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## Distal Radius Fractures

## Outcome and New Methods of Surgical Treatment

Marcus Landgren



#### DOCTORAL DISSERTATION

By due permission of the Faculty of Medicine, Lund University, Sweden. To be defended at lecture room F2, Skåne University Hospital, Lund. Date: Friday May 5, 2017 at 1 pm.

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#### Abstract

Stable distal radius fractures are treated non-surgically in a cast. Unstable distal radius fractures are treated with surgery. The majority of patients have good outcome, but up to one fifth are not satisfied. In this thesis the overall aim was to compare newer surgical techniques, evaluate our treatment over a longer time-period, and identify risk factors for poor outcome.

In a previous randomized study of unstable distal radius fractures, better grip strength and pronation-supination were found at one year in patients treated with open reduction and fragment-specific fixation compared to closed reduction and external fixation. In a follow up at five years, both grip strength as well as pronation-supination had normalized in both groups and no clinical or radiographic differences were found.

In a new randomized trial of unstable distal radius fractures, comparing the fragment-specific fixation and the newer volar locking plate, no difference was found in the primary outcome – grip strength at one year. Both the fragment-specific fixation and the volar locking plate achieved good subjective, objective and radiological outcome, with more complications in the fragment-specific group.

In a prospective and consecutive distal radius fracture registry, a retrospective decade-long study analyzed the subjective outcome at one year, using the Disabilities of Arm Shoulder and Hand (DASH) questionnaire. At one year, good outcome was found for both non-surgically and surgically treated patients, but despite a shift of implant over the 10-year period, with volar locking plates replacing the external fixators and fragment-specific fixation, no change was found in subjective outcome.

Finally, patients with major disability at one year, identified in the distal radius fracture registry, were re-evaluated at 2-12 years. Half of the patients improved, but only a small proportion returned to normal scores and the rest improved to a moderate level of disability.

In conclusion, the surgical methods to treat distal radius fractures are good. But, a limited proportion of both non-surgically and surgically treated patients has an inferior outcome. In the future, we need to focus on this subgroup and find better ways to identify causes to inferior outcome and try to prevent these complications before they become irreversible.

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# Distal Radius Fractures

## Outcome and New Methods of Surgical Treatment

Marcus Landgren



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Cover illustrations by my mother Elisabeth Grönvall:

Front – A sketch of a comminuted and intra-articular distal radius fracture.

Back – An aquarelle illustrating pain after a wrist trauma.

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To my family

"...One consolation only remains, that the limb will at approximately 12 months again enjoy 90–95% in all its motions of the contralateral wrist, and with a DASH  $\leq 10...$ "

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I. External or internal fixation in the treatment of non-reducible distal radial fractures? A 5-year follow-up of a randomized study involving 50 patients.

Landgren M, Jerrhag D, Tägil M, Kopylov P, Geijer M, and Abramo A. *Acta Orthop 2011; 82 (5): 610–613*.

II. Fragment-specific fixation versus volar locking plates in primary non-reducible or secondarily redisplaced distal radius fractures. A randomized controlled study.

Landgren M, Abramo A, Geijer M, Kopylov P, and Tägil M. *J Hand Surg Am 2017; 42(3): 156–165.* 

III. Similar 1-year subjective outcome after a distal radius fracture during the 10-year-period 2003–2012. A longitudinal register-based study involving 3,666 patients.

Landgren M, Abramo A, Geijer M, Kopylov P, and Tägil M. *Acta Orthop 2017; 88. Epub March 14, 2017 ahead of print.* 

IV. Do patients with an inferior subjective result 12 months after a distal radius fracture improve over time? A long-term 2–12 year register follow-up.

Landgren M, Teurneau V, Abramo A, Geijer M, and Tägil M. *Submitted*.

## **Abbreviations**

**ADL** Activities of Daily Living

BMD Bone Mineral Density

CTS Carpal Tunnel Syndrome

**CRPS** Complex Regional Pain Syndrome

**DASH** Disabilities of the Arm, Shoulder and Hand, 30-item

**DRF** Distal Radius Fracture

MCID Minimal Clinical Important Difference

**PRWE** Patient-Rated Wrist Evaluation

**PROM** Patient Reported Outcome Measurement

**RCT** Randomized Controlled Trial

**ROM** Range Of Motion

**QoL** Quality-of-Life

SF-12 Short Form Survey, 12-item SF-36 Short Form Survey, 36-item

**QuickDASH** Quick Disabilities of the Arm, Shoulder and Hand, 11-item

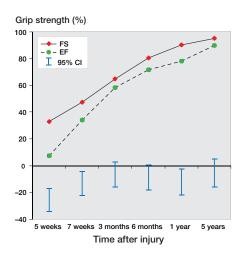
# Thesis at a glance

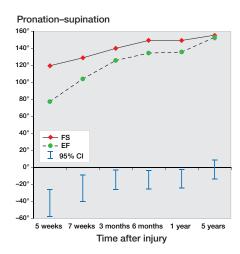
### Paper I. Long-term outcome after a surgically treated distal radius fracture

External or internal fixation in the treatment of unstable distal radius fractures?

