcaneal Fracture Treatment. Clin Orthop Surg. 2015;7(4):483-9.
10. Qiang M, Chen Y, Zhang K, Li H, Dai H. Effect of sustentaculum screw placement on outcomes of intra-articular calcaneal fracture osteosynthesis: A prospective cohort study using 3D CT. Int J Surg. 2015;19:72-7.
11. Mohamed A, Rajeev AS. Clinical outcomes and complications of titanium versus stainless steel elastic nail in management of paediatric femoral fractures-a systematic review. Eur J Orthop Surg Traumatol. 2017;27(2):157-67.
12. Radzi S, Cowin G, Robinson M, Pratap J, Volp A, Schuetz MA, et al. Metal artifacts from titanium and steel screws in CT, 1.5T and 3T MR images of the tibial Pilon: a quantitative assessment in 3D. Quant Imaging Med Surg. 2014;4(3):163-72.

Chapter 5

Functional outcome and patient satisfaction after displaced intra-articular calcaneal fractures: a comparison among open, percutaneous, and nonoperative treatment

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ABSTRACT

Introduction: The aim of the present study was to compare the outcomes of patients with a displaced calcaneal fracture treated by open reduction and internal fixation (ORIF), percutaneous treatment, or nonoperative methods.

Methods: A retrospective cohort study was conducted at a level I trauma center of patients with a displaced intra-articular calcaneal fracture treated from January 1, 2002 to December 31, 2011. The patient-reported outcome measures included the Foot Function Index, American Orthopaedic Foot and Ankle Society hindfoot scale, Short Form-36, the EQ-5D from the EuroQol Group, and a 10-point visual analog scale.

Results: Clinical data were collected from 169 patients, and questionnaires were obtained from 78 patients (18 nonoperatively, 27 ORIF, and 33 percutaneously). The late intervention rate was significantly greater in the percutaneous group (N=18; 30%) than in the ORIF group (N=6; 12%) or the nonoperative group (N=8; 13%; p=0.030). Significantly more disability was reported in the nonoperative group (median Foot Function Index score, 40 points) than in the ORIF group (median, 16 points; p=0.010) or in the percutaneous group (median, 21 points; p=0.034).

Conclusion: The operatively treated patients (ORIF and percutaneous treatment) reported better functional outcome scores (Foot Function Index and American Orthopaedic Foot and Ankle Society hindfoot scale) than did the nonoperatively treated patients.

INTRODUCTION

Displaced intra-articular calcaneal fractures will occur mainly (60%) in patients who are still in their wage-earning period (*i.e.,* 30 to 50 years old). The interval to work resumption has often been 5 to 10 months (1). A considerable number of patients will not be able to resume work within 1 year (2,3). These fractures can remain symptomatic for 1 to 2 years and can lead to the need for secondary arthrodesis in up to 16% of the nonoperatively treated patients (1,4).

In the Netherlands, the most frequently applied treatment modalities have been open reduction and internal fixation (ORIF; 46%), nonoperative treatment (39%), and percutaneous treatment (10%) (5).

Six meta-analyses of 4 randomized controlled trials, 1 prospective cohort study, and 3 retrospective studies have indicated a trend toward an overall improved outcome (*e.g.,* work resumption, prevalence of complications, functional outcome, and shoe adjustments) in patients treated with ORIF (6–11). However, because most studies were powered for specific outcomes and used different outcome scores, no definitive answer to the best treatment can be given. To minimize surgical complications such as infection or nerve damage after calcaneal fracture repair, different minimally invasive, percutaneous techniques have been introduced (12,13). The percutaneous techniques have not been investigated as extensively as ORIF.

The primary aim of the present study was to examine the effect of ORIF, percutaneous, and nonoperative treatment using the Foot Function Index in adult patients who had sustained a displaced intra-articular calcaneal fracture. In addition, the effect of treatment on health-related quality of life, overall patient satisfaction, interval to work resumption, and the prevalence of complications and late interventions was examined.

PATIENTS AND METHODS

All consecutive patients with a displaced intra-articular calcaneal fracture ("International Classification of Diseases, 10th revision" code S92.06) (14) treated at a level I trauma center from January 1, 2002 to December 31, 2011 were considered eligible for the present retrospective case series. The patients were identified from patient registries using the Diagnosis Related Group for both diagnosis (code 236; calcaneal fracture) and surgery (code 339732; operative treatment calcaneal fracture). Fracture management consisted of ORIF, percutaneous treatment, or nonoperative treatment.

The patients were treated by a general orthopedic surgeon (Monday and Thursday) or an orthopedic trauma surgeon (the rest of the week). Both had different local preferences. Because of the retrospective nature of our study, the treatment choice could not be determined on a case basis. A general orthopedic surgeon (B.W.) primarily conducted the nonoperative management (19 of 24 patients, 79%), and the orthopedic trauma

surgeons (D.D.H., T.S.) preferred operative management (105 of 145 patients, 72%). Until June 1, 2005, the primary operative management in this group was percutaneous treatment (33 of 33 patients, 100%). After June 1, 2005, the policy was changed to ORIF (48 of 72 patients, 67%), based on the available evidence. Surgeon experience with a certain technique and preference was the decisive factor between the choice of ORIF and percutaneous treatment. The other reasons for surgery included open or fracture dislocation.

The inclusion criteria for patient selection were an intra-articular calcaneal fracture with more than 2 mm of displacement (*i.e.,* Sanders type II to IV) and age 16 to 70 years. The exclusion criteria were primary arthrodesis or amputation, a Gustilo grade III open fracture, known alcohol or drug abuse, and wheelchair-bound patients with a neurologic disability before, or caused by, the injury. Secondary arthrodesis was considered a complication of primary treatment and was included in the analysis. Functional outcome was determined after the patients had provided written informed consent. Patients with American Society of Anesthesiologists class IV, those who had died, those with an unknown address or who had moved abroad, patients without trauma radiographs, and patients with an ongoing psychiatric illness or insufficient comprehension of the Dutch or English language to understand the study documents were also excluded. The local medical research ethics committee approved the study.

The patients received 1 of 3 different treatment modalities. Nonoperative management consisted of early non-weightbearing movement exercises or a plaster-of-Paris cast. In this cohort, closed reduction by external compression (molding) was not performed. The current reference standard for the treatment of displaced intra-articular calcaneal fractures is ORIF using an extended lateral approach. In most cases, a sharp 100° to 110° angled incision was used, with the vertical limb situated almost over the lateral edge of the Achilles tendon. The fracture was fixed using a titanium nonlocking calcaneal plate (Synthes Bettlach GmbH, Bettlach, Switzerland), using titanium 3.5-mm screws (15).

Percutaneous treatment, as described by Forgon and Zadravecz (16) and Zadravecz and Szekeres (17) was performed using three 3.0-mm Kirschner wires inserted through the tuberosity of the calcanei, talar neck, and cuboid. A distracting force was applied with an external fixator between the talus and calcaneus and between the talus and cuboid. Additional Kirschner wires were used as “joysticks” to reduce the posterior facet. Osteosynthesis was performed under fluoroscopic control with 6.5-mm cannulated Biomet (Biomet NL, Dordrecht, The Netherlands) or 7.3-mm Synthes (Synthes Bettlach GmbH) screws (18).

The patient characteristics (*i.e.,* gender, age at trauma, and comorbidities), fracture characteristics (*i.e.,* affected side, trauma mechanism, and injury classification), treatment characteristics (*i.e.,* treatment type, open or closed approach, and duration of plaster immobilization and non-weightbearing), complications, and late interventions

were obtained from the electronic patient files. Data were collected by 5 of us (A.S.D.B., B.W., D.D.H., E.M.M.V.L., and T.S.).

Infectious complications were divided into superficial (*i.e.,* minor) and deep (*i.e.,* major) using the criteria from the Centers for Disease Control and Prevention to define a surgical site infection (19). Superficial infections could be treated nonoperatively (*e.g.,* using oral antibiotics). Infections that required surgical intervention, readmission, or intravenous antibiotics were classified as deep infections (15).

The fractures were classified according to Essex-Lopresti (20) and Sanders et al (21). Böhler's angle was measured from the trauma and follow-up radiographs. The patients were queried regarding their dominant side, smoking habits, and work and sports activities at the age of trauma and at follow-up. Furthermore, the cosmetic result observed by the patients and any shoe adjustments were queried.

Patient-reported functional outcome was measured using validated questionnaires, which were sent by mail in September 2012. The Foot Function Index (primary outcome measure) was developed to measure the effect of the foot pathologic features on function in terms of pain, disability, and activity restriction (22). Twenty-three questions were scored from 1 (no pain, no difficulty, none of the time) to 10 (worst pain imaginable, so difficult or unable, all the time). The final maximum score could reach 100 points, with a higher score indicating more disability.

The American Orthopaedic Foot and Ankle Society hindfoot scale includes 9 questions related to the subdomains of pain (1 question; 40 points), function (7 questions; 50 points), and alignment (1 question; 10 points) (23,24). The maximum score is 100.

The Short Form-36 (SF-36) questionnaire is a validated multipurpose health survey with 36 questions, representing 8 health domains that are combined into physical (PCS) and mental component summaries (25,26). Scores from 0 to 100 points are derived for each domain, with lower scores indicating poorer function. The 1998 U.S. population was used as the reference because weighing factors for the PCS and mental component summary for the Dutch population are not available.

The EQ-5D is a validated questionnaire for health-related quality of life (27,28). The EQ-VAS is a standard vertical 20-cm visual analog scale for recording an individual's rating of their current health-related quality of life.

A 10-point visual analog scale, with 0 implying maximum dissatisfaction and 10, full satisfaction, was used to measure patient satisfaction with the overall outcome (18).

The assessors of outcome (A.S.D.B., E.M.M.V.L.) were not involved in patient treatment. The data were analyzed by E.M.M.V.L. and T.S. using the Statistical Package for the Social Sciences, version 20 (SPSS, Chicago, IL). Continuous data were found to deviate from a standard normal distribution (determined by inspecting frequency histograms and Q–Q plots) and are expressed as the median and first to third quartile (P_{25}-P_{75}). Kruskal-Wallis analysis of variance with post hoc pairwise comparison using a Mann-Whitney U test was performed to assess the statistical significance of the continuous

data among the treatment groups. Categorical data are presented as numbers and percentages and were analyzed using chi-square tests. A p value of < .05 was taken as the threshold of statistical significance.

RESULTS

Demographic data

During the 10-year study period, 178 patients were treated for a displaced intra-articular calcaneal fracture. Nine patients were excluded from the present study because the Sanders classification could not be determined owing to missing radiologic images or insufficient image quality. Clinical data were collected for the remaining 169 patients. Of the 169 patients, 59 had been treated nonoperatively, 49 with ORIF, and 61 percutaneously (Table 1). The median age at trauma was 41 years (P_{25}-P_{75} 33 to 50), and 130 patients (77%) were male. The right calcaneus was fractured in 77 patients (46%), and 23 patients (14%) had a bilateral calcaneal fracture. The fractures had mainly resulted from a fall from a height (n = 104; 62%) or low energy trauma (n = 38; 22%). Of the 169 patients, 45 (27%) had additional injuries. These baseline characteristics were not significantly different statistically among the 3 treatment groups.

When classified according to Essex-Lopresti (20), most of the fractures were of a joint depression type (n = 97; 57%) or a tongue type (n = 58; 34%). Comminuted fractures (not classifiable as joint depression or tongue type) were found in only 8 patients, 7 of which were treated with ORIF (p = 0.007). In each of the 3 groups, approximately 80% of fractures were Sanders type II.

Table 1: Characteristics and outcome for entire study population (N=169)

	Overall (N=169)	Non-operative (N=59)	ORIF (N=49)	Percutaneous (N=61)	P-value*
Age at trauma† (years)	41 (33-50)	40 (32-50)	41 (33-50)	44 (34-51)	0.573 / 0.542
Male gender‡	130 (77%)	46 (78%)	38 (78%)	46 (75%)	0.939 / 0.825
Affected side‡					
Right side	77 (46%)	27 (46%)	24 (49%)	26 (43%)	0.551 / 0.649
Left side	69 (41%)	21 (36%)	21 (43%)	27 (44%)	
Bilateral	23 (14%)	11 (19%)	4 (8%)	8 (13%)	
Trauma mechanism‡					
LET	38 (22%)	13 (22%)	13 (27%)	12 (20%)	0.130 / 0.453
HET fall from height	104 (62%)	32 (54%)	32 (65%)	40 (66%)	
HET other	5 (3%)	1 (2%)	1 (2%)	3 (5%)	
Other	1 (1%)	0 (0%)	1 (2%)	0 (0%)	
Unknown	21 (12%)	13 (22%)	2 (4%)	6 (10%)	
Concomitant injuries‡	45 (27%)	17 (29%)	12 (24%)	16 (26%)	0.238 / 0.528
Essex-Lopresti classification‡					
Tongue Type	58 (34%)	18 (31%)	17 (35%)	23 (38%)	0.007§/ 0.011§
Joint depression	97 (57%)	36 (61%)	25 (51%)	36 (59%)	
Comminuted	8 (5%)	1 (2%)	7 (14%)	0 (0%)	
Sanders classification‡					
Sanders II	132 (78%)	48 (81%)	38 (78%)	46 (75%)	0.291 / 0.919
Sanders III	27 (16%)	5 (8%)	10 (20%)	12 (20%)	
Sanders IV	7 (4%)	4 (7%)	1 (2%)	2 (3%)	
Surgical delay† (days)	5 (2-7)	N.A.	6 (3-11)	2 (1-6)	N.A./ <0.001§
Clinical follow-up† (months)	12 (5-19)	9 (1-16)	13 (9-19)	13 (6-25)	0.001§‖/ 0.907
Follow-up > 30 d‡	149 (88%)	44 (75%)	47 (96%)	58 (95%)	<0.001§/ 1.000
Adverse event (incl. infection) ‡	56 (33%)	14 (24%)	14 (29%)	28 (46%)	0.026§/ 0.077
Infection[2]	16 (9%)	N.A.	8 (16%)	8 (13%)	N.A./ 0.787
Surgical site infection	7 (44%)	N.A.	5 (63%)	2 (25%)	N.A./ 0.315
Deep infection	9 (56%)	N.A.	3 (38%)	6 (75%)	
Late intervention (excl. implant removal) ‡	32 (19%)	8 (14%)	6 (12%)	18 (30%)	0.030§/0.037§
Subtalar arthrodesis	19 (59%)	7 (88%)	0 (0%)	12 (67%)	0.002§/0.004§
Exostosis resection	5 (16%)	1 (13%)	1 (17%)	3 (17%)	
Wound debridement	5 (16%)	0 (0%)	2 (33.3)	3 (17%)	
Revision surgery	3 (9%)	0 (0%)	3 (50.0)	0 (0%)	
Implant removal‡	59 (35%)	N.A.	19 (39%)	40 (66%)	N.A./ 0.007§
Time until implant removal† (weeks)[1]	28 (17-52)	N.A.	55 (36-69)	22 (16-30)	N.A./ <0.001§

Abbreviations: HET, high energy trauma; LET, low energy trauma; NA, not applicable; ORIF, open reduction and internal fixation.

Data presented as median (25th percentile to 75th percentile) or n (%).

* First P-value from comparison of the 3 treatment groups; second *p* value for comparison of 2 surgical groups.

† Kruskal-Wallis analysis of variance.

‡ Chi-square analysis.

§ Difference found between nonoperative group and ORIF and percutaneous groups (both p = .001).

‖ Statistically significant.

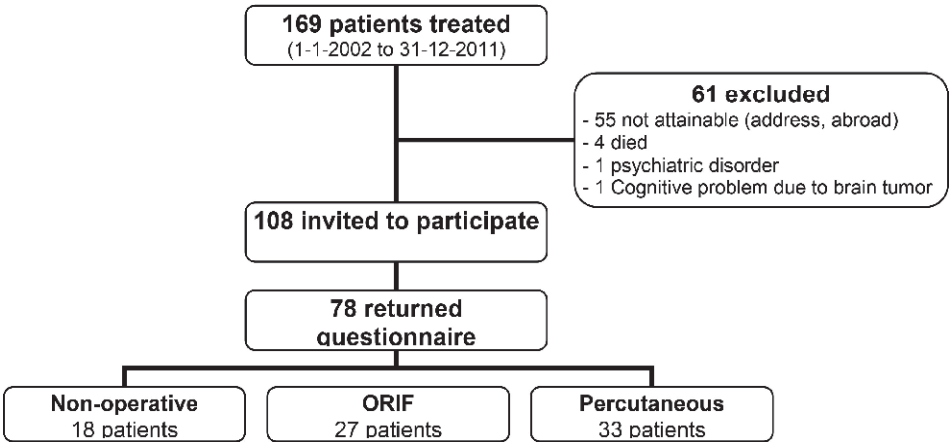

Figure 1 Study flowchart. ORIF, open reduction and internal fixation.

Of the 169 patients, 108 were invited to complete the questionnaires because 61 had met an exclusion criterion (Fig. 1). Of the 108 patients, 78 returned the questionnaire (response rate 72%). Of the 78 respondents, 18 (23.1%) had been treated nonoperatively, 27 (34.6%) with ORIF, and 33 (42.3%) percutaneously (Table 2). The respondents had patient and fracture characteristics similar to those for the total study population of 169 patients. The median body mass index was 25 kg/m^2, 10 patients reported cardiovascular disease or diabetes, and 42% smoked at the time they had sustained the trauma. The patients' preferred (dominant) side was affected in 60% of the patients (Table 2). These characteristics were not significantly related to the treatment received. The same was true for the duration of plaster immobilization and non-weightbearing (Table 2).

Table 2: Characteristics of patients who returned the questionnaire (N=78)

	Overall (N=78)	Non-operative (N=18)	ORIF (N=27)	Percutaneous (N=33)	P-value*
Age at trauma (years) †	46 (36-55)	44 (34-59)	45 (34-56)	47 (40-54)	0.697 / 0.435
Male gender‡	59 (76%)	14 (78%)	20 (74%)	25 (76%)	0.960 / 1.000
BMI (kg/m^2) †	25 (22-27)	24 (22-27)	23 (22-27)	26 (23-28)	0.174 / 0.070
Affected side[2]:					
Right side	33 (42%)	6 (33%)	15 (52%)	13 (39%)	0.511 / 0.292
Left side	36 (46%)	9 (50%)	12 (44%)	15 (45%)	
Bilateral	9 (12%)	3 (17%)	1 (4%)	5 (15%)	
Dominant side affected‡	47 (60%)	13 (72%)	15 (56%)	19 (58%)	0.491 / 1.000
Trauma mechanism‡					
LET	20 (26%)	3 (17%)	10 (37%)	7 (21%)	0.479 / 0.311
HET fall from height	47 (60%)	11 (61%)	15 (56%)	21 (64%)	
HET other	2 (3%)	1 (6%)	0 (0%)	1 (3%)	
Other	1 (1%)	0 (0%)	1 (4%)	0 (0%)	
Unknown	8 (10%)	3 (17%)	1 (4%)	4 (12%)	
Concomitant injury‡	18 (23%)	7 (39%)	4 (15%)	7 (21%)	0.253 / 0.457
Co-morbidity‡	10 (13%)	4 (22%)	0 (0%)	6 (18%)	0.044§ / 0.028§
Cardiovascular disease	6 (8%)	3 (17%)	0 (0%)	3 (9%)	0.112 / 0.245
Diabetes mellitus	4 (5%)	1 (6%)	0 (0%)	3 (9%)	0.282 / 0.245
Smoking at age of trauma‡	33 (42%)	9 (50%)	9 (33%)	15 (45%)	0.482 / 0.430
Essex-lopresti classification‡					
Tongue Type	35 (45%)	8 (44%)	13 (48%)	14 (42%)	0.060 / 0.053
Joint depression	39 (50%)	10 (56%)	10 (37%)	19 (58%)	
Comminuted	4 (5%)	0 (0%)	4 (15%)	0 (0%)	
Sanders classification‡					
Sanders II	63 (81%)	16 (89%)	21 (78%)	26 (79%)	0.236 / 1.000
Sanders III	14 (18%)	1 (6%)	6 (22%)	7 (21%)	
Sanders IV	1 (1%)	1 (6%)	0 (0%)	0 (0%)	
Surgical delay (days) †	5 (2-7)	N.A.	6 (3-8)	3 (1-7)	N.A. / 0.011§
Clinical follow-up (months) †	14 (9-24)	13 (6-24)	16 (12-21)	14 (8-30)	0.406 / 0.899
Follow-up >30 days‡	77 (99%)	17 (94%)	27 (100%)	33 (100%)	0.185 / 1.000
Plaster immobilization‡	33 (42%)	10 (56%)	10 (37%)	13 (39%)	0.230 / 1.000
Plaster immobilization (weeks) ‡	6 (3-10)	9 (4-13)	4 (1-8)	6 (6-9)	0.184 / 0.117
Non-weight bearing (weeks) †	12 (8-13)	12 (8-14)	12 (12-13)	12 (7-13)	0.534 / 0.278

Abbreviations: HET, high energy trauma; LET, low energy trauma; NA, not applicable; ORIF, open reduction and internal fixation.

Data presented as median (25th percentile to 75th percentile) or n (%).

* First P-value from comparison of the 3 treatment groups; second *p* value for comparison of 2 surgical groups.

† Kruskal-Wallis analysis of variance.

‡ Chi-square analysis.

§ Statistically significant.

The period of clinical follow-up differed significantly among the 3 treatment groups for the overall population of 169 patients (Kruskal-Wallis p = 0.001; Table 1). The median clinical follow-up at the outpatient department was shorter in the nonoperative group (median 9 months, P_{25}-P_{75} 1 to 16) than in the ORIF group (median 13 months, P_{25}-P_{75} 10 to 19; *p* = 0.001) or the percutaneous group (13 months, P_{25}-P_{75} 6 to 25; p = 0.001). In the nonoperative group, 75% of the patients were seen at regular intervals extending to 30 days. In the ORIF and percutaneous groups, 96% and 95% of patients were seen at the outpatient department for longer than 30 days. Transfer to a hospital abroad and refusal were the main reasons for not returning to the outpatient department. Only the patients who had attended the outpatient department for their entire clinical follow-up period were invited for the present study to report on their long-term functional outcome (Table 3). This resulted in monitoring for longer than 30 days in 99% of the responders, with a median follow-up period of 14 months. A total of 108 patients were sent the questionnaires, of whom 78 responded (72% response rate).

Table 3: Clinical and cosmetic outcome in patients who returned the questionnaire (N=78)

	Overall (N=78)	Non-operative (N=18)	ORIF (N=27)	Percutaneous (N=33)	P-value*
Follow-up (months)[†]	76 (54-88)	78 (51-88)	56 (28-76)	88 (68-107)	<0.001[‡]/<0.001[‡]
Working pre-fracture[‡]	78 (100%)	18 (100%)	27 (100%)	33 (100%)	1.000 / 1.000
Heaviness of work[‡]					
Heavy	19 (24%)	6 (33%)	7 (26%)	6 (18%)	0.515 / 0.777
Mild	33 (42%)	9 (50%)	10 (37%)	14 (42%)	
Light	25 (32%)	3 (17%)	10 (37%)	12 (36%)	
Work resumption at FU[‡]	63 (81%)	13 (72%)	26 (96%)	24 (73%)	0.052 / 0.031[‡]
Returned to same position	44 (56%)	7 (39%)	21 (78%)	16 (48%)	0.016[‡] / 0.043[‡]
Returned to changed position	19 (24%)	7 (39%)	5 (19%)	7 (21%)	
Unable to work due to complaints	10 (13%)	4 (22%)	1 (4%)	5 (15%)	
Pension or unknown	5 (6%)	0 (0%)	0 (0.0)	5 (15%)	
Sports activities pre-fracture[‡]	37 (47%)	9 (50%)	14 (52%)	14 (42%)	0.744 / 0.604
Sports activities resumed at FU[‡]	28 (36%)	5 (28%)	10 (37%)	13 (39%)	0.702 / 1.000
Walking barefoot[‡]					
No problems	46 (59%)	8 (44%)	19 (70%)	19 (57%)	0.360 / 0.545
With problems	30 (38%)	10 (56%)	7 (26%)	13 (39%)	
Unable to do	2 (3%)	0 (0%)	1 (4%)	1 (3%)	
Able to run[‡]	43 (55%)	9 (50%)	17 (63%)	17 (52%)	0.596 / 0.438
Stiffness[‡]	61 (78%)	18 (100%)	23 (85%)	20 (61%)	0.003[‡] / 0.046[‡]
Continuous	31 (51%)	10 (56%)	12 (52%)	9 (45%)	0.799 / 0.763
Only in the morning	30 (49%)	8 (44%)	11 (48%)	11 (55%)	
Change in shoe size[‡]	22 (28%)	5 (28%)	8 (30%)	9 (27%)	0.979 / 1.000
Size change[†]	1.0 (1.0-1.0)	1.0 (-0.1-1.0)	1.0 (0.6-1.0)	1.0 (1.0-2.0)	0.184 / 0.131

	Overall (N=78)	Non-operative (N=18)	ORIF (N=27)	Percutaneous (N=33)	P-value*
Changes in type of shoe‡					
Unchanged / mild concession	53 (68%)	8 (44%)	21 (78%)	24 (73%)	0.186 / 0.885
Slight orthopedic changes (insoles)	12 (15%)	5 (28%)	3 (11%)	4 (12%)	
Orthopedic shoes / shoe impossible	13 (17%)	5 (28%)	3 (11%)	5 (15%)	
Change in foot shape‡					
Unchanged	19 (24%)	3 (17%)	6 (22%)	10 (30%)	0.440 / 0.295
Mild changes	42 (54%)	9 (50%)	18 (67%)	15 (45%)	
Moderate changes	13 (17%)	4 (22%)	3 (11%)	6 (18%)	
Major changes	4 (5%)	2 (11%)	0 (0%)	2 (6%)	
Adverse event (incl. infection) ‡	27 (5%)	4 (22%)	9 (33%)	14 (42%)	0.345 / 0.595
Infection‡	11 (14%)	N.A.	5 (19%)	6 (18%)	N.A. / 1.000
Surgical site infection	6 (55%)	N.A.	4 (80%)	2 (33%)	N.A. / 0.242
Deep infection	5 (45%)	N.A.	1 (20%)	4 (67%)	
Late intervention (ex. implant removal)‡	14 (18%)	1 (6%)	4 (15%)	9 (27%)	0.135 / 0.348
Subtalar arthrodesis	7 (50%)	1 (100%)	0 (0%)	12 (67%)	0.187 / 0.057
Exostosis resection	2 (14%)	0 (0%)	1 (25%)	1 (11%)	
Wound debridement	3 (21%)	0 (0%)	1 (25%)	2 (22%)	
Revision surgery	2 (14%)	0 (0%)	2 (50%)	0 (0%)	
Implant removal‡	36 (46%)	N.A.	10 (37.0)	26 (78.8)	N.A. / 0.001‡
Time until implant removal† (weeks)	25 (14-42)	N.A.	55 (30-71)	23 (12-32)	N.A. / 0.014‡

Abbreviations: FU, follow-up; NA, not applicable; ORIF, open reduction and internal fixation.
Data presented as median (25th percentile to 75th percentile) or n (%).
* First P-value from comparison of the 3 treatment groups; second *p* value for comparison of 2 surgical groups.
† Kruskal-Wallis analysis of variance.
‡ Chi-square analysis.
§ Statistically significant.

Adverse Events, Late Interventions, and Implant Removal

Of all 169 patients, 56 (33%) experienced an adverse event, including 16 patients who developed an infection. The prevalence of adverse events was lowest in the nonoperative group (n = 14; 24%) and greatest in the percutaneous group (n = 28; 46%; p =0.026; Table 1).

The difference in the prevalence of infections between the 2 operative methods was not significant 16% (5 superficial and 3 deep) in the ORIF group and 13% (2 superficial and 6 deep) in the percutaneous group (p = 0.315 comparing superficial and deep infection in the operative groups; Table 1).

Late intervention (excluding implant removal) was performed in 32 patients (19%).

This percentage was significantly greater in the percutaneous group (n = 18; 30%) than in the ORIF group (n = 6; 12%) or nonoperative group (n = 8; 14%; p = 0.030; Table 1).

The main late intervention (excluding implant removal) was subtalar arthrodesis in 19 patients, followed by exostosis resection in 5, wound debridement in 5, and revision of the osteosynthesis surgery in 3. Secondary arthrodesis was performed most frequently in the nonoperative group (7 of 8 patients undergoing late intervention; 88%; p = 0.002), followed by the percutaneous group (12 of 18, 67%; p = 0.004), and was not needed in the ORIF group.

Overall, arthrodesis was performed in 12% of patients in the nonoperative group and 20% of patients in the percutaneous group.

Implants were removed more frequently in the percutaneous group (n = 40; 66%) than in the ORIF group (n = 19; 39%; p = 0.007; Table 1). In addition to the lower prevalence of removal, the implants remained in situ for a significantly longer period in the ORIF group (median 55 weeks, P_{25}-P_{75} 36 to 69) than in the percutaneous group (median 22 weeks, P_{25}-P_{75} 16 to 30; p < 0.001; Table 1).

Patient-reported Outcome Measures

Questionnaires were completed by 78 patients (18 treated nonoperatively, 27 with ORIF, and 33 percutaneously). The Functional Foot Index score differed significantly among the treatment groups, with the greatest disability reported by the nonoperative group (median overall score 40 points; Table 4 and Fig. 2A). This was significantly greater than in the ORIF group (16 points; p = 0.010) or the percutaneous group (21 points; p = 0.034). This was mainly attributable to differences in the subdomain activity limitation. The median American Orthopaedic Foot and Ankle Society hindfoot score ranged from 61 points in the nonoperative group to 81 in the percutaneous group. No statistically significant relation with treatment was found, neither in the overall score nor in the individual subdomains. However, the data suggested a trend in favor of operative treatment.

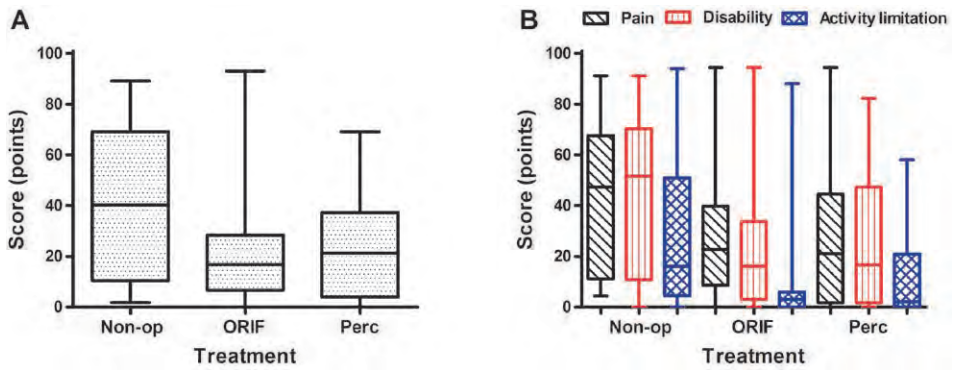

Figure 2. (**A**) Foot Function Index total score. (**B**) Foot Function Index subdomain scores. Nonop, nonoperative; ORIF, open reduction and internal fixation; Perc, percutaneous.

The median visual analog scale score for patient satisfaction ranged from 6.3 in the nonoperative group to 8.5 in the percutaneous group ($p > 0.05$).

The SF-36 mental component summary score was similar in all treatment groups, with all median values within the normal range of 50 ± 10 points (Table 4 and Fig. 3B). However, the median PCS score was below the normality boundaries in the nonoperative group (38 points). The median PCS score was 50 in the percutaneous group and 52 in the ORIF group. The difference between the operative and nonoperative groups did not reach statistical significance ($p = 0.050$; Table 4 and Fig. 3A).

The EQ-5D utility score (median 0.78, P_{25}-P_{75} 0.77 to 0.93) and EQ-visual analog scale score (median 80, P_{25}-P_{75} 70 to 89) were unrelated to the treatment used.
operative groups.

Table 4: Functional outcome and quality of life in patients who returned the questionnaire (N=78)

	Overall (N=78)	Non-operative (N=18)	ORIF (N=27)	Percutaneous (N=33)	P-value
FFI					
Overall score	22 (7-37)	40 (10-69)	16 (7-29)	21 (4-37)	0.031*
Pain	26 (9-48)	47 (11-68)	20 (9-41)	21 (2-45)	0.063
Disability	19 (8-50)	52 (11-70)	16 (1-34)	17 (2-47)	0.077
Activity limitation	5 (0-17)	16 (5-51)	4 (0-6)	2 (0-21)	0.017†
AOFAS					
Overall score	77 (59-89)	61 (43-78)	76 (64-85)	81 (66-95)	0.060
Pain	30 (20-30)	20 (20-30)	30 (20-30)	30-(20-40)	0.132
Function	40 (32-47)	31 (20-41)	41 (34-47)	42 (34-48)	0.069
Alignment	10 (5-10)	10 (4-10)	10 (5-10)	10 (8-10)	0.208
SF-36					
PCS	48 (36-54)	38 (27-53)	52 (42-57)	50 (38-54)	0.050
MCS	57 (47-61)	54 (45-60)	58 (56-61)	57 (45-62)	0.490
EQ-5D					
EQUS	0.78 (0.77-0.93)	0.78 (0.52-0.81)	0.81 (0.78-0.93)	0.78 (0.78-0.93)	0.095
EQVAS	80 (70-89)	75 (63-83)	80 (75-90)	80 (70-90)	0.102
Patient satisfaction					
(VAS)	8.0 (6.0-9.5)	6.3 (3.8-9.5)	8.0 (6.0-9.5)	8.5 (7.0-10.0)	0.081

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society hindfoot score; CI, confidence interval; EQ-5D, EuroQol-5D; EQUS, EuroQol utility score; EQVAS, EuroQoL visual
analog scale; FFI, Foot Function Index; MCS, mental component summary; PCS, physical component summary; SF-36, Short Form-36; VAS, visual analog scale.
Data presented as median (25^{th} to 75^{th} percentile).
Kruskal-Wallis analysis of variance used to assess statistical significance between the treatment groups, followed by post hoc pairwise comparisons using the Mann-Whitney U test if
significantly different.

* Statistically significant difference found between nonoperative and ORIF groups (p = 0.010) and nonoperative and percutaneous groups (p = 0.034).

† Statistically significant difference found between nonoperative and ORIF groups (p = 0.004) and nonoperative and percutaneous groups (p = 0.025).

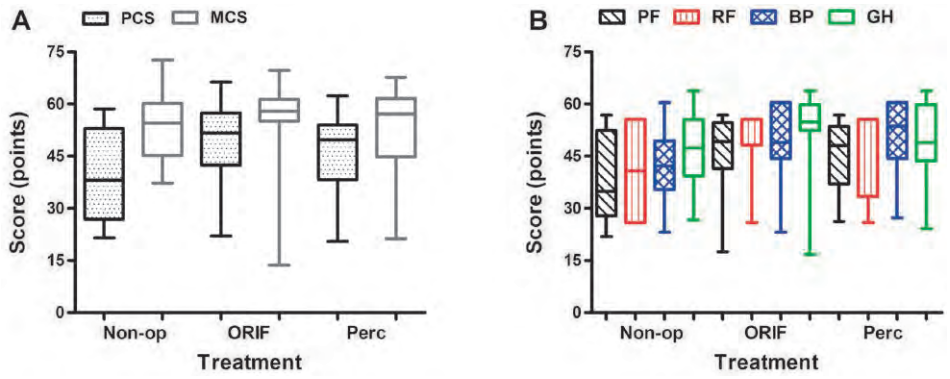

Figure 3. (**A**) Short Form-36 (SF-36) and physical component summary (PCS) scores. (**B**) SF-36 physical component summary score for the subdomains. BP, bodily pain; GH, general health; PF, physical functioning; RF, role physical.

Work Resumption, Sports Resumption, and Cosmesis

All 78 patients had worked before their trauma, with no significant difference in the number of patients performing heavy labor among the treatment groups (Table 3). Patients in the ORIF group had resumed work in 96% of cases, significantly more than that in the percutaneous group (75%; $p = 0.045$). In the nonoperative group, 72% had returned to work at the time of completing the questionnaires. Because of the lower number of patients in the nonoperative group, this was not significantly different statistically from the rate in the operative groups. In addition to resuming work more often, a significantly greater proportion of the ORIF group had returned to the same position as before their injury.

Of the 78 patients, 37 (47%) had participated in sports activities before their injury. At the last follow-up point, 28 (76%) had resumed their sports activities, irrespective of the treatment type.

Also, 46 patients (59%) were able to walk barefoot without problems, and 43 were able to run. Again, no relation with treatment was found. All patients in the nonoperative group reported stiffness of the ankle compared with 85% in the ORIF group and 61% in the percutaneous group ($p = 0.003$; Table 3). A total of 22 patients reported changes in shoe size, 59 reported a change in foot shape, and 25 reported the use of adjusted shoes at follow-up compared with before fracture. These findings were not associated with the treatment modality (Table 3).

DISCUSSION

In the present retrospective study, patients with a displaced intra-articular calcaneal fracture generally showed better functional outcomes after operative treatment (*i.e.,* ORIF and percutaneous treatment) than after nonoperative treatment. Although a greater percentage of patients in the operative treatment groups had adverse events (including infections) and late interventions, the patient-reported outcome scores were better in the operative group.

The nonoperatively treated patients reported more difficulties, such as shoe adjustments and hindfoot stiffness, and returned to work later. Of the 2 surgical procedures, the results were in favor of the ORIF treatment strategy. In the percutaneous group, more complications were seen, implants had to be removed more often, and patients required late intervention more frequently.

The published data have indicated that less invasive procedures might allow accelerated weightbearing, less joint stiffness, and greater patient' satisfaction compared with ORIF (29,30). However, in the present study, ORIF provided better results. Almost one fifth of the percutaneously treated patients required secondary arthrodesis compared with none in the ORIF group. The 20% secondary arthrodesis rate after percutaneous treatment found in the present study was comparable to the previously reported 15% (18).

ORIF treatment has been known for infectious complications (1). In our study, 16% of patients in the ORIF group (8 of 49) experienced an infectious complication, which was not much different from the 13% in the percutaneous group. This infection rate of 13% was comparable to that in previous reports (31). Thus, the functional results in our study were not negatively affected by a learning curve of the surgeons in our medical center or a high infection rate. Although the implant removal rate of 39% for ORIF was comparable to that of other reports (39% to 49%) (32,33), the 57% rate in the percutaneous group was much greater than the 12% reported previously (34). Considering the complaints of the patients in our study, it is plausible that the large screw head of the implants used for the percutaneous treatment was the cause of the high rate of implant removal (18,31). Especially for percutaneous treatment, less prominent implants (*i.e.,* headless screws) should be considered (35,36).

The response percentage for the different treatments groups was 31% (18 of 59 patients) in the nonoperative group, 55% (27 of 49 patients) in the ORIF group, and 54% (33 of 61 patients) in the percutaneous group, indicating that fewer conservatively treated patients completed the questionnaires. The response percentage of both operative treatment groups was nearly identical.

Although nonoperative treatment of calcaneal fractures did not lead to the best results, it could still be a viable treatment modality given the noncompliance of some patients concerning mobilization advice during follow-up. Early studies (37,38) showed that early exercise will be the best nonoperative modality. The nonoperatively treated

patients reported inferior functional outcomes and more disability in the questionnaires than did the operatively treated patients. This might explain why the vast majority of late interventions in the nonoperative group were secondary arthrodesis.

Several comparative studies have described the results of ORIF and nonoperative management but did not use a standardized functional outcome scoring system (39–42). Studies comparing ORIF and nonoperative management that did use a disease-specific outcome score have shown conflicting results. Three studies reported a significantly greater outcome for operatively treated fractures (43–46). In another study, only a trend toward a better outcome in the operative group was seen (47). Two studies failed to find a significant difference (48,49).

Just as with any retrospective study, we acknowledge the presence of limitations. The follow-up duration was different among the treatment groups because of a changes in the local protocol during the study period. The preferred surgical treatment changed from percutaneous to ORIF from 2005 onward. To some extent, the difference in functional outcome scores could have resulted from the differences in the interval between the trauma and questionnaire completion. With a median follow-up of 56 and 88 months, the ORIF and percutaneous groups had, overall, significantly better outcomes than did the nonoperatively treated patients, who had completed the questionnaires after 78 months. Clinical data could be retrieved for 9 months in the nonoperative group compared with 13 months in both operative groups. A shorter clinical follow-up period for the conservative group might have resulted in an underestimation of the true rate of complications and late interventions. This underestimation for the infectious complication rate in the present study was probably minimal, because more than 95% of the patients in the operative groups were followed up for at least 30 days, which we believed would be a relevant period for the identification of delayed or problematic wound healing.

Another limitation was that of the 169 patients, only 108 (64%) met the eligibility criteria for an invitation to complete the questionnaires. The clinical data from the sample of 108 patients were similar to the data from the total population of 169 patients, supporting the idea that the invitees were representative of the total population. The response rate for the questionnaires was 72%, consistent with that previously reported (50). This could have introduced some selection bias. Because the response percentage was comparable in each treatment group, the bias could not explain the differences found.

Minimally invasive, percutaneous treatment has often been chosen in patients with comorbidities, which might explain the complications in the percutaneous group. The differences in the complication rates between the percutaneous and ORIF groups should thus be interpreted with care. No difference in any of the observed patient characteristics (*i.e.,* gender, age at trauma, smoking, diabetes mellitus and other comorbidities) or injury characteristics (*i.e.,* affected side, trauma mechanism, injury classification,

and concomitant injuries) among the treatment groups was noted in our study. Therefore, any consequent bias can be assumed to be, at most, marginal.

Concomitant injuries are not rare with calcaneal fractures. In the published data, there are indications that polytrauma patients with calcaneal fractures have had a worse clinical outcome than patients with isolated calcaneal fractures. The present study lacked statistical power to evaluate the relationship between polytrauma and functional outcome stratified by treatment modality.

CONCLUSION

Our results have indicated that operatively treated patients report improved outcomes and better Foot Function Index and American Orthopaedic Foot and Ankle Society hindfoot scale score compared with the nonoperatively treated patients. These results support previous data (51–53). Patients treated with ORIF had the best outcome measures. In the present study, both functional and patient-related outcomes from the 3 different treatment strategies for displaced intra-articular calcaneal fractures were investigated. Overall, ORIF resulted in superior functional outcomes and greater patient satisfaction, with an acceptable complication rate and no secondary arthrodesis required.

REFERENCES

1. Buckley R, Tough S, McCormack R, Pate G, Leighton R, Petrie D, Galpin R. Operative compared with nonoperative treatment of displaced intra-articular calcaneal fractures: a prospective, randomized, controlled multicenter trial. J Bone Joint Surg Am 84-A:1733–1744, 2002.
2. Pozo JL, Kirwan EO, Jackson AM. The long-term results of conservative management of severely displaced fractures of the calcaneus. J Bone Joint Surg Br 66:386–390, 1984.
3. Mortelmans LJ, Du Bois M, Donceel P, Broos PL. Impairment and return to work after intra-articular fractures of the calcaneus. Acta Chir Belg 102:329–333, 2002.
4. Crosby LA, Fitzgibbons T. Intraarticular calcaneal fractures. Results of closed treatment. Clin Orthop Relat Res 290:47–54, 1993.
5. Schepers T, van Lieshout EM, van Ginhoven TM, Heetveld MJ, Patka P. Current concepts in the treatment of intra-articular calcaneal fractures: results of a nationwide survey. Int Orthop 32:711–715, 2008.
6. AO Publishing. Intraarticular calcaneal fractures: operative management. Orthop Trauma Dir 2:9–16, 2004.
7. Bajammal S, Tornetta P III, Sanders D, Bhandari M. Displaced intra-articular calcaneal fractures. J Orthop Trauma 19:360–364, 2005.
8. Bridgman SA, Dunn KM, McBride DJ, Richards PJ. Interventions for treating calcaneal fractures. Cochrane Database Syst Rev:CD001161, 2000.
9. Gougoulias N, Khanna A, McBride DJ, Maffulli N. Management of calcaneal fractures: systematic review of randomized trials. Br Med Bull 92:153–167, 2009.
10. Randle JA, Kreder HJ, Stephen D, Williams J, Jaglal S, Hu R. Should calcaneal fractures be treated surgically? A meta-analysis. Clin Orthop Relat Res:217–227, 2000.
11. Bruce J, Sutherland A. Surgical versus conservative interventions for displaced intra-articular calcaneal fractures. Cochrane Database Syst Rev 1:CD008628, 2013.
12. Levine DS, Helfet DL. An introduction to the minimally invasive osteosynthesis of intra-articular calcaneal fractures. Injury 32(suppl 1)):SA51–SA54, 2001.
13. Biggi F, Di Fabio S, D'Antimo C, Isoni F, Salfi C, Trevisani S. Percutaneous calcaneoplasty in displaced intraarticular calcaneal fractures. J Orthop Traumatol 14:307–310, 2013.
14. The International Conference for the Tenth Revision of the International Classification of Diseases. Strengthening of Epidemiological and Statistical Services Unit. World Health Organization, Geneva. World Health Stat Q 43:204–245, 1990.
15. Schepers T, Den Hartog D, Vogels LM, Van Lieshout EM. Extended lateral approach for intra-articular calcaneal fractures: an inverse relationship between surgeon experience and wound complications. J Foot Ankle Surg 52:167–171, 2013.
16. Forgon M, Zadravecz G. Die Kalkaneusfraktur, Springer-Verlag, Berlin, 1990, pp. 1–104.
17. Zadravecz G, Szekeres P. Late results of our treatment method in calcaneus fractures. Aktuelle Traumatol 14:218–226, 1984. in German.
18. Schepers T, Schipper IB, Vogels LM, Ginai AZ, Mulder PG, Heetveld MJ, Patka P. Percutaneous treatment of displaced intra-articular calcaneal fractures. J Orthop Sci 12:22–27, 2007.
19. Mangram AJ, Horan T,C, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999: Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. Am J Infect Control 27:97–132, 1999. quiz 133–134; discussion 196.
20. Essex-Lopresti P. The mechanism, reduction technique, and results in fractures of the os calcis. Br J Surg 39:395–419, 1952.
21. Sanders R, Fortin P, DiPasquale T, Walling A. Operative treatment in 120 displaced intraarticular calcaneal fractures. Results using a prognostic computed tomography scan classification. Clin Orthop Relat Res 290:87–95, 1993.
22. Budiman-Mak E, Conrad KJ, Roach KE. The Foot Function Index: a measure of foot pain and disability. J Clin Epidemiol 44:561–570, 1991.

23. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int 15:349–353, 1994.
24. Ibrahim T, Beiri A, Azzabi M, Best AJ, Taylor GJ, Menon DK. Reliability and validity of the subjective component of the American Orthopaedic Foot and Ankle Society clinical rating scales. J Foot Ankle Surg 46:65–74, 2007.
25. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 30:473–483, 1992.
26. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, Sprangers MA, te Velde A, Verrips E. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. J Clin Epidemiol 51:1055–1068, 1998.
27. Brooks R. The Measurement and Valuation of Health Status Using EQ-5D: A European Perspective, Kluwer Academic Publishers, Dordrecht, The Netherlands, 2003.
28. Lamers LM, Stalmeier PF, McDonnell J, Krabbe PF, van Busschbach JJ. Measuring the quality of life in economic evaluations: the Dutch EQ-5D tariff. Ned Tijdschr Geneeskd 149:1574–1578, 2005.
29. Chen L, Zhang G, Hong J, Lu X, YuanW. Comparison of percutaneous screw fixation and calcium sulfate cement grafting versus open treatment of displaced intraarticular calcaneal fractures. Foot Ankle Int 32:979–985, 2011.
30. Wu Z, Su Y, Chen W, Zhang Q, Liu Y, Li M, Wang H, Zhang Y. Functional outcome of displaced intra-articular calcaneal fractures: a comparison between open reduction/internal fixation and a minimally invasive approach featured an anatomical plate and compression bolts. J Trauma Acute Care Surg 73:743–751, 2012.
31. Tomesen T, Biert J, Frolke JP. Treatment of displaced intra-articular calcaneal fractures with closed reduction and percutaneous screw fixation. J Bone Joint Surg Am 93:920–928, 2011.
32. Benirschke SK, Kramer PA. Wound healing complications in closed and open calcaneal fractures. J Orthop Trauma 18:1–6, 2004.
33. Harvey EJ, Grujic L, Early JS, Benirschke SK, Sangeorzan BJ. Morbidity associated with ORIF of intra-articular calcaneus fractures using a lateral approach. Foot Ankle Int 22:868–873, 2001.
34. DeWall M, Henderson CE, McKinley TO, Phelps T, Dolan L, Marsh JL. Percutaneous reduction and fixation of displaced intra-articular calcaneus fractures. J Orthop Trauma 24:466–472, 2010.
35. Gokce A. Stabilization of calcaneus fractures in a closed manner with a distraction screw. Eklem Hastalik Cerrahisi 20:62, 2009.
36. Kadas I, Szita J, Zadravecz G, Hangody L, Doczi J. Stabilization of calcaneus fractures in a closed manner with a distraction screw. Joint Dis Relat Surg 19:45–49, 2008.
37. Barnard L, Odegard JK. Conservative approach in the treatment of fractures of the calcaneus. J Bone Joint Surg Am 37-A:1231–1236, 1955.
38. Carothers RG, Lyons JF. Early mobilization in treatment of os calcis fractures. Am J Surg 83:279–280, 1952.
39. Kundel K, Funk E, Brutscher M, Bickel R. Calcaneal fractures: operative versus nonoperative treatment. J Trauma 41:839–845, 1996.
40. Nouraei MH, Moosa FM. Operative compared to non-operative treatment of displaced intra-articular calcaneal fractures. J Res Med Sci 16:1014–1019, 2011.
41. Paul M, Peter R, Hoffmeyer P. Fractures of the calcaneum. A review of 70 patients. J Bone Joint Surg Br 86:1142–1145, 2004.
42. Robb CA, Deans V, Iqbal MJ, Cooper JP. Comparison of non-operative and surgical treatment of displaced calcaneal fractures. Foot 17:169–173, 2007.
43. Basile A. Operative versus nonoperative treatment of displaced intra-articular calcaneal fractures in elderly patients. J Foot Ankle Surg 49:25–32, 2010.
44. Leung KS, Yuen KM, Chan WS. Operative treatment of displaced intra-articular fractures of the calcaneum. Medium-term results. J Bone Joint Surg Br 75:196–201, 1993.
45. Zwipp H, Rammelt S, Barthel S. Calcaneal fractures–open reduction and internal fixation (ORIF). Injury 35(suppl 2):SB46–SB54, 2004.

46. Schofer M, Schoepp C, R€ulander C, Kortmann HR. Operative und konservative Behandlung der Kalkaneusfrakturen. Trauma Berufskrankh 7:S156–S161, 2005.
47. Kennedy JG, Jan WM, McGuinness AJ, Barry K, Curtin J, Cashman WF, Mullan GB. An outcomes assessment of intra-articular calcaneal fractures, using patient and physician's assessment profiles. Injury 34:932–936, 2003.
48. Thornes BS, Collins AL, Timlin M, Corrigan J. Outcome of calcaneal fractures treated operatively and non-operatively: the effect of litigation on outcomes. Ir J Med Sci 171:155–157, 2002.
49. Sharma V, Dogra A. Sanders type II calcaneum fracturesdsurgical or conservative treatment? A prospective randomized trial. J Clin Orthop Trauma 2:35–38, 2011.
50. Murnaghan ML, Buckley RE. Lost but not forgotten: patients lost to follow-up in a trauma database. Can J Surg 45:191–195, 2002.
51. O'Farrell DA, O'Byrne JM, McCabe JP, Stephens MM. Fractures of the os calcis: improved results with internal fixation. Injury 24:263–265, 1993.
52. Parmar HV, Triffitt PD, Gregg PJ. Intra-articular fractures of the calcaneum treated operatively or conservatively. A prospective study. J Bone Joint Surg Br 75:932–937, 1993.
53. Thordarson DB, Krieger LE. Operative vs. nonoperative treatment of intra-articular fractures of the calcaneus: a prospective randomized trial. Foot Ankle Int 17:2–9, 1996.

Chapter 6

Computer-controlled cooling in operatively treated ankle or hindfoot fractures: a retrospective case-control study

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ABSTRACT

Introduction: Ankle and hindfoot fractures are often accompanied by a considerable amount of pain and associated need for systemic analgesics. Cooling devices have been developed in order to reduce swelling, pain, the need for analgesics, and complications. The primary aim was to examine the effect of cooling versus no cooling on pain levels in adult patients treated operatively for an ankle or hindfoot fracture. Secondary aims were to assess 1) the effect of cooling on analgesics use, 2) patient satisfaction with cooling or non-cooling, 3) hospital length of stay (HLOS), 4) the rate of complications, and 5) the rate of secondary interventions.

Methods: Single center, retrospective case-control study. Patients who used a computer-controlled cooling device before and after surgery of an ankle or hindfoot fracture between January 1, 2015 and January 1, 2017 were included. Matched patients without using cooling served as control. Patient, injury and treatment characteristics, pain scores and analgesics use during hospital admission were extracted from patient's medical files.

Results: Pain scores in the cooling group (18 patients) did not statistically differ from the non-cooling group (17 patients). After surgery, less patients in the cooling group used paracetamol (p=0.041), and NSAIDs (p=0.006). Patient satisfaction of both cooling and non-cooling was rated with an eight out of ten points. The total HLOS was 14 days (P25-P75 9.0-17.3) in the cooling group and 9 days (P25-P75 5.0-16.5) in the non-cooling group, this difference is mostly contributable to the difference in pre-operative HLOS (8 days; P25-P75 4.8-13.0 versus 4 days; P25-P75 2.0-7.0) and time to surgery (13.5 days; P25-P75 9.3-16.3) versus 8 days; P25-P75 2.5-12.0). No statistical differences in complications and revision surgery were found.

Conclusion: Patients with ankle or hindfoot fractures seem to benefit from computer-controlled cooling, since equal pain sensation is feasible with less analgesics post-operatively, whereas rates of complications and revision surgeries were comparable in both groups. Patients were highly satisfied with cooling. Prospective studies are required in order to strengthen these findings.

