

VILLE PONKILAINEN

# Incidence, Diagnostics and Treatment of Midfoot Injuries



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of Midfoot Injuries

ACADEMIC DISSERTATION

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## ACADEMIC DISSERTATION

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# ABSTRACT

The main purpose our study was to investigate the incidence, diagnostic accuracy, and outcomes after non-operative treatment and the validity of the most commonly used outcome measure for midfoot injuries.

The materials of this study were collected retrospectively from the patient records at Tampere University Hospital during a five-year period from 1.1.2012 to 31.12.2016. All computed tomography (CT) images taken due to an acute foot and ankle injury during this period were assessed and all patients with midfoot injuries were included. The data were used to investigate the incidence, trauma mechanisms, diagnostic accuracy, and the validity of an outcome measure and outcomes after nonoperative treatment.

The primary findings of this study were that Lisfranc injuries are more frequent injuries than previously thought with an incidence of 9.2/100 000 person-years. However, Chopart injuries are more infrequent with an annual incidence of 2.2/100 000 person-years in our study population. The majority of Chopart (86%) and Lisfranc (55%) injuries were caused by low-energy trauma. Most (56%) of the Lisfranc-Chopart combination injuries occurred in high-energy traffic accidents.

The conventional radiograph-based diagnosis of a Lisfranc injury has moderate agreement between observers ( $\kappa = 0.50$  (95% CI: 0.45 – 0.55) (first evaluation) and  $\kappa = 0.58$  (95% CI: 0.52 – 0.63) (second evaluation) and substantial agreement between the same observer at different moments ( $\kappa = 0.71$ , from 0.64 to 0.85). Even experienced clinicians seem to lack a high consensus on standard radiograph findings of Lisfranc injuries. The sensitivity of radiographs was 76% and specificity 85% for detecting Lisfranc injuries. Therefore, a substantial number (24%) of injuries are missed when only conventional radiographs are used in the diagnostics. As presumed, subtle, nondisplaced injuries were more commonly missed than displaced injuries.

The American Orthopaedic Foot & Ankle Society Midfoot Scale is the most commonly used outcome measure among studies investigating foot and ankle surgery. Its validity, however, has been questioned. According to the findings of this study, the internal consistency and convergent validity of the scale are

acceptable, yet the coverage and targeting of the scale has raised some concerns because it does not discriminate patients with relatively few symptoms well. The scale has too many 'easy' items, and therefore it is too easy to score the maximum points.

Our study supports the view that nondisplaced injuries, regardless of the number of affected columns or the type of the injury (avulsion or simple intra-articular fracture) of the Lisfranc joint, can be treated non-operatively with 4 to 6 weeks non-weightbearing cast with good clinical outcome. It may be the case that some types of nondisplaced Lisfranc injuries would benefit from surgical intervention. However, the criteria for identifying these injuries remain unknown. Moreover, our ongoing randomized trial will yield important information on the treatment of these injuries in the future.

In conclusion, this study has shown that Lisfranc injuries are more common than previously thought. If the radiological diagnostics are based only on standard radiographs, a considerable number of injuries may be missed. We suggest therefore that a computed tomography (CT) scan of the injured foot is performed when there is high clinical suspicion of a midfoot injury (pain in active and passive movements, swelling, or plantar ecchymosis). Non-operative treatment certainly has role to play in the treatment of Lisfranc injuries, but the clinical and radiological criteria for injuries that can be successfully treated without surgery are still unknown. In addition, due to flaws in the American Orthopaedic Foot & Ankle Society Midfoot Scale and other problems reported in the previously published literature, the scale is not recommended as a primary outcome measure for the evaluation of outcomes after Lisfranc injury. Thus, outcomes after Lisfranc injury should be evaluated using other properly validated outcome measures.

Finally, the current literature on these injuries is limited, and further high-quality studies are urgently needed. In the near future, our prospective randomized controlled trial will yield important knowledge for the treatment of these injuries. Additionally, it is important to find reliable diagnostic tools that can identify those injuries that require surgical treatment.



# TIIVISTELMÄ

Tämän tutkimuksen tarkoituksena oli arvioida keskijalkaterän vammojen ilmaantuvuutta, diagnostista tarkkuutta, tuloksien arvioinnissa käytetyn toimintakykymittarin pätevyyttä sekä tuloksia konservatiivisen hoidon jälkeen.

Tutkimuksen aineisto kerättiin retrospektiivisesti potilastietojärjestelmästä Tampereen yliopistollisessa sairaalassa 1.1.2012 ja 31.12.2016 välisenä aikana. Kaikki nilkasta ja jalkaterästä akuutin vamman vuoksi otetut tietokonetomografiakuvat arvioitiin ja niistä poimittiin kaikki keskijalkaterän alueen vammat. Tätä aineistoa käytettiin selvittämään keskijalkaterävammojen ilmaantuvuutta, vammamekanismeja, diagnostista tarkkuutta, tuloksien arvioinnissa käytetyn toimintakykymittarin pätevyyttä, sekä tuloksia konservatiivisen hoidon jälkeen.

Tutkimuksen yhtenä tärkeimmistä löydöksistä oli, että keskijalkaterävammojen ilmaantuvuus näyttää olevan selvästi korkeampi kuin aiemmin kirjallisuudessa on esitetty. Lisfrancin vammojen ilmaantuvuus oli 9.2 / 100 000 henkilövuotta kohden. Chopartin vammat olivat selvästi harvinaisempia (2.2 / 100 000 henkilövuotta kohden). Lisäksi suurin osa Chopartin (86%) sekä Lisfrancin (55%) vammoista syntyi lievillä vammamekanismeilla. Suurin osa (56%) Lisfranc-Chopart yhdistelmävammoista syntyi korkeaenergisillä vammamekanismeilla.

Röntgenkuvaan perustuvan Lisfrancin -vamman diagnoosin yksimielisyys eri arvioijien välillä oli kohtalainen (ensimmäinen arvio:  $\kappa = 0.50$  [95% luottamusväli: 0.45 – 0.55], toinen arvio:  $\kappa = 0.58$  [95% luottamusväli: 0.52 – 0.63]). Arvioiden yksimielisyys saman arvioijan kahden arvion välillä oli huomattava ( $\kappa = 0.71$ , vaihteluväli: 0.64 - 0.85). Röntgenkuvauksen herkkyys oli 76% ja tarkkuus 85% Lisfrancin vammojen tunnistamisessa. Tutkimuksemme perustella merkittävä määrä (24%) Lisfrancin vammoja jää diagnosoimatta, mikäli diagnostiikassa käytetään ainoastaan perinteistä röntgenkuvausta. Ymmärrettävästi hyväasentoiset vammat jäivät useammin huomaamatta verrattuna huonoasentoisiin vammoihin.

Tutkimuksemme tulosten perusteella American Orthopaedic Foot & Ankle Society Midfoot Scale -toimintakykymittarin kattavuudessa ja kohdentamisessa

on merkittäviä ongelmia. Tässä yleisimmin jalkateräkirurgiassa käytetyssä mittarissa on liikaa helppoja kysymyksiä, joten suuri osa potilaista saa täydet pisteet, eikä erottele potilaita toisistaan riittävän tehokkaasti.

Tutkimuksemme tulosten perusteella suuri osa hyväasentoisista Lisfrancin vammoista voidaan hoitaa konservatiivisesti 4-6 viikon kipsillä vamman sijainnista ja laajuudesta riippumatta. Tietyt hyväasentoiset vammat saattavat hyötyä kirurgisesta hoidosta, mutta diagnostisia kriteerejä näille vammoille emme pysty tämän tutkimuksen perusteella määrittelemään. Käynnissä oleva prospektiivinen randomoitu tutkimus tulee antamaan tärkeää lisätietoa tulevaisuudessa näiden vammojen hoidosta.

Yhteenvetona, Lisfrancin vammat ovat yleisempiä, kuin mitä aiemmin on ajateltu, eikä diagnoosin pitäisi perustua ainoastaan röntgenkuvaukseen. Suosittelemme, että epäiltäessä kyseistä vammaa kliinisten merkkien (kipu jalkaterässä aktiivisissa sekä passiivisissa liikkeissä, turvotus tai jalkapohjan hematooma) perusteella, olisi suositeltavaa kuvata jalkaterä tietokonetomografia -kuvauksella. American Orthopaedic Foot & Ankle Society Midfoot Scale -toimintakykymittaria ei tulisi käyttää ensisijaisena mittarina hoidon tulosten arvioinnissa. Tähän arviointiin tulisi käyttää muita toimintakykymittareita, joiden pätevyys ja luotettavuus on asianmukaisesti todettu. Konservatiivisella hoidolla on oma paikkansa näiden vammojen hoidossa. Kuitenkaan emme vielä pysty sanomaan, että millä kliinisillä ja radiologisilla löydöksillä konservatiivinen hoito on indisoitu.

Lisfrancin vammoja käsittelevä kirjallisuus on suppeaa, ja laadukkaita tutkimuksia tulisi tulevaisuudessa tehdä. Käynnissä oleva etenevä satunnaistettu tutkimus tulee antamaan tärkeää lisätietoa tulevaisuudessa näiden vammojen hoidosta. Lisäksi olisi tärkeää löytää luotettava kuvantamismenetelmä, jolla pystyttäisiin tunnistamaan ne epästabiilit vammat, jotka voisivat hyötyä operatiivisesta hoidosta.

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# ABBREVIATIONS

AOFAS	American Orthopaedic Foot and Ankle Society
CBCT	Cone-beam computed tomography
CT	Computed tomography
CTT	Classical Test Theory
COSMIN	COnsensus-based Standards for the selection of health status Measurement INstruments
ER	Emergency room
ICD	International Statistical Classification of Diseases and Related Health Problems
IRT	Item Response Theory
K-Wire	Kirschner-Wire
MT	Metatarsal bone
MRI	Magnetic resonance imaging
ORIF	Open reduction and internal fixation
PA	Primary arthrodesis
PFC score	Painful Foot Center score
PROM	Patient reported outcome measure
RCT	Randomized controlled trial
ROM	Range of motion
SF-36	Short-Form 36
SMFA	Short Musculoskeletal Functioning Assessment
TMT	Tarsometatarsal
VAS	Visual-Analogue-Scale
VAS-FA	Visual Analogue Scale Foot and Ankle
WBCBCT	Weightbearing cone-beam computed tomography



# ORIGINAL PUBLICATIONS

This dissertation is based on the following original publications referred to in the text by their Roman numerals I to V.

- Publication I **Ponkilainen Ville**, Laine Heikki-Jussi, Mäenpää, Heikki, Mattila Ville, Haapasalo Heidi. Incidence and characteristics of midfoot injuries. *Foot Ankle Int.*, 2019, Jan;40:105-112.
- Publication II **Ponkilainen Ville**, Partio Nikke, Salonen Essi, Riuttanen Antti, Luoma Emma-Liisa, Kask Gilber, Laine Heikki-Jussi, Mäenpää Heikki, Päiväniemi Outi, Mattila Ville, Haapasalo Heidi. Inter- and intraobserver reliability of non-weight-bearing foot radiographs compared with CT in Lisfranc injuries. *Arch. Orthop. Trauma Surg.* 2020 [published online ahead of print].
- Publication III **Ponkilainen Ville**, Uimonen Mikko, Repo Jussi, Mattila Ville, Haapasalo Heidi. Validity and internal consistency of the American Orthopaedic Foot and Ankle Society Midfoot Scale in patients with Lisfranc injury. *Foot Ankle Surg.*, Jun 21:S1268-7731(19)30101-8
- Publication IV **Ponkilainen Ville**, Partio Nikke, Salonen, Essi, Laine Heikki-Jussi, Mäenpää Heikki, Mattila Ville, Haapasalo Heidi. Outcomes after nonoperatively treated Lisfranc injury: A Retrospective Case series of 60 patients. (Submitted)
- Publication V **Ponkilainen Ville**, Mattila Ville, Laine Heikki-Jussi, Paakkala Antti, Mäenpää Heikki, Haapasalo Heidi. Nonoperative, open reduction and internal fixation or primary arthrodesis in the treatment of Lisfranc injuries: a prospective, randomized, multicenter trial – study protocol. *BMC Musculoskelet. Disord.* 2018 Aug;19:301.





# 1 INTRODUCTION

The midfoot region contains two adjacent joints: the Lisfranc and the Chopart joints. The Lisfranc joint is named after the 18<sup>th</sup> century surgeon Jacques Lisfranc de Saint-Martin (1790-1847) who performed the first foot amputations on the tarsometatarsal joint (Fischer, 2005; Lau, Bozin, & Thillainadesan, 2016; Wolf, 2000). Similarly, the Chopart joint carries the name of Francois Chopart, a surgeon who performed amputations on the transverse tarsal joint (Wolf, 2000). Nowadays, the term 'Lisfranc injury' is used to describe a wide spectrum of injuries to the tarsometatarsal joint complex (TMT), ranging from minor midfoot sprains to severely dislocated high-energy injuries (Hardcastle, Reschauer, Kutscha-Lissberg, & Schoffmann, 1982; Myerson, 1999; Myerson & Cerrato, 2008; Turco, 1972). The Chopart injury, in turn, does not have a specific consensus-based definition. Thus, studies investigating injuries to the Chopart joint usually describe the injuries as affecting the bones of the proximal midfoot, the navicular, and the cuboid and cuneiform bones (Main & Jowett, 1975; Richter et al., 2001).

The epidemiology of midfoot injuries is poorly understood (Court-Brown, Zinna, & Ekrol, 2006; Eleftheriou, Rosenfeld, & Calder, 2013), but most midfoot injuries occur during the third decade of life, and males are 2-4 times more likely to sustain these injuries than females (Desmond & Chou, 2006; Richter et al., 2001). It has been reported that Lisfranc injuries account for 0.2% of all fractures, and that they are known to be missed in up to 20-24% of cases (Chiodo & Myerson, 2001; English, 1964; Haapamaki, Kiuru, & Koskinen, 2004a; Myerson, Fisher, Burgess, & Kenzora, 1986; Stavlas, Roberts, Xypnitos, & Giannoudis, 2010; Thompson & Mormino, 2003). An incidence rate of 1/55 000 person-years has been reported and cited in multiple publications that have investigated Lisfranc injuries (Eleftheriou et al., 2013; Faciszewski, Burks, & Manaster, 1990; Hardcastle et al., 1982; Herscovici & Scaduto, 2018; Lau et al., 2016; Mulier, de Haan, Vriesendorp, & Reynders, 2010; Qiao et al., 2017; Shapiro, Wascher, & Finerman, 1994; Siddiqui, Galizia, Almusa, & Omar, 2014). Interestingly, the cited original publications do not report this incidence rate, and the authors who cite these studies do not provide any basis or supporting data for how they achieved this figure (Aitken & Poulson, 1963; English, 1964). The

current literature does not contain studies that investigate the incidence of Chopart injuries. It has been estimated, however, that the incidence of injuries affecting the proximal midfoot is 3.6/100 000 person-years (Court-Brown et al., 2006), with Chopart fracture dislocations accounting for 16% of all high-energy midfoot injuries (Richter et al., 2001).

The most frequent trauma mechanisms for midfoot injuries are motor vehicle accidents, falling from height, sports injuries, and crush injuries (Hardcastle et al., 1982; Richter et al., 2001; Stavlas et al., 2010; Thompson & Mormino, 2003; Wiss, Kull, & Perry, 1987). Though midfoot injuries are fairly rare, they can cause difficult complications, such as vascular impairment, skin complications, and osteoarthritis, and lead to severe functional impairment (Desmond & Chou, 2006; Hardcastle et al., 1982; Philbin, Rosenberg, & Sferra, 2003; Rammelt et al., 2008). Although the clinical signs may be obvious after high energy trauma, subtle injuries are a diagnostic challenge (Eleftheriou et al., 2013; Welck, Zinchenko, & Tudor, 2016). Conventional radiographs have traditionally been the primary diagnostic tool used to detect these injuries (Hardcastle et al., 1982; Myerson et al., 1986). However, recent studies have shown that computed tomography (CT) is a more sensitive imaging tool (Goiney, Connell, & Nichols, 1985; Haapamaki et al., 2004a; Haapamaki, Kiuru, & Koskinen, 2004b; Sherief, Mucci, & Greiss, 2007). Moreover, it has also been suggested that weightbearing radiographs and magnetic resonance imaging (MRI) can be used to detect these less severe injuries (Arntz, Veith, & Hansen, 1988; Coss et al., 1998; Curtis, Myerson, & Szura, 1993; Goossens & Stoop, 1983; MacMahon et al., 2009; Potter, Deland, Gusmer, Carson, & Warren, 1998; Preidler et al., 1996a; Preidler et al., 1996b; Raikin et al., 2009).

The treatment of Lisfranc injuries can be conducted either non-operatively with a boot cast or operatively with open reduction and internal fixation (ORIF) or primary arthrodesis. There is, however, controversy as to which treatment option should be chosen for each individual patient (Crates, Barber, & Sanders, 2015; Faciszewski et al., 1990; Henning, Jones, Sietsema, Bohay, & Anderson, 2009; Ly & Coetzee, 2006; Meyer, Callaghan, Albright, Crowley, & Powell, 1994; Nunley & Vertullo, 2002; Shapiro et al., 1994). The evidence regarding non-operative treatment is based on a few case-series and retrospective cohort studies (Crates et al., 2015; Curtis et al., 1993; Faciszewski et al., 1990; Myerson et al., 1986; Nunley & Vertullo, 2002; Shapiro et al., 1994). It has been suggested that only subtle injuries without displacement should be treated non-operatively (Nunley & Vertullo, 2002). However, it has also been argued that even these subtle injuries would benefit from surgery (Crates et al., 2015). Despite the controversy in treatment, there is consensus

that poorly treated or missed injuries may lead to remarkable disability, deformity, and dysfunction (Curtis et al., 1993; Kuo et al., 2000; Ly & Coetzee, 2006; Mulier, Reynders, Dereymaeker, & Broos, 2002; Myerson et al., 1986).

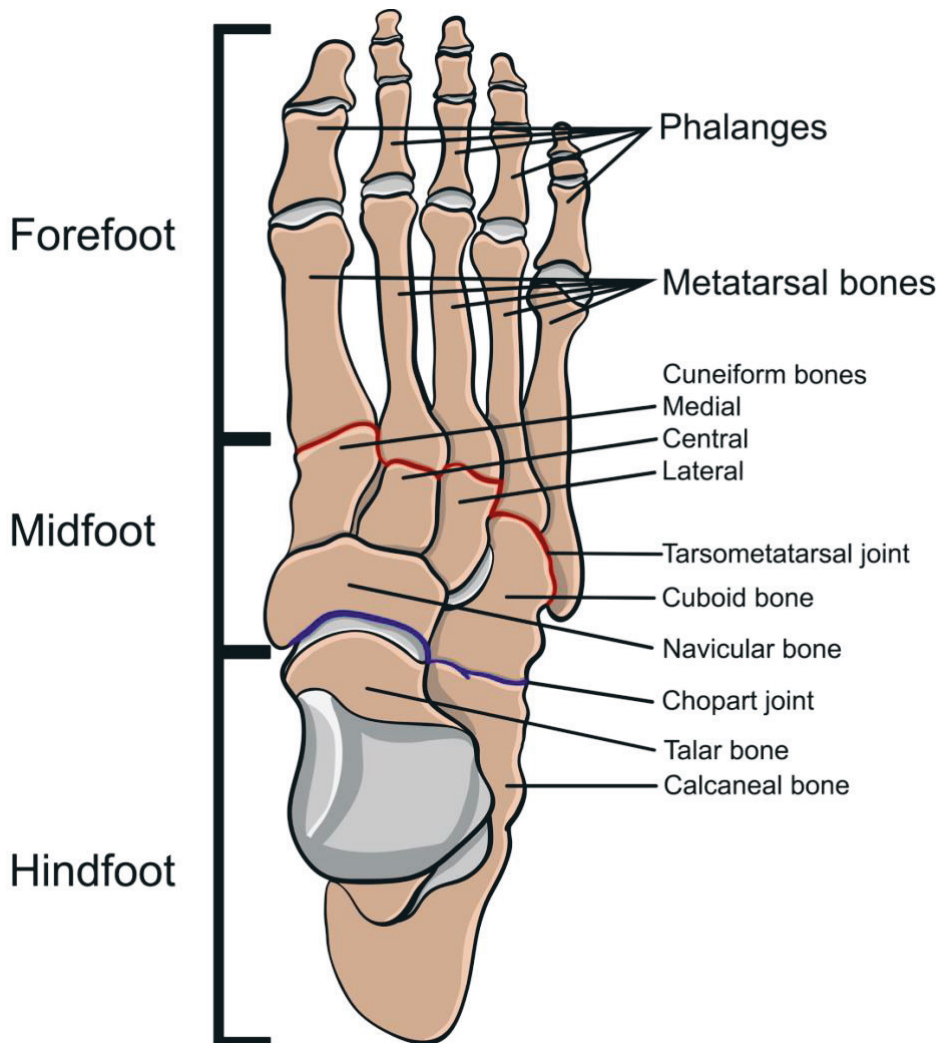
Severe Lisfranc injuries with displacement of 2 mm or more are considered to be unstable and it is suggested that such injuries are treated with ORIF to prevent the development of posttraumatic osteoarthritis (Arntz et al., 1988; Curtis et al., 1993; Faciszewski et al., 1990; Goossens & Stoop, 1983; Hardcastle et al., 1982; Kuo et al., 2000; Myerson, 1999; Ouzounian & Shereff, 1989; Philbin et al., 2003; Rammelt et al., 2008; Shapiro et al., 1994). Interestingly, no randomized controlled trials comparing non-operative treatment and ORIF exist. Further, despite having undergone adequate operative treatment, between 40% and 94% of patients will still develop post-operative osteoarthritis (Kuo et al., 2000; Ly & Coetzee, 2006; Mulier et al., 2002; Myerson et al., 1986), and conversion to an arthrodesis to ease pain may be inevitable (Johnson & Johnson, 1986; Mann, Prieskorn, & Sobel, 1996; Sangeorzan, Veith, & Hansen, 1990). Therefore, primary arthrodesis is suggested to prevent reoperations and the development of painful posttraumatic osteoarthritis (Cochran, Renninger, Tompane, Bellamy, & Kuhn, 2017; Henning et al., 2009; Ly & Coetzee, 2006; Smith, Stone, & Furey, 2015). The findings of two randomized controlled studies (Henning et al., 2009; Ly & Coetzee, 2006), a meta-analysis (Smith et al., 2015), and a cost-effectiveness study (Albright et al., 2018) slightly favor primary arthrodesis, although definitive conclusions cannot be made.

This dissertation summarizes the main aspects of epidemiology, diagnostics, evaluation of outcomes, and treatment of midfoot injuries. The epidemiological part of this dissertation includes both, Lisfranc and Chopart injuries (I). However, the remainder of the study focuses solely on Lisfranc injuries. We aim to investigate how often these injuries are misdiagnosed, and to learn which injuries are the most commonly missed (II). In addition, the psychometric properties of the most used foot and ankle patient reported outcome measure (PROM), the American Orthopaedic Foot & Ankle Society Midfoot Scale will be investigated (III). The treatment of Lisfranc injuries is an interesting but poorly covered subject in the literature. Hence, the treatment of these injuries will be covered by presenting the results after non-operatively treated Lisfranc injuries (IV). Additionally, we will present the protocol for a 2-arm randomized controlled trial (V). The trial compares non-operative treatment to ORIF, and ORIF to primary arthrodesis. The results of the randomized controlled trial will be completed after the publication of this dissertation.

## 2 REVIEW OF THE LITERATURE

### 2.1 Anatomy and biomechanics of the midfoot

The foot can be categorized anatomically into hindfoot, midfoot, and forefoot (Figure 1). The midfoot plays an important role in providing stability for the whole foot. The midfoot is divided into medial and lateral compartments. The medial compartment includes the navicular bone, three cuneiform bones (medial, central, and lateral), and three metatarsal bones (first, second, and third). The lateral compartment includes the cuboid and two lateral metatarsal (fourth and fifth) bones. The midfoot region also includes two transverse joints that provide minimal movement over the foot: the Chopart joint and the Lisfranc joint. (Pearce & Calder, 2010)



**Figure 1.** Bony anatomy of the foot.

### 2.1.1 Lisfranc joint

De Palma et al. published a comprehensive study on the anatomy of the Lisfranc joint in 1997. The Lisfranc joint is formed around the five tarsometatarsal joints (TMT). The bony structure comprises the medial, intermediate, and lateral cuneiform and cuboid bones, which are articulated against the five metatarsal bones. All articular surfaces are covered with a chondral layer. The triangular shaped heads of the metatarsal bones form the transversal arc of the foot. The base of the second

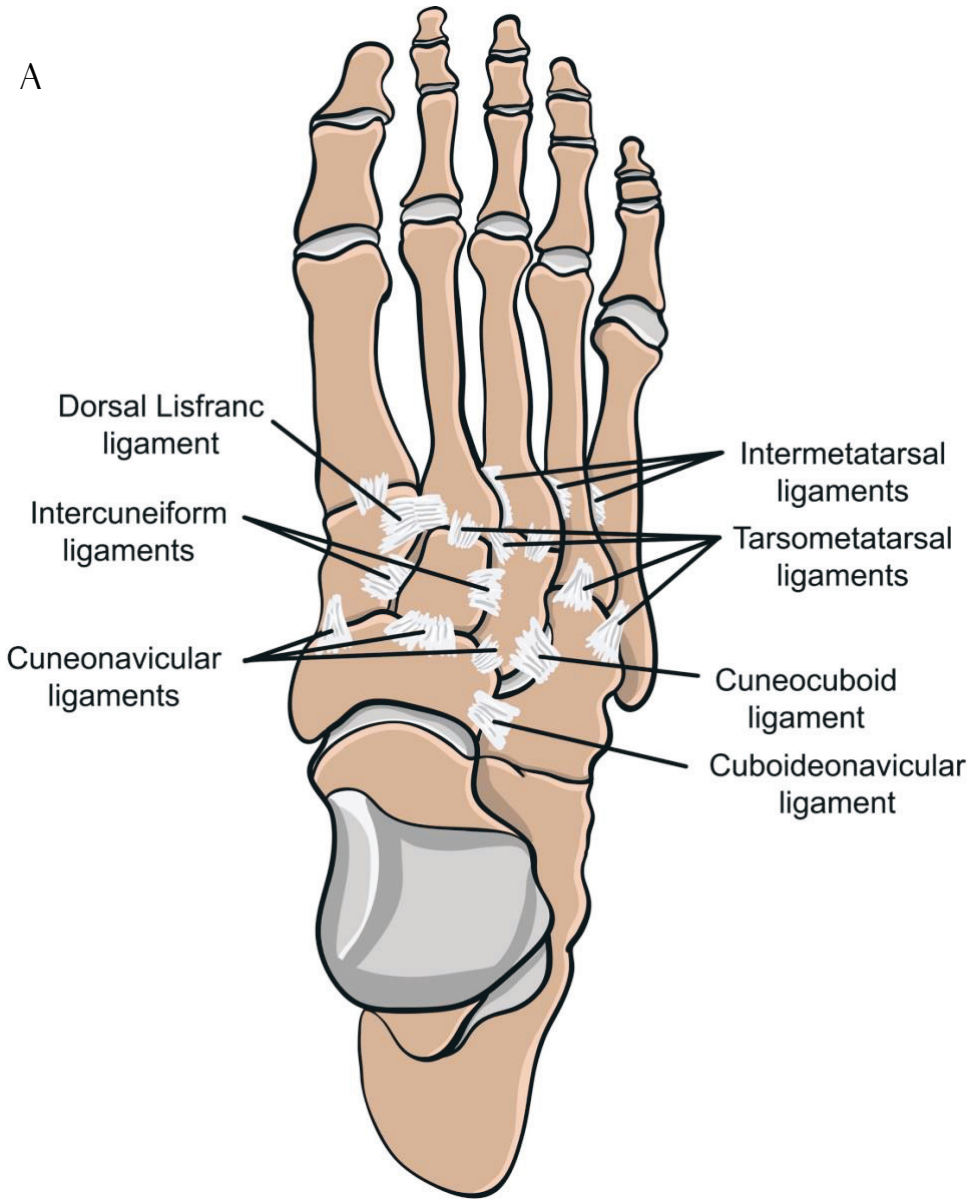
metatarsal bone reaches more proximally and it is wedged between the medial and lateral cuneiform bones (Figure 1). The lateral cuneiform bone is similarly wedged between the second and the fourth metatarsals. (de Palma et al., 1997)

The first and the second metatarsal bases do not usually articulate with each other. Only occasionally a small facet in the medial side of second metatarsal bone exists. The second and the third metatarsals have two round articular surfaces in between the bones. The third and the fourth metatarsals share single articulation in between, which is a continuation from the TMT joint and located on the dorsal part of their sides. The fourth and the fifth metatarsals also have a common articulation, which is an extension from the TMT joints, but wider than in the third and fourth metatarsals. (de Palma et al., 1997)

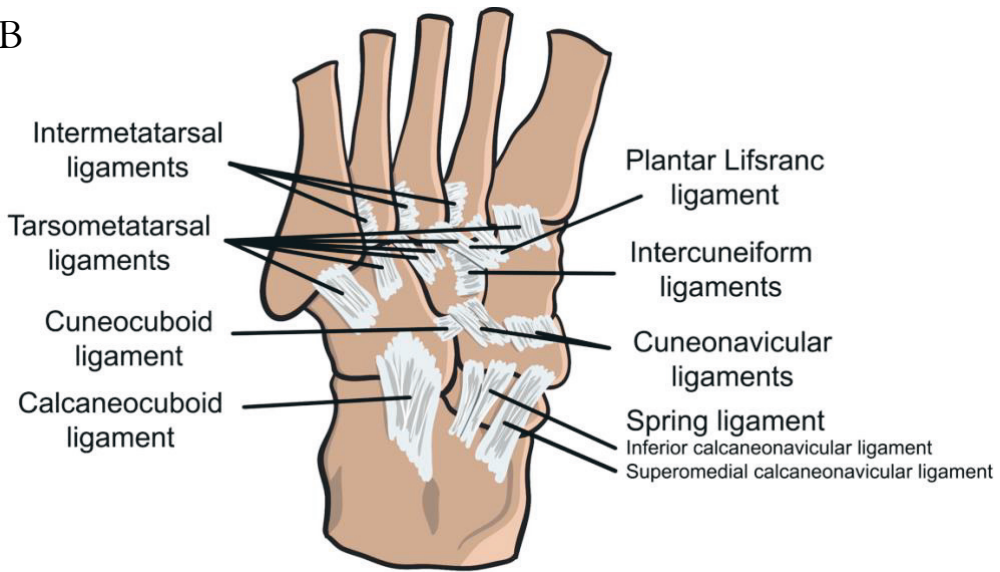
Due to the bony anatomy, the stability of the articulations is based purely on the articular capsules and numerous ligamentous structures (Figure 2). Articular capsules are formed by fibrous membranes that are attached near the articular surfaces constituting three articular columns: medial, central, and lateral. The medial column is formed by the first metatarsal bone and the medial cuneiform bone. The central column is formed by the second and third metatarsal bones and the intermediate and lateral cuneiform bones. The lateral column is formed by the fourth and fifth metatarsal bones and the cuboid bone. The medial and central columns are in contact, but the lateral column is separated from the other columns. (de Palma et al., 1997)

Numerous ligaments around the TMT joints reinforce the articular capsules and provide stability over the bony structures. Some of the ligaments are just capsular thickenings, as some of them have individual structures. The ligaments are known to have wide variability between individuals in terms of course, number, and insertions. The ligamentous structures around TMT joints are divided into dorsal, interosseous, and plantar. (de Palma et al., 1997)

A



B



**Figure 2.** Ligamentous anatomy of the midfoot. (A) Dorsal view. (B) Plantar view

Dorsal ligaments include intertarsal and intermetatarsal ligaments which are formed by 6 to 8 short flat bands (Figure 2A). They connect the cuneiform bones and the cuboid bones to the metatarsal bones in longitudinal and transverse course. Interosseous ligaments include the Lisfranc ligament, the central ligament, and the lateral longitudinal ligament. The interosseous ligaments have wide variability in strength and disposition. The Lisfranc ligament is a medial interosseous ligament, and it is an oblique ligament between the first cuneiform and the second metatarsal bones. Moreover, it is the largest ligament of the TMT joint complex, and it is 5 to 6 mm thick and 8 to 10 mm long. (de Palma et al., 1997)

Plantar ligaments include longitudinal and transverse ligaments and they have wide variability in number and course (Figure 2B). Usually, there are more than 5 plantar ligaments, and the medial ligaments tend to be stronger than the lateral ones. The plantar ligaments are usually stronger than the dorsal ligaments, while the second plantar ligament (plantar Lisfranc ligament) is the strongest. This ligament arises from the medial cuneiform bone and separates into two parts: the thinner one inserts into the second metatarsal bone, and the thicker one into the third metatarsal bone. (de Palma et al., 1997)

The plantar ligaments between the medial cuneiform and the second and third metatarsal bone have been presented to be the most important ligaments of the



Lisfranc joint, since these are the ones that often disrupt in midfoot injuries (Chiodo & Myerson, 2001; Kura, Luo, Kitaoka, Smutz, & An, 2001; Solan, Moorman, Miyamoto, Jasper, & Belkoff, 2001). The plantar and interosseus ligaments are stronger and stiffer than the dorsal ligaments, and therefore play an important role in providing stability over the joint (Kaar, Femino, & Morag, 2007; Solan et al., 2001).

### 2.1.2 Chopart joint

The Chopart joint, also known as the transverse tarsal joint, comprises two adjacent joints: the talonavicular joint and the calcaneocuboid joint (Figure 1) (Pearce & Calder, 2010). The convex head of the talus is articulated to the navicular bone which, in turn, is articulated distally to three cuneiform bones. The navicular bone is covered with cartilage on its proximal and distal sides, and the blood supply is received from the medial and lateral non-articulated parts of the navicular bone. The talonavicular joint includes complex ligamentous structures that provide stability around the joint. (Sammarco, 2004)

The spring ligament complex comprises two separate ligaments that provide important stability over the talonavicular joint. The inferior calcaneonavicular ligament arises from the inferior part of the sustentaculum tali and anterior calcaneus and attaches to the inferior border of the navicular bone (Figure 2). This ligament plays an important role in providing stability over the joint. The second part of the spring ligament, the superomedial calcaneonavicular ligament, arises from the medial border of the sustentaculum, and it is adjacent to the superficial deltoid ligament. It attaches to the plantar, medial, and dorsal third of the navicular bone. These ligamentous structures are the most important stabilizers of the talonavicular joint, although among individuals there is a lot of variance in the osseous articulations and form of the talar and navicular bones. (Sammarco, 2004)

The calcaneocuboid joint is a saddle-shaped joint that is formed in between the anterior process of the calcaneus and the proximal side of the cuboid bone. The joint is concave transversely and convex vertically, and the axis has been shown to range from 43 to 72 degrees from anterosuperior to posteroinferior direction. The inferior calcaneocuboid ligament extends from the inferior calcaneus to the inferior side of the cuboid and it consists of weaker superficial and stronger deep branches. This ligament is the most important soft-tissue structure to support the calcaneocuboid joint, and it prevents the dorsal subluxation of the articulation. The superior side of the joint is supported by the medial calcaneocuboid ligament, although this ligament

may be absent in 40% of individuals. The dorsolateral calcaneocuboid ligament extends from the anterior process of the calcaneus and inserts into the dorsal side of the cuboid bone, forming a part of the joint capsule. (Sammarco, 2004)

### 2.1.3 Biomechanics

Since our ancestors started to walk on two feet, evolution has occurred in the construct and mechanics of the modern day midfoot (Bates et al., 2013). To the best of our knowledge, the first study on foot biomechanics was conducted by Hicks in 1953. The movement (flexion-extension) of the whole midfoot was evaluated from the navicular bone to the base of the metatarsal bone. The first ray had a range of motion (ROM) of 22 degrees, while the third ray had a ROM of 10 degrees (Hicks, 1953). When the TMT joint was evaluated separately, it was discovered that the movement of the normal Lisfranc joint is usually minimal (Ouzounian & Shereff, 1989). In the study by Ouzonian et al. (1989) on a cadaveric and amputation specimen, the first TMT joint (medial column) allowed movement of 3.5 (range from 1.9 to 5.3) degrees. The central column was more stable, as the second TMT allowed movement of 0.6 (from 0.1 to 1.0) degrees and the third 1.6 (from 0.1 to 6.3) degrees of movement. The lateral column had the widest range of motion, since the fourth TMT had 9.6 (from 5.8 to 19.4) degrees and the fifth TMT had 10.2 (from 1.1 to 29.6) degrees of motion (Ouzounian & Shereff, 1989). The lateral column plays a significant role in gait because a wide ROM helps the foot to adjust on uneven ground (Leardini et al., 2007).

## 2.2 Epidemiology of midfoot injuries

### 2.2.1 Lisfranc injuries

The epidemiology of midfoot injuries is not fully understood (Court-Brown et al., 2006; Eleftheriou et al., 2013). According to English (1964), Lisfranc injuries account for 0.2% of all fractures. Furthermore, Lisfranc fracture dislocations may account for 32% of all midfoot injuries (Richter et al., 2001). Although the incidence of 1/55 000 person-years is presented and cited in multiple publications (Eleftheriou et al., 2013; Faciszewski et al., 1990; Hardcastle et al., 1982; Herscovici & Scaduto,

2018; Lau et al., 2016; Mulier et al., 2010; Qiao et al., 2017; Shapiro et al., 1994; Siddiqui et al., 2014) concerning Lisfranc injuries, the origin of this incidence rate is unclear even in the cited studies (Aitken & Poulson, 1963; English, 1964).

