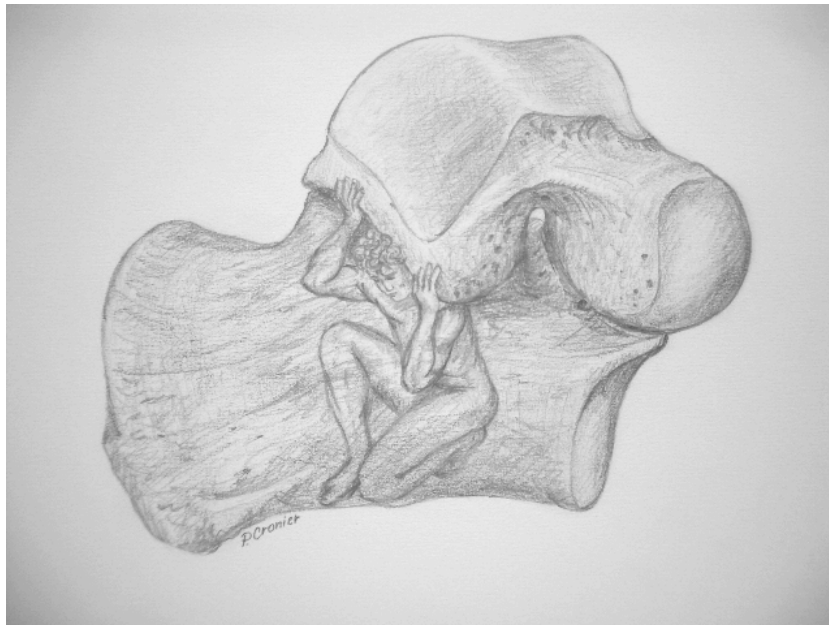


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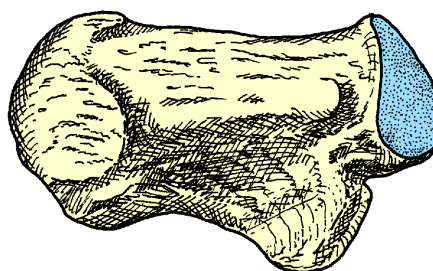
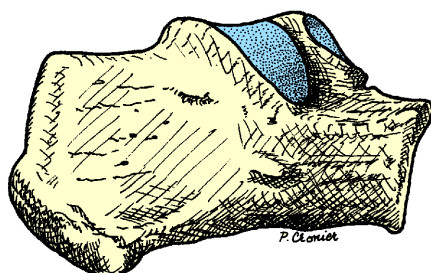
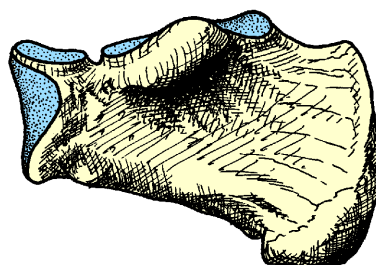
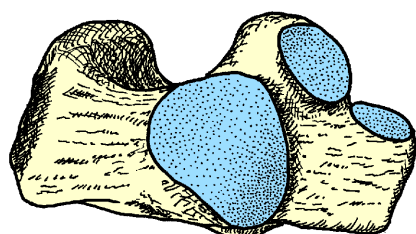
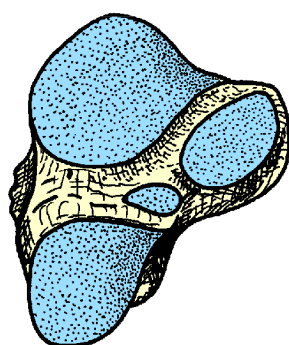
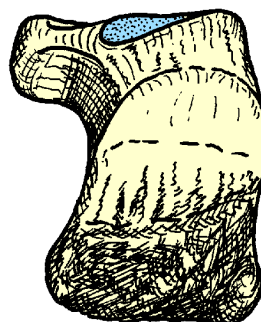
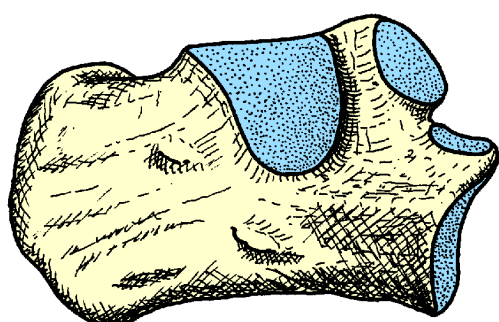
ASPECTS ON CALCANEAL FRACTURES

Per-Henrik Ågren



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Institutet**

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ABSTRACT

This thesis deals with calcaneal fractures. The impetus for this work was to answer the question as to whether to operate or not on calcaneal fractures.

The thesis consists of 4 articles. Two of these are interpretations of the results from a clinical multicentre randomized controlled trial (RCT) that was performed in the Stockholm area between 1994-98. Eighty-two patients were randomized to either surgical or non-surgical treatment. The inclusion criteria were intra-articular calcaneal fractures with a minimum displacement of 2mm, as shown by CT-radiograms.

The first article is a presentation of the study in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement. The material is presented as the result from the effect of either surgical or non-surgical treatment.

The non-surgical treatment was elevation and early movement without weight bearing until healed. The surgical treatment was open reduction and internal fixation (ORIF) when a reduction in swelling and blisters made it possible. The surgery was performed with a lateral extensile approach, aiming for anatomical reconstruction and fixation with plates and screws. The postoperative regimen was similar to the non-surgical treatment. The treating doctor evaluated the cohort clinically several times during the first months.

The patients were followed-up by an unbiased surgeon at 1 year and 8-12 years after the fracture. The primary outcome instruments used were the SF-36 and the VAS-Calcaneal score. We also used the American Orthopaedic Foot and Ankle Society (AOFAS) hind foot score and Olerud Molander Ankle (OM) score.

At 1 year, 76 patients were available and at 8-12 years, 58 patients were available for follow-up. At both times demographic data was similar in both groups in all aspects. In 57% of the patients the surgical result of reduction was <2mm step or gap and in 10% >5mm (failure). This was evaluated with CT postoperatively. Postoperative superficial infections occurred in 8 patients (19%) and deep infections in 2 patients (4%). (One fistula and one uncontrolled infection leading to BKA)

In the first study it was found that there was no statistical significance in the outcome regardless of whether operated or not. There was a tendency towards superiority of surgery after 8-12 years in both SF-36 and VAS-calcaneal scores. The risk for complications was higher with surgical treatment. The prevalence of post-traumatic radiographically diagnosed arthrosis was higher in the non-surgical group, but the need for subtalar arthrodesis was not increased.

In the second article we evaluated the intra- and interobserver reliability and reproducibility of three different classifications for calcaneal fractures. Three examiners (2 radiologists and 1 orthopaedic surgeon) evaluated the films of 51 calcaneal fracture patients, twice with an interval of 5 months. Interobserver reliability was measured with Fleiss' kappa and the intraobserver reproducibility with Cohen's Kappa.

Poor agreement was found both between observers and within observers for Sanders, Zwipp's and Letournel's classifications. The results of this study showed that the tested fracture classification systems (FCS) had some limitations regarding their interobserver reliability and intraobserver reproducibility. All of the obtained kappa values were less than 0.5 indicating less than 50% agreement, which limits the usefulness of the classifications. However, Sanders and Zwipp's classifications have correlated with guiding the treatment and predicting the prognosis. All these parameters should be

borne in mind when using these FCSs in clinical practice. CT scanning helped evaluate the extension of fracture lines into the calcaneo-cuboid joint better than plain X-ray. In the third article the RCT material is analysed from a different viewpoint: Which treatment performs best? The same patients were divided according to their results in the VAS-calcaneal score at 8-12 years follow-up. This gave two groups with 28 patients in each. (2 patients were excluded as they had a result on the median value of the cut-off).

The results of scoring with SF-36, AOFAS and the OM score showed good correlation with the VAS-calcaneal score. The demographic data between the groups showed no difference. It was found that in the better group significantly more patients were involved in light labour and underwent operative treatment with better restoration of the anatomy (Bohler's angle and articular anatomy).

Even though the sample size is small the study suggests that operative treatment with restoration of Bohler's angle and articular surface in patients with light labour and no secondary gain provide superior results in Dislocated Intra Articular Calcaneal Fractures (DIACF). This emphasizes that the definitive decision-making of DIACF is multi-factorial and there is a spectrum of results and trends such as patient demographic features that should be considered in choosing the treatment option.

The fourth article is a retrospective study on a patient data that was developed from all hospitals in Stockholm. All patients that had been operated with an arthrodesis following a calcaneal fracture between 1970-90 were asked to participate and all 29 patients agreed. They were evaluated with Plain WB X-ray, and CT in two planes (as in the RCT). The same patient outcome protocol with VAS-calcaneal score, SF-36, AOFAS and OM-score were used. The radiographic elements were evaluated according to the residual deformity classification developed by Zwipp and Rammelt. These patients had a poor clinical outcome and it was noted that they had major anatomic residual deformities. The poor outcome was compared to our earlier data in the RCT and compared to other studies. This pointed towards the remaining deformity as the likely cause of pain and that in the case of a reconstruction, care should be taken to correct all possible pain causes with the reconstruction.

Perspective:

From this study the impression is gained that the benefits with surgery for calcaneal fractures are outweighed by the risks of surgery. To end up with an amputation is not what patients have in mind. With the increasing risks of infection a less invasive approach or non-surgical management seems to be the solution for many calcaneal fractures. The lower the risk the more benefit of surgical handling. From the conclusions gained in these studies, surgery will not be for everyone. Careful selection of patients and evaluation of their individual needs is mandatory. To avoid surgery when comorbidities are present as well as risk factors is a skill that cannot be underestimated. After all the non-surgical functional treatment can be good in most patients.

It is my opinion that calcaneal fractures primarily and even for late reconstructions, would benefit from being handled by calcaneal specialists. There is enough information suggesting that these fractures and the complexity involved in their handling will benefit from a systematic evolution in care and technical know-how. These injuries should be referred to those surgeons who treat enough cases to maintain their skill and knowledge.

SAMMANFATTNING

Denna avhandling behandlar olika aspekter kring calcaneusfrakturer. Ingressen till mitt arbete var frågan huruvida man bör eller inte bör operera calcaneusfrakturer?

Avhandlingen består av fyra artiklar. Två av dessa handlar om resultaten från en klinisk RCT - multicenterstudie som genomfördes i Stockholmsområdet mellan 1994-1998. Åttiotvå patienter randomiserades till antingen kirurgisk eller icke-kirurgisk behandling. Inklusionskriterierna var en intraartikulär calcaneusfraktur med en minsta förskjutning av 2 mm, mätt på CT-rtg.

Den första artikeln är en presentation av materialet enligt CONSORT. Materialet presenteras som ett resultat av effekten av respektive behandling enligt principen ”intention-to-treat”.

Den icke-kirurgiska behandlingen innebar högläge för avsvällning och tidiga aktiva rörelser utan viktbelastning tills läkt. Den kirurgiska behandlingen var ORIF när svullnad och blåsor gjort det möjligt. Operationen utfördes med en lateral ”extensile” L-formad lateral lambå och målet var en anatomisk rekonstruktion och fixering med plattor och skruvar. Den postoperativa behandlingen liknade den icke-kirurgiska. Patienterna följdes kliniskt av den behandlande läkaren flera gånger de första månaderna.

Patienterna inbjöds till uppföljning av en opartisk kirurg vid 1 år och 8-12 år efter frakturen. De primära utfallsinstrumenten var SF-36 och VAS-Calcaneal score. Vi använde också AOFAS hindfoot score och OM score.

Vid 1 år var 76 patienter tillgängliga och vid 8-12 år 58 patienter tillgängliga för utvärdering. Båda gånger var de demografiska uppgifterna statistiskt likartade i båda grupperna i alla aspekter.

I 57 % av de opererade patienterna var felställningen $< 2\text{mm}$ (step eller gap) och i 10 % $> 5\text{mm}$ (failure). Detta utvärderades med CT postoperativt.

Postoperativa ytliga infektioner uppträdde hos 8 patienter (19 %) och djupa infektioner i två patienter (4%) (en fistel och en okontrollerbar infektion ledande till underbensamputation).

Våra resultat i den första studien var att det inte fanns någon statistisk signifikans i resultatet vare sig man opererats eller inte. Det fanns en tendens att operation verkade vara bättre efter 8-12 år mätt i SF-36 och VAS- calcaneal score. Risken för komplikationer var högre med kirurgisk behandling. Den allmänna förekomsten av posttraumatiskt radiografiskt diagnostiserad artros var högre i den icke-kirurgiska gruppen, men behovet av subtalar artrodes ökade inte.

I den andra artikeln utvärderades intra- och interobserver tillförlitlighet och reproducerbarhet av tre olika klassificeringar för calcaneusfrakturer (FCS). Tre undersökare (2 radiologer och 1 ortoped) utvärderade röntgenfilmer från 51 calcaneus fraktur-patienter två gånger med ett intervall på 5 månader.

Mätningen av interobserver tillförlitlighet gjordes med Fleiss' kappa och intraobserver reproducerbarhet mättes med Cohens Kappa.

Vi fann dålig överensstämmelse både mellan observatörer och inom observatörer för Sanders, Zwipps och Letournels klassificeringar. Resultaten av denna studie visade att de testade klassificeringssystemen (FCS) hade begränsningar när det gäller interobserver tillförlitlighet och intraobserver reproducerbarhet. Alla erhållna kappa värden var mindre än 0,5 vilket indikerar mindre än 50 % överensstämmelse, vilket begränsar användbarheten av klassificeringarna. Emellertid har Sanders och Zwipps klassificeringar visats korrelera med resultat av behandling och vara prognostiserande. Alla dessa parametrar bör beaktas när man använder dessa FCS i klinisk praxis. Datortomografi underlättade detektionen av brottlinjer i calcaneocuboidaleden jämfört med vanlig röntgen.

I den tredje artikeln analyseras RCT materialet från en annan vy: Vilken behandling fungerar bäst? Samma patienter delades enligt deras resultat vid 8-12 år med VAS-calcaneal score. Detta gav två grupper med 28 patienter i varje grupp, där 2 patienter uteslöts eftersom de hade ett resultat på medianvärdet av ”cut-off”.

Resultaten av scoring med SF-36, AOFAS och OM-score visade god korrelation med VAS-calcaneal poäng. De demografiska data mellan grupperna visade ingen skillnad.

Vi fann att i den bättre gruppen signifikant fler patienter hade lätt arbete och hade fått operativ behandling med bättre restaurering av anatomin (Böhler-vinkel och led-anatomi).

Även om urvalet är litet i studien tyder den på att operativ behandling med återställande av Böhler-vinkel och ledytan hos patienter med lätt arbete och inga sekundära vinster ger bättre resultat för Dislocerade Intra Artikulära Calcaneus Frakturer (DIACF). Detta understryker att det slutliga beslutsfattandet vid DIACF är multifaktoriellt och det finns ett spektrum av resultat och trender som patientens demografiska egenskaper som bör beaktas vid val av behandlingsalternativ.

Den fjärde artikeln är en retrospektiv studie på ett patientmaterial som utvecklades från alla sjukhus i Stockholm. Alla patienter som hade behandlats med en steloperation efter en calcaneus fraktur mellan 1970-1990 ombads att delta och alla 29 patienterna medgav detta. De utvärderades med belastade bilder vid slätröntgen och CT i två plan (som RCT). Samma patient-uppföljningsprotokoll med VAS-calcaneus score, SF - 36, AOFAS och OM-Score användes.

Vi utvärderade sedan den kvarstående felställningen med de radiografiska elementen enligt den klassificering som utvecklats av Zwipp och Rammelt.

Vårt material hade ett dåligt kliniskt utfall och vi noterade att stora anatomiska felställningar kvarstod. Det dåliga utfallet jämfördes med våra tidigare data i RCT-studien och jämfört med andra studier. Det talar för att kvarvarande felställningar är en trolig orsak till smärta och att i händelse av en rekonstruktion efter calcaneusfraktur bör noggrannhet iaktas för att rätta till alla möjliga smärtorsaker vid operationen.

Perspektiv:

Från denna studie har jag fått intrycket att fördelarna med kirurgi för calcaneusfrakturer kan uppvägas av riskerna med kirurgi. Att sluta med en amputation är inte vad våra patienter har i åtanke.

Med de ökande riskerna för infektioner är en mindre invasiv metod eller icke-kirurgisk behandling sannolikt lösningen för många calcaneusfrakturer. Ju lägre risk desto mer nytta av den kirurgiska hanteringen.

Från de slutsatser vi kan göra i dessa studier framgår att kirurgi inte kommer att vara för alla. Ett noggrant urval av patienter och utvärdering av de individuella behoven är nödvändigt. Att undvika operation när andra sjukdomar föreligger eller andra riskfaktorer är en färdighet som inte kan underskattas. Trots allt är icke-kirurgi en fungerande behandling som inte är så illa för de flesta patienter.

Därför tror jag att calcaneusfrakturer primärt och ännu mer för sena rekonstruktioner skulle vinna på att hanteras av ”hålbens-specialister”. Det finns tillräckligt med data som tyder på att dessa frakturer och den komplexitet som det innebär att handlägga dem skulle gynnas av en systematisk utveckling inom vård och tekniskt kunnande, och att vi bör hänvisa dessa skador till dem som ser och behandlar tillräckligt många för att uppehålla sin skicklighet och kunskap.

LIST OF PUBLICATIONS

- I. **Operative versus non-operative treatment of displaced intra-articular calcaneal fractures: a prospective, randomized, controlled multicentre trial.** Ågren P-H, Wretenberg P, Sayed-Noor AS.
Published in Journal of Bone Joint Surg Am. 2013 Aug 7; 95(15): 1351-7.
- II. **Interobserver Reliability and Intraobserver Reproducibility of Three Radiological Classification Systems for Intra-articular Calcaneal Fractures**
Arkan S. Sayed-Noor, MD, PhD; Per-Henrik Ågren, MD; Per Wretenberg, MD, PhD
Published in Foot and Ankle International sept 2011, vol 32, 861-66.
- III. **Factors Affecting Long-Term Treatment Results of Displaced Intra-Articular Calcaneal Fractures A Post-hoc Analysis of a Prospective, Randomized, Controlled Multicentre trial.** Per-Henrik Ågren MD ¹, Sebastian Mukka MD ², Tycho Tullberg MD, PhD ³, Per Wretenberg MD, PhD ⁴, Arkan S Sayed-Noor MD, PhD, FRCS
Accepted for publication in Journal of Orthopaedic Trauma
- IV. **Posttraumatic fusion after calcaneal fracture. A retrospective 7-28 years follow up study.**
Per-Henrik Ågren, MD; Tycho Tullberg, MD, PhD; Sebastian Mukka, MD, PhD; Arkan S Sayed-Noor, MD, PhD, FRCS; Per Wretenberg, MD, PhD, professor
Submitted

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LIST OF ABBREVIATIONS

AO	Arbeitsgemeinschaft für Osteosynthesenfragen
ASIF	Association for the study of Internal Fixation
AOFAS	American Orthopaedic Foot and Ankle Surgeons
BKA	Below Knee Amputation
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CT	Computerized Tomography
DIACF	Dislocated Intra Articular Calcaneal Fracture
FCS	Fracture Classifications System
OM-score	Olerud Molander Ankle score
OR	Operating Room
ORIF	Open Reduction and Internal Fixation
PROM	Patient Reported Outcome Measurement
RCT	Randomized Controlled Trial
RR	Relative Risk
SD	Standard deviation
SF-36	Short Form 36
ST	Subtalar (joint)
VAS	Visual Analogue Scale
WB	Weight-Bearing

1 THESIS SUMMARY - MAIN SECTION

1.1 INTRODUCTION

Calcaneal fractures are the most common tarsal fractures in the foot (>60%). In epidemiological studies about 2% of all fractures in the adult population are calcaneal fractures. Out of these approximately 70% affect the joints of calcaneus.