INTRODUCTION

Ankle and hindfoot fractures can be challenging to treat and are associated with long-term disability (1). They are often associated by a considerable amount of (pre-and postoperative) pain and need for systemic analgesics (2). Postoperative pain may prolong hospital length of stay and delay mobilization, which could increase the risk of postoperative complications and inferior functional long term outcome. To improve quality of care and for above mentioned reasons, (postoperative) pain should be reduced as soon as possible. Continuous peripheral nerve block (CPNB), patient-controlled analgesia with morphine (PCA), oral and intravenous analgesics are used (2).

Swelling is another crucial factor in lower extremity fracture treatment. The most traditional and simplest way to reduce swelling is to apply a pressure bandage or plaster cast and to elevate the leg on one or two pillows, with the heel free from pressure. Some surgeons prefer to use pneumatic compression instead. The use of such a foot pump has been shown to decrease the foot volume and swelling (3). But, patients often complain of associated pain (3).

Cryocompression, combining cryotherapy and static compression, can be an alternative way to reduce swelling. Cryocompression therapy is hypothesized to result in earlier surgery, hospital discharge, and mobilization. A potential concomitant positive effect of cooling is pain relief and reduced need for analgesics. Pain relief could be explained by the swelling reduction or inhibition of inflammatory response induced by cooling.

The primary aim of this study was to examine the effect of (preoperative and postoperative) cooling versus non-cooling on the pain level in adult patients who sustained an ankle or hindfoot fracture that was treated operatively. Secondary aims were to assess the effect of cooling on analgesics use, patient satisfaction, hospital length of stay, and the rate of complications with associated secondary interventions.

METHODS

Study design

In this single center (level 1 trauma center), retrospective case-control study patients were identified from hospital records based upon their ICD-10 (International Coding of Diseases, 10th revision) code, Diagnosis Related Group (DRG; in Dutch, DBC) code, or surgical intervention code. ICD-10 codes are S92.0 and S82.0, DRG codes are 224 (Ankle), 236 (Calcaneus), 237 (Tarsus), 241 (Talus) and surgical interventions codes are 338633I, 338636C, 338720, 338730P, 338731A, 338732D, 338740A, 338875E. Data were extracted from the patient's medical files.

All adult persons aged 18 years or older who were treated in a level 1 trauma center, between January 1, 2015 and January 1, 2017 for an ankle (uni-, bi-, or trimalleolar)

or hindfoot (*i.e.,* talus or calcaneus) fracture, with and without using a computer-controlled cooling device pre- and postoperatively, were eligible for inclusion. Exclusion criteria were; 1) patients with a known pre-existing pain disorder (*e.g.,* Complex Regional Pain Syndrome); 2) additional traumatic injuries that might have influenced pain; 3) patients with a bilateral, pathological, recurrent, or open fracture; and 4) patients with decreased sensory function in any leg that might have affected pain sensation.

The total group was divided in a cooling group and a matched non-cooling control group. In the control group, patients were matched on age (± 15 years), gender, injured region (*i.e.,* ankle, talus, calcaneus or a combination), malleolar involvement (*i.e.,* uni-, bi-, trimalleolar), and Hawkins fracture classification. For some cases a match based on Essex-Lopresti and/or Sanders classification could not be found, since these classification differences are assumed to hardly effect pain and analgesia, this was accepted. Cryotherapy was performed using a computer-controlled cooling device, the Zamar Therapy cooling device (Zamar Medical, Poreč, Croatia), Figure 1.

Figure 1. Computer-controlled cooling device
The Zamar ZT-cube (Zamar Medical, Poreč, Croatia) computer-controlled cooling device on the left. On the right the ankle and foot wrap. Image from www.zamar.care.com.

Data collection

Patient characteristics (*i.e.,* gender, age at trauma, ASA grade, and comorbidities) and injury characteristics *i.e.,* date of trauma, affected side, trauma mechanism, fracture classifications (4-11) were obtained from the electronic patients' medical files. Furthermore, treatment characteristics, complications (*i.e.,* persistent pain, necrosis, superficial and deep infections, intra-articular implants, and arthrosis), and late interventions (*e.g.,* implant removal, debridement, and revision osteosynthesis) were obtained. Surgical site infections were defined by applying the criteria of the Centers for Disease Control and Prevention (12).

Outcome measures

The primary outcome measure was the level of pain during hospital admission. Data on pain were routinely registered in the patient's medical files during hospital admission. These registered scores were mostly a 10-point Numeric Rating Scale (NRS), which is a verbally administered pain rating scale in which patients rate their pain ranging from 0 (no pain) to 10 (maximum pain) (13). Pain scores may also be registered based upon a 10-centimeter Visual Analog Scale (VAS), in which 0 implies no pain and 10 implies the worst possible pain.

Secondary outcome measures were the use of analgesics, hospital length of stay, patient satisfaction, complications, and secondary interventions.

The dosage analgesics per intervention-day (*i.e.,* cooling or non-cooling) was calculated by dividing the total dosage of administered analgesics during hospital admission by the intervention time during hospital admission. Opioids such as OxyContin, OxyNorm, and Morphine (administered orally, intravenously, or intramuscularly) were converted to an oral opioid equivalence using algorithms from a dedicated software package (Omrekenapp, Version 1.5, EverywhereIM Ltd., Takeda Nederland B.V., Netherlands). Patient satisfaction with regard to the cooling device or non-cooling methods was determined prospectively using a 10-point NRS, in which 0 implies extremely dissatisfied and 10 implies extremely satisfied.

Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.0 (SPSS, Chicago, Ill., USA). Normality of continuous data was tested with the Shapiro-Wilk test, and homogeneity of variances was tested using the Levene's test. A p-value < 0.05 was taken as threshold of statistical significance in all statistical tests, and all tests were two-sided. Missing values were not imputed.

Descriptive analysis was performed in order to report data per group. Continuous data are shown as median and percentiles (P25-P75). Crude numerical data were compared with a Mann-Whitney U-test (non-parametric data), matched data were analyzed using the Wilcoxon Signed Rank test. Categorical data (*e.g.,* rate of adverse events), numbers and frequencies are shown as N (%) and reported per treatment group. Crude categorical data were analyzed using a Fisher's Exact test or Chi-squared test, as applicable. Matched categorical data were analyzed using the McNemar test.

RESULTS

In this case-control study 35 patients were included, 18 patients in the cooling and 17 patients in the non-cooling group (*e.g.,* pressure bandage, plaster cast, or pneumatic compression). One case (patient who used the cooling device) could not be matched to a

control. In the cooling group the median age at trauma was 53 years, 13 patients (72%) were male and most patients (N=11, 31%) had American Society of Anaesthesiologists (ASA) classification of 2, 39% (N=7) of the patients had comorbidities. In the control group, the median age was lower, 44 years (p=0.468), 71% (N=12) was male and an equal percentage was classified as ASA class 1, eight patients (47%) had comorbidities (Table 1).

Table 1: Demographic and injury data for the study population, separated with and without cooling

Parameter	Cooling Crude (N=18)	Cooling Matched (N=17)	No cooling Matched (N=17)	P-value Crude	P-value Matched
Age (years)	53 (39-61)	53 (40-62)	44 (34-64)	0.468	0.031
Male gender	13 (72.2%)	12 (70.6%)	12 (70.6%)	1.000[A]	1.000
ASA					
ASA 1	5 (27.8%)	5 (29.4%)	12 (70.6%)	0.040[B]	0.042
ASA 2	11 (61.1%)	10 (58.8%)	4 (23.5%)		
ASA 3	2 (11.1%)	2 (11.8%)	1 (5.9%)		
ASA 4	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Comorbidities	7 (38.9%)	7 (41.2%)	8 (47.1%)	0.738[A]	1.000
Affected side - Right	9 (50.0%)	9 (52.9%)	6 (35.3%)	0.500[A]	0.453
Trauma					
HET, fall (height)	11 (61.1%)	10 (58.8%)	12 (70.6%)	0.540[B]	N.D.
HET, traffic	4 (22.2%)	4 (23.5%)	3 (17.6%)		
HET, other	0 (0.0%)	0 (0.0%)	1 (5.9%)		
LET, fall	3 (16.7%)	3 (17.6%)	1 (5.9%)		
LET, other	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Ankle fracture	3 (16.7%)	3 (17.6%)	3 (17.6%)	1.000[A]	1.000
Malleolar involvement				1.000[B]	N.D.
Unimalleolar	1 (33.3%)	1 (33.3%)	1 (33.3%)		
Bimalleolar	1 (33.3%)	1 (33.3%)	1 (33.3%)		
Trimalleolar	1 (33.3%)	1 (33.3%)	1 (33.3%)		
Foot fracture	17 (94.4%)	16 (94.1%)	16 (94.1%)	1.000[A]	1.000
Talus fracture	5 (27.8%)	4 (23.5%)	4 (23.5%)	1.000[A]	1.000
Calcaneal fracture	14 (77.8%)	13 (76.5%)	13 (76.5%)	1.000[A]	1.000
Essex-Lopresti				0.695[A]	0.727
Tongue	7 (53.8%)	6 (50.0%)	4 (33.3%)		
Depression	6 (46.2%)	6 (50.0%)	8 (66.7%)		
Additional injuries	8 (44.4 %)	7 (41.2%)	4 (23.5%)	0.289[A]	0.375
Injured regions				0.361[B]	0.172
1	4 (50.0%)	4 (57.1%)	3 (75.0%)		
2	0 (0.0%)	0 (0.0%)	0 (0.0%)		
≥ 3	4 (50.0%)	3 (42.9%)	1 (25.0%)		

N, Number of patients; ASA, America Society Anesthesiologists score; HET, High Energy Trauma; LET; Low Energy Trauma. For the 'Matched p-value' 17 patients in each group were analyzed. For the 'Non-matched p-value' N=18 in the cooling group and N=17 in non-cooling group.

Categorical data are shown as N (%). Crude categorical data were analyzed using a [A]Fisher's Exact test or [B]Chi-squared test. Matched categorical data using the McNemar test.
Continuous data are shown as median (P_{25}-P_{75}). Crude numerical data were analyzed using the Mann-Whitney U-test. Matched numerical data using the Wilcoxon Signed Rank test.

In both groups the most frequent trauma mechanism was fall from height (Table 2). The study population included three ankle fractures in both groups, four talus and thirteen calcaneal fractures in the non-cooling group, and in the cooling group one more talus and one more calcaneal fracture occurred. Multiple ankle or hindfoot injuries per person occurred.

Treatment characteristics are shown in Table 3. After trauma, the median time to surgery was longer in the cooling group (13.5 days; P25-P75 9.3-16.3) than in the control group (8 days; P25-P75 2.5-12.0; p=0.023). The pre-operative hospital length of stay (HLOS) was longer in the cooling group (8 days; P25-P75 4.8-13.0) than in the control group (4 days; P25-P75 2.0-7.0; p=0.008). The most commonly used non-cooling method was plaster cast, nine patients (69.2%).

A significant difference (p=0.020) was found in surgical techniques, in the cooling group more patients (94.4%) were treated with Open Reduction and Internal Fixation (ORIF) compared with 58.5% of the patients in the control group. The latter more often underwent percutaneous (Closed Reduction and Internal Fixation, CRIF) or primary arthrodesis.

Table 2: Treatment data for the study population, separated with and without cooling

Parameter	Cooling Crude (N=18)	Cooling Matched (N=17)	No cooling Matched (N=17)	P-value Crude	P-value Matched
Pre-operative period					
Time trauma to surgery (days)	13.5 (9.3-16.3)	14.0 (10.0-16.5)	8.0 (2.5-12.0)	0.023	0.042
HLOS (days)	8.0 (4.8-13.0)	9.0 (5.0-13.0)	4.0 (2.0-7.0)	0.008	0.021
(Non-)Cooling period (days)	7.0 (4.5-9.0)	7.0 (5.0-9.0)	7.0 (3.3-11.0)	0.928	0.776
Type of non-cooling method				0.530[B]	N.D.
Pressure bandage	N.A.	N.A.	3 (23.1%)		
Plaster cast	N.A.	N.A.	9 (69.2%)		
Pneumatic pump	N.A.	N.A.	0 (0.0%)		
Other	N.A.	N.A.	1 (7.7%)		
Analgesics	16 (88.9%)	15 (88.2%)	11 (64.7%)	0.121[A]	0.219
Paracetamol	16 (88.9%)	15 (88.2%)	11 (64.7%)	0.121[A]	0.219
Total dosage (g)	23.5 (15.5-31.0)	24.0 (17.0-31.0)	16.0 (6.0-24.0)	0.108	0.084
Dosage / day (g)	3.3 (2.9-3.6)	3.3 (2.7-3.5)	2.0 (0.0-3.0)	0.004	0.008
NSAID	9 (50.0%)	8 (47.1%)	6 (35.3%)	0.500[A]	0.727
Total dosage (g)	3.0 (1.6-4.1)	2.9 (1.3-4.2)	0.75 (0.30-3.3)	0.086	0.109
Dosage / day (g)	45 (0-516)	0 (0-457)	0 (0-48)	0.200	0.266
OxyNorm*	12 (66.7%)	11 (64.7%)	8 (47.1%)	0.315[A]	0.549
OxyContin*	9 (50.0%)	8 (47.1%)	5 (29.4%)	0.305[A]	0.453

Parameter	Cooling Crude (N=18)	Cooling Matched (N=17)	No cooling Matched (N=17)	P-value Crude	P-value Matched
Morphine*	0 (0.0%)	0 (0.0%)	1 (5.9%)	0.486[A]	N.D.
Opioid equivalence	13 (72.2%)	12 (70.6%)	9 (52.9%)	0.305[A]	0.508
Total dosage (mg)	188 (56-246)	195 (90-248)	120 (31-274)	0.574	1.000
Dosage / day (mg)	13 (0-29)	11 (0-29)	0 (0-14)	0.049	0.064
PCA	3 (16.7%)	2 (11.8%)	2 (11.8%)	1.000[A]	1.000
Days	2 (N.D.)	1.5 (N.D.)	3 (N.D.)	0.767	N.D.
Surgery				0.020[B]	N.D.
ORIF	17 (94.4%)	16 (94.1%)	10 (58.8%)		
CRIF	0 (0.0%)	0 (0.0%)	4 (23.5%)		
Arthrodesis	0 (0.0%)	0 (0.0%)	3 (17.6%)		
Other	1 (5.6%)	1 (5.9%)	0 (0.0%)		
Post-operative period					
HLOS (days)	5.5 (4.5-8.3)	5.5 (4.5-8.3)	6.0 (2.5-8.0)	0.654	0.592
Total HLOS (days)	14.0 (9.0-17.3)	14.0 (9.0-17.3)	9.0 (5.0-16.5)	0.132	0.305
(Non-)Cooling period (days)	5.0 (0.0-8.0)	5.0 (0.0-7.5)	14.0 (6.0-68.0)	0.002	0.016
Analgesics	12 (66.7%)	11 (64.7%)	16 (94.1%)	0.088[A]	0.125
Paracetamol	11 (61.1%)	10 (58.8%)	16 (94.1%)	0.041[A]	0.070
Total dosage (g)	15.0 (11.0-19.0)	15.5 (10.5-19.5)	16.0 (5.0-28.0)	0.962	0.203
Dosage / day (g)	1.8 (0-3.3)	1.9 (0-3.3)	2.6 (2.0-3.7)	0.037	0.078
NSAID	6 (33.3%)	5 (29.4%)	14 (82.4%)	0.006[A]	0.004
Total dosage (mg)	2.6 (1.6-3.6)	2.0 (1.5-3.4)	1.0 (0.29-3.8)	0.160	0.588
Dosage / day (mg)	0 (0-430)	0 (0-352)	75 (25-474)	0.071	0.363
OxyNorm*	9 (50.0%)	8 (47.1%)	14 (82.4%)	0.075[A]	0.146
OxyContin*	11 (61.1%)	10 (58.8%)	10 (58.8%)	1.000[A]	1.000
Morphine*	0 (0.0%)	0 (0.0%)	0 (0.0%)	N.D.	1.000
Opioid equivalence	11 (61.1%)	10 (58.8%)	14 (82.4%)	0.264[A]	0.344
Total dosage (mg)	150 (83-225)	150 (79-242)	113 (71-311)	0.661	0.150
Dosage / day (mg)	16.9 (0-29.3)	15.0 (0-30.6)	24 (3-41)	0.341	0.523
PCA	3 (16.7%)	2 (11.8%)	4 (23.5%)	0.691[A]	0.625
Days	2 (N.D.)	1.5 (N.D.)	3 (1.5-9.8)	0.589	N.D.

* OxyContin, OxyNorm, and Morphine per os, intravenous, or intramuscular were converted to an opioid equivalence. N, number of patients; HLOS, Hospital length of Stay; NSAID, Non-Steroidal Anti-Inflammatory Drugs; ORIF, Open Reduction and Internal Fixation; CRIF, Closed Reduction and Internal Fixation; PCA, Patient Controlled Analgesia pump.

Categorical data are shown as N (%). Crude categorical data were analyzed using a [A]Fisher's Exact test or [B]Chi-squared test. Matched categorical data using the McNemar test.

Continuous data are shown as median (P_{25}-P_{75}). Crude numerical data were analyzed using the Mann-Whitney U-test. Matched numerical data using the Wilcoxon Signed Rank test.

Analgesics

Table 3 shows that 16 patients (88.9%) in the cooling group used at least one analgesic during hospital stay, 11 patients (64.7%) in the non-cooling group used analgesics (p=0.219). Pre-operatively patients in the cooling group used significantly more paracetamol (3.3 grams versus 2.0 grams, p=0.004) and opioids (13 mg versus 0 mg, p=0.049) per day.

After surgery, eleven patients (61.1%) in the cooling group used paracetamol, in contrast with 16 patients (94.1%) in the non-cooling group (p=0.041). Not only the number of patients but also the dose of paracetamol per day was higher in the non-cooling group (2.6 grams versus 1.8 grams, p=0.037). The same applies to the Non-Steroidal Anti-Inflammatory Drugs (NSAID). Six versus 14 patients (p=0.006) in respectively the cooling and non-cooling group used a NSAID. No significant difference could be demonstrated concerning the number of patients using opioids (p=0.264) and the daily dosage opioids (p=0.341). Same accounts for the number of patients (p=0.691) using Patient Controlled Analgesia (PCA) and the amount of days using PCA (p=0.589).

Pain

The median VAS pain scores for the case and control groups are depicted in Figure 2A. The difference (cooling minus non-cooling) of the matched case-control sets is shown in Figure 2B. On most days the line lies below zero, which suggests that cooling provides pain reduction. However, due to the fact the confidence band is intersecting the x-axis, it is not possible to conclude this is statistically significant different. Six days before surgery the median VAS pain in the cooling group was 1.5 points (P25-P75 0.0-3.3) versus 5.0 points (P25-P75 4.0-6.0) in the non-cooling group (p=0.051). The day before surgery patients who used the cooling device reported a VAS pain of 2.5 points (P25-P75 1.7-3.5) versus a median of 4.0 points (P25-P75 2.3-5.4; p=0.062) in the non-cooling group. One week after surgery, the difference was again less pronounced, a median of 1.0 points (P25-P75 1.0-1.0) in the cooling group versus 3.5 points (P25-P75 1.5-6.1; p=0.277) in the non-cooling group.

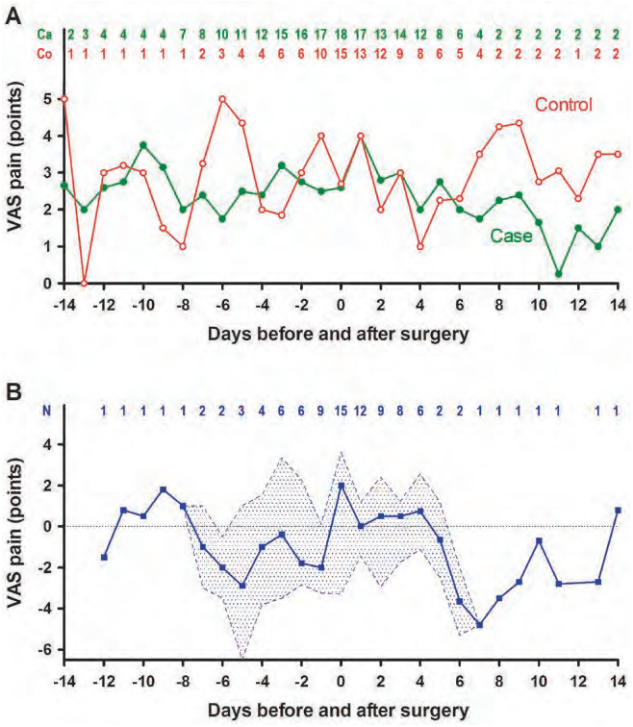

Figure 2. Pain scores

A. An overview of the median VAS pain scores per day from 14 days before and after surgery, the case and control group separated. The day of surgery is indicated as '0' on the x-axis. In the rows in the upper part of the figure 'Ca' is the number of cases and 'Co' is the number of controls at each time point with available VAS pain scores. **B.** The median VAS pain scores for matched case-control sets, the blue line is the result of cooling minus non-cooling VAS pain scores. Data are reported as median with confidence band (blue dotted area). Data below the zero-line suggests that cooling provides pain reduction. N; number of patients and VAS pain scores used to calculate the case-control sets.

Adverse events and revision surgery

In Table 4 the adverse events and revision surgeries are shown. In the cooling group 33.3% (six patients) developed an adverse event versus 35.3% (six patients) in the non-cooling group. Six patients (33.3%) in the cooling group versus three (17.6%) in the non-cooling group (p=0.375) had complaints of persistent pain. Although overall less (five, 27.8%) patients required revision surgery in the cooling group, versus six patients (35.3%) in the non-cooling group, a significant difference could not be demonstrated. In the non-cooling group more patients had to undergo implant removal (N=5, 29.4%), debridement (N=1, 5.9%), subtalar arthrodesis (N=1, 5.9%) and myocutaneous flap reconstructions (N=1, 5.9%), compared with the cooling group.

Table 3: Outcome parameters, separated with and without cooling

Outcome	Cooling Crude (N=18)	Cooling Matched (N=17)	No cooling Matched (N=17)	P-value Crude	P-value Matched
VAS Satisfaction	8 (8-9)	8.5 (7.8-9.3)	8 (4.8-9)	0.233	0.285
Adverse events	6 (33.3%)	5 (29.4%)	6 (35.3%)	1.000[A]	1.000
Persistent Pain	6 (33.3%)	5 (29.4%)	3 (17.6%)	0.443[A]	0.375
Necrosis	0 (0.0%)	0 (0.0%)	1 (5.9%)	0.486[A]	N.D.
Infection superficial	1 (5.6%)	1 (5.9%)	0 (0.0%)	1.000[A]	N.D.
Infection deep	0 (0.0%)	0 (0.0%)	1 (5.9%)	0.486[A]	N.D.
Intra-articular screw	0 (0.0%)	0 (0.0%)	2 (11.8%)	0.229[A]	N.D.
Arthrosis	0 (0.0%)	0 (0.0%)	1 (5.9%)	0.486[A]	N.D.
Non-union	0 (0.0%)	0 (0.0%)	0 (0.0%)	N.D.	N.D.
Revision surgery	5 (27.8%)	4 (23.5%)	6 (35.3%)	0.725[A]	0.727
Implant removal	5 (27.8%)	4 (23.5%)	5 (29.4%)	1.000[A]	1.000
Debridement	0 (0.0%)	0 (0.0%)	1 (5.9%)	0.486[A]	N.D.
Subtalar arthrodesis	0 (0.0%)	0 (0.0%)	1 (5.9%)	0.486[A]	N.D.
Myocutaneous flap	0 (0.0%)	0 (0.0%)	1 (5.9%)	0.486[A]	N.D.

Categorical data are shown as N (%). Crude categorical data were analyzed using a [A]Fisher's Exact test or [B]Chi-squared test. Matched categorical data using the McNemar test.
Continuous data are shown as median (P_{25}-P_{75}). Crude numerical data were analyzed using the Mann-Whitney U-test. Matched numerical data using the Wilcoxon Signed Rank test.

Patient satisfaction

Patients rated cooling versus non-cooling similar. An eight (P25-P75 8-9) out of ten points was given by patients in the cooling group, and also an eight (P25-P75 4.8-9) in the non-cooling group, p=0.233.

DISCUSSION

In this study a beneficial effect on pain and post-operative need for analgesics was seen in patients with ankle or hindfoot fractures using cryocompression therapy via a computer-controlled cooling device. Before surgery, the dosage per day of paracetamol and opioids was higher in the cooling group than in the non-cooling group, however the number of patients using these analgesics did not statistically differ. No differences in complications and revision surgery rates were found. Patients were highly and equally (compared with non-cooling) satisfied with cooling before and after surgery.

Cryocompression therapy has been investigated in the past, often in elective knee surgery (*e.g.,* arthroscopy and anterior cruciate ligament reconstructions). Although effects on pain could not always demonstrated (14, 15), the positive effect of cooling on VAS and Likert pain scores, analgesics use, and range of motion is described (16-18).

Iatrogenic hypothermic injury in the treatment of traumatic injuries is a rare complication and to our knowledge only described once in literature (19). Treatment with the computer-controlled cooling device is widely used and assumed safe, however research on cryotherapy for traumatic injuries is scarce. In this study none of the patients reported severe cryotherapy-related (*e.g.,* hypothermia) complications of the ankle or foot.

A significant difference in age between the cooling and non-cooling group was noted. As patients were matched among others on age (± 15 years), this difference occurred due to chance. The age difference is however not likely relevant for the primary clinical outcome measures. Besides, patients in the control group are younger, suggesting results of the cooling effects are underestimated.

Despite cooling is intended to result in earlier surgery, the time to surgery was significantly longer in the cooling group (13 days) than in the non-cooling group (8 days).

This might be explained by coincidence. However, not the time to surgery but the time to 'fit' for surgery is important, which could be determined based on the wrinkle sign. A significant difference in surgical techniques was found, ORIF was statistically significant more often performed in the cooling group than in the non-cooling group. It is unknown whether this difference could be explained by less swelling (more wrinkling) due to cooling. The more invasive ORIF might also be associated with more pain. Unfortunately, the sample size is too low for a multivariable analysis in which a potentially confounding effect of treatment on pain could be analyzed. If the only effect of cooling is pain reduction, in terms of less paracetamol and lower VAS pain scores, then cooling would be an expensive option. Therefore, prospective studies are required with an actual time to 'fit for surgery', pain levels, analgesic use, swelling reduction, cost effectiveness and complications.

Also the hospital length of stay was longer in the cooling group than in the non-cooling group. These findings can be explained due to guidelines for new implemented techniques, in which patients who used the computer-controlled cooling device had to be admitted pre-operatively for a (longer) period of time. Nowadays, more than two years of experience, all patients can be and are treated in an outpatient setting.

Remarkably, the daily amount of paracetamol and opioids taken before surgery were higher in the cooling group than in the non-cooling group. An association between opioids use and hospital length of stay seems logical, since a patient can be checked regularly the threshold to prescribe opioids is much lower during clinical admission. Furthermore, of the patients who were not admitted, mostly patients in the non-cooling group, the medication data was less accurate as only the administered analgesics during hospital admission were concerned in this study. Above mentioned might distort the findings on pre-operatively used analgesics.

A limitation of this study is the lack of one single outcome for analgesic use, an increase in administered opioids does not naturally mean an increase or decrease in paracetamol or NSAID use. For this reason, individual analgesic requirements are hard to compare. Another limitation associated with the retrospective design of the study is the

fact that patients received medication following standard hospital protocols, ideally (or in a prospective study) patients would receive analgesics on request to truly measure the analgesic need. Otherwise it is uncertain whether the patient actual requested the analgesics to control the pain or just followed hospital protocols. Furthermore, it is unclear whether patients were actually cooling at the moment of pain assessment, an inherent limitation of a retrospective study. Some patients in the cooling group were treated partly with a non-cooling method before and after surgery. This study however solely focused on the analgesics, VAS pain scores, and other outcome measures during the actual cooling-period.

CONCLUSION

Patients with ankle or hindfoot fractures seem to benefit from computer-controlled cooling, since equal pain sensation is feasible with less analgesics post-operatively, whereas rates of complications and revision surgeries were comparable in both groups. Patients were highly satisfied with cooling. Prospective studies are required in order to strengthen these findings.

REFERENCES

1. Buckley R, Tough S, McCormack R, Pate G, Leighton R, Petrie D, et al. Operative compared with nonoperative treatment of displaced intra-articular calcaneal fractures: a prospective, randomized, controlled multicenter trial. J Bone Joint Surg Am. 2002;84-A(10):1733-44.
2. Luiten WE, Schepers T, Luitse JS, Goslings JC, Hermanides J, Stevens MF, et al. Comparison of continuous nerve block versus patient-controlled analgesia for postoperative pain and outcome after talar and calcaneal fractures. Foot Ankle Int. 2014;35(11):1116-21.
3. Thordarson DB, Greene N, Shepherd L, Perlman M. Facilitating edema resolution with a foot pump after calcaneus fracture. J Orthop Trauma. 1999;13(1):43-6.
4. Fracture and dislocation compendium. Orthopaedic Trauma Association Committee for Coding and Classification. J Orthop Trauma. 1996;10(Suppl : v-ix):1-154.
5. Sanders R, Fortin P, DiPasquale T, Walling A. Operative treatment in 120 displaced intraarticular calcaneal fractures. Results using a prognostic computed tomography scan classification. Clin Orthop Relat Res. 1993(290):87-95.
6. Essex-Lopresti P. The mechanism, reduction technique, and results in fractures of the os calcis. Br J Surg. 1952;39(157):395-419.
7. Hawkins LG. Fractures of the neck of the talus. J Bone Joint Surg Am. 1970;52(5):991-1002.
8. Danis R. Theorie et pratique de l' osteosynthese. Paris, France: Masson & Cie. 1949.
9. Weber BG. Die verletzungen des oberen sprunggelenkes 2nd ed Bern, Switzerland: Huber. 1972.
10. Muller ME AM, Schneider R, Willenegger H. . Manual of internal fixation 3rd ed Bern, Switzerland: Springer. 1991:595-612.
11. Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: retrospective and prospective analyses. J Bone Joint Surg Am. 1976;58(4):453-8.
12. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. Am J Infect Control. 1999;27(2):97-132; quiz 3-4; discussion 96.
13. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Res (Hoboken). 2011;63 Suppl 11:S240-52.
14. Daniel DM, Stone ML, Arendt DL. The effect of cold therapy on pain, swelling, and range of motion after anterior cruciate ligament reconstructive surgery. Arthroscopy. 1994;10(5):530-3.
15. Kraeutler MJ, Reynolds KA, Long C, McCarty EC. Compressive cryotherapy versus ice-a prospective, randomized study on postoperative pain in patients undergoing arthroscopic rotator cuff repair or subacromial decompression. J Shoulder Elbow Surg. 2015;24(6):854-9.
16. Martimbianco AL, Gomes da Silva BN, de Carvalho AP, Silva V, Torloni MR, Peccin MS. Effectiveness and safety of cryotherapy after arthroscopic anterior cruciate ligament reconstruction. A systematic review of the literature. Phys Ther Sport. 2014;15(4):261-8.
17. Barber FA, McGuire DA, Click S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. Arthroscopy. 1998;14(2):130-5.
18. Murgier J, Cassard X. Cryotherapy with dynamic intermittent compression for analgesia after anterior cruciate ligament reconstruction. Preliminary study. Orthop Traumatol Surg Res. 2014;100(3):309-12.
19. Hoiness PR, Hvaal K, Engebretsen L. Severe hypothermic injury to the foot and ankle caused by continuous cryocompression therapy. Knee Surg Sports Traumatol Arthrosc. 1998;6(4):253-5.

Chapter 7

Soft tissue complications in patients with a tongue-type versus non-tongue-type displaced intra-articular calcaneal fracture: an international retrospective cohort study

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ABSTRACT

Introduction: Tongue-type displaced intra-articular calcaneal fractures (DIACF) are associated with a specific pattern of fracture displacement in contrast to joint depression fractures. This may result in tension of soft tissue in the posterior part of the heel. Tension-induced ischemia can result in skin necrosis. The objectives of this study were to investigate whether patients with tongue-type calcaneal fractures exert a higher risk of complications, especially of the posterior soft tissues, than joint depression type fractures. Also, late interventions (*e.g.,* antibiotics, debridements, and amputations) and the effect of timing of surgery on the complication rate was assessed.

Methods: In this international retrospective cohort study, data of adult patients with a DIACF in the period January 1, 2005 to December 31, 2015 were extracted from patients' medical files. Descriptive, univariate, and multivariable analyses were performed in SPSS.

Results: A total of 560 patients with 632 DIACF were included (295 tongue-type and 337 non-tongue-type fractures). At hospital presentation, 20.3% of the patients with a tongue-type fracture had compromised posterior soft tissue versus 12.8% with non-tongue-type fractures (p=0.032). However, corrected for potential confounders the risk was no longer statistically significant (OR 1.497; 95% CI 0.831-2.696). Patients with a TT-DIACF had a 1.2 to 3.4-fold higher rate of any local wound complication (deep infections, and full thickness lesions, p<0.03). In addition, they had 2.0 to 8.0-fold more intravenous antibiotics, debridements, soft tissue coverage procedures and amputations (p<0.03). Patients who underwent surgery within two days after trauma had a higher risk to develop any complication, in particular superficial infections, when compared to surgery between 3-7 days, but no significant difference between 3-7 and ≥ 8 days could be demonstrated.

Conclusion: Despite the fact that patients with a tongue-type fracture developed posterior skin and soft tissue compromise nearly twice as often, this difference disappeared after correction for confounders. The overall complication risk was increased in patients with tongue-type calcaneal fractures as compared to patients with a non-tongue-type fracture. Whether or not patients with tongue-type fractures require immediate surgery cannot be concluded from the data.

INTRODUCTION

According to Essex-Lopresti displaced intra-articular calcaneal fractures (DIACFs) can be divided, into either tongue-type or joint depression patterns (1). In a tongue-type DIACF, the fracture line disperses longitudinally from the articular surface and exits posteriorly through the calcaneal tuberosity. Hereby, the posterior tuberosity fragment is displaced superiorly and dorsally due to traction of the Achilles tendon and plantar fascia. This specific pattern of fracture displacement easily results in significant pressure on and tension to the skin covering the posterior part of the calcaneus. Too much or prolonged tension may aggravate trauma-induced soft tissue injury, due to additional soft tissue ischemia, and finally necrosis, and thus converting a closed fracture into an open one (Figure 1). Posterior skin compromise is described to occur in 21% of the patients with tongue-type calcaneal fractures (2).

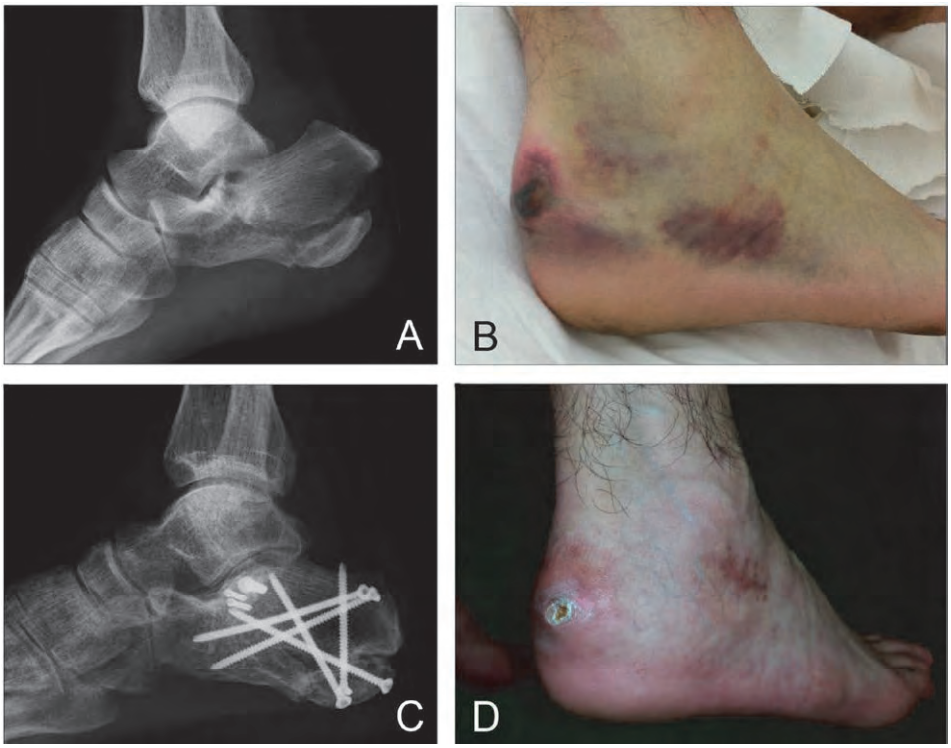

Figure 1. A. Lateral radiograph of a tongue-type DIACF at first hospital presentation, with severe displacement of the posterior tuberosity of the calcaneus. **B.** Presence and impending posterior soft tissue compromise (*e.g.,* hematoma, blisters, and necrosis) due to the specific fracture displacement resulting in high tension on the skin. **C.** Status after Open Reduction and Internal Fixation (ORIF), 5 months after trauma. **D.** Wound healing after ORIF via Sinus Tarsi Approach.

Displaced intra-articular calcaneal fractures are often managed operatively (3). Postoperative wound infections occur frequently, often resulting in delayed wound healing and prolonged length of hospital stay, and sometimes in permanent iatrogenic disability (4, 5). In order to decrease the number of wound complications, it was thought that patients would benefit from delayed operative fixation of calcaneal fractures (6). However, failure to detect ongoing soft tissue deterioration during the (preoperative) period may also lead to additional soft tissue morbidity (1, 5). It is the question whether a delayed surgical procedure is suitable for all calcaneal fractures.

Reversible skin ischemia (*i.e.,* compromised skin perfusion due to the specific fracture displacement) may progress into irreversible skin necrosis if patients with tongue-type DIACFs are not operated on immediately (2, 7). To date, little has been reported on posterior soft tissue complications associated with tongue-type calcaneal fractures.

The primary aim, of this study was to compare the rate of posterior soft tissue compromise in adult patients with a tongue-type versus non-tongue-type DIACF. Secondary aims were 1) to compare the rate of other complications; 2) to compare the rate of late interventions; and 3) to examine the effect of timing of surgery on the complication rate.

METHODS

Study design

In this international, retrospective cohort study patients were identified from hospital records based upon their ICD-10 (International Coding of Diseases, 10th revision) code S92.0, Diagnosis Related Group (DRG; in Dutch, DBC) code 236, or hospital specific surgical intervention codes. Data were extracted from the patient's medical files in the three participating hospitals.

Adult patients aged 18 years or older who were treated for a unilateral or bilateral DIACF (Essex-Lopresti tongue-type or joint depression type and Sanders type II-IV) between January 1, 2005 and December 31, 2015 were eligible for inclusion if a clinical follow-up of at least three months was documented. Patients suffering from local skin conditions that were not related to the fracture itself, but could influence outcome (*e.g.*, burn or chemical wounds or pre-existing skin conditions in the affected foot region for example resulting from diabetes mellitus or venous insufficiency) and patients with a pathological calcaneal fracture were excluded. Open fractures, not caused by direct external trauma, were not excluded

Data collection

Patient characteristics (*i.e.,* gender, age at trauma, ASA grade, Body Mass Index (BMI), comorbidities, and medication use), injury characteristics (*i.e.,* date of trauma, affected side, trauma mechanism, fracture classifications (1, 8), soft tissue compromise, injury classifications (9), and radiographic measurements (2, 10)), treatment characteristics (*i.e.,* admission duration, method of swelling reduction, treatment type: Open Reduction and Internal Fixation (ORIF), Closed Reduction and Internal Fixation (CRIF), primary arthrodesis or non-operative treatment (*i.e.,* plaster cast, a pressure bandage or PTB-Brace), initial soft tissue coverage), complications, and late interventions were obtained from the electronic patient's medical files.

Compromise was defined as the lack of sufficient blood supply for soft tissue to remain viable. Compromise is defined as a reversible condition, but could potentially result in more severe (*e.g.,* infection), or irreversible conditions (*e.g.,* necrosis). Soft tissue compromise is limited to the posterior part of the foot. Compromise at the anterior, lateral, and medial side were not registered as compromise, nor was compromise caused by external trauma. In this study the following conditions are registered as compromise, when occurred within three weeks post trauma (or until the start of initial operative intervention, for patients treated operatively): hematoma, contusion, blisters, threatened skin (*i.e.,* pallor or collateral blanchable redness of the skin), ischemia, partial thickness lesion (*i.e.,* loss of integrity of the skin and subcutaneous tissue as result of prolonged ischemia), and full thickness lesion (i.e. communicating with periosteum, open fracture).

The following post-operative complications, although not all causally related to the operation, were collected: abrasion, hematoma, swelling, blisters, pallor, partial or full thickness lesion, necrosis, superficial infection (*i.e.,* non-operative treatment, no admission, possibly oral antibiotics), deep infection (*i.e.,* surgical intervention, admission, possibly intravenous antibiotics), compartment syndrome, implant failure, secondary dislocation, malalignment, non-union, sural nerve injury, tendon injury, paresthesia, persistent pain, or arthritis.

The research physician and research assistant measured Böhler's angles and classified radiographs according to the Essex-Lopresti classification.Any disputes were dissolved by consensus. Patients with bilateral fractures consisting of one tongue-type and one non-tongue-type fracture were placed (and analyzed) based on the type of fracture at the right side. Patients who had additional injuries were described as 'polytrauma'.

Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.0 (SPSS, Chicago, Ill., USA). The Youden index was analyzed using MedCalc version 14.10.2 (MedCalc Software, Ostend, Belgium). This index is the difference between the true positive rate and the false positive rate and respresents the optimal cut-off point

for timing of surgery. Normality of continuous data were tested with the Shapiro-Wilk test, and homogeneity of variances was tested using the Levene's test. A p-value < 0.05 was taken as threshold of statistical significance in all statistical tests, and all tests were two-sided. Missing values were not imputed.

Descriptive analysis was performed in order to report patient characteristics, injury-related variables and treatment-related variables per group. Differences between groups were tested using Student's T-test or Mann-Whitney U-test (parametric and non-parametric continuous data, respectively) or a Chi-squared or Fisher's exact test (categorical data).

Univariate analysis of the rate of posterior soft tissue compromise was done using a Chi-squared test. Multivariable analysis was done as secondary analysis. Treatment and other variables that could potentially distort the association between fracture type and soft tissue compromise were included in this model as covariates. Covariates were selected based upon literature data, by eyeballing the descriptive statistics and the covariates with a p<0.200 in the univariate analysis (Supplemental Tables 2-12). Odd's ratio (OR) are reported with 95% confidence interval and p-value.

RESULTS

In total 735 patients were identified of whom 565 patients met the inclusion criteria. Five patients were excluded; one patient had a pre-existent local skin condition that was not related to the fracture, two patients had a primary amputation, and two patients had an unknown Essex-Lopresti classification). This resulted in 560 included patients with 632 fractures (72 bilateral fractures); 295 (46.7%) had a tongue-type calcaneal fracture and 337 (53.3%) a non-tongue-type fracture (*i.e.,* joint-depression type or severely comminuted calcaneal fractures). Of the patients with bilateral fractures, 18 patients had a tongue-type fracture on the right side and a non-tongue-type fracture on the left side and were thus analyzed in the tongue-type group. The reverse applied to 11 patients.

The mean age of the patients in the tongue-type group was significantly lower than in the non-tongue-type group (42 versus 46 years, p = 0.006; Supplemental Table 1). Other covariates such as gender, BMI, ASA scores, smoking status, alcohol consumption, comorbidities (except psychiatric), and medication usage did not differ significantly between the two groups. Significantly more patients had a psychiatric disorder in the tongue-type fracture group (18.6% versus 11.6%, p = 0.027). In the tongue-type group 247 (83.7%) patients were treated operatively compared with 285 (84.6%) patients in the non-tongue-type group (p = 0.827). Significantly more polytrauma patients were observed in the tongue-type group (47.6% versus 38.9%, p = 0.040, Supplemental Table 1).

Posterior soft tissue compromise

Posterior soft tissue compromise at hospital presentation was documented in 37 (20.3%) of 182 tongue-type fractures, versus 26 (12.8%) of the 203 non-tongue-type fractures (p = 0.032). A tongue-type fracture appeared to be a risk factor for developing posterior soft tissue compromise (OR 1.715; 95% CI 1.012-2.909; Table 1), but after correction for confounders this was no longer significant (OR 1.497; 95% CI 0.831-2.696). Supplemental Tables 1-12 show the various covariates used in the multivariable analysis.

Table 1: Posterior soft tissue compromise and complications in tongue-type versus non-tongue-type DIACFs

Variable	OR (95% CI) Crude	P-value	OR (95% CI) Adjusted	P-value
Posterior soft tissue compromise[A]	**1.715 (1.012-2.909)**	**0.045**	1.497 (0.831-2.696)	0.179
Complications				
Any complication[B]	**1.546 (1.121-2.130)**	**0.008**	**1.813 (1.178-2.791)**	**0.007**
Infection[C]	1.351 (0.925-1.974)	0.120	**1.728 (1.082-2.761)**	**0.022**
Superficial[D]	1.003 (0.622-1.618)	0.989	1.209 (0.700-2.088)	0.496
Deep[E]	**1.695 (1.074-2.673)**	**0.023**	1.619 (0.948-2.767)	0.078
Lesions				
Full Thickness[F]	**3.585 (1.404-9.155)**	**0.008**	**3.043 (1.063-8.714)**	**0.038**
Partial Thickness[G]	1.208 (0.674-2.164)	0.526	0.702 (0.329-1.498)	0.360
Necrosis[H]	1.777 (0.925-3.413)	0.084	1.244 (0.590-2.621)	0.566
Non-union[I]	1.236 (0.586-2.605)	0.578	1.172 (0.454-3.024)	0.743

OR is shown for tongue-type fractures compared with non-tongue-type fractures.

Data are shown as Odds Ratio (OR) with (95% Confidence Interval (CI)) and analyzed using a multivariable logistic regression model. Outcomes are corrected for all relevant covariates with p<0.200 after univariate analysis (shown in supplemental tables 2-12).

A. Corrected for Böhler's angle at trauma, smoking, psychiatric disorder.

B. Corrected for BMI, Delay to Emergency Department, Böhler's angle at trauma, Hospital length of stay, ASA class, smoking, open or closed fractures, soft tissue injury at trauma, Diabetes Mellitus, additional injury, operative or non-operative treatment.

C. Corrected for BMI, Böhler's angle at trauma, Hospital length of stay, smoking, open or closed fractures, operative or non-operative treatment.

D. Corrected for Age, BMI, smoking, open or closed fractures, comorbidities, medication, soft tissue injury at trauma, operative or non-operative treatment.

E. Corrected for Böhler's angle at trauma, Hospital length of stay, smoking, open or closed fractures, operative or non-operative treatment.

F. Corrected for Hospital length of stay, smoking, operative or non-operative treatment.

G. Corrected for Delay to Emergency Department, Böhler's angle at trauma, Hospital length of stay, smoking, trauma mechanism, unilateral or bilateral fractures, additional injury, operative or non- operative treatment.

H. Corrected for Hospital length of stay, ASA class, smoking, open or closed fractures, soft tissue injury at trauma, time to surgery, operative or non-operative treatment.

I. Corrected for BMI, Böhler's angle at trauma, Hospital length of stay, smoking, trauma mechanism, open or closed fractures, soft tissue injury at trauma, operative or non-operative treatment.

Complications and late interventions

As secondary objectives the rate of other complications and late interventions in patients with a tongue-type versus non-tongue-type calcaneal fracture was examined. In total 59.2% of the patients developed a complication. In patients with a tongue-type fracture significantly higher rates of overall complications (64.7% versus 54.3%, p = 0.009), deep infections (17.3% versus 11.0%, p = 0.028), and full thickness lesions (6.1% versus 1.8%, p = 0.006) occurred.

Patients with a tongue-type fracture had an 1.5 to 3.6 fold higher odds of developing any complication, posterior soft tissue compromise, deep infection, and full thickness lesion. In a subgroup of operatively treated patients, patients with a tongue-type fracture had a 1.7 to 3.2 fold higher odds to develop any complication, deep infection, and full thickness lesion. No significant difference between fracture types were found in non-operated patients. A multivariable analysis (Table 1) showed a 1.8 to 3.0 fold higher odds for patients with tongue-type fractures of developing any complication or full thickness lesion, but no significant higher risk of deep infection.

Although the total rate of late interventions did not differ between the two groups, significantly more amputations (2.4% versus 0.3%, p = 0.028), more debridements (14.9% versus 7.1%, p = 0.002), more treatment with intravenous antibiotics (15.3% versus 7.7%, p = 0.003), and more soft tissue coverage procedures (12.2% versus 5.3%, p = 0.003) were performed in patients with a tongue-type fracture.

Timing of surgery in patients with tongue-type calcaneal fractures

Next, the association between time to surgery and rate of (soft tissue) complications in patients with tongue-type DIACFs was investigated. Patients were stratified in four groups; operated between 0-2 days, 3-7 days, 8-14 days, and ≥ 15 days. The surgical delay differed significantly in patients who developed infections (p=0.009), deep infections (p=0.034), full thickness lesions (p=0.002), and non-union (p=0.016; Supplemental Tables 6, 8, 9, and 12).

Any complication ($OR_{surgery}$ 2.312; 95% CI 1.236-4.324) or infection (OR 4.197; 95% CI 1.446-12.073) occurred more often in operatively treated patients than non-operatively treated patients (Figure 2). Patients who underwent (and most likely needed, because of their soft tissue conditions) surgery within two days after trauma (t=0-2d) had a higher odds to develop any complication (OR 3.548; 95% CI 1.176-10.711) or infection (OR 2.920; 95% CI 1.095-7.787), in particular superficial infections (OR 4.144; 95% CI 1.230-13.763) than surgery between 3-7 days after trauma. The other outcomes seemed unrelated to surgical timing.

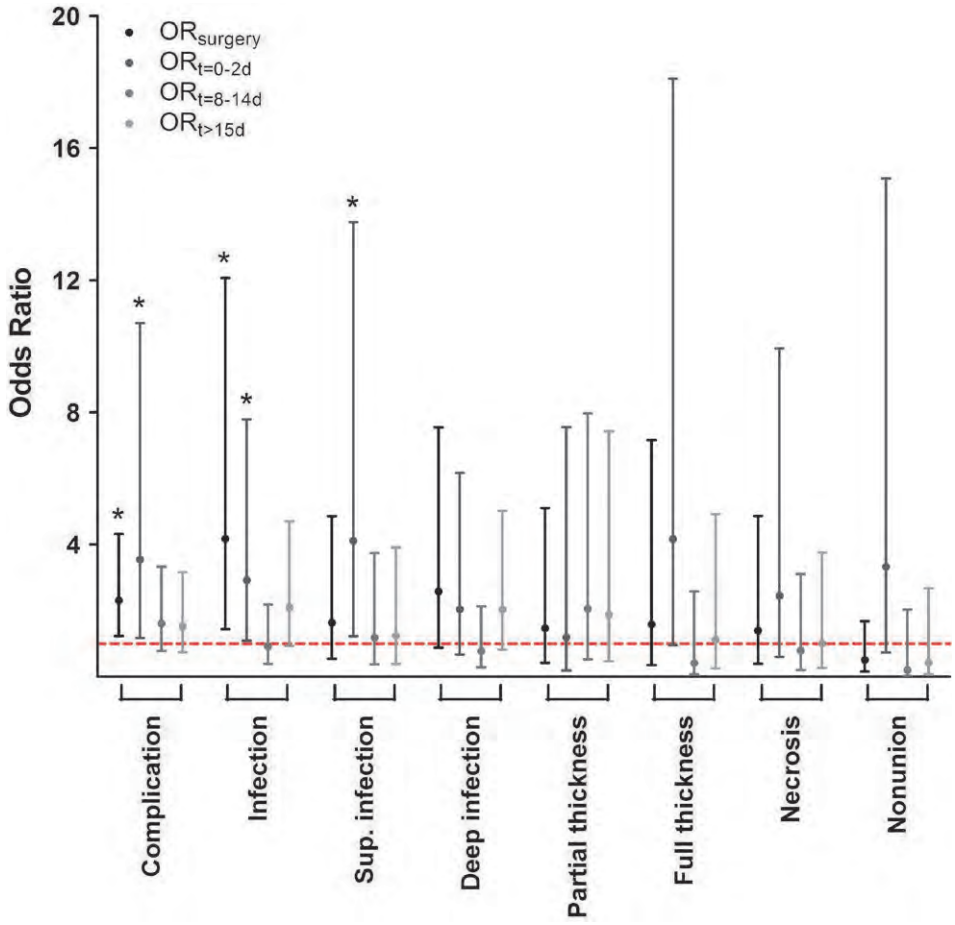

Figure 2. Odds Ratios (OR) for patients with a tongue-type DIACF. The 'time to surgery' categories (t=0-2, t=8-14, and t ≥ 15 days) are shown with 3-7 days as reference. OR are shown with a 95% Confidence Interval. The dotted red line represents OR=1. Complication is the overall complication risk, and is subdivided in infection, partial and full thickness laesions, necrosis and nonunion. Infection in turn is subdivided in superficial and deep infections. $OR_{surgery}$, OR for operated patients; *, significance.

DISCUSSION

This study shows that posterior skin and soft tissue compromise at hospital presentation occurred in 20.3% of the patients with a tongue-type fracture versus 12.8% in patients with a non-tongue-type fracture. This result is in line with the findings of Gardner *et al.*, who studied solely tongue-type calcaneal fractures and found posterior skin compromise in 20.9% (29 of total 139) of the tongue-type fractures at hospital presentation (2). Although posterior skin and soft tissue compromise occurred nearly twice as often in patients with a tongue-type fracture than in patients with a non-tongue-type frac-

ture, this statistically significant difference disappeared after correction for confounders. Nevertheless, our findings and the current literature should alert clinicians about the potential pathomechanism of the specific fracture displacement in tongue-type calcaneal fractures (2, 7, 11, 12), to prevent soft tissue damage and the disastrous sequelae (13). Awareness of orthopaedic trauma surgeons about these risks should guide treatment decision (*e.g.,* urgent fracture reduction and frequent monitoring of soft tissue conditions) to improve patient' outcomes and reduce complications.

The results of this study furthermore demonstrated an increased risk of developing overall complications, deep infections, and full thickness lesions in patients with a tongue-type DIACF compared with patients with a non-tongue-type fracture. To our knowledge, no other studies did investigate these specific outcomes in tongue-type fractures.

