

CALCANEAL FRACTURES:

A TRAUMA SYSTEM WIDE EVALUATION OF PATIENT, INJURY AND FRACTURE
CHARACTERISTICS AND THEIR ASSOCIATION
WITH PATIENT-REPORTED OUTCOME MEASUREMENTS

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Calcaneusfracturen: Een traumasysteem brede evaluatie van patiënten, letsel en
fractuur karakteristieken en de associatie met patiënt gerapporteerde uitkomst metingen

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CHAPTER 1

INTRODUCTION

General introduction

Trauma in general is an important cause for disability and accounts for ten percent of the world's deaths. [1] Moreover, trauma impose heavy costs (economically and emotionally) on individuals and society. [1]

The calcaneus is the most often fractured bone of all the tarsal bones in the human skeleton, accounting for 60 to 75 percent of all tarsal fractures. [2] Though, calcaneal fractures are a relatively uncommon injury, with a reported incidence that varies from 11.5 to 13.7 per 100,000 persons per year. [3-5] They are known to cause a significant long-term disability that influence the daily lives of the affected individual negatively. Furthermore, the sequelae of the injury may place a substantial economic burden on the individual and the community. [6-8]

Calcaneal fractures

The calcaneus is the largest tarsal bone. It has an irregular, solid and rectangular shape and articulates with two other bones, the cuboid anteriorly and the talus superiorly. It presents six surfaces with four articular facets. Three from the four articulate with the talus, the so-called subtalar facets. The talus distributes the body loads over the calcaneus and the navicular. Therefore the subtalar facets receive the body loads, which have been redistributed by the talus. Hence, the calcaneus functions as a support for the human body and therefore has to endure a high degree of force during standing, walking, jumping, running, kicking and similar activities.

Most intra-articular calcaneal fractures are caused by an axial loading mechanism such as a fall from height (usually 2 meters or more), a motor vehicle accident, or an impact on a hard surface. Extra-articular calcaneal fractures are more likely to occur with a sudden twisting force applied to the hind foot. The most typical symptoms of a calcaneal fracture are swelling and hematoma of the hind foot and ankle. Other symptoms can be pain, bruising, heel deformity, seen as widening or broadening of the heel and inability to put weight on the heel or to walk.

Initial evaluation of a suspected calcaneal fracture is often assessed with conventional radiographic imaging. To inform patients in an early stage on how their fracture might influence their lives or to customize management of a patient, radiographic images can be assessed. In conventional radiographic images Böhler's angle is frequently measured. Böhler's angle (see Figure 1a in chapter 5), also known as the tuber-joint angle, is the angle formed by two intersecting lines: a line between the highest point of the posterior facet to the highest point of the anterior surface, and a line connecting the highest point of the posterior tuberosity of the calcaneus and the posterior facet. A negative angle in a displaced intra-articular calcaneal fracture is associated with an unfavorable outcome. [6]

Nowadays, the initial assessment is frequently followed by a CT because it allows better visualization of the subtalar joint and whether other osseous structures in the foot are fractured or displaced. [9] The Sanders classification is frequently used to categorize intra-articular calcaneal fractures that involve the posterior facet of the calcaneus. The classification is divided into four types: type I is a non-displaced fracture that is defined as less than two millimeter displacement, regardless of the number of fracture lines, type II, III and IV are more than two millimeter displaced fractures, and have respectively one, two, or three and more fracture lines. [10]

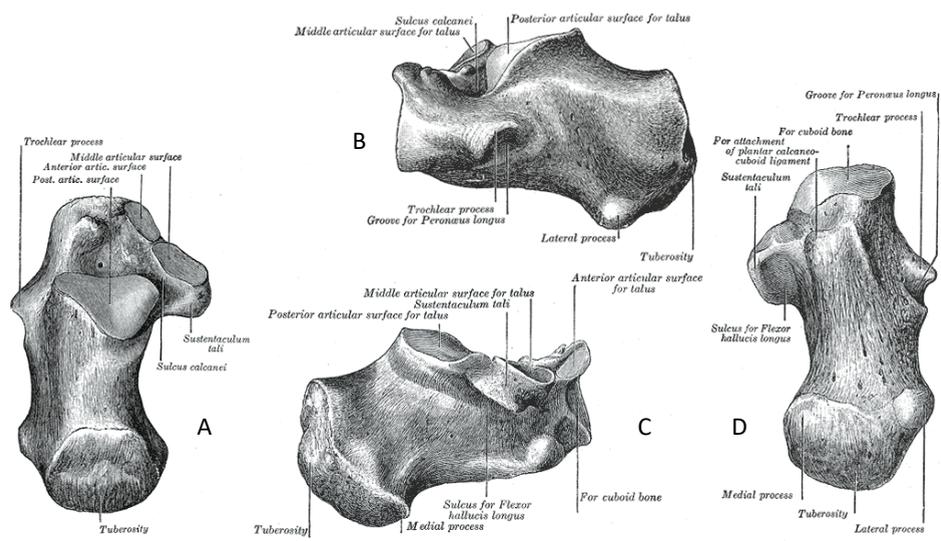


Figure 1: Left calcaneus. A is view from superior. B is view from lateral. C is view from medial. D is view from ferior. [15]

Health-related quality of life

To improve the outcome of patients with a calcaneal fracture knowledge of the health-related quality of life (HRQoL) of these patients after the injury is needed. Several outcome instruments have been used in studies measuring the quality of life in patients with calcaneal fractures [11]. Most of these instruments are limited because they are disease-specific and focus mainly on the clinical outcome of the foot and ankle; moreover, the majority of these instruments reflect the clinician's view rather than the perspective of the patient.

Frequently used instruments to determine the health of individuals are the patient-reported instruments that are utilized to measure the HRQoL. HRQoL can be defined as the functioning of persons in their physical, psychological and social domains and the subjective evaluation of these domains. Objective aspects are whether the individual has a certain limitation with their health, while subjective aspects evaluate how a person judges his domains. For example, it does not only evaluate how many meters a person can walk in a certain timeframe, but also how this is experienced. Multiple surveys for assessment of these domains have been developed such as the short-form 36 (SF-36) and the EuroQol 5D (EQ-5D). [12, 13] The advantages of HRQoL outcome measurements are the reflection of the patient's perspective on their health or measuring whether a certain treatment truly increases the patient's health. It further makes it possible to perform cost-analyses between different treatments and comparison with other morbidities. [14] For policy makers this outcome is useful to allocate scarce resources and through this achieve highest possible value for the patient in which all stakeholders (e.g. health insurance-payer, patient, or surgeon) benefit.

Trauma system

Trauma systems were established worldwide to improve the quality of trauma care. The goal of such a system is to reduce morbidity and mortality. The approach is to transport the right patients to the right center within the right time, to match the patient needs for trauma care and to optimize the use of scarce available trauma resources. The assignment of the level of trauma care are dependent on the acute care facilities and personnel in that particular center. A level I trauma center has all the needed facilities and personnel available, and therefore the capacity to provide care for all severely injured patients. A trauma level II center is a large general hospital that is capable to treat major traumas; though, not all facilities and specialties are available in such centers. Level III trauma centers have limited capacity of trauma care, patients with a single injury should be treated in these centers.

The Dutch trauma care system consists of eleven level I trauma centers each covering a specific region. The University Medical Center Utrecht covers the central region in the Netherlands. Three trauma level II centers in this region are connected to this network (St. Antonius Hospital, Diakonessen Hospital and Meander Medical Center). Close collaboration between these centers was needed to accurately reflect the diversity of patients with a calcaneal fracture.

Identification of patients with a calcaneal fracture in registries

Prospectively collected data of patients based upon diagnosis are registered in hospital registries. This data is limited because it contains little information about aspects of treatment and comorbidities. Hence, a separate registration of acutely admitted trauma patients at the emergency department was introduced that contains more information on the patient and trauma characteristics. Moreover, the data of all admitted patients to the hospital are registered in a separate national database. All together there are three databases that collect data on patients with a calcaneal fracture that all register different characteristics on the patient and trauma; furthermore, not all patients with a calcaneal fracture were included in every registry. To reflect the population as accurately as possible all the patient data of the three registries were combined. This makes it possible to identify all patients with a calcaneal fracture; thus, to get a detailed understanding of the causes, treatments and outcomes of a calcaneal fracture.

Thesis outline

The research presented in this thesis is the result of a cooperation between the surgery departments of the four trauma centers in the central region in the Netherlands (University Medical Center Utrecht, St. Antonius Hospital, Diakonessen Hospital and Meander Medical Center).

The main goal of this project was to evaluate the consequences of a calcaneal fracture on the affected individual and to gain insight on aspects that may determine outcome in order to develop accurate and efficient treatment strategies and provide reliable information on the prognosis to patients.

Chapter 2 provides an extensive overview of the available evidence on calcaneal fractures that used HRQoL measured with the EQ-5D and SF-36 as outcome. The aim of this systematic review was to gain insight on the quality of studies in patients with a displaced intra-articular calcaneal fracture. In *chapter 3* the HRQoL state of patients with a calcaneal fracture was evaluated. This study was performed in order to quantify the impact in specific patient groups and to describe the patient characteristics extensively. *Chapter 4* evaluates the diversity of patient, trauma, fracture characteristics and outcome of patients with a calcaneal fracture between the different level trauma centers in a regional inclusive trauma system. In *chapter 5* the association of characteristics of conventional radiographs and CT-images with patient-reported outcomes (i.e. HRQoL, complications, patients' satisfaction and capability to work) was analyzed in patients who endured a calcaneal fracture. *Chapter 6* describes the follow-up of patients who sustained a displaced intra-articular calcaneal fracture and the discomforts these patients might face after such an injury. In addition, this study evaluates whether there is a relationship between calcaneal-related complications and several patient-reported outcomes. *Chapter 7* focuses on the differences between patients with a comorbid psychiatric disorder differ from patients without a comorbid psychiatric disorder. In this part the patients', trauma and fracture characteristics, and outcomes were compared and evaluated. *Chapter 8* evaluates the patients who had a subtalar arthrodesis. Subtalar arthrodesis is for many patients with continuing pain and dysfunction after a calcaneal fracture the final solution. At last, in chapter 9, the general conclusions and future perspectives are outlined to conclude the content of this thesis.

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CHAPTER 2

PATIENT-REPORTED HEALTH-RELATED QUALITY OF LIFE AFTER A DISPLACED INTRA-ARTICULAR CALCANEAL FRACTURE: A SYSTEMATIC REVIEW

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Abstract

Background

A displaced intra-articular calcaneal fracture (DIACF) is known for having a negative influence on the daily activities of patients. A health-related quality of life (HRQoL) outcome instrument is used to quantify the impact of DIACF. It seems that these studies used restrictive inclusion criteria and observe specific patient groups; consequently, an increased risk of bias that results in incorrect estimation of the impact. Therefore, we will systematically review the current literature.

Materials and methods

A systematic search was performed in PubMed, Embase and Cochrane library. Inclusion criteria were studies reporting DIACF and HRQoL, measured with SF-36, SF-36v2, EQ-5D or EQ-6D. The identified articles were critically appraised for their relevance and validity. The overall risk of bias was determined. The studies with a low to medium risk of bias were used for data extraction.

Results

32 articles were available for the critical appraisal. 13 articles had a medium risk of bias. All studies reported the SF-36 and two studies also reported the EQ-5D.

Conclusions

This systematic review indicates that DIACF is a life-changing event for most patients. The HRQoL is substantially lower in comparison to the period before the trauma and to the general population, in particular the subdomains related to the physical domain are affected. In addition, this review reveals that the identified studies have a medium to high risk of bias. Consequently, it is challenging to make reliable and valid conclusions. Therefore, we provided recommendations to decrease the risk of bias in order to improve future research.

Introduction

It is well-known among orthopedic healthcare providers that a displaced intra-articular calcaneal fracture (DIACF) has a negative influence on the daily activities of patients and affects their quality of life substantially. [1, 2] Moreover, this fracture has an adverse economic impact on society. Buckley et al. (2002) showed that approximately 20% of these patients do not return to work after 1 year. [1]

A health-related quality of life (HRQoL) outcome instrument is used to quantify the impact of a DIACF on the daily activities of these patients. [1, 3-8] Policy makers use these HRQoL outcomes for economic assessments and to optimize the use of the scarce resources. Improving HRQoL might result in an increased number of patients who return to work, and consequently this will increase the cost-effectiveness of the management of patients with a DIACF.

In current literature studies were performed that use HRQoL as outcome. These studies demonstrated to have lower HRQoL scores in comparison to the general population. [1, 7-8] However, these studies tend to use restrictive inclusion criteria and to observe specific patient groups. [1, 6-8] As a consequence, these studies are prone to provide results that seem too positive to us, and might underestimate the need for advancements of research to improve the daily lives of patients with a DIACF.

Previous systematic reviews have reported HRQoL on DIACF, but focused mainly on comparing treatments with outcomes such as complications, return to work rate, or the ability to wear certain shoes. As a result, these reviews have not included all the available original studies on HRQoL after a DIACF; subsequently, this may bias the HRQoL outcome after a DIACF. [9-17]

Therefore, a thoroughly and explicit assessment of the validity of primary studies that use HRQoL as an outcome is required. With this knowledge, more insight in the disease specific progression could be established and the rehabilitation process could be improved.

This is the first systematic review, which focuses solely on the HRQoL in adult patients who sustained a traumatic DIACF. We will critically appraise the validity of current literature. As a result, we will present a comprehensive overview of the quality of these studies and provide a thorough update on the best available evidence of the HRQoL status in patients with a DIACF.

Materials and Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline was used to conduct this review. [18]

Health related quality of life (HRQoL)

HRQoL is the subjective evaluation of the aspects that affect a person's health. These aspects are classified into the physical, psychological, and social domain. These domains can be further specified into subdomains. Pain and physical functioning are subdomains of the physical domain. The psychological domain is further specified in emotional and mental health. The quality of social contacts and behavior are subdomains of the social domain.

For the assessment of HRQoL, several instruments have been developed and validated, such as the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) and the EuroQol 5D (EQ-5D). [19-22] There is, to our knowledge, no validated patient reported outcome which specifically addresses patients with a DIACF or patients with an ankle or foot disorder. The literature states that SF-36 can be used as a valid instrument to measure HRQoL in these patients. [3-5]

Search strategy

A computerized search was conducted on March 15, 2015 in the search engines PubMed, Cochrane library and Embase. The search syntax encompassed *calcaneus*, *fracture*, and the outcome instruments: *SF-36*, *SF-36v2*, *EQ-5D* and *EQ-6D* (including their respective synonyms). [19-22] Table 1 contains an overview of the complete search syntax. We searched titles and abstracts. All articles, which met the search terms, were exported from the search engines to Reference Manager version 12.0.

Selection

Our aim was to analyze all articles evaluating the HRQoL in patients with DIACF; therefore, we have included all articles written in English, German, French or Dutch that assessed patients who had a primary treated DIACF and reported results of SF-36, SF-36v2, EQ-5D, or EQ-6D.

At first, all duplicates were excluded. The titles and abstracts of the articles were screened by one reviewer (GA), based on the inclusion criteria (Figure 1). We have excluded articles that assessed patients who were aged younger than 16 years. In addition, we

excluded articles that are reviews. The full text of the remaining articles was screened by two reviewers (GA, ACG). From these articles and the identified systematic reviews, all references were screened using the same criteria. In case of overlapping patient data, the article with the highest number of patients was included.

Table 1: Search syntax per search engine. Search conducted on 15th March of 2015.

<p>PubMed:</p> <p>(calcaneus[tiab] OR calcaneum[tiab] OR calcaneal[tiab] OR calcis[tiab] OR kalkaneus[tiab] OR (heel[tiab] AND bone[tiab]) OR fersenbein[tiab] OR hielbeen[tiab] OR hielbot[tiab] OR calcanean[tiab] OR calcanea[tiab]) AND (fracture[tiab] OR fractures[tiab] OR lesion[tiab] OR lesions[tiab] OR broken[tiab] OR fractured[tiab] OR splintered[tiab] OR displaced[tiab] OR displacement[tiab] OR discontinuity[tiab] OR discontinuities[tiab] OR gebroken[tiab] OR fracture[tiab] OR frakturen[tiab] OR fractuur[tiab] OR fracturen[tiab] OR fragmentation[tiab] OR fragmented[tiab] OR fragment[tiab] OR cleavage[tiab] OR cleavages[tiab]) AND (sf36[tiab] OR sf-36[tiab] OR (sf[tiab] AND 36[tiab]) OR (health[tiab] AND (survey[tiab] OR surveys[tiab] OR review[tiab] OR reviews[tiab] OR questionnaire[tiab] OR questionnaires[tiab])) OR (short[tiab] AND (form[tiab] OR form-36[tiab])) OR short-form[tiab] OR euroqol[tiab] OR euroqol-5[tiab] OR euroqol-6[tiab] OR eq-5d[tiab] OR eq-6d[tiab] OR (quality[tiab] AND life[tiab]) OR ((clinical[tiab] OR functional[tiab]) AND (assessment[tiab] OR score[tiab] OR scores[tiab] OR outcome[tiab] OR outcomes[tiab])))</p>
<p>Embase:</p> <p>calcaneus:ab,ti OR calcaneum:ab,ti OR calcaneal:ab,ti OR calcis:ab,ti OR kalkaneus:ab,ti OR (heel:ab,ti AND bone:ab,ti) OR fersenbein:ab,ti OR hielbeen:ab,ti OR hielbot:ab,ti OR calcanean:ab,ti OR calcanea:ab,ti AND (fractures:ab,ti OR lesion:ab,ti OR lesions:ab,ti OR broken:ab,ti OR fractured:ab,ti OR splintered:ab,ti OR displaced:ab,ti OR displacement:ab,ti OR discontinuity:ab,ti OR discontinuities:ab,ti OR gebroken:ab,ti OR fracture:ab,ti OR frakturen:ab,ti OR fractuur:ab,ti OR fracturen:ab,ti OR fragmentation:ab,ti OR fragmented:ab,ti OR fragment:ab,ti OR cleavage:ab,ti OR cleavages:ab,ti) AND (sf36:ab,ti OR 'sf 36':ab,ti OR (sf:ab,ti AND 36:ab,ti) OR (health:ab,ti AND (survey:ab,ti OR surveys:ab,ti OR review:ab,ti OR reviews:ab,ti OR questionnaire:ab,ti OR questionnaires:ab,ti)) OR (short:ab,ti AND (form:ab,ti OR 'form 36':ab,ti)) OR 'short form':ab,ti OR euroqol:ab,ti OR 'euroqol 5':ab,ti OR 'euroqol 6':ab,ti OR 'eq 5d':ab,ti OR 'eq 6d':ab,ti OR (quality:ab,ti AND life:ab,ti) OR (clinical:ab,ti OR functional:ab,ti AND (assessment:ab,ti OR score:ab,ti OR scores:ab,ti OR outcome:ab,ti OR outcomes:ab,ti)))</p>
<p>Cochrane Library: searched in title, abstract and keywords</p> <p>(calcaneus OR calcaneum OR calcaneal OR calcis OR kalkaneus OR (heel AND bone) OR fersenbein OR hielbeen OR hielbot OR calcanean OR calcanea) AND (fracture OR fractures OR lesion OR lesions OR broken OR fractured OR splintered OR displaced OR displacement OR discontinuity OR discontinuities OR gebroken OR fracture OR frakturen OR fractuur OR fracturen OR fragmentation OR fragmented OR fragment OR cleavage OR cleavages) AND (sf36 OR sf-36 OR (sf AND 36) OR (health AND (survey OR surveys OR review OR reviews OR questionnaire OR questionnaires)) OR (short AND (form OR form-36)) OR short-form OR euroqol OR euroqol-5 OR euroqol-6 OR eq-5d OR eq-6d OR (quality AND life) OR ((clinical OR functional) AND (assessment OR score OR scores OR outcome OR outcomes)))</p>

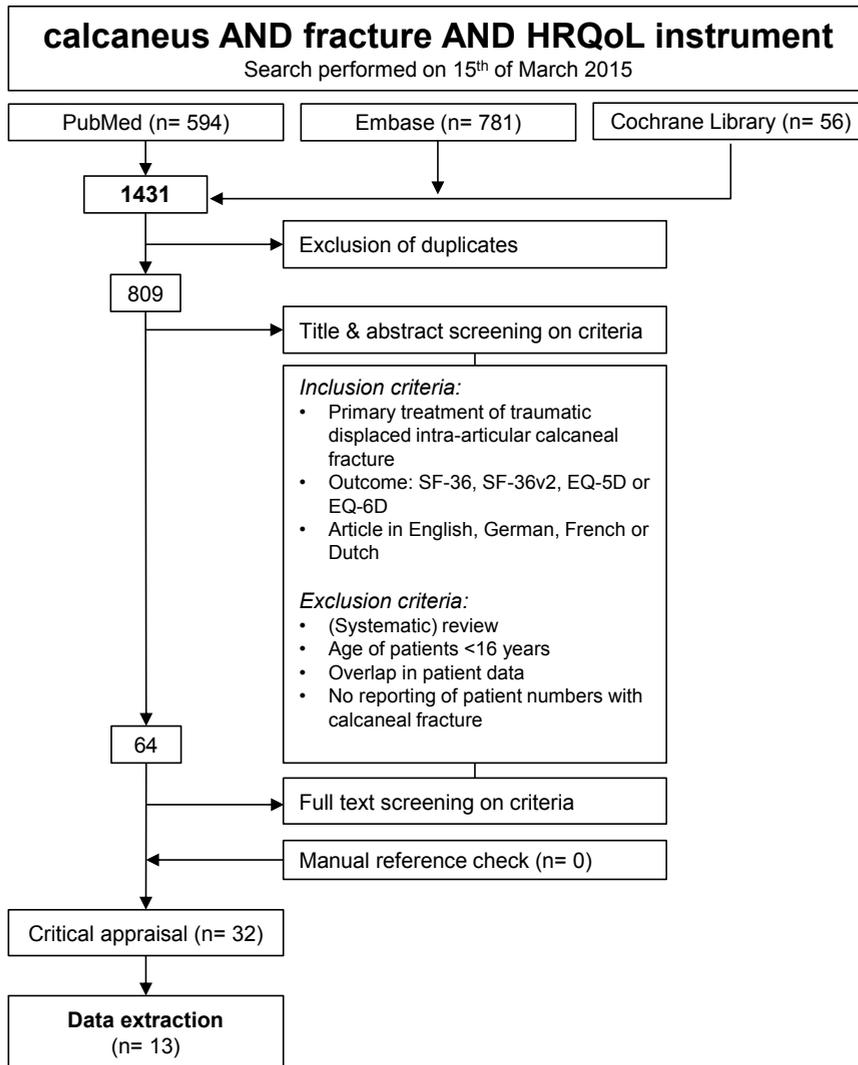


Figure 1: Flow-chart of search strategy and selection

Critical appraisal

Predefined criteria were used for the assessment of validity and relevance in the selected articles; these criteria are presented in the Legend of Table 2. Relevance concerned the applicability of the study findings to adult patients who sustained a DIACF. The preference was to use calcaneal fracture classification to determine intra- versus extra-articular fractures. In case a calcaneal fracture classification was not reported, we used the population criteria whether there were patients with intra- and extra-articular calcaneal fractures included.

Validity assessment established the extent of selection and information bias. For the assessment of the risk of bias we used the criteria for a prognostic study design from the Centre for Evidence Based Medicine of the University of Oxford, and criteria used in previous systematic reviews, which addressed HRQoL. [23-26] Two reviewers (GA, ACG) appraised the identified articles separately. In case of a difference in the critical appraisal of the selected articles between the two reviewers (GA, ACG), consensus was reached through discussion or a third reviewer (LPHL) was asked.

We developed a scoring system to determine the overall methodological quality of the studies, due to the large heterogeneity in the designs of the studies. As presented in the literature, priority criteria which are likely to be essential for the methodological quality have the highest weight in our scoring system. [26] Description of population characteristics is important for the interpretation of the results; it is generally accepted that the type of fracture and the length of follow-up have a substantial influence on the outcome. [27, 28] Nevertheless, as described in the *Cochrane Handbook for Systematic Reviews of Interventions*, we did not value the transparency of methodology and reporting of population characteristics, because it is an uncertainty in the assessment of the risk of bias. [29]

Eventually, we assigned points for each 'validity' criterion (Legend of Table 2 demonstrated the scores per criterion). Afterwards, we summed all these points per study (possible range -3 to 18 points). The total points of the studies were separated in three levels: high (-3 to 9 points), medium (10 to 13 points) or low risk of bias (14 to 18 points). Only articles with a low or medium risk of bias will be included in this systematic review and used for data extraction.

Table 2: Critical appraisal

	Study design	Relevance				Validity					
		Domain	Outcome	Transparency of methodology	Characteristics of population	Minimal selection bias	Outcome assessment	Lost to follow-up	Missing data	Standardization of conduction	Risk of Bias
Hildebrand (1996) [32]	RCS	+	+	+	-	-	-	+	NA	-	-
Heffernan (2000) [33]	RCS	+	+	-	-	+	±	+	-	-	±
Kennedy (2003) [34]	RCS	+	+	-	-	-	-	+	NA	-	-
Berry (2004) [35]	RCS	+	+	+	+	±	±	-	-	+	-
Van Tetering (2004) [7]	RCT	+	+	+	-	±	+	±	-	+	±
Westphal (2004) [8]	RCS	+	+	+	+	±	+	+	-	-	±
Herscovici (2005) [36]	RCS	±	+	+	+	±	-	±	-	+	-
Allmacher (2006) [27]	RCS	+	+	+	-	±	±	-	-	-	-
Robb (2007) [37]	RCS	+	+	+	-	-	+	±	-	+	-
Johal (2009) [38]	RCT	+	+	+	-	+	+	±	-	-	±
Rubino (2009) [28]	RCS	+	+	+	-	±	-	-	-	+	-
Wee (2009) [39]	PCS	+	+	+	+	±	-	-	+	-	-
DeWall (2010) [40]	RCS	+	+	+	-	+	±	-	-	-	-
Kinner (2010) [41]	PCSS	+	+	+	+	±	+	NR	-	+	±
Makki (2010) [6]	RCS	+	+	+	+	±	±	+	-	+	±
Hirschmüller (2011) [42]	RCS	±	+	+	+	-	+	+	-	-	-
Tomesen (2011) [43]	RCS	+	+	+	+	±	-	±	-	+	-
Woon (2011) [44]	PCS	+	+	+	-	±	-	NR	-	-	-
Beltran (2012) [45]	RCS	+	+	+	-	±	±	+	-	-	±
Brunner (2012) [46]	RCS	+	+	+	-	±	+	±	-	+	±
Ågren (2013) [47]	RCT	+	+	+	-	±	±	-	-	+	-
De Groot (2013) [48]	RCS	+	+	+	-	±	+	-	-	+	±
Demiralp (2013) [49]	RCS	±	+	+	-	-	-	NR	-	+	-
Kline (2013) [50]	RCS	+	+	+	-	±	-	-	-	+	-
Rammelt (2013) [51]	RCS	+	+	+	-	+	±	-	-	-	-
Tornetta (2013)[52]	PCS	±	+	+	-	-	±	NR	-	-	-
Buckley (2014) [53]	RCT	+	+	+	±	±	±	±	-	+	±
Chen (2014) [54]	RCS	+	+	+	±	±	-	NR	-	+	-
De Boer (2014) [55]	RCS	+	+	+	+	±	±	-	+	+	±
Griffin (2014) [56]	RCT	+	+	+	+	±	±	±	+	+	±
Persson (2014) [57]	RCS	±	+	+	+	±	±	-	-	+	-
Sanders (2014) [58]	PCS	+	+	+	+	±	±	-	+	+	±

RCT = randomized controlled trial, PCS = prospective cohort study, PCSS = prospective cross sectional study, RCS = retrospective cohort study, NA = not applicable, NR = not reported

Legend by Table 2: Critical appraisal

Study design	+	Prospective study or randomized controlled trial	
	±	Retrospective study	
	-	Other, such as case report	
<i>Relevance</i>			
Domain	+	Studies including adult trauma patients with DIACF	
	±	Studies including adult trauma patients with other calcaneal fractures	
	-	Studies including adult trauma patients with other solitary non-calcaneal fractures	
Outcome	+	SF-36, SF-26v2, EQ-5D, EQ-6D or RAND-36	
	-	Other	
<i>Validity</i>			Points
Transparency of methodology	+	Clearly described methodology	-
	-	Not clearly described methodology or not reported	-
Characteristics of study population (age, classification of calcaneal fracture, length of follow-up, and associated injuries)	+	Clearly described study population characteristics and inclusion of all characteristics	-
	-	Not clearly described study population characteristics or missing description of characteristics	-
Minimal selection bias	+	All eligible patients included in the study population	+5
	±	Pre-selected patient groups or subgroups	+3
	-	Subjective selection of eligible patients or not reported	-3
Outcome assessment	+	Complete mean crude scores per subdomain in patient group, or crude scores per subdomain	+6
	±	Incomplete mean crude scores per subdomain, or mean cumulative scores or EQ-5D index scores	+4
	-	No subdivision of the mean total scores in the subdomains or cumulative scores	0
Lost to follow-up	+	<15%	+4
	±	15 to 25%	+2
	-	>25% or not reported	0
Missing data	+	Description of patient characteristics who are lost to follow-up and how the missing data was handled	+1
	-	No description of patient characteristics who are lost to follow-up or how missing data was handled	0
Standardization of the conduction of the questionnaires	+	Standardized	+2
	-	Not standardized or not reported	0
Overall risk of bias	+	Low risk of bias	14 to 18
	±	Medium risk of bias	10 to 13
	-	High risk of bias	-3 to 9

Data extraction

The SF-36 and SF-36v2 score ranges from 0 to 100 per subdomain; the higher the score the better the outcome. [21, 22] These instruments measure HRQoL across eight subdomains. The subdomain 'physical functioning' scores the performance of physical activities, 'role-physical' grades the limitations in daily activities as a result of physical health, and 'bodily pain' assesses the restrictions due to pain. 'General health' evaluates personal health, and 'vitality' measures energy and fatigue. 'Social functioning' is the subdomain score for interference due to emotional and physical problems with normal social activities. The 'role-emotional' subdomain measures the problems of daily activities as a result of emotional problems, and 'mental health' determines the psychological distress and well-being. These subdomains can be reduced to a 'physical component summary' (PCS) and a 'mental component summary' (MCS) score. [21, 22]

The SF-36 and SF-36v2 have some differences in response choices, questions and in the calculation of the scores; the scores of the SF-36 and the SF-36v2 are comparable and can be combined. [21, 22, 30]

The index score for EQ-5D ranges from below zero to one. A score of 1.00 is the highest possible score and indicates a patient who experiences no limitations in any of the subdomains, 0 indicates a HRQoL comparable to death, and a value below zero indicates a HRQoL worse than death. [20]

We preferred to extract mean scores with standard deviation per subdomain. If these data were not available, we have calculated this data from the data presented in the studies. All data per group in the study were summed to calculate one overall mean score. In case we were not able to calculate mean scores from the presented data, we have contacted the authors by e-mail or telephone to ask for these data.