The two most cited studies investigating the epidemiology of Lisfranc injury were published in the 1960s (Aitken & Poulson, 1963; English, 1964). Aitken and Poulson (1963) reported that 16 patients with Lisfranc injury were treated during a 15-year period in a hospital where 5 500 fractures were treated annually. English (1964) reported that 24 Lisfranc injuries were treated in their hospital among 11,000 fractures, which gives a rate of 0.2% of all fractures. There is also one previous study from Finland by Vuori & Aro (1993). They reviewed all radiographs of treated tarsometatarsal injuries in a catchment area of 250 000 residents. In total, 66 Lisfranc injuries were detected over ten years, resulting in an incidence rate of 2.6/100 000 person-years. These previous studies have notable limitations. Since the Lisfranc injury was previously defined as a complete dislocation of the TMT joints, all less severe injuries were neglected. In addition, the diagnosis was based on conventional radiographs, leaving many injuries outside this study sample.

## 2.2.2 Chopart injuries

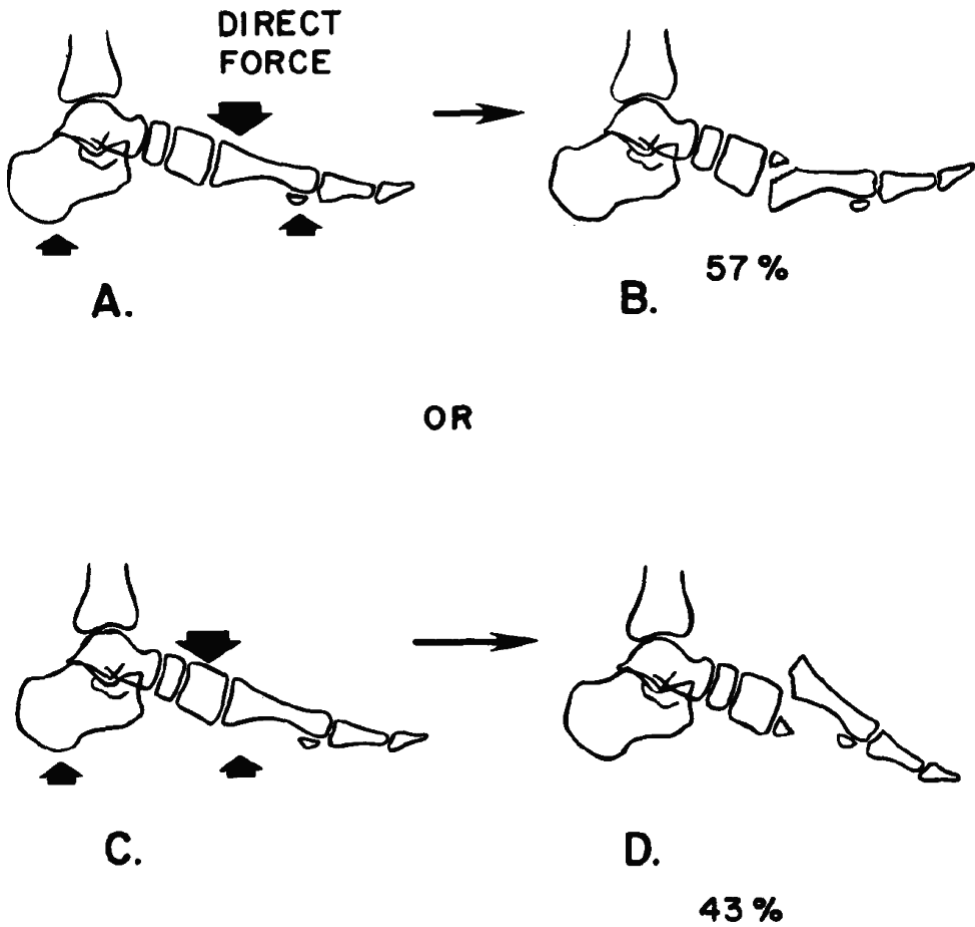
To the best of our knowledge, there have been no previous studies presenting population-based epidemiological figures for Chopart injuries. Nonetheless, a study by Richter et al. in 2001 reported that Chopart fracture dislocations account for 16% of all midfoot injuries. In addition, Court-Brown et al. (2006) studied the incidence of midfoot injuries, including fractures of the navicular, cuboid and cuneiform bones. In their study, the annual incidence of these injuries was assessed to be 3.6/100 000 person-years in a trauma center serving a catchment population of 650 000. The diagnostics of all these previous studies are based on standard radiographs only and have divergence among the definitions of the injury.

## 2.3 Injury mechanisms

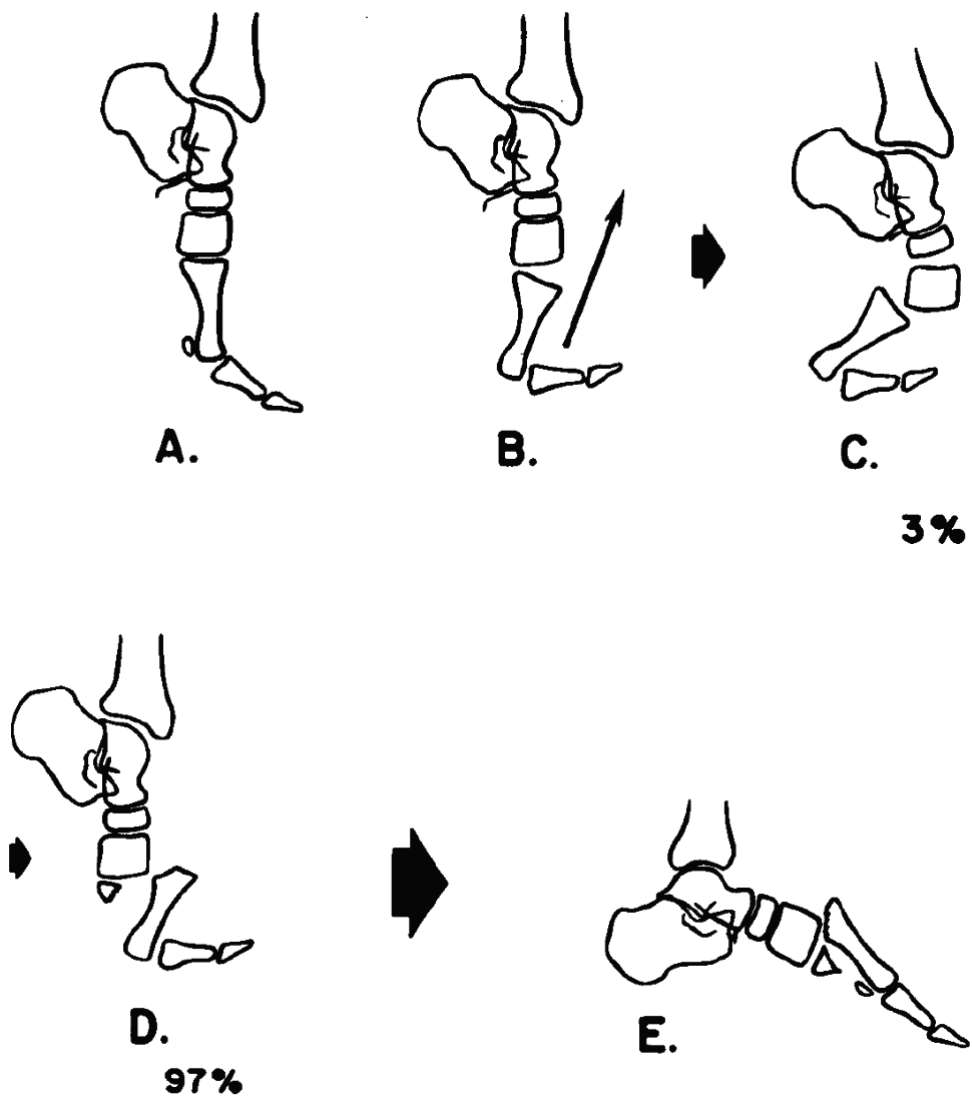
### 2.3.1 Lisfranc injuries

Jeffreys (1963) performed cadaveric studies to investigate the mechanisms of Lisfranc injury. Two different injury patterns were presented: pronation (the foot rolls inwards) of the hindfoot resulting in a simple lateral dislocation and supination (the foot rolls outwards) of the hindfoot resulting in a medial dislocation of the first TMT joint. Myerson et al. published a study in 1986 where they described the trauma mechanisms and pathology of Lisfranc injuries in detail. They reported that Lisfranc injury usually occurs as the result of either direct or indirect forces, similar to previous definitions, and those injuries that are caused by direct force have wide variability depending on where the force is applied (Figure 3). They showed that the direct force can lead to plantar or dorsal dislocation.

The indirect trauma mechanism accounts for all twists and torsions of the midfoot. The most typical indirect injury occurs when the foot is plantarflexed at the time of the impact (Figure 4). Hyperplantarflexion causes the weaker dorsal ligaments to rupture and leads to dorsal dislocation of the involved metatarsal bones. In order that dorsal dislocation can occur, the plantar parts of the metatarsal heads must fracture or the capsuloligamentous structures must rupture. There are usually also additional forces that are responsible for the indirect injury, resulting in a wide variety of injury types.



**Figure 3.** Direct injury mechanism by Myerson et. al (1986). (copyright SAGE publications. Published with permission from SAGE publications)



**Figure 4.** Indirect injury mechanism by Myerson et. al (1986). (copyright SAGE publications. Published with permission from SAGE publications)

More recently, multiple studies have reported that the most common causes of Lisfranc injury are road accidents, falling from height, and crush injuries (Arntz et al., 1988; Hardcastle et al., 1982; Kuo et al., 2000; Lievers, Frimenko, Crandall, Kent,

& Park, 2012; Myerson et al., 1986; Vuori & Aro, 1993; Wilppula, 1973; Wiss et al., 1987). Since the classification by Nunley and Vertullo (2002) was published, a subtle Lisfranc injury type has been widely recognized. They presented that the subtle injury type is the most prevalent in athletes, such as football or soccer players.

Renninger et al. (2017) studied the characteristics of Lisfranc injuries detected with CT. They suggested that these injuries should be classified according to the trauma energy, i.e., low energy and high energy injuries. They found that most (60%) of the Lisfranc injuries were caused by low-energy trauma mechanisms, such as sports, ground-level twisting, and falling from a height of less than 1.2 m. The results of their study were contradictory to those of the previous studies. However, the use of CT might have provided the ability to detect injuries that were missed in the previous studies with conventional radiographs.

### 2.3.2 Chopart injuries

Definitive injury mechanisms were first explained by Main and Jowett (1975). In their study, the most common trauma mechanisms were high energy traumas, such as motorbike accidents and high falls. More recently, similar results have been published by Richter et al. (2001). In their study, the most common trauma mechanisms were traffic accidents (72%), falls (12%), and blunt injuries (8%). The most recent study by Court-Brown et al. (2006) reported that only 13% of midfoot injuries occurred in traffic accidents, whereas 31% occurred by twisting and 37% by falling.

## 2.4 Classifications

In general, fracture classifications are developed to describe different injury types and as tools for surgeons and physicians to provide guidelines for choosing adequate treatment options. In addition, the fracture classifications should provide estimates of the outcomes of the chosen treatment. It has been suggested that when developing a classification, it is essential that the evaluator produces the same result as other evaluators (interobserver reliability) and that the evaluator produces the same result when the same patient is evaluated multiple times (intraobserver reliability). (Burststein, 1993)

## 2.4.1 Lisfranc injuries

There are at least 14 different classifications for Lisfranc injuries (Hardcastle et al., 1982; Jeffreys, 1963; Lau et al., 2017; Myerson et al., 1986; Nunley & Vertullo, 2002; Quenu E, 1909; Schepers & Rammelt, 2018). Only the most commonly used classifications are discussed in this chapter. The first classification for Lisfranc injuries was published by Quenu and Küss in 1909. They classified these injuries into three groups based on the direction of the metatarsal dislocation, and the most commonly used classifications are still based on this concept.

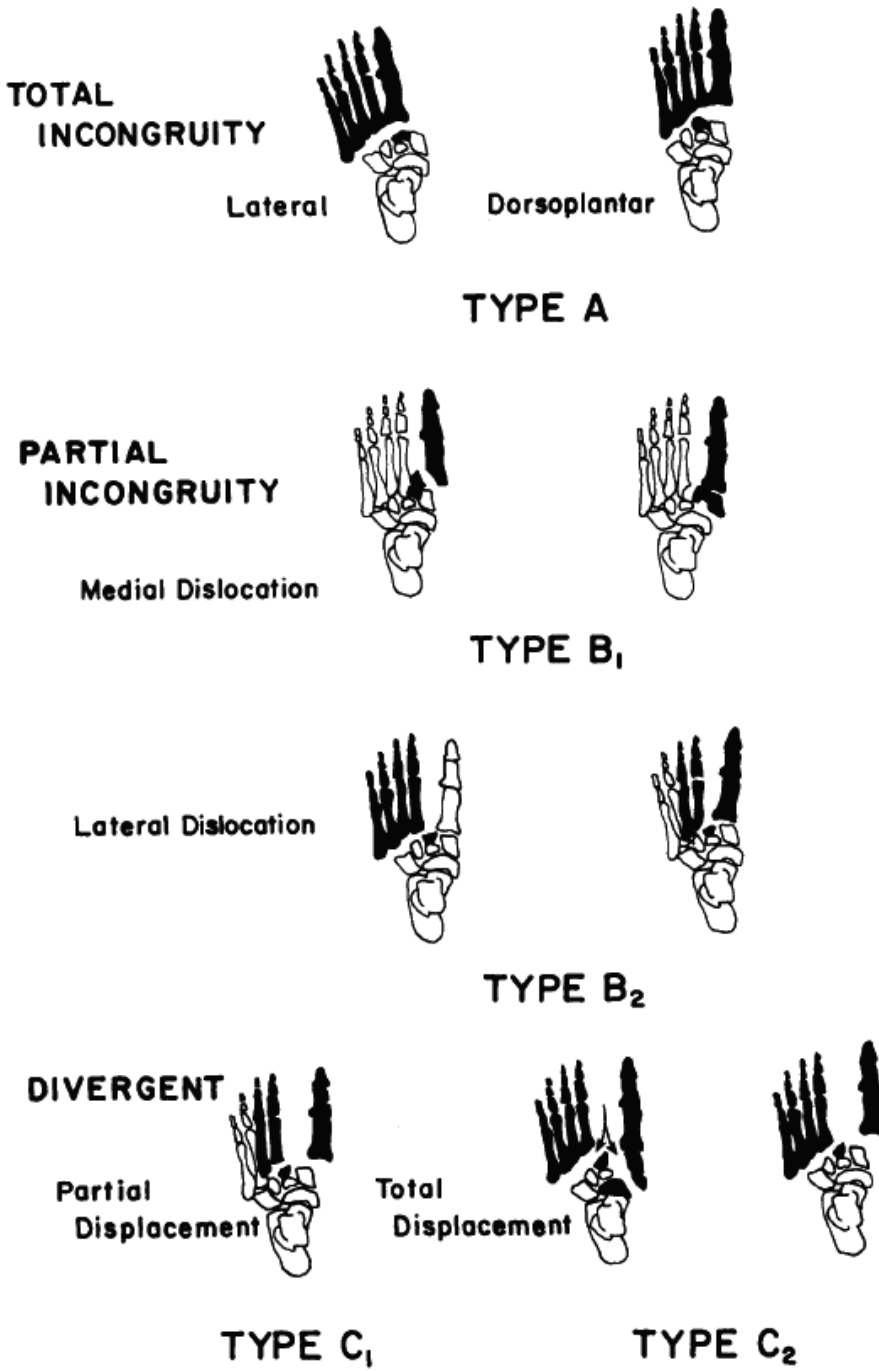
Hardcastle et al. (1982) adjusted this classification and categorized these injuries into A, B, and C types based on the dislocation of the columns in the midfoot. In Type A (total incongruity) injuries, the whole metatarsal row is completely dislocated. The direction of the dislocation can be either medial or lateral. In Type B (partial incongruity) injuries, the dislocation is incomplete because only parts of the metatarsal row dislocate. Type B is further divided into medial and lateral dislocations. In medial dislocation, only the first metatarsal bone dislocates in medial direction. In lateral dislocation, one or more of the second, third, or fourth metatarsal bones dislocate in lateral direction. In Type C injuries, the first metatarsal and the other four metatarsals are dislocated in different directions.

Myerson et al. improved on Hardcastle's classification in 1986 (Figure 5). They categorized B and C types into two subgroups. In Type B1 (medial dislocation) injuries, either the first metatarsal bone or the first metatarsal bone with the medial cuneiform dislocates in medial direction. In Type B2 (lateral dislocation) injuries, either one or more of the lateral four metatarsals or the metatarsals from first to third dislocate in lateral direction. In Type C1 (partial displacement) injuries, one or more of the lateral four metatarsals dislocate in lateral direction and the first metatarsal dislocates in medial direction. In Type C2 (total displacement) injuries, the first metatarsal and the four lateral metatarsals dislocate in opposite directions. Myerson et al. suggested that the name "Lisfranc joint complex" should be used because these injuries often included damage between the cuneiform, navicular, and cuboid bones, not only the TMT joints.

The interobserver reliability of the Hardcastle classification has been evaluated by Talarico et al. 2006 (Talarico, Hamilton, Ford, & Rush, 2006) and the inter- and intraobserver reliability of the Myerson version of the classification by Mahmoud et al. in 2015 (Mahmoud et al., 2015). Talarico et al. reported a kappa value of 0.54 indicating moderate interobserver reliability for the classification (0.00 to 0.20, slight agreement; 0.21 to 0.40, fair agreement; 0.41 to 0.60, moderate agreement; 0.61 to

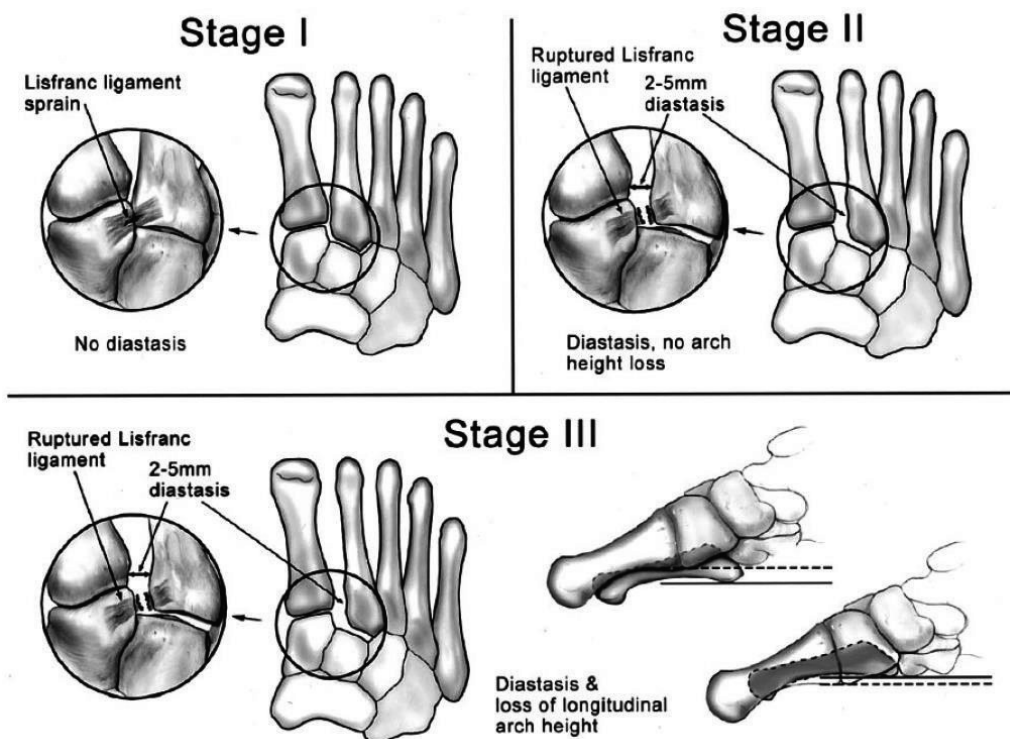


0.80, substantial agreement; and 0.81 to 1.00) (Landis & Koch, 1977; Talarico et al., 2006). Mahmoud reported an intraclass correlation coefficient (ICC) from 0.83 to 0.96 indicating excellent interobserver reliability and an ICC from 0.62 to 0.92 (Mahmoud et al., 2015). High intra- and interobserver reliability may result from the characteristics of the used patient sample. If the patients have severely displaced injuries, they can be easily diagnosed from radiographs, and therefore they are clear enough to be classified precisely.



**Figure 5.** The classification for Lisfranc injuries by Myerson et al. (1986), modified from the classifications by Quenu and Küss and Hardcastle. (copyright SAGE publications. Published with permission from SAGE publications)

Nunley and Vertullo (2002) approached the classification from a different view point, as the previous classifications only accounted for high energy injuries (Figure 6). They created a classification for ligamentous Lisfranc injuries based on weightbearing radiographs. The injuries were categorized into three stages. In Stage I injuries, there was no dislocation between the medial cuneiform and the base of the second metatarsal, and the patient was able to bear weight on the affected limb. However, they reported that there were still findings in bone scintigrams that indicated a sprain of the Lisfranc ligament. In Stage II injuries, the dislocation is from 1 to 5 mm, yet the arch height of the foot is restored in the lateral weightbearing radiographs. In Stage III injuries, the dislocation between the medial cuneiform and the second metatarsal bone is over 5 mm and the arch height is decreased. The loss of height can be detected from the lateral weightbearing radiographs because the distance between the fifth metatarsal and the medial cuneiform is decreased. In their classification, the fracture morphology is not taken into account and only the displacement between the medial cuneiform and the second metatarsal base matters.



**Figure 6.** The classification for subtle Lisfranc injuries by Nunley and Vertullo (2002). (copyright SAGE Publications. Published with permission from SAGE publications)

Sivakumar et al. (2018) published a classification that was developed to cover both subtle and severe injuries. Basically, the Nunley and Vertullo classification was applied to the Myerson classification as a new group: Type D. Type D injuries are divided into Type D1 (no diastasis) and Type D2 (>2 mm of diastasis). This classification was a combination of previous classifications and did not provide any new information.

Chiodo and Myerson published a brand-new perspective on the classifications of these injuries in 2001. They divided the joint into three columns similar to the classification by De Palma et al. (1997). Type A includes the medial column (first metatarsal), Type B includes the central column (second to third metatarsals), and Type C includes the lateral column (fourth to fifth metatarsals). They explained that it is not wise to think of metatarsal bones as individual units since the bones of the columns have common characteristics and it would be unusual for only one bone of the column to be affected.

Lau et al. (2017) further developed the classification by Chiodo and Myerson. This classification was the first to be based on CT imaging. They used the columnar approach and divided the injuries according to the number of affected columns. They presented five categories: 1 - single affected column, with or without sagittal displacement over 2 mm. 2 - two columns are affected, either without sagittal displacement (2A) or with at least 2 mm of sagittal displacement in one of the affected columns (2B). 3 - all three columns are affected, either without sagittal displacement (3A) or with at least 2 mm of sagittal displacement in one of the affected columns (3B).

Schepers and Rammelt (2018) published a review of the literature and a new classification. They proceeded with the columnar approach, presenting a system for the severity of the injury: the injuries are classified in the form of Mx-Cy-Lz, where M is for medial column, C is for central column, and L for lateral column. The characters x, y, and z are represented as numbers, where 0 means joint not included, 1 means purely ligamentous injury with or without avulsion fractures, 2 means simple fracture and 3 means comminuted fracture with involvement of over 50% of the articular surface.

Though the previous literature provides multiple classifications for these injuries, we have to conclude that all of the classifications fail to provide any prediction of the prognosis after treatment and they do not offer any guidelines on how these injuries should be treated to achieve the best result for the patient. Therefore, we are still lacking a single reliable classification system for these injuries. The classification

by Myerson et al. is the only classification with tested inter- and intraobserver reliability with moderate results (Mahmoud et al., 2015; Talarico et al., 2006).

## 2.4.2 Chopart injuries

Main and Jowett published a descriptive fracture classification for Chopart injuries in 1975. Interestingly, since then, no other classifications on Chopart injuries have been published. Main and Jowett categorized these injuries into five categories according to the direction of the trauma energy: medial, longitudinal, lateral, plantar, and crush injuries. All categories are further divided into subcategories depending on the severity of the injury.

Medial injuries occur when medial forces are applied, causing a fracture-sprain, fracture-subluxation, fracture-dislocation, or a swivel dislocation type injury. Medial fracture sprains may present 'snowflake' fractures of the dorsal side of the talus or navicular bone and the lateral side of the calcaneus or cuboid bone. Medial fracture-subluxations and dislocations occur when the forefoot is forced to displace medially and the hindfoot stays in the neutral position. Medial swivel dislocations are caused by strong medial force, and the talonavicular joint is disrupted, but the calcaneocuboid joint remains intact. (Main & Jowett, 1975)

Longitudinal injuries occur when the foot is plantar-flexed during the impact and the energy follows through the metatarsals, causing a compression of the navicular bone in between the talar head and the cuneiform bones. This causes one or more vertical fracture lines in the navicular bone, depending on the energy of the trauma. Longitudinal injuries with medial compression may occur if there are also longitudinal forces affecting the lateral rays. These forces may push the forefoot medially, causing a lateral crush fracture to the lateral fourth of the navicular bone and medial dislocation of the medial part of the navicular bone. The longitudinal forces may also cause a wide range of injuries around the talonavicular joint, ranging from avulsion fractures to severe crush fractures. (Main & Jowett, 1975)

Lateral injuries occur when lateral forces are applied, causing fracture-sprains or swivel dislocations. Fracture-sprains result from falling from low height, causing the forefoot into valgus-positioned dislocation, and crushing the calcaneocuboid joint. Lateral swivel dislocation, similarly to medial swivel dislocation, is caused by lateral force which laterally dislocates the talonavicular joint, yet the calcaneocuboid joint remains intact. (Main & Jowett, 1975)

Plantar injuries occur when the foot is trapped under the body or a heavy object. A strong plantar force causes either fracture-sprains or fracture-subluxations and dislocations. In fracture-sprains, avulsion fractures to the dorsal side of the navicular, talar, or the anterior process of the calcaneal bone are seen. Fracture-dislocations are caused by high force inducing plantar subtalar dislocation and a rupture of the interosseous talocalcaneal ligament. Crush injuries were reported to result from high energy trauma, such as motor vehicle injuries, although a constant pattern was not detected. (Main & Jowett, 1975)

Although the classification by Main and Jowett is the only classification for Chopart injuries, it was developed based on a study sample of only 31 patients, and therefore the results of the study must be interpreted with caution. The classification describes the trauma mechanisms properly, yet the choice of appropriate treatment option and the prognosis after treatment are lacking.

## 2.5 Diagnostics of Lisfranc injury

### 2.5.1 Clinical signs

Severe Lisfranc injuries are obvious due to the traumatic history and very distinct clinical findings (Eleftheriou et al., 2013). Subtle Lisfranc injuries, however, may be challenging to detect due to a less traumatic history and less distinct clinical findings (Welck et al., 2016). The most typical clinical signs of Lisfranc injury are swelling, tenderness, and pain in the midfoot (Curtis et al., 1993). Increased tenderness across the midfoot during passive plantar flexion or dorsiflexion simultaneously with passive pronation and abduction of the forefoot can indicate Lisfranc injury (Curtis et al., 1993). Ross et al. (1996) were the first to describe the “plantar ecchymosis sign”. This term refers to a round ecchymosis area in the middle of the plantar side of the foot that may be visible in patients who have a significant Lisfranc injury (Ross et al., 1996). The “gap” sign was described by Davies and Saxby in 1999, and it refers to an extended space between the first and second toe in weightbearing. The gap sign may be prevalent if the Lisfranc ligament is ruptured during injury (Davies & Saxby, 1999). Keiserman et al. introduced a clinical test called the “Piano key test” in 2003. The Piano key test is performed by fixing the midfoot and the hindfoot and then applying a dorsal force towards the plantar side of the foot to an individual metatarsal bone, as if striking a piano key (Keiserman et al., 2003). The test is

considered to be positive if the applied force causes localized pain in the metatarsal base (Keiserman et al., 2003).

## 2.5.2 Conventional radiographs

Lisfranc injuries are known to be injuries that are easily overlooked (Arntz et al., 1988; Calder, Whitehouse, & Saxby, 2004; Englanoff, Anglin, & Hutson, 1995; Goossens & Stoop, 1983). It has been suggested that between 20% and 76% of Lisfranc injuries can be missed at initial evaluation (Haapamaki et al., 2004a; Myerson et al., 1986; Preidler et al., 1999). Since the first description of these injuries in 1909, conventional radiographs have been the primary diagnostic tool for Lisfranc injuries (Quenu E, 1909). As the evaluation of the Lisfranc joint can be difficult due to overlapping bones and articulations, it has been suggested that multiple projections are used to achieve the best view (Norfray, Geline, Steinberg, Galinski, & Gilula, 1981). It has been suggested that anteroposterior (Figure 7A) and lateral (Figure 7C) projections are used to detect the displacement in dorsoplantar and lateral directions of the first two TMT joints (Englanoff et al., 1995; Norfray et al., 1981; Vuori & Aro, 1993). Moreover, oblique (30-45 degrees) (Figure 7B) projection is recommended for a better view of the third, fourth, and the fifth TMT joints (Figure 7B) (Englanoff et al., 1995; Norfray et al., 1981; Vuori & Aro, 1993).



**Figure 7.** Anteroposterior (A), oblique (30-45 degrees) (B), and lateral (C) radiograph projections of the foot.



In 1976, Foster and Foster performed a study where they compared 6 Lisfranc injuries to 200 normal radiographs of the foot. They concluded that the evaluation of the second TMT joint is the most reliable from the radiographs, as it is involved in most Lisfranc injuries. However, the widening of the first and second metatarsal bases should not be considered as an injury if there is not a step-off between the second metatarsal base and the medial cuneiform bone. (Foster & Foster, 1976)

The “Fleck sign”, a bony avulsion of intra-articular bone between the first and the second metatarsal bases in conventional radiographs, was introduced by Myerson et al. in 1986. The bony avulsion arises from either the first or the second metatarsal base or from the medial cuneiform bone. They suggested that the fleck sign prevents closed reduction, and therefore better outcomes can be obtained using open reduction and Kirchner-wire reduction. They estimated that the fleck sign can be detected radiologically in 90% of cases where the dislocation between first and second metatarsal is greater than 4 mm. (Myerson et al., 1986)

Sherief et al. (2006) evaluated the accuracy of the diagnosis based on conventional radiography. Nine senior clinicians (3 radiologists, 3 orthopaedic surgeons, 3 accident doctors) reviewed 30 sets of foot radiographs which contained 18 Lisfranc injuries. Only 11 of 18 (61%) cases were identified by all evaluators. The sensitivity was on average 92% (95% confidence interval: 89-95%) and the rate of missed injuries was 19% (Sherief et al., 2007). Despite the small sample size, the results were significantly better than the previous results reported by Haapamäki et al. (2004) who estimated the sensitivity of conventional radiographs to be 76%. It must also be taken into account that sensitivity is associated with the severity of the injuries included in the study. Regardless, both of these studies concluded that if there is any suspicion of Lisfranc injury, it is recommended to proceed with CT (Haapamaki et al., 2004a; Sherief et al., 2007).

### 2.5.3 Weightbearing radiographs

The disadvantages of conventional radiographs have been discussed in the previous literature, as they seem to only detect severe incongruity (Foster & Foster, 1976;

Goossens & Stoop, 1983; Norfray et al., 1981; Stein, 1983). For higher sensitivity to detect subtle injuries of the TMT joint, weightbearing radiographs (or stress radiographs) have been suggested (Arntz et al., 1988; Coss et al., 1998; Curtis et al., 1993; Goossens & Stoop, 1983). Furthermore, it has been proposed that the false-negative findings of weightbearing radiographs may result from the fact that weightbearing is often not tolerated due to pain (Vuori & Aro, 1993). Therefore, it has been proposed that weightbearing radiographs be obtained under anesthesia to relieve the pain (Arntz et al., 1988; Curtis et al., 1993). However, it has been estimated that up to 81% of patients with severe Lisfranc injury also have other lower extremity injuries, and thus it might be impossible to obtain the weightbearing images (Myerson et al., 1986; Vuori & Aro, 1993). Despite the support for weightbearing radiographs (Arntz et al., 1988; Coss et al., 1998; Curtis et al., 1993; Nunley & Vertullo, 2002), to date there has only been one study that has compared the radiological findings of non-weightbearing and weightbearing radiographs among the same patient sample (Preidler et al., 1999). This study showed that there were no differences in the number of detected displacements or fractures between the imaging techniques (Preidler et al., 1999). However, they only obtained the weightbearing radiographs only during the primary visit, and no radiographs were obtained at a later stage (Preidler et al., 1999). A recent study showed that the displacement between the medial cuneiform and the second metatarsal base was not detectable from weightbearing radiographs until a median of 18 days after the injury (Chen et al., 2020).

#### 2.5.4 Computed tomography (CT)

The study by Goiney et al. (1985) was the first to suggest CT as an imaging modality for the detection of Lisfranc injuries. They concluded that CT provides multiple advantages when compared with conventional radiographs. In CT, it is possible to produce images in a variety of planes, which is impossible with conventional radiography. Other advantages of CT imaging are the detection of small intra-articular or avulsion fragments and joint displacements. Therefore, it is possible to detect injuries that would have been missed using conventional radiography. (Goiney et al., 1985)

After the study by Goiney, the use of CT slowly gained more popularity for the imaging of midfoot injuries (Leenen & Van der Werken, 1992). In 1997, Lu et al.

showed that diastasis of 1 mm could not be detected in conventional radiography, yet it was detectable in CT. In their study, 66% of patients with 2 mm displacement were missed using conventional radiography (Lu, Ebraheim, Skie, Porshinsky, & Yeasting, 1997).

It has been argued that although CT has higher sensitivity and provides accurate anatomic details, it should not replace the stress radiographs because CT cannot be used to detect instability in the Lisfranc joint (Chiodo & Myerson, 2001). Evidence supporting the use of weightbearing radiographs is, however, scarce, and multiple studies have suggested that CT is the most sensitive imaging modality for the detection of Lisfranc injuries (Goiney et al., 1985; Haapamaki et al., 2004a, 2004b; Li et al., 2017; Preidler et al., 1999).

### 2.5.5 Magnetic resonance imaging (MRI)

Magnetic resonance imaging has been proposed as a useful tool to detect ligamentous Lisfranc injuries (Nunley and Vertullo Stages I-III) (MacMahon et al., 2009; Potter et al., 1998; Preidler et al., 1996a; Preidler et al., 1996b; Raikin et al., 2009). The advantages of MRI include the extent of the visualization of the soft-tissues and ligaments around the Lisfranc joint (Potter et al., 1998; Preidler et al., 1996a; Preidler et al., 1996b). Furthermore, MRI is suggested to be the best imaging modality to detect a rupture of the Lisfranc ligament (Potter et al., 1998; Preidler et al., 1996a; Preidler et al., 1996b). However, some studies have reported difficulties in differentiating a normal Lisfranc ligament from a subtle ligament sprain (MacMahon et al., 2009; Preidler et al., 1999). Potter et al. (1998) suggested that MRI can be a useful tool to detect a rupture of the Lisfranc ligament in patients who have displacement under 2 mm between the first and the second metatarsal bones. If the displacement is more than 2 mm, the displacement can be seen in conventional radiographs, and therefore MRI is unnecessary (Potter et al., 1998).

To the best of our knowledge, the study by Preidler et al. (1999) is the only study to compare the diagnostic differences between MRI and CT imaging among the same patient sample. In their study, 49 patients with Lisfranc injuries were evaluated. CT detected 53 metatarsal fractures and MRI revealed 41. Both imaging modalities detected the same number of joint malalignments (n=16). In 11 (22%) cases, it was impossible to confirm rupture of the Lisfranc ligament due to edema of the surrounding tissues. Their conclusion was that CT is the most sensitive imaging modality to detect Lisfranc injuries, and MRI did not provide any benefit in the

detection of these injuries or change in the chosen treatment. They did not report any purely ligamentous injuries that would have been missed with CT. (Preidler et al., 1999)

## 2.5.6 Weightbearing cone beam computed tomography (WBCBCT)

Weightbearing cone beam computed tomography (WBCBCT) is the newest imaging modality in foot and ankle surgery. Reduced costs and lower radiation dose combined with a device that is easily movable and provides high image quality are the benefits of CBCT. In theory, weightbearing CBCT could combine the benefits of weightbearing radiographs and the precision of CT. However, more studies are needed to identify the real advantages and capabilities of weightbearing CBCT. (Penev et al., 2020; Tuominen, Kankare, Koskinen, & Mattila, 2013)

## 2.5.7 Instability

Instability of the Lisfranc joint has been proposed to be an indication for surgical treatment (Arntz et al., 1988; Raikin et al., 2009; Seo, Lee, Lee, Lee, & Kim, 2017). It has been suggested that the isolated rupture of the dorsal Lisfranc ligament does not produce a detectable instability of the foot because both the interosseus and the plantar ligament have to be ruptured to produce instability (Kaar et al., 2007). Although multiple methods have been suggested to detect instability, the reference method remains intraoperative testing under fluoroscopy (Raikin et al., 2009). As instability is one indication for surgical treatment, it is essential to have a reliable method to evaluate the instability prior to surgery (Raikin et al., 2009). Weightbearing radiographs and MRI imaging have both been suggested as such a method (Arntz et al., 1988; Coss et al., 1998; Curtis et al., 1993; Goossens & Stoop, 1983; Raikin et al., 2009), but the poor sensitivity to detect the bony fractures of both modalities supports the use of CT instead (Preidler et al., 1999). Additionally, weightbearing ultrasound has also been suggested, but the lack of evidence has restricted its popularity (Graves, Rettedal, Marshall, Frush, & Vardaxis, 2014). Weightbearing CBCT is one possible future option, but the technique has not yet been tested in detecting instability of the Lisfranc joint (Tuominen et al., 2013).

