DEPARTMENT OF ORTHOPAEDIC SURGERY-INSTITUTE OF CLINICAL MEDICINE-UNIVERSITY OF OSLO AND DIVISION OF SURGERY AND CLINICAL NEUROSCIENCE- OSLO UNIVERSITY HOSPITAL ULLEVÅL

Diagnosis and treatment of 5th metacarpal neck fractures

PhD thesis

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1.0 PREFACE

1.1 Acknowledgements

hospital, Vestre Viken Hospital Trust, for the inclusion and follow-up of additional patients in the randomised controlled study. Many thanks to all colleagues and friends in Oslo University Hospital, Ullevål for valuable advice and help, especially to Ragnhild Øydna Støen, Frede Frihagen, Jan Erik Madsen and Gunnar Flugsrud. Thanks also to my present leader in Oslo University Hospital, Rikshospitalet, Magne Røkkum, for good advice and for allowing me extra time in preparation for the dissertation.

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Oslo, 20.10.2014

Ida Neergård Sletten

1.2 List of papers

Paper 1

Sletten IN, Nordsletten L, Husby T, Ødegaard RA, Hellund JC, Kvernmo HD.

Isolated, extra-articular neck and shaft fractures of the 4th and 5th metacarpals: a comparison of transverse and bouquet (intra-medullary) pinning in 67 patients.

J Hand Surg Eur Vol. 2012, 37: 387-95.

Paper 2

Sletten IN, Nordsletten L, Hjorthaug GA, Hellund JC, Holme I, Kvernmo HD.

Assessment of volar angulation and shortening in 5th metacarpal neck fractures. An inter- and intra-observer validity and reliability study.

J Hand Surg Eur Vol. 2013, 38: 658-66.

Paper 3

Sletten IN, Nordsletten L, Hjorthaug GA, Holme I, Hellund JC, Kvernmo HD.

Identification of neck versus shaft fractures (INS method). A new definition of metacarpal neck area and metacarpal neck fractures.

Manuscript.

Paper 4

Sletten IN, Hellund JC, Olsen B, Clementsen S, Kvernmo HD, Nordsletten L.

Conservative treatment without fracture reduction does not give worse clinical outcome than bouquet pinning of 5th metacarpal neck fractures. A multicenter, noninferiority, randomized, controlled trial of 85 patients with one year follow-up.

Manuscript.

1.3 Table 1: Abbreviations

AP view	Antero-posterior view
C-Square	Collateral ligament line (c-line) square (neck area definition)
C-Square-100	C-Square-100 % (neck fracture definition)
C-Square-75	C-Square-75 % (neck fracture definition)
C-Square-C	C-Square-Center (neck fracture definition)
C-Square-I	C-Square-Involved (neck fracture definition)
CMCJ	Carpo-metacarpal joint
CT	Collateral ligament to Transition zone (neck area definition)
CT scan	Computed tomography scan
CT-C	CT-Center (neck fracture definition)
DASH	Disability of the Arm, Shoulder and Hand Outcome Measure (30-item patient-reported questionnaire)
DC-30	Dorsal cortex- 30° pronated oblique view (fracture angle measuring method)
DC-90	Dorsal cortex- lateral view (fracture angle measuring method)
DIPJ	Distal inter-phalangeal joint
EQ-5D-3L	EuroQol 5 Dimensions 3 Levels
EQ-5D-index	Calculated index based on 5 questions in EQ-5D-3L (0-1, 1 best)
EQ-VAS	Global rating of life quality (0-100, 100 best)
HNH	Head Neck Height (neck area definition)
HNH-75	HNH-75 % (neck fracture definition)
HNH-C	HNH-Center (neck fracture definition)
HNH-I	HNH-Involved (neck fracture definition)
INS method	Identification of Neck versus Shaft method (re-naming of C-Square-75)
LTFU	Lost to follow-up (patients)
MC-30	Medullary canal- 30° pronated oblique view (fracture angle measuring method)
MC-90	Medullary canal- lateral view (fracture angle measuring method)
MCPJ	Metacarpo-phalangeal joint
MDC-95	Minimal detectable change at the 95 % confidence level (of patient-reported outcomes)
OTA	Orthopaedic Trauma Association
PA view	Postero-anterior view
PIPJ	Proximal inter-phalangeal joint

POP	Plaster-of-Paris
Quick-DASH	Quick- Disability of the Arm, Shoulder and Hand Outcome Measure (11-item patient-reported questionnaire)
RCT	Randomised, controlled trial
ROM	Range of motion
SD	Standard deviation
SH-Abs	Shortening Absolute (method for measuring fracture shortening)
SH-Stip	Shortening Stipulated (method for measuring fracture shortening)
TAM	Total active motion (of finger)
TP	Today's Practice (intuitive judging whether an injury represents a shaft or a neck fracture)
TPM	Total passive motion (of finger)
VAS	Visual analogue scale

1.4 Summary

This Ph.D. project deals with extra-articular fractures of the metacarpals of the hand, in particular fractures of the neck of the 5th metacarpal ("boxer's fracture"), the most common fracture site distal to the radiocarpal joint. Four papers are included in the thesis, based on two clinical studies on patients who were treated for metacarpal fractures in our department (Department of orthopaedic surgery, Oslo University Hospital, Ullevål, Oslo, Norway). The first clinical study was a retrospective comparison of two cohorts of patients treated operatively for extra-articular fractures in the neck or shaft of the 4th and 5th metacarpals. The second clinical study was a prospective, randomized controlled trial (RCT), comparing conservative and operative treatment of 5th metacarpal neck fractures. Paper two and three were methodological, radiological spin-off studies from the RCT. In paper two, we compared different methods for measuring volar angulation and shortening in 5th metacarpal neck fractures. In paper three, we presented a new definition of metacarpal neck area and metacarpal neck fractures.

2.0 INTRODUCTION/BACKGROUND

2.1 Anatomy

The hand skeleton distal to the radiocarpal joint consists of 27 bones and 21 joints (1-3). Proximally, the eight carpal bones articulate to each other and to the distal radius and ulna. The fingers' skeleton consists of 14 tubular bones, connected to the carpus by the metacarpals (Figure 1). The metacarpals are five tubular bones, resembling miniature versions of the long bones of the femur and the humerus. They are numbered as metacarpal I-V from the radial side, which means that the thumb is numbered the 1st metacarpal, and the small finger metacarpal is numbered the 5th. The relative length of the metacarpals are as follows: 2>3>4>5>1. The ulnar four metacarpals lie in approximately the same plane, while the 1st metacarpal occupies a more anterior position. It is also positioned in about 45 degrees internal rotation compared to the other metacarpals and can be translated in front of these, crucial to the grip function of the hand.

Radius   Ulna   8 Carpal bones

Metacarpals   Phalanges
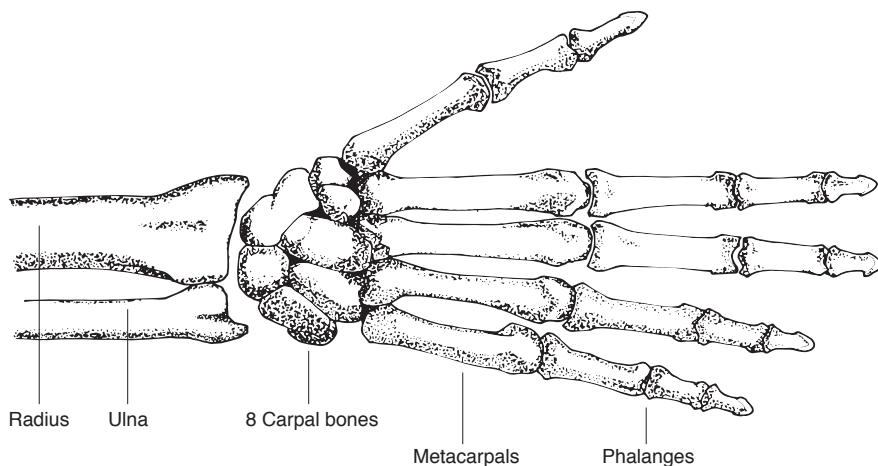
Figure 1: The hand skeleton: The five metacarpals (the mid-hand) connect the eight carpal

bones in the distal part of the wrist to the five proximal phalanges of the fingers.

The distal carpal row and the proximal part of the ulnar four metacarpals (the bases) are connected in the carpometacarpal joints (CMCJs) by ligaments. The ligaments are tight in the 2nd and 3rd CMCJ, and more lax in the 4th and especially the 5th CMCJ. This results in the mobility of the 4th and 5th finger rays compared to the more fixed rays of the 2nd and 3rd finger. The large mobility of the 1st CMCJ is responsible for the major part of the range of motion (ROM) of the thumb. In contrast to the ulnar four CMCJs, the function of the 1st CMCJ is independent of the function of the radiocarpal and intercarpal joints. The metacarpophalangeal joints (MCPJs) constitute the proximal finger joints, and the heads of the metacarpals in the ulnar four rays are dorsally known as the knuckles. Superficial to the joint capsules, strong
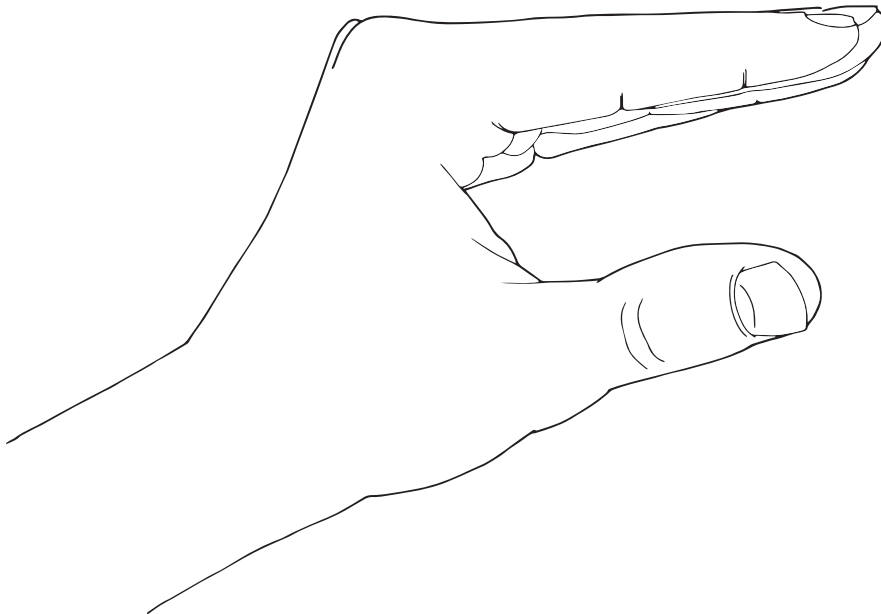
Figure 2: The safe position of the hand

The finger joint ligaments are maximally stretched when the interphalangeal joints are extended and the metacarpophalangeal joints are flexed. This position (also called "intrinsic plus") is recommended when the hand is immobilized, to avoid shrinkage of the ligaments followed by stiffness of the joints.

collateral ligaments are connecting the heads of the metacarpals and the bases of the proximal phalanges. In the ulnar four rays, the ligaments are stretched when the MCPJs are flexed, which necessitates immobilisation of the joints in the flexed position to avoid shrinkage of the ligaments and thereby joint contracture (Figure 2). Palmar to the MCPJs, the volar plate and the profound transverse metacarpal ligament are important stabilizers. The volar plates connect the distal metacarpals and the proximal phalanges, and are connected to the annular pulleys that stabilize
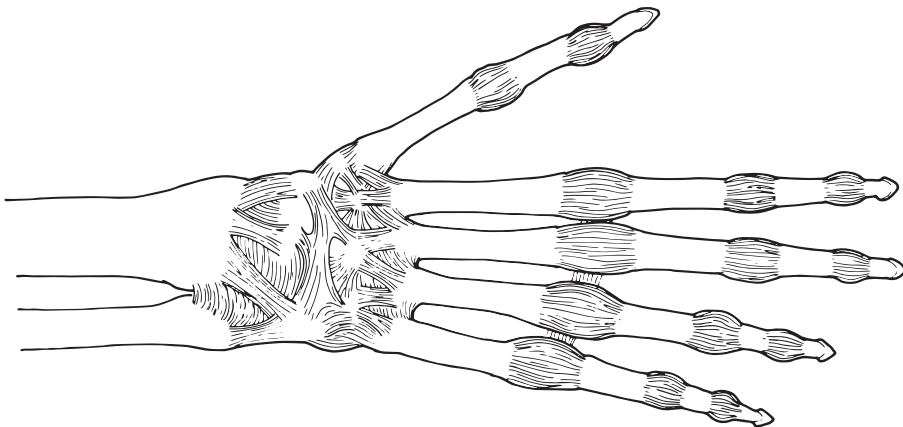
Figure 3: Hand skeleton with ligaments

The hand skeleton is connected by a complex system of both intrinsic and extrinsic ligaments. For the carpometacarpal joints, the ligaments are significantly more lax in the 4th and 5th ray compared to the 2nd and 3rd ray, allowing for greater mobility of the 4th and 5th finger.

the flexor tendons to the skeleton of the finger rays. The profound transverse metacarpal ligament connects the four ulnar metacarpals two and two, missing between the 1st and the 2nd ray (Figure 3). This ligament prevents separation of the metacarpal heads when heavy load is applied to the palm of the hand. The ulnar four MCPJs function as ball-and-socket joints when extended, and as hinge joints when flexed. Consequently, the ulnar four fingers can be abducted and adducted when the MCPJs are extended, giving seeking and sensing hand function. In contrast, when

the hand is closed, it functions as a tight claw as the fingers cannot diverge (abduct) much in the MCPJs.

Palmarly, the tendons of the abductor pollicis longus and the flexor carpi radialis are attached to the bases of the 1st-3rd metacarpals. In the shafts of the 1st and 5th metacarpals, the intrinsic muscles opponens pollicis and opponens digiti minimi are inserted. From the bases and shafts of all metacarpals arise the muscle bellies of the adductor pollicis and the palmar interossei. Dorsally, the tendons of the long and short radial wrist extensors and the ulnar wrist extensor are attached at the bases of the 2nd, 3rd and 5th metacarpal. Four dorsal interossei muscles arise from the shafts of the five metacarpals.

The deep and superficial flexor tendons flex the ulnar four fingers in the distal and proximal interphalangeal joints (DIPJs and PIPs) (Figure 4). Both tendons also contribute to flexion of the MCPJs, but the main flexors of these joints are the volar and dorsal interossei muscles, assisted by the lumbrical muscles arising from the deep flexor tendons of the fingers. The interossei and lumbrical muscles are intrinsic muscles of the hand, as opposed to the extrinsic long finger tendons that arise from
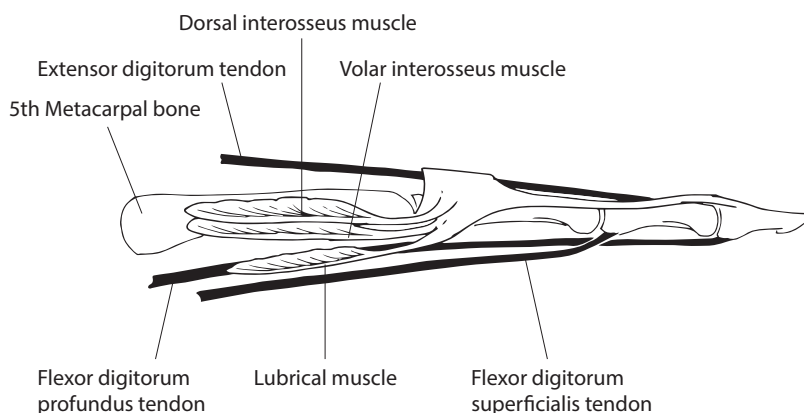
Figure 4: Flexors and extensors of the 5th ray

As for all the fingers, both intrinsic and extrinsic muscles control the 5th finger. The metacarpophalangeal joint is mainly flexed by the intrinsic muscles, and extended by the extrinsic.

the forearm.

The extensor digitorum extends the MCPJs, and contributes to the extension of the PIPJs. The interossei and lumbrical muscles are the main extensors in the PIPJs, and the only extensors in the DIPJs. The long flexor tendons assist the volar interossei muscles in adduction of the fingers, while the dorsal interossei muscles assisted by the extensor tendons abduct the fingers.

Anatomically, the metacarpal bones are divided into a base proximally, a head distally, and a shaft between the two expansions of the bones. There are no distinct landmarks that define the transition between the base and the shaft proximally, and

Figure 5: OTA segments

The Orthopaedic Trauma Association (OTA) divides the metacarpals into three segments: distal, shaft and proximal. The sizes of the segments are defined by the "rule of squares". OTA has no definition of metacarpal neck area, which is the area in the transition zone of the shaft and the distal segment.

α: The size of the square that constitutes the distal segment is determined by the width of the metacarpal head

β: The size of the square that constitutes the proximal segment is determined by the width of the metacarpal base

between the shaft and the head distally. Radiological, the Orthopaedic Trauma Association (OTA) has sub-classified the metacarpal bones as three segments corresponding to the three anatomical parts, the proximal segment, the shaft and the distal segment (4, 5). The size of the proximal and distal segments are determined by the "rule of squares", where the width of the broadest part of the base and the head defines the size of the segments in the longitudinal direction (Figure 5). This classification is parallel to the OTA classification of the long bones of the humerus, the forearm, the femur and the leg. The inter- and intra-observer reliability of the OTA classification for metacarpal fractures was recently tested (6), and the relatively poor reliability were attributed to the large proportion of fractures that involved several bone segments.

2.2 Hand injuries and hand fractures

Of all emergency department visits 16-29 % are constituted by hand injuries (7-10). Hand fractures are amongst the most common in the skeletal system, with proportions varying between 12-28 % in different papers (11-19) (Table 2) (20-25).

Table 2: Hand fracture epidemiology

Author	Location	Year	Material/conclusion	Comments on 5th ray/5th mc
Roberts	Liverpool, England	1938	1200 tubular hand fx 700 mc fx	241 (34 %) in 5th mc, 120 (50 %) in distal part 5th mc
Emmett and Breck	Texas, US	1958	10768 fx Hand fx 12 % of total, most numerous fx 30 % of hand fx was mc fx	
Butt	Ontario, Canada	1962	Hand injuries 29 % of all injuries. Hand fx most frequent fx (14 % of hand injuries)	
Hunter and Cowen	Philadelphia, US	1970	390 hand fx	133 (34 %) 5th mc fx 60 % head/neck, 6 % shaft, 34 % base
Frazier	Connecticut, US	1978	7041 injuries 17 % hand injuries 143 hand fx- 26 % mc fx Mc fx more frequent in right hand (67 %) Male: female ratio 1.7: 1 for all hand injuries	5th mc and distal 3rd phalanx most common fx Fx of 5th ray most numerous due to a large number of Boxer's fx
Broback et al.	Eskilstuna, Sweden	1978	910 hand (16 % of all) injuries during one year 162 hand fx (18 %): distal phalanx fx (n=53), mc fx (n=43) 77 % male pt Peak incidence 15-30 years	
Abdon et al.	Lund, Sweden	1984	391 mc fx during two years.	45 % in 5th mc, 54 % subcapital
Sahlin	Trondheim, Norway	1990	3060 fx during one year Hand fx (15 %): 242 carpal and mc fx, 223 phalangeal fx Peak incidence carpal/mc fx in age group 20-39 (second only to rib/sternum and foot fx).	
Shaheen et al.	Riyadh, Saudi Arabia	1990	4230 pt with fx and dislocations Hand fx 17 %, second most common to forearm fx Mc fx 30 % of hand fx Male: female ratio for hand fx 8:1	
Hove	Bergen, Norway	1993	7312 fx- 18 % hand fx 1000 consecutive hand fx recorded: 459 (46 %) phalangeal fx, 358 (36 %) mc fx	5th mc most commonly affected (166 fx) 58 % of 5th mc fx distal fx Neck of 5th mc most common fx site of hand

Author	Location	Year	Material/conclusion	Comments on 5th ray/5th mc
Packer and Shaheen	Cleveland, UK	1993	2655 pt with fx/dislocations 28 % hand injuries: right: left ratio 64 %, male: female ratio 3:1 (1:1 for other fx), 70 % occurred at age 11-40 (40 % of other fx)	5th ray involved in 48 % of all hand injuries, 5th mc fx 30 % of all fx Fighting mechanism: 67 % in 5th ray, 90 % in 5th mc.
De Jonge et al.	Groningen, the Netherlands	1994	235 427 pt during 23 years 6857 phalangeal, 3858 mc fx Male: female ratio mc fx 3.7:1 (1.8:1 for all fx) Transport accidents major causes of mc fx Purposely-inflicted fx: 15 % in males, 4 % in females 65 % of pt 10-30 years	
Johansen et al.	Cardiff, UK	1997	6467 fx during 12 months Hand fx: highest incidence (6.56/1000/year) of all fx for males (wrist/forearm fx and foot fx more numerous in females) Hand fx: peak incidence female 5-14, male 15-24 years Hand fx: highest male: female incidence rate	
van Onselen et al.	Amsterdam, the Netherlands	2003	4303 pt 855 hand fx (19 %) Hand fx: male: female ratio 1.8:1 (1.3:1 for other fx) Hand fx: Phalangeal fx most numerous (59 %) Hand fx: Right hand 52 %	5th mc by far most often fx bone (n=155); 55 % of mc fx and 18 % of all hand fx Right hand involved in 60 % of mc fx, because of high number of 5th mc fx
Larsen et al.	The Netherlands and Denmark	2004	National register data from emergency departments Hand (including wrist) injuries 29 % of all injuries Peak incidence 10-14 years	
Chung and Spilson	US	2001	National database Mc fx frequency second to phalangeal fx 5-14-year-olds largest proportion all fx, except mc fx (highest rate 15-24-year-olds) Women higher rate forearm/carpal fx, men higher rate mc/phalangeal fx	