**Patients:** 50 patients (18 to 65 years) from a previous randomized trial, were treated with either fragment-specific fixation (FS) or external fixation (EF) for a distal radius fracture.

**Methods:** Objective, subjective and radiographic follow-up at mean 5 (3–7) years **Conclusion:** Previous difference at one year regarding grip strength and range of motion decreased with time and both groups had approached normal values at five years.





Paper II. Comparison between two surgical techniques in distal radius fractures

Fragment-specific fixation or volar locking plate in the treatment of unstable distal radius fractures?

**Patients:** 50 patients (18 to 70 years) with a primarily non-recducible or a secondarily redisplaced distal radius fracture.

**Methods:** Randomized study. Primary outcome: grip strength at 12 months. Secondary outcomes: ROM, DASH, SF-12 and radiography.

**Conclusion:** Good and similar subjective and objective outcome with both surgical techniques, although more complications in the fragment-specific group.

	Volar locking plate (n = 24)	Fragment-specific (n = 25)	P-value
Grip strength (%) <sup>a</sup>	90 (16)	87 (13)	NS
QuickDASH <sup>b</sup>	5 (0–68)	5 (0–32)	NS

<sup>&</sup>lt;sup>a</sup> Mean (SD), <sup>b</sup> Median (min-max), NS = Not significant

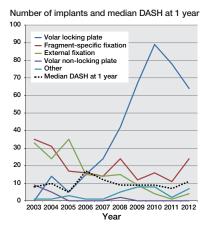
# Paper III. Epidemiology and subjective outcome one year after a distal radius fracture

Did a shift in surgical techniques change the outcome of distal radius fractures?

**Patients:** 3,666 patients (18 to 98 years) prospectively and consecutively included in a longitudinal outcome database during a 10-year period 2003 to 2012.

**Methods:** Patients were sent the subjective outcome questionnaire (DASH). At one year, 2,571 patients (70%) returned the questionnaire, 1,938 non-surgically and 633 surgically treated. Medical records and radiographs were analyzed retrospectively.

**Conclusion:** Good outcome (median 9) both in surgically and non-surgically treated, with a radical shift in implants.



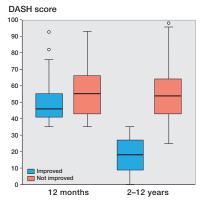
## Paper IV. A long-term 2 to 12 year register follow-up

Do patients with an inferior subjective result 12 months after a distal radius fracture improve over time?

**Patients:** 445 patients in the longitudinal outcome database had DASH >35 at 1 year during a 10-year period 2003 to 2012.

**Methods:** 346 surviving patients were sent a new DASH, 2-12 year after fracture. 269 patients (70%) returned the questionnaire.

**Conclusion:** Subjective outcome after a distal radius fracture improved over time for half the patients with inferior subjective result at 12 months, but more than half remained in the group with major disability.



## Introduction

In 1814, when Abraham Colles wrote the article "On the Fracture of the Carpal Extremity of the Radius" (Colles 1814), he probably did not know that the best treatment of distal radius fractures would still be discussed today. Over the last 200 years, the treatment of distal radius has improved. For years, treatment of stable fractures included immobilization in cast or splints, with or without closed reduction, and surgical treatment using pinning and external fixation was introduced first in the middle of the 20th century (Cooney et al. 1979; Diaz Garcia and Chung 2012). The definition of stability is not fully agreed upon (Walenkamp et al. 2015) and the challenge thus remains to identify which fractures are best treated surgically and which are not (Chen and Jupiter 2007). In the last decades, open reduction and internal fixation has gradually become the preferred method for unstable distal radius fractures. The majority, 70% to 80% of adult patients, are still treated using closed reduction and splints (Chung et al. 2009; Mellstrand-Navarro et al. 2014).

An important factor in assessing successful outcome in any treatment is the rate of complications. Depending on the definition, the overall rate of complications in non-surgical and surgical treatment, spans from as low as 6% to as high as 80% (McKay et al. 2001). Treatment and research should aim at minimizing the rate of complications to achieve an optimal outcome. Early surgical methods have focused on optimal anatomical and radiographic outcome (Batra and Gupta 2002), to obtain a good objective and subjective patient outcome (Ritting and Wolf 2012), but the correlation is not evident (Leung et al. 2013).

The distal radius fracture is the most common fracture (Court-Brown and Caesar 2006). Today, the vast majority achieve a good subjective result (Abramo et al. 2008a), but as many as 21% still have remaining disability one year after the injury (MacDermid et al. 2003). Due to the high incidence of the fracture, an improved outcome in just a small percentage of patients would result in improved quality of life for a substantial number.

With this in mind, the intriguing challenge today is how to measure and interpret the outcome of current treatment and analyzing whether these lead to an acceptable outcome. The objective in the present thesis was to evaluate treatment over a longer time-period, identify risk factors for poor outcome, and compare the newer surgical techniques, in order to contribute to an improved outcome for this patient population.