The effectiveness of different imaging techniques for the detection of Lisfranc joint instability were evaluated by Kaar et al. in 2007. Ten cadaveric feet were examined with weightbearing, abduction, and adduction stress radiographs before and after dissection of the Lisfranc ligament. The abduction test was performed by keeping the ankle in plantar flexion, then turning the second metatarsal head to abduction, while turning the calcaneus in the opposite direction while pushing the calcaneocuboid joint with a thumb. The adduction stress test was also performed in plantar flexion, and the first metatarsal head was turned into adduction and pronation while the other hand provided counter pressure to the calcaneus while adding pressure with a thumb medially over the navicular bone. The injuries were divided into two groups: transverse injury (sectioning the plantar ligament between the medial cuneiform and the second and the third metatarsal bases) and longitudinal injury (sectioning the interosseus ligament between the first and second cuneiforms). The adduction stress test was used to detect the longitudinal injury and the abduction stress test to detect the transverse injury pattern. They tested different settings and investigated which techniques enabled the detection of the instability (widening of 2 mm or more between the medial cuneiform and the base of the second MT). They concluded that the transverse injury pattern was detected by abduction stress radiography in every specimen, whereas they were detected by weightbearing radiographs in only one out of five specimens (20%). Nevertheless, the longitudinal injury pattern was detected correspondingly in one out of five specimens (20%) using weightbearing radiographs and adduction stress radiographs. (Kaar et al., 2007)

Although stress evaluation under fluoroscopy has been the reference or gold standard for the testing of instability, evidence on how to perform and interpret this technique is scarce (Naguib & Meyr, 2018). Naguib and Meyr (2018) evaluated the reliability of abduction stress radiography among 12 surgeons, 12 residents, and 12 students. The kappa value for interobserver reliability was 0.28 (surgeons: 0.18; residents: 0.42; students: 0.26). The results indicated fair agreement, even though they only used three specimens, two still images, and one video. All of the surgeons and 67% of the residents reported that they used stress radiographs as a part of their normal diagnostic protocol. The poor results are therefore interesting since the use of stress radiographs has been proposed to be the gold standard for evaluating instability and for making the decision to proceed with surgery. Interestingly, the results of the surgeons were notably lower than the results of the medical students, even though the surgeons reported using the method frequently. Moreover, this study presents a couple of notable limitations. For example, they did not present a threshold value for instability that was established beforehand and therefore the

observers categorized the findings subjectively as “positive” or “negative”. Furthermore, the study design did not include a view of the contralateral foot, nor were the observers able to examine the feet themselves. As a result, the study setting differs markedly from daily clinical practice. (Naguib & Meyr, 2018)

Although instability has been suggested to be the main indication for surgery, the current methods used to detect it needs further investigation before they can be reliably used in daily practice.

## 2.6 Outcome measures

Physical symptoms, functioning, and disability are an important part of the quality of life. The aim of medical and more specific surgical treatment should therefore be focused on relieving the symptoms, improving the functioning, and reducing the disability of patient using the most cost-effective treatment methods. As quality of life can be judged from both the objective and subjective point of views, it is crucial to also evaluate the outcomes after treatment from the patient’s point of view. (Testa & Simonson, 1996)

Since evidence-based medicine was first introduced in 1992, the evaluation of the outcomes of treatment with outcome rating scales has gained more interest (Garratt, Schmidt, Mackintosh, & Fitzpatrick, 2002; Guyatt, Cairns, Churchill, & et al., 1992; Hunt & Hurwit, 2013). The benefits of using outcome rating scales include evaluating the differences between patients with similar conditions and evaluating the effectiveness of different treatments in clinical trials, and benchmarking the patients (Button & Pinney, 2004; Nelson et al., 2015). Patient-reported outcome measures (PROMs) are nowadays frequently used outcome measures in evaluating outcomes after foot surgery (Button & Pinney, 2004; Hunt & Hurwit, 2013). Because the use of the PROMs has become more common, COnsensus-based Standards for the selection of health status Measurement INstrument (COSMIN) published a checklist to assess the validity of the instruments. The instrument should fulfill the checklist criteria before it can be reliably used in the evaluation of the outcomes. Reliability, validity, responsiveness, and interpretability of all the instruments should be evaluated before the validity of the instrument is assessed by applying the methods of item response theory (Mokkink et al., 2010b).

Before validated PROMs were adopted, outcomes after surgery were evaluated using various techniques. Some studies focused on secondary surgery or reoperations, which is an objective way to evaluate the success of treatment. One of

the first evaluation systems for foot injuries was presented by Main and Jowett in 1975. In their study, clinicians classified the outcomes after surgery in four classes based on residual pain, stiffness, and impairment of function. Excellent indicates the absence of symptoms or signs, Good indicates minor symptoms or signs, Fair indicates residual symptoms and signs with some disability, and Poor indicates marked symptoms and limitations of function. Although the classification has been used in multiple studies, it is a subjective way to evaluate outcomes and its validity has not been proven. (Main & Jowett, 1975)

There are at least 139 different PROMs used in foot and ankle surgery (Hunt & Hurwit, 2013). Of these, the American Orthopaedic Foot & Ankle Society (AOFAS) Clinical Rating Systems are to date the most extensively used foot and ankle PROMs (Hunt & Hurwit, 2013; Kitaoka et al., 1994). However, the validity and reliability of the AOFAS Clinical Rating Systems have been shown to be poor (Pinsker & Daniels, 2011; SooHoo, Shuler, & Fleming, 2003). Indeed, even the developers of the AOFAS scales no longer recommend their use (Kitaoka et al., 2018).

There are, however, multiple valid and reliable instruments that can be used to evaluate the outcomes after foot and ankle surgery. For example, the Visual-Analogue Foot and Ankle (VAS-FA), European Foot and Ankle Society Score, Foot Function Index, Ankle Osteoarthritis Scale, Foot and Ankle Disability Index, Foot and Ankle Ability Measure, Short Musculoskeletal Function Assessment, and Foot and Ankle Outcome Score are shown to have acceptable validity (Richter et al., 2018; Richter et al., 2006; Shazadeh Safavi et al., 2018). Even though the validity of all of these instruments have been evaluated for foot and ankle surgery, the AOFAS scoring systems are still the most commonly used (Hunt & Hurwit, 2013; Kitaoka et al., 1994). Due to this inconsistency, there is a lack of consensus on which PROM to use to evaluate the outcomes after foot and ankle surgery.

## 2.7 Treatment of Lisfranc injuries

Since the divergence among these injuries is wide, there is no single evidence-based policy to treat Lisfranc injuries (Qiao et al., 2017). When the first classifications of Lisfranc injury were presented, they were considered to be totally or partially displaced injuries (Hardcastle et al., 1982; Myerson et al., 1986). Therefore, the best results were achieved with exact anatomic reduction and internal fixation (Myerson et al., 1986; Nunley & Vertullo, 2002). After the widening of the definition and the

introduction of subtle Lisfranc injuries, the treatment of these injuries has changed (Nunley & Vertullo, 2002).

The first treatment algorithm for choosing the treatment for Lisfranc injuries was developed by Chiodo and Myerson in 2001. Their algorithm was based on evaluating the instability from weightbearing radiographs. They suggested that patients with injuries with more than 2 mm of displacement between the medial cuneiform and the second MT bones in weightbearing radiographs should be treated with open reduction and internal fixation (ORIF). If a patient has 2 mm or less displacement, the weightbearing radiographs should be repeated after 10 to 14 days and the instability evaluated again. If the injury still seems to be stable and the pain is decreasing, it can be treated non-operatively. Although the algorithm was the first to provide clear guidance for choosing suitable treatment for Lisfranc injury, the authors did not provide the scientific evidence behind the algorithm (Chiodo & Myerson, 2001).

Since the weaknesses of weightbearing radiographs had been demonstrated (Preidler et al., 1999), Raikin et al. (2009) developed an algorithm for treating Lisfranc injuries based on MRI imaging. Their suggestion was to treat all patients who had a torn/grade 2 sprain in the plantar ligament between the medial cuneiform and the second and the third metatarsal bones (pC1-M2M3) operatively. If the same ligament was intact or had only grade 1 sprain and there was fleck sign, the instability should be tested with stress radiographs under anesthesia. If the joint was unstable, it should be treated with open reduction and internal fixation, and if it was stable, it could be treated non-operatively. Patients with intact/grade 1 sprains on the pC1-M2M3 without fractures could be treated non-operatively without stress radiographs. Similar to the algorithm by Chiodo and Myerson, the scientific evidence behind this algorithm is lacking (Raikin et al., 2009).

### 2.7.1 Non-operative treatment

The current literature does not provide any randomized controlled studies (RCT) investigating non-operative versus operative treatment for Lisfranc injuries, and thus the treatment of subtle injuries (< 2 mm of displacement) is controversial (Crates et al., 2015; Faciszewski et al., 1990; Meyer et al., 1994; Nunley & Vertullo, 2002; Shapiro et al., 1994). Even though some stable injuries might need temporary immobilization, surgery has also been recommended for even minimally displaced injuries (Myerson et al., 1986; Nunley & Vertullo, 2002). There is consensus,



however, that poor functional outcomes are associated with delayed diagnosis or the inadequate treatment of instable or displaced injuries (Stavlas et al., 2010; Weatherford, Anderson, & Bohay, 2017). It has been argued that inadequately treated or missed non-dislocated injuries may also lead to substantial disability, deformity, and dysfunction (Curtis et al., 1993).

The current literature on non-operative treatment only includes retrospective case-series and cohort studies with relatively small patient samples (Crates et al., 2015; Curtis et al., 1993; Faciszewski et al., 1990; Myerson et al., 1986; Nunley & Vertullo, 2002; Shapiro et al., 1994) (Table 1). For example, the study by Myerson et al. (1986) presented results after the non-operative treatment of dislocated Lisfranc injury. A total of 5 from 52 patients were treated non-operatively because they were initially missed. Four of the patients resulted in a poor result and one resulted in a fair result according to the Painful Foot Center scoring systems (Myerson et al., 1986). Nunley and Vertullo (2002) performed a study in 15 patients with subtle Lisfranc injuries, where seven patients were treated non-operatively. They suggested that only non-dislocated injuries (Stage 1) should be treated non-operatively and the injuries with displacement (Stage 2, >2 mm) between the first and second metatarsal should be treated with open or closed reduction and internal fixation (Nunley & Vertullo, 2002). Naturally, the possibility of selection bias must be kept in mind when interpreting these results.

Curtis et al. (1993) published a study investigating the treatment of subtle Lisfranc injuries in athletes. From 19 patients, 14 stable injuries were treated non-operatively. Patient reported outcome measures were not used in this study, and the authors classified the outcomes of treatment themselves as follows: absence of symptoms was considered as excellent, minor symptoms or signs was considered as good, residual signs of symptoms with some disability was considered as fair, and marked symptoms or signs with disability was considered as poor. The results were excellent with six patients, good with three patients, fair with four, and poor with one patient. The non-operative protocol used was very heterogenous ranging from “none” to “cast for ten weeks”. (Curtis et al., 1993)

**Table 1.** Previous studies including nonoperatively treated Lisfranc injuries.

Study	Patients	Intervention	Primary outcome	Secondary outcomes	Results	Other
Myerson et al. 1986	5 Lisfranc fracture dislocations based on conventional radiographs.	No treatment	Foot Function Form	-	Painful Foot Center (PFC) score: four had Poor result and one had Fair.	The patients had either missed diagnosis or were overlooked, and therefore did not receive any treatment
Faciszewski et al. 1990	13 subtle Lisfranc injuries with diastasis (2-5 mm) between the medial cuneiform and 2 <sup>nd</sup> metatarsal base in weightbearing radiographs.	Below-knee cast immobilization from 3 to 7 weeks (n=9), ORIF (n=2) or no treatment (n=4)	Evaluation system by Hardcastle et al.	-	Cast: 5 Good, 2 Fair, 2 Poor results. ORIF: 2 Good results. No treatment: 1 Good, 1 Fair and 2 Poor results.	Duration from injury to diagnosis was from 1 month to 1 year.
Curtis et al. 1993	19 athletes with subtle or severe Lisfranc injury based on conventional radiography and stress fluoroscopy.	Cast immobilization from 2 to 8 weeks (n=9), crutches without cast from 2 to 4 weeks (n=2), ORIF	Main and Jowett criteria	-	Cast: 4 Excellent, 1 Good, 3 Fair, 1 Poor Crutches without cast: 1 Excellent, 1 Good. ORIF: 4 Excellent, 1 Good, 1 none:1 Excellent, 1 Good, 1 Fair.	The subtle injuries were classified in 3 groups, severe injuries according to Myerson et al. Resulting in heterogeneous patient sample.

	(n=5) or none (n=3)				
Shapiro et al. 1994	9 elite athletes with diastasis (2-5 mm) between the 1 <sup>st</sup> and 2 <sup>nd</sup> TMT joints in weightbearing radiographs.	Splint for 6 weeks (n=7), ORIF (n=1) or none (n=1)	Return to sports (weeks)	-	Cast: average 12 weeks. ORIF: 24 weeks. none: 20 weeks. Average follow-up was 34 months.
Nunley and Vertullo 2002	15 athletes: 7 with positive scintigraphy (normal weightbearing radiographs), 8 with diastasis (2-5 mm) between the medial cuneiform and 2 <sup>nd</sup> metatarsal base in weightbearing radiographs	Cast for 6 weeks (n=7), early CRIF (n=6) or late ORIF (n=2)	Main and Jowett criteria	-	Cast: 7 Excellent, early CRIF: 6 Excellent late ORIF: 1 Excellent, 1 Good All nonoperatively treated patients were diagnosed with bone scintigraphy. Average follow-up was 27 months.
Crates et al. 2015	36 patients with tenderness and pain in the 1 <sup>st</sup> and 2 <sup>nd</sup> TMT region, weightbearing radiographs findings from none to up to 2 mm of diastasis between the medial cuneiform and 2 <sup>nd</sup> metatarsal base	orthosis for 6 weeks with weightbearing allowed as tolerated (n=36)	Conversion to operative treatment (surgeons' decision)	AOFAS Midfoot Scale	20/36 (56%) patients were converted to fixation with screws either mini Tight-Rope. AOFAS score, mean (range): Nonoperative 75.3 (53-100); Converted to operative treatment 92.3 (72-100). Clinical diagnosis without findings in weightbearing radiographs. 'Failed' nonoperative treatment was determined by a surgeon.

Crates et al. (2015) presented a retrospective cohort study investigating the nonoperative treatment of subtle Lisfranc injuries. Altogether, 36 athletes were treated non-operatively with orthosis for six weeks, and weightbearing was allowed as tolerated. The injury diagnosis was based on clinical evaluation, i.e., if the patient had tenderness and pain in the medial TMT region combined with positive piano key test, diagnosis was confirmed without any radiological findings. Patients were then categorized into 5 groups by weightbearing radiographs. The first group comprised patients without any findings and the fifth group comprised patients with diastasis of less than 2 mm between the second metatarsal base and the medial cuneiform. The treatment was considered successful in 16 patients and the treatment failed in 20 patients, leading to conversion to operative treatment. The failure of the non-operative treatment was subjectively determined by a surgeon and the treatment was considered to have failed if the pain persisted and there were difficulties in returning to previous activities. The improvement in mean AOFAS Midfoot Score after the treatment was higher in the operatively treated patients when compared with non-operative treatment (from 64 to 92,  $p < 0.0001$  vs. from 62 to 75,  $p = 0.0029$ ). They concluded that some of the patients with Nunley and Vertullo Stage 1 injuries may require surgery. The diagnosis and the definition of failed treatment were purely based on the opinion of surgeons causing a significant bias. A further limitation of this study was that they included patients with clinical symptoms without radiographic findings. Therefore, some of these patients may not have even had a Lisfranc injury. (Crates et al., 2015)

There is no consensus on the non-operative treatment protocol for non-dislocated Lisfranc injuries. Nunley and Vertullo (2002) used a protocol where stable injuries were treated non-operatively with a non-weightbearing cast for six weeks. If the patient was painless at 6 weeks, the patient could return gradually to normal activity with an orthosis during the following 4 weeks (Nunley & Vertullo, 2002). In the review by Myerson and Cerrato (2008), they suggested stable injuries should be treated with immobilization in a cast for six to eight weeks. The instability should then be assessed at two weeks with weightbearing radiographs, and if the injury remains stable, operative treatment is not needed. They suggested that weightbearing can be permitted as tolerated during the immobilization (Myerson & Cerrato, 2008).

In the presented studies, the evaluation of outcomes is conducted using non-validated foot and ankle scoring systems (Main and Jowett system, PFC score,

AOFAS Midfoot Scale), the generic health related quality of life instrument (SF-36) or the generic musculoskeletal functioning instrument (SMFA). Indeed, none of these tools have been proven to be valid or reliable in assessing outcomes after the treatment of foot and ankle injuries. Obviously, without valid PROM's and an exact description of non-operative treatment, it is challenging to draw conclusions on the results of non-operative treatment.

## 2.7.2 Operative treatment

Based on retrospective studies, displacement of 2 mm or more between the medial cuneiform and the second MT bone in weightbearing radiographs or stress test has been considered to be a sign of unstable midfoot injury, and it is suggested that these injuries are treated operatively to achieve higher functional outcomes and lower risk for post-traumatic osteoarthritis (Arntz et al., 1988; Curtis et al., 1993; Ebraheim, Yang, Lu, & Biyani, 1996; Faciszewski et al., 1990; Goossens & Stoop, 1983; Hardcastle et al., 1982; Kuo et al., 2000; Myerson, 1999; Ouzounian & Shereff, 1989; Philbin et al., 2003; Rammelt et al., 2008; Shapiro et al., 1994).

Sometimes, the displacement is extensive causing remarkable soft tissue damage (Benirschke, Meinberg, Anderson, Jones, & Cole, 2012; Eleftheriou et al., 2013). In these cases, primary closed reduction is necessary to save the soft tissue. Some patients may require open reduction and fixation with external fixator or Kirchner-wires (K-wire) before the definitive treatment. K-wire fixation (Goossens & Stoop, 1983; Hardcastle et al., 1982; Myerson et al., 1986; Perez Blanco, Rodriguez Merchan, Canosa Sevillano, & Munuera Martinez, 1988) and screw fixation (Arntz et al., 1988; Coetzee & Ly, 2006; Curtis et al., 1993; Kuo et al., 2000) have previously been considered equal treatment options. However, K-wire fixation has resulted in more failures, and hence screw fixation has become the primary choice (Kuo et al., 2000; Lee et al., 2004). Indeed, screw fixation is nowadays considered to be the primary fixation method for Lisfranc injuries (Kuo et al., 2000; Mulier et al., 2002). Dorsal plating has also been suggested as an alternative fixation method, and it has been reported to have similar results as screw fixation (Alberta et al., 2005; Hu, Chang, Li, & Yu, 2014). The suggested benefit of the dorsal plate is that the plate does not damage the articular surface; however, problems with soft-tissue irritation may be more frequent and reoperation to remove the plate may be needed (Alberta et al., 2005). Even though damage to the articular surface is more extensive when using

screw fixation, the clinical significance of the damage remains unknown (Alberta et al., 2005).

There are different policies for postoperative hardware removal. Some authors suggest routine removal at 8 or 12 weeks (Henning et al., 2009; Mulier et al., 2002; Rajapakse, Edwards, & Hong, 2006; Rammelt et al., 2008), whereas others suggest the routine removal only after full recovery (Aronow, 2006; Teng, Pinzur, Lomasney, Mahoney, & Havey, 2002). Bioabsorbable screws have been suggested as an alternative to metal screw fixation, and the results have been similar when compared to metal screws (Ahmad & Jones, 2016).

Even though the treatment of Lisfranc injuries has changed over the years, the importance of achieving anatomic reduction was noted years ago (Cassebaum, 1963). This finding has also been prevalent in more recent studies, where patients with non-anatomical reduction have developed post-operative osteoarthritis more often and resulted in lower clinical scores (Arntz et al., 1988; Buzzard & Briggs, 1998; Kuo et al., 2000; Myerson et al., 1986). Other noteworthy surgical complications are painful and/or broken hardware, nonunion, compartment syndrome, wound healing problems, deep vein thrombosis, the development of painful neuromas, and other causes of chronic pain (Buzzard & Briggs, 1998; Kuo et al., 2000; Ly & Coetzee, 2006; Myerson et al., 1986).

Interestingly, despite appropriate treatment with ORIF, between 40% and 94% of patients seem to develop post-operative osteoarthritis due to damage caused to the articular surface (Arntz et al., 1988; Kuo et al., 2000; Ly & Coetzee, 2006; Mulier et al., 2002; Myerson et al., 1986). However, mild radiographic findings of osteoarthritis have been found to be present in almost every patient treated with ORIF, yet the functional results do not associate with the radiologic findings (Mulier et al., 2002; Myerson et al., 1986). If the foot is painful with the presence of radiological osteoarthritis, conversion to an arthrodesis may be necessary to relieve the pain (Johnson & Johnson, 1986; Mann et al., 1996; Sangeorzan et al., 1990). Primary arthrodesis has been presented to be an option for ORIF to prevent reoperations and the development of painful posttraumatic osteoarthritis (Cochran et al., 2017; Henning et al., 2009; Ly & Coetzee, 2006; Smith et al., 2015).

The current literature only provides two previous RCTs investigating the differences between ORIF and primary arthrodesis (PA) in ligamentous (avulsion fractures) Lisfranc injuries (Table 2). A study by Ly and Coetzee was published in 2006. They recruited 41 patients with fleck sign in conventional radiographs to ORIF or PA groups. All patients with comminuted fractures or dislocation, diabetes mellitus, other substantial foot, ankle, or leg injury, peripheral vascular disease, or

rheumatoid arthritis were excluded. However, the demographic and clinical data of the patients were not presented. Their main finding was that patients treated with ORIF underwent more reoperations, as 16 (25%) patients underwent screw removal and for 5 (25%) patients the treatment was converted to arthrodesis due to deformity and joint degeneration during two years of follow-up. In addition, patients treated with primary arthrodesis had better functional outcomes with regard to AOFAS Score (88 vs. 69 points,  $P<0.005$ ), a higher return to previous activity level (92% vs. 65%,  $P<0.005$ ), and less pain during two years of follow-up. (Ly & Coetzee, 2006)

The second RCT by Henning et al. was published in 2009. They randomized 40 patients with instability or fracture dislocations in weightbearing radiographs to either ORIF or PA groups. Patients with Lisfranc injury within 3 months were included. Diagnosis was based on conventional, weightbearing, or stress radiographs. Patients with major intra-articular fracture pattern, prior injuries, diabetes mellitus, peripheral vascular disease, neuropathy, or autoimmune disease were excluded. The ORIF group included 14 patients and the PA group 18 patients. There were 9 males and 5 females with a mean age of 37 in the ORIF group and there were 12 males and 6 females with a mean age of 40 years in the PA group. The reoperation rate (including screw removals) was significantly higher in the ORIF group (79% vs. 17%). However, statistically significant differences were not detected between the groups in physical function according to the SF-36 (Ware Jr & Sherbourne, 1992) or SMFA (Swiontkowski, Engelberg, Martin, & Agel, 1999) instruments at any follow-up time point. (Henning et al., 2009)

ORIF versus PA has also been studied with meta-analysis by Smith et al. (2015). They stated that ORIF carries a higher risk of hardware removal. There were, however, no statistically significant differences in reoperation rate, functional outcomes, or the development of deformities (Smith et al., 2015). Buda et al. (2018) also found that patients treated with ORIF underwent hardware removal more frequently than patients treated with PA (75% vs 25%). However, no difference was found if the planned removals were not taken into account (30% vs 30%) (Buda et al., 2018).

The cost-effectiveness of ORIF versus PA was evaluated by Albright et al. in 2018. Their results clearly suggest that primary arthrodesis is a more cost-effective treatment option when compared with ORIF (Albright et al., 2018). However, Barnds et al. (2018) presented contradictory results, indicating that ORIF is more effective with lower costs and lower reoperation rate.

The results of the previous two RCTs and the meta-analysis slightly favor the use of primary arthrodesis as the initial treatment option for Lisfranc injury, although no consensus at present exists.



**Table 2.** Previous RCTs investigating the operative treatment of Lisfranc injuries.

Study	Patients	Intervention	Primary outcome	Secondary outcomes	Results	Other
Ly and Coetzee. 2006.	41 patients with a fleck sign in conventional radiographs.	ORIF (n=20) vs primary arthrodesis (n=21)	Secondary surgery	AOFAS Midfoot Scale, VAS pain	Reoperations: Screw removal: ORIF 16/20 (80%), Arthrodesis 4/21 (19%) Secondary fusion: ORIF, 5/20 (25%); Arthrodesis 1/21 (5%). Functional outcomes: AOFAS, mean (range): ORIF, 68.6 (16 – 100) points; Arthrodesis 88.0 (63 – 100) points at 2 years.	Diagnosis based on conventional radiography, all patients with major fractures and dislocation excluded. Open-randomization.
Henning et al. 2009.	40 patients with acute Lisfranc injury based on conventional, weightbearing or stress radiographs. 32 patients remained for follow-up.	ORIF (n=14) vs primary arthrodesis (n=18).	Secondary surgery	Short form 36 (SF-36), Short Musculoskeletal Functioning Assessment (SMFA)	Reoperations: Screw removal: ORIF 11/14 (79%), Arthrodesis 3/18(17%) Secondary fusion: ORIF, 1/14 (7%); Arthrodesis 0/18 (0%). Functional outcomes: SF-36 Physical Functioning, mean: ORIF, 44.0 points, Arthrodesis, 46.7 points after 2 years. SMFA Daily Activity, mean: ORIF, 17.0 points; Arthrodesis, 8.6 points.	Power calculation was not reached (40/60), Diagnosis based on radiographs. High drop-out rate: n=20 (50%) at 2 years follow-up. Screw removal was routinely suggested for the patients.



### 3 AIMS OF THE STUDY

The aim of this study was to study midfoot injuries and to investigate their incidence, injury mechanisms, diagnosis, and treatment.

The specific aims of the studies are as follows:

- 1) To assess the incidence and characteristics of midfoot injuries.
- 2) To assess the inter- and intraobserver reliability, sensitivity and specificity of non-weightbearing radiographs compared with CT in Lisfranc injuries.
- 3) To compare the validity and internal consistency between the AOFAS Midfoot Scale and VAS-FA in patients with Lisfranc injury.
- 4) To examine outcomes after non-operatively treated Lisfranc injuries.
- 5) To present a protocol for a randomized controlled study to compare: a) non-operative versus operative treatment and b) ORIF versus primary arthrodesis in the treatment of acute Lisfranc injuries.

## 4 MATERIALS AND METHODS

The materials for this study were collected retrospectively from the patient records at Tampere University Hospital during a five-year period from 1.1.2012 to 31.12.2016. The prospective data are currently being collected at Tampere University Hospital and at Seinäjoki Central Hospital.

### 4.1 Retrospective data (I, II, III, IV)

To gather the retrospective data, all foot and ankle CT-studies (traditional CT and cone beam CT) performed due to acute injury at Tampere University Hospital and Valkeakoski Hospital were reviewed by two members of the study group (V.P. and H.H.). All CT-scans and the primary radiologic reports were reviewed separately, and any contradictory cases were evaluated together to achieve consensus on all cases. All patients with an injury in the midfoot region in CT were included. Our hospital policy is that a CT scan is always performed when there is a high suspicion of intra-articular midfoot injury based on clinical examination and/or conventional radiographs. Patient characteristics, trauma mechanisms, primary radiological findings, other associated injuries, and the chosen treatment option were reviewed from the electronic patient record systems. Exclusion criteria were initially missed injuries (>30 days), Jones fractures (isolated fractures of the fifth metatarsal base), distal foot injuries (simple metatarsal fractures or injuries only in the metatarsophalangeal joint or toe region), and patients residing outside the catchment area.

The incidence of injuries was calculated based on the annual population of the Pirkanmaa Region, which was obtained from Official Statistics of Finland, an electronic population register. At the end of the data collection in December 2016, the population of the region was 509 279 residents. The incidence is presented per 100,000 person-years. The trauma mechanisms were categorized into low energy and high energy trauma mechanisms, according to previous studies (Renninger et al., 2017; Vuori & Aro, 1993). Tumbling or slipping, tumbling on stairs and sports activities were all considered to be low-energy trauma mechanisms, and falling from

height (at least 1 meter), direct injury, and traffic accidents were considered to be high-energy trauma mechanisms.

#### 4.1.1 CT and CBCT settings (I, II, IV, V)

All patients included in the study underwent either CT or CBCT imaging. CT imaging was performed using a 64-slice or a 128-slice CT-scanner. Both bone and soft tissue rendering was used with 0.5 to 0.63 mm slice thickness. CBCT imaging was performed with extremity CT (Planmed Verity, Planmed Oy, Helsinki Finland) using a limited field of view (FOV) of 12 cm and a slice thickness of 0.2 mm. Image data were analyzed with a GE AW Server workstation and 1 mm true axial, sagittal, and coronal reformates, and 3-dimensional (3D) volume rendering reformates were obtained. Furthermore, similar post-processing for 2-dimensional (2D) and 3D reformates was performed.

#### 4.1.2 Definition of Lisfranc injury (I, II, III, IV)

In our retrospective data, midfoot injuries were categorized into Lisfranc and Chopart injuries. Lisfranc injury was determined to be an injury presenting intra-articular- or avulsion fractures around the TMT joints. All clearly extra-articular fractures of the metatarsals were excluded. Chopart injury was determined to be an injury presenting intra-articular or avulsion fractures affecting the talonavicular and calcaneocuboid joints. Combined or miscellaneous injuries were determined to be injuries that either affected both of these joints or injuries that could not be clearly classified as Lisfranc or Chopart injuries. The severity of the injury was assessed based on the displacement of the TMT joint or fracture line measured from CT scans. Displacement of less than 2 mm was considered to be a non-displaced injury and displacement of 2 mm or more was considered to be displaced. The Lisfranc injuries were also classified based on the Myerson classification and the Chiodo and Myerson classification where possible (Chiodo & Myerson, 2001; Myerson et al., 1986).

### 4.1.3 Radiograph data (II)

To assess the accuracy of the conventional radiographs of Lisfranc injuries, patients who had appropriate initial radiographs in the emergency room were reviewed. In total, 456 patients with CT confirmed foot trauma were included into random selection: 202 patients who did not have any bony injury, 21 patients with distal foot fractures, and 174 patients with non-displaced and 59 patients with displaced Lisfranc injury.

A patient sample including 34 patients without Lisfranc injury, 33 patients with non-dislocated Lisfranc injury, and 33 patients with dislocated Lisfranc injury were randomly selected using statistics software (IBM© SPSS Statistics, version 22). The primary radiographs of these patients were anonymized and saved as a list without any identification information or radiologists reports in the picture archiving and communications system. All 100 sets of radiographs included anteroposterior, lateral, and 30° oblique views of the foot. Three senior orthopaedic surgeons and three orthopaedic surgery residents assessed the radiographs independently. The observers answered the following questions: “Is there an injury at the Lisfranc joint?”, (Yes/No); “If you answered yes, describe the findings” and “Are there any other fractures”, (Yes/No).

### 4.1.4 Validation data (III)

To assess the validity and internal consistency of the American Orthopaedic Foot and Ankle Society Midfoot Scale in patients with Lisfranc injury, we combined the retrospective (previous chapters) and prospective (next chapter) datasets. All patients included in the retrospective data who returned adequately filled out questionnaires and the patients included in the prospective data who completed the questionnaires at 12 or 24-month follow-up visits were included in the validation data. All patients completed the VAS-FA and AOFAS Midfoot Scale instruments at the same time point.

#### 4.1.5 Retrospective case-series (IV)

To evaluate the outcomes after nonoperative treatment of Lisfranc injury, patients with Lisfranc injury were included from the retrospective dataset. The background characteristics of the patients were collected from medical records. Patients were contacted by mail 2 to 6 years after the injury. All recruited patients were requested to fill out the VAS-FA (Richter et al., 2006). Information from secondary operations were collected from the electronic medical records and also requested from the patients by mail. All non-operatively treated patients who completed the questionnaires adequately were included in the study. Patients who had undergone previous surgical operations on the foot or ankle were excluded from the study.

The standard non-operative treatment of a non-displaced Lisfranc injury was conducted with non-weightbearing immobilization in a cast for 4 to 6 weeks. Thereafter, progressive weightbearing towards full weightbearing was started. The decision about treatment policies was taken by the physician in the emergency room, although final agreement on treatment was made at a daily trauma meeting, where foot and ankle surgeons were present.

The patients were categorized into three grades by modifying the recent CT-based classification by Schepers and Rammelt (2018). Although this classification has certain advantages, it also has a few drawbacks. For example, it classifies each column (medial, central, or lateral) and type of the injury (ligamentous, simple, or comminuted) separately, resulting in dozens of different types of injuries, which makes it difficult in everyday clinical use. Secondly, the classification does not take dislocation into account at all, which may be one of the most important factors when choosing between non-operative and operative treatment. To further simplify and clarify the classification, the patients of this study were classified into three different grades: 1 – ligamentous injuries with avulsions, 2 – simple intra-articular fractures, and 3 – comminuted or more than 2 mm dislocated fractures.

## 4.2 Prospective data (V)

The prospective trial has started at Tampere University Hospital and at Seinäjoki Central Hospital. The trial comprises two strata: the first stratum compares non-operative treatment and operative treatment with ORIF for patients with non-dislocated Lisfranc injuries. The second stratum compares ORIF and primary arthrodesis in patients with dislocated Lisfranc injuries.

## 4.2.1 Patient selection and methods

The study sample includes patients with acute Lisfranc joint injury. The diagnosis and morphology of the injury will be confirmed with CT imaging because clinical suspicion (pain, swelling, plantar ecchymosis, and gap sign) and typical findings on conventional radiography ('fleck sign', avulsion, or intra-articular fracture) require further imaging. Eligible patients will receive information about the study in the emergency room from the surgeon on call. The final eligibility and study strata will be decided based on CT findings and baseline information. The final decision on the inclusion will be made after a discussion between the patient and one of the foot surgeons in the study group. The recruited patients will give written consent for their participation. The Ethics Committee of Pirkanmaa Hospital District has reviewed and approved the study protocol (R11152).

Inclusion criteria for stratum I will be as follows:

- non-dislocated (<2 mm) fractures affecting TMT joints II and III
- and /or dislocation <5 mm between the medial cuneiform and the base of MT II
- no fractures affecting TMT joints IV and V.

Inclusion criteria for stratum II will be as follows:

- affected joints TMT II - III with any other TMT
- any dislocation 2 mm or more (fracture or TMT joint)
- and dislocation >5 mm between the medial cuneiform and the base of MT II.

Exclusion criteria for both strata will be as follows:

- age less than 18 years
- age more than 60 years
- open fractures, extra-articular metatarsal fractures
- extremely comminuted fractures with bone loss
- and poor chance of gaining proper fixation with screws
- patients with polytrauma
- patients with weak cooperation (dementia, alcohol use, etc.)
- significant neuropathy or some other neurological condition
- diabetes
- rheumatoid arthritis
- patients with severe circulatory disorder of the lower limb



- delay in diagnosis over 14 days
- patients with previous foot injury or surgery of the injured foot
- pregnancy
- patients who refuse to participate

Randomization will be performed by the research coordinator at Tampere University Hospital who will not otherwise participate in the study. Eligible patients for strata I will be randomized into the non-operative or ORIF group. Eligible patients for strata II will be randomized into the ORIF or primary arthrodesis groups. All randomizations will be performed in blocks of ten. The result of the randomization will be retained in sealed envelopes and opened in numerical order after the recruitment has been confirmed. The study flow will be monitored by the research coordinator.

#### 4.2.2 Treatment protocols

Follow-up visits will take place at 6 weeks, 10 weeks, 6 months, 12 months, and 24 months after the injury (Figure 8). All follow-up visits will be arranged in the outpatient clinic of the hospital where the patient was first treated. Weightbearing radiographs of the injured foot and VAS pain score will be obtained at every visit. The AOFAS Midfoot Scale and VAS-FA instruments will be obtained during the follow-up visits at 6, 12, and 24 months.

The AOFAS Midfoot Scale will be used as the main outcome measure, since it is the only PROM with a known minimal clinically important change (MCID), which is needed to do the power calculations (Dawson et al., 2007). The MCID in AOFAS has been reported to be 8.34 (SD = 11) points (Dawson et al., 2007). In the power calculations, we used a 10-point difference in the AOFAS scale with a SD of 12 points, which gave a sample size of 23 patients in each group ( $\Delta=10$ ,  $SD=12$ ,  $\alpha=0.05$ ,  $\text{power}=0.8$ ). A drop-out rate of 20% was assumed in both groups, and therefore the total number of patients needed in both strata will be 56 patients. The data of the randomized controlled trial will be analyzed and reported in accordance with the intention-to-treat principle, if the patients change groups during the study.