Patients with a tongue-type fracture were significantly more often polytrauma patients (47.6% versus 38.9%). This might be caused by the higher rate of high energy trauma (falls from height) in the tongue-type group. Whether this in turn is due to the significant higher rate of psychiatric disorders in this group was not investigated in this study. Gardner *et al.* found 54% additional injuries in patients with tongue-type fractures (2), which is in line with our findings.

The question whether earlier surgery of (tongue-type) calcaneal fractures would reduce the rate of complications could not be answered based on the current data. Based on, among others, patients numbers, the earliest group was chosen as surgery within two days. Since ischemia by then will often already progressed into necrosis, the optimal time window for immediate surgery should be (much) shorter.. In this study, very few patients (N=20) underwent surgery at the day of trauma. Data suggests that these patients were selected for immediate surgery based on their overall worse clinical conditions or injury severity at hospital presentation. These 20 patients had a higher rate of comorbidities (62.5% versus 39.8%), High Energy Trauma (100% versus 61.0%), additional injuries (72.2% versus 41.2%), open fractures (55.0% versus 4.4%), and posterior compromise (25.0% versus 9.9%). The Böhler's angle was more flattened (-5.5° (P50-P75 -38.3 – 18.5) versus 8.0° (P50-P75 -4.0 – 17.0)), In addition to a poorer clinical condition, these patients also had poorer outcome as shown by higher rates of any complication (85.0% versus 61.3%), infection (35.0% versus 23.9%), necrosis (20.0% versus 5.8%), and revision surgery (80.0% versus 51.5%), and consequently a prolonged hospital length of stay was longer (23 days (P50-P75 7 – 54) versus 7 days (P50-P75 5-15)). Without prospective data, no conclusion can be drawn regarding the need for immediate surgery of tongue-type fractures.

One of the limitations associated with the retrospective design of this study is the data completeness in medical files. In daily practice, the post-traumatic skin condition is often not noted in medical files or noted without the exact location of a lesion. Without prospective outcome assessment, underreporting of soft tissue compromise cannot be excluded. Partly due to the lack of details about location of the soft tissue compromise,

the statistical power was insufficient to adequately answer the primary objective. With the current sample size the statistical power was 50.1%; an adequate power would require twice as many patients. As consecutive patients were included based on predefined eligibility criteria, a representative population is investigated and selection bias is minimised. As with any retrospective study, (some) bias likely has occurred due to surgeon-specific criteria for surgery and timing of surgery, and due to incomplete reporting of data in the patients' medical files. Strengths of this international retrospective cohort study are the large patient population with a relative rare traumatic injury, strong methodological design, and the relevant clinical topic for orthopaedic trauma surgeons.

CONCLUSION

Despite the fact that patients with a tongue-type fracture developed posterior skin and soft tissue compromise nearly twice as often, this significant difference disappeared after correction for confounders. Patients with tongue-type calcaneal fractures had an increased risk of developing local soft tissue complications compared with patients with a non-tongue-type fracture. This study could not prove that patients with tongue-type fractures require immediate surgery.

SUPPLEMENTAL MATERIAL

Table 1: Demographic data for the study population, separated as tongue-type or non-tongue-type DIACF

Variable	Total group			Tongue-type			Non-tongue-type			P
	N			N			N			
***Patient characteristics*[1]**	**560**			**253**			**307**			
Age (years)	558	44	(34-56)	252	42	(33-55)	302	46	(36-58)	0.006
Male gender	560	424	(75.7%)	254	192	(75.9%)	307	232	(75.6%)	1.000[A]
BMI	491	24.2	(21.6-27.4)	224	23.7	(21.4-27.1)	268	24.8	(21.6-27.5)	0.066
ASA										
ASA 1	493	274	(55.6%)	222	128	(57.7%)	271	146	(53.9%)	0.702[B]
ASA 2		192	(38.9%)		84	(37.8%)		108	(39.9%)	
ASA 3		23	(4.7%)		9	(4.1%)		14	(5.2%)	
ASA 4		4	(0.8%)		1	(0.5%)		3	(1.1%)	
Smoking										
Current	477	250	(52.4%)	213	110	(51.6%)	264	140	(53.0%)	0.422[B]
Previous		53	(11.1%)		20	(9.4%)		33	(12.5%)	
Never		174	(36.5%)		83	(39.0%)		91	(34.5%)	
Alcohol	469	307	(65.5%)	211	137	(64.9%)	258	170	(65.9%)	0.846[A]
Comorbidities										
Diabetes Mellitus	535	25	(4.7%)	242	8	(3.3%)	293	17	(5.8%)	0.218[A]
Arterial insufficiency		13	(2.4%)		5	(2.1%)		8	(2.7%)	0.780[A]
Venous insufficiency		3	(0.6%)		3	(1.2%)		0	(0.0%)	0.093[A]
Psychiatric		79	(14.8%)		45	(18.6%)		34	(11.6%)	0.027[A]
Cardiac		52	(9.7%)		17	(7.0%)		35	(11.9%)	0.058[A]
Respiratory		24	(4.5%)		10	(4.1%)		14	(4.8%)	0.835[A]
Alcohol abuse		27	(5.0%)		14	(5.8%)		13	(4.4%)	0.553[A]
Narcotic abuse		54	(10.1%)		23	(9.5%)		31	(10.6%)	0.773[A]
Medication	520	132	(25.4%)	234	58	(24.8%)	286	74	(25.9%)	0.840[A]
NSAID		11	(2.1%)		3	(1.3%)		8	(2.8%)	0.360[A]
***Injury characteristics*[1]**	**560**			**253**			**307**			
Trauma										
HET, fall (height)	538	266	(49.4%)	244	130	(53.5%)	296	136	(46.1%)	0.261[B]
HET, traffic		41	(7.6%)		14	(5.8%)		27	(9.2%)	
HET, other		18	(3.3%)		8	(3.3%)		10	(3.4%)	
LET, stairs		93	(17.3%)		35	(14.4%)		58	(19.7%)	
LET, fall (other)		106	(19.7%)		51	(21.0%)		55	(18.6%)	
LET, other		14	(2.6%)		5	(2.1%)		9	(3.1%)	
Affected side										
Unilateral	560	488	(87.1%)	253	204	(80.6%)	307	284	(92.5%)	<0.001[A]
Bilateral		72	(12.9%)		49	(19.4%)		23	(7.5%)	

Variable	Total group			Tongue-type			Non-tongue-type			P
	N			N			N			
Additional injuries										
Polytrauma	558	239	(42.8%)	252	120	(47.6%)	306	119	(38.9%)	0.040[A]
Additional injured regions										
1	558	122	(21.9%)	252	55	(21.8%)	306	67	(21.9%)	0.124[B]
2		40	(7.2%)		20	(7.9%)		20	(6.5%)	
≥ 3		76	(13.6%)		45	(17.9%)		31	(10.1%)	
Injury characteristics[2]	**632**			**295**			**337**			
Affected side										
Right	632	333	(52.7%)		155	(52.5%)		178	(52.8%)	1.000[A]
Sanders classification IIA	584	128	(21.9%)	270	47	(17.4%)	314	81	(25.8%)	0.027[B]
IIB		163	(27.9%)		82	(30.4%)		81	(25.8%)	
IIC		60	(10.3%)		36	(13.3%)		24	(7.6%)	
IIIAB		98	(16.8%)		39	(14.4%)		59	(18.8%)	
IIIAC		40	(6.8%)		23	(8.5%)		17	(5.4%)	
IIIBC		31	(5.3%)		15	(5.6%)		16	(5.1%)	
IV		64	(11.0%)		28	(10.4%)		36	(11.5%)	
Open fractures	632	37	(5.9%)	295	21	(7.1%)	337	16	(4.7%)	0.236[A]
Gustilo & Anderson										
1	25	10	(40.0%)	14	6	(42.9%)	11	4	(36.4%)	0.563[A]
2		4	(16.0%)		3	(21.4%)		1	(9.1%)	
3		11	(44.0%)		5	(35.7%)		6	(54.5%)	
Treatment characteristics[2]	**632**			**295**			**337**			
Operative treatment	632	532	(84.2%)	295	247	(83.7%)	337	285	(84.6%)	0.827[A]
Non-operative										
Plaster cast	93	67	(72.0%)	44	35	(79.5%)	49	32	(65.3%)	0.062[B]
Pressure bandage		6	(6.5%)		4	(9.1%)		2	(4.1%)	
Other		20	(21.5%)		5	(11.4%)		15	(30.6%)	
Delayed treatment	560	277	(49.5%)	253	122	(48.2%)	307	155	(50.5%)	0.611[A]
Logistics	276	187	(67.8 %)	121	73	(60.3%)	155	114	(73.5%)	0.027[B]
Treatment other injury		61	(22.1%)		36	(29.8%)		25	(16.1%)	
Other		24	(8.7%)		12	(9.9%)		2	(7.7%)	
General condition		3	(1.1%)		0	(0.0%)		3	(1.9%)	
Clinical deterioration		1	(0.4%)		0	(0.0%)		1	(0.6%)	

Continuous data are shown as median (P_{25}-P_{75}) and analyzed using a Mann-Whitney U-test. Categoric data are shown as N (%) and analyzed using a [A]Fisher's Exact test or [B]Chi-squared test, as applicable. Data are expressed per patient[1] or per fracture[2].

Table 2: Covariates for the total study population separated as TT versus non-TT

Variable	Non-tongue-type	Tongue-type	P-value
Gender (Male)	232 (75.6%)	192 (75.9%)	1.000[A]
Age (years)	45 (36-57)	42 (32-54)	0.006
BMI	24.8 (21.6-27.5)	23.7 (21.4-27.1)	0.066
ASA			
I	146 (53.9%)	128 (57.7)	0.702[B]
II	108 (39.9%)	84 (37.8%)	
III	14 (5.2%)	9 (4.1%)	
IV	3 (1.1%)	1 (0.5%)	
Smoking			
Current	140 (53.0%)	110 (51.6%)	0.422[B]
Previous	33 (12.5%)	20 (9.4%)	
Never	91 (34.5%)	83 (39.0%)	
Medication use	212 (74.1%)	176 (75.2%)	0.840
Trauma mechanism			0.129[A]
LET	127 (39.1%)	94 (33.0%)	
HET	198 (60.9%)	191 (67.0%)	
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.260
Böhler's angle	9.0 (-3.0-18.0)	6.0 (-6.3-17.0)	**0.022**
Side			**0.000[A]**
Unilateral	284 (92.5%)	204 (80.6%)	
Bilateral	23 (7.5%)	49 (19.4%)	
Fracture			0.236[A]
Open	321 (95.3%)	274 (92.9%)	
Closed	16 (4.7%)	21 (7.1%)	
Soft tissue compromise	86 (25.5%)	92 (31.2%)	0.132[A]
Posterior	26 (7.7%)	37 (12.5%)	**0.047[A]**
Additional injury	119 (38.9%)	120 (47.6%)	**0.040[A]**
Time trauma to surgery	11.0 (5.0-17.0)	10.0 (6.0-16.0)	0.363
Hospital length of stay	7.0 (5.0-14.0)	8.0 (5.0-18.0)	0.167

[A], Fisher's Exact Test; [B], Pearson Chi-Square test. ED, Emergency Department.

Table 3: Covariates for operated patients separated as TT versus non-TT

Variable	Non-tongue-type	Tongue-type	P-value
Gender (Male)	200 (75.5%)	163 (75.8%)	1.000[A]
Age (years)	45 (36-57)	41 (32-53)	**0.004**
BMI	24.8 (21.8-27.4)	23.7 (21.4-26.6)	0.068
ASA			
I	139 (55.2%)	124 (61.1%)	0.294[B]
II	98 (38.9%)	70 (34.5%)	
III	12 (4.8%)	9 (4.4%)	
IV	3 (1.2%)	0 (0.0%)	
Smoking			
Current	125 (52.7%)	95 (50.3%)	0.751[B]
Previous	25 (10.5%)	18 (9.5%)	
Never	87 (69.7%)	76 (40.2%)	
Medication use	60 (23.8%)	46 (22.5%)	0.824
Trauma mechanism			0.172[A]
LET	112 (40.3%)	82 (34.3%)	
HET	166 (59.7%)	157 (65.7%)	
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.210
Böhler's angle	8.0 (-3-18.0)	6.0 (-8.0-15.0)	**0.025**
Side			0.001[A]
Unilateral	246 (92.8%)	178 (82.8%)	
Bilateral	19 (7.2%)	37 (17.2%)	
Fracture (Open/Closed)			0.480[A]
Open	16 (5.6%)	18 (7.3%)	
Closed	269 (94.4%)	229 (92.7%)	
Soft tissue compromise	71 (24.9%)	82 (33.2%)	**0.044**
Posterior	23 (8.1%)	32 (13.0%)	0.086
Additional injury	102 (38.5%)	100 (46.5%)	0.078
Time trauma to surgery	11.0 (5.0-17.0)	10.0 (6.0-16.0)	0.363
Hospital length of stay	7.0 (5.0-14.0)	7.5 (5.0-17.0)	0.304

[A], Fisher's Exact Test; [B], Pearson Chi-Square test. ED, Emergency Department.

Table 4: Covariates for the study population with versus without posterior compromise

Variable	No posterior compromise	Posterior compromise	P-value	OR (95% CI) adjusted
Gender (Male)	376 (74.9%)	48 (82.8%)	0.257[A]	
Age (years)	43 (33-56)	46 (37-56)	0.334	
BMI	24.5 (21.5-27.4)	23.6 (21.6-26.9)	0.803	
ASA				
I	244 (55.7%)	30 (54.5%)	0.259[B]	
II	168 (38.4%)	24 (43.6%)		
III	23 (5.3%)	0 (0.0%)		
IV	3 (0.7%)	1 (1.8%)		
Smoking				
Current	224 (52.2%)	26 (54.2%)	0.874[B]	1.236 (0.649-2.355)
Previous	47 (11.0%)	6 (12.5%)		1.497 (0.550-4.076)
Never	158 (36.8%)	16 (33.3%)		
Comorbidities	278 (57.8%)	29 (53.7%)	0.565[A]	
Diabetes Mellitus	24 (5.0%)	1 (1.9%)	0.498[A]	
Psychiatric disorder	68 (14.1%)	11 (20.4%)	0.226[A]	
Medication use	117 (25.1%)	15 (28.3%)	0.619[A]	
Trauma mechanism			0.212[A]	
LET	194 (35.4%)	27 (43.5%)		
HET	354 (64.6%)	35 (56.5%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.962	
Böhler's angle	8.0 (-5.0-18.0)	6.5 (-6.0-12.5)	0.132	0.997 (0.980-1.014)
Side			1.000[A]	
Unilateral	437 (87.1%)	51 (87.9%)		
Bilateral	65 (12.9%)	7 (12.1%)		
Fracture (Open/Closed)			0.402[A]	
Open	32 (5.6%)	5 (7.9%)		
Closed	537 (94.4%)	58 (92.1%)		
Fracture type			**0.047[A]**	1.497 (0.831-2.696)
Non-tongue-type	311 (54.7%)	26 (41.3%)		
Tongue-type	258 (45.3%)	37 (58.7%)		
Soft tissue compromise	115 (20.2%)	63 (100.0%)	**0.000[A]**	
Time trauma to surgery	11.0 (6.0-17.0)	8.0 (4.0-13.0)	**0.008**	
Hospital length of stay	7.0 (5.0-16.0)	8.0 (5.0-11.0)	0.655	

Univariate OR (95% CI) for tongue-type fractures: **1.715 (95% CI 1.012-2.909, p=0.045).**
[A], Fisher's Exact Test; [B], Pearson Chi-Square test; OR, Odds Ratio. Significant p-values and OR are marked bold. The 95% CI spanning 1 means no significant difference. A univariate p-value < 0.200 was chosen as threshold for including covariates (relevant for the outcome) in the multivariate analysis. In the multivariate analysis Gardner's angle was not included since the angle was only measured in tongue-type calcaneal fractures.

Table 5: Covariates for the study population with versus without complications

Variable	No Complications	Complications	P-value	OR (95% CI) adjusted
Gender (Male)	171 (77.0%)	253 (74.9%)	0.615[A]	
Age (years)	43 (34-57)	44 (34-56)	0.464	
BMI	23-8 (21.2-26.8)	24.7 (21.8-27.5)	0.067	**1.074 (1.016-1.135)**
ASA				
I	99 (52.9%)	175 (57.2%)	**0.047[B]**	
II	71 (38.0%)	121 (39.5%)		1.166 (0.738-1.840)
III	15 (8.0%)	8 (2.6%)		**0.097 (0.011-0.867)**
IV	2 (1.1%)	2 (0.7%)		
Smoking				
Current	105 (57.1%)	145 (49.5%)	0.268[B]	0.653 (0.411-1.036)
Previous	19 (10.3%)	34 (11.6%)		0.939 (0.431-2.046)
Never	60 (32.6%)	114 (38.9%)		
Comorbidities	87 (41.0%)	141 (43.7%)	0.592[A]	
Diabetes Mellitus	14 (6.6%)	11 (3.4%)	0.096[A]	0.507 (0.180-1.424)
Medication use	49 (24.0%)	83 (26.3%)	0.607[A]	
Trauma mechanism			0.347[A]	
LET	95 (38.55)	126 (34.7%)		
HET	152 (61.5%)	237 (65.3%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	**0.014**	0.947 (0.872-1.028)
Böhler's angle	0.0 (10.0-19.0)	6.0 (-7.0-16.0)	**0.001**	**0.984 (0.970-0.997)**
Side			0.439[A]	
Unilateral	197 (88.7%)	291 (86.1%)		
Bilateral	25 (11.3%)	47 (13.9%)		
Fracture (Open/Closed)			**0.000[A]**	3.010 (0.631-14.362)
Open	3 (1.2%)	34 (9.1%)		
Closed	255 (98.8%)	340 (90.9%)		
Fracture type			**0.009[A]**	**1.813 (1.178-2.791)**
Non-tongue-type	154 (59.7%)	183 (48.9%)		
Tongue-type	104 (40.3%)	191 (51.1%)		
Soft tissue compromise	56 (21.7%)	122 (32.6%)	**0.003[A]**	**1.777 (1.087-2.905)**
Posterior	23 (8.9%)	40 (10.7%)	0.501[A]	
Additional injury	86 (38.9%)	153 (45.4%)	0.138[A]	0.950 (0.586-1.540)
Surgery	206 (79.8%)	326 (87.2%)	**0.015[A]**	1.646 (0.783-3.461)
Time trauma to surgery	10.0 (5.0-16.0)	11.0 (6.0-16.0)	0.527	
Delay to surgery			0.080[B]	
0-2 days	22 (10.8%)	42 (13.1%)		
3-7 days	57 (28.1%)	59 (18.4%)		
8-14 days	62 (30.5%)	110 (34.4%)		
>15 days	62 (30.5%)	109 (34.1%)		
Hospital length of stay	7.0 (4.0-14.0)	8.0 (5.0-18.0)	**0.013**	1.012 (0.996-1.028)

Univariate OR (95% CI) for tongue-type fractures: **1.546 (95% CI 1.121-2.130, p=0.008).**
[A], Fisher's Exact Test; [B], Pearson Chi-Square test.

Table 6: Covariates for the study population with versus without infections

Variable	No Infection	Infection	P-value	OR (95% CI) adjusted
Gender (Male)	329 (75.6%)	95 (76.0%)	1.000[A]	
Age (years)	44 (34-56)	45 (33-56)	0.976	
BMI	24.1 (21.4-26.9)	25.0 (22.0-28.7)	0.072	**1.109 (1.047-1.174)**
ASA				
I	209 (56.0%)	65 (54.2)	0.293[B]	
II	140 (37.5%)	52 (43.3%)		
III	20 (5.4%)	3 (2.5%)		
IV	4 (1.1%)	0 (0.0%)		
Smoking				
Current	194 (53.3%)	56 (49.6%)	0.780[B]	1.124 (0.682-1.853)
Previous	40 (11.0%)	13 (11.5%)		1.289 (0.579-2.870)
Never	130 (35.7%)	44 (38.9%)		
Comorbidities	173 (42.1%)	55 (44.4%)	0.679[A]	
Diabetes Mellitus	20 (4.9%)	5 (4.0%)	0.812[A]	
Medication use	98 (24.4%)	34 (28.6%)	0.401[A]	
Trauma mechanism			1.000[A]	
LET	174 (36.3%)	47 (35.9%)		
HET	305 (63.7%)	84 (64.1%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.915	
Böhler's angle	9.0(-4.0-18.0)	7.0 (-10.0-17.0)	**0.028**	0.989 (0.976-1.003)
Side			0.547[A]	
Unilateral	381 (87.6%)	107 (85.6%)		
Bilateral	54 (12.4%)	18 (14.4%)		
Fracture (Open/Closed)			**0.003[A]**	2.233 (0.874-5.704)
Open	21 (4.2%)	16 (11.7%)		
Closed	474 (95.8%)	121 (88.3%)		
Fracture type			0.123[A]	**1.728 (1.082-2.761)**
Non-tongue-type	272 (54.9%)	65 (47.4%)		
Tongue-type	223 (45.1%)	72 (52.6%)		
Soft tissue compromise	133 (26.9%)	45 (32.8%)	0.198[A]	
Posterior	50 (10.1%)	13 (9.5%)	1.000[A]	
Additional injury	183 (42.3%)	56 (44.8%)	0.682[A]	
Surgery	404 (81.6%)	128 (93.4%)	**0.001[A]**	2.491 (0.965-6.431)
Time trauma to surgery	9.0 (5.5-15.0)	13.0 (5.8-17.3)	**0.044**	
Delay to surgery			**0.009[B]**	
0-2 days	47 (11.9%)	17 (13.4%)		
3-7 days	95 (24.0%)	21 (16.5%)		
8-14 days	139 (35.1%)	33 (26.0%)		
>15 days	115 (29.0%)	56 (44.1%)		
Hospital length of stay	7.0 (5.0-15.0)	8.0 (5.0-20.0)	**0.034**	1.003 (0.990-1.016)
Complication	237 (47.9%)	137 (100.0%)	**0.000[A]**	
Partial thickness	27 (5.5%)	22 (16.1%)	**0.000[A]**	
Full thickness	8 (1.6%)	16 (11.7%)	**0.000[A]**	
Necrosis	19 (3.8%)	21 (15.3%)	**0.000[A]**	

Univariate OR (95% CI) for tongue-type fractures: 1.351 (95% CI 0.925-1.974, p=0.120).
[A], Fisher's Exact Test; [B], Pearson Chi-Square test

Table 7: Covariates for the study population with versus without superficial infections

Variable	No Superficial Infection	Superficial Infection	P-value	OR (95% CI) adjusted
Gender (Male)	369 (75.8%)	55 (75.3%)	1.000[A]	
Age (years)	43 (33-55)	47 (36-57)	0.178	1.003 (0.982-1.024)
BMI	24.2 (21.5-26.9)	25.2 (22.0-28.7)	0.073	**1.102 (1.031-1.178)**
ASA				
I	236 (55.9)	38 (53.5%)	0.331[B]	
II	160 (37.9%)	32 (45.1%)		
III	22 (5.2%)	1 (1.4%)		
IV	4 (0.9%)	0 (0.0%)		
Smoking				
Current	220 (53.9%)	30 (43.5%)	0.254[B]	0.809 (0.447-1.465)
Previous	43 (10.5%)	10 (14.5%)		1.074 (0.449-2.571)
Never	145 (35.5%)	29 (42.0%)		
Comorbidities	191 (41.3%)	37 (50.7%)	0.161[A]	1.318 (0.629-2.765)
Diabetes Mellitus	21 (4.5%)	4 (5.5%)	0.764[A]	
Medication use	107 (23.8%)	25 (35.2%)	0.055[A]	1.708 (0.779-3.744)
Trauma mechanism			1.000A	
LET	195 (36.3%)	26 (35.6%)		
HET	342 (63.7%)	47 (64.4%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.421	
Böhler's angle	8.0 (-5.0-18.0)	7.0 (-8-17.0)	0.433	
Side			0.710A	
Unilateral	423 (86.9%)	65 (89.0%)		
Bilateral	64 (13.1%)	8 (11.0%)		
Fracture (Open/Closed)			0.113[A]	2.011 (0.732-5.529)
Open	29 (5.2%)	8 (10.4%)		
Closed	526 (94.8%)	69 (89.6%)		
Fracture type			1.000[A]	1.209 (0.700-2.088)
Non-tongue-type	296 (53.3%)	41 (53.2%)		
Tongue-type	259 (46.7%)	36 (46.8%)		
Soft tissue compromise	148 (26.7%)	30 (39.0%)	**0.030[A]**	1.606 (0.896-2.878)
Posterior	56 (10.1%)	7 (9.1%)	1.000[A]	
Additional injury	207 (42.7%)	32 (43.8%)	0.899[A]	
Surgery	462 (83.2%)	70 (90.9%)	0.096[A]	1.511 (0.573-3.987)
Time trauma to surgery	10.0 (6.0-16.0)	13.0 (5.0-18.0)	0.151	
Delay to surgery			0.121[B]	
0-2 days	53 (11.7%)	11 (15.9%)		
3-7 days	106 (23.3%)	10 (14.5%)		
8-14 days	153 (33.7%)	19 (27.5%)		
>15 days	142 (31.3%)	29 (42.0%)		
Hospital length of stay	8.0 (5.0-15.0)	7.0 (5.0-17.3)	0.959	
Complication	297 (53.3%)	77 (100.0)	**0.000[A]**	
Partial thickness	40 (7.2%)	9 (11.7%)	0.173[A]	
Full thickness	16 (2.9%)	8 (10.4%)	**0.005[A]**	
Necrosis	29 (5.2%)	11 (14.3%)	**0.005A**	

Univariate OR (95% CI) for tongue-type fractures: 1.003 (95% CI 0.622-1.618, p=0.989).
[A], Fisher's Exact Test; [B], Pearson Chi-Square test

Table 8: Covariates for the study population with versus without deep infections

Variable	No Deep Infection	Deep Infection	P-value	OR (95% CI) adjusted
Gender (Male)	367 (76.0%)	57 (74.0%)	0.775[A]	
Age (years)	44 (34-56)	44 (32-54)	0.503	
BMI	24.2 (21.4-27.0)	24.7 (22.1-28.9)	0.181	
ASA				
I	237 (56.6%)	37 (50.0%)	0.324[B]	
II	157 (37.5%)	35 (47.3%)		
III	21 (5.0%)	2 (2.7%)		
IV	4 (1.0%)	0 (0.0%)		
Smoking				
Current	211 (51.3%)	39 (59.1%)	0.499[B]	1.392 (0.784-2.471)
Previous	47 (11.4%)	6 (9.1%)		0.996 (0.350-2.838)
Never	153 (37.2%)	21 (31.8%)		
Comorbidities	197 (42.9%)	31 (40.8%)	0.803[A]	
Diabetes Mellitus	21 (4.6%)	4 (5.3%)	0.769[A]	
Medication use	113 (25.2%)	19 (26.4%)	0.884[A]	
Trauma mechanism			0.715[A]	
LET	189 (35.9%)	32 (38.1%)		
HET	337 (64.1%)	52 (61.9%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.283	
Böhler's angle	9.0 (-4-18.0)	5.0 (-14.0-15.5)	**0.023**	0.993 (0.978-1.008)
Side			0.143[A]	
Unilateral	425 (88.0%)	63 (81.8%)		
Bilateral	58 (12.0%)	14 (18.2%)		
Fracture (Open/Closed)			**0.011[A]**	**2.504 (1.001-6.262)**
Open	26 (4.8%)	11 (12.5%)		
Closed	518 (95.2%)	77 (87.5%)		
Fracture type			**0.028[A]**	1.619 (0.948-2.767)
Non-tongue-type	300 (55.1%)	37 (42.0%)		
Tongue-type	244 (44.9%)	51 (58.0%)		
Soft tissue compromise	150 (27.6%)	28 (31.8%)	0.444[A]	
Posterior	52 (9.6%)	11 (12.5%)	0.441[A]	
Additional injury	206 (42.8%)	33 (42.9%)	1.000[A]	
Surgery	452 (83.1%)	80 (90.9%)	0.082[A]	1.544 (0.626-3.807)
Time trauma to surgery	10.0 (6.0-16.0)	12.5 (5.5-17.0)	0.210	
Delay to surgery			**0.034[B]**	
0-2 days	54 (12.2%)	10 (12.5%)		
3-7 days	102 (23.0%)	14 (17.5%)		
8-14 days	153 (34.5%)	19 (23.8%)		
>15 days	134 (30.2%)	37 (46.2%)		
Hospital length of stay	7.0 (5.0-15.0)	9.5 (6.0-21.0)	**0.006**	1.010 (0.997-1.024)
Complication	286 (52.6%)	88 (100.0%)	**0.000[A]**	
Partial thickness	31 (5.7%)	18 (20.5%)	**0.000[A]**	
Full thickness	9 (1.7%)	15 (17.0%)	**0.000[A]**	
Necrosis	21 (3.9%)	19 (21.6%)	**0.000[A]**	

Univariate OR (95% CI) for tongue-type fractures: **1.695 (95% CI 1.074 – 2.673 , p=0.023)**.
[A], Fisher's Exact Test; [B], Pearson Chi-Square test

Table 9: Covariates for the study population with versus without full thickness lesion

Variable	No Full thickness lesion	Full thickness lesion	P-value	OR (95% CI) adjusted
Gender (Male)	409 (75.7%)	15 (75.0%)	1.000[A]	
Age (years)	44 (34-56)	43 (31-54)	0.440	
BMI	24.2 (21.5-27.2)	26 (22-28)	0.146	
ASA				
I	266 (56.2%)	8 (40.0%)	0.482[B]	
II	181 (38.3%)	11 (55.0%)		
III	22 (4.7%)	1 (5.0%)		
IV	4 (0.8%)	0 (0.0%)		
Smoking				
Current	243 (52.6%)	7 (46.7%)	0.896[B]	1.019 (0.373-2.786)
Previous	51 (11.0%)	2 (13.3%)		1.316 (0.257-6.751)
Never	168 (36.4%)	6 (40.0%)		
Comorbidities	218 (42.3%)	10 (50.0%)	1.000[A]	
Diabetes Mellitus	24 (4.7%)	1 (5.0%)		
Medication use	126 (25.2%)	6 (30.0%)	0.606[A]	
Trauma mechanism			0.185[A]	
LET	216 (36.8%)	5 (21.7%)		
HET	371 (63.2%)	18 (78.3%)		
Time trauma to ED	0.0 (0.0-0.0)	0 (0-0)	0.477	
Böhler's angle	8.0 (-5.0-18.0)	9.0 (-25.0-20.0)	0.580	
Side			0.733[A]	
Unilateral	471 (87.2%)	17 (85.0%)		
Bilateral	69 (12.8%)	3 (15.0%)		
Fracture (Open/Closed)			**0.000[A]**	
Open	25 (4.1%)	12 (50.0%)		
Closed	583 (95.9%)	12 (50.0%)		
Fracture type			**0.006[A]**	**3.043 (1.063-8.714)**
Non-tongue-type	331 (54.4%)	6 (25.0%)		
Tongue-type	277 (45.6%)	18 (75.0%)		
Soft tissue compromise	162 (26.6%)	16 (66.7%)	**0.000[A]**	
Posterior	59 (9.7%)	4 (16.7%)	0.286[A]	
Additional injury	228 (42.4%)	11 (55.0%)	0.358[A]	
Surgery	510 (83.9%)	22 (91.7%)	0.403[A]	1.197 (0.265-5.399)
Time trauma to surgery	10.5 (6.0-16.0)	5.0 (0.0-17.0)	**0.022**	
Delay to surgery			**0.002[B]**	
0-2 days	56 (11.2%)	8 (36.4%)		
3-7 days	112 (22.4%)	4 (18.2%)		
8-14 days	170 (33.9%)	2 (9.1%)		
>15 days	163 (32.5%)	8 (36.4%)		
Hospital length of stay	7.0 (5.0-15.0)	15.0 (7.0-54.8)	**0.002**	**1.020 (1.002-1.037)**
Complication	350 (57.6%)	24 (100.0%)	**0.000[A]**	
Infection	121 (19.9%)	16 (66.7%)	**0.000[A]**	
Sup. infection	69 (11.3%)	8 (33.3%)	**0.005[A]**	
Deep infection	73 (12.0%)	15 (62.5%)	**0.000[A]**	
Necrosis	28 (4.6%)	12 (50.0%)	**0.000[A]**	

Univariate OR (95% CI) for tongue-type fractures: **3.585 (95% CI 1.404-9.155, p = 0.008)**.
[A], Fisher's Exact Test; [B], Pearson Chi-Square test

Table 10: Covariates for the study population with versus without partial thickness lesion

Variable	No Partial thickness lesion	Partial thickness lesion	P-value	OR (95% CI) adjusted
Gender (Male)	391 (75.3%)	33 (80.5%)	0.572[A]	
Age (years)	44 (34-56)	43 (34-57)	0.850	
BMI	24 (21-27)	25.1 (22.6-27.2)	0.439	
ASA				
I	255 (56.2%)	19 (48.7%)	0.529[A]	
II	175 (38.5%)	17 (43.6%)		
III	21 (4.6%)	2 (5.1%)		
IV	3 (0.7%)	1 (2.6%)		
Smoking				
Current	226 (51.2%)	24 (66.7%)	0.087[B]	1.822 (0.790-4.205)
Previous	48 (10.9%)	5 (13.9%)		1.041 (0.211-5.143)
Never	167 (37.9%)	7 (19.4%)		
Comorbidities	207 (41.8%)	21 (52.5%)	0.244[A]	
Diabetes Mellitus	25 (5.1%)	0 (0.0%)	0.244[A]	
Medication use	118 (24.5%)	14 (35.9%)	0.127[A]	
Trauma mechanism			**0.049[A]**	0.666 (0.260-1.705)
LET	209 (37.3%)	12 (24.5%)		
HET	352 (62.7%)	37 (75.5%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.096	0.552 (0.131-2.327)
Böhler's angle	8.5 (-4-18.0)	-5.0(-18.0-11.0)	**0.001**	0.983 (0.964-1.002)
Side			**0.029[A]**	1.269 (0.534-3.016)
Unilateral	457 (88.1%)	31 (75.6%)		
Bilateral	62 (11.9%)	10 (24.4%)		
Fracture (Open/Closed)			**0.018[A]**	
Open	30 (5.1%)	7 (14.3%)		
Closed	553 (94.9%)	42 (85.7%)		
Fracture type			0.553[A]	0.702 (0.329-1.498)
Non-tongue-type	313 (53.7%)	24 (49.0%)		
Tongue-type	270 (46.3%)	25 (51.0%)		
Soft tissue compromise	158 (27.1%)	20 (40.8%)	**0.047[A]**	
Posterior	59 (10.1%)	4 (8.2%)	0.807[A]	
Additional injury	215 (41.6%)	24 (58.5%)	**0.048[A]**	1.618 (0.664-3.944)
Surgery	488 (83.7%)	44 (89.8%)	0.313[A]	1.605 (0.449-5.741)
Time trauma to surgery	10.0 (6.0-16.0)	13.0 (5.8-18.0)	0.336	
Delay to surgery			0.149[A]	
0-2 days	57 (11.9%)	7 (16.3%)		
3-7 days	112 (23.3%)	4 (9.3%)		
8-14 days	158 (32.9%)	14 (32.6%)		
>15 days	153 (31.9%)	18 (41.9%)		
Hospital length of stay	7.0 (5.0-15.0)	13.0 (8.0-31.0)	**0.001**	**1.022 (1.004-1.040)**
Complication	325 (55.7%)	49 (100.0%)	**0.000[A]**	
Infection	115 (19.7%)	22 (44.9%)	**0.000[A]**	
Sup. infection	68 (11.7%)	9 (18.4%)	0.173[A]	
Deep infection	70 (12.0%)	18 (36.7%)	**0.000[A]**	
Necrosis	27 (4.6%)	13 (26.5%)	**0.000[A]**	

Univariate OR (95% CI) for tongue-type fractures: 1.208 (95% CI 0.674-2.164, p = 0.526)
[A], Fisher's Exact Test; [B], Pearson Chi-Square test

Table 11: Covariates for the study population with versus without necrosis

Variable	No Necrosis	Necrosis	P-value	OR (95% CI) adjusted
Gender (Male)	395 (75.4%)	29 (80.6%)	0.553[A]	
Age (years)	44 (33-56)	46 (37-58)	0.463	
BMI	24 (21-27)	25 (20-28)	0.851	
ASA				
I	258 (56.2%)	16 (47.1%)	0.147[B]	
II	175 (38.1%)	17 (50.0%)		1.303 (0.613-2.768)
III	23 (5.0%)	0 (0.0%)		N.D.
IV	3 (0.7%)	1 (2.9%)		
Smoking				
Current	235 (52.7%)	15 (48.4%)	0.650[B]	1.766 (0.625-4.984)
Previous	48 (10.8%)	5 (16.1%)		0.795 (0.344-1.837)
Never	163 (36.3%)	11 (35.5%)		
Comorbidities	216 (42.9%)	12 (37.5%)	0.585[A]	
Diabetes Mellitus	24 (4.8%)	1 (3.1%)	1.000[A]	
Medication use	124 (25.4%)	8 (25.0%)	1.000[A]	
Trauma mechanism			1.000[A]	
LET	207 (36.3%)	14 (35.9%)		
HET	364 (63.7%)	26 (64.1%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.371	
Böhler's angle	8.0 (-5-17.8)	9.0 (-10.0-20.0)	0.962	
Side			0.798[A]	
Unilateral	457 (87.2%)	31 (86.1%)		
Bilateral	67 (12.8%)	5 (13.9%)		
Fracture (Open/Closed)			**0.000[A]**	2.693 (0.874-8.302)
Open	27 (4.6%)	10 (25.0%)		
Closed	565 (95.4%)	30 (75.0%)		
Fracture type			0.101[A]	1.244 (0.590-2.621)
Non-tongue-type	321 (54.2%)	16 (40.0%)		
Tongue-type	271 (45.8%)	24 (60.0%)		
Soft tissue compromise	156 (26.4%)	22 (55.0%)	**0.000[A]**	**3.174 (1.411-6.995)**
Posterior	55 (9.3%)	8 (20.0%)	**0.049[A]**	
Additional injury	222 (42.5%)	19 (52.8%)	0.605[A]	
Surgery	498 (84.1%)	34 (85.0%)	1.000[A]	0.545 (0.183-1.623)
Time trauma to surgery	10.0 (6.0-16.0)	9.0 (2.8-18.0)	0.362	
Delay to surgery			0.223[B]	
0-2 days	57 (11.6%)	7 (21.2%)		
3-7 days	111 (22.7%)	5 (15.2%)		
8-14 days	164 (33.5%)	8 (24.2%)		
>15 days	158 (32.2%)	13 (39.4%)		
Hospital length of stay	7.0 (5.0-15.0)	12.0 (6.0-21.0)	**0.041**	1.010 (0.991-1.029)
Complication	334 (56.4%)	40 (100.0%)	**0.000[A]**	
Infection	116 (19.6%)	21 (52.5%)	**0.000[A]**	
Sup. infection	66 (11.1%)	11 (27.5%)	**0.005[A]**	
Deep infection	59 (11.7%)	19 (47.5%)	**0.000[A]**	
Partial thickness	36 (6.1%)	13 (32.5%)	**0.000[A]**	
Full thickness	12 (2.0%)	12 (30.0%)	**0.000[A]**	

Univariate OR (95% CI) for tongue-type fractures: 1.777 (95% CI 0.925-3.413, p=0.084)
[A], Fisher's Exact Test; [B], Pearson Chi-Square test

Table 12: Covariates for the study population with versus without non-union

Variable	No Non-union	Non-union	P-value	OR (95% CI) adjusted
Gender (Male)	130 (24.3%)	6 (25.0%)	1.000[A]	
Age (years)	44 (34-56)	48 (35-57)	0.716	
BMI	24.2 (21.5-27.2)	25.4 (23.0-30.8)	0.034	**1.191 (1.077-1.317)**
ASA				
I	265 (56.3%)	9 (40.9%)	0.208[A]	
II	179 (38.0%)	13 (59.1%)		
III	23 (4.9%)	0 (0.0%)		
IV	4 (0.8%)	0 (0.0%)		
Smoking				
Current	241 (52.9%)	9 (52.9%)	0.554[B]	0.201 (0.019-2.174)
Previous	51 (11.2%)	2 (9.5%)		1.162 (0.439-3.072)
Never	164 (36.0%)	10 (47.6%)		
Comorbidities	215 (42.0%)	13 (56.5%)	0.198[A]	
Diabetes Mellitus	25 (4.9%)	0 (0.0%)	0.617[A]	
Medication use	124 (24.9%)	8 (34.8%)	0.327[A]	
Trauma mechanism			0.064[A]	1.365 (0.440-4.235)
LET	216 (37.0%)	5 (18.5%)		
HET	367 (63.0%)	22 (81.5%)		
Time trauma to ED	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.372	
Böhler's angle	8.0 (-5.0-18.0)	2.0 (-20.0-13.0)	**0.042**	0.980 (0.956-1.004)
Side			0.534[A]	
Unilateral	468 (87.3%)	20 (83.3%)		
Bilateral	68 (12.7%)	4 (16.7%)		
Fracture (Open/Closed)			**0.005[A]**	2.489 (0.540-11.473)
Open	31 (5.1%)	6 (20.7%)		
Closed	572 (94.9%)	23 (79.3%)		
Fracture type			0.704[A]	1.172 (0.454-3.024)
Non-tongue-type	323 (53.6%)	14 (48.3%)		
Tongue-type	280 (46.4%)	15 (51.7%)		
Soft tissue compromise	166 (27.5%)	12 (41.4%)	0.137[A]	2.127 (0.759-5.962)
Posterior	60 (10.0%)	3 (10.3%)	1.000[A]	
Additional injury	226 (42.2%)	13 (56.5%)	0.200[A]	
Surgery	512 (84.9%)	20 (69.0%)	0.033[A]	0.158 (0.053-0.472)
Time trauma to surgery	10.0 (6.0-16.0)	6.5 (0.8-14.3)	0.070	
Delay to surgery			0.016[B]	
0-2 days	57 (11.3%)	7 (35.0%)		
3-7 days	113 (22.5%)	3 (15.0%)		
8-14 days	168 (33.4%)	4 (20.0%)		
>15 days	165 (32.8%)	6 (30.0%)		
Hospital length of stay	7.0 (5.0-15.0)	9.0 (6.0-34.0)	0.081	1.017 (0.997-1.038)
Complication	345 (57.2%)	29 (100.0%)	**0.000[A]**	
Infection	124 (20.6%)	13 (44.8%)	**0.004[A]**	
Sup. infection	69 (11.4%)	8 (27.6%)	**0.017[A]**	
Deep infection	78 (12.9%)	10 (34.5%)	**0.003[A]**	
Partial thickness	45 (7.5%)	4 (13.8%)	0.271[A]	
Full thickness	22 (3.6%)	2 (6.9%)	0.303[A]	

Univariate OR (95% CI) for tongue-type fractures: 1.236 (95% CI 0.586-2.605, p=0.578)
[A], Fisher's Exact Test; [B], Pearson Chi-Square test

REFERENCES

1. Essex-Lopresti P. The mechanism, reduction technique, and results in fractures of the os calcis. Br J Surg. 1952;39(157):395-419.
2. Gardner MJ, Nork SE, Barei DP, Kramer PA, Sangeorzan BJ, Benirschke SK. Secondary soft tissue compromise in tongue-type calcaneus fractures. J Orthop Trauma. 2008;22(7):439-45.
3. De Boer AS, Van Lieshout EM, Den Hartog D, Weerts B, Verhofstad MH, Schepers T. Functional outcome and patient satisfaction after displaced intra-articular calcaneal fractures: a comparison among open, percutaneous, and nonoperative treatment. J Foot Ankle Surg. 2015;54(3):298-305.
4. Gitajn IL, Abousayed M, Toussaint RJ, Vrahas M, Kwon JY. Calcaneal avulsion fractures: a case series of 33 patients describing prognostic factors and outcomes. Foot Ankle Spec. 2015;8(1):10-7.
5. Kwon JY, Guss D, Lin DE, Abousayed M, Jeng C, Kang S, et al. Effect of Delay to Definitive Surgical Fixation on Wound Complications in the Treatment of Closed, Intra-articular Calcaneus Fractures. Foot Ankle Int. 2015;36(5):508-17.
6. Fulkerson EW, Egol KA. Timing issues in fracture management: a review of current concepts. Bull NYU Hosp Jt Dis. 2009;67(1):58-67.
7. Chhabra N, Sherman SC, Szatkowski JP. Tongue-type calcaneus fractures: a threat to skin. Am J Emerg Med. 2013;31(7):1151 e3-4.
8. Sanders R, Fortin P, DiPasquale T, Walling A. Operative treatment in 120 displaced intraarticular calcaneal fractures. Results using a prognostic computed tomography scan classification. Clin Orthop Relat Res. 1993(290):87-95.
9. Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: retrospective and prospective analyses. J Bone Joint Surg Am. 1976;58(4):453-8.
10. Böhler L. Diagnosis, pathology and treatment of fractures of the os calcis. J Bone Joint Surg 1931;13: 75-89
11. Snoap T, Jaykel M, Williams C, Roberts J. Calcaneus Fractures: A Possible Musculoskeletal Emergency. J Emerg Med. Volume 52, Issue 1, January 2017, Pages 28-33
12. Ghorbanhoseini M, Ghaheri A, Walley KC, Kwon JY. Superior Tuber Displacement in Intra-articular Calcaneus Fractures. Foot Ankle Int. 2016;37(10):1076-83.
13. Watson TS. Soft tissue complications following calcaneal fractures. Foot Ankle Clin. 2007;12(1):107-23.

Chapter 8

The effect of time to post-operative weightbearing on functional and clinical outcomes in adults with a displaced intra-articular calcaneal fracture: a systematic review and pooled analysis

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ABSTRACT

Background: Post-operative weightbearing guidelines for displaced intra-articular calcaneal fractures (DIACF) have been pragmatically developed in the past, however hardly adapted to current health care insights. A period of six to nine weeks of non-weightbearing is usually recommended. It is unknown whether an earlier start of weightbearing is advisable.

Objectives: The primary aim was to evaluate the effect of time to post-operative weightbearing on Böhler's angle. Secondary aims were to determine the effect on functional outcome (*e.g.,* The American Orthopedic Foot and Ankle Society Scale), post-operative pain score, complications (*e.g.,* infections, nonunion, implant removal), and revision surgeries. Finally, the effect of bone void filling on these outcomes was investigated.

Data source: A literature search was performed on January 24, 2017 in the Cochrane Library, Medline Ovid, Embase, Web of Science, Google Scholar, and CINAHL.

Literature selection: Studies reporting on operatively treated patients with a DIACF and time to weightbearing were eligible for inclusion. Studies were excluded when not reporting primary data, solely reporting on open fractures, bilateral fractures, or polytrauma patients. Based upon the time to starting partial weightbearing, patient cohorts were stratified into very early (0-4 weeks), early (4-6 weeks), intermediate (6-8 weeks), or late (8-12 weeks) start of partial weightbearing.

Data extraction: Two investigators extracted data independently using a predefined data sheet.

Results: After applying exclusion criteria, 72 studies remained eligible for analysis. Böhler's and Gissane's angles, calcaneal height, AOFAS, pain scores, and complications had overlapping confidence intervals in all weightbearing groups.

Conclusion: The adverse sequelae which are assumed to be associated with starting partial weightbearing already within six weeks after internal fixation of calcaneal fractures, is not supported by literature data. This systematic review suggests that early weightbearing does not result in impaired outcomes compared with more conservative weightbearing regimes.

INTRODUCTION

After fracture reduction of displaced intra-articular calcaneal fractures (DIACFs), it is important to avoid fracture displacement during rehabilitation. In order to maintain reduction, the initial guidelines developed by the Arbeitsgemeinschaft für Osteosynthesefragen (AO) described non-weightbearing until fracture healing was radiographically proven, back then usually after three months (1). Despite improved operation techniques and materials which allow earlier weightbearing without displacement or implant failure since then, the current guidelines are not much adjusted and non-weightbearing is often recommended for six to nine weeks (2-4). To reduce the risk of secondary displacement this period is followed by increased restricted weightbearing as tolerated (5).

Non-weightbearing is negatively contributing to long-term rehabilitation and associated high socio-economic costs (4-8), it also affects patients' physical conditions by decreasing muscle strength and bone mass (8-10). Early partial weightbearing might be a safe option, reduce these physical disadvantages and accelerate mental and physical recovery, daily activities, and work resumption (11). It is unknown whether early (progressive) weightbearing after calcaneal surgery is as safe as the often recommended start of weightbearing after six to nine weeks.

The primary aim of this systematic review was to evaluate the effect of time to post-operative weightbearing on Böhler's angle in operatively treated adult patients with a closed DIACF. Secondary aims were to determine the effect of early weightbearing on post-operative pain, (wound related) complications, functional outcomes (*e.g.,* The American Orthopedic Foot and Ankle Society Scale (AOFAS)), and revision surgeries (*i.e.,* implant removal). Finally, the effect of bone void filling on these radiographic parameters, functional outcomes, complications, and revision surgeries was evaluated.

METHODS

Search strategy

This systematic review and pooled analysis was conducted following the PRISMA guidelines (12). To assess the methodological quality of studies, the methodological items for non-randomized studies (MINORS) instrument was used (13). The global ideal score is 16 for non-comparative studies and 24 for comparative studies (13). A literature search was performed on January 24, 2017 in the Medline Ovid, Cochrane Central Register of Controlled trials, Embase, Web of Science, Google Scholar, and CINAHL. The databases were searched on the terms related to 'weightbearing' combined with 'intra-articular', 'calcaneal fractures', and their abbreviations and synonyms. The full search strings per database are shown in Supplement Table 1.

Inclusion criteria were; studies reporting on patients with a displaced intra-articular calcaneal fracture that were treated operatively with internal fixation. Also, the moment at which weightbearing started had to be mentioned explicitly. Exclusion criteria were; studies that did not report primary data for the operatively treated patients, studies that solely reported on open fractures, bilateral fractures, or polytrauma patients, and studies that reported on fractures in patients with congenital deformities of the foot. Furthermore, non-clinical or clinical studies with a level of evidence higher than five according to Mahid *et al*. (*e.g.,* case reports (level VI), opinions (level VII)) were excluded (14). There was no language restriction or time period selection.

Selected studies were screened on title and abstract for the exclusion criteria by two investigators (ASDB and GVM) independently (15). Inconsistencies were resolved by consensus. If a full-text version of a manuscript was not available for the investigators, a request for the full-text version was sent to the author. If no response was received, a single reminder was sent after two weeks.

Data extraction

Two investigators (ASDB and GVM) extracted the data independently, again inconsistencies were resolved by consensus. Study design, patient characteristics, treatment characteristics, injury characteristics, radiographic parameters (*i.e.*, Böhler's and Gissane's angle pre-operatively, post-operatively, and at follow-up, and arthrosis), visual analog scale (VAS) for pain (16), complications (*e.g.,* superficial infection (*i.e.,* can be treated non-operatively, *e.g.,* using oral antibiotics), deep infection (*i.e.,* requiring surgical intervention, readmission or intravenous antibiotics) (17), necrosis, nonunion), functional outcomes (*e.g.,* AOFAS), implant removal (due to implant failure or symptoms), and weightbearing regimes (*i.e.*, time to partial weightbearing and full weightbearing) were extracted.

The time to partial weightbearing was stratisfied into four groups: very early (0-4 weeks), early (4-6 weeks), intermediate (6-8 weeks), and late (8-12 weeks). The time to full weightbearing was stratisfied into three groups: early (0-8 weeks), intermediate (8-12 weeks), and late (> 12 weeks).

Statistical analysis

Radiographic parameters, functional outcome scores, and complication rates for both partial and full weightbearing were pooled using MedCalc for Windows, version 16.4.3 (MedCalc Software bvba, Ostend, Belgium; https://medcalc.org;2016 MedCalc). Pooled estimates are reported with their 95% confidence intervals (CI). Heterogeneity was quantified with Cochran's Q test and I^2 statistic, a fixed effects model was used when the I^2 was < 40%. A random effects model was used for the pooled analysis when the heterogeneity test was ≥ 40%. A subanalysis was performed for internal fixation com-

bined with a bone void filling (*i.e.,* autologous, allogenic bone grafts or synthetic bone void fillers).

RESULTS

A total of 2,688 studies were found with the initial database searches (Figure 1). After removal of duplicate studies and selecting the studies on title and abstract, 131 studies remained. After reading the full-texts, 59 studies were excluded based on predefined exclusion criteria. In total, 72 studies (86 cohorts, 6,064 patients) were analyzed in this review. Patients were stratified into a partial, full, or both weightbearing groups. The partial weightbearing group analysis included 507 patients (nine cohorts) in the very early partial weightbearing group; 327 patients (six cohorts) in the early partial weightbearing; 1,461 patients (26 cohorts) in the intermediate partial weightbearing, and 1,964 patients (34 cohorts) in the late partial weightbearing group. In the full weightbearing groups 2,921 patients were analyzed; 318 patients (five cohorts) in the early full weightbearing; 871 patients (10 cohorts) in the intermediate full weightbearing; and 1,732 patients (34 cohorts) in the late full weightbearing group. A subanalysis of 16 studies (518 patients in 16 cohorts) was done for internal fixation combined with bone void fillers.

The pooled analysis included studies with different methodological quality (Supplemental Table 1): eight randomized controlled trials, 31 prospective studies (two case series, three case control and 26 cohort studies, with MINORS ranging from 3 to 21) and 33 retrospective studies (one chart review, four case series, and 28 cohort studies, with MINORS ranging from 5 to 20).