In order to present the development of the HRQoL through the years, we have reported the results in order of mean follow-up time. If possible, the data of the studies will be pooled to calculate the mean scores per subdomain. The homogeneity of the articles will be determined with eyeballing. [31]

Results

Search strategy & selection

The search resulted in 1431 articles. First of all, we have excluded the duplicates, as a result 810 articles remained. Title and abstract screening was performed using predefined inclusion criteria, 64 articles were left for full text and reference screening. No additional articles were identified during the reference check. Sixteen articles had overlap in patient data. Eventually, 32 articles were available for the critical appraisal. [6-8, 27, 28, 32-58] The flowchart is presented in Figure 1.

Critical appraisal

An overview of the critical appraisal is presented in Table 2. Prior to critical appraisal, the authors of 24 articles were contacted for the necessary data. [6-8, 28, 32-36, 39-41, 43-45, 47-52, 55, 58] Only De Groot et al. (2013) provided their study data, and gave permission to present their data in this review.⁴⁸

Ten of the 32 articles have a prospective study design. [7, 38, 39, 41, 44, 47, 52, 53, 56, 58] Five articles did not entirely fulfill the criteria for relevance; these studies included non-displaced calcaneal fractures or other foot/ankle fractures. [36, 42, 49, 52, 57] The majority of the articles did not provide all the patient characteristics of the population they have studied. [7, 27, 28, 32-34, 37, 38, 40, 44-54] In the greater proportion of these studies, the associated injuries were not clearly described. [7, 27, 28, 33, 34, 37, 38, 40, 42, 43, 47-51, 53, 54, 56-58] Several studies did not report the classification of calcaneal fracture. [7, 27, 32, 33, 48, 49, 52]

Four of the 32 articles have a minimal selection bias. [33, 38, 40, 51] The other studies excluded specific patient groups, such as patients with open fractures, concomitant injuries, primary or secondary subtalar arthrodesis, systemic comorbidities or bilateral fractures. Furthermore, some studies only included one specific patient group with DIACF, e.g. solely patients with open fractures or one specific treatment. [45, 53]

The complete mean crude scores per subdomain were presented in seven [7, 8, 37, 38, 41, 42, 46]; the other articles provided cumulative scores or did not report all the scores per subdomain. Ten articles provided a 'total' of SF-36 scores, which represents the mean score of all the eight subdomains of the SF-36. [28, 32, 34, 36, 39, 43, 44, 49, 50, 54]

Seven articles had a follow-up rate above 85%. [6, 8, 32-34, 42, 45] Five articles did not present any follow-up data. [41, 44, 49, 52, 54]

The authors of four studies presented data of patients who were lost to follow up. [39, 55, 56, 58]

In 13 studies the inclusion of patients and the collection of patient data were not standardized or this information was not described in the studies. [8, 27, 32-34, 38-40, 42, 44, 45, 51-53] After the critical appraisal, 13 articles were scored with a medium risk of bias and were selected for the data extraction, none of the articles had a low risk of bias. [6-8, 33, 38, 41, 45, 46, 48, 53, 55, 56, 58]

Data extraction

The results of the data extraction are presented in Table 3.

Patient characteristics

All studies, except two, had a number of patients which ranged from 15 to 78. [7, 56] The number of patients in the study of van Tetering et al. (2004) and Griffin et al. (2014) was 312 and 116 patients respectively. [7, 56]

Mean age of the patients in the studies ranged from 36 to 60 years. Van Tetering et al. (2004) only provided the range of age (25 to 64 years), and Brunner et al. (2014) did not present any data about the age of the patients in their study. [7, 46] All studies evaluated operatively treated; the studies of Van Tetering et al. (2004), Griffin et al. (2014) and de Boer et al. (2014) also included non-operatively treated patients. [7, 55, 56]

Fracture characteristics

Ten studies reported the classification of the type of calcaneal fracture, nine according to the Sanders classification, of which two also presented the Essex-Lopresti classification. [6, 8, 38, 41, 45, 53, 55, 56, 58] One study used the Orthopaedic Trauma Association (OTA) classification. [46] Three studies also reported the associated injuries of the studied population. [41, 47, 55]

Follow-up time

In eleven studies the mean follow-up time ranged from 12 to 78 months. [7, 8, 33, 38, 41, 45, 46, 48, 53, 55, 56] Two studies had a substantial longer follow-up time, Makki et al. patients (2004) had a mean follow-up time of 120 months and Sanders et al. (2014) 181 months. [6, 58]

HRQoL

Ten studies used the SF-36 and three studies used the updated version, SF-36v2. Moreover, the studies of Griffin et al. (2014) and De Boer et al. (2014) also reported the mean EQ-5D index score. [55, 56] Six studies presented the SF-36 results for all the subdomains. [7, 8, 38, 41, 46, 48] In one study the results are presented graphically; the numerical values were obtained from this graph. [41] In seven studies we have calculated the mean scores from the results in the study. [6, 7, 38, 41, 45, 48, 58]

In the majority of the studies the SF-36 subdomain scores were similar. Several studies showed to be outliers in some subdomains. In the subdomain 'physical functioning' Heffernan et al. (1999) and Beltran et al. (2012) scored respectively the highest (83) and the lowest (40) score. [33, 45] The 'bodily pain' score was remarkably higher for Heffernan et al. (1999) and De Groot et al. (2013) which measured mean scores of respectively 84 and 71. [33, 48] Beltran et al. (2012) showed to have a lower score of 43 in 'social functioning'. [45] The mean score of Brunner et al. (2012) scored exceptionally lower in 'mental health' with a mean score of 41. [46]

Beltran et al. (2012) had the lowest scores in almost all the subdomains, in contrast to the study of Heffernan et al. (1999) which had the highest scores in their reported subdomains 'physical functioning' and 'bodily pain'. [33, 45] Brunner et al. (2012) showed relatively low scores in the subdomains 'general health', 'vitality', and 'mental health', while the score in the subdomain 'role-emotional' was the highest of all studies. [46]

The PCS and MCS are reported in six studies, of which only De Boer et al. (2014) reported which reference population they used for calculating these scores. [6, 45, 53, 55, 56, 58] Buckley et al. (2014) reported just the PCS. [53]

The mean EQ-5D index score was 0.69 in Griffin et al. (2014), and the median EQ-5D index score in the study of De Boer et al. (2014) was 0.78. [55, 56] The study of Griffin et al. (2014) reported SF-36 MCS, SF-36 PCS and EQ-5D index score before and after trauma. [56] The EQ-5D index showed a clinically significant decrease of the score with 0.21 points in patients with a DIACF. Also, the PCS and the MCS from the SF-36 survey decreased with respectively 11.9 and 2.0 points.

In one study, patients with DIACF are matched with a subject from the general population. [8] They are matched by age, gender, social state, comorbidity and place of residence.

Table 3: Study population characteristics and SF-36 outcome results of selected studies

	Questionnaire	Number of patients (n=)	Reported classification of calcaneal fracture type	Mean age in years (range)	Other characteristics of studied population	Treatment
Johal (2009) [38]	SF-36	41	Sanders	36 (18-61)	Exclusion of open fractures, aged >65 years, medical contraindications or intoxication abuses	ORIF
Van Tetering (2004) [7]	SF-36	312	NR	NR (25-64)	Exclusion of open fractures and age <25 and >65 years. Possible exclusion of patients who received secondary subtalar arthrodesis	ORIF or non-operative
Griffin (2014) [56]	SF-36	116	Sanders	47 (18-80)	Exclusion of open fractures, gross deformity, other serious leg injury or peripheral vascular disease	Operative (n= 62), non-operative (n= 54)
Buckley (2014) [53]	SF-36 version 2	24	Sanders	40 (SD 13)	Closed Sanders type IV fractures; exclusion age <16 and >59 years, inability of diminishing smoking after injury	ORIF (n= 11), ORIF and primary arthrodesis (n= 13)
Heffernan (2000) [33]	SF-36	25	NR	44 (22-65) at time of injury	-	ORIF
Westphal (2004) [8]	SF-36	71	Sanders	42 (22-73) at time of injury	Exclusion of bilateral or open fractures, or having other injuries	ORIF, secondary arthrodesis (n=4)
Brunner (2012) [46]	SF-36	54	OTA	NR	Exclusion of other fixation systems	ORIF
Kinner (2010) [41]	SF-36	44	Sanders	46 (18-65)	Complete clinical and radiographic documentation. Exclusion aged <65.	ORIF (n=32), percutaneous (n= 12)
Beltran (2012) [45]	SF-36	15	Sanders	43 (16-67)	High-grade open calcaneal fractures only	Percutaneous
De Boer (2014) [55]	SF-36	78	Sanders / Essex-Lopresti	46 (30-55) at time of injury	Exclusion of age >70, primary arthrodesis or amputation, Gustilo grade III, intoxication abuses or wheelchair-bound.	ORIF (n= 27), non-operative (n= 18), percutaneous (n= 33)
De Groot (2013) [48]	SF-36	41	NR	46 (SD 11) (21-66)	Exclusion of open fractures, severe mental illness or do not reside nearby	ORIF (n= 39), unknown (n= 2)
Makki (2010) [6]	SF-36 version 2	41	Sanders	56 (27-85) at time of follow-up	Exclusion of comminution of sustentacular fragment; open fractures; exclusion of secondary arthrodesis	ORIF
Sanders (2014) [58]	SF-36 version 2	66	Sanders / Essex-Lopresti	60 (SD 15) (29-91) at time of follow-up	Exclusion of open fractures, concomitant injuries, incomplete radiographic documentation, Sanders type IV, unsuited for operative treatment or subtalar fusion	ORIF

ORIF = open reduction, internal fixation, NR = not reported, SD = standard deviation; *Norm based scoring weighed upon the United States general population (1998) [59]; † Norm based scoring: mean 50 (SD 10); ‡ Not reported how it was calculated

Mean follow-up time in months (range)	SF-36 mean scores									
	Physical functioning	Role-physical	Bodily pain	General health	Vitality	Social functioning	Role-emotional	Mental health	Physical component summary	Mental component summary
>12 (NR)	59	40	51	77	63	67	65	74	-	-
23 (12-24)	67 (SD 27)	54 (SD 43)	57 (SD 26)	69 (SD 20)	60 (SD 21)	73 (SD 27)	72 (SD 38)	72 (SD 19)	-	-
24 (NR)	-	-	-	-	-	-	-	-	40 [†] (SD 13)	54 [†] (SD 12)
≥24 (24-84)	-	-	-	-	-	-	-	-	34 [†] (SD 11)	-
30 (12-48)	median83 (range 70-100)	-	median84 (range 27-100)	-	-	-	-	-	-	-
32 (11-90)	61 (SD 25)	52 (SD 43)	49 (SD 27)	58 (SD 20)	56 (SD 20)	79 (SD 23)	74 (SD 40)	69 (SD 21)	-	-
42 (24-82)	62	68	53	43	49	83	90	41	-	-
42 (12-60)	66	66	58	64	60	81	79	76	-	-
49 (13-106)	40 (SD 13)	43 (SD 16)	48 (SD 10)	52 (SD 8)	48 (SD 10)	44 (SD 10)	-	-	44 [†] (SD 12)	49 [†] (SD 13)
76 (54-88)	-	-	-	-	-	-	-	-	median 48 [†]	median 57 [†]
78 (24-192)	74 (SD 21)	65 (SD 41)	71 (SD 22)	70 (SD 19)	70 (SD 20)	85 (SD 22)	81 (SD 35)	79 (SD 20)	-	-
120 (84-180)	-	-	-	-	-	-	-	-	50 ^{††} (SD 7)	54 ^{††} (SD 4)
181 (126-256)	-	-	-	-	-	-	-	-	46 [†] (SD 9)	55 [†] (SD 11)

The results showed a statistically significant lower score in each subdomain for patients with DIACFs. [8]

The data of the studies were not pooled because of a lack of homogeneity between studies; the studies have a great disparity in patient characteristics, type of fracture, treatment, and follow-up time. [31]

Table 3 contains an overview of the subdomain scores, the studies are presented in order of follow-up time. The development of the scores through the years is graphically presented in the Appendix A. The subdomain scores of 'bodily pain', 'general health', 'vitality', and 'role-physical' remained somewhat equal over time. The score of the 'social functioning', 'mental health', 'role-emotional', and 'physical functioning' increased over time.

Discussion

A DIACF is an injury known to cause impairments, which have a significant impact on a person's HRQoL, and on society and public health costs in terms of personal suffering and monetary losses.

Prior to this review we have observed numerous studies which evaluate the HRQoL. These studies tend to use different inclusion criteria and in particular observe specific patient groups. This might lead to skewed results and a misleading underestimation of the impact of a DIACF on the HRQoL. This in turn could limit the urge for improvements in the management of these fractures. We have performed this systematic review and aimed to evaluate the current literature on HRQoL in adult patients after sustaining a DIACF. This is the first systematic review that focuses solely on HRQoL after a DIACF.

This systematic review demonstrates that a lot of the studies have an increased risk of bias, mainly caused by the high lost to follow-up, selection bias and incomplete data reporting of patient and fracture characteristics. Moreover, this review shows that the SF-36 subdomains and the EQ-5D index scores are substantially lower in comparison to the period before the trauma and to the general population. [46, 56, 60-64] The results further present that the HRQoL after a DIACF is in particular affected in the subdomains related to the physical domain.

Several studies demonstrated scores in the SF-36 subdomains which were out of the range of the scores of the majority of the articles. [33, 45, 46, 48] The lower scores of Beltran et al. (2012) can be explained by the inclusion of only patients with high-grade open fractures. [45] These patients have a more severe injury and are more likely to have worse outcomes. We were not able to clarify why the scores of the other studies deviated. Possible other factors, besides the DIACF, might have influenced the HRQoL, for instance socio-economic status or severity of fracture. [33, 46, 48] These factors were not always reported in these studies.

The designation of these studies is very challenging; the focus in these studies should be on decreasing the risk of bias. The following suggestions might decrease the risk of bias and benefit future research. Patients who sustained a DIACF are considered to be a group who are difficult to follow-up. Nonetheless, all the studies with a medium risk of bias have a decent follow-up of 75% or better. To increase the follow-up rate in future studies; it may

be worthwhile to use a shorter questionnaire (e.g. EQ-5D). In addition, we recommend that patient and fracture characteristics of the eligible population are reported to interpret the bias caused by loss to follow-up.

Furthermore, we suggest that future studies include data regarding factors that influence HRQoL, such as socio-economic status, acceptability of the disease in the population, and the quality of health care. [61, 65, 66] Also data of certain patient and injury characteristics, e.g. age, concomitant injuries, and classification of calcaneal fracture, are important to report because these factors influence HRQoL substantially. [28] Adding this information in these studies increases the generalizability and applicability to other study populations and the individual patient.

We have demonstrated in the critical appraisal (Table 2) that the majority of the studies had a selection bias. These studies excluded patients with open or bilateral fractures, multiple injured patients, patients who received secondary subtalar arthrodesis ('failure' of treatment), and patients who were not eligible for a certain treatment (Table 2). It is likely that these patients have worse HRQoL outcome compared to patients with an isolated and closed DIACF. Therefore, the results may be distorted and the impact on the HRQoL might be even worse than presented in this review. Thus, ideally, future studies include all type of patients and fractures, and all their characteristics should be reported as discussed above. The development of the subdomain scores over time (Table 3 and Appendix A) shows that 'social functioning', 'physical functioning', 'mental health', and 'role-emotional' improve over time. This could indicate that the rehabilitation period for this injury is a very time-consuming process or that patients learn to cope with their limitations. Given the changes in HRQoL over time, we might suggest that it is important to measure HRQoL during a long follow-up period.

Several studies in our review only reported the SF-36 PCS and MCS results. These scores are useful to summarize the HRQoL. Though, some studies demonstrated that these summarized scores possibly do not reflect accurately the HRQoL in comparison to the scores per subdomain. [67, 68] Moreover, an advantage of the scores per subdomain is the possibility to compare the survey with other surveys, such as the Maryland Foot Score, AOFAS Ankle Hindfoot Scale, and Iowa Calcaneal Score or to combine the result in a meta-analysis. [8, 27, 33, 52, 68-71]

The significantly decrease in HRQoL indicates that a DIACF is a life-changing event, regardless of HRQoL status before the DIACF, type of fracture, non-operative or operative treatment, or additional injuries. It has a great impact on a person's physical and social function.

The considerable loss in HRQoL shows the need for advancements in the management strategy of a DIACF in order to improve functional outcome. In current literature there is no consensus yet what the best treatment of these patients should be. A recently published randomized controlled trial demonstrated that there actually is no difference in subjective and objective outcomes after two years between non-operative and operative treatment of DIACF. [56] Although operative treatment is considered the gold standard nowadays in treatment of DIACF, this study suggests that patients who were operatively treated could still endure a severe loss in their HRQoL. Apart from the treatment of a fracture, other management strategies may be introduced. Physical functioning might be improved by early involvement of the rehabilitation physician, and psychotherapy might be helpful to cope with potentially impaired mental functioning after a trauma that caused a DIACF.

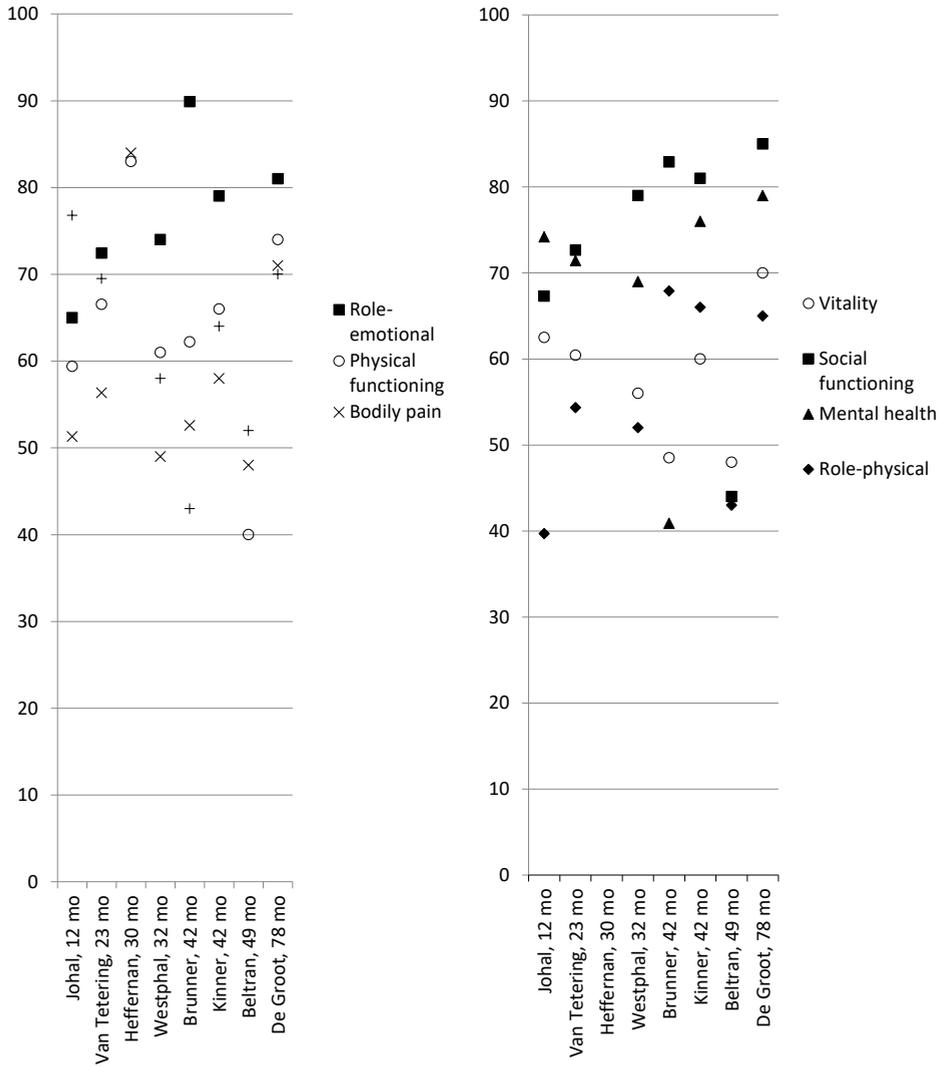
In conclusion, this systematic review indicates that DIACF is a life-changing event for most patients. However, we should be careful to deduct definite conclusions; we revealed that the identified studies have a medium to high risk of bias that might cause underestimation of the HRQoL after a DIACF. Thus, it is challenging to make reliable and valid conclusions. In future, we recommend that research aims to decrease risk of bias. Ideally, future studies on HRQoL should use shorter questionnaires to aim for a higher follow-up rate, present data on the patients which were not included, and preferably include all patients with DIACF despite their characteristics which likely influence the HRQoL outcome negatively. Furthermore, it would be useful to present all relevant patient characteristics and injury characteristics. All of this is necessary to lower the risk of bias as best as possible in this challenging population; in order to interpret the results better and to create a more representative, inclusive image on the consequences on the daily lives of patients who endured a DIACF.

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Appendix A: The SF-36 subdomain scores development in time



CHAPTER 3

HEALTH-RELATED QUALITY OF LIFE IN TRAUMA PATIENTS WHO SUSTAINED A CALCANEAL FRACTURE

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Abstract

Background

Calcaneal fractures are known to cause a considerable long-term disability; disability influences the public health negatively in terms of personal suffering and monetary losses. Health-related quality of life (HRQoL) in general is influenced by various patient-specific factors, and possibly trauma and fracture characteristics. Previous studies might have underestimated the impact of this injury because of several injury and patient specific exclusion criteria. In this study we provide an overview of the patient characteristics and outcome of patients with a calcaneal fracture in a Dutch level I trauma population.

Methods

We have performed a retrospective cohort study in a trauma level 1 centre. All patients who sustained a calcaneal fracture and were 16 years or older at time of admission were included. We have retrieved the relevant patient and fracture characteristics from the medical status and evaluated current health status with a questionnaire. We have used the EQ-6D for quantification of the HRQoL. Moreover, the patient's capability to work was evaluated.

Results

125 patients with 151 calcaneal fractures were identified of which 93 patients with 114 calcaneal fractures participated in this study. The median EQ-5D index value is 0.78. All dimensions of the EQ-6D are affected in particular the dimensions 'mobility', 'pain / discomfort' and 'usual activity'. 85% is capable to work. Female patients or patients with a relevant comorbidity or a psychiatric history have a significantly lower HRQoL score. In this study population no difference in HRQoL results was demonstrated among different socio-economic status, associated injuries, or severity of injury.

Conclusions

This study demonstrates that patients who sustained a calcaneal fracture have a significantly lower HRQoL than the Dutch reference population and suffer from a chronic disability. Moreover, patients that have a comorbidity, a relevant psychiatric history or are female have significantly lower HRQoL scores. Furthermore, this study shows that socio-economic status, associated injuries, or severity of injury did not influence the HRQoL in this study population.

Introduction

Calcaneal fractures are a relatively uncommon injury; the reported incidence varies from 11.5 to 13.7 per 100,000 persons per year. [1-3] This fracture is known to influence the daily activities of patients negatively and to affect their quality of life substantially. [4-6] Moreover, this fracture has an adverse economic impact. Buckley et al. (2002) showed that approximately 20% of these patients will not return to work after 1 year. [4]

In order to evaluate the severe consequences of the disabilities, several authors have studied and quantified the impact of this injury. [5-6] The literature shows that the impact of a displaced intra-articular calcaneal fracture (DIACF) or other ankle pathology can be evaluated with a health related quality of life (HRQoL) instrument. [7-9]

A lot of studies address the HRQoL in patients with a DIACF. [4-6, 10] In these patients the quality of life might be influenced by comorbidities, socio-economic status, concomitant injuries, age or the classification of the calcaneal fracture. [11-14] We have reviewed and evaluated the current literature and have demonstrated that in a significant number of these studies some of these factors are poorly or not reported. [15] Moreover, patients who are likely to have worse outcomes, e.g. patients with open fractures, or with concomitant injuries, are excluded in these studies.[4-6, 15-18] Therefore, these studies might underestimate the impact of a calcaneal fracture on the HRQoL.

The aim of this study is to evaluate the HRQoL in patients after a traumatic calcaneal fracture, extensively describe the patient characteristics of the included patients, and quantify the impact of this fracture in specific patient groups.

Materials and Methods

Hospital setting

This study was performed at the University Medical Centre Utrecht (UMCU) in the Netherlands. UMCU is a Level I trauma centre and an academic teaching hospital located in the central region of the Netherlands.

Study design

This is a retrospective study and is performed according to the criteria of Efficace et al. (2003) for evaluating HRQoL studies, and approved by the medical ethics committee of the UMCU. [17]

The patients were retrieved from the Dutch National Medical registration. [19] This registry is a national database in which all hospital admissions are collected with the concomitant diseases or injuries, and coded according to the International Classification of Diseases. [20]

All admitted patients with a calcaneal fracture aged 16 years or older at the time of admission at UMCU in the period 2000 to 2010 were included.

Data collection

All data were extracted from the patient's medical record. We have collected age, gender, trauma mechanism, type of calcaneal fracture (open/closed, bilateral/unilateral), fracture classification by Sanders, concomitant injuries, Injury Severity Score (ISS), comorbidities, socio-economic status, occupational status and relevant psychiatric history. [11-13, 21-24] Patients with a bilateral fracture with one open and one closed fracture were categorized in the open fracture group. The Sanders classification was only determined if CT-images of the fracture was available. The socio-economic status was determined by the highest level of education a patient had received. The comorbidities were categorised according to the ASA Physical Status Classification System. [25] All patients with a psychiatric history, who were treated with psychiatric medication, or psychotherapy were identified as patients with a relevant psychiatric history.

Follow-up

Follow-up data was retrieved from the electronic patient data (EPD) management system. A questionnaire was sent to all identified patients, along with an informed consent form. After four weeks a reminder was sent to all non-responders. At last, all patients were

contacted by phone to collect missing data or non-registered comorbidities. Furthermore, all non-responders were asked one more time for their consent to participate in the study (performed by GA).

Outcomes

To our knowledge, there is no validated patient-reported outcome measurement available for foot and ankle disorders specifically. In addition, the validity, responsiveness and reliability of the EQ-5D, a standardized generic measure of HRQoL, has been tested in studies for other extremity morbidities. [26-30] Therefore, the EQ-6D, an extended version of the EQ-5D, was chosen as primary outcome. [31]

The EQ-6D consists of six dimensions: 'mobility', 'self-care', 'usual activities', 'pain / discomfort', 'depression / anxiety' and 'cognition'. All the dimensions questions have three response opportunity: no problems, some problems, and severe problems. Based on these answers the EQ-5Di can be calculated; the additional dimension in the EQ-6D 'cognition' was ignored for the calculation of the EQ-5Di. The EQ-5Di ranges from -0.33 to 1.00. [26, 31] The best health state is represented by 1.00, 0 represents a health state comparable to death, and a negative score represents a health state worse than death.