## Aims

The specific aims of the thesis were:

- I. To investigate whether the superior short-term results in a previous study, comparing internal fixation to external fixation in unstable distal radius fractures persists over time.
- II. To compare, in a randomized way, two methods of internal fixation, the fragment-specific fixation and the newer volar locking plate, in primarily non-reducible as well as in secondarily redisplaced distal radius fractures.
- III. To evaluate the subjective outcome one year after a distal radius fracture, in both surgically and non-surgically treated patients, over a 10-year period using the Disabilities of the Arm, Shoulder and Hand (DASH) score.
- IV. To evaluate if the long-term subjective outcome would improve over time, in patients with major disability (DASH >35) one year after a distal radius fracture.

# Background

## History – treatment evolution or revolution?

Hippocrates (460–371 BC) described traumatic injuries of the wrist as being carpal dislocations. First in the 18th century, the French surgeon Jean-Louis Petit (1705) interpreted the carpal dislocation as an actual fracture. Another French surgeon Claude Pouteau (1783), was the first to describe the dorsally displaced distal radius fracture, still therefore bearing the eponym *Pouteau-Colles* fracture in some regions. Today, we are most familiar with the fracture bearing the name of Abraham Colles, the Irish surgeon and Professor of Anatomy in Dublin, who in 1814, wrote the classic article, describing the fracture. Colles described, more than 80 years before the x-ray was invented by Wilhelm Conrad Röntgen, how the broken pieces should be brought back into an anatomic position and suggested the use of a splint, still today the basic treatment of a distal radius fractures (Fernandez and Jupiter 2002; Diaz Garcia and Chung 2012; Hove et al. 2014). Abraham Colles was succeeded in Dublin by another surgeon, Robert William Smith, accredited for the Smith's fracture, the volarly displaced mirrored distal radius fracture of Colles (1847). A French surgeon, Jean-Gaspard-Blaise Goyrand, described the volar displacement of the distal fragment already in 1832 (Fernandez and Jupiter 2002). Another French surgeon, Guillaume Dupuytren (1847), made important contributions to the description of the morphology of the different fracture patterns, based on postmortem examinations. The American surgeon John Rhea Barton (1838) described a dorsal or volar fracture-dislocation, due to an intra-articular fracture of the distal radiocarpal joint, which was given the eponym *Barton's fracture*. After Röntgen's discovery of x-rays in 1895, which quickly came to be used for fracture diagnosis, a greater understanding of the fracture was natural. Carl Beck (1898) presented the use of the x-ray technique in distal radius fractures (Fernandez and Jupiter 2002; Hove et al. 2014).

The distal radius fracture treatment has in many aspects remained unchanged for the majority of fractures. In the 1814 classic quote, Abraham Colles claims that "... the limb will at some remote period again enjoy perfect freedom in all its motions, and be completely exempt from pain..." (Colles 1814). For a majority of the patients with a distal radius fracture this may be true, but even after all these years and with hopefully improved treatment, still a substantial portion of patients have reduced motion and remaining discomfort or even pain as the end result.

## Epidemiology – size of the problem

The distal radius fracture is the most common fracture and accounts in adults for 18% of the fractures in an orthopedic trauma unit (Court-Brown and Caesar 2006). There are three major subgroups to consider: 1) children/adolescents, 2) young adults, and 3) the elderly (Nellans et al. 2012). In children/adolescents, the most common fracture site is the distal forearm, which represents 24-26% of all fractures in this group (Tiderius et al. 1999; Hedström et al. 2010). In young adults, the bone quality is good. In this group, approximately 75% of the fractures are caused by high-energy trauma, more than 2/3 of the fractures are intra-articular, and more than 50% are initially displaced (Lindau et al. 1999). In the elderly the distal radius fracture is considered to be an early manifestation of osteoporosis, and the fracture a predictor of both later hip fracture (Mallmin et al. 1993) and increased mortality (Øyen et al. 2014). The incidence of the distal radius fracture represents a bimodal distribution with the peak incidence in children/adolescents (boys over-represented) and the elderly (women over-represented) (Court-Brown and Caesar 2006). The increasing incidence noted for adults above after the age of 50 years, is due to lower bone mineral density (BMD) (Van Staa et al. 2001). The independent predictors of a distal radius fracture for women over 65 years are reduced BMD, a previous fracture between age 50 and 65 years and a history of recurrent falls (Vogt et al. 2002). Interestingly, for a woman, regardless if younger or older than 50 years, the wrist is the most common fracture site. In contrast, the hand is the most common site for men under 50 years, and the hip in men older than 50 years (Rosengren et al. 2015).