Author	Location	Year	Material/conclusion	Comments on 5th ray/5th mc
Aitken and Court-Brown	Edinburgh, UK	2008	1430 hand fx (24 % of all) Mc fx 49 %, phalangeal fx 40 %, carpal fx 11 % 22 % sporting injuries: fx of mc and phalanges 39 % of all sports-related fx	Fifth mc fx most common Shaft fx more common than neck fx (except 1st/2nd mc), a pattern not seen elsewhere for non-sporting injuries
Feehan and Sheps	British Colombia, Canada	2006	Population-based epidemiological study 43230 (50 %) isolated phalangeal fx, 36359 (42 %) isolated mc fx, 8 % multiple fx Annualized incidence rate hand fx 3.63/1000, mc fx 1.52/1000 Mean, median, most frequent ages of pt 31, 27, 14 years Incidence rates of hand fx higher for males than females for all types of hand fx, highest male: female rate for mc fx (2.58:1)	
Yang et al.	Taiwan	2010	Cross-sectional study based on nationwide insurance data Hand fx incidence 3.15/1000, second only to forearm fx Fx incidences markedly higher for men in all age groups except >65 years Peak male incidence 20-45 years, while >65 years for females	
Stanton et al.	Derby, UK	2007	701 tubular hand fx during 6 months Male: female ratio 2.9:1 Dominant hand 65 % Mc fx most common (47 %) Mc neck fx 29 % of all fx (children, young adults), 19 % (older adults), 14 % (retirement age) In retired population, diaphyseal mc fx more common than neck fx, and basal fx almost as common 302 mc fx: 3 % head, 61 % distal, 21 % middle, 16 % base	5th mc highest fx incidence of all tubular bones in all age groups Children: 5th mc fx 29 % of all fx, young adults: 37 %

fx: fracture, fractures

mc: metacarpal, metacarpals

pt: patient, patients

2.3 Fractures of the metacarpals

As a group, metacarpal fractures are reported to account for 26-36 % of hand fractures (7, 12, 13, 16, 26). All parts of the metacarpal can be fractured, both by direct force and indirect force. The most common mechanism is patients hitting a solid object with a clenched fist, alternatively falling onto a clenched fist, resulting in a direct force to the metacarpal head applied in the retrograde direction. This direct force can result in fractures of the metacarpal head, the neck, the shaft, and the base, both intra-articular and extra-articular fractures (Figure 6).
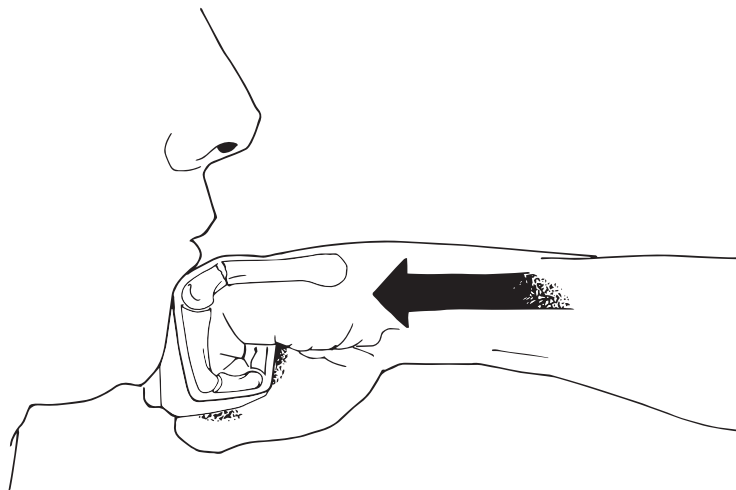
Figure 6: Injury mechanism for 5th metacarpal neck fractures

The fracture is often called "boxer's fracture" due to the most common injury mechanism; an axial blow to a clenched fist, often during fighting or other aggressive behaviour.

There has only been performed one thorough epidemiological study on internal distribution of hand fractures (13). However, many authors report that the 5th metacarpal is the most commonly fractured hand bone, with a proportion varying between 17-37 % of all hand fractures (13, 14, 17, 26-28) (Table 2). Some authors of epidemiological studies report in number more phalangeal than metacarpal fractures, while other report metacarpal fractures to be the most numerous (Table 2). As there are almost three times as many phalanges as metacarpals (14 versus five), fractures

of the metacarpals are indisputably the most common per bone of the hand skeleton including the eight carpal bones. The mechanism behind phalangeal fractures is different to metacarpal fractures, as the distal, mobile parts of the finger skeleton (the phalanges) are more susceptible to crushing injuries (fingers trapped in doors, machines, e.g.).

2.4 5th metacarpal neck fracture (boxer's fracture)

The aim of this project was to study fractures of the neck of the 5th metacarpal, commonly known as the "boxer's fracture" due to the fact that the mechanism of injury often is patients fighting or punching solid objects with clenched fists. Of the extra-articular fractures, fracture of the neck of the metacarpal is particularly common, as this sub-capital transition zone between the head and the shaft is a weak part of the bone. This area has to our knowledge never been defined in any anatomical or radiological study. However, it is a commonly known area for all hand and orthopaedic surgeons and emergency department doctors, as the neck of the 5th metacarpal is reported to be the most common fracture site of the hand (13).

Due to the pulling effect of the intrinsic muscles of the hand (the interossei), the distal fragment always angulates volarly (Figure 7). If the fracture mal-unite in an excessive volar angulation, the dorsal knuckle prominence of the 5th metacarpal head

Figure 7: Volar angulated 5th metacarpal neck fracture

Due to intrinsic muscle pull, metacarpal neck and shaft fractures always angulate volarly.

will be lost, and the patient may have some impairment in hand function due to a possible painful bony prominence in the palm. Impairment of hand function is probably also due to altered function of the intrinsic muscles (the interossei) and the extrinsic tendons (the two flexor tendons and the two extensor tendons) of the 5th finger. If the bony angulation is severe enough to alter these muscle's lever arms, it is believed that diminished grip strength and a lesser ROM in the 5th MCPJ may be the consequence (29). So-called pseudoclawing is a rare clinical presentation, where the MCPJ is hyperextended with an extensor lag in the PIPJ (30). Other fracture sequelae commonly seen in other parts of the skeletal system, like non-union and secondary arthritis in the adjacent joints, are rare after metacarpal fractures.

Figure 8: Dorsal swelling

The typical clinical appearance of a patient with an acute 5th metacarpal neck fracture

The diagnosis is often obvious clinically as the patients present with a painful swelling over the dorsum of the hand with maximum tenderness over the 5th metacarpal (Figure 8). It is easily confirmed on plain x-rays, which are normally captured as frontal view (antero-posterior (AP) or postero-anterior (PA)), lateral view, and oblique (30 or 45 degrees) view. Generally, computed tomography (CT) scans are not necessary to confirm the diagnosis (Figure 9).

Figure 9: 5th metacarpal neck fracture

A 5th metacarpal neck fracture is usually evident in plain radiographs (pronated oblique view 30°).

Although a bit misleading, the term boxer's fracture is well established in the literature. Professional boxers rarely suffer fractures of the 5th metacarpal. They are well trained to punch with maximal force through the 2nd and 3rd ray of the clenched fist, as these rays are the two stable rays of the hand, compared to the two flexible ulnar rays. The term "brawler's fracture" (26) can be more appropriate for 5th metacarpal neck fractures, as the mechanism of injury most frequently is patients fighting and hitting solid objects in anger, often under the influence of alcohol.

2.5 Mechanism of injury and personality features in patients with 5th metacarpal neck fractures

In West-Virginia, US, sixty-two patients presented with 65 5th metacarpal neck fractures during 1995-96 (31). Punching an object (37 %) or another person (24 %)

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was the mechanism of injury in 61 % of the cases, and all but one were intentional hits. Twenty-seven per cent of the patients were injury recidivists, and the authors conclude that this patient group has a high risk for recurrent injury. Ninety-two per cent of the patients were men, in contrast to 58 % of patients with other injuries. Patients with 5th metacarpal neck fracture were younger (mean 22 years) than the rest of the injured population (mean 29 years).

The incidence of metacarpal fractures in US soldiers stationed in South Korea was studied in 2005-06 (32). Forty-eight of 76 fractures (63 %) occurred to the 5th metacarpal. The most prevalent method of injury was from striking a person or object in an angry state of mind, regardless of the soldiers' rank or age.

In Drammen, Norway, 1475 hand fractures were studied in 2004-06 (26). Thirty-four per cent were metacarpal fractures. Two hundred and seventy-one fractures were located in the 5th metacarpal, accounting for 55 % of all metacarpal fractures, and 18 % of all fractures of the hand. As many as 48 % of 5th metacarpal fractures were attributed to an intentional act of aggression, were patients had hit something or somebody. Both in this group (65 %) and in the non-aggression group (38 %), neck fractures were most numerous. The median age was 22 years in the aggression group and 34 years in the non-aggression group.

The epidemiology of hand fractures, and the influence of social deprivation was studied in 2007-08 in Edinburgh, UK (33). Hand fractures were registered in all patients over 16 years of age, who were classified into one of ten deprivation categories. Nineteen per cent of all patients with acute fractures had metacarpal or phalangeal fractures (incidence 3.7/1000 for men, and 1.3/1000 for women). Males had 62 % metacarpal fractures, while females had 58 % phalangeal fractures. The most common mechanism of injury for men was an assault/punch (32 %), while fall from standing (40 %) was the most common mechanism for women. The 5th ray was most frequently injured (42 %), due to a large number of 5th metacarpal fractures (27 % of all isolated hand fractures). Only isolated fractures of the 5th metacarpal in men were associated with greater social deprivation. The authors concluded that this relates to the specific mechanisms of injury connected with 5th metacarpal fractures (assaults, fights, blunt and crush injuries). The association between 5th metacarpal fractures and greater social deprivation was in consistence with another report on non-operative treatment of fractures in 2000 from Edinburgh, UK (34). In this study, it

was demonstrated that metacarpal fractures were the only adult fractures where social deprivation correlated with a lesser rate of operative treatment. The authors noted that 46 % of the adult metacarpal fractures in their material were a result of fighting or an assault, and stated that metacarpal fractures tend to occur more often in the socially deprived.

In Boston, US, factors associated with non-attendance to the 1-month follow-up for patients with metacarpal fractures treated non-operatively were studied retrospectively in 336 patients over 18 years during 2004-09 (35). Thirty-one per cent of the patients did not attend the planned 1-month follow up appointment, out of which 60 % did not inform the clinic. Four independent risk factors were identified; unmarried status, free or no insurance, unemployed/disabled/unknown work status, and 5th metacarpal neck fracture.

From Istanbul, Turkey, two papers on the psychiatric state of patients with 5th metacarpal neck fractures have recently been published (36, 37). Mercan and co-workers (2005) compared 14 consecutive patients with 5th metacarpal neck fractures to 13 patients with other types of fractures, and 11 healthy control subjects. All the study participants with 5th metacarpal neck fracture had an intentional punch as injury mechanism. There was not found any difference in depressive symptoms or anxiety between the three groups. Patients with 5th metacarpal neck fracture had significantly higher scores for self-defeating, borderline and anti-social personality disorders than the two control groups. Compared to the group of patients with other fractures, patients with 5th metacarpal neck fractures had higher scores for passive aggressive personality disorder. Compared to the group of healthy controls, the patients with 5th metacarpal neck fracture had higher scores for schizotypal personality disorder. Anger and cynicism scores were higher in patients with 5th metacarpal neck fractures than in both control groups. The authors concluded that patients with 5th metacarpal neck fractures are characterized by impulsive behaviour, and have problems in controlling their anger. They suggest that psychiatric assessment should be an additional treatment aspect for these patients when seen in an orthopaedic department. Kural and co-workers (2011) compared 30 male patients with 5th metacarpal neck fractures to 30 healthy subjects. Twelve of the metacarpal neck fracture patients had been fighting, while the rest had punched a wall. Four of the fracture patients admitted to having been under the influence of alcohol. There was

no difference in the anger scale scores between the two groups, but there were high scores in the sub-section of impulsive behaviour in 82 % of the fracture patients. The authors concluded that patients with 5th metacarpal neck fractures often have difficulties in controlling and directing their anger, and that psychiatric support often is necessary.

The above-cited findings in personality features are also reflected in the well-documented low compliance to treatment protocols and follow-up appointments for this particular patient group. In a prospective study from Manchester, UK, 35 of 138 (25 %) patients did not show up for their follow up appointments four months after the injury (38). In Oxford, UK, 57 patients of 73 (78 %) could be followed up one year after the injury in a prospective study (39). In a prospective study in Preston, UK, only 32 of 42 (76 %) patients returned for the planned two-weeks control, and as few as 38 % returned for the planned follow-up two months after treatment (40). In Stoke-on-Trent, UK, only 48 of 74 (65 %) patients met at the planned one-year control in a prospective study (41). In Nijmegen, the Netherlands, 45 of 71 (63 %) patients agreed to be followed up retrospectively at least one year after treatment (42). In Birmingham, UK, four out of 40 patients treated with a cast in a prospective study did not even show up for removal of their casts, and another 17 of 33 (52 %) appointments for further follow-up visits were not attended (43). The majority of the patients attributed the no-show to the fact that they were managing well and had resumed their normal activities.

This low follow-up rate inspired researchers in Nottingham, UK, to develop a clinical method for assessment for mal-union of 5th metacarpal fractures. Two methods were developed, which both compared the relative lengths of the 4th and 5th fingers in the injured and contralateral hands. Consequently, the patients could be examined in their own homes instead of in the outpatient clinic, where radiographs normally are captured to document the degree of mal-union (44). In spite of this possibility of examining patients in their own homes, the same authors did not obtain a higher than 17 % follow-up rate (218 of 1280 patients) in a retrospective cohort treated non-operatively for 5th metacarpal neck fracture, compared to 54 % follow-up rate (44 out of 82 patients) in an operatively treated cohort (45).

2.6 Treatment options of 5th metacarpal neck fracture- including historical overview

Although several clinical studies regarding treatment and outcome of extra-articular metacarpal fractures in general, and of 5th metacarpal fractures in particular, have been published, no treatment guidelines have been established. Results from many clinical studies on 5th metacarpal neck fracture have been published, but most are retrospective reports on cohorts of patients given a particular treatment, not allowing for comparison between groups. As demonstrated in a recent survey of current practice in Wales, UK, the treatment being offered varies extensively between different orthopaedic surgeons, even those dedicated to upper limb surgery (46).

2.6.1 Conservative treatment

Some decades ago, 5th metacarpal neck fractures, as well as other extra-articular metacarpal fractures, were mainly treated conservatively. The author of the first epidemiological study on metacarpal fractures we could find (1938) also commented on the treatment of 5th metacarpal neck fractures: "Correction of the deformity in recent cases is easily accomplished, but the fracture is unstable and the deformity tends to recur. The corrected position is held by a dorsal plaster cast including the proximal phalanx of the affected finger. Traction is of no value in correcting the deformity and its use is unnecessary. Three or four weeks' splintage is necessary and the hand quickly returns to normal. If mal-union occurs the function of the hand is not impaired, and no interference is advisable if more than a week or two has elapsed since the fracture" (27).

Many different conservative regimes have been proposed. Some authors recommend conservative treatment consisting of closed reduction under local anaesthetics if the fracture is dislocated, followed by immobilization (20, 25, 47-49). Other authors state that the reduction is not kept in a traditional plaster cast (39, 42, 50-55). Thus, it seems likely that reduction of the fractures without operative fixation has little value due to inevitable recurrent dislocation in a traditional cast during treatment, if not the MCPJs are kept extended and not in the "position of safety" (48).

Recommendations on indication for reduction vary between 30-70° volar angulation in the fracture. Many authors believe that the functional impairment of the hand is minimal even after mal-union in a fracture angulated up to 60-70° (25, 38-41, 43, 50, 53, 56-59). These papers conclude that the prognosis for 5th metacarpal neck fractures is excellent, and that patients are best treated with adequate pain relief and early rehabilitation without any attempt of reducing the fracture. In contrast, in metacarpal neck fractures of the less flexible 2nd-4th ray it is generally recommended not to accept the same degree of fracture dislocation (30).

Another controversy is the type and length of immobilization when conservative treatment is chosen. The traditional type of immobilization is a plaster-of-Paris (POP) that includes the affected and the neighbouring finger ray, that extends proximally to the upper forearm. The 4th and 5th fingers are immobilized with at least 60-70° of flexion in the MCPJs, and slight extension in the wrist joint. If the PIPJ and DIPJ are immobilized, they are kept in the extended position ("intrinsic plus" or "safe position of the hand"). However, some authors have recommended immobilization of the affected ray in special-made braces that do not necessarily include the MCPJ or the wrist joint (54, 58, 60, 61). In some studies the reduced position of the fracture was better kept with a brace than with a traditional POP (54, 61). One randomized study concluded that a brace could not be recommended due to pressure ulcers and skin necrosis, and that the reduction could not be held by the brace (49). Other authors have recommended elastic bandage and/or simple buddy strapping of the affected finger to the neighbouring finger (43, 50, 51, 56, 59, 62), a pressure bandage for one week (57), or no immobilisation at all (38, 41).

The recommendations for length of immobilization vary from one to six weeks, and the position of the MCPJ during the immobilization if a cast is utilized has also been debated (48, 63). Even though they recommend closed reduction of the fracture under local anaesthesia and a plaster cast, some authors recommend short immobilization time (one week) before active rehabilitation is encouraged (25, 47).

Several RCTs comparing different conservative regimes have been performed (49-51, 54, 57, 58, 60, 63). When the four best scientific studies were compared in a meta-analysis, still no specific guidelines could be given due to the poor quality of the studies (64). From the papers included in the review, one can conclude that many different conservative regimes yields restoration of an adequate hand function for

fractures angulated up to 70°, that reduction of the fracture without operative fixation has little value, and that regimes that emphasis early mobilization yields a quicker recovery with less sick-leave for the patients (50, 51, 57, 60).

We have only found one paper that reports on patients with more than 70° volar angulation (59), and no reports on patients with inadequate bony contact between the proximal and the distal fragments in the fracture. This is probably due to the exclusivity of highly angulated or laterally displaced fractures, as most fractures are aligned in the frontal projection and volarly angulated 10-60°. The normal volar angulation in the 5th metacarpal neck, measured by a standardized method, has been described as 14 (SD 2)° (20).

2.6.2 Operative treatment

During the last decades there has been a trend to operate extra-articular metacarpal fractures, including 5th metacarpal neck fractures, based on the belief that restoration of hand function is closely linked to restoration of the normal anatomy. On the other hand, it has been demonstrated that the total number of metacarpal and phalangeal fractures treated operatively has not increased, when data from 2000 and the thirties, the forties and the fifties were compared (34). The authors concluded that the spectrum of hand injuries probably was more severe in earlier decades, as protection utilities for industrial workers have improved.

Regarding 5th metacarpal neck fractures, the belief of the closely linked hand anatomy and hand function cannot be said to build on evidence-based medicine, as former studies have demonstrated that the patients regain good hand function after many different conservative regimes. The good results of conservative treatment can be a result of the great mobility of the 5th ray of the hand, which make it more forgiving to permanent changes in the skeletal anatomy than the fixed 2nd and 3rd ray. This may apply for mal-union in a volar direction in the fracture, but not for mal-rotation. It is generally recommended to operate fractures which present with a rotational deformity, or the clinical picture of pseudoclawing (30).

In the nineties, cadaver studies performed in the US indicated that a volar mal-union in 5th metacarpal neck fractures of more than 30° resulted in a decreased

functional length of the muscle groups and less efficient flexor system, theoretically impairing grip strength and ROM in the MCPJ (29, 65). In a cadaver metacarpal shaft fracture model from Singapore, 30° of volar angulation and 3 millimetres of shortening were considered cut-off values for diminished hand function (66). Perhaps based on these findings, practice has gradually changed towards operative treatment, even though these cadaver studies findings so far have not been proven to have clinical implications.

Operative treatment of metacarpal and phalangeal fractures was first described by Albin Lambotte in his text book of 1913 (67). Later authors have advocated operative treatment since the 30-ies (68-72), and there exist a variety of different techniques to stabilize a reduced 5th metacarpal fracture. Most surgeons reduce the fracture by closed techniques, of which the Jahss manoeuvre (73) is the most common in use. By this technique, the volar angulation in the fracture is reduced by maximum passive flexion of the MCPJ, PIPJ and DIPJ. The manoeuvre relaxes the interossei, and the distal phalanx creates a volar force to the metacarpal head of the fracture's distal fragment, resulting in a neutralization of the volar angulation.

After closed reduction, the fracture is usually fixated with Kirchner-wires (K-wires), that can be placed as crossed pins across the fracture site (74), as transverse pins to the neighbouring metacarpal (68, 69, 72, 75, 76) or as intra-medullary mini-nails (62, 70, 71, 77-84). To our knowledge, the Rush brothers (1949) first reported intramedullary fixation of two metacarpals by a modified version of their intramedullary pin. Lord (1957) described the technique of retrograde intramedullary pinning by a single, large (1.6 millimetre) K-wire. Foucher (1976, in French and 1995, in English) described antegrade intramedullary pinning by several thin (0.8 millimetre) K-wires, and named the technique "bouquet pinning", due to the resemblance of a flower bouquet of the osteosynthesis in postoperative x-rays (Figure 10).

Most studies report good results with only minor complications after pin fixation of 5th metacarpal neck fractures (62, 69, 74, 76-82, 85, 86). Based on these results, some authors recommend routinely pin fixation of 5th metacarpal neck fractures with more than 30° of volar angulation (62, 80, 87).