1.2 HISTORICAL PERSPECTIVE

Already in the 5th–4th century B.C., Hippocrates gathered remarkable knowledge and experience about calcaneal fractures. He published in his collection of works a chapter "On fractures of the calcaneus" where he describes the mechanism of the injury and the development of haematoma, oedema and tenderness. He recommended treatment by ointments and linen fixation bandages that should be flexible. He also described the danger of gangrene that he called "black heel". He pointed out that the treatment was lengthy, tends to reverse and mentions also septic conditions and the importance of elevation of the affected limb.

Since then orthopaedics has advanced but has the treatment for calcaneal fractures advanced similarly? There have been numerous trends and advice together with a long debate about the most appropriate treatment.

The clinical outcome after a calcaneal fracture has been described as very poor. For example, relating to non-surgical treatment, Conn in 1926 wrote that these are "serious and disabling injuries in which the results continue to be incredibly bad". Cotton and Henderson in 1916 wrote that "when the heel is done the man is done", referring to the ability to continue in industrial labour. Thus the orthopaedic community has been challenged to improve these results.

Pioneers like Lenormant in 1928 and later Palmer in 1948 recommended surgery through a lateral approach with elevation of the subtalar joint surface and stabilisation with bone grafts. Lorenz Böhler paid special interest to calcaneal fractures and several times changed his opinion as for or against surgery. He abandoned this method because of problems with infections and used the method described by Westhues in 1935. This meant that a percutaneous Steinman pin was used to manipulate and stabilise the fracture and then left inside the applied cast. This method was later popularised by Gissane and subsequently by Essex-Lopresti whose name it usually bears.

The French school with Leriche prompted open reduction, bone grafting and screw fixation. The first to introduce a bilateral approach with a screw osteosynthesis was Merle d'Aubigné in 1936.

Even in the early 1990's there were only a few reports on and recommendations about surgical primary reconstruction for calcaneal fractures (Bezes, Burdeaux, Letournel, McReynolds, Ross, Stephenson, Zwipp). Most of these were rather short series with

different approaches, lateral, medial and bilateral and different implants as well as differences regarding surgical timing. However what they had in common was the aim to restore the calcaneus without joint transfixation, aiming for a restoration of function.

Complications in these series were high with a high risk of serious complications such as wound edge necrosis, infection with deep infection and the need for debridement, with a prevalence of 7-18% and even worse.

Functionally the outcome in these earlier surgically managed fracture series were not as well defined as we are used to today. In most articles the outcome is often described in a subjective way like very good-good-fair-bad. In an overall rating, 50-80% of the patients had reached a result with no functional limitation and only occasional pain.

In 1975 Soeur and Remy reported on their experience with calcaneal fractures and also described a rationale for their reduction as well as a classification system. This work was further developed by Sanders et al who in 1993 described a rationale with a lateral approach based on their new classification based on Computerized Tomography (CT) imaging. They also observed a learning curve effect with improving results over time.

Concluding this historical perspective, the means of improvement has until now been threefold:

Firstly, with the evolution of imaging, the diagnostic tools have been improved in the last century. First by Brodén with a series of angulated pictures of the heel bone to further clarify the dislocations and fractures in the subtalar joint and later with the development of CT-scanning that has improved the understanding of the fracture patterns of calcaneus immensely. Lately during the last decade, 3D imaging has become more popular and seems to unmask further the details and pathologies of interest.

Secondly, a huge step is the development of the fixation techniques for fractures and also the reduction techniques associated with Open Reduction and Internal Fixation. (ORIF)

Thirdly, the development of soft-tissue management including the understanding of the fascio-cutaneous blood-supply in the heel area and the development of the extended lateral approach of calcaneus described by Benirschke. In this method the entire heel bone can be exposed laterally and treated with much less complications with wound healing than other approaches. Timing of surgery vs. swelling and the use of antibiotics have further improved the results.

2 STUDY BACKGROUND

The popularisation and encouraging reports on improvement in results with an improved rationale for surgical management led to the initiation of a Randomised Controlled Study (RCT) that is the back-bone of this thesis.

My personal challenge and goal with this thesis was to improve the management of calcaneal fractures and within that goal lay the hope to show by scientific means why these new developments would lead to a much better outcome for patients. I also wanted to be able to give some advice for the clinically active surgeons on how to treat calcaneal fractures and give some clues to other clinicians.

In the early 90's calcaneal fractures in Stockholm were generally treated with non-surgical management and some of the patients kept returning with problems and pain that was difficult to handle and to treat. This led to further reading and discussions where it seemed we should be able to improve our results with the new surgical approach that was recommended. In centres abroad the rumour was circulating that calcaneal fractures could be treated operatively with success. I attended a course in which the French surgeon Emile Letournel was convincingly arguing for surgical treatment of calcaneal fractures.

After this we occasionally started to treat fractures surgically and at the clinic a debate started on the topic. I soon realised that the best way to answer the question as to whether to operate or not was to set up a study and patient recruitment started in 1994. By 1998 more than 80 patients had been included which was our goal.

2.1 ETHIOLOGY OF CALCANEAL FRACTURES:

Most calcaneal fractures occur from high impact injuries, when the victim gets a severe blow on the heel. Today this most often seems to happen when falling from construction sites, or when doing handy-man work at home, like pruning trees or working on roofs. Another common cause is jumping out or down from a building or construct during attempted suicide. With the improvement of cars now equipped with air bags more drivers and passengers survive road accidents and thus severe foot injuries increase.

Interestingly the results of the treatment of foot injuries after blunt trauma are not very satisfactory and has in USA been reported to hold up to 80% of the remaining invalidity after all injuries caused by blunt trauma. Thus there is a big possible improvement possibility in the treatment of foot injuries.

2.2 DIAGNOSTICS

The diagnostic generally means that there has to be an awareness of the possibility of a heel bone injury. If the patient is conscious this is usually easy as normally a calcaneal fracture is quite a painful condition. In the unconscious patient the attending doctor has to look for swelling and possible signs for fracture like instability, which demands for diagnostic imaging. The first imaging is usually Plain films with a lateral and an axial view.

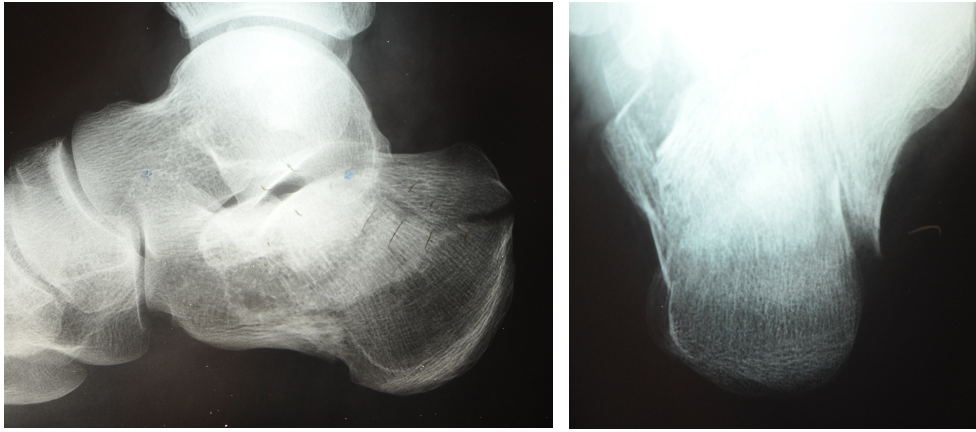


Fig 1. Lateral and Axial Plan X-rays of fractured calcaneus

Formerly sets of oblique pictures were taken according to Brodén. Either rotated inwards or outwards, the subtalar joint can be visualised with plain films.

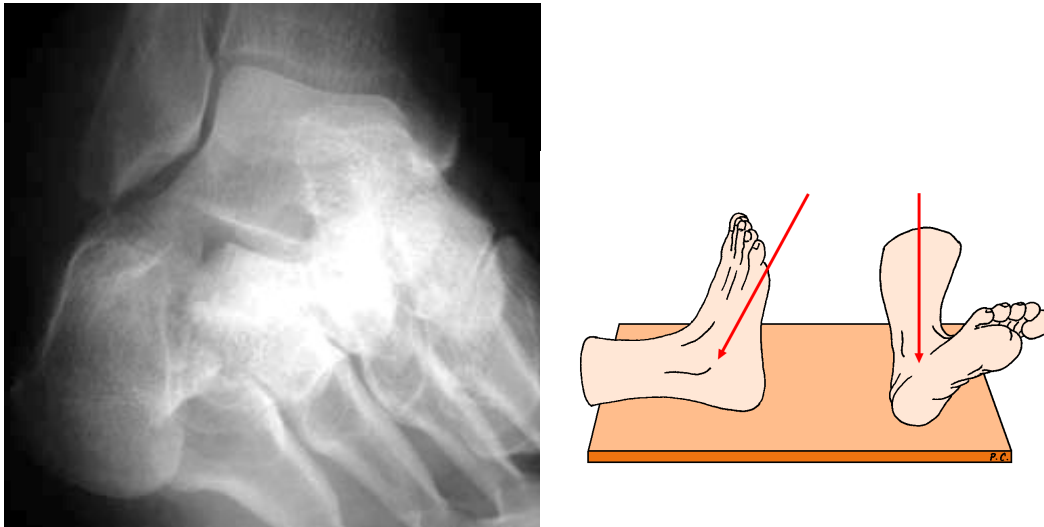


Fig 2. Oblique Broden projection showing the split in the subtalar joint

Nowadays we usually ask for a diagnostic CT, to further explore or identify the different pathologies of the fracture. With CT, slices are constructed using software and the bone is visualised in two types of sections, the longitudinal and the coronal plane. New software has made it possible to do reconstructions of the bone and to visualise it further by a virtual 3-D picture.



Fig 3. The same fracture as in fig 2 examined by CT, the rotation and size of fragments is visualised better.

With three-dimensional CT (3D-CT) it has become easier to understand the extent of any fracture and to plan the treatment. It is possible to make a virtual spin of the bone to see it from different sides, and it is possible to virtually remove surrounding bones like the talus to expose only the calcaneus.

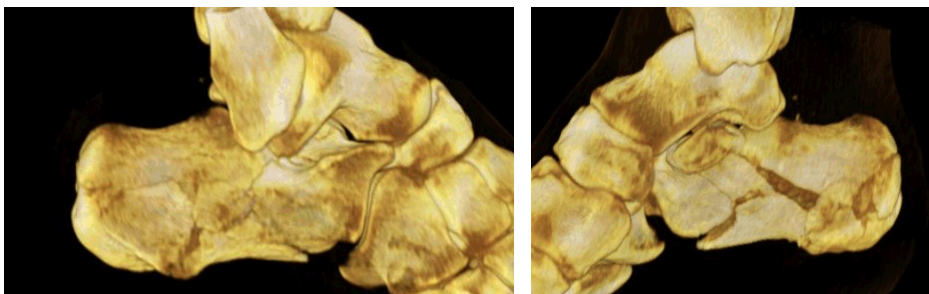


Fig 4. 3D-CT with fractured calcaneus seen both from lateral and medial side

Another feature that is possible is that the soft tissues and their location can be superimposed if wanted. This is useful especially on the lateral side as tendons are commonly dislocating with calcaneal fractures.



Fig 5. 3D-CT with superimposed tendons

Some examples of calcaneus with fracture and virtually removed surrounding bones seen from different views.

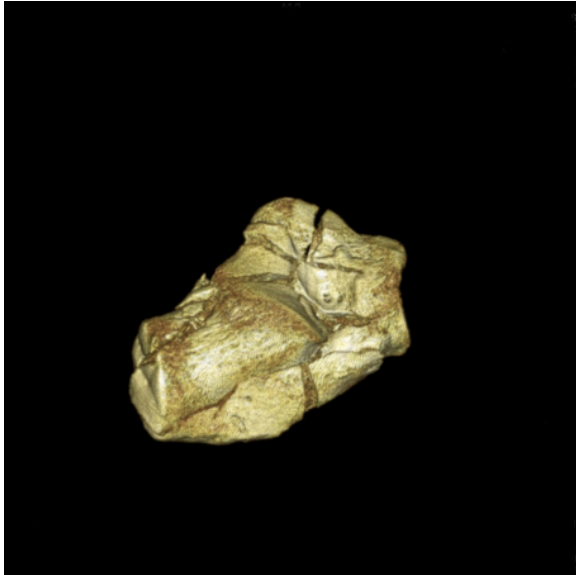


Fig 6. Fractured Calcaneus from above



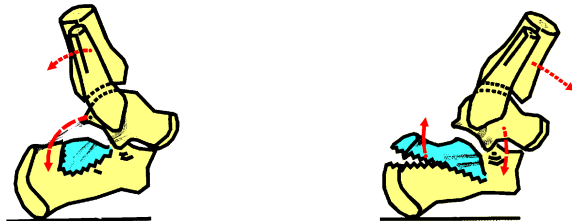
Fig 7. Fractured Calcaneus seen from distally without overlying bones exposing the fractured joints

In practice today the Brodén projections are mainly used in the OR to visualise the reduction of the fragments and with a mobile C-arm. Lately the possibility of 3D imaging has become possible also in the OR, but has not yet become widely available.

2.3 THE PATHOANATOMY OF CALCANEAL FRACTURES

It has been observed that the fracture pattern in different fractures is almost constant. With the impaction the fracture develops from the angle of Gissane (see fig 24) with the talus anterior process breaking the bone in the primary fracture line. Depending on the position of the foot in inversion-eversion, flexion-extension at the time of impact a

wide variety of different patterns can develop. The primary fracture line can cross the subtalar joint medially or laterally. Further lines will develop with higher impact and thus the amount of energy from the injury will be reflected in the fracture pattern. Two major differences occur as the fracture develops into the subtalar joint. These are the depression–type of fractures and the tongue-type. Many authors noted these observations, but it was Duparc who in 1967 described the biomechanical reason for the development of the two fracture types:



Horizontal depression
(Joint depression)

Vertical depression
(Tongue type)

Fig 8. Schematic of the development of the two fracture types depending on the position of the foot at the impact (straight to plantar flexion or with dorsal extension in the ankle)

Utheza in 1993 described a theory as to how the fractures develop with the information gained from CT. He describes the primary fracture line according to Palmer and then if we make a three-stage classification of horizontal-vertical or mixed based on radiological appearance, shows a correlation of the location of these types and the location of the primary fracture line. In the vertical type the primary fracture line runs medially whereas it runs laterally in the horizontal fractures and in the mixed type it is located centrally through the ST joint.

Utheza also observed that the laterally detached fragment is always tilted to a vertical slope and the medially detached fragment is tilted horizontally. In all this suggests that the positioning of the foot at the time of impact is the main factor causing the different fracture types.

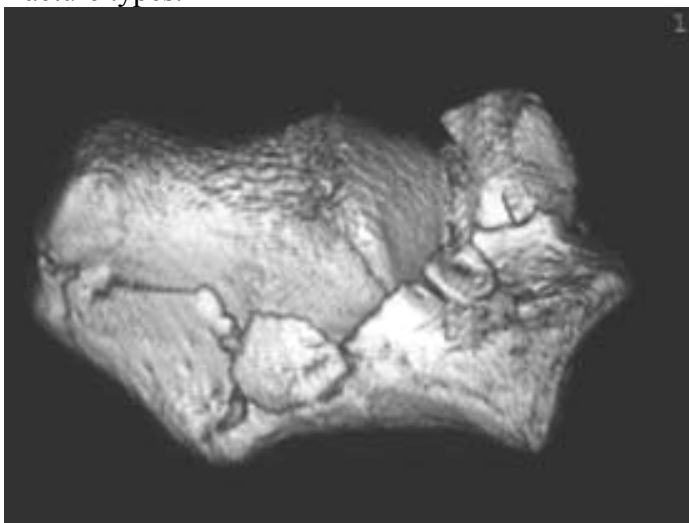


Fig 9. 3D-CT showing vertical depression:

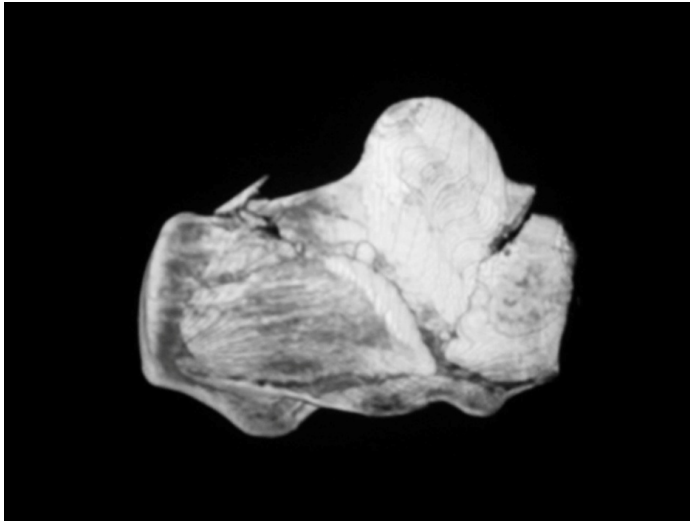


Fig 10. 3D-CT showing horizontal depression:

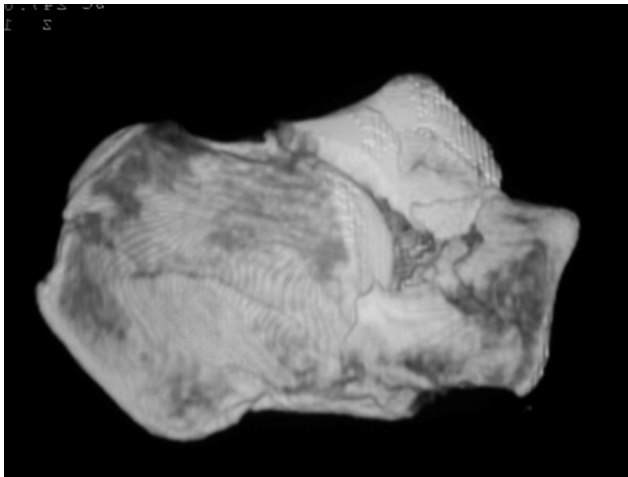


Fig 11. 3D-CT showing a case of the combined form:

The tongue type develops with the fractured joint as one piece extending horizontally into the tuber. The fracture then can exert just below the insertion of the Achilles tendon with the tendon pulling at the fragment. This gives it the typical tongue-appearance on the lateral X-ray view. This fracture type is the one that due to the pressure on the soft tissues and the risk for skin ischemia and ulceration is often an indication for acute intervention in order to avoid skin necrosis due to pressure.