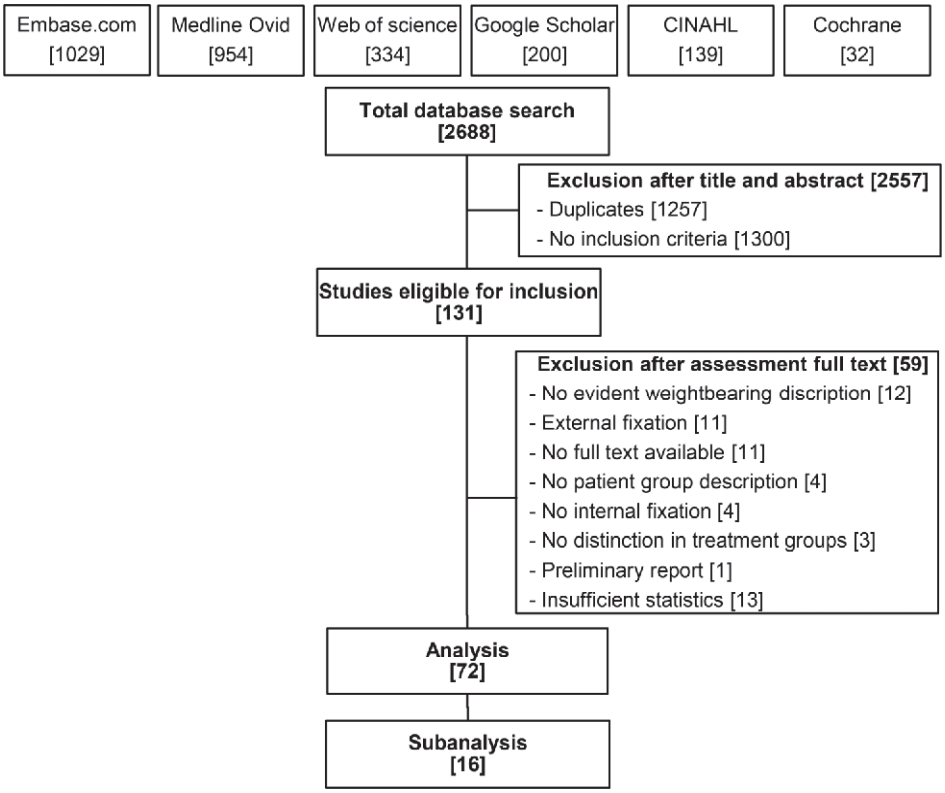

Figure 1. Flowchart of literature search

Radiographic parameters

Böhler's angles at three moments; pre-operative, post-operative, and at follow-up differed only marginal between the weightbearing groups (Figure 2 and Table 1). The 95% CI in pre-operative Böhler's angle overlapped in all partial weightbearing groups: early 7° [95% CI, -3-18] and late 4° [95% CI, 1-6°]. Also, in the post-operative Böhler's angle the 95% CIs overlapped 27° [95% CI, 26-29°] in the early and 27° [95% CI, 24-30°] in the late partial weightbearing group. In addition, overlap of the 95% CI was found in the Böhler's angle at final follow-up: 25° [95% CI, 23-27°], 23° [95% CI, 21-25°], and 24° [95% CI, 17-32] in the early, intermediate, and late partial weightbearing groups, respectively. There were not enough data to determine Böhler's angles in the very early partial weightbearing.

Table 1. Radiographic outcomes, functional outcomes, and, after partial weightbearing in patients with a DIACF

Outcome	Partial WB	N_s	N_p	N_f	Q	P-value	I^2 (95% CI)	Method	Pooled estimate (95% CI)
Böhler pre									
	Very early*								
	Early	3	76	76	1120	<0.001	99.8 (99.8-99.9)	Random	7.3 (-3.2-17.8)
	Intermediate	8	384	451	22	0.002	69 (34.4-85.0)	Random	3.1 (1.2-5.1)
	Late	6	333	407	67	<0.001	93(86.4-95.9)	Random	3.8 (1.1-6.4)
Böhler post									
	Very early*								
	Early	4	93	93	11	<0.001	73 (22.5-90.3)	Random	27.5 (25.8-29.1)
	Intermediate	8	553	577	29	<0.001	76 (52.1-88.0)	Random	28.4 (27.2-29.8)
	Late	5	317	391	67	<0.001	94 (88.9-96.8)	Random	26.7 (23.5-29.9)
Böhler FU	Very early*								
	Early	3	49	49	8	0.017	76 (19.1-92.6)	Random	25.0 (22.9-27.2)
	Intermediate	8	531	633	62	<0.001	89 (79.9-93.6)	Random	22.7 (20.7-24.6)
	Late	4	139	156	102	<0.001	97 (94.8-98.3)	Random	24.2 (16.6-31.8)
Gissane pre									
	Very early*								
	Early*								
	Intermediate*								
	Late	3	248	319	5476	<0.001	100 (100.0-100.0)	Random	112.4 (66.9-177.9)
Gissane post									
	Very early*								
	Early*								
	Intermediate	3	429	435	6	0.058	65 (0.0-89.9)	Random	119.2 (117.5-120.8)
	Late	3	248	319	49	<0.001	96 (91.2-98.1)	Random	121.5 (114.7-128.3)
Gissane FU									
	Very early*								
	Early*								
	Intermediate	3	429	435	7	0.028	72 (5.6-91.7)	Random	122.9 (121.2-124.6)
	Late	2	92	109	22	<0.001	96 (86.9-98.5)	Random	119.5 (106.7-132.3)
CalcH pre									
	Very early								
	Early*								
	Intermediate	4	94	103	92	<0.001	97 (94.1-98.2)	Random	37.8 (33.1-42.4)
	Late*								
CalcH post									
	Very early*								
	Early*								
	Intermediate	5	469	478	134	<0.001	97 (95.1-98.2)	Random	44.3 (42.5-46.0)
	Late	2	187	241	7	0.010	85 (38-2-96.3)	Fixed	42.9 (40.3-45.5)

Outcome	Partial WB	N_s	N_p	N_f	Q	P-value	I^2 (95% CI)	Method	Pooled estimate (95% CI)
CalcH FU									
	Very early*								
	Early*								
	Intermediate	6	484	493	289	<0.001	95 (97.5-98.8)	Random	41.9 (39.4-44.5)
	Late*								
AOFAS									
	Very early*								
	Early	4	405	459	40	<0.001	90 (79.9-94.6)	Random	82.4 (78.0-86.8)
	Intermediate	7	557	566	122	<0.001	95 (92.1-97.0)	Random	80.7 (77.5-83.9)
	Late	6	486	559	48	<0.001	93 (84.0-96.5)	Random	83.2 (79.5-86.5)
VAS pain									
	Very early*								
	Early	2	64	64	2	0.180	44 (0.0-0.0)	Random	1.6 (1.3-1.9)
	Intermediate*								
	Late	2	107	125	123	<0.001	99 (98.5-99.6)	Random	5.2 (1.3-9.1)
Superficial									
	Very early	6	349	399	4	0.587	0 (0.0-67.1)	Fixed	6.9 (4.6-9.8)
infection									
	Early	4	545	572	27	<0.001	89 (74.4-95.2)	Random	8.9 (2.2-19.6)
	Intermediate	13	860	906	65	<0.001	82 (69.7-88.9)	Random	14.0 (8.9-20.2)
	Late	18	1241	1323	108	<0.001	84 (76.3-89.5)	Random	7.4 (4.1-11.5)
DeepVery early		6	451	472	3	0.757	0 (0.0-53.2)	Fixed	1.6 (0.7-3.2)
infection									
	Early	3	374	425	20	<0.001	90 (72.9-96.2)	Random	2.6 (0.0-10.4)
	Intermediate	5	474	479	4	0.402	1 (0.0-80.6)	Fixed	6.0 (4.1-8.6)
	Late	14	984	1137	59	<0.001	78 (63.4-86.7)	Random	3.8 (1.6-6.8)
Necrosis									
	Very early	3	154	160	6	0.059	65 (0.0-89.9)	Fixed	3.7 (1.4-7.8)
	Early	3	117	125	2	0.331	9 (0.0-97.0)	Random	4.4 (0.4-12.4)
	Intermediate	5	259	287	9	0.054	57 (0.0-84.1)	Random	6.4 (2.4-12.1)
	Late	8	730	807	11	0.144	36 (0.0-71.6)	Fixed	5.5 (4.0-7.3)
Nonunion									
	Very early	3	190	210	0	0.914	0 (0.0-62.9)	Fixed	1.5 (0.3-4.4)
	Early*								
	Intermediate	3	113	122	0	0.944	0 (0.0-42.0)	Fixed	0.6 (0.0-4.3)
	Late*								
Implant									
	Very early	2	156	156	7	0.007	86 (45.4-96.6)	Random	5.9 (0.4-27.7)
removal									
	Early*								
	Intermediate	3	152	164	7	0.026	73 (7.4-91.9)	Random	12.7 (4.6-23.9)
	Late	9	479	520	22	0.006	63 (24.3-82.1)	Random	6.8 (3.5-11.2)

Outcome	Partial WB	N_s	N_p	N_f	Q	P-value	I^2 (95% CI)	Method	Pooled estimate (95% CI)
Arthrodesis									
Very early*									
Early*									
Intermediate		4	469	481	10	0.023	68 (8.4-89.1)	Random	5.5 (2.1-10.3)
Late		6	547	613	71	<0.001	93 (87.4-96.1)	Random	10.2 (2.4-22.5)

* Insufficient data available

Partial WB, time to partial weightbearing; N_p, number of operatively treated patients; N_s, number of studies; N_f, number of fractures; Böhler pre, Pre-operative Böhler's angle; Böhler post, Post-operative Böhler's angle; Böhler FU, Böhler's angle at follow-up; Gissane pre, Pre-operative Gissane's angle; Gissane post, Post-operative Gissane's angle; Gissane FU, Gissane's angle at follow-up; CalcH pre, Pre-operative calcaneal height; CalcH post, Post-operative calcaneal height; CalcH FU, Calcaneal height at follow-up; AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analog scale for pain (0-10).

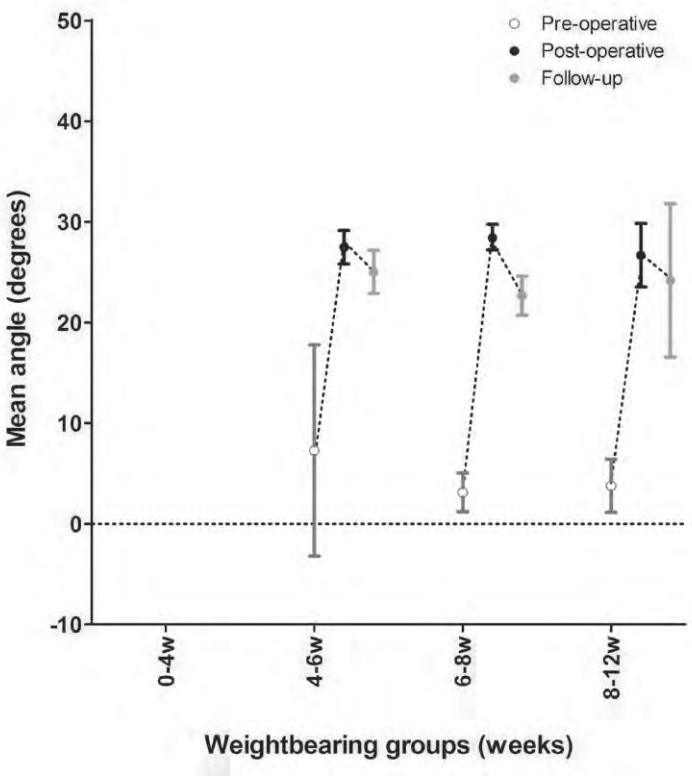

Figure 2. Böhler's angle at different time points in the partial weightbearing groups
Time to partial weightbearing: very early (0-4 weeks), early (4-6 weeks), intermediate (6-8 weeks), and late (8-12 weeks).

The overlaps in CIs do not support a relation between the time to partial weightbearing and calcaneal height and the angle of Gissane (Table 1). No data were available for the very early and the early partial weightbearing groups. The post-operative angle of Gissane was 119° [95% CI, 118-121°] in the intermediate and 122° [95% CI, 115-128°] in the late partial weightbearing group. At follow-up, again overlap in confidence intervals was found in Gissane's angle: 123° [95% CI, 121-125°] and 120° [95% CI, 107-132°] in the intermediate and late partial weightbearing group, respectively. The post-operative calcaneal height data were only available in two weightbearing groups: intermediate; 44 mm [95% CI, 43-46 mm] and late partial weightbearing 43 mm [95% CI, 40-46 mm].

Functional outcomes

The AOFAS Ankle-Hindfoot Scale (18) was used as an instrument to measure functional outcome. In the very early partial weightbearing group insufficient data were available for analysis. In the other three groups the mean score was 82 points [95% CI, 78-87 points] in the early, 81 points [95% CI, 78-84 points] in the intermediate, and 83 points [95% CI, 79-87 points] in the late partial weightbearing group (Table 1). In all three groups, overlap in the 95% CI was found (Figure 3). Other patient reported outcome scores were reported in only a few studies and did not provide sufficient data for the individual weightbearing groups (Foot Function Index, ShortForm-36, EuroQol-5D, Lower extremity functional scale, Maryland Foot Score, Creighton-Nebraska Score, and short musculoskeletal functional assessment).

Pain

The 95% CIs of VAS pain scores overlapped in the early and the late partial weightbearing groups: 1.6 points [95% CI, 1.3-1.9 points] in the early and 5.2 points [95% CI, 1.3-9.1 points] in the late partial weightbearing group. In the other two partial weightbearing groups, insufficient data were available for analysis. Insufficient primary statistics were reported for other pain scores (NRS and Likert scale).

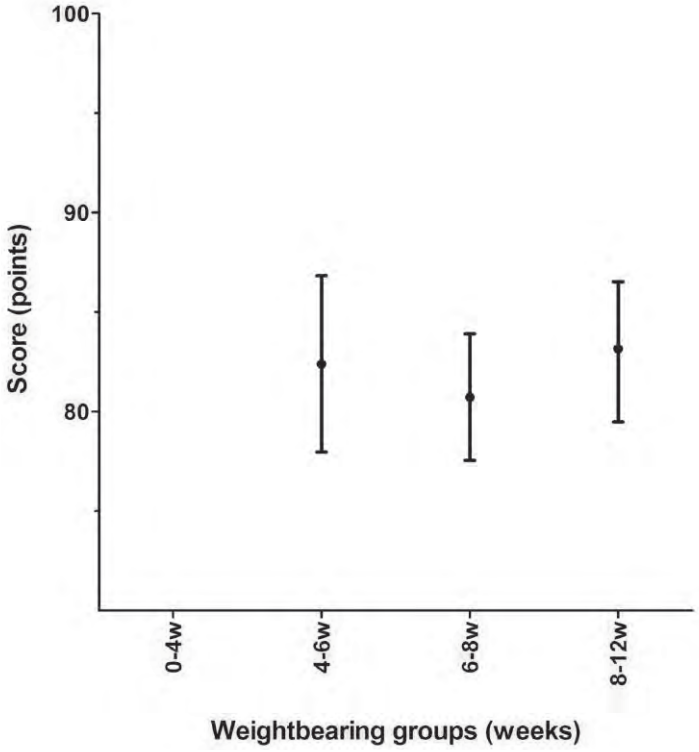

Figure 3. American Orthopedic Foot and Ankle Society (AOFAS) in partial weightbearing groups
Time to partial weightbearing: very early (0-4 weeks), early (4-6 weeks), intermediate (6-8 weeks), and late (8-12 weeks).

Complications and revision surgery

The 95% CIs of all complications, except for deep infections, overlapped in every weightbearing group (Figure 4 and Table 1). Most superficial infections were found in the intermediate partial weightbearing group: 14% [95% CI, 9-20%], however with consistently overlapping 95% CI of very early; 7% [95% CI, 5-10%], early; 9% [95% CI, 2-20%], and late; 7% [95% CI, 4-11%]. Also, the highest rate of deep infections were found in the intermediate partial weightbearing group: 6% [95% CI, 4-9%], compared with the lowest rate of 2% [95% CI, 1-3%] in the very early partial weightbearing group. The highest wound necrosis rate was noted in the intermediate partial weightbearing group (6% [95% CI, 2-12%]), compared with 4% [95% CI, 1-8%] in the very early; 4% [95% CI, 0-12%] in the early, and 5% [95% CI, 4-7%] in the late partial weightbearing group. Concerning the remaining VAS pain, nonunion, implant removal, or arthrodesis (for subtalar arthrosis), no analysis could be performed since insufficient data was available, or 95% CIs were consistently overlapping for the various weightbearing groups.

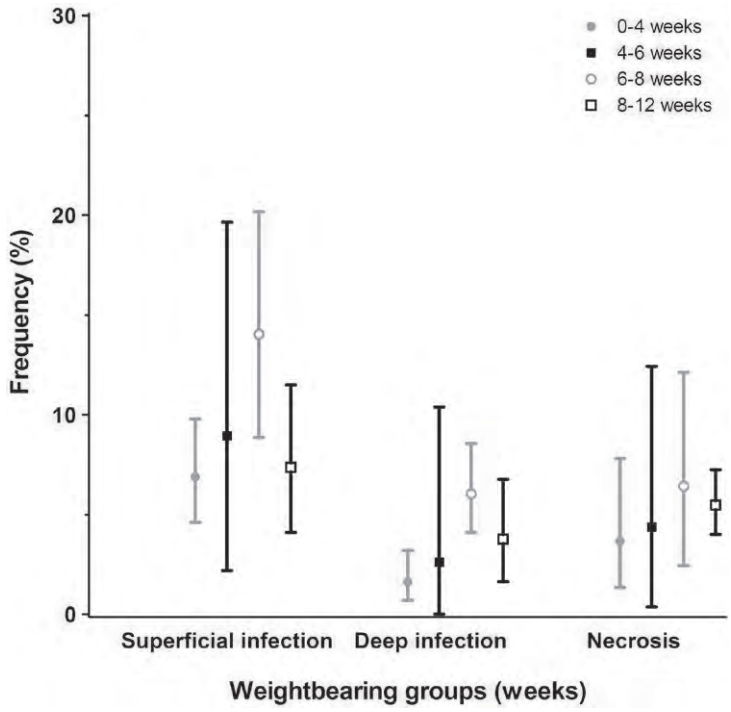

Figure 4. Complications in partial weightbearing groups
Time to partial weightbearing: very early (0-4 weeks), early (4-6 weeks), intermediate (6-8 weeks), and late (8-12 weeks).

Full weightbearing

The overlapping 95% CIs of the post-operative Böhler's angle, do not suggest a relation between the intermediate and late full weightbearing groups: 28° [95% CI, 25-32°] versus 28° [95% CI, 27-29°] (Table 2). Böhler's angle at follow-up was 22° [95% CI, 19-25°] for the intermediate and 24° [95% CI, 22-26°] in the late weightbearing group. Insufficient data on calcaneal height were available for the early full weightbearing group. But again no relation between the remaining full weightbearing groups could be noted. The 95% CI of the AOFAS in the intermediate full weightbearing group (86 points [95% CI, 84-89 points]) overlapped with that of the late full weightbearing group (82 points [95% CI, 79-85]).

Table 2. Radiographic outcomes, functional outcomes, and complications after full weightbearing in patients with DIACF

Outcome Full WB	N_s	N_p	N_f	Q	P-value	I^2 (95% CI)	Model	Pooled estimate (95% CI)
Böhler pre								
Early	2	248	291	20	<0.001	95 (84.9-98.3)	Random	6.2 (-3.1-15.4)
Intermediate	3	73	76	7	0.026	72 (7.2-91.8)	Random	6.0 (1.5-10.5)
Late	5	288	331	12	0.016	67 (14.8-97.3)	Random	1.6 (0.7-2.5)
Böhler post								
Early*								
Intermediate	3	73	76	11	0.004	82 (42.9-94.1)	Random	28.3 (24.8-31.9)
Late	7	678	742	22	0.001	73 (41.2-87.3)	Random	28.3 (27.5-29.1)
Böhler FU								
Early*								
Intermediate	2	40	43	2	0.218	34 (0.0-0.0)	Fixed	21.9 (18.9-24.9)
Late	5	485	485	48	<0.001	92 (83.7-95.8)	Random	24.1 (22.2-26.1)
Gissane pre								
Early*								
Intermediate*								
Late*								
Gissane post								
Early*								
Intermediate*								
Late	3	546	600	73	<0.001	97 (94.6-98.6)	Random	121.4 (117.6-125.2)
Gissane FU								
Early*								
Intermediate*								
Late	2	390	390	4	0.036	77 (0.0-94.8)	Random	123.4 (121.6-125.1)
CalcH pre								
Early*								
Intermediate	2	40	40	1	0.432	0 (0.0-0.0)	Fixed	35.4 (34.1-36.6)
Late*								
CalcH post Early*								
Intermediate	2	40	40	1	0.469	0 (0.0-0.0)	Fixed	42.8 (42.2-43.3)
Late	4	577	631	13	0.005	76 (35.0-91.4)	Random	42.6 (41.9-43.3)
CalcH FU								
Early*								
Intermediate	2	40	40	14	<0.001	93 (76.3-97.9)	Random	40.6 (38.5-42.6)
Late	2	390	390	0	0.814	0 (0.0-0.0)	Fixed	40.1 (39.6-40.5)
AOFAS								
Early*								
Intermediate	2	40	40	0	0.502	0 (0.0-0.0)	Fixed	86.1 (83.7-88.6)
Late	7	576	578	160	<0.001	96 (94.2-97.6)	Random	81.6 (78.5-84.7)
VAS pain								
Early*								
Intermediate*								
Late	3	121	128	58	<0.001	97 (92.8-98.3)	Random	2.2 (1.2-3.2)

Outcome Full WB	N_s	N_p	N_f	Q	P-value	I^2 (95% CI)	Model	Pooled estimate (95% CI)
Superficial Early infection	3	223	242	1	0.646	0 (0.0-92.3)	Fixed	15.2 (11.0-20.4)
Intermediate	9	499	527	10	0.266	20 (0.0-61.5)	Fixed	12.9 (10.2-16.0)
Late	18	1319	1414	136	<0.001	88 (81.8-91.5)	Random	10.2 (6.0-15.4)
DeepEarly infection	4	241	261	2	0.544	0 (0.0-81.9)	Fixed	5.4 (3.0-8.8)
Intermediate	5	521	564	5	0.258	25 (0.0-69.5)	Fixed	2.8 (1.6-4.5)
Late	12	1023	1111	46	<0.001	76 (58.1-86.3)	Random	3.9 (1.7-6.8)
Necrosis Early*								
Intermediate	5	252	282	4	0.374	6 (0.0-81.6)	Fixed	6.7 (4.1-10.2)
Late	9	502	528	17	0.030	53 (0.0-77.7)	Random	7.5 (4.4-11.4)
Nonunion Early*								
Intermediate	2	79	84	0	0.721	0 (0.0-0.0)	Fixed	0.6 (0.0-5.6)
Late	4	224	248	0	0.954	0 (0.0-0.0)	Fixed	1.4 (0.3-3.9)
Implant removal Early*								
Intermediate	3	246	248	10	0.008	79 (34.6-93.5)	Random	8.7 (1.0-23.2)
Late	5	322	337	8	0.096	49 (0.0-81.4)	Random	5.1 (2.2-9.0)
Arthrodesis Early*								
Intermediate*								
Late	4	523	544	60	<0.001	95 (90.1-97.4)	Random	12.1 (2.4-27.9)

* Insufficient data available

Full WB, time to full weightbearing; N_p, number of operatively treated patients; N_s, number of studies; N_f, number of fractures; Böhler pre, Pre-operative Böhler's angle; Böhler post, Post-operative Böhler's angle; Böhler FU, Böhler's angle at follow-up; Gissane pre, Pre-operative Gissane's angle; Gissane post, Post-operative Gissane's angle; Gissane FU, Gissane's angle at follow-up; CalcH pre, Pre-operative calcaneal height; CalcH post, Post-operative calcaneal height; CalcH FU, Calcaneal height at follow-up; AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analog scale for pain (0-10).

Bone void fillers

To assess whether bone void filling would allow earlier weightbearing, a subanalysis was done for bone void fillers combined with internal fixation. For all outcomes (*e.g.,* radiographic parameters, complications, and revision surgery) in the bone void filling group, the very early and early partial weightbearing data was insufficient to analyze (Table 3). Information of the intermediate partial weightbearing bone void filling group was mostly available, the AOFAS score was 81 points [95% CI, 71-92 points]) in this group.

Table 3. Radiographic outcomes, functional outcomes, and complications after partial weightbearing in patients with DIACF treated with internal fixation combined with bone void filling

Outcome Partial WB	N_s	N_p	N_f	Q	P-value	I^2 (95% CI)	Model	Pooled estimate (95% CI)
Böhler pre								
Intermediate	2	N.S.	50	1	0.245	26 (0.0-0.0)	Fixed	1.6 (-2.2-5.4)
Böhler post								
Intermediate	3	N.S.	252	4	0.117	53 (0.0-86.7)	Random	28.5 (26.6-30.3)
Böhler FU								
Intermediate	3	N.S.	252	1	0.521	0 (0.0-94.9)	Fixed	25.3 (24.5-26.0)
CalcH post								
Intermediate	2	222	224	0	0.737	0 (0.0-0.0)	Fixed	42.8 (42.5-43.2)
CalcH FU								
Intermediate	2	222	224	11	0.001	90 (65.5-97.4)	Random	40.8 (39.2-42.4)
AOFAS								
Intermediate	2	222	224	40	<0.001	97 (93.8-99.0)	Random	81.5 (71.3-91.7)
Superficial infection								
Intermediate	6	334	347	17	0.004	71 (33.0-87.6)	Random	15.0 (7.7-25.1)
Late	3	67	69	1	0.734	0 (0.0-89.2)	Fixed	2.5 (0.3-9.3)
Deep infection								
Very early	2	37	39	1	0.295	9 (0.0-0.0)	Fixed	3.6 (0.2-14.6)
Intermediate	2	233	237	0	0.955	0 (0.0-0.0)	Fixed	7.1 (4.2-11.1)
Necrosis								
Intermediate	3	100	106	4	0.106	55 (0.0-87.3)	Random	8.7 (2.1-19.2)
Nonunion								
Intermediate	2	90	99	0	0.836	0 (0.0-0.0)	Fixed	0.5 (0.0-4.5)
Implant removal								
Late	2	49	51	1	0.271	17 (0.0-0.0)	Fixed	4.6 (0.8-14.2)
Arthrodesis								
Intermediate	2	242	248	7	0.007	86 (44.7-96.5)	Random	8.3 (0.6-23.4)

Partial WB, time to partial weightbearing; N.S., Not specified; N_p, number of operatively treated patients; N_s, number of studies; N_f, number of fractures; Q, Q-value; I^2, Inconsistency; Böhler pre, Pre-operative Böhler's angle; Böhler post, Post-operative Böhler's angle; Böhler FU, Böhler's angle at follow-up; CalcH pre, Pre-operative calcaneal height; CalcH post, Post-operative calcaneal height; CalcH FU, Calcaneal height at follow-up; AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analog scale for pain (0-10).

DISCUSSION

This systematic review shows that the 95% CIs of most outcomes overlapped. This might implicate that there is actually no relationship between the different weightbearing regimes and radiographic and clinical outcomes. However, because of the heterogeneity in terms of methodological designs, treatment, and weightbearing protocols, a spurious relation might be possible.

In this review, both Böhler's angle post-operatively as at follow-up were similar between the different partial weightbearing groups. This suggests that the loss of reduction measured by these Böhler's angles, is not influenced regardless of whether patients start partial weightbearing early or late. Outcomes in all partial weightbearing groups were comparable, suggesting that partial weightbearing within six weeks after surgery has similar effects on maintaining reduction, functional outcome, and complications as the current most commonly recommended weightbearing regimes; intermediate and late partial weightbearing (>6 weeks). In addition, these findings are supported by literature describing surgically treated ankle fractures and other lower extremity fractures. Which reported that early weightbearing regimes do not result in more negative effects on functional outcome, secondary displacement, loss of fixation, and complication rates than more conservative weightbearing regimes (1-5). A systematical review and meta-analysis showed that active exercises (compared to immobilization) and early weightbearing (compared to late weightbearing) after ankle surgery tends to accelerate return to work (6).

The authors acknowledge that the weightbearing-mechanism in patients with ankle fractures differ from weightbearing in patients with calcaneal fractures. However, Dehghan *et al.* (3) found no difference regarding wound complications, surgical site infections, fixation failure, or loss of reduction in unstable ankle fractures when weightbearing and range of motion exercises started after two weeks compared with non-weightbearing and cast immobilization for six weeks. Weightbearing guided by pain in patients with ankle fractures has shown to have similar functional results (activity limitation, range of motion, delayed union, infections, and adverse events) as patients with six weeks of non-weightbearing (2). Even complications linked to early weightbearing as secondary displacement, malunions, and arthrodesis are not significantly higher in early weightbearing groups (2, 3).

Bone void filling (*i.e.,* autologous, allogenic bone grafts or synthetic bone void fillers) aims to speed bone healing, and provides osteoconduction and osteoinduction. The use of such bone void fillers is often recommended for complex lower extremity fractures to speed up the healing process (7). Therefore, a bone void filling subanalysis was done (due too low numbers no specific bone void filler is analysed). Unfortunately, data were only available for the intermediate and late partial weightbearing groups. Therefore, no conclusions could be drawn from this subanalysis. Also locking plates are assumed to allow earlier weightbearing without displacement or implant failure (8, 9). A subanalysis on this group was not possible due to the limited number of studies.

With comparable results in the different weightbearing groups, the negative effects of non-weightbearing need to be addressed. Walking without weightbearing (*i.e.,* crutches) requires four times more energy than a normal walk (10). Furthermore, patients often start weightbearing sooner than their physician recommends (27.5% of the patients is not compliant), but this non-compliance does not increase the risk of complications (11). Since literature on patient compliance is scarce, it is not discussed in this

review. Weightbearing compliance could be monitored via flexible shoe insoles. The insole includes pressure and force sensor that measure the force applied at key bearing points under the foot. Such a self-learning adaptive weightbearing monitoring system also can deliver electrical, mechanical, and/or audio feedback to encourage a patient to load the optimal target weight, the patient is given continuous feedback for improving rehabilitation (12, 13). Another recommendation for future research is the use of Virtual Stress Testing, which provide a non-invasive estimate of a healing bone through a CT scan and has the potential to provide a quantitative, objective measure to identify fractures who could safely handle bearing weight (14).

Prospective clinical studies are required to support this review data and to optimize post-operative weightbearing regimes. This review suggests that such studies could be conducted safely but should be performed using objective and validated parameters, and a weightbearing monitoring system (*i.e.,* shoe insoles to monitor weightbearing compliance).

Limitations of this review are the heterogeneity in used outcomes and reported data, studies reporting no primary data (and therefore had to be excluded), the varying definition of partial weightbearing in the selected studies (e.g., toe touching, walking with crutches; restricted partial weightbearing of 10 kg with increasing amount of weight), and insufficient insight into (non-)weightbearing compliance. Furthermore, factors such as patients' age, injury severity (i.e., fracture (sub)type), the presence of additional injuries, counseling of physical therapy training programs, and the use of analgesics could not be analyzed separately (due to low numbers of available data). These factors are likely to have impact on the study outcomes (e.g., Böhler's angle (secondary displacement), functional outcome, post-operative pain score, complications, revision surgeries and bone void filling). Unfortunately, due to the lack of (randomized) comparative studies this review was limited to studies with a lower scientific level of evidence, and to pooled analysis instead of a meta-analysis. Finally, not all study designs are comparable, as some studies also included bilateral and open calcaneal fractures. Above mentioned reduces the impact of conclusions in this review.

CONCLUSION

The adverse sequelae which are assumed to be associated with starting partial weightbearing already within six weeks after internal fixation of calcaneal fractures, is not supported by literature data. This systematic review suggests that early weightbearing does not result in impaired outcomes compared with the current (more conservative) weightbearing regimes.

SUPPLEMENTAL MATERIAL

Embase.com: 1029 publications

('calcaneus fracture'/exp OR (calcaneus/de AND (fracture/de OR 'orthopedic fixation device'/exp OR 'fracture treatment'/exp)) OR ((calcane* OR heel OR os-calc*) NEAR/10 (fracture* OR trauma* OR screw* OR plate* OR fixat* OR orif OR crif OR arthrode* OR osteosynthes*)):ab,ti) AND ('immobilization'/exp OR 'mobilization'/exp OR 'weightbearing'/exp OR 'physical activity'/de OR walking/de OR 'standing'/de OR 'kinesiotherapy'/exp OR 'physical medicine'/de OR physiotherapy/exp OR 'physiotherapist'/exp OR rehabilitation/de OR Exercise/de OR (mobilizat* OR immobilizat* OR mobilisat* OR immobilisat* OR ((weight OR load) NEAR/3 bear*) OR weightbear* OR loadbear* OR axial-load* OR walking OR standing OR kinesiotherap* OR kinesitherap* OR exercis* OR ((movement* OR phys*) NEAR/3 (therap* OR treat* OR technique* OR medicine* OR activ*)) OR physiotherap* OR rehabilitat* OR ambulat*):ab,ti) NOT ([Conference Abstract]/lim OR [Letter]/lim OR (15)/lim OR [Editorial]/lim) NOT ([animals]/lim NOT [humans]/lim)

Medline Ovid: 954 publications

("calcaneus"/in OR (calcaneus/ AND (Fractures, Bone/ OR exp "Orthopedic Fixation Devices"/)) OR ((calcane* OR heel OR os-calc*) ADJ10 (fracture* OR trauma* OR screw* OR plate* OR fixat* OR orif OR crif OR arthrode* OR osteosynthes*)).ab,ti,kf.) AND ("immobilization"/ OR "Early Ambulation"/ OR "Weight-Bearing"/ OR "Exercise"/ OR walking/ OR "Exercise Therapy"/ OR "Physical and Rehabilitation Medicine"/ OR "Physical Therapy Modalities"/ OR "Physical Therapists"/ OR Rehabilitation/ OR (mobilizat* OR immobilizat* OR mobilisat* OR immobilisat* OR ((weight OR load) ADJ3 bear*) OR weightbear* OR loadbear* OR axial-load* OR walking OR standing OR kinesiotherap* OR kinesitherap* OR exercis* OR ((movement* OR phys*) ADJ3 (therap* OR treat* OR technique* OR medicine* OR activ*)) OR physiotherap* OR rehabilitat* OR ambulat*).ab,ti,kf.) NOT (letter OR news OR comment OR editorial OR congresses OR abstracts).pt. NOT (exp animals/ NOT humans/)

CINAHL EBSCOhost: 139 publications

(MH "Calcaneus Fractures" OR (MH calcaneus AND (MH Fractures OR MH "Orthopedic Fixation Devices+")) OR TI ((calcane* OR heel OR os-calc*) N9 (fracture* OR trauma* OR screw* OR plate* OR fixat* OR orif OR crif OR arthrode* OR osteosynthes*)) OR AB ((calcane* OR heel OR os-calc*) N9 (fracture* OR trauma* OR screw* OR plate* OR fixat* OR orif OR crif OR arthrode* OR osteosynthes*))) AND (MH "immobilization" OR MH "Early Ambulation" OR MH "Weight-Bearing" OR MH "Exercise" OR MH walking OR MH "Therapeutic Exercise" OR MH "Physical Medicine" OR MH "Physical Therapy" OR

MH "Physical Therapists" OR MH Rehabilitation OR TI (mobilizat* OR immobilizat* OR mobilisat* OR immobilisat* OR ((weight OR load) N2 bear*) OR weightbear* OR loadbear* OR axial-load* OR walking OR standing OR kinesiotherap* OR kinesitherap* OR exercis* OR ((movement* OR phys*) N2 (therap* OR treat* OR technique* OR medicine* OR activ*)) OR physiotherap* OR rehabilitat* OR ambulat*) OR AB (mobilizat* OR immobilizat* OR mobilisat* OR immobilisat* OR ((weight OR load) N2 bear*) OR weightbear* OR loadbear* OR axial-load* OR walking OR standing OR kinesiotherap* OR kinesitherap* OR exercis* OR ((movement* OR phys*) N2 (therap* OR treat* OR technique* OR medicine* OR activ*)) OR physiotherap* OR rehabilitat* OR ambulat*)) NOT PT (letter OR news OR comment OR editorial OR congresses OR abstracts) NOT (MH animals+ NOT MH humans+)

Cochrane: 32 publications

(((calcane* OR heel OR os-calc*) NEAR/10 (fracture* OR trauma* OR screw* OR plate* OR fixat* OR orif OR crif OR arthrode* OR osteosynthes*)):ab,ti) AND ((mobilizat* OR immobilizat* OR mobilisat* OR immobilisat* OR ((weight OR load) NEAR/3 bear*) OR weightbear* OR loadbear* OR axial-load* OR walking OR standing OR kinesiotherap* OR kinesitherap* OR exercis* OR ((movement* OR phys*) NEAR/3 (therap* OR treat* OR technique* OR medicine* OR activ*)) OR physiotherap* OR rehabilitat* OR ambulat*):ab,ti)

Web of Science: 334 publications

TS=((((calcane* OR heel OR os-calc*) NEAR/9 (fracture* OR trauma* OR screw* OR plate* OR fixat* OR orif OR crif OR arthrode* OR osteosynthes*))) AND ((mobilizat* OR immobilizat* OR mobilisat* OR immobilisat* OR ((weight OR load) NEAR/2 bear*) OR weightbear* OR loadbear* OR axial-load* OR walking OR standing OR kinesiotherap* OR kinesitherap* OR exercis* OR ((movement* OR phys*) NEAR/2 (therap* OR treat* OR technique* OR medicine* OR activ*)) OR physiotherap* OR rehabilitat* OR ambulat*))) AND DT=(article) AND LA=(english)

Google Scholar: 200 publications

"calcaneus|calcaneal|calcis fracture|fractures|trauma|fixation|fixator"mobilization|immobilization|mobilisation|immobilisation|"weight|loadbearing"|weightbearing|loadbearing|walking|standing|"physical activity|activities"|ambulation

SUPPLEMENTAL TABLE 1

Publication	Study design	M	WB time	BVF	N_p	N_f	N Male (%)	FU (mo)
Duymus *et al.* (1)	Prospective case control	16	N.D.	N.D.	40	43	35 (88)	N.D.
Duymus *et al.* (1)_A	Prospective case control	16	6	Yes	20	22	N.D.	24.8
Duymus *et al.* (1)_B	Prospective case control	16	6	No	20	21	N.D.	22.7
Gamal *et al.* (2)	Prospective cohort	11	6-8	No	57	64	40 (70)	16
Hegde *et al.* (3)	Prospective cohort	3	6	No	23	23	22 (96)	N.D.
Li *et al.* (4)	RCT *	20	4-6	No	64	64	47 (74)	12
Li *et al.* (4)_A	RCT *	20	4-6	No	32	32	24 (75)	12
Li *et al.* (4)_B	RCT *	20	4-6	No	32	32	23 (72)	12
Long *et al.* (5)	Prospective cohort	13	8-12	No	23	23	8 (35)	13.7
Pompach *et al.* (6)	Prospective cohort	12	1	No	107	107	N.D.	12
Scott *et al.* (7)	Retrospective cohort	9	8	No	35	39	21 (60)	10
Zwipp *et al.* (8)	Prospective case control	8	6-10	No	103	106	89 (86)	12
Cao *et al.*(9)	Prospective cohort	7	3	No	33	33	25 (76)	21
Chen *et al.* (10)	Prospective cohort	4	8-12	N.D.	42	48	27 (64)	17
Farell *et al.* (11)	Retrospective case series	6	8	No	9	10	N.D.	2
Gomaa *et al.*(12)	Prospective cohort	12	6	No	52	61	43 (83)	31.4
Gusic *et al.* (13)	Retrospective cohort	19	N.D.	N.D.	103	105	82 (80)	12
Gusic *et al.* (13)_A	Retrospective cohort	19	6-8	No	16	N.D.	N.D.	N.D.
Gusic *et al.* (13)_B	Retrospective cohort	19	6-8	No	67	N.D.	N.D.	N.D.
Gusic *et al.* (13)_C	Retrospective cohort	19	6-8	Yes	20	N.D.	N.D.	N.D.
De Vroome *et al.* (14)	Retrospective case series	10	8-12	No	38	41	29 (76)	75.6
Griffin *et al.* (15)	RCT *	21	6	No	73	73	64 (88)	24
Hetsroni *et al.* (16)	Retrospective cohort	9	8-12	No	16	16	13 (81)	40
Kayali *et al. (17)*	Retrospective cohort	11	6-8	Yes	15	15	12 (80)	19
Sanders *et al*. (18)	Prognostic case control	11	12	No	93	108	73 (88)	182.5
Sivakumar *et al.* (19)	Retrospective cohort	6	10	N.D.	13	13	11 (85)	19.9
Su *et al*. (20)	Retrospective cohort	12	4-6	No	12	12	10 (83)	93.9
Vittore *et al*. (21)	Prospective cohort	8	1	Yes	20	20	11 (55)	12.3
Ågren *et al. (22)*	RCT *	21	6	N.D.	42	42	29 (69)	120
De Groot *et al.* (23)	Retrospective cohort	10	6-8	No	39	45	26 (67)	78
Gülabi *et al*. (24)	Retrospective cohort	8	10.4	Yes	26	27	21 (81)	34.4
Hammond *et al.* (25)	Prospective case series	9	8	No	14	17	N.D.	3
Jain *et al.* (26)	Prospective cohort	8	12	No	24	26	21 (83)	14.5
Naik *et al.* (27)	Prospective cohort	7	6	No	37	47	30 (81)	31.2
Singh *et al.* (28)	Retrospective cohort	20	N.D.	N.D.	390	390	N.D.	24
Singh *et al.* (28)_A	Retrospective cohort	20	6-8	Yes	202	202	152 (75)	24
Singh *et al.* (28)_B	Retrospective cohort	20	6-8	No	188	188	130 (58)	24
Wu *et al.* (29)	Retrospective cohort	13	N.D.	N.D.	329	383	307 (93)	12
Wu *et al.* (29)_A	Retrospective cohort	13	5.6	No	181	213	168 (93)	12
Wu *et al.* (29)_B	Retrospective cohort	13	9.4	N.D.	148	170	139 (94)	12

Publication	Study design	M	WB time	BVF	N_p	N_f	N Male (%)	FU (mo)
Chen *et al.* (30)	Prospective cohort	21	N.D.	N.D.	78	78	44 (56)	24
Chen *et al.* (30)_A	Prospective cohort	21	8	N.D.	40	40	24 (60)	24
Chen *et al.* (30)_B	Prospective cohort	21	6	Yes	38	38	20 (53)	24
DeWall *et al.* (31)	Retrospective cohort	15	N.D.	N.D.	120	125	N.D.	N.D.
DeWall *et al.* (31)_A	Retrospective cohort	15	8-10	No	41	42	35 (88)	24.7
DeWall *et al.* (31)_B	Retrospective cohort	15	8-10	No	79	83	66 (80)	21.9
Hyer *et al.* (32)	Retrospective cohort	13	4.88	No	17	17	12 (71)	237.7
Mostafa *et al.* (33)	Prospective cohort	12	8-10	Yes	18	18	16 (89)	24.1
Rammelt *et al.* (34)	Retrospective cohort	10	6-8	No	33	33	21 (88)	29
Wang *et al.* (35)	Prospective cohort	9	8	No	156	210	144 (92)	9.7
Demcoe *et al.* (36)	Retrospective chart review	10	8-12	No	246	278	207 (84)	6
Johal *et al.* (37)	RCT *	19	N.D.	N.D.	47	52	N.D.	N.D.
Johal *et al.* (37)_A	RCT *	19	6	Yes	N.D.	28	N.D.	12
Johal *et al.* (37)_B	RCT *	19	6	No	N.D.	24	N.D.	12
Kienast *et al.* (38)	Retrospective cohort	14	1	No	136	136	112 (82)	8.6
Rak *et al.* (39)	Prospective cohort	15	N.D.	N.D.	67	76	57 (85)	N.D.
Rak *et al.* (39)_A	Prospective cohort	15	8-12	No	N.D.	N.D.	N.D.	N.D.
Rak *et al.* (39)_B	Prospective cohort	15	8-12	No	N.D.	N.D.	N.D.	N.D.
Rak *et al.* (39)_C	Prospective cohort	15	8-12	No	N.D.	N.D.	N.D.	N.D.
Rak *et al.* (39)_D	Prospective cohort	15	6-8	No	N.D.	N.D.	N.D.	N.D.
Rak *et al.* (39)_E	Prospective cohort	15	6-8	No	N.D.	N.D.	N.D.	N.D.
Rak *et al.* (39)_F	Prospective cohort	15	6-8	No	N.D.	N.D.	N.D.	N.D.
Wee *et al.* (40)	Prospective cohort	8	4	Yes	10	12	9 (90)	7
Schepers *et al.* (41)	Prospective cohort	8	12	No	50	61	36 (72)	35
Walde *et al.* (42)	Retrospective case series	9	8	No	88	92	63 (72)	68.4
Zeman *et al.* (43)	Prospective cohort	7	0-4	N.D.	29	33	27 (93)	N.D.
Ibrahim *et al.* (44)	RCT *	16	6-8	No	15	15	11 (73)	180
Besse *et al.* (45)	Prospective case series	9	10	No	31	31	27 (84)	53
Stulik *et al.* (46)	Retrospective cohort	9	8.4	No	247	287	210 (85)	43.4
Elsner *et al.* (47)	Prospective cohort	11	0-4	Yes	18	19	13 (72)	22.3
Emara *et al.* (48)	Prospective cohort	15	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
Emara *et al.* (48)_A	Prospective cohort	15	12	No	18	20	18 (90)	10.7
Koski *et al.* (49)	Retrospective cohort	7	6	No	126	148	101 (80)	10.7
Howard *et al.*(50)	RCT *	21	6	No	161	180	N.D.	N.D.
Buckley *et al.* (51)	RCT *	21	6	No	206	249	N.D.	N.D.
Geel *et al.* (52)	Retrospective cohort	8	6-10	No	29	33	22 (76)	20
Longino *et al.* (53)	Prospective case control	13	6	N.D.	40	40	38 (95)	29
Shuler *et al.* (54)	Retrospective cohort	11	12	N.D.	62	63	51 (82)	6
Tennent *et al.* (55)	Prospective cohort	10	6	N.D.	47	51	36 (77)	44
Park *et al.* (56)	Retrospective cohort	7	6	No	92	103	73 (79)	28
Schildhauer *et al.* (57)	Prospective cohort	7	N.D.	Yes	32	36	32 (100)	21
Rodriguez *et al.* (58)	Retrospective cohort	15	10-12	Yes	28	28	23 (82)	46

Publication	Study design	M	WB time	BVF	N_p	N_f	N Male (%)	FU (mo)
Strømsøe *et al.* (59)	Retrospective case series	8	6	Yes	40	46	28 (7)	N.D.
Burdeaux *et al.* (60)	Prospective cohort	6	8	No	53	61	36 (68)	52.8
Crosby *et al.* (61)	Retrospective cohort	8	8	No	21	23	15 (71)	26
Laughlin *et al.* (62)	Prospective cohort	11	8-12	No	31	33	27 (87)	18
Thordarson *et al.* (63)	RCT *	17	10	No	15	15	12 (80)	17
Chan *et al.* (64)	Retrospective cohort	9	6-8	Yes	31	35	29 (94)	44.3
Monsey *et al.* (65)	Retrospective cohort	7	8	Yes	18	18	14 (78)	32
Hutchinson *et al.* (66)	Retrospective cohort	8	8	No	43	47	29 (67)	N.D.
Bezes *et al.* (67)	Retrospective cohort	6	8	No	205	205	N.D.	39
Prats *et al.* (68)	Retrospective cohort	9	1	No	20	20	9 (45)	60
Sanders *et al.* (69)	Retrospective cohort	8	8	No	132	132	N.D.	29.3
Zwipp *et al.* (70)	Prospective cohort	10	1.5	No	141	157	98 (70)	36
Leung *et al.* (71)	Prospective cohort	11	6	No	59	64	53 (90)	10.6
Stephenson *et al.* (72)	Retrospective case series	5	8-12	No	12	14	9 (75)	22

*M; MINORS is usually used for non-randomized studies. No randomization was performed for weightbearing starting time. Publications presented in chronological order, at the top the most recent studies. MINORS, methodological items for non-randomized studies; WB time, weightbearing time; BVF, Bone Void Filling; N.D., Not determined, Np, number of patients; Nf, number of fractures; FU, follow-up; mo; months.

REFERENCES

1. Rüedi TP, Buckley RE, Moran CG. AO principles of fracture management. New York: Thieme; 2007.
2. Hyer CF, Atway S, Berlet GC, Lee TH. Early weight bearing of calcaneal fractures fixated with locked plates: a radiographic review. Foot Ankle Spec. 2010;3(6):320-3.
3. Buckley R, Tough S, McCormack R, Pate G, Leighton R, Petrie D, et al. Operative compared with nonoperative treatment of displaced intra-articular calcaneal fractures: a prospective, randomized, controlled multicenter trial. J Bone Joint Surg Am. 2002;84-A(10):1733-44.
4. Schepers T, van Lieshout EM, van Ginhoven TM, Heetveld MJ, Patka P. Current concepts in the treatment of intra-articular calcaneal fractures: results of a nationwide survey. Int Orthop. 2008;32(5):711-5.
5. Haller JM, Potter MQ, Kubiak EN. Weight bearing after a periarticular fracture. What is the evidence? Orthop Clin North Am. 2013;44(4):509-19.
6. Sanders R. Displaced intra-articular fractures of the calcaneus. J Bone Joint Surg Am. 2000;82(2):225-50.
7. Brauer CA, Manns BJ, Ko M, Donaldson C, Buckley R. An economic evaluation of operative compared with nonoperative management of displaced intra-articular calcaneal fractures. J Bone Joint Surg Am. 2005;87(12):2741-9.
8. Westerman RW, Hull P, Hendry RG, Cooper J. The physiological cost of restricted weight bearing. Injury. 2008;39(7):725-7.
9. Rezen T, Kovanda A, Eiken O, Mekjavic IB, Rogelj B. Expression changes in human skeletal muscle miRNAs following 10 days of bed rest in young healthy males. Acta Physiol (Oxf). 2014;210(3):655-66.
10. Van der Wiel HE, Lips P, Nauta J, Patka P, Haarman HJ, Teule GJ. Loss of bone in the proximal part of the femur following unstable fractures of the leg. J Bone Joint Surg Am. 1994;76(2):230-6.
11. Smeeing DP, Houwert RM, Briet JP, Kelder JC, Segers MJ, Verleisdonk EJ, et al. Weight-bearing and mobilization in the postoperative care of ankle fractures: a systematic review and meta-analysis of randomized controlled trials and cohort studies. PLoS One. 2015;10(2):e0118320.
12. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ. 2009;339:b2700.
13. Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological index for non-randomized studies (minors): development and validation of a new instrument. ANZ J Surg. 2003;73(9):712-6.
14. Mahid SS, Hornung CA, Minor KS, Turina M, Galandiuk S. Systematic reviews and meta-analysis for the surgeon scientist. Br J Surg. 2006;93(11):1315-24.
15. Bramer WM, Giustini D, de Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. J Med Libr Assoc. 2016;104(3):240-3.
16. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. Pain. 1983;17(1):45-56.
17. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. Am J Infect Control. 1999;27(2):97-132; quiz 3-4; discussion 96.
18. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int. 1994;15(7):349-53.
19. Lin CW, Donkers NA, Refshauge KM, Beckenkamp PR, Khera K, Moseley AM. Rehabilitation for ankle fractures in adults. Cochrane Database Syst Rev. 2012;11:CD005595.
20. Dehghan N, McKee MD, Jenkinson RJ, Schemitsch EH, Stas V, Nauth A, et al. Early Weightbearing and Range of Motion Versus Non-Weightbearing and Immobilization After Open Reduction and Internal Fixation of Unstable Ankle Fractures: A Randomized Controlled Trial. J Orthop Trauma. 2016;30(7):345-52.
21. Egol KA, Nauth A, Lee M, Pape HC, Watson JT, Borrelli J, Jr. Bone Grafting: Sourcing, Timing, Strategies, and Alternatives. J Orthop Trauma. 2015;29 Suppl 12:S10-4.
22. Pennal GF, Yadav MP. Operative treatment of comminuted fractures of the Os calcis. Orthop Clin North Am. 1973;4(1):197-211.

23. Bergmann G, Graichen F, Rohlmann A. Hip joint contact forces during stumbling. Langenbecks Arch Surg. 2004;389(1):53-9.
24. Chiodo CP, Macaulay AA, Palms DA, Smith JT, Bluman EM. Patient Compliance with Postoperative Lower-Extremity Non-Weight-Bearing Restrictions. J Bone Joint Surg Am. 2016;98(18):1563-7.
25. Braun BJ, Veith NT, Rollmann M, Orth M, Fritz T, Herath SC, et al. Weight-bearing recommendations after operative fracture treatment-fact or fiction? Gait results with and feasibility of a dynamic, continuous pedobarography insole. Int Orthop. 2017;41(8):1507-12.
26. North K, Maass SD, Hitchcock RW. An insole sensor for recording weight bearing behavior during tibial fracture rehabilitation. Conf Proc IEEE Eng Med Biol Soc. 2010;2010:1856-9.
27. Petfield JL, Hayeck GT, Kopperdahl DL, Nesti LJ, Keaveny TM, Hsu JR, et al. Virtual stress testing of fracture stability in soldiers with severely comminuted tibial fractures. J Orthop Res. 2017;35(4):805-11.
28. Kenny AM, Smith J, Noteroglu E, Waynik IY, Ellis C, Kleppinger A, et al. Osteoporosis risk in frail older adults in assisted living. J Am Geriatr Soc. 2009;57(1):76-81.
29. Duymus TM, Mutlu S, Mutlu H, Ozel O, Guler O, Mahirogullari M. Need for Bone Grafts in the Surgical Treatment of Displaced Intra-Articular Calcaneal Fractures. J Foot Ankle Surg. 2017;56(1):54-8.
30. Gamal O, Shams A, El-Sayed Semaya A. A Protocol for Percutaneous Transarticular Fixation of Sanders Type II and III Calcaneal Fractures With or Without an Added Mini-Open Approach. J Foot Ankle Surg. 2016;55(6):1202-9.
31. Hegde A, Mathias LJ, Ballal A, Shetty V, Shetty A. A prospective study on radiological and functional outcome of displaced tongue type intra-articular calcaneal fractures treated by percutaneous screw fixation. J Clin Diagn Res. 2016;10(2):RC01-RC4.
32. Li LH, Guo YZ, Wang H, Sang QH, Zhang JZ, Liu Z, et al. Less wound complications of a sinus tarsi approach compared to an extended lateral approach for the treatment of displaced intraarticular calcaneal fracture A randomized clinical trial in 64 patients. Medicine. 2016;95(36).
33. Long C, Fang Y, Huang FG, Zhang H, Wang GL, Yang TF, et al. Sanders II-III calcaneal fractures fixed with locking plate in elderly patients. Chin J Traumatol Eng Ed. 2016;19(3):164-7.
34. Pompach M, Carda M, Amlang M, Zwipp H. Treatment of calcaneal fractures with a locking nail (C-Nail). Oper Orthop Traumatol. 2016;28(3):218-30.
35. Scott AT, Pacholke DA, Hamid KS. Radiographic and CT Assessment of Reduction of Calcaneus Fractures Using a Limited Sinus Tarsi Incision. Foot Ankle Int. 2016;37(9):950-7.
36. Zwipp H, Paša L, Žilka L, Amlang M, Rammelt S, Pompach M. Introduction of a New Locking Nail for Treatment of Intraarticular Calcaneal Fractures. J Orthop Trauma. 2016;30(3):e88-e92.
37. Cao L, Weng W, Song S, Mao N, Li H, Cai Y, et al. Surgical Treatment of Calcaneal Fractures of Sanders Type II and III by a Minimally Invasive Technique Using a Locking Plate. J Foot Ankle Surg. 2015;54(1):76-81.
38. Chen XD, Zhang CC, Li ZC, Zhang H, Zhou XS, Deng M. Clinical Analysis of Internal Fixation Treatment of Intra-articular Calcaneal Fractures with Titanium Plate. Cell Biochem Biophys. 2015;72(1):153-6.
39. Farrell BM, Lin CA, Moon CN. Temporising external fixation of calcaneus fractures prior to definitive plate fixation: a case series. Injury. 2015;46:S19-S22.
40. Gomaa MA, El Naggar A, Anbar A. A modified minimally invasive technique for treatment of intra-articular fractures of the calcaneus. Mid-term results and review of the literature. Eur Orthop Traumatol. 2015;6(4):305-13.
41. Gusic N, Fedel I, Darabos N, Lovric Z, Bukvic N, Bakota B, et al. Operative treatment of intraarticular calcaneal fractures: Anatomical and functional outcome of three different operative techniques. Injury. 2015;46 Suppl 6:S130-3.
42. De Vroome SW, Van Der Linden FM. Cohort study on the percutaneous treatment of displaced intra-articular fractures of the calcaneus. Foot Ankle Int. 2014;35(2):156-62.
43. Griffin D, Parsons N, Shaw E, Kulikov Y, Hutchinson C, Thorogood M, et al. Operative versus non-operative treatment for closed, displaced, intra-articular fractures of the calcaneus: Randomised controlled trial. BMJ (Online). 2014;349.