The epidemiology of the distal radius fracture has been studied in the Scandinavian countries with particular interest. Alffram and Bauer investigated the incidence of distal radius fractures in Malmö, Sweden in 1955, and found the annual incidence rate to be 19/10,000 person-years (Alffram and Bauer 1962). In several studies, an increasing incidence was reported in the last half of the 20th century, at least in an urban population in Malmö, and rising from 19 to 43 per 10,000 person-years between 1950-1980 (Bengnér and Johnell 1985). More recent studies indicate that the increase of incidence rate has slowed down or even started to decrease after the turn of the century (Brogren et al. 2007; Flinkkilä et al. 2011; Sigurdardottir et al. 2011; De Putter et al. 2013; Wilcke et al. 2013; Dimai et al. 2014; Mellstrand-Navarro et al. 2014; Rosengren et al. 2015). The overall incidence was 26/10,000 person-years in a neighboring area in southern Sweden (Brogren et al. 2007), similar to the incidence in a large Swedish database study (Mellstrand-Navarro et al. 2014). Before the age of 50 years, the difference in incidence between genders is small. After the age of 50 years, women have a greater risk of sustaining a distal radius fracture with an incidence three to five times higher in women than in men (Melton III et al. 1998; Brogren et al. 2007; Lofthus et al. 2008; Flinkkilä et al. 2011; Sigurdardottir et al. 2011; Diamantopoulos et al. 2012; Wilcke et al. 2013).

### Classification

Numerous classifications exist for distal radius fracture. Two of the most commonly used are the AO Classification with 9 main subgroups and the Frykman classification with 8 subgroups (Frykman 1967; Müller et al. 1990). The prognostic value of these classifications, to determine the outcome of a distal radius fracture is limited (Flinkkila et al. 1998), especially regarding inter- and intra-observer agreement (Andersen et al. 1996; Kreder et al. 1996). The AO classification was used in **Paper I–IV**, but only using the three main groups (A, B and C), due to a better inter- and intra-observer agreement than when using all subgroups (Kreder et al. 1996).

### **Treatment**

#### Non-surgical treatment

Non-surgical treatment is the preferred treatment for 3/4 of all adult distal radius fractures (Mellstrand-Navarro et al. 2014). Approximately 2/3 of all fractures will have an acceptable outcome with plaster treatment (Hove et al. 2014).

#### Stable non-displaced fractures

Primarily non-displaced distal radius fractures, defined as fractures with minimal displacement and minimal shortening are considered as stable and treated with cast immobilization or even elastic bandage (Abbaszadegan et al. 1989; Adolphson et al. 1993; Abramo et al. 2008a).

### *Unstable and displaced fractures*

Instability has been based on the Lafontaine criteria and three or more risk factors need to be present: dorsal angulation  $>20^\circ$  (perpendicular to a the long axis of the radius); dorsal comminution; intra-articular radio-carpal fracture; an associated ulnar styloid fracture; and age  $\ge 60$  years (Lafontaine et al. 1989). In consensus protocols and clinical studies, instability is often defined as a fracture exceeding a defined radiographic displacement cut-off (Walenkamp et al. 2015), but obviously bone quality, axial compression, metaphyseal comminution, concomitant ligament injuries and patient's age are also important factors (Mackenney et al. 2006). According to a recent publication, volar comminution and displacement constitutes the greatest risk of instability (Wadsten et al. 2014) and the restoration of the volar cortex a strong predictor of both final volar tilt and carpal alignment at closed reduction (LaMartina et al. 2015).

Closed reduction with cast immobilization still remains the standard treatment for displaced distal radius fractures. The classic procedure is longitudinal traction, combining volar flexion, ulnar deviation and pronation of the wrist (Fernandez and Jupiter 2002). The longitudinal traction distracts the strong volar ligaments of the wrist (uniplanar ligamentotaxis) and when combined with a multiplanar technique, causing a volar translation of the distal fragments, the volar tilt will be restored (Agee 1994). After reduction, a forearm cast or above elbow cast is applied. Traditionally, dorsal plaster slabs molded around the wrist are used in Scandinavian countries (Hove et al. 2014). No evidence exists, based on randomized trials, on which type of cast to use. A Cochrane review found no method of reduction or immobilization to be superior in the non-surgical treatment of a distal radius fracture (Handoll and Madhok 2003). The authors suggested the physician to use an accepted technique, cost-effective, and familiar to everyone at their health care unit. A cast provides comfort, but only relative stability and it appears to be the properties of the fracture that predict the stability (Mackenney et al. 2006). With cast treatment there is a significant risk of secondary displacement especially in volar comminution, and in severely comminuted and intra-articular fractures (Wadsten et al. 2014; Walenkamp et al. 2015).

#### Closed reduction and pinning/external fixation

Surgical treatment is recommended for unstable and non-reducible distal radius fractures (Chen and Jupiter 2007; Downing and Karantana 2008). The method of choice for decades has been pinning and external fixation (Atroshi et al. 2006; Krukhaug et al. 2009). As in orthopedics in general, a technical evolution has taken place in the treatment for distal radius fractures in the last 30 years. New implants and techniques have been developed and marketed, especially evident in the last decade with a major shift towards more open reduction and internal fixation (Chung et al. 2009; Mattila et al. 2011; De Putter et al. 2013; Wilcke et al. 2013; Mellstrand-Navarro et al. 2014).