The other fracture types with a more or less depressed and dislocated subtalar joint and calcaneal body will all give a similar pattern. When the fractured subtalar joint is jacked down into the calcaneal body the weakest part of the bone will fail and blow out. This is what happens with the lateral wall of calcaneus, and this blow out occurs with an impressive power, able to dislocate the peroneal tendons up outside the lateral malleolus.

The medial wall, being more solid and firmly attached to the talus with strong ligaments in the anterior part, will in almost all cases be fractured and dislocated in such a manner that the sustentacular part is kept in place, whereas the tuber part is transferred/ shifted laterally. By doing so it moves out under the lateral malleolus and also has a tendency to varisate. Together with the lateral blowout this will lead to a

lateralisation of calcaneal bone under the tip of fibula and a possibility of malalignment of the calcaneal tuber into varus or sometimes a valgus.

With both types of fractures, the tongue-type and the depression type, the calcaneal body might become grossly disturbed. If untreated the appearance might be such that the fundamentation for the talar bone, which is the bone above the calcaneus, might be disturbed with a backwards rotation into the calcaneus and a malalignment with the ankle. This will cause impingement anteriorly on the talar neck, or even subluxation out of the ankle joint.

2.4 FRACTURE CLASSIFICATION

Several authors have described the fracture extension. The lack of a classification system that constantly gives good intra- and inter-observer reliability and reproducibility stands out as a conceptual problem. The older classifications have been shown to have very low predictive values regarding outcome. However the odd thing is that statistically a really simple system such as fracture yes / no would satisfactorily be able to give a prognosis. It is when we sub divide different patterns into the classification that the problems of interpretation start.

The more complex a system is, the more likely there will be different views of opinion between different investigators. This means that a really complex and descriptive system that needs interpretation will be likely to end up as non-reliable. Because of that it is unlikely to have any predictive value or impact on the treatment.

Today most fracture surgeons believe that we need at least CT scanning in 2 planes or 3D-CT to interpretate and classify the fracture pattern. The classifications that were used in this study were the following:

Sanders classification.

This is the most commonly used classification today, as well as when the project began. It is based on the coronal section (on CT) of the subtalar joint at the widest part of the bone with the sustentaculum. Based on the number of fractured parts, 2, 3, 4 or more and the location of the fracture lines, 7 different classes are possible.

Zwipp Classification

Another classification derives from Zwipp and is based on the number of joints injured (3 possible: subtalar joint, calcaneo-cuboid joint, anterior subtalar joints) and bone segments injured (5 possible: sustentaculum, tuberosity, subtalar joint fragment, anterior process, anterior subtalar joint fragment). This makes it possible to define 8 different classes. This is less widely used in the literature than the other classifications.

Letournel classification

Another classification was described by Letournel and is based on the premise of Tongue-type or Joint depression type fractures with 2-4 articular segments, making a division into 6 classes possible.

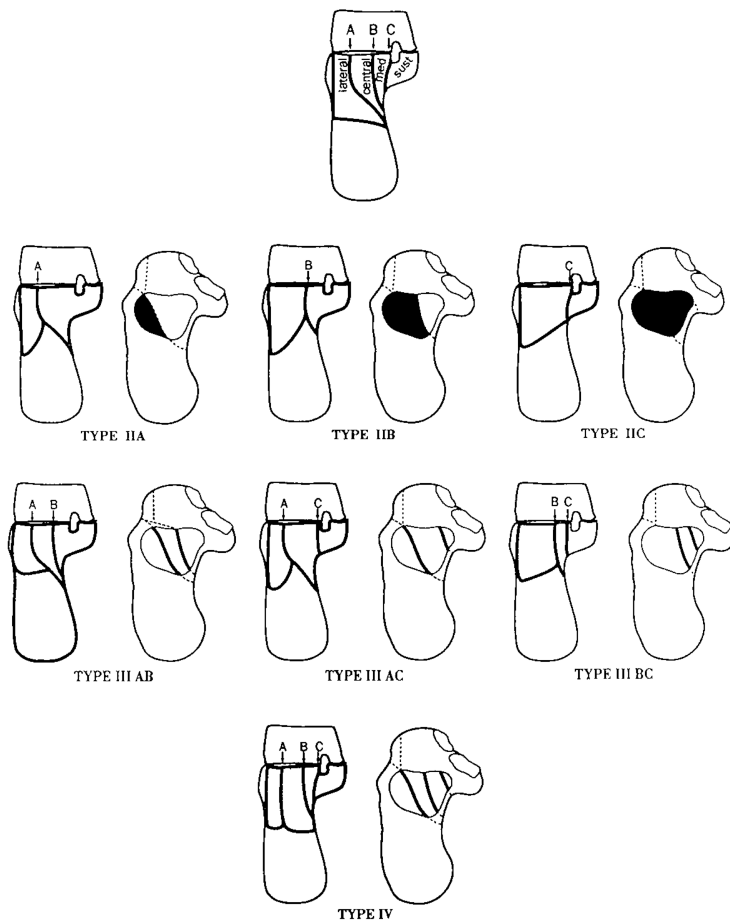


Fig 12. Schematic of the Sanders Classification (Sanders et al -92)

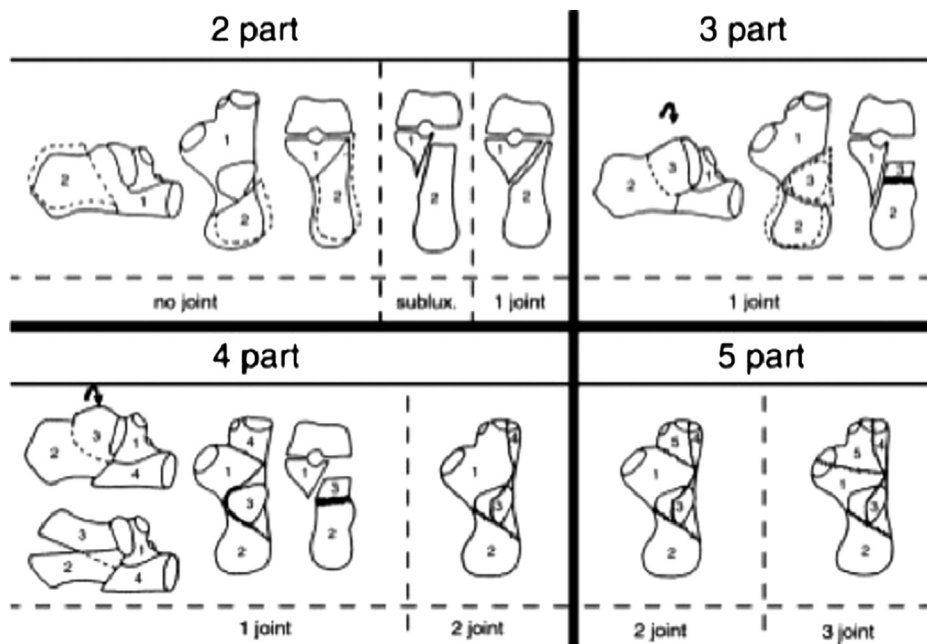


Fig 13. Schematic of the Zwipp classification for calcaneal fractures (Zwipp et al-88.)

Newer classifications have been developed but none of these have been shown to have any better correlation with the outcome.

The advantage of fracture classification systems is not that they can be used to predict outcome or used as a measuring tool in scientific work, but rather that they encourage viewing of the films in a different way so as to better understand the fracture. Thus one goal is achieved, i.e. a better planning of the management of the actual fracture.

2.5 OUTCOME SCORES

To evaluate the outcome for patients with orthopaedic injuries, a number of different scoring systems are available. In modern orthopaedic research these scores have become essential to be able to compare results of different treatments. Today many outcome scores are available but when this study started the use of outcome scores was unusual. Over the years it has become obvious that outcome scores are the most valid tools to measure treatment success and I am fortunate that we thought of this when the study was started 20 years ago.

In general there are two types of outcome instruments:

Disease specific functional questionnaires and general health related quality of life questionnaires. Both types have been used in this thesis.

Many scores were originally described and developed for a specific follow-up and not scientifically developed, validated and controlled. Today therefore there are many instruments with unknown reliability and validity. In the literature there are many articles about this problem and comparisons between the resulting scores in different situations.

It has been shown that different instruments might have different problems with thresholds, difficulties in handling missing data, inability to differentiate between groups, unknown validity etc.-Translation of outcome questionnaires must take into account cultural differences between countries to ensure validity and not just be word for word translations.

Basically outcome questionnaires can be divided either into *functional scores* or *Quality of Life (QOL)-scores*.

SF-36

This is the most established HrQOL-score (Health related Quality of Life). A functional assessment is gained as well as mental and psychometric parameters and this is a score that has been validated in many languages and also in Swedish. The SF36 has been used extensively and described in numerous publications. It is well accepted as a measurement tool. It consists of 36 questions with multiple-choice answers.

SF-36® Measurement Model

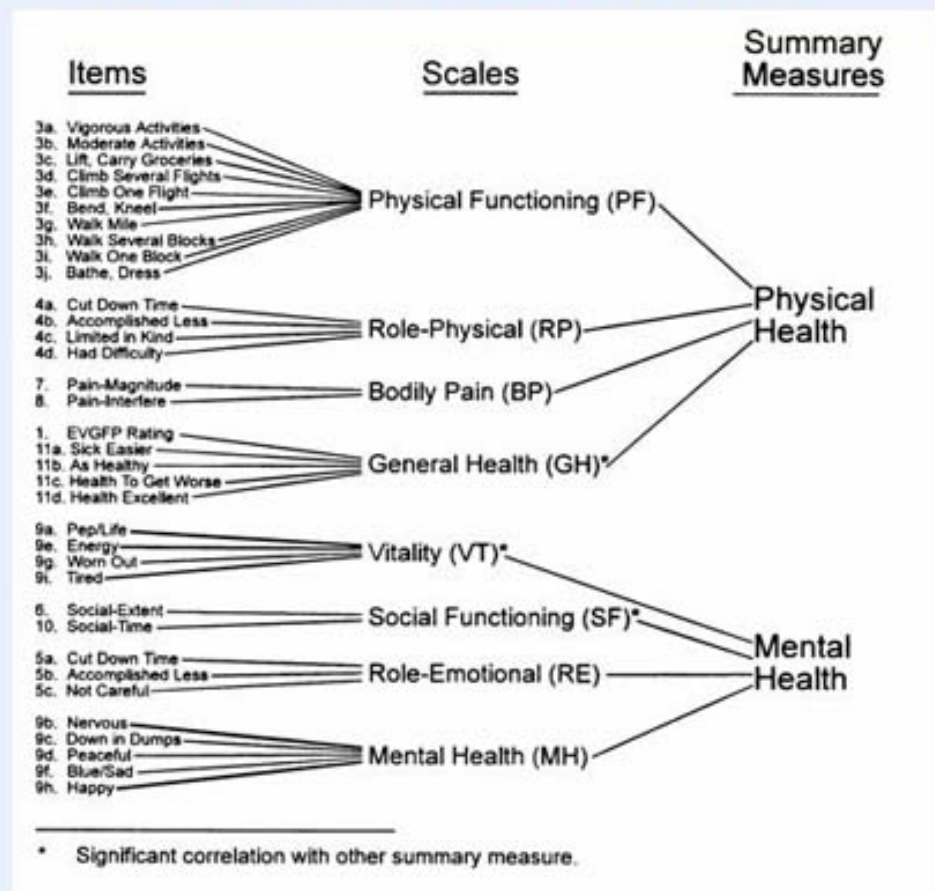


Fig 14. SF-36 model for data collection

The SF-36 contains 36 items which measure 8 dimensions: physical functioning (10 items), social functioning (2 items), role limitations due to physical problems (4 items), role limitations die to emotional problems (3 items), mental health (5 items), energy/vitality (4 items), pain (2 items) and general health perception (5 items). There is also a single item about perceptions of health changes over the past 12 months. The 8 dimensions can be combined to give 2 standardised summary scales: the mental component scale and the physical component scale (see diagram)

Three scales (PF, RP, and BP) correlate most highly with the physical component and contribute most to the scoring of the Physical Component Summary (PCS) measure (Ware et al., 1994). The mental component correlates most highly with the MH, RE, and SF scales, which also contribute most to the scoring of the Mental Component Summary (MCS) measure. Three of the scales (VT, GH, and SF) have noteworthy correlations with both components.

The evaluation of the scores can be performed with a computer program.

Summary of Information about SF-36 Scales and Physical and Mental Component Summary Measures

Scales	Correlations		Number of		Mean	SD	Reliability	CI ^a	Definition (% observed)	
	PCS	MCS	Items	Levels					Lowest Possible Score (Floor) ^c	Highest Possible Score (Ceiling) ^c
Physical Functioning	.85	.12	10	21	84.2	23.3	.93	12.3	Very limited in performing all physical activities, including bathing or dressing (0.8%)	Performs all types of physical activities including the most vigorous without limitations due to health (38.8%)
Role-Physical (RP)	.81	.27	4	5	80.9	34.0	.89	22.6	Problems with work or other daily activities as a result of physical health (10.3%)	No problems with work or other daily activities (70.9%)
Bodily Pain	.76	.28	2	11	75.2	23.7	.90	15.0	Very severe and extremely limiting pain (0.6%)	No pain or limitations due to pain (31.9%)
General Health (GH)	.69	.37	5	21	71.9	20.3	.81	17.6	Evaluates personal health as poor and believes it is likely to get worse (0.0%)	Evaluates personal health as excellent (7.4%)
Vitality	.47	.65	4	21	60.9	20.9	.86	15.6	Feels tired and worn out all of the time (0.5%)	Feels full of pep and energy all of the time (1.5%)
Social Functioning	.42	.67	2	9	83.3	22.7	.68	25.7	Extreme and frequent interference with normal social activities due to physical and emotional problems (0.6%)	Performs normal social activities without interference due to physical or emotional problems (52.3%)
Role-Emotional (RE)	.16	.78	3	4	81.3	33.0	.82	28.0	Problems with work or other daily activities as a result of emotional problems (9.6%)	No problems with work or other daily activities (71.0%)
Mental Health (MH)	.17	.87	5	26	74.7	18.1	.84	14.0	Feelings of nervousness and depression all of the time (0.0%)	Feels peaceful, happy, and calm all of the time (0.2%)
Physical Component Summary			35	567 ^b	50.0	10.0	.92	5.7	Limitations in self-care, physical, social, and role activities, severe bodily pain, frequent tiredness, health rated "poor" (0.0%)	No physical limitations, disabilities, or decrements in well-being, high energy level, health rated "excellent" (0.0%)
Mental Component Summary			35	493 ^b	50.0	10.0	.88	6.3	Frequent psychological distress, social and role disability due to emotional problems, health rated "poor" (0.0%)	Frequent positive affect, absence of psychological distress and limitations in usual social/role activities due to emotional problems, health rated "excellent" (0.0%)

Note. From Ware, Kosinski, and Keller (1994).

^aCI=95% confidence interval

^b Number of levels observed at baseline; scores rounded to the first decimal place ($n=2,474$).

^cPercentage observed comes from general U.S. population sample.

^d Scores for eight scales are the percentage of the total possible score achieved for each of these scales. Scores for PCS and MCS are *T-scores*.

Fig 15. Summary of Information about SF-36® Scales and Physical and Mental Component Summary Measures

The SF-36 has been shown to have a good validity and correlation to outcome. It has been used to verify correlations for other scores and has been used as a correlation-validation test for other scores. All the scales in the SF36 have been shown to have a reliability measured as internal consistency of >0.7 which exceeds the requested level.

VAS-Calcanear score (Hildebrand et al-96)

When this study was started another similar study had begun in Canada. They developed a score that was validated thoroughly for calcaneal fractures in Canada. We made a translation into Swedish without further testing. The patient's response is measured on a VAS-scale. This scoring system has not been widely used, mainly in this

and the Canadian study. Using this as our primary outcome measure would enable a direct comparison of this study with the Canadian one.

Olerud –Molander score (Olerud et al-84)

This score was originally developed to screen patients with ankle fractures. It consists of nine questions. The first three are about pain, the following four about function and the last two about activities of daily living. This is also a score that has not been validated in the way that today is regarded as essential but it has been evaluated towards three different modalities namely a linear analogue scale (total assessment of my ankle), Range of Movement in loaded dorsal extension and radiological appearance especially Osteoarthritis and congruity/dislocation. It has been shown to correlate well with the SF-36.

AOFAS-score (Kitaoka et al -94)

The American Orthopaedic Foot and Ankle Society developed this score. It is the most commonly used scoring system in the foot and ankle research literature. However over the years it has been criticised mainly because some parts of the score relating to alignment and mobility are semi-objective. Additionally it has not been validated, but it does seem to correlate well with the SF-36.

3 TREATMENT ALGORITHMS:

For non-surgical management several treatment algorithms exist, the oldest one being no treatment at all. This method today is directed towards a functional treatment. This means elevation and non-weight-bearing as tolerated, usually around 6 weeks. During this time the patient is encouraged to start early movement with active means that is to try to move the affected parts of the foot as much as possible. The reason for this might be that hopefully this gives less arthrofibrosis and better mobility.

In comparison, the alternative would be to immobilise the heel with a cast.

Although in the short term this gives better pain relief it has a tendency to give less satisfactory results, probably because the movement and muscular function are not preserved as well. Other non-surgical treatments, such as compression-boot treatment also exist but they have not yet been shown to improve the results.

For surgical treatment generally there are two goals. The first one is the goal of anatomic restoration of the fractured heel. This requires a thorough understanding of the fracture pattern and this of course incorporates the surgeon's experience. If the surgeon can imagine what will be under the skin and what manoeuvres he or she has to do to reduce it, the surgical exposure can become shorter and more efficient. Not everyone can make drawings as shown in the example (Fig 16), but surgeons should be able to visualise within their minds a similar picture.

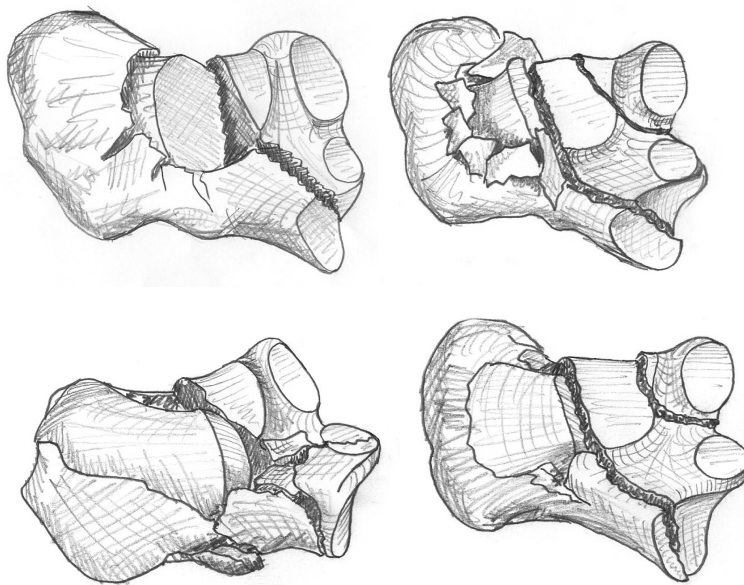


Fig 16. Artistical fracture drawings –a way to do a preoperative planning of the surgery (P Cronier)

A modification of this would be the goal of restoration of the gross anatomy (height and alignment of the rear foot) but probably not perfect restoration of the joints and their anatomy.