So far, there has been published one RCT comparing different K-wire techniques (85) favouring bouquet pinning to transverse pinning at follow-up three

months, due to a marginally better ROM in the MCPJ. Another prospective, but not randomized, study (86) found no difference in hand function two years after operative fixation with either transverse or bouquet pins. Retrograde, crossed pins were inferior to bouquet pinning in a retrospective study due to less ROM in the MCPJ (74), but there was not found any difference in Disability of the Arm, Shoulder and Hand (DASH) Outcome Measure (88).

Another alternative is to perform an open reduction of the fracture, and to fixate it with either K-wires, an expandable intramedullary device (89) or mini-screws and -plates. The latter two of these three methods has the advantage that the fracture is immediately stabilized and can therefore be directly mobilized, while fractures that have been stabilized with K-wires traditionally have been additionally secured by a cast (POP or brace) for 3-6 weeks, thereby delaying hand therapy. Despite aggressive hand therapy, tendon adhesions complicate plate-fixation of metacarpal fractures (90-93). Adhesions may lead to stiffness in the fingers, and is therefore often reserved for complex injuries affecting several metacarpals ("floating hand"), or combined injuries with both fractures and soft tissue injury, where aggressive early hand therapy is required to obtain adequate long-term hand function

Figure 10: Bouquet pinning

This three-pin, intramedullary osteosynthesis is named after the appearance as a flower bouquet.

postoperatively. A recent paper reported significant reduced finger ROM following open reduction and internal fixation (ORIF) of 5th metacarpal neck fractures with a mini-plate, compared to intra-medullary K-wire fixation, despite immediate mobilization in the ORIF-group and six weeks of splinting in the K-wire group (94). Another paper reported similar finger ROM and DASH scores when plate fixation and intramedullary nailing of metacarpal neck and shaft fractures were compared prospectively, but would not recommend intramedullary nailing over plate fixation in fractures of the distal third of the metacarpal due to the risk of penetration of the MCPJ (95).

2.6.3 Operative versus conservative treatment of 5th metacarpal neck fracture

Compared to ORIF, there are fewer complications associated with closed reduction and pin fixation, which intuitively can be regarded as a good treatment option for very angulated or laterally displaced fractures. However, the many reports on good results after conservative treatment without reduction of the fractures, contradict the results of the biomechanical studies that suggest operative treatment of fractures with more than 30° of volar angulation.

We have found three papers comparing conservative and operative treatment of 5th metacarpal neck fracture (45, 52, 96), only one of these with a prospective design (96). From these papers, there is no evidence that operative treatment is superior to conservative treatment. However, the quality of the studies is poor as none are randomized studies with a validated hand function score as the primary end-point.

The first retrospective comparative study came from the University Hospital of Saskatoon, Saskatchewan in Canada, where 63 consecutive patients treated for 5th metacarpal neck fracture in a 18 month period in 1983-84 where invited for an examination and follow-up x-rays, 3-20 months after the initial treatment (52). The follow-up rate was 63 % as 25 patients treated conservatively and 15 patients treated operatively attended the examination. In the conservative group several different regimes were utilized; including no immobilization at all, buddy strapping of the two ulnar fingers, immobilization in a bulky dressing or a cast, varying from 5-21 days.

Only five patients underwent closed reduction of the fracture. The operative group was also heterogeneous, as two thirds was treated with closed reduction and intramedullary pinning, while one third was treated with open reduction and intramedullary or interosseous crossed pin fixation. At follow-up, all 40 patients were pain-free, expressed satisfaction with the outcome, and had resumed their normal activities. Time off work was 23 (range 0-56) days in the conservative group, and 58 (4-180) days in the operative group (p=0.001). Loss of knuckle prominence was more common and more marked in the conservative group, but none of the patients felt this cosmetically unacceptable, and the extension lag was in fact more common in the operative group (four versus two patients). Grip strength was excellent in both groups. Unfortunately for the quality of the study, only eight patients in the conservative group and six patients in the operative group had a pre-operative volar angulation in the fracture of more than 30°, and only two patients in each group had an angulation of more than 45°. Based on their results, the authors recommended operative treatment exclusively for open fractures, rotational or malalignment deformities, and volar angulation "sufficiently to produce a dorsal prominence and knuckle deformity in patients who demand perfect cosmesis", and who are "willing to accept a longer period of disability". All other patients were recommended conservative treatment, with a bulky dressing or a plaster cast for analgetic purposes for one week, followed by early mobilization to avoid stiffness of the fingers. Despite this clear recommendation published in 1987, though based on a small and heterogeneous patients series, many hand surgery and orthopaedic departments have continued to treat 5th metacarpal neck fractures operatively. Partly responsible for this practice can be the results of the cadaveric studies in the nineties (29, 65).

More than 20 years later, the next paper comparing operative and conservative treatment of neck and shaft fractures of the 5th metacarpal was published, based on a retrospective study of 1280 patients treated non-operatively and 82 patients treated operatively in Nottingham and Derby, England (45). The follow-up rate was 17 % in the non-operative group, and 54 % in the operative group. One hundred and fifteen patients with neck fractures treated non-operatively and 18 patients treated operatively were examined minimum two years post-injury. The follow-up was performed in the patients' homes to secure even this low follow-up rate. The patients who were treated conservatively, all without any attempt of

reduction of the fracture deformity, were divided into three groups according to the primary volar angulation in the fracture (<30° (n=30), 30-39° (n=58), ≥40 ° (n=17)). There were no differences in grip strength, contribution of little finger to grip strength, DASH score, DASH Sports/Performing Arts, or cosmetic score (scale 1-5) between the three groups. The 18 patients in the operative group had been treated with intramedullary pinning (n=13), and ORIF/plating (n=5). The endpoint clinical mal-union in the fracture, measured as relative length between the ring and little finger (44), was significantly larger in the non-operative group than in the operative group, but there could not be found any influence of this skeletal abnormality on the clinical hand function. The authors concluded that except when a rotational deformity or a complete step-off is present, 5th metacarpal neck fractures with up to 50° of volar angulation (maximum angulation in fractures in the study participants) should be treated conservatively, with no attempt of reducing the fracture, as long as the patients accept the risk of visible deformity.

In St. Gallen, Switzerland, patients with isolated, closed, extra-articular 5th metacarpal neck fractures were recruited to a prospective, comparative study during a 16-month interval in 2005-06 (96). The fractures were angulated 30-70° at inclusion. Patients who presented with a rotational deformity were excluded. Included patients were allocated to either conservative treatment (no reduction of the fracture, five days of cast followed by metacarpal brace for five weeks) or to operative treatment (closed reduction of the fracture, intramedullary, antegrade, bouquet pinning followed by the same immobilization regime as the patients in the conservative group, pin removal after tree months). The allocation was not randomized, as the patients were assigned consecutively and alternately to the two treatment groups. Follow-up was performed after two and six weeks, and after tree, six and 12 months. Admirably, no patients were lost to follow-up. The hypothesis was that operative treatment would "result in better function at the small finger MCP joint". Sample size of 20 patients in each group was based on a power of 80 % and an alpha value <0.05 to detect a difference in 5 (SD 5)° in the primary endpoint ROM in the MCPJ. One year after treatment, there was not found any differences in flexion or extension of the MCPJ, nor any difference in grip strength measured by a Jamar® dynamometer between the two groups. The treatment satisfaction was very high in both groups, marginally better in the operative group. Some of the patients in the

operative group complained of scarring and complexity of treatment, while some of the patients in the conservative group complained of a disturbing feeling in the palm during force grip, and impaired cosmesis. There were no major complications in any of the patients, only four minor complications in the operative group (pins almost perforating the skin requiring immediate removal, delayed wound healing, secondary displacement of the fracture after wire removal). The authors concluded that the patient satisfaction and aesthetic outcome was better in the operative group, and that the decision of treatment should be based on an individual basis of the patient's demands, with special emphasis of manual workers where volar mal-union of the metacarpal head can lead to a disturbing feeling (tender swelling in the palm) during forced grip.

2.7 Weaknesses in previous research

2.7.1 Definition of metacarpal neck area and metacarpal neck fractures

Indication for surgery and the choice between different conservative or operative regimes is complicated by the fact that there has never been established commonly used definitions of metacarpal neck area and metacarpal neck fractures. This lack of basal definitions gives rise to a potential inclusion bias in clinical studies, impeding comparison of results. The OTA classification of the three metacarpal segments (5) is not implemented in clinical use to the same extent as in the long bones (the humerus, the forearm, the femur and the leg). This is probably due to the lesser clinical relevance of the classification, as neck fractures, which are the most numerous of the different sub-types of metacarpal fractures, are not defined in the OTA system. The neck area represents the transition zone between area 77-A3 (metacarpal, distal, extra-articular) and area 77-A2/77-B2/77-C2 (metacarpal, diaphysis, non-comminuted/wedge/comminuted). The OTA segment "Metacarpal, distal" includes the head and the distal part of the neck area. Four groups of totally nine different types of 5th metacarpal neck fractures have been described: The true cervical fractures, the cervico-cephalic fractures, the cervico-diaphysary fractures, and the epiphyseal separations (62). Of these, the cervico-diaphysary fractures can

be difficult to classify as either shaft or neck fractures. Frere (1982) claimed that these can be treated as cervical or as diaphyseal lesions, but as long as the guidelines for treatment of shaft and neck fractures differs (30), it is important to distinguish between them by a reliable classification. Consequently, it became evident during this thesis that creation of a definition of metacarpal neck area and neck fractures was mandatory.

2.7.2 Methods used for measuring volar angulation and shortening in metacarpal neck fractures

It is generally recommended to treat operatively metacarpal neck fractures with complete step-off (45), or fractures that results in pseudoclawing or rotational deformities of the 5th finger (30), but this is rarely the case when patients present with acute fractures. Volar angulation and shortening are the main indicators for choice of treatment for the majority of fractures, and the controversy remains to what extent these parameters can be tolerated before hand function is impaired. According to this, a significant methodological weakness is the many methods for measuring angulation and shortening, and that comparisons of these methods only have been performed to a limited extent. The use of different methods of measurements can give rise to a major inclusion bias when patients are recruited to clinical studies, and hence give rise to different recommendations on indication for reduction of the fracture and operative treatment (39).

In general, dislocation in the coronal plane (dorsal/volar) in skeletal bones is given in the straight lateral view. For metacarpals (and metatarsals), the partial overlap of the bones in the lateral view makes outlining of the individual metacarpals difficult, secondarily affecting measurements of fracture angulation. For this reason, many emergency departments routinely include oblique view of 30° or 45° in the radiological series, along with the need to detect the fractures not easily seen in AP and lateral view. It has previously been stated that the lateral view is useless in measuring fracture angulation in the 5th metacarpal (97). This is in contrast to the findings of a cadaveric study of 30 human hand specimens, where two observers investigated the validity of different methods for estimating volar angulation of 5th

metacarpal neck osteotomies mimicking fractures (98). Measurement lines in the medullary canal on the pronated oblique view (45°) produced a significantly higher reading of mean 10.8 (SD 11.6)° volar angulation than the study's defined gold standard, which was based on measurement on Kirchner wires in the lateral view. In contrast, lines in the medullary canal on lateral view did not give a significant different result than the gold standard, and was hence recommended for use in clinical practice. Lamraski and co-workers (2006) found excellent inter-observer reliability (ICC 0.89), and substantial to excellent (ICC 0.76-0.84) intra-observer reliability for their recommended method. The higher readings of mean 10° demonstrated in oblique view compared to the lateral view has earlier been hypothesised to be due to the fact that the oblique view of the hand gives a better lateral projection of the 5th metacarpal than the lateral view of the hand (39).

In addition to the controversy of which radiological view should be utilized, the measurement lines can be placed differently for each view. Intra -and inter-observer reliability of measurement of volar angulation in 5th metacarpal neck fractures was tested, as three observers read the radiological series of 32 consecutive patients (99). Solely the lateral view was used for the interpretations, and two methods were used for measurements (Central Canal Method (CCM) and Dorsal Cortex Method (DCM)). The authors found an inter-observer reliability of average 0.16 (range 0.00-0.39) for CCM, and 0.19 (range 0.07-0.40) for DCM (weighted Kappa coefficients). Intra-observer reliability was average 0.31 for CCM and average 0.21 for DCM. The authors concluded that the reliability was poor for both methods, and claimed that this could be a major factor in the existing controversy in the literature.

The mean volar angulation in 24 normal 5th metacarpals was found to be 14 (SD 2)° (20). In this study, a Plexiglas device to standardize the radiographic lateral view was used, and the angle was measured by a medullary method. To our knowledge, this is the only paper that refers to a standardized method for measuring fracture angulation in metacarpal neck fractures. A reference guide gives the mean mid-medullary neck volar angulation in the lateral view as 11 (SD 7)° for men and 10 (SD 7)° for women (97). The guide was based on 225 "total hand" radiographs, but it was not stated whether a position device was used for the radiological series. Reference values for volar angulation in all ulnar four metacarpals, and for the relative shortening in the 2nd and 5th metacarpal were given for 50 normal hand

radiographs, but no information of standardization of the radiographes was given (80). The normal 5th metacarpal volar angulation was mean 13 (SD 3)°. In another series of 12 patients, the normal volar angulation was 17 (SD 3)° in the lateral view, and 26 (SD 4)° in the oblique view (39).

2.8.3 Other methodological weaknesses in previous clinical studies

Most previous clinical studies on metacarpal neck fractures have been prospective or retrospective case-reports, without comparison of different treatment regimes. Some RCTs have been performed; all except one have compared different conservative regimes. The five RCTs of the highest quality comparing different conservative regimes were included in a meta-analysis (64). The authors of this Cochrane paper could not draw any conclusions on which regime was superior due to the sub-optimal quality of the RCTs. Validated hand function was not reported in any of the studies included in the review. ROM in the MCPJ was often used as the primary endpoint, but Cochrane emphasised that this is not a validated or reproducible measure. CONSORT (Consolidated Standards of Reporting Trials) guidelines were not followed, including criteria for inclusion and exclusion of patients. Sealed-envelope method for allocation to the different regimes, which is considered acceptable, but suboptimal, was used in most cases. Blinding of outcome assessors was only performed in two of the included studies. Patient occupations were not described in any of the studies. Pain and amount of analgesic medication taken was not documented, as well as duration of sick leave. Non-union, mal-union and rotational deformities were not described. Length of follow-up was inadequate, and patients lost to follow-up were not accounted for or analysed adequately. Cost effectiveness of the different regimes was not calculated or discussed.

A recent review regarding 5th metacarpal neck fractures criticised many of the same aspects in the previous literature (100). Sample sizes have generally been small, and most clinical studies have focused on patients with limited deformity as these are the most numerous, which according to many old studies do well with conservative, functional treatment. Most previous studies have only reported short-term follow-up (six weeks or three months), and lack standardized assessments of hand function. As well as the Cochrane's meta-analysis (64), Beredjiklian (2009)

focus on the lack of a commonly accepted, accurate (valid) and reproducible (reliable) method for measuring of fracture angulation.

2.8 Patient ratings of hand function: The Quick-DASH Outcome Measure

As stated in the Cochrane meta-analysis, the most valid endpoints in clinical trials on metacarpal fractures are functional hand scores (64). The current best-validated functional upper extremity score is the Disability of the Arm, Shoulder and Hand Outcome Measure (DASH) (101). This is a patient-reported 30-item questionnaire that quantifies physical function in the upper extremities on a 0-100 scale, where the value 0 implies perfect function and the value 100 implies worst possible function. The DASH can be used for all conditions that affect upper extremities, and allows for comparison between different injuries and diseases. A short 11-item version is available as the Quick-DASH, demonstrated to have comparable construct validity, reliability and responsiveness as the original version (102). According to the designers, the minimal detectable change at the 95 % confidence level (MDC-95) in the DASH and Quick-DASH score is between 7.9-17.2 points (88). It is hypothesised that the MDC-95 will be smaller in the extremes of the scores, but this has not yet been tested for DASH Outcome Measure. Two optional modules exist for both DASH and Quick-DASH, the Sports/Performing Arts Module and the Work Module. In the general US population, the mean DASH score is 10.1 points, while the DASH Work is 8.81 and the DASH Sports/Performing Arts is 9.75. The corresponding median (50 % percentiles) values are 4, 0 and 0. Sixty-nine per cent of the general population score between 0-9 points, and 26 % score zero points (88). This is due to a left skewed distribution in the population, as healthy people have very low scores. The 26 % of the normal population that score zero points represent a floor effect, where the DASH Outcome Measure does not detect subtle changes in upper extremity function. This phenomenon is particular important when healthy patient groups with minor injuries in their upper extremities are investigated, as the DASH Outcome Measure can be unaffected even though patients are not satisfied with their final outcome after treatment.

For metacarpal fractures, and 5th metacarpal neck fractures in particular, most of the patients are young men with normal upper extremity function prior to the injury. Regardless of the treatment applied, one can assume that the DASH Outcome Measure will be normalized within one or two years after the injury. Therefore, additional endpoints as ROM in the finger joints and grip strength are necessary when clinical studies are conducted. Even the latter endpoints are usually preserved with displaced fractures of the 5th metacarpal neck fractures (100). This implies that specific questionnaires on the patients' subjective hand function before and after the injury may be indicated, as well as recordings of pain during the treatment period, analgesic medication used, length of sick leave, satisfaction with the treatment and final outcome. Nevertheless, functional scores as the DASH and Quick-DASH Outcome Measure are the best endpoints for measuring outcome after treatment for different injuries, and should be used as the primary endpoint in clinical trials upon which the power calculations for sample sizes are performed (64). For comparison, measurement of ROM in the finger joints with a goniometer is associated with observer error, probably at least 5° for each measurement.

2.9 Health economic aspects

As operative treatment so far never have been compared to conservative treatment in a RCT, the effect of operative treatment versus the natural history of healing in a mal-united position is not known. Regarding cost-benefit, it was calculated in one paper that operative treatment was four times more expensive than conservative treatment in the Swiss tax system (56).

Independently of the national standards for treatment, operative treatment is naturally more expensive than conservative treatment, as the latter does not require more than the expenses for outpatient radiographs, cast, brace or buddy strapping equipment by experienced staff. It can even be conducted without any fixed follow-up attendance for the patients, as long as they are well informed of the natural history of the injury (43). Operative treatment can also be performed on an outpatient basis, and the cost of the necessary operative material is low (2-3 Kirchner wires and skin suture material). Nevertheless, it requires surgical and anaesthetic personnel,

operative facilities and equipment, both for the primary operation and the usual planned pin removal procedure.

The total costs of the society would of course be lessened if patients treated operatively returned to work at an earlier stage, but there is so far no indication in the literature of this (52, 96). Intuitively, the cost of sick leave is higher when patients are treated operatively, as they must attend at least three outpatient visits (first diagnostic visit, closed reduction and pinning of the fracture, pin removal) compared to minimum one visit it a conservative regime is chosen. In addition, patients who are blue-collar workers will probably need a longer period of sick leave, as they must protect the fracture site to avoid infection and re-dislocation despite pin fixation.

3.0 AIM OF THE THESIS

The primary aim of this Ph.D. project was to investigate how displaced 5th metacarpal neck fractures should be managed, operatively or conservatively. The first clinical study retrospectively compared transverse pinning to bouquet pinning, seeking the best possible form of operative treatment (Paper 1). The second clinical study, an RCT comparing operative treatment to conservative treatment, was a contribution to future construction of clinical guidelines for treatment of this very common fracture (Paper 4). Sub-goals of the project was to create a definition of metacarpal neck area and extra-articular metacarpal neck fractures, as opposed to shaft fractures, and to find the best possible method for measuring volar angulation and shortening in 5th metacarpal neck fractures. These questions were investigated in the two spin-off studies from the RCT (Paper 2 and 3), where radiological examinations of two patients series are subjected to extensive inter- and intra-observer validity and reliability testing (Table 3).

Table 3: Ph.D. thesis

Paper	Aim	Study design	Conclusion
1	To find the best pinning method for acute, isolated, extra-articular neck and shaft fractures in the 4th and 5th metacarpal	Retrospective comparison of two cohorts of operatively treated patients (transverse pinning versus bouquet pinning)	The clinical outcome did not differ, but the complication rate favoured bouquet pinning
2	To investigate which methods were best for measuring volar angulation and shortening in 5th metacarpal neck fractures	Radiological comparison of four methods for angle measurement and two methods for shortening, testing validity and reliability for all methods	Volar angulation should be measured by method MC-90 as measurement lines in the medullary canal in the lateral view. Shortening can be stipulated from the neighbouring metacarpals if radiographs of the contralateral hand are not available
3	Develop a definition of metacarpal neck area and metacarpal neck fractures, as opposed to shaft fractures	Validity and reliability testing of nine different radiological neck fracture definitions	Method C-Square-75 (=INS method) is recommended as a new definition of metacarpal neck fractures
4	Investigate if conservative treatment of displaced 5th metacarpal neck fractures did not give worse outcome than operative treatment	Noninferiority, parallel-group, multicentre, prospective, randomised, controlled trial comparing conservative treatment and bouquet pinning	The clinical outcome was equivalent in the two groups, but the complexity of treatment and the complication rate was higher in the operative group, favouring conservative treatment

4.0 PATIENTS AND METHODS

4.1 Paper 1

Sixty-seven out of 325 patients operated for metacarpal fractures in our department in 2007-08 were identified and invited for a late follow-up in 2009-10. The patients who were included were aged 18-50, and had been treated with closed reduction followed by transverse or bouquet pinning of isolated, extra-articular neck and shaft fractures of the 4th and 5th metacarpals. Patients with fractures older than 10 days at time of surgery were excluded, as well as patients with acute concomitant injuries in the ipsilateral upper limb, previous fractures in the actual hand or wrist, or in the corresponding contra-lateral metacarpal. Thirty-six patients (54 %) met for consultation and radiographs, 20 patients (30 %) were interviewed by telephone, while 11 (16 %) were lost to follow-up. The two patient groups (transverse pinning or bouquet pinning) were compared with respect to demographics, clinical outcome including complications, and radiological outcome.