In addition, the EQ-VAS, a visual analogue scale, measures the self-rated health status of the participant. This scale ranges from 0 (the worst imaginable health state) to 100 (the best imaginable health state).

Statistical analysis

At first, we have compared the patient and injury characteristics of the eligible and the participating population. For continuous variables the Student's T test, Kruskal-Wallis test or Mann-Whitney U test was used, and for categorical variables the Chi-square test. A post-hoc analysis was performed when indicated. [32] The Kolmogorov-Smirnov test was used to evaluate the distribution of a variable. A P value lower than 0.05 was considered statistically significant.

To express the value of differences between health states a tariff is used; a tariff is culture-dependent. We have used the Dutch tariff for the calculation of the EQ-5Di, a difference of ≥ 0.032 points was considered a clinically relevant difference. [33] The correlation between EQ-VAS and EQ-5Di was established using Pearson's correlation. In addition, the EQ-5Di scores were compared with the Dutch reference population. We have used the EQ-5Di

United Kingdom (UK) tariff for this, because the scores of the Dutch reference population are derived with the UK tariff. At that time the Dutch tariff was not available in literature. [12, 34] The two-sample T-test was used to calculate statistical significance in this comparison. In line with the EQ-6D study of the Dutch reference population, the outcomes per dimension were dichotomised into problems versus no problems. [12]

All data were analysed using IBM SPSS Statistics for Windows Version 20.0. [35]

Results

We have identified 125 patients with 151 calcaneal fractures of which 93 patients with 114 calcaneal fractures participated in this study (follow-up rate 74%). Nine patients died of which seven had a relevant psychiatric history. Three patients had a severe psychiatric state and were institutionalised. We were not able to reach these patients for the study and have excluded these three patients. Mean follow-up time was 86 months with a standard deviation (SD) of 40 and a range from 30 to 156 months.

The baseline characteristics are outlined in Table 1. The majority of the patients are male, have multiple associated injuries, and were treated operatively. The most common cause of the injury was a fall from height.

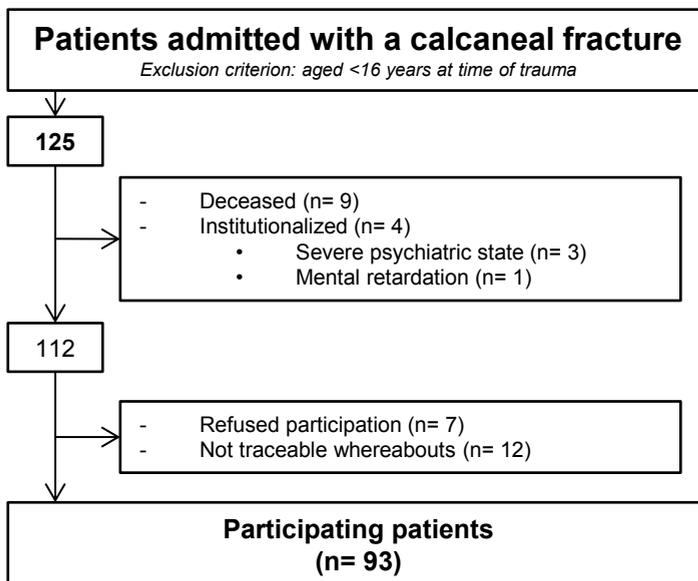


Figure 1: Flow-chart.

Table 1: Baseline characteristics

	Eligible	Participating
Number of patients	125	93
Age at trauma in years*	39 (15)	39 (14)
Male[†] §	86 (69)	69 (74)
Relevant psychiatric history before trauma[†] §	28 (22)	13 (14)
Injury Severity Score[†]	4 (4-11)	4 (4-10)
Injury Severity Score \geq 16[†]	21 (17)	13 (14)
Associated injuries[†]		
No associated injuries	42 (34)	33 (36)
Only lower limb associated injuries	20 (16)	14 (15)
Only one other associated injury	10 (8)	8 (9)
Multiple injuries	48 (38)	38 (41)
Mechanism of trauma[†]		
Fall from height \geq 1.5 meter	60 (48)	43 (46)
Simple fall <1.5 meter	23 (18)	17 (18)
Crush	5 (4)	3 (3)
Road traffic accident	24 (19)	20 (22)
Sports / leisure	5 (4)	4 (4)
Blast trauma	3 (2)	3 (3)
Other or unknown	5 (4)	3 (3)
Bilateral calcaneal fracture[†]	26 (21)	21 (23)
Number of calcaneal fractures[†]	151 (100)	114 (100)
Open calcaneal fracture[†]	18 (12)	12 (11)
Type of calcaneal fracture[†]		
Fracture into talar surface	115 (76)	91 (80)
Isolated anterior surface fracture	10 (7)	8 (7)
Isolated extra-articular fracture	14 (9)	7 (6)
Undeterminable	12 (8)	8 (7)
CT-imaging[†] §		
Sanders type I	4 (3)	1 (1)
Sanders type II	43 (28)	36 (32)
Sanders type III	26 (17)	23 (20)
Sanders type IV	11 (7)	9 (8)
Isolated extra-articular fracture	9 (6)	5 (4)
Isolated anterior surface fracture	10 (7)	8 (7)
Not available	48 (32)	32 (28)
Primary operative treatment[†] §	97 (64)	81 (71)

* = mean (standard deviation); † = number (percent); ‡ = median (interquartile range); § = $p < 0.05$; || = deviating group, established by post-hoc analysis. [31]

The median EQ-5Di in the study population is 0.78 with an interquartile range (IQR) of 0.71 to 0.84. The EQ-VAS median is 75 (IQR 64-85). The correlation between the EQ-5Di and the EQ-VAS is high ($r = 0.717$, $p < 0.001$).

The mean EQ-5Di UK tariff score of our study population is 0.67 with a SD of 0.27; the mean score of the Dutch reference population is 0.87 (SD 0.19). Our study population has a statistically significant lower HRQoL outcome in comparison to the Dutch reference population ($p < 0.001$).

As demonstrated in Table 2, the comorbidities have a significant influence on the HRQoL. Patients with ASA II have a significantly lower HRQoL compared to patients with ASA I. Also patients with a relevant psychiatric history have a significantly lower HRQoL. The educational status or age of patients did not influence the HRQoL, nor did trauma and fracture specific factors (e.g. concomitant injuries, ISS, type of fracture). Eighty-five percent of the patients were capable to work after the injury.

Table 2: Outcome results

Age at follow-up in years*	45 (14)			
	n= (%)	EQ-5Di†	EQ-VAS†	P value
Total patients	93 (100)	0.78 (0.72-0.84)	75 (64-85)	
Gender				
Female	24 (26)	0.78 (0.65-0.78)	70 (55-70)	EQ-5Di 0.012
Male	69 (74)	0.81 (0.78-0.84)	79 (70-85)	EQ-VAS 0.002
Age				
16 to 25	6 (22)	0.81 (0.77-0.82)	77 (74-83)	
26 to 45	43 (44)	0.78 (0.65-0.84)	70 (50-80)	EQ-5Di 0.091
46 to 65	34 (34)	0.78 (0.78-0.84)	75 (68-81)	EQ-VAS 0.407
66 or older	10 (0)	0.84 (0.78-1.00)	81 (68-90)	
Comorbidities by ASA classification				
ASA I	60 (65)	0.81 (0.78-0.84)	76 (70-80)	Overall:
ASA II	32 (34)	0.78 (0.65-0.81)	70 (51-80)	EQ-5Di 0.109
				EQ-VAS 0.026
ASA III	1 (1)	0.78	70	ASA I vs. ASA II:
				EQ-5Di 0.040
				EQ-VAS 0.008

Table 2: Continued.

Relevant psychiatric history				
Yes	15 (16)	0.65 (0.22-0.81)	69 (50-75)	EQ-5Di 0.024
No	78 (84)	0.79 (0.78-0.84)	75 (69-85)	EQ-VAS 0.018
Educational status				
High	25 (33)	0.76 (0.78-0.85)	80 (73-90)	EQ-5Di 0.908 EQ-VAS 0.107
Middle	37 (40)	0.81 (0.69-0.84)	70 (64-80)	
Low	31 (27)	0.78 (0.65-0.84)	70 (60-85)	
Capability for work				
Capable to work	79 (85)	0.81 (0.78-0.84)	75 (70-85)	EQ-5Di 0.000
Incapable to work	14 (15)	0.48 (0.21-0.67)	50 (45-61)	EQ-VAS 0.000
Associated injuries				
No associated injuries	33 (36)	0.81 (0.78-0.84)	79 (61-86)	
Only lower limb associated injuries	14 (15)	0.79 (0.57-0.88)	75 (61-87)	EQ-5Di 0.787 EQ-VAS 0.847
Only one other associated injury	8 (9)	0.79 (0.71-0.90)	73 (69-84)	
Multiple associated injuries	38 (41)	0.78 (0.65-0.84)	73 (60-80)	
Injury Severity Score				
≥ 16	13 (14)	0.81 (0.65-0.92)	75 (70-88)	EQ-5Di 0.579 EQ-VAS 0.548
< 16	80 (86)	0.78 (0.73-0.84)	75 (61-84)	
Unilateral vs. bilateral fractures				
Unilateral	72 (77)	0.78 (0.78-0.84)	75 (63-86)	EQ-5Di 0.248 EQ-VAS 0.116
Bilateral	21 (23)	0.78 (0.65-0.83)	70 (63-78)	
Open vs. closed fractures				
Open	10 (11)	0.78 (0.70-0.86)	75 (65-80)	EQ-5Di 0.749 EQ-VAS 0.813
Closed	83 (89)	0.72 (0.69-0.84)	75 (62-85)	
Primary treatment				
Operative	68 (73)	0.78 (0.73-0.84)	75 (61-84)	EQ-5Di 0.755 EQ-VAS 0.931
Non-operative	25 (27)	0.81 (0.67-0.87)	75 (67-85)	

* = mean (standard deviation); † = median (interquartile range)

As demonstrated in Table 3, all dimensions of the EQ-6D are affected. In particular the dimensions 'mobility', 'pain / discomfort' and 'usual activities'; though the majority of the problems are moderate.

Table 3: Outcome per dimension

	Mobility*	Self-care*	Usual activity*	Pain / discomfort*	Anxiety / depression*	Cognition*
No problems	28 (30)	84 (90)	40 (43)	20 (22)	72 (77)	78 (84)
Some problems	65 (70)	9 (10)	49 (52)	65 (70)	16 (17)	14 (15)
Severe problems	-	-	4 (4)	8 (9)	5 (5)	1 (1)

* = number (percent)

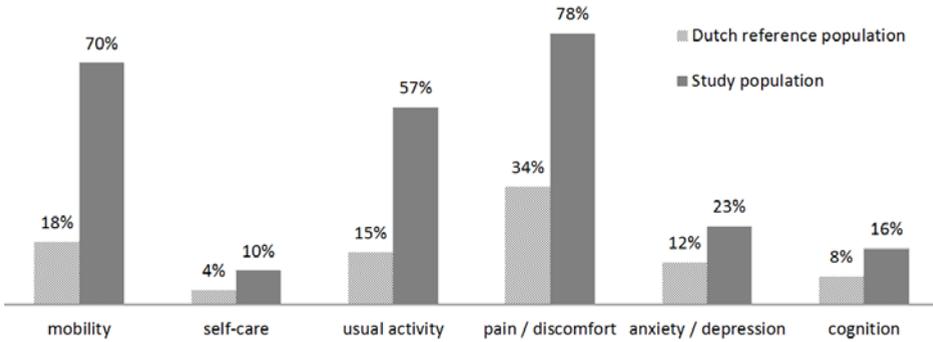


Figure 2: Reporting of problems per dimension of the EQ-6D.

Figure 2 illustrates that all dimensions of the study population are negatively affected in comparison to the Dutch reference population after the injury.

Discussion

The aim of this study was to provide an overview of the HRQoL in adult patients with a traumatic calcaneal fracture. In addition to the current literature, this study quantifies the impact on HRQoL in specific patient groups. This is important because HRQoL is influenced by multiple patient characteristics. Therefore, this should be accounted for in order to provide reliable conclusions of the impact of a calcaneal fracture in the individual patient.

We have included all patients independently of fracture type, treatment or comorbidities, and have reported all patients and fracture characteristics that are likely to influence the HRQoL outcome (e.g. comorbidities or type of fracture). Furthermore, we have strived for the highest possible follow-up rate. Therefore, the results give a reliable reflection of the outcome of patients with a calcaneal fracture in a level I trauma population.

This study demonstrates that adult patients who sustained a traumatic calcaneal fracture have a life-altering trauma resulting in a chronic morbidity. In particular the HRQoL dimensions 'mobility', 'pain / discomfort' and 'usual activities' are affected. In comparison to the Dutch reference population, these patients have a significantly lower HRQoL.

Recently, three studies on displaced intra-articular calcaneal fractures have reported the EQ-5Di. [10, 18, 36] However, we were not able to compare the outcomes with our study, because none of the studies specified the tariff that was used to calculate the EQ-5Di. Specification of the tariff is important because it determines the impact of a certain problem per dimension on the EQ-5Di. The tariffs are culture-specific, therefore the EQ-5Di score might have a different outcome when the Dutch tariff or UK tariff is applied in a study. [12, 13, 26]

The study of Griffin et al. (2014) determined the mean EQ-5Di before trauma, 0.90, and after 24 months, 0.69. [18] In line with the study of Griffin et al. (2014), nor did we demonstrate a significant HRQoL outcome between operative and non-operative treatment. [18]

De Boer et al. (2014) showed a median EQ-5Di score of 0.78 at a mean follow-up of 76 months. [36] In addition, De Boer et al. (2014) presented the EQ-VAS score, a median of 80 (IQR 70-89). [36] Compared to our study population the EQ-VAS was lower. This could be explained by the fact that we have included patients with a relevant psychiatric history. This patient group showed to have a substantially lower HRQoL in our study. Furthermore,

the presence of a relatively high number of patients with a Sanders type III or IV fracture in our study might also be an explanation of the lower EQ-VAS score in our study. [14]

The study of Backes et al. (2015) addressed only patients who were treated operatively with an open reduction and internal fixation method. [10] These patients showed to have a mean EQ-5Di of 0.83 (SD 0.11) at a median follow-up of 33 months. In addition, they have presented the percentage of problems per EQ-5D dimension, these results were similar to our study.

Our study differs from Griffin et al. (2014), De Boer et al. (2014) and Backes et al. (2015), because we have included all types of patients and fractures, independently of associated injuries. [10, 18, 36]

In concordance with the Canadian study of Van Tetering et al. (2004), the Swedish study of Westphal et al. (2004) and the Swiss study of Brunner et al. (2012) we have also demonstrated a lower HRQoL in our study population in comparison to the reference population. [5, 6, 37] This may implicate that adult patients who sustained a calcaneal fracture had a life-altering event that resulted in a chronic disability that decreases the HRQoL, regardless of country standards and HRQoL outcome measurement.

In current literature a lot of studies described how to improve the outcome after a calcaneal fracture. Most of these studies have focused mainly on different operative interventions or comparisons of operative and non-operative treatment. However, none of the published randomized controlled trials, comparing non-operative and operative treatment demonstrated superiority of treatment regarding the HRQoL outcome, yet all these studies reported decreased HRQoL outcome. [4, 15, 18] Other ways to improve the outcome of these patients should be further explored and quantified. Our study is the first study that reports and addresses all patient characteristics that may affect the HRQoL, such as fracture, trauma or patient characteristics. Moreover, we have reported the outcome per dimension, which allows orthopaedic health care providers to determine goals for improvement.

The results of our study did not demonstrate a significant difference between patients with an isolated calcaneal fracture, multiple injured patients, type of primary treatment or patients with bilateral fractures. This might indicate that the calcaneal fracture itself has a pivotal influence on the quality of life and causes a high rate of disability.

We acknowledge that our retrospective study has its limitations. Alike most retrospective studies, data collection is limited by information that was not or incorrectly recorded. In our study, missing data was below the ten percent. Moreover, not all type of fractures could be classified according to the Sanders' classification because CT-images were not available for all the included patients. The follow-up duration has a wide range which could influence the results; the longer the follow-up, the more likely it is that other comorbidities are introduced. Furthermore, our study showed a slight selection bias because the follow-up group had fewer patients with a relevant psychiatric history. This bias may be attributed due to the fact that a large proportion of these patients died or were institutionalised (Figure 1). Also, the primary treatment may bias the outcome scores. The preferred treatment for displaced intra-articular calcaneal fractures is in our centre operatively; in case a calcaneal fracture was treated non-operatively than there was no indication for operative treatment, or the patient refused operative treatment or it was not possible.

In summary, this study demonstrates that patients who sustained a calcaneal fracture have a significantly lower HRQoL compared to the reference population.¹² In particular the EQ-6D dimensions 'mobility', 'pain / discomfort', and 'usual activities' are affected. Moreover, patients that have a comorbidity, a relevant psychiatric history or female patients have significantly lower HRQoL scores. Furthermore, this study shows that socio-economic status, associated injuries, or severity of injury does not influence the HRQoL in this study population. This should be further studied in this specific patient group. In future research, we would recommend that future studies include all patient and injury characteristics and separate the patients based on the specific characteristics in the analysis.

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CHAPTER 4

A TRAUMA SYSTEM WIDE EVALUATION OF THE DEMOGRAPHIC, INJURY AND FRACTURE CHARACTERISTICS OF PATIENTS WITH CALCANEAL FRACTURES: A COMPARISON OF TRAUMA LEVEL I AND II CENTERS

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Abstract

Introduction

Calcaneal fractures are known to influence patients' daily lives negatively. Different levels of trauma centers face a diversity of patients who sustained a calcaneal fracture. Little is known about the demographic, trauma and fracture characteristics for these patients. Moreover, the differences in these characteristics between different levels of trauma care. Knowledge of this is needed, to improve the outcome in these patients. In this study we evaluate in detail the characteristics of patients with a calcaneal fractures in a regional inclusive trauma system.

Material and Methods

This is a retrospective regional cohort study of prospectively collected data. All patients aged 16 years or older with a calcaneal fracture admitted in one of the participating trauma level I or II hospitals were included. Patients', trauma and fracture characteristics were collected.

Results

A total of 285 patients with 307 calcaneal fractures were eligible for analysis. A mechanism of trauma was in most patients a fall from height, followed by a simple fall. The greater majority of the accidents occurred in domestic circumstances, 70% of the patients had an isolated calcaneal fracture. The trauma level I population (n= 72) was significantly younger, sustained a more severe injury with more concomitant injuries, and 26% had a psychiatric history.

Conclusion

This study demonstrates, that there are substantial differences between the level I and II trauma centers in the demographic patterns and injury characteristics in patients with a calcaneal fracture. These differences should be accounted for in the interpretation of results according to the level of trauma care that a particular hospital offers. Additionally, in the trauma level II centers more low-complex calcaneal fractures and distinctively other subgroups (e.g. elderly) are admitted that might benefit from customized management to adapt to their specific needs.

Introduction

Calcaneal fractures are a relatively uncommon injury that are known to influence the daily lives of patients negatively. [1-4] Most studies tend to focus on comparing treatments in patients with an intra-articular fracture including all different levels of trauma centers, mainly from trauma level I centers. The inclusion of patients from different trauma center levels might skew the outcome results. [1] To gain knowledge in the likely heterogeneity of demographic and injury characteristics in patients with calcaneal fractures, evaluation of patients in a large and consecutive cohort is needed.

Furthermore, in current trauma care, different levels of trauma centers face a diversity of patients who sustained a calcaneal fracture. Many countries developed a trauma system to improve and coordinate the care for the injured. [5] A regionalized care approach was established with a combination of levels of designated trauma centers; the efficacy of this approach has been demonstrated in terms of better triage and improved patient outcomes [6-9]. Knowledge on the demographic and injury patterns, and the differences in these patterns between level I and II centers may help improve the expectations of the outcome in patients with a calcaneal fracture. In addition, insight in these patterns may aid interpreting the results from different levels of trauma care and might help policy makers in optimizing the use of the scarce resources (e.g. to establish clinical pathways).

The aim of this study is two-fold. First, to evaluate in detail the demographic, injury and fracture patterns within a trauma region. Second, to study the differences in patient, trauma and fracture characteristics between trauma centers of different level of trauma care in a regional inclusive trauma system. To our knowledge, this is the first study on calcaneal fractures that compares trauma centers with a different care level.

Material and Methods

Hospital setting

This study was conducted in the central trauma region of the Netherlands. Four trauma centers, functioning in this region, participated in this study; one level I trauma center (University Medical Center Utrecht) and three level II trauma centers (St. Antonius Hospital, Diaconessen Hospital and Meander Medical Center).

Study design

This is a retrospective study of prospectively collected data, performed under the approval of the medical ethics committee of the University Medical Center Utrecht in the Netherlands.

Data collection

We used three databases to identify all patients diagnosed with a calcaneal fracture. The Dutch National Medical registration, this registry is a national database in which all hospital admissions are collected with concomitant diseases or injuries coded according to the International Classification of Diseases (ICD). [10, 11] The hospital databases, in which calcaneal fractures are coded based upon diagnosis. The regional trauma registry, which records all admitted trauma patients in the trauma region and codes all injuries according to the Abbreviated Injury Scale score and ICD. [10, 12] All three databases register patients prospectively and in a standardized manner. We have excluded all duplicates and patients that were initially diagnosed with a calcaneal fracture in another hospital.

We have included all patients aged 16 years or older diagnosed with a calcaneal fracture in 2010 through 2012. All data were extracted from the patients' medical record or trauma registry. We collected all patient demographic data such as age, gender, comorbidities categorized according to the ASA Physical Status Classification System, psychiatric history, trauma mechanism, circumstances of trauma, Injury Severity Score (ISS), concomitant injuries, type of calcaneal fracture, fracture classification by Sanders and primary treatment of fracture. [13-15] Preferable, CT-images were used to assess the type of fracture. When no CT-image was available, the conventional radiographic images were used.

Statistical analysis

A descriptive analysis was performed to compare patient, trauma and fracture characteristics between the trauma level I and level II populations. Categorical variables were compared using Chi-square test, and continuous variables were compared using Student's T or Mann-Whitney U test. A P-value < 0.05 was considered statistically significant. All data were analyzed with IBM SPSS Statistics for Windows Version 20.0. [16]

Results

A total of 321 patients who sustained a calcaneal fracture were identified in the databases. Twenty patients were incorrectly registered with a calcaneal fracture; these patients were excluded after revision of the medical records and radiographic images. In total 285 patients with 307 calcaneal fractures were available for analysis. The majority of the patients (n= 219) were diagnosed at the level II trauma centers. Table 1 and 2 show the baseline patient', trauma and fracture characteristics.

Table 1: Baseline of patients' and trauma characteristics

	Level I	Level II	Total
Number of patients	66	219	285
Age at trauma in years^{†‡}	37 (25-50)	49 (35-64)	47 (33-60)
Age at trauma 70 years or older[‡]	0 (0)	24 (11)	24 (8)
Female[†]	27 (41)	89 (41)	116 (41)
Comorbidities before trauma[†]			
ASA I	52 (79)	157 (72)	209 (73)
ASA II	12 (18)	51 (23)	63 (22)
ASA III	2 (3)	11 (5)	13 (5)
Diabetes mellitus before trauma[†]	2 (3)	15 (7)	17 (6)
Psychiatric history before trauma^{†‡}	17 (26)	18 (8)	35 (12)
Circumstances of trauma^{†‡}			
Domestic [†]	22 (33)	129 (59)	151 (53)
Psychiatric episode [†]	10 (15)	1 (1)	11 (4)
Recreational	5 (8)	24 (11)	29 (10)
Road traffic accident [†]	19 (29)	22 (10)	41 (14)
Work	9 (14)	21 (10)	30 (11)
Unknown or other [†]	1 (2)	22 (10)	23 (8)
Mechanism of trauma^{†‡}			
Fall from height ≥ 1.5 meter	37 (56)	95 (43)	132 (46)
Simple fall < 1.5 meter [†]	2 (3)	76 (35)	78 (27)
Crush	3 (5)	4 (2)	7 (3)
Motor vehicle accident [†]	19 (29)	9 (4)	28 (10)
Sports / leisure	0 (0)	7 (3)	7 (3)
Other or unknown	0 (0)	5 (3)	5 (2)
Inversion trauma	5 (8)	21 (10)	26 (9)
Injury Severity Score^{†‡}	5 (4-14)	4 (4-4)	4 (4-4)
Injury Severity Score ≥ 16^{†‡}	16 (24)	1 (0)	17 (6)

Table 1: Continued.

	Level I	Level II	Total
Associated injuries[‡]			
Isolated calcaneal fracture [‡]	18 (27)	181 (83)	199 (70)
Only lower limb associated injuries [‡]	13 (20)	19 (9)	32 (11)
Only one other associated injury	5 (8)	9 (4)	14 (5)
Multiple injuries [‡]	30 (50)	10 (5)	40 (14)
Concomitant injuries per region[†]			
Spinal fracture [‡]	19 (29)	5 (2)	24 (8)
Pelvic fracture (excluding sacrum) [‡]	12 (18)	1 (0)	13 (5)
Upper limb injury [‡]	16 (24)	8 (4)	24 (8)
Head injury [‡]	15 (23)	3 (1)	18 (6)
Thoracic injury [‡]	13 (20)	5 (2)	18 (6)
Abdominal injury [‡]	6 (9)	0 (0)	6 (2)
Lower limb injury [‡]	38 (58)	28 (13)	66 (23)
Bilateral calcaneal fracture[†]	7 (11)	15 (7)	23 (8)

* = number (percent within population); † = median (interquartile range); ‡ = $p < 0.05$ in level I versus level II

Patient characteristics

Patients who have been diagnosed with a calcaneal fracture in the level I trauma center are significantly younger than patients in the level II trauma centers ($p = 0.014$). Moreover, none of the patients in the level I population was 70 years or older in contrast to the 11% in the level II centers ($p = 0.005$). Independently of level of trauma care, a calcaneal fracture occurred approximately 1.5 times more often in males.

There was no difference in the severity of the comorbidities of the patients between the different levels of trauma care. The majority ($\pm 75\%$) had an ASA I classification. However, a significant number of patients (26%) admitted at the trauma level I center had a psychiatric history ($p < 0.001$).

Trauma mechanism and injury characteristics

The calcaneal fractures occurred most often in domestic circumstances independently of trauma level. However, in the level I trauma center the calcaneal fracture occurred significantly more often during a psychiatric episode (e.g. during psychosis, depression or schizophrenic episode; $p < 0.001$) or road traffic accident ($p < 0.001$) in comparison with the level II trauma centers.

Table 2: Baseline of fracture characteristics

	Level I	Level II	Total
Number of patients	66	219	285
Number of calcaneal fractures	73	234	307
Open calcaneal fracture[‡]	13 (18)	5 (2)	18 (6)
Type of calcaneal fracture^{*‡}			
Fracture into talar surface	41 (56)	109 (47)	15 (49)
Isolated anterior surface fracture	15 (21)	32 (14)	110 (15)
Isolated extra-articular fracture [‡]	17 (23)	93 (40)	47 (36)
CT-imaging[‡]			
Sanders type I	2 (3)	7 (3)	9 (3)
Sanders type II	14 (19)	52 (22)	66 (22)
Sanders type III	10 (14)	34 (15)	44 (14)
Sanders type IV [‡]	12 (16)	7 (3)	19 (6)
Isolated extra-articular fracture [‡]	10 (14)	24 (10)	34 (11)
Isolated anterior surface fracture [‡]	10 (14)	15 (6)	25 (8)
Not available [‡]	15 (21)	95 (41)	110 (36)
Primary treatment^{*‡}			
Operative [‡]	28 (38)	56 (24)	84 (27)
Non-operative [‡]	42 (58)	172 (74)	214 (70)
Unknown	3 (4)	6 (3)	9 (3)

* = number (percent within population); † = median (interquartile range); ‡ = $p < 0.05$ in level I versus level II

Furthermore, there is a significant difference between the trauma mechanisms of the injured patients in the centers ($p < 0.001$). In both populations a fall from height was in $\pm 50\%$ of the patients the most common cause of a calcaneal fracture, followed by minor falls in the level II trauma centers and motor vehicle accidents in the level I trauma center. Twenty-five percent of all patients with a calcaneal fracture admitted to a level trauma I center had an ISS above 15 ($p < 0.001$). More concomitant and associated injuries were seen in this population ($p < 0.001$), e.g. more concomitant spinal injuries were present in the level I trauma population, 29% versus 2% ($p < 0.001$).

In 49% of the cases, the calcaneal fracture affected the talar surface of the calcaneus, respectively 56% and 47% in the level I and II centers. Isolated extra-articular calcaneal fractures are more often seen in the level II trauma centers in comparison to the level I center (40% vs. 23%, $p < 0.001$).