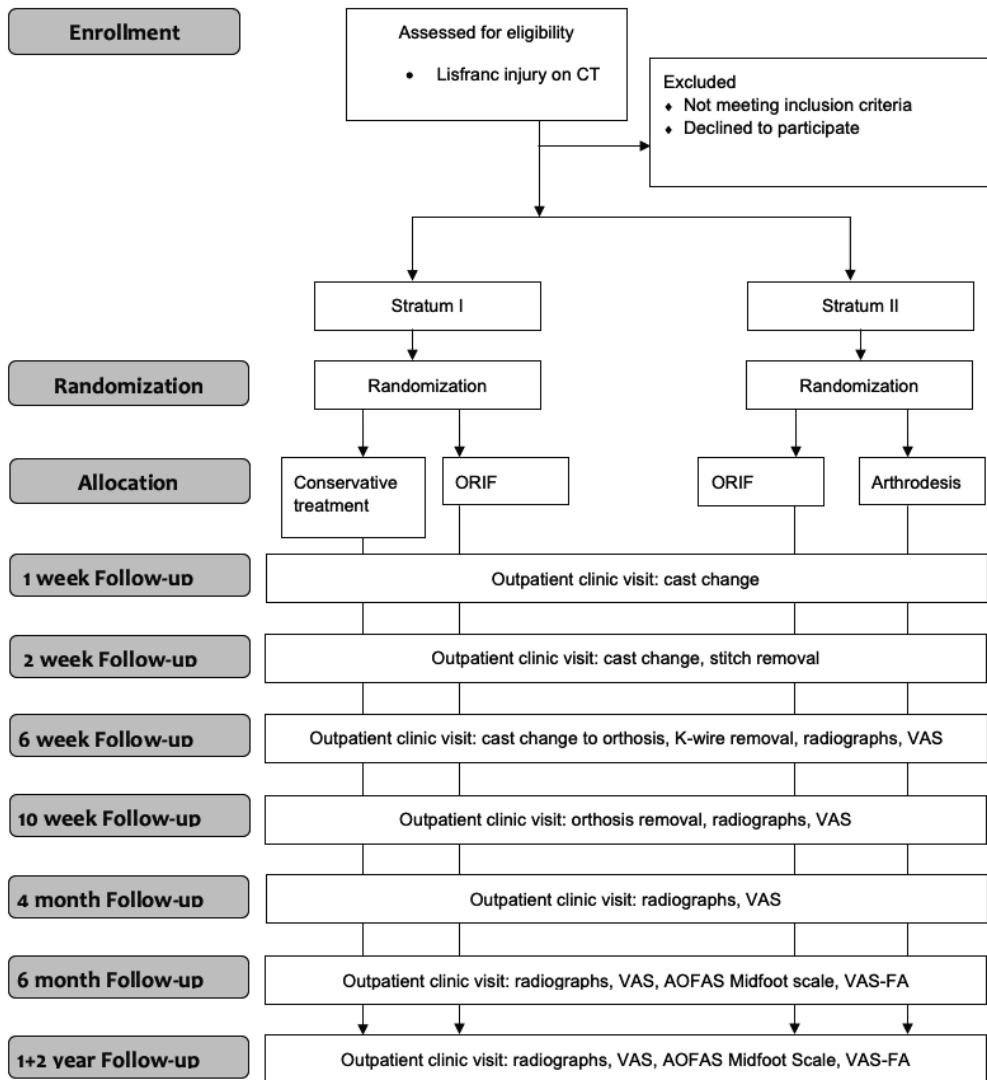


Figure 8. Flow diagram of the randomized controlled study.

### 4.3 Treatment techniques (IV, V)

Non-operative treatment will be conducted with six weeks of non-weightbearing cast. If necessary, the cast will be changed at two weeks during the outpatient visit. The cast will be removed after six weeks, and patients will start using a walking boot

for 4 weeks. Weightbearing will be limited to half-bodyweight for the next two weeks and, thereafter weightbearing will be allowed as tolerated.

All surgeries will be performed by experienced foot and ankle surgeons. Patients will receive an antibiotic prophylaxis before the operation. The surgical operations will be performed using one or two incisions, depending on the location of the injury. The first incision will be located between MT I-II and the second incision at the base of MT IV, with the aim of maximizing visibility. In both ORIF and primary arthrodesis, open anatomical reduction and fixation with screws will be performed with 4.0 cannulated screws (Synthes, Stryker) for the affected first, second, and third TMT joints. If there are displaced injuries in the TMT IV or V joints, open reduction and temporary K-wire fixation will be performed for these injured joints. K-wires will be shortened, bent, and left visible on the skin during the operation and removed at the outpatient clinic after six weeks. In primary arthrodesis, a chisel will be used to remove the cartilage and fibrous tissue from the articular surfaces of the affected TMT I to III joints. If TMT IV or V joints are affected, removal of the cartilage and fibrous tissue will not be done. However, temporary fixation will be performed as previously described. Despite the removal of the articular surfaces, both operations will be performed in a similar manner in terms of incisions, fixation, and temporary fixation of the lateral TMT joints. Wounds will be closed with dermal sutures. If the fixation screws cause no symptoms, they will not be removed.

Postoperative aftercare will be performed identically to non-operative treatment. First, six weeks with a non-weightbearing cast followed by four weeks with a walking boot. At the 2-week postoperative visit, sutures will be removed and the cast changed. At the 6-week postoperative visit, the cast and K-wires will be removed.

#### 4.4 Outcome measures (III, IV, V)

Patient reported outcome measures are used to evaluate the outcomes in both the retrospective cohort study and the randomized controlled trial. In the retrospective cohort, the VAS-FA was measured from 2 to 6 years after the injury. In the randomized controlled trial, the VAS-FA, AOFAS, and VAS pain are measured at 6, 12, and 24 months after the treatment. The secondary outcome measures are conversion to operative treatment, reoperations (hardware removal or secondary arthrodesis), and other complications.

#### 4.4.1 Visual Analogue Scale Foot and Ankle

The VAS-FA was developed and published by Richter et al. in 2006. The scale contains 20 items, which are scaled on a visual analog scale, giving a score from zero to 100, where zero is the worst and 100 the best score. The items are divided into three submodules: Pain, containing four items; Function, containing 11 items, and Other complaints, containing five items (Richter et al., 2006). The VAS-FA has been shown to have acceptable validity in the evaluation of outcomes after foot or ankle surgery (Anghthong, Chernchujit, Suntharapa, & Harnroongroj, 2011; Gur et al., 2017; Repo et al., 2018). Internal consistency has been shown to be high, as Cronbach's alphas for the subscales of the instrument have been 0.91 for Pain, 0.94 for Function, and 0.81 for Other complaints (Repo et al., 2018). Intra-class correlation coefficient (ICC) for the total score has been 0.97 and its different subscales from 0.95 to 0.97, indicating high reliability (Repo et al., 2018). The Finnish version of the VAS-FA has also been proven to have high validity and reliability (Repo et al., 2018).

#### 4.4.2 American Orthopaedic Foot and Ankle Society Midfoot Scale

The AOFAS Clinical Rating Systems, including the Midfoot Scale, were introduced in 1994 by Kitaoka et al. The Midfoot Scale consists of seven items that are divided into three subscales: Pain, Function, and Alignment. The items are scored differently between the questions. The Pain subscale includes one item with four response choices that are scored from zero to 40. The Function subscale includes five items that are scored from zero to 10 or from zero to 5, resulting in a total score of 45 points. The Alignment subscale includes one item that is scored from zero to 15. Therefore, the total score is 100. (Kitaoka et al., 1994)

The AOFAS is the most used outcome measure in the field of foot and ankle surgery, and it has been estimated that the scale has been used in at least 393 published research articles (Shazadeh Safavi et al., 2018).

### 4.5 Statistical analysis

Clinical data are presented as means (standard deviation; SD), medians (interquartile range; IQR), 95% confidence intervals (95% CI), or as counts (percentage). Continuous variables were compared with Mann-Whitney test and categorical

variables were compared with Chi-Square test, depending on the distribution of the data. Confidence interval was determined at 95%, and therefore p-values < 0.05 were considered to be statistically significant.

The inter and intraobserver reliability (study II) was assessed using Fleiss and Cohen kappa ( $\kappa$ ) statistics. The evaluation was performed twice with a three-month interval. The strength of agreement was presented according to Landis and Koch criteria (Landis & Koch, 1977): <0.00, poor; 0.00-0.20, slight agreement; 0.21-0.40, fair; 0.41-0.60, moderate; 0.61-0.80, substantial; and 0.81-1.00, almost perfect. False positive rate was calculated by dividing the false positive cases with CT negative cases, and miss rate was calculated as false negatives divided with CT positive cases.

For the validation of the AOFAS Midfoot Scale, hypotheses were defined beforehand and the results were interpreted according to the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist (Mokkink et al., 2010b). Coverage and targeting were assessed by evaluating the floor and ceiling effects: if the minimum or the maximum points were scored by more than 15% of the patients, the threshold was considered achieved (McHorney & Tarlov, 1995). In addition, the coverage and targeting were further evaluated by constructing a person-item distribution map to see how well the distribution of patients matched with item difficulty of the AOFAS Midfoot Scale.

Convergent validity was evaluated by calculating Spearman correlation coefficients and regression  $\beta$  between the AOFAS Midfoot Scale and the VAS-FA instruments. The correlation coefficients were interpreted according to the thresholds presented in the literature (Mukaka, 2012): 0.00–0.30 negligible, 0.30–0.50 low, 0.50–0.70 moderate, 0.70–0.90 high, and 0.90–1.00 very high correlation. Linear regression analyses were used to assess the strength of the relationship between the AOFAS Midfoot Scale and the VAS-FA. Age-, and gender-standardized regression coefficient  $\beta$  indicates how strongly the score of the AOFAS Midfoot Scale is related to the total and the sub-scores of the VAS-FA. The  $\beta$  values over 0.5 indicates strong relationship.

Thresholds between each response category for each item were investigated to see whether the response categories were correctly ordered. The threshold of the response category represents the location where the chance for the answer to end up in adjacent response categories is 50%.

Analyses were performed using R (version 1.1.453) with “dplyr”, “car”, “ggplot2”, “ggthemes”, and “lrm” packages, IBM© SPSS Statistics (version 22) and Microsoft Excel© (version 16.15). The results are presented in accordance with the Consensus-based Standards for the selection of health status Measurement

INstruments (COSMIN) (Mokkink et al., 2010b) and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (Von Elm et al., 2007).

## 4.6 Ethical considerations

The study protocol was reviewed and approved by the Ethics Committee of Pirkanmaa Hospital district (R11152). All patients provided written informed consent. The studies were performed in accordance with the Helsinki Declaration.

# 5 RESULTS

## 5.1 Incidence and characteristics of midfoot injuries (I)

In total, 953 foot and ankle CT scans were performed due to acute injuries to the foot and ankle. By evaluating all CT scans, 307 injuries affecting the midfoot were identified. Of these, the Lisfranc joint was affected in 233 (76%) patients, the Chopart joint was affected in 56 (18%) patients and combined or miscellaneous injuries were found in 18 (6%) patients (Figure 9). The incidences of midfoot injuries were evaluated among the catchment population of Pirkanmaa Hospital District (Table 3).

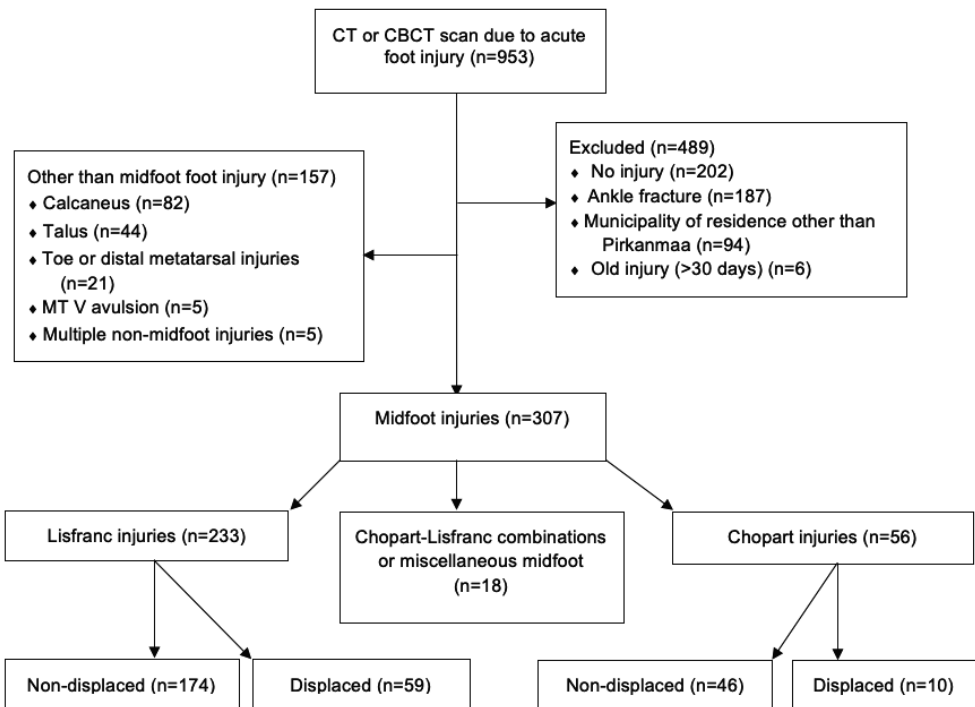


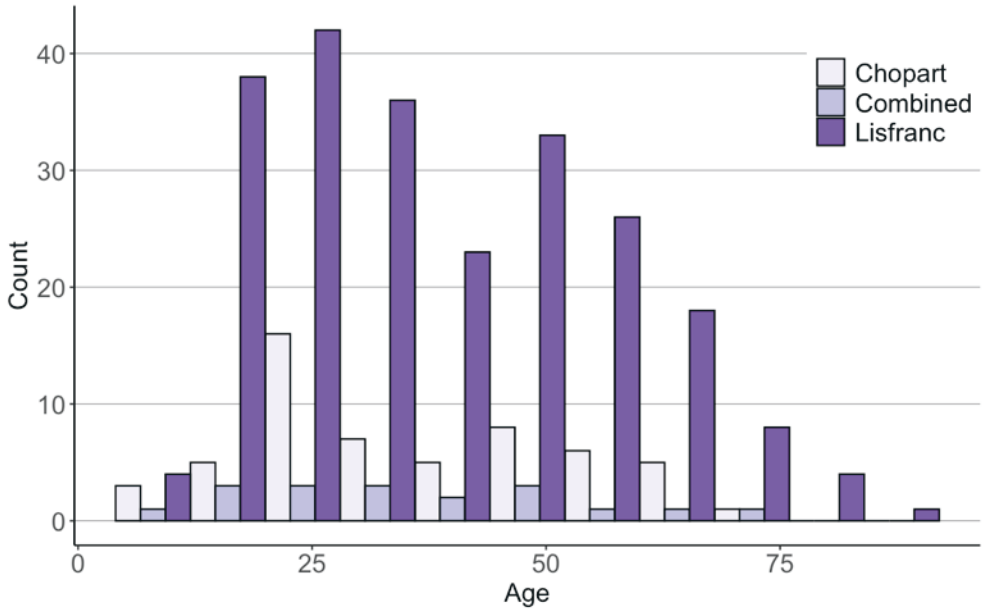
Figure 9. Flow chart of the retrospective data.

**Table 3.** Frequency and incidence of the midfoot injuries

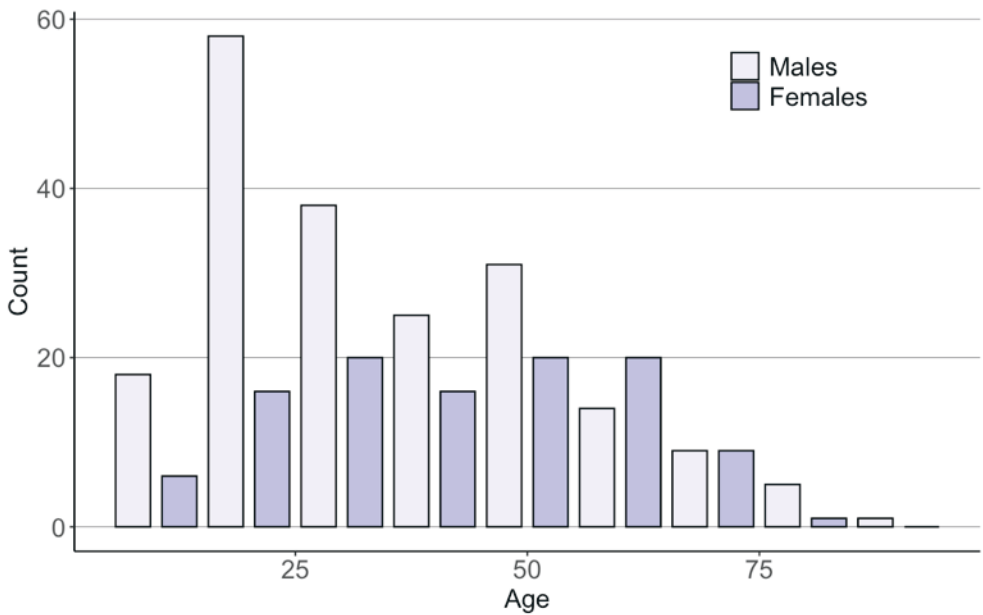
Region	n (%)	Incidence in person-years
Midfoot	307 (100)	12.1/100 000
Nondisplaced	234 (76.2)	9.2/100 000
Displaced	73 (23.8)	2.9/100 000
Lisfranc	233 (75.9)	9.2/100 000
Nondisplaced	174 (74.7)	6.8/100 000
Displaced	59 (25.3)	2.3/100 000
Chopart	56 (18.2)	2.2/100 000
Nondisplaced	46 (82.1)	1.8/100 000
Displaced	10 (17.9)	0.4/100 000
Combined	18 (5.9)	0.7/100 000
Nondisplaced	14 (77.8)	0.5/100 000
Displaced	4 (22.2)	0.2/100 000

The median age for all patients with midfoot injuries was 35 (IQR: 24 to 51) (Figure 10). From all the midfoot injuries, males accounted for 69% (n=199) and females for 35% (n=108) (Figure 11). Males accounted for the larger proportion of all Lisfranc injuries (70% vs. 30%, p-value < .001), whereas females accounted for a larger proportion of all Chopart injuries (57% vs. 43%, p-value < .0001). Statistically significant differences between genders were not found in the combined or miscellaneous injuries (67% vs. 33%, p-value < .866).





**Figure 10.** Age distribution of the midfoot injuries divided by the injury site.



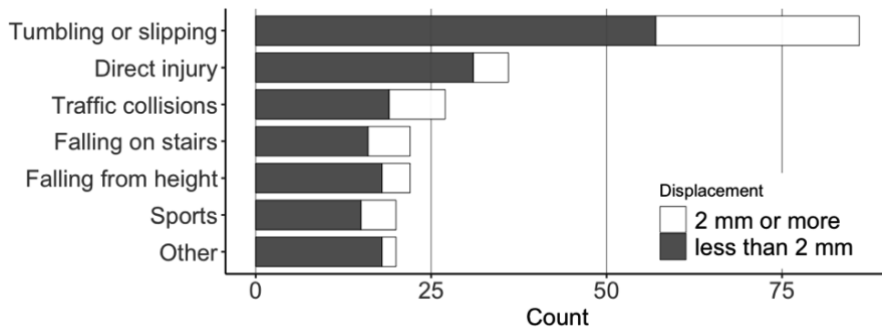
**Figure 11.** Age distribution of the midfoot injuries divided by gender.

In Lisfranc injuries, the most common trauma mechanisms were tumbling or slipping (37%) or direct injury (16%) (Figure 12). Traffic collisions comprised 25 motorbike accidents and 2 car accidents. The 'other' mechanism group included seven bicycle accidents, six falls from a chair, five kicks towards a solid object, and two unknown mechanism. High energy mechanisms accounted for 37% (n=85) and low energy mechanisms accounted for 55% (n=128) of the Lisfranc injuries. Up to 9% (n=20) were not classifiable by trauma mechanism. Association between the trauma energy and the severity of the injury was not found in Lisfranc injuries (p=0.069). However, a difference between genders was detected, as males had a higher rate of high-energy Lisfranc injuries than females (49% vs. 19%, p < .0001).

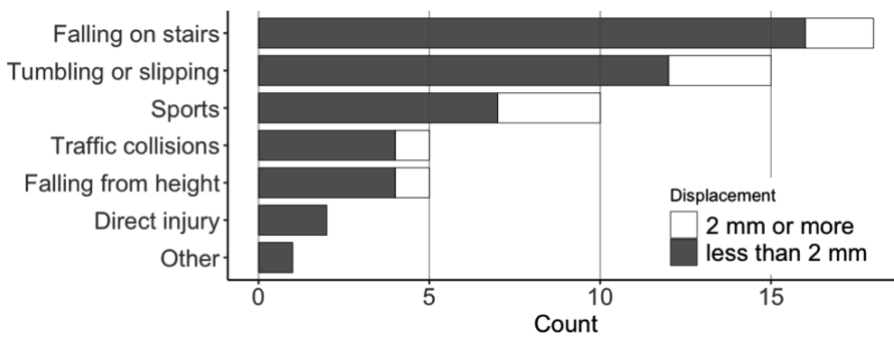
From all Lisfranc injuries, nondisplaced injuries accounted for 75% (n=174) and displaced injuries accounted for 25% (n=59). The most frequent trauma mechanisms for nondisplaced injuries were tumbling or slipping (Figure 12).

Similar to Lisfranc injuries, nondisplaced injuries accounted for 78% (n=46) and displaced injuries accounted for 22% (n=10) of all Chopart injuries. Most of the nondisplaced Chopart injuries occurred in low-energy accidents, such as tumbling on stairs (n=16, 35%) and tumbling or slipping (n=12, 26%) (Figure 13). In displaced Chopart injuries, the most frequent trauma mechanisms were sports (n=3) and tumbling or slipping (n=3). High-energy mechanisms accounted for 14% (n=8), and low-energy mechanisms accounted for 86% (n=48) of the Chopart injuries.

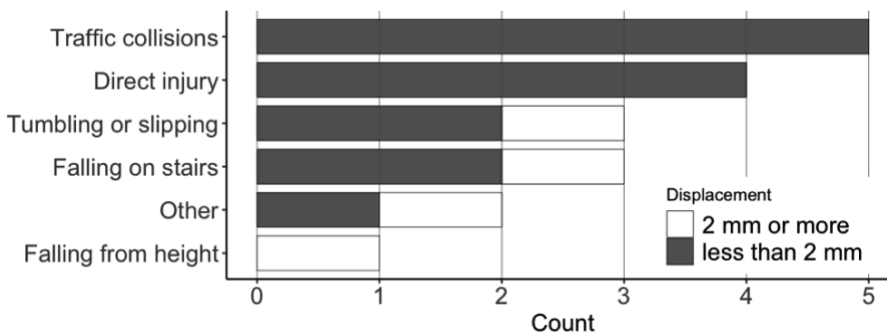
In Chopart-Lisfranc combinations or miscellaneous injuries, the majority of the injuries were caused by high-energy trauma mechanisms (56%), such as traffic collisions 28% (n=5) and direct injury 22% (n=4) (Figure 14). Only 25% (n=4) of patients with combined midfoot injuries had displaced injuries.



**Figure 12.** Injury mechanisms for Lisfranc injuries divided into nondisplaced and displaced injuries.



**Figure 13.** Injury mechanisms for Chopart injuries divided into nondisplaced and displaced injuries.



**Figure 14.** Injury mechanisms for combined midfoot injuries divided into nondisplaced and displaced injuries.

In our study, only 6% (n=13) of the Lisfranc injuries had such morphology that they could be classified using the Myerson classification. From these 13 classifiable injuries, 54% (n=7) were type A, 23% (n=3) were type B2, 15% (n=2) were type B2, 8% (n=1) were type C2, and none were type C1.

According to the columnar classification by Chiodo and Myerson, one column was affected in 29% (n=68) of cases, two columns in 40% (n=92) of cases, and three columns in 31% (n=73) of cases (Table 4).

**Table 4.** The combinations of affected columns

Affected columns	n	%
Isolated medial	21	9.0
Isolated central	32	13.7
Isolated lateral	15	6.4
Medial + Central	42	18.0
Medial + Lateral	2	0.9
Central + Lateral	48	20.6
All columns	73	31.3

## 5.2 Inter and intraobserver reliability of radiographs (II)

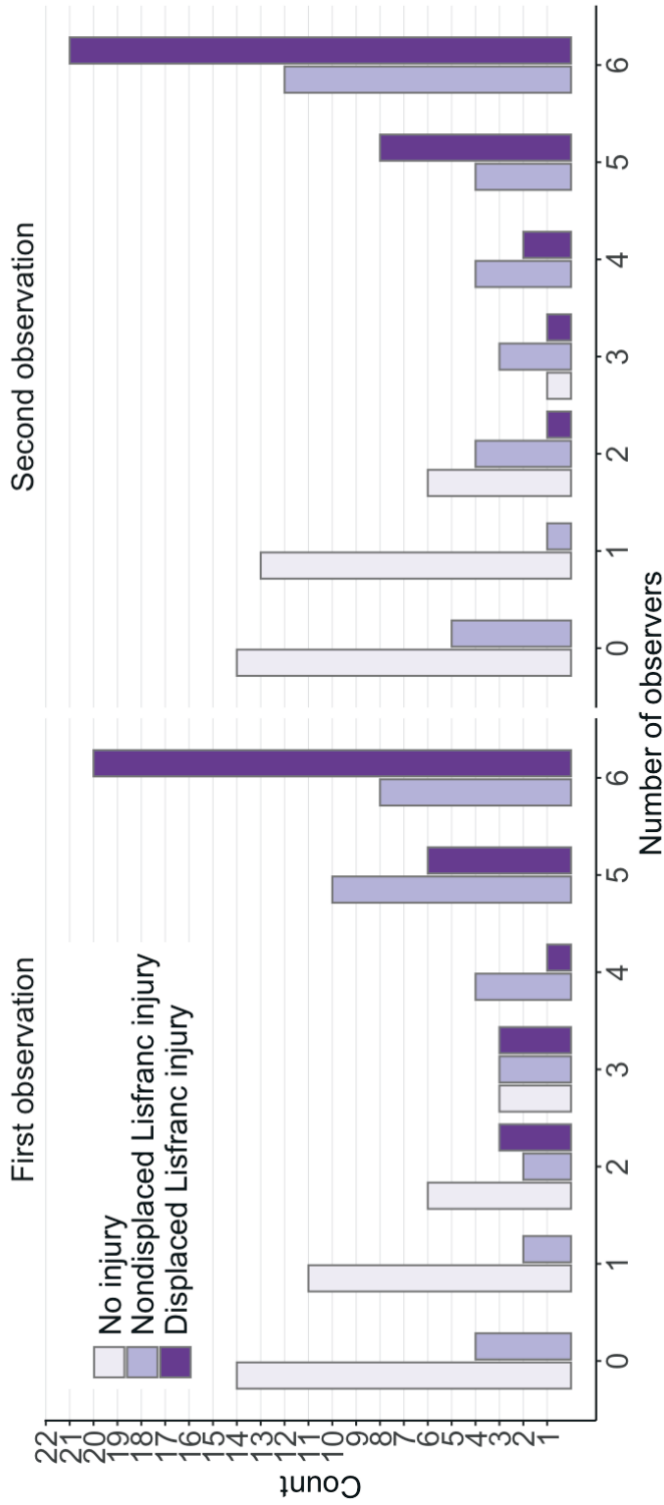
The interobserver reliability of radiographs in Lisfranc injury resulted in moderate correlation  $\kappa = 0.50$  (95% CI: 0.45 – 0.55) (first evaluation) and  $\kappa = 0.58$  (95% CI: 0.52 – 0.63) (second evaluation). When the evaluation was performed after the three-month interval, the  $\kappa$  coefficient for intraobserver reliability was  $\kappa = 0.71$  (from 0.64 to 0.85), indicating substantial correlation.

The mean sensitivity was 76.1% (from 60.6 to 92.4) and specificity was 85.3% (52.9 to 100) (Table 5). The mean positive predictive value was 87.0% (SD: 12) and the negative predictive value 71.0% (SD: 16). The subtle injuries with less than 2 mm of displacement were detected with lower sensitivity (65.4% vs 87.1% p=0.002). Nondisplaced injuries were more commonly missed than dislocated injuries (11 vs 4 p=0.003). The rate of false negative cases was 24% and the rate of false positive cases was 15%. No differences between foot surgeons and residents were found in sensitivity (72.5% vs. 79.8%, p=0.44), specificity (87.7 vs. 82.8%, p=0.92), positive predictive value (85.8% vs. 91.2%, p=0.31), or negative predictive value (76.5% vs. 69.4%, p=0.31).

**Table 5.** Results of the observers' two evaluations.

Occasion	Observer 1		Observer 2		Observer 3		Observer 4		Observer 5		Observer 6	
	I	II	I	II	I	II	I	II	I	II	I	II
Sensitivity	83.3	83.3	63.6	69.7	60.6	74.2	74.2	75.8	92.4	89.4	77.3	69.7
Specificity	79.4	76.5	100.0	94.1	94.1	82.4	94.1	88.2	52.9	76.5	85.3	100.0
PPV	88.7	87.3	58.6	95.8	95.2	89.1	96.1	92.6	79.2	88.1	91.1	100.0
NPV	71.1	70.3	100.0	61.5	94.1	62.2	65.3	65.2	78.2	78.8	65.9	63.0
Missed cases	11	11	24	20	26	17	17	15	5	7	15	20
False positive	7	8	0	2	2	6	2	4	16	8	5	0
Subtle												
Sensitivity	72.7	75.8	45.5	57.6	51.5	60.6	66.7	69.7	84.8	78.8	69.7	51.5
Missed	9	8	18	14	16	13	11	10	5	7	10	16
Severe												
Sensitivity	93.9	90.9	81.8	81.8	69.7	87.9	81.8	84.8	100.0	100.0	84.8	87.9
Missed	2	3	6	6	10	4	6	5	0	0	5	4
Cohen's kappa (95% CI)	0.85 (0.74 - 0.96)		0.68 (0.53 - 0.82)		0.67 (0.53 - 0.81)		0.70 (0.56 - 0.84)		0.71 (0.56 - 0.86)		0.64 (0.50 - 0.79)	

PPV = Positive predictive value, NPV = Negative predictive value



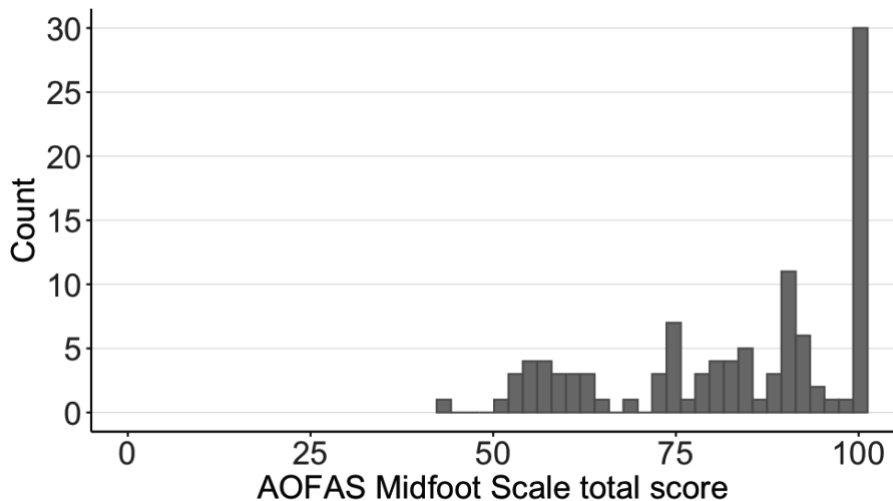
**Figure 15.** The distribution of the agreement between the observers. Light bars indicate that the non-injured patients were detected with relatively high consensus. Darker bars represent the agreement between the patients with Lisfranc injury.

### 5.3 Validation of the AOFAS Midfoot Scale (III)

Altogether, 117 patients were included in the study (Table 6). The mean (SD) follow-up time was 3.9 (1.5) years after the injury. Half (n=58) of the patients were treated non-operatively and half (n=59) operatively. The AOFAS Midfoot Scale total points were skewed towards maximum points (Figure 16). Since 30 (28%) patients reached the maximum points, the ceiling effect was confirmed for the AOFAS Midfoot Scale (Table 7). The ceiling effect was not confirmed for the VAS-FA, since only 10 (9%) of the patients scored the maximum points. The floor effect was not confirmed for either of the scales, since none of the patients scored the minimum points. The Cronbach's alpha for the AOFAS Midfoot Scale was 0.75, indicating acceptable internal consistency.

**Table 6.** Demographic and clinical information of the patients.

	N = 117
Age, mean (SD)	41 (17)
Male, n (%)	75 (64)
Treatment, n (%)	
Non-operative	58 (50)
ORIF	21 (18)
Arthrodesis	23 (20)
Multiple operations	12 (10)
Closed reduction with K-wire fixation	1 (1)
Follow-up, months (SD)	46 (18)
AOFAS	
Median (IQR)	88 (73 to 100)
Floor, n (%)	0 (0)
Ceiling, n (%)	30 (28)
VAS-FA	
Median (IQR)	89 (72 to 98)
Floor, n (%)	0 (0)
Ceiling, n (%)	10 (9)



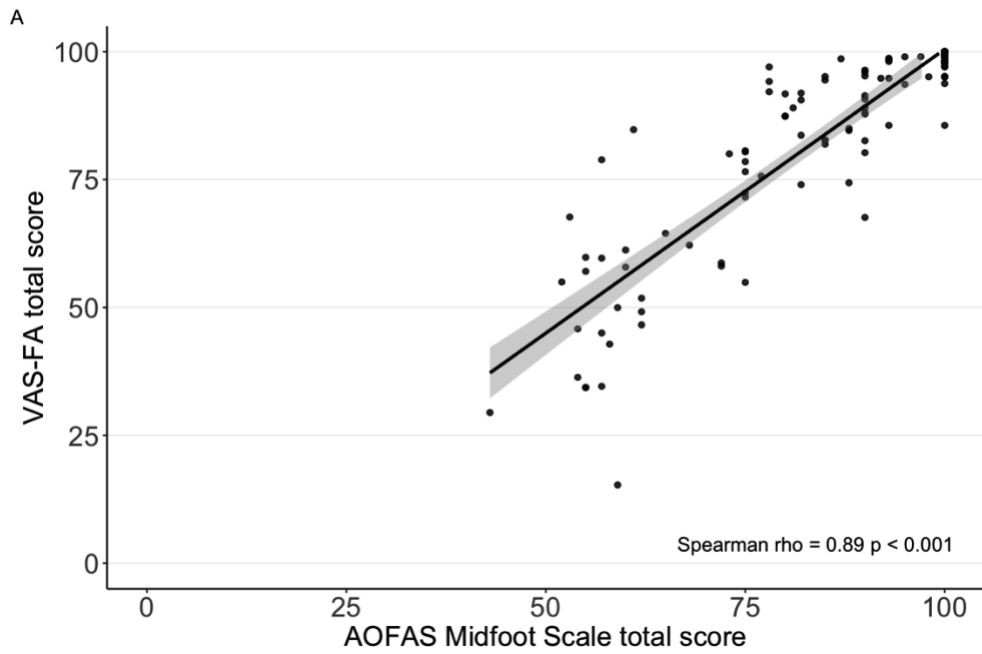
**Figure 16.** Distribution of the total scores of the AOFAS Midfoot Scale.