4.3 Paper 2

The study was designed as a methodological, radiological spin-off from the RCT (Paper 4). The primary radiographs from the first 30 patients assessed for eligibility, which satisfied the criteria necessary for performing the investigation, were included in the study. At two time points, four observers (one radiologist and three orthopaedic surgeons) measured the volar angulation by four different methods, and the shortening by two alternative methods. The outcome was compared in inter- and intra-observer validity and reliability analyses. To ensure that two methods were not performed on the same patient's radiographs consecutively and thereby minimizing observer memory bias, the patient list was randomized by patient and method at both occasions. The four angle measurements methods were: measurement lines in the medullary canal in the lateral view (MC-90), measurement lines in the medullary canal in the 30° oblique, pronated view (MC-30), measurement lines at the dorsal
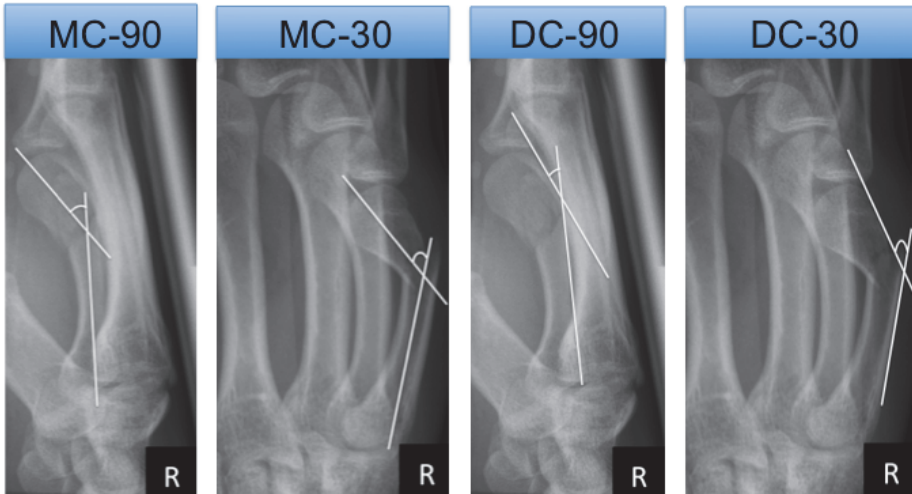
Figure 11: Angle measuring methods

The four different methods for assessment of volar angulation in 5th metacarpal neck fractures tested in Paper 2.
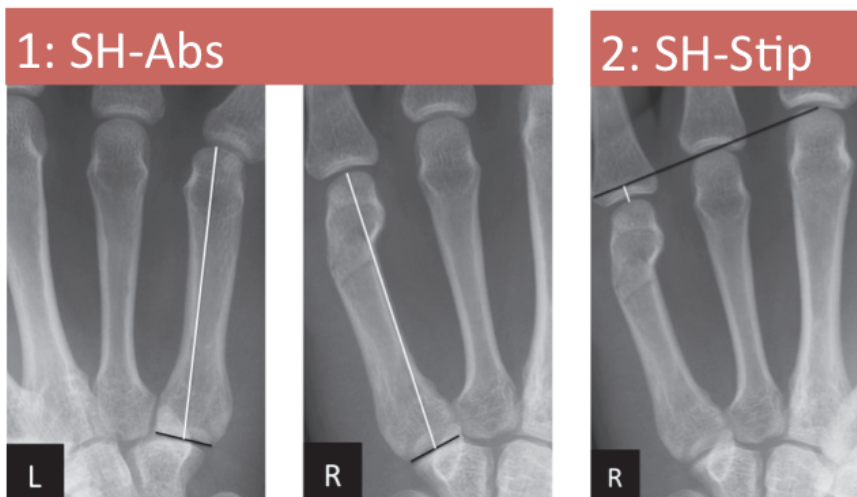

Figure 12: Shortening measuring methods

The two different methods for assessment of shortening of 5th metacarpal neck fractures tested in Paper 2.

cortices in the lateral view (DC-90), and measurement lines at the dorsal cortices in the 30° oblique, pronated view (DC-30) (Figure 11). Based on previous research (98), method MC-90 was set as the gold standard for measuring volar angulation when the validity of the latter three methods was tested. The two methods for measuring shortening were: subtraction of the fractured metacarpal's length from the length of the contralateral, uninjured metacarpal (SH-Abs), and estimating the shortening from the length of the neighbouring 3rd and 4th metacarpal in the injured hand (SH-Stip) (Figure 12). A priori, SH-Abs was set as the gold standard for measuring shortening when the validity of SH-Stip was tested.

4.4 Paper 3

As Paper 2, this study was also designed as a methodological, radiological spin-off from the RCT (Paper 4). During a six-month period in 2010, 179 patients presented with an acute, isolated fracture of the 5th metacarpal in our department. One hundred and ten of these fractures were extra-articular shaft and neck fractures, and their radiographs were included in the study. Three observers (orthopaedic surgeons) evaluated the radiological series (AP, lateral and 30° pronated oblique view), and classified the fractures as either neck or shaft fractures according to their own intuition (method "Today's Practice", TP), and according to totally nine suggested definitions of 5th metacarpal neck fracture. Eight of the nine neck fracture definitions were based on three alternative neck area definitions (Figure 13). Totally, 6600 categorical observations were collected over a time period of approximately one year. To minimize memory bias, randomisation of the patient lists was performed for both patient and method, and there was at all occasions at least one month between two readings of the same radiograph by the same method. The outcome "neck" or "shaft" was compared for TP and the nine neck fracture definitions, as TP was set as a reference for the validity of the methods. The reliability of the methods was also subject to extensive analysis.
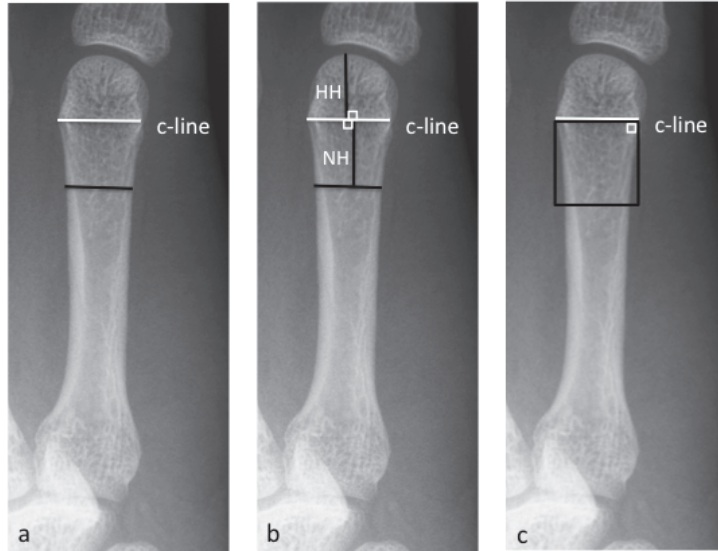
4.2 Paper 4

The null hypothesis was that conservative treatment was inferior to operative treatment, and the alternative hypothesis was that conservative treatment was noninferior to operative treatment.

Eighty-five patients were randomly assigned to either conservative or operative treatment for acute 5th metacarpal neck fractures angulated more than 30° in the lateral view, with no upper limit. Between May 2010-October 2012, 515 patients over 18 years old who presented with an acute fracture of the 5th metacarpal neck were consecutively registered and assessed for eligibility in three hospitals.

Four hundred and thirty patients were excluded, 344 from pre-designed criteria, while 57 patients declined to participate in the study. The latter were all treated conservatively. Twenty-nine patients were excluded for other reasons; 14 of these due to initial exclusion criteria that were later modified, and 15 due to errors.

The patients in the operative group had their fractures reduced under plexus or general anaesthesia, thereafter stabilized by antegrade intramedullary K-wires. The hand and wrist was immobilized in a plaster cast extending from the 4th and 5th PIPJ to the proximal underarm in the functional position for 7-10 days (Figure 14), followed by buddy strapping for another five weeks (or as long as the patients tolerated it). There was not made any attempt of reduction of the fracture in the conservative group, and the hand was immobilized after an identical regime. The patients were followed-up clinically after one week, six weeks, three months and one year (Figure 15). At six weeks and one year, radiographs were also captured.

Assessed for eligibility (n=515)

Enrollment

Excluded (n=430)

♦ Not meeting inclusion criteria (n=344)
♦ Declined to participate (n=57)
♦ Other reasons (n=29)

Randomized (n=85)

Allocation

Allocated to conservative treatment (n=43)
♦ Received allocated intervention (n=43)

Allocated to operative treatment (n=42)
♦ Received allocated intervention (n=38)
  (4 withdrew from study)

Follow-Up

Lost to follow-up:
♦ 1 week (n=5)
♦ 6 weeks (n=7)
♦ 3 months (n=9)
♦ 1 year (n=3)

Lost to follow-up:
♦ 1 week (n=2)
♦ 6 weeks (n=2)
♦ 3 months (n=0)
♦ 1 year (n=1)

Analysis

Analysed:
♦ Inclusion (n=43)
♦ 1 week (n=38)
♦ 6 weeks (n=36)
♦ 3 months (n=34)
♦ 1 year (n=40, including 5 phone interviews)

Analysed:
♦ Inclusion (n=42)
♦ 1 week (n=36)
♦ 6 weeks (n=36)
♦ 3 months (n=38)
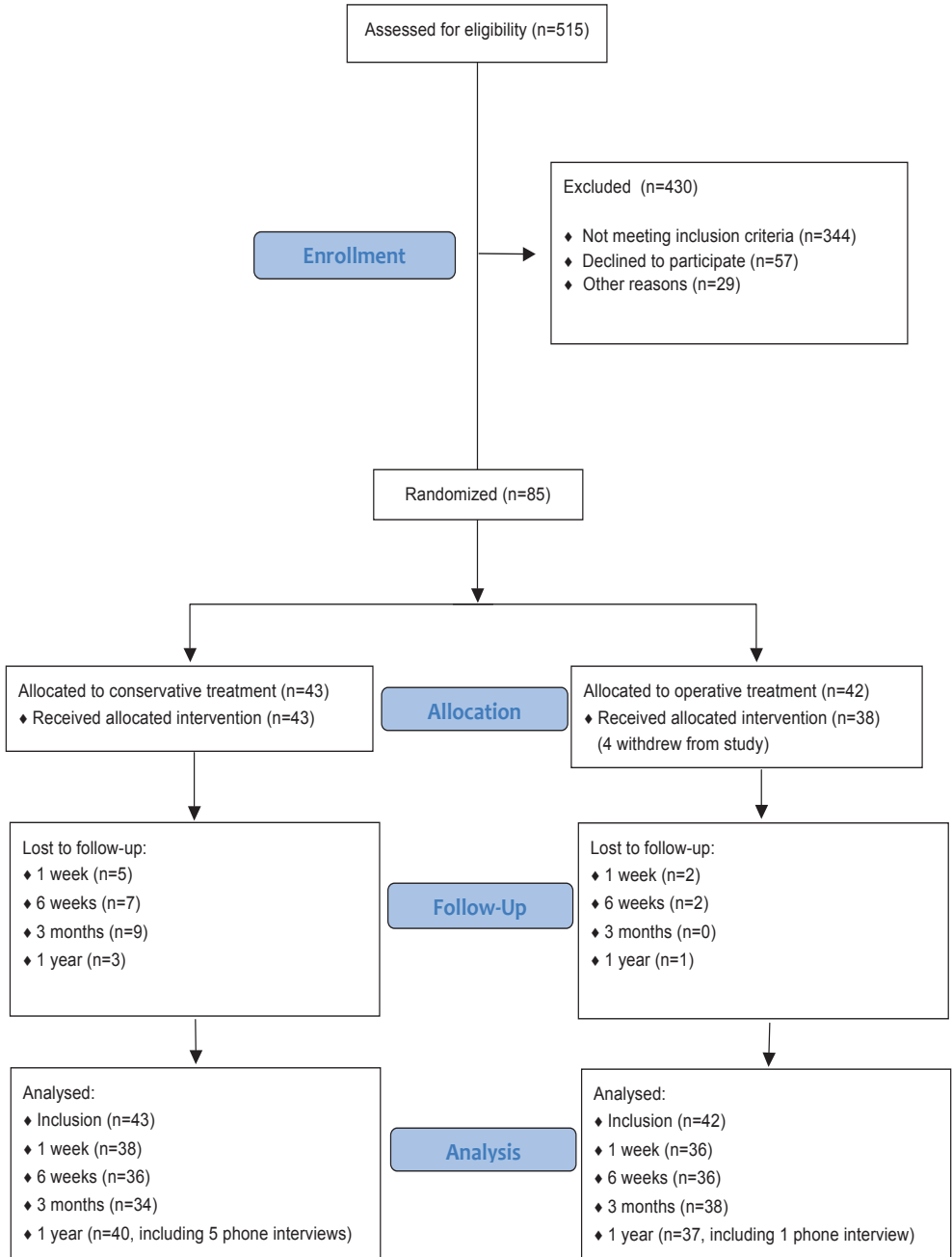♦ 1 year (n=37, including 1 phone interview)

Figure 15: Paper 4 participant flow

Flow diagram (simplified) for participants in the randomised controlled trial in Paper 4.

4.5 Demographic parameters

For both clinical studies, the following demographic parameters were registered: Age, gender, hand dominance, smoking habits, profession, mechanism of injury, alcohol intake at time of injury, time from injury to treatment, and eventual new injuries in the upper extremities in the follow-up period. In the RCT we also registered sport participation and playing of musical instruments.

4.6 Clinical evaluation

The primary endpoint in both clinical studies was Quick-DASH (88, 101,102). Additional clinical endpoints in both studies were: Visual Analogue Scale (VAS) Pain, VAS Satisfaction, ROM in the MCPJ and in the whole finger (total active motion (TAM) and total passive motion (TPM)), grip strength, rotational deformities, complications, and sick leave. The VAS ranged from 0-100, where 0 implied the best value for pain, and the worst value for satisfaction. ROM was measured in degrees (°) by a finger goniometer. Grip strength was given as the best of three attempts, measured by a Jamar® dynamometer. For both ROM and grip strength, both hands were examined for comparison.

In the RCT, the EQ-5D-3L (EuroQol 5 Dimensions 3 Levels; consists of EQ-5D and EQ-VAS) was used to quantify life quality (103, 104). EQ-5D is a five-item measure that includes five health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). An EQ-5D index on a scale from 0 to 1 is calculated from the patient's self-rating of one of three levels in each dimension, where 1 is the best possible heath and 0 equals death (any negative values implies a health state considered worse than death). The EQ-VAS is a global rating of self-related health using a VAS ranging from 0-100 on a vertical scale, where the endpoints are labeled 'Best imaginable health state' (100) and 'Worst imaginable health state' (0).

As Quick-DASH can exhibit a floor effect in our patient group, a self-made (no data on validity or reliability) yes/no questionnaire was applied at three months and one year follow-up in the RCT:

1) Do you experience that your hand function is as it was prior to the injury?
2) Do you experience that the range of motion in your hand is as good as it was prior to the injury?
3) Do you experience that your hand is as strong as it was prior to the injury?
4) Do you experience that there are activities that you no longer can perform due to this injury? If so, specify:
5) Are you satisfied with the cosmetic outcome?

In both studies, the following complications were registered at all time points: infection, change in skin sensibility, mechanical pin problems (pin bending, pin migration, problems with insertion or removal), skin complications/excessive scarring, cold sensitivity, and chronic regional pain syndrome. In addition, any other possible complaints by the patients were noted.

In the retrospective study, the 36 patients who came for a follow-up visit were interviewed by one of three surgeons, and examined clinically by one hand therapist. In the RCT at hospital A, multiple (10-20) orthopaedic residents and consultants included 72 patients. Resident doctors performed the one-week follow-up for all patients, and for patients treated operatively at the six-weeks follow-up (combined with pin removal). Two hand therapists performed all the interviews and hand examinations at three months and one year for all patients, and the patients in the conservative group at six weeks. In hospital B, the 12 patients were included and followed-up at all time points by two senior resident orthopaedic surgeons. In hospital C, a consultant orthopaedic surgeon included one single patient, and performed the one- and six-week controls. This patient was transferred to hospital A for three-months and one-year follow-up.

4.7 Radiological evaluation

In the retrospective study, anteroposterior (AP), lateral and oblique radiographs were captured of the 36 patients who met for a follow-up visit. Position devices were not used for standardizing the radiographs. For all the 67 patients included, pre-operative and postoperative radiographs from the time of injury were examined, as well as any

radiographs from the initial follow-up period. One radiologist with special competence in musculoskeletal radiology read all the x-ray images. Mid-medullary measurement of volar angulation was unfortunately performed in both lateral and oblique views, as there was no standardization of former radiographs.

For the RCT, two special-made position devices were utilized to standardize the lateral and the 30° oblique pronated view in all three hospitals (Figure 16 and 17). In contrast to many other studies, which have used 45° pronated view, 30° was chosen, as this was the standard in our department. AP view was used instead of PA view, as this gives a better and more symmetrical frontal projection of the 5th metacarpal (62). The same radiologist as for the retrospective study interpreted all the radiographs from all three hospitals. Mid-medullary measurement of volar angulation in both lateral (MC-90) and 30° pronated oblique view (MC-30) was performed at all time points. Shortening was measured both by method SH-Abs and SH-Stip at all time points. At inclusion, the volar angulation in the uninjured hand was measured by MC-90 and MC-30, and "shortening" by SH-Stip.

The 30 radiograph series that were chosen for the radiological study that constitutes Paper 2, were the first consecutive 30 inclusions in the RCT that satisfied the following criteria:

1)   Position devices used.
2)   Series included three views of the contra-lateral, uninjured hand.
3)   The AP view included the most distal point of the 3rd metacarpal's hemisphere (for method SH-Stip).

In Paper 3, most of the radiographs were captured by the use of the position devices. The AP view was used for classification to shaft or neck fracture, supplied by the oblique and lateral view in cases where the fracture line was not sufficiently visible in the AP view.
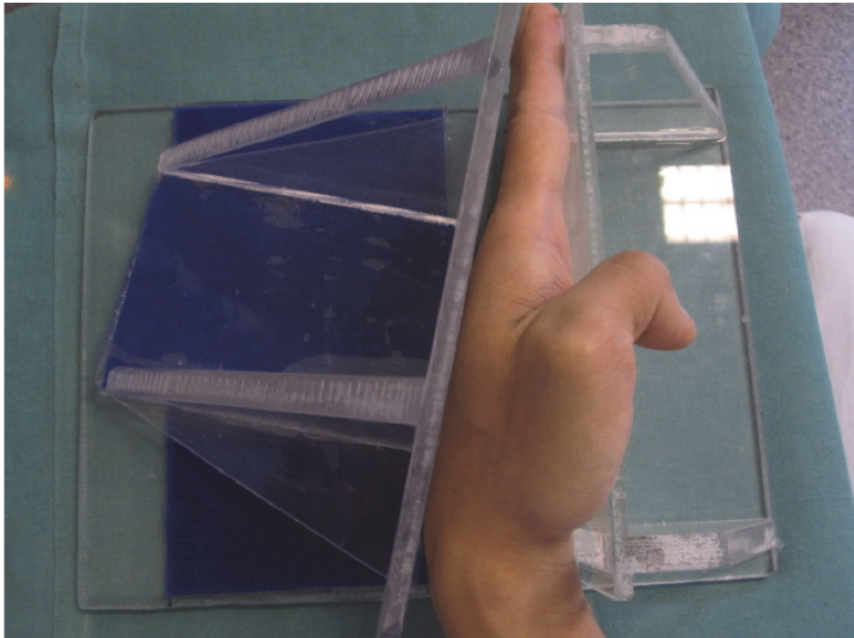
Figure 16: Position device 1

The position device used for lateral view of the 5th metacarpal neck fractures in Papers 2-4.

Figure 17: Position device 2

The position device used for pronated oblique 30° view of the 5th metacarpal neck fractures in Papers 2-4.

4.8 Statistics

For all four papers, statistical significance was set at alpha ≤0.05. In the two clinical studies, non-parametric statistical tests (Chi-Square test and Fischer`s exact test for categorical outcome, and the Mann-Whitney test for continuous outcome) were used, and data was given as median and range. This was performed as the primary endpoint Quick-DASH was not normally distributed, but exhibited a left skewed distribution in both studies (Figure 18 and 19). Correlations between clinical outcome and final volar angulation in the fractures were investigated by linear regression.