Table 3 demonstrates that the treatment of Sanders II and III fractures did not differ between the two trauma level populations. The level I population had more often a severe displaced intra-articular fracture (Sanders type IV, $p < 0.001$) and were more often operatively treated in comparison to the population in the level II centers ($p < 0.001$).

Table 3: Differences in treatment per level of trauma in the eligible population

CT-imaging	Treatment	Trauma level I*	Trauma level II*	Total*
Sanders type I	Operative	0 (0)	0 (0)	0 (0)
Sanders type II	Operative	7 (50)	25 (50)	32 (49)
	Missing	0 (0)	1 (0)	1 (5)
Sanders type III	Operative	9 (90)	21 (62)	30 (68)
	Missing	0 (0)	1 (3)	1 (2)
Sanders type IV†	Operative	10 (83)	4 (57)	14 (74)
	Missing	1 (8)	1 (14)	2 (11)
Isolated anterior surface fracture	Operative	0 (0)	1 (7)	1 (4)
Isolated extra-articular fracture	Operative	0 (0)	1 (4)	1 (3)
No CT-imaging available†	Operative	2 (13)	4 (4)	6 (6)
	Missing	2 (13)	1 (1)	3 (3)

* n = (percent within treatment per CT-imaging type); † = $p < 0.05$

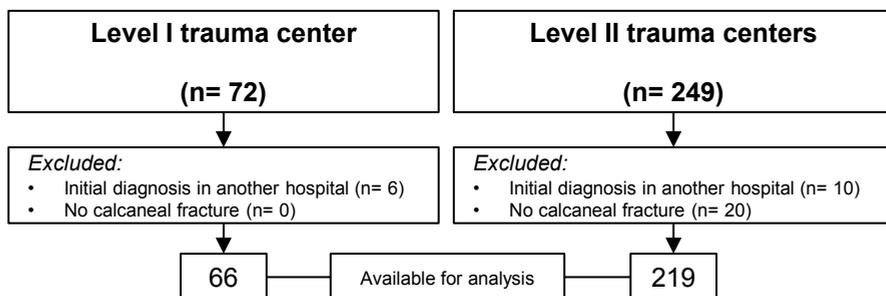


Figure 1: Flow-chart of enrolled patients

Discussion

In this study we have evaluated patient, trauma and fracture characteristics in patients with a calcaneal fracture; moreover, these characteristics were compared between the different levels of trauma care in a regional inclusive trauma system. Knowledge on these matters could help in the interpretation of results from different trauma centers and might help to stimulate improvements in management of these fractures. The main finding in this study is that the level I population differed substantially in patient, and injury characteristics compared to the level II population.

Two previous studies examined demographics and injury characteristics in patients with a calcaneal fracture. [4, 17] The Scottish study of Mitchell et al. (2009) reviewed the characteristics of patients with calcaneal fractures in a single institution. [4] Our study was more or less in line with their study; however, our study demonstrated that the female-male rate is slightly more equally distributed (1.5:1 vs 2.4:1).

The large cohort study from Bohl et al. (2016) selected patients from a nationwide trauma databank in the USA (the American College of Surgeons National Trauma Data Bank [NTDB]) that prospectively collected patients that were admitted to a hospital. [17] Our study results differed substantially from their study. Our study showed less patients with a calcaneal fracture caused by a motor vehicle accident (Bohl's study 49% vs. this study 10%) and had less associated injuries. Furthermore, a greater proportion of our patients had an ISS score less than 16 (Bohl's study 76% vs. this study 94%). This difference could be explained by the inclusion criteria of this study and the inclusion criteria of the NTDB. We have included all patients who were diagnosed with a calcaneal fracture, thus also minor injured patients with an isolated calcaneal fracture who did not require an admission. In comparison to the NTDB, which only includes patient who are admitted to the hospital. The results from Bohl's study resembled more closely to the results from our level I population. Possibly, the difference is due to inclusion of patients that were admitted to the hospital that involved patients with a higher energy trauma; consequently, lead to more severely injured patients.

Spinal fractures are well-known concomitant injuries in patients who sustained a calcaneal fracture. [18-22] Previous studies reported a concomitant spinal fracture in 6% to 22% in these patients. [18, 20-22] Our study also demonstrated a high percentage in the level I trauma population, this might suggest that additional imaging of the spine in a patient with a

calcaneal fracture in a level I trauma center would be meaningful, also taken the mechanism of trauma into account.

The patients in the trauma level II population were significantly older; moreover, a substantial proportion was older than 70 years at the time of trauma. Recognition of this subgroup is valuable, because their optimal management might be different due to treatment and rehabilitations limitations caused by their comorbidities. Older patients are more likely to be treated conservatively if the long- term outcomes are expected to be similar; moreover, elderly are generally frail; thus, are more likely to develop complications, such as delirium, or remain bedridden that may cause pneumonia or other infections. These patients may benefit from geriatric physician consultation. In addition, a considerable number of the injuries occurred in the residential area or were the result of a simple fall. Prevention of these simple falls in the residential area might be beneficial in this subgroup.

This study further shows a significant difference between the numbers of patients treated operatively and conservatively in the level I versus II trauma centers. This could be due to the larger proportion of patients with extra-articular calcaneal fractures in the level II trauma population. The patients are more likely to be treated conservatively. We did not specifically evaluate this aspect because this study has a retrospective design and the reasoning for the chosen treatment is unfortunately in most cases non-traceable. More operatively treated patients in the level I population could be a consequence of the multiple injured origin in these patients in this center and the expected better outcome on the short term after surgery. Because, the rehabilitation and weight bearing exercises can start in an early stage. This has also been demonstrated in other trauma patients groups with extremity injuries. [24] Furthermore, Sanders type IV fractures were significantly more often treated operatively in the trauma level I population. Though, due to the small sample size, and the high rate of missings (>10%) the validity of such a statement could be subject of discussion. Furthermore, it would be interesting to evaluate the long term follow-up in these specific patients and study the differences.

The trauma level II population demonstrated to have substantially more isolated calcaneal fractures (low-complex). As demonstrated in the study of Van Laarhoven et al. (2015), clinical pathways might improve the outcome of these patients and reduce hospital length of stay. [23] Clinical pathways may contain early consultation of a rehabilitation physician and a physiotherapist. In the elderly it can be beneficial to have early geriatric consultation and a specialized combined geriatric medicine and traumatology ward. [23] In contrast,

the level I population showed to have a higher heterogeneity in injuries which might not fit in a clinical pathway. However, a large proportion of the trauma level I population have a psychiatric history that may benefit from early involvement of a psychiatric nurse.

Alike most retrospective studies, data collection is limited by information that was not or incorrectly recorded. Missing data in our study was lower than 10%. CT-imaging was not performed in 36% of the cases. This could be explained by the fact that in these patients the conventional radiographs showed an extra-articular fracture and no other indication for an additional CT-image. In these patients CT-imaging is not required in the diagnostic process and only leads to unnecessary exposure to radiation and higher monetary costs. We have further performed a thorough search in three different databases to minimize the chance of missing patients who meet the inclusion criteria. Due to the regional design of the study, these results represent a reliable reflection from the demographics and trauma characteristics of patients with a calcaneal fracture in a trauma population and allow us to generalize the results to countries with similar demographics and economic welfare.

In conclusion, our study demonstrates, that there are remarkable differences between the level I and II trauma centers in the demographic patterns, injury and fracture characteristics of patients with a calcaneal fracture. These differences should be accounted for in the interpretation of results according to the level of trauma care provided in the particular trauma center. Additionally, in the trauma level II centers more low-complex calcaneal fractures and distinctively other subgroups, such as elderly, are admitted that might benefit from customized management. This customized management may involve, among other things, early consultation of a rehabilitation physician or a geriatric nurse.

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CHAPTER 5

ASSOCIATION OF PRE-TREATMENT RADIOGRAPHIC CHARACTERISTICS OF CALCANEAL FRACTURES ON PATIENT-REPORTED OUTCOMES

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Abstract

Purposes

Calcaneal fractures are known to influence patients' quality of life negatively. The type of calcaneal fracture might have a relation with the patient outcome. To inform patients in an early stage on how their calcaneal fracture may affect their lives knowledge of the fracture characteristics are necessary. This study evaluates the association of type of calcaneal fracture, measurement of conventional radiograph angles and the Sanders classification with patient-reported outcomes.

Material and Methods

This is a retrospective study based on a prospective trauma database including all patients aged 16 years or older with a calcaneal fracture admitted in one of the participating trauma level I or II hospitals. Patients', trauma and fracture characteristics were collected. The conventional radiographs were evaluated in which type of fracture and Böhler's, Gissane's and calcaneal compression angle were determined. Also, the CT-images were classified according to Sanders. In addition, displaced intra-articular calcaneal fractures were separately analyzed. A questionnaire was sent to the included patients that consisted of the EQ-6D, patient-specific characteristics, satisfaction with foot appearance and wearable shoe range, complications, and capability to work.

Results

A total of 396 patients with 442 calcaneal fractures were eligible for follow-up. 215 patients with 246 calcaneal fractures participated. Patients with a calcaneal fracture into the talar surface reported a worse quality of life ($p= 0.010$), were less satisfied with their feet ($p< 0.001$) and had more complications ($p= 0.001-0.006$); extra-articular fractures had significantly opposite result. A negative Böhler's or calcaneal compression angle was related with unfavorable outcomes. Sanders classification was not related with any patient-reported outcome.

Conclusion

Our study implies that patients with an intra-articular calcaneal fracture into the talar surface have a lower health-related quality of life, will be less satisfied with the outcome of their feet and have more complications compared to patients with other type of calcaneal fractures. Furthermore, the Sanders classification was not associated with the patient-reported outcomes.

Introduction

Calcaneal fractures occur with a reported incidence that varies from 11.5 to 13.7 per 100,000 persons per year. [1-3] These fractures are known, among orthopedic healthcare providers, to influence gait and functional outcome negatively [4, 5]; moreover, these patients experience a lower quality of life than the general population. [6-8]

To inform patients in an early stage (e.g. in the emergency department [ED]) on how their fracture could influence their lives and to customize the management of a patient, radiographic images may be evaluated. In order to evaluate patients' experiences with their outcome after a calcaneal fracture patient-reported outcomes should be utilized [9]. Several studies have reported patient-reported outcomes [4, 7, 8]; however, most studies were performed in trauma level 1 patients. As a result, there is insufficient information in the current literature that includes trauma level 2 patients. Trauma level 2 centers have a different trauma population in comparison to trauma level 1 centers. [10]

Moreover, the literature reports contrasting results on the predictive value of the measured angles in the conventional radiographs (e.g. Böhler's angle). On one hand they are associated with functional outcome [11, 12], on the other hand they correlate poorly with the final outcome. [13]

A prior study showed that CT-image classification systems for calcaneal fractures have a predictive value on disease-specific questionnaire outcomes. [14] An additional CT-scan is performed when a patient is suspected for an intra-articular fracture or when better imaging is required to determine the treatment of the fracture. To classify these CT-images, several classification systems have been developed. However, many of these classification systems are difficult to use because they classify calcaneal fractures in many groups. [14]

The purpose of our study is to evaluate the association of type of calcaneal fracture, measurement of conventional radiograph angles (Böhler's, Gissane's and calcaneal compression angles) and the Sanders classification with patient-reported outcomes (i.e. health-related quality of life, calcaneal-related complications, patients' satisfaction and capability to work).

Material and Methods

Hospital setting

Four trauma centers participated in this study; one level I trauma center (University Medical Center Utrecht) and three level II trauma centers (St. Antonius Hospital, Diakonessen Hospital and Meander Medical Center). All four centers belong to the central trauma region in the Netherlands.

Study design

This is a retrospective study based on a prospective trauma database and a prospective patient-reported outcomes evaluation that has been performed according to the criteria for evaluating health-related quality of life studies, and under the approval of the medical ethics committee of the University Medical Center Utrecht in the Netherlands. [15]

Study population

We have included all patients aged 16 years and older at time of trauma and diagnosed with a calcaneal fracture. Two datasets were combined. In dataset #1 the patients were selected from three different databases covering the years 2010 through 2012: the hospital databases, the regional trauma registry, and the Dutch National Medical Registration (DNMR). [16] In these prospective databases the calcaneal injuries were identified based on the descriptive diagnosis or International Classification of Diseases (ICD). [17] We further added a dataset (dataset #2) that contained patients from the DNMR of the trauma level I center from 2000 through 2010; in this particular dataset, the patients diagnosed with a calcaneal fracture in another hospital were also included. Patients were registered more than once for the same injury event were only included once.

Data collection

All data were extracted from the trauma registry and patients' medical record. We collected all patient demographic data such as gender, age, comorbidities categorized according to the ASA Physical Status Classification, psychiatric history, trauma mechanism, circumstances of trauma, Injury Severity Score (ISS), concomitant injuries and the primary treatment of fracture. [18-20]

Radiographic characteristics

All radiographic images were revised (performed by GA). The CT-images and conventional radiographic images were used to determine the type of calcaneal fracture and whether

there was a fracture into the anterior surface.

The CT-images were classified with the Sanders classification. [21] The Sanders classification is used to categorize intra-articular fractures that involve the posterior facet of the calcaneus. As illustrated in Figure 1, the classification is divided into four types: type I is a non-displaced fracture that is defined as less than two millimeter displacement, regardless of the number of fracture lines, type II, III and IV are more than two millimeter displaced fractures, and have respectively one, two, or three and more fracture lines (see Figure 2 for images of the four different types of calcaneal fractures that were classified according to Sanders).

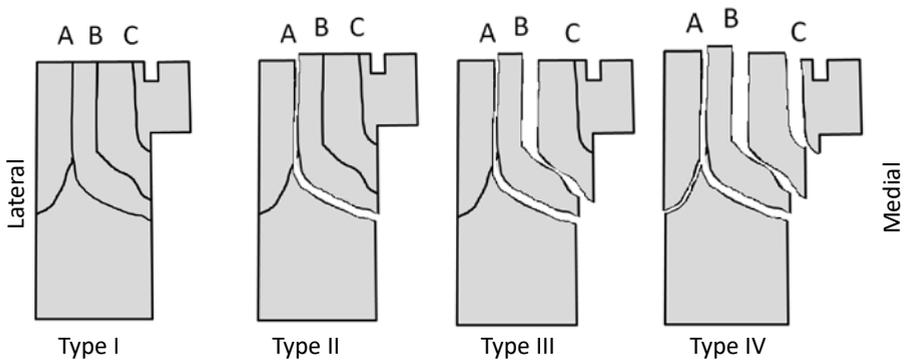


Figure 1: Sanders classification. Line drawing of a semi-coronal image of the calcaneus showing all three fracture lines (A, B and C) [Illustration made by GA]

In the conventional lateral radiographs three angles were measured. Böhler's angle (Figure 3a), also known as the tuber-joint angle, is the angle formed by two intersecting lines: a line between the highest point of the posterior facet to the highest point of the anterior surface, and a line connecting the highest point of the posterior tuberosity of the calcaneus and the posterior facet. Böhler's angle normal values in the uninjured population has been reported as a mean angle of 36 degrees (standard deviation 4 degrees, range 25 to 49 degrees, and the normal range that incorporates 95% of the subjects is 28 to 45 degrees). [22] In line with the study of Loucks et al. (1999), the measurements were divided in four predefined groups. [11]

Figure 2: (Semi)-coronal CT images of calcaneal fractures classified in accordance to the Sanders classification. The white arrow points to the fracture line(s). In parentheses respectively the pre-treatment angle versus finale angle.



Figure 2a: Type I. Non-operatively treated. Böhler's angle (38 vs. 38) degrees , Gissane's angle (122 vs. 126) degrees, and calcaneal compression angle (32 vs. 36) degrees.



Figure 2b: Type II. Operatively treated with open reduction and internal plate fixation. Böhler's angle (17 vs. 41) degrees , Gissane's angle (103 vs. 108) degrees, and calcaneal compression angle (16 vs. 40) degrees.

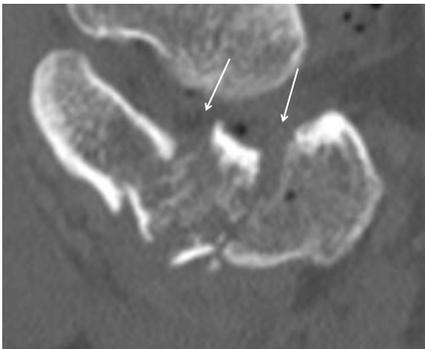


Figure 2c: Type III. Operatively treated with open reduction and screw fixation. Böhler's angle (7 vs. -14) degrees , Gissane's angle (125 vs. 109) degrees, and calcaneal compression angle (18 vs. 23) degrees.



Figure 2d: Type IV. Operatively treated with open reduction and internal plate fixation. Böhler's angle (3 vs. 29) degrees , Gissane's angle (139 vs. 128) degrees, and calcaneal compression angle (30 vs. 42) degrees.

Figure 3: Calcaneal angles in the conventional radiographs.



Figure 3a: Böhler's angle (dot is the measured angle, in this image 27 degrees).

Figure 3b: Gissane's angle (dot is the measured angle, in this image 114 degrees).

Figure 3c: Calcaneal compression angle (dot is the measured angle, in this image 29 degrees).

Gissane's crucial angle (Figure 3b) is formed by the line from the calcaneal sulcus to the tip of the anterior surface of the calcaneus, and the posterior facet. This angle was divided in three predefined groups based upon the normal values for Gissane's angle (mean 123 to 127 degrees, with a standard deviation 6 to 8 degrees, and a range from 108 to 138 degrees). [23, 24]

The calcaneal compression angle (Figure 3c) is created from two intersecting lines: a line between the highest point of the posterior facet and the anterior surface, and a line in the plane of the inferior surface of the calcaneus. The normal values for calcaneal compression angles (mean is 31 degrees, with a standard deviation of 4 degrees, and a range from 24 to 44 degrees) were used to divide the measurements in three predefined groups. [24]

Outcomes

Health-related quality of life is our primary outcome. Currently, there is no specific validated patient-reported outcome measurement available for foot and ankle injuries. One of the most used instrument in trauma care is the EQ-5D. The EQ-5D is a standardized generic measure of health-related quality of life whose validity, reliability and responsiveness has been tested in studies for other extremity morbidities. [25-31] We have used the EQ-6D that is an extended version of the EQ-5D questionnaire and has an additional question addressing the cognitive function. [30, 31]

The EQ-6D consists of six dimensions: 'mobility', 'self-care', 'usual activities', 'pain / discomfort', 'depression / anxiety' and 'cognition'. These dimensions have three levels of response: no problems, moderate problems, and severe problems. The EQ-5D index

score can be calculated based upon the levels of response of the dimensions. [32] With the exception of the dimension cognition, because there is no validated tariff for the EQ-6D. [32]

In general, health-related quality of life is influenced by various patient-specific characteristics, such as current comorbidities and socio-economic status [33-35]. Therefore, we have added questions on these aspects. Socio-economic status was determined by the highest level of education a patient has received.

Furthermore, patients were asked how satisfied they were with the appearance of the affected foot and range of shoes they could currently wear. The study of Dawson et al. (2012) showed that these factors are important for a patients' satisfaction after foot and ankle surgery. [35]

In addition, the patients were for their capability to work. Moreover, a question on whether they have experienced a complication was included. Based on their answer and on the medical records, we have determined whether it was a calcaneal-related complication. The calcaneal-related complications were divided into two groups: the early calcaneal-related complications that occurred within six weeks after trauma (i.e. wound infection, malalignment or compartment syndrome) and late calcaneal-related complications that occurred six weeks after their trauma (i.e. wound infection, impingement of peroneal tendons, claw or hammer toes or malunion).

Follow-up

The EQ-6D questionnaire with the additional questions was sent to all eligible patients, along with an informed consent form. After four weeks a reminder was sent to all non-responders. The patients in dataset #2 were also contacted by phone after another four weeks to collect missing data from participating patients and to ask non-responders one more time to participate in the study (performed by GA).

Statistical analysis

A descriptive analysis was performed to compare patient, trauma and fracture characteristics. We have analyzed the total included population; in addition, a sub analysis was performed of the patients with a displaced intra-articular calcaneal fracture (DIACF) determined by CT-imaging (Sanders II to IV) because it might be helpful to stratify this subgroup in order to inform patients more accurately.

Multiple patients had bilateral fractures; these patients were categorized into the group with the worst type of fracture. An open fracture was considered worse than a closed fracture. The highest Sanders type in intra-articular fractures were considered worse than other type of fractures, when Sanders classification was not applicable or there was no intra-articular fracture into the posterior facet than anterior surface involvement was considered worse than extra-articular. In the case of bilateral calcaneal fractures with the same Sanders type, the patient was categorized in the group with the lowest Böhler's angle.

To compare categorical variables the Chi-square test was used, and in the case of continuous variables the Student's T or Mann-Whitney U test were used. Furthermore, a linear regression analysis was performed to examine the relationship between the conventional radiograph angles and the EQ-5D index score.

The Dutch tariff for the calculation of the EQ-5D index score was used because there is no international validated tariff for the EQ-6D. [32] A difference of ≥ 0.032 points between two EQ-5D index scores is a clinically relevant difference. [32]

A P-value < 0.05 was considered statistically significant and all data were analyzed with SPSS version 20.0 (IBM Corp., Armonk, NY), for Windows.

Results

Study population

A total of 446 patients who sustained a calcaneal fracture were identified in the databases. As demonstrated in Figure 4, a total of 215 patients with 246 calcaneal fractures participated in this study. Their baseline patients', trauma and fracture characteristics are outlined in Table 1. The mean age of the participants at time of trauma was 45 years and 64% was male. Approximately 50% had an isolated calcaneal fracture. The most common cause of the injury was fall from height from 1.5 meters or higher, followed by a simple fall from less than 1.5 meter. The majority (65%) of the fractures were into the talar surface of the calcaneus. On CT-image, 65% of the fractures were a Sanders type II or III fracture. The primary treatment was non-operative in 119 cases; the other 125 fractures were treated operatively, of which 103 with open reduction and internal fixation, 15 with percutaneous reduction and fixation. One patient had subtalar arthrodesis, and in six patients the operation technique was not described. In two cases the treatment was not mentioned.

Table 1: Baseline characteristics

	Total		DIACF-only	
	Eligible	Participating	Eligible	Participating
Number of patients	396	215	180	117
Age at trauma in years[†]	45 (17)	45 (16)	43 (15)	45 (15)
Male[†]	245 (62)	138 (64)	125 (69)	80 (68)
Psychiatric history before trauma^{† †}	61 (15)	29 (14)	31 (17)	15 (13)
Injury Severity Score[*]	4 (4-5)	4 (4-8)	4 (4-8)	4 (4-8)
Injury Severity Score \geq 16[†]	34 (4)	19 (9)	18 (10)	11 (9)
Associated injuries[†]				
No associated injuries	237 (60)	116 (54)	100 (56)	62 (53)
Only lower limb associated injuries	48 (12)	29 (14)	20 (11)	14 (12)
Only one other associated injury	24 (6)	17 (8)	16 (9)	12 (10)
Multiple injuries	87 (22)	53 (25)	44 (24)	29 (25)
Mechanism of trauma[†]				
Fall from height \geq 1.5 meter	182 (46)	98 (46)	109 (61)	64 (55)
Simple fall <1.5 meter	100 (25)	49 (23)	42 (23)	29 (25)
Crush	12 (3)	9 (4)	1 (1)	1 (1)
Motor vehicle accident	49 (12)	31 (14)	21 (12)	17 (15)
Sports / leisure	12 (3)	6 (3)	5 (3)	4 (3)
Blast trauma	3 (1)	3 (1)	1 (1)	1 (1)

Table 1: Continued.

	Total		DIACF-only	
	Eligible	Participating	Eligible	Participating
Inversion trauma	26 (7)	13 (6)	0 (0)	0 (0)
Other or unknown	12 (3)	6 (3)	1 (1)	1 (1)
Bilateral calcaneal fracture[†]	46 (11)	31 (14)	30 (17)	22 (19)
Number of calcaneal fractures[†]	442	246	210	139
Open calcaneal fracture[†]	35 (8)	24 (10)	18 (9)	14 (10)
Anterior surface fracture involvement^{†§}				
Yes [§]	189 (43)	118 (48)	131 (62)	84 (60)
No [§]	212 (48)	100 (41)	79 (38)	55 (40)
Undeterminable	41 (9)	28 (11)	0 (0)	0 (0)
Type of calcaneal fracture^{†§}				
Fracture into talar surface [§]	254 (58)	164 (65)	200 (95)	134 (96)
Isolated anterior surface fracture	55 (12)	33 (13)	2 (1)	1 (1)
Isolated extra-articular fracture [§]	121 (27)	41 (17)	8 (4)	4 (3)
Undeterminable	12 (3)	8 (3)	0 (0)	0 (0)
CT-imaging^{† §}				
Sanders type I	13 (3)	5 (2)	0 (0)	0 (0)
Sanders type II	103 (23)	63 (26)	103 (49)	63 (45)
Sanders type III [§]	68 (15)	51 (21)	68 (32)	51 (37)
Sanders type IV	28 (6)	19 (8)	28 (13)	19 (14)
Isolated extra-articular fracture [§]	41 (9)	16 (7)	6 (3)	3 (2)
Isolated anterior surface fracture	33 (8)	22 (9)	2 (1)	1 (1)
Not available [§]	156 (35)	70 (29)	3 (1)	2 (1)
Primary operative treatment^{† §¶}	173 (39)	125 (51)	132 (63)	96 (73)

* = mean (standard deviation); † = number (percent); ‡ = median (interquartile range); § = $p < 0.05$ in eligible versus participating total population; ¶ = $p < 0.05$ in eligible versus participating DIACF-only population;

DIACF = displaced intra-articular calcaneal fracture

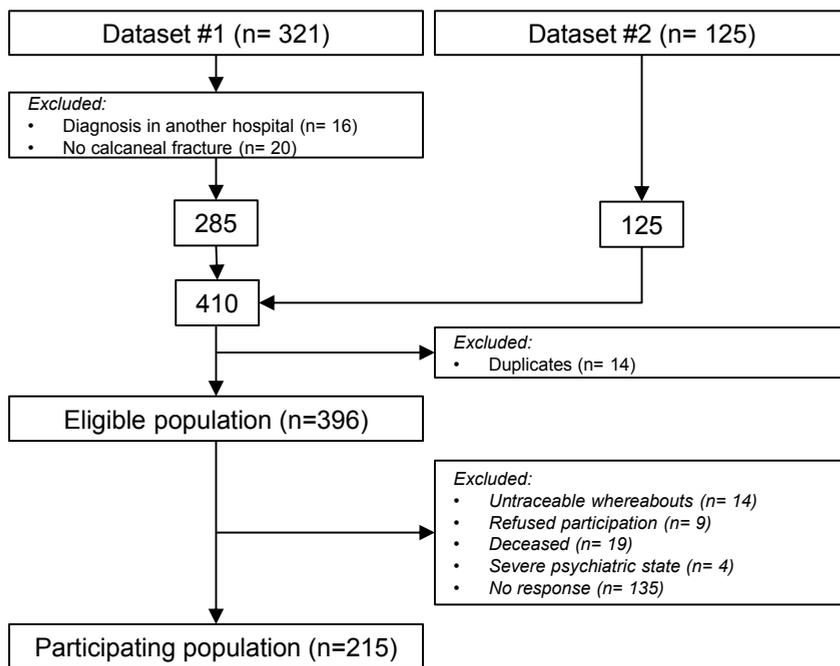


Figure 4: Flow-chart of enrolled patients.

The follow-up characteristics are outlined in Table 2. The mean follow-up time of the participants was 62 months. The mean age at follow-up was 50 years. Approximately 40% were ASA II or III and 15% had a psychiatric history.