#### Percutaneous pinning

Many methods of percutaneous pinning have been described. In 1908, Lambotte suggested a concept of two pins inserted into the radial styloid for distal radius fractures (Rayhack 1993). In the 1950's, DePalma described a technique inserting the pins from the distal ulna to the fractured radius transfixing the bones until healing (DePalma 1952). In 1959 Willenegger and Guggenbuhl presented the first case report using only one pin for radial styloid fractures (Willenegger and Guggenbuhl 1959). In 1976, Kapandji advocated a technique with intrafocal pinning of unstable extra-articular fractures in young patients (Kapandji 1976). In fractures with two articular fragments a two-pin technique is used with one pin inserted from the

radial styloid and one into the dorso-ulnar corner of the radius (Clancey 1984). A Cochrane review concluded that there is some evidence for the technique, but due to the high rates of complications, the precise role of the method is yet to be established (Handoll et al. 2007).

#### External fixation

The external fixator relies on indirect reduction of the fracture using ligamentotaxis to maintain the radial length (Cooney et al. 1979). Early versions of the external fixator were described in the beginning of the 20th century with Lambotte in 1908 as one of the pioneers. Anderson in 1932 and Hoffmann in 1938, both designed wrist-bridging frames for the distal radius (Hove et al. 2014). In the middle of the 1970s, the static external fixator was increasingly used for comminuted distal radius fractures (Jakob and Fernandez 1982). A new concept was introduced to reduce wrist stiffness. A wrist bridging fixator with a mobile hinge joint or using a non-bridging fixator with pins only inserted in the radius, both techniques allowing wrist motion (Clyburn 1987; Pennig 1993). Better range of motion, better grip strength and improved radiographic outcome were found in one study comparing non-bridging versus static bridging external fixation (McQueen 1998), and no difference in clinical outcome was noted in two other studies (Krishnan et al. 2003; Atroshi et al. 2006). Further development included the dynamic bridging wrist fixator, which allowed early wrist motion and was compared to a static bridging external fixation. The radiographic and functional outcome was similar (Krukhaug et al. 2009). In another study, dynamic bridging fixation resulted in better radial length and wrist extension at one year, but with a higher rate of superficial pin-track infections in the dynamic (43%), compared to the static (11%) external fixation group (Hove et al. 2010). Other studies comparing dynamic to static external fixation found similar rates (30%) of pin-track infections in both groups (Krishnan et al. 2003). The Cochrane institute found no robust evidence of an advantage of any external fixation method over the other (Handoll et al. 2008).

## Open reduction and internal fixation

Although plaster cast, pinning, and external fixation were the standard treatments of distal radius fractures, open methods started to be discussed, based on findings of dissatisfactory results in 30% of the patients (Cooney et al. 1980). New treatment concepts were developed in the 1970–1990s, with open reduction and internal fixation and concepts like anatomical reduction, stable fixation and early mobilization were stressed (Augereau et al. 1983; Keating and McQueen 1994; Jupiter et al. 1996; Carter et al. 1998; Kambouroglou and Axelrod 1998; Fernandez and Jupiter 2002). The advantage of internal fixation over external fixation is maybe no longer controversial (Chen and Jupiter 2007) but it was first after the introduction of the

volar locking plate in 2002 (Orbay and Fernandez 2002), open reduction became the preferred surgical treatment option for the general orthopedic surgeon. Still today, the advantage of internal fixation is discussed. The Cochrane institute withdrew a previously published review regarding surgical intervention of distal radius fractures (Handoll and Madhok 2009) but is currently recruiting papers for a new review of *Internal fixation versus other surgical methods for treating distal radius fractures*, to be published in the future (Jariwala et al. 2014)

#### Non-locking volar plates

Fractures with a *volar displacement*, i.e. Smith and volar Barton fractures, have been treated with volar standard AO T-plates for years with acceptable functional results (Keating and McQueen 1994; Jupiter et al. 1996). Dorsal plates have been used with acceptable results (Carter et al. 1998; Kambouroglou and Axelrod 1998; Grewal et al. 2005), but the complication rates were high (47–72%) especially using the Pi plate (Kambouroglou and Axelrod 1998; Rozental et al. 2003; Grewal et al. 2005) due to conflicts with the extensor tendon. In a meta-analysis of 46 studies (randomized controlled trials, prospective studies, and case series) between 1980 and 2004 (Margaliot et al. 2005), no evidence was found to support open reduction and internal fixation, with the older techniques, over closed reduction and external fixation.