The power analysis in the RCT (Paper 4) was based on the primary endpoint Quick-DASH (noninferiority, continuous outcome). As the authors of the Quick-DASH score have estimated the MDC-95 between 7.9-17.2 points (88), we chose the

Paper 1: Quick-DASH in 56 out of 67 patients at follow-up

Mean = 5.55
Std. Dev. = 8.288
N = 56
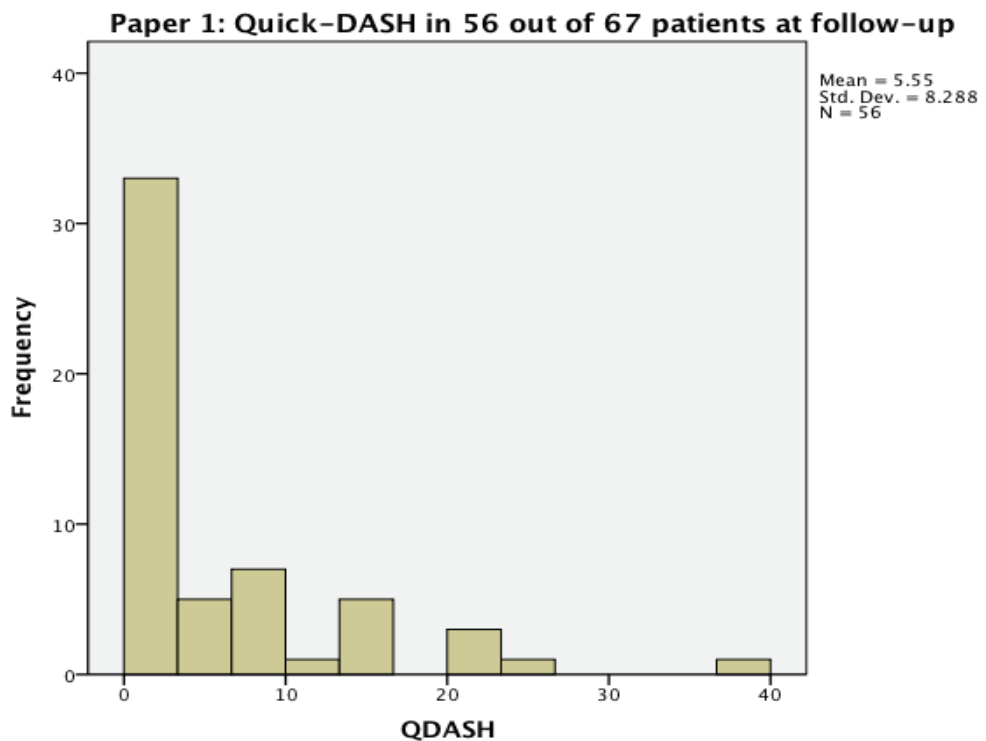
Figure 18: Quick-DASH in Paper 1

The histogram demonstrates that the primary outcome Quick-DASH Outcome Measure in Paper 1 was not following the normal distribution, but had a left skewed distribution (floor effect).
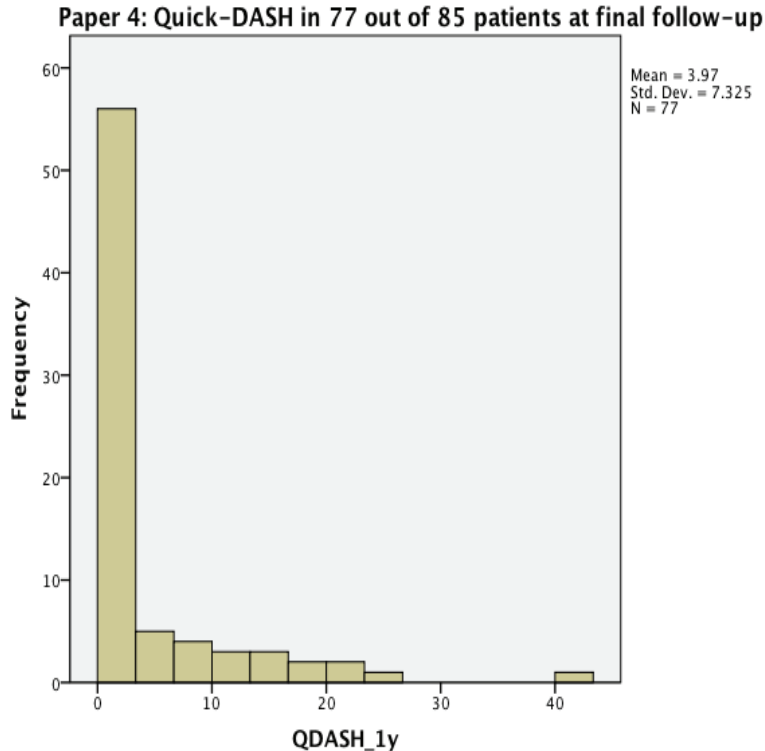
Figure 19: Quick-DASH in Paper 4

The histogram demonstrates that the primary outcome Quick-DASH Outcome Measure in Paper 4

was not following the normal distribution, but had a left skewed distribution (floor effect).

margin (Δ) eight points in the Quick-DASH score. The mean Quick-DASH value for 67 patients in the retrospective study was six (standard deviation (SD) eight). As we did not have a SD for patients treated conservatively in the retrospective study, we estimated the SD in the present RCT as 10. With a significance level (alpha) of 5 % (one-sided confidence interval of 95 %), and a power (1-beta) of 95 %, it was calculated that the sample size was 34 patients in each allocation arm, yielding totally minimum 68 patients to be included in the trial. We chose to include additional 25 % patients because of the high risk of patients lost to follow-up for this particular diagnosis, and randomized therefore totally 85 patients (42 to operative treatment and 43 to conservative treatment).

In Paper 2, student's t-test for paired data was used to compare the mean outcome with their standard deviations (SD) when validity of the different methods
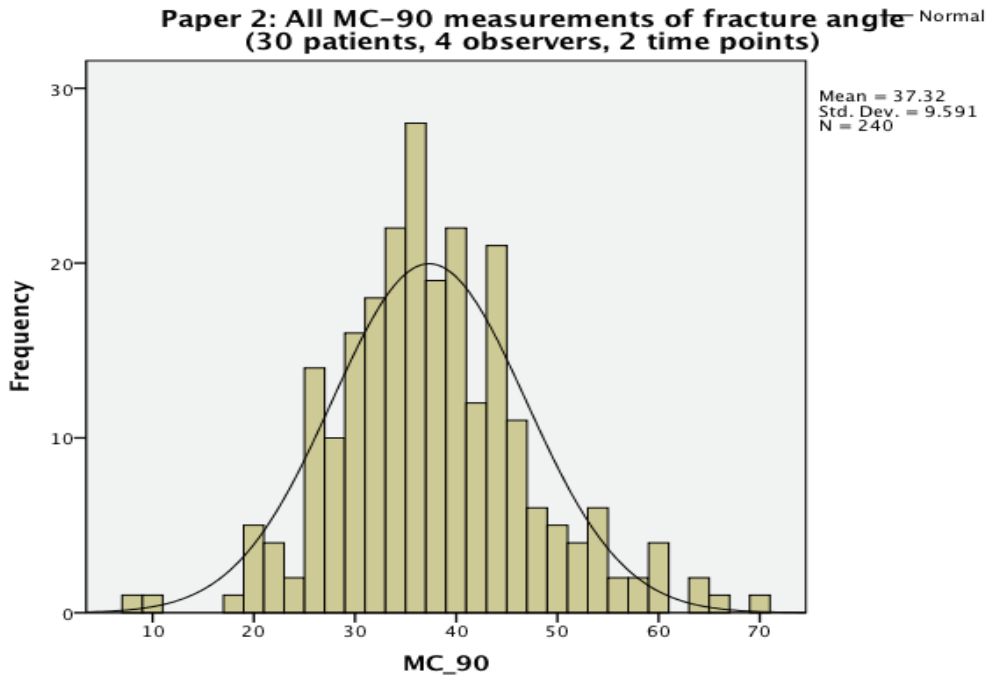
Figure 20: MC-90 Paper 2

The histogram demonstrates that the measurements of volar angulation in the 5th metacarpal fractures in Paper 2 followed the normal distribution.

was investigated. This could be done as data for volar angulation and shortening in the 30 fractures was normally distributed (Figure 20). Linear regression was performed to investigate degree of association between shortening and volar angulation in the fractures. In Paper 3, validity of the nine neck fracture definitions with TP as the reference was tested by logistic regression, with the dichotomous categorical dependent variable "Outcome" (neck or shaft). In addition, validity of the methods was estimated by two-rater Kappa coefficients for each observer for the outcome neck/shaft for TP versus the nine definitions, to find which definition correlated best with each observer's intuitive judgment. Intraclass correlation coefficients (ICC) and their 95 % confidence intervals (95 % CI) for continuous data (Paper 2), and Kappa coefficients for categorical data (Paper 3) were used to estimate inter- and intra-observer reliability. For both ICCs and Kappa values, values below zero were considered as "poor", values 0.00-0.19 as "slight", values 0.20-0.39

56

as "fair", values 0.40-0.59 as "moderate", values 0.60-0.79 as "substantial" and values over 0.80 as "excellent" (105).

4.9 Ethics

In both clinical studies, the participants signed a written consent at inclusion after being thoroughly informed by an orthopaedic surgeon. The Norwegian Data Inspectorate approved the studies, including storage of data. The Regional Ethical Committee of South-Eastern Norway Regional Health Authority approved both studies before registration and inclusion started. In the RCT, we had allowance to register and include both 5th metacarpal neck and shaft fractures, but chose to only include neck fractures in the trial. The projects were conducted in accordance with the Helsinki Declaration, and the RCT was registered at www.clinicaltrial.gov under the identifier NCT 01139528 before inclusion of participants began. There was not considered to be any ethical problems related to the allocation arms in the RCT, as both conservative and operative treatment of 5th metacarpal fractures have been well documented to yield long-term adequate hand function.

5.0 SUMMARY OF RESULTS OF EACH PAPER

5.1 Paper 1

Patients treated with transverse or bouquet pinning for isolated, extra-articular fractures of the neck and shaft of the 4th and 5th metacarpal regained good hand function, but were at risk for surgery-related complications. There was not found any differences in the clinical outcome depending on operative method. Due to the risk of fracture of the neighbouring metacarpal after transverse pinning, we concluded that bouquet pinning was superior. Furthermore, we recommended burying pins under the skin surface to minimize the risk of postoperative infection.

5.2 Paper 2

The recommended method for measuring volar angulation in 5th metacarpal fractures was mid-medullary in the lateral view (method MC-90), based on earlier research (98). Although not as reliable as the two methods for measuring volar angulation in the oblique view (methods MC-30 and DC-30), it was considered reliable enough for clinical use. Furthermore, we recommended estimating the shortening in the fracture from the neighbouring 3rd and 4th metacarpals (method SH-Stip), as this method does not imply the need for radiographs of the contralateral hand. The reliability of SH-Stip was excellent, but the measured value was one millimetre more than the actual shortening measured from subtraction of metacarpal length in the ipsilateral, non-injured hand (method SH-Abs). The normal volar angulation in the 5th metacarpal neck was found to be 15° in a large, standardized radiological material of 60 uninjured metacarpals, measured by MC-90.

5.3 Paper 3

Our preferred new definition of metacarpal neck fractures (C-Square-75; renamed Identification of Neck versus Shaft (INS) method) was valid compared to today's

practise of scoring by intuition (TP), with high inter- and intra-observer reliability (Kappa 0.84-0.94). INS method was set as the definition when neck fractures were assessed for inclusion in the RCT. It was recommended for use when future trials on metacarpal neck fractures are performed, to ensure a valid comparison of results between studies.

5.4 Paper 4

The main finding was that conservative treatment of 5th metacarpal neck fractures was not inferior to bouquet pinning quantified by Quick-DASH and measured hand function (ROM and grip strength). The patients treated operatively had a trend versus better satisfaction than the conservatively treated patients, but this can have been a result of inclusion bias and operative placebo effect. The complications were worse and more numerous in the operative group, and the duration of sick leave was four times longer. Hence, conservative treatment was recommended for fractures with up to 60° volar angulation (the maximum fracture angulation in the trial) due to less complexity of the regime and fewer complications.

6.0 GENERAL DISCUSSION (METHODS, RESULTS)

6.1 Paper 1

The study would have been of better quality if the design had been prospective. Then the indication for surgery would have been clearly defined, and the treatment arms, as well as the radiographs and the early follow-ups, would have been standardized.

The paper would also have been stronger if the patients included had been more homogenous. Although treatment algorithms for neck and shaft fractures in the 4th and 5th metacarpals in our department during the particular time interval were quite similar, there were some differences. The study design was altered during the review process, as originally, 93 patients were included in the study. They represented patients treated operatively for one or two extra-articular fractures in all localizations in all four ulnar metacarpals, treated by all surgical methods in 2007-08. Of the 93 invited patients, fifty-six met for a clinical examination, 26 were interviewed by the telephone, and 14 patients were lost to follow-up. There were 85 patients treated by closed reduction and pin osteosynthesis (28 bouquet, 57 transverse), and eight patients treated by ORIF (5 open reduction and screw fixation, 3 open reduction and plate osteosynthesis). As there were very few fractures in the 2nd and 3rd metacarpals (3+6), few base fractures (4), only eight patients with two fractures and only eight ORIFs, these were excluded during the review process to make the data material more homogenous. The remaining 67 patients had been treated for neck and shaft fractures in the 4th and 5th metacarpals, by closed reduction and bouquet or transverse pin fixation. The paper would thus have been stronger if the design had been better from the planning phase, for instance inclusion of only 5th metacarpal neck fractures (the most numerous) treated by closed reduction and pin fixation in a four-year interval.

The patients in both groups had generally good clinical results, with very little pain, good satisfaction and almost complete normalisation of hand function. No serious complications were noted, but many patients had minor complications like superficial skin infection, changes in skin sensitivity and cold intolerance. We demonstrated a risk of weakening of the neighbouring metacarpal after transverse

pinning, and it is known that patients with metacarpal fractures are prone to recurrent injury (7). On this basis, we recommended bouquet pinning. In addition, we recommended burying pins below skin surface, as infection was significantly more common when pins were left prone.

Originally, we had planned to perform an RCT of 5th metacarpal neck fractures comparing two different operative methods. After the retrospective study, we realized that results after different pinning procedures probably do not differ much, and that the main issue to solve is when this particular injury is in need of operative treatment, if ever. It was not possible to include a conservatively treated cohort of patients in the retrospective study, as we had a common policy to operate all 5th metacarpal neck fractures with volar angulation more than 30° in the given time period (2007-08). We must therefore suppose that the conservatively treated fractures in our department therefore had a volar angulation in the fractures of less than 30°, and a comparison to the operatively treated cohorts would therefore have been of little value.

6.2 Paper 2

Our recommendation of method MC-90 for measuring volar angulation in 5th metacarpal neck fractures was based on the cadaveric study of Lamraski and co-workers (98), and a fundamental research question was whether the recommendations in this study were reasonable. Reasons for including an oblique view in the radiological series of metacarpals are the overlapping of the bones in the lateral view (106), and the curved arc of the ulnar four metacarpals. The latter anatomical fact is responsible for the problem that a straight lateral view of the hand does not give a straight lateral view of all four ulnar metacarpals (39, 106). The deviations from a straight lateral metacarpal view in a straight lateral hand view are largest for the 2nd and 5th metacarpals, as the 2nd metacarpal is some degrees internally rotated, and the 5th metacarpal is some degrees externally rotated. We have not found any anatomical studies that have found the mean degree of the external rotation of the 5th metacarpal, thus the "ideal lateral view" of this knuckle is not known. The view that is true lateral to the 5th metacarpal will give the true volar angulation, given that there is no rotation in the fracture. If there is no rotation in the

other planes of the view, the true lateral view will give the largest volar angulation, as any oblique plane to the fractured metacarpal will give lesser volar angulation. We demonstrated that mid-medullary measurement in the 30° oblique hand view gave mean 9° higher readings of volar angulation than the lateral hand view, which can indicate that the 30° oblique view is more close to the "ideal lateral view" of the 5th metacarpal, given that there is no rotational component.

Lamraski and co-workers (2006) concluded that mid-medullary measurement lines in the lateral view of the hand (corresponding to our method MC-90) gave the correct readings of the volar angulation, when compared to their gold standard of measuring along K-wires at the osteotomy sites. This was based on the higher readings of the mid-medullary measurements in the PA 45° oblique view (hereafter named method MC-45), demonstrated by Bland and Altman plots. It was referred that MC-45 produced a significant bias, but some main topics were not discussed. First, the mean volar angulation in an un-fractured metacarpal is demonstrated to be 14 (SD 2)° in the lateral view of the hand (20), and 11 (SD 7)°/10 (SD 7)° (men/women) in the 45° pronated oblique view (97), both measured mid-medullary. One must assume that an angulation in the K-wires of 0° (before the osteotomies were made) would have corresponded to a mean mid-medullary measurement in the lateral view of 15° in Lamraski and co-workers' cadaveric model. Hence, MC-90 in this cadaveric study measured correctly the induced deformity of the 5th metacarpal, not the actual fracture angulation, which was better visualized in the MC-45 with higher readings of about 15° seen in the Bland and Altman plot. Second, the fact that it is probably the highest reading that gives the true angulation (given there is no rotation in other planes of the view) was not discussed. Third, pronated oblique radiographs of cadaveric hands stripped of most of the soft tissues did probably not correspond adequately to pronated oblique radiographs of normal hands.

Therefore, a direct comparison of this cadaveric study and clinical studies of living hands with acute fractures is not straightforward. In our study, we based the validity of the three other methods (MC-30, DC-90 and DC-30) at the assumption that MC-90 gave the true volar angulation in the fractures based on the study of Lamraski and co-workers. This assumption is probably correct as long as one bears in mind that this represents the induced deformity of the fracture, not the total volar angulation in the neck-shaft axis. We demonstrated that MC-30 produced 9° higher

readings than MC-90, and that the corresponding difference between DC-30 and DC-90 was 7°. Leung and co-workers (99) did not compare the absolute values for MC-90 and DC-90, but we found a difference of means of 9° less angulation for DC-90. In accordance with Leung and co-workers' we did not demonstrate better reliability for DC-90 than for MC-90. Our results were in agreement with Lamraski and co-workers' with better reliability for MC-30 and DC-30 than for MC-90 and DC-90.

The possibilities for different methods for measuring volar angulation in 5th metacarpal fractures are many, and even a reverse 45° pronated oblique view that is perpendicular to the standard 45° pronated oblique view have been suggested (107). Our paper would have been stronger if we had used the 45° pronated oblique view instead of the 30° pronated oblique view, as this is more common in previous research. The reason for this was local tradition in our department. It would also have been stronger if we had discussed the problem of validity assumption based on

Figure 21: Definition CT-C

According to definition Collateral ligament to Transition zone-Center (CT-C), a metacarpal neck fracture was a fracture with the center (red dot) of the fracture within the CT area (borders marked by black lines; distal line (c-line) between the tuberosities where the collateral ligaments of the metacarpophalangeal joint insert proximally, proximal line where the transition between cancellous and cortical bone is perceived).

Lamraski and co-workers' cadaveric study, and pointed out that MC-90 probably reflects the induced deformity in the neck fractures, not the total deformity. However, the main aim of Paper 2 was to focus on the demonstrated lack of common understanding between researchers, and to encourage future investigators to report sufficiently how they have measured the volar angulation in metacarpal fractures, to allow for comparison of results from different trials.

6.3 Paper 3

The development of recommendable definitions of metacarpal neck area and metacarpal neck fractures was a two years' process. The work started when
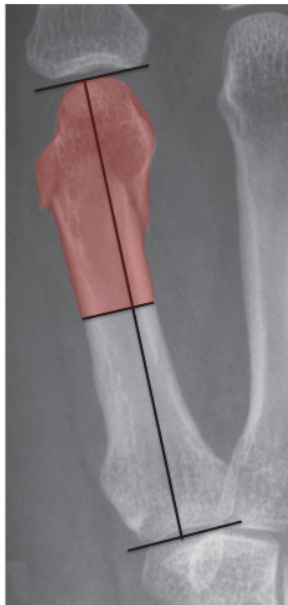
Figure 22: Definition DM50

According to Distal metacarpal 50 % (DM50), a metacarpal neck fracture was defined as having all of the fracture line distal to the middle of the metacarpal's length.

inclusion of patients in the RCT (Paper 4) commenced in hospital A (May 2010). To distinguish between neck fractures and distal shaft fractures in the RCT, we developed definition Collateral ligament to Transition zone- Center (CT-C) (Figure 21), as we could not find any previous definitions in the literature. The work on Paper

3 started as reliability testing of CT-C, as we interpreted all 110 radiological series (captured July-December 2010) in January and February 2011 by methods CT-C and Distal Metacarpal 50 % (DM50, Figure 22). The latter method was included for its simplicity, for reliability comparison. DM50 was not considered valid, and never intended for clinical use. The radiological series were then interpreted by method TP (March and April 2011), to be able to investigate the validity of method CT-C and

Figure 23: Area definition HNH

Area Head Neck Height (HNH) was defined as the area between the c-line (line between the tuberosities where the collateral ligaments of the metacarpophalangeal joint insert proximally; here named α); and γ, a line parallel to the c-line in the distance β from the latter, where the length β (NH in Figure 15) was defined as identical to the length of a normal from the c-line to the most distal point of the metacarpal head (also named β in the figure, HH in Figure 15).

DM50. Resident doctors that included patients in the RCT reported that CT-C was difficult in practical use, which led to the development of area definition Head Neck Height (HNH, Figure 23). This definition was intuitively considered as more reliable than area definition CT, as the proximal border was set in a fixed distance from the

C-line. Neck fracture definitions HNH-Center (HNH-C), HNH-75 % (HNH-75) and HNH-Involved (HNH-I) were tested on the radiological series in May and June 2011. Like DM50, HNH-I was not intended for clinical use. It was included to find the proportion of fractures that at all involved the neck area as defined by HNH. From the data analysed during the following months, we found that CT-C and HNH-C were valid definitions compared to the old standard TP, and that HNH-C was the most reliable of these. A problem with HNH area was that it diminished as the volar angulation in the fractures increased. This might be a theoretical problem, but it led to the development of neck area Collateral ligament (c-line) Square (C-Square, Figure 24). Winter 2012, we tested neck fracture definitions C-Square-Center (C-Square-C), C-Square-75 % (C-Square-75), C-Square-100 % (C-Square-100) and C-Square-Involved (C-Square-I). When the data was interpreted in May 2012, of these only C-Square-75 was found valid compared to TP. On the other hand, this definition was very reliable, more reliable than both CT-C and HNH-C. C-Square-75 consequently became our recommended method, re-named INS method (Identification of Neck versus Shaft fractures).