In order to achieve either of these goals a series of choices lie ahead:

The obvious surgical one is the ORIF (Open Reduction, Internal Fixation), which has been the investigated means of treatment in this thesis. The recommendation today is to perform this through the extensile lateral approach (Benirschke). This incision respects

the fascio-cutaneous blood-supply of the lateral heel and gives very good access to the fracture.



Fig 17. Approach on lateral calcaneus and on the right showing the hole under the joint when reduced and the lateral wall of the calcaneus in the pickers grip.

Combinations of indirect and direct manipulations reduce the fracture and often a pin is put into the tuberosity to be used as a “joy-stick” for the portion of the heel that is attached to the Achilles tendon. This fragment, the tuberosity is then manipulated to:
 (1) restore height, (2) restore valgus and (3) be medially translated (Soeur et Remy-75)

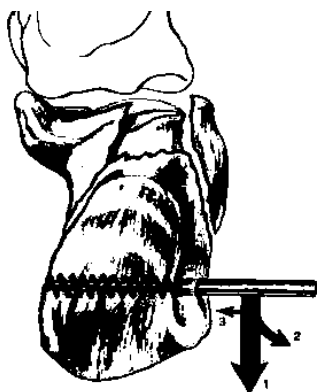


Fig 18. Schematic Tuber reduction-manoeuvre as described by Soeur and Remy

At first the fragments are reduced to an anatomic alignment and fixed with temporary pins. Thereafter these pins are changed, to usually a plate with screws, to hold the fragments in the reduced position.

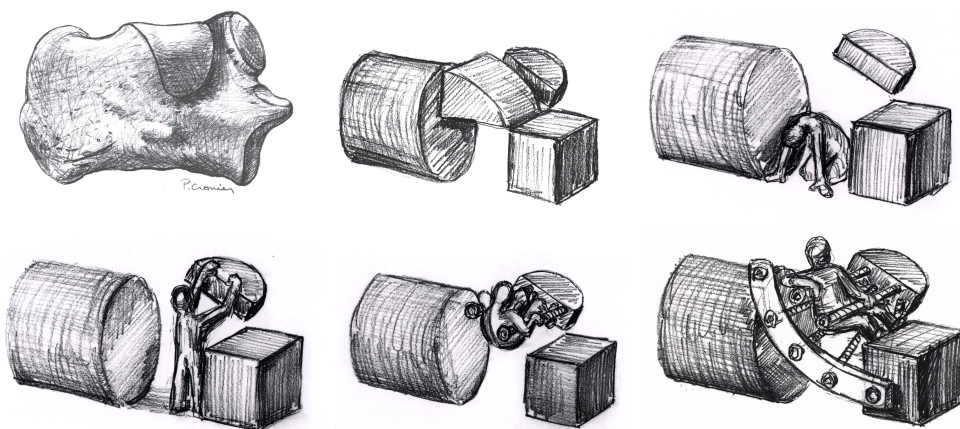


Fig 19. Schematic principles on fracture reduction and fixation (P Cronier)

Currently the popular tendency is the development of fracture reduction without the open technique. The advantage of this is that the risk for soft tissue problems and secondary fibrosis should be reduced. The reductions can be made closed, percutaneous or mini-invasive and also with the aid of arthroscopic techniques. With the aid of external fixation-distraction and newly designed fixation plates it is possible to reduce very well and fix the fractures in a stable manner. This however is not possible for all fractures yet, so still there still seems to be a need for the open technique. When reduced the fracture needs to be fixed with some means, Palmer in 1948 described a technique to stabilise using bone graft under the depressed joint fragment (fig 20).

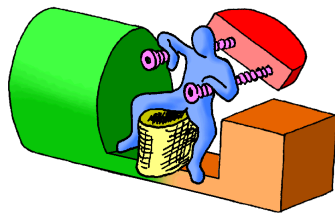


Fig 20. The thalamic segment illustrated by the little blue man is reduced and held in place with screws and some bonegraft below. This is an adaptive osteosynthesis, and can normally not take early exercise without risk for dislocation (P Cronier)

This is sometimes performed today but with the development of specific calcaneal fracture implants, bone grafting is usually not necessary.

In most of our cases we used standard reconstruction implants and screws. This is a demanding technique that needs training and the main idea is to insert as many screws as possible into the sustentaculum of calcaneus, which is the strongest part of the bone, and less likely to be fragmented due to the fracture. An example of this is shown in Fig 22.

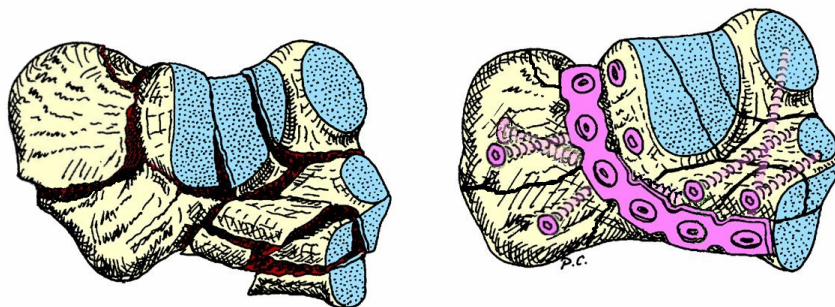


Fig 21. Schematic of the Osteosynthesis with screws and reconstruction plate. Most screws converging into the strong sustentacular segment (P Cronier)

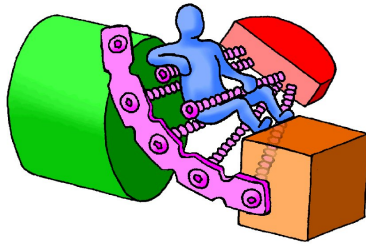


Fig 22. Schematic with the thalamic segment held in place and secured comfortably with the screws converging into the red sustentacular segment medially (P Cronier)

In order to aid the surgeon a variety of implants have been developed. These are anatomic and can be used with locking or non-locking screws.

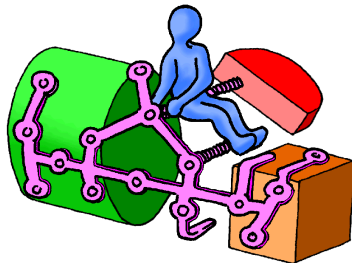


Fig 23. Anatomic plate schematically (P Cronier) and on X-ray

However the implants themselves do not solve the problem of fracture fixation. It is the technique and know-how that are most important. The newest plate designs have been developed for mini-invasive techniques and are used with smaller less invasive incisions than mentioned above.

An alternative technique is using a medial external fixator that is left during consolidation of the fracture. Good results, similar to the open technique, have been reported from Magnan and his group using this.

Another alternative is percutaneous stabilisation with screws or other specially designed implants such as Intra Medullary (IM) nails with screw stabilisation that have been developed.

3.1 POSTOPERATIVE REGIMEN:

In most series as well as in ours, the patients are urged not to weight-bear until the fracture is consolidated, which usually occurs at about 6 weeks postoperatively. Until then elevation in order to rest the soft tissues is recommended. Sutures can usually be removed after 2 weeks. If the wound is well healed early movements can be started with active exercises.

The evidence base for post-operative regimen is sparse. In fact there are authors that recommend weight bearing after a couple of days post-operatively below the pain

threshold if it can be tolerated. This seems to help in diminishing swelling and speed up rehabilitation.

3.2 COMPLICATIONS

There are complications after both surgical and non-surgical treatments.

Some are specific to the type of treatment some are universal to calcaneal fractures.

When the calcaneus is fractured the inter-relations between the joints is lost (Fig 24).

At the level of the heel bone the surrounding tissue is minimal. On the lateral side there is a periosteum and subcutaneous fascia with subcutaneous fat, and then the skin is directly there. Nervous structures and tendons are embedded in the fat. (Fig 25)

On the medial side there are more structures (tendons, and vessels and nerves) that are vital for the function of the foot. There is also the abductor hallucis muscle that inserts at the tuber calcanei.

On the plantar side of the heel bone are some deeper structures that are vulnerable to bleeding and pressure developed due to the fracture. The most obvious one is the Musculus quadratus planta and superficially oriented to this, the Musculus flexor digitorum brevis muscles that are located in the deep calcaneal fascial compartment. The heel pad is usually preserved but can be avulsed or damaged and scarred and left with painful scars.

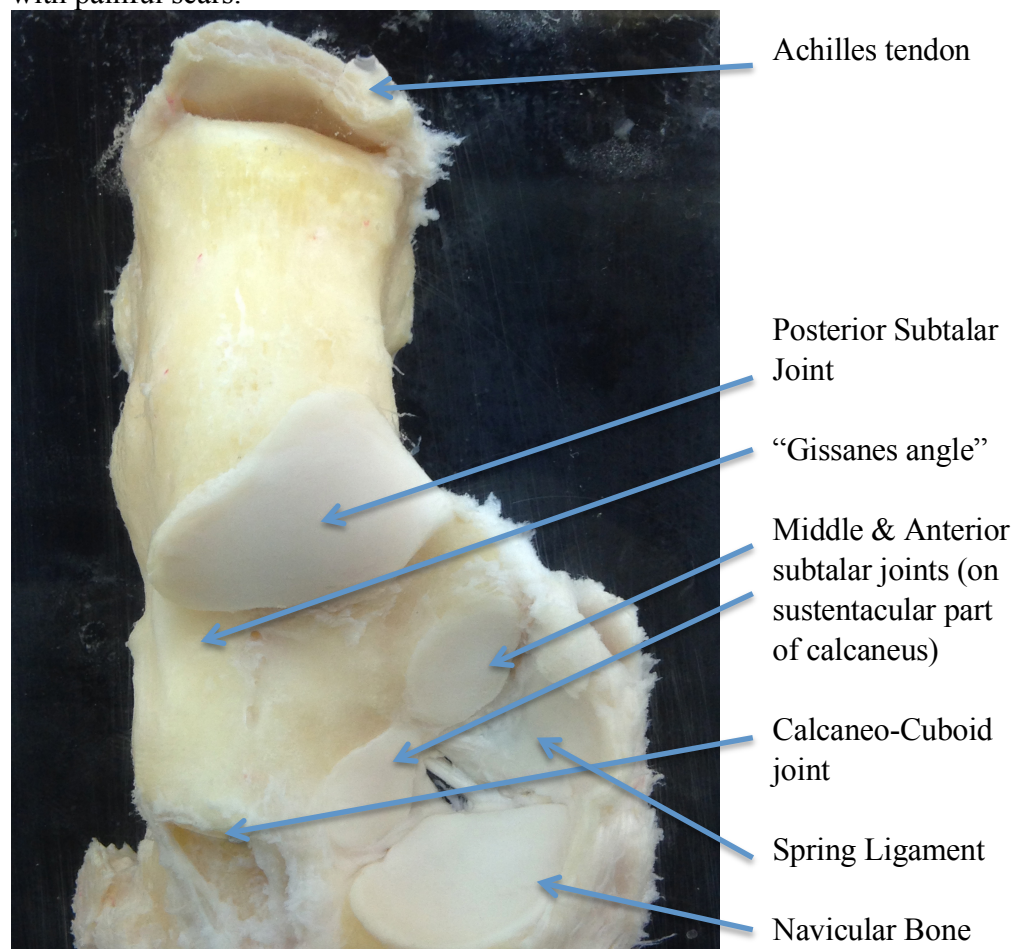


Fig 24. Anatomic specimen showing calcaneus's joints from above, after talus is removed.



Fig 25. Anatomic specimen showing calcaneus and plantar fat, lateral ligaments and vessels

Compartment syndrome

These structures are commonly affected by a fracture with dislocation and bleeding leading to hyper pressure and necrosis of the tissue, a compartment syndrome. This can lead to clawing of the toes and a shortening of the foot. This is not a rare condition. It has been reported in about 1/5 of all calcaneal fractures. The main symptom is intractable pain and also an inability to move other parts of the foot like the toes in extension. If untreated the small muscles usually of the deeper calcaneal foot compartment will necrotise and give rise to a flexion contracture in the lesser toes, claw toes.

Fracture blisters

It is common that after a calcaneal fracture patients develop a large and painful swelling. This often leads to such oedema and pressure in the fasciae and skin that blisters develop. These fracture blisters will usually heal and shrink without any need for specific treatment, but can postpone the possibility for surgical management.



Fig 26. Fracture blisters

Tendon dislocation

Another possible soft tissue problem that is universal is that the peroneal tendons, located behind the lateral malleolus, commonly are dislocated laterally-anteriorly by the lateral bulge of the os calcis when the fracture occurs.

Pressure skin necrosis

A rare but specific soft tissue problem that can occur is with the tongue-type fractures that may cause skin pressure and secondary ulceration if grossly dislocated. This is the most obvious indication for an acute need of intervention in a calcaneal fracture.

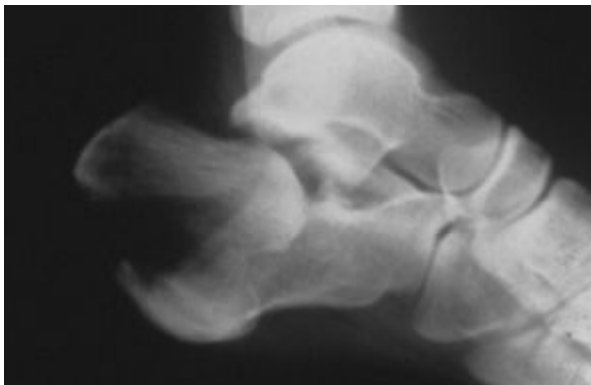


Fig 27. Tongue-type fracture with high risk for skin necrosis due to pressure

Complex Regional Pain Syndrome

In the late stages after a sustained calcaneal fracture a Complex Regional Pain Syndrome (CRPS) may develop either with or without surgery. This leads to swelling, alterations of the local circulation with stasis on the venous side and pain. The general management includes a systematic loading, rehabilitation with increasing weight bearing. This is usefully beneficial. Water rehabilitation can be very useful. These

patients are often treated in conjunction with anaesthesiologists with special interest in pain treatment or at specific pain clinics. Sometimes sympathetic nerve blocks are used by injections or medication. The outcome is commonly not very satisfactory, and leads to a functional impairment.

Late complications due to deformity, joint damage and incongruity

In the non-surgically treated patients there is always a residual displacement in the fracture. Whether small or large secondary arthrosis can develop. This can happen also in the surgically treated cases. With the displacement of the fracture several types of deformity might persist. This is described in the 4th article. The following deformity complications can occur if treated non-surgically: remaining residual varus or valgus deformity *and/or* loss of height of calcaneus with dorsal rotational malalignment of talus *and/or* lateral translation of calcaneus with abutment on fibula with ST-joint *and/or* lateral tilt out of ankle joint of talus.

Complications relating to surgery

With surgical management there are specific problems. The first is that with any surgical incision it is possible to damage the underlying structures like nerves. With the commonly used extensile lateral approach the nerve at risk is the sural nerve that is a sensory nerve on the outside of the foot. If the exposure is correctly performed this risk in practice is very low, but still nerve damages occurs. However with a poor placement of osteosynthesis or unskilful handling of instruments / power tools etc. it is possible to endanger also the medial vessels and the large nerve (tibial nerve) that is sensory to the plantar surface of the foot. This also holds motor fibres to the small muscles of the foot.

Osteosynthesis problems

With surgical management there is also the possible problems of osteosynthesis including failure of material, which might occur in calcaneus in the rare possibility of non-healing. The most likely part of this to occur is with the larger articular segments that might not heal into the rest of the construct as they are deprived of their blood perfusion and this might give rise to segmental non-unions. The metal that passes through such sections will also be likely to fail.

Another possible problem is that screws might back out during the healing and cause soft tissue pain. This is normally due to some movements in the fracture that is setting in the construct. This might need further surgery for removal of the osteosynthesis or revision and restabilisation.

Skin necrosis & Infection

Infection related to surgery of the calcaneus is quite common. This is due to the large exposure and the swelling of the vulnerable tissues surrounding the heel bone. The result is commonly a superficial problem with skin necrosis at the edge of the wound. Sometimes this leads to exposed bone or osteosynthesis. Whenever such problems occur meticulous management is important and if a defect develops it might be necessary to involve reconstructive plastic surgeons to cover the fractured area. When an infection occurs meticulous cleaning and resection of devitalised tissue should be performed in order to minimise the continuation of the problem. A long-standing open wound that is colonised with bacteria can eventually lead to a very problematic deep

infection with the bone and other deep structures affected. This so-called osteomyelitis can become a non-salvageable problem leading to amputation or at least resection of the heel bone.



Fig 28. Skin necrosis and infection, metal implant shown in the bottom

3.3 RISK FACTORS, COMORBIDITIES

When the study was set up it was decided to include all patients aged 18 or more with some exclusions. The patient should have a health situation suitable for surgery both generally and locally with sufficient function of vascularity and sensation.

Patients with diabetes mellitus were excluded.

Smokers and obese patients were included even though there were no patients with obesity. Out of the soft tissue problems with infections, some of them were smokers.

(An observation that we today would have handled by excluding smokers from the study)

4 AIMS OF THE THESIS

The general aims of this thesis were to evaluate whether a surgical management is superior to non-surgical management for calcaneal fractures. To answer this we set up a randomized controlled trial. The results that we achieved were used in Papers 1,2 and 3. The 4th paper reports on the effect of treatment sequelae for calcaneal fractures. It is a long-term follow-up of a retrospective cohort treated with similar non-reconstructive surgery.

Specific aims:

Functional outcome of an RCT study with 8-12 years Follow-up.
(I and III)

Incidence of complications and occurrence of treatment related sequelae after calcaneal fractures
(I and III)

Assessment of risk factors and definition of potential groups to benefit from different treatment for calcaneal fractures
(I and III)

Radiological evidence of reconstructive quality and occurrence of posttraumatic degenerative signs (arthrosis)
(I and III)

Evaluation of fracture classifications with respect to reliability and reproducibility
(II)

Which treatment recommendations should be advocated for a calcaneal fracture?
(III)

Long term evaluation of in-situ fusion without consideration of deformity after calcaneal fractures. Is there a correlation between deformity and result?
(IV)

5 PATIENTS AND METHODS

5.1 IN STUDY 1 AND 3 THE DATA CONSISTS OF THE RCT MATERIAL.

Eighty-two patients who presented to five trauma centres between 1994 and 1998 with an intra-articular calcaneal fracture with a minimum of 2 mm of displacement (as verified by CT) were randomized to operative or non-operative treatment. Independent observers followed the two groups radiographically and clinically at one year and then at eight to twelve years. The primary outcome measures were a visual analog scale (VAS) for pain and function (Hildebrand et al-96) and the self-administrated Short Form (SF-36) general health status questionnaire. The secondary outcome measures were residual pain evaluated with a VAS, the American Orthopaedic Foot & Ankle Society (AOFAS) scale (Kitaoka et al-94), and the Olerud-Molander (OM) scale (Olerud et al-84).