#### Fragment-specific fixation

A new concept of internal fixation was introduced using the three-column theory, with two plating concepts launched almost at the same time. The three-column theory is based on the understanding of the distal radius and ulna as a biomechanical construct consisting of three units; the lateral, the intermediate, and the medial columns (Rikli and Regazzoni 1996). The lateral (radial) column is the lateral part of the radius including the styloid and the scaphoid fossa. The intermediate (middle) column is the medial part of the radius with the lunate fossa and the sigmoid notch. The medial (ulnar) column is the distal ulna, the triangular fibrocartilage, and the distal radio-ulnar joint. The fragment-specific fixation system, also based on the three column theory was developed by Medoff and introduced at our department in 1996. It uses low profile plates and wire forms to stabilize the individual columns (Medoff and Kopylov 1998; Konrath and Bahler 2002). The technique uses a minimally invasive anatomic approach to individually stabilize the radial styloid, the dorsal ulnar corner, the dorsal wall and volar rim. (Konrath and Bahler 2002; Benson et al. 2006). Biomechanical studies showed good mechanical stability by the small implants (Taylor et al. 2006). The fragment-specific fixation system was compared at our department to the external fixator in a randomized study, showing better range of motion and grip strength, not only at earlier time points, but as late as after one year (Abramo et al. 2009). The rationale for Paper I was to determine if the fragment-specific system, as an example of a method of open reduction and internal fixation, was superior to the external fixation technique, in a longer time frame than one year.

#### Volar locking plates

The fragment specific fixation is technically demanding and it was first with the introduction of the volar locking plate, that surgery of the distal radius became popular to the greater orthopedic community. Technically, the new idea was to treat also dorsally dislocated fractures by a volar approach (Orbay and Fernandez 2002). This was made possible by having the distal screws locked to the plate, lifting and securing the subchondral bone, thereby retaining the joint surface in an anatomical position during healing. With the technique, the locking screws are kept unicortical with no osteosynthesis material protruding dorsally, thereby avoiding the risk of interfering with the extensor tendons. Most volarly and dorsally dislocated fractures could be addressed, and the pronator quadratus muscle could be used as a protective layer between the plate and the tendons. The volar locking plates have since its introduction in 2002 become popular, and is now the most frequently used method of surgical treatment for distal radius fractures (Koval et al. 2008; Chung et al. 2009; Mattila et al. 2011; Wilcke et al. 2013; Mellstrand-Navarro et al. 2014). The method has proven to be biomechanically stable in studies using cadaver specimens and synthetic bone models (Koh et al. 2006; Willis et al. 2006). In clinical studies, good results have been found in patients of all ages (Orbay and Fernandez 2004; Chung et al. 2008; Jupiter and Marent-Huber 2009), but the method was spread in the orthopedic community without randomized comparisons to the old techniques. Several randomized studies have been published in the last decade comparing volar locking plates to external fixation, with and without adjuvant pins (Egol et al. 2008; Abramo et al. 2009; Wei et al. 2009; Wilcke et al. 2011; Jeudy et al. 2012; Karantana et al. 2013; Williksen et al. 2013; Roh et al. 2015; Navarro et al. 2016). In general, the volar locking plates yield quicker early recovery and a better anatomical reduction, but the conclusions regarding the functional and subjective outcome are not conclusive (Table 1). In a randomized study comparing volar locking plates or dorsal plates to external fixation, similar outcomes were found (Xu et al. 2009). Further, in a randomized study of older patients, comparing non-bridging external fixation to volar locking plates, the outcome were found equal (Gradl et al. 2013), but a high number of extensor tendon injuries was found due to dorsal screw penetrations, a complication that should not occur in a series with experienced surgeons. In patients 65 years and older, similar outcomes were found in volar locking plate when compared with closed reduction and cast (Arora et al. 2011; Bartl et al. 2014). Recently, a large randomized multicenter trial found percutaneous pinning to be superior to volar plates. The 461 fractures were operated by 244 surgeons (Costa et al. 2014), implying that pinning might be better in low volume centers due to potential complications in the open techniques. In the two meta-analyses of the existing RCTs comparing volar locking plates with percutaneous pinning, a lower DASH score

**Table 1.**Literature review of recent randomized controlled trials of closed reduction and external fixation +/- pinning versus open reduction and internal fixation with newer techniques