Originally, a skeletal radiologist with special competence in hand fractures was one of the observers in addition to the three orthopaedic surgeons. He was omitted from the study after interpretation of the HNH-series (Summer 2011), when it became evident that he had used a radiological screen with higher resolution than the three surgeons.

The results from Paper 3 led to the use of definition C-Square-75/INS method in inclusion of patients in the RCT (Paper 4) from May 2012. As first definition CT-C and later HNH-C were in use when patients were included, all radiographs of included and excluded patients (n=417) from May 2010-May 2012 in hospital A were re-investigated to find possible errors. None of the patients included during the first two years had to be excluded due to the new definition, but in total 11 patients had been erroneously excluded as shaft fractures during the full time interval May 2010-October 2012 (including the first six exclusions the first six months due to "a certain shaft component").

Figure 24: Area definition C-Square

Area definition C-line Square (C-Square) was defined as the proximal squared area of the c-line (line between the tuberosities where the collateral ligaments of the metacarpophalangeal joint insert proximally).

6.4 Paper 4

The main aim of the Ph.D. project; to find the best possible treatment of 5th metacarpal neck fractures was investigated by the means of an RCT. An RCT is regarded as level Ib/II evidence of therapeutic studies according to Oxford Centre for Evidence-based Medicine. Most of the study participants in hospital A were approved for inclusion by the primary investigator (Ph.D. student), but other surgeons implemented the allocated treatment. In addition, other surgeons and hand therapists performed all outcome assessments to avoid researcher bias.

      The general limitation of an RCT is mainly related to inclusion/selection bias, as many patients refuse to participate, or are excluded due to different criteria. For our particular patient group, problems regarding inclusion bias were significant, as

the majority of the patients were young men who had suffered the fracture due to aggression under the influence of alcohol, and did not represent the average population. Totally, 85 patients were included from a pool of 171 eligible patients (50 %). Of the 86 "missing inclusions", 15 were errors (neck fractures (according to INS method) interpreted as shaft fractures (n=5), under-estimation of volar angulation (n=3), no obvious reason for exclusion/study forgotten by emergency department (ED) doctor (n=7)) and 14 were excluded due to stricter exclusion criteria the first six months in hospital A. The latter 57 patients refused to participate in the study after oral and written information. They were all treated conservatively, as they justified their refusal as a fear of being allocated to operative treatment. It is of interest that 57 of 142 patients (40 %) interviewed for study participation refused to participate because they had a baseline preference for conservative treatment. Before the study started, we had anticipated that inclusion could be difficult because the two allocated treatment arms were operative and non-operative, as we stipulated that the patients would prefer to have their fractures operated (more advanced and "modern" treatment). In addition, four of the 42 included patients allocated to operative treatment withdraw from the study after the randomization was performed, either immediately or by no-show to the scheduled appointment for operative treatment and were thus treated conservatively without follow-up. The inclusion bias in our study would therefore most likely result in a more favourable result in the operative group than if the treatment was applied to the general population, as the patients with their minds set negatively to operative treatment had been excluded (n=57) or had withdrawn from the study after allocation to operative treatment (n=4).

In addition to the missing inclusions, 344 of 515 patients were correctly excluded when assessed for eligibility due to predesigned criteria. These criteria were all well justified, to minimize interference/bias affecting the results that were not directly related to the fracture itself. The criterion responsible for the largest number of exclusions was volar angulation <30° (n=219). Thirty degrees was set as a lower limit, as it was not considered ethical to operate on patients with too small deformities due to the good reports of conservative treatment in the literature. A maximum limit was not applied, and the maximum fracture angulation for patients included in the trial appeared to be 59°. The second two largest exclusion groups were multiple injuries (n=33) and intra-articular fractures (n=27). Both groups are considered as

other types of injury than simple extra-articular neck fractures, and are thus not valid for comparison of the clinical outcome. Fractures complicated with rotational deformities (n=15) or ad latus deformity (lateral displacement) more than half the bone width (n=2) were excluded, as these could not be left unreduced in the conservative group. Patients who presented later than 14 days (n=18) were excluded as the reduction of the fractures would have been difficult at this stage. Patients with particular poor compliance (n=30) were excluded to be able to implement the study (language problems, chronic drug abuse, dementia, and patients who lived too far away to be followed-up at our hospital).

When inclusion of patients in the RCT started in May 2010, it was estimated that the inclusion period would be approximately one year, based on the annual number of patients with 5th metacarpal neck fractures in our department. Unfortunately, it soon became evident that a large proportion of the patients had fractures with <30° volar angulation, and were therefore not fit for inclusion. Other exclusion criteria contributed to a very low inclusion rate the first six months, which made protocol adjustments necessary. Some of the originally exclusion criteria had to be removed, to ensure that the study population did not suffer too extensively from selection/inclusion bias. The regional ethical committee approved the changes after a formal request, and the changes were also submitted to the international RCT database clinicaltrials.gov. The following exclusion criteria were removed in November 2010 and the number of patients excluded by these are identified in brackets (total n=14): Open fractures (n=0), previous injury to the upper extremity with persisting sequelae (n=0), previous fracture of the affected metacarpal or the opposite hand's corresponding metacarpal (n=3). Many of the patients who were fit for inclusion in the study had suffered previous 5th metacarpal fractures, and the original plan to exclude them was made to have radiological examinations only on skeletal bones without malformation. The radiological parameters were secondary to the hand function measurements performed at follow-up, and the wish for "perfect" radiographs could not justify the exclusion of these patients. The patients with former injury to the upper extremity were, as every other study subject, monitored by a baseline Quick-DASH, and changes in the hand function score could thus have been registered. The time limit for inclusion was first set to 10 days (excluded patients: n=5), and in November adjusted to 14 days. The introduction of definition CT-C in

November 2010 solved the problem of the exclusion of fractures of the neck that "had a certain shaft component" (n=6).

The patients were recruited to the study from three emergency departments in hospitals A, B and C, and the three supervisor surgeons in these hospitals had to communicate regularly with the ED doctors, and to pay continuously attention to the inclusion of patients so that as few patients as possible were lost for the study. This was a challenging task, as there were multiple ED doctors (in hospital A at least 40 at any time point) that had to be supervised and informed at all times. The ED doctors registered all patients with 5th metacarpal neck fractures, and in addition the three supervisors had to control all radiographs for patients who had been given the ICD-10 diagnosis S62.3 to ensure that the patients were assessed for eligibility in the study. As diagnosis S62.3 includes all sub-types of fractures in the ulnar four metacarpals, a very large number of radiographs have been interpreted to identify the 515 patients assessed for eligibility in the study.

Patients treated conservatively had a cast applied for 7-10 days followed by buddy strapping of the 5th and 4th fingers for five weeks, and there was not made any attempt to reduce the fracture prior to splinting. Patients treated operatively had their fractures reduced under general or regional anaesthesia, followed by operative stabilization by intra-medullary bouquet pins. The two treatment arms were chosen as these were considered as the two best alternatives within conservative and operative treatment, based on the previous literature. The problem of causality in the RCT was attempted minimized by creating as similar study allocation arms as possible. After the initial implementation of operative or conservative treatment, the protocol was identical for the two patient groups, including length of immobilization in a cast (POP) followed by buddy strapping and allowances in mobilization. This was performed deliberately to avoid obvious confounding factors that could affect the primary end-point Quick-DASH one year postoperatively.

When performing an RCT, the double-blind design is preferred. In our study, the patients and the care providers could of obvious reasons not be blinded for the treatment, but it would have been beneficial if the outcome assessors (hand therapists and orthopaedic surgeons) had been blinded. Placing a small bandage over the base of the 5th metacarpal in all patients before the interviews and physical examinations could have been acceptable blinding. It was discussed in the planning

phase, but abandoned due to the need of an extra coordinator to place the bandages and instruct the patients before each follow-up appointment. These were organized as ordinary, in-between consultations in the out-patient clinics and not on dedicated research days, as it was difficult enough to encourage the patients to meet for free follow-up visits at any time point of their own choice, including refund of all expenses.

Ideally, the definitions of neck area and neck fracture should have been pre-designed and tested for validity and reliability before inclusion of patients commenced in May 2010. Unfortunately, this work was a long process (Paper 3), and the first six months of the inclusion period we had no fixed definition other than "5th metacarpal neck fracture", where "fractures with a certain shaft component" was a exclusion criteria. As explained above, this was altered in November 2010 when the exclusion criteria were modified in accordance with the local ethical committee, when definition CT-C was developed and came in use. As the ED doctors who included patients in the study reported this definition difficult to use, definition HNC-C was developed, tested and found valid and reliable. The reason for developing neck area C-Square was to avoid the influence of the volar angulation in the fracture on neck area, and after validating of C-Square-75, this replaced HNH-C as the neck fracture definition in the RCT. The few erroneous excluded patients are already encountered for (n=5).

When inclusion of patients started in May 2010, we had already decided to set the inclusion limit of 30° of volar angulation in the fracture according to method MC-90, based on the previous research by Lamraski (2006). As discussed under Paper 2, the validity of this method can be debated, as one probably only measure the induced deformity of the fracture by this method, and not the total angulation in the fracture (normal volar angulation + induced deformity). Our group did not realize this until 2012, after publication of Paper 2. Based on this insight, we chose to report the volar angulation in the fractures included in the RCT both from MC-90 and MC-30. The latter method probably reflect the total volar angulation in the fractures more accurate than MC-90, thus the fractures in our RCT were all a little more angulated that initially assumed. This had only a positive effect on the study's conclusions, as it is the most angulated fractures that are subject to debate on different treatment regimes as the little and moderate angulated fractures safely can be treated conservatively according to previous studies.

After a meticulous, time-consuming effort, the rate of patients lost to follow-up (LTFU) was lower than could be expected from previous studies. Only two of the seven patients at one week were true LTFUs, as the resident doctors in hospital A that performed the early controls forgot to fill in the protocol in five instances. At six weeks, only the seven patients in the conservative group were true LTFU, as the two patients in the operative group came for pin removal, but the resident doctors forgot to fill in the protocols. At three months, there were no LTFUs or forgotten protocols in the operative group, and nine true LFTUs in the conservative group. At one year, we managed to get 35/43 participants in the conservative group and 36/38 participants in the operative group to meet for final follow-up including radiographs. By phone interviews five participants in the conservative group and one participant in the operative group were added, giving a total follow-up rate on the primary outcome Quick-DASH of 77/81 (95 %). The last four LTFU patients could not be localized in spite of many attempts. Originally, it was planned to follow the patients for two years, even though Quick-DASH at one year was chosen as the primary end-point. The plan was adjusted, as the problems of LTFUs became evident already at six weeks and three months. Most probably, complete restoration of hand function lowered the patients' motivation for attending the follow-up regime. Theoretically, it is not very likely that the hand function improves further one year after the treatment, so this adjustment should not have had major implications on the clinical outcome.

Even though both the internal and the external validity were influenced by inclusion (selection) bias, the null hypothesis (conservative treatment was inferior to operative treatment) could be rejected, supporting the alternative hypothesis that conservative treatment was noninferior. As already accounted for in chapter 2.6.3, our findings and conclusions were in coherence with the previous, limited, and lesser systematic research comparing conservative and operative treatment. The noninferior design has the possibility of rejecting a null hypothesis due to a type II-error (that there exists a clinical difference in outcomes that we have not been able to detect). The extensive protocol including a large variety of outcomes, the implementation of allocated treatments without any crossovers and the few patients lost to follow-up all contributed to minimize this potential research problem.

7.0 CONCLUSIONS OF THE THESIS AND SUGGESTIONS FOR FURTHER RESEARCH

Our proposed conservative regime of one week cast wear applied on an unreduced fracture followed by buddy-strapping is not invasive, costs less and is associated with less complications and shorter duration of sick leave than bouquet pinning. As particular many patients with 5th metacarpal neck fractures are non-compliant to follow-ups, a low-complexity regime is preferable when possible. We recommend our conservative regime instead of operative treatment, as it is demonstrated not to be inferior, based on both subjective and objective measures. The recommendation can be applied to isolated, extra-articular, frontally aligned fractures angulated volarly up to 60° (measured mid-medullary in the lateral view) without rotational deformities or extensor lag at presentation, as these were the fractures studied in our RCT.

Our study is to our knowledge the first RCT comparing conservative and operative treatment on 5th metacarpal neck fractures. When performing future studies, researchers should use standardized methods for fracture angle and shortening measurements, and give descriptions of fracture type(s) included. We recommend to measure angulation along lines mid-medullary in the metacarpal in the lateral view (MC-90), and to define metacarpal neck fractures according to our proposed definition INS method (C-Square-75).

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9.0 APPENDIX (QUICK-DASH, EQ-5D) AND PAPER I-IV

QUICK-DASH

(NORWEGIAN EDITION)

Poengberegning av Kvikk-DASH

Dysfunksjon i arm, skulder og hånd

Dysfunksjon/symptom (De første 11 spørsmålene)

Svaralternativene for hvert spørsmål poengsettes fra 0 (ingen funksjonsnedsettelse/symptomer) til 4 (verste funksjonsnedsettelse/symptom).
N.B. Dette er en endring fra tidligere der score gikk fra 1 til 5 og en så trakk ifra 1.

Beregning av DASH score:

N.B: Det må være svar på minst 10 spørsmål for å beregne Kvikk-DASH

Legg sammen poengene, del på antall svar, og gang med 25
        Dvs: Kvikk-DASH score = (Poeng/antall svar) x 25

- Det gjør det lettere om en teller opp hvor mange "=0-ere" det er, hvor mange "1-ere", hvor mange "2-ere" osv og så ganger ut og legger sammen for å få poengsummen. Det er da også lett å se hvor mange spørsmål som er besvart.

Arbeid (4 spørsmål, det er valgfritt om denne delen brukes)

Svaralternativer for hvert spørsmål poengsettes fra 0 (ingen) til 4 (ikke mulig).

Beregning av score:
Legg sammen poengene og del på 0,16
        Dvs: Poeng / 0,16

- Alle 4 spørsmålene må være besvart for å kunne beregne denne score.

Musikk/idrett

Samme regler som for "Arbeid"

Denne norske oversettelsen er vurdert og offisielt godkjent av AAOS. Vennligst henvis til denne nettadressen hvis den norske utgaven av skjemaet brukes i en publikasjon.

HELSEUNDERSØKELSE
(arm/skulder/hånd)

Dette skjemaet tar for seg dine symptomer og dine evner til å utføre visse aktiviteter.

Vær snill å svare på **alle** spørsmål, basert på hvordan det har gått **den siste uken**.

Dersom det er noen aktiviteter du ikke har utført siste uken, skal du krysse for det svaret som du mener ville stemme best om du hadde utført aktiviteten.

Det har ingen betydning hvilken arm eller hånd du bruker for å utføre aktiviteten. Basere svarene på hva du får til, uansett hvordan du utfører oppgaven.

Vennligst sett kryss for ett svaralternativ for hvert spørsmål.

Kvikk-DASH

Navn: født: Dato:

	Ingen vanskelig-heter	Lette vanskelig-heter	Middels vanskelig-heter	Svære vanskelig-heter	Umulig å gjøre
1. Åpne et nytt syltetøyglass	☐	☐	☐	☐	☐
2. Utføre tungt husarbeide (f.eks. vaske gulv eller vegger)	☐	☐	☐	☐	☐
3 Bære dokumentmappe eller handlebose	☐	☐	☐	☐	☐
4. Vaske ryggen	☐	☐	☐	☐	☐
5. Skjære opp mat med kniv	☐	☐	☐	☐	☐
6. Fritidsaktiviteter som krever en viss kraft eller styrke i arm, skulder eller hånd (f.eks spille golf, bruke hammer, spille tennis)	☐	☐	☐	☐	☐

7. I hvilken grad har dine arm   , skulder eller håndproblemer hemmet din vanlige omgang med slektninger, venner, naboer eller andre **den siste uken? (**Sett ett kryss.)

☐ Ikke hemmet i det hele tatt   ☐ Litt   ☐ Moderat   ☐ Ganske mye   ☐ Ekstremt

8. Var du begrenset på grunn av dine arm   , skulder eller håndproblemer i ditt arbeide eller andre vanlige daglige aktiviteter i løpet av **den siste uken?**

☐ Ikke begrenset i det hele tatt   ☐ Litt   ☐ Moderat begrenset   ☐ Svært begrenset   ☐ Umulig

Angi alvorlighetsgraden av de følgende symptomene i **den siste uken**

	Ingen	Lett	Moderat	Sterk	Ekstrem
9. Smerte i arm, skulder eller hånd	☐	☐	☐	☐	☐
10. Prikking ("mauring", "sovnet") arm, skulder eller hånd	☐	☐	☐	☐	☐

11. Hvor mye vansker har du hatt **den siste uken** med å sove på grunn av smerte i arm, skulder eller hånd?

☐Ingen vansker ☐ Litt vansker ☐Moderate vansker ☐ Betydelige vansker ☐Har ikke fått sove

De følgende spørsmålene dreier seg om hvor mye dine arm-, skulder- eller håndproblemer påvirker din evne til å arbeide (inklusiv husarbeid om dette er din hovedbeskjeftigelse).

Arbeider du?	Ja ☐	Nei ☐

Dersom svaret er nei, kan du hoppe over de fire spørmålene

Hva er ditt yrke/arbeid (Hva gjør du)?

Kryss av for den påstanden som best beskriver dine fysiske prestasjoner **den siste uken.** Hadde du noen vanskeligheter med å…:

	Ingen	Litt	Moderate	Store	Ikke mulig
1. …bruke din vanlige teknikk i ditt arbeide?	☐	☐	☐	☐	☐
2. …utføre ditt vanlige arbeide pga smerte i arm, skulder eller hånd?	☐	☐	☐	☐	☐
3. …utføre ditt arbeid så bra som du skulle ønske?	☐	☐	☐	☐	☐
4. …utføre arbeidet på den tid du vanligvis bruker?	☐	☐	☐	☐	☐

De følgende spørsmålene dreier seg om hvor mye dine arm-, skulder- eller håndproblemer har påvirket dine evner til å spille ditt musikkinstrument og/eller drive idrett.

Spiller du noe instrument eller driver noen idrett?	Ja ☐	Nei ☐

Dersom svaret er nei, kan du hoppe over resten av spørsmålene

Om du spiller mer enn ett musikkinstrument eller driver mer enn en idrett, skal du svare med hensyn til den aktiviteten som er viktigst for deg.

Hvilket instrument eller idrett er viktigst for deg: _____

Kryss av for påstanden som best beskriver dine fysiske prestasjoner **den siste uken**. Hadde du noen vanskeligheter med å…:

	Ingen	Litt	Moderate	Store	Ikke mulig
1. …bruke din vanlige teknikk for å spille instrument/drive idrett?	☐	☐	☐	☐	☐
2. …spille instrument/drive idrett pga smerte i arm, skulder eller hånd?	☐	☐	☐	☐	☐
3. …spille instrument/drive idrett så bra som du skulle ønske?	☐	☐	☐	☐	☐
4. …bruke like mye tid som vanlig på å spille instrument/drive idrett?	☐	☐	☐	☐	☐

EQ-5D

(NORWEGIAN EDITION)

EQ - 5D

Spørreskjema om helse

Norsk version
(Norwegian version)

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette et kryss i en av rutene utenfor hver av gruppene nedenfor.

Gange

Jeg har ingen problemer med å gå omkring. ☐

Jeg har litt problemer med å gå omkring. ☐

Jeg er sengeliggende. ☐

Personlig stell

Jeg har ingen problemer med personlig stell. ☐

Jeg har litt problemer med å vaske meg eller kle meg. ☐

Jeg er ute av stand til å vaske meg eller kle meg. ☐

Vanlige gjøremål *(f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter).*

Jeg har ingen problemer med å utføre mine vanlige gjøremål ☐

Jeg har litt problemer med å utføre mine vanlige gjøremål. ☐

Jeg er ute av stand til å utføre mine vanlige gjøremål. ☐

Smerte/ubehag

Jeg har verken smerte eller ubehag. ☐

Jeg har moderat smerte eller ubehag. ☐

Jeg har sterk smerte eller ubehag. ☐

Angst/depresjon

Jeg er verken engstelig eller deprimert. ☐

Jeg er noe engstelig eller deprimert. ☐

Jeg er svært engstelig eller deprimert. ☐

For å hjelpe folk til å si hvor god eller dårlig en helsetilstand er, har vi laget en skala (omtrent som et termometer) hvor den beste tilstanden du kan tenke deg er merket 100 og den verste tilstanden du kan tenke deg er merket 0.

Vi vil gjerne at du viser på denne skalaen hvor god eller dårlig helsetilstanden din er i dag, etter din oppfatning. Vær vennlig å gjøre dette ved å trekke en linje fra boksen nedenfor til det punktet på skalaen som viser hvor god eller dårlig din helsetilstand er i dag.

**Din egen
helsetilstand
i dag**

Best tenkelige
helsetilstand

100

900

800

700

600

500

400

300

200

100

0

Verst tenkelige
helsetilstand

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II

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III

IV

Conservative treatment without fracture reduction does not give worse clinical outcome than bouquet pinning of 5th metacarpal neck fractures. A multicenter, noninferiority, randomized, controlled trial of 85 patients with one year follow-up.

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ABSTRACT

Background and purpose

Even though current literature gives few guidelines regarding indication for operative treatment of 5th metacarpal neck fractures, many hand fracture centers chose operative treatment when the volar angulation exceed 30°. The objective was to determine whether conservative treatment was noninferior to bouquet pinning in a randomized, controlled trial.