44. Hetsroni I, Ben-Sira D, Nyska M, Ayalon M. Plantar pressure anomalies after open reduction with internal fixation of high-grade calcaneal fractures. Foot Ankle Int. 2014;35(7):712-8.
45. Kayalı C, Altay T, Kement Z, Çıtak C, Yağdı S. The effect of early weight-bearing on comminuted calcaneal fractures treated with locking plates. Eklem Hastalik Cerrahisi. 2014;25(2):85-90.
46. Sanders R, Vaupel ZM, Erdogan M. Operative treatment of displaced intraarticular calcaneal fractures: long-term (10–20 years) results in 108 fractures using a prognostic CT classification. Journal of orthopaedic trauma. 2014.
47. Sivakumar BS, Wong P, Dick CG, Steer RA, Tetsworth K. Arthroscopic reduction and percutaneous fixation of selected calcaneus fractures: Surgical technique and early results. J Orthop Trauma. 2014;28(10):569-76.
48. Su Y, Chen W, Zhang Q, Liu S, Zhang T, Zhang Y. Bony destructive injuries of the calcaneus: long-term results of a minimally invasive procedure followed by early functional exercise: a retrospective study. BMC Surg. 2014;14:19.
49. Vittore D, Vicenti G, Caizzi G, Abate A, Moretti B. Balloon-assisted reduction, pin fixation and tricalcium phosphate augmentation for calcanear fracture. Injury. 2014;45(S6):S72-S9.
50. Ågren PH, Wretenberg P, Sayed-Noor AS. Operative versus nonoperative treatment of displaced intraarticular calcaneal fractures. J Bone Joint Surg Am. 2013.
51. De Groot R, Frima AJ, Schepers T, Roerdink WH. Complications following the extended lateral approach for calcaneal fractures do not influence mid- to long-term outcome. Injury. 2013;44(11):1596-600.
52. Gülabi D, Sari F, Şen C, Avci CC, Sağlam F, Erdem M, et al. Mid-term results of calcaneal plating for displaced intraarticular calcaneus fractures. Ulusal Travma Acil Cerrahi Derg. 2013;19(2):145-51.
53. Hammond AW, Crist BD. Percutaneous treatment of high-risk patients with intra-articular calcaneus fractures: A case series. Injury. 2013;44(11):1483-5.
54. Jain S, Jain AK, Kumar I. Outcome of open reduction and internal fixation of intraarticular calcaneal fracture fixed with locking calcaneal plate. Chin J Traumatol Eng Ed. 2013;16(6):355-60.
55. Naik NP, Deshpande SB. Evaluation of treatment of calcaneal fractures with a modified approach in a peripheral setting: A cost-effective model. Eur Orthop Traumatol. 2013;4(3):153-60.
56. Singh AK, Vinay K. Surgical treatment of displaced intra-articular calcaneal fractures: Is bone grafting necessary? J Orthop Traumatol. 2013;14(4):299-305.
57. Wu Z, Su Y, Chen W, Zhang Q, Liu Y, Li M, et al. Functional outcome of displaced intra-articular calcaneal fractures: A comparison between open reduction/internal fixation and a minimally invasive approach featured an anatomical plate and compression bolts. J Trauma Acute Care Surg. 2012;73(3):743-51.
58. Chen L, Zhang G, Hong J, Lu X, Yuan W. Comparison of percutaneous screw fixation and calcium sulfate cement grafting versus open treatment of displaced intra-articular calcaneal fractures. Foot Ankle Int. 2011;32(10):979-85.
59. DeWall M, Henderson CE, McKinley TO. Percutaneous reduction and fixation of displaced intra-articular calcaneus fractures. Journal of orthopaedic trauma. 2010.
60. Mostafa MF, El-Adl G, Hassanin EY. Surgical treatment of displaced intra-articular calcaneal fracture using a single small lateral approach: Springer; 2010.
61. Rammelt S, Amlang M, Barthel S, Gavlik JM. Percutaneous treatment of less severe intraarticular calcaneal fractures. Clinical Orthopaedics and Related Research®. 2010.
62. Wang Q, Chen W, Su Y, Pan J, Zhang Q. Minimally invasive treatment of calcaneal fracture by percutaneous leverage, anatomical plate, and compression bolts—the clinical evaluation of cohort of 156 patients. Journal of Trauma and Acute Care Surgery. 2010.
63. Demcoe AR, Verhulsdonk M, Buckley RE. Complications when using threaded K-wire fixation for displaced intra-articular calcaneal fractures. Injury. 2009;40(12):1297-301.
64. Johal HS, Buckley RE, Le ILD. A prospective randomized controlled trial of a bioresorbable calcium phosphate paste (α-BSM) in treatment of displaced intra-articular calcaneal fractures. Journal of Trauma 2009.

65. Kienast B, Gille J, Queitsch C, Kaiser MM, Thietje R, Juergens C, et al. Early Weight Bearing of Calcaneal Fractures Treated by Intraoperative 3D-Fluoroscopy and Locked-Screw Plate Fixation. Open Orthop J. 2009;3:69-74.
66. Rak V, Ira D, Masek M. Operative treatment of intra-articular calcaneal fractures with calcaneal plates and its complications: ijoonline.com; 2009.
67. Wee AT, Wong YS. Percutaneous reduction and injection of Norian bone cement for the treatment of displaced intra-articular calcaneal fractures. Foot Ankle Spec. 2009;2(2):98-106.
68. Schepers T, Vogels LMM, Schipper IB, Patka P. Percutaneous reduction and fixation of intraarticular calcaneal fractures. Oper Orthop Traumatol. 2008;20(2):168-75.
69. Walde TA, Sauer B, Degreif J, Walde HJ. Closed reduction and percutaneus Kirschner wire fixation for the treatment of dislocated calcaneal fractures: surgical technique, complications, clinical and radiological results after 2-10 years.: Springer; 2008.
70. Zeman P, Zeman J, Matějka J, Koudela K. Long-term results of calcaneal fracture treatment by open reduction and internal fixation using a calcaneal locking compression plate from an extended lateral approach. Acta Chir Orthop Traumatol Cech. 2008;75(6):457-64.
71. Ibrahim T, Rowsell M, Rennie W, Brown AR. Displaced intra-articular calcaneal fractures: 15-year follow-up of a randomised controlled trial of conservative versus operative treatment. Injury. 2007.
72. Besse JL, Avaro JP, Chotel F, Lerat JL, Moyen B. Calcaneal intra-articular fracture osteosynthesis: Clinical and radiological prospective study of 31 cases. Foot Ankle Surg. 2006;12(1):19-27.
73. Stulik J, Stehlik J, Rysavy M. Minimally-invasive treatment of intra-articular fractures of the calcaneum. Bone & Joint Journal. 2006.
74. Elsner A, Jubel A, Prokop A, Koebke J, Rehm KE, Andermahr J. Augmentation of intraarticular calcaneal fractures with injectable calcium phosphate cement: Densitometry, histology, and functional outcome of 18 patients. J Foot Ankle Surg. 2005;44(5):390-5.
75. Emara KM, Allam MF. Management of calcaneal fracture using the Ilizarov technique. Clinical orthopaedics and related research. 2005.
76. Koski A, Kuokkanen H. Postoperative wound complications after internal fixation of closed calcaneal fractures: a retrospective analysis of 126 consecutive patients with 148 fractures. Scandinavian Journal of Surgery. 2005.
77. Howard JL, Buckley R, McCormack R. Complications following management of displaced intra-articular calcaneal fractures: a prospective randomized trial comparing open reduction internal fixation with …. Journal of orthopaedic trauma. 2003.
78. Geel CW, A. S. Flemister J. Standardized treatment of intra-articular calcaneal fractures using an oblique lateral incision and no bone graft. Journal of Trauma and Acute Care Surgery. 2001.
79. Longino D, Buckley RE. Bone graft in the operative treatment of displaced intraarticular calcaneal fractures: is it helpful? Journal of orthopaedic trauma. 2001.
80. Shuler FD, Conti SF, Gruen GS, Abidi NA. Wound-healing risk factors after open reduction and internal fixation of calcaneal fractures: does correction of Bohler's angle alter outcomes? Orthopedic Clinics of North America. 2001.
81. Tennent TD, Calder PR, Salisbury RD, Allen PW. The operative management of displaced intra-articular fractures of the calcaneum: a two-centre study using a defined protocol. Injury. 2001.
82. Park IH, Song KW, Shin SI, Lee JY, Kim TG, Park RS. Displaced intra-articular calcaneal fracture treated surgically with limited posterior incision. Foot Ankle Int. 2000;21(3):195-205.
83. Schildhauer TA, Bauer TW, Josten C, Muhr G. Open reduction and augmentation of internal fixation with an injectable skeletal cement for the treatment of complex calcaneal fractures. J Orthop Trauma. 2000;14(5):309-17.
84. Rodriguez-Merchan EC, Galindo E. Intra-articular displaced fractures of the calcaneus. Operative vs non-operative treatment. Int Orthop. 1999;23(1):63-5.
85. Strømsøe K, Mørk E, Hem ES. Open reduction and internal fixation in 46 displaced intraarticular calcaneal fractures. Injury. 1998.

86. Burdeaux Jr BD. Fractures of the calcaneus: Open reduction and internal fixation from the medial side a 21-year prospective study. Foot Ankle Int. 1997;18(11):685-92.
87. Crosby LA, Fitzgibbons TC. Open Reduction and Internal Fixation of Type II Intra-Articular Calcaneus Fractures∗. Foot & ankle international. 1996.
88. Laughlin RT, Carson JG, Calhoun JH. Displaced intra-articular calcaneus fractures treated with the Galveston plate. Foot Ankle Int. 1996;17(2):71-8.
89. Thordarson DB, Krieger LE. Operative vs. nonoperative treatment of intra-articular fractures of the calcaneus: A prospective randomized trial. Foot Ankle Int. 1996;17(1):2-9.
90. Chan S, Ip FK. Open reduction and internal fixation for displaced intra-articular fractures of the os calcis. Injury. 1995.
91. Monsey RD, Levine BP, Trevino SG. Operative treatment of acute displaced intra-articular calcaneus fractures. Foot & ankle International. 1995.
92. F. Hutchinson I, Huebner MK. Treatment of os calcis fractures by open reduction and internal fixation. Foot & ankle international. 1994.
93. Bezes H, Massart P, Delvaux D, Fourquet JP, Tazi F. The operative treatment of intraarticular calcaneal fractures: Indications, technique, and results in 257 cases. Clinical orthopaedics and related research. 1993(290):55-9.
94. Prats AD, Munoz AS, Liopis FS, Perello EB, Garcia AD. Surgery for fracture of the calcaneus: 5 (2-8) year follow-up of 20 cases. Acta Orthop Scan. 1993;64(2):161-4.
95. Sanders R, Fortin P, DiPasquale T. Operative Treatment in 120 Displaced Intraarticular Calcaneal Fractures Results Using a Prognostic Computed Tomography Scan Classification. Orthopaedics and related research. 1993.
96. Zwipp H, Tscherne H, Thermann H. Osteosynthesis of Displaced Intraarticular Fractures of the Calcaneus Results in 123 Cases. Clinical Orthopaedics and related research. 1993.
97. Leung KS, Chan WS, Shen WY, Pak PP, So WS, Leung PC. Operative treatment of intraarticular fractures of the os calcis--the role of rigid internal fixation and primary bone grafting: preliminary results. J Orthop Trauma. 1989;3(3):232-40.
98. Stephenson JR. Displaced fractures of the os calcis involving the subtalar joint: The key role of the superomedial fragment. Foot Ankle. 1983;4(2):91-101.

Chapter 9

American Orthopaedic Foot and Ankle Society ankle-hindfoot scale: a study protocol for the translation and validation of the Dutch language version

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ABSTRACT

Introduction: The AOFAS Ankle-Hindfoot Scale is among the most commonly used instrument for measuring outcome of treatment in patients who sustained a complex ankle or hindfoot injury. It combines a clinician-reported and a patient-reported part. A valid, Dutch version of this instrument is currently not available. Such a translated and validated instrument would allow objective comparison across hospitals or between patient groups, and with shown validity and reliability it may become a quality of care indicator in future. The main aims of this study are to translate and culturally adapt the AOFAS Ankle-Hindfoot Scale questionnaire into Dutch according to international guidelines, and to evaluate the measurement properties of the AOFAS Ankle-Hindfoot Scale-Dutch Language Version (DLV) in patients with a unilateral ankle or hindfoot fracture.

Methods and analysis: The design of the study will be a multicenter, prospective, observational study (case series) in patients who presented to the Emergency Department with a unilateral ankle or hindfoot fracture or (fracture) dislocation. A research physician or research assistant will complete the AOFAS Ankle-Hindfoot Scale-DLV based upon interview for the subjective part and physical examination for the objective part. In addition, patients will be asked to complete the Foot Function Index (FFI) and the Short Form-36 (SF-36). Descriptive statistics (including floor and ceiling effects), internal consistency, construct validity, reproducibility (*i.e.,* test-retest reliability, agreement, and smallest detectable change), and responsiveness will be assessed for the AOFAS DLV.

Ethics and dissemination: This study has been exempted by the medical research ethics committee (MREC) Erasmus MC (Rotterdam, The Netherlands). Each participant will provide written consent to participate and remain anonymized during the study. The results of the study are planned to be published in an international, peer-reviewed journal.

Registration details: The study is registered at the Netherlands Trial Register (NTR5613; 05-jan-2016).

INTRODUCTION

Complex foot and ankle injuries cause a, usually temporary, loss of function and quality of life. Patient-Reported Outcome Measures (PROMs) are essential in both clinical practice and clinical research; they enable detailed evaluation of (functional) outcome or quality of life after (non-)operative treatment of musculoskeletal (traumatic) injuries from a patient's perspective. Generic instruments such as quality of life questionnaires allow comparison across populations with different injuries or medical conditions. Region-specific instruments, on the other hand, may give more detailed insight into the disabilities, pain, and problems caused by a specific injury. Some instruments are solely PROMs, and others combine a patient-reported with a physician-reported part. Numerous generic and region-specific instruments are available (1-6).

A frequently used instrument for assessing outcome after ankle and hindfoot injuries is the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale. This clinical rating system, developed by Kitaoka *et al.*, combines subjective scores of pain and function provided by the patient with objective scores based on the surgeon's physical examination of the patient (to assess sagittal motion, hindfoot motion, ankle-hindfoot stability, and alignment of the ankle-hindfoot) (7). The scale includes nine items that can be divided into three subscales (pain, function, and alignment). Pain consists of one item with a maximal score of 40 points, indicating no pain. Function consists of seven items with a maximal score of 50 points, indicating full function. Alignment consists of one item with a maximal score of 10 points, indicating good alignment. The maximal score is 100 points, indicating no symptoms or impairments. In the original publication, the AOFAS Ankle-Hindfoot Scale was described to be used for ankle replacement, ankle arthrodesis, ankle instability operations, subtalar arthrodesis, subtalar instability operations, talonavicular arthrodesis, calcaneocuboid arthrodesis, calcaneal osteotomy, calcaneus fracture, talus fracture, and ankle fractures (7).

Evidence that the AOFAS Ankle-Hindfoot Scale (as a complete scale) is valid in its original version, is limited (7-9). Poor to moderate correlation of the AOFAS scores to the SF-36 subscales may also suggest poor construct validity (10). Adequate responsiveness has been shown (8, 9). The physician-reported part of the scale has been shown to be valid and reliable (11). Westphal *et al.* showed correlations between SF-36 and the AOFAS Ankle-Hindfoot Scale were strong regarding function and pain subscales, but moderate for all other subscales (12). Previous studies involved a wide spectrum of diagnoses, such as general ankle-hindfoot complaints (9), pending ankle or foot surgery (11), surgically treated calcaneal fractures (12), and end-stage ankle arthritis (8). Some of these studies have included mixed populations.

Despite some favourable results, there is also criticism to the use of the AOFAS Clinical Rating Systems, which includes the AOFAS Ankle-Hindfoot Scale (13). Criticism, which includes the limited number of answers per item as well as linguistic issues, may negatively affect reliability and validity, and makes it more prone to ceiling effects (13,

14). Despite these concerns, the AOFAS Ankle-Hindfoot Scale remains among the most commonly used instruments, especially for patients with hindfoot fractures. It is especially an interesting instrument because it asks for hindfoot-specific complaints or deviations, which are not included in other lower extremity-specific instruments.

Currently, a validated Dutch translations of the AOFAS Ankle-Hindfoot Scale is not available. Therefore, the aim of the first part of the study is to translate and culturally adapt the AOFAS Ankle-Hindfoot Scale questionnaire into Dutch. The aim of the second part is to evaluate the measurement properties of the AOFAS Ankle-Hindfoot Scale-Dutch language version (DLV) in patients who sustained a unilateral ankle or hindfoot fracture or (fracture) dislocation by assessing descriptive statistics (including floor and ceiling effects), internal consistency, construct validity, reproducibility (*i.e.*, test-retest reliability, agreement, and smallest detectable change), and responsiveness. Measurement properties will be calculated for the ankle and hindfoot separately.

METHODS AND ANALYSIS

Study design

This study (protocol version 1.0, date March 24, 2014) will follow a multicenter, prospective, observational study design (*i.e.*, case series). As the research physician and patients will complete questionnaires starting at variable time points during treatment, this study will have a prospective study design with retrospective data collection with regards to the injury and treatment. Three hospitals in Rotterdam (The Netherlands) will participate: Erasmus MC, University Medical Center Rotterdam, Ikazia Hospital, and Maasstad Hospital. The study is registered at the Netherlands Trial Register (NTR5613), registration date January 05, 2016.

Recruitment and consent

All consecutive patients meeting the eligibility criteria (and none of the exclusion criteria) will be included. Participation in this study will not have any influence on treatment. Prior to their outpatient department visit, eligible patients will be invited to participate. Verbal and written information will be given by the principal investigator, research physician, or a research assistant. Written materials will include an information letter, informed consent form, and return envelope. A reminder will be sent to those patients who did not respond within two weeks, in order to ensure a high response rate. If no response is received within three weeks, the patient will be contacted by telephone.

In order to reduce bias as much as possible, a research physician (MD with clinical experience) or research assistant (with a BSc in Medicine) will perform the physical examination that is part of the physician-reported part of the AOFAS Ankle-Hindfoot Scale-DLV using a standardized protocol. Both assessors received elaborate training on

the administration and physical examination of the AOFAS Ankle-Hindfoot Scale by an experienced trauma surgeon.

Study population

All adult patients who visited the Emergency Department of any of the participating hospitals and were diagnosed with a unilateral ankle or hindfoot fracture or (fracture) dislocation will be considered eligible for inclusion. Measurement properties will be assessed for the ankle and the hindfoot subgroups separately. Patients will be identified from hospital records based upon their ICD-10 (International Coding of Diseases, 10th revision) code or Diagnosis Related Group (DRG; in Dutch, DBC) code.

Three subgroups of patients will be enrolled. In group 1 (test of pre-final version) the pre-final version of the AOFAS Ankle-Hindfoot Scale-DLV will be completed. In group 2 (responsiveness) and group 3 (test-retest) the final version of the Dutch AOFAS Ankle-Hindfoot-DLV questionnaire will be completed on two occasions, with 5-6 months (group 2) or 2-3 weeks (group 3) in between.

In order to be eligible to participate in this part of the study, a patient must meet all of the following criteria:

1) Patients with a unilateral ankle or hindfoot fracture or (fracture) dislocation (*i.e.*, Ankle-Hindfoot: ankle fracture, calcaneal fracture, talar fracture, subtalar dislocation, tibiotalar dislocation, or Chopart's fracture dislocation)
2) Age 18 years or older
3) Group 2 only: Treatment started between six weeks and three months (ankle) or between three and six months (hindfoot) prior to the start of the study
4) Group 3 only: treatment has started between seven and nine months (ankle) or between six and 24 months (hindfoot) prior to the start of the study
5) Provision of informed consent by patient

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1) Multiple trauma patient (only if functional recovery of additional injuries was not achieved at time of enrolment, as that likely affects the outcome scores)
2) Pathological fracture
3) Severe physical comorbidity (*i.e.*, American Society of Anesthesiologists (ASA) ≥3)
4) Patient was non-ambulatory prior to the injury (*i.e.*, bed or wheelchair-bound)
5) Insufficient comprehension of the Dutch language to understand and complete the questionnaires
6) Patient with expected problems of maintaining follow-up (*e.g.*, no fixed address)

For testing the pre-final version of the Dutch AOFAS Ankle-Hindfoot Scale-DLV (group 1), only exclusion criteria 5 and 6 will apply.

Patients are allowed to participate in group 2 and 3, and if so, the second questionnaire for responsiveness will also be used as first questionnaire for test-retest reliability. Table 1 shows a summary of the injuries, identifying codes, and measurements times of this study.

Table 1: Overview of injuries, identifying codes, and measurement times

Group	Injury	Identifying code		Responsiveness		Test retest reliability	
		ICD-10	DRG	t=1	t=2	t=1	t=2
Ankle	Ankle fracture	S825, S826	224	1.5-3 mo	+ 5-6 mo	7-9 mo	+ 2-3 we
Hindfoot	Calcaneal fracture	S920	236, 237	3-6 mo	+ 5-6 mo	6-24 mo	+ 2-3 we
	Talar fracture	S921	241				
	Subtalar dislocation						
	Tibiotalar dislocation	S930					
	Chopart's fracture Dislocation						

ICD-10, International Coding of Diseases, 10th revision; DRG, Diagnosis Related Group; mo, months; we, weeks.

Outcome measures

The measurement properties of the AOFAS Ankle-Hindfoot Scale-DLV will be evaluated in this validation study. The following parameters will be determined:

- Construct validity
- Reliability / Internal consistency
- Reproducibility: Test-retest reliability, agreement, and Smallest Detectable Change
- Floor and ceiling effects
- Responsiveness

In addition to the outcome variables mentioned above, the following data will be collected from the patients' medical files:

a) Intrinsic variables (baseline data): age, gender, and dominant side.
b) Injury-related variables: affected side, trauma mechanism, type of injury.
c) Intervention- and outcome-related variables: type of treatment (operative or non-operative), time between injury and start of treatment, achievement of anatomic restoration as judged from X-ray or CT-scan (*i.e.*, < 2mm articular step-off or gap).

Study procedures

The study will be divided into two stages. First, the American (original) version of the AOFAS Hindfoot-Ankle Scale will be translated into Dutch according to a standardized

procedure (15). Second, the translated version will be tested for measurement properties in a prospective study.

Step 1: Translation of the questionnaire

The translation and cultural adaptation of the AOFAS Ankle-Hindfoot Scale questionnaire will be done according to the guideline for Cross Cultural Adaptation of Self-Report Measures by Beaton *et al.* (15). This guideline is based on the review of Guillemin *et al.* (16) and is the official guideline of the American Academy of Orthopaedic Surgeons. The guideline consists of five stages: (1) translation; (2) synthesis; (3) back translation; (4) evaluation by a team of experts; and (5) tests.

In stage one, the English version of the questionnaire will be translated into Dutch independently by two Dutch native speakers who are fluent in English. One person will have knowledge of medicine and the questionnaire, the other will not necessarily.

In stage two, both translations will be combined by the two translators and a team of experts; this team will consist of at least two independent observers. The synthesis process will be carefully documented in a written report. Differences will be resolved by consensus.

In stage three, two persons will independently translate the synthesized Dutch questionnaire back into English. Both translators will be bilingual native English speakers. Neither translator will receive any background information on the study or the questionnaire. They will have no medical background, will be blind to the original version of the questionnaire and will not be aware or informed about the concepts explored in it. With this back-translation process, the content validity of the questionnaire is checked in order to make sure that the translated version is reflecting the same item content as the original version. Unclear wording in the translated version can be discovered in this stage.

In stage four, the investigator, the translators and the same team of experts will review the two back-translations. Equivalence between the original and Dutch versions of the questionnaire shall be reached in four areas: semantic equivalence (ensuring that the words mean the same thing), idiomatic equivalence (ensuring that colloquialisms or idioms are formulated in equivalent expressions), experiential equivalence (ensuring that each item captures the experience of daily life in the target culture), and conceptual equivalence (ensuring that words hold the same conceptual meaning). Discrepancies will be resolved by consensus. This stage will result in the pre-final Dutch versions of the questionnaire.

In stage five, these pre-final Dutch version will be tested in a group of 20 patients (group 1) presenting themselves with various foot/ankle problems to the outpatient clinic of one of the participating hospitals. These patients will be asked if they understand the questions and if they are able to provide answers to the questions. If all patients report that this is the case and if there are no ambiguities, no further changes to the questionnaires will be necessary; at that point the translated questionnaire will be

considered final. The measurement properties of this version will be assessed in Dutch patients as described below.

Step 2: Determining measurement properties of the AOFAS Ankle-Hindfoot Scale-DLV
Patient groups 2 and 3 will be used for this evaluation.

- Group 2 (responsiveness) will consist of patients who were (surgically) treated at a participating hospital, between six weeks and three months earlier (ankle) or between three and six months earlier (hindfoot).
- Group 3 (test-retest) will consist of patients who were (surgically) treated at a participating hospital, between seven and nine months earlier (ankle) or between six and 24 months earlier (hindfoot).

In groups 2 and 3 three questionnaires will be completed during the patient's outpatient department visit; the AOFAS Ankle-Hindfoot Scale-DLV, the Foot Function Index (FFI-DLV) (2), and the Short Form Health Survey (SF-36-DLV) (17). These instruments were chosen since they were also used for the validation of the original language version (8). The research physician or research assistant will complete the AOFAS Ankle-Hindfoot Scale-DLV during the outpatient department visit. If a patient is unable or unwilling to come to the hospital, a home visit may be planned.

The Foot Function Index (FFI) measures the effect of foot pathology on function in terms of pain and disability. The FFI consists of 23 items divided into three subscales: limitation, pain, and disability. The items are scored on a 10-point Likert scale. For each subscale, the raw score is transformed to a 100-point score; the higher the score, the more limitation/pain/ disability is present. The total score on the FFI is the mean of the subscale scores (2). Adequate internal consistency, reproducibility and reliability as well as strong correlation with SF-36 have been reported for patients with traumatic foot disorders in some languages (2, 18, 19). The FFI-DLV will be used (2).

The Short Form Health Survey (SF-36) is a generic health status questionnaire that gives an indication of health-related quality of life (20-27). The SF-36 consists of 36 items (questions) and provides scores on eight dimensions (subscales): physical functioning (PF), role limitations due to physical health problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and general mental health (MH). These eight domains are combined into a Physical Component Summary (PCS) and a Mental Component Summary (MCS). The raw score on each subscale is transferred to a 100-point scale, with a higher score indicating better quality of life. These scores will be converted to a norm-based score and compared with the norms for the general population of the United States (1998), in which each scale was scored to have the same average (50 points) and the same standard deviation (10 points). Dutch norms are available, but will not be used. The Dutch norms were calculated using a smaller sample size than the American study. Moreover, most published studies have used the American norms. On a study

population level the means and median values were similar when using the Dutch or American norms, but variance was larger using the Dutch norms than when using the US norms (28). The SF-36 is the most widely evaluated patient-reported outcome measure for assessing general health (29). It is reliable and easy to complete. A validated Dutch version will be used (17).

In order to determine whether the AOFAS Ankle-Hindfoot Scale-DLV is able to detect clinical change over time, patients in group 2 will be asked to complete all questionnaires again after five to six months after completing them the first time. A research physician or research assistant will complete the AOFAS Ankle-Hindfoot Scale-DLV. For responsiveness, this time interval should be sufficiently long enough for clinical improvement to occur. We consider a time interval of five to six months to be appropriate for all three groups of injuries.

In order to determine the reproducibility (*i.e.*, test-retest reliability) of the AOFAS Ankle-Hindfoot Scale-DLV, all questionnaires will be completed again at two to three weeks after completing them the first time (group 3). For test-retest reliability, this time interval needs to be sufficiently short to support the assumption that the patient remains stable and sufficiently long to prevent recall. We consider a time interval of 2-3 weeks to be appropriate. Patients are asked about presence or absence of change between the two questionnaire administrations. They were asked to complete a transition item (anchor question) evaluating their perception of change in the general condition of their affected ankle. The question was: How would you judge the condition of your ankle, compared with the last time you completed this questionnaire? Patients were given the answer options 'better', 'no change', or 'worse'. Patients reporting a change (either improvement or deterioration) will be excluded from the analysis. Patients who replied 'no change' were considered stable between the two measurements.

Sample size calculation

The pre-final Dutch version of the instrument will be tested in a group of 20 patients (group 1) presenting themselves with various foot/ankle problems to the outpatient clinic of the Erasmus MC (Rotterdam), Ikazia Hospital (Rotterdam), or Maasstad Hospital (Rotterdam).

For groups 2 and 3, recruitment of both the ankle and the hindfoot injury subgroups will continue until complete follow up is ensured for 100 patients. The minimum number of patients needed for determining measurement properties of a PROM depends on the property evaluated. Validity can only be rated positive if at least 75% of the results are in correspondence with prespecified hypotheses, in (sub)groups of at least 50 patients (30). For calculating the Smallest Detectable Change (SDC) as well as for the assessment of the agreement parameters (reproducibility), a sample size of at least 50 patients is generally considered adequate (30, 31). The (absence of) floor and ceiling effects also requires a sample size of at least 50 patients. In order to perform a factor

analysis (to determine if the AOFAS Ankle-Hindfoot Scale-DLV consists of multiple subscales), however, four to ten patients for each item are advised with a minimum of 100 patients (30, 32). The sample size needed applies both to patients with ankle injuries and hindfoot injuries.

Statistical analysis

Data will be entered into an OpenClinical database. Data will be encoded, and a random sample of entered data will be checked by an independent data monitoring committee. Only the research team, the Medical Research Ethics Committee (MREC), and the health inspection will have legal access to the data.

All statistical analyses will be performed with the Statistical Package for Social Sciences (SPSS, version 21 or higher) and will be reported following the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) and the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines. Descriptive statistics will be used in order to describe the main characteristics of the study participants and the questionnaire scores at the different time points. Data for patients with ankle or hindfoot injuries will be evaluated as two separate groups.

As the raw data for individual items will be analyzed, missing values will not be imputed. Normality of continuous data will be tested with the Shapiro-Wilk test. Descriptive analysis will be performed; continuous data will be reported as mean ± standard deviation (SD) (parametric) or median with percentiles (non-parametric) and categorical data as numbers with percentages.

In order to evaluate if a representative sample participated in this study, the age, gender, and injury location of responders will be compared with that of the non-participants. The categorical variables gender and injury location will be assessed using a Chi-squared test. Age will be compared using a Student's T-test (parametric data) or Mann-Whitney U-test (parametric data).

Construct validity

Validity is the degree to which a patient-reported outcome instrument measures the construct it is supposed to measure. As there is no gold standard in the current study, the validity of the AOFAS Ankle-Hindfoot Scale-DLV will be expressed in terms of the construct validity. Construct validity refers to the extent to which scores on a specific questionnaire relate to other measures in a way that is in agreement with prior theoretically derived hypotheses concerning the concepts that are being measured (30). In order to evaluate the construct validity of the AOFAS Ankle-Hindfoot Scale-DLV, we will formulate a set of hypotheses about the expected magnitude and direction of relationships between the AOFAS (sub)scores and the FFI and the SF-36 (sub)scores. Pearson's product-moment correlation coefficients (parametric data) or Spearman's Rho (rank correlation) coefficients (non-parametric correlation) will be calculated in order to as-

sess construct validity. Correlation coefficients above 0.6, between 0.6 and 0.3 and less than 0.3 will be considered high, moderate, and low correlations, respectively (33). The AOFAS Ankle-Hindfoot Scale is expected to have a high correlation with pain and function (sub)scales (*i.e.*, FFI total score and all three subscales, SF-36 PF, RP, BP, and PCS), a moderate correlation with the SF-36 VT, SF and RE subscales, and a low correlation with SF-36 GH, MH, and MCS. Construct validity will be given a positive rating if at least 75% of the results are in accordance with predefined hypotheses in a (sub)sample of at least 50 patients (30).

Reliability / internal consistency

Reliability is defined as the degree to which the measurement is free from measurement error (34). Three elements of reliability will be determined: internal consistency, reproducibility, and measurement error.

Internal consistency is defined as the extent to which items in a (sub)scale are intercorrelated, thus measuring the same construct (30). The correlation between items on a (sub)scale will be evaluated by calculating Cronbach's alpha for every (sub)scale. Since future use of the AOFAS instrument will be at a group level, internal consistency is considered sufficient if the value for Cronbach's alpha is between 0.70 and 0.95, provided that the scale is unidimensional (30, 35). If necessary, confirmatory or exploratory factor analysis will be performed, as applicable.

Reproducibility

Reproducibility concerns the degree to which repeated measurements in stable persons (test-retest) provide similar answers (30). Reproducibility is suggested to consist of two parts: reliability and agreement (36, 37). The data of group 3 will be used; they will complete all questionnaires twice, with 2-3 weeks in between. Only data for patients reporting 'no change' on the transition item are included as they were considered to be stable between the measurements.

Reliability concerns the degree to which patients can be distinguished from each other, despite measurement error (30, 38). Evaluation of the test-retest reliability of the AOFAS Ankle-Hindfoot Scale-DLV will be performed by calculating the intraclass correlation coefficient ($ICC_{agreement}$) with corresponding 95% confidence interval (CI). An ICC two-way random effects model, type absolute agreement (ICC(2,1)), will be used (39). Reliability will be given a positive rating when the ICC is at least 0.70 in a sample size of at least 50 patients (30).

Agreement concerns the absolute measurement error, *i.e.*, how close the scores on repeated measures are, expressed in the unit of the measurement scale at issue (30). The degree of absolute agreement of the AOFAS Ankle-Hindfoot Scale-DLV will be expressed as the standard error of measurement ($SEM_{agreement}$). This SEM equals the square root of the error variance of an analysis of variance (ANOVA) analysis, including the systematic differences ($SEM = \sqrt{(variance_{patient} + variance_{residual})}$) (30, 40, 41).

Based upon the SEM, the Smallest Detectable Change (SDC) will be calculated using the formula; SDC = 1.96 x √2 x SEM.(30) The SDC reflects the smallest within-person change in a score that, with $P < 0.05$, can be interpreted as a ''real'' change, above measurement error, in one individual (SDC_{ind}).(30, 42, 43) The SDC measurable in a group of people (SDC_{group}) will be calculated by dividing the SDC_{ind} by √n (43, 44). Finally, the reliable change index (RCI) will be calculated, representing the SDC as a percentage of the maximum obtainable score.

The degree of absolute agreement of the AOFAS Ankle-Hindfoot Scale-DLV will also be determined with a Bland and Altman analysis (45). The limits of agreement equal the mean change in scores of repeated measurements ($mean_{change}$) ± 1.96 x standard deviation of these changes (SD_{change}) (30). Zero falling outside this interval indicates a bias in the measurements.

Floor and ceiling effects

The validity, reliability and responsiveness of a questionnaire may be jeopardized if floor or ceiling effects are present. It is then likely that extreme items are missing in the lower or upper ends of the questionnaire. As a consequence, respondents with the lowest or highest possible score cannot be distinguished from each other (indicating limited reliability) and changes in these patients cannot be measured (indicating limited responsiveness) (30). Floor and ceiling effects will be determined by calculating the number of individuals that obtained the lowest (0 points; floor) or highest (100 points; ceiling) scores possible and will be considered present if more than 15% of the respondents achieved the lowest or highest score in a sample size of at least 50 patients (30, 46). Floor and ceiling effects will be determined separately for the different time points.

Responsiveness

Responsiveness is defined as the ability of a questionnaire to detect clinically important changes over time, even if these changes are small (30, 47). The data of group 2 will be used; they will complete all questionnaires twice, with 5-6 months in between.

The effect size (ES) and standardized response mean (SRM) of the (sub)scales of the AOFAS Ankle-Hindfoot Scale-DLV will be determined as measures of the magnitude of change over time. The ES will be calculated by dividing the mean change in score between the two time points by the standard deviation of the first measurement (48). The SRM will be calculated by dividing the mean change in score between two time points by the standard deviation of this change (48). These effect estimates will be interpreted according to Cohen: a SRM of 0.2-0.4 is considered a small effect, 0.5-0.7 a moderate, and 0.8 or higher a large effect (49).

Responsiveness can be considered to be a measure of longitudinal validity. In analogy to construct validity, this longitudinal validity will be assessed by testing predefined hypotheses about expected correlations between changes in AOFAS Ankle-Hindfoot Scale-DLV (sub)scales versus changes in FFI and SF-36 (sub)scales (30). Change scores of

the AOFAS Ankle-Hindfoot Scale are expected to have a moderate correlation with changes in the FFI (sub)scales, SF-36 PF, RP, BP, VT, SF, RE, and PCS. A low correlation is expected with changes in the SF-36 GH, MH, and MCS.

ETHICS AND DISSEMINATION

This study will be conducted according to the principles of the Declaration of Helsinki (64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013). This study has been exempted by the medical research ethics committee (MREC) Erasmus MC (Rotterdam, The Netherlands). This MREC acts as central ethics committee for this trial (reference number MEC-2014-215). Approval has been obtained from the local hospital boards in all participating centers. Following review of the protocol, the MREC concluded that this study is not subject to the Medical Research Involving Human Subjects Act (WMO). They concluded that the study is a medical/scientific research, but no patients are subjected to procedures or are required to follow rules of behavior. Consequently, the statutory obligation to provide insurance for subjects participating in medical research (article 7 of the WMO) was also waived. Any important changes in the protocol will be submitted to the accredited MREC. The results of the study are planned to be published in an international, peer reviewed journal. Results of the ankle and hindfoot injury subgroups will be published separately.

DISCUSSION

Modern studies that evaluate treatment efficacy are expected to also take into account the treatment outcome from a patient's perspective. Clinical measures such as mortality, radiographic healing, and rates of complications, re-operation, and readmission are relevant; however, they do not reflect to what extent a patient is able to function in daily living. For that purpose, PROMs and mixed instruments, which combine a patient-reported and a physician-reported part, have been developed. There is a great need for valid instruments in different languages.

The AOFAS Ankle-Hindfoot Scale is commonly used in patients with an ankle or hindfoot injury. This instrument combines functional outcome and pain, which are both critical for patients. The AOFAS Ankle-Hindfoot Scale is only valid if the score truly reflects function and pain. Completing the questionnaire in duplicate should result in the same score, and during recovery, the change in score should reflect change in functional status of the patient. Both elements of validity of the instrument are determined as part of this study. We expect that the AOFAS Ankle-Hindfoot Scale-DLV will prove valid and reliable, giving objective quantitative scores for patients' function and pain after trauma to the ankle or hindfoot. If the data confirm this, the instrument will be available

for comparing outcome in future studies, and for comparing treatment outcome across hospitals or between patient groups. Especially the SDC and MIC will reveal important information for sample size calculations in future studies.

Three hospitals in the Netherlands will participate. Inclusion of patients has started May 2014 and the expectation is to include all patients within two years for ankle injuries and three years for hindfoot injuries. With a maximum follow-up of 6.5 months the presentation of data will be expected by end-2016 and end-2017, respectively.

REFERENCES

1. De Groot IB, Favejee MM, Reijman M, Verhaar JA, Terwee CB. The Dutch version of the Knee Injury and Osteoarthritis Outcome Score: a validation study. Health Qual Life Outcomes. 2008;6:16.
2. Kuyvenhoven MM, Gorter KJ, Zuithoff P, Budiman-Mak E, Conrad KJ, Post MW. The foot function index with verbal rating scales (FFI-5pt): A clinimetric evaluation and comparison with the original FFI. J Rheumatol. 2002;29(5):1023-8.
3. De Groot IB, Reijman M, Terwee CB, Bierma-Zeinstra SM, Favejee M, Roos EM, et al. Validation of the Dutch version of the Hip disability and Osteoarthritis Outcome Score. Osteoarthritis Cartilage. 2007;15(1):104-9.
4. Shearer D, Morshed S. Common generic measures of health related quality of life in injured patients. Injury. 2011;42(3):241-7.
5. Reininga IH, el Moumni M, Bulstra SK, Olthof MG, Wendt KW, Stevens M. Cross-cultural adaptation of the Dutch Short Musculoskeletal Function Assessment questionnaire (SMFA-NL): internal consistency, validity, repeatability and responsiveness. Injury. 2012;43(6):726-33.
6. Van Son MA, Den Oudsten BL, Roukema JA, Gosens T, Verhofstad MH, De Vries J. Psychometric properties of the Dutch Short Musculoskeletal Function Assessment (SMFA) questionnaire in patients with a fracture of the upper or lower extremity. Qual Life Res. 2014;23(3):917-26.
7. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int. 1994;15(7):349-53.
8. Madeley NJ, Wing KJ, Topliss C, Penner MJ, Glazebrook MA, Younger AS. Responsiveness and validity of the SF-36, Ankle Osteoarthritis Scale, AOFAS Ankle Hindfoot Score, and Foot Function Index in end stage ankle arthritis. Foot Ankle Int. 2012;33(1):57-63.
9. SooHoo NF, Vyas R, Samimi D. Responsiveness of the foot function index, AOFAS clinical rating systems, and SF-36 after foot and ankle surgery. Foot Ankle Int. 2006;27(11):930-4.
10. SooHoo NF, Shuler M, Fleming LL. Evaluation of the validity of the AOFAS Clinical Rating Systems by correlation to the SF-36. Foot Ankle Int. 2003;24(1):50-5.
11. Ibrahim T, Beiri A, Azzabi M, Best AJ, Taylor GJ, Menon DK. Reliability and validity of the subjective component of the American Orthopaedic Foot and Ankle Society clinical rating scales. J Foot Ankle Surg. 2007;46(2):65-74.
12. Westphal T, Piatek S, Halm JP, Schubert S, Winckler S. Outcome of surgically treated intraarticular calcaneus fractures--SF-36 compared with AOFAS and MFS. Acta Orthop Scand. 2004;75(6):750-5.
13. Pinsker E, Daniels TR. AOFAS position statement regarding the future of the AOFAS Clinical Rating Systems. Foot Ankle Int. 2011;32(9):841-2.
14. Guyton GP. Theoretical limitations of the AOFAS scoring systems: an analysis using Monte Carlo modeling. Foot Ankle Int. 2001;22(10):779-87.
15. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976). 2000;25(24):3186-91.
16. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol. 1993;46(12):1417-32.
17. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. J Clin Epidemiol. 1998;51(11):1055-68.
18. Huh JW, Eun IS, Ko YC, Park MJ, Hwang KM, Park SH, et al. Reliability and Validity of the Korean Version of the Foot Function Index. J Foot Ankle Surg. 2016;55(4):759-61.
19. Wu SH, Liang HW, Hou WH. Reliability and validity of the Taiwan Chinese version of the Foot Function Index. J Formos Med Assoc. 2008;107(2):111-8.
20. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992;30(6):473-83.

21. Mahabier KC, Van Lieshout EMM, Bolhuis HW, Bos PK, Bronkhorst MWGA, Bruijninckx MMM, et al. HUMeral shaft fractures: measuring recovery after operative versus non-operative treatment (HUMMER): a multicenter comparative observational study. BMC Musculoskelet Disord. 2014;15:39.
22. Den Hartog D, Van Lieshout EMM, Tuinebreijer WE, Polinder S, Van Beeck EF, Breederveld RS, et al. Primary hemiarthroplasty versus conservative treatment for comminuted fractures of the proximal humerus in the elderly (ProCon): a multicenter randomized controlled trial. BMC Musculoskelet Disord. 2010;11:97.
23. De Haan J, Den Hartog D, Tuinebreijer WE, Iordens GIT, Breederveld RS, Bronkhorst MWAG, et al. Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomized trial. BMC Musculoskelet Disord. 2010;11:263.
24. Schep NWL, De Haan J, Iordens GIT, Tuinebreijer WE, Bronkhorst MWAG, De Vries MR, et al. A hinged external fixator for complex elbow dislocations: a multicenter prospective cohort study. BMC Musculoskelet Disord. 2011;12:130.
25. Pan SL, Liang HW, Hou WH, Yeh TS. Responsiveness of SF-36 and Lower Extremity Functional Scale for assessing outcomes in traumatic injuries of lower extremities. Injury. 2014;45(11):1759-63.
26. Obremskey WT, Dirschl DR, Crowther JD, Craig WL, 3rd, Driver RE, LeCroy CM. Change over time of SF-36 functional outcomes for operatively treated unstable ankle fractures. J Orthop Trauma. 2002;16(1):30-3.
27. van Tetering EA, Buckley RE. Functional outcome (SF-36) of patients with displaced calcaneal fractures compared to SF-36 normative data. Foot Ankle Int. 2004;25(10):733-8.
28. Schep NWL, van Lieshout EMM, Patka P, Vogels LMM. Long-term functional and quality of live assessment following post-traumatic distraction osteogenesis of the lower limb. Strategies Trauma Limb Reconstr. 2009;4(3):107-12.
29. Garratt A, Schmidt L, Mackintosh A, Fitzpatrick R. Quality of life measurement: bibliographic study of patient assessed health outcome measures. Bmj. 2002;324(7351):1417.
30. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34-42.
31. Altman DG. Practical statistics for medical research. London: Chapman and Hall. 1991.
32. De Vet HCW, Terwee CB, Mokkink LB, Knol DL. Measurement in medicine. New York: Cambridge University Press. 2011.
33. Hinkle DE, Wiersma W, Jurs SG. Applied statistics for the behavioral sciences. Boston USA: Houghton MiZin. 1998.
34. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010;63(7):737-45.
35. Streiner D, Norman G. Health Measurement Scales: A Practical Guide to Their Development and Use. 2nd ed. Oxford, UK: Oxford Medical; 1996. And Nunnally J, Bernstein I. Psychometric Theory. 3rd ed. New York, NY: McGraw-Hill; 1994.
36. De Vet HCW. Observer reliability and agreement. In: Armitage P, Colton T, editors. Encyclopedia of biostatistics. Boston: John Wiley & Sons Ltd. pp. 3123e8. 1998.
37. Stratford P. Reliability: consistency or differentiating among subjects? Phys Ther. 1989;69(4):299-300.
38. Streiner DL, Norma GR. Health measurement scales. A practical guide to their development and use. New York: Oxford University Press. 2003.
39. McGraw KO, Wong SP. Forming inferences about some intraclass correlation coefficients. Psychol Methods. 1996;1(1):30-46.
40. Scholtes VA, Terwee CB, Poolman RW. What makes a measurement instrument valid and reliable? Injury. 2011;42(3):236-40.
41. de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. J Clin Epidemiol. 2006;59(10):1033-9.
42. Beckerman H, Roebroeck ME, Lankhorst GJ, Becher JG, Bezemer PD, Verbeek AL. Smallest real difference, a link between reproducibility and responsiveness. Qual Life Res. 2001;10(7):571-8.

43. de Vet HC, Bouter LM, Bezemer PD, Beurskens AJ. Reproducibility and responsiveness of evaluative outcome measures. Theoretical considerations illustrated by an empirical example. Int J Technol Assess Health Care. 2001;17(4):479-87.
44. De Boer MR, De Vet HC, Terwee CB, Moll AC, Volker-Dieben HJ, Van Rens GH. Changes to the subscales of two vision-related quality of life questionnaires are proposed. J Clin Epidemiol. 2005;58(12):1260-8.
45. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1(8476):307-10.
46. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995;4(4):293-307.
47. Guyatt GH, Deyo RA, Charlson M, Levine MN, Mitchell A. Responsiveness and validity in health status measurement: a clarification. J Clin Epidemiol. 1989;42(5):403-8.
48. Angst F, Verra ML, Lehmann S, Aeschlimann A. Responsiveness of five condition-specific and generic outcome assessment instruments for chronic pain. BMC Med Res Methodol. 2008;8:26.
49. Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale (NJ): Lawrence Erlbaum Associates. 1988.

Chapter 10

Validation of the American Orthopaedic Foot and Ankle Society ankle-hindfoot scale Dutch language version in patients with hindfoot fractures

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ABSTRACT

Objectives: The American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale is among the most used questionnaires for measuring functional recovery after a hindfoot injury. Recently this instrument was translated and culturally adapted into a Dutch version. In this study the measurement properties of the Dutch Language Version (DLV) were investigated in patients with a unilateral hindfoot fracture.

Design: Multicenter, prospective observational study.

Setting: This multicenter study was conducted in three Dutch hospitals.

Participants: In total 118 patients with a unilateral hindfoot fracture were included. Three patients were lost to follow up.

Primary and secondary outcome measures: Patients were asked to complete the AOFAS-DLV, the Foot Function Index (FFI), and the Short Form-36 (SF-36) on three occasions. Descriptive statistics (including floor and ceiling effects), reliability (*i.e.*, internal consistency), construct validity, reproducibility (*i.e.*, test-retest reliability, agreement, and smallest detectable change), and responsiveness were determined.

Results: Internal consistency was inadequate for the AOFAS-DLV total scale (α=0.585), but adequate for the function subscale (α=0.863). The questionnaire had adequate construct validity (82.4% of predefined hypotheses were confirmed), but inadequate longitudinal validity (70.6%). No floor effects were found, but ceiling effects were present in all AOFAS-DLV (sub)scales, most pronounced from 6-24 months after trauma onwards. Responsiveness was only adequate for the pain and alignment subscales, with a smallest detectable change of 1.7 points.

Conclusions: The AOFAS Ankle-Hindfoot Scale DLV has adequate construct validity and is reliable, making it a suitable instrument for cross-sectional studies investigating functional outcome in patients with a hindfoot fracture. The inadequate longitudinal validity and responsiveness, however, hamper the use of the questionnaire in longitudinal studies and for assessing long-term functional outcome.

Trial Registration: Netherlands Trial Register (NTR5613; 05-jan-2016).

BACKGROUND

Hindfoot fractures are rare, but invalidating injuries. Since most patients are in their wage-earning age combined with the long-term disabilities, these injuries have a high socio-economic impact (1, 2). The incidence rate of calcaneal fractures is 11.5 per 100,000 person years and these fractures occur 2.4 times more frequently in males than females (3). Fractures of the talus are even more rare with a reported annual incidence of 3.2 per 100,000, and occur 4.5 times more often in men (4). Despite the facts that these fractures are relative rare they have received considerable attention in recent literature, presumable by the long-term recovery and therewith-socioeconomic burden.

In order to monitor functional outcome, quality of life, and recovery after treatment, Patient-Reported Outcome Measures (PROMs) and other instruments are increasingly used in clinical practice and clinical research. The American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale is one of the most used assessment tools in foot surgery (5). This clinical rating system combines a patient-reported part and a physician-reported part. In its original language version the AOFAS Ankle-Hindfoot Scale, as a complete scale has been shown to be responsive and valid (6-9). The study populations involved non-traumatic diagnoses, such as general ankle-hindfoot complaints (8), pending ankle or foot surgery (10), and end-stage ankle osteoarthritis (7).

Recently, a Dutch version of the AOFAS Ankle-Hindfoot Scale became available (11). It was translated and culturally adapted to the Dutch population according to the guideline for Cross Cultural Adaptation of Self-Report Measures (12, 13). The AOFAS Ankle-Hindfoot Scale was shown to be valid, reliable, and responsive in patients with an ankle fracture (11). The current study aimed to determine the measurement properties of the AOFAS-DLV in patients who sustained a hindfoot fracture.

METHODS

Study design and ethics statement

This multicenter, prospective, observational study was performed at three hospitals. The study is registered at the Netherlands Trial Register (NTR5613). A detailed study protocol is published elsewhere (13). The Medical Research Ethics Committees or Local Ethics Boards of all participating centers approved the study.

Patient recruitment

Patients were recruited from May 1, 2014 to November 1, 2016. Patients were identified from hospital records, based upon their ICD-10 (International Coding of Diseases, 10th revision) code or Diagnosis Related Group code. Inclusion criteria were; 1) unilat-

eral hindfoot fracture; 2) age 18 years or older; and 3) provision of informed consent. Exclusion criteria were; 1) multiple trauma affecting the outcome scores); 2) pathological fracture; 3) severe physical comorbidity (*i.e.*, American Society of Anaesthesiologists (ASA) ≥3); 4) patient was non-ambulatory prior to the injury; 5) insufficient comprehension of the Dutch language; and 6) expected problems of maintaining follow-up.