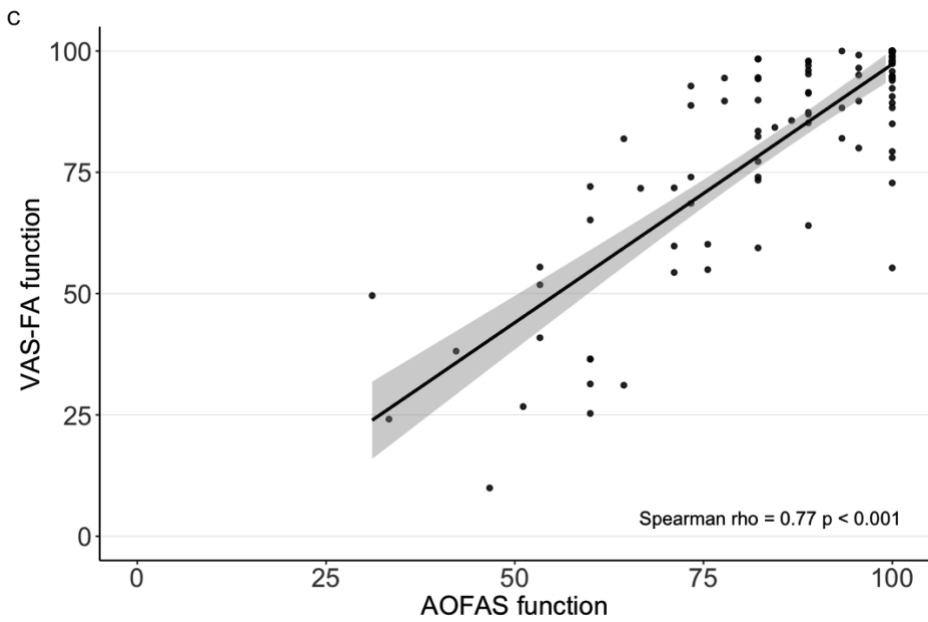
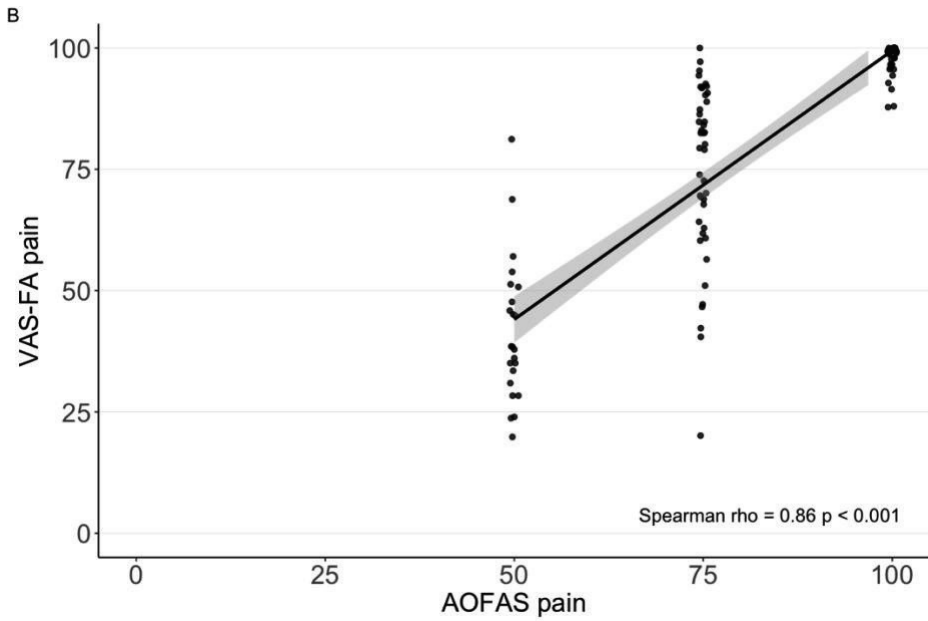


**Table 7.** Predefined hypotheses for the validation of the American Orthopaedic Foot & Ankle Society Midfoot Scale.

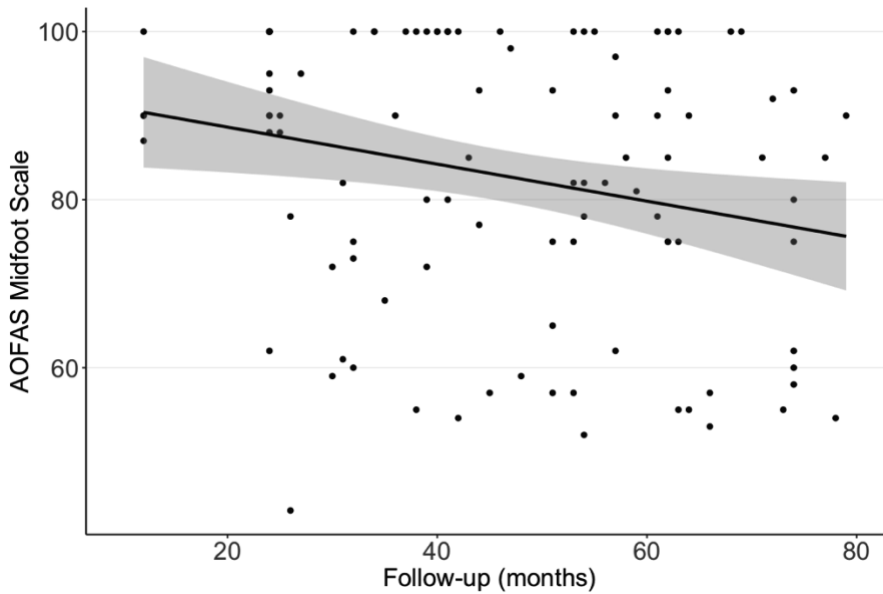
Feature	Hypothesis	Result	Confirmed/ Rejected
Internal consistency	Cronbach alpha is $\geq 0.70$	0.75	Confirmed
Validity	Coverage	Floor effect $\leq 15\%$	Confirmed
		Ceiling effect $\leq 15\%$	Rejected
Convergent validity		Correlation with VAS-FA is $\geq 0.50$	Confirmed
		Correlation with VAS-FA Pain is $\geq 0.50$	Confirmed
		Correlation with VAS-FA Function is $\geq 0.50$	Confirmed
	Item difficulty matches with the coverage of the study sample	Good coverage	Rejected

The correlation between the total scores of the instruments ( $r= 0.89$ ) and between the Pain ( $r= 0.86$ ) and Function ( $r= 0.77$ ) subscales was high (Figure 17). The AOFAS Midfoot Scale total score and follow-up time had negligible correlation. (Figure 18). All correlations were statistically significant ( $P< 0.001$ ).



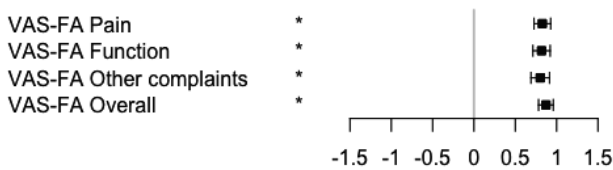


**Figure 17.** A: Correlation between the VAS-FA and AOFAS Midfoot Scale. B: Correlation between the VAS-FA and AOFAS Midfoot Scale Pain subscales. C: Correlation between the VAS-FA and AOFAS Midfoot Scale Function subscales.



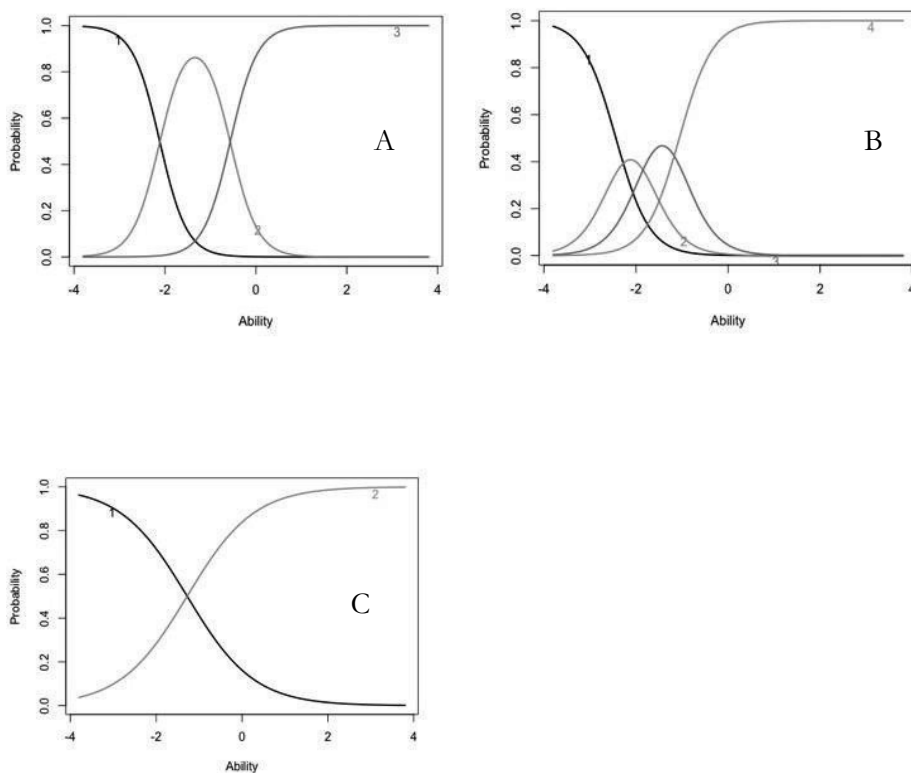
**Figure 18.** Correlation between the follow-up time and the AOFAS Midfoot Scale total score was negligible ( $r=0.23$ ,  $p=0.017$ )

The age- and sex-adjusted regression coefficient  $\beta$  between the AOFAS Midfoot Scale total score and the VAS-FA total and subscale scores was 0.87, 0.83, 0.82, and 0.80 for Overall, Pain, Function, and Other complaints, respectively (Figure 19). The regression and correlation coefficients indicate a strong relationship between the AOFAS Midfoot Scale and the VAS-FA.



**Figure 19.** Relationships between the AOFAS Midfoot Scale and the VAS-FA subscales. Boxes represent regression coefficients for the mean scores (VAS-FA: Pain, Function, Other complaints and Overall) and whiskers show the 95% CIs.

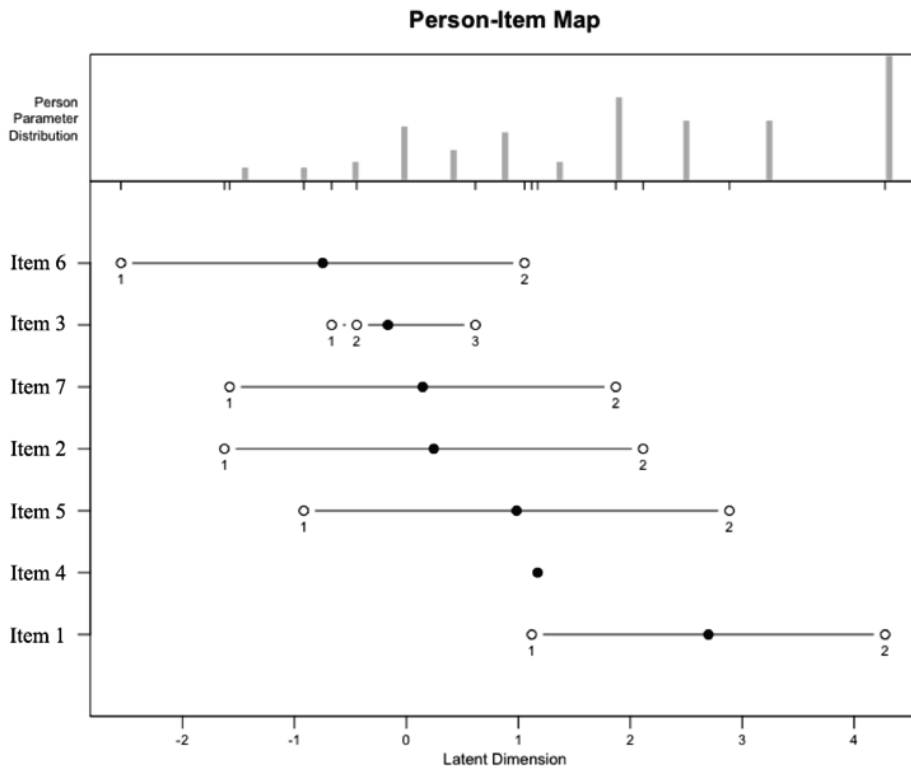
All items of the AOFAS Midfoot Scale had correctly ordered thresholds between the response categories (Figure 20). Item 3 (“Maximum walking distance, blocks”) had correctly ordered response categories. However, the gap between categories 2 (“4-6”) and 3 (“1-3”) was narrow. None of the patients gave the worst answers to items 1 (“Pain”), 2 (“Activity limitations, support”), or 4 (“Footwear requirements”).



**Figure 20.** Thresholds of response categories for items 2 (A), 3 (B), and 4 (C) of the AOFAS Midfoot Scale. All response categories are ordered correctly. Item 2 (A) has evenly distributed response categories. Response categories of item 3 (B) showed misfunction, as there is only a narrow gap between the thresholds between response categories 2 and 3. Item 4 (C) had ordered threshold values, but none of the patients answered the worst response category.

A person-item distribution map shows that item difficulty matched relatively well with the coverage of the study sample of the AOFAS Midfoot Scale (Figure 21). However, many of the patients scored the maximum scores, which was not covered

by the instrument, indicating that the instrument has limitations regarding its coverage and targeting for less symptomatic patients.

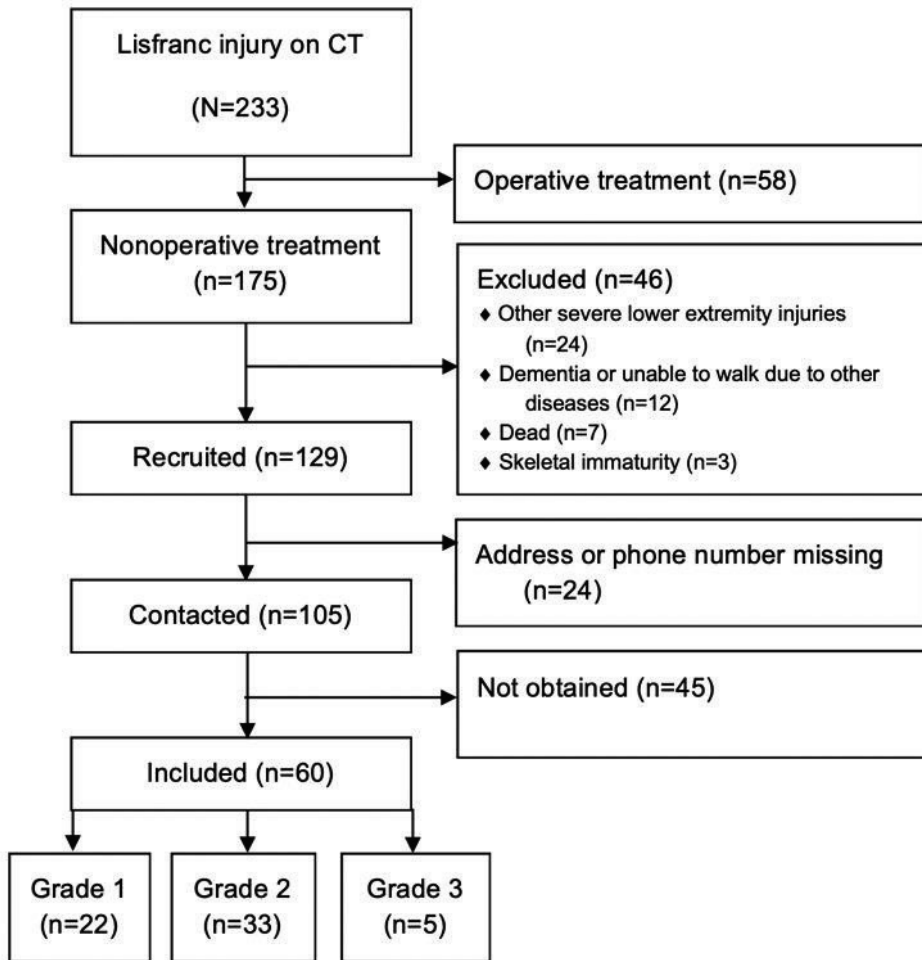


**Figure 21.** Person-Item distribution of the seven items of AOFAS Midfoot Scale. Bars representing the location of the patients and circles representing the difficulty of the items.

## 5.4 Retrospective case-series (IV)

In total, 233 patients with Lisfranc injuries were identified from the original data: 175 (75%) were treated non-operatively and 58 (25%) operatively. Of these, 46 patients were excluded due to other lower extremity injuries (n=24), dementia or the inability to walk (n=12), death (n=7), or skeletal immaturity (n=3) (Figure 22). The

final analysis comprised 60 patients with an answer rate of 47% (Mean follow-up time 4.2 years).



Grade 1 – ligamentous injuries with avulsions,  
Grade 2 – simple intra-articular fractures  
Grade 3 – comminuted or >2 mm dislocated fractures.

**Figure 22.** Flow chart of the retrospective data

The 60 non-operatively treated patients had similar characteristics to other non-operatively treated patients (Table 8). Up to 88% (n=53) of the patients were immobilized with a non-weightbearing cast for at least 4 weeks, and 72% (n=43) of the patients for at least 6 weeks. Only 10% (n=6) of the patients underwent shorter than the standard immobilization period.

**Table 8.** Background and clinical characteristics of the participants.

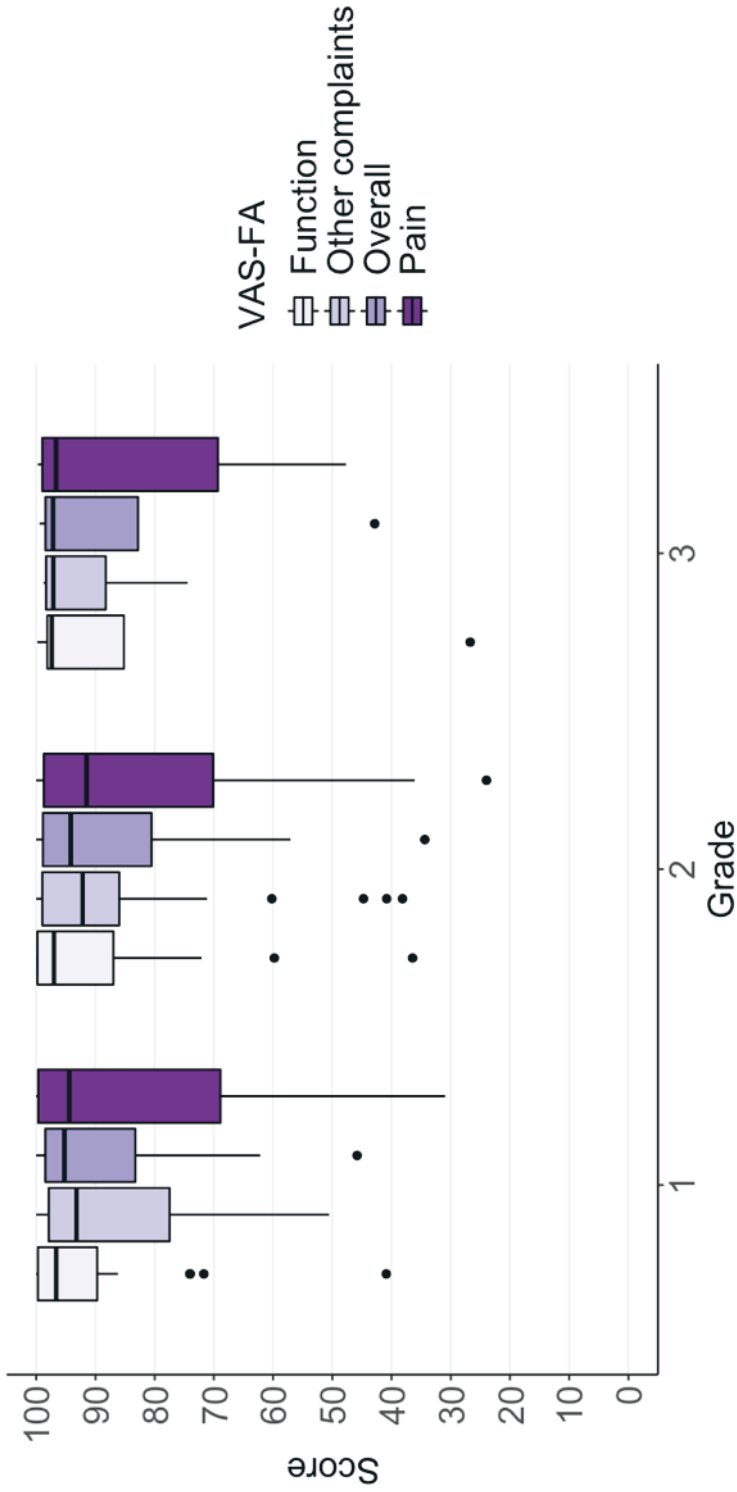
	All* (N=175)	Included** (n=58)
Age, mean (sd)	38 (18)	42 (18)
Male, n (%)	124 (71)	34 (59)
Follow-up (years), mean (SD)	-	4 (1)
Delay from injury to CT (days), median (range)	1 (0-29)	1 (0-29)
Trauma mechanism, n (%)		
Tumbling or twisting	63 (36)	22 (38)
Crush injury	32 (18)	12 (21)
Sports	12 (7)	6 (10)
Falling on stairs	12 (7)	-
Falling	17 (10)	5 (9)
Motor vehicle collisions	21 (12)	5 (9)
Bicycle collisions	7 (4)	3 (5)
Other	11 (6)	5 (9)

\* All non-operatively treated patients

\*\*All non-operatively treated patients who adequately completed the questionnaires

The median VAS-FA scores after 4.2 years of follow-up of all non-operatively treated patients were 95.1, 93.4, 97.2, and 92.5 for Overall, Pain, Function, and Other complaints, respectively. Of all the patients, 55% (n=33) scored over 90 points in both the Pain and Function subscales of the VAS-FA, and 63% (n=38) scored over 90 points overall (Figure 23). In total, 64% (n=37) of patients scored over 80 points in both the Pain and Function subscales of the VAS-FA, and 78% (n=45) scored over 80 points overall. Of all patients, 7% (n=4) scored under 60 points in both the Pain and Function subscales of the VAS-FA, and 9% (n=5) scored under 60 points overall.





Grade 1 – ligamentous injuries with avulsions,

Grade 2 – simple intra-articular fractures and

Grade 3 – comminuted or >2 mm dislocated fractures.

**Figure 23.** The Visual Analogue Scale Foot and Ankle Overall, Pain, Function and Other complaints scores of the patients with non-operatively treated Lisfranc injuries.

In 22 patients, the Lisfranc injuries were nondisplaced avulsion fractures affecting from one to three TMT joints (Grade 1) (Table 9). The median VAS-FA scores after 3.7 years of follow-up were 95.2, 94.4, 96.6, and 93.2 for Overall, Pain, Function and Other complaints, respectively (Figure 23). Pain and Function subscales were over 90 points in 59% (n=13) of the patients and over 80 in 68% (n=15) of the patients. From these patients, 64% (n=14) scored over 90 points overall, and 77% (n=17) scored over 80 points overall. One of the Grade 1 patients underwent secondary surgery (arthrodesis of the second TMT joint) ten months after the primary injury.

**Table 9.** Characteristics of the non-operatively treated Lisfranc injuries classified by the modified Schepers and Rammelt classification.

	n	Follow-up (years) Mean	Number of TMT joints, median (range)	Medial column n (%)	Central column n (%)	Lateral column n (%)
All*	175	-	3 (1-5)	97 (55)	140 (80)	98 (56)
Included**	60	4.0	2 (1-5)	31 (52)	49 (82)	29 (48)
Grade 1***	22	3.7	2 (1-3)	10 (45)	15 (68)	7 (32)
Grade 2***	33	4.1	3 (1-5)	17 (52)	30 (91)	21 (64)
Grade 3***	5	5.1	3 (1-3)	4 (80)	4 (80)	1 (20)

\* All non-operatively treated patients

\*\*All non-operatively treated patients who adequately completed the questionnaires

\*\*\*Modified Schepers and Rammelt classification 1: Avulsion fractures, 2: Simple intra-articular fractures, 3: Comminuted intra-articular fractures

In total, 33 patients suffered from simple nondisplaced intra-articular fractures in the Lisfranc joint region and were included to Grade 2. The injuries of the patients in this grade affected from one to five TMT joints (Table 9). After the mean of 4.1 years of follow-up, the median VAS-FA scores were 94.2, 91.5, 97.0, and 92.2 for Overall, Pain, Function and Other complaints, respectively (Figure 23). Of the Grade 2 patients, 52% (n=17) scored over 90 points in both the Pain and Function subscales of the VAS-FA, and 64% (n=21) scored over 80 points. The overall score was over 90 points in 64% (n=21) of patients and over 80 in 79% (n=26) of patients. An injury of one patient had been primarily missed, and therefore non-operative treatment was only started one month after the injury, resulting in an unsatisfactory result. None of the patients with Grade 2 injury underwent secondary surgery.

In 5 patients, the injury was Grade 3 with comminuted fractures in the Lisfranc joint region. The number of affected TMT joints in these injuries ranged from one to three, and in all patients only one TMT joint was comminuted (Table 9). After the mean of 5.1 years of follow-up, the median VAS-FA scores were 97.2, 96.6, 97.4, and 97.1 for Overall, Pain, Function and Other complaints, respectively (Figure 23). From the Grade 3 patients, 60% (n=3) scored over 90 points in both the Pain and Function subscales of the VAS-FA. The overall score was over 90 points in 60% (n=3) of patients and over 80 in 80% (n=4) of patients. One patient with TMT I-III fractures with comminuted MT I scored under 60 points from the VAS- FA. None of the Grade 3 patients underwent secondary surgery.

## 5.5 Randomized controlled study (V)

The RCT study is currently running, and Tampere University Hospital and Seinäjoki Central Hospitals are recruiting patients. So far, we have included half of the planned patient sample (1.5.2020). The results will not, however, be ready before the publication of this dissertation.

## 6 DISCUSSION

### 6.1 Incidence (I)

In this study, we found out that the annual incidence of Lisfranc injuries is 9.2/100 000 person-years. This number is five times higher than in the first studies investigating the incidence of Lisfranc injuries (Aitken & Poulson, 1963; English, 1964; Vuori & Aro, 1993). However, the origin of the previous commonly cited rate of 1/55 000 person-years remains unknown. Additionally, the incidence of Chopart injuries was 2.2/100 000 person-years. As previous studies have included all midfoot injuries, there are no previous incidence rates for Chopart injuries (Court-Brown et al., 2006). In our study, the incidence of Lisfranc-Chopart combinations was 0.7/100 000 person-years. The incidence of the Lisfranc-Chopart injuries have not previously been presented. Moreover, after the publication of our results, a study from Norway was published introducing an incidence of 14/100 000 person-years for Lisfranc injuries (Stødle et al., 2019). The definition of injury was identical, and they also used CT-scan to detect the injuries. However, in their study the incidence was notably higher than in our study, which may be the result of more precise imaging, as they used plain radiographs, CT scans, MRI, stress fluoroscopy and/or weightbearing radiographs. Nevertheless, it is evident that these injuries are more common than the figures presented in the radiograph-based studies, and our results seems to be generalized to other nations as well.

As previously stated, studies that have investigated the incidences of midfoot injuries have had major limitations in terms of injury definitions, imaging modalities, and the reporting of data. The strength of our study was the use of CT imaging for the diagnosis. The disadvantages of radiographic imaging were first described in 1985 (Goiney et al., 1985), and therefore it is important to diagnose these injuries with CT. Since all previous studies are based on conventional radiographs, it is plausible that the rate of missed injuries is relatively high. The increased awareness of midfoot injuries and the availability of CT imaging may be the reason behind the higher incidence of Lisfranc injuries. At our hospital, the indication for CT imaging of the foot after acute trauma is the suspicion of an intra-articular injury or displacement in radiographs or a high suspicion of midfoot injury based on clinical

findings. Although our study is not nationwide, it is notably more precisely conducted when compared to the previous studies. Moreover, as there are no International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes for Lisfranc or Chopart injuries, it would be impossible to conduct a nationwide epidemiological study.

In addition to incidence rates, the use of CT has shed light on the characteristics of midfoot injuries. As the most commonly used injury classifications are based on radiographs, many nondisplaced injuries have not been detected (Myerson et al., 1986; Nunley & Vertullo, 2002). There have also been controversies in the injury definitions (Crates et al., 2015; Ly & Coetzee, 2006; Myerson et al., 1986; Nunley & Vertullo, 2002; Schepers & Rammelt, 2018). Some authors define the Lisfranc injury as an injury between the first and the second ray (Nunley & Vertullo, 2002). The current trend in the literature to use a columnar approach to describe injuries in the TMT area is more reasonable and should be used in the future. For example, in our study, 21% of injuries in the Lisfranc joint affected only the lateral column.

Lisfranc injuries have been classified as “high-energy” and “low-energy” based on the trauma mechanism (Rajapakse et al., 2006; Renninger et al., 2017; Rosenbaum, Dellenbaugh, Dipreta, & Uhl, 2011). A study by Renninger et al. (2017) investigated the differences between low- and high-energy Lisfranc injuries. They classified sports activities and twisting and falling from less than 4 feet (1.2 m) as low-energy injuries. Car and motorcycle vehicle collisions, crush injuries, and falling from more than 4 feet (1.2 m) were classified as high-energy injuries. CT and weightbearing radiographs were used and both bony and ligamentous injuries were included. Low-energy injuries were more common than high-energy injuries (48 vs. 32). In their study, patients with high-energy injuries were more likely to have associated non-foot fractures (37% vs 6%), metatarsal base fractures (84% vs 29%), displaced intra-articular TMT fractures (59% vs 4%), and involvement in all TMT joints (23% vs 6%). Similarly, we found that the majority of the midfoot injuries diagnosed in our region are caused by low-energy trauma mechanisms. However, in our data, no association between trauma energy and the severity of the injury was found. As the trauma mechanisms are most often reported by the patients, the precise characteristics may be unreliable. Nonetheless, these findings may result from the fact that the energy affecting the foot is difficult to determine.

## 6.2 Diagnostics (II)

As our first study showed, most of the midfoot injuries were subtle, non-displaced injuries that were visible in CT. Knowing that over 20% of these injuries are missed, we were interested in evaluating how precisely these injuries are diagnosed from radiographs (Chiodo & Myerson, 2001; English, 1964; Haapamaki et al., 2004a; Myerson et al., 1986; Stavlas et al., 2010; Thompson & Mormino, 2003).

We found out that the diagnosis of Lisfranc injury based on radiographs has moderate agreement between the observers and substantial agreement between the same observer in two different evaluations. Therefore, the inter- and intraobserver reliabilities in detecting Lisfranc injuries depend on the observer. Furthermore, if the same observer repeats the evaluation, the result will have notable variability. The intraobserver reliability had some variance among the observers because the results varied from substantial agreement to almost perfect.

The accuracy of standard radiographs has previously been evaluated by Sherief et al. (2007). In their study, the mean sensitivity of nine observers was 92% (95% CI: 89-95%), and the rate of missed injuries was 19%. Significant differences between radiologists, orthopaedic surgeons, or physicians was not found (Sherief et al., 2007). In the study by Haapamäki et al. (2004), a sensitivity of 76% and a miss rate of 24% for detecting Lisfranc injuries was reported. In our study with a fivefold higher number of radiographs, the sensitivity (76%) was comparable to that presented in earlier studies, where the sensitivity had been reported to be between 76% and 92% (Haapamaki et al., 2004b; Sherief et al., 2007). Similar to the study by Sherief, in our study, there were no statistically significant differences between senior orthopaedic surgeons and residents (Sherief et al., 2007). We also noted that the severity of the injury affects the diagnostic accuracy remarkably.

There have also been many other previous studies that have criticized the accuracy of standard radiographs in the diagnostics of Lisfranc injuries, since it might be impossible to detect nondisplaced injuries and instability (Foster & Foster, 1976; Goossens & Stoop, 1983; Norfray et al., 1981; Stein, 1983). Hence, it has been suggested that weightbearing radiographs be used (Arntz et al., 1988; Coss et al., 1998; Curtis et al., 1993; Goossens & Stoop, 1983). However, weightbearing radiographs have also been shown to be unreliable in detecting instability, and sensitivity is no better when compared with standard radiographs (Kaar et al., 2007; Preidler et al., 1999). Stress testing under fluoroscopy has been presented as the reference method to detect even minimal instability (Raikin et al., 2009), yet there is no standard protocol for performing the test, imaging projection, or thresholds

presented for this method (Naguib & Meyr, 2018). Moreover, the interobserver reliability of this method has been shown to be low (Naguib & Meyr, 2018). Hence, the current methods to detect and evaluate the instability of the Lisfranc joint seem to be unreliable. In addition, there is still no consensus on how to evaluate the instability of the Lisfranc injury.

Recently, weightbearing CBCT imaging has been introduced as an alternative modality for the radiologic imaging of midfoot injuries (Tuominen et al., 2013). The potential benefits of CBCT are lower costs and radiation dose combined with high image quality (Tuominen et al., 2013). Theoretically, the precision of standard CT and the stress aspect of weightbearing radiographs could be combined in weightbearing CBCT. Therefore, in future, CBCT might be the highly sought-after tool for assessing the instability of the Lisfranc injury. However, the use of weightbearing CBCT in primary diagnostics may be a notable problem due to pain and difficulties in bearing weight right after the injury. Further studies are therefore needed to identify the real benefits of weightbearing CBCT.

### 6.3 Outcome measures (III)

The AOFAS Midfoot Scale, the most commonly used PROM for midfoot injuries, has been extensively used to evaluate the outcomes after Lisfranc injury (Button & Pinney, 2004; Shazadeh Safavi et al., 2018). As the validity of the AOFAS Midfoot Scale has been questioned, the findings of these previous studies have been questionable too (Button & Pinney, 2004; Kitaoka et al., 2018). However, the scale has not been evaluated using the widely accepted psychometric methods Classical Test Theory (CTT) or Item Response Theory (IRT), which are the two methods used for evaluating the validity and reliability of the instruments (Mokkink et al., 2010a; Mokkink et al., 2010b). The COSMIN checklist requires the evaluation of the validity, reliability, and responsiveness of the instrument to decide whether or not it can be used before applying it in clinical practice (Mokkink et al., 2010a; Mokkink et al., 2010b). After the instrument has been tested with CTT, it should be further assessed with IRT to reliably conclude the performance of the instrument (Mokkink et al., 2010a; Mokkink et al., 2010b).

The VAS-FA and the AOFAS Hindfoot Scale have previously been compared by Nair et al. (2015) who evaluated the performance of the scales in patients with malleolar fractures. They noted that both of the instruments resulted in similar functional scores. They did not, however, evaluate the psychometric properties using

CTT or IRT. In our study, the principles of both CTT (internal consistency) and IRT (person-item distribution, thresholds between response categories) were combined.

Our study showed that the AOFAS Midfoot Scale had a strong convergent validity, since the correlations and relationship were high with the VAS-FA and its subscale (Pain, Function) scores. In addition, the internal consistency (Cronbach's alpha, 0.75) was acceptable for the AOFAS Midfoot scale, a finding that contradicts the results of a previous study that investigated patients with hallux valgus (Cronbach's alpha, 0.59) (Dawson et al., 2007). On the other hand, there were notable concerns about the coverage and targeting of the scale, since the ceiling effect and person-item distribution map showed that a notable number of patients scored maximum points, and therefore the instrument fails to discriminate the less symptomatic patients well enough. Nevertheless, the correlation between the AOFAS Midfoot Scale total score and follow-up time was negligible and the VAS-FA had no ceiling effect even though the follow-up time was relatively long (2-6 years). Hence, it seems that the flaws in coverage and targeting were caused by an imbalance of the hard and easy items of the instrument, not the relatively healthy patient group.

Although the AOFAS Clinical Rating Systems (including the Midfoot Scale) have been the most widely used PROMs in foot and ankle surgery, their validity has been questioned, since it does not fulfill the acceptable criteria for PROMs (Button & Pinney, 2004; Kitaoka et al., 2018; SooHoo et al., 2003). Additionally, there are a few other drawbacks concerning the use of the scale in clinical trials or in practice. The total score of the instrument cannot be calculated if one or more answers is missing, resulting in a higher drop-out rate if applied in clinical trials (SooHoo et al., 2003). It has also been pointed out that the AOFAS Midfoot Scale uses somewhat non-specific expressions, such as gait abnormality being graded as "none, slight", "obvious" or "marked", and alignment as "good, plantigrade, well-aligned", "fair, plantigrade, some degree of malalignment" or "poor, non-plantigrade, severe malalignment" (Richter et al., 2006). In our current study, despite the non-specific answer categories, all items had correctly ordered thresholds between each response category and did not show any significant malfunctions. Item 3 ("Maximum walking distance, blocks") had narrow thresholds for responses 2 ("4-6") and 3 ("1-3"), and therefore the answers could be combined and the number of possible answer categories reduced. In addition, items 1, 2, and 4 did not receive any answers to the lowest (worst) categories. Although the categories were properly ordered, the problem of the non-specific explanations of the answer categories may have caused



problems for the patients to understand the meaning of each category. Hence, the reliability of the instrument may have been affected. Due to these previously stated concerns, even the developers of the AOFAS Clinical Rating Systems suggest that other outcome measures, such as the PROMIS Physical Function Computerized Adaptive Test (CAT) or the Lower Extremity CAT combined with an additional pathology-specific instrument, should be considered instead of the AOFAS scales (Kitaoka et al., 2018).

Despite these aforementioned flaws, many previous studies have used the AOFAS Midfoot Scale as a primary outcome measure to evaluate outcomes after Lisfranc injuries (Crates et al., 2015; Kuo et al., 2000; Ly & Coetzee, 2006; Rajapakse et al., 2006; Rammelt et al., 2008; Richter et al., 2001; Teng et al., 2002). Since we observed deficiencies in the coverage and targeting of the scale, the present results suggest that the previous studies (Crates et al., 2015; Kuo et al., 2000; Ly & Coetzee, 2006; Rajapakse et al., 2006; Rammelt et al., 2008; Richter et al., 2001; Teng et al., 2002) that used the AOFAS Midfoot Scale might have missed some information on the less symptomatic patients.

Our primary interest was in evaluating the validity of the instrument since it was the only commonly used foot score with previously published MCID values (Dawson et al., 2007). Therefore, it was the only reasonable PROM that could be used to perform the power calculations.

The main finding of our study was that the AOFAS Midfoot Scale has a high convergent validity and acceptable internal consistency. However, the instrument has notable flaws (ceiling effect and person-item distribution) with regard to its coverage and targeting in assessing outcomes after Lisfranc injury. As our findings do not encourage us to use the instrument, it is necessary that we also have the VAS-FA as the secondary PROM, an instrument that has been shown to perform well in multiple studies, and its validity has been shown to be acceptable in the Finnish language version (Repo et al., 2018; Richter et al., 2006).