Table 2: Follow-up characteristics and outcome results

	Total	DIACF only
Number of patients	215	117
Follow-up time in months[†]	62 (35)	60 (32)
Age in years[†]	50 (15)	50 (15)
Comorbidities[*]		
ASA I	132 (62)	70 (59)
ASA II	72 (34)	43 (23)
ASA III	10 (5)	6 (3)
Psychiatric history[*]	33 (15)	18 (15)
Educational status[*]		
High	58 (27)	27 (23)
Middle	71 (33)	42 (36)
Low	84 (39)	49 (42)

Table 2: Continued

	Total	DIACF only
Satisfaction with wearable range of shoes[†]		
Satisfied	78 (36)	35 (30)
Moderately satisfied	97 (45)	55 (47)
Unsatisfied	39 (18)	28 (24)
Capable to work[†]	182 (85)	99 (84)
EQ-5D index value[‡]	0.81 (0.78-0.90)	0.78 (0.69-0.84)
Number of fractures	246	128
Pre-treatment angles[‡]		
Böhler's	19 (6-29)	16 (3-25)
Gissane's	110 (100-117)	109 (100-116)
Calcaneal compression	27 (20-32)	25 (18-30)
Final angles[‡]		
Böhler's	27 (14-33)	24 (13-31)
Gissane's	108 (100-117)	108 (101-117)
Calcaneal compression	27 (23-33)	27 (23-32)
Satisfaction with appearance of affected foot[†]		
Satisfied	133 (54)	55 (41)
Moderately satisfied	81 (33)	58 (44)
Unsatisfied	30 (12)	19 (14)
Amputation	2 (1)	1 (1)
Calcaneal-related complication[†]		
Before 6 weeks	50 (21)	36 (27)
After 6 weeks	64 (26)	44 (34)

DIACF = displaced intra-articular calcaneal fracture (Sanders type II to IV); * = number (percent of population); † = mean (standard deviation); ‡ = median (interquartile range)

Association of fracture characteristics and patient reported outcomes

As demonstrated in Table 3, Table 4, Figure 5 and Figure 6, the type of calcaneal fracture is associated with several patient-reported outcomes. Patients with a fracture in the talar surface of the calcaneus reported the worst outcomes; these patients reported significantly more problems with washing or dressing themselves ('self-care'), walking ('mobility'), and experienced more pain or discomfort compared to the other fracture types. Consequently, these patients had a significantly lower EQ-5D index score ($p = 0.010$). Moreover, these patients were less satisfied with the appearance of their affected foot ($p = 0.001$) and range of wearable shoes ($p = 0.042$). Also, these patients had more often early and late calcaneal-related complications (respectively, $p = 0.001$ and $p = 0.006$). In contrast, patients with an extra-articular fracture reported less often problems in the EQ-6D dimensions (see Figure 5)

Table 3: Patient-reported outcome results per type of fracture and Sanders classification

	Number of patients*	EQ-5D index score [‡]	Satisfied with appearance of affected foot [†]
Type of calcaneal fracture			
		§	§
Fracture into talar surface	143 (67)	0.78 (0.78-0.84)[§]	76 (46)[§]
Isolated anterior surface fracture	32 (15)	0.81 (0.78-1.00)	21 (64)
Isolated extra-articular fracture	34 (16)	0.95 (0.80-1.00)[§]	33 (81)[§]
Undeterminable	6 (3)	0.78 (0.56-0.82)	3 (38)
CT-imaging			
			§
Sanders type I	5 (2)	0.81 (0.73-1.00)	3 (60)
Sanders type II	55 (26)	0.78 (0.65-0.84)	28 (44)
Sanders type III	46 (21)	0.81 (0.78-0.89)	22 (43)
Sanders type IV	16 (7)	0.78 (0.65-0.80)	5 (26)[§]
Isolated extra-articular fracture	10 (5)	0.84 (0.66-1.00)	10 (63)
Isolated anterior surface fracture	21 (10)	0.81 (0.58-1.00)	11 (50)
Not available	62 (29)	0.84 (0.78-1.00)	57 (77)[§]
Anterior surface fracture involvement			
		§	
Yes	109 (51)	0.78 (0.78-0.89)[§]	55 (47)[§]
No	84 (39)	0.81 (0.78-1.00)	61 (61)
Undeterminable	22 (10)	0.81 (0.78-0.85)	17 (61)

* = number (percent); † = number of outcome with that result (percent with outcome result within category); ‡ = median (interquartile range); § = p < 0.05

compared to the other type of calcaneal fractures; as a result, they had a higher EQ-5D index score (p= 0.003). However, these patients reported noticeably more problems per EQ-6D dimension than the Dutch reference population. The patients who had a fracture line in the anterior surface had a lower EQ-5D index score (p= 0.046). This patient group further had more complications, were less satisfied with appearance foot and wearable range of shoes.

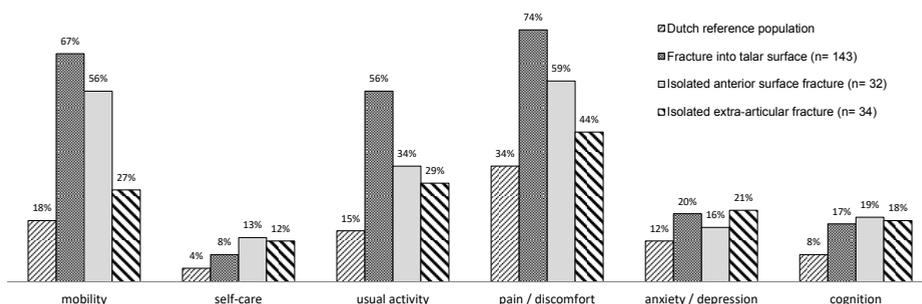


Figure 5: Reported problems per dimension of the EQ-6D per type of fracture.

Calcaneal-related complication before 6 weeks [‡]	Calcaneal-related complication after 6 weeks [‡]	Capable to work [†]	Satisfied with wearable range of shoes [†]
§	§		§
44 (27)[§]	53 (33)[§]	121 (85)	45 (32)[§]
3 (9)	6 (18)	25 (78)	11 (34)
3 (7)[§]	4 (10)[§]	30 (91)	21 (62)[§]
1 (13)	3 (38)	6 (100)	1 (17)
§			
1 (20)	0 (0)	5 (100)	2 (40)
11 (18)	18 (29)	48 (87)	20 (36)
17 (33)[§]	19 (37)	36 (80)	13 (29)
8 (42)[§]	8 (42)	13 (81)	2 (13)[§]
3 (19)	3 (19)	8 (89)	5 (50)
3 (14)	6 (27)	16 (76)	5 (24)
8 (11)[§]	12 (17)[§]	56 (90)	31 (50)[§]
§	§		§
38 (29)[§]	45 (37)[§]	90 (83)	31 (29)[§]
12 (12)[§]	17 (17)[§]	72 (87)	40 (47)[§]
7 (23)	12 (39)	20 (91)	7 (35)

Association of radiographic characteristics and patient reported outcome

Böhler's angle before treatment was not associated to the EQ-5D index score ($r = 0.098$, $\beta = 0.001$, $t = 1.325$, $p = 0.187$). However, a negative Böhler's angle demonstrated to have worse outcome results, reflected in a lower EQ-5D index score ($p = 0.006$) and more early calcaneal related complications ($p < 0.001$).

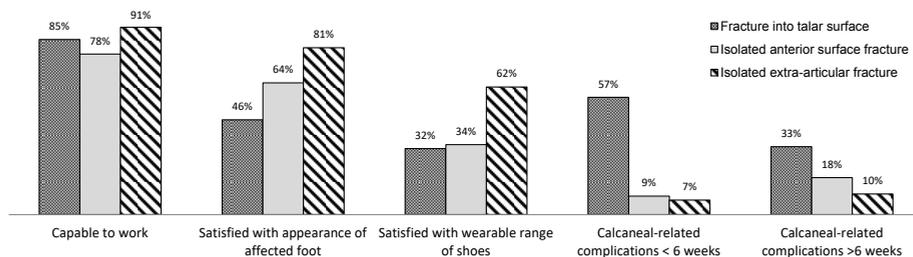


Figure 6: Patient-reported outcome results per type of fracture.

Table 4: Patient-reported outcome results per measured angles in the conventional radiographs

	Number of patients*	EQ-5D index score [†]	Satisfied with appearance of affected foot [‡]
Pre-treatment Böhler's angle			
		§	§
<0 degrees	22 (10)	0.75 (0.65-0.82)[§]	9 (35)[§]
0-14 degrees	42 (20)	0.78 (0.78-0.89)	21 (44)
15-45 degrees	112 (53)	0.81 (0.78-1.00)[§]	74 (61)[§]
>45 degrees	6 (3)	0.72 (0.57-0.88)	5 (83)
Undeterminable	33 (15)	0.81 (0.78-0.85)	20 (51)
Pre-treatment Gissane's angle			
<95 degrees	24 (11)	0.81 (0.78-0.84)	13 (48)
95-135 degrees	145 (67)	0.81 (0.75-1.00)	89 (56)
>135 degrees	7 (3)	0.78 (0.78-0.84)	4 (50)
Undeterminable	39 (18)	0.81 (0.78-0.84)	23 (50)
Pre-treatment calcaneal compression angle			
		§	§
<25 degrees	64 (30)	0.78 (0.65-0.84)[§]	28 (38)[§]
25-45 degrees	114 (53)	0.84 (0.78-1.00)[§]	79 (64)[§]
>45 degrees	3 (1)	0.78 (0.69-)	2 (50)
Undeterminable	34 (16)	0.81 (0.78-0.85)	20 (50)

* = number (percent); † = number of outcome with that result (percent with outcome result within category); ‡ = median (interquartile range); § = p< 0.05

Gissane's angle was not related to the EQ-5D index score ($r= 0.051$, $\beta < 0.001$, $t= -0.110$, $p= 0.913$). A Gissane's angle of more than 135 degrees was associated with more early calcaneal-related complications ($p= 0.004$) and a poor satisfaction with the wearable range of shoes ($p= 0.042$).

The calcaneal compression angle was poorly correlated to the EQ-5D index score ($r= 0.157$, $\beta= 0.004$, $t= 2.149$, $p= 0.033$). Patients who had a negative calcaneal compression angle reported in all six dimensions of the EQ-6D more problems ($p= 0.001$ to 0.023) that resulted in a substantial lower EQ-5D index score ($p= 0.001$).

The Sanders classification (type I to IV) was not associated with the EQ-5D index score ($p= 0.215$), or any of the other measured outcomes ($p= 0.109$ to 0.556).

Calcaneal-related complication before 6 weeks [†]	Calcaneal-related complication after 6 weeks [†]	Capable to work [†]	Satisfied with wearable range of shoes [†]
§		§	
14 (52)[§]	11 (41)	13 (59)[§]	3 (14)[§]
11 (23)	12 (25)	36 (88)	14 (33)
21 (17)	29 (24)	97 (87)	46 (41)
1 (17)	1 (17)	6 (100)	3 (50)
4 (10)	13 (33)	30 (91)	12 (36)
§			§
4 (15)	7 (26)	20 (83)	5 (21)
37 (23)	42 (26)	119 (83)	59 (41)[§]
5 (63)[§]	2 (25)	7 (100)	0 (0)[§]
5 (11)	15 (33)	36 (92)	14 (36)
§			
24 (32)[§]	24 (32)	47 (76)[§]	16 (25)[§]
23 (19)	27 (22)	101 (89)	49 (43)[§]
0 (0)	1 (25)	3 (100)	1 (33)
4 (10)	14 (35)	31 (91)	12 (35)

Patient reported outcome in patients with DIACF (Sanders type II to IV)

We performed an additional analysis of patients with a CT confirmed DIACF (Sanders type II to IV). None of the measured angles in the conventional radiographs (Böhler's, Gissane's or calcaneal compression angle) showed to be associated with the EQ-5D index score ($p= 0.227$ to 0.790); nor was anterior surface fracture involvement ($p= 0.503$). Patient with a DIACF and a negative calcaneal compression angles were less satisfied with the appearance of their foot (68%, $p= 0.040$); all the other measured angles were not associated with the outcomes ($p= 0.058$ to 0.865). Interestingly, patients who had anterior surface involvement and a DIACF experienced more early calcaneal-related complications (36%, $p= 0.013$) and more late calcaneal-related complications (45%, $p= 0.024$); involvement of the anterior surface was not associated with any of the other outcome results ($p= 0.327$ to 0.630).

Discussion

This study demonstrates that the type of fracture is related with outcomes such as the health-related quality of life, calcaneal-related complications, and satisfaction with the appearance of the foot and the shoes they can wear. Patients with fractures into the talar surface of the calcaneus report substantial unfavorable outcomes in comparison to the other type of fractures. In contrast, patients with extra-articular fractures report significantly better results. Patients with extra-articular fractures are in particular negatively affected in the EQ-6D dimensions 'self-care', 'usual activity' and 'cognition'. Possibly a great proportion of patients with an extra-articular fracture are elderly that might have had a negative influence on the EQ-6D outcome; this could not be reduced from our presented data. The study of Hoeymans et al. (2005) on the health-related quality of life in the Dutch population shows that elderly report significantly more problems than younger patients in all six dimensions of the EQ-6D. [33]

In addition, a negative Böhler's angle, a negative calcaneal compression angle or a fracture into the anterior surface of the calcaneus are associated with worse patient outcomes. The literature reports contrasting results in the predictive value of the Böhler's angle. [11-13, 40] The studies from Loucks et al. (1999) and Persson et al. (2015) demonstrated that a negative Böhler's angle in patients with an intra-articular calcaneal fracture is negatively related to health-related quality of life outcome. [11, 12] The results in this study do not support those findings. This could be due to different inclusion criteria, our study includes also patients with an open calcaneal fracture, and due to a different trauma level population, our study also includes patients from level II trauma centers. Including these patients may cause a greater heterogeneity of patients. Patients from the trauma level II have in general a less severe injury in comparison to trauma level I patients; while, patients with an open fracture likely meet more complications that might result in an unfavorable outcome. Furthermore, the inter- and intraobserver reliability has been reported limited in several occasions [36-40]; therefore the correct measurement of this angle is questionable. Therefore, we do not advise to use Böhler's angle for estimating the patient-reported outcomes. Further investigation by means of a systematic review and meta-analysis may elaborate to which extent the Böhler's angle could be utilized.

In line with several studies on Gissane's angle, this angle does not appear to be related to final outcome. [13, 42, 43] Consequently, we do not recommend the measurement of this angle.

The Sanders classification is one of the most reported systems to classify intra-articular fractures in the posterior facet of the talar surface. [13] The literature showed that the interobserver and intraobserver reliability is poor to mediocre. [37-39] This study shows that the Sanders classification is not related to any of the patient-reported outcomes which indicates that the Sanders' classification cannot be used to make reliable assumptions of the expected outcome.

In comparison with the study of Kinner et al. (2010) we did not demonstrate a significant difference in health-related quality of life in patients who had a DIACF and a fracture in the anterior surface of the calcaneus. [44] Moreover, our complication rate was twice as high. A possible explanation is that Kinner et al. (2010) excluded patients that might influence the results, for example patient who did not have postoperative CT-imaging, patients older than 65 years or patients with a bilateral fracture. [44]

Alike most retrospective studies, data collection was limited by information that was not or incorrectly recorded. Less than 10% of data was missing in our study. Moreover, not all type of fractures could be classified according to the Sanders' classification because CT-images were not available for all the included patients. The follow-up duration has a wide range, which could influence the results; the longer the follow-up, the more likely it is that other comorbidities are introduced that might influence the outcome. [45]

Due to the inclusion of patients admitted in level I and II trauma centers belonging to the same trauma region, these results represent a reliable reflection from the demographics and outcome of patients with a calcaneal fracture in a regionalized trauma population and allows us to generalize the results.

In conclusion, the study results demonstrate that patients with an intra-articular calcaneal fracture into the talar surface have a lower health-related quality of life, will be less satisfied with the outcome of their feet and have more complications compared to patients with other types of calcaneal fractures. In contrast, extra-articular fractures have significantly favorable results. The Sanders classification was not associated with patient-reported outcomes. Furthermore, we do not recommend the measurement of angles in conventional radiographs to inform patients on the possible outcome of their lives because of the poor relationship with patient-reported outcome results and the limited reliability of accurate measurement of these angles.

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CHAPTER 6

LONG-TERM FOLLOW-UP AFTER DISPLACED INTRA-ARTICULAR CALCANEAL FRACTURES: PATIENT-REPORTED OUTCOMES, COMPLICATIONS AND DEVELOPMENT AFTER PRIMARY FRACTURE TREATMENT

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Abstract

Introduction

Calcaneal fractures are known to have a major negative impact on the daily lives of patients. In order to inform patients early and accurately on how their calcaneal fracture may affect their lives, knowledge about the course of this injury is needed. For this purpose we have evaluated the long-term outcomes in patients with a displaced intra-articular calcaneal fracture, based on patient-reported outcomes, complications, and developments after primary fracture treatment.

Material and Methods

This multicenter retrospective study is based on prospective trauma databases including all patients aged 16 years or older. Patients without a CT-image of their calcaneal fracture or their calcaneal fracture could not be classified as a Sanders type II, III or IV fracture, were excluded. For all patients, trauma and fracture characteristics were collected. To evaluate long-term results, a questionnaire was sent that consisted of the EQ-6D, patient-specific characteristics, satisfaction with foot appearance and wearable shoe range, discomforts, complications, and capability to work.

Results

117 patients with 133 calcaneal fractures participated, with a mean follow-up time of five years. 56% of the fractures had additional operative treatment. Approximately ten percent had a subtalar arthrodesis eventually. Patients frequently reported discomfort with a wide range in severity. Moreover, the EQ-5D index score was significantly lower than the reference population. 48% of the early calcaneal-related complications led to a late calcaneal-related complication, such as wound infection and post-traumatic subtalar arthritis. Patients with a late-calcaneal related complication reported significantly unfavorable patient-reported outcome results.

Conclusion

Our study demonstrates that a large proportion of patients with a displaced intra-articular fracture report multiple discomforts that influence their lives negatively and needed additional operative treatment. Moreover, calcaneal-related complications that are identified after 6 weeks are associated with significantly unfavorable patient-reported outcomes.

Introduction

Calcaneal fractures are rare: they have a reported incidence that varies from 11.5 to 13.7 per 100,000 persons per year. [1-3] These fractures are known to have a major negative impact on the quality of life of patients. [4, 5]

Much has been published about the results after treatment of calcaneal fractures; yet, little has been reported about the long-term course of these fractures. [4] Thus, in order to be able to inform patients early and more accurately and to improve future research, it is necessary to gain knowledge about the development of these fractures after primary treatment.

The aim of our study is to describe the long-term follow-up of patients who sustained a displaced intra-articular calcaneal fracture (Sanders type II, III or IV fracture); furthermore, we aim to investigate the problems that patients may face, determined by several patient-reported outcomes (e.g. health-related quality of life, satisfaction with wearable shoe range, and discomforts). In addition, this study evaluates whether there is an association between calcaneal-related complications and patient-reported outcomes.

Material and Methods

Hospital setting

Four trauma centers in the central trauma region of the Netherlands, participated in this study: they are a level I trauma center (University Medical Center Utrecht) and three level II trauma centers (St. Antonius Hospital, Diakonessen Hospital, and Meander Medical Center).

Study design

This is a retrospective cohort study based on prospective trauma databases and a prospective patient-related outcomes evaluation that has been performed according to the criteria for evaluating health-related quality of life studies. [6] The study was performed under the approval of the medical ethics committee of the University Medical Center Utrecht in the Netherlands.

Study population

We have included all patients aged 16 years or older at the time of trauma who were diagnosed with a calcaneal fracture. Afterwards, all radiographic images were revised (performed by GA). The CT-images were classified with the Sanders classification. [7] We excluded patients without a CT-image of their calcaneal fracture or with a fracture that could not be classified as a Sanders type II, III or IV fracture.

Two datasets were combined. In dataset 1 the patients were selected from three different databases covering the period 2010 - 2012: the hospital databases, the regional trauma registry from the central trauma region, and the Dutch National Medical Registration (DNMR). [8] In these prospective databases the calcaneal injuries were identified based on the descriptive diagnosis, International Classification of Diseases (ICD) or Abbreviated Injury Scale score. [9, 10] We further added a dataset (dataset 2) that contained patients from a previous study. [5] In this particular dataset only patients with a calcaneal fracture were collected from the DNMR of the trauma level I center (period 2000- 2010).

Patients diagnosed with a calcaneal fracture in another hospital were not excluded. Patients registered more than once for the same injury event were only included once.

Data collection

All data was extracted from the trauma registry and patients' medical records. We collected all patient demographic data such as gender; age; comorbidities categorized according to the American Society of Anesthesiologists Physical Status Classification System (ASA) [11]; psychiatric history; trauma mechanism; circumstances of trauma; Injury Severity Score (ISS) [12]; concomitant injuries and the primary treatment of fracture.

Outcomes

Our primary outcome is health-related quality of life. Currently, there is no specific validated patient-reported outcome measurement available for foot and ankle injuries. One of the most commonly used instruments in trauma care is the EQ-5D. The EQ-5D is a standardized generic measure of health-related quality of life whose validity, reliability, and responsiveness have been tested in studies for other extremity morbidities. [13-18] In this study we utilized the EQ-6D, an extended version of the EQ-5D questionnaire with an additional question addressing the cognitive function. [17, 18]

The EQ-6D consists of six dimensions: 'mobility', 'self-care', 'usual activities', 'pain / discomfort', 'depression / anxiety', and 'cognition'. These dimensions have three levels of response: no problems, moderate problems, and severe problems. The responses on these dimensions can be combined to form a numerical score (the EQ-5D index score). To calculate this score, the dimension 'cognition' is ignored because there is no validated tariff for the EQ-6D. The Dutch tariff for the calculation of the EQ-5D index score was used because there is no international validated tariff for the EQ-6D. [19] This EQ-5D index score ranges from -0.33 to 1.00; a value of 0 can be interpreted as a state of living equal to death, whereas a value of 1 equals a perfectly healthy state of living. [17-19] Also, the EQ-5D index scores were compared with the Dutch reference population. The EQ-5D index United Kingdom was utilized, because the scores of the Dutch reference population are derived from this tariff. [20, 21]

In general, health-related quality of life is influenced by various patient-specific characteristics, such as current comorbidities and socio-economic status. [20, 22, 23] Therefore, we have added questions about these aspects. Socio-economic status was determined by the highest level of education a patient has completed.

The study of Dawson et al. (2012) demonstrated that satisfaction with the appearance of the affected foot and range of shoes patients are able to wear are important factors for determining patients' satisfaction after foot and ankle surgery. [24] Therefore, questions about these factors were also included. In addition, we have asked the patients about their capability to work. A further aim was to reflect types of discomfort from the patient's perspective. Hence, an open question was included on which discomforts patients currently experience. We also included an open question on whether they have experienced a complication. Based on their answers and on the medical records, we have determined whether this was a calcaneal-related complication. We have subsequently divided the calcaneal-related complications into two groups: the early calcaneal-related complications that occurred within six weeks after trauma (i.e. wound infection, malalignment, or compartment syndrome) and late calcaneal-related complications, which occurred after six weeks (i.e. wound infection, impingement of peroneal tendons, claw or hammer toes or malunion).

Follow-up

The EQ-6D questionnaire with the additional questions was sent to all eligible patients, along with an informed consent form. After four weeks a reminder was sent to all non-responders.

Statistical analysis

A descriptive analysis was performed to compare patient, trauma and fracture characteristics. Multiple patients had bilateral fractures while several patient-reported outcomes (e.g. EQ-6D) were not side-specific. In these cases, patients with a bilateral fracture were categorized into the worst side fracture group. An open fracture was considered worse than a closed fracture. A Sanders type IV fracture was classified worse than a type III, and a type III fracture was classified worse than a type II fracture.

Categorical variables were compared using the Chi-square test, and continuous variables were compared using the Student's T or Mann-Whitney U test. A P-value < 0.05 was considered statistically significant and all data were analyzed with SPSS version 20.0 (IBM Corp., Armonk, NY), for Windows.

Results

As Figure 1 illustrates, a total of 180 patients were eligible for this study; 117 patients with 133 calcaneal fractures participated. The mean follow-up time was five years. Their mean age was 45 years and the greater majority is male (see Table 1 for the baseline characteristics). In 55 percent the mechanism of injury was a fall from more than 1.5 meters. Most fractures were primarily operatively treated; 84 percent of the operatively treated fractures had open reduction and internal fixation (ORIF), eight percent had screw fixation, and six percent had another type of operative treatment. These other operative treatments consisted of primary arthrodesis (n= 1), an external fixator (n=3), external fixator followed by closed reduction and percutaneous fixation with Kirschner-wires (n= 1), and external fixator followed by closed reduction and screw fixation (n= 1).

Table 2 outlines the follow-up results. Approximately 55 percent of the calcaneal fractures had additional operative treatment; this occurred with a mean of 9 months (range 1 to 60 months). Thirty-eight percent of the operatively treated fractures in which their first treatment was their final treatment still had hardware removal. Approximately ten percent had a subtalar arthrodesis eventually. One of these secondary subtalar arthrodesis resulted in an amputation because of severe infection of the calcaneus and ankle. Forty-seven percent of the calcaneal fractures had an early or late calcaneal-related complication (details are shown in Tables 3 and 4).

Patients frequently reported discomforts with a wide range in severity (see Table 2 and 3). Most often they reported pain that is reflected by a low EQ-5D score. [5] Moreover, the EQ-5D index UK tariff score of patients with a displaced intra-articular calcaneal fracture is significantly lower than the index score of the Dutch reference population (respectively, 0.68 vs. 0.88, $p < 0.001$). [20, 21]

As demonstrated in Table 4, 48 percent of the early calcaneal-related complications also had a late calcaneal-related complication. Patients who had a late-calcaneal related complication reported significantly unfavorable patient-reported outcome results.