Patients and Methods

Noninferiority would be declared if the median Quick-DASH one year after conservative treatment was no worse than after operative treatment with the margin of eight points. Secondary outcomes were: pain, satisfaction, range of motion, grip strength, quality of life (EQ-5D-3L™), complications, and sick leave. Eighty-five patients above 18 years with isolated, extra-articular 5th metacarpal neck fractures with ≥30° volar angulation without rotational deformities or unacceptable lateral displacement were included in three hospitals. Patients were randomized to either conservative treatment without any attempt of reducing the fracture (n=43), or closed reduction and bouquet pinning (n=42). There was no blinding for the treatment.

Results

Forty-three patients received conservative and 38 received operative treatment, with no crossovers. Four patients were lost to final follow-up. At

one year, Quick-DASH was median 0 (0-25) points in the conservative group (n=40) and median 0 (0-41) points in the operative group (n=37) (p=0.54), establishing noninferiority of conservative treatment. The only detectable differences between the groups regarding the secondary outcomes at one-year follow-up were longer sick leave and more complications in the operative group.

<u>Interpretation</u>

We recommend cast treatment of displaced 5th metacarpal fractures for one week followed by early, active mobilization.

INTRODUCTION

Fifth metacarpal neck fracture is the most common fracture of the hand (Abdon et al. 1984, Frazier et al. 1978, Gudmundsen and Borgen 2009, Hove 1993, Hunter and Cowen 1970, Packer and Shaheen 1993, Roberts 1938, Stanton et al. 2007, van Onselen et al. 2003), accounting for approximately 10 % of all hand fractures (Hove 1993). It is often related to aggressive, intentional punching (Anakwe et al. 2011, Court-Brown et al. 2010, Greer 2008, Greer and Williams 1999, Gudmundsen and Borgen 2009, Sletten et al. 2012) Due to intrinsic muscle pull, the metacarpal head angulates volarly. Operative treatment has never been demonstrated to be superior to conservative treatment in comparative trials (McKerrell et al. 1987, Strub et al. 2010, Westbrook et al. 2008). Nevertheless, many hand fracture centers (including our own department prior to this study) regard this as the reference treatment when the fracture angulation exceeds 30°. This may be based on cadaveric studies which have indicated that 30° is the maximum mal-union

where normal hand function can be maintained (Ali et al. 1999, Birndorf et al. 1997). To keep the reduction of the distal fragment, bouquet pinning has been recommended in studies comparing different operative regimes (Schadel-Hopfner et al. 2007, Sletten et al. 2012, Winter et al. 2007). However, many different conservative regimes have been reported to restore excellent hand function (Arafa et al. 1986, Braakman et al. 1998, Breddam and Hansen 1995, Poolman et al. 2005, Roberts 1938, Statius Muller et al. 2003, Viegas et al. 1987).

The aim of this noninferiority, randomized, controlled trial (RCT) was to establish that the outcome of conservative treatment was not worse (not below a pre-stated noninferiority margin Δ; alternative hypothesis) than bouquet pinning (Piaggio et al. 2012). In case of noninferiority, conservative treatment has the advantage of greater availability and ease of administration, no invasiveness, reduced cost and probably fewer complications. Hence, the null hypothesis (due to the noninferiority design) was that conservative treatment was inferior to operative treatment, measured by the patient reported outcome (PRO) Quick-DASH Outcome Measure (Quick-DASH) one year after treatment (Beaton et al. 2005, Calvert et al. 2013, Kennedy et al. 2011).

PATIENTS AND METHODS

Trial design and participants

This was a multicenter RCT with equal-sized parallel groups conducted in Norway (three sites). All patients above 18 years referred with 5th metacarpal neck fractures were consecutively registered and assessed for eligibility

(Figure 1). Radiographs of both hands were standardized by the use of plexi glass devices for 30° oblique pronated and lateral view in addition to the standard reversed frontal projection (anteroposterior (AP) view) (Frere et al. 1982, Sletten et al. 2012). Volar angulation was measured by methods Medullary Canal-lateral (MC-90) and Medullary Canal-oblique (MC-30), and shortening by methods Shortening Absolute value (SH-Abs) and Shortening Stipulated (SH-Stip) (Sletten et al. 2012). As the OTA fracture classification does not define metacarpal neck fractures (Marsh et al. 2007), these were identified by the *INS method* (Figure 2).

Exclusion criteria for enrolment in the study were: <30° volar angulation (measured by MC-90 by mid-medullary lines in the lateral view), clinically detectable rotational deformity of the 5th finger, extensor lag/pseudoclawing (Day and Stern 2010), lateral displacement of the metacarpal head more than half the bone width, fracture extension on to the articular surface, concomitant injury (e.g. multiple fractures), fractures more than 14 days old, particular low-compliant participants (defined as: not speaking Norwegian or English, habitat too far away from the hospitals, drug abuse, or dementia). There was no upper limit of volar angulation in the fracture for inclusion of a participant in the study. Hospitals A and B were Norway's two largest orthopedic departments treating trauma, hospital A with the country's largest hand trauma surgical unit. Hospital C was a small hospital in the proximity of the two large hospitals. Patients were recruited by resident doctors in the emergency departments, and included in collaboration with consultant orthopedic surgeons who were familiar with the criteria and the interventions.

Interventions

In the conservative group, no attempt was made to reduce the fractures as this is regarded as futile when the reduced position is not secured by internal fixation (Braakman 1997, Braakman et al. 1998, Holst-Nielsen 1976, Konradsen et al. 1990, Kuokkanen et al. 1999, Lowdon 1986, McKerrell et al. 1987, Theeuwen et al. 1991). After an initial one-week plaster-of-Paris (POP) applied for pain relief (Hansen and Hansen 1998, Harding et al. 2001), a buddy-strap was applied over the proximal phalanges of the little and ring finger, and the patient was encouraged to start active exercises (Bansal and Craigen 2007, Braakman et al. 1998, Kuokkanen et al. 1999, Statius Muller et al. 2003). The operatively treated fractures underwent closed reduction and internal fixation by antegrade, intramedullary bouquet pinning (Foucher 1995). The pre-bent wires were cut below skin surface to minimize the risk for infection (Hargreaves et al. 2004, Sletten et al. 2012). The postoperative regime was identical to the conservative regime. Operations were standardized by a protocol.

Outcomes and sample size

The PRO Quick-DASH was chosen as the primary endpoint, and the patients filled in the formulas themselves. Secondary outcomes were pain, satisfaction, range of motion (ROM), grip strength, and quality of life (EQ-5D-3L™)(EuroQolGroup 1990, Rabin et al. 2011), complications and sick leave. ROM in both 5th fingers was measured by a goniometer, and grip strength of both hands was given as the best of three attempts with Jamar® dynamometer. These measurements were performed by two hand therapists

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at three months and one year follow up in hospital A for patients included in hospitals A and C, and two orthopedic surgeons in hospital B. A radiologist with special competence in musculoskeletal radiology read all the x-ray images at inclusion (pre- and postoperatively), at six weeks and one year follow-up.

Quick-DASH ranges 0-100, with the worst possible outcome as 100. According to the designers of the Quick-DASH, the minimal detectable change at the 95 % confidence level (MDC-95) is between 7.9-17.2 points (Kennedy et al. 2011). Hence, we chose the non-inferiority limit Δ of eight points. Long-term mean Quick-DASH was 6 with a standard deviation (SD) 8 in a previous cohort of operated patients (Sletten et al. 2012). As we did not have a SD for patients treated conservatively, we estimated the SD in the present RCT as 10. With a significance level (alpha) of 5 % (one-sided confidence interval of 95 %), and a power (1-beta) of 95 %, the sample size was calculated to 34 patients in each group.

Randomization, allocation concealment and blinding

Sealed envelopes containing written information about treatment arm were mixed by outsiders and generated the allocation sequence, unknown for all care providers. The envelopes were not opened until the patient had signed a written consent for participation after oral and written information.

Neither the participants, nor the care providers (the surgeons, the radiologist) or the data collectors (the surgeons and the hand therapists) were blinded for the treatment, neither was the first author when the outcomes were adjudicated and the data was analyzed.

STATISTICS

As the primary endpoint Quick-DASH was left skewed and not normally distributed, non-parametric statistical tests were used. Therefore, continuous data are consistently presented as medians with total ranges in parentheses. Comparisons between groups were analyzed by the Chi-Square test and Fischer's exact test for categorical outcomes, and the Mann-Whitney test for continuous outcomes. Correlations were investigated by linear regression/ANOVA. Statistical significance was set at alpha ≤ 0.05. Subgroup analyses (e.g. groups of patients with highly angulated fractures) were not performed because of the risk for spurious findings, and the under-powering of data.

ETHICS

The regional ethical committee of South-Eastern Norway Regional Health Authority approved the research protocol (reference 2010/710a, dated 12.04.2010), and the study was conducted according to the Helsinki declaration. The study was registered at clinicaltrials.com (NCT01139528) before inclusion of patients started.

RESULTS

Totally, 43 patients were allocated to conservative treatment and 42 patients to operative treatment (Figure 1) (Boutron et al. 2008, Boutron et al. 2008, Moher et al. 2010, Schulz et al. 2010). As there were no crossover participants, discontinued interventions or other deviations from the protocol

except four patients lost to final follow-up, all analyses were by original assigned groups (per protocol analyses equaled intention to treat analyses). The trial was ended in hospitals B and C before in hospital A due to difficulties in recruiting participants. In hospital A, the recruitment of participants was stopped after two and a half years when the total sample size was reached.

Reduction of the fractures in the operative group was secured by median 3 (2-4) wires under regional plexus anesthesia (n=27) or general anesthesia (n=11), median 5 (1-15) days after the injury (Figure 3). Operating time (skin incision-skin closure) was median 30 (17-65) minutes, while anesthesia time (patient in OR) was median 60 (45-110) minutes. A consultant orthopedic surgeon operated on one patient Experienced residents with direct attending physician supervision operated on the other 37, and also removed all wires six weeks postoperatively under local anesthesia.

Besides a higher rate of blue-collar workers in the operative group, no baseline differences were found at inclusion (Table 1). The groups were comparable regarding volar angulation and shortening in the fractures at inclusion (Table 2). In the operative group, angulation was reduced with median 22° (8-57°) measured by MC-90; closely back to the normal volar angulation of 15° (Abdon et al. 1984, Sletten et al. 2012). All fractures but one were healed at six weeks, and all at one year. At one year, there was one patient in the operative group with minimal arthritis in the metacarpo-phalangeal joint (MCPJ), unchanged from preoperative radiographs. Forty-four patients had ≥40° volar angulation measured by MC-90 at inclusion, of whom 40 were interviewed at one year follow-up. Seven patients had 50-60°

volar angulations at inclusion, four of these were treated conservatively of whom one was lost to follow-up.

Primary outcome

Quick-DASH was median zero in both groups at one-year follow-up, also for the Work Module and the Sports/Performing Arts Module (Table 3). There were no statistical significant, clinical relevant differences in median Quick-DASH or EQ-5D-3L™ scores at any time point, but a trend towards clinical relevant worse Quick-DASH Work in the operative group at six weeks (median 25 versus median 6 points, p=0.07). Totally, 12 patients had Quick-DASH higher than 10 points, and four patients higher than 20 points at one year follow-up. Linear regression could not demonstrate any correlation (R=0.02, p=0.88) between final volar angulation in the healed fracture and Quick-DASH at one year (Figure 4).

Secondary, subjective outcomes

The patients in both groups reported pain as median zero on visual analogue scale (VAS) at one year (0-100, 0 best). There were no clinical relevant differences between the two groups regarding pain at any time point (Table 4). The median VAS satisfaction (0-100, 100 best) was very high in both groups, at one year median 97 (19-100) in the conservative group and median 100 (25-100) in the operative group (Table 4). At this final follow-up, only 11 patients scored less than 80 on VAS satisfaction and six patients less than 70. No significant correlation (R=0.18, p=0.13) between final VAS satisfaction and final volar angulation in healed fractures could be found by linear regression.

When asked five additional questions about their hand function (questionnaire created by the authors, no data about their reliability or validity), the patients treated conservatively were less content with their hand function at three months, in particular with the ROM in the affected hand (Table 5). At one year there were no differences between the two groups' answers to the questions regarding function, but a trend towards worse cosmetic outcome in the conservative group. The 8/77 patients who were discontent with the cosmetic outcome had median 43° (24-53°) mal-united fractures measured by MC-90 at one year.

Secondary, objective outcomes

At one year, both groups had lost median five degrees of active flexion in the MCPJ compared to the uninjured side. The loss of active extension was even less. Both groups had lost median less than 10 degrees of total active motion (TAM) in the 5th finger, all within the range of possible measurement bias. Neither could there be found any differences in passive ROM in the MCPJ or total passive motion (TPM) in the 5th finger between the two groups (Table 6). Grip strength was median 49 kg in both groups at one year, yielding median 100 % (conservative group) and median 103 % (operative group) of the opposite hand (Table 6). There was not found any correlation by linear regression between loss of total active motion (R=0.10, p=0.44) or grip strength % (R=0.12, p=0.32) and final volar angulation in the healed fractures after one year. Only seven patients had a TAM <240° (not "excellent") (Page and Stern 1998) at one year, and only six patients who had injured their dominant hand had a grip strength of less than 90 % of the opposite hand.

Secondary outcomes; complications and sick-leave

The total complication rate was higher in the operative group (p=0.02, Table 7). Two patients in this group developed chronic regional pain syndrome (CRPS), both severely disabled and not fully recovered at one year. These were the only patients who required hand therapy during the study period. The rotational deformities that developed during treatment (noted by the hand therapists at follow-up without quantification) were all mild, with no patients complaining of functional deficit requiring surgical correction.

The occupied patients in the operative group (n=35) were on sick leave median 42 (0-406) days, compared to median 8 (0-65) days in the conservative group (n=35, p<0.001). Blue-collar workers in the operative group (n=17) were on sick-leave median 49 (1-84) days, compared to median 13 (0-65) days in the conservative group (n=7).

DISCUSSION

Conservatively and operatively treated patients had equivalent outcomes measured by Quick-DASH. The null hypothesis could thus be rejected, confirming noninferiority of conservative treatment according to the alternative hypothesis.

The overall outcome was very good, confirming that this fracture is a minor injury to the hand in most patients, yielding complete restitution without risk for delayed union or early arthritis. The trend towards better hand function satisfaction in the operative group at three months may have been related to worse cosmesis and a transient subjective reduced ROM in the conservative

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group. This gain must be weighted against the risk of more numerous and serious complications and a longer period of disability, as we could not demonstrate any objective differences in ROM or grip strength between the two groups. The risk for CRPS is in general larger in operated than in conservatively treated patients, but the finding of more patients in the operative group who had gained a rotational deformity during treatment was not anticipated. Also interesting was the finding of lesser serious complications as sensitivity changes and cold intolerance in the conservative group, demonstrating that this is not only associated with operative treatment as previously assumed (Sletten et al. 2012).

In previous studies lack of functional hand scores as primary endpoints was noted as serious methodological weaknesses in a Cochrane meta-analysis on conservative treatment of 5th metacarpal neck fractures (Poolman et al. 2005). Hence, Quick-DASH was chosen in our RCT, as it is the most widely used PRO for upper extremity function. However, a limitation was the floor effect of Quick-DASH (Kennedy et al. 2011, Sletten et al. 2012). The median Quick-DASH was zero points in both allocation groups at the final follow-up, while normative data collected in a US population survey found DASH norms as median four points (Kennedy et al. 2011). The sample size estimate was the minimum number of individuals required to satisfy the research question. There was a chance that it might have been too small to provide meaningful results given that Quick-DASH could be relatively insensitive to subtle differences in outcome. However, as the research protocol was extensive with multiple subjective and objective secondary endpoints where no clinical detectable differences between the two groups

could be demonstrated, we believe that the research question has been subject to meticulous investigation.

Other limitations of our study were mainly related to inclusion bias. The 57 patients (out of totally 171 includible subjects) who declined trial participation (Figure 2) had baseline preference for the conservative treatment, and were thus all treated conservatively as well as the four participants who withdraw from the study when allocated to operative treatment. On the contrary, we can assume that the 81 participants who received the allocated treatment were indifferent or positive-minded to operative treatment, as they were willing to enter the trial. This inclusion bias favoring operative treatment can be added to the general operative placebo effect when the results are interpreted.

The baseline difference of more blue-collar workers in the operative group was a result of chance, and was likely to yield a worse Quick-DASH Work and a longer period of sick leave in this group. This bias was not recognized until the statistical analyses, when the trial was ended. To avoid it, we would have had to re-open the trial for additional inclusions to equal the groups. This was not an option after three and a half years of recruitments and follow-ups. However, Quick-DASH Work and sick leave duration were not the basis for the conclusion in the study, only supporting issues.

The expertise of the care providers in the three centers was to some extent unequal, as hospital A treated the patients in a specialized hand fracture unit.

Most patients with 5th metacarpal neck fractures are completely recovered at one year, and a prolonged follow-up period was therefore considered unnecessary.

Even though recruitment of participants lasted two and a half years and there was no upper limit for volar angulation in the fracture as an exclusion criterion, few patients had large volar angulation at inclusion (maximum angulation 60°). We chose to study angulation over 30°, as this was the previous indication for surgery in hospital A, and the cut-off value for tolerable angulation suggested from cadaveric studies. We chose to have no upper limit, as the most angulated fractures are the subjects of debate. One can argue that the paper would have been stronger if we had included only fractures angulated more than 60-70°, significant metacarpal head displacement, or extensor lag (pseudoclawing). As demonstrated in Figure 1, only two patients were excluded due to ad latus displacement more than half the bone width, none were excluded due to pseudoclawing, and there were no eligible participants during the time period with angulation over 60° measured mid-medullary in the lateral view. Hence, these most challenging fractures seem to be rarer than authors previously have estimated. Anyhow, this important limitation of the study demand caution when applying the treatment recommendation for the most severely angulated fractures.

The paper would also have been stronger if the data collectors and the outcome adjudicator had been blinded for the treatment options. This was not performed for practical reasons, as masking the hand with a bandage would have required the assistance of a research fellow whenever the participants came for follow-up appointments (which could not be limited to special dates

or time points to achieve the high follow-up rate). In addition, the hand therapist would not have had access to the patients' medical journals, and there would always have been the danger that the patients gave away their assigned treatment options to the hand therapists by mistake.

The strength of our study was the true comparison of restoration of anatomy versus the natural history of mal-united fracture healing, as there was not performed any attempt of reducing the fractures in the conservative group and the treatment regimes were elsewhere identical. The first author did not implement any of the treatment arms, examine any of the patients, nor interpret any of the radiographs at follow-up to avoid researcher bias. The follow-up rate of 95 % at one year was very high for this particular patient group (Sletten et al. 2012, Westbrook et al. 2008) even though only seven low-compliant patients were excluded due to drug dependence or dementia, leaving many traditionally low-compliant participants that had fractured their 5th metacarpal neck after an axial blow to a clenched fist (n=56) under the influence of alcohol (n=41).

The generalizability of the trial findings is expected to be high as resident doctors operated the patients in all three hospitals, although in a specialized hand fracture unit in hospital A. The inclusion bias influenced the external validity, but in our opinion strengthened the trial's conclusion, as the patients who refused to be included preferred the conservative regime.

We have not found any previous RCTs comparing conservative and operative treatment of 5th metacarpal neck fractures, only comparing different conservative or operative regimes. However, our results are in coherence with three not randomized, comparative studies of operative and conservative

treatment, two with a retrospective (McKerrell et al. 1987, Westbrook et al. 2008), and one with a prospective design (Strub et al. 2010). McKerrell and co-workers' (McKerrell et al. 1987) main finding was that residual angulation with depression of the knuckle was more common and marked in the conservative group, of little bother for most of the patients. They recommended operative treatment to be reserved for "patients demanding perfect cosmesis, and willingness to accept a longer period of disability", in addition to patients with open fractures, rotational or lateral displacement. Westbrook and co-workers (Westbrook et al. 2008) did not find any differences in grip strength, DASH Outcome measure or aesthetic scores, and concluded that fractures without rotational deformities or complete fracture step-off up to 50° volar angulation could be managed conservatively without reduction. Strub and co-workers (Strub et al. 2010) found more satisfied patients in the operative group, but no differences regarding pain, ROM, or grip strength. They recommended operative treatment for patients who desire to avoid a cosmetic deformity, or for manual workers who might feel a disturbing displaced metacarpal head in the palm during heavy gripping. All three previous studies included few patients with severely displaced fractures and can neither give adequate information about the outcome after mal-united fractures in this position.

We conclude there is no medical indication for operative treatment of isolated, extra-articular, aligned 5th metacarpal neck fractures at least up to 60° volar angulation. This implies the waste majority of these fractures. We recommend a conservative regime that focus on early mobilization, where the first week's POP is for analgetic purposes and not for maintaining fracture

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reduction. The latter demands casting until healing, which postpones

mobilization and is previously reported as futile. Routine follow-up of these

patients probably have little consequence (Bansal and Craigen 2007), as long

as they are informed to return for an early follow-up if there are any problems

including initially un-noted rotational deformities. Conservative treatment has

the advantage of fewer complications, and reduced medial expenses.

Concerning the rare cases of fractures angulated more than 60 degrees in the

lateral view, severe lateral displacement or clinical extensor

lag/pseudoclawing at presentation, there is not adequate information in our

study or in the previous literature to conclude.

Table 1: Baseline characteristics

	Conservative	n	Operative	n
Female (n)	4	43	3	42
Age (years)	29 (18-67)	43	25 (18-68)	42
Time from injury to randomization (days)	4 (1-13)	43	4 (1-13)	41
Injured dominant hand (n)	31	40	31	37
Axial blow as injury mechanism (n)	31	43	25	41
Sports mechanism (n)	3	43	4	41
Alcohol intake (n)	17	43	24	41
Plays music instrument (n)	4	42	10	41
Sportsman (n)	27	43	24	41
Blue-collar worker (n)	7	43	18	41
Smoker (n)	17	42	15	41

Continuous data are given as median and total range.