## 6.4 Outcomes after non-operatively treated Lisfranc injury (IV)

During recent years, only four retrospective studies on the non-operative treatment of Lisfranc injury have been published (Crates et al., 2015; Curtis et al., 1993; Nunley & Vertullo, 2002; Shapiro et al., 1994). All of these previous studies share the same flaws. First, the diagnosis of the injury was based on plain radiographs. Second, the

evaluation of the outcomes had been conducted without using properly validated outcome measures. Third, the non-operative treatment protocol varied between none to six weeks of cast immobilization followed by four weeks of orthosis (Crates et al., 2015; Faciszewski et al., 1990; Myerson et al., 1986; Nunley & Vertullo, 2002; Shapiro et al., 1994). Non-weightbearing during the immobilization was only used by a few studies (Faciszewski et al., 1990; Nunley & Vertullo, 2002). Moreover, some authors have suggested that only stable injuries without any displacement should be treated non-operatively (Nunley & Vertullo, 2002). Nevertheless, there is no consensus on which techniques should be used to determine whether an injury is stable or not, and therefore this statement needs to be considered carefully (Naguib & Meyr, 2018; Preidler et al., 1999). Moreover, after completing our study, another retrospective case series was published by Chen et al. (2020). They reported that 54% of 26 patients developed an instability during the conservative treatment, and were converted to operative treatment. Surprisingly, they also reported that the functional outcomes were comparable in both groups, regardless of the timing of the surgery. After all, there are no RCTs in the literature that have compared operative with non-operative treatment.

The literature provides at least 15 different classification systems for Lisfranc injuries (Hardcastle et al., 1982; Lau et al., 2017; Myerson et al., 1986; Nunley & Vertullo, 2002; Schepers & Rammelt, 2018; Sivakumar et al., 2018). Ideally, injury classifications should be developed as tools to help doctors in decision making and in choosing the optimal treatment for each patient (Burstein, 1993). Accurately working classifications should also provide estimates of the outcomes after the chosen treatment (Burstein, 1993). The original classification by Schepers and Rammelt (2018) was developed to patch the flaws of the previous radiograph-based classifications that do not take into account all TMT injuries (Hardcastle et al., 1982; Myerson et al., 1986; Nunley & Vertullo, 2002). This latest classification classifies these injuries based on fracture type (avulsion, simple, or comminuted) and the columns affected, resulting in dozens of different groups. Although this classification seems to be the most suitable classification system for Lisfranc injuries, it would benefit from a reduction in the number of different groups and further studies to guide the treatment of these injuries. Additionally, the classification does not take into account displacement or stability, which seem to be the factors that have an influence on the treatment. Although the results of the surgery might not be dependent on the primary dislocation, it is an important factor when non-operative treatment is considered. As this classification takes all bony injuries into account, it results in multiple classes of injuries. Since it is important to evaluate the results after

treatment of these injuries, the large number of classes makes it impossible to compare them. Therefore, we deemed it necessary to reduce the number of classes to three main groups. Moreover, the inter- and intraobserver reliability of the classification should also be evaluated to assess its reliability.

The main finding of the retrospective case series was that nondisplaced Lisfranc injuries affecting up to three TMT joints can be treated non-operatively with good functional outcomes. More than half of the patients in all groups scored over 90 points in both the Pain and Function subscales and more than 60% scored over 90 points overall. The mean VAS-FA scores for patients without previous foot injuries have been reported in a previous study as follows: 94.5 for Overall, 92.5 for Pain, 95.4 for Function, and 75.6 for Other Complaints (Faciszewski et al., 1990). Therefore, the results of this series show that most of the non-operatively treated patients in our study recovered close to the level of healthy patients after 2 to 6 years of follow-up. The VAS-FA scores seemed to be following a similar distribution between bony avulsions and simple intra-articular fractures.

In the largest previous study investigating the non-operative treatment of Lisfranc injuries (Crates et al., 2015), up to 20 out of 36 patients underwent secondary surgery during the three-year follow-up period. The non-operative protocol in their study was conducted with 6 weeks of orthosis and weightbearing was allowed as tolerated. In addition, the diagnosis of subtle Lisfranc injury was based on standard radiographs and patients with remarkable clinical symptoms (even without findings in the radiographs) were included in the study. Moreover, “failed nonoperative treatment” was determined by a surgeon, but no further details of the reasons behind the conversion to operative treatment were given. Due to these flaws, the results of this previous study can be questioned.

The non-operative protocol in our study was more careful than the one used by Crates et al. (Crates et al., 2015). Our protocol with non-weightbearing and longer immobilization was adopted from a previous study by Nunley and Vertullo (2002). With this non-operative treatment, our secondary operation rate was low, as only 1 of the 60 patients underwent an arthrodesis performed 10 months after the injury. As our outcomes suggest, the results of non-operative treatment may be better if the non-operative protocol is started with non-weightbearing and the immobilization lasts for 6 to 10 weeks.

## 6.5 Randomized controlled study (V)

The prospective study has several strengths. The prospective randomized controlled study setting is the highest quality study setting to be used to compare different treatment options. To date, our study is the first to compare operative and non-operative treatments, and only the third study to compare PA and ORIF in an RCT setting in the treatment of Lisfranc injuries. As mentioned earlier, previous RCTs have used plain radiographs in the diagnostics of the injury and the outcomes have been evaluated with the AOFAS Midfoot Scale, which does not differentiate patients well enough (Henning et al., 2009; Ly & Coetzee, 2006).

## 6.6 General consideration

The strength of our studies was the representative study group. The study sample included all patients from minimal avulsion fractures up to patients with severe dislocation of all TMT joints. Since most of the previous studies have either evaluated only subtle or severe injuries, it is important to understand that these injuries are not pathologically divided into two distinct groups but are a wide spectrum of different injuries in the same anatomical region. Another strength of the studies was the use of CT. Although the benefits of CT for diagnosing Lisfranc injuries was first described in 1985 (Goiney et al., 1985), CT has not been consistently used in consistently previous studies and classifications (Crates et al., 2015; Myerson et al., 1986).

When assessing incidence rates, the most accurate results could be obtained with nationwide register data. However, there are no distinct International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes for Lisfranc injuries, and therefore it was not possible to conduct a register study. Due to this flaw, it is possible that some of the patients may have been treated in private hospitals or in different regions. Nonetheless, the hospital district policy is that these injuries should be referred to our University Hospital, and therefore we believe that the incidences presented in our study are close to the actual incidence rate.

When assessing the inter- and intraobserver reliability for Lisfranc injuries, our observers were either experienced foot and ankle surgeons or orthopedic surgery residents with at least three years of experience in the field of trauma. As these injuries are often initially diagnosed by general practitioners, the real accuracy of

diagnostics can be even lower. In addition, we decided not to use radiologists as observers because orthopaedic surgeons and residents are the ones who make the decisions between different treatments, and therefore we felt that it was necessary to evaluate the accuracy between these two groups of clinicians.

When assessing the validity of the AOFAS Midfoot Scale, the main strength of the study was the large group of patients with Lisfranc injury, half of whom were treated non-operatively and half operatively. The major limitation of the study was that we did not use other reference instruments other than the VAS-FA, nor we did use any general health-related quality of life instruments to evaluate how well the AOFAS Midfoot Scale correlates with quality of life. In addition, we did not test the responsiveness of the scale. To do so, would have given us important information on how the scale performs when the same patients respond to the same questions after a short period of time.

When investigating the outcomes after the non-operative treatment of Lisfranc injuries, the main strength was that the sample size of this study was notably larger than in previous studies (Crates et al., 2015; Curtis et al., 1993; Faciszewski et al., 1990; Shapiro et al., 1994). Our study was also the first to evaluate the outcomes after non-operatively treated Lisfranc injuries where the diagnosis of the injury was confirmed with CT imaging, long non-weightbearing protocol, and properly validated outcome measures.

One obvious limitation of the study investigating the outcomes after non-operatively treated Lisfranc injuries was not to use any clinical examination or imaging of the patients. This decision was taken based on the findings of previous studies that have shown that radiological findings and the symptoms of posttraumatic osteoarthritis are not related (Mulier et al., 2002; Myerson et al., 1986). Secondly, other limitations were the retrospective nature and relatively low response rate (47%), which may have caused noteworthy selection bias. As our response rate remained low, we decided to compare the clinical characteristics of all non-operatively treated patients to the included sample and the characteristics seemed to be similar.

The limitation of the prospective study is that the power calculations are based on the AOFAS Midfoot Scale, and it is therefore currently reported as the primary outcome measure. However, as our own results show, the VAS-FA would be a more valid instrument to be used as a primary outcome measure. As the MCID value for the VAS-FA has not yet been determined, it cannot be used to evaluate the sample size. A second limitation of the study is that the inclusion criteria for subtle and severe injuries were based on our study group. Hence, there are no consensus-based

criteria or classification based on CT for these injuries, and we therefore needed to create our own criteria. Although it was thought that our inclusion criteria accounted for most of the injuries, there are still some types of injuries of the Lisfranc joint, such as lateral injuries that only affect the TMT joints IV and V, that are not included in the study.

## 7 CONCLUSIONS

The present study provides data to support the following conclusions:

1) Lisfranc injuries are more frequent injuries than previously thought with an incidence of 9.2/100 000 person-years. Chopart injuries are less frequent with an annual incidence of 2.2/100 000 person-years in our study population. In addition, a high number of Chopart and Lisfranc injuries are caused by low-energy trauma mechanisms, whereas high-energy trauma mechanisms were more unusual. Most of the Lisfranc-Chopart combination injuries occur in high-energy traffic accidents.

2) The conventional radiograph-based diagnosis of a Lisfranc injury has moderate ( $\kappa$ : 0.50-0.58) agreement between observers and substantial ( $\kappa$ : 0.71) agreement between the same observer in different moments. The sensitivity (76%) and specificity (85%) for detecting Lisfranc injuries indicated moderate accuracy. Therefore, a substantial number (24%) of injuries are missed if only conventional radiographs are used. Subtle, nondisplaced injuries were more commonly missed than displaced injuries.

3) The AOFAS Midfoot Scale has acceptable validity and internal consistency, but when compared to the VAS-FA, the scale's coverage and targeting raises some concerns, and therefore it does not discriminate patients with relatively few symptoms well. The scale has too many 'easy' items, and it is therefore too easy to score the maximum points.

4) Non-operative treatment certainly has a role to play in the treatment of Lisfranc injuries. Our study supports the view that nondisplaced injuries, regardless of the number of affected columns or the type of the injury (avulsion or simple intra-articular fracture) of the Lisfranc joint, can be treated non-operatively with 4 to 6 weeks non-weightbearing cast with good clinical outcomes.

5) Our prospective randomized controlled study is currently ongoing, and we have included half of the planned patient sample. Once published, the trial will provide important knowledge on the treatment of Lisfranc injuries.

## 7.1 Challenges for future studies

Although these injuries have been known for over 100 years, there are still plenty of aspects that we do not yet understand. Even the definition of 'Lisfranc injury' varies extensively between multiple studies. Even though there are over 14 classifications, none of them has achieved consensus between clinicians. The first step to further understand these injuries would be to create a clear definition and properly working classification. Instability has previously been stated to be one of the main factors that influences the outcomes of these injuries.

Most of the previous studies have focused on comparing different surgical interventions. Nevertheless, there is no consensus about surgical treatment; whether, for example, primary arthrodesis would be better than open reduction and internal fixation. Furthermore, there is no evidence that one fixation method (screws, plates) is better than another. The findings of our study support the view that certain groups of patients can be treated non-operatively. Therefore, more research using valid methods is needed in future to ensure patients with midfoot injuries get the best possible treatment.





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# PUBLICATIONS





# PUBLICATION

I

## **Incidence and characteristics of midfoot injuries**

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Heidi


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# Incidence and Characteristics of Midfoot Injuries

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## Abstract

**Background:** The epidemiology of midfoot injuries is poorly known. It has been estimated that the incidence of Lisfranc injuries (intra-articular injury in the tarsometatarsal joint) is 1/55 000 person-years and the incidence of Chopart injuries (intra-articular injury in the talonavicular and calcaneocuboidal joint) 4/100 000 person-years. The purpose of our study was to assess the computed tomography (CT) imaging-based incidence (per 100 000 person-years) and trauma mechanisms of midfoot injuries.

**Methods:** All CT studies performed due to acute injury of the foot and ankle region between January 1, 2012, and December 31, 2016, at Tampere University Hospital were reviewed. Patients presenting with an injury in the midfoot region in the CT scan were included in this study, and their records were retrospectively evaluated to assess patient characteristics.

**Results:** During the 5-year study period, 953 foot and ankle CT scans were obtained because of an acute injury of the foot and ankle. Altogether, 464 foot injuries were found. Of these, 307 affected the midfoot area: 233 (75.9%) the Lisfranc joint area, 56 (18.2%) the Chopart joint area, and 18 (5.9%) were combined injuries or miscellaneous injuries in the midfoot. The incidence of all midfoot injuries was 12.1/100 000 person-years. The incidence of Lisfranc injuries was 9.2/100 000 person-years. The incidence of Chopart injuries was 2.2/100 000 person-years.

**Conclusions:** The incidence of Lisfranc injuries was higher and the incidence of Chopart injuries lower than previously estimated. More than two-thirds of the midfoot injuries in this study were nondisplaced (<2 mm displacement in fracture or joint) and were caused by low-energy trauma.

**Level of Evidence:** Level III, epidemiologic study.

**Keywords:** Lisfranc, Chopart, tarsometatarsal, joint, trauma, injury, incidence, epidemiology

Lisfranc injury was originally described as a partial or complete dislocation of the tarsometatarsal (TMT) joints by Quenu and Kuss in 1909.<sup>18</sup> Nunley and Vertullo<sup>16</sup> described that the injury can also be subtle when there is no detectable dislocation in nonweightbearing radiographs. Recently, however, Chiodo and Myerson<sup>2</sup> introduced a new approach to these injuries where they suggested to divide the injuries in medial (TMT 1), central (TMT 2-3), and lateral (TMT 4-5) columns. Lau et al<sup>10</sup> completed the columnar approach with a classification where the prognosis of injury is related to number of affected columns and displacement (less or more than 2 mm) instead of the diastasis between I and II TMT joints. Main and Jowett<sup>13</sup> developed a classification for Chopart injuries, where they stated that these injuries vary from small avulsion fragments to severe subluxation

of the whole joint. Diagnostics have become more precise as a result of the more common use of computed tomography (CT). It is unclear whether there is such a type of injury as “purely ligamentous injury,” or whether is it detectable from bony avulsion fragments.<sup>7,8,17</sup> The definitions and classifications of these injuries has changed, and still, 100

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years after the first classification there is no clear consensus on how these injuries should be defined.<sup>20</sup>

The epidemiology of midfoot (Lisfranc and Chopart joint) injuries is poorly known.<sup>3,5</sup> It has been estimated that Lisfranc injuries account for 0.2% of all fractures, and the annual incidence is reported to be 1/55 000 person-years.<sup>1,6</sup> It has also been estimated that between 20% and 24% of midfoot injuries are undiagnosed during initial clinical examination.<sup>2,8,14,26,27</sup> The 2 most cited studies of Lisfranc injury incidence were published in the early 1960s.<sup>1,6</sup> In a study by Aitken and Poulson<sup>1</sup> published in 1963, 16 patients with Lisfranc injury were treated during a 15-year period in a hospital where 5500 fractures were treated annually. In a study by English<sup>6</sup> in 1964, there were 24 Lisfranc injuries among 11 000 fractures, which gives an incidence rate of 0.2% of all fractures. These 2 studies are often cited when the incidence rate of 1/55 000 person-years for Lisfranc injuries is presented. However, the authors who cite these studies fail to provide any basis or supporting data for how they achieved this figure. In a study by Court-Brown et al,<sup>3</sup> 116 midfoot injuries (navicular, cuneiform and cuboid) were treated in 113 patients during a 5-year period in a catchment area of 650 000 residents. The resulting incidence rate for midfoot injuries diagnosed with plain radiographs was 3.6/100 000 person-years. A study by Richter et al<sup>22</sup> reported that the proportion of combined (Lisfranc-Chopart) injuries of the midfoot was 16.8% of all midfoot injuries, and such injuries are often caused by high-energy trauma. The incidence of these injuries is, however, still unknown. Because the International Statistical Classification of Diseases and Related Health Problems (ICD) offers no codes for midfoot injuries, it is impossible to conduct a register-wide epidemiological study.

Lisfranc injuries are traditionally divided into subtle and severe injuries based on the trauma mechanism.<sup>16,21,28</sup> Subtle injuries are suggested to be the result of indirect low-energy trauma, such as twists and sprains that often occur during sports.<sup>15,16</sup> Severe injuries are thought to result from high-energy trauma, such as traffic accidents, falling from height, or direct crush injuries.<sup>15</sup> Subtle injuries present a significant diagnostic challenge because it has been suggested that ligamentous injuries are impossible to detect without weight-bearing.<sup>16</sup> The previous classification of Lisfranc injuries by Myerson<sup>14</sup> is based on plain radiographs and the classification by Nunley and Vertullo<sup>16</sup> is based on weightbearing radiographs. CT and magnetic resonance imaging (MRI) are now recommended to be used for defining midfoot injuries. There is, however, no consensus as to when these modalities should be used or how the findings should be interpreted.<sup>7,8,12,25</sup> The aim of this study was to assess the CT-based incidence (per 100 000 person-years) and characteristics of midfoot injuries at a Level I trauma hospital, which was the only public hospital providing acute trauma care for the half-million residents of the region.

## Methods

To assess the incidence of midfoot injuries, all CT studies (traditional CT or cone-beam CT) performed due to acute injury to the foot and ankle region during a 5-year period (January 1, 2012, to December 31, 2016) were reviewed. Patients presenting with an injury to the midfoot region in CT scans were included in the study. In accordance with hospital policy, CT was always performed when there was an intra-articular fracture or midfoot joint displacement in radiographs or a high suspicion of midfoot injury based on clinical examination. Patient records were retrospectively evaluated to assess patient characteristics, trauma mechanism, primary radiologic findings, associated injuries, and treatment. Patients with injuries older than 30 days, isolated fractures of the fifth metatarsal base, injuries only in the distal foot (simple metatarsal fractures or injuries only in the metatarsophalangeal joint or toe region), or patients residing outside the catchment area were excluded from the study.

To compute the incidence of injuries, the annual population of the Pirkanmaa region was obtained from Official Statistics of Finland, an electronic population register of the country. The injury incidence was calculated by the annual number of injuries with the population of the region, which was 509 279 residents in December 2016. The incidence is presented per 100 000 person-years.

Tumbling or slipping, tumbling on stairs and sports-related activities were considered to be low-energy trauma mechanisms. Falling from height, direct injury and traffic collisions were considered to be high-energy trauma mechanisms. Midfoot injuries were divided into Lisfranc (tarsometatarsal joint, TMT) and Chopart (talonavicular and calcaneocuboid joint) injuries. Intra-articular and avulsion fractures of the TMT were considered to be Lisfranc injuries (Figure 1). Extra-articular fracture of a metatarsal base was not defined as Lisfranc injury. Fractures and avulsions affecting the talonavicular and calcaneocuboid joints were considered to be Chopart injuries (Figure 2). Combined or miscellaneous injuries were injuries that affected both anatomic areas or injuries that could not be classified as pure Lisfranc or Chopart injuries.

The injuries were classified into 2 groups based on the displacement of the fracture or the dislocation of the affected joint measured from CT scans. Displacement of 2 mm or below was considered a nondisplaced injury, and over 2 mm a displaced injury. Lisfranc injuries were also classified based on the Myerson classification for Lisfranc injuries where possible.<sup>14</sup>

Categorical variables were compared with chi-square test. Confidence interval was 95%, and therefore *P* values <.05 were considered to be statistically significant. Statistical analysis was performed using IBM SPSS Statistics, version 22.



**Figure 1.** (A-D) Computed tomographic findings of Lisfranc injury.

## Results

During the 5-year study period, 953 foot and ankle CT scans were obtained for acute injuries to the foot and ankle (Figure 3). Of these, 307 injuries affected the midfoot: 233 (75.9%) in the Lisfranc joint area, 56 (18.2%) in the Chopart joint area, and 18 (5.9%) were combined injuries or miscellaneous injuries in the midfoot. Of all patients presenting with midfoot injuries, 199 (68.8%) were male and 108 (35.2%) female (Table 1). Males were more likely to have Lisfranc injuries (70% vs 30%,  $P < .001$ ) and females were more likely to have Chopart injuries (57% vs 43%,  $P < .0001$ ). Differences between gender was not found in combined or miscellaneous injuries (67% vs 33%,  $P < .866$ ). The male-female ratio was 1.8:1. The mean age of the males was 35.7 (9-88) years and 42.5 (10-76) years for females. In total, 25.4% of all midfoot injuries occurred in the 21 to 30 years age group. Concomitant foot or ankle injuries were found in 37 (12.1%) of the patients. Of all midfoot injuries, 73 (23.8%) were displaced more than 2 mm in CT and 234 (76.2%) were nondisplaced (less than 2 mm).

The incidence of all midfoot injuries in our study was 12.1/100 000 person-years. The incidence of Lisfranc injuries was 9.2/100 000 person-years while the incidence of Chopart injuries was 2.2/100 000 person-years. The

occurrence of Chopart-Lisfranc combinations or miscellaneous injuries was rare, being 0.7/100 000 person-years.

The most frequent trauma mechanisms for Lisfranc injury were tumbling or slipping (36.9%) or direct injury (15.5%) (Table 2). Traffic accidents included 25 (92.6%) motorcycle accidents, and 2 (7.4%) car accidents. The “other” mechanism group comprised bicycle accidents ( $n=7$ ), falling from chair ( $n=6$ ), kick toward a solid object ( $n=5$ ), and unknown mechanism ( $n=2$ ). Low-energy trauma mechanisms caused 128 (54.9%) of the Lisfranc injuries and high-energy trauma mechanisms caused 85 (36.5%) of the injuries. We were not able to classify 20 (8.6%) injuries by trauma mechanism. No association between trauma energy and the severity of the injury (nondisplaced/displaced) was found in Lisfranc injuries ( $P = .069$ ). Males had a higher rate of high-energy Lisfranc injuries than females (49% vs 19%,  $P < .0001$ ).

Displaced Lisfranc injuries accounted for 25.3% ( $n=59$ ) of all Lisfranc injuries. The most frequent trauma mechanism in displaced injuries was tumbling or slipping ( $n=29$ , 49.2%) (Table 2). Nondisplaced Lisfranc injuries accounted for 74.6% ( $n=174$ ) of all Lisfranc injuries. The most frequent trauma mechanisms for nondisplaced injuries were tumbling or slipping (32.8%), direct injury (17.8%), and traffic collisions (10.9%) (Table 2).

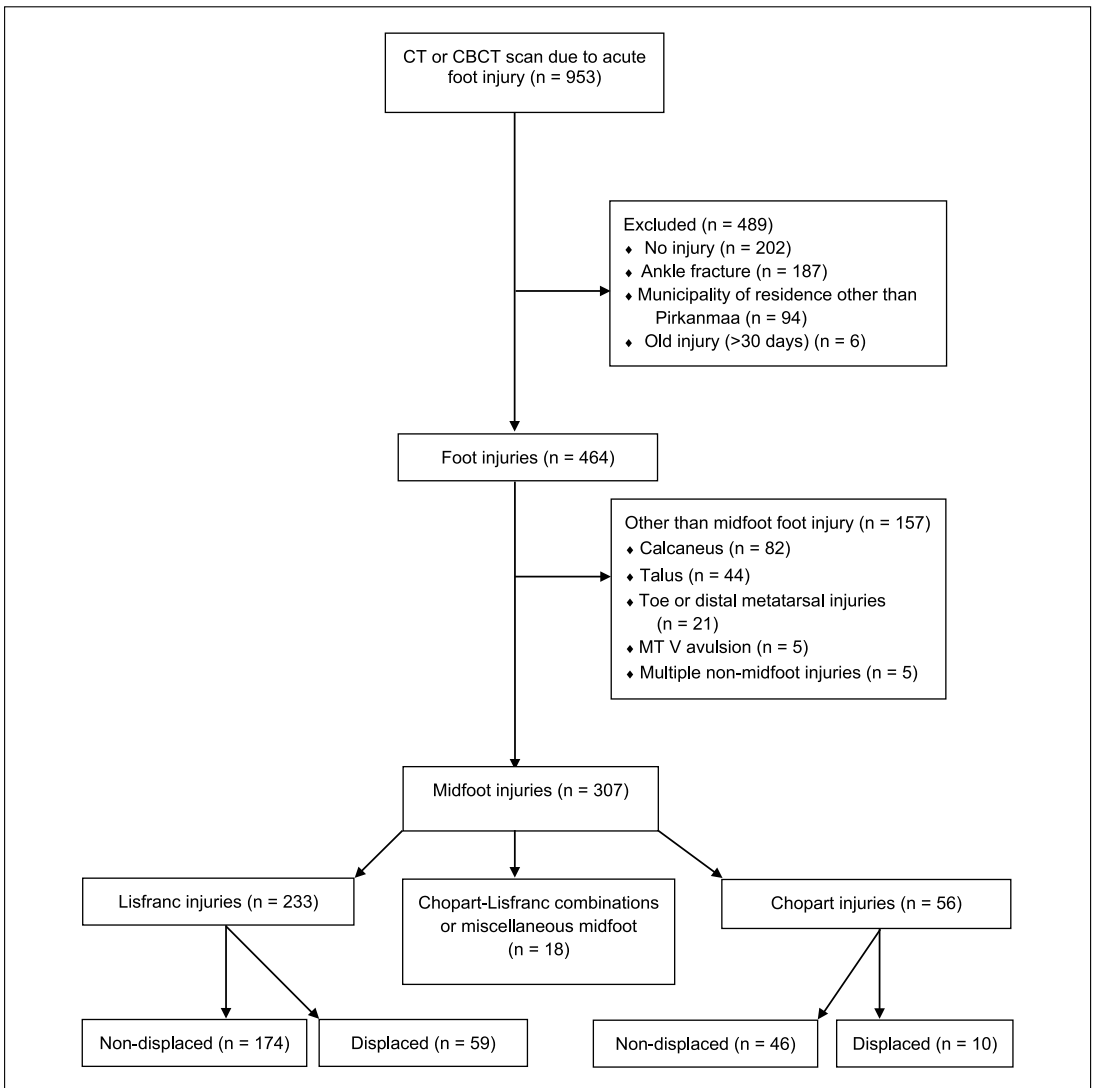


**Figure 2.** (A-D) Computed tomographic findings of Chopart injury.

Of all Lisfranc injuries, only 13 (5.6%) injuries were displaced in such a way that they could be classified with the Myerson classification. The most frequent injury types were A (n=7, 53.8%), B2 (n=3, 23.1%), B1 (n=2, 15.4%), and C2 (n=1, 7.7%). Type C1 was not found in our study. Altogether, 220 (94.4%) injuries were not classifiable according to the Myerson classification. According to the Lau classification, 1 column was injured in 68 (29.2%) cases, 2 columns in 92 (39.5%) cases, and all columns in 73 (31.3%) cases (Table 3). Medial column was injured in 138 (59.2%) cases, central column in 195 (83.7%) cases, and lateral column in 138 (59.2%) cases.

Most of the Chopart injuries were nondisplaced (n=46, 78.0%), and most of the nondisplaced injuries were the result of low-energy trauma mechanisms, such as tumbling on stairs (n=16, 34.8%) and tumbling or slipping (n=12, 26.1%). Ten patients (22.0%) had displaced Chopart injuries. The most frequent trauma mechanisms for displaced injuries were sports-related activities (n=3, 30.0%) and tumbling or slipping (n=3, 30.0%) (Table 2).

The most frequent trauma mechanisms for Chopart-Lisfranc combinations or miscellaneous injuries were traffic collisions (n=5, 27.8%) and direct injury (n=4, 22.2%) (Table 2). Only 4 (25%) of these patients had displaced injuries.



**Figure 3.** Flow chart of the study.

## Discussion

To our knowledge, this is the first CT-based study on the incidence of midfoot fractures. The strengths of our study are the precise imaging and diagnostics of these injuries. There is an ongoing RCT on Lisfranc injuries at our hospital, and therefore the awareness of these injuries in our institution is probably higher than on average. Our indication for CT imaging of the foot in acute trauma is an intra-articular injury or midfoot displacement seen in radiographs or a

high suspicion of a midfoot injury based on clinical findings. Typical clinical findings of Lisfranc injury are swollen midfoot, tenderness and pain in the midfoot during movements and weightbearing, and plantar ecchymosis.<sup>4,24</sup> Although not a nationwide study, the present study is significantly larger than any of the previous studies on the incidence of midfoot injuries. The weakness of this study is that MRI or weightbearing radiographs were not obtained, therefore some purely ligamentous injuries could have been

**Table 1.** Gender and Age Distribution of Patients.

Gender	Lisfranc		Chopart		Combined		Total	
	n	%	n	%	n	%	n	%
Male	163	70.0	24	42.9	12	66.7	199	68.8
Female	70	30.0	32	57.1	6	33.3	108	35.2
Age, y								
<21	42	18.0	8	14.3	4	22.2	54	17.4
21-30	55	23.6	19	33.9	4	22.2	79	25.4
31-40	33	13.7	6	10.7	4	22.2	43	13.8
41-50	41	17.6	10	17.9	3	16.7	54	17.4
51-60	32	13.7	7	12.5	1	5.6	41	13.2
>60	31	13.3	6	10.7	2	11.1	40	12.9

missed. There are no studies where purely ligamentous injuries were scanned with CT, therefore it is not certain that purely ligamentous injuries would not include avulsion fractures that could not be detected under CT. In addition, even though severe foot injuries in our catchment area are mainly diagnosed and treated in our hospital, it is possible that some injuries may also be treated in private hospitals or public health centers. Therefore, our findings might underestimate the true incidence of midfoot injuries.

In our study, the annual incidence of Lisfranc injuries was 5 times higher than previously suggested.<sup>1,6</sup> Even the incidence of displaced fractures was 1.3 times higher than the numbers presented in earlier studies. In a 10-year Finnish study, Vuori and Aro (1993)<sup>28</sup> reviewed 750 plain radiographs of treated tarsometatarsal injuries or metatarsal fractures from a catchment area of 250 000 residents at Turku University Hospital. A total of 66 Lisfranc injuries were found during this 10-year period, giving an incidence of 2.6/100 000 person-years compared with an incidence of 9.2/100 000 person-years in our study. The incidence of Chopart injuries, in turn, was slightly lower compared with earlier studies (2.2/100 000 person-years vs 3.6/100 000 person-years<sup>3</sup>). All previous studies have been based on plain radiographs, and thus the proportion of undiagnosed injuries will have been higher than in our CT-based study. The higher incidence of Lisfranc injuries in our study is probably the result of increased knowledge of midfoot injuries and the better availability of CT imaging. The low incidence of Chopart injuries seen in our study compared with earlier studies probably results from the differences in injury definitions. The widely cited study by Court-Brown et al (2006)<sup>3</sup> included midfoot (navicular, cuneiform and cuboid) injuries, whereas we concentrated on injuries affecting the Chopart joint. Therefore, we may conclude that the present study is the first to investigate the incidence of Chopart joint injuries.

Lievers et al (2012)<sup>11</sup> conducted a literature review of Lisfranc dislocations. The most frequently reported injury mechanisms were traffic accidents (43%), fall from height

(24%), direct crush (13%), sports (10%), and equestrian (1%). In our study, the most common trauma mechanism for Lisfranc injury was tumbling or slipping (37%). This mechanism was more than 2 times more frequent than direct injury (16%) and 3 times more frequent than traffic collisions (12%). Age distribution and gender ratio were quite similar in our study compared with Lievers et al's analysis: about half of the patients were less than 35 years old, male-female ratio was 2:1. Their study showed that the injury mechanism was significantly related to age and sex. Crushing injuries (m/f 8) and motorcycle crashes (m/f 7) were significantly more prevalent in males, whereas low-energy falls were more prevalent in females (m/f 0.77). This finding is in line with the results of our study, as males sustained Lisfranc injuries from high-energy trauma mechanisms more often than females. Most of the traffic collisions were motorcycle accidents (93%). Of the 66 Lisfranc injuries found in the study by Vuori and Aro (1993),<sup>28</sup> 12 (18%) were total dislocations, 47 (71%) were classified as partial dislocations, and 7 (11%) as subtle Lisfranc injuries based on the classification by Quenu and Kuss.<sup>18</sup> In their study, one-third of all Lisfranc injuries were caused by low-energy trauma mechanism. In our study, however, the number of subtle injuries (75%) and the proportion of injuries caused by low-energy trauma (55%) were significantly higher.

The traditional Lisfranc injury classifications by Quenu and Kuss (1909),<sup>18</sup> Hardcastle (1982),<sup>9</sup> and Myerson (1986)<sup>14</sup> are based on findings in plain foot radiographs. Basically, these classifications describe the pattern and direction of the displacement of bones in the Lisfranc joint region. Only 6% of patients in our study could be classified according to the Myerson<sup>14</sup> classification. Furthermore, none of the classifications have been useful in predicting outcomes or choosing the right treatment for Lisfranc injury.<sup>29</sup> The classification by Nunley and Vertullo (2002)<sup>16</sup> was developed primarily for low-energy trauma. The classification is based on the weightbearing radiographs of 15 patients with a "midfoot sprain" injury in the Lisfranc region<sup>16</sup> that are classified into 3 different stages. The classification has a few limitations: weightbearing may be impossible because of pain in the injured foot, and the sensitivity of plain radiographs is low when compared with CT.<sup>8,28</sup> Therefore, more research on the clinical importance of the findings in CT and MRI studies and the treatment of the subtle injuries in the midfoot region is needed. Since these classifications, Chiodo and Myerson (2001)<sup>2</sup> and Lau et al (2017)<sup>2</sup> have changed the approach to these injuries. They have introduced a column-based classification, which also accounts for the subtle injuries and it is applicable with CT. Yet the evidence on how well the classification leads toward the best treatment is scarce, although the classification provides a fresh perspective on these injuries.<sup>2,10</sup>



**Table 2.** Trauma Mechanisms of Midfoot Injuries.

Trauma mechanism	Lisfranc						Chopart						Combined	
	All		Nondisplaced		Displaced		All		Nondisplaced		Displaced		All	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Tumbling or slipping	86	36.9	57	32.8	29	49.2	15	26.8	12	26.1	3	30.0	3	16.7
Direct injury	36	15.5	31	17.8	5	8.5	2	3.6	2	4.3	0	0.0	4	22.2
Traffic collisions	27	11.6	19	10.9	8	13.6	5	8.9	4	8.7	1	10.0	5	27.8
Tumbling on stairs	22	9.4	16	9.2	6	10.2	18	32.1	16	34.8	2	20.0	3	16.7
Falling from height	22	9.4	18	10.3	4	6.8	5	8.9	4	8.7	1	10.0	1	5.6
Sports	20	8.6	15	8.6	5	8.5	10	17.9	7	15.2	3	30.0	0	0.0
Other	20	8.6	18	10.3	2	3.4	1	1.8	1	2.2	0	0.0	1	11.1
Total	233	100.0	174	100.0	59	100.0	56	100.0	46	100.0	10	100.0	18	100.0

**Table 3.** Classification of Lisfranc Injuries by Lau.

Lau Classification <sup>a</sup>	n	%
I	68	29.2
2A	67	28.8
2B	25	10.7
3A	48	20.6
3B	25	10.7
Combinations of injured columns		
Isolated medial	21	9.0
Isolated central	32	13.7
Isolated lateral	15	6.4
Medial + Central	42	18.0
Medial + Lateral	2	0.9
Central + Lateral	48	20.6
All columns	73	31.3

<sup>a</sup>Number of injured columns combined with a letter indicating the sagittal displacement (A ≤ 2 mm, B > 2 mm).

Some authors classify these injuries as “high-energy” and “low-energy” based on the trauma mechanism.<sup>19,21,23</sup> Renninger et al<sup>21</sup> studied the differences between low- and high-energy injuries. Low-energy injuries included athletic activity, ground-level twisting, and fall from less than 4 feet. High-energy injuries included motor vehicle crash, motorcycle crash, direct crush, and fall from greater than 4 feet. They reviewed all operatively treated Lisfranc injuries at a single military tertiary referral center for 5 years. Patients with high-energy injuries were more likely to have concomitant nonfoot fractures (37% vs 6%), concomitant foot fractures, cuboid fractures (31% vs 6%), metatarsal base fractures (84% vs 29%), displaced intra-articular fractures (59% vs 4%), and involvement in all TMT joints (23% vs 6%). We did not find any association between trauma mechanism and energy and the severity of the injury. This may be because energy affecting the foot is difficult to evaluate.

In conclusion, the incidence of Lisfranc injuries was significantly higher than previously thought. This finding could result

from increased knowledge concerning midfoot injuries and more precise imaging (CT). Up to three-quarters of the midfoot injuries in our study population were nondisplaced injuries. No association was found between trauma energy and the displacement of the fracture. Therefore, we suggest that the classification of these injuries should be based on radiologic findings rather than on trauma energy. More research is needed on the treatment of these subtle injuries because the current classifications and the literature on the treatment of midfoot injuries focus mainly on more severe or displaced injuries.

#### Declaration of Conflicting Interests

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# PUBLICATION II

## **Inter- and intraobserver reliability of non-weight-bearing foot radiographs compared with CT in Lisfranc injuries**

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# Inter- and intraobserver reliability of non-weight-bearing foot radiographs compared with CT in Lisfranc injuries

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## Abstract

**Background** Injury of the tarsometatarsal (TMT) joint complex, known as Lisfranc injury, covers a wide range of injuries from subtle ligamentous injuries to severely displaced crush injuries. Although it is known that these injuries are commonly missed, the literature on the accuracy of the diagnostics is limited. The diagnostic accuracy of non-weight-bearing radiography (inter- or intraobserver reliability), however, has not previously been assessed among patients with Lisfranc injury.