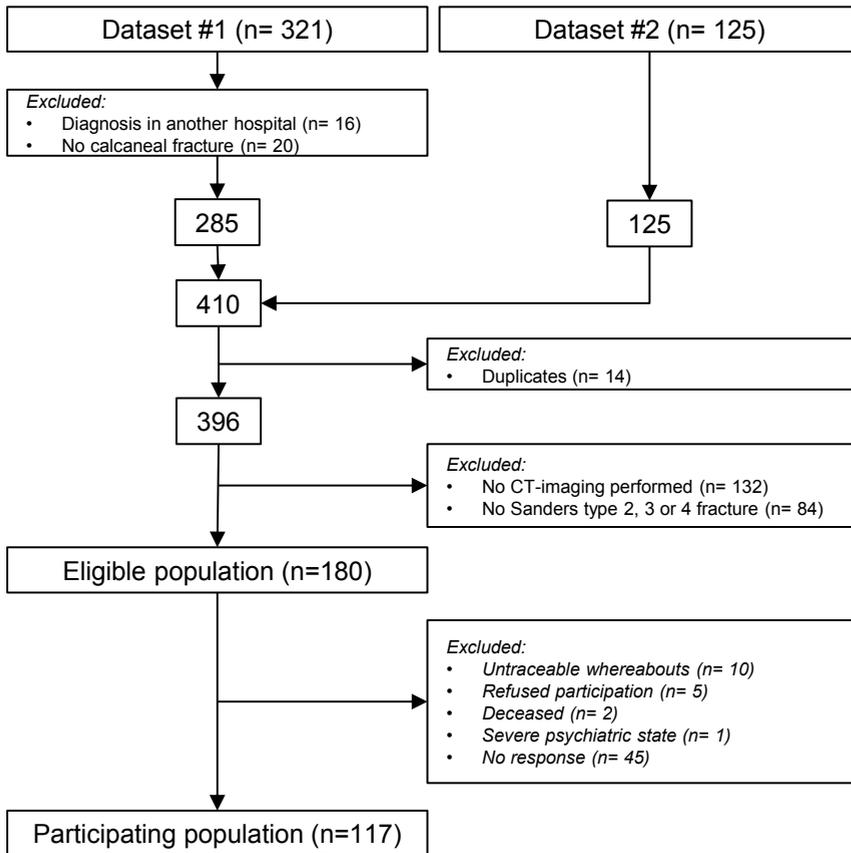


Figure 1: Flowchart of enrolled patients

Table 1: Baseline characteristics

	Eligible	Participating
Number of patients	180	117
Age at trauma in years[*]	43 (15) [§]	45 (15) [§]
Male[†]	125 (69)	80 (68)
Psychiatric history before trauma[†]	31 (17) [§]	15 (13) [§]
Injury Severity Score[*]	4 (4-8)	4 (4-8)
Injury Severity Score \geq 16[†]	18 (10)	11 (9)
Associated injuries[†]		
No associated injuries	100 (56)	62 (53)
Only lower limb associated injuries	20 (11)	14 (12)
Only one other associated injury	16 (9)	12 (10)
Multiple injuries	44 (24)	29 (25)
Mechanism of trauma[†]		
Fall from height \geq 1.5 meter	109 (61)	64 (55)
Simple fall <1.5 meter	42 (23)	29 (25)
Crush	1 (1)	1 (1)
Motor vehicle accident	21 (12)	17 (15)
Sports / leisure	5 (3)	4 (3)
Blast trauma	1 (1)	1 (1)
Other or unknown	1 (1)	1 (1)
Bilateral DIACF[†]	19 (11)	16 (12)
Number of DIACF	199	133
CT-imaging[†]		
Sanders type II	103 (52)	63 (47)
Sanders type III	68 (34)	51 (38)
Sanders type IV	28 (14)	19 (14)
Open fracture[†]	16 (8)	12 (9)
With anterior surface fracture involvement[†]	129 (65)	83 (62)
Primary treatment[†]		
Non-operative	62 (31)	36 (27)
Open reduction, internal fixation	109 (55)	80 (60)
Screw fixation	13 (7)	8 (6)
Primary arthrodesis	1 (1)	1 (1)
Other operative treatment	8 (4)	5 (4)
Missing	6 (3)	3 (2)
Time to primary operative treatment in days[†]	12 (9-17)	13 (10-17)

DIACF = displaced intra-articular calcaneal fracture

* = mean (standard deviation); † = number (percent); ‡ = median (interquartile range); § = $p < 0.05$ in eligible versus participating population

Table 2: Follow-up characteristics and outcome results

Number of patients	117
Follow-up time in months[†]	60 (32)
Age in years[†]	50 (15)
Comorbidities[*]	
ASA I	70 (59)
ASA II	43 (23)
ASA III	6 (3)
Psychiatric history[*]	18 (15)
Educational status[*]	
High	27 (23)
Middle	42 (36)
Low	49 (42)
Discomfort with foot[*]	95 (83)
Satisfaction with wearable range of shoes[*]	
Satisfied	35 (30)
Moderately satisfied	55 (47)
Unsatisfied	28 (24)
Capability to work[*]	99 (84)
EQ-5D index score[‡]	0.78 (0.69-0.84)

* = number (percent); † = mean (standard deviation); ‡ = median (interquartile range)

Number of calcaneal fractures	133
Pre-treatment angles*	
Böhler's	15 (2-33)
Calcaneal compression	25 (18-30)
Final angles*	
Böhler's	23 (8-31)
Calcaneal compression	27 (22-32)
Additional operative treatment	
None	69 (44)
Secondary subtalar arthrodesis	7 (5)
Hardware removal	26 (17)
Other or multiple	28 (17)
Unknown / missing	3 (2)
Time to additional operative treatment in months†	9 (10)
Hardware removal	44 (29)
Time to hardware removal in months*	12 (9-24)
Secondary subtalar arthrodesis	18 (12)
Time to secondary subtalar arthrodesis in months*	16 (11-29)
Final treatment status	
Primary open reduction, internal fixation	69 (52)
Primary other operative	9 (5)
Primary non-operative	28 (14)
Primary subtalar arthrodesis	1 (1)
Secondary reconstructive surgery	5 (3)
Secondary subtalar arthrodesis	17 (9)
Secondary amputation	1 (1)
Unknown / missing	3 (2)
Satisfaction with appearance of affected foot*	
Satisfied	55 (41)
Moderately satisfied	58 (44)
Unsatisfied	19 (14)
Amputation	1 (1)
Calcaneal-related complication*	
Before 6 weeks	35 (27)
After 6 weeks	45 (34)

Table 3: Calcaneal-related complications and patient-reported discomforts

Calcaneal-related complications per fracture	
<i>Before 6 weeks*</i>	
Wound infection	31
Compartment syndrome	3
Blood blister	3
Peroneal nerve injury	1
<i>After 6 weeks*</i>	
Wound infection	21
Osteitis	3
Posttraumatic subtalar arthritis	9
Malunion	5
Dystrophy	3
Claw toes	5
Hammer toes	2
Peroneal impingement	2
Malalignment	3
Delayed union	2
Fasciitis plantaris	1
Amputation	1
Complex regional pain syndrome	1
Equinus deformity of foot	1
Leg length discrepancy	2
Discomforts per patient†	
Pain or tenderness scar	17
Pain or tenderness calcaneus	35
Loss of strength	3
Pain by exercise, or to stand for a long time	43
Swollen ankle (after exercise)	12
Shoe discomforts	13
Start pain or stiffness	19
Foot settlement	22
Phantom pain	1
Paresthesia	1
Corns and callus formation	3
Cold foot	4
Out of balance	7

* = number of fractures; †= number of patients

Table 4: Outcomes per calcaneal-related complication

	Early calcaneal-related complication		Late calcaneal-related complication	
	Yes	No	Yes	No
Late calcaneal-related complication*	17 (48) [‡]	28 (29) [‡]	-	-
Discomforts per patient*	29 (91)	65 (79)	40 (98) [‡]	54 (74) [‡]
Satisfied with wearable range of shoes*	4 (12) [‡]	30 (37) [‡]	7 (21) [‡]	27 (37) [‡]
Satisfied with appearance of foot*	11 (31)	43 (44)	10 (22) [‡]	44 (51) [‡]
EQ-5D index value[†]	0.73 (0.18)	0.74 (0.25)	0.68 (0.25) [‡]	0.77 (0.21) [‡]
Capable to work*	26 (88)	70 (85)	33 (81)	63 (85)

* = number (percent); † = mean (standard deviation); ‡ = $p < 0.05$

Discussion

The aim of this study was to describe the long-term patient-reported outcomes, complications, and development after primary fracture treatment in patients that sustained a displaced intra-articular calcaneal fracture; in addition, we evaluated whether the endurance of a calcaneal-related complication was associated with patient-reported outcomes. Calcaneal fractures are known to influence the daily lives of patients negatively; insight into the long-term consequences of this fracture is needed in order to inform patients early and accurately about the problems they might experience in the future. Accurately informing patients about the long-term outcomes of their calcaneal fracture might avoid disappointment with their treatment, and may help them to cope with their altered lives.

This study demonstrates that the vast majority of patients with a displaced intra-articular calcaneal fracture reported discomforts with their foot which needed additional operative treatment. Moreover, almost fifty percent of the patients experienced a calcaneal-related complication. In addition, late calcaneal-related complications, such as wound infection and post-traumatic subtalar arthritis were affiliated with significantly unfavorable patient-reported outcomes.

Furthermore, our study demonstrates that patients who endured a displaced intra-articular calcaneal fracture experienced a life-changing event that resulted in a chronic disability. Consequently, they have a significantly lower health-related quality of life than the reference population. This result is in line with other studies that reported health-related quality of life outcomes in patients with calcaneal fractures. [25-27]

Recently, a systematic review has described long-term outcomes of calcaneal fractures and reported a wound infection rate of 20%, which is comparable to the rate in our study. [28] Moreover, this review showed a hardware removal rate of 11% which is substantially lower than our rate of 38%. The difference could be due to the difference in the selected patient group (e.g. inclusion of patients with a low-complex injury such as a Sanders type II fracture) or a certain operative technique that might need less hardware removals. The secondary subtalar arthrodesis rate is comparable to ours.

Patients frequently reported a wide range of discomforts. Therefore, we recommend that patients be informed about the expected discomforts such as chronic pain in the heel or scar tissue, pain during vigorous exercise, starting pain, or problems with foot settlement

or wearable shoes. To inform patients accurately about the problems they could face, might enable them to cope better with the results after the fracture treatment and perhaps ease their rehabilitation process.

The rate of calcaneal-related complications depends on what is recorded in the medical records and what the patients reported. This might lead to an underestimation of the number of complications because patients might not be able to identify a discomfort as a complication. For example, posttraumatic subtalar arthritis has been reported to be 18 to 42 percent; our study has a substantially lower rate of seven percent. [29, 30]

The follow-up time in many prospective studies on the treatment of displaced intra-articular calcaneal fractures is approximately two years. [31-33] Taking the results of our study into account, a longer follow-up time would be more appropriate because a significant proportion of patients with calcaneal fractures had an additional operative treatment after two years. Thus, a follow-up period of two years might underestimate the long-term outcome.

As is the case with most retrospective studies, our data collection is limited by information that was not recorded or erroneously recorded. The missing data in our study is lower than ten percent.

Furthermore, since not all identified calcaneal fractures had a CT-image (because of the severity of the injury needing immediate intervention) they were not included in this study. In addition, the follow-up period had a wide range that could have influenced the results. On the one hand, a follow-up that is too short might lead to an overestimation of favorable outcome results; on the other hand, a long follow-up time might introduce other comorbidities. Finally, our study showed a slight selection bias because the follow-up group had fewer patients with a psychiatric history. A large proportion of these patients were in a severe psychiatric state, were deceased or we were unable to trace their whereabouts (Figure 1).

Due to the inclusion of trauma level I and II centers that belong to the same trauma region, these results are a reliable reflection of long-term patient-reported outcomes of patients with a displaced intra-articular calcaneal fracture allowing us to generalize the results.

In summary, our study shows that a large proportion of patients with a displaced intra-articular fracture report multiple discomforts that influence their lives negatively, which

is reflected in the lower health-related quality of life scores. Moreover, calcaneal-related complications that are identified after 6 weeks seem to be affiliated with unfavorable patient-reported outcomes. Furthermore, a substantial number of patients had additional operative treatment after two years. For future studies we recommend a follow-up period of minimally up to four years for reliable and valid results.

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CHAPTER 7

A COMPARISON OF CALCANEAL FRACTURE PATIENTS WITH AND WITHOUT A PSYCHIATRIC DISORDER: DEMOGRAPHIC PATTERNS AND PATIENT-REPORTED OUTCOMES

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Abstract

Introduction

20 to 26 percent of the trauma patients have a comorbid psychiatric disorder. A comorbid psychiatric disorder in trauma patients are, among other things, associated with a more complicated course. Moreover, calcaneal fracture patients in general report a low quality of life. Calcaneal fracture patients with a comorbid psychiatric disorder have never been extensively evaluated; in order to stimulate improvements in patients with calcaneal fractures knowledge is needed. In this study we compare the characteristics and outcomes of patients with a calcaneal fracture with and without a comorbid psychiatric disorder within a regional inclusive trauma system.

Material and Methods

This is a retrospective regional cohort study including all patients aged 16 years or over with a calcaneal fracture admitted to one of the participating trauma level I or II hospitals. Patients', trauma and fracture characteristics were collected. The eligible patients received a questionnaire that consisted of a health-related quality of life questionnaire (EQ-6D), patient-specific characteristics, satisfaction with foot appearance and wearable range of shoes, calcaneal-related complications, and capability to work.

Results

126 patients were available for follow-up. The patients with a comorbid psychiatric disorder (n= 16) had a substantially severe trauma that did not result in unfavorable patient-reported outcomes in comparison with patients without a comorbid psychiatric disorder (n=110). However, patients with a comorbid psychiatric disorder were less frequently capable to work (p= 0.009) and reported more problems with their cognition (p= 0.038).

Conclusion

There are limited differences in injury characteristics between psychiatric and non-psychiatric patients with a calcaneal fracture, which do not result in significant unfavorable outcome results.

Introduction

20 to 26 percent of the trauma patients have a psychiatric disorder [1-3]. Moreover, a systematic review demonstrated that patients with a psychiatric disorder have a trend to a higher risk or a higher risk of mortality. [4] In addition, there seems to be an association between trauma patients with a comorbid psychiatric disorder and having a more complicated course after trauma, such as more respiratory complications and more postoperative complications. [1, 3, 5, 6] Furthermore, trauma patients with a comorbid psychiatric disorder showed to be an independent risk factor for having recidivism of injury. [1, 3, 5, 6] It has been reported that a comorbid psychiatric disorder with a somatic disorder might have a negative impact on the health care resources, e.g. a prolonged length of hospital stay and more postoperative complications that might need additional treatment. [6-8] In contrast, the annual total work loss costs per million works in patients with a mental disorder are significantly lower than in patients with a physical disorder (respectively, €360 million versus €706 million). [9]

To our knowledge, patients that endured a calcaneal fracture and have a comorbid psychiatric disorder have never been extensively evaluated. Calcaneal fractures are an uncommon injury with a reported incidence of 11.5 to 13.7 per 100,000 persons per year. [10, 11] Also, these fractures are known to influence the quality of life of patients negatively. [12, 13] Our previous study in patients that sustained a calcaneal fracture demonstrated that patients with a comorbid psychiatric disorder have substantially less favorable patient-reported outcomes compared to patients without a comorbid psychiatric disorder. [14] That particular study was performed in a trauma level I center; however, vast differences exist between patients in trauma level I and II centers. [15] It is needed to gain knowledge in the differences between the injury and patient characteristics of patients with a calcaneal fracture with and without a comorbid psychiatric disorder; in order to interpret the results and stimulate improvements in patients with a calcaneal fracture.

The purpose of our study is to compare the patients', trauma and fracture characteristics, and outcomes in calcaneal fracture patients with and without a comorbid psychiatric disorder. Several patient-reported outcome results were compared such as the health-related quality of life (HRQoL), capability to work, patients' satisfaction with foot appearance and wearable range of shoes.

Material and Methods

Hospital setting

This study was conducted in the central trauma region of the Netherlands. Four trauma centers, functioning in this region, participated in this study; one level I trauma center (University Medical Center Utrecht) and three level II trauma centers (St. Antonius Hospital, Diaconessen Hospital and Meander Medical Center).

Study design

This is a retrospective cohort study based on a prospective trauma database and a prospective patient-reported outcome evaluation that has been performed according to the criteria for evaluating HRQoL studies. [16] This study was conducted under the approval of the medical ethics committee of the University Medical Center Utrecht in the Netherlands.

Data collection

We used three databases to identify all patients diagnosed with a calcaneal fracture. First, the Dutch National Medical registration, this registry is a national database in which all hospital admissions are collected with concomitant diseases or injuries and coded according to the International Classification of Diseases (ICD). [17, 18] Second, the hospital databases, in which calcaneal fractures are registered based upon their diagnosis code. The last database, is the regional trauma registry, which records all admitted trauma patients in the trauma region and codes all injuries according to the Abbreviated Injury Scale score and ICD. [18, 19] All three databases register patients prospectively and in a standardized manner. We have excluded all duplicates and patients that were initially diagnosed with a calcaneal fracture in a hospital outside the trauma region.

Study population

We have included all patients aged 16 years and older diagnosed with a calcaneal fracture in the period 2010 through 2012.

Data extraction

All data were extracted from the patients' medical record or trauma registry. We collected all patient demographic data such as age, gender, comorbidities categorized according to the ASA Physical Status Classification System, comorbid psychiatric disorder, trauma mechanism, circumstances of trauma, Injury Severity Score (ISS), concomitant injuries, type of calcaneal fracture, fracture classification by Sanders and primary treatment of fracture.

[20-22] All patients who were treated with psychiatric medication or had a psychiatric diagnosis in their medical history were considered patients with a comorbid psychiatric disorder. Circumstances of trauma include the subcategory of psychiatric episode that we arbitrarily defined as the fact the injury was incurred during an active comorbid psychiatric disorder, e.g. psychosis or depression. CT-images were preferably used to assess the type of fracture. When no CT-image was available, the conventional radiographic images were used.

Outcomes

Our primary outcome is HRQoL measured with the EQ-6D [23]. The EQ-6D is a questionnaire that focuses on determining the HRQoL. Dimensions included in the EQ-6D are mobility, self-care, usual activities, pain / discomfort, depression / anxiety and cognition. The EQ-6D is an extended version of the EQ-5D questionnaire including a sixth dimension, namely cognition. [23, 24] Each dimension has three possible levels of response: no problems, moderate problems, and severe problems. Based upon the levels of response of the dimensions the EQ-5D index score can be calculated, with the exception of the dimension cognition, because there is no validated tariff for the EQ-6D. The score ranges from -0.33 to 1.00, with a negative value representing a health state worse than death, 0 representing worst health state and 1.00 represents the best health status. [23-25] In addition, the EQ-VAS, a visual analogue scale, measures a person's self-rated health status. This scale ranges from 0 (the worst imaginable health state) to 100 (the best imaginable health state). HRQoL is influenced by various patient-specific characteristics, such as current comorbidities and socio-economic status; hence, questions were added to the questionnaire on these aspects. [26-28] Socio-economic status was determined by the highest level of education a patient has had.

As demonstrated in the study of Dawson et al. (2012) satisfaction with the appearance of the affected foot and the range of shoes a patient could currently wear are important factors for a patients' satisfaction after foot and ankle surgery; consequently, we have added questions about these factors. [29] In addition, we have asked the patients for their capability to work and included a question on complications. Based on the medical records and their answers in the questionnaire, we determined whether it was a calcaneal-related complication. The calcaneal-related complications were categorized into two groups: the early calcaneal-related complications that occurred within six weeks after trauma (i.e. wound infection, malalignment or compartment syndrome) and late calcaneal-related complications, which occurred after six weeks (i.e. wound infection, impingement of peroneal tendons, claw or hammer toes or malunion).

Follow-up

The EQ-6D questionnaire with the additional questions was sent at one time to all eligible patients, along with an informed consent form. After four weeks a reminder was sent to all non-responders.

Statistical analysis

A descriptive analysis was performed to compare patient, trauma and fracture characteristics between the populations with and without a comorbid psychiatric disorder. Categorical variables were compared using Chi-square test, and continuous variables were compared using Student's T or Mann-Whitney U test. A P-value < 0.050 was considered statistically significant. All data were analyzed with SPSS version 20.0 (IBM Corp., Armonk, NY), for Windows.

The Dutch tariff for the calculation of the EQ-5D index score was used because there is no international validated tariff for the EQ-6D [25]. We have compared all outcomes of the population with a comorbid psychiatric disorder with the population without a comorbid psychiatric disorder. In line with the EQ-6D study of the Dutch reference population, the outcomes per dimension were dichotomized into problems versus no problems, and compared with the Dutch reference population. [27]

Results

A total of 321 patients with a calcaneal fracture were identified in the three databases (see Figure 1). Sixteen patients were excluded because their initial presentation was in a hospital outside of our trauma region. Another twenty patients were incorrectly recorded with a calcaneal fracture; these patients were excluded after revision of the medical records and radiographic images. In total 285 patients with 307 calcaneal fractures were available for analysis.

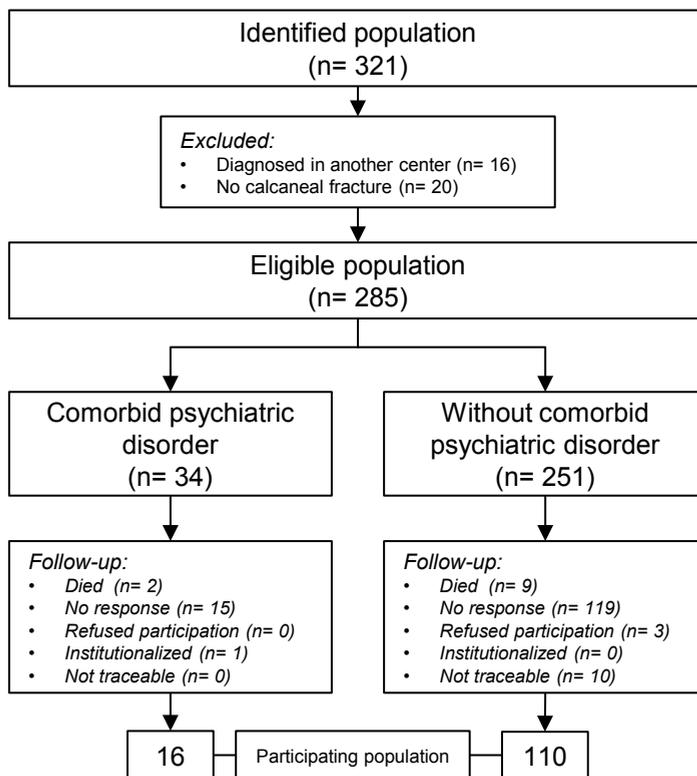


Figure 1: Flow-chart of enrolled patients

Patient, trauma mechanism and injury characteristics

Table 1 shows the patients', trauma and fracture characteristics and Table 2 demonstrates the details of the patients with a comorbid psychiatric disorder (extensive details are reported in Appendix A). The majority of the patients (n= 251) did not have a comorbid psychiatric disorder. 34 patients were recorded as having a comorbid psychiatric disorder.

Patients with a psychiatric disorder were more severely injured ($p < 0.001$) as compared to those without a comorbid psychiatric disorder. 27% had an ISS of 16 or more ($p < 0.001$). Moreover, the trauma mechanism in these patients was more frequently a fall from height from 1.5 meter or higher ($p = 0.014$). All suicide attempts in this study consisted of fall from height from at least 1.5 meters. The calcaneal fracture characteristics were equally distributed between the psychiatric and non-psychiatric population.

Table 1: Baseline of patients', trauma and fracture characteristics

	Eligible		Participating	
	Comorbid psychiatric disorder	Without comorbid psychiatric disorder	Comorbid psychiatric disorder	Without comorbid psychiatric disorder
Number of patients*	34 (12)	251 (88)	16 (13)	110 (87)
Age at trauma in years[†]	42 (34-54)	47 (33-61)	43 (36-55)	51 (39-64)
Age at trauma 70 years or older*	2 (6)	22 (9)	0 (0)	10 (9)
Female*	19 (56)	97 (39)	10 (63)	44 (40)
Comorbidities before trauma*				
ASA I	23 (68)	183 (73)	14 (88)	79 (72)
ASA II	6 (18)	57 (23)	2 (13)	26 (24)
ASA III	2 (6)	11 (4)	0 (0)	5 (5)
Diabetes mellitus before trauma*	3 (9)	14 (6)	1 (6)	6 (6)
Circumstances of trauma^{*§}				
Domestic	19 (56)	132 (53)	10 (63)	68 (62)
Psychiatric episode	11 (32)	0 (0)	4 (25)	0 (0)
Recreational	1 (3)	28 (11)	0 (0)	7 (6)
Road traffic accident	1 (3)	40 (16)	1 (6)	15 (14)
Work	1 (3)	29 (12)	1 (6)	12 (11)
Unknown or other	1 (3)	22 (9)	0 (0)	8 (7)
Mechanism of trauma*				
Fall from height ≥ 1.5 meter	23 (68)	109 (44)	9 (56)	48 (44)
Simple fall < 1.5 meter	4 (11)	74 (30)	1 (6)	32 (29)
Crush	1 (3)	6 (2)	1 (6)	5 (5)
Motor vehicle accident	1 (3)	27 (11)	1 (6)	11 (10)
Sports / leisure	1 (3)	6 (2)	0 (0)	2 (2)
Other or unknown	1 (3)	6 (2)	1 (6)	2 (2)
Inversion trauma	3 (9)	23 (9)	3 (19)	10 (9)
Admitted at trauma level I center^{*§}	16 (47)	50 (20)	9 (56)	21 (19)
Injury Severity Score[†]	5 (4-14)	4 (4-4)	5 (4-16)	4 (4-4)
Injury Severity Score ≥ 16^{*§}	9 (27)	8 (3)	4 (25)	3 (3)

Table 1: Continued.

	Eligible		Participating	
	Comorbid psychiatric disorder	Without comorbid psychiatric disorder	Comorbid psychiatric disorder	Without comorbid psychiatric disorder
Associated injuries^{*§}				
Isolated calcaneal fracture	14 (41)	185 (74)	6 (38)	77 (70)
Only lower limb associated injuries	3 (9)	29 (12)	2 (13)	15 (14)
Only one other associated injury	3 (9)	11 (6)	1 (6)	8 (7)
Multiple injuries	14 (41)	26 (10)	7 (44)	10 (9)
Concomitant injuries per region[†]				
Spinal fracture [§]	10 (29)	14 (6)	4 (25)	6 (6)
Pelvic fracture (excluding sacrum) [§]	8 (24)	5 (2)	4 (25)	1 (1)
Upper limb injury	5 (15)	19 (8)*	2 (12)	13 (12)*
Head injury [§]	7 (21)	11 (4)	4 (25)	4 (4)
Thoracic injury [§]	5 (15)	13 (5)	3 (19)	6 (6)
Abdominal injury [§]	2 (6)	4 (2)	1 (6)	0 (0)
Lower limb injury [§]	15 (44)	51 (20)	8 (50)	24 (22)
Bilateral calcaneal fracture[†]	5 (15)	18 (7)	1 (6)	10 (9)
Number of calcaneal fractures[†]	39 (13)	268 (87)	18 (13)	118 (87)
Open calcaneal fracture[†]	2 (5)	16 (6)*	1 (6)	11 (9)*
Type of calcaneal fracture[†]				
Fracture into talar surface	21 (55)	129 (48)*	8 (44)	66 (56)*
Isolated anterior surface fracture	7 (18)	40 (15)*	6 (33)	20 (17)*
Isolated extra-articular fracture [§]	10 (26)	100 (37)*	4 (22)	32 (27)*
CT-imaging[†]				
Sanders type I	1 (3)	8 (3)	1 (6)	3 (3)
Sanders type II	9 (24)	57 (21)	4 (22)	23 (20)
Sanders type III	8 (21)	36 (13)*	3 (17)	25 (21)*
Sanders type IV	3 (8)	16 (6)	0 (0)	10 (9)
Isolated extra-articular fracture	5 (13)	29 (11)	1 (6)	12 (10)
Isolated anterior surface fracture	4 (11)	21 (8)	3 (17)	12 (10)
Not available	8 (21)	102 (38)*	6 (33)	33 (28)*
Primary treatment[†]				
Operative	12 (32)	72 (27)	6 (33)	39 (33)
Non-operative	26 (68)	188 (70)	12 (67)	77 (65)
Unknown	0 (0)	9 (3)	0 (0)	2 (2)

* = number (percent within population); † = median (interquartile range); ‡ = p < 0.05 in eligible versus participating population; § = p < 0.05 in psychiatric disorder versus without psychiatric disorder eligible population; || = p < 0.05 in psychiatric disorder versus without psychiatric disorder participating population

Table 2: Details of comorbid psychiatric disorders and psychiatric episodes

	Eligible	Participating
Psychiatric disorder	Depression (n= 9) Multiple psychiatric diagnoses (n= 11) Alcohol abuse (n= 3) Borderline personality disorder (n= 1) ADHD (n= 1) Bipolar disorder (n= 1) Mood disorder not specified (n= 1) Substance abuse (n= 1) Unknown (n= 6)	Depression (n= 3) Multiple psychiatric diagnoses (n= 5) Alcohol abuse (n= 1) ADHD (n= 1) Bipolar disorder (n= 1) Mood disorder not specified (n= 1) Unknown (n= 4)
Psychiatric episode specified	Suicide attempt (n= 10) Psychotic episode (n= 1)	Suicide attempt (n= 4)

Follow-up

47% (n= 16) of the patients with a comorbid psychiatric disorder and 44% (n= 110) of the patients without psychiatric disorder were available for follow-up. As shown in Table 3, the patients' characteristics at follow-up, such as socio-economic status and comorbidities, were equally distributed in both populations. The severity of injury determined with the ISS did not differ significantly between the eligible and the participating populations.

Table 3: Outcome results

	With comorbid psychiatric disorder	Without comorbid psychiatric disorder
Number of patients	16	110
Follow-up time in months*	47 (12) CI 95% (40-53)	42 (11) CI 95% (40-44)
Age at follow-up in years†	48 (39-59) CI 95% (42-55)	55 (41-67) CI 95% (50-56)
Comorbidities‡		
ASA I	10 (63)	64 (59)
ASA II	5 (31)	37 (34)
ASA III	1 (6)	8 (7)
Educational status‡		
High	7 (44)	28 (26)
Middle	4 (25)	31 (29)
Low	5 (31)	49 (45)
EQ-5D index score*	0.67 (0.26) CI 95% (0.56-0.84)	0.82 (0.20) CI 95% (0.78-0.86)
EQ-VAS*	71 (22) CI 95% (59-82)	77 (16) CI 95% (75-80)
Capability to work‡	10 (63) [§]	96 (89) [§]

Table 3: Continued.

	With comorbid psychiatric disorder	Without comorbid psychiatric disorder
Satisfaction with wearable range shoe range*		
Satisfied	7 (44)	45 (41)
Moderately satisfied	7 (44)	43 (39)
Unsatisfied	2 (13)	21 (19)
Number of calcaneal fractures	17	114
Satisfaction with appearance of affected foot†		
Satisfied	12 (71)	69 (61)
Moderately satisfied	3 (18)	34 (30)
Unsatisfied	2 (12)	11 (10)
Calcaneal-related complication‡		
Before 6 weeks	6 (25)	29 (27)
After 6 weeks	7 (35)	27 (23)

* = mean (standard deviation); † = median (interquartile range); ‡ = number (percent within population); § = $p < 0.05$ with versus without comorbid psychiatric disorder

Outcomes

Table 3 demonstrates that the HRQoL, determined with the EQ-5D index score, did not differ significantly between the two populations ($p = 0.159$). Furthermore, the EQ-VAS, satisfaction with wearable range of shoes or appearance of affected foot, and calcaneal-related complications were comparable. However, a substantial number of patients with a comorbid psychiatric disorder were not capable to work (35% versus 23%, $p = 0.009$).

Figure 2 shows the percentage of reported problems per dimension of the EQ-6D; there seems to be a trend towards that patients with a comorbid psychiatric disorder report more frequently problems in comparison with patients without a comorbid psychiatric disorder or the Dutch reference population. For the dimension ‘cognition’ patients with a comorbid psychiatric disorder ($n = 6$) reported more often problems in comparison to patients without a comorbid psychiatric disorder ($p = 0.038$).