Study Su (year)	ubjects (n)	Mean age (range)	AO	Treatment	FU	Outcome (variables)	Outcome (findings)	p-value
Egol (2008)	77	51 (18–78)	A,B,C	VLP vs. EF+P	12	Primary outcome not def Grip strength <sup>b</sup> Pronation <sup>b</sup> Radiographic Less physiotherapy	Similar 95% vs. 100% Similar VLP in favor	- NS 0.04 NS 0.02
Abramo (2009)	50	48 (20–65)	A,C	FS vs. EF±P	12	Complications Grip strengtha Forearm rotation DASH Radiographic Complications (major)	21% vs. 18% 90% vs. 78% 136° vs. 149° Similar Similar 8 vs. 2	NS 0.03 0.03 NS NS 0.04
Wei (2009)	46	59 (18–78)	A,C	VLP vs. RCP vs. EF+P	12	DASH <sup>a</sup> Lateral pinch strength ROM Radiographic (inclination) Radiographic (length) Complications (overall)	VLP in favor VLP in favor Similar	0.04 0.03 0.04 NS <0.05 <0.05
Xu (2009)	30	44 (21–56)	С	VLP/DP vs. EF±P	24	GO <sup>a</sup> GW Grip strength Pronation-supination Radiographic Complications (overall)	Similar Similar Similar Similar Similar Similar	NS NS NS NS NS
Wilcke (2011)	63	56 (20–69)	A,C1	VLP vs. EF±P	12	DASH <sup>a</sup> Grip strength Extension Supination Radiographic (height) Overall complications	Similar Similar VLP in favor VLP in favor VLP in favor 21% vs. 36%	NS NS 0.04 0.02 <0.001
Jeudy (2012)	75	65 (40–80)	С	VLP vs. EF+P	6	GO <sup>a</sup> Grip strength <sup>b</sup> Flexion-extension Radiographic Complications PRWE	VLP in favor 84% vs. 76% Similar Similar Similar Similar Similar	- <0.05 0.02 NS NS NS
Karantana (2013)	130	49 (18–73)	A3, C2,C3	VLP vs. EF+P	12	PEM <sup>a</sup> DASH Grip strength <sup>b</sup> ROM Radiographic (volar tilt) Radiographic (height) Complications	Similar Similar 95% vs. 84% Similar VLP in favor VLP in favor 24% vs. 42%	NS NS <0.001 NS <0.001 <0.004 NS
Williksen (2013)	102	54 (20–84)	A,C	VLP vs. EF	12	Mayo wrist score <sup>a</sup> Supination Grip strength Ulnar sided pain Radiographic (variance) Operative time Complications (overall)	VLP in favor VLP in favor Similar VLP in favor VLP in favor VLP in favor 88 vs. 77 min 29% vs. 30%	0.02 0.03 NS 0.02 0.02 0.02 NS
Gradl (2013)	102	63 (18–88)	A3, C	VLP vs. Nb-EF	12	Not defined a ROM Grip strength GW Radiographic Operative time Complications	Similar Similar Similar Similar Similar 59 vs. 43 min 21% vs. 20%	NS NS NS NS <0.05
Roh (2015)	74	55 (18–70)	C2,C3	VLP vs. EF+P	12	MHQ <sup>a</sup> ROM Grip strength Radiographic (variance) Operative time Complications	Similar Similar Similar Similar VLP in favor 59 vs. 49 min 17% vs. 29%	NS NS NS 0.02 <0.001 NS

Navarro	140	63 (50-74)	A2,	VLP vs. EF±P	12	DASH <sup>a</sup>	Similar	NS
(2016)			A3,C			Radial deviation	VLP in favor	0.02
						Grip strength	Similar	NS
						Radiographic (variance)	VLP in favor	< 0.001
						Operative time	70 vs. 42 min	< 0.001
						Complications (overall)	51% vs. 45%	NS

#### Legends to Table 1:

<sup>a</sup> Primary outcome. <sup>b</sup> percent of uninjured side.

FU = Follow-up (months)

DASH = Disabilities of the Arm, Shoulder, and Hand score. GO = Green and O'Brian score,

GW = Gartland and Werley score, PEM = Patient Evaluation Measure, PRWE = Patient-Rated Wrist Evaluation.

DP = Dorsal plate, EF = External fixation, FS = Fragment-Specific fixation, Nb = Non-bridging,

±P = with or without pinning, +P = all patients received pins, RCP = Radial Column plate, VLP = Volar locking plate, VP = Volar non-locking plate.

NS = Not significant, -= No statistic calculation.

and reduced total postoperative complications were found with volar locking plates (Chaudhry et al. 2015; Zong et al. 2015). Seven meta-analyses state some evidence of an improved subjective outcome, better anatomic restoration, and better range of motion with volar locking plates compared with external fixation (Cui et al. 2011; Wei et al. 2012; Esposito et al. 2013; Walenkamp et al. 2013; Wang et al. 2013; Xie et al. 2013; Li-hai et al. 2015).

Comparisons of the volar locking plate with the fragment specific technique are few. A prospective cohort study compared the volar locking plate with the fragment-specific fixation finding the volar locking plate to be a more stable fixation, with better objective and subjective outcomes in the early postoperative period, and with fewer complications (Sammer et al. 2008). To date, no randomized controlled trials comparing the fragment-specific fixation to the volar locking plate have been published, which was the rationale for **Paper II**.

#### Rehabilitation

In the immediate phase after a distal radius fracture, physiotherapy is started to reduce finger edema. Shoulder and elbow motion are endorsed to reduce stiffness (Oskarsson et al. 1997). After cast removal, early active wrist motion is initiated, with increasing load to the wrist. Rehabilitation after wrist fractures by means of a home exercise program can be effective in improvement of grip strength and range of motion (Krischak et al. 2009). Although, rehabilitation is a cornerstone of eliminating and preventing dysfunction, few randomized controlled trials exists (Hove et al. 2014; Handoll and Elliott 2015).