Exclusion criteria included peripheral neurovascular disease, an open fracture, uncontrolled diabetes mellitus, and medical contraindications to surgery. Demographic data were obtained from the patients.



Fig 29. The wrinkle test is shown

Surgery was performed within two weeks after injury, once the local soft-tissue swelling had subsided, which was considered when a positive wrinkle sign was present (Fig 29). It included open reduction with use of the lateral extensile approach as described by Benirschke and Sangeorzan and manipulation of the fragments as described by Soeur and Remy to achieve anatomic reduction. The aim of the surgery was to reduce the fracture anatomically with careful reduction of the fractured bone and alignment of the joint fragments. Then after temporary fixation with wires the bone was gradually stabilised with plates and /or screws.

Perioperative imaging was done with Brodén views (Brodén-49) and C-arm. The fractures were fixed with screws (n = 2), reconstruction plates (n = 29), or calcaneal plates (n = 11). Bone graft was used in four cases (10%). Postoperative radiographs and CT scans were used to evaluate the quality of the fracture reduction. Six weeks of non-weight-bearing was recommended for patients in both treatment

arms with ankle range-of-motion exercises allowed during this period. Subsequently, the patients were allowed full weight bearing and participation in a standardized physiotherapy regimen.

Non-operative treatment included rest, elevation, and non-weight-bearing. Early ankle range-of-motion exercises were encouraged as tolerated. Weight bearing was allowed after six to eight weeks. None of the patients were managed with impulse compression therapy.

When the study was designed, operative treatment was considered superior to non-operative treatment. A power analysis was therefore performed on the basis of a 30% improvement in the primary outcome measures with operative treatment. It was estimated that seventy-nine patients would be required to attain a power of 80% with a p value of <0.05 and a confidence interval (CI) of 95%. During the patient inclusion period and the following year, it became evident that we would need a larger sample size to prove the superiority of the operative treatment. However, the high infection rate following operative treatment reduced our enthusiasm for expanding the trial.

Block randomization was utilized. An equal number of operative and non-operative interventions (fifty each) were assigned prior to the recruitment of patients, and sealed opaque envelopes containing these assignments were prepared. The envelopes were divided randomly into five groups and sent to the participating centres; the treating surgeons were blinded to the size of each block. When a patient with a CT-verified displaced intra-articular calcaneal fracture presented and was deemed eligible for the trial, he or she was given full information about the study and was then randomized by choosing an envelope. No stratification was performed. The randomization took place before further classification of the fracture was performed.

The treating surgeon performed clinical review of the patients in both groups at two weeks, eight weeks, three months, and six months. At one year and at eight to twelve years (mean, ten years) after injury, the patients were evaluated by one of two surgeons who had not been involved in the treatment in order to minimise bias.

At the one-year and eight to twelve-year follow-up, the patient and surgeon completed various outcome instruments. VAS-calcaneal score, SF-36, AOFAS and OM score was completed.

A clinical examination was also performed during each evaluation to measure the range of motion of the ankle and subtalar joints and the length and width of the hind foot. The contralateral, nonfractured foot was used for comparison. Shoe problems, complications and the outcome of their treatment, and work-related injury compensation status were documented.

Radiology:

All patients were evaluated with plain X-ray and Brodén views (Brodén -49) for the diagnosis. Further examination with CT in 2 planes was done before randomization. The group that underwent surgery were re-examined with plain films and CT to evaluate the reduction. Further X rays with plain films were taken at 6 weeks, and then at a follow-up at 1 year and 4 years with both plain films and CT. Senior radiologists together with the orthopaedic surgeon evaluated all X-rays.



Fig 30. Better result group (study3) treated surgically, but still with step in joint post surgery

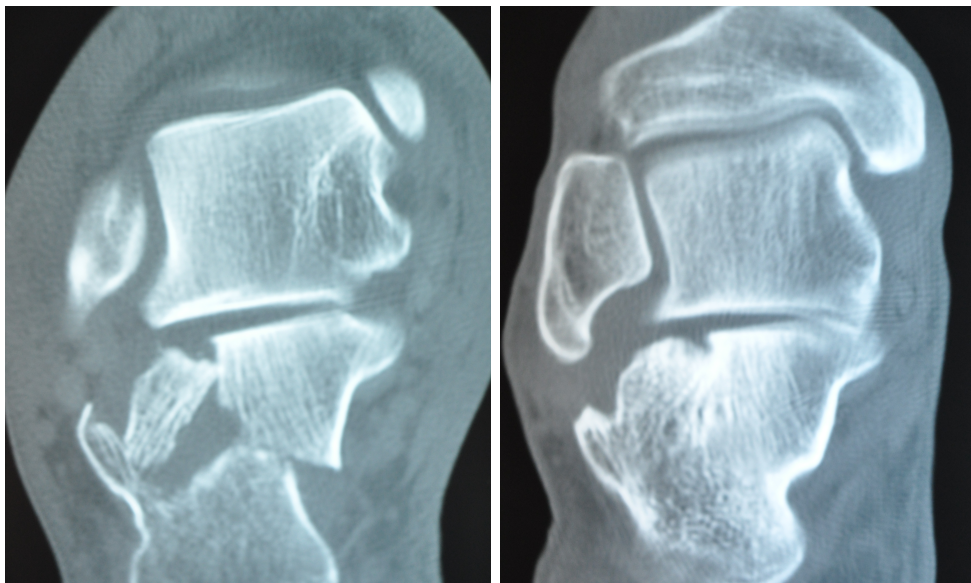


Fig 31. Better result group (study 3) treated nonsurgically

Statistical Analysis

Outcomes were analysed on the basis of the intention-to-treat principle. The mean, standard deviation, and 95% CI were calculated for each variable of interest. Only bivariate comparisons were made; multivariate analysis was not performed. The Mann-Whitney U test was used for the comparison of all outcome indices between the two groups, and a two-sample t test was used for the comparison of the Bohler angles. A p value of <0.05 was considered significant.

5.2 STUDY 2

In study 2 the radiographs of 51 intra-articular calcaneal fractures were analysed. The films were derived from a consecutive group of patients included in the prospective RCT. We had plain X-ray images (lateral and axial view, as well as a series of Brodén

projections) and a series of CT scan images from two planes with 2 mm slices (one coronal, perpendicular to the posterior talocalcaneal articulation, and one longitudinal parallel to the sole of the foot). Before starting the study, several calcaneal fractures were assessed by the observers in order to come to agreement about how to apply the tested classification systems.

The plain X-ray and CT scan images of the calcaneal fractures were assessed twice at a five monthly interval, by three observers; two radiologists with a special interest in musculoskeletal injuries and one orthopaedic surgeon with training in elective and trauma foot and ankle surgery. During the entire study, the observers were blinded to each other's results.

First, the fractures were evaluated with plain X-ray images including Brodén projections. At that stage, the Bohler's angle was measured as the angle formed by a line drawn between the highest part of the anterior process and the highest part of the posterior articular surface and a line drawn between the highest part of the posterior articular surface and the highest part of the calcaneal tuberosity. The Bohler's angle (Bohler-31) measurements were grouped in 10-degree intervals for statistical analysis. Thereafter, the extension of the fracture into the calcaneo-cuboid joint was determined. The fractures were then classified according to Sanders (Sanders et al-93) (using the seven subgroups), Zwipp (Zwipp et al-89), and Letournel (Letournel-84) using the CT scan images. Moreover, CT scan images were also used to evaluate the extension of the fracture to the calcaneo-cuboid joint (answered as yes or no).

Statistical analysis

Interobserver reliability, determined by comparing the measurements made by the three observers, was accomplished using Fleiss kappa while intraobserver reproducibility, comparing the first with the second measurements of each observer, was assessed with Cohen's kappa. This was achieved by using the JMP program (SAS software; SAS Institute Inc., Cary, NC). Kappa values range from -1.0 (complete disagreement) through 0.0 (chance agreement) to 1.0 (complete agreement).

Interpretation of kappa statistics varies in the literature. According to Fleiss, values exceeding 0.75 represent excellent agreement, 0.4 to 0.75 represent fair to good agreement and values less than 0.4 as poor agreement. Negative Kappa values represent a negative or reverse correlation according to Landis and Koch (-77). Svanholm et al. (-89) recommend other values of interpretation: 0.0, poor agreement; 0.0 to 0.20, slight agreement; 0.21 to 0.40, fair agreement; 0.41 to 0.60, moderate agreement; 0.61 to 0.80; substantial agreement; and 0.81-1.00, excellent agreement. In paper 2, the mean kappa values were used, leaving the evaluation of the degree of their reliability and reproducibility to the reader's judgment.

5.3 STUDY 4

By searching all hospital archives in the Stockholm area, 29 patients were found who had been fused after calcaneal fractures between 1970 and 1990. They had all been treated with in-situ single or multiple fusions. Since none of the patients had been treated with osteotomies or a distraction-bone-block procedure to correct the deformity, all 29 patients were included in the study.

All 29 patients were evaluated radiologically with plain weight bearing radiograms as well as 2-plane CT-scan in axial and coronar planes. Healing of the fusion and also the deformity were evaluated. We also evaluated the remaining deformity according to a classification developed by Zwipp and Rammelt (2006). This classification stepwise adds further possible pathology that may need to be addressed when treating a posttraumatic painful condition after a calcaneal fracture.

The patients were also evaluated at a hospital visit with an interview and a study protocol that included, VAS score for calcaneal fractures, the SF-36 and also Olerud- Molander score and AOFAS hind foot score. Reoperations, time of casting and return to work was also registered as well as remaining invalidity as scored by insurance company and problems with shoe wear.

Bony situation>	A (Malunions)	B (Non-Unions)	C (Aseptic/ septic Necrosis of bone)
Deformity			
I no deformity only posttraumatic arthritis	AI	BI	CI
II added varus or valgus of hindfoot	AII	BII	CII
III : added loss of height and dorsal tilt of talus	AIII	BIII	CIII
IV : added lateral translation of calcaneus, with abutment of fibula to dorsal facet of ST- joint	AIV	BIV	CIV
V : Adds with a talar tilt out of the ankle joint	V	BV	CV

Fig 32. Deformity classification after calcaneal fractures by Zwipp & Rammelt

6 RESULTS:

6.1 STUDY 1

Eighty-two patients were recruited; forty-two (twenty-nine men and thirteen women) were randomized to the operative group and underwent surgery, and forty (thirty men and ten women) were assigned to the non-operative group. Three patients in the operative group and two patients in the non-operative group had bilateral fractures. No demographic differences between the two groups were observed with respect to age or fracture type (Fig 31), suggesting integrity of the randomization process. All patients received the type of treatment to which they had been allocated (Fig. 32).

The senior radiologists at the centres evaluated the preoperative radiographs and CT scans where the patients had surgery. The Bohler angle was measured at the intersection of two lines drawn from the posterosuperior aspect of the calcaneal tuberosity to the highest point of the posterior articular facet and to the anterior process of the calcaneus. The preoperative Bohler angles are given in fig 33, and the postoperative angles ranged from 0° to 40° (mean and standard deviation, 26° ± 9°).

	Operative Group (N = 42)	Nonoperative Group (N = 40)	P Value
Sex	29 M, 13 F	30 M, 10 F	0.34
Age* (yr)	49 ± 14 (24 to 76)	48 ± 13 (20 to 72)	0.81
Sanders fracture type ⁸ (no.)			0.18
2A	13	11	
2B	4	9	
2C	3	2	
3AB	7	8	
3AC	7	5	
3BC	3	2	
4ABC	5	3	
Preop. Böhrer angle* (deg)	11 ± 12 (−20 to 40)	11 ± 10 (−10 to 30)	0.97
Work-related injury compensation (no.)	0	2	

*The values are given as the mean and the standard deviation, with the range in parentheses.

Fig 33. Demographic data RCT

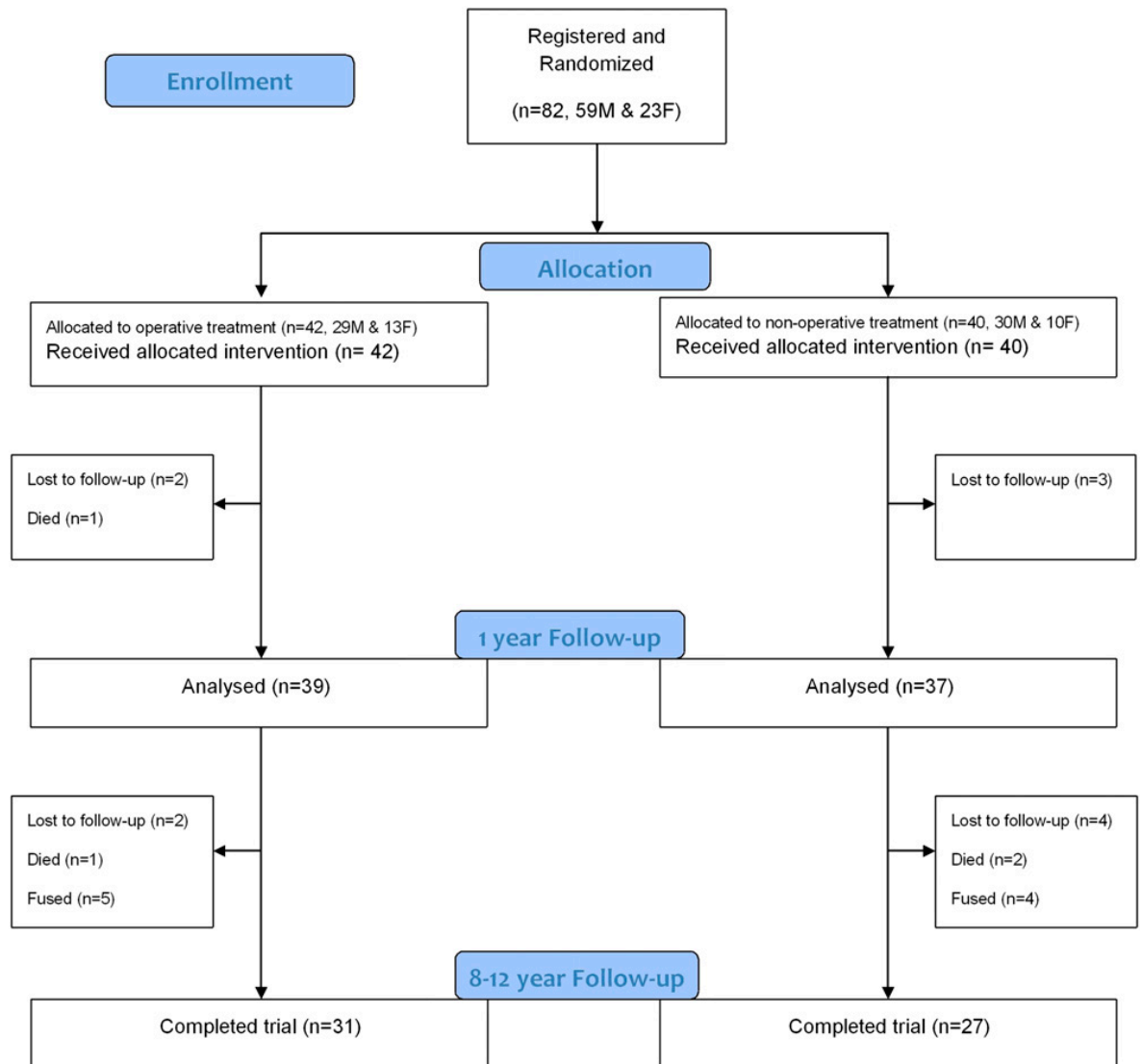


Fig 34. Flow chart of patients in the RCT

Operative Treatment

The local senior radiologists evaluated postoperative axial and coronal CT scans. The scans revealed that the fractures in twenty-four (57%) of the forty-two patients had been reduced to <2 mm of displacement, eleven (26%) had been reduced to 2 to 5 mm, and four (10%) had been reduced to >5 mm. The CT scans of the remaining three patients were unavailable for review.

Postoperative complications during the first twelve weeks included superficial wound infections in eight patients (19%), treated successfully with dressing and antibiotics; a chronic MRSA (methicillin-resistant *Staphylococcus aureus*) infection in one patient (2%), treated with amputation and a deep infection and fistula in one patient (2%) treated with implant removal and antibiotics. One patient developed compartment syndrome and was treated with foot fasciotomy.

Thirty-nine patients were available at one year of follow-up and thirty-one were available at eight to twelve years (mean, ten years).

Non-operative Treatment

One patient developed compartment syndrome and was treated with foot fasciotomy. Two patients had severe symptoms in the foot after non-operative treatment and retired from their employment. These were the only patients in either group who had work-related injury compensation.

Thirty-seven patients were available at one year of follow-up, and twenty-seven were available at eight to twelve years (mean, ten years).

Primary and Secondary Outcome Measures

At one year of follow-up, no significant differences were found between the two groups with respect to the primary outcome measures (VAS pain and function score and SF-36 score) or the secondary measures (VAS pain at rest and during weight-bearing, AOFAS score, and OM score) (Fig 35). Nine (23%) of thirty-nine patients in the operative group and seven (19%) of thirty-seven in the non-operative group had difficulty using their previous shoes and needed orthopaedic shoes.

At one year of follow-up, the axial and coronal CT scans revealed that twelve patients in the operative group and twenty in the non-operative group had signs of subtalar arthritis, characterized by diminished joint space, sclerosis, osteophytes, and subchondral cysts. Calculation of the relative risk (RR) of developing radiographically evident subtalar arthritis indicated that operative treatment reduced the risk by 41%.

At eight to twelve years (mean, ten years) of follow-up, the primary VAS score for pain and function and the physical component of the SF-36 were higher in the operative group ($p = 0.07$ and 0.06 , respectively) (fig 36). The secondary outcome measures did not differ significantly between the two groups. Only one of the patients with bilateral fractures was available for follow-up at this time point. Ten (24%) of the patients in the operative group had undergone implant removal. Five (12%) of the patients in the operative group and four (10%) of the patients in the non-operative group had undergone subtalar arthrodesis.

	Operative Group*	Nonoperative Group*	P Value
VAS pain and function scoring by patients	56.9 ± 26.4 (48.6-65.2)	54.8 ± 23.7 (47.1-62.4)	0.71
VAS pain and function scoring by surgeon	66.1 ± 25.6 (58.0-74.1)	66.9 ± 22.6 (59.6-74.2)	0.90
SF-36 physical	48.0 ± 20.8 (41.5-54.5)	42.5 ± 21.4 (35.6-49.4)	0.40
SF-36 mental	52.5 ± 23.3 (45.2-59.8)	50.5 ± 21.9 (43.5-57.5)	0.70
*The values are given as the mean and the standard deviation, with the 95% CI in parentheses.			