Table 2: Radiological outcome

	Conservative	n*	Operative	n*	p
MC-90 inclusion (°)	41 (30-58)	42	40 (30-59)	41	
MC-30 inclusion (°)	50 (32-71)	40	51 (32-75)	42	
SH-Abs inclusion (mm)	2 (0-5)	39	2 (-3-6)	32	
SH-Stip inclusion (mm)	4 (0-9)	25	3 (0-7)	25	
MC-90 postoperative (°)	-	-	17 (-9-31)	36	-
MC-30 postoperative (°)	-	-	22 (-19-42)	36	-
SH-Abs postoperative (mm)	-	-	-1(-5-4)	30	-
SH-Stip postoperative (mm)	-	-	0 (-6-6)	28	-
MC-90 6 weeks (°)	37 (25-61)	36	16 (-11-46)	38	<0.001
MC-30 6 weeks (°)	49 (38-68)	36	23 (-16-54)	37	<0.001
SH-Abs 6 weeks (mm)	4 (0-8)	33	0 (-6-5)	31	<0.001
SH-Stip 6 weeks (mm)	5 (2-8)	17	2 (-3-5)	22	<0.001
MC-90 1 year (°)	36 (24-57)	35	16 (-10-36)	34	<0.001
MC-30 1 year (°)	48 (34-69)	35	23 (-15-44)	36	<0.001
SH-Abs 1 year (mm)	5 (1-8)	33	1 (-2-6)	29	<0.001
SH-Stip 1 year (mm)	4 (1-9)	17	2 (-3-5)	21	<0.001

Continuous data are given as median and total range.

*Some of the radiographs had to be excluded from the analyses due to unsatisfactory quality, especially regarding the SH-Stip method for measuring shortening as the 3rd metacarpal head had to be included in the reversed

frontal projection to draw a line tangentially towards the 4th metacarpal head. The patients who were lost to follow up or interviewed by phone did not have radiographs captured at these time points.

n gives the number of radiographs that were good enough for interpretation by the radiologist in both groups at all time points.

MC-90: Volar angulation in the fracture measured by mid-medullary lines in the lateral view

MC-30: Volar angulation in the fracture measured by mid-medullary lines in the 30° oblique pronated view

SH-Abs: Shortening of the fractured metacarpal estimated relative to the ipsilateral metacarpal in reversed frontal view

SH-Stip: Shortening of the fractured metacarpal estimated by neighboring 3rd and 4th metacarpal in reversed frontal view (tangential line)

Table 3: Quick-DASH and EQ-5D-3L™

	Time	Conservative	n	Operative	n	p
Quick-DASH (0-100, 0 best)	Baseline	0 (0-66)	43	0 (0-43)	38	
	6 weeks	11 (0-64)	35	16 (0-68)	36	0.16
	3 months	5 (0-39)	33	5 (0-48)	38	0.52
	1 year	0 (0-25)	40	0 (0-41)	37	0.54
Quick-DASH Work Module (0-100, 0 best)	Baseline	0 (0-69)	33	0 (0-38)	34	
	6 weeks	6 (0-100)	26	25 (0-88)	22	0.07
	3 months	0 (0-81)	29	0 (0-38)	33	0.69
	1 year	0 (0-38)	36	0 (0-19)	35	0.67
Quick-DASH Sports/Performing Arts Module (0-100, 0 best)	Baseline	0 (0-75)	23	0 (0-13)	23	
	6 weeks	19 (0-100)	21	25 (0-100)	19	0.98
	3 months	7 (0-81)	18	0 (0-100)	21	0.13
	1 year	0 (0-63)	27	0 (0-63)	23	0.04
EQ-5D index (-0.594-1.000, 1.000 best)	Baseline	1.000 (0.255-1.000)	43	1.000 (0.516-1.000)	38	
	6 weeks	0.796 (0.255-1.000)	35	0.760 (-0.181-1.000)	37	0.33
	3 months	1.000 (0.093-1.000)	33	1.000 (0.124-1.000)	37	0.46
	1 year	1.000 (0.291-1.000)	40	1.000 (0.587-1.000)	37	0.55
EQ-VAS (0-100, 100 best)	Baseline	85 (50-100)	42	90 (35-100)	39	
	6 weeks	85 (20-100)	35	80 (20-100)	37	0.50
	3 months	90 (34-100)	33	85 (10-100)	38	0.91
	1 year	95 (25-100)	40	90 (45-100)	37	0.49

Continuous data are given as median and total range.

Baseline values of Quick-DASH Outcome Measure Score and EQ-5D-3L™

represented the patients' recall function one week before the injury.

Quick-DASH: Quick- Disability of arm, shoulder and hand Outcome Measure

EQ-5D-3L: EuroQol 5 Dimensions 3 Levels; consists of EQ-5D index and EQ-

VAS

EQ-5D index: EuroQol 5 Dimensions, descriptive system (mobility, self-care,

usual activities, pain/discomfort, anxiety/depression; index calculated from

three levels in each dimension)

EQ-VAS: EuroQol Visual Analogue Scale (self-related health on a vertical

scale where the endpoints are labeled 'best imaginable health state' and

'worst imaginable health state')

Table 4: Pain and satisfaction

	Time	Conservative	n	Operative	n	p
VAS pain at rest (0-100, 0 best)	1 week	5 (0-75)	38	9 (0-65)	36	0.29
	6 weeks	0 (0-40)	36	3 (0-80)	36	0.01
	3 months	0 (0-40)	34	0 (0-45)	38	0.07
	1 year	0 (0-35)	40	0 (0-70)	37	0.43
VAS pain in activity (0-100, 0 best)	1 week	31 (0-80)	38	38 (2-90)	36	0.23
	6 weeks	15 (0-75)	36	27 (0-92)	36	0.08
	3 months	6 (0-80)	34	0 (0-80)	38	0.28
	1 year	0 (0-69)	40	0 (0-80)	37	0.75
Painkiller use (n)	1 week	6	38	12	36	0.11
	6 weeks	4	36	4	37	1.00
	3 months	2	34	3	38	1.00
	1 year	2	40	1	37	1.00
VAS satisfaction (0-100, 100 best)	6 weeks	80 (10-100)	36	85 (5-100)	36	0.35
	3 months	89 (5-100)	34	95 (50-100)	38	0.09
	1 year	97 (19-100)	40	100 (25-100)	37	0.17

Continuous data are given as median and total range.

VAS: Visual analogue scale

Table 5: Subjective hand function

	Time	Conservative	Operative	p
The hand does not function as before the injury	3 months	20/34	13/38	0.06
	1 year	11/40	6/37	0.28
The range of motion in the hand is not as good as before the injury	3 months	21/34	10/37	0.004
	1 year	9/39	6/36	0.57
The hand is not as strong as before the injury	3 months	18/34	18/38	0.81
	1 year	7/40	4/37	0.52
There are activities I can no longer perform due to the injury	3 months	6/34	10/38	0.41
	1 year	2/40	3/37	0.67
I am not content with the cosmetic outcome	3 months	8/34	3/38	0.10
	1 year	7/40	1/36	0.06

Table 6: Objective hand function

	Time	Conservative	n*	Operative	n*	p
Active flexion	3 months	72 (45-94)	34	70 (50-100)	38	0.98
MCPJ (°)	1 year	75 (35-100)	35	75 (50-100)	36	0.99
Loss of active flexion	3 months	4 (-5-30)	34	3 (-10-26)	38	0.39
MCPJ (°)	1 year	5 (-3-45)	33	5 (-10-25)	35	0.14
Active extension	3 months	19 (0-30)	34	20 (0-45)	38	0.04
MCPJ (°)	1 year	20 (0-40)	35	25 (-30-40)	36	0.61
Loss of active extension	3 months	6 (-15-34)	34	5 (-10-30)	38	0.20
MCPJ (°)	1 year	4 (-15-30)	33	2 (-10-40)	35	0.85
Passive flexion	3 months	95 (60-115)	34	103 (67-115)	38	0.10
MCPJ (°)	1 year	105 (70-115)	35	105 (70-115)	36	0.47
Loss of passive flexion	3 months	6 (0-38)	34	7 (0-43)	38	0.78
MCPJ (°)	1 year	5 (-5-30)	33	5 (0-18)	35	0.55
Passive extension	3 months	31 (0-55)	34	31 (10-65)	38	0.28
MCPJ (°)	1 year	40 (20-70)	35	40 (0-60)	36	0.69
Loss of passive extension	3 months	10 (-25-41)	34	10 (-20-60)	38	0.60
MCPJ (°)	1 year	0 (-10-32)	33	10 (-5-40)	35	0.14
TAM	3 months	250 (200-277)	21	257 (142-287)	35	0.18
(°)	1 year	261 (200-286)	29	260 (188-297)	32	0.68
Loss TAM	3 months	8 (-10-68)	21	10 (-69-103)	35	0.78
(°)	1 year	8 (-13-65)	28	7 (-18-70)	31	0.66
TPM	3 months	285 (200-315)	21	299 (170-330)	34	0.05

(°)	1 year	295 (240-335)	29	300 (199-325)	32	0.85
Loss TPM	3 months	15 (0-60)	21	10 (-20-110)	34	0.25
(°)	1 year	6 (-10-40)	28	10 (-1-91)	31	0.22
Grip strength	3 months	46 (22-62)	33	43 (20-70)	38	0.46
(kg)	1 year	49 (29-70)	35	49 (28-64)	36	0.78
Grip strength	3 months	97 (51-113)	33	92 (52-120)	38	0.59
(% of uninjured hand)	1 year	100 (66-159)	34	103 (59-141)	36	0.24

Continuous data are given as median and total range.

*Due to a protocol error, TAM and TPM were not measured for the first 13
patients at three months follow-up and the first two patients at one year follow-
up in hospital A. In hospital B, some additional patients did not get their TAM
and TPM measurements performed.

MCPJ: Metacarpo-phalangeal joint

TAM: Total active motion (in small finger)

TPM: Total passive motion (in small finger)

Loss: compared to uninjured, ipsilateral small finger at same time point. These
values are given in addition to the actual values to demonstrate that patient-
specific differences in active and passive movements of the joints did not
influence the results

Table 7: Complications

	Conservative (n=40)	Operative (n=37)	p
Perioperative complications	-	1	
Mechanical pin complications	-	3	
Operation wound infection	-	2	
Temporary* sensibility change	3	8	0.11
Temporary* cold sensitivity	5	1	0.20
Permanent** sensibility change	3	5	0.47
Permanent** cold sensitivity	1	2	0.61
Final rotational deformity small finger	1	4	0.19
Chronic regional pain syndrome (CRPS)	0	2	0.23
Other complications	2	4	0.42
Combination of complications	3	8	0.11
Total number of patients with any complication(s)	10	19	0.02

* *Temporary*: resolved at one year follow-up

** *Permanent*: present at one year follow-up

Perioperative complication (one patient):

One of three pins protruded through the fracture site in a volar direction,

requiring re-operation seven days later due to the fear of flexor tendon injury,

later complicated by CRPS

Mechanical pin complications (three patients):

a) Pin migration and excessive pain before pin removal

b) Pin migration

c) Time-consuming pin removal (many hours, painful procedure) later complicated by infection and CRPS

Other complications (six patients, two in the conservative group and four in the operative group):

a) Permanent pain dorsally over PIPJ during palpation and flexion (conservative)

b) Re-fracture 5,5 weeks after operation, volar angulated pins 30° (operative)

c) Acute Dupytrens contracture development in volar 4th and 5th ray post-operatively (operative)

d) Excessive pain before pin removal necessitating large amount of painkillers, suspected nerve irritation (operative)

e) Wound under POP (conservative)

f) Wound under POP (operative)

The p-values are certainly sensitive to small changes, as the study was not powered to show differences in complications.
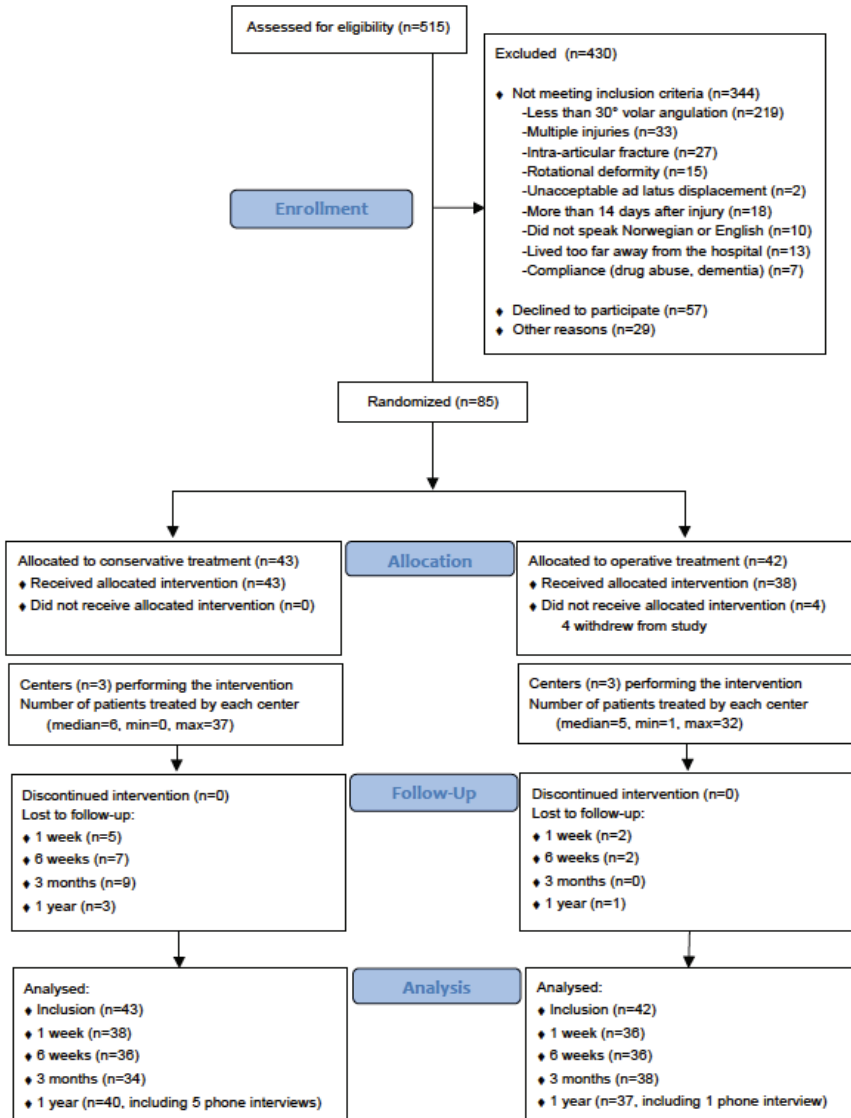
Figure 1

Participant flow: In hospital A, 72 patients of 140 eligible were included from

May 2010 to October 2012 (37 conservative and 35 operative). In hospital B,

12 patients of 20 eligible were included from December 2010 to June 2012

(six conservative and six operative). In hospital C one patient of three eligible was included from November 2010 to June 2012 (operative). The patients came for follow-up appointments at one and six weeks, three months and one year. Out of the total 85 (52 %) included patients, 81 received the allocated treatment as three patients in hospital A and one patient in hospital B withdrew from the study when randomized to operative treatment.

During the first six months in hospital A, the exclusion criteria also included open fractures, fractures with a "certain shaft component" (before the INS method came in use), previous fracture to the actual or ipsilateral metacarpal, injury sequelae to the upper extremities, and fractures older than 10 days. The change was performed before inclusions started in hospitals B and C, to allow for a better recruitment. Fourteen of the 29 exclusions of "other reasons" represent participants excluded in hospital A the first six months; three exclusions due to previous fracture in the same metacarpal, five due to patient presenting more than 10 days after the injury, six due to perception of the fracture as having a "certain shaft component". None were excluded due to open fractures, previous fracture in the opposite 5th metacarpal, or to injury sequelae in the upper extremity.

The additional 15 exclusions for "other reasons" were errors during the last two years of recruitment in all three hospitals, as the fractures were perceived as a shaft fractures (five cases), the fracture angle was misinterpreted as below 30° (three cases), and the patients were not assessed for eligibility of unknown reasons (seven cases).

Figure 2

Identification of Neck versus Shaft Method (INS method) was used for
identification of neck fractures. This definition has been subject to extensive
validity and reliability testing (own, unpublished data). Metacarpal neck
fractures assessed for eligibility was defined as having ≥75 % of the fracture
line distal to the proximal border of the squared distance of the C-line (which
spans the broadest part of the metacarpal head between the tuberosities
where the collateral ligaments insert). Consequently, fractures with >25 % of
the fracture line proximal to the proximal border of the square were defined as
shaft fractures and thus not assessed for eligibility.

　　　　The fracture in Figure 1 had 100 % of the fracture line distal to the
proximal border of the square, and the patient was included in the trial.
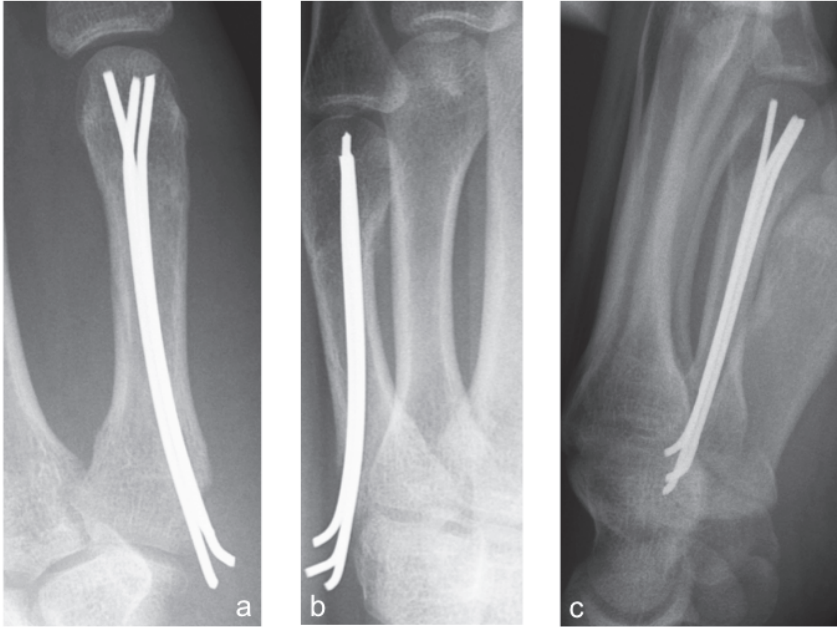
Figure 3

Bouquet pinning of a small finger metacarpal neck fracture in a: reversed

frontal view, b: pronated oblique 30° view, c: lateral view, demonstrated in a

patient at six weeks follow-up before pin removal.

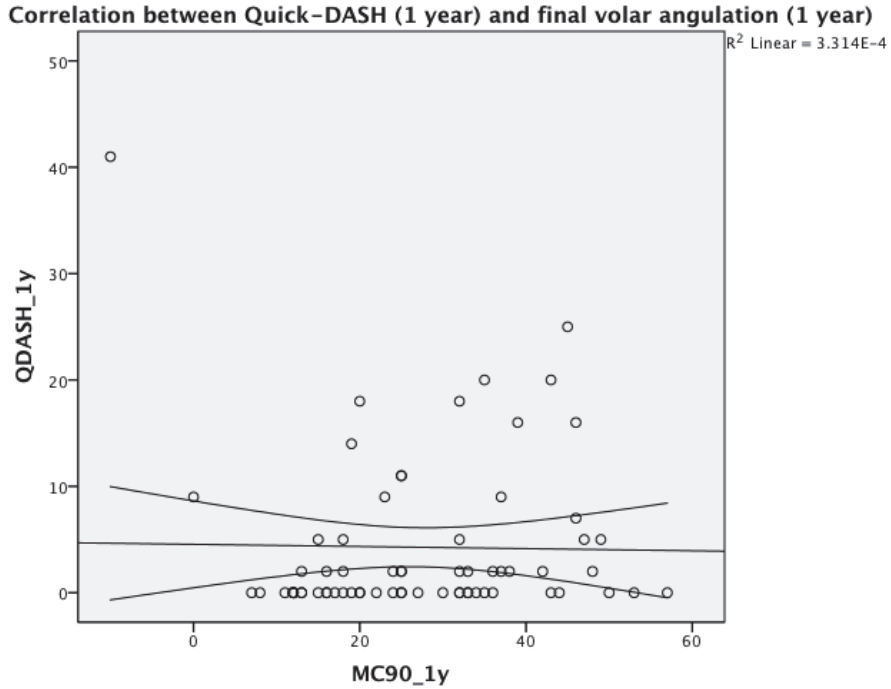Correlation between Quick–DASH (1 year) and final volar angulation (1 year)

Figure 4

Scatterplot where the circles represent all the patients' final Quick-DASH Outcome measure score related to their final volar angulation in the healed (mal-united) fractures at one year. The x-axis represent the volar angulation (in degrees), and the y-axis the Quick-DASH score (0-100 points). The regression line (with the 95 % confidence intervals) is completely flat, hence demonstrating that there was no significant correlation between hand function (as measured by Quick-DASH) and fracture angulation. The median Quick-DASH score was 0 in both allocation groups, because more than half of the patients in both groups had a Quick-DASH score of 0.

QDASH_1y: Quick-DASH Outcome measure at one year follow-up (0-100 points)

MC90_1y: volar angulation (in degrees) at one year follow-up measured by method MC-90 (mid-medullary measurement lines in the lateral view)

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