**Methods** One hundred sets of foot radiographs acquired due to acute foot injury were collected and anonymised. The diagnosis of these patients was confirmed with a CT scan. In one-third of the radiographs, there was no Lisfranc injury; in one-third, a nondisplaced (< 2 mm) injury; and in one-third, a displaced injury. The radiographs were assessed independently by three senior orthopaedic surgeons and three orthopaedic surgery residents.

**Results** Fleiss kappa ( $\kappa$ ) coefficient for interobserver reliability resulted in moderate correlation  $\kappa=0.50$  (95% CI: 0.45–0.55) (first evaluation) and  $\kappa=0.58$  (95% CI: 0.52–0.63) (second evaluation). After three months, the evaluation was repeated and the Cohen's kappa ( $\kappa$ ) coefficient for intraobserver reliability showed substantial correlation  $\kappa=0.71$  (from 0.64 to 0.85). The mean (range) sensitivity was 76.1% (60.6–92.4) and specificity was 85.3% (52.9–100). The sensitivity of subtle injuries was lower than severe injuries (65.4% vs 87.1%  $p=0.003$ ).

**Conclusions** Diagnosis of Lisfranc injury based on non-weight-bearing radiographs has moderate agreement between observers and substantial agreement between the same observer in different moments. A substantial number (24%) of injuries are missed if only non-weight-bearing radiographs are used. Nondisplaced injuries were more commonly missed than displaced injuries, and therefore, special caution should be used when the clinical signs are subtle.

**Level of evidence** III.

**Keywords** Lisfranc · Injury · Radiographs · X-ray · Interobserver · Intraobserver · Reliability · Responsiveness

## Introduction

Lisfranc injury was originally described as a partial or complete dislocation of the tarsometatarsal (TMT) joints, although the definition and classifications of the injury have altered over the years [39, 45]. Indeed, multiple classifications have been presented, yet there is still no consensus on the precise definition of Lisfranc injuries [6, 25, 33]. Nevertheless, Lisfranc injury is recognized nowadays as a wide variety of both bony and ligamentous injuries of the TMT joint region ranging from subtle ligamentous injuries to severely displaced or crush injuries [21, 25, 33, 35, 43, 45].

The incidence of Lisfranc injuries has been presented to be 9.2/100 000 person-years when diagnosed with computed tomography (CT) [34]. Furthermore, it has been estimated

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that even Lisfranc injuries resulting from high-energy trauma mechanisms can be initially overlooked or misdiagnosed in 20%–24% of cases [17, 30]. However, the current literature on the accuracy of the diagnostics is limited. Primary diagnosis is usually based on non-weight-bearing radiographic imaging, though its sensitivity has been estimated to be quite low (24%–50%) when compared with CT [17, 38]. Weight-bearing radiographs or magnetic resonance imaging (MRI) are suggested modalities for detecting ligamentous injuries [33, 36–38], yet it may be impossible to acquire weight-bearing images due to the extensively painful foot at the first presentation [33, 36–38, 40, 53]. In their systematic review, Sripanich and colleagues [50] reported that CT scans seem to be currently the most precise imaging modality in detecting bony injuries; whereas, MRI seems to be the most precise in detecting ligamentous injuries. It has also been reported that the sensitivity of the weightbearing radiograph is not higher compared with the non-weight-bearing radiograph and is less sensitive than CT [38]. Nevertheless, many of the previously published studies have still relied on non-weight-bearing or weight-bearing radiographs [8, 9, 12, 20, 23, 29, 33, 35, 41, 47].

When evaluating the accuracy of the diagnosis, it is important to evaluate the reliability (interobserver reliability) and the reproducibility (intraobserver reliability) of the diagnostic test [22]. The interobserver reliability is a method to evaluate the correlations between the observers as mathematical measures [5, 19]. The intraobserver reliability, in turn, is a method to evaluate the test–retest reliability of the diagnostic test [11]. In addition to inter- and intraobserver reliability, it is important to take into account other statistical measures, such as sensitivity, specificity and positive and negative predictive value, when evaluating the accuracy of a diagnostic test [1, 2, 10, 28].

The aim of this study is to assess the inter- and intraobserver reliability and other diagnostic parameters of non-weight-bearing foot radiographs compared with CT in Lisfranc injuries.

## Materials and methods

To assess the accuracy of the diagnostics of Lisfranc injuries, we analysed all foot and ankle CT and CBCT scans acquired due to acute foot trauma at one university hospital and one regional hospital during the period 1.1.2012–31.12.2016. Intra-articular fractures and avulsion fractures around the TMT joint complex were defined as Lisfranc injury. Patients with extra-articular metatarsal injuries were excluded. In addition to the radiologists' report, the CT scans were separately evaluated by two experienced foot surgery experts. In the case of disagreement, the final diagnosis was made together.

In total, the data comprised 456 patients with acute foot injuries. The CT scans revealed 202 patients without any signs of injury, 21 patients with distal metatarsal or toe fractures and 233 patients with a bony injury (joint displacement, intra-articular or avulsion fracture) affecting the Lisfranc joint complex. The patients were divided into displaced and nondisplaced injuries with a threshold of 2 mm of displacement according to the previous literature [6]. Therefore, injuries with a fracture displacement or TMT joint dislocation of less than 2 mm were considered to be non-displaced and those with 2 mm or more were considered to be displaced. Altogether, 174 patients had a non-displaced Lisfranc injury and 59 patients had a displaced Lisfranc injury. IBM SPSS 24.0 statistical software was used to randomly select 100 patients for the present (reliability) study: 34 patients without a Lisfranc injury (some had distal foot fractures), 33 patients with a non-displaced Lisfranc injury and 33 patients with a displaced Lisfranc injury. The characteristics of the patients are presented in Table 1.

The anonymised primary non-weight-bearing foot radiographs were assessed independently by three senior orthopaedic surgeons (with a minimum of 10 years' experience) and three orthopaedic surgery residents (from 4 to 6 years' experience) twice at intervals of three months. All 100 sets of radiographs were performed in antero-posterior, 30° oblique and lateral views. The observers were asked to answer the following questions: "Is there an injury at the Lisfranc joint?"; (Yes/No), "If you answered yes, describe the findings" and "Are there any other injuries?"; (Yes/No).

The sequence of the sets was randomly mixed for the second observation. Picture archiving and communications system (PACS) software was used to display the radiographs.

## Statistical analysis

Fleiss kappa ( $\kappa$ ) was used to evaluate the interobserver reliability between all six observers in two different moments. Cohen kappa ( $\kappa$ ) was used to assess the intraobserver reliability between the same observer in two

**Table 1** Characteristics of the patients

	<i>n</i> = 100
Age, mean (SD)	40.9 (18)
Males, <i>n</i> (%)	55 (55%)
Right foot, <i>n</i> (%)	58 (58%)
Patients with Lisfranc injury	<i>n</i> = 66
Trauma mechanism, <i>n</i> (%)	
Tumbling or slipping	25 (38)
Traffic collisions	11 (17)
Direct injury	8 (6)
Other	22 (37)

different moments at an interval of three months. Results were presented according to Landis and Koch criteria: 0.00–0.20, slight agreement; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; and 0.81–1.00, almost perfect [24]. The clinical characteristics of the patients are presented as means with standard deviations (SD), medians with interquartile ranges (IQR), as counts with percentages, or as ranges. Differences between means of continuous variables were compared with Mann–Whitney test. False-positive rate was calculated as false negatives divided with CT-positive cases, and false-negative rate was calculated by dividing the false-positive cases with CT-negative cases. Microsoft Excel (version 16.15) and R (version 3.6.0) statistical software were used to conduct statistical analyses.

## Results

When interobserver reliability of non-weight-bearing radiographs in Lisfranc injury was assessed between 6 observers, the  $\kappa$  coefficient for interobserver reliability resulted in moderate correlation from  $\kappa=0.50$  (95% CI 0.45–0.55) (first evaluation) to  $\kappa=0.58$  (95% CI 0.52–0.63) (second evaluation). The evaluation was repeated after three months and the  $\kappa$  coefficient for intraobserver reliability between the two evaluations of individual observers showed substantial correlation of mean  $\kappa=0.71$  (from 0.64 to 0.85) (Table 2).

The mean (range) sensitivity of all observers was 76.1% (60.6–92.4) and specificity was 85.3% (52.9–100) (Table 2). The sensitivity of the diagnostics in non-displaced injuries was lower than in displaced injuries (65.4% vs 87.1%  $p=0.003$ ). The number of missed cases was higher among non-displaced injuries than in displaced injuries ( $n=11$  vs 4  $p=0.002$ ). The false-negative rate was 23.9% and the false-positive rate was 14.7%. There were no statistically significant differences between senior orthopaedic surgeons and residents in sensitivity (72.5% vs. 79.8%,  $p=0.44$ ), specificity (87.7 vs. 82.8%,  $p=0.92$ ), positive predictive value (85.8% vs. 91.2%,  $p=0.31$ ) or negative predictive value (76.5% vs. 69.4%,  $p=0.31$ ).

Consensus between all evaluators was achieved in 38 (38%) cases: 26 cases with an injury and 9 cases without an injury were identified correctly by all evaluators during both evaluations. Three cases with a non-displaced Lisfranc injury were missed by all evaluators (Fig. 1a–c). The agreement was compared with the true positive cases detected by CT (Fig. 2). Results demonstrate that a mild consensus was achieved among most of the non-injured patients, without a significant number of false positives. In the case of injured patients, the consensus was not achieved as precisely, and multiple patients were missed by most of the observers.

**Table 2** Results of the observers' two evaluations

	Observer 1	Observer 2	Observer 3	Observer 4	Observer 5	Observer 6
Sensitivity	83.3	63.6	60.6	74.2	75.8	77.3
Specificity	79.4	100.0	94.1	94.1	88.2	85.3
PPV	88.7	58.6	95.8	89.1	92.6	91.1
NPV	71.1	100.0	61.5	62.2	65.2	65.9
Missed cases	11	24	20	17	15	7
False positive	7	0	2	6	4	8
Subtle						
Sensitivity	72.7	45.5	57.6	60.6	69.7	69.7
Missed	9	18	14	13	10	7
Severe						
Sensitivity	93.9	81.8	81.8	87.9	84.8	84.8
Missed	2	6	6	4	5	0
Cohen's kappa (95% CI)	0.85 (0.74–0.96)	0.68 (0.53–0.82)	0.67 (0.53–0.81)	0.70 (0.56–0.84)	0.71 (0.56–0.86)	0.64 (0.50–0.79)

PPV positive predictive value, NPV negative predictive value, CI confidence interval

**Fig. 1 a–c** Radiological findings of the three undisplaced injuries ► which were missed by all observers. **a** No specific findings with standard radiographs, yet CT revealed fractures of the first metatarsal base and medial cuneiform. **b** No specific findings with standard radiographs, yet avulsion fractures of the second, third and the fourth metatarsal bases were detected in CT. **c** No specific findings with standard radiographs, yet avulsion fractures of the fourth metatarsal base were detected in CT

## Discussion

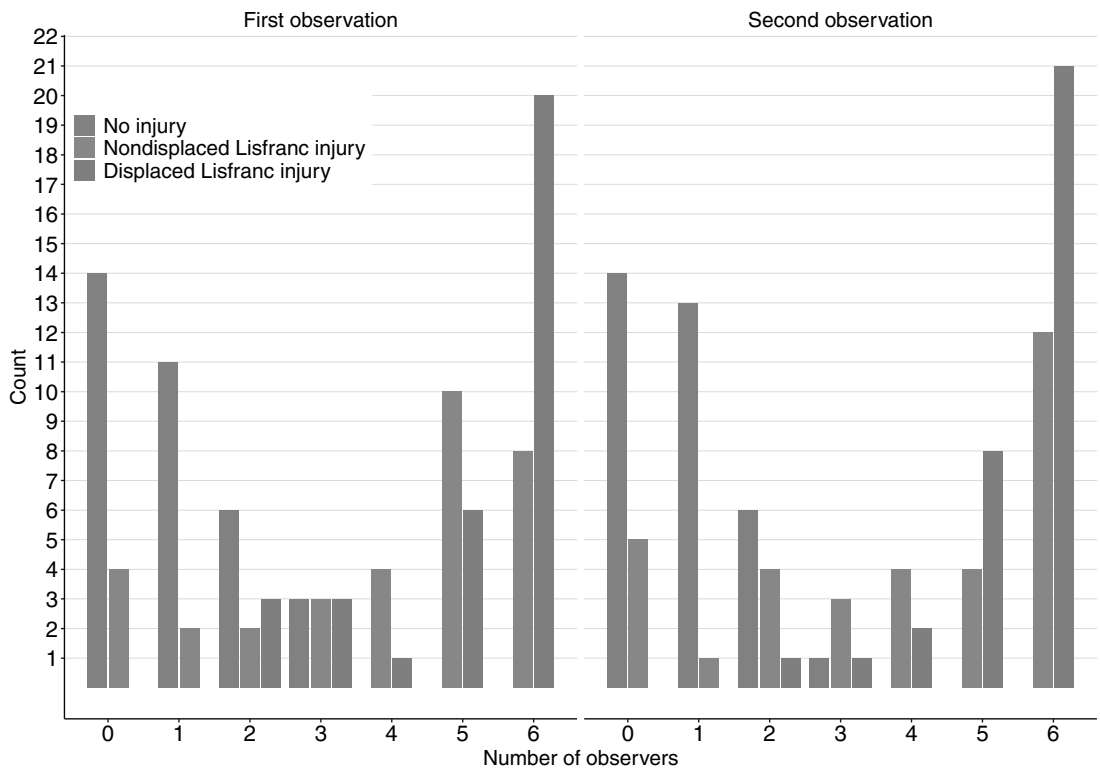
The diagnosis of Lisfranc injury based on conventional radiographs had moderate agreement between observers and substantial agreement between the same observer at different time moments. To the best of our knowledge, our study is the first to evaluate the inter- and intraobserver reliability among non-weight-bearing radiographs in the detection of Lisfranc injuries. The main results of our study were that the inter- and intraobserver reliabilities in detecting Lisfranc injuries from non-weight-bearing radiographs depend on the observer, and if the same observer evaluates the same images in different moments, the results will fluctuate. There was some variance in intraobserver reliability among the observers, ranging from substantial agreement to almost perfect. Nondisplaced injuries were significantly more commonly missed than the displaced injuries.

In a previous study by Sherief et al. [48], three radiologists, three orthopaedic surgeons and three physicians evaluated 30 sets of radiographs [48]. The mean sensitivity for Lisfranc injuries was 92% (95% CI 89–95%), and the rate of missed injuries was 19% [48]. They did not report differences between the radiologists, orthopaedic surgeons or physicians. Haapamäki et al. [16] studied the accuracy of the radiological diagnostics of Lisfranc injuries by comparing the findings of 17 conventional radiographs with CT. They presented a sensitivity of 76% and a missed injury rate of 24% for Lisfranc injuries [16]. In addition, Rankine et al. [42] presented a study with 60 non-weight-bearing foot radiographs with 45 CT-positive cases were evaluated by two independent radiologists. They presented a sensitivity of 84.4%, specificity of 53.3% positive predictive value of 84.4% and negative predictive value of 53.3% [42]. In our study with 100 cases, the sensitivity (76%) was comparable to the numbers presented in earlier studies, where the sensitivity has been between 76 and 92% [16, 42, 48]. There were no differences between the senior orthopaedic surgeons and residents in our study, a similar finding to the study of Sherief et al. [48].

Instability of the foot arch, seen as widening of the space between the first and second TMT joints, has been suggested to be the main indication to proceed with operative treatment [3, 40, 46]. Previous studies have criticised the accuracy of non-weight-bearing radiographs in the diagnostics of Lisfranc injuries, since they can only reliably detect severe displacement of the Lisfranc joint and instability is difficult







**Fig. 2** The distribution of the agreement between the observers. Green bars indicate that the non-injured patients were detected with relatively high consensus. Blue (displaced) and orange (nondisplaced) bars represent the agreement between the patients with Lisfranc injury

to assess [13, 15, 32, 51]. To correct this flaw, it has been suggested that weight-bearing radiographs are used [3, 7, 9, 15]. However, the problem with weight-bearing radiographs is that the severity of pain usually prevents the patients from reliably bearing weight, and therefore it is impossible to obtain reproducible images [50].

The study by Goiney et al. [14] was the first to describe the benefits of using CT over non-weight-bearing radiography. Since then, the advantages of CT have attracted more interest [26, 38]. The biggest benefit of CT is that small bony displacements, avulsion fragments and fractures are detectable; whereas, they would be missed in non-weight-bearing radiography [26]. To the best of our knowledge, the only study comparing these different imaging modalities in the same sample of Lisfranc injuries was performed by Preidler et al. [38]. They compared the differences between conventional radiography, weight-bearing radiography, CT and MRI with a sample of 49 patients. Their conclusion was that weight-bearing radiographs or MRI do not provide any additional benefit when compared with conventional radiography, and that CT is the most sensitive imaging modality for detecting Lisfranc injuries.

The previous literature provides at least 15 different classification systems for Lisfranc injuries [18, 25, 30, 33, 45, 49]. Injury classifications should be developed as tools to help doctors in decision-making and in choosing the optimal treatment for each patient [4]. Accurately working classifications should also provide estimates of the outcomes after the chosen treatment [4]. In addition, the classifications should have a high inter- and intraobserver reliability to ensure reliability and responsiveness [4]. The inter- and intraobserver reliabilities have been evaluated for the radiograph-based Hardcastle [18] and Myerson [30] classifications for dislocated Lisfranc injuries [27, 52]. Moreover, the inter- and intraobserver reliabilities for these classifications have varied from moderate to excellent [27, 52]. Since most of the previous classifications are based on non-weight-bearing radiographs, we feel it is essential to evaluate the reliability and responsiveness of this imaging modality.

As the use of CT as a diagnostic tool has gained more popularity, the most recently published classifications for Lisfranc injuries have been based on CT imaging [25, 45]. The most recent CT-based classification, the Column Involvement Severity System by Schepers and Rammelt [45], divides

Lisfranc injuries according to the columns of the midfoot. The classification represents the affected columns: medial, central and lateral, with the severity of the injury, classified as 0—no joint involved, 1—pure ligamentous with avulsions, 2—simple fracture and 3—comminuted fracture. They suggest that instability is evaluated either by weight-bearing radiographs or stress radiographs under anaesthesia one week after the injury. However, as previously stated, neither of these modalities has been shown to be reliable in detecting the instability [31, 38]. In addition, this classification does not help to choose between nonoperative or operative treatment or to predict the outcome after the chosen treatment.

The strength of our study was the large data sample that included a broad range of Lisfranc injuries. Since the term ‘Lisfranc injury’ is indicative of a wide variety of different injuries in terms of severity, displacement and number of affected joints, it is essential to evaluate the diagnostics with an appropriate study sample [18, 30, 33, 43]. The limitation of our study was that the radiographs were only evaluated by orthopaedic surgeons and orthopaedic surgery residents who are familiar with Lisfranc injuries. However, most of the initial diagnostics occurs in primary healthcare, and patients are then referred to specialized medical care units. Hence, the initial evaluation is often performed by general physicians and it can be assumed that the precision of the diagnostics may be even weaker than the results presented in this work. In addition, the lack of using MRI, weight-bearing CT or weight-bearing radiographs can be considered as a limitation, since some patients with purely ligamentous injuries could be missed.

Since our results show that a significant number of patients would be missed by conventional radiographs, we feel that it is essential to confirm the diagnosis with CT imaging if the clinical suspicion of the injury is high (plantar ecchymosis, pain in active and passive movements or swelling) [9, 44]. Furthermore, there is a need for an accurate injury classification for Lisfranc injuries, based on CT, that would help the clinician with the decision-making and would predict the outcomes after the chosen treatment. Although the classification by Schepers and Rammelt [45] has introduced a novel approach to these injuries, it still requires some further evaluation before it can be used as a tool for choosing the correct treatment for patients.

To conclude, the radiologic diagnosis of a Lisfranc injury based on conventional radiographs has moderate agreement between observers and substantial agreement between the same observer in different time moments. The sensitivity and reliability for detecting Lisfranc injuries with conventional radiographs indicated relatively moderate accuracy. In other words, a substantial number (24%) of injuries are missed if only non-weight-bearing radiographs are used.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** This article does not contain any studies with human participants or animals performed by any of the authors.

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**PUBLICATION**  
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**Validity and internal consistency of the American Orthopaedic Foot and Ankle Society Midfoot Scale in patients with Lisfranc injury.**

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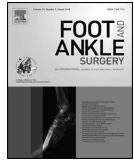


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## Validity and internal consistency of the American Orthopaedic Foot and Ankle Society Midfoot Scale in patients with Lisfranc injury

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### ABSTRACT

**Background:** The American Orthopaedic Foot and Ankle Society (AOFAS) Midfoot Scale is an extensively used outcome measure instrument for evaluating outcomes after foot and ankle surgery or trauma.

**Methods:** In total, 117 patients with Lisfranc injury completed the AOFAS Midfoot Scale and the Visual Analogue Scale Foot and Ankle (VAS-FA) instruments. Internal consistency (correlation between different items), floor and ceiling values, convergent validity, item threshold distribution, and the coverage (item difficulty) of the AOFAS Midfoot scale were tested.

**Results:** AOFAS Midfoot Scale had high convergent validity and acceptable internal consistency (Cronbach's alpha >0.70). The ceiling effect was confirmed. The person-item distribution indicated that the scale had a lack of coverage and targeting in our sample.

**Conclusions:** Our data suggests that the AOFAS Midfoot Scale has acceptable validity and internal consistency. However, due to the lack of coverage and targeting, it should not be the primary outcome measure to be used to evaluate the outcomes after Lisfranc injury in the future studies.

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### 1. Introduction

Injuries affecting the tarsometatarsal joint, also known as the Lisfranc joints, are relatively rare injuries (9/100 000/person-years) which can lead to pain and loss of function if inadequately treated [1,2]. To date, there have only been two randomized controlled studies that have investigated the operative treatment of Lisfranc injury [3,4]. The results of both of these studies suggest that primary arthrodesis might be a better long-term treatment option than open reduction and internal fixation (ORIF) [3,4]. However, the problem with these studies is that various patient-reported outcome measures (PROMs) that were not specific to the foot were used to evaluate treatment outcomes.

The evaluation of clinical outcomes with rating scales has become common in the field of surgery [5–7]. The potential benefits of using outcome rating scales include benchmarking, comparing the outcomes between patients with similar foot and

ankle conditions, and evaluating the outcomes in clinical trials [8,9]. PROMs are potential tools to evaluate treatment outcomes from the perspective of the patient [6,8]. For example, a lack of correspondence between radiographic measures and patients' symptoms has been noted in hallux valgus surgery as well as in other fields of orthopaedic surgery, suggesting that radiographic measures are providing different types of information than the assessment of clinical outcomes after treatment [10–12]. For these reasons, at least 140 PROMs are used in foot and ankle surgery to provide the patient perspective [6,8].

The American Orthopaedic Foot & Ankle Society (AOFAS) Clinical Rating Systems are one of the most widely used outcome measures for foot and ankle patients [6,13]. Although the minimal important changes of the AOFAS Clinical Rating Systems have been defined, their validity and reliability have been questioned [11,14–16]. Validity refers to the extent to which the scale measures what it is designed to measure, whereas reliability indicates the general consistency of the scale [17–20]. Hence, the Visual Analogue Scale Foot and Ankle (VAS-FA) was developed in 2006 to correct the flaws in the validity of the widely used AOFAS Midfoot Scale [16]. The VAS-FA has been validated and psychometrically tested for evaluating outcomes after foot and ankle surgery [16,21].

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**Table 1**

Clinical information and distributions of the patient reported outcome measure scores of patients with Lisfranc injuries.

	N = 117
Age, mean	41 ± 17
Male, n (%)	75 (64)
Treatment, n (%)	
Non-operative	58 (50)
ORIF	21 (18)
Arthrodesis	23 (20)
Multiple operations	12 (10)
Closed reduction with K-wire fixation	1 (1)
Follow-up, mean months	46 ± 18
AOFAS	
Median (IQR)	88 (73–100)
Floor, n (%)	0 (0)
Ceiling, n (%)	30 (28)
VAS-FA	
Median (IQR)	89 (72–98)
Floor, n (%)	0 (0)
Ceiling, n (%)	10 (9)

ORIF: Open reduction and internal fixation.

±: Standard deviation.

IQR: Interquartile range.

VAS-FA: Visual analogue scale foot and ankle.

AOFAS: The American Orthopaedic Foot & Ankle Society Midfoot Scale.

Floor: The number of patients who reached the minimum score.

Ceiling: The number of patients who reached the maximum score.

In addition to the foot-specific PROMs, general health-related quality of life instruments, Main and Jowett criteria, radiographic evaluation, reoperation rate, return to sports and surgeons' opinion have all been used to evaluate outcomes after a Lisfranc injury [3,4,22–25]. However, it may be advantageous to evaluate the outcomes with properly validated instruments developed for the specific clinical situation [17,20]. In terms of practical use (if the patient has clinically significantly improved) as well as improving the quality of the studies (calculating the correct sample size), knowing the minimal important change of the instrument would be crucial [17,26]. The aim of this study is therefore to test the validity and internal consistency of the AOFAS Midfoot Scale in patients treated for a Lisfranc injury.

## 2. Materials and methods

The patients in this study were collected during a 5-year period (January 1, 2012–December 31, 2016) in a Level One Trauma Center serving a catchment population of 500 000. The data used in this

study was gathered from two studies: one retrospective and one prospective. The retrospective data were collected by reviewing all CT-scans that were performed due to an acute injury of the foot and ankle. All patients with a CT-verified Lisfranc joint injury (N = 233) were included in the study. These patients were contacted via postal mail between 2 and 6 years after the injury. The prospective data were collected from a prospective trial, where patients were recruited directly from the emergency room. The PROMs used in the prospective study were completed at 12-month and 24-month follow-up visits. The demographic data of the study population are provided in Table 1. The recruited patients provided a written consent form for participation in the study according to the Declaration of Helsinki. The patients completed two foot and ankle-specific PROMs: the AOFAS Midfoot Scale and the VAS-FA [13,16]. The study protocol was approved by the Regional Ethics Committee of the Hospital District.

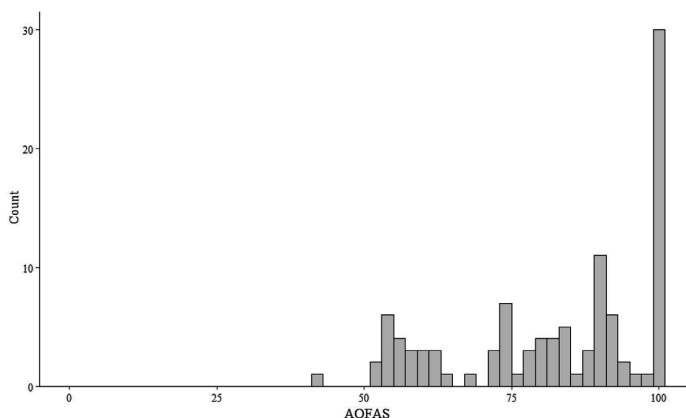
## 3. Outcome measures

### 3.1. American orthopaedic foot and ankle society midfoot scale

The AOFAS Midfoot Scale is a hybrid outcome measure that can be reported either by clinician or patient and it has been developed to evaluate the pain and function of the foot [13]. The scale comprises 7 items, and each item has either three or four answer categories with various scorings [13]. The total score is calculated as a sum of all 7 items. If any of the items are missing, the total score cannot be calculated [13]. The total score ranges from 0 to 100 with a higher score indicating a better outcome [13]. The AOFAS scale is one of the most widely used outcome measure instruments in foot and ankle research [6,8,27]. The scale has not, however, been validated for midfoot-specific conditions. The Cronbach's alpha has previously been found to be 0.59 [11].

### 3.2. Visual analogue scale foot and ankle

The VAS-FA is a foot and ankle-specific PROM that has been validated to assess pain, function, and other complaints [16,21,28,29]. The scale contains 20 items scaled on a visual analog scale from 0 to 100 mm, with 0 indicating the worst, and 100 indicating the best result. The VAS-FA allows the items to be divided into three modules: Pain (4 items), Function (11 items), and Other complaints (5 items) [16]. The overall score and the scores of the modules are computed as the mean scores of the completed



**Fig. 1.** Distribution of the total scores of the the American Orthopaedic Foot & Ankle Society Midfoot Scale for patients with Lisfranc injury.



items of the instrument or its modules [16]. The normative VAS-FA scores for normal and various foot pathologies have been previously presented [30].

4. Statistical analysis

Clinical and demographic data are presented as medians and interquartile ranges (IQR) or as counts and percentages based on the distribution of the data. Hypotheses of the measured features were defined beforehand in accordance with the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist (Table 2) [18]. Floor and ceiling effects were assessed, and if more than 15% of the patients scored the minimum or the maximum points, the threshold was considered to have been achieved [31].

Convergent validity was evaluated by calculating Spearman correlation coefficients between the AOFAS Midfoot Scale and the VAS-FA. The correlation coefficients were interpreted according to the previous literature: 0.00–0.30 negligible, 0.30–0.50 low, 0.50–0.70 moderate, 0.70–0.90 high, and 0.90–1.00 very high correlation [32]. Linear regression analyses were used to evaluate the strength of the relationship between the instruments. Age-, and gender-standardized regression coefficient  $\beta$  indicates how strongly the score of the AOFAS Midfoot Scale predicts the total score of the VAS-FA. The  $\beta$  values of 0.1, 0.3 and 0.5 were interpreted as small, moderate, and strong relationship, respectively.

Thresholds between the response categories of each item were investigated. The thresholds of the response category represent the location where there is a similar (50%) chance for the answer to end up in an adjacent response category.

To investigate scale targeting and coverage, a person-item distribution map was constructed to see how well the distribution of item difficulty matched with the coverage of the study sample within the AOFAS Midfoot Scale. The results of this analysis provided information on how well the scale performs in a distinct group of patients. The statistical analyses were performed using R (version 1.1.453) and SPSS (IBM® version 25.0) statistics software.

5. Results

The sample comprised 117 patients. The questionnaires were completed on average (SD) 3.9 (1.5) years after the injury. Altogether, 58 (50%) patients were treated nonoperatively and

59 (50%) operatively. The distribution of the AOFAS Midfoot Scale was skewed towards higher scores (Fig. 1). The ceiling effect was confirmed for the AOFAS Midfoot Scale because 30 (28%) of the patients scored maximum points (Tables 2 and 3). For the VAS-FA Score, the ceiling effect was not confirmed because only 10 (9%) patients scored the maximum points. None of the patients scored

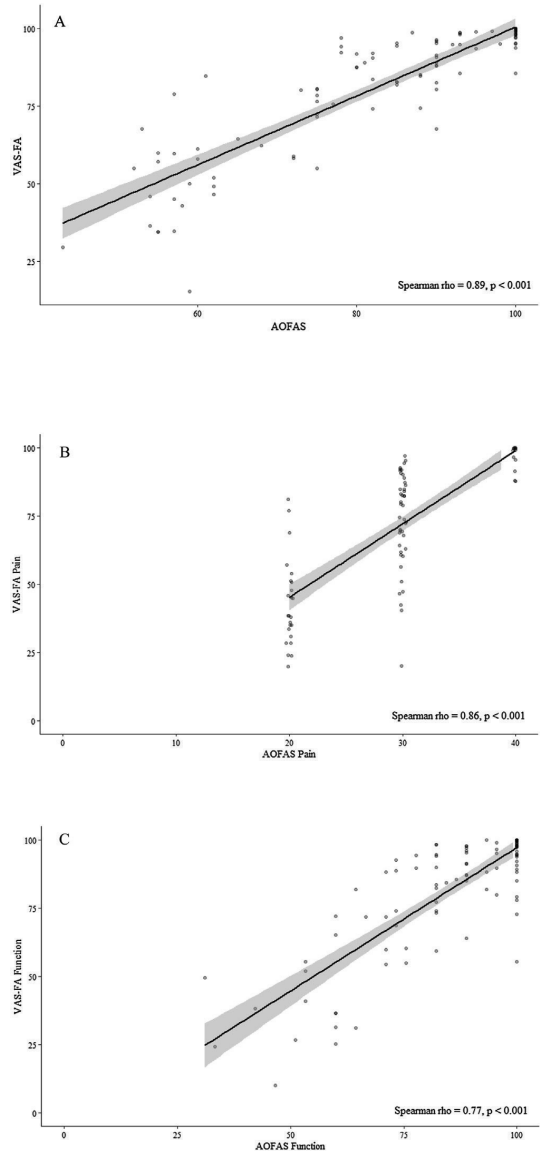


Fig. 2. A–C: A: Correlation between the Visual Analogue Scale Foot and Ankle (VAS-FA) and the American Orthopaedic Foot & Ankle Society (AOFAS) Midfoot Scale among patients with Lisfranc injury. B: Correlation between the VAS-FA and AOFAS Midfoot Scale Pain subscales. C: Correlation between the VAS-FA and AOFAS Midfoot Scale Function subscales.

VAS-FA: Visual analogue scale foot and ankle.  
AOFAS: The American Orthopaedic Foot & Ankle Society Midfoot Scale.

Table 2  
Predefined hypotheses for the validation of the American Orthopaedic Foot & Ankle Society Midfoot Scale.

Feature	Hypothesis	Result	Confirmed/rejected
Internal consistency	Cronbach alpha is >0.70	0.75	Confirmed
Validity	Floor effect <15%	0%	Confirmed
	Ceiling effect <15%	28%	Rejected
Convergent validity	Correlation with VAS-FA is $\geq 0.50$	$r = 0.89$	Confirmed
	Correlation with VAS-FA Pain is $\geq 0.50$	$r = 0.86$	Confirmed
	Correlation with VAS-FA Function is $\geq 0.50$	$r = 0.79$	Confirmed
	Item difficulty matches with the coverage of the study sample	Good	Rejected
		coverage	

VAS-FA: Visual analogue scale foot and ankle.

**Table 3**  
The mean scores and floor and ceiling values of the American Orthopaedic Foot & Ankle Society Midfoot Scale.

Item	Response categories (points)	Mean (SD)	Floor (%)	Ceiling (%)
1. Pain	4 (0–40)	32 (8)	0	38
2. Activity limitations, support	4 (0–10)	9 (2)	0	63
3. Maximum walking distance	4 (0–10)	9 (2)	2	79
4. Footwear requirements	3 (0–5)	5 (1)	0	76
5. Walking surfaces	3 (0–10)	7 (3)	6	55
6. Gait abnormality	3 (0–10)	9 (2)	1	76
7. Alignment	3 (0–15)	13 (4)	3	66

the minimum points in either of the instruments, and therefore the floor effect was not confirmed. The VAS-FA and its subscales had high Cronbach's alpha: 0.90 (Pain), 0.96 (Function), 0.82 (Other complaints), and 0.97 (Overall). The results indicate high internal consistency for the VAS-FA total score and its subscales. The AOFAS Midfoot Scale had Cronbach alpha of 0.75 (>0.70), indicating acceptable internal consistency.

There was a high correlation between the total scores of the instruments ( $r=0.89$ ) indicating good correspondence between the scores of the instruments (Fig. 2A–C.). The correlations were also high between the Pain ( $r=0.86$ ) and Function ( $r=0.77$ )

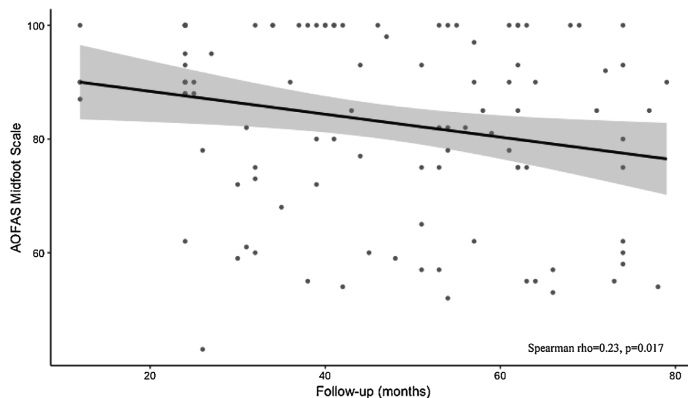
subscales. All correlations were statistically significant ( $P < 0.001$ ). The correlation between follow-up time and the AOFAS Midfoot Scale total score was negligible (Fig. 3). The age- and sex-adjusted regression coefficient  $\beta$  of the VAS-FA subscales (Pain, Function, Other complaints, and Overall) against AOFAS Midfoot Scale total score were 0.83, 0.82, 0.80, and 0.87, respectively (Fig. 4). The coefficients indicate a strong relationship between the VAS-FA and the AOFAS Midfoot Scale.

All items had ordered thresholds between the response categories (Fig. 5A–C). Item 3 (“Maximum walking distance, blocks”) had only a narrow gap between the thresholds between the response categories 2 (“4–6”) and 3 (“1–3”). None of the patients gave the worst answers to items 1, 2, or 4.

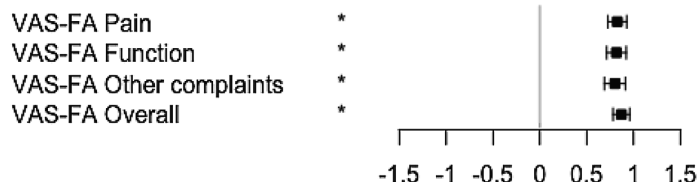
The person-item distribution map shows that item difficulty matched well with the coverage of the study sample of the AOFAS Midfoot Scale (Fig. 6). Many of the patients scored high scores, which was not covered by the instrument, and indicates that the instrument has deficiencies in its coverage and targeting for this patient group.