### How to evaluate outcome

Wrist fractures traditionally were evaluated using objective measurements, i.e. the view of the medical professionals of how the patient was influenced by an injury. Traditionally, radiographic appearances, range of motion, and/or grip strength (MacDermid 1996) have been evaluated. At the end of the 20th century a more patient-centered view became common and several patient-reported outcome instruments were developed for the upper extremity (Hudak et al. 1996; MacDermid 1996; Chung et al. 1998) to capture the experience of the patient's own view on how the injury or disease influenced their daily life. An overview of the various outcome assessments is found in the following section.

#### Radiographic assessment

Posterior-anterior (PA) and lateral views are used for measuring radial height, radial inclination, ulnar variance, intra-articular joint step-off and dorsal angulation (Mann et al. 1992). Ulnar variance was measured according to the method of perpendiculars (Parker et al. 2014). Osteoarthritis of the wrist can be classified according to Kellgren and Lawrence (Kellgren and Lawrence 1957). It is generally agreed that the two surfaces of the distal radius, the scaphoid fossa and the lunate fossa, should be restored to avoid future posttraumatic arthritis (Knirk and Jupiter 1986; Karnezis et al. 2005). The correlation between objective and subjective outcomes and the degree of radiographic deformity is still controversial (McQueen and Caspers 1988; Batra and Gupta 2002; Fujii et al. 2002; Anzarut et al. 2004; Wilcke et al. 2007; Plant et al. 2017) as well as the results in the few exiting long term outcome-studies (McQueen and Caspers 1988; Kopylov et al. 1993; Földhazy et al. 2007; Brogren et al. 2011a; Finsen et al. 2012). Radiographic assessment can be helpful in predicting the stability, as described in the paragraph regarding unstable distal radius fractures (Lafontaine et al. 1989; Mackenney et al. 2006; Wadsten et al. 2014).

## **Grip strength**

Grip strength captures pain besides strength and can be seen as an objective surrogate variable of hand function. A common tool to measure grip strength is the Jamar hand dynamometer (Sammons Preston. Inc., Bolingbrook, IL, USA). Since grip strength varies between individuals, the patient often serves as his or her own control and the strength is often given as a ratio of the uninjured hand. Grip strength was the primary outcome in **Paper I** and **Paper II**. Grip strength is a reliable outcome measurement, as neither time nor age appear to affect the test-retest reliability (Bohannon and Schaubert 2005). The minimal clinically important difference (MCID)

is considered the smallest change or difference in an outcome measure that is perceived to be clinically important (Wells et al. 2001). In a study attempting to establish the MICD for grip strength, an absolute value of 6.5 kg or a grip ratio 19.5% of the uninjured side one year after a DRF has been suggested (Kim et al. 2014). Grip strength is sensitive in detecting a small clinical difference, and with good responsiveness (the ability to detect a change when a true change has occurred), in the evaluation of the objective outcome after distal radius fractures (MacDermid et al. 2000). Grip strength was one of the most significant factors related to patient satisfaction (Fujii et al. 2002).

### Range of motion

The clinical examination includes evaluation of the three axes of rotation in the wrist. The range of motion (ROM) in the radio-carpal joint is extension-flexion and radial-ulnar deviation, while pronation-supination occurs in the distal and proximal radio-ulnar joints with the radius rotating around the head of ulna. A goniometer is used to measure the angle in degrees and estimates for good patient satisfaction after a distal radius fracture is 95% of the contralateral side (Ritting and Wolf 2012). ROM was used in **Paper I** and **Paper II** as a secondary outcome parameter.

#### Physician-based assessment instruments

Historically, different physician-based assessment instruments have been used. The Gartland and Werley point system using objective measures such as range of motion (Gartland and Werley 1951), further developments have included grip strength, but despite of the common use in hand and wrist surgery the score system no validation studies exits (Changulani et al. 2008). A clinical grading system, the Green and O'Brian, based on range of motion, grip strength and patient satisfaction is also at times used (Green and O'Brien 1978), further development is the Modified Mayo Wrist Score (Cooney et al. 1987).

## Patient-reported outcome measures

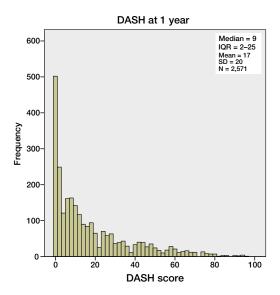
A patient-reported outcome measure (PROM) is a tool used to measure the patient's own view of function, pain and quality of life without the involvement of a researcher or clinician. Different types of PROMs have been available since the first were developed in the 1970s, either disease-specific or generic evaluating the general health (Weldring and Smith 2013). The most commonly used outcome instruments will be described below with an emphasis on the PROM used in this thesis.

#### Disabilities of Arm Shoulder and Hand (DASH)

The DASH questionnaire, used in **Papers I–IV**, was initiated and developed in 1994 by the Institute for Work and Health in Ontario, Canada together with the American Academy of Orthopedic Surgeons (Hudak et al. 1996). It is a regional