Fig 35. Primary outcomes at 1 year

	Operative Group*	Nonoperative Group*	P Value
VAS pain and function scoring by patients	72.0 ± 21.7 (64.4-79.6)	61.0 ± 24.4 (51.3-70.6)	0.07
VAS pain and function scoring by surgeon	80.0 ± 20.3 (72.8-87.1)	73.0 ± 24.0 (63.5-82.5)	0.25
SF-36 physical	47.6 ± 9.8 (44.1-51.0)	40.8 ± 11.9 (36.1-45.5)	0.06
SF-36 mental	49.8 ± 9.9 (46.3-53.3)	51.0 ± 10.3 (46.9-55.1)	0.66
*The values are given as the mean and the standard deviation, with the 95% CI in parentheses.			

Fig 36. Primary outcomes at 8-12 year

6.2 STUDY 2

Letournel (with CT) Possible interpretation of fracture	Tongue type 2T, 3T, 4T	Joint depression type 2D, 3D, 4D	
Sanders	A	B	C
Fracture line (in Subtalar joint)			
Possible interpretation of fracture	2A, 3AB, 3AC, 4ABC	2B, 3AB, 3BC, 4ABC	2C, 3AC, 3BC, 4ABC
Zwipp	x affected joints	y affected fragments	Sum of x + y
Possible interpretation of fracture	1,2,3	1,2,3,4,5	1,2,3,4,5,6,7,8

The **Letournel classification** is based on the premise of a constant separation line that runs longitudinally along the sagittal axis of calcaneus from the posterior facet through the anterior portion to the calcaneocuboid joint, always behind the interosseus ligament. This line gives rise to a two-part injury. An injury can create further secondary, tertiary etc. fracture lines and turning the fracture into a three-part or four-part fracture. If the fracture lines end in the subtalar joint it becomes a depression injury whereas if it extends into the tuberosity it becomes a tongue type. So, a 2-part depression would be 2D and a 4-part tongue type 4T.

The **Sanders classification** is based on coronal and longitudinal CT-images through the widest portion of the posterior facet. Type 1 represents a non-displaced fracture, Type 2 (A/B/C) a two-part fracture, Type 3 (AB/AC/BC) a three-part fracture and Type 4 a fracture of 4 or more fragments in the posterior facet. The fracture lines are defined A, B or C meaning lateral, central or medial thirds of the joint span.

The **Zwipp classification** is derived from the number of joints being damaged, one, two or three plus the number of fragments being damaged (one to five). These possible five fragments consist of the sustentaculum, tuberosity, subtalar joint fragment, anterior process and the anterior subtalar joint fragment.

Fig 37. The details of the Fracture classifications used

The Fleiss kappa for the measurement of inter-observer reliability of the studied fracture classification systems is shown in fig 38, while the Cohen's kappa for the assessment of intraobserver reproducibility is shown in fig 39. The mean of all Bohler's angle plain X-ray measurements was 12.5 (range, 10.6 to 14.5). We found that one third of the time the observers agreed with each other (kappa value ranging from 0.28 to 0.45) and with themselves (kappa value ranging from 0.32 to 0.32) on two separate occasions within 10-degree intervals when measuring Bohler's angle.

Fracture extension into the calcaneo-cuboid joint was reported in more patients (mean, 34.5) when CT scan images were added compared to plain X-ray images (mean, 13.3) ($p < 0.05$). The observers agreed with each other two-thirds of the time and with themselves half of the time on two separate occasions in exploring the involvement of calcaneo-cuboid joint when using the CT scan images.

Classification	Kappa	Mean Kappa
Sanders	0.03–0.65	0.25
Zwipp fragments	0.10–0.51	0.30
Zwipp joints	0.30–0.79	0.51
Zwipp	0.06–0.43	0.24
Letournel	0.20–0.77	0.50

Fig 38. The Interobserver Reliability using the Fleiss Kappa

Classification	Kappa	Mean Kappa
Sanders	0.27–0.42	0.39
Zwipp fragments	0.15–0.32	0.24
Zwipp joints	0.15–0.53	0.39
Zwipp	0.07–0.27	0.16
Letournel	0.02–0.69	0.42

Fig 39. The Intraobserver Reproducibility using the Cohen's Kappa

6.3 STUDY 3

In this study the RCT data was re-evaluated from a different perspective. Which treatment can be shown to predetermine the result in the treatment of dislocated intra-articular calcaneal fractures?

The data from the RCT study that we reported in paper 1 was stratified differently using the functional VAS-calcaneal score as a determinant. By splitting the whole cohort in two groups, 50% better and 50% worse, based on the functional result we evaluated the differences between the two groups.

	Superior group	Inferior group	p-value
VAS (ref)	87.8 (SD 7)	48.7 (SD 16)	<0.01
SF-36 physical	52.2 (SD 6)	37.7 (SD 10)	<0.01
SF-36 mental			
AOFAS	88.2 (SD 10)	70.2 (SD 14)	<0.01
OM score	92.1 (SD 12)	68.0 (SD 23)	<0.01

Fig 40. The measured outcome indexes of the superior and inferior groups.

Two patients were excluded from the measurements because they had the same VAS measure that was the median value of the new group (i.e. the cut-off value between the superior and inferior groups) and therefore could not be placed in one of these groups. This left 28 patients in the superior group and 28 patients in the inferior group. There were 22 men and 6 women in the superior group and 22 men and 6 women in the inferior group while the mean age of the patients in the superior group was 46 years (SD 13) and in the inferior group was 48 years (SD 14) ($p=0.7$). The mean of the determinant outcome measure (VAS) in the superior group was 87.8 (SD 8) and in the inferior group it was 48.4 (SD 16) ($p<0.01$). The other outcome measures (SF-36, AOFAS, OM index) in both groups are listed in fig 38.

The results for comparing the fracture type according to Sanders classification, treatment given (operative vs. non-operative), pre-treatment Böhler angle, Böhler angles at healing, residual articular surface step-off at healing, type of occupation and presence or absence of injury insurance between the two groups are listed in fig 39. This table shows that light labourer/retired, operative treatment, restoration of Böhler angle at healing and absence of injury insurance were associated with the best outcome. Restoration of the articular surface at healing was commoner in the best outcome group ($p=0.07$). No difference between the two groups was found in regard to the pre-treatment Böhler angle and fracture type.

	Superior group	Inferior group	Odds ratio (CI)	p-value
Fracture type (Sanders)	S2=17 S3=7 S4=4	S2=13 S3=13 S4=2	1.8 (0.6-5.1)	0.16
Treatment	Operative=20 Nonoperative=8	Operative=9 Nonoperative=19	5.3 (1.7-16.5)	0.02
Pre treatment Böhler's angle (degrees)	1.1 (SD 12.4)	4.7 (SD 14.1)	NA	0.68
Böhler's angle at healing (degrees)	17.6 (SD 12)	12.1 (SD 11)	NA	0.05
Operative Treatment	22.15 (SD 11)	22 (SD 10.3)	NA	0.97
Non-operative Treatment	6.25 (SD 8.7)	6.6 (SD 9.1)	NA	0.92
Residual articular surface step-off	< 2 mm=11 > 2 mm=17	< 2 mm=5 > 2mm=23	3.0 (0.9-10.1)	0.07
Occupation	Heavy=11 Light/retired=17	Heavy=18 Light/retired=10	0.3 (0.1-1.0)	0.06
Injury insurance	Present=11 Not present=17	Present=19 Not present=9	0.3 (0.1-0.9)	0.04

Fig 41. The comparison between the results obtained from the superior and inferior groups. NA=not available.

6.4 STUDY 4

The mean age of injury (age at fracture incidence) was 34 years and the fusions were performed at a mean age of 37 years. (Fig 42) Several techniques had been used, with and without bone grafting in the joint space, but without any distraction, osteotomy or anatomical restoration. The fusions had sometimes been secured with casting, (no internal fixation), and sometimes with internal fixation i.e. staples or screws. All fusions were united.

COHORT	29 (20 men, 9 female) 23 unilateral, 6 bilateral		
AGE when fractured	34 SD 9,17		
AGE when Fusion after fracture	37 SD 10,15		
Reoperations	12/29 (41%)	1-12 occasions	
Infection	4 (14%)		
Invalidity (13/29)	17,2% SD 8,73	Range 7-35%	
Shoe-fit problems	16/29 (55%)		
Return to work	13/29 Full-time 45%	1/29 halftime	15/29 retired / disabled 52%
Post-compartment syndrome (clawing toes)	10/29 (35%)		
Signs of CRPS	8/29 (28%)		
Iatrogenic nerve damage	13/29 (45%)		

Fig 42. Demographic data and results

Return to work was accomplished in 13 patients full-time and in one patient half time. In 12 of the patients reoperations /revisions had been performed, mainly due to non-healing, but also due to infection and hardware problems. The range for reoperations was 1-12 further procedures. In 4 of the fusions, infection problems occurred during the treatment. (14%). The rest, 15 patients (52%), were all disabled also after surgery to such an extent that working was no longer possible. The worst cases were using a wheel-chair for ambulation 98% of the time whereas the best post-surgery were able to do long-distance running.

Signs of or sequelae after compartment syndrome (with clawing of toes) were noted in 10 patients (35%) .

In 13 patients the degree of invalidity was noted (after decision by insurance companies). The mean invalidity was 17,2% ranging from 7-35%.

Signs of CRPS (Complex Regional Pain Syndrome) were noted in 8 patients (28%), (oedema, allodynia, dull sensation, bluish skin etc.). Signs of sensory impairment (due to iatrogenic damage) were noted in 13 patients (45%). Sixteen of the patients still claimed they had problems with shoe fitting (55%)

	Mean	Std deviation	Std error	Comparison from published RCT data 8-12 years
VAS (pain)at rest	1,5	2,23	0,4141	0,8
VAS (pain) at exertion	4.1	3,28791	0,61055	1,7-2,1
Max exp VAS (pain)	6,1	3,83913	0,61055	
Olerud-Molander	46,7	28,57558	5,30635	76,3-83,2
AOFAS hindfoot	56,9	24,75933	4,59769	77,2-81,0
VAS pain & function score patient	49,8	28,4727	5.28725	61,0-72,0
VAS pain & function score (doctor)	56,9	32.05345	5.95218	73,0-80,0
SF36 mental	65,9	21.60827	4.15851	49,8-51,0
SF36 physical	46.5	15.98568	2.96847	40,8-47,6

Fig 43. The pain measured by VAS at rest and exertion and PROM-data

Zwipp-Rammelt Class	Unilat cases	Bilat cases
AI	3	
AII		
AIII	18 (1 with remaining considerable varus)	6
AIV	2	6

Fig 44. Distribution of deformity evaluated by CT and plain films according to the deformity classification

As the same measuring instruments were used in our study for calcaneal fractures the data after 8-12 years are included for comparison.

In fig 44 the results of the radiological deformity evaluation according to Zwipp and Rammelt (-06) are shown. As shown there was a large degree of remaining deformity in the study that was treated with in-situ fusions. We also determined if there was a correlation between the clinical result and the deformity-analysis. A correlation analysis was made between the results of the PROM-scores and the deformity classification of Zwipp-Rammelt (fig 45 & 46)

Fracture class	No.	VAS score Mean (SD)	AOFAS Mean (SD)	OM Score Mean (SD)	SF-36 physical Mean (SD)	SF-36 mental Mean (SD)
AI	3	71.0 (12.7)	76.3 (12.0)	51.6 (20.2)	86.6 (5.7)	56.0 (14.4)
AIII	20	52.7 (30.2)	61.6 (23.1)	43.7 (31.5)	51.3 (30.5)	68.0 (23.6)
AIV	6	29.6 (14.5)	31.5 (15.8)	54.1 (22.6)	37.5 (14.4)	64.0 (17.8)

Fig 45. Results according to the fracture class by Zwipp & Rammelt.

	AI vs AIII	AI vs AIV	AIII vs AIV
<u>VAS scoring</u>	0,06	0,02*	0,12
<u>AOFAS</u>	0,31	0,02*	0,003*
<u>SF-36 physical</u>	0,10	0,02*	0,40
<u>SF-36 mental</u>	0,40	0,57	0,40
<u>OM score</u>	0,45	0,71	0,29

The * shows where there is sign of significance

Fig 46. Correlation between deformity and score-result (Mann-Whitney U-test (two- tailed))



Fig 47. Example of remaining deformity after healed fusion with dorsal rotation of talus into calcaneus

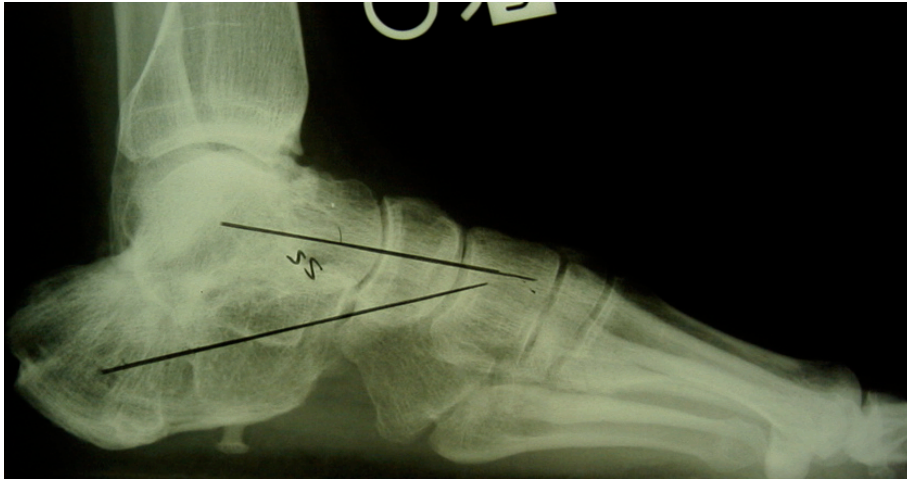


Fig 48. Example of healed fusion with more normal alignment of talus

6.5 METHODOLOGICAL CONSIDERATIONS

Statistical analysis:

In paper one, three and four, the statistics used are mainly descriptive including standard deviations and confidence intervals. Univariate inferential statistics with significance as p-values are also calculated.

In paper two Fleiss kappa was used to calculate the Interobserver reliability and Cohen's kappa, the intraobserver reproducibility.

7 DISCUSSION

In paper 1 the results after the RCT study, which included patients between 1994-98, were presented.

In this study a so-called block randomization was used. This means that the treatment given to the patient was decided upon opening a sealed opaque envelope with instructions to the attending surgeon. There were very few dropouts (patients admitted but not included during our study). The amount of non-surgical compared to surgical patients was almost equal as was the distribution in gender and age and also in severity. This implies that the randomization process has been successful.

Whereas the non-surgical management is straightforward, the surgery is more problematical. Were the surgeons good enough? Surgeons who had extensive experience of fracture treatment treated all of the patients that were operated on. However at the start of the study none of the surgeons had done more than a couple of calcaneal fractures and it was mainly general training in fracture surgery that was relied upon. In a way we can therefore say that our study reflects what will be the success of calcaneal fracture treatment if a change from conservative to operative treatment is implied?

All surgeons participated in-group discussions about the various aspects of the surgeries and decisions were made about how patients should be managed. Some of us even used the possibility to double up for some of the surgeries. In the literature there have been numerous reports about the learning curve for a calcaneal fracture surgeon. (Sanders et al-1993, Thordarsson et al-1996, Buckley et al.-2002, Howard et al-2003, Gougolias et al-2009)

In this study we were able to reduce the fractures to anatomic or close to anatomic (0-2 mm residual displacement left) in no more than 64% of patients. But even reducing the fragments to anatomic or near anatomic configuration, the joints that form the subtalar joint complex and are located on the heel bone have a very specific three-dimensional relationship. This needs to be exact in order to form a functional complex. Having a very small rotation or angulation of one of these joints severely disables the joint complex and this could be very difficult to measure. It appears that on an individual basis there are large variations in the configuration and orientation of these joints. The ankle is much more consistent. Clinically this is observed as different varieties of foot shape varying from flatfoot to cavus foot. This gives rise to a different appearance of the joint complexes.

Of course, the fracture reduction could be made against the talus and the talar part of the joint that usually is not damaged, but even so there seems to be very limited tolerance to malalignment in the complex of the joints around calcaneus.

Being a surgeon I find that when the mount of the fixation has been done and the joint is checked for mobility and is found to move nicely, this tends to correlate with a well functioning result. If the subtalar motion is severely impaired I tend to check again if the implants are hindering the motion. Usually they are not, but I probably then have

not managed to reduce the joints in such a way that the motion is free. When checking the reduction with CT postoperatively step-offs and gaps can be measured between fragments but this possible mal-rotation of fragments is difficult to measure.

In my opinion the alignment of the subtalar joint segments and the relationship between them seems to be one clue to understand why it is difficult to fully restore the subtalar motion.

It has been shown that for the severely damaged fractures with multiple segments or fracture-lines in the ST joint, a reduction of the bone morphology in combination with a primary subtalar fusion seems to get the best results. (Swanson et al-2008).

The other obvious problem that comes into mind with the limited difference between the two treatment groups is the problem of a double soft tissue injury in the handling of calcaneal fractures. As we generally do not operate as an emergency, but usually after the swelling has subsided after about a week, this can cause a second injury. By this time those patients that have gone to non-surgical management are usually pain-free and have already regained some motion and showing improvement. Aggressive exposure and stripping of the fragments and manipulation of the broken bone will increase the soft tissue swelling and damage again, and probably even further initiate the fibrosis of the soft tissues, tendon sheaths, intrinsic muscles etc.

If the surgery then is not very successful and leads to a good or excellent congruity and restoration of the bone we are likely to do more harm than good.

The question is, are we optimal in our handling of the soft tissues? In the long bones a primary stabilisation is recommended to minimise the bleeding and soft tissue problems.

To my knowledge no studies have been described that have tried some type of preliminary spanning or stabilisation with calcaneal fractures. This could be done with an external frame or something similar, to further decrease the bleeding and to keep the shape and length of the bone. This is surprising, as a tibial pilon fracture would never be treated similarly. They are always stabilised in some way in order to keep the length and to lower the stress on the skin and soft tissues.

How should we present data and report on studies like the RCT?

Should studies be reported as in paper 1 or 3? (Younger-2013)

I find this academically very intriguing and debatable. In orthopaedic surgery we cannot get endless numbers of cases like for example in the pharmaceutical industry. Therefore RCT studies might not be the best way of showing evidence in treatment? It is far more interesting to me as a clinician to discuss which of two named treatment options performs best and gives the best results? In fracture studies it is always very difficult to get sufficient numbers in a reasonable time. And in fracture studies there are so many pitfalls that can manipulate the results.

Are the fractures reduced in an expert way? Is the fixation solid enough? Did the fracture heal without complications? Soft-tissue problems? Infection? Fibrosis?