**6. Discussion**

High correlations and relationship with the VAS-FA indicated the strong convergent validity of the subscale (Pain, Function) scores of the AOFAS Midfoot Scale. In addition, the AOFAS Midfoot scale has acceptable internal consistency (Cronbach's alpha, 0.75), which diverges from the results of a previous study that investigated patients with hallux valgus (Cronbach's alpha, 0.59)

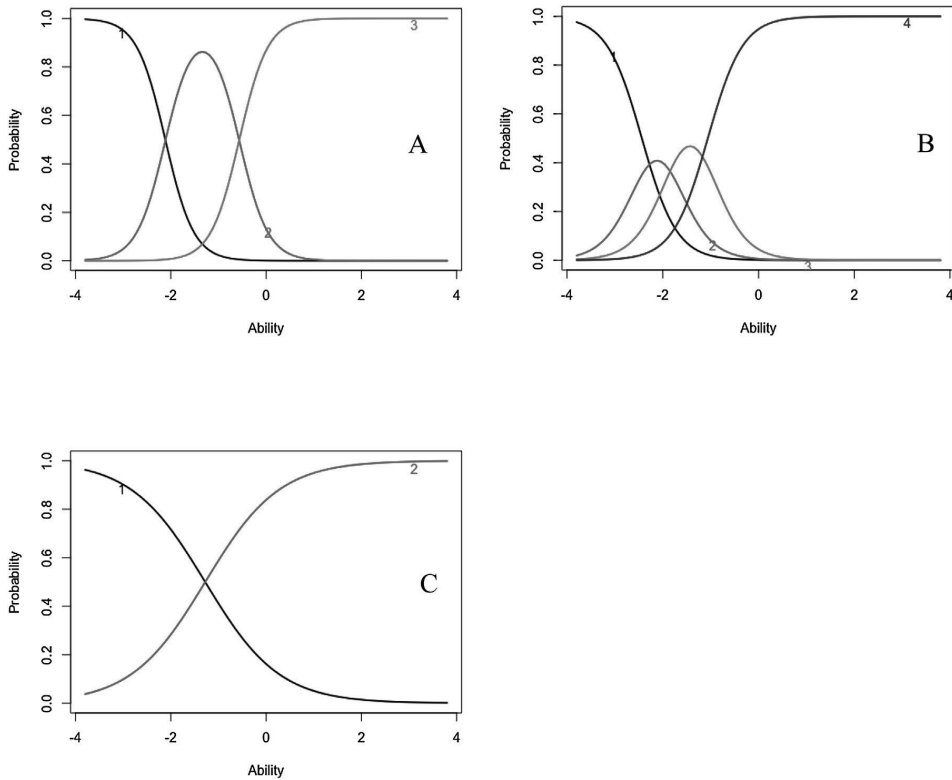


**Fig. 3.** Correlation between the follow-up time and the American Orthopaedic Foot & Ankle Society Midfoot Scale total score was negligible. AOFAS: The American Orthopaedic Foot & Ankle Society Midfoot Scale.



**Fig. 4.** Relationships between the Visual Analogue Scale Foot and Ankle subscales and the American Orthopaedic Foot & Ankle Society Midfoot Scale total score. Cohen's standard for  $\beta$ -values above 0.10 for small, 0.30 for moderate and 0.50 for large relationships. Boxes represent the mean scores (VAS-FA: Pain, Function, Other complaints, and Overall) with 95% CIs.

VAS-FA: Visual Analogue Scale Foot and Ankle.  
AOFAS: The American Orthopaedic Foot & Ankle Society Midfoot Scale.  
 $^*P < 0.001$ .



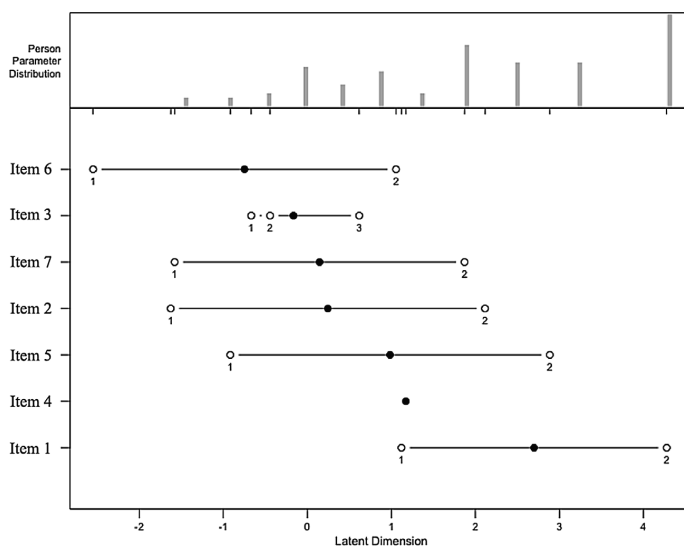
**Fig. 5.** A–C. Thresholds of response categories for items 2 (A), 3 (B), and 4 (C) of the American Orthopaedic Foot & Ankle Society Midfoot Scale. All response categories are ordered correctly. Item 2 (A) has evenly distributed response categories. Response categories of item 3 (B) showed malfunction as there is only a narrow gap between the thresholds between the response categories 2 and 3. Item 4 (C) had ordered threshold values, yet none of the patients answered the worst response category. AOFAS: The American Orthopaedic Foot & Ankle Society Midfoot Scale. Colors represent the different answer categories.

[11]. In contrast, the ceiling effect suggests potential flaws in the coverage of the AOFAS Midfoot Scale among patients with Lisfranc injury. Similarly, the person-item distribution map also showed inappropriate coverage and targeting. In addition, there was negligible correlation between the follow-up time and the AOFAS Midfoot Scale total score, and the VAS-FA did not have the ceiling effect despite the long follow-up time (2–6 years). Therefore, the long follow-up time did not explain the ceiling effect. The main result of our study was that the AOFAS Midfoot Scale has high convergent validity and acceptable internal consistency, but the instrument had a notable drawback (ceiling effect and person-item distribution) concerning its coverage and targeting in the assessment of the outcomes after Lisfranc injury.

The differences between the VAS-FA and the AOFAS Ankle-Hindfoot Score in patients with ankle fractures has been evaluated in a previous study [33]. The finding of this study was that both instruments have a similar pattern to extract the functional outcome scores. However, they did not compare the psychometric properties with regard to Classical Test Theory (CTT) or Item Response Theory (IRT), which are the two methods used to compare the validity and reliability of the instruments [17]. The COSMIN checklist requires that the validity, reliability, and responsiveness of the PROM are assessed prior to applying the PROM in practice [17,20]. Furthermore, once the PROM has been tested with the CTT methods, it should be further assessed with IRT

methods [17,20]. In our study, the principles of both CTT (internal consistency) and IRT (person-item distribution, thresholds between response categories) were combined.

The use of the AOFAS Clinical Rating Systems has been questioned, since their psychometric properties do not fulfill the acceptable criteria set for PROMs [8,14,34]. In addition, the score cannot be obtained if even one answer is missing [14]. Even the developers of the AOFAS Clinical Rating Systems suggest that the scale is not reliable, and that other outcome measures, such as the PROMIS Physical Function Computerized Adaptive Test (CAT) or Lower Extremity CAT combined with an additional pathology-specific instrument, should be considered [34]. In addition, it has been pointed out that the AOFAS Midfoot Scale uses non-specific expressions [16]. For example, gait abnormality is assessed as “none, slight”, “obvious”, or “marked”, and alignment is defined as “good, plantigrade, well-aligned”, “fair, plantigrade, some degree of malalignment”, or “poor, non-plantigrade, severe malalignment”. In the present study, the thresholds between the response categories of each item were ordered and did not show significant malfunctions. Item 3 (“Maximum walking distance, blocks”) had relatively narrow thresholds for the responses 2 (“4–6”) and 3 (“1–3”), and therefore the answers could be united. Additionally, items 1, 2, and 4 did not receive any worst responses. This may have been due to the relatively long follow-up time of the patients. However, the properly ordered categories do not solve the problems of the non-specific explanations of the answer categories.



**Fig. 6.** Person-Item distribution of the seven items of the American Orthopaedic Foot & Ankle Society Midfoot Scale. Bars represent the location of the patients and circles represent the difficulty of the items.

Despite these flaws, many of the previous studies investigating Lisfranc injuries have used the AOFAS Midfoot Scale as a primary outcome measure [3,23,35–39]. Based on the findings of the present study, it would seem that the AOFAS Midfoot Scale has an imbalance of difficult and easy items, and therefore it does not differentiate the patients well enough. The term “difficult items” refers to those items that need higher levels of the latent trait to achieve high scores, whereas the “easy items”, in contrast, can provide high scores even at lower levels of the latent trait. Since we observed deficiencies concerning the scale’s coverage and targeting, the results of this study suggest that the previous studies that used the AOFAS Midfoot Scale might have missed some information on less symptomatic patients due to the outcome measure used [3,23,35–39]. Other foot and ankle specific PROMs, such as the VAS-FA [16], the Lower Extremity Functional Scale (LEFS) [40,41], the Foot and ankle ability measure (FAAM) [42], the Self-reported Foot and Ankle Score (SEFAS) [43], and the European Foot and Ankle Society (EFAS) score [44], might have psychometric properties that could potentially fill the gap that the AOFAS has in assessing outcomes in the treatment of foot and ankle injury. Future studies should therefore focus on assessing the measurement properties and minimal important change for the validated foot and ankle PROMs.

The strength of our study was the large group of patients with Lisfranc injury treated both nonoperatively and operatively. The limitations of the study were the cross-sectional study design, the use of only one reference outcome measure, and the lack of reproducibility testing (test-retest).

**7. Conclusions**

As a conclusion, the present study found that the AOFAS Midfoot Scale has high convergent validity and acceptable internal consistency when used to evaluate the long-term outcomes after treatment of Lisfranc injury. The scale seems to have deficiencies regarding its coverage and targeting, and there are flaws with the non-specific

expressions of the responses. Based on the relatively high ceiling effect, the scale seems to be inappropriately targeted when assessing long-term outcomes in the treatment of Lisfranc injury. Because it is the most frequently used instrument in the published literature, this study provides information that can be used when interpreting the results of these previous studies. However, it should not be the preferred instrument to be used as the primary outcome measure in patients with Lisfranc injuries in the future studies.

**Conflict of interest**

The authors declared that they have no conflict of interest.

**Acknowledgements**

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# PUBLICATION IV

**Outcomes after nonoperatively treated Lisfranc injury: A Retrospective Case series of 60 patients**

Ponkilainen Ville, Partio Nikke, Salonen, Essi, Laine Heikki-Jussi, Mäenpää Heikki, Mattila Ville, Haapasalo Heidi

Submitted

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# PUBLICATION V

**Nonoperative, open reduction and internal fixation or primary arthrodesis in the treatment of Lisfranc injuries: a prospective, randomized, multicenter trial – study protocol.**

Ponkilainen Ville, Mattila Ville, Laine Heikki-Jussi, Paakkala Antti, Mäenpää Heikki, Haapasalo Heidi

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STUDY PROTOCOL

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# Nonoperative, open reduction and internal fixation or primary arthrodesis in the treatment of Lisfranc injuries: a prospective, randomized, multicenter trial – study protocol

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## Abstract

**Background:** Lisfranc injuries are known to be rare and often overlooked injuries that can cause long-term disability and pain when missed or treated incorrectly. The wide variety of Lisfranc injuries ranges from subtle ligament distensions to open fracture dislocations. The treatment of Lisfranc joint injuries is still controversial and very little is known about what types of injury can be treated nonoperatively. The current literature provides only two randomized studies on dislocated Lisfranc injuries. These studies have shown that primary arthrodesis (PA) leads to a similar or better outcome and results in fewer secondary operations when compared with open reduction and internal fixation (ORIF) in ligamentous injuries. There have been no previous randomized studies of the nonoperative versus operative treatment of Lisfranc injuries. Therefore, the purpose of this study is to compare the operative and nonoperative treatment of non-dislocated Lisfranc injuries and to compare the ORIF and PA treatment of dislocated Lisfranc injuries.

**Methods:** This study is a prospective, randomized, national multi-center trial. The trial comprises two strata: Stratum I compares cast-immobilization versus open reduction and internal fixation (ORIF) treatment of non-dislocated Lisfranc joint injuries. Stratum II compares PA versus ORIF in the treatment of dislocated injuries of the Lisfranc joint. The main hypothesis of stratum I is that the nonoperative treatment of non-dislocated Lisfranc injuries achieves a similar outcome compared with operative treatment (ORIF). The hypothesis of stratum II is that PA of dislocated Lisfranc injuries yields a similar functional outcome compared with ORIF, but that PA results in fewer secondary operations than ORIF. The main outcome measure is the American Orthopaedic Foot and Ankle Society (AOFAS) Midfoot score and the secondary outcome measures are Visual-Analogue-Scale Foot and Ankle (VAS-FA), Visual-Analogue-Scale (VAS), rate of secondary operations and other treatment-related complications. The results will be analyzed after the 2-year follow-up period.

**Discussion:** This publication presents a prospective, randomized, national multi-center trial study protocol. It provides details of patient flow, randomization, aftercare and methods of analysis of the material and ways to present and publish the results.

**Trial registration:** ClinicalTrials.gov identifier: NCT02953067 24.10.2016.

**Keywords:** Lisfranc, Conservative treatment, Operative treatment, ORIF, Arthrodesis

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## Background

Named after Jaques Lisfranc, an eighteenth century surgeon who performed the first foot amputations at the tarsometatarsal (TMT) joint, the Lisfranc joint is an anatomic area where a broad spectrum of injuries from subtle distensions to open fracture dislocations occur [1, 2]. The incidence of Lisfranc injuries is estimated to be 1/55000/year and they are believed to account for 0.2% of all fractures [3, 4]. These figures have, however, been challenged as up to 24% of Lisfranc injuries are either misdiagnosed or overlooked during initial evaluation [5–7]. Injuries to the Lisfranc joint occur most often during the third decade of life and men are 2 to 4 times more likely to suffer from these injuries than women [8]. Lisfranc injuries are caused either by direct or indirect forces to the foot [9]. Indirect injuries are more common and occur during bending or twisting movements applied to the midfoot [9]. Injuries caused by direct forces are often induced by a heavy object falling on top of the foot or by crush injuries, such as in motor vehicle accidents [6, 7]. A wide spectrum of injuries to the TMT and interrelated joints have been recognized, and range from severely dislocated high-energy open injuries to minor midfoot sprains suffered during sports activities [10–12].

An untreated or inadequately treated Lisfranc injury results in multiple late complications, the severity of which depends on the severity of the primary injury [13]. The most common complications are painful instability of the joint, malformation and arthritis [5]. All these complications can lead to remarkable dysfunction and foot pain [5]. Secondary arthrodesis may be used to treat these injuries, but the outcome is poorer the longer the treatment is delayed [14–16]. Therefore, the initial recognition of these injuries is a crucial step in ensuring optimal treatment is provided.

## Diagnosis and treatment

Fractures of the Lisfranc joint are known to be rare and are often overlooked [7, 17–19]. Approximately 20 to 24% of these fractures are missed at initial evaluation [5, 7]. High-energy injuries are often the most obvious due to traumatic history and very apparent clinical findings [20]. Low-energy injuries, however, are harder to detect because of less traumatic history and less apparent clinical findings [21]. Typical clinical findings of fracture of the Lisfranc joint are a swollen midfoot, tenderness and pain in the midfoot during passive movements and weight-bearing [22], plantar ecchymosis [23] and an extended space between the first and second toe seen in x-ray radiographs that is also known as the ‘gap’ sign [24].

Although sensitivity is relatively low when compared with CT-imaging, primary diagnosis of Lisfranc injuries is usually based on plain x-ray imaging [7]. False-negative findings on x-ray radiographs may be the result of

weight-bearing not tolerated due to pain [6]. A typical finding ‘fleck sign’ in plain x-ray radiographs, an avulsion of intra-articular bone, is estimated to be detectable in 90% of cases where the dislocation between the first and second metatarsal is greater than 4 mm [5]. As the radiographic findings of Lisfranc injuries can be subtle, CT is an important imaging modality in detecting these injuries, and furthermore serves as a useful tool for preoperative planning [25, 26]. Although the current literature introduces classifications that provide general characteristics for Lisfranc injuries, none of the classifications are useful in predicting treatment or outcome of a Lisfranc injury [27]. Moreover, the current literature fails to offer a classification based on computed tomography.

Due to the diversity of injuries, there is no single evidence-based policy for treating all Lisfranc injuries in a similar manner [28]. Nowadays, there is strong consensus that in dislocated injuries it is crucial to achieve exact anatomic reduction and stable internal fixation, which is best obtained with open reduction and screw fixation (ORIF) [5, 29]. However, even after appropriate treatment with ORIF, up to 40 to 94% of patients will develop post-traumatic arthritis [5, 13, 30, 31], necessitating conversion to an arthrodesis to relieve pain [14–16]. To prevent the need for secondary operations and the development of post-traumatic arthritis, primary arthrodesis (PA) is suggested [30, 32–34]. The treatment of non-dislocated injuries, in turn, is controversial [29, 35–38]. Some stable injuries might need activity modification only, but surgery is often recommended for even minimally displaced injuries [5, 29]. There is general agreement, however, that poor functional results are commonly correlated with a delay in diagnosis or the inadequate treatment of unstable or dislocated injuries [19, 27].

Fixation with screws is the primary fixation technique used to treat dislocated Lisfranc injuries [13, 31]. K-wire fixation [5, 12, 39, 40] and screw fixation [13, 22, 41, 42] are both controversial, but the higher failure rates associated with K-wire fixation have led to an increase in screw fixation [13, 43, 44]. Another fixation technique, dorsal plate fixation, has been reported to produce similar results as ORIF [45]. An advantage of dorsal plate fixation is that the plate causes no damage to the articular surface. However, soft-tissue irritation may be more prevalent, and second surgery is often needed to remove the plates [45].

There is, however, no general agreement on what is the correct nonoperative protocol for treating non-dislocated Lisfranc injuries. In their review, Myerson and Cerrato [11] concluded that if the foot remains stable in weight-bearing radiographs 2 weeks after the injury, the injury can be treated with immobilization in a boot and weight-bearing is permitted as tolerated until the boot is removed at six to eight weeks. In the study

by Nunley & Vertullo [29], stable injuries were treated nonoperatively. Furthermore, it was suggested that treatment begin with a non-weight-bearing cast for 6 weeks. If the patient is painless at 6 weeks, treatment should continue with a gradual return to normal function with a weight-bearing orthosis for the following 4 weeks.

The commonly used postoperative protocol is nearly identical to nonoperative treatment. In their study, Ly & Coetzee [30] used a short leg splint for 2 weeks followed by a short leg cast for four to six weeks. The patients advanced to full weight-bearing during the following 4 weeks while wearing a prefabricated fracture boot. In the study by Henning et al. [33], weight-bearing began at three months with a controlled ankle motion walker.

Interestingly, there are several opinions about postoperative implant removal. Some studies suggest routine screw removal at 8 or 12 weeks [31, 33, 46, 47], while others prefer routine removal only after the recovery is complete or only if the screws cause irritation or pain [48–50]. Ahmad and Jones [51] have suggested the use of bioabsorbable screws to remove the need for screw removal. In addition, bioabsorbable screws achieve similar functional results compared with metal screws.

#### Evaluation of treatment

Most of the previous studies have used Patient Reported Outcome Measures (PROMs) to evaluate treatment. The most common PROM used in Lisfranc injury studies is the American Orthopaedic Foot and Ankle Society Midfoot Score (AOFAS) [13, 28, 30, 38, 47]. Other commonly used PROMs include Visual-Analogue-Scale Foot and Ankle (VAS-FA) [52] (also validated in the Finnish language [53]), Visual-Analogue-Scale (VAS) [28], Short Form 36 (SF-36) [28, 33], Baltimore Painful Foot Score (PFS) [31], Short Musculoskeletal Function Assessment (SMFA) [33], long-form Musculoskeletal Function Assessment (MFA) [13], the Maryland foot score [47] and activities of daily living (ADL) [47]. In our study, we decided to use AOFAS because it is the most commonly used PROM for Lisfranc injuries and VAS-FA as it is validated in the Finnish language [53].

#### Previous studies

The literature does not provide any prospective randomized controlled studies on the nonoperative versus the operative treatment of Lisfranc injuries. Current knowledge is based on a few case-series [35, 37] and retrospective studies [5, 22, 38]. Nunley and Vertullo [29] suggested in their series of midfoot sprains in athletes that only totally non-dislocated sprain injuries should be treated nonoperatively, and that all injuries where the diastasis between the first and second metatarsal is 2 mm or more would benefit from ORIF. Myerson et al. [5] were the first to study the nonoperative

treatment of Lisfranc injury. In their study, only 5 out of a total of 52 patients were treated nonoperatively, and these patients received the treatment unintentionally, due to incorrect diagnosis. Of these five patients, four resulted in a poor result and one resulted in a fair result. Curtis et al. [22] organized a retrospective study of the treatment of 19 athletes with Lisfranc injuries. Only 14 stable injuries were treated nonoperatively. An excellent functional result was obtained with six patients, a good result with three patients, a fair result in four and a poor result with one patient. An excellent result implied the absence of symptoms or signs; a good result implied minor symptoms or signs; a fair result implied residual signs of symptoms with some disability, and a poor result implied marked symptoms or signs with limitation of function and a request for further treatment, such as arthrodesis. The treatment protocol between patients differed from “none” to “cast for ten weeks”. Crates et al. [38] studied nonoperative treatment and operative treatment after the failed nonoperative treatment of subtle Lisfranc injuries in 36 patients. The nonoperative protocol consisted of 6 weeks of a short leg walking orthosis and weight-bearing was progressed as tolerated. Progressed weight-bearing in an orthotic was begun after boot removal. Nonoperative treatment was successful in 16 patients, and the treatment failed in 20 patients. The mean AOFAS midfoot score in the successfully treated patients was 62 (49–72) before treatment and 75 (53–100) after treatment.

There have only been two previous prospective randomized studies on ORIF vs PA. Ly and Coetzee [30] randomly assigned 41 patients with ligamentous Lisfranc injuries to either an ORIF group or a PA group. The PA group had a slightly better functional outcome (AOFAS score 88 vs. 69), a higher return to preinjury activity level (92% vs. 65%), a lower rate of revision surgery and less pain in the final follow-up. Implant removal due to prominent or painful screws was performed on 16 of the 20 patients in the ORIF group and on 4 of the 21 patients in the PA group. The implant removal was only performed due to painful hardware, on average at 6.5 months (range: from five to ten months). Follow-up radiographs showed loss of correction, increasing deformity, and degenerative joint disease in 15 of the 20 patients in the ORIF group and 7 of them required conversion to an arthrodesis. In the PA group, one patient had delayed union at seventeen weeks and one patient required a revision arthrodesis with bone graft. One patient suffered from a post-traumatic intrinsic compartment syndrome that resulted in claw toes. In the study by Henning et al. [33], 40 patients with acute Lisfranc joint fractures or fracture dislocations were randomized to primary ORIF or PA. A total of 8 patients dropped out before 3-months follow-up. There was a significantly

higher rate of secondary surgery in the ORIF group. Statistically significant differences were not found in physical functioning with regard to SF-36 or SMFA scores at any follow-up time interval. In their systematic review and meta-analysis, Smith et al. [34] concluded that ORIF has a higher risk of implant removal compared with PA (risk ratio 0.23 (0.11–0.45)  $p < 0.001$ ), although there were no statistically significant differences in revision surgery, PROMs or non-anatomic alignment. Cochran et al. [32] organized a retrospective comparative cohort study on PA versus ORIF in young athletic military personnel with low-energy Lisfranc injury. In their study, PA resulted in a faster return to military service, a lower implant removal rate and better fitness scores after 1 year.

In conclusion, PA seems to result in less secondary surgery, less implant removal and a faster return to activity. There is some evidence of a better functional outcome after arthrodesis, but the result is still controversial. Nevertheless, the current overall evidence slightly favors arthrodesis as a primary treatment of dislocated Lisfranc injuries.

#### Aims of this study

The aim of this two-armed randomized controlled trial is to I) compare nonoperative treatment with ORIF in non-dislocated Lisfranc injuries and II) to compare ORIF with PA in dislocated Lisfranc injuries.

#### Methods/design

The study is a prospective, randomized, national multicenter trial. The trial centers are Tampere University Hospital and Seinäjoki Central Hospital. The trial has been designed to compare the nonoperative and operative treatment of Lisfranc injuries. The trial includes two strata: Stratum I compares nonoperative treatment and operative treatment with ORIF for non-dislocated Lisfranc injuries. Stratum II compares ORIF and PA in dislocated Lisfranc injuries.

The primary outcome in this study is the AOFAS [54] measured after 6, 12 and 24 months. The secondary measured outcomes after 6, 12 and 24 months are VAS [55], VAS-FA [52], number of secondary operations (implant removal, secondary arthrodesis) and number of other treatment-related complications.

#### Hypotheses

Our primary hypotheses in the study are the following:

- i) The hypothesis of stratum I is that nonoperative treatment of non-dislocated Lisfranc injuries yields better outcome in terms of AOFAS, VAS and VAS-FA score compared with operative treatment (ORIF).

- ii) The hypothesis of stratum II is that PA of dislocated Lisfranc injuries yields better functional outcome in terms of AOFAS, VAS and VAS-FA score compared with ORIF, and PA results in fewer secondary operations than ORIF.

The results of both strata will be analyzed and reported separately.

#### Patient selection and methods

The study population comprises patients suffering from acute Lisfranc joint injury (Fig. 1). Clinical suspicion (pain, swelling, plantar ecchymosis or gap sign) or typical findings on plain x-ray ('fleck sign', avulsion or fracture) leads to CT where the diagnosis and morphology of the injury is confirmed. Eligible patients are informed about the study at the emergency room (ER) by the surgeon on call. The final eligibility of patients and correct study strata is determined based on CT findings and other medical information and discussion with the patient by one of the foot and ankle surgeons in the study group (HH, H-JL, HMM, JJ, OV).

#### Inclusion criteria

Stratum I (nonoperative treatment vs. ORIF):

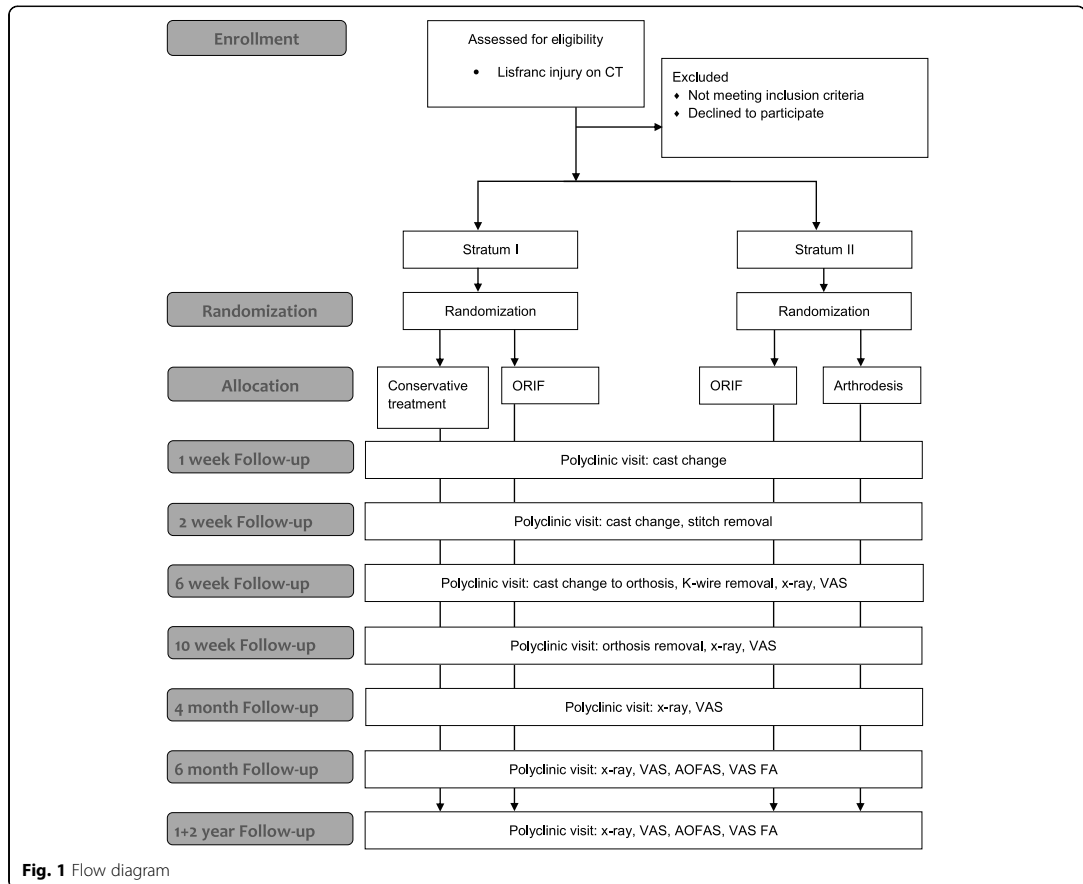
- Non-dislocated (< 2 mm) fractures affecting TMT joints II and III
- And/or Dislocation < 5 mm between medial cuneiform and base of MT II
- And no fractures affecting TMT joints IV and V

Stratum 2 (ORIF vs. PA):

- Affected joints TMT II - III + any other TMT
- Any dislocation > 2 mm (fracture or TMT joint)
- Dislocation > 5 mm between medial cuneiform and base of MT II

#### Exclusion criteria

- Aged under 18 or over 60
- Open fractures
- Extra-articular metatarsal fractures
- Extremely comminuted fractures with bone loss and poor chance of gaining proper fixation with screws
- Polytrauma patients
- Patients with weak co-operation (dementia, alcohol use, etc.)
- Patients with significant neuropathy or some other neurological condition
- Diabetes
- Rheumatoid arthritis



**Fig. 1** Flow diagram

- Patients with severe circulatory disorder of the lower limb
- A delay in diagnosis of more than 14 days
- Patients with a previous foot injury or surgery of the injured foot
- Pregnancy
- Patients who refuse to participate

#### Randomization

All patients will be randomized by the research coordinator at Tampere University Hospital who will not participate in the study. Patients with non-dislocated injuries are randomized into a nonoperative or ORIF group. Patients with dislocated injuries will be randomized into ORIF or PA groups. Both injury types will be randomized in blocks of ten. The treatment allocations from the randomization will be sealed in envelopes which will be then used and opened in numerical order after patient enrolment has been confirmed by the research physician. The research coordinator will monitor the study flow.

#### Nonoperative treatment

Nonoperative treatment is conducted with non-weight-bearing cast-immobilization for 6 weeks. The cast is changed at 1 and 2 week controls. The cast is removed at 6 weeks and patients are prescribed a walking boot for 4 weeks. Weight-bearing with a walking boot is limited to half-bodyweight for the first 2 weeks and the last 2 weeks as tolerated. At 10 weeks, patients will be allowed to use their own shoes and walk as tolerated.

#### Surgical technique

The surgical procedures will be performed by experienced foot and ankle surgeons (HH, H-JL, HM, JJ and OV). All patients will receive an antibiotic prophylaxis preoperatively. The operation is performed under tourniquet at 280 mmHg to 300 mmHg pressure.

#### Open reduction and internal fixation

One or two incisions will be made depending on the location of the injury. Only the affected and instable

TMT joints are fixed. The first incision is made between MT I-II and the second incision (if necessary) at the base of MT IV. Open anatomical reduction and screw fixation of the 2nd metatarsal to the medial cuneiform bone ('home run screw') and affected TMT joints will be performed with 4.0 cannulated screws (DePuySynthes®, Stryker®). If TMT IV or V joints are dislocated, after open reduction of those joints, temporary fixation with Kirschner-wires will be used (Fig. 2). Fixation will be performed under fluoroscopic guidance. K-wires will be cut, bent and left visible on the skin and removed at the 6 week postoperative visit. Wounds will be closed with dermal sutures. Fixation screws will be removed only if they cause any symptoms.

### Primary arthrodesis

Incisions will be made as described for ORIF. Cartilage and fibrous tissue will be removed from the affected TMT joints with a chisel. Fixation for the medial cuneiform bone to the base of 2nd metatarsal and TMT I-III will be performed with 4.0 cannulated screws in a similar manner to ORIF. If TMT IV or V joints are affected, arthrodesis will not be done, but temporary fixation will be performed, as described for ORIF.

### Postoperative aftercare

Postoperative aftercare is identical to nonoperative treatment with 6 weeks of non-weight-bearing cast-immobilization and 4 weeks of walking boot. Stitches are removed, and cast changed at 2-week visit. The cast and K-wires stabilizing the TMT IV and/or V joints are removed at 6-week visit.



**Fig. 2** Intraoperative view of the screw and K-wire fixation of the TMT joints

Thrombosis prophylaxis and analgesic medication is planned individually.

### Follow-up

All follow-up visits will be conducted in the trauma outpatient clinic of the hospital where the patient was primarily treated (Table 1). The visits are at 6 weeks, 10 weeks, 6 months, 12 months and 24 months after the injury. Standing x-ray of the injured foot and VAS score is obtained during every visit. AOFAS and VAS Foot and Ankle questionnaires will be completed during the 6, 12 and 24-month visits.

### Power analysis

In this trial, the widely recognized AOFAS will be used as the main outcome measure. The clinically significant difference in AOFAS has been reported to be 8.36 (SD 11.16) points [56]. Assuming a 10-point difference in the AOFAS score and a standard deviation of 12 points, the estimated sample size is 23 patients (delta = 10, sd = 12, alpha = 0.05, power 0.8). We will assume a 20% drop-out rate in both groups, and therefore the total patient count needed for both strata will be 56 patients. Due to block randomization in blocks of ten, 60 patients will be recruited.

### Statistical analysis

The baseline characteristics will be reported as mean (standard deviation), median (quartiles) or proportion. Study groups will be compared using t-test, Mann-Whitney U or Fisher's exact test. Primary (AOFAS) and secondary outcomes (VAS-FA, VAS, complications, secondary surgery) will be compared at 12 months and 24 months using the Mann-Whitney U test. The results will be presented with 95% confidence intervals, and therefore a *p*-value of < 0.05 will be considered statistically significant. The data will be analyzed according to the intention-to-treat principle, assuming the patients change group during the study. The statistical analysis will be performed with SPSS® version 22.

**Table 1** Assessments and procedures of the trial

	Medical history	Radiograph	CT	VAS	AOFAS	VAS FA
Baseline	X	X	X			
6 weeks		X		X		
10 weeks		X		X		
4 months		X		X		
6 months		X		X	X	X
1 year		X		X	X	X
2 years		X		X	X	X



## Study material

All information will be sent to Tampere University Hospital and the gathered material will be stored in a study registry. The registry is protected with passwords given only to the authors and the secretary of the study group and the data will be deleted 15 years after the end of the study.

## Ethics

The study protocol and additional papers, including consent form, patient information form and questionnaires have been approved by the Regional Ethics Committee of Tampere University Hospital. (Approval number R11152, 11th November 2011). All participants will provide a written consent to participate.

## Time schedule

The recruitment of patients started in 2011 and it will be continued until the number of patients achieves the estimated volume of power analysis. The final results will be analyzed after the 2-year follow-up period of the last recruited patient. In October 2017, 51 patients had been included in the study. The final report will be published by the end of 2021.

## Discussion

This publication presents a prospective, randomized, national multi-center trial. It gives details of patient flow, randomization, aftercare and methods of analysis of the material and ways to present and publish the results. The limitations of this study are limited patient blinding due to the nature of the treatment (operative versus nonoperative) and using a primary outcome measure (AOFAS) that has not been validated in Finnish. The strength of this study is that this is the first study to compare the nonoperative and operative treatment of Lisfranc joint injuries in a prospective and randomized study setting with an adequate number of patients. As the previous literature provides only two contradictory randomized controlled trials on this matter, the benefits of this study are to provide evidence-based knowledge on the treatment of these injuries.

## Abbreviations

ADL: Activities of daily living; AOFAS: American Orthopaedic Foot and Ankle Society; CT: Computed tomography; ER: Emergency room; K-Wire: Kirschner-Wire; MFA: Long-Form Musculoskeletal Function Assessment; MT: Metatarsal; ORIF: Open reduction and internal fixation; PA: Primary arthrodesis; PFS: Baltimore Painful Foot Score; SF-36: Short-Form 36; SMFA: Short-Form Musculoskeletal Function Assessment; TMT: Tarsometatarsal; VAS FA: Foot and Ankle Visual-Analogue-Scale; VAS: Visual-Analogue-Scale

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## Authors' contributions

VP, VM, HJL, AP, HM and HH are responsible for developing the trial. VP, HH and VM wrote the first draft of this manuscript. VP, H-JL, HM and AP are responsible for data analysis. In addition, HH, H-JL, and HM will recruit the patients and perform operations. VP, VM, HJL, AP, HM and HH have read and approved the final manuscript.

## Ethics approval and consent to participate

The study was approved by the Regional Ethics Committee of Tampere University Hospital in November 2011. All participants will provide a written consent to participate.

## Consent for publication

Not applicable.

## Competing interests

All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: no support from any organization for the submitted work; HH has been paid for educational presentations and travel expenses by DePuySynthes and Stryker. The authors declare that they have no competing interests.

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