A total of 118 individual patients were included; 78 completed t=1 and t=2, 113 completed t=2 and t=3 (Figure 1). Three patients were lost to follow-up during the course of the study.

The median age was 51 years (P_{25} -P_{75} 36-58) and the majority of patients (N=69; 61.1%) were male (Table 1). The most common injuries were calcaneal fractures (N=82; 72.6%) and talar fractures (N=36; 31.9%). Fractures were mostly treated non-operatively (N=72; 73.6%)

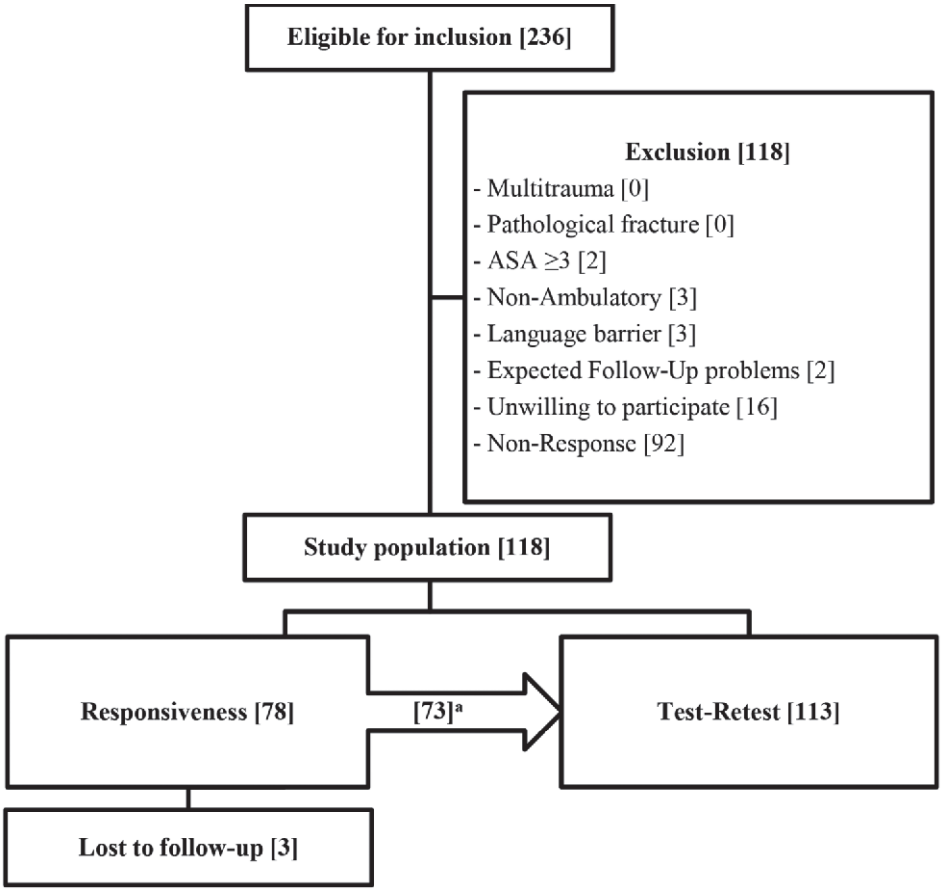

Figure 1: Flowchart
The number of patients in each particular group is shown between square brackets.
[a] Patients who participated in both groups

Table 1: Demographic data for the study population

Variable		Outcome
Age (years)		51 (36-58)
Male gender		69 (61.1%)
Right side affected		101 (89.4%)
Dominant side affected		60 (53.1%)
Calcaneal fracture		82 (72.6%)
Talar fracture		36 (31.9%)
Chopart luxation		1 (0.9%)
Closed fracture		113 (100.0%)
Treatment	Non-operative	72 (73.6%)
	Operative	41 (36.3%)

Data are shown as median (P_{25}-P_{75}) or as N (%), as applicable.

Questionnaires and data collection

Demographic, injury, and treatment data were collected from the patient's medical files. To complete the physician-reported part of the AOFAS Ankle-Hindfoot Scale-DLV, a research physician or research assistant performed the physical examination using a standardized protocol. Patients were asked to complete the AOFAS-DLV patient-reported part, Foot Function Index (FFI-DLV), and the Short Form Health Survey (SF-36-DLV) questionnaires on three occasions: between 3-6 months after trauma (t=1), 5-6 months later (t=2), and 2-3 weeks later (t=3). Patients were allowed to participate in both the responsiveness and test-retest part. A physician completed the physician-reported part of the AOFAS-DLV.

The AOFAS Ankle-Hindfoot Scale consists of three subscales; pain, function, and alignment and includes a total of nine items. The minimum score is 0 points (indicating severe pain and impairment), the maximum score is 100 points (no impairment).

The FFI is a questionnaire, which focusses on disabilities and measures the impact of foot disorders. The FFI includes three subscales: pain, disability, and activity limitations, which are spread over a total of 23 items. In this scoring system a score of 0 points means 'no disability', 100 points implies the highest level of disability (14).

The SF-36 Health Survey is a generic measure of health status (15-22). It consists of 36 items, representing eight domains that are grouped into a Physical Component Summary (PCS) and a Mental Component Summary (MCS). All (sub)scales are normalized to a mean of 50 points with a standard deviation of 10 points.

Statistical analysis

Statistical Package for Social Sciences (SPSS, version 21) was used for analysis. Data are reported following the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) (23). Missing data were not imputed. Patient characteristics and

questionnaire scores were analyzed using descriptive statistics. Measurement properties of the AOFAS Ankle-Hindfoot Scale were determined in compliance with the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines (24). The already validated FFI and SF-36 (sub)scales were used to compare the AOFAS-DLV with. A summary of the measurement properties and statistical analysis is given in Table 2. A more detailed description is published in the study protocol (13).

Table 2: Overview of measurement properties and definitions used

Measurement property	Definition/calculation	Result	Data
Floor and ceiling effects	Percentage of participants with lowest or highest possible score	>15% (13, 30, 31)	T1-T3
Reliability			
Internal consistency	Cronbach's alpha value for (sub)scales	0.70-0.95 for unidimensional (sub)scale (31)	T1
Construct validity	Spearman rank correlation (r) of scores between (sub)scales (31). Strength of correlation categorized as high (r > 0.6), moderate (0.3 < r < 0.6), or low (r < 0.3) (32)	≥75% of correlations in line with predefined hypotheses at n ≥ 50 (Supplemental Table 1A, B) (31)	T1
Test-retest reliability			
$ICC_{agreement}$	$ICC_{agreement}$ with 95% CI	>0.70 at n ≥ 50 (31)	T2, T3
Absolute agreement			
$SEM_{agreement}$ and SDC	$SDC_{individual}$ = 1.96 x √2 x SEM (31) SDC_{group} = SDC_{ind} / √n (33, 34)		T2, T3
RCI	RCI = SDC_{group} / maximum score * 100%		T2, T3
Bland Altman analysis	95% Limits of agreement = ($mean_{change\ T3-T2}$) ± 1.96 x SD_{change} (31) (35)	Zero outside interval indicates measurement bias	T2, T3
Responsiveness			
Longitudinal validity	Spearman rank correlation of changes in scores (Score $_{T2}$ – Score $_{T1}$) between (sub)scales (31). Strength of correlation categorized as high (r > 0.6), moderate (0.3 < r < 0.6), or low (r < 0.3) (32)	≥75% of correlations in line with predefined hypotheses at n ≥ 50 (Supplemental Table 1A, B) (31)	T1, T2
Magnitude of change			
ES	ES = (Score $_{T2}$ – Score $_{T1}$) / SD $_{T1}$ (31). Effect rated as small (0.2-0.4), moderate (0.5-0.7), or large (≥0.8) (36)		T1, T2
SRM	SRM = (Score $_{T2}$ – Score $_{T1)}$ / SD $_{change}$ (31). Effect rated as small (0.2-0.4), moderate (0.5-0.7), or large (≥0.8) (36)		T1, T2

RESULTS

The changes over time in AOFAS-total, FFI-total, SF-36 PCS and SF-36 MCS are shown in Figure 2. In the period from t=1 to t=2, the AOFAS, SF-36 PCS, and (less pronounced) SF-36 MCS increased in scores. The FFI score decreases as expected, since this questionnaire focusses on disabilities. Scores at t=2 and t=3 were similar for all instruments.

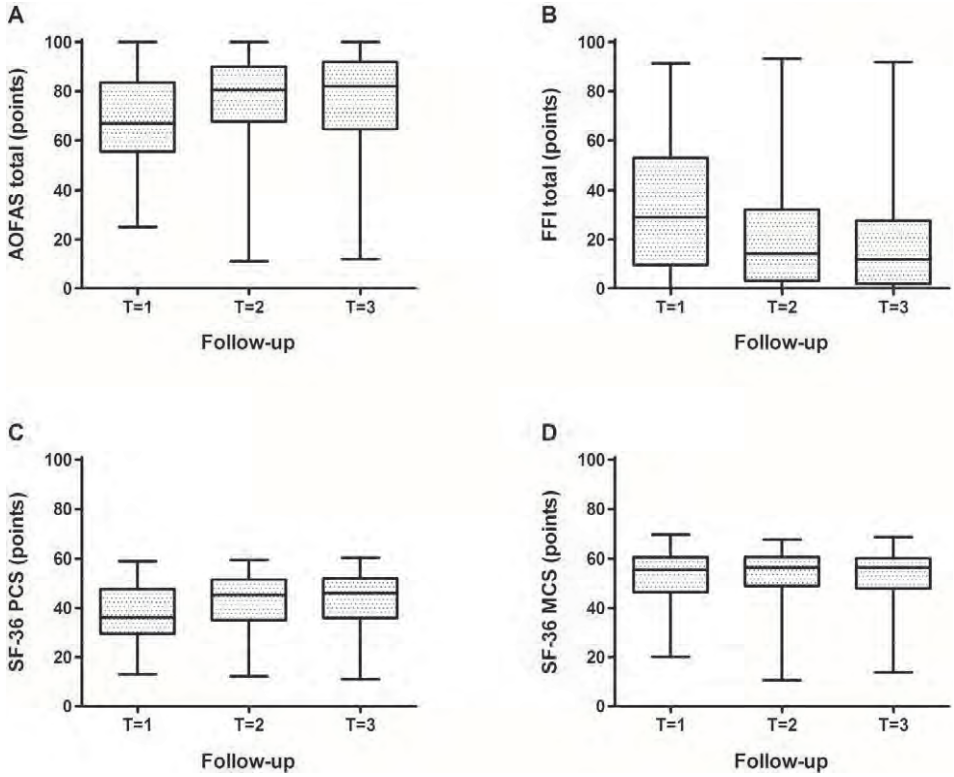

Figure 2: AOFAS Ankle-Hindfoot (**A**), Foot Function Index (**B**), Short Form-36 PCS (**C**), and SF-36 MCS (**D**) scores at each follow-up visit in patients with an ankle fracture
AOFAS, American Orthopedic Foot and Ankle Society; FFI, Foot Function Index; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-36, Short Form-36.

Floor and ceiling effects

A floor effect was only present in the SF-36 RP and RE subscales at all follow-up moments. The percentage of patients reporting the minimum score varied between 52.6% (t=1) and 32.4% (t=3) for SF36 RP and between 25.6% (t=1) and 19.0% (t=3) for the SF36 RE subscale (Figure 3A).

Ceiling effects were seen in several (sub)scales, especially at longer follow-up (Figure 3B). The AOFAS as a total scale only showed a ceiling effect at t=3; 16.2% of patients reported the maximum score. The AOFAS pain and alignment subscales had a ceiling

effect from the t=1 onwards (12.8% and 62.8%, respectively). The AOFAS function subscale showed ceiling effects from t=2 onwards (22.7%). The FFI pain and disability subscales showed ceiling effects from t=2 onwards. The FFI limitation, SF-36 RP, SF, and RE subscales showed ceiling effects at all follow-up moments.

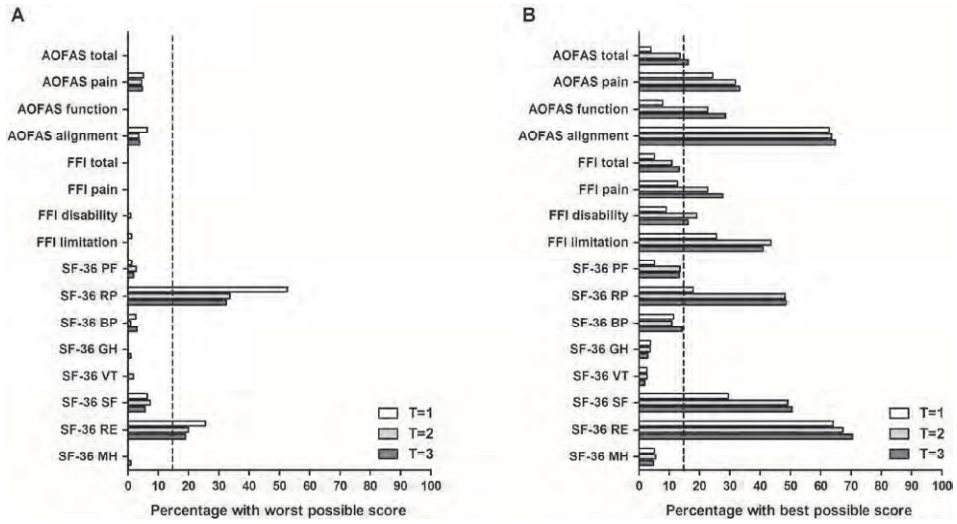

Figure 3. Floor effects (**A**) and ceiling effects (**B**) of the instruments used in patients with a hindfoot fracture

Out of a maximum of 78 at t=1, N=77 for AOFAS function and total, N=78 for AOFAS pain and alignment, and for all (sub)scales of FFI and SF-36.

Out of a maximum of 113 at t=2, N=109 for SF-36 GH, PCS, and MCS, and N=110 for all (sub)scales of the AOFAS and FFI, and for all other subscales of the SF-36.

Out of a maximum of 113 at t=3, N=105 for all (sub)scales of the AOFAS, FFI, and SF-36.

The dotted line represents the acceptable 15% of patients with the maximum score. Since for the SF-36 PCS and MCS none of the patients reported the worst or best possible score, they are not shown.

RELIABILITY

Internal consistency

For the AOFAS total scale the Cronbach's alpha was 0.585 (Table 3). This may suggest inadequate internal consistency, but as the entire scale contains three subscales, this value should however be interpreted carefully. The Cronbach's alpha for the AOFAS function subscale was 0.863, representing adequate internal consistency. Being single-item domains, Cronbach's alpha could not be determined for the AOFAS pain and alignment subscales.

The FFI scale only showed adequate internal consistency for the subscale Activity limitation (α=0.841). The internal consistency was not adequate for the FFI scale as a

total (α=0.599) and for the subscales pain (α=0.653) and disability (α=0.558). For the total scale, this may be due to the fact that it is not unidimensional. Except for the subscale GH (α=0.627), all SF-36 (sub)scales showed adequate internal consistency.

Table 3: Internal consistency of the instruments used in patients with a hindfoot fracture

(Sub)scale		N	Number of items	Cronbach's alpha
AOFAS	Total	77	8*	**0.585**[a]
	Pain	77	1	N.A.[b]
	Function	77	6*	0.863
	Alignment	77	1	N.A.[b]
FFI	Total	78	23	**0.599**[a]
	Pain	78	9	**0.635**
	Disability	78	9	**0.558**
	Activity limitation	78	5	0.841
SF-36	Total	78	35	0.916[a]
	PF	78	10	0.932
	RP	78	4	0.875
	BP	78	2	0.769
	GH	78	5	**0.627**
	VT	78	4	0.757
	SF	78	2	0.841
	RE	78	3	0.939
	MH	78	5	0.803
	PCS	78	21	0.875[a]
	MCS	78	14	0.879[a]

Data for t=1 were used.

[a] Values should be interpreted carefully because the total scale is not unidimensional.

[b] Not applicable, as this subscale consists of one item only.

Bold and underlined Cronbach alpha values did not exceed the threshold of 0.70.

AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; N.A., not applicable; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; VT, vitality, energy, or fatigue.

* Question about stability has been removed as all patients scored identical answers.

Construct validity

Spearman's rank correlations regarding construct validity are shown in Table 4. Construct validity was only adequate for the AOFAS scale as a total and the function subscale, in both (sub)scales 82.4% of the predefined hypotheses were predicted correctly. For the pain subscale, only 8 out of 17 correlations (47.1%) were in accordance with predefined hypotheses. This was 12 (70.6%) for the alignment subscale. Both percentages were below the 75% threshold.

Table 4. Construct validity of the instruments in patients with a hindfoot fracture

(Sub)scale		AOFAS			
		Pain	Function	Alignment	Total
AOFAS	Pain	1	**0.12 [77]**	-0.02 [78]	**0.54 [77]**
	Function	**0.12 [77]**	1	**0.31 [77]**	0.86 [77]
	Alignment	-0.02 [78]	**0.31 [77]**	1	0.43 [77]
	Total	**0.54 [77]**	0.86 [77]	**0.43 [77]**	1
FFI	Pain	-0.70 [78]	-0.38 [77]	-0.18 [78]	-0.63 [77]
	Disability	**-0.28 [78]**	-0.85 [77]	**-0.30 [78]**	-0.84 [77]
	Activity limitation	**-0.22 [78]**	-0.80 [77]	-0.37 [78]	-0.79 [77]
	Total	-0.40 [78]	-0.82 [77]	**-0.34 [78]**	-0.88 [77]
SF-36	PF	**0.16 [78]**	0.79 [77]	0.30 [78]	0.73 [77]
	RP	**0.30 [78]**	**0.65 [77]**	0.20 [78]	0.66 [77]
	BP	**0.56 [78]**	0.48 [77]	0.16 [78]	0.65 [77]
	GH	-0.06 [78]	0.15 [77]	0.22 [78]	0.13 [77]
	VT	0.18 [78]	0.23 [77]	0.13 [78]	**0.29 [77]**
	SF	0.20 [78]	0.54 [77]	0.06 [78]	0.53 [77]
	RE	**0.17 [78]**	0.30 [77]	-0.02 [78]	0.31 [77]
	MH	0.15 [78]	0.29 [77]	0.09 [78]	**0.31 [77]**
	PCS	**0.29 [78]**	0.74 [77]	**0.33 [78]**	0.75 [77]
	MCS	0.12 [78]	0.12 [77]	-0.08 [78]	0.15 [77]

Data for t=1 were used. Spearman's rank correlation coefficients are given for all possible combinations of (sub)scales, with the N between square brackets. The maximum possible number of patients was 78.
$r > 0.6$ indicates high correlation, $0.3 < r > 0.6$ moderate correlation, and $r < 0.3$ low correlation. Bold and underlined correlations were not hypothesized correctly.
AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; VT, vitality, energy, or fatigue.

Reproducibility

Test-Retest reliability

The intraclass correlation coefficient, indicating the reliability, of each (sub)scale is shown in Table 5. The ICC for all AOFAS (sub)scales ranged from 0.89 to 0.97, indicating adequate test-retest reliability. For all FFI and SF-36 (sub)scales, the ICC was also adequate (> 0.70).

Table 5. Intraclass correlation coefficient (ICC) and Bland-Altman analysis of the instruments in patients with a hindfoot fracture

(Sub)scale	N	ICC(2,1) (95% CI)	SEM	$SDC_{patient}$	Max score	RCI (%)	$Mean_{difference}$ (SD)	95% Limits of agreement
AOFAS								
Pain	105	0.89 (0.84-0.92)	0.4	1.1	40	2.8	0.6 (4.8)	-8.8 to 9.9
Function	105	0.97 (0.95-0.98)	0.1	0.4	50	0.8	0.2 (2.6)	-5.0 to 5.4
Alignment	105	0.97 (0.96-0.98)	0.1	0.2	10	1.9	0.1 (0.7)	-1.3 to 1.4
Total	105	0.96 (0.93-0.97)	0.6	1.7	100	1.7	0.9 (5.7)	-10.3 to 12.1
FFI								
Pain	105	0.92 (0.88-0.95)	-1.0	-2.8	100	-2.8	-1.4 (8.8)	-18.8 to 15.9
Disability	105	0.95 (0.92-0.96)	-1.1	-2.9	100	-2.9	-1.5 (8.0)	-17.1 to 14.1
Limitation	105	0.95 (0.92-0.97)	-1.0	-2.9	100	-2.9	-1.5 (6.1)	-13.5 to 10.5
Total	105	0.95 (0.92-0.96)	-1.0	-2.9	100	-2.9	-1.5 (6.6)	-14.5 to 11.5
SF-36								
PF	105	0.91 (0.87-0.94)	0.09	0.24	56.76	0.4	0.12 (4.67)	-9.03 to 9.28
RP	105	0.81 (0.73-0.86)	0.10	0.28	55.56	0.5	0.14 (8.46)	-16.43 to 16.72
BP	105	0.82 (0.74-0.87)	0.08	0.22	60.40	0.4	0.11 (6.14)	-11.90 to 12.14
GH	104	0.92 (0.89-0.95)	-0.27	-0.76	63.78	-1.2	-0.39 (4.20)	-8.62 to 7.85
VT	105	0.91 (0.87-0.94)	-0.37	-1.03	68.66	-1.5	-0.52 (4.14)	-8.63 to 7.58
SF	105	0.94 (0.91-0.96)	0.38	1.04	57.33	1.8	0.53 (4.68)	-8.64 to 9.71
RE	105	0.84 (0.77-0.89)	0.27	0.75	55.66	1.4	0.38 (6.85)	-13.03 to 13.80
MH	105	0.93 (0.90-0.95)	-0.34	-0.95	63.97	-1.5	-0.49 (4.30)	-8.92 to 7.94
PCS	104	0.85 (0.78-0.89)	0.06	0.16	70.30	0.2	0.08 (5.78)	-11.26 to 11.42
MCS	104	0.94 (0.92-0.96)	-0.11	-0.29	77.92	-0.4	-0.15 (4.24)	-8.47 to 8.17

Change scores were calculated from t=2 to t=3. The maximum possible number of patients was 113. The ICC is shown as correlation coefficient with the 95% CI between brackets. The difference in score from t=2 to t=3 is shown as mean change with SD.

Agreement and Smallest Detectable Change

The level of agreement is indicated by the SDC and the corresponding RCI (Table 5). The SDC was 1.7 (RCI: 1.7%) for the AOFAS total scale, -2.9 (RCI: -2.9%) for the FFI total scale, 0.16 (RCI: 0.2%) for the SF-36 PCS subscale, and -0.29 (RCI: -0.4%) for the SF-36 MCS subscale.

The Bland and Altman analysis shows that for each (sub)scale the 95% Limits of Agreement for the mean change in scores contains zero; this confirms that there is no bias in measurements (Figure 4 and Table 5).

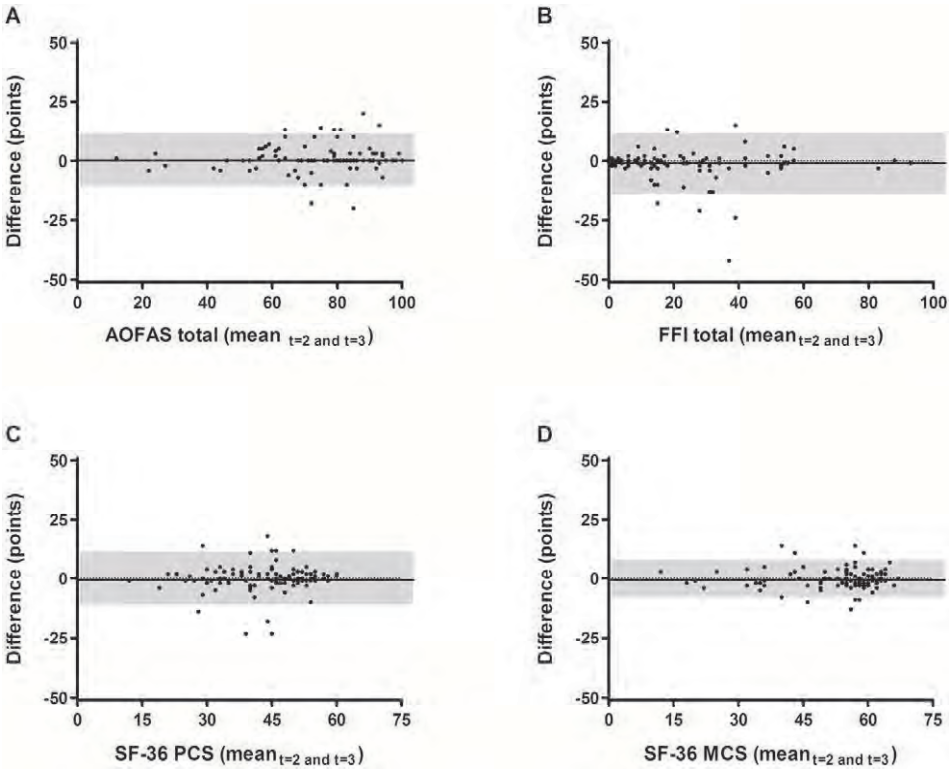

Figure 4. Bland-Altman plots for AOFAS Ankle-Hindfoot (**A**), Foot Function Index (**B**), Short Form-36 PCS (**C**), and SF-36 MCS (**D**) scores in patients with a hindfoot fracture
Change scores were calculated from t=2 to t=3.
Each dot represents a single patient. The black line indicates the mean difference. The upper and lower edges of the grey box are the 95% limits of agreement.
AOFAS, American Orthopedic Foot and Ankle Society; FFI, Foot Function Index; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-36, Short Form-36.

Responsiveness

Spearman's rank correlation coefficients for longitudinal validity are shown in Table 6. Longitudinal validity was adequate for the AOFAS pain and alignment subscale; out of 17 correlations, 15 (88.2%) were in line with predefined hypotheses for the pain subscale and 17 (100.0%) for the AOFAS alignment subscale. Longitudinal validity was not sufficient for the function subscale (10/17; 58.8%) and for the total scale (12/17; 70.6%).

Table 6. Longitudinal validity of the instruments in patients with a hindfoot fracture

(Sub)scale		AOFAS			
		Pain	Function	Alignment	Total
AOFAS	Pain	1	-0.02 [74]	-0.02 [75]	0.80 [74]
	Function	-0.02 [74]	1	-0.07 [74]	0.52 [74]
	Alignment	-0.02 [75]	-0.07 [74]	1	0.10 [74]
	Total	0.80 [74]	**0.52 [74]**	0.10 [74]	1
FFI	Pain	-0.64 [75]	**-0.08 [74]**	0.08 [75]	-0.57 [74]
	Disability	-0.11 [75]	**-0.50 [74]**	0.04 [75]	-0.39 [74]
	Activity limitation	-0.03 [75]	-0.63 [74]	-0.06 [75]	-0.39 [74]
	Total	**-0.32 [75]**	**-0.44 [74]**	0.02 [75]	-0.54 [74]
SF-36	PF	0.11 [75]	**0.43 [74]**	-0.07 [75]	0.32 [74]
	RP	0.13 [75]	0.02 [74]	-0.04 [75]	**0.15 [74]**
	BP	0.33 [75]	**0.05 [74]**	0.06 [75]	0.33 [74]
	GH	-0.07 [74]	0.07 [73]	0.29 [74]	0.07 [73]
	VT	0.00 [75]	0.21 [74]	0.09 [75]	**0.18 [74]**
	SF	-0.11 [75]	0.31 [74]	-0.10 [75]	**0.14 [74]**
	RE	-0.12 [75]	0.13 [74]	0.00 [75]	**-0.04 [74]**
	MH	0.02 [75]	0.20 [74]	0.09 [75]	0.14 [74]
	PCS	**0.23 [74]**	**0.10 [73]**	0.09 [74]	0.33 [73]
	MCS	-0.17 [74]	0.13 [73]	-0.02 [74]	-0.05 [73]

Change in scores between t=1 and t=2 were used. The maximum possible number of patients was 75. Spearman's rank correlation coefficients are given for all possible combinations of (sub)scales, with the N between square brackets. The rest of Table caption is identical to Table 4.

The Standardized Response Mean (SRM) and the Effect Size (ES) of the instruments are shown in Table 7. The magnitude of change was large for the AOFAS total scale (SRM 0.79, ES 0.63) and moderate for the function subscale (SRM 0.94, ES 0.61). The effect sizes were small for the one-item subscales pain (SRM 0.26) and alignment (SRM 0.06).

Table 7. Responsiveness: Standardized Response Mean (SRM) and Effect Size (ES) of the instruments in patients with a hindfoot fracture

(Sub)scale		N	Mean change	SD_{change}	SRM	$SD_{t=1}$	ES
AOFAS	Pain	75	3.2	12.4	0.26	10.1	0.32
	Function	74	7.7	8.2	0.94	12.7	0.61
	Alignment	75	0.1	2.2	0.06	3.1	0.04
	Total	74	11.3	14.3	0.79	17.9	0.63
FFI	Pain	75	-9.2	22.9	-0.40	25.1	-0.37
	Disability	75	-17.4	20.2	-0.86	29.6	-0.59
	Activity limitation	75	-15.4	23.4	-0.66	29.6	-0.52
	Total	75	-14.6	16.3	-0.89	24.5	-0.60
SF-36	PF	75	8.15	9.89	0.82	13.06	0.62
	RP	75	7.59	12.46	0.61	11.72	0.65
	BP	75	3.53	10.32	0.34	11.16	0.32
	GH	74	-0.21	8.18	-0.03	9.23	-0.02
	VT	75	0.70	8.73	0.08	9.73	0.07
	SF	75	6.18	15.05	0.41	14.00	0.44
	RE	75	1.08	15.35	0.07	13.17	0.08
	MH	75	0.74	8.89	0.08	10.11	0.07
	PCS	74	6.60	7.65	0.86	10.28	0.64
	MCS	74	-0.39	11.36	-0.03	11.16	-0.03

Change scores were calculated from t=1 to t=2. The maximum possible number of patients was 75.
AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; ES, effect size; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; SRM, standardized response mean; VT, vitality, energy, or fatigue.

DISCUSSION

The results of this study showed that the AOFAS Ankle-Hindfoot Scale Dutch Language Version (AOFAS-DLV) has adequate construct validity and is reliable for measuring functional outcome in patients with a hindfoot fracture. However, longitudinal validity and responsiveness were inadequate in the study population.

Floor effects were not present for the AOFAS-DLV, but all (sub)scales showed an increasing ceiling effect over time. That suggests that an increasing number of patients achieved full recovery over time. This is in line with previous findings (1, 2). The single-item subscales pain and alignment showed a ceiling effect from t=1 onwards. This could be due to the fact that (minor) extra-articular fractures may not be an issue with alignment. The high rate of operative treatment may also have improved alignment, especially for the intra-articular fractures. Alternatively, the limited answers for the pain and

alignment subscales and the choice of administering the AOFAS-DLV at 3 to 6 months after trauma for the first time, may also have contributed to the ceiling effects.

Adequate construct validity of the AOFAS total scale and function subscale is also in correspondence with previous research (2, 3). The AOFAS subscales pain and alignment did not show adequate construct validity, in contrast with earlier data in ankle fractures (2). The AOFAS pain and alignment subscales consist only of one item. In the hindfoot series, the correlations with other (sub)scales were generally overestimated for the pain subscale and underestimated for the alignment subscale. This difference is unlikely due to the (heterogeneity) in (sub)scale scores between the ankle and hindfoot fracture cohorts. There is also no clear pathophysiological explanation for this difference, other than the fact that hindfoot and ankle fractures are different injuries. Another possible explanation may be a difference in follow-up moment used for hindfoot and ankle fractures.

With a Cronbach's alpha above 0.7, internal consistency of the AOFAS-DLV function subscale was adequate. For the total scale, this remains inconclusive; the Cronbach's alpha of 0.585 should be interpreted carefully as the total scale is not unidimensional. In ankle fractures (2), ankle sprains (4), and ankle arthroplasty and arthrodesis (5), the Cronbach alpha for the total scale ranged from 0.92-0.95. To our knowledge, no recent literature on this topic is available for hindfoot fractures. Deleting the pain question increases Cronbach's alpha to 0.843 (data not shown). This may suggest that the pain question is difficult to answer for patients. This could be due to the fact that three out of four answers combine pain severity and frequency. Such linguistic issues have been noted before (5, 6).

The ICC values between 0.89 and 0.97 confirm adequate test-retest reliability of the AOFAS-DLV total scale and all subscales. Similar ICC's (ranging from 0.89 to 0.95) were found for the Turkish and Portuguese version of the AOFAS Ankle-Hindfoot Scale in patients with foot and ankle disorders (2, 7, 8).

Responsiveness is a product of magnitude of change and longitudinal validity. The longitudinal validity of the AOFAS subscales pain and alignment was adequate (*i.e.*, >75% of the hypothesized correlations predicted correctly). However, the AOFAS subscale function and the total scale were not proven adequate, as only 58.8% and 70.6% of the predefined hypothesis were confirmed, respectively. The inadequate longitudinal validity makes the AOFAS-DLV less useful for longitudinal studies measuring recovery over time in patients with a hindfoot fracture. Longitudinal validity was adequate for all (sub)scales of the AOFAS-DLV in patients with ankle fractures in previous research (2). In the hindfoot series, the correlations of the difference in score between t=1 and t=2 with other (sub)scales were generally overestimated for the AOFAS function subscale and total scale. Similar as for the construct validity, there is no clear pathophysiological explanation for this difference, other than the difference in (severity of) the injuries and follow-up moments used.

The magnitude of change was moderate for the AOFAS Ankle-Hindfoot scale DLV as a total, with a SRM of 0.79 and an ES of 0.63. This is comparable to the magnitude of change for the total FFI (SRM 0.89, ES 0.60) and the SF-36 subscales PCS, PF, and RP as in our recent study on ankle fractures (2). Previous data for hindfoot injuries are not available.

The Bland and Altman analysis confirmed absence of systematic bias for repeated recordings of the AOFAS Ankle-Hindfoot Scale-DLV. With a SDC of 1.7 points, the measurement error is very small. This measurement error was lower than reported for a variety of foot and ankle disorders in the Turkish population (SDC 13.3) and for ankle fractures in the Dutch population (SDC 12.0) (2, 7).

CONCLUSION

The AOFAS Ankle-Hindfoot Scale Dutch Language Version has adequate construct validity and is reliable, making it a suitable instrument for cross-sectional studies investigating functional outcome in patients with a hindfoot fracture. The inadequate longitudinal validity and responsiveness, however, hamper the use of the questionnaire in longitudinal studies and for assessing long-term functional outcome.

REFERENCES

1. Brauer CA, Manns BJ, Ko M, Donaldson C, Buckley R. An economic evaluation of operative compared with nonoperative management of displaced intra-articular calcaneal fractures. J Bone Joint Surg Am. 2005;87(12):2741-9.
2. De Boer AS, Schepers T, Panneman MJ, Van Beeck EF, Van Lieshout EM. Health care consumption and costs due to foot and ankle injuries in the Netherlands, 1986-2010. BMC Musculoskelet Disord. 2014;15:128.
3. Mitchell MJ, McKinley JC, Robinson CM. The epidemiology of calcaneal fractures. Foot (Edinb). 2009;19(4):197-200.
4. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. Injury. 2006;37(8):691-7.
5. Schneider W, Jurenitsch S. Normative data for the American Orthopedic Foot and Ankle Society ankle-hindfoot, midfoot, hallux and lesser toes clinical rating system. Int Orthop. 2016;40(2):301-6.
6. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int. 1994;15(7):349-53.
7. Madeley NJ, Wing KJ, Topliss C, Penner MJ, Glazebrook MA, Younger AS. Responsiveness and validity of the SF-36, Ankle Osteoarthritis Scale, AOFAS Ankle Hindfoot Score, and Foot Function Index in end stage ankle arthritis. Foot Ankle Int. 2012;33(1):57-63.
8. SooHoo NF, Vyas R, Samimi D. Responsiveness of the foot function index, AOFAS clinical rating systems, and SF-36 after foot and ankle surgery. Foot Ankle Int. 2006;27(11):930-4.
9. Westphal T, Piatek S, Halm JP, Schubert S, Winckler S. Outcome of surgically treated intraarticular calcaneus fractures--SF-36 compared with AOFAS and MFS. Acta Orthop Scand. 2004;75(6):750-5.
10. Ibrahim T, Beiri A, Azzabi M, Best AJ, Taylor GJ, Menon DK. Reliability and validity of the subjective component of the American Orthopaedic Foot and Ankle Society clinical rating scales. J Foot Ankle Surg. 2007;46(2):65-74.
11. De Boer AS TR, Van Der Sijde F, Meuffels DE, Den Hoed PT, Van Der Vlies CH, Tuinebreijer WE, Verhofstad MHJ, Van Lieshout EMM. The American Orthopedic Foot and Ankle Society Ankle-Hindfoot Scale; Translation and Validation of the Dutch Language Version for ankle fractures. BMJ Open. 2017;In Press.
12. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976). 2000;25(24):3186-91.
13. Van Lieshout EM, De Boer AS, Meuffels DE, Den Hoed PT, Van der Vlies CH, Tuinebreijer WE, et al. American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score: a study protocol for the translation and validation of the Dutch language version. BMJ Open. 2017;7(2):e012884.
14. Budiman-Mak E, Conrad KJ, Roach KE. The Foot Function Index: a measure of foot pain and disability. J Clin Epidemiol. 1991;44(6):561-70.
15. de Haan J, den Hartog D, Tuinebreijer WE, Iordens GI, Breederveld RS, Bronkhorst MW, et al. Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomized trial. BMC Musculoskelet Disord. 2010;11:263.
16. Den Hartog D, Van Lieshout EM, Tuinebreijer WE, Polinder S, Van Beeck EF, Breederveld RS, et al. Primary hemiarthroplasty versus conservative treatment for comminuted fractures of the proximal humerus in the elderly (ProCon): a multicenter randomized controlled trial. BMC Musculoskelet Disord. 2010;11:97.
17. Mahabier KC, Den Hartog D, Theyskens N, Verhofstad MHJ, Van Lieshout EMM, Hummer Trial Investigators. Reliability, validity, responsiveness, and minimal important change of the Disablities of the Arm, Shoulder and Hand and Constant-Murley scores in patients with a humeral shaft fracture. J Shoulder Elbow Surg. 2016.
18. Obremskey WT, Dirschl DR, Crowther JD, Craig WL, 3rd, Driver RE, LeCroy CM. Change over time of SF-36 functional outcomes for operatively treated unstable ankle fractures. J Orthop Trauma. 2002;16(1):30-3.
19. Pan SL, Liang HW, Hou WH, Yeh TS. Responsiveness of SF-36 and Lower Extremity Functional Scale for assessing outcomes in traumatic injuries of lower extremities. Injury. 2014;45(11):1759-63.

20. Schep NW, De Haan J, Iordens GI, Tuinebreijer WE, Bronkhorst MW, De Vries MR, et al. A hinged external fixator for complex elbow dislocations: a multicenter prospective cohort study. BMC Musculoskelet Disord. 2011;12:130.
21. van Tetering EA, Buckley RE. Functional outcome (SF-36) of patients with displaced calcaneal fractures compared to SF-36 normative data. Foot Ankle Int. 2004;25(10):733-8.
22. Ware JE, Jr., Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. J Clin Epidemiol. 1998;51(11):903-12.
23. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008;61(4):344-9.
24. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010;19(4):539-49.
25. da Cunha RA, Hazime FA, da Silva Martins MC, Ferreira M, de Castro Pochini A, Ejnisman B. Translation, Cross-cultural Adaptation, and Clinimetric Testing of Instruments Used to Assess Patients With Ankle Sprain in the Brazilian Population. J Orthop Sports Phys Ther. 2016;46(12):1042-50.
26. Pinsker E, Inrig T, Daniels TR, Warmington K, Beaton DE. Reliability and validity of 6 measures of pain, function, and disability for ankle arthroplasty and arthrodesis. Foot Ankle Int. 2015;36(6):617-25.
27. Guyton GP. Theoretical limitations of the AOFAS scoring systems: an analysis using Monte Carlo modeling. Foot Ankle Int. 2001;22(10):779-87.
28. Analay Akbaba Y, Celik D, Ogut RT. Translation, Cross-Cultural Adaptation, Reliability, and Validity of Turkish Version of the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale. J Foot Ankle Surg. 2016;55(6):1139-42.
29. Rodrigues RC MD, Mizusaki JM, Imoto AM, Peccin MS, Cohen M, Alloza JFM. Translation, cultural adaptation and validity of the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale. Acta Ortop Bras 2008;16:107–11.
30. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995;4(4):293-307.
31. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34-42.
32. Hinkle DE WW, Jurs SG. Applied statistics for the behavioral sciences. Boston USA: Houghton MiZin. 1998.
33. de Vet HC, Bouter LM, Bezemer PD, Beurskens AJ. Reproducibility and responsiveness of evaluative outcome measures. Theoretical considerations illustrated by an empirical example. Int J Technol Assess Health Care. 2001;17(4):479-87.
34. de Boer MR, de Vet HC, Terwee CB, Moll AC, Volker-Dieben HJ, van Rens GH. Changes to the subscales of two vision-related quality of life questionnaires are proposed. J Clin Epidemiol. 2005;58(12):1260-8.
35. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1(8476):307-10.
36. Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale (NJ): Lawrence Erlbaum Associates. 1998.

Chapter 11

The American Orthopaedic Foot and Ankle Society ankle-hindfoot scale: Translation and validation of the Dutch language version for ankle fractures

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ABSTRACT

Objectives: The American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale is among the most commonly used instruments for measuring outcome of treatment in patients who sustained a complex ankle or hindfoot injury. It consists of a patient-reported and a physician-reported part. A validated, Dutch version of this instrument is currently not available. The aim of this study was to translate the instrument into Dutch and to determine the measurement properties of the AOFAS Ankle-Hindfoot Scale Dutch Language Version (DLV) in patients with a unilateral ankle fracture.

Setting: Multicenter (two Dutch hospitals), prospective observational study.

Participants: In total 142 patients with a unilateral ankle fracture were included. Ten patients were lost to follow up.

Primary and secondary outcome measures: Patients completed the subjective (patient-reported) part of the AOFAS Ankle-Hindfoot Scale-DLV. A physician or trained physician-assistant completed the physician-reported part. For comparison and evaluation of the measuring characteristics, the Foot Function Index (FFI) and the Short Form-36 (SF-36) were completed by the patient. Descriptive statistics (including floor and ceiling effects), reliability (*i.e.*, internal consistency), construct validity, reproducibility (*i.e.*, test-retest reliability, agreement, and smallest detectable change), and responsiveness were determined.

Results: The AOFAS-DLV and its subscales showed good internal consistency (Cronbach's alpha > 0.90). Construct validity and longitudinal validity were proven to be adequate (76.5% of predefined hypotheses were confirmed). Floor effects were not present. Ceiling effects were present from six months onwards, as expected. Responsiveness was adequate, with a smallest detectable change of 12.0 points.

Conclusions: The AOFAS-DLV is a reliable, valid, and responsive measurement instrument for evaluating functional outcome in patients with a unilateral ankle fracture. This implies that the questionnaire is suitable to compare different treatment modalities within this population or to compare outcome across hospitals.

Trial Registration: Netherlands Trial Register (NTR5613; 05-jan-2016).

BACKGROUND

Ankle fractures are common injuries with a reported incidence rate of 187 fractures per 100,000 people each year (1). Due to an increasing number of people involved in sports and the growing elderly population, this rate is rising significantly in many industrialized countries (1). Ankle fractures can cause a temporary loss of function and quality of life. In order to monitor recovery after treatment, questionnaires regarding functional outcome are increasingly used in clinical practice and clinical research. They enable detailed evaluation of functional outcome and quality of life after (non-)operative treatment of musculoskeletal injuries from a patient's perspective.

Although questionnaires completed by patients alone (so called patient-reported outcome measures; PROMs) may be preferred, many scores combine a patient-reported and a physician-reported part. Examples of PROMs used in foot and ankle research are the Maryland Foot Score (MFS) (2), Foot and Ankle Ability Measure (FAAM) (3), the Foot Function Index (FFI) (4), the Manchester-Oxford Foot Questionnaire (MOXFQ) (5, 6), and the Self-Reported Foot and Ankle Score (SEFAS) (7).

The clinical rating system published by the American Orthopedic Foot and Ankle Society, the AOFAS Ankle-Hindfoot Scale, is one of the mostly used assessment tool in foot surgery (8). This clinical rating system, developed by Kitaoka *et al.*, combines subjective scores of pain and function provided by the patient and objective scores based on the physician's physical examination (*i.e.*, gait, sagittal motion, hindfoot motion, ankle-hindfoot stability, and alignment of the ankle-hindfoot) (9). The questionnaire includes nine items that can be divided into three subscales (pain, function, and alignment). Each of the nine items is scored, accumulating to a total score ranging from 0 points (indicating severe pain and impairment) to 100 points (no symptoms or impairment).

Limitations on the use of the AOFAS Ankle-Hindfoot Scale are the fact that questions have a limited number of answers, some of which can be interpreted differently (10, 11). An advantage is that the physician-reported questions on gait and range of motion provide relevant information that the PROMs do not provide.

The AOFAS Ankle-Hindfoot Scale as a complete scale has been shown to be responsive and valid in its original language version (9, 12-14). The patient-reported part of the scale has been shown to be valid and reliable (15). Reliability of the objective (physician-reported) portion of the scale has not been published. Previous studies involved a wide spectrum of diagnoses, such as general ankle-hindfoot complaints (13), pending ankle or foot surgery (15), surgically treated calcaneal fractures (14), and end-stage ankle osteoarthritis (12).

A validated Dutch version of the AOFAS Ankle-Hindfoot Scale is not available. The aim of this study was to translate the questionnaire into Dutch and to culturally adapt it to the Dutch population. The next aim was to determine the measurement properties of the AOFAS Ankle-Hindfoot Scale Dutch Language Version (AOFAS-DLV) in patients who sustained an ankle fracture.

METHODS

Study design and ethics statement

This study followed a multicenter, prospective, observational study design (*i.e.*, case series) and was performed at two Dutch hospitals. The study is registered at the Netherlands Trial Register (NTR5613). A detailed study protocol is published elsewhere (16). The study was approved by the Medical Research Ethics Committees or Local Ethics Boards of all participating centers. All patients provided informed consent.

Translation

First, the American (original) version of the AOFAS Hindfoot-Ankle Scale was translated and cultural adapted into Dutch according to the guideline for Cross Cultural Adaptation of Self-Report Measures by Beaton *et al*. (17), as described in detail in the published study protocol (16). In the last stage of this guideline the pre-final Dutch version was tested in a group of 20 patients, presenting themselves with various foot/ankle problems in one of the participating hospitals. Since there were no ambiguities or misunderstandings of the questions in this group, the translated questionnaire was considered the final AOFAS Ankle-Hindfoot Scale-DLV (Supplemental Table 1).

VALIDATION

Patient recruitment

Patients were recruited from May 1, 2014 to March 29, 2016. Patients were identified from hospital records, based upon their ICD-10 (International Coding of Diseases, 10th revision) code or Diagnosis Related Group (DRG; in Dutch, DBC) code. Inclusion criteria were; 1) unilateral ankle fracture; 2) age of 18 years or older; and 3) provision of informed consent by the patient. Treatment should have been started between six weeks and three months and/or between seven and nine months prior to the start of the study. Exclusion criteria were; 1) multiple trauma (only if functional recovery of additional injuries was not achieved at time of enrolment, as that likely affects the outcome scores); 2) pathological fracture; 3) severe physical comorbidity (*i.e.*, American Society of Anaesthesiologists (ASA) ≥3); 4) patient was non-ambulatory prior to the injury; 5) insufficient comprehension of the Dutch language to understand and complete the questionnaires; and 6) expected problems of maintaining follow-up.

In total 142 individual participants were included, 70 completed t=1 and t=2, 132 completed t=2 and t=3 (Figure 1). During the course of the study ten patients were lost to follow up. One patient, who participated in the test-retest part, had to be removed

from the analysis; due to removal of osteosynthesis material, the patient reported a change in function between both recordings.

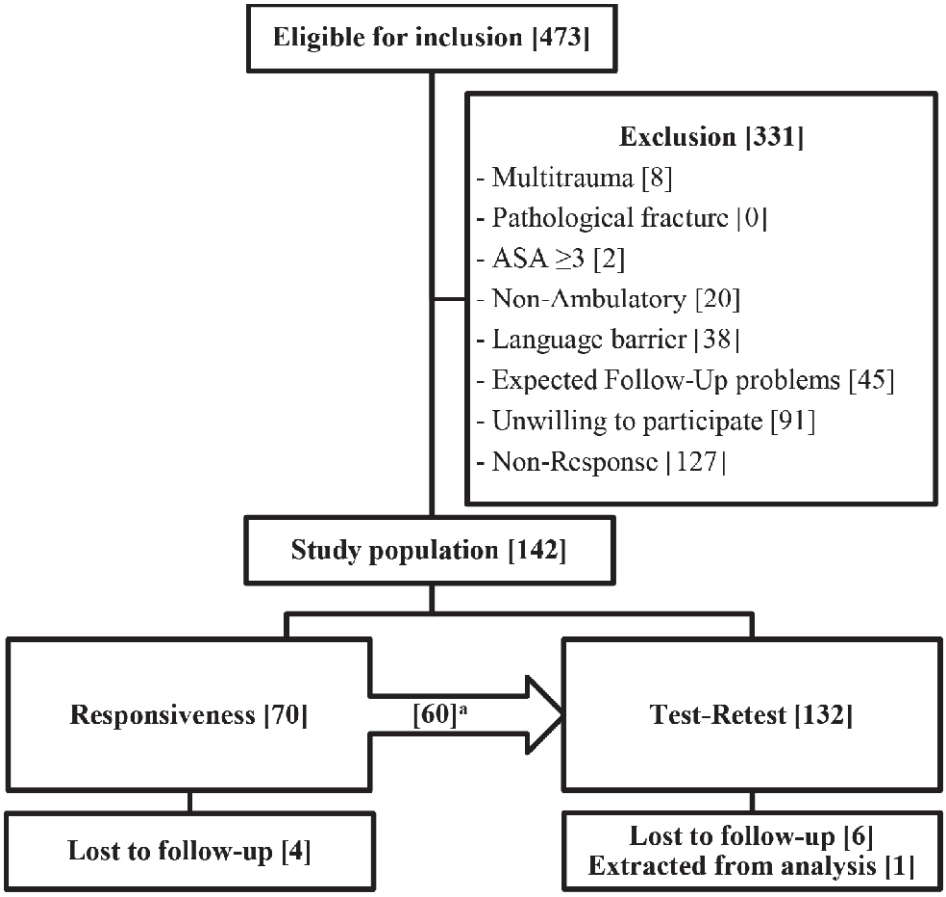

Figure 1: Flowchart

The number of patients in each particular group is shown between square brackets.
[a] Patients who participated in both groups

The median age was 46 years (P_{25} -P_{75} 35-60), see Table 1. The majority of patients (N=75; 52.8%) were male. Most ankle fractures were unimalleolar (N=100; 70.4%), and the majority (N=84; 59.2%) were treated operatively.

Table 1: Demographic data for the study population

Variable		Outcome
Age (years)		46 (35- 60)
Male gender		75 (52.8%)
Right side affected		58 (40.8%)
Dominant side affected		60 (42.3%)
Malleolar involvement	Unimalleolar	100 (70.4%)
	Bimalleolar	23 (16.2%)
	Trimalleolar	19 (13.4%)
Classification	Weber A	29 (20.4%)
	Weber B	56 (39.4%)
	Weber C	13 (9.2%)
	Unknown	44 (31.0%)
Open fracture		6 (4.2%)
Treatment	Nonoperative	58 (40.8%)
	Operative	84 (59.2%)

Data are shown as median (P_{25}-P_{75}) or as N (%), as applicable.

The AOFAS Ankle-Hindfoot Scale-DLV, the Foot Function Index (FFI-DLV), and the Short Form Health Survey (SF-36-DLV) questionnaires could be completed in total on three occasions: at 2 months (t=1), 7 months (t=2), and 7.5 months (t=3) after trauma. Two months was chosen as first moment after start of weight bearing where both the questions of the patient and physician-reported part could be answered; a low score was expected. At seven months the majority of patients were expected to have reached their maximum recovery, giving the highest possible AOFAS score. That score was also expected at t=3. The time between the recordings was 5-6 months (responsiveness, t=1 and t=2) and/or 2-3 weeks (test-retest, t=2 and t=3) in between. Patients were allowed to participate in both the responsiveness and test-retest part, and if so, the questionnaires at t=2 were also used as first questionnaire for test-retest reliability.

Questionnaires and data collection

The FFI is a scoring system developed to measure the impact of foot pathology. It consists of 23 items, which are grouped into the subscales pain, disability, and activity limitation. Scores for all (sub)scales range from zero (no disability) to 100 (highest level of disability) (4).

The SF-36 Health Survey is a generic measure of health status (18-25). It consists of 36 items, representing eight domains that are grouped into a Physical Component Summary (PCS) and a Mental Component Summary (MCS).

One research physician and one research assistant performed the physical examination that is part of the physician-reported part of the AOFAS Ankle-Hindfoot Scale-DLV using a standardized protocol. Both assessors received elaborate training by an experi-

enced trauma surgeon. Data for each patient was completed by the same assessor. Patients completed the patient-reported part, as well as the FFI and SF-36. Demographic, injury and treatment data were collected from the patient's medical files.

Statistical analysis

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS, version 21). Data are reported following the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) (26). Since raw data for individual items were analyzed, missing data were not imputed. Descriptive statistics was used in order to describe the main characteristics of the study participants and the questionnaire scores at the different time points. Measurement properties of the AOFAS-DLV (sub)scales were determined by comparing these (sub)scales with the FFI and SF-36 (sub)scales. They were determined in compliance with the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines (27). A detailed description of the measurement properties and statistical analysis is shown in the published study protocol (16). A summary is given below.

Floor and ceiling effects are present if more than 15% of the study population rates the lowest or highest possible score (16, 28, 29). Data for each time point were evaluated separately.