The results regarding the quality of the fracture reduction were checked with CT. This is a more precise way of evaluation than plain films. We actually believe that it is not possible to check the fracture reduction with plain films. In our study, at least 36% of the surgically treated patients had a residual subtalar displacement of ≥ 2 mm. Other authors have reported a greater proportion of patients in whom subtalar reduction was < 2 mm and better final results compared with our study. (Buckley et al-2002, Basile - 2010, Thordarsson et al-1996)

Another goal was detecting possible compartment syndromes during the immediate post injury period. In order to do this we distributed a catheter that should be inserted medially into the deep calcaneal compartment. This could be done without any anaesthesia, and made it possible to repeatedly check the pressure several times. However, this was a difficult procedure with many practical problems and we could therefore not acquire enough data for publication. Our statistics on compartment syndrome refers to the occurrence of clawing toes as a late sign of this event.

We also wanted to measure the occurrence of complex regional pain syndrome or reflex dystrophy. An anaesthesiologist with a special interest and knowledge in this was involved. His role was to examine and document all patients who had some clinical signs of this syndrome. Unfortunately, during the study period very few patients were referred to him due to different reasons.

The study was set up as a multi-centre study. The reason for this was that these fractures are rare. When the present trial was started in the early 1990s, we were convinced of the superiority of operative treatment of calcaneal fractures. However, the results of the trial have refuted this hypothesis.

We used four different Patient Reported Outcome Measurements (PROM's). One of the primary ones was the SF-36. This is the only one with multi-lingual validation. This PROM reflects not only the function of the patient but also their social and psychological condition. Overall this is a score that is very interesting as it makes different medical conditions comparable, for example the outcome of hip arthroplasty can be compared or myocardial infarction (SooHoo et al-2006, Nilsson et al-2007).

The other primary outcome was the VAS-calcaneal score. This was being used in a Canadian study and as we thought it seemed to reflect the functional status of the heel bone and rear foot in a very good way it was used in this study. However, it had not been validated for Sweden, only translated. Looking at the questions makes it obvious that it is an instrument that is very focused on assessment of the foot. The interesting feature with bringing this score into our study is that we could extend the Canadian study with our material and combine the interpretation of them. (Hildebrand et al-1996)

The AOFAS score was and is, the most widely used scoring instrument in the literature. However it has many drawbacks from a scientific point of view. It has not been validated properly and is simply translated into Swedish. It does not allow for missing values, and it is pseudo-subjective as it includes questions that ask the surgeon to quantify alignment and movement. (Kitaoka-1994)

The Olerud-Molander score was published in the context for ankle fractures. However we thought that this should be close enough for calcaneus. It was originally developed in Sweden, but never rigorously validated in the way that is accepted today. It uses, as does the AOFAS, a Lickert scale with 4 answers to every question that is an accepted way of obtaining patient responses. (Olerud et al –1984)

We also used the VAS as a means of pain measurement. This is a widely accepted method. At eight to twelve years of follow-up, two important primary outcome measures (the VAS pain and function score reported by the patient and the SF-36 physical component summary scale) were obviously better in the operative group but the differences did not reach statistical significance.

The reasons that operative treatment failed to demonstrate better results could be multifactorial. First, the cohort size could have been insufficient to demonstrate a difference in the outcome measures between the two treatments. Another possible reason involves the complex pathoanatomy of displaced intra-articular calcaneal fractures, as the subtalar joint has a unique motion pattern in relation to the adjacent talo-navicular and calcaneo-cuboid joints. Any residual displacement might lead to a disturbance of the motion pattern among these three joints 17 with subsequent pain and walking difficulty. (Mulcahy et al -1998). A third possibility involves the associated joint-surface injury and soft-tissue trauma sustained at the time of injury. Aggressive exposure and osseous reduction may be required to achieve proper alignment during surgery, potentially adding new trauma to the original injury. (Howard et al-2003)

DeWall et al. compared open reduction and internal fixation with use of a lateral extensile approach with percutaneous reduction. They found comparable results for the two surgical approaches with significantly fewer wound complications in the percutaneous group. (DeWall et al-2010). Minimally invasive techniques such as closed, limited open and arthroscopic-assisted reduction with percutaneous or external fixation have been advocated for these fractures to reduce the surgical trauma. (Weber et al -2008, Magnan et al-2006)

At one year of follow-up, the results of operative and non-operative treatment were comparable. At eight to twelve years of follow-up, operative treatment yielded a better mean patient-reported primary VAS score for pain and function, although this did not reach statistical significance ($p = 0.07$). Moreover, the mean VAS score for pain and function was better at eight to twelve years of follow-up compared with one year, probably indicating an improvement in the evaluated parameters during the study period.

In the present study, the SF-36 scores in the two treatment groups were comparable at one year of follow-up. At eight to twelve years of follow-up, operative treatment resulted in a trend toward a higher mean SF-36 physical component ($p = 0.06$). However, the mean SF-36 scores in the present study were generally lower than those in a previous study. (Buckley et al-2002) This might be due to greater residual fracture displacement in the patients in our study as well as possible cultural and expectation-level differences between the patients in the two studies.

As secondary outcome measures, we used a VAS to evaluate the residual pain at rest and during weight bearing, and we used the AOFAS and OM scores to evaluate the functional outcome. The residual pain at rest and during weight bearing did not differ

significantly between the operative and non-operative treatment groups at either one or eight to twelve years of follow-up. This agrees with the findings of a recent meta-analysis of current evidence by Jiang et al. -2012 and a Cochrane report by Bridgman et al.-2000. Other investigators (Buckley et al -2002, Dooley et al-2000, Basile-2010) found better VAS pain scores only in certain subgroups, such as patients with no residual subtalar displacement or those who did not receive workers' compensation. The mean VAS pain score in our study also improved slightly at eight to twelve years of follow-up compared with one year.

The AOFAS score is a widely used outcome measure in patients with foot and ankle conditions (Naal et al-2009). However, debate exists regarding its limited validity and responsiveness. According to the most recent meta-analyses, (Gougoulas et al-2009, Jiang et al-2012) it is unclear whether the AOFAS score improves after operative compared with non-operative treatment of displaced intra-articular calcaneal fractures. In the present study, no significant difference between the two groups was found at either one or eight to twelve years of follow-up. Rammelt et al. (-2010) reported a higher mean AOFAS score after percutaneous arthroscopically assisted reduction and screw fixation of selected Sanders type-II calcaneal fractures compared with that reported in the present study, possibly as a result of the less traumatic percutaneous technique.

The OM score is typically used to evaluate residual symptoms and functional outcome after ankle fractures. (Olerud et al-1984) The results at both one and eight to twelve years were comparable after operative and non-operative treatment.

In a previous study, men who had a severely displaced fracture and received workers compensation had worse results and a higher risk of subtalar arthrodesis if they were treated non-operatively. (Buckley et al-2002) In our study, only two patients had such compensation; both were in the non-operative group and retired because of the injury. Therefore, no stratification of the results according to work-related injury compensation status was performed. Compensation systems vary among countries; furthermore, the validity of the outcome scores for patients receiving such compensation has not been documented.

The present study revealed a risk reduction of 41% for radiographically evident subtalar arthritis after operative compared with non-operative treatment. However, that reduction did not result in a significant difference in the measured outcomes. This might indicate a discrepancy between the radiographic changes and the clinical outcome. Furthermore, the risk of arthrodesis at the end of the present trial was not higher in the non-operative group (four patients, 10%) compared with the operative group (five patients, 12%).

A meta-analysis of previous studies has shown a clear advantage of operative treatment of displaced intra-articular calcaneal fractures with respect to shoe wears. In that meta-analysis, patients could use the same shoes as before the injury. (Jiang et al-2012) This was not the case in the present study, in which nine (23%) of thirty-nine patients in the operative group and seven (19%) of thirty-seven in the non-operative group had difficulty with shoe wear and needed special shoes or customisations.

The present study has some limitations. The sample size was relatively small. However, compared with other published randomized controlled trials, (Gougoulas et al-2009) the number of included patients and the extent of dropout make the

present study valuable. Another limitation is our inability to report the number of patients excluded from the study, as this information was not documented by some of the participating centres. However, we estimate that no more than ten patients were excluded. These limitations are counterbalanced by the strengths of the study, which was a prospective randomized multicentre trial with long-term follow-up.

In conclusion, the results of this study show comparable outcomes following operative and non-operative treatment of displaced intra-articular calcaneal fractures at one year of follow-up. There was a trend toward a better VAS pain and function score reported by the patients and a better physical component of the SF-36 score in the operative treatment group at eight to twelve years of follow-up. The risk of complications was higher with operative treatment. The prevalence of radiographically documented posttraumatic subtalar arthritis was higher, but the need for secondary subtalar arthrodesis was not increased, following non-operative treatment.

In paper 2 we evaluated fracture classifications for DIACF's.

For a Fracture Classification system (FCS) to be considered useful it should possess a number of characteristics. These include good Interobserver reliability and intraobserver reproducibility, ability to assess the degree of fracture severity, and ability to guide treatment plans and predict prognosis. Unfortunately, many of the commonly used FCSs lack these characteristics. The experience of the observers, the complexity of the tested FCS, the addition of CT scan to plain X-ray images, and the quality of the studied images have all been shown not to affect the reliability of the tested FCS.

The problem with any type of classification is that the judgment is subjective. Even if the examiners meet and discuss how they should evaluate certain conditions, it is generally difficult to get full agreement.

Also with numeric measurements such as angular measurements it is generally difficult to get total agreement between observers. However when evaluating an angular measurement it could be done as absolute i.e. for example 24 degrees or as agreement within a range 24 degrees +/-, for example 10 degrees. This is more appropriate in a clinical environment and makes more sense and is recommended.

With the classifications, different values have different problems. In the Letournel classification the more important part is whether a tongue type or depression type is present. If there are 2,3, or 4 segments it is more subjective.

In the Sanders classification the crucial point is which slice of the coronal CT-scan to use to decide the amount of fragments? It would make sense to guess that a classification done with CT in 3D would be more precise here.

In the classification of Zwipp the difficult part is the different parts of the calcaneal body and whether the fracture extends into them or not. Also this would be far easier with 3D-CT.

Our findings, on the whole, agree with those of other authors that have made an analysis of fracture classification. This means that there is a low grade of agreement between different examiners and also a low grade of agreement for the same examiner investigating twice.

For calcaneal fractures, Schepers et al. (-2009) evaluated the interobserver reliability and variability for Essex-Lopresti, Crosby and Sanders classification systems. Twelve observers (six radiologists and six traumatologists) evaluated randomly selected plain radiographs and CT scans of 30 intra-articular calcaneal fractures. The Berstein grading system was used to determine the ability of these classification systems to guide treatment. Furthermore, the authors studied the available evidence in the literature for the correlation of these classification systems with the outcome. They found that, for the interobserver reliability, the overall kappa value for Sanders classification system without subgroups was 0.48 ± 0.02 while with subgroups 0.49 ± 0.02 , for Essex-Lopresti 0.26 ± 0.03 and for Crosby system 0.48 ± 0.02 . None of these classification systems was found to guide treatment. However, evidence was found that they could correlate with the outcome. The authors concluded that Sanders and Crosby classification systems were likely to be useful for the classification of intra-articular calcaneal fractures.

The Orthopaedic Trauma Association (OTA) classification is a commonly used CT scan based classification system. (Marsh JL et al -2007) For calcaneal fractures, there are three major types: Type A consists of avulsion, process, or tuberosity fracture; Type B consists of nonarticular body fractures; and Type C consists of articular body fractures involving the posterior facet. Type C is sub classified into three groups: C1, two part; C2, three part; and C3, four part.

The included groups are similar to those of Sanders classification but simpler in that identification of specific locations for those fracture lines is not required. This might improve the interobserver agreement for this classification since observers can more readily make the identification of these fracture patterns.

Humphrey et al. (-2005) tested the interobserver reliability among ten experienced traumatologists using the Sanders classification to classify 30 calcaneal fractures. Each of these fractures was represented by a single, carefully defined CT image. The mean kappa value was 0.41 ± 0.02 , i.e. no better than the results obtained using full CT scan imaging. Furthermore, the authors found that the Sanders classification had poorer reliability in discriminating between fractures in the mid range of the classification system (type 2 and 3) than it did between fractures at the extremes (type 1 and 4). Despite its popularity and based on the results of this and other studies, we believe clinicians should be aware of the reliability and reproducibility limitations of Sanders classification when using it in routine clinical practice.

Zwipp et al. first introduced the integration of CT scan images into the rational understanding of calcaneal fractures in 1993. A 12-point fracture classification was introduced, taking into consideration the number of main fragments (max, 5 points), the involved joint surfaces (max, 3 points) as well as the extent of soft tissue trauma and accompanying fractures of the adjacent bones (max, 4 points). Thereafter, Zwipp's classification has been evaluated and found to be of value in guiding therapy and predicting prognosis. (Andermahr J et al-2002) However, we are unaware of any published data testing the interobserver reliability and intraobserver reproducibility of Zwipp classification.

For the number of involved fragments, the mean kappa value of 0.30 for the interobserver reliability and of 0.24 for the intraobserver reproducibility was found. While for the involved joints the mean kappa values reached 0.51 for the interobserver reliability and 0.39 for the intraobserver reproducibility. Therefore, despite the ability of Zwipp classification to guide therapy and predict prognosis, clinicians should be aware of this classification's limitations regarding its reliability and reproducibility.

The Letournel classification had not been previously tested for interobserver reliability and intraobserver reproducibility. In the present study we found that the mean kappa value for the interobserver reliability and intraobserver reproducibility of the Letournel classification reached 0.50 and 0.42, respectively. This makes the classification somewhat more reliable and reproducible than Sanders and Zwipp classifications. However, the ability of Letournel classification to guide therapy and predict prognosis has not been proved.

The measurement of Bohler's angle is almost always included in the plain X-ray examination of calcaneal fractures and intends to evaluate the degree of intra-articular fracture displacement. Normally, it ranges from 25 to 40 degrees although wider ranges have been reported in the literature. (Bohler-1931, Khoshhal KI et al-2004) Contralateral Bohler's angle measurement is beneficial for comparison. The significance of operative restoration of Bohler's angle has been investigated. (Loucks et al -1999) Failure of restoration was associated with poorer outcome. (Cohen J-1968, Paul M et al-2003) However, no correlation was found between Bohler's angle and functional outcome in other studies. (Jiang S D-2008) In this study we found that one third of the time observers agreed with each other and with themselves on two separate occasions within 10-degree intervals when measuring Bohler's angle. These results reflect the limitation of a commonly used parameter in clinical practice.

A possible alternative to form a new classification system for intra-articular calcaneal fractures might include an evaluation of the site, number and extension of the fracture fragments (as with Sanders and OTA classification), the degree of fracture displacement (as by using the Bohler's angle) and the degree of soft tissue injury (with a Gustilo-like classification). Such an all-inclusive system would take into consideration the factors that may affect the treatment options and outcome. In the best of worlds an improved classification should be made on ideal radiological investigations. The best possible imaging today would be the reconstruction 3D-CT where the calcaneus can be spinned virtually and investigated from all possible views.

With the best possible imaging and a simplified interpretation with a classification rather like the one from Zwipp, a fair interpretation should be possible. As it seems that the amount of dislocation makes a difference, a further interpretation of the amount of dislocation should add to the ability of prediction of a classification system. If could be possible to classify according to the change in volume/shape. This would probably improve on the older classifications from a clinical aspect with a better correlation to outcome. In calcaneal fractures soft tissues around the heel bone are very likely to get damaged. Therefore a proper classification should probably not only discuss the fracture itself but also include the soft tissues. On the larger bones Gustilo classification is commonly used. The problem with such a system might be the complexity of the classification that the reliability and reproducibility may be negatively affected.

The results of this study showed that the tested FCSs had some limitations regarding their interobserver reliability and intraobserver reproducibility. All of the obtained kappa values were less than 0.5 indicating less than 50% agreement that limits the usefulness of the classifications. However, Sanders and Zwipp classifications have correlated with guiding the treatment and predicting the prognosis. All these parameters should be borne in mind when using these FCSs in clinical practice. CT scanning helped evaluate the extension of fracture lines into the calcaneo-cuboid joint better than plain X-ray.

In paper 3 the aim was to analyse the results of our published randomized trial using the post-hoc analysis model. By this way, we looked at the obtained results from a different angle. Classically this is not the way to stratify or report on a RCT-study, but it is the question anyone with a clinical interest wants to know? Which treatment gives the best result?

For me the evaluation of the material from this point of view is what I want to know as a clinician: If I can choose between two different treatments, what should I look for to make my choices?

Open reduction and internal fixation continues to be the treatment of choice for many DIACFs especially in the absence of contra-indications such as smoking, diabetes, peripheral vascular diseases and older age. However, the current evidence that supports operative treatment is insufficient and based on few randomized trials with relatively small sample size. (Gougoulas et al-2009, Jiang et al-2012, Bruce et al -2013) This leaves the results of these trials with some uncertainty as whether they have a type II error giving a false negative outcome.

The required number of patients that should be included in each treatment option to meet the power analysis depends on the study hypothesis and the required minimum clinically significant improvement in the primary outcome measure. For example, if the study hypothesis is based on the assumption that operative treatment gives a 20% improvement in the primary outcome compared to non-operative treatment (SD 40, power of 90% and α of 0.05), then nearly 100 patients are needed in each treatment group, while for a 10% improvement, more than 400 patients will be needed in each group. No study could reach such a large sample size. The only exception is the Canadian trial that included a large sample size and showed a better outcome after operative treatment in certain subgroups. (Buckley et al-2002) Therefore there is still a need for better understanding of any possible factors that affects the long-term treatment outcome of DIACFs.

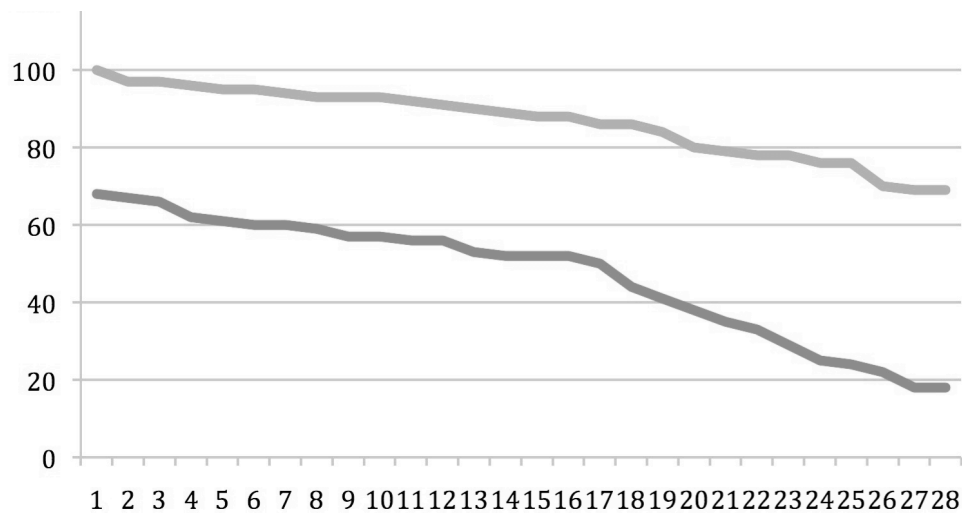


Fig 49. The distribution of VAS measures of the superior (light grey) versus inferior (dark grey) group. The vertical axis represents the VAS measures while the horizontal axis represents the patients.