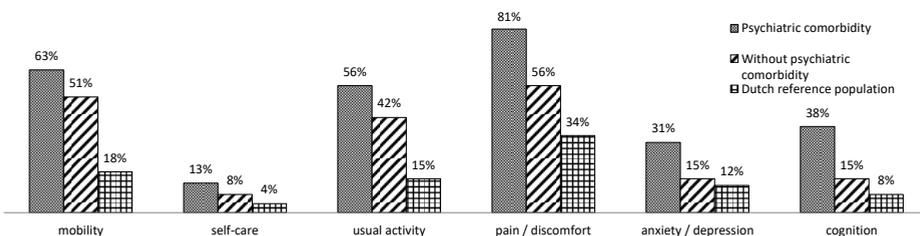


Figure 2: Reporting of problems per dimension of the EQ-6D

Discussion

It has been reported that trauma patients with a comorbid psychiatric disorder are associated among other things with a more complicated course [1, 3, 5, 6]; however this has not been studied in patients that endured a calcaneal fracture. Therefore, we have performed this study and compared the patients', trauma and fracture characteristics, and outcomes in patients with a calcaneal fracture with and without a comorbid psychiatric disorder. Our findings may help to stimulate improvements in the management of patients with calcaneal fractures.

This current study demonstrates that patients with a comorbid psychiatric disorder had a substantially severe trauma that does not result in significant unfavorable patient-reported outcomes in comparison with patients without a comorbid psychiatric disorder. Though, in follow-up patients with a comorbid psychiatric disorder reported more cognitive problems and were less frequently capable to work.

Our previous study on calcaneal fractures demonstrated that patients with a comorbid psychiatric disorder have considerably unfavorable outcomes than non-psychiatric patients. [14] That particular study was performed in a trauma level I center in which the most severe trauma patients are admitted in our region. Due to the regional design of this current study, the results represent a more accurate reflection of the demographics and outcome of patients with a calcaneal fracture in an entire region. It further allows us to generalize the results to a national level.

Furthermore, it is stated in literature that patients with a comorbid psychiatric disorder have a higher risk for the development of complications, such as wound infections, pneumonia and delirium. [1] In this study, the calcaneal-related complications were not substantially higher in the population with a comorbid psychiatric disorder.

Moreover, a number of patients with a psychiatric disorder are not capable to work; also, many of the patients with a comorbid psychiatric disorder experience problems with their cognition. Possibly a number of the comorbid psychiatric disorder patients use medication that may negatively influence their cognition e.g. benzodiazepines. The problems that these patients experience with their cognitive capability might have a negative effect on their capability to work. It could be that patients with a comorbid psychiatric disorder may benefit from a different management that addresses their cognitive abilities; for example,

early additional psychiatric counseling or psychological counseling. [9] However, these are hypotheses which have not been tested thoroughly in this study.

As in most retrospective studies, data collection is limited by information that was not or incorrectly recorded. Less than 10% of that data were missing in this study. Psychiatric diagnoses have a wide range in severity and subgroups. In a general population about 1 in 4 is thought to have a psychiatric diagnosis of some kind. [30] The fact that the total study population only 34 out of 285 patients were registered with a comorbid psychiatric diagnosis suggests that these diagnoses are not always registered at admission because they may not be considered relevant for the injury. This might cause under-reporting that may influence the interpretation of the results.

Furthermore, in case a patient has a psychiatric diagnosis in their medical history, though their prior psychiatric condition is solved, than this particular patient is still included in the group of patient with a comorbid psychiatric disorder. Possibly, this might show outcome results that are too favorable. Loss to follow-up might bias the results in cohort studies. [31] The patients that participated in our study had significantly less often an extra-articular fracture. Still, the distribution of type of calcaneal fracture between the patients with and without a comorbid psychiatric disorder was more or less similar. Therefore, bias on that ground is expected to be minimal.

In conclusion, our study demonstrates that there are limited differences between psychiatric and non-psychiatric patients with a calcaneal fracture in injury characteristics that do not result in significant unfavorable outcome results.

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Appendix A: Details of the patients with a psychiatric disorder

Participation	Trauma level	Psychiatric disorder
Yes	1	Unknown
Yes	1	Alcohol abuse, depression
Yes	1	Unknown
Yes	1	Depression, autism
Yes	1	Psychosis, alcohol abuse, borderline personality disorder
Yes	1	Bipolar disorder
Yes	1	Borderline personality disorder, PTSS, eating disorder
Yes	1	Depression
Yes	1	Schizo-affective disorder, bipolar disorder
Yes	2	Alcohol abuse
Yes	2	ADHD
Yes	2	Unknown
Yes	2	Unknown
Yes	2	Depression
Yes	2	Depression
Yes	2	Mood disorder not otherwise specified
No	1	Schizo-affective disorder, mental retardation
No	1	Borderline personality disorder
No	1	Borderline personality disorder, PTSS, eating disorder
No	1	Depression, adjustment disorder with depression and anxiety, cocaine abuse
No	1	Bipolar disorder, anxiety/panic disorder
No	1	Depression
No	1	Alcohol abuse
No	2	Alcohol abuse, bipolar disorder
No	2	Depression
No	2	Unknown
No	2	Alcohol abuse
No	2	Depression, borderline personality disorder
No	2	Depression
No	2	Depression
No	2	Substance abuse disorder
No	2	Depression
No	2	Depression
No	2	Unknown

Circumstance of trauma	Mechanism of trauma	Psychiatric medication usage
Domestic	Fall from height ≥ 1.5 meter	Anti-depressant
Domestic	Fall from height ≥ 1.5 meter	Benzodiazepines
Domestic	Inversion trauma	Anti-depressant
Suicide attempt	Fall from height ≥ 1.5 meter	SSRI, anti-psychotic medication , benzodiazepines
Suicide attempt	Fall from height ≥ 1.5 meter	TCA, lithium
Domestic	Fall from height ≥ 1.5 meter	Lithium, anti-psychotic medication
Suicide attempt	Fall from height ≥ 1.5 meter	TCA
Road traffic accident	Motor vehicle accident	Anti-depressant
Suicide attempt	Fall from height ≥ 1.5 meter	Anti-psychotic medication, benzodiazepines, lithium
Domestic	Inversion trauma	None
Domestic	Inversion trauma	TCA, amfetamines
Domestic	Fall from height ≥ 1.5 meter	SSRI
Work	Crush injury	TCA
Domestic	Fall from height ≥ 1.5 meter	TCA
Domestic	Simple fall < 1.5 meter	SSRI
Domestic	Other	Anti-psychotic medication
Suicide attempt	Fall from height ≥ 1.5 meter	Anti-psychotic medication
Suicide attempt	Fall from height ≥ 1.5 meter	SSRI, benzodiazepines, tertiary amine
Suicide attempt	Fall from height ≥ 1.5 meter	SSRI, anti-epileptica, benzodiazepines, anti-psychotic medication
Domestic	Fall from height ≥ 1.5 meter	None
Suicide attempt	Fall from height ≥ 1.5 meter	Benzodiazepine, lithium, TCA, anti-psychotic medication
Suicide attempt	Fall from height ≥ 1.5 meter	SSRI
Suicide attempt	Fall from height ≥ 1.5 meter	SSRI
Recreational	Sports injury	anti-psychotic medication, benzodiazepines
Domestic	Simple fall < 1.5 meter	Unknown
Domestic	Fall from height ≥ 1.5 meter	Anti-psychotic medication
Domestic	Fall from height ≥ 1.5 meter	Unknown
Domestic	Fall from height ≥ 1.5 meter	Unknown
Domestic	Simple fall < 1.5 meter	TCA, SSRI
Domestic	Simple fall < 1.5 meter	Anti-depressant
Domestic	Fall from height ≥ 1.5 meter	Anti-psychotic medication
Unknown	Fall from height ≥ 1.5 meter	Unknown
Domestic	Fall from height ≥ 1.5 meter	Benzodiazepines
Psychosis	Fall from height ≥ 1.5 meter	Unknown



CHAPTER 8

FUNCTIONAL OUTCOMES AND QUALITY OF LIFE IN PATIENTS WITH SUBTALAR ARTHRODESIS FOR POSTTRAUMATIC ARTHRITIS

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Abstract

Introduction

Subtalar arthrodesis is a common salvage operation for posttraumatic subtalar arthritis, a condition frequently seen in patients who suffered major trauma. Functional outcomes in trauma patients may be influenced by concomitant injuries and the severity of the initial trauma. The aim of this study was to evaluate quality of life and functional outcomes of subtalar arthrodesis for posttraumatic arthritis in patients with severe or complex foot injuries.

Materials and methods

This is a retrospective single center study with prospective follow-up. Patients who underwent subtalar arthrodesis for posttraumatic arthritis between 2000 and 2016 were included and invited to complete a Maryland Foot Score (MFS), a EuroQol five-dimensional (EQ-5D™) and Visual Analog Scale (EQ-VAS™) questionnaire, and four additional questions.

Results

Forty patients were included in the study, functional outcome scores were available for 30 patients (response rate 75%). Additional surgery of the fused foot was performed in 29 patients and 15 suffered multiple lower extremity injuries. Six patients were polytraumatized. Ninety percent of all patients would recommend the procedure to others, walking abilities improved in 69% and less pain was experienced in 76%. Median MFS score was 61 (IQR 53 – 72). Quality of life was significantly lower when compared to a reference population ($p < 0.001$).

Conclusion

Satisfaction was high, as 90% of all patients would recommend subtalar fusion to others, even though the relatively poor outcome measures would suggest differently. Existing functional outcomes measures were influenced by concomitant injuries and additional procedures. This demands development of instruments suitable for severely injured patients with multiple or complex injuries.

Introduction

Subtalar arthrodesis is used for a variety of conditions, such as primary subtalar arthritis, congenital deformities, and inflammatory deformities. [1-3] The goals of subtalar fusion include pain relief, deformity correction, and functional improvement. [4] In trauma patients, subtalar arthrodesis is a common salvage operation for posttraumatic subtalar arthritis, mainly caused by calcaneal or talar fractures. [2, 5-8] Patients who sustain these types of fractures frequently have additional injuries, such as trauma to the midfoot or ankle joints. Furthermore, fractures of the hindfoot are often found in polytraumatized patients and it has been demonstrated that lower extremity injuries have a detrimental impact on the functional recovery. [9] As a result of the above, outcomes in a population of patients who undergo subtalar fusion for posttraumatic arthritis may be influenced by concomitant injuries and a poorer overall state of health.

There is paucity of data on subtalar fusion focusing on trauma patients explicitly and the best results for posttraumatic arthritis have been described after arthroscopic procedures in patients with isolated subtalar arthritis with minimal or no deformity, no significant bone loss, and no need for a concomitant anterior foot procedure. [4, 10-12] However, it might be that most patients with severe foot injuries do not fit these criteria, causing an overestimation of functional outcomes of subtalar arthrodesis after major trauma. In addition, as poor quality of life after calcaneal fractures has been described, subtalar fusion might lead to improvement of this poor baseline situation. [13, 14] The aim of the present study was to evaluate quality of life and functional outcomes of subtalar arthrodesis for posttraumatic arthritis in patients with severe or complex foot injuries.

Materials and Methods

Study design and settings

A single level 1 trauma centre retrospective cohort study with a follow-up by questionnaire was performed after institutional review board approval. Patients were selected by searching for operation codes for subtalar arthrodesis. All patients who underwent a subtalar arthrodesis for posttraumatic arthritis between January 2001 and January 2016 were invited to complete two questionnaires and four additional questions. Patients who deceased, resided in a foreign country, had amputation of the fused foot, were under the age of 16 at date of trauma or under the age of 18 during the conduct of the study, were excluded from participation. Patients who did not respond within 3 weeks were contacted by telephone to verbally administer the questionnaires.

Outcome measures and explanatory variables

Explanatory variables were derived from the Dutch National Trauma Database (DNTD) and electronic patient documentation. The DNTD contains prospectively collected documentation on demographics, trauma mechanism, sustained injuries, findings from radiologic imaging, and department of admission for all patients admitted to the University Medical Center Utrecht (UMCU) after a trauma. Data on smoking and BMI were omitted when recorded more than two months before or after the arthrodesis. A second researcher (GA) crosschecked a random 20% sample of the retrospectively collected data to ensure a robust database. Patients were considered polytrauma when an ISS of 16 or higher as a result of injury in two or more body regions was found.

The indication to perform a subtalar arthrodesis was made by a trauma surgeon based on clinical and radiologic assessment. Radiologic examination of the subtalar joint focused on signs of arthritis such as subchondral sclerosis, osteophytes, joint space narrowing, and deformation of the joint space. Clinical assessment was based on the expertise of the surgeon; in some cases effects of diagnostic steroid injection or diagnostic cast immobilization attributed to the decision-making. Postoperatively, the position of hardware and the degree of consolidation were assessed by radiologic imaging. Standard X-ray examination included antero-posterior and lateral weight-bearing views. In case a patient underwent bilateral subtalar fusion, only data on the first procedure were studied as not to violate the statistical assumption of independence.

Quality of life was assessed using the EuroQol five-dimensional (EQ-5D™) questionnaire. The EQ-5D™ covers five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) that are all divided into three levels (no problems, moderate problems, or extreme problems) with lower scores representing poorer quality of life. [15] EQ-5D™ scores for the study population were calculated using the Dutch tariff. [16] Additionally, the EuroQol Visual Analog Scale (EQ-VAS™) was assessed. This score represents a patient's self-rated health status on a scale from 0 to 100, a score of 0 being the worst imaginable and a score of 100 being the best imaginable health state.

Functional outcomes were evaluated by the Maryland Foot Score (MFS). The MFS consists of 10 questions assessing pain and function, with a score of 100 representing a normal pain-free foot. MFS outcome scores are categorized into four categories; failure (<50), fair outcome (50-74), good outcome (75-89), and excellent outcome (90-100). [17]

In addition to the questionnaires, patients were asked whether 1) they underwent surgery to their feet in another hospital, 2) the subtalar arthrodesis reduced the pain in their feet, 3) the subtalar arthrodesis improved their walking abilities, and 4) they would recommend the subtalar arthrodesis to family and friends if they were in exactly the same situation as they were before the subtalar arthrodesis.

Statistical analysis

Continuous variables are presented as medians with interquartile ranges (IQR), categorical variables as frequencies with percentages. The Shapiro-Wilk test was performed to determine if continuous variables were normally distributed; non-parametric tests were used for further analyses. Categorical variables were analyzed using the chi-square test and, in case of a cell count of 5 or less, the Fisher's exact test. The relations between continuous outcome measures and explanatory variables were assessed using the Mann-Whitney U test for dichotomous variables, the Kruskal-Wallis test for categorical variables, and the Spearman's rank correlation for continuous variables. EQ-5D™ scores were compared with values of a Dutch reference population of approximately the same age as the study subjects by the two-sample T-test. [18] Correlations between the EQ-5D™ and MFS scores were established using Pearson's correlation coefficient. Statistical analyses were performed using IBM SPSS Statistics version 24 (IBM Corp., Armonk, NY) for Mac. A p-value of <0.05 was considered significant.

Results

Baseline characteristics

A total of 40 patients met the inclusion criteria. Thirty out of 40 questionnaires (75%) were completed. An overview of the inclusion and response process is shown in figure 1. Two patients had to be excluded because of ineligibility for follow-up due to severe complications after the arthrodesis (amputation of the fused foot and talar extirpation because of avascular necrosis). Demographics, trauma mechanisms and initial injuries of all patients are depicted in table 1. No significant differences were found between responders and non-responders. The major part of the study population consisted of middle-aged men. The median ISS was 4 and 6 patients were polytrauma patients. All polytrauma patients had additional lower extremity injuries and an extra 9 patients suffered additional injuries to the lower extremities, making a total of 15 patients with multiple injuries to the affected limb. Most common were injuries to the ipsilateral foot or ankle (33%). Nineteen subtalar arthrodeses were performed for posttraumatic arthritis after a calcaneal fracture, a talar fracture (6 in total) being the second most frequent indication for subtalar fusion. Twenty patients received operative treatment for their initial foot injury, with four patients developing malunion of their fracture. An overview of the initial treatment and complications is provided in table 2.

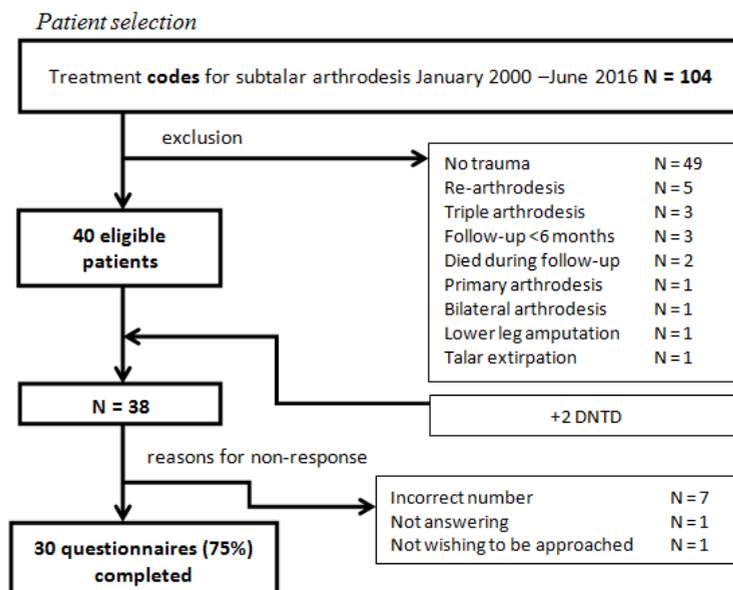


Figure 1: Flow-chart on inclusion and response

Table 1: Baseline characteristics (n = 40).

	Median	IQR
Age (years)		
At trauma	37	26 – 47
At subtalar arthrodesis	45	33 – 53
At follow-up	51	42 – 58
Body Mass Index*	26	22 – 28
Injury Severity Score	4	4 – 9
	N	%
Men	29	73
Diabetes	2	5
Polytrauma	6	15
Mechanism of injury		
Fall <3m	11	28
Fall ≥3m	7	18
Motor vehicle accident	8	20
Motorcycle accident	3	8
Other/unknown	11	28
Additional lower extremity injuries		
Ipsilateral	13	33
Contralateral	11	28
None	25	63
Initial foot injury		
Calcaneal fracture	19	48
Talar fracture	6	15
Calcaneal + talar fracture	4	10
Ankle fracture	1	3
Ankle fracture + calcaneal/talar fracture	2	5
Luxation + calcaneal/talar fracture	3	8
Luxation	3	8
Minor trauma**	2	5

IQR = interquartile range; N = number

*Body Mass Index available for 26 patients (65%)

**Minor trauma includes ankle sprain and unknown minor trauma

Table 2: Initial treatment and complications of initial treatment and subtalar arthrodesis (n = 40).

	N	%
Initial treatment		
Operative management	20	50
Non-operative management	14	35
External fixation	4	10
Unknown	2	5
	N (OM/NOM/ex-fix)	%
Complications of initial treatment		
Superficial wound infection	0 (0/0/0)	0
Deep wound infection	7 (4/0/3)	18
Osteomyelitis	0 (0/0/0)	0
Malunion	4 (3/1/0)	10
No complications	17 (11/5/1)	43
Unknown	12* (2/8/0)	30
	N	%
Complications of subtalar arthrodesis		
Superficial wound infection	1	3
Deep wound infection	4	10
Failed arthrodesis	5	13
No consolidation	2	5
Delayed consolidation	9	23
Consolidation unknown	7	18
No complications	12	29
Other**	5	12

N = number; OM = operative management; NOM = non-operative management; ex-fix = external fixation

*Complications unknown for the unknown initial treatments (n = 2)

**Other complications include impingement, dystrophy

Subtalar arthrodesis

The median interval between trauma and subtalar arthrodesis was 23 months (IQR 13 – 50), the median interval between arthrodesis and follow-up by questionnaire 6.8 years (IQR 3.7 – 9.9). All arthrodeses were performed during an open procedure, no arthroscopic procedures took place. In most cases (31 patients) a single screw procedure was performed, 6 patients underwent treatment with two screws and in 3 cases no hardware was used. After nine months, in 22 patients good subtalar fusion was reached. Nine additional patients reached consolidation after this time span; resulting in a fusion rate of 94% (fusion was unknown in 7 cases). Additional procedures to the fused foot, including arthrodeses of other parts of the foot, alignment corrections, and tendon corrections, were performed in 29 patients.

Questionnaire results

The median EQ-5D™ score was 0.78 (IQR 0.41 – 0.78), the median EQ-VAS™ score 53 (IQR 44 – 75) (table 3). For the MFS, the median score was 61 (IQR 53 – 72) with 60% of all patients having a ‘fair’ MFS score (score 50 – 74) (table 3). Correlation between the MFS and EQ-5D™ scores was 0.69 ($p < 0.001$). In comparison with a Dutch reference population (mean EQ-5D™ 0.89), (19) quality of life in our study population was significantly lower ($p < 0.001$).

Table 3: Outcome scores (n = 30).

Questionnaire	Median	IQR
EQ-5D™	0.78	0.41 – 0.78
EQ-VAS™	53	44 – 75
MFS	61	53 – 72
	N	%
Excellent (MFS 90 – 100)	1	3
Good (MFS 75 – 89)	4	13
Fair (MFS 50 – 74)	18	60
Failure (MFS <50)	7	23
Additional questions*		
Less pain after arthrodesis	22	76
Improved walking abilities	20	69
Would recommend to family and friends	26	90

EQ-5D™ = EuroQol five-dimensional questionnaire; EQ-VAS™ = EuroQol Visual Analog Scale; MFS = Maryland Foot Score; N = number

*Additional questions were completed by 29 patients

When comparing scores of those patients with additional injuries to the lower extremities and scores of those without, MFS scores were respectively 56 and 61 ($p = 0.502$). Patients who underwent additional procedures to the foot had median MFS scores of 55, compared with 67 in patients who did not undergo additional surgery ($p = 0.162$). In the group of patients who underwent additional procedures, a ‘good’ MFS score (score ≥ 75) was reported by only one patient (outcomes available for 21).

Patient satisfaction

Ninety percent of all patients would recommend a subtalar fusion to their family and friends if they had been in the exact same situation as they were before the procedure. Less pain was experienced by 76% ($n = 22$) and improved walking abilities by 69% ($n = 20$). The patients who would not recommend the procedure were found to have high pain scores,

severe limitations in walking abilities, low quality of life, and low MFS scores. Interestingly, the two patients with the worst quality of life scores would still recommend subtalar fusion.

Patients with poor outcome scores

Seven patients had an MFS score <50. Quality of life in this subgroup was lower when compared to patients with MFS scores ≥75 (n = 5) as well; 0.27 versus 0.81. Explanatory variables and outcome scores for patients with poor MFS scores versus good and excellent scores are presented in table 4. In the poor outcome group, 4 patients (75%) developed a complication after the subtalar fusion (infection, no consolidation) versus 0 (0%) in the other group. Furthermore, 6 patients (86%) with poor scores underwent additional procedures to the foot against 1 (20%) in group with better outcomes.

Table 4: Comparison of patients with poor and better MFS scores.

	MFS <50 (n = 7)	MFS ≥75 (n = 5)
	Median (IQR)	Median (IQR)
Age (years)		
At trauma	33 (25 – 42)	40 (26 – 49)
At subtalar arthrodesis	36 (27 – 55)	48 (27 – 55)
At follow-up	40 (45 – 64)	53 (37 – 62)
Injury Severity Score	9 (4-13)	4(4-8)
	N (%)	N (%)
Men	3 (43)	4 (80)
Polytrauma	1 (14)	0 (0)
Additional lower extremity injuries	4 (57)	2 (40)
Operative treatment for initial trauma	7 (100)	2 (40)
Additional procedures to foot	6 (86)	1 (20)
Complications of subtalar arthodesis	4 (57)	0 (0)
	Median (IQR)	Median (IQR)
EQ-5D™	0.27 (0.15 – 0.43)	0.81 (0.78 – 0.87)
EQ-VAS™	40 (20 – 70)	75 (63 – 90)

MFS = Maryland Foot Score; IQR = interquartile range; N = number; EQ-5D™ = EuroQol five-dimensional questionnaire; EQ-VAS™ = EuroQol Visual Analog Scale

Discussion

This study shows that patients who underwent subtalar arthrodesis for posttraumatic arthritis after severe or complex foot injuries experienced less pain and had improved walking abilities after the procedure. In total, 90% of all patients were satisfied with the results and would recommend a subtalar fusion to others. However, functional outcome scores in our cohort seem to be poor when compared to the sparse previously published data.

In only two out of 16 articles included in a review on outcomes of tarsal fusions for a variety of hindfoot conditions, [4] a substantial amount of the included patients underwent open arthrodesis for posttraumatic arthritis. [19, 20] Outcomes in these studies were assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot scale, ranging from 0 to 100 with a higher score representing a better outcome, similar to the MFS. [21] Garras et al. found a mean AOFAS score of 70.9 after subtalar distraction arthrodesis with allograft, [20] Eid et al. reported an average score of 78 after minimally invasive arthrodesis with autograft. [20] A statistically significant correlation between MFS and AOFAS scores ($r = 0.84$, $p < 0.001$) in patients who underwent subtalar fusion for calcaneal fractures has been described. [7] Taking that into account, our median MFS score of 61 after subtalar fusion still appears to be slightly worse than previously described outcomes. The relatively poor outcome scores of our patients may be influenced by the concomitant injuries and the severity of the initial foot trauma since 15 patients (38%) suffered additional lower extremity injuries. Most likely, this is a result of the field triage as nearly only patients who underwent high-energy trauma were treated at our level 1 center. For example, Eid and colleagues excluded patients with severe varus malalignment of the heel and symptomatic calcaneocuboid arthritis, which may be responsible for the relatively good functional outcome scores in their study. [19] In addition, the majority of patients included in the present study required additional surgery to their feet due to concomitant injuries. This implicates that the outcome scores in the present study might not depict functional outcomes of subtalar arthrodesis alone; they may be affected by other injuries and procedures, leading to an underestimation of functional outcomes of subtalar arthrodesis on its own. This hypothesis is supported by the fact that nearly all patients with poor outcomes underwent additional surgery and that only one of these patients reported a 'good' MFS score. Even though not statistically significant, poorer MFS scores were found in patients with additional lower extremity injuries (56 versus 61) and additional surgery (55 versus 67). In a previously published study, 77% of 47 patients who underwent subtalar arthrodesis for either primary or secondary osteoarthritis reported that if given the choice once again, they would pursue

the same course of treatment despite dissatisfaction with the postoperative results in 62%. [22] The recommendation rate in our cohort was slightly higher, as 90% would recommend this procedure to friends and family. The fact that even the patients with the poorest MFS scores experienced improvement and would recommend the procedure supports our hypothesis that existing questionnaires may not be suitable to measure specific outcomes in severely injured patients, because they do not account for concomitant injuries and other circumstantial factors. This is also implicated by the finding that the two patients with the worst quality of life scores would still recommend a subtalar fusion to others, as their disability may not be related to their hindfoot injury.

When compared with the general Dutch population, quality of life of the patients included in this study was significantly lower. Regardless of treatment type, calcaneal fractures are known to cause impaired health status. [23] In line with our results, Alexandridis et al. showed that calcaneal fractures, the most common cause of subtalar arthritis in the present study, sustain a life-altering trauma resulting in chronic disability and lower QOL when compared to a reference population. [14] In addition, MFS and EQ-5D™ scores were found to be highly correlated (Pearson's r 0.69; $p < 0.001$). Correlation between foot injuries and quality of life has been reported before, with presence of a foot injury causing poorer quality of life. [24, 25]

A majority of the patients with poor functional outcome scores (57%) developed a complication after the subtalar fusion against none in the group of patients with good outcomes. This suggests that a complicated postoperative course is an indicator of poor functionality. To our knowledge, no previous study reported the association between outcome after subtalar arthrodesis and postoperative complications. [22]

This study has several limitations. First, due to the retrospective design of part of the study, information bias may have occurred. Twenty percent of the database has been verified by another researcher (GA) to detect inconsistencies in all retrospectively collected data; less than 5% of the data were discrepant, and discrepancies were not consistent within one variable. Therefore, we consider this a minor limitation. Second, there is a risk of non-response bias. Because no significant differences in baseline characteristics were found between responders and non-responders and because of the high response rate, we believe that this was of limited influence on our results. Third, no baseline functional outcome scores were available. We tried to account for this by asking patients whether their walking abilities and level of pain improved after the subtalar arthrodesis. Fourth, functional

outcomes were assessed by using the Maryland Foot Score. Both the AOFAS hindfoot scale and the MFS are two widely accepted scoring systems to assess functional outcomes after intra-articular fractures of the calcaneus, and are both highly correlated with indication for arthrodesis. [7] In contrast with the AOFAS hindfoot score, the MFS does not demand a clinical examination, which might lead to increased response rates. Unfortunately, the MFS has not yet been validated in Dutch. We reached group consensus on translation of the original English questionnaire and are convinced of its accuracy.

Conclusion

This study demonstrated that 90% of all patients who underwent subtalar fusion for posttraumatic arthritis were satisfied with the results of the procedure, even though the relatively poor functional outcome scores would suggest differently. In 29 patients additional surgery of the fused foot was performed and 15 suffered multiple (lower extremity) injuries with 6 patients being polytraumatized. Most likely, functional outcome scores have been influenced by these additional injuries and procedures. Since existing questionnaires on functional outcomes do not take these factors into account, we would like to emphasize the need for development of instruments to assess outcomes in severely injured patients with complex or multiple injuries.

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CHAPTER 9

GENERAL DISCUSSION AND FUTURE CONSIDERATIONS

General discussion and future considerations

Calcaneal fractures are relatively rare; however, these fractures are known to cause significant long-term disabilities that influence the daily life of the affected individual negatively. [1] The aim of this project was to evaluate the consequences of a calcaneal fracture on the affected individual and to gain knowledge on aspects that determine the patient-reported outcome. Furthermore, to develop accurate and efficient management strategies and inform patients more accurately about possible outcomes.

The data presented in this thesis are the result of a cooperation between four trauma centers participating in the central trauma region in the Netherlands. One level I trauma center (University Medical Center Utrecht) and three level II trauma centers (St. Antonius Hospital, Diaconessen Hospital and Meander Medical Center).

From this thesis two general conclusions may be deduced. Firstly, patients that endured a calcaneal fracture have a lower health-related quality of life (HRQoL) than the Dutch reference population. [2] Secondly, there is a large heterogeneity in the demographic, injury and fracture characteristics in patients who sustained a calcaneal fracture.

In this thesis, HRQoL measured with the EuroQol 6D (EQ-6D) was used as primary outcome [3, 4]; *chapter 2* shows that all dimensions of the EQ-6D are negatively affected, independently of socio-economic status, associated injuries, or severity of injury. The EQ-6D dimensions that address the physical aspects, such as 'mobility' and 'pain / discomfort' are notably negatively affected in comparison to the Dutch reference population.

Chapter 3, 6 and 8 demonstrate that a substantial proportion of the patients with a displaced intra-articular calcaneal fracture experienced problems with pain or problems with their mobility after their primary operative treatment that later needed additional operative treatment; also, the greater majority of patients with a calcaneal fracture is not completely satisfied with the range of shoes that they can wear and experience discomfort in their affected foot. These results are reflected in the EQ-6D dimensions 'mobility' and 'pain / discomfort' where many patients experience problems (respectively, 70% and 78%).

Not only the physical dimensions of the EQ-6D are affected, but also the mental dimensions 'anxiety / depression' and 'cognition' are affected. Interestingly, *chapter 7* compares patients with a comorbid psychiatric disorder to patients without a comorbid psychiatric disorder;

that particular chapter shows that patients with a comorbid psychiatric disorder report more problems with their cognitive abilities. Though, the overall results show no significant unfavorable patient-reported outcomes in patients with a comorbid psychiatric disorder.

All these findings on HRQoL provide direction to improve the outcome results in patients with a calcaneal fracture with a change in management strategy. Perhaps addressing the mental dimensions in close cooperation with other specialties such as the rehabilitation physician, psychiatric or psychological consultation, might improve the outcome in these particular dimensions. To improve the outcomes in the physical dimensions it may be helpful to have a close cooperation between a rehabilitation physician, an orthopedic (trauma) surgeon, a physiotherapist and a podiatrist. Also, the further development of current orthotics may be useful to limit the sequelae of the calcaneal fracture, such as long-term complications (wound infection and posttraumatic subtalar arthritis) because long-term complications showed to be associated with unfavorable patient-reported outcomes (see *chapter 6*) and led to more additional operative treatments (see *chapter 6 and 8*).

The second general conclusion states that there is heterogeneity in the demographic, injury and fracture characteristics. As for the heterogeneity in demographic characteristics *chapter 4* provides the insight that the trauma level II population differs substantially from the trauma level I population. It further reveals that the trauma level II center has a substantial proportion of patients that were 70 years or older at time of trauma. Also, the trauma level I population had a large proportion of patients that have a comorbid psychiatric disorder that reported significantly unfavorable patient-reported outcomes in comparison to patients without a psychiatric disorder.

As for the heterogeneity in injury characteristics *chapter 4* demonstrates that the trauma level II population have substantially more isolated calcaneal fractures in comparison to the trauma level I center.

As shown in *chapter 5*, there is also a heterogeneity in the radiographic images of the fracture characteristics. None of the measured angles (Böhler, Gissane and calcaneal compression angle) in the conventional radiographic images are reliably associated with patient-reported outcomes; nor is the Sanders classification. In addition, it is shown that patients with an intra-articular calcaneal fracture into the talar surface have a lower HRQoL, are less satisfied with the outcome of their feet and have more complications compared to patients with other types of calcaneal fractures.

Heterogeneity in the calcaneal fracture population makes it impossible to have an one-size-fits-all policy. All these findings concerning the heterogeneity in demographics, injury and fracture characteristics may contribute to the development of effective management strategies that accounts for the characteristics of the individual patient; acknowledging the existence of different subgroups and creating awareness that these specific subgroups might benefit from customized management can be seen as a first step.

Relevant subgroups that can be distinguished in this thesis are elderly and patients with a comorbid psychiatric disorder. Elderly patients are in general frail; hence, are more likely to develop complications, such as delirium or remain bedridden. They further are more prone to develop urinary tract infection, pneumonia or other infections. It may be a beneficial management strategy in this subgroup to include a geriatric physician in an early stage to optimize the treatment of these patients. In the elderly it can be beneficial to have early geriatric consultation and a specialized combined geriatric medicine and traumatology ward [5]. Moreover, many of the elderly patients endured their fracture due to a simple fall in the residential area. Prevention of these accidents should be explored in cooperation with the local public healthcare services and local government in areas where a high number of elderly live.

Patients with a comorbid psychiatric disorder may benefit from a different management that addresses their cognitive abilities; for example, early additional psychiatric counseling or psychological counseling. Further investigation is needed to which extent calcaneal fracture patients benefit from early additional psychiatric or psychological counseling, or cooperation with a rehabilitation physician.

Moreover, the trauma level II centers showed to have more isolated calcaneal fractures (low-complex) compared to the trauma level I center. As reported in the study of Van Laarhoven et al. implementing a clinical pathway might improve the outcome of these patients and reduce hospital length of stay. [5] A clinical pathway as a management strategy may contain early consultation of a rehabilitation physician and a physiotherapist.

In addition, early expectation management may be useful. It seems that the measured angles in conventional radiographs and Sanders classification is not useful to inform patients with a calcaneal fracture. However, patient with an intra-articular calcaneal fracture into the talar surface should be informed on the significant unfavorable patient-reported outcome results in comparison to other type of fractures; in contrast, patients with an extra-articular

fracture have the opposite result. Based on the aforementioned results and the results from *chapter 6* it is advised that patients should be informed on the wide spectrum of limitations, discomforts and complications they might develop after enduring a calcaneal fracture.

There are aspects that are in favor of this thesis. Firstly, there is a general consensus that nonfatal outcomes should be used in the trauma population. [6-9] The EQ-6D survey is in line with the recommendation of the European Consumer Safety Association (ECOSA). [10] The advantage of using HRQoL as outcome measurement is that it can be utilized to evaluate success of treatment and to identify dimensions within the HRQoL that may need improvements. Moreover, the criteria of Efficace et al. for evaluating and reporting HRQoL were used in order to improve the quality of the studies in this thesis. [11] These criteria are a helpful checklist which may support clinical decision making, e.g. reporting of psychometric properties and rationale for use of instrument.

Secondly, several databases were used to identify patients with a calcaneal fracture. With this method we have strived to include all patients with a calcaneal fracture within our trauma region. In every database new patients were identified that were missing in the other databases. The fact that data was missing in some databases might imply that other studies that rely on one database might have missed eligible patients.

Thirdly, the radiographic images in the identified patients were revised in order to check whether the identified patients were truthfully included. The revision of the radiographic images showed that several identified patients did not have a calcaneal fracture.

Fourthly, due to the regional design of most studies in this thesis, these results represent a reliable reflection from the patients', fracture and injury characteristics and the patient-reported outcome result in a trauma population; hence, allow us to generalize the results to other countries with similar demographics and economic welfare.

As most studies, the studies presented in this thesis have some limitations. The studies presented in this thesis have a retrospective design based on prospectively collected data from medical records and multiple databases. Alike most retrospective studies, data collection may be limited by information that was not or incorrectly recorded. The presented studies show to have missing data that was lower than 10%. As a recommendation for the future it may be useful to collaborate more closely on collection of data on trauma patients in a standardized manner. In addition, patterns and injury characteristics may be collected

to inform authorities and policy makers about the resources, investments and improvement programs needed to optimize the care and improve the quality of life of patients with a calcaneal fracture.

In order to gain knowledge on the introduction of new comorbidities and the development in patients with a calcaneal fracture; future research should focus on conducting a longitudinal study with multiple moments of assessment. Preferable assessments over time after 1 year, 3 years, 5 years and perhaps even a longer follow up. Moreover, this thesis shows heterogeneity in the population with calcaneal fractures. In order to demonstrate convincing results the number of participating patients should be increased. To increase the number of participating patients cooperation with other trauma regions (national or international) might be needed because the incidence of calcaneal fractures is relatively low (11.5 to 13.7 per 100,000 persons). [12-14] Further investigation in the prevention of these long-term complications may be beneficial, e.g. preventing posttraumatic arthritis on a molecular level, or further exploration of implant, transplant, regenerative or reconstructive means.

Overall, this thesis demonstrates that patients who endured a calcaneal fracture have a lower HRQoL than the reference population; implicating that these patients had a life-altering event that resulted in a chronic disability. Moreover, this thesis offers multiple opportunities to improve the outcomes of these patients that may be directly implemented in current practice such as tailor-made management for specific subgroups and close cooperation between healthcare providers. Also, this thesis reveals fracture characteristics that are associated with patient-reported outcomes that may be used to inform patients early and more accurately. In addition, further research is needed to improve the outcomes of these patients, e.g. a longitudinal study in multiple trauma regions that evaluate different management strategies per subgroup.

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APPENDIX

ENGLISH SUMMARY

Summary

Calcaneal fractures are relatively rare; however, these fractures are known to cause significant long-term disabilities that influence the daily life of the affected individual negatively. The aim of this project was to benchmark the consequences of a calcaneal fracture on the affected individual and to gain knowledge on aspects that could determine the outcome. In order to develop accurate and efficient management strategies and inform patients more accurately about possible outcomes.

A part of the data presented in this thesis are the result of a cooperation between four trauma centers participating in the central trauma region in the Netherlands. One level I trauma center (University Medical Center Utrecht) and three level II trauma centers (St. Antonius Hospital, Diaconessen Hospital and Meander Medical Center).

Chapter 2 presents a systematic review of the literature concerning the health-related quality of life after a displaced intra-articular calcaneal fracture. Thirty-two articles were available for critical appraisal; afterwards, thirteen studies were available for extracting data. This review shows that a displaced intra-articular calcaneal fracture is a life-changing event for most patients. The health-related quality of life is substantially lower in comparison to the period before the trauma and to the general population, in particular the subdomains related to the physical domain are affected. In addition, this review reveals that the identified studies have a medium to high risk of bias. Consequently, it is challenging to make reliable and valid conclusions.

In *chapter 3* an overview of patient characteristics and outcome results of patients with a calcaneal fracture in a Dutch trauma level 1 center are provided. This was a retrospective cohort study in which all patients that sustained a calcaneal fracture and were 16 years or older at time of admission were included. Ninety-three patients with 114 calcaneal fractures participated in this study. The median EQ-5D index value is 0.78. All dimensions of the EQ-6D are affected, in particular the dimensions 'mobility', 'pain/discomfort' and 'usual activity'. This chapter demonstrates that patients who sustained a calcaneal fracture have a significantly lower health-related quality of life than the Dutch reference population and suffer from a chronic disability. Moreover, patients that have comorbidity, a relevant psychiatric disorder or are female have significantly lower health-related quality of life scores. Furthermore, this chapter shows that socio-economic status, associated injuries, or severity of injury did not influence the health-related quality of life in this study population.

Chapter 4 evaluates in detail the characteristics of patients with a calcaneal fracture in a regional inclusive trauma system; moreover, compares these characteristics between level 1 and 2 trauma care centers. This is a retrospective regional cohort study of prospectively collected data. All patients aged 16 years or older with a calcaneal fracture admitted in one of the participating trauma level I or II hospitals were included. A total of 285 patients with 307 calcaneal fractures were eligible for analysis. A mechanism of trauma was in most patients a fall from height, followed by a simple fall. The greater majority of the accidents occurred in domestic circumstances, 70% of the patients had an isolated calcaneal fracture. The trauma level I population was significantly younger, sustained a more severe injury with more concomitant injuries, and 26% had a psychiatric disorder. These differences should be accounted for in the interpretation of results according to the level of trauma care that a particular hospital offers. Additionally, in the trauma level II centers more low-complex calcaneal fractures and distinctively other subgroups (e.g. elderly) are admitted that might benefit from customized management to adapt to their specific needs.

The association of type of calcaneal fracture, measurement results of conventional radiograph angles and the Sanders classification with patient-reported outcomes are evaluated in *chapter 5*. 215 patients with 246 calcaneal fractures participated. Patients with a calcaneal fracture into the talar surface reported a lower quality of life, were less satisfied with their feet and had more complications; extra-articular fractures had significantly opposite result. A negative Böhler's or calcaneal compression angle was related with unfavorable outcomes. Sanders classification was not related with any patient-reported outcome. This chapter implies that patients with an intra-articular calcaneal fracture into the talar surface have unfavorable patient-reported outcomes compared to patients with other type of calcaneal fractures. Furthermore, the Sanders classification was not associated with the patient-reported outcomes.

In *chapter 6* the long-term outcomes in patients with a displaced intra-articular calcaneal fracture, based on patient-reported outcomes, complications, and developments after primary fracture treatment were evaluated. 117 patients with 133 calcaneal fractures participated in this multicenter retrospective study based on prospective trauma databases. 56% of the fractures had additional operative treatment. Approximately ten percent had a subtalar arthrodesis eventually. Patients frequently reported discomfort with a wide range in severity. Moreover, the EQ-5D index score was significantly lower than the reference population. 48% of the early calcaneal-related complications led to a late calcaneal-related complication, such as wound infection and post-traumatic subtalar arthritis. Patients

with a late-calcaneal related complication reported significantly unfavorable patient-reported outcome results. This chapter demonstrates that a large proportion of patients with a displaced intra-articular fracture report multiple discomforts that influence their lives negatively and needed additional operative treatment. Moreover, calcaneal-related complications that are identified after 6 weeks are associated with significantly unfavorable patient-reported outcomes.

In *chapter 7* the characteristics and outcomes of patients with a calcaneal fracture with and without a comorbid psychiatric disorder within a regional inclusive trauma system are compared. Patients with a comorbid psychiatric disorder had a substantially severe trauma that did not result in unfavorable patient-reported outcomes in comparison with patients without a comorbid psychiatric disorder. However, patients with a comorbid psychiatric disorder were less frequently capable to work and reported more problems with their cognition.

Subtalar arthrodesis is a common salvage operation for posttraumatic subtalar arthritis, a condition frequently seen in patients who suffered major trauma. Functional outcomes in trauma patients may be influenced by concomitant injuries and the severity of the initial trauma. The aim of *chapter 8* was to evaluate health-related quality of life and functional outcomes of subtalar arthrodesis for posttraumatic arthritis in patients with severe or complex foot injuries. This is a retrospective single center study with prospective follow-up. Patients who underwent subtalar arthrodesis for posttraumatic arthritis were included and invited to complete a Maryland Foot Score (MFS), a EQ-5D and Visual Analog Scale (EQ-VAS) questionnaire. Forty patients were included in the study. Additional surgery of the fused foot was performed in 29 patients and 15 suffered multiple lower extremity injuries. This chapter demonstrates that the satisfaction was high, as 90% of all patients would recommend subtalar fusion to others, even though the relatively poor outcome measures would suggest differently.



APPENDIX

NEDERLANDSE SAMENVATTING

Samenvatting

Calcaneusfracturen zijn relatief zeldzaam. Echter, deze fracturen staan bekend dat ze een significante lange-termijn handicap veroorzaken die het dagelijkse leven van het getroffen individu negatief beïnvloedt. Het doel van dit project was om de gevolgen van een calcaneusfractuur op het getroffen individu te benchmarken en kennis te krijgen van aspecten die het resultaat zouden kunnen bepalen. Tevens om nauwkeurige en efficiënte managementstrategieën te ontwikkelen en patiënten beter te informeren over mogelijke uitkomsten.

Een deel van de gegevens die in dit proefschrift worden gepresenteerd, zijn het gevolg van een samenwerking tussen vier trauma centra die deelnemen aan de centrale traumaregio in Nederland. Één trauma level 1 centrum (Universitair Medisch Centrum Utrecht) en drie traumalevel 2 centra (St. Antonius Ziekenhuis, Diaconessen Ziekenhuis en Meander Medisch Centrum).

Hoofdstuk 2 presenteert een systematische review van de huidige literatuur over de gezondheidsgerelateerde kwaliteit van het leven na een verplaatste intra-artculaire calcaneusfractuur. Tweeëndertig artikelen waren beschikbaar voor een kritische beoordeling. Na de kritische beoordeling waren er dertien studies beschikbaar voor data extractie. De kritische beoordeling toont aan dat een verplaatste intra-artculaire calcaneusfractuur een levensveranderende gebeurtenis is voor de meeste patiënten. De gezondheidsgerelateerde kwaliteit van het leven is aanzienlijk lager in vergelijking met de periode voor het trauma en de algemene bevolking, met name de subdomeinen die verband houden met het fysieke domein zijn aangetast. Bovendien blijkt uit deze systematische review dat de geïdentificeerde studies een medium tot hoog risico op bias hebben. Daarom is het uitdagend om betrouwbare en valide conclusies te trekken.

In *hoofdstuk 3* wordt een overzicht gegeven van de patiëntkenmerken en de uitkomst resultaten van patiënten met een calcaneusfractuur in een Nederlands trauma level 1 centrum. Dit was een retrospectieve cohortstudie waarbij alle patiënten geïnccludeerd werden die een calcaneusfractuur hadden en op het moment van opname 16 jaar of ouder waren. Drieënzestig patiënten met 114 calcaneusfracturen hebben deelgenomen aan deze studie. De gemiddelde EQ-5D-index waarde is 0,78. Alle dimensies van de EQ-6D waren lager dan die van de algemene bevolking, met name de dimensies 'mobiliteit', 'pijn / ongemak' en dagelijkse activiteit'. In dit hoofdstuk wordt aangetoond dat patiënten die

een calcaneusfractuur hebben, een significant lager gezondheidskwaliteit hebben dan de Nederlandse referentiepopulatie en een chronische handicap hebben. Bovendien hebben patiënten met een comorbiditeit, een relevante psychiatrische aandoening of een vrouw zijn een aanzienlijk lagere gezondheidsgerelateerde kwaliteit van het leven score. Bovendien blijkt uit dit hoofdstuk dat socio-economische status, andere letsels of ernstig letsel de gezondheidsgerelateerde kwaliteit van het leven in deze studiepopulatie niet beïnvloeden.

Hoofdstuk 4 evalueert de kenmerken van patiënten met een calcaneusfractuur in een regionaal inclusief trauma systeem. Bovendien worden deze kenmerk tussen level 1 en 2 traumacentra vergeleken. Dit is een retrospectieve regionale cohortstudie van prospectief verzamelde data. Alle patiënten van 16 jaar of ouder met een calcaneusfractuur die gezien zijn in een van de deelnemende trauma level 1 of 2 ziekenhuizen werden geïdentificeerd. In totaal kwamen 285 patiënten met 307 calcaneusfracturen in aanmerking voor analyse. Een mechanisme van trauma was in de meeste patiënten een val van hoogte, gevolgd door een eenvoudige val. De meerderheid van de ongevallen vond plaats in de huiselijke sferen, 70% van de patiënten had een geïsoleerde calcaneusfractuur. De populatie van het trauma level 1 was significant jonger, bleek een ernstiger letsel te hebben met meer verwondingen en 26% had een psychiatrische aandoening. Deze verschillen dienen in de interpretatie van de resultaten te worden vergeleken volgens het niveau van de traumazorg die een bepaald ziekenhuis aanbiedt. Daarnaast worden op in de trauma level 2 centra meer laag-complexe calcaneusfracturen en andere onderscheidende andere subgroepen (bijvoorbeeld ouderen) gezien. Deze zouden kunnen profiteren van een aangepast management die voldoet aan hun specifieke behoeften.

In *hoofdstuk 5* werd de associatie van het type calcaneusfractuur, de meetresultaten van de conventionele röntgenhoeken en de Sanders-classificatie met door de patiënt zelf gerapporteerde resultaten geëvalueerd. 215 patiënten met 246 calcaneusfracturen hebben deelgenomen. Patiënten met een calcaneusfractuur in het talaire gewrichtsoppervlak meldden een lagere gezondheidsgerelateerde kwaliteit van het leven, ze waren minder tevreden met hun voeten en hadden meer complicaties. Extra-articulaire fracturen hadden een significant tegengesteld resultaat. Een negatieve Böhler of calcaneus- compressiehoek was gerelateerd aan ongunstige resultaten. De Sanders classificatie was niet gerelateerd aan een door patiënt gerapporteerde uitkomst. Dit hoofdstuk impliceert dat patiënten met een intra-articulaire calcaneusfractuur in het talaire gewrichtsoppervlak ongunstigere patiëntgerelateerde resultaten hebben vergeleken met patiënten met ander type calcaneusfracturen. Bovendien was de Sanders classificatie niet geassocieerd met door de patiënt gerapporteerde resultaten.

In *hoofdstuk 6* werden de lang termijn uitkomsten bij patiënten met een verplaatste intra-articulaire calcaneusfractuur, gebaseerd op door de patiënt gemelde resultaten, complicaties en ontwikkelingen na primaire fractuurbehandeling geëvalueerd. 117 patiënten met 133 calcaneusfracturen hebben deelgenomen aan deze multicenter retrospectieve studie op basis van prospectieve trauma databases. 56% van de fracturen had een aanvullende operatieve behandeling. Ongeveer tien procent had uiteindelijk een subtalar arthrodese. Patiënten meldden vaak ongemak met een breed spectrum in ernst. Bovendien was de EQ-5D index score significant lager dan de referentiepopulatie. 48% van de vroege calcaneus-gerelateerde complicaties leidden tot een late calcaneus-gerelateerde complicatie, zoals wondinfectie en posttraumatische subtalare artritis. Patiënten met een late calcaneale-gerelateerde complicatie meldden significant ongunstige resultaten van de patiënt gerapporteerde uitkomsten. In dit hoofdstuk wordt aangetoond dat een groot deel van de patiënten met een verplaatste intra-articulair fractuur veel ongemakken heeft die hun leven negatief beïnvloeden en extra operatieve behandeling nodig hadden. Bovendien worden calcaneus-gerelateerde complicaties die na 6 weken worden geïdentificeerd geassocieerd met significant ongunstige door de patiënt gerapporteerde resultaten.

In *hoofdstuk 7* worden de kenmerken en resultaten van patiënten met een calcaneusfractuur met en zonder een psychiatrische aandoening in een regionaal trauma systeem vergeleken. Patiënten met een psychiatrische aandoening hadden een substantieel ernstig trauma dat niet noodzakelijk resulteerde in ongunstige patiënt gerelateerde resultaten in vergelijking met patiënten zonder een psychiatrische aandoening. Patiënten met een psychiatrische aandoening waren echter minder vaak in staat om te werken en rapporteerde meer problemen met hun cognitie.

Subtalare arthrodese is een gebruikelijke operatie na posttraumatische subtalare artritis, een aandoening die vaak voorkomt bij patiënten die ernstig trauma hebben gehad. Functionele resultaten bij traumapatiënten kunnen beïnvloed worden door gelijktijdige verwondingen en de ernst van het initiële trauma. Het doel van *hoofdstuk 8* was het evalueren van de gezondheidsgerelateerde kwaliteit van het leven en de functionele resultaten van subtalair arthrodese voor posttraumatische artritis bij patiënten met ernstige of complexe voetbeschadigingen. Dit is een retrospectieve single-center studie met prospectieve follow-up. Patiënten die een subtalare arthrodese ondergaan voor posttraumatische artritis werden opgenomen en uitgenodigd om een Maryland Foot Score (MFS), een EQ-5D en Visual Analog Scale (EQ-VAS) vragenlijst te voltooien. Veertig patiënten werden geïnccludeerd in deze studie. Aanvullende operatie van de voet na subtalare arthrodese

werden uitgevoerd in 29 patiënten en 15 hadden meerdere lage extremiteitsverwondingen. Dit hoofdstuk laat zien dat de tevredenheid hoog was, aangezien 90% van alle patiënten subtalar arthrodese aan anderen zouden aanraden, hoewel de relatief slechte uitkomst resultaten anders zouden voorstellen.



APPENDIX

PUBLICATIONS

Published articles

Patient-reported health-related quality of life after a displaced intra-articular calcaneal fracture: a systematic review.

Alexandridis G, Gunning AC, Leenen LP.

World J Emerg Surg. 2015 Dec 30;10:62.

Health-related quality of life in trauma patients who sustained a calcaneal fracture.

Alexandridis G, Gunning AC, Leenen LP.

Injury. 2016 Jul;47(7):1586-91.

Functional outcomes and quality of life in patients with subtalar arthrodesis for posttraumatic arthritis.

Hollman EJ, van der Vliet QMJ, **Alexandridis G**, Hietbrink F, Leenen LPH.

Injury. 2017 Jul;48(7):1696-1700.

A trauma system wide evaluation of the demographic, injury and fracture characteristics of patients with calcaneal fractures: a comparison of trauma level I and II centers

Alexandridis G, Gunning AC, Van Olden GDJ, Verleisdonk EJMM, Segers MJM, Leenen LPH.

Clin Res Foot Ankle. 2017 5:237.

Submitted articles

Association of pre-treatment radiographic characteristics of calcaneal fractures on patient-reported outcomes.

Alexandridis G, Gunning AC, Van Olden GDJ, Verleisdonk EJMM, Segers MJM, Leenen LPH.

Long-term follow-up outcomes after displaced intra-articular calcaneal fractures: patient-reported outcomes, complications and development after primary fracture treatment.

Alexandridis G, Gunning AC, Van Olden GDJ, Verleisdonk EJMM, Segers MJM, Leenen LPH.

A comparison of calcaneal fracture patients with and without a psychiatric comorbidity: demographic patterns and patient-reported outcomes.

Alexandridis G, Gunning AC, Kromkamp M, Van Olden GDJ, Verleisdonk EJMM, Segers MJM, Leenen LPH.

Conference abstracts

Health-related quality of life after a calcaneal fracture.

Alexandridis G, Leenen LPH.

14th European Congress of Trauma & Emergency Surgery, May 2013, Lyon, France. (Poster)

Health-related quality of life in trauma patients who sustained a calcaneal fracture: a retrospective cohort study.

Alexandridis G, Leenen LPH.

15th European Congress of Trauma & Emergency Surgery & 2nd World Trauma Congress, May 2014, Frankfurt, Germany. (Oral presentation)

Demographic patterns and injury characteristics of patients with a calcaneal fracture in a regional trauma system.

Alexandridis G, Gunning AC, Van Olden GDJ, Verleisdonk EJMM, Segers MJM, Leenen LPH.

17th European Congress of Trauma & Emergency Surgery & 2nd World Trauma Congress, April 2016, Vienna, Austria. (Oral presentation)

Predictive value of pre-treatment radiographic characteristics of calcaneal fracture on patient-reported outcomes

Alexandridis G, Gunning AC, Van Olden GDJ, Verleisdonk EJMM, Segers MJM, Leenen LPH.

9th Dutch North Sea Emergency Medicine Conference, June 2016, Egmond aan Zee, The Netherlands. (Oral presentation)



APPENDIX

CURRICULUM VITAE

Curriculum vitae

Georgios Alexandridis was born on May 30, 1983 in Amsterdam, The Netherlands.

- 2003-2013 Master of Medicine, Universiteit Utrecht, Utrecht, The Netherlands.
- 2013-2018 PhD candidate at University Medical Center Utrecht, Utrecht, The Netherlands.
- 2013-2014 Resident Intensive Care (not-in-training) at St. Elisabeth Hospital, Tilburg, The Netherlands.
- 2014-2015 Resident Intensive Care (not-in-training) at Haga Hospital, The Hague, The Netherlands.
- 2015-2015 Traineeship Emergency Medicine at UZ Leuven, Leuven, Belgium.
- 2016-2017 Resident Emergency Medicine and Intensive Care (not-in-training) at St. Anna Hospital, Geldrop, The Netherlands.
- 2017-2017 Resident Emergency Medicine (not-in-training) at Franciscus Gasthuis, Rotterdam, The Netherlands.
- 2018- Resident Emergency Medicine (in-training) at Franciscus Gasthuis, Rotterdam, The Netherlands.



APPENDIX

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Georgios Alexandridis
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