Internal consistency (measure of reliability) was considered adequate if the Cronbach's alpha value is between 0.70 and 0.95, provided that the scale is unidimensional (28). For reasons of heterogeneity in scores, data for t=1 were used.

Construct validity was assessed by determining the correlation of the AOFAS-DLV (sub)scales with (sub)scales of the FFI and SF-36. Spearman's Rho (rank correlation) coefficients (*r*) were calculated since data were non-parametric. Data of t=1 were used. Strength of correlation was categorized as high ($r > 0.6$), moderate ($0.3 < r < 0.6$), or low ($r < 0.3$) (30). Construct validity was considered adequate if at least 75% of the results were in line with the predefined hypotheses in a (sub)sample of at least 50 patients (28). Expected correlations are given in Supplemental Table 2A.

Evaluation of the test-retest reliability was performed by calculating the intraclass correlation coefficient ($ICC_{agreement}$) of (sub)scales administered at t=2 and t=3. ICC is reported with 95% confidence interval (CI). Reliability was given a positive rating when the ICC is at least 0.70 in a sample size with a minimum of 50 patients (28).

The degree of absolute agreement was expressed as the standard error of measurement ($SEM_{agreement}$). For individual patients, the smallest detectable change (SDC) was calculated as $1.96 \times \sqrt{2} \times SEM$ (28). The SDC measurable in a group of people (SDC_{group}) was calculated by dividing the SDC in individuals (SDC_{ind}) by $\sqrt{n}$ (31, 32). Finally, the reliable change index (RCI) was calculated, representing the SDC as a percentage of the maximum obtainable score.

The degree of absolute agreement was also determined with a Bland and Altman analysis (33). The limits of agreement equal the mean change in scores of repeated measurements ($mean_{change}$) ± 1.96 x standard deviation of these changes (SD_{change}) (28). Zero falling outside this interval indicates bias in the measurements.

Analogous to construct validity, longitudinal validity (a measure of responsiveness) was assessed by testing predefined hypotheses (Supplemental Table 2B) about expected correlations between changes in AOFAS Ankle-Hindfoot scale-DLV (sub)scales versus changes in FFI and SF-36 (sub)scales (28). Change scores were calculated from t=1 to t=2. Since data were non-parametric, Spearman's rank correlation coefficients were calculated. Longitudinal validity was considered adequate if at least 75% of the results were in line with the predefined hypotheses in a (sub)sample of at least 50 patients (28).

The effect size (ES) and standardized response mean (SRM) were determined as measures of the magnitude of change over time, using the data of t=1 and t=2. ES was calculated as change in score (t=2 - t=1)/SD_{T1} (28). SRM was calculated as change in score (t=2 – t=1)/SD_{change} (28). Values of 0.2-0.4 were considered a small effect, 0.5-0.7 a moderate, and 0.8 or higher a large effect (34). Large effect sizes were expected a priori, since at t=1 patients were expected to have functional limitations, whereas at t=2 full recovery was expected for most patients.

RESULTS

The changes over time in AOFAS-total, FFI-total, SF-36 PCS, SF-36 MCS, SF-36 PF, and SF-36 BP are shown in Figure 2. The AOFAS and SF-36 (all subscales) show an increase in scores in the period from t=1 to t=2. The FFI, focusing on disabilities rather than function, shows a decrease in score. Scores at t=2 and t=3 were similar for all instruments.

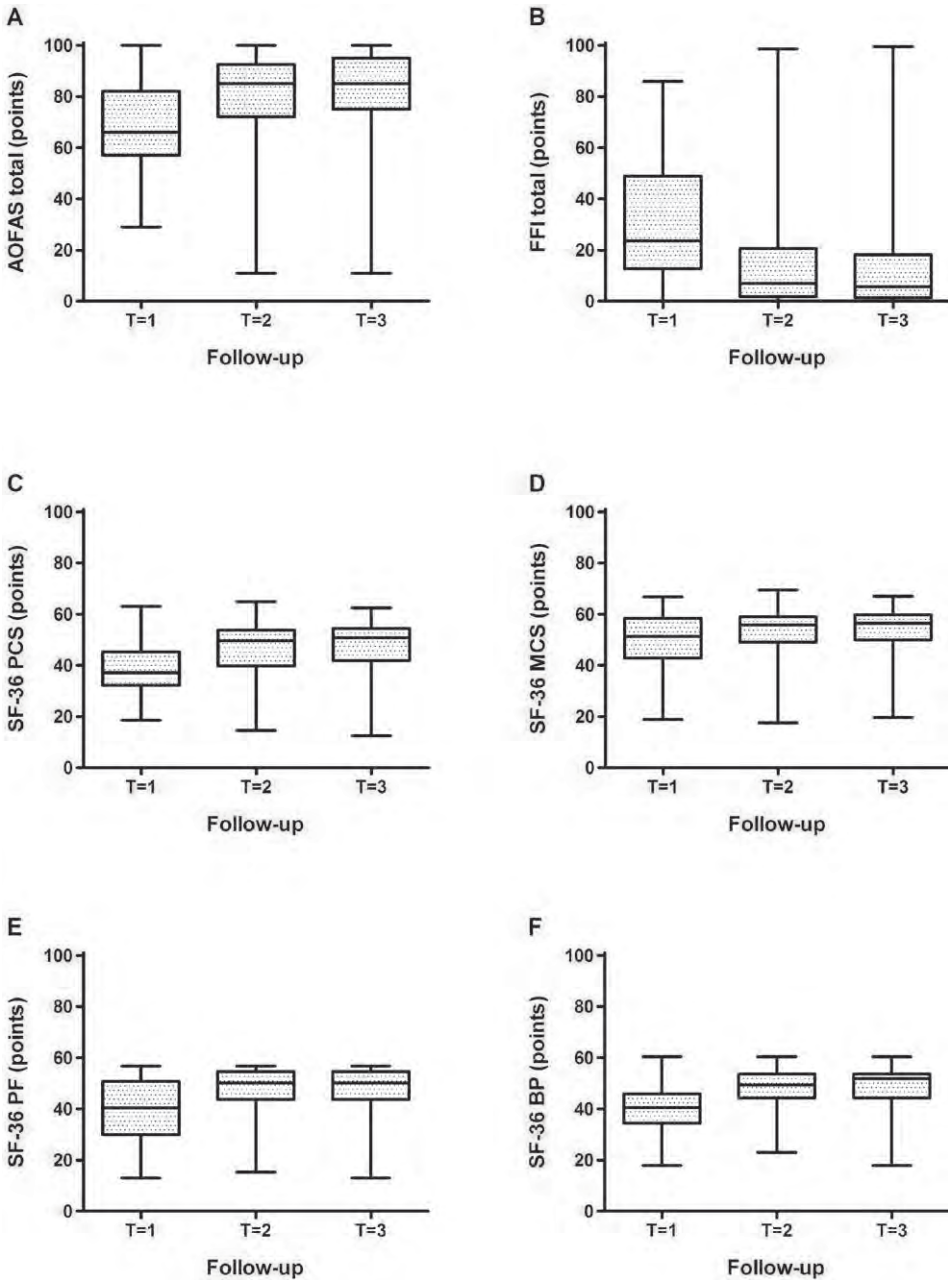

Figure 2: AOFAS Ankle-Hindfoot (**A**), Foot Function Index (**B**), Short Form-36 PCS (**C**), SF-36 MCS (**D**), SF-36 PF (**E**), and SF-36 BP (**F**) scores at each follow-up visit in patients with an ankle fracture

AOFAS, American Orthopedic Foot and Ankle Society; BP, Bodily Pain; FFI, Foot Function Index; MCS, Mental Component Summary; PCS, Physical Component Summary; PF, Physical Functioning; SF-36, Short Form-36.

Floor and ceiling effects

A floor effect was only present in two SF-36 subscales; namely SF-36 RP subscale at t=1; 58.6% of the patients reported the minimum score, at t=2 (19.7%) and t=3 (17.6%), and the SF-36 RE subscale at t=1 (28.6%); Figure 3a).

A ceiling effect was present in several (sub)scales, and became more evident at longer follow-up (Figure 3b). The AOFAS pain subscale had a ceiling effect from the t=1 onwards, where 22.9% of patients reported the maximum score. From t=2 onwards, ceiling effects were also noted for AOFAS function (27.0%) and alignment (65.9%) subscales, FFI pain (16.7%) and disability (21.0%) subscales, and SF-36 BP (21.9%) and PF (19.5%) subscales. The AOFAS as a total scale only showed a ceiling effect at t=3; 17.7% of patients reported the maximum score.

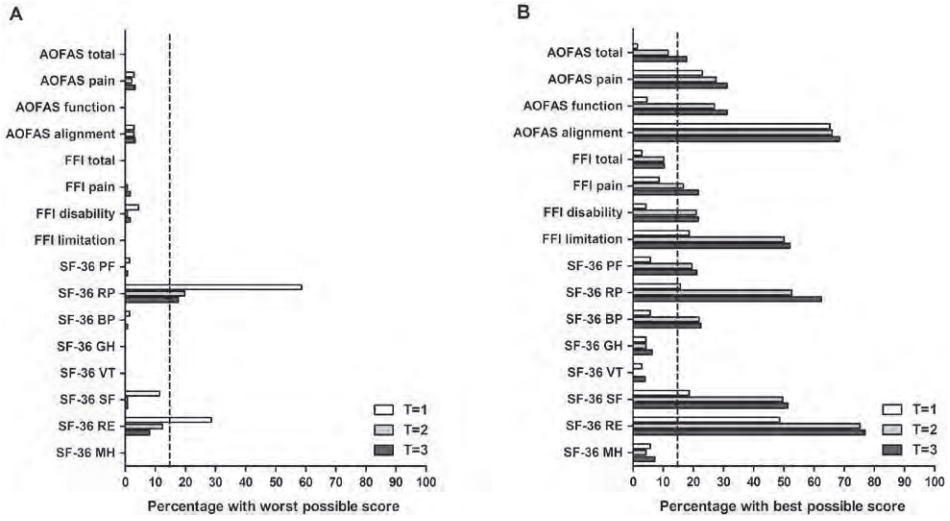

Figure 3. Floor effects (**A**) and ceiling effects (**B**) of the instruments used in patients with an ankle fracture
Out of a maximum of 70 at t=1, N=65 for AOFAS function and total, N=69 for AOFAS alignment, and N=70 for AOFAS pain and all (sub)scales of FFI and SF-36.
Out of a maximum of 138 at t=2, N=131 for SF-36 PCS and MCS, N=133 for SF-36 PF, N=136 for SF-36 VT, N=137 for AOFAS function, AOFAS total, and SF-36 RP, BP, SF, and RE, N=138 for AOFAS pain and alignment, all FFI (sub)scales, and SF-36 GH and MH
N=138 for AOFAS pain and alignment, 137 for AOFAS function and AOFAS total.
Out of a maximum of 125 at t=3, N=123 for SF-36 PF, PCS, and MCS, N=124 for AOFAS alignment and total, and SF-36 VT, and N=125 for AOFAS pain and function, all FFI (sub)scales, and SF-36 RP, BP, GH, SF, RE, and MH.
The dotted line represents the acceptable 15% of patients with the maximum score. The SF-36 PCS and MCS did not demonstrate a floor or a ceiling effect and are not displayed.

Reliability

Internal consistency

The Cronbach's alpha for the AOFAS total scale and function subscale were 0.947 and 0.927, respectively, representing adequate internal consistency (Table 2). The value for the total scale should be interpreted carefully as it contains three subscales. Cronbach's alpha could not be calculated for AOFAS pain and alignment subscales, since these have one item only.

The FFI total scale (α = 0.649) and pain subscale (α = 0.687) did not show adequate internal consistency. For the total scale, this may be explained by the fact that it is not unidimensional. All SF-36 (sub)scales showed adequate internal consistency, with the exception of the subscales general health (α = 0.621) and vitality (α = 0.648).

Table 2: Internal consistency of the instruments used in patients with an ankle fracture

(Sub)scale		N	Number of items	Cronbach's alpha
AOFAS	Total	70	9	0.947[a]
	Pain	70	1	N.A.[b]
	Function	70	7	0.927
	Alignment	70	1	N.A.[b]
FFI	Total	70	23	**0.649**[a]
	Pain	70	9	**0.687**
	Disability	70	9	0.707
	Activity limitation	70	5	0.854
SF-36	Total	70	35	0.882[a]
	PF	70	10	0.932
	RP	70	4	0.885
	BP	70	2	0.733
	GH	70	5	**0.621**
	VT	70	4	**0.648**
	SF	70	2	0.832
	RE	70	3	0.870
	MH	70	5	0.799
	PCS	70	21	0.846[a]
	MCS	70	14	0.861[a]

Data for t=1 were used.

[a] Values should be interpreted carefully because the total scale is not unidimensional.

[b] Not applicable, as this subscale consists of one item only.

Bold and underlined Cronbach alpha values did not exceed the threshold of 0.70.

AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; N.A., not applicable; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; VT, vitality, energy, or fatigue.

Construct validity

Spearman's rank correlations regarding construct validity are shown in Table 3. Construct validity was adequate for all AOFAS (sub)scales; out of 17 correlations, 14 (82.4%) were in line with predefined hypotheses for the total scale, 13 (76.5%) for the pain subscale, 15 (88.2%) for the function subscale, and 16 (94.1%) for the alignment subscale.

Table 3. Construct validity of the instruments in patients with an ankle fracture

(Sub)scale		AOFAS			
		Pain	**Function**	**Alignment**	**Total**
AOFAS	Pain	1	**0.23 [65]**	0.01 [69]	0.66 [65]
	Function	**0.23 [65]**	1	0.28 [65]	0.85 [65]
	Alignment	0.01 [69]	0.28 [65]	1	**0.35 [65]**
	Total	0.66 [65]	0.85 [65]	**0.35 [65]**	1
FFI	Pain	-0.81 [70]	-0.41 [65]	-0.14 [69]	-0.70 [65]
	Disability	-0.41 [70]	-0.75 [65]	-0.19 [69]	-0.74 [65]
	Activity limiation	-0.34 [70]	-0.80 [65]	-0.23 [69]	-0.77 [65]
	Total	-055 [70]	-0.73 [65]	-0.21 [69]	-0.80 [65]
SF-36	PF	**0.21 [70]**	0.64 [65]	0.21 [69]	0.60 [65]
	RP	0.32 [70]	0.50 [65]	0.19 [69]	**0.58 [65]**
	BP	**0.59 [70]**	0.53 [65]	0.03 [69]	0.67 [65]
	GH	0.15 [70]	-0.01 [65]	-0.09 [69]	0.04 [65]
	VT	0.28 [70]	0.19 [65]	-0.02 [69]	**0.27 [65]**
	SF	0.14 [70]	**0.65 [65]**	0.18 [69]	0.56 [65]
	RE	**0.10 [70]**	0.32 [65]	0.22 [69]	0.33 [65]
	MH	0.24 [70]	0.20 [65]	0.02 [69]	0.24 [65]
	PCS	0.40 [70]	0.62 [65]	0.11 [69]	0.65 [65]
	MCS	0.11 [70]	0.24 [65]	0.13 [69]	0.24 [65]

Data for t=1 were used. Spearman's rank correlation coefficients are given for all possible combinations of (sub)scales, with the N between square brackets. The maximum possible number of patients was 70.
r > 0.6 indicates high correlation, 0.3 < r > 0.6 moderate correlation, and r < 0.3 low correlation. Bold and underlined correlations were not hypothesized correctly.
AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; VT, vitality, energy, or fatigue.

Reproducibility

Test-Retest reliability

The intraclass correlation coefficient indicates the reliability of each (sub)scale (Table 4). The calculated ICC for the total AOFAS (sub)scales ranged from 0.85 to 0.93, indicating adequate test-retest reliability. The ICC was also proven to be adequate (> 0.70) for all

FFI and SF-36 (sub)scales, with the exception of SF-36 subscale General Health perceptions (ICC = 0.64).

Table 4. Intraclass correlation coefficient (ICC) and Bland-Altman analysis of the instruments in ankle fracture patients

(Sub)scale	N	ICC(2,1) (95% CI)	SEM	SDC $_{patient}$	Max score	RCI (%)	Mean $_{difference}$ (SD)	95% Limits of agreement
AOFAS								
Pain	125	0.85 (0.78-0.89)	3.5	9.7	40	24.3	1.1 (5.0)	-8.6 to 10.8
Function	124	0.92 (0.89-0.95)	2.1	5.9	50	11.9	0.6 (3.0)	-5.4 to 6.5
Alignment	124	0.89 (0.85-0.92)	0.9	2.5	10	24.8	0.2 (1.3)	-2.3 to 2.6
Total	123	0.93 (0.89-0.95)	4.3	12.0	100	12.0	1.8 (6.1)	-10.2 to 13.9
FFI								
Pain	125	0.83 (0.76-0.87)	9.4	26.1	100	26.1	-1.5 (13.3)	-27.6 to 24.6
Disability	125	0.90 (0.86-0.93)	7.4	20.5	100	20.5	-1.5 (10.5)	-22.0 to 19.0
Activity limitation	125	0.81 (0.74-0.86)	7.9	22.0	100	22.0	-0.2 (11.2)	-22.2 to 21.8
Total	125	0.92 (0.89-0.94)	5.9	16.4	100	16.4	-1.2 (8.4)	-17.5 to 15.2
SF-36								
PF	120	0.90 (0.87-0.93)	3.18	8.83	56.76	15.6	1.40 (4.50)	-8.43 to 9.23
RP	124	0.71 (0.59-0.79)	6.36	17.64	55.56	31.7	2.56 (9.00)	-15.07 to 20.20
BP	124	0.78 (0.70-0.85)	4.07	11.29	60.40	18.7	1.48 (5.76)	-9.80 to 12.77
GH	125	**0.64 (0.52-0.73)**	5.12	14.20	63.78	22.3	-0.27 (7.24)	-14.47 to 13.93
VT	123	0.77 (0.68-0.83)	4.06	11.25	68.66	16.4	0.74 (5.74)	-10.51 to 11.99
SF	124	0.70 (0.60-0.78)	4.89	13.56	57.33	23.7	0.77 (6.92)	-12.79 to 14.32
RE	124	0.72 (0.63-0.80)	5.31	14.71	55.66	26.4	0.90 (7.50)	-13.81 to 15.60
MH	125	0.79 (0.70-0.85)	3.86	10.70	63.97	16.7	-1.21 (5.46)	-9.49 to 11.91
PCS	118	0.85 (0.79-0.89)	3.87	10.72	70.30	15.3	1.10 (5.47)	-9.62 to 11.83
MCS	118	0.78 (0.70-0.84)	4.10	11.36	77.92	14.6	0.96 (5.80)	-10.42 to 12.30

Change scores were calculated from t=2 to t=3. The maximum possible number of patients was 125. The ICC is shown as correlation coefficient with the 95% CI between brackets. The difference in score from t=2 to t=3 is shown as mean change with SD.

Agreement and Smallest Detectable Change

The level of agreement is indicated by the SDC and the corresponding RCI, as listed in Table 4. The SDC was 12.0 (RCI: 12.0%) for the AOFAS total scale, 16.4 (RCI: 16.4%) for the FFI total scale, 10.7 (RCI: 15.3%) for the SF-36 PCS subscale, and 11.36 (RCI: 14.6%) for the SF-36 MCS subscale.

The Bland and Altman analysis (Figure 4 and Table 4) there is no bias in measurements, as the 95% Limits of Agreement for the mean change in scores contains zero for every single (sub)scale.

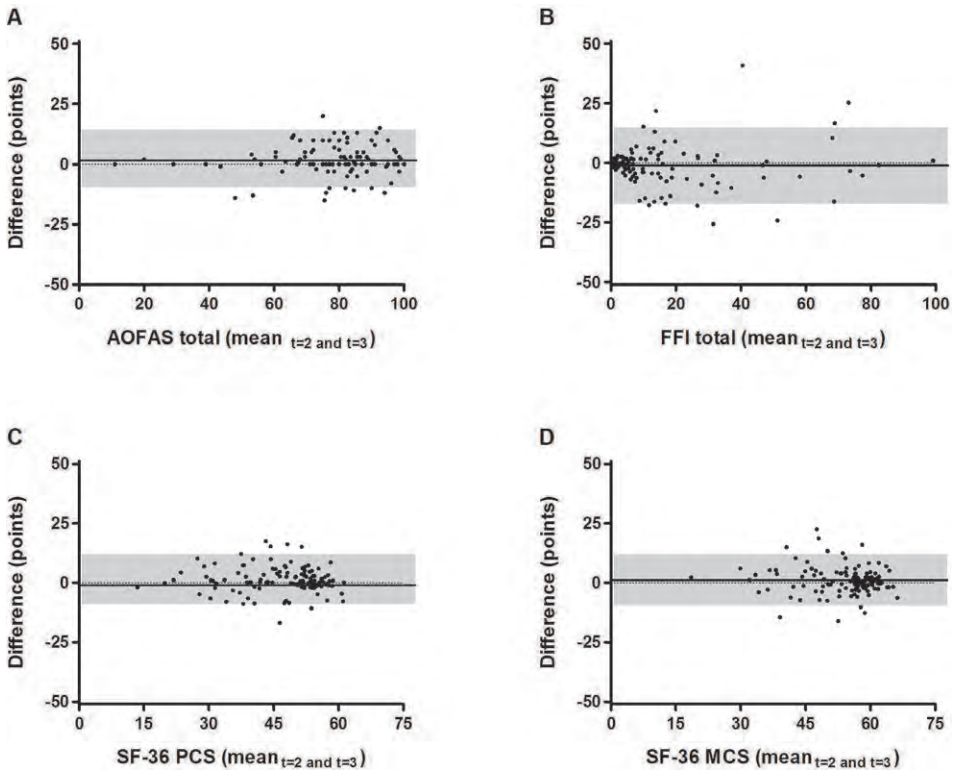

Figure 4. Bland-Altman plots for AOFAS Ankle-Hindfoot (**A**), Foot Function Index (**B**), Short Form-36 PCS (**C**), and SF-36 MCS (**D**) scores in patients with an ankle fracture

Change scores were calculated from t=2 to t=3.

Each dot represents a single patient. The black line indicates the mean difference. The upper and lower edges of the grey box are the 95% limits of agreement.

AOFAS, American Orthopedic Foot and Ankle Society; FFI, Foot Function Index; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-36, Short Form-36.

Responsiveness

Spearman's rank correlation coefficients for longitudinal validity are shown in Table 5. Longitudinal validity was adequate for all AOFAS (sub)scales; out of 17 correlations, 15 (88.2%) were in line with predefined hypotheses for the total scale, 14 (82.5%) for the AOFAS pain subscale, 13 (76.5%) for function subscale, and 17 (100%) for alignment subscale.

Table 5. Longitudinal validity of the instruments in patients with an ankle fracture

(Sub)scale		AOFAS			
		Pain	**Function**	**Alignment**	**Total**
AOFAS	Pain	1	0.21 [61]	0.12 [65]	0.70 [61]
	Function	0.21 [61]	1	0.05 [61]	0.81 [61]
	Alignment	0.12 [65]	0.05 [61]	1	0.22 [61]
	Total	0.70 [61]	0.81 [61]	0.22 [61]	1
FFI	Pain	**-0.56 [66]**	**-0.19 [61]**	-0.17 [65]	-0.43 [61]
	Disability	-0.24 [66]	-0.66 [61]	-0.07 [65]	-0.60 [61]
	Activity limitation	-0.06 [66]	**-0.59 [61]**	0.09 [65]	-0.50 [61]
	Total	**-0.33 [66]**	-0.61 [61]	-0.03 [65]	**-0.65 [61]**
SF-36	PF	0.25 [66]	**0.44 [61]**	-0.12 [65]	0.48 [61]
	RP	0.26 [65]	**0.34 [60]**	0.01 [64]	0.37 [60]
	BP	0.39 [65]	0.36 [60]	0.06 [64]	0.46 [60]
	GH	-0.02 [66]	-0.13 [61]	0.13 [65]	-0.05 [61]
	VT	**0.38 [66]**	0.26 [61]	0.10 [65]	0.38 [61]
	SF	0.20 [65]	0.54 [60]	0.03 [64]	0.47 [60]
	RE	-0.08 [65]	0.19 [60]	0.15 [64]	**0.14 [60]**
	MH	0.13 [66]	0.09 [61]	0.08 [65]	0.11 [61]
	PCS	0.34 [65]	0.39 [60]	-0.06 [64]	0.45 [60]
	MCS	-0.07 [65]	0.15 [60]	0.14 [64]	0.06 [60]

Change in scores between t=1 and t=2 were used. The maximum possible number of patients was 70. Spearman's rank correlation coefficients are given for all possible combinations of (sub)scales, with the N between square brackets.

The rest of Table caption is identical to Table 3.

The Standardized Response Mean (SRM) and the Effect Size (ES) of the instruments are presented in Table 6. The AOFAS total scale (SRM 1.07, ES 0.89) and function subscale (SRM 1.29, ES 1.06) had a large magnitude of change. The one-item subscales showed a moderate effect size for pain (SRM 0.27) and a small effect size for alignment (SRM < 0.2).

Table 6. Responsiveness: standardized response mean (SRM) and Effect Size (ES) of the instruments in patients with an ankle fracture

(Sub)scale		N	Mean change	SD_{change}	SRM	$SD_{t=1}$	ES
AOFAS	Pain	66	2.3	8.4	0.27	8.9	0.26
	Function	61	12.3	9.5	1.29	11.5	1.06
	Alignment	65	-0.2	1.8	-0.09	2.7	-0.06
	Total	61	15.1	14.1	1.07	16.9	0.89
FFI	Pain	66	-9.1	18.7	-0.49	21.9	-0.42
	Disability	66	-23.3	25.3	-0.92	29.9	-0.78
	Activity limitation	66	-17.9	22.9	-0.78	27.1	-0.66
	Total	66	-17.6	18.9	-0.93	23.9	-0.74
SF-36	PF	66	9.04	10.94	0.83	12.98	0.70
	RP	65	11.95	13.25	0.90	10.94	1.09
	BP	65	7.85	10.33	0.76	9.50	0.83
	GH	66	-0.83	8.56	-0.10	8.42	-0.10
	VT	66	1.74	8.89	0.20	8.06	0.22
	SF	65	13.49	13.53	1.00	14.67	0.92
	RE	65	5.28	12.11	0.44	13.36	0.40
	MH	66	1.31	8.40	0.16	9.10	0.14
	PCS	65	8.88	10.03	0.89	9.65	0.92
	MCS	65	2.68	11.21	0.24	11.61	0.23

Change scores were calculated from t=1 to t=2. The maximum possible number of patients was 70.
AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; ES, effect size; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; SRM, standardized response mean; VT, vitality, energy, or fatigue.

DISCUSSION

The results of this study showed that the AOFAS Ankle-Hindfoot scale Dutch Language Version (AOFAS-DLV) is a valid, reliable, and responsive instrument for measuring symptoms and disability in patients who suffered an ankle fracture.

Floor effects were not present for the AOFAS-DLV in this study. Ceiling effects, on the other hand, did occur. The AOFAS total scale showed a ceiling effect at t=3. Ceiling effects were expected to occur at follow-up moments t=2 and t=3, as most patients were expected to have achieved full recovery (and thus the maximum score) at those follow-up moments. Ceiling effects have been reported in another study for the same reason (20). ‚Another study found no ceiling effects for the AOFAS Ankle Hindfoot Scale at six months after elective surgery for a variety of chronic ankle and hindfoot disorders (7).

Evaluating the predictions about Spearman's rank correlations between all (sub)scales, the AOFAS scale as a total showed adequate construct validity. This is in correspondence with previous research, conducted by Ibrahim *et al*. (15). Construct validity also showed to be adequate for all AOFAS subscales separately. The correlations between the AOFAS total score and the SF-36 did show to be higher than the correlations found by SooHoo *et al.* (35). Instead of a high correlation, they found the SF-36 subscales bodily pain, and physical functioning to have a moderate correlation with the AOFAS total scale. The difference in correlation was even bigger for the SF-36 PCS, which SooHoo *et al.* found to have a low, instead of a high correlation with the AOFAS total scale in this study (35). A possible explanation for these differences is the difference in study population, as this study only focused on ankle fractures and SooHoo *et al.* included all injuries of the ankle and hindfoot (35).

As far as conclusions can be drawn, the AOFAS Ankle-Hindfoot scale DLV appears to have adequate internal consistency. Cronbach's α for the AOFAS-scale as a total is 0.947. This value however, should be interpreted carefully as this scale is not unidimensional. Pinsker *et al.* also did find Cronbach's α to be adequate (α = 0.84) for the five patient-reported items of the AOFAS Ankle-Hindfoot scale in the original language (10).

The reliability of the AOFAS DLV is proven to be sufficient, as the ICC for the total AOFAS scale was 0.93. Sufficient reliability has been shown before (7, 15).This reflects the instrument as a whole. Being interested in the performance of the AOFAS DLV as a whole, the intraobserver or interobserver reliability of the physician-reported part alone was not analyzed. The separate subscales also showed to be reliable on an independent level, with ICC of > 0.70 for all AOFAS subscales. Validation studies for the Portuguese and Turkish version of the AOFAS Ankle-Hindfoot scale in patients with variable chronic pathologies and joint injuries, respectively, found similar ICC values of 0.92 ($p < 0.001$) and 0.89 ($p= 0.001$), respectively (36, 37).

Responsiveness of the AOFAS-DLV, considered being a product of longitudinal validity and magnitude of change, was adequate in this study. Concerning longitudinal validity, > 75% of all hypothesized correlations for Spearman's Rho were confirmed, indicating adequate longitudinal validity. This confirms previous studies (9, 12-14). Magnitude of change for the outcome measures was high for the AOFAS Ankle-Hindfoot scale DLV as a whole, with an SRM of 1.07 and ES of 0.89. This is comparable to the magnitude of change for the total FFI (SRM -0.93, ES -0.74) and the SF-36 subscales with the highest magnitude of change (PCS, PF, RP and SF) in our study. Values for SRM and ES of the AOFAS-DLV found in this study are in correspondence with the values found in previous research by SooHoo *et al.* (13), regarding the original AOFAS Ankle-Hindfoot scale (SRM 1.10, ES 1.12). They are also in line with other studies evaluating the AOFAS and the SEFAS (7).

The level of agreement of the AOFAS total scale compared well to the FFI and SF-36 in this study. The SEM for the AOFAS-DLV was 4.3 points. The SDC was 12.0 points.

Similar values for SEM and SDC were found in the validation study of the AOFAS Ankle-Hindfoot Scale in Turkish (SEM, 4.8 points and SDC 13.3 points) (36).

The Bland and Altman analysis showed there is no bias in measurements, as the 95% Limits of Agreement for the mean change in scores contained zero for every single (sub)scale. As the AOFAS-DLV shows sufficient reliability and the level of agreement is equivalent to the level of agreement of the SF-36 and FFI (which are both validated patient-reported outcome measures), the reproducibility of the questionnaire is proven to be acceptable.

A limitation could be the arbitrary choice of t=1 and t=2 for calculating longitudinal validity, ES, and SRM. These measurement properties require the largest change scores. Completing the questionnaires early after trauma (*i.e.*, at two months, low scores expected) and at seven months (*i.e.*, maximum recovery expected) was aimed to achieve the largest change score. Despite good measurement properties of the AOFAS-DLV, a limitation of its use is the fact that a physician has to complete a part of the questionnaire. That makes it unsuitable for, *e.g.*¸ use in large scale registers. For that purpose, PROMs like the FFI, MOXFQ, and SEFAS may be interesting. The last two have sufficient response rates, internal consistency, test-retest reliability, and responsiveness in patients with surgically treated chronic ankle and hindfoot disorders (6, 7). Data for ankle fractures are not yet available. Current data are in support of using the FFI as PROM.

CONCLUSION

This study evaluated the measurement properties of the AOFAS Ankle-Hindfoot scale Dutch Language Version and confirmed it is a reliable, valid, and responsive measurement instrument for evaluating functional outcome in Dutch patients with a unilateral ankle fracture. This makes the questionnaire suitable for comparing outcome in future studies and after different treatment modalities within this study population or for comparing outcome across hospitals or between patient groups.

Supplemental Table 1: AOFAS Ankle-Hindfoot Scale Dutch Language Version

Pijn
- ☐ Geen
- ☐ Mild, af en toe
- ☐ Matig, dagelijks
- ☐ Ernstig, bijna altijd aanwezig

Functie

Beperkingen in activiteiten, hulpmiddelengebruik
- ☐ Geen beperkingen; geen hulpmiddelen nodig
- ☐ Geen beperkingen bij dagelijkse activiteiten, wel beperkingen bij recreatieve activiteiten; geen hulpmiddelen nodig
- ☐ Beperkingen bij dagelijkse en recreatieve activiteiten; gebruik van een stok
- ☐ Ernstige beperkingen bij dagelijkse en recreatieve activiteiten; gebruik van een brace, krukken, looprek, rollator of rolstoel

Maximale loopafstand
- ☐ Meer dan 600 meter
- ☐ 400 tot 600 meter
- ☐ 100 tot 400 meter
- ☐ Minder dan 100 meter

Loopondergrond
- ☐ Op geen enkele ondergrond problemen
- ☐ Enige moeite met lopen op oneffen terrein, trappen, hellingen of ladders
- ☐ Veel moeite met lopen op oneffen terrein, trappen, hellingen of ladders

Let op: onderstaande vragen worden door de arts ingevuld.

Afwijkende loopgang
- ☐ Geen tot gering
- ☐ Duidelijk
- ☐ Zeer opvallend

Sagittale beweging (dorsoflexie plus plantairflexie)
- ☐ Normaal of geringe beperking (30° of meer)
- ☐ Matige beperking (15-29°)
- ☐ Ernstige beperking (minder dan 15°)

Achtervoetbeweging (inversie plus eversie)
- ☐ Normaal of geringe beperking (75%-100% van normaal)
- ☐ Matige beperking (25-74% van normaal)
- ☐ Opvallende beperking (minder dan 25% van normaal)

Enkel-achtervoet stabiliteit (anteroposterieur, varus-valgus)
- ☐ Stabiel
- ☐ Evident instabiel

Alignement
- ☐ Goed, plantigrade voet, enkel-achtervoet fraai gealigneerd
- ☐ Redelijk, plantigrade voet, enige mate van enkel-achtervoet malalignement, geen klachten of symptomen
- ☐ Slecht, geen plantigrade voet, ernstige malalignement met klachten of symptomen

Supplemental Table 2A. Hypothesized correlations between the instruments for construct validity in patients with an ankle fracture

(Sub)scale		AOFAS			
		Pain	**Function**	**Alignment**	**Total**
AOFAS	Pain	N.A.	moderate	low	high
	Function	moderate	N.A.	low	high
	Alignment	low	low	N.A.	low
	Total	high	high	low	N.A.
FFI	Pain	high	moderate	low	high
	Disability	moderate	high	low	high
	Activity limitation	moderate	high	low	high
	Total	moderate	high	low	high
SF-36	PF	moderate	high	low	high
	RP	moderate	moderate	low	high
	BP	high	moderate	low	high
	GH	low	low	low	low
	VT	low	low	low	moderate
	SF	low	moderate	low	moderate
	RE	moderate	moderate	low	moderate
	MH	low	low	low	low
	PCS	moderate	high	low	high
	MCS	low	low	low	low

Expected strength of correlation for all possible combinations; $r > 0.6$ indicates high correlation, $0.3 < r > 0.6$ moderate correlation, and $r > 0.6$ low correlation.

AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; VT, vitality, energy, or fatigue.

Supplemental Table 2B. Hypothesized correlations between the instruments for longitudinal validity in patients with an ankle fracture

(Sub)scale		AOFAS			
		Pain	**Function**	**Alignment**	**Total**
AOFAS	Pain	N.A.	low	low	high
	Function	low	N.A.	low	high
	Alignment	low	low	N.A.	low
	Total	high	high	low	N.A.
FFI	Pain	high	moderate	low	moderate
	Disability	low	high	low	moderate
	Activity limitation	low	high	low	moderate
	Total	low	high	low	moderate
SF-36	PF	low	high	low	moderate
	RP	low	low	low	moderate
	BP	moderate	moderate	low	moderate
	GH	low	low	low	low
	VT	low	low	low	moderate
	SF	low	moderate	low	moderate
	RE	low	low	low	moderate
	MH	low	low	low	low
	PCS	moderate	moderate	low	moderate
	MCS	low	low	low	low

Expected strength of correlation for all possible combinations; $r > 0.6$ indicates high correlation, $0.3 < r > 0.6$ moderate correlation, and $r > 0.6$ low correlation.

AOFAS, American Orthopedic Foot and Ankle Society; BP, bodily pain; FFI, Foot Function Index; GH, general health perceptions; MCS, mental component summary; MH, general mental health; PCS, physical component summary; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning; SF-36, Short Form-36; VT, vitality, energy, or fatigue.

REFERENCES

1. Daly PJ, Fitzgerald RH, Jr., Melton LJ, Ilstrup DM. Epidemiology of ankle fractures in Rochester, Minnesota. Acta Orthop Scand. 1987;58(5):539-44.
2. Heffernan G, Khan F, Awan N, Riordain CO, Corrigan J. A comparison of outcome scores in os calcis fractures. Ir J Med Sci. 2000;169(2):127-8.
3. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Van Swearingen JM. Evidence of validity for the Foot and Ankle Ability Measure (FAAM). Foot Ankle Int. 2005;26(11):968-83.
4. Budiman-Mak E, Conrad KJ, Roach KE. The Foot Function Index: a measure of foot pain and disability. J Clin Epidemiol. 1991;44(6):561-70.
5. Dawson J, Coffey J, Doll H, Lavis G, Cooke P, Herron M, et al. A patient-based questionnaire to assess outcomes of foot surgery: validation in the context of surgery for hallux valgus. Qual Life Res. 2006;15(7):1211-22.
6. Dawson J, Boller I, Doll H, Lavis G, Sharp R, Cooke P, et al. The MOXFQ patient-reported questionnaire: assessment of data quality, reliability and validity in relation to foot and ankle surgery. Foot (Edinb). 2011;21(2):92-102.
7. Coster MC, Rosengren BE, Bremander A, Brudin L, Karlsson MK. Comparison of the Self-reported Foot and Ankle Score (SEFAS) and the American Orthopedic Foot and Ankle Society Score (AOFAS). Foot Ankle Int. 2014;35(10):1031-6.
8. Schneider W, Jurenitsch S. Normative data for the American Orthopedic Foot and Ankle Society ankle-hindfoot, midfoot, hallux and lesser toes clinical rating system. Int Orthop. 2016;40(2):301-6.
9. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int. 1994;15(7):349-53.
10. Pinsker E, Inrig T, Daniels TR, Warmington K, Beaton DE. Reliability and validity of 6 measures of pain, function, and disability for ankle arthroplasty and arthrodesis. Foot Ankle Int. 2015;36(6):617-25.
11. Guyton GP. Theoretical limitations of the AOFAS scoring systems: an analysis using Monte Carlo modeling. Foot Ankle Int. 2001;22(10):779-87.
12. Madeley NJ, Wing KJ, Topliss C, Penner MJ, Glazebrook MA, Younger AS. Responsiveness and validity of the SF-36, Ankle Osteoarthritis Scale, AOFAS Ankle Hindfoot Score, and Foot Function Index in end stage ankle arthritis. Foot Ankle Int. 2012;33(1):57-63.
13. SooHoo NF, Vyas R, Samimi D. Responsiveness of the foot function index, AOFAS clinical rating systems, and SF-36 after foot and ankle surgery. Foot Ankle Int. 2006;27(11):930-4.
14. Westphal T, Piatek S, Halm JP, Schubert S, Winckler S. Outcome of surgically treated intraarticular calcaneus fractures--SF-36 compared with AOFAS and MFS. Acta Orthop Scand. 2004;75(6):750-5.
15. Ibrahim T, Beiri A, Azzabi M, Best AJ, Taylor GJ, Menon DK. Reliability and validity of the subjective component of the American Orthopaedic Foot and Ankle Society clinical rating scales. J Foot Ankle Surg. 2007;46(2):65-74.
16. Van Lieshout EMM, De Boer AS, Meuffels DE, Den Hoed PT, Van Der Vlies CH, Tuinebreijer WE, et al. The American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score; Study Protocol for the Translation and Validation of the Dutch Language Version. BMJ Open 2016:In press.
17. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976). 2000;25(24):3186-91.
18. de Haan J, den Hartog D, Tuinebreijer WE, Iordens GI, Breederveld RS, Bronkhorst MW, et al. Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomized trial. BMC Musculoskelet Disord. 2010;11:263.
19. Den Hartog D, Van Lieshout EM, Tuinebreijer WE, Polinder S, Van Beeck EF, Breederveld RS, et al. Primary hemiarthroplasty versus conservative treatment for comminuted fractures of the proximal humerus in the elderly (ProCon): a multicenter randomized controlled trial. BMC Musculoskelet Disord. 2010;11:97.
20. Mahabier KC, Den Hartog D, Theyskens N, Verhofstad MHJ, Van Lieshout EMM, Hummer Trial Investigators. Reliability, validity, responsiveness, and minimal important change of the Disablities of the Arm,

Shoulder and Hand and Constant-Murley scores in patients with a humeral shaft fracture. J Shoulder Elbow Surg. 2016.
21. Obremskey WT, Dirschl DR, Crowther JD, Craig WL, 3rd, Driver RE, LeCroy CM. Change over time of SF-36 functional outcomes for operatively treated unstable ankle fractures. J Orthop Trauma. 2002;16(1):30-3.
22. Pan SL, Liang HW, Hou WH, Yeh TS. Responsiveness of SF-36 and Lower Extremity Functional Scale for assessing outcomes in traumatic injuries of lower extremities. Injury. 2014;45(11):1759-63.
23. Schep NW, De Haan J, Iordens GI, Tuinebreijer WE, Bronkhorst MW, De Vries MR, et al. A hinged external fixator for complex elbow dislocations: a multicenter prospective cohort study. BMC Musculoskelet Disord. 2011;12:130.
24. van Tetering EA, Buckley RE. Functional outcome (SF-36) of patients with displaced calcaneal fractures compared to SF-36 normative data. Foot Ankle Int. 2004;25(10):733-8.
25. Ware JE, Jr., Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. J Clin Epidemiol. 1998;51(11):903-12.
26. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008;61(4):344-9.
27. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010;19(4):539-49.
28. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34-42.
29. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995;4(4):293-307.
30. Hinkle DE WW, Jurs SG. Applied statistics for the behavioral sciences. Boston USA: Houghton MiZin. 1998.
31. de Vet HC, Bouter LM, Bezemer PD, Beurskens AJ. Reproducibility and responsiveness of evaluative outcome measures. Theoretical considerations illustrated by an empirical example. Int J Technol Assess Health Care. 2001;17(4):479-87.
32. de Boer MR, de Vet HC, Terwee CB, Moll AC, Volker-Dieben HJ, van Rens GH. Changes to the subscales of two vision-related quality of life questionnaires are proposed. J Clin Epidemiol. 2005;58(12):1260-8.
33. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1(8476):307-10.
34. Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale (NJ): Lawrence Erlbaum Associates. 1998.
35. SooHoo NF, Shuler M, Fleming LL, American Orthopaedic F, Ankle S. Evaluation of the validity of the AOFAS Clinical Rating Systems by correlation to the SF-36. Foot Ankle Int. 2003;24(1):50-5.
36. Analay Akbaba Y, Celik D, Ogut RT. Translation, Cross-Cultural Adaptation, Reliability, and Validity of Turkish Version of the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale. J Foot Ankle Surg. 2016;55(6):1139-42.
37. Rodrigues RC MD, Mizusaki JM, Imoto AM, Peccin MS, Cohen M, Alloza JFM. Translation, cultural adaptation and validity of the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale. Acta Ortop Bras 2008;16:107–11.

Chapter 12

General discussion and future perspectives

The research questions as described in the outline of this thesis and the answers found in the subsequent chapters are discussed following the different clinical perspectives on complex ankle and hindfoot injuries. This chapter also elaborates on how the study results support these answers and how they fit in already existing knowledge on the topic. Finally, implications of the current study findings are outlined and suggestions for future research are made.

EPIDEMIOLOGY

In the last decades several studies have shown increased incidence rates of foot and ankle injuries (1-3). This is in line with the strong increase in incidence rate of patients with osseous injuries since 1986 (especially in admitted patients) as found in our epidemiology study (Chapter 2). Osseous injuries were also the most expensive type of injury. The main cost determinants were in-hospital care and physical therapy.

The emergency attendance rate of ligamentous foot and ankle injuries however consistently decreased since 1986. This could be explained by the introduction of new guidelines and After Hours Medical Clinics (4, 5) that were established during the study period. Patients with minor injuries nowadays can get general practitioner consultations and treatment 24/7. This may indicate a shift towards more complex injuries over time or an increase in the number of surgically treated fractures which is especially seen in ankle fractures (3, 6, 7).

Injury cases were extracted from the National Injury Surveillance System (LIS) and the National Medical Registration (LMR), both systems have their own limitations. The LIS is a 12% sample of all injury-related emergency department visits in the Netherlands and the LMR only collects data regarding hospital admissions. No national data on patients who visited a general practitioner could be included. Unfortunately, nowadays no main registry is available which includes all aspects of healthcare (*i.e.,* hospital admissions, emergency department visits, general practitioner visits, in both rural and urban areas combined). Such a national registry is desirable to accurately monitor healthcare shifts in the Netherlands.

DIAGNOSTICS

Over time, many imaging techniques were used to detect ankle or foot injuries. In particular for fractures, the most commonly used technique is a plain radiograph. In the past, plain radiographs were used for screening, to choose treatment strategy, and during follow-up. These plain radiographs are still used for screening and follow-up, but Computed Tomography (CT) with optional 3D reconstructions is often added to choose treatment strategy. The use of intra-operative 3D imaging such as 3D C-arm based im-

aging devices are gaining popularity, they seem to have a positive effect on the anatomical reduction of the posterior facet and visualization of screw positions, theoretically resulting in less re-interventions. In calcaneal fractures, Böhler's and Gissane's angles measured on plain radiographs, are of both therapeutic and prognostic value in the pre- and postoperative assessment. Surgeons should be aware that the accuracy of radiographs, and hence radiographic measurements, can be influenced by multiple factors.

This thesis (Chapter 3) clearly showed that foot positioning during the making of a lateral radiograph hardly affects Böhler's angle and angle of Gissane. If used for clinical decision making in initial treatment and during follow up of calcaneal fractures, these parameters can reliably be taken from any lateral radiograph. Gonzalez *et al.* (8) found similar results concerning the influence of obliquity on accuracy, despite the fact that the orthopedic surgeons' ability to identify the landmarks required to measure Böhler's angle significantly decreased with increasing obliquity of the lateral radiograph (which was also noticed in our study).

Currently, CT imaging is not only used to choose treatment strategy but also more often during clinical follow-up. CT images depict in more detail intra-articular incongruences and the process of (non)union than plain radiographs. For these reasons, it is likely that the CT-scan will play are more prominent role during follow-up in the near future. Also not unthinkable are the use of Magnetic Resonance Imaging (MRI) with or without contrast (*e.g.,* to assess viability of fracture fragments and cartilage) or other diagnostic modalities in the future.

In the near future, 3D printing, computer-assisted navigation and augmented reality might improve the results of foot and ankle surgery. Research on the role these techniques can play to assist pre-operative planning, has already started. 3D printing can not only be used to gain more insight into the three-dimensional anatomy, but also for example to determine the trajectory of sustentaculum tali screws after bending a plate in the correct position. In this manner the risk of intra-articular screws can be minimized. By using these new techniques, management of patients with ankle and foot injuries can be more and more tailored to an individual patient. Concomitant damage can be limited even more by these new techniques.

TREATMENT

Since patients with ankle and foot injuries, especially displaced intra-articular calcaneal fractures, are known for their poor outcomes (9), long-term disabilities and rehabilitation (10-12), high complication rates (13-15), high socio-economic impact (16-20) and long interval to work resumption (10-12), many trials (19, 21-36) have been conducted in the past few years in order to define the best treatment. Non-operative treatment is most used for the non-displaced or extra-articular fractures, percutaneous treatment is in particular developed for tongue-type calcaneal fractures, and open reduction and inter-

nal fixation (ORIF) for displaced intra-articular fractures. In the Netherlands, the most frequently applied treatment modalities have been open reduction and internal fixation (ORIF; 46%), non-operative treatment (39%), and percutaneous treatment (10%) (20).

There is still a lot controversy about the best treatment strategy and literature has not been definitive in its treatment guidance. There are trends in literature that suggest that anatomic reduction and stable fixation is the best treatment strategy to optimize functional outcome, patient satisfaction and minimalize posttraumatic arthritis (37-40). Besides, some say that surgery decreases the risk for arthrodesis, but if arthrosis occurs the outcomes of secondary subtalar arthrodesis are better than after initial non-operative treatment (since calcaneal broadening and loss of height are more reduced after surgery).

Whether anatomic reduction and stable fixation is the best treatment strategy is questioned by critics because the number of postoperative complications is considered high. Authors of a randomized controlled trial comparing operative versus non-operative treatment (41), state that operative treatment by ORIF is no longer recommended for displaced intra-articular calcaneal fractures because no significant difference in Kerr-Atkins score were found, and complications and reoperations were more common in the operative group. However, this study seem to have a selection bias since extra-articular fractures, open fractures and 'grossly' (undefined) displaced fractures were excluded. The last two were presumably all treated surgically. Patients had the opportunity to select their own management option (depending on informed consent). Furthermore, among the eligible patients 70% declined to participate (*i.e.,* recruitment rate was only 30%). No individual surgeon undertook more than six procedures (median number of procedures per surgeon was two). These low number could negatively affect the surgical outcomes, since the complicated surgical procedure of calcaneal fractures require experienced surgeons. In the operated group, a residual articular step (greater than 2 mm) was noted on the postoperative CTs of 11 out of 51 patients (22%), indicating an inaccurate operative reduction.

New (minimally invasive) techniques and surgical approaches are frequently developed in order to improve results (Chapter 4). In this thesis, operatively treated patients reported better functional outcome scores than non-operatively treated patients with displaced intra-articular calcaneal fractures (Chapter 5). ORIF, through an extended lateral approach has been the most frequently utilized technique for surgically restoring the calcaneal anatomy through the last three decades (20, 42-45). The sinus tarsi approach (STA) is gaining popularity the last years (35, 46-48). Since less wound complications, including flap necrosis seem to occur (49). Moreover, shorter operative time is needed (46), and the amputation rate (49) seems lower, while maintaining the possibility to reduce the fracture adequately. Again on this topic controversy exists, with high incidence of postoperative infections after STA and surgical expertise is required for the anatomical reduction (49). Finally, primary subtalar arthrodesis for most severe calcaneal fractures (Sanders IV) is recently increasingly advocated (50-53), as patients seem to have better functional outcome, fewer wound complications (50) and heal more quickly than treated with ORIF.

Surgical interventions are increasingly tailored not only to the fracture type and severity but also to the individual patient needs (*e.g.,* a primary arthrodesis in the middle-aged, no high activity demanding patient with a severe comminuted fracture). This requires knowledge and surgical expertise of the orthopaedic trauma surgeons managing these fractures. Combined with new minimal invasive procedures restricted for the most experienced foot and ankle surgeons, the risk of complications might be further reduced and outcomes can be optimized.

PAIN AND ANALGESICS

Patients with a calcaneal fracture are initially treated with rest, compression, elevation, and ice (11, 54). Recently, computer-controlled cooling devices are developed to extend this last 'ice-period'. In Chapter 6 of this thesis, a computer-controlled cooling device (Zamar Therapy) was used to examine the effect of cryocompression therapy (cooling) on swelling, time to surgery, complications, pain, and use of analgesics.

Cryocompression therapy has been described in literature, mostly for elective orthopaedic knee surgery. The positive effects on pain and analgesics consumption as described in literature (55-57) is also found in this retrospective case-control study (Chapter 6). No hypothermic or other cooling-related injuries occurred in this population. Although the findings in this study not overwhelmingly favors cooling, differences between the cooling and non-cooling group might be underestimated. Due to guidelines for new implemented techniques, patients who used the computer-controlled cooling device were pre-operatively admitted for a (longer) period of time. Of the patients who were not admitted, mostly patients in the non-cooling group, the data on medication use was less accurate as only the administered analgesics during hospital admission were concerned in this study. Recurring in patients feedback was the pain reducing effect; for this reason patients often used the cooling device for a longer period of time than initially recommended, or directly post-surgery instead of analgesics. This almost unanimous positive feedback is very valuable for future clinical practice, despite the absence of level 1 evidence.

SOFT TISSUE COMPLICATIONS

After trauma of the foot, swelling, ecchymosis and blistering often onsets rapidly. In order to avoid soft tissue complications, an appropriate delay of timing for surgery with respect for the soft tissue is paramount. Usually the soft tissue allows surgery within two weeks (37). However reduction and fixation after two weeks is suggested to increase the risk of complications (58), in some cases surgery may be delayed up to four weeks. In particular patients with a tongue-type displaced calcaneal fracture are be-

cause of the specific fracture displacement pattern, at risk to develop lesions at the posterior part of the heel where the skin is tented over the fracture fragment. If the skin is threatened and secondary soft tissue deterioration is lurking to develop in an open injury, surgical intervention at an early stage may be necessary. In Chapter 7, this matter is discussed. Unfortunately, no actual risk model for posterior skin compromise or complications could be composed. This chapter however shows that patients with tongue-type fractures are at risk for soft tissue complications. Especially during the preoperative period (*i.e.,* not reduced fracture), early and frequent assessment of the skin is advised to detect and treat the soft tissue as soon as possible to prevent further deterioration. Because closed or minimally invasive reduction and fixation techniques have lower risk of wound complications, these techniques may allow early surgery in these patients (59). To avoid wound complications after ORIF, a percutaneous closed suction drain is often applied (60). However, wound healing problems are among the most common complications after ORIF (39, 41, 61-64), and the interventions associated with these wound complications impede early rehabilitation.