All patients received the treatment option they were randomized to. This means that any possible selection bias was eliminated. The results were evaluated using well-known and commonly used outcome indexes and this makes the results obtained reliable. We divided the results of the patients available at the 8-12 years follow-up (n=56) to the superior half and inferior half. We did not want to select only small numbers of patients e.g. the best and worst one quarter of patients because we aimed to include sufficient sample size. We chose the primary outcome index of the randomized trial, the VAS score for pain and function developed by Hildebrand et al (-96), to be the determinant of this division because this index was a reliable and informative parameter that covered both pain and function. Despite the previously mentioned favourable aspects of this study, the sample size is still relatively small to give concrete recommendations. But the results do add to the existing literature body and thereby enhance our understanding of the management of this difficult group of patients.

We found that patients in the superior group also had a significantly higher SF-36 physical component score (but not the mental component), AOFAS and OM scores than patients in the inferior group ($p < 0.01$). This could mean that the VAS correlated well with these scores, and this agrees with the finding of Hildebrand et al (-96). However, to evaluate this correlation, a test like Pearson's should be used. This was not done as it was beyond the scope of this work. We noticed that the SF-36 mental component summary scale did not follow the physical component or the other scores both in the randomized trial and in this study. The reason for this is not fully understood. It could be due to the discrepancy among patients to mental cope with the physical handicap caused by these fractures or could reflect the disappointment or depression that some patients experienced.

We analysed the age and sex of patients in the superior and inferior groups. There were a similar number of men and women in each group. The ages were also comparable. This could mean that age and sex had no effect on the long-term results in this study population, as reported by others. (Gaskill et al-2010, Basile -2010) To the contrary, Tufescu et al (-2001) and Buckley et al (-2002) found that men had less

favourable outcome than women. This was explained by the severity of soft-tissue and bony trauma in men owing to their high incidence of work-related injuries and WCB. Furthermore, some reports (Buckley et al-2002, Paley et al-1993) found that patients younger than 50 years did better than elderly patients, while others reported good results even in the elderly patients. (Gaskill et al-2010)

The Bohler angle is an important parameter in the radiological assessment of DIACFs both preoperatively and postoperatively. Preoperatively, this angle can be used as an indication for the severity of the trauma (negative values indicate more severe trauma). Csizy et al (-2003) found that initial Bohler angle $<0^{\circ}$ was prognostic for increased risk of late subtalar arthrodesis while others report that severely depressed Bohler angle gave poor two-year function and quality of life regardless of treatment and vice versa. (Buckley et al-2002, Thordarson et al-1996, Loucks et al-1999) In our study, this association was not found and patients of the superior and inferior groups had comparable pre-treatment Bohler angle values. On the other hand, better restoration of this angle at healing was significantly more common in the superior group (mean 17.6 vs. 12.1, $p=0.05$). This restoration could indicate better anatomical reconstruction and less residual articular displacement. We also found more patients with better articular surface reduction (<2 mm residual step-off) in the superior group than the inferior group (11 vs. 5, OR 3.0 with CI 0.9-10.1, $p=0.07$). These observations agree with the results published by others. Rammelt et al investigated whether the severity of DIACFs was related to subsequent foot function and quality of life. They found that fracture severity classifications predicted function and anatomic reconstruction of the shape and articular surfaces of the calcaneus lead to predictable function in the medium to long term.

In the present study, the fracture types in the superior and inferior groups were comparable, although the superior group had more Sanders II and less Sanders III fractures than the inferior group (OR 1.8 with CI 0.6-5.1, $p=0.16$). The type of patient's occupation and the role of WCB in fracture outcome assessment studies have gained increasing importance. (Bruce et al-2013, Buckley et al-2002, Tufescu et al-2001) In patients with work-related DIACFs, the WCB was associated with poor functional outcome, especially if they were heavy labourers. However, it is worthy to emphasize that WCB systems vary among countries and the outcome scores used to evaluate the results in these patients are not adequately validated. In our RCT, we had 2 patients who gained compensation after DIACFs that resulted in early retirement. In the present study, we reported the presence of any type of injury insurance. We found that the presence of such insurance was less common in the superior group (11 vs. 19, OR 0.3 with CI 0.1-0.9, $p=0.04$). A possible explanation for the difference is secondary financial gain in patients with injury insurance. On the other hand, more patients of the superior group were involved in light work or were retired compared to the inferior group (11 vs. 18, OR 0.3 with CI 0.1-1.0, $p=0.06$). This agrees with previous reviews (Gougoulas et al-2009) where heavy work was considered as a negative prognostic factor. The operative treatment was more commonly used in the superior group (20/28, 71%) than in the 10 inferior group (9/28, 32%), OR 5.3 with CI 1.7-16.5, $p=0.02$. This obvious favourable effect of operative treatment together with the previously discussed factors may indicate that operative treatment is the treatment of choice for many DIACFs.

Factors like more comminute fracture, failure to restore Böhler angle and articular surface, heavy labour and possible secondary gain with WCB or injury insurance were negative prognostic factors for long-term treatment results in the present study

population. Every effort should therefore be made to minimize the impact of these factors, for instance, by improving the surgical techniques for better anatomical reconstruction and fewer postoperative complications. Patients with negative prognostic factors should be informed and realistic expectations presented.

CONCLUSION

The results of this post-hoc analysis suggest that operative treatment with restoration of Bohler's angle and articular surface in patients involved in light labour and no secondary gains would provide superior results in the management of DIACFs. This emphasizes that the definitive decision-making of DIACFs is multi-factorial and there is a spectrum of results and trends such as patient demographic features that should be considered in choosing the treatment option.

In paper 4 our findings reveals-poor results from in-situ fusions after calcaneal fractures. When comparing our findings with other studies, the results, as measured by any of the PROM's (SF-36, AOFAS, OM or VAS-score), are worse in this study. Our series included patents with very badly displaced fractures and this led to major residual deformities after the surgery. In our radiographic studies we noticed that many of these fractures were grossly deformed and malaligned. This was not only with varus/valgus deformities, which were not so common, but mainly with loss of calcaneal height and thus malrotation of talus backwards into the ankle mortise secondarily. Also commonly we found a massive lateral protrusion under fibula. Even though all had healed in the fusions none had had any further surgery to restore hind foot anatomy. This meant that in many cases the talus was rotated dorsally and impinging anteriorly (where tenderness appeared on the anterior aspect of the ankle) or had pain laterally (maybe because of impingement of fibula to the lateral wall of calcaneus or impingement or dislocation of the peroneal tendons).

We noticed that no means at all had been undertaken to decompress the lateral wall or to restore the height of the heel bone in our patients. The restoration of hind foot alignment, and resection of bony prominences as well as corrective osteotomies after calcaneal fractures has become the trend today in the treatment of malunions and non-union or bone loss problems after calcaneal fractures.

In our study patients have been treated according to the principal that it is mainly the disrupted and arthritic joints around os calcis that cause the post-traumatic painful conditions. However the results after this surgery obviously leaves a lot of persistent pain and problems. This is reflected in the PROM and overall by the results of this retrospective analysis. In the era when these surgeries were performed, the different sources of pain around the hind foot after calcaneal fractures were poorly understood. No caution had been undertaken to lateral & peroneal tendon impingement, nor to anterior impingement in the ankle or neither to varus or valgus malalignment of the heel nor to the width of the heel. Upon examination we found, that still after surgery, there were according to the deformity classification of Zwipp and Rammelt, many patients where the deformity and possible cause for the pain still remained. In Fig 44.

the remaining deformities are shown and thus it is obvious that most of these patients still had many possible causes of pain. Even though the sample size is small correlations were calculated between deformity and outcome. Figures 45 and 46 show that signs of correlation were found. This suggests that a correlation of deformity as recorded in the Zwipp and Rammelt deformity classification exists with the clinical outcome.

The outcome of overall satisfaction after only subtalar in situ fusion with lateral calcaneal osteotomy has been reported to be worse than if combined with a plantarly directed sliding tuber osteotomy (Huang PJ et al-1999) This suggests that in the cases where we have an anterior impingement of the ankle due to loss of height in the ST-joint, a sliding osteotomy is a way of solving this clinical problem. Our data show that we still had several patients with deformity type 3A that possibly would have benefited from such a procedure.

Another way to solve the dorsal rotation of calcaneus is to perform a distraction fusion with a tricortical bone bloc, commonly harvested at the posterior iliac crest (Carr J B et al-1988) The results of this procedure vary a lot in the literature, from overall good in 28 patients to 50% good with remaining malunions (Bednarz PA et al-1997, Myerson M et al-1993). In a prospective study on 31 patients, Rammelt et al noticed a significant improvement, clinically and radiologically, with a normalized pressure distribution during roll-over together with a more energetic gait (Rammelt et al-2004) Superior results after subtalar fusion in situ after previous ORIF for os calcis fracture have been reported compared to that of distraction fusion after non-operative treatment (Radnay C S et al -2009) The idea of restoring height and alignment with shape and possibly articular congruity leads to a simpler procedure than if the fracture is treated non-operatively and there is a need to supplement the loss of bone. This is supported in our study as we had many reoperations and healing problems and even though the fusions were healed the patients experienced pain and dysfunction to a high degree.

In situ-fusion with lateral-wall osteotomy was shown to perform better than the distraction bone block arthrodesis in an Australian study that suggested that the incidence of anterior impingement is not so high. (Savva N et al-2007) In our study we had many patients still with a substantial loss of height that were classified to type IIIA. (Zwipp H et al-2006) We think that a good method of treatment would be to thoroughly evaluate the deformity taking all the different deformities under consideration and then treating accordingly. The effect of subtalar in situ fusion compared to triple in situ fusion was shown to be similar (Schepers T et al-2010) This finding is also supported by our findings as we saw no significant arthritis in the other subtalar joints if not fused or different clinical findings in those who were treated with triple fusions or only subtalar fusions.

The outcome of subtalar fusions after failed ORIF, for malunion or when performed primarily for highly comminuted fractures all turned out with similar results (Flemister A S et al-2000). So if the known pain-causing problems have been dealt with, the function of a calcaneal fracture that has lead to a fusion the function should be similar. Therefore their findings that the patient revealed an AOFAS score as a mean value in all groups of about 75 but with a wide range (values between 20-94)

Today the following causes that are treatable have been defined (Chandler J T et al-1999) as:

- Anterior impingement in the ankle (at dorsiflexion, due to dorsal rotation of talus due to bone loss)
- Pain along or due to impingement of Peroneal tendons (tenderness around and below fibula)
- Neuralgic pain from the Sural nerve (percussion-test, impaired sensation)
- Pain at Plantar heel aspect (focal tenderness to palpation, due to bone spurs or protrusions /tears in heel pad)
- CC-joint tenderness-or discomfort (probably not so common even though calcaneal fractures often extend into CC- joint)
- Secondary-post-traumatic arthrosis of Subtalar joint

Chandler et al discussed these different pathologies for residual pain after calcaneal fractures and also found that radiographic angular measurements did not correlate with the functional outcome. However if evaluating the pathology with the classification designed by Zwipp and Rammelt it seems that we could readily understand that all these pathologies have not been dealt with in our material.

We conclude that a simple in-situ fusion without consideration of the deformity at hand is not an adequate treatment for sequelae after a calcaneal fracture. It is the treatment of choice for the cases with a reasonably aligned anatomy together with lateral wall decompression, that is, if ankle joint symptoms can be ruled out. If there is a disabling ankle pain and less than 10 degrees of dorsiflexion which in our patients seems to be a common problem, a distraction-fusion with a tricortical bone bloc or a plantarly directed sliding tuber osteotomy should be performed to restore the hind foot architecture. If sural nerve symptoms are evident a sural neurectomy should be considered. For the cases with pain at plantar heel, usually a non-surgical treatment is recommended, whereas anecdotal surgeries of bone spurs have proven to be successful. Radiographic CC-joint changes rarely seems to require surgery if the Subtalar joint is fused.

8 FUTURE PERSPECTIVES

The treatment of dislocated intra-articular calcaneal fractures will no doubt evolve further. From this study I have gained the impression that the benefits of surgery are outweighed by the risks. To end with an amputation is not what our patients have in mind.

With the increasing risk of multi-resistant bacteria resulting in hazardous infections, a less invasive approach has to be the solution for most fractures. The lower the risk the more benefit of the surgical handling.

In order to lower the risks of contracture and soft tissue problems and also to further speed up the reduction in swelling of the oedematous limb, it would be interesting to see a trial where a stabilisation, perhaps with compressive properties and ability to span the heel, would be used as a primary treatment. When the fracture is reduced to a more anatomically heel-looking status I think that a mini-invasive approach for stabilisation with percutaneous implants and even percutaneous plates will be used in the future.

The decisional process would benefit if a reliable predictive and reproducible classification system could be developed. My suggestion for such a system would be to try a fracture classification based on 3D-CT. The things that we would want to notice are the amount of joints being damaged. As the different joints seem to vary in importance, they should possibly have a different impact on the score, for example the CC-joint could be 1/3 of the importance of the ST-joint. That could mean for example that 1 fracture line in the ST-joint gives the same impact as 3 lines in the CC-joint. I think that the segmental interpretation of Zwipp should remain, but an estimation of volume/ impaction should be added, as it seems to add to the morbidity. Probably the worse comminutions of calcaneus should be separated and instead of a reconstruction they should be treated with primary fusion.

From the conclusions gained in these studies, surgery will not be for all patients. A careful selection of the patients and evaluation of their individual needs is mandatory. To avoid surgery when comorbidities are present as well as risk factors is a skill that cannot be underestimated. After all the non-surgical functional treatment is not so bad in most patients.

Therefore I think that calcaneal fractures primarily and even further for late reconstructions would benefit from being handled by calcaneal specialists. There is enough data suggesting that these fractures and the complexity of their treatment will benefit from a systematic evolution in care and technical know-how. These injuries should be referred to those surgeons who perform sufficient numbers to keep up their skill and knowledge.

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11 APPENDIX :OUTCOME SCORES

11.1 THE VAS-CALCANEAL SCORE (HILDEBRAND, BUCKLEY, MOHTADI):

PATIENT VISUAL ANALOGUE SCALE FORM

NAME: _____ DATE _____
(day/month/year)

PATIENT I.D.#: _____
STUDY VISIT #: _____

For each question or statement below place a mark on the line between the two descriptions which you think describes your fractured heel relative to the two extremes.

The first five questions or statements refer to the amount of pain or discomfort you are having.

1. HOW OFTEN DOES YOU HEEL/FOOT HURT?
Always _____ Never
2. HOW BAD IS THE PAIN IN YOUR HEEL/FOOT?
Pain as bad _____ No Pain
as it could be
3. I HAVE HEEL/FOOT PAIN AT NIGHT MAKING IT DIFFICULT FOR ME TO SLEEP.
Always _____ Never
4. I HAVE STIFFNESS OR DISCOMFORT IN MY HEEL/FOOT IN THE MORNING WHEN I FIRST GET UP.
Always _____ Never
5. I HAVE ACHING IN MY HEEL/FOOT AT THE END OF THE DAY.
Always _____ Never

The following seven questions refer to your physical function.

6. I HAVE DIFFICULTY WALKING ON LEVEL GROUND.
Extreme _____ No
Difficulty _____ Difficulty

- (continued)*

[illegible]

11.2 THE VAS CALCANEAL SCORE, PHYSICIANS PART:

SURGEON AND INDEPENDENT ASSESSOR VISUAL ANALOGUE SCALE FORM

NAME: _____
DATE: (day/mo/yr) ____ / ____ / ____
PATIENT I.D. #: _____
STUDY VISIT #: _____

THE TREATING SURGEON WILL RATE EACH PATIENT ON THE FOLLOWING SCALES

1. THE FIRST SCALE REFERS TO THE AMOUNT OF PAIN THAT THE PATIENT IS HAVING.

Pain as bad as it could be _____ No Pain

2. THE SECOND SCALE REFERS TO GAIT AND RELATED ACTIVITIES.

Extreme Difficulty _____ No Difficulty

3. RATE THE OVERALL RESULT OF THIS FRACTURED CALCANEUS, AT THIS POINT IN TIME.

The worst possible result _____ Perfect

11.3 OLERUD MOLANDER SCORE: 0-30 POOR, 31-60 FAIR, 61-90 GOOD, 91-100 EXCELLENT

Parameter	Degree	Score
I. Pain	None	25
	While walking on uneven surface	20
	While walking on even surface outdoors	10
	While walking indoors	5
	Constant and severe	0
II. Stiffness	None	10
	Stiffness	0
III. Swelling	None	10
	Only evenings	5
	Constant	0
IV. Stair-climbing	No problems	10
	Impaired	5
	Impossible	0
V. Running	Possible	5
	Impossible	0
VI. Jumping	Possible	5
	Impossible	0
VII. Squatting	No problems	5
	Impossible	0
VIII. Supports	None	10
	Taping, wrapping	5
	Stick or crutch	0
IX. Work, activities of daily life	Same as before injury	20
	Loss of tempo	15
	Change to a simpler job/ part-time work	10
	Severely impaired work capacity	0

11.4 AOFAS-HINDFOOT SCALE

Ankle-Hindfoot Scale (100 Points Total)

Pain (40 points)	
None	40
Mild, occasional	30
Moderate, daily	20
Severe, almost always present	0
Function (50 points)	
<i>Activity limitations, support requirement</i>	
No limitations, no support	10
No limitation of daily activities, limitation of recreational activities, no support	7
Limited daily and recreational activities, cane	4
Severe limitation of daily and recreational activities, walker, crutches, wheelchair, brace	0
<i>Maximum walking distance, blocks</i>	
Greater than 6	5
4-6	4
1-3	2
Less than 1	0
<i>Walking surfaces</i>	
No difficulty on any surface	5
Some difficulty on uneven terrain, stairs, inclines, ladders	3
Severe difficulty on uneven terrain, stairs, inclines, ladders	0
<i>Gait abnormality</i>	
None, slight	8
Obvious	4
Marked	0
<i>Sagittal motion (flexion plus extension)</i>	
Normal or mild restriction (30° or more)	8
Moderate restriction (15°-29°)	4
Severe restriction (less than 15°)	0
<i>Hindfoot motion (inversion plus eversion)</i>	
Normal or mild restriction (75%-100% normal)	6
Moderate restriction (25%-74% normal)	3
Marked restriction (less than 25% normal)	0
<i>Ankle-hindfoot stability (anteroposterior, varus-valgus)</i>	
Stable	8
Definitely unstable	0
Alignment (10 points)	
Good, plantigrade foot, midfoot well aligned	15
Fair, plantigrade foot, some degree of midfoot malalignment observed, no symptoms	8
Poor, nonplantigrade foot, severe malalignment, symptoms	0
Total=	100

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