As the treatment of ankle and hindfoot fractures, in particular calcaneal fractures, is dependent on the condition of the soft tissue, one focus of future research should be on optimizing the local surgical environment in order to minimize the risk of wound complications. Widely accepted is delayed surgery, the return of skin wrinkles to the lateral aspect of the foot at the surgical incision site is often used as a guide for timing surgery, which is usually possible at about seven to 14 days after injury (65). But in fact, it is unknown if delayed surgery is better than acute surgery. The organizational problem of acute surgery is the need for further concentration of operative care. Since longer delay may be associated with increased difficulty in obtaining a reduction and closing the surgical incision, achieving swelling reduction should be achieved as soon as possible after trauma. A randomized controlled trial on a computer-controlled cooling device was started in late 2015 by our research unit. It was hypothesized that continuous cryotherapy combined with static compression was a better alternative to the current swelling reduction methods (*i.e.,* pressure bandage, plaster cast, and pneumatic compression). To lower the temperature of the injured tissue, which would reduce the tissue's metabolic rate, the tissue was assisted to survive the period following the injury. The expected preoperative and postoperative swelling reduction was also thought to result in earlier surgery, shorter hospital length of stay and earlier mobilization, which in turn reduces the risk of adverse events, reliefs pain (less analgesics use). Despite the participation of six Dutch high volume centers, unfortunately this study has been stopped due to a low inclusion rate.

POSTOPERATIVE REGIME

The non-weightbearing rehabilitation period of patients after ankle or foot trauma and surgery is often invalidating. This period is not only associated with high social-

economic costs (19, 20, 66-68), but also psychological and physical (*e.g.*, muscle and bone mass degeneration) impairments. In Chapter 8 a review is presented on (early) weightbearing after calcaneal surgery. This review depicts that the time to post-operative partial weightbearing has no effect on the Böhler's angle at follow-up, other radiographic parameters, functional outcomes, and complications. The data suggest that early (< 6 weeks after surgery) partial weightbearing after calcaneal surgery does not result in impaired outcome compared with the current (more conservative) weightbearing regimes with their accompanying disadvantages. Of course there are limitations of this review and no hard conclusions can be drawn, but literature on ankle fractures found comparable results (10, 69-71).

Prospective studies need to be conducted to assess and change current post-operative weightbearing guidelines. In such studies the effect of non-resorbable bone void fillers in the subtalar defect, which are assumed to allow direct full weightbearing, should also be further investigated. In the future new developments like Virtual Stress Testing (VST), which provides a non-invasive estimate of bone healing through a CT scan, has the potential to provide a quantitative, objective measure to identify fractures who could safely handle bearing weight (72). Weightbearing compliance could be monitored via flexible shoe insoles. The insole includes pressure and force sensors that measure the force applied at key bearing points under the foot. Such a self-learning adaptive weightbearing monitoring system also can deliver electrical, mechanical, and/or audio feedback to encourage a patient to load the optimal target weight. With continuous feedback patients are able to improve their rehabilitation (73, 74).

Another new technology to measure the amount of joint loading are smart implants. Smart orthopedic implants can provide real-time biofeedback, measure joint loads (via multichannel telemetry systems), and detect infections to researchers, physicians, or patients on how implants are performing. Although this technology is not used in calcaneal surgery, it is theoretically promising to provide loading information on the osteosynthesis material and therewith the possibility to adapt weightbearing recommendations (75, 76).

Radiostereometric Analysis (RSA) could also be used in the future. Implanted markers are currently used to evaluate prosthesis migration. If those marker beads are inserted in specific landmarks (*e.g.,* processus anterior, superior tip of the posterior facet and calcaneal tuberosity) RSA could be used to monitor changes in calcaneal height during follow-up for example (77).

FUNCTIONAL OUTCOME

Besides clinical measures such as mortality, radiographic healing, complication rate, re-operation, and readmission also to what extent a patient is able to function in daily living is relevant in modern clinical practice and clinical research. To monitor recovery

after (non-) operative treatment of musculoskeletal injuries from a patient's perspective, functional outcome scores are frequently used. In Chapter 9 to 11, the use of the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale is translated and validated. This questionnaire enables detailed evaluation of functional outcome and quality of life of patients. For patients with a hindfoot fracture (Chapter 10), the AOFAS-DLV has adequate construct validity and is reliable. However, the inadequate longitudinal validity and responsiveness hamper the use of the questionnaire in longitudinal studies and for assessing long-term functional outcome. In patients who suffered an ankle fracture (Chapter 11), the Dutch language version is a reliable, valid, and responsive measurement instrument.

In contrast to Patient-Reported Outcome Measures (PROMs), the AOFAS-DLV consists of a patient-reported and a physician-reported part. The latter makes the questionnaire less feasible in clinical practice. Also recently criticism is raised against the AOFAS Clinical Rating Systems (78). The skewed behavior of the score is questioned, with for example only one question concerning the pain subscale, contributing 40% of the total score. Furthermore linguistic issues, may negatively affect reliability and validity, and makes it more prone to ceiling effects (78, 79). Despite these concerns, the AOFAS Ankle-Hindfoot Score remains among the most commonly used instruments, especially for patients with hindfoot fractures. It is especially an interesting instrument because it asks for hindfoot-specific complaints or deviations, which are not included in other lower extremity-specific instruments.

The AOFAS-DLV can be built in electronic patient record systems to score functional outcome at follow-up on a regular base or to use it for national hospital registries. The main disadvantage of the AOFAS-DLV for such purposes is the physician-reported part which is time consuming and will be at the expense of other work-related activities. Actual PROMs (*e.g.,* EuroQol-5D) or, even better, PROMIS (Patient-Reported Outcomes Measurement Information System) are likely to be more suitable for registries or regular evaluations in the future. PROMIS is a set of patient-centered measures that evaluates and monitors physical, mental, and social health in patients. PROMIS is designed by the National Institutes of Health to enhance communication between clinicians and patients in research and clinical settings. This involved the creation of question banks for major health domains using item response theory and computerized adaptive test tools. With computerized adaptive testing, responses to individual questions as well as the relations between questions in a specific health domain are examined, and only the most appropriate questions for the respondent's level are administered from the item bank. With the use of PROMIS there will be less question burden than the currently used PROMs. The brevity of PROMIS questionnaires is helpful for efficient data collection in the future (80, 81).

REFERENCES

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. Injury. 2006;37(8):691-7.
2. Regel G, Lobenhoffer P, Grotz M, Pape HC, Lehmann U, Tscherne H. Treatment results of patients with multiple trauma: an analysis of 3406 cases treated between 1972 and 1991 at a German Level I Trauma Center. J Trauma. 1995;38(1):70-8.
3. Richter M, Thermann H, Wippermann B, Otte D, Schratt HE, Tscherne H. Foot fractures in restrained front seat car occupants: a long-term study over twenty-three years. J Orthop Trauma. 2001;15(4):287-93.
4. Bajammal S, Tornetta P, 3rd, Sanders D, Bhandari M. Displaced intra-articular calcaneal fractures. J Orthop Trauma. 2005;19(5):360-4.
5. Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Worthington JR. A study to develop clinical decision rules for the use of radiography in acute ankle injuries. Ann Emerg Med. 1992;21(4):384-90.
6. Kannus P, Palvanen M, Niemi S, Parkkari J, Jarvinen M. Increasing number and incidence of low-trauma ankle fractures in elderly people: Finnish statistics during 1970-2000 and projections for the future. Bone. 2002;31(3):430-3.
7. Richter M, Thermann H, von Rheinbaben H, Schratt E, Otte D, Zwipp H, et al. [Fractures of the foot region of car drivers and passengers. Occurrence, causes and long-term results]
   Frakturen der Fussregion bei PKW-Insassen. Haufigkeit, Ursachen und Langzeitergebnisse. Unfallchirurg. 1999;102(6):429-33.
8. Gonzalez TA, Ehrlichman LK, Macaulay AA, Gitajn IL, Toussaint RJ, Zurakowski D, et al. Determining Measurement Error for Bohler's Angle and the Effect of X-Ray Obliquity on Accuracy. Foot Ankle Spec. 2016;9(5):409-16.
9. Lui TH, Ling SKK. Randomised controlled trial: Calcaneal fractures have universally poor outcomes regardless of management. Evid -Based Med. 2015;20(1):13.
10. Buckley R, Tough S, McCormack R, Pate G, Leighton R, Petrie D, et al. Operative compared with nonoperative treatment of displaced intra-articular calcaneal fractures: a prospective, randomized, controlled multicenter trial. J Bone Joint Surg Am. 2002;84-A(10):1733-44.
11. Pozo JL, Kirwan EO, Jackson AM. The long-term results of conservative management of severely displaced fractures of the calcaneus. J Bone Joint Surg Br. 1984;66(3):386-90.
12. Mortelmans LJ, Du Bois M, Donceel P, Broos PL. Impairment and return to work after intra-articular fractures of the calcaneus. Acta Chir Belg. 2002;102(5):329-33.
13. Gardner MJ, Nork SE, Barei DP, Kramer PA, Sangeorzan BJ, Benirschke SK. Secondary soft tissue compromise in tongue-type calcaneus fractures. J Orthop Trauma. 2008;22(7):439-45.
14. Gitajn IL, Abousayed M, Toussaint RJ, Vrahas M, Kwon JY. Calcaneal avulsion fractures: a case series of 33 patients describing prognostic factors and outcomes. Foot Ankle Spec. 2015;8(1):10-7.
15. Kwon JY, Guss D, Lin DE, Abousayed M, Jeng C, Kang S, et al. Effect of Delay to Definitive Surgical Fixation on Wound Complications in the Treatment of Closed, Intra-articular Calcaneus Fractures. Foot Ankle Int. 2015;36(5):508-17.
16. Lin CW, Haas M, Moseley AM, Herbert RD, Refshauge KM. Cost and utilisation of healthcare resources during rehabilitation after ankle fracture are not linked to health insurance, income, gender, or pain: an observational study. Aust J Physiother. 2008;54(3):201-8.
17. Meerding WJ, Mulder S, van Beeck EF. Incidence and costs of injuries in The Netherlands. Eur J Public Health. 2006;16(3):272-8.
18. Murray AM, McDonald SE, Archbold P, Crealey GE. Cost description of inpatient treatment for ankle fracture. Injury. 2011;42(11):1226-9.
19. Brauer CA, Manns BJ, Ko M, Donaldson C, Buckley R. An economic evaluation of operative compared with nonoperative management of displaced intra-articular calcaneal fractures. J Bone Joint Surg Am. 2005;87(12):2741-9.

20. Schepers T, van Lieshout EM, van Ginhoven TM, Heetveld MJ, Patka P. Current concepts in the treatment of intra-articular calcaneal fractures: results of a nationwide survey. Int Orthop. 2008;32(5):711-5.
21. Agren PH, Wretenberg P, Sayed-Noor AS. Operative versus nonoperative treatment of displaced intra-articular calcaneal fractures: a prospective, randomized, controlled multicenter trial. J Bone Joint Surg Am. 2013;95(15):1351-7.
22. Bakir CP, McGarvey WC. Use of small-wire external fixation as a minimally invasive technique for calcaneus fractures: Surgical technique. Tech Orthop. 2014;29(1):20-3.
23. Battaglia A, Catania P, Gumina S, Carbone S. Early Minimally Invasive Percutaneous Fixation of Displaced Intra-Articular Calcaneal Fractures With a Percutaneous Angle Stable Device. J Foot Ankle Surg. 2015;54(1):51-6.
24. Cao L, Weng W, Song S, Mao N, Li H, Cai Y, et al. Surgical Treatment of Calcaneal Fractures of Sanders Type II and III by a Minimally Invasive Technique Using a Locking Plate. J Foot Ankle Surg. 2015;54(1):76-81.
25. De Vroome SW, Van Der Linden FM. Cohort study on the percutaneous treatment of displaced intra-articular fractures of the calcaneus. Foot Ankle Int. 2014;35(2):156-62.
26. Gomaa MA, El Naggar A, Anbar A. A modified minimally invasive technique for treatment of intra-articular fractures of the calcaneus. Mid-term results and review of the literature. Eur Orthop Traumatol. 2015;6(4):305-13.
27. Griffin D, Parsons N, Shaw E, Kulikov Y, Hutchinson C, Thorogood M, et al. Operative versus non-operative treatment for closed, displaced, intra-articular fractures of the calcaneus: Randomised controlled trial. BMJ (Online). 2014;349:1-13.
28. Gusic N, Fedel I, Darabos N, Lovric Z, Bukvic N, Bakota B, et al. Operative treatment of intraarticular calcaneal fractures: Anatomical and functional outcome of three different operative techniques. Injury. 2015;46 Suppl 6:S130-3.
29. Jiang N, Song HJ, Xie GP, Wang L, Liang CX, Qin CH, et al. Operative vs nonoperative treatment of displaced intra-articular calcaneal fracture: A meta-analysis of randomized controlled trials. World Journal of Meta-Analysis. 2015;3(1):61-71.
30. Li B, Wu GB, Yang YF. Conservative versus surgical treatment for displaced fracture of the medial process of the calcaneal tuberosity. J Orthop Surg. 2016;24(2):163-6.
31. Pompach M, Carda M, Amlang M, Zwipp H. Treatment of calcaneal fractures with a locking nail (C-Nail). Oper Orthop Traumatol. 2016;28(3):218-30.
32. Takahashi M, Noda M, Saegusa Y. A new treatment for avulsion fracture of the calcaneus using an Ilizarov external fixator. Injury. 2013;44(11):1640-3.
33. Vittore D, Vicenti G, Caizzi G, Abate A, Moretti B. Balloon-assisted reduction, pin fixation and tricalcium phosphate augmentation for calcanear fracture. Injury. 2014;45(S6):S72-S9.
34. Wu Z, Su Y, Chen W, Zhang Q, Liu Y, Li M, et al. Functional outcome of displaced intra-articular calcaneal fractures: A comparison between open reduction/internal fixation and a minimally invasive approach featured an anatomical plate and compression bolts. J Trauma Acute Care Surg. 2012;73(3):743-51.
35. Zhang T, Su Y, Chen W, Zhang Q, Wu Z, Zhang Y. Displaced intra-articular calcaneal fractures treated in a minimally invasive fashion: Longitudinal approach versus sinus tarsi approach. J Bone Jt Surg Ser A. 2014;96(4):302-9.
36. Zhang W, Lin F, Chen E, Xue D, Pan Z. Operative Versus Nonoperative Treatment of Displaced Intra-Articular Calcaneal Fractures: A Meta-Analysis of Randomized Controlled Trials. J Orthop Trauma. 2016;30(3):e75-e81.
37. Sharr PJ, Mangupli MM, Winson IG, Buckley RE. Current management options for displaced intra-articular calcaneal fractures: Non-operative, ORIF, minimally invasive reduction and fixation or primary ORIF and subtalar arthrodesis. A contemporary review. Foot Ankle Surg. 2016;22(1):1-8.
38. Randle JA, Kreder HJ, Stephen D, Williams J, Jaglal S, Hu R. Should calcaneal fractures be treated surgically? A meta-analysis. Clin Orthop Relat Res. 2000(377):217-27.
39. Veltman ES, Doornberg JN, Stufkens SA, Luitse JS, van den Bekerom MP. Long-term outcomes of 1,730 calcaneal fractures: systematic review of the literature. J Foot Ankle Surg. 2013;52(4):486-90.

40. Buckley RE, Tough S. Displaced intra-articular calcaneal fractures. J Am Acad Orthop Surg. 2004;12(3):172-8.
41. Griffin D, Parsons N, Shaw E, Kulikov Y, Hutchinson C, Thorogood M, et al. Operative versus non-operative treatment for closed, displaced, intra-articular fractures of the calcaneus: Randomised controlled trial. BMJ (Online). 2014;349.
42. Benirschke SK, Sangeorzan BJ. Extensive intraarticular fractures of the foot. Surgical management of calcaneal fractures. Clin Orthop Relat Res. 1993(292):128-34.
43. Eastwood DM, Langkamer VG, Atkins RM. Intra-articular fractures of the calcaneum. Part II: Open reduction and internal fixation by the extended lateral transcalcaneal approach. J Bone Joint Surg Br. 1993;75(2):189-95.
44. Sanders R. Intra-articular fractures of the calcaneus: present state of the art. J Orthop Trauma. 1992;6(2):252-65.
45. Thordarson DB, Krieger LE. Operative vs. nonoperative treatment of intra-articular fractures of the calcaneus: A prospective randomized trial. Foot Ankle Int. 1996;17(1):2-9.
46. Schepers T, Backes M, Dingemans SA, de Jong VM, Luitse JSK. Similar Anatomical Reduction and Lower Complication Rates With the Sinus Tarsi Approach Compared With the Extended Lateral Approach in Displaced Intra-Articular Calcaneal Fractures. J Orthop Trauma. 2017;31(6):293-8.
47. Zhang F, Tian H, Li S, Liu B, Dong T, Zhu Y, et al. Meta-analysis of two surgical approaches for calcaneal fractures: sinus tarsi versus extensile lateral approach. ANZ J Surg. 2017;87(3):126-31.
48. Xia S, Lu Y, Wang H, Wu Z, Wang Z. Open reduction and internal fixation with conventional plate via L-shaped lateral approach versus internal fixation with percutaneous plate via a sinus tarsi approach for calcaneal fractures - a randomized controlled trial. Int J Surg. 2014;12(5):475-80.
49. Rawicki N, Wyatt R, Kusnezov N, Kanlic E, Abdelgawad A. High incidence of post-operative infection after 'sinus tarsi' approach for treatment of intra-articular fractures of the calcaneus: a 5 year experience in an academic level one trauma center. Patient Saf Surg. 2015;9:25.
50. Radnay CS, Clare MP, Sanders RW. Subtalar fusion after displaced intra-articular calcaneal fractures: does initial operative treatment matter? J Bone Joint Surg Am. 2009;91(3):541-6.
51. Csizy M, Buckley R, Tough S, Leighton R, Smith J, McCormack R, et al. Displaced intra-articular calcaneal fractures: variables predicting late subtalar fusion. J Orthop Trauma. 2003;17(2):106-12.
52. Holm JL, Laxson SE, Schuberth JM. Primary subtalar joint arthrodesis for comminuted fractures of the calcaneus. J Foot Ankle Surg. 2015;54(1):61-5.
53. Buckley R, Leighton R, Sanders D, Poon J, Coles CP, Stephen D, et al. Open reduction and internal fixation compared with ORIF and primary subtalar arthrodesis for treatment of Sanders type IV calcaneal fractures: a randomized multicenter trial. J Orthop Trauma. 2014;28(10):577-83.
54. Barei DP, Bellabarba C, Sangeorzan BJ, Benirschke SK. Fractures of the calcaneus. Orthop Clin North Am. 2002;33(1):263-85.
55. Martimbianco AL, Gomes da Silva BN, de Carvalho AP, Silva V, Torloni MR, Peccin MS. Effectiveness and safety of cryotherapy after arthroscopic anterior cruciate ligament reconstruction. A systematic review of the literature. Phys Ther Sport. 2014;15(4):261-8.
56. Barber FA, McGuire DA, Click S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. Arthroscopy. 1998;14(2):130-5.
57. Murgier J, Cassard X. Cryotherapy with dynamic intermittent compression for analgesia after anterior cruciate ligament reconstruction. Preliminary study. Orthop Traumatol Surg Res. 2014;100(3):309-12.
58. Rammelt S, Zwipp H. Calcaneus fractures: facts, controversies and recent developments. Injury. 2004;35(5):443-61.
59. Arastu M, Sheehan B, Buckley R. Minimally invasive reduction and fixation of displaced calcaneal fractures: surgical technique and radiographic analysis. Int Orthop. 2014;38(3):539-45.
60. Backes M, Schepers T, Beerekamp MS, Luitse JS, Goslings JC, Schep NW. Wound infections following open reduction and internal fixation of calcaneal fractures with an extended lateral approach. Int Orthop. 2014;38(4):767-73.

61. Al-Mudhaffar M, Prasad CV, Mofidi A. Wound complications following operative fixation of calcaneal fractures. Injury. 2000;31(6):461-4.
62. Benirschke SK, Kramer PA. Wound healing complications in closed and open calcaneal fractures. J Orthop Trauma. 2004;18(1):1-6.
63. Harvey EJ, Grujic L, Early JS, Benirschke SK, Sangeorzan BJ. Morbidity associated with ORIF of intra-articular calcaneus fractures using a lateral approach. Foot Ankle Int. 2001;22(11):868-73.
64. Koski A, Kuokkanen H, Tukiainen E. Postoperative wound complications after internal fixation of closed calcaneal fractures: a retrospective analysis of 126 consecutive patients with 148 fractures. Scand J Surg. 2005;94(3):243-5.
65. Shuler FD, Conti SF, Gruen GS, Abidi NA. Wound-healing risk factors after open reduction and internal fixation of calcaneal fractures: does correction of Bohler's angle alter outcomes? Orthop Clin North Am. 2001;32(1):187-92.
66. Sanders RW. Displaced intra-articular fractures of the calcaneus. J Bone Joint Surg Am. 2000;82(2):225-50.
67. Haller JM, Potter MQ, Kubiak EN. Weight bearing after a periarticular fracture. What is the evidence? Orthop Clin North Am. 2013;44(4):509-19.
68. Westerman RW, Hull P, Hendry RG, Cooper J. The physiological cost of restricted weight bearing. Injury. 2008;39(7):725-7.
69. Lin CW, Donkers NA, Refshauge KM, Beckenkamp PR, Khera K, Moseley AM. Rehabilitation for ankle fractures in adults. Cochrane Database Syst Rev. 2012;11:CD005595.
70. Dehghan N, McKee MD, Jenkinson RJ, Schemitsch EH, Stas V, Nauth A, et al. Early Weightbearing and Range of Motion Versus Non-Weightbearing and Immobilization After Open Reduction and Internal Fixation of Unstable Ankle Fractures: A Randomized Controlled Trial. J Orthop Trauma. 2016;30(7):345-52.
71. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ. 2009;339:b2700.
72. Petfield JL, Hayeck GT, Kopperdahl DL, Nesti LJ, Keaveny TM, Hsu JR, et al. Virtual stress testing of fracture stability in soldiers with severely comminuted tibial fractures. J Orthop Res. 2017;35(4):805-11.
73. Braun BJ, Veith NT, Rollmann M, Orth M, Fritz T, Herath SC, et al. Weight-bearing recommendations after operative fracture treatment-fact or fiction? Gait results with and feasibility of a dynamic, continuous pedobarography insole. Int Orthop. 2017;41(8):1507-12.
74. North K, Maass SD, Hitchcock RW. An insole sensor for recording weight bearing behavior during tibial fracture rehabilitation. Conf Proc IEEE Eng Med Biol Soc. 2010;2010:1856-9.
75. O'Connor C, Kiourti A. Wireless Sensors for Smart Orthopedic Implants. Journal of Bio- and Tribo-Corrosion. 2017;3(2):20.
76. Parvizi J, Antoci V, Jr., Hickok NJ, Shapiro IM. Selfprotective smart orthopedic implants. Expert Rev Med Devices. 2007;4(1):55-64.
77. Stentz-Olesen K, Nielsen ET, De Raedt S, Jorgensen PB, Sorensen OG, Kaptein BL, et al. Validation of static and dynamic radiostereometric analysis of the knee joint using bone models from CT data. Bone Joint Res. 2017;6(6):376-84.
78. Pinsker E, Daniels TR. AOFAS position statement regarding the future of the AOFAS Clinical Rating Systems. Foot Ankle Int. 2011;32(9):841-2.
79. Guyton GP. Theoretical limitations of the AOFAS scoring systems: an analysis using Monte Carlo modeling. Foot Ankle Int. 2001;22(10):779-87.
80. Anthony CA, Glass N, Hancock K, Bollier M, Hettrich CM, Wolf BR. Preoperative Performance of the Patient-Reported Outcomes Measurement Information System in Patients With Rotator Cuff Pathology. Arthroscopy. 2017;33(10):1770-4 e1.
81. Beach WR. Editorial Commentary: Patient Reported Outcomes Measurement Information System (PROMIS) May Be Our Promise for the Future. Arthroscopy. 2017;33(10):1775-6.

Chapter 13

Summary and conclusions in English and Dutch

SUMMARY

Chapter 1 is a general introduction to the topics and an overview of literature on ankle and hindfoot injuries. It shows that calcaneal fractures are relatively rare. The calcaneus however is the most commonly fractured tarsal bone in adults, representing 60% of all tarsal fractures, they are associated with a long-term rehabilitation period, burden, and high socio-economic costs. The fundamental anatomy, fracture classification systems, clinical assessment, and management of patients with ankle or hindfoot fractures are discussed. This chapter also provides an overview of this thesis.

In Chapter 2 population-based trends in attendance and health care costs due to ankle and foot injuries in the Netherlands from 1986 to 2010 were presented. The overall emergency department attendance rate of ankle and foot injuries in the Netherlands decreased by 25% since 1986, from 858 per 100,000 to 640 per 100,000 persons in 2010. The attendance rate of ligamentous injuries strongly reduced, whereas the rate of osseous injuries nearly doubled. The total costs were 161.9 million euro in 2010. The direct health care costs per case were highest for osseous injuries of the ankle (€ 3,461). Costs per case were higher for females and increased with age to € 6,023 in elderly males and € 10,949 in elderly females. The main cost determinants were in-hospital care (56% of total costs), rehabilitation/nursing care (15%), and physical therapy (12%). Indirect health care costs like absenteeism and work disability were not taken into account, but often higher than direct health care costs.

Chapter 3 is a radio-anatomical study in which the effect of lower leg position on Böhler's and Gissane's angle was evaluated by simulating malposition with craniocaudal and posteroanterior angular variations from the true lateral radiograph. Böhler's angle decreased with increasing caudal angular variations (max. -4.3° deviation at -30°). With increasing the posterior angular variations, Böhler's angle increased (max. 5.0° deviation at +30°) from the true lateral radiograph, but all deviations were within the measurement error. The deviation of the angle of Gissane was most pronounced in the cranial direction, with the mean angle decreasing by -8.8° at +30° angular variation. Varying angular obliquity in the caudal and posteroanterior direction hardly affected Gissane's angle. Thus, foot positioning during the making of a lateral radiograph has little influence on Böhler's and Gissane's angle. If used for clinical decision making in initial treatment and during follow up of calcaneal fractures, these parameters can reliably be taken from any lateral radiograph.

An adequate reduction of displaced calcaneal bone fragments provides the best basis for good functional outcomes. However, reduction and fixation can be challenging due to the small target area and the presence of neurovascular structures on the medial side of the calcaneus. In Chapter 4 a Screw Targeting Clamp, which facilitates surgeons in sustentaculum tali screw placement was investigated. Data suggest that this Screw

Targeting Clamp can be of additional value for adequate positioning sustentaculum tali screws, especially for relative inexperienced surgeons. Furthermore, perioperative 3D recordings facilitate identification of malpositioned screws better than with 2D evaluation (five additional screws would have required repositioning based on 3D evaluation).

Many aspects of calcaneal fracture management are controversial. Treatment of fractures requires a comprehensive understanding of its complicated anatomy and fracture displacements and a lot of surgical experience. In order to find out what the optimal treatment for displaced intra-articular calcaneal fractures was, the outcomes (*e.g.*, health-related quality of life, overall patient satisfaction, interval to work resumption, and the prevalence of complications and late interventions) of different treatments were discussed in Chapter 5. Patients with calcaneal fractures treated by open reduction and internal fixation (ORIF), percutaneous treatment, or non-operative methods were studied. Significantly more disability was reported in the non-operative group (median Foot Function Index score, 40 points) than in the ORIF group (16 points; p=0.010) or in the percutaneous group (21 points; p=0.034). Patients treated with ORIF or percutaneous screw fixation reported better functional outcome scores than did the non-operatively treated patients.

Pain and therewith the need for analgesics are common in patients with lower extremity injuries. Cooling devices have been developed in order to reduce swelling, pain, need for analgesics, and wound complications. In Chapter 6 the effect of such a computer-controlled cooling device on pain levels and the need for analgesics was investigated in adult patients who sustained an ankle or hindfoot fracture. In this retrospective case-control study, 18 patients (cases) with cooling and 17 patients (controls) without cooling were evaluated. Patients seem to benefit from computer-controlled cooling regarding pain sensation and analgesics use in particular after surgery. After surgery, fewer patients in the cooling group used paracetamol (p=0.041) and NSAIDs (p=0.006). No statistically significant differences in opioids (p=0.264) and Patient Controlled Analgesia (PCA-pump) (p=0.691) use were found. Furthermore, comparable rates of complications and secondary interventions were found in both groups. Patients were highly satisfied (eight out of ten points) with cooling as swelling reduction method but equally satisfied if no cooling was used.

Chapter 7 focused on soft tissue complications in particular in tongue-type displaced intra-articular calcaneal fractures. This international, retrospective cohort study showed that patients with a tongue-type displaced intra-articular calcaneal fracture were at increased risk of developing overall complications compared with patients with a non-tongue-type fracture. Despite a study population size of 560 patients (with 632 displaced intra-articular calcaneal fractures), after correction for confounders no statistically significant higher risk (OR 1.497; 95% CI 0.831-2.696) could be demonstrated concerning posterior skin and soft tissue compromise at hospital presentation. For patients

with severe (soft tissue) injuries immediate surgery is necessary, but apart from those patients postponing surgery (3-7 days or ≥ 8 days) does not affect outcome.

Chapter 8 is a systematic review and pooled analysis of 72 studies reporting on weightbearing regimes in patients with surgically managed closed displaced intra-articular calcaneal fractures. Non-weightbearing is usually recommended for six to nine weeks after surgery. The long-term rehabilitation period accompanied with these fractures often results in high socio-economic costs, delayed work resumption, and loss of muscle and bone mass. Böhler's angle and angle of Gissane, calcaneal height, AOFAS ankle-hindfoot score, pain, and complications were examined in relation to different weightbearing regimes, they all had overlapping confidence intervals. For example, the 95% confidence intervals of Böhler's angle at final follow-up were: 25° [95% CI, 23-27°], 23° [95% CI, 21-25°], and 24° [95% CI, 17-32] in the early, intermediate, and late partial weightbearing groups, respectively. The results of this review showed that weightbearing within six weeks after internal fixation of calcaneal fractures does not result in impaired outcomes compared with the current (more conservative) weightbearing regimes.

In this thesis the translation and validation of the American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot scale is discussed. The study protocol is described in Chapter 9. The measurement properties of the questionnaire were examined in 118 patients with unilateral hindfoot fracture in Chapter 10, in this population the Dutch translation of this instrument (AOFAS-DLV) showed adequate construct validity (82.4% of predefined hypotheses were confirmed) and reliability (70.6%). The inadequate longitudinal validity and responsiveness, however, hamper the use of the questionnaire in longitudinal studies and for assessing long-term functional outcome. In Chapter 11, 142 patients with an ankle fracture were investigated. This study showed that the AOFAS-DLV is a reliable, valid, and responsive measurement instrument for evaluating functional outcome in patients with a unilateral ankle fracture. The AOFAS-DLV subscales showed good internal consistency (Cronbach's alpha > 0.90), adequate construct and longitudinal validity (76.5% of predefined hypotheses were confirmed), adequate responsiveness (smallest detectable change of 12.0 points), no floor effects, and as expected ceiling effects present from six months onwards. These results imply that the questionnaire is suitable to compare different treatment modalities within this population or to compare outcome across hospitals.

Finally, the general discussion and future perspectives are discussed in Chapter 12.

SAMENVATTING

Hoofdstuk 1 is een inleiding in het onderwerp en presenteert een overzicht van de belangrijkste literatuurgegevens over enkel en achtervoetletsels. Hierin wordt beschreven dat calcaneusfracturen zeldzaam zijn maar als ze optreden er een langdurige revalidatie periode en hoge socio-economische kosten verwacht kunnen worden. De anatomie, fractuur classificatiesystemen, klinische beoordelingen en behandelmogelijkheden van patiënten met enkel- en achtervoetletsel worden in de hoofdstuk beschreven.

In Hoofdstuk 2 worden op populatie-gebaseerde trends in ziekenhuisopnames en zorgkosten als gevolg van enkel- en voetletsel in Nederland in de periode 1986 tot 2010 beschreven. Spoedeisende Hulp bezoeken vanwege enkel- en voetletsel is in deze periode in Nederland afgenomen met 25%. Met name ligamentair letsel was sterk afgenomen, terwijl patiënten die wegens ossaal letsel de Spoedeisende Hulp bezochten bijna was verdubbeld. De zorgkosten per persoon waren het hoogst voor ossaal enkelletsel (€ 3.461). De kosten waren hoger voor vrouwen en namen toe met toenemende leeftijd tot € 6.023 in oudere mannen en € 10.949 in oudere vrouwen. De belangrijkste kosten determinanten waren ziekenhuiszorg (56% van de totale kosten), revalidatie en verpleegkundige zorg (15%) en fysiotherapie (12%).

Hoofdstuk 3 is een radio-anatomische studie waarin het effect van malpositie van de voet op de hoeken van Böhler en Gissane werden geëvalueerd. Deze malpositie werd nagebootst met craniocaudale en posteroanterieure variaties in inschiethoeken ten opzichte van de daadwerkelijke laterale röntgenfoto. De hoek van Böhler nam af met toenemende inschiethoeken in de caudale richting (maximaal -4.3° afname bij een inschiethoek van -30°). Met toenemende inschiethoek variatie in posterieure richting, nam de hoek van Böhler toe (maximaal 5.0° bij een inschiethoek van +30°), echter waren alle afwijkingen binnen de meetfout. De afwijkingen in de hoek van Gissane waren het meest uitgesproken in de craniale richting, de hoek nam met 8.8° af bij een inschiethoek van +30°. In de caudale en posteroanterieure richting wijzigde de hoek van Gissane nauwelijks. Concluderend heeft malpositie van de voet gedurende röntgenopnamen nauwelijks invloed op de hoeken van Böhler en Gissane. Deze hoeken worden gebruikt als hulpmiddel bij diagnostiek, behandelkeuze en gedurende klinische follow-up van patiënten, voor deze doeleinden kunnen ze betrouwbaar worden gemeten op elke laterale röntgenfoto.

Een adequate reductie van gedisloceerde calcaneus botfragmenten lijkt essentieel te zijn voor een goed functioneel resultaat. Reductie en fixatie kan echter uitdagend zijn door de smalle landingszone en de neurovasculaire bundel aan de mediale zijde van de calcaneus. In Hoofdstuk 4 wordt een Screw Targeting Clamp, welke de chirurg faciliteert bij het plaatsen van sustentaculum tali schroeven, onderzocht. Uit deze studie blijkt dat de Screw Targeting Clamp van toegevoegde waarde is voor het plaatsen van sustenta-

culum tali schroeven, met name voor relatief onervaren chirurgen. Perioperatieve 3D opnamen helpen beter bij de identificatie van verkeerd gepositioneerde schroeven dan 2D opnamen (gebaseerd op 3D opnamen zouden vijf extra schroeven in deze studie gerepositioneerd moeten worden).

Vele aspecten in de behandeling van calcaneusfracturen zijn controversieel. Voor de behandeling van calcaneusfracturen is kennis van de ingewikkelde anatomie en fractuurverplaatsingspatronen vereist. Om uit te zoeken wat de optimale behandeling is voor gedisloceerde intra-articulaire calcaneus fracturen, werden diverse uitkomstmaten (b.v. gezondheid-gerelateerde kwaliteit van leven, patiënttevredenheid, tijd tot werkhervatting en het voorkomen van complicaties en late interventies) na verschillende behandelingen besproken in Hoofdstuk 5. Patiënten met een calcaneusfractuur welke behandeld zijn met open reductie en interne fixatie (ORIF), percutane behandeling of niet-operatieve methoden werden bestudeerd. Significant meer beperkingen werden gerapporteerd in de niet-operatieve groep (mediane Foot Function Index score van 40 punten) in vergelijking met de ORIF groep (mediane score 16 punten, p=0.010) of de percutane groep (mediane score 21 punten, p=0.034). De geopereerde patiënten (ORIF en percutane behandeling) rapporteerde betere functionele uitkomst scores dan de niet-operatief behandelde patiënten.

Pijn en het bijbehorende analgetica gebruik komen vaak voor bij patiënten met letsels van de onderste extremiteit. Koelapparatuur is ontwikkeld om deze pijn, analgetica gebruik en wondcomplicaties te beperken. In Hoofdstuk 6 wordt het effect van een computergestuurde koelbrace op pijn en analgetica gebruik in patiënten met een enkel of voetfractuur onderzocht. In deze retrospectieve case-controle studie zijn 18 patiënten (cases) met koeling en 17 patiënten (controles) zonder koeling onderzocht. De computergestuurde koeling lijkt met name postoperatief de pijnsensatie en analgetica gebruik te reduceren. Postoperatief gebruikten in de koeling groep minder patiënten paracetamol (p=0.041) en NSAID (p=0.006). Er werden geen statistisch significante verschillen in het gebruik van opioïden (p=0.264) en Patient Controlled Analgesia pompen (p=0.691) gevonden. In beide groepen (koeling versus geen koeling) werden vergelijkbare percentages complicaties en secundaire interventies gevonden. Patiënten waren zeer tevreden (acht van de tien punten) met koeling als zwelling reductie methode.

In Hoofdstuk 7 kwamen weke delen complicaties aan bod, met name in tongue-type gedisloceerde intra-articulaire calcaneusfracturen. Deze internationale, retrospectieve cohort studie liet zien dat patiënten met een tongue-type calcaneusfractuur een verhoogd risico hebben op het ontwikkelen van complicaties vergeleken met patiënten met een niet-tongue-type calcaneusfractuur. Ondanks dat in deze studie 560 patiënten met 632 gedisloceerde intra-articulaire calcaneusfracturen werden onderzocht, kon in multivariate analyse geen statistisch significant hoger risico (OR 1.497; 95% CI 0.831-2.696) op posterieure huid en weke dele schade bij ziekenhuispresentatie worden aan-

getoond. Voor patiënten met ernstige (weke delen) letsels is directe chirurgie vaak noodzakelijk, maar behalve voor deze patiënten beïnvloedt het uitstellen van een operatie (3-7 dagen of 8 dagen of meer) de uitkomsten niet.

Hoofdstuk 8 is een systematisch review van 72 studies welke diverse belastbaarheid strategieën beschreven in patiënten met een operatief behandelde gesloten gedisloceerde intra-articulaire calcaneusfractuur. Patiënten met calcaneusfracturen worden normaliter aangeraden pas te starten met partieel belasten na zes tot negen weken postoperatief. De langdurige revalidatie periode die gepaard gaat met deze fracturen resulteert vaak in hoge socio-economische kosten, vertraagde werkhervatting en verlies van spier- en botmassa. In deze studie werden onder andere de hoek van Böhler, hoek van Gissane, calcaneus hoogte, AOFAS, pijnscores en complicaties in relatie tot verschillende belastingperioden onderzocht, alle betrouwbaarheidsintervallen overlapten. De resultaten van dit review toonden dat belasten binnen zes weken na interne fixatie van calcaneusfracturen niet resulteerde in slechtere uitkomsten in vergelijking met de huidige (meer conservatieve) belastbaarheid strategieën.

In dit proefschrift is de vertaling en validering van de American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot scale besproken. Het studieprotocol is beschreven in Hoofdstuk 9. De meeteigenschappen van de Nederlandse vertaling van het instrument (AOFAS-DLV) werden in 118 patiënten met een unilaterale achtervoetfractuur onderzocht in Hoofdstuk 10. In deze populatie bleek de construct validiteit en de betrouwbaarheid van de vragenlijst adequaat. De inadequate longitudinale validiteit en de responsiviteit belemmeren echter het gebruik van de vragenlijsten in longitudinale studies en om lange termijn functionele resultaten te beoordelen. In Hoofdstuk 11 zijn 142 patiënten met een enkelfractuur geïncludeerd. De resultaten van deze studies toonden dat de AOFAS-DLV een betrouwbare, valide en responsief meetinstrument is voor het evalueren van functionele uitkomsten in patiënten met een unilaterale enkelfractuur. De AOFAS-DLV subschalen lieten goede interne consistentie (Cronbach's alfa > 0.90), adequate construct- en longitudinale validiteit, geen bodemeffecten en zoals verwacht plafondeffecten vanaf zes maanden zien. De resultaten impliceren dat de vragenlijst geschikt is om verschillende behandelmethoden in deze populatie te vergelijken of resultaten tussen ziekenhuizen te vergelijken.

De algemene discussie en toekomstperspectieven worden beschreven in Hoofdstuk 12.

Appendices

List of Publications
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List of Publications

THIS THESIS

Health Care Consumption and Costs due to Foot and Ankle Injuries in the Netherlands, 1986-2010.
***De Boer A.S.**, Schepers T., Panneman M.J.M., Van Beeck E.F., Van Lieshout E.M.M.*
BMC Musculoskelet Disord. 2014 Apr 12;15(1):128. PMID: 24725554

The Influence of Radiograph Obliquity on Böhler's and Gissane's Angle in Calcanei.
***De Boer A.S.**, Van Lieshout E.M.M., Vellekoop L., Den Hartog D., Kleinrensink G.J., Verhofstad M.H.J.*
Submitted

2D and 3D Assessment of Sustentaculum Tali Screw Fixation with or without Screw Targeting Clamp.
***De Boer A.S.**, Van Lieshout E.M.M., Vellekoop L., Knops S.P., Kleinrensink G.J., Verhofstad M.H.J.*
Injury. 2017 Dec;48(12):2864-2871. PMID: 29102369

Functional Outcome and Patient Satisfaction after Displaced Intra-articular Calcaneal Fractures: a Comparison Among Open, Percutaneous, and Nonoperative Treatment.
***De Boer A.S.**, Van Lieshout E.M.M., Den Hartog D., Weerts B., Verhofstad M.H.J., Schepers T.*
J Foot Ankle Surg. 2015 May-Jun;54(3):298-305. PMID: 24891090

Computer-Controlled Cooling in Operatively Treated Ankle or Hindfoot Fractures: a Retrospective Case-Control Study.
***De Boer A.S.**, Van Lieshout E.M.M., Van Moolenbroek G., Verhofstad M.H.J., Den Hartog D.*
Submitted

Soft Tissue Complications and Timing of Surgery in Patients with a Tongue-type Displaced Intra-Articular Calcaneal Fracture: an International Retrospective Cohort Study.
***De Boer A.S.**, Van Lieshout E.M.M., Van 't Land F., Misselyn D., Schepers T., Den Hartog D., Verhofstad M.H.J.*
Injury. 2017 Dec 11. In press.

The Effect of Time to Post-Operative Weightbearing on Functional and Clinical Outcomes in Adults with a Displaced Intra-Articular Calcaneal Fracture: a Systematic Review and Pooled Analysis.
De Boer A.S., Van Moolenbroek G., Den Hartog D., Van Lieshout E.M.M., Verhofstad M.H.J.
Injury. 2018 Feb 18. In press.

American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score: a Study Protocol for the Translation and Validation of the Dutch Language Version.
Van Lieshout E.M.M., De Boer A.S., Meuffels D.E., Den Hoed P.T., Van der Vlies C.H., Tuinebreijer W.E., Verhofstad M.H.J.
BMJ Open. 2017 Feb 27;7(2):e012884. PMID 28242768

Validation of the American Orthopedic Foot and Ankle Society Ankle-Hindfoot Scale Dutch Language Version in Patients with Hindfoot Fractures.
De Boer A.S., Meuffels D.E., Van der Vlies C.H., Den Hoed P.T., Tuinebreijer W.E., Verhofstad M.H.J., Van Lieshout E.M.M., AOFAS Study Group
BMJ Open. 2017 Nov 14;7(11):e018314. PMID: 29138208

The American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale; Translation and Validation of the Dutch Language Version for Ankle Fractures.
De Boer A.S., Tjioe R.J.C., Van der Sijde F., Meuffels D.E., Den Hoed P.T., Van der Vlies C.H., Tuinebreijer W.E., Verhofstad M.H.J., Van Lieshout E.M.M., AOFAS Study Group
BMJ Open. 2017 Aug 3;7(8):e017040. PMID: 28775193

OTHER PUBLICATIONS

A New Approach to Assess the Gastrocnemius Muscle Volume in Rodents using Ultrasound; Comparison with the Gastrocnemius Muscle Index.
Nijhuis T.H., De Boer A.S., Wahegaonkar A.L., Bishop A.T., Shin A.Y., Hovius S.E., Selles R.W.
PLoS One. 2015 Jul 20;10(7):e0133944. PMID: 26192186

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Acknowledgements

Dit proefschrift ontleent zijn bestaansrecht aan de toewijding, inzet, enthousiasme en aanmoedigingen van vele collega's en vrienden. Graag wil ik hen die hebben geholpen hartelijk bedanken! Een aantal mensen wil ik in het bijzonder noemen, omdat zij nóg meer dan anderen hebben bijgedragen aan de totstandkoming van dit proefschrift.

Geachte prof. dr. M.H.J. Verhofstad, beste Michiel, dank voor je toegankelijkheid en je intensieve betrokkenheid bij dit proefschrift. Tientallen uren in de snijzaal, radiologische beoordelingen, discussies over terminologie, statiegeld bonnetjes en zorgvuldige revisies zijn een onmisbare bijdrage geweest voor dit proefschrift. Je bent kritisch, doortastend en reëel, daar ben ik je zeer dankbaar voor.

Geachte dr. E.M.M. van Lieshout, beste Esther, jij hebt mij geleerd dat het SPSS is en niet SBS6. Wie had gedacht dat ik in het vervolg met vlag en wimpel zou slagen voor mijn statistiek cursus. Het is mij nog steeds een raadsel hoe een mens zoveel werk kan verrichten in een week. Jouw hulp op vele fronten is van weergaloos belang geweest. Van jou heb ik echt geleerd wat het uitoefenen van wetenschap betekent.

Geachte dr. D. den Hartog, beste Dennis, als onuitputtelijke bron van ideeën heb je geholpen bij de totstandkoming van dit proefschrift. Ik hoor je nog zeggen: 'leuk idee én in een paar dagen uitgewerkt', bedankt voor je revisies van datzelfde manuscript zeven maanden later! Onderzoek doen we om uiteindelijk een klinisch effect te bewerkstelligen, veel dank voor je input vanuit een klinisch perspectief.

Hooggeleerde leden van de promotiecommissie, prof.dr.ir. R.H.M. Goossens, dr. D.E. Meuffels, prof.dr. M. Poeze, dr. T. Schepers, prof.dr. H. Hoekstra en dr. M. Reijman. Hartelijk dank voor het beoordelen van mijn proefschrift en het zitting nemen in de promotiecommissie.

Geachte co-auteurs, het was me een genoegen met jullie te werken. Jullie bijdrage vanuit verschillende invalshoeken hebben tot dit proefschrift geleid. In het bijzonder prof.dr. G.J. Kleinrensink bedankt voor het beschikbaar stellen van de preparaten (en natuurlijk voor de 'snijdende jazz' tijdens het Wondcongres).

Beste Guido en Auke, beste paranimfen. Wat fijn dat jullie mij bijstaan op deze bijzondere dag. Guido, Gaydo, Achilles (zelfbenoemd); van collega arts-assistent via lotgenoot-onderzoeker naar een dierbare vriend. We hebben elkaar er doorheen gesleept, nog even en dan is voor jou de finishlijn ook in zicht! Papa, je stond me bij toen we tegelijkertijd ons zwemdiploma A behaalden, nu sta je me weer bij op een gedenkwaardige dag. Bijzonder dat je er bij bent, bedankt!

Alle lokale hoofdonderzoekers, arts-assistenten en polidames van de deelnemende klinieken, bedankt voor jullie hartelijke ontvangsten, flexibiliteit en behulpzaamheid.

Graag wil ik alle chirurgen; Ted, Kees, Wouter, Boudewijn, Annemarie, Nike, Akkie, Joost, Gwendolyn, Simon, Tim en Dirk-Jan en alle arts-assistenten uit het Ikazia Ziekenhuis bedanken. Sinds mijn tijd als Forgeron heeft het Ikazia mij ervan overtuigd dat chirurgie het mooiste vak is! Bedankt voor de mogelijkheden mijzelf te ontwikkelen. Met name dr. P.T. den Hoed, beste Ted, je lijkt de rode draad in mijn (korte) carrière: Forgeron, (oudste) co-assistent, ANIOS, arts-onderzoeker en inmiddels AIOS, jij hebt altijd met mij meegedacht over de 'volgende stap'. Dank voor het vertrouwen en de kansen die je me geboden hebt!

Mijn collega-onderzoekers van de Trauma Research Unit: Kiran, Steven, Guido, Mandala, Hans, en Daan, wat ga ik de failcompilaties na een patatje van Robbie missen. Bedankt voor jullie aanwezigheid en ontspanning op de zesde verdieping! Ook medeonderzoekers bedankt voor de gezellige momenten tijdens lunches, borrels en congressen.

Behulpzame onderzoekstudenten Fleur, Leonie, Roderik, Freek en Gerson, ook jullie wil ik bedanken voor jullie substantiële bijdrage aan dit proefschrift.

Clubgenoten, Meisjes, mijn proefschrift is af! Dat betekent dat er weer spannende verhalen uit de kliniek aankomen…

Lieve Harrie, Coby, Bart en Loes. Als je een meisje ontmoet realiseer je je dat er een dag komt dat je ook haar familie zal ontmoeten. Al ruim tien jaar zijn deze ontmoetingen hartstikke gezellig. Tijdens onze mooie reizen heb ik zelfs het een en ander over zeilen geleerd, hopelijk zullen er nog vele reizen volgen. De afgelopen tien jaar zijn voorbij gevlogen, ik waardeer de door jullie getoonde interesse en steun enorm.

Lieve papa, mama en Marieke. Mijn zorgeloze jeugd, jullie steun en betrokkenheid door de jaren heen hebben mij gebracht waar ik nu ben. Ik heb snel leren eten, want 'snelle eters zijn harde werkers' en te genieten van bijzondere momenten in het leven. We hebben gedurende mijn onderzoeksperiode moeilijke tijden moeten doormaken, maar wat een steun hebben we als familie aan elkaar gehad. Hopelijk volgen er nog een aantal mooie jaren!

Lieve Puck, jij bent een ware aanvulling op mijn leven, al ruim tien jaar ben jij in staat om mij te kalmeren en te helpen relativeren op de juiste momenten. Thuiskomen is echt ontspannen. Ik voel me een gelukkig man met jou aan mijn zijde, de reden waarom we dat dit jaar gaan bezegelen met een huwelijk. Zonder jouw eindeloze geduld en luisterend oor, was dit proefschrift geëindigd in een boek vol frustraties.
Gup, ontzettend bedankt!

PhD Portfolio

Name PhD student:	**A.S. de Boer**	PhD period:	**June 2015 – April 2018**
Erasmus MC Department:	**Trauma Surgery**	Promotor:	**Prof.dr. M.H.J. Verhofstad**
Research School:	**Erasmus MC**	Supervisors:	**Dr. E.M.M. van Lieshout, Dr. D. den Hartog**

1. PhD training

	Year	Workload (ECTS)
General courses		
- Biomedical English Writing and Communication	2016 Nov	3 ECTS
- Integrity in Science	2016 Oct	0.3 ECTS
- Biostatistics and research (Biostatistical Methods I)	2016 Sept	3 ECTS
- Basiscursus Regelgeving Klinisch Onderzoek (BROK)	2015 Sept	1 ECTS
- OpenClinica training	2015 Oct	1 ECTS
- Research Manager	2015 Dec	1 ECTS
Specific courses (e.g. Research school, Medical Training)		
- ANIOS surgery – Ikazia hospital, Rotterdam	2014 – 2015	
Seminars and workshops		
- Advanced Trauma Life Support (ATLS) course	2014	1 ECTS
- Advanced Life Support (ALS) course	2015	1 ECTS
- OTC Research Course in Orthopaedics and Trauma	2017	1 ECTS
Presentations		
- Presentations calcaneal RCT at various hospitals	2015	2 ECTS
- National Conference		
• NVT Assistenten Symposium 2013	2013	1 ECTS
• NVvH Najaarsdag 2014	2014	1 ECTS
• NVvH Najaarsdag 2016	2016	1 ECTS
• Wetenschapsdag Erasmus MC 2017	2017	1 ECTS
• NVvH Chirurgendagen 2017	2017	1 ECTS
• NVT Traumadagen 2017	2017	1 ECTS
(Inter)national conferences		
- Traumadagen 2015	2015	1 ECTS
- NVvH Chirurgendagen 2016	2016	1 ECTS

2. Teaching	Year	Workload (ECTS)
Lecturing		
- Teaching	2014 - 2017	
Supervising practicals and excursions, Tutoring		
- Basic Life Support examinator	2015 - 2017	1 ECTS
Supervising Master's theses		
- F. van der Sijde (AOFAS-DLV)	2015	2 ECTS
- L. Vellekoop (AOFAS-DLV / RASFIX)	2015 / 2016	2 ECTS
- R. Tjioe (AOFAS-DLV)	2016	2 ECTS
- F. van 't Land (TT-DIACF)	2016	2 ECTS
- G. van Moolenbroek (Weightbearing)	2017	2 ECTS
Other		
- Supervising (Bachelor) research students	2015 - 2017	3 ECTS
- P. Janssens	2016	
- J. van Dijk	2016	
- G. de Smet	2016	

Curriculum Vitae

Auke Siebren (Siebe) de Boer was born on May 8th, 1988 in Utrecht, Netherlands. He attended secondary school at the Sint-Janslyceum in 's-Hertogenbosch from 2000 to 2006.

Next he started Medicine at the Erasmus University Medical School in Rotterdam. In 2007, Siebe became chairman of the Mara Foundation Rotterdam, a national humanitarian organization which provides humanitarian aid in the Balkans. With contributions of Dutch students, he visited Albania and Moldova, twice. During Medical School he joined the student team 'Les Forgerons' of the Department of Emergency Medicine of the Ikazia Hospital in Rotterdam, where he really became interested in the field of surgery. In the beginning of 2010 he went to the Hospital Rafael Ángel Calderón Guardia in San José, Costa Rica (dr. A. Fonseca) for a clinical internship. He visited the Department of Surgery at the Rui Jin Hospital, Shanghai, China (prof.dr. Yiming Lu) for a research internship in 2011. In the same year, before his clinical internships, the groundwork for this thesis was laid at the Erasmus MC, Rotterdam.

He obtained his medical degree in April 2014, after which he started working as senior house officer at the Ikazia Hospital under supervision of dr. P.T. den Hoed. In June 2015 he continued his research career fulltime as a PhD candidate at the Department of Surgery-Traumatology (Trauma Research Unit Erasmus MC) under supervision of prof.dr. M.H.J. Verhofstad. He focused on lower extremity injuries, mainly on displaced intra-articular calcaneal fractures. In January 2018, Siebe started the surgical residency training in Rotterdam (dr. B.P.L. Wijnhoven) at the Ikazia Hospital (dr. P.T. den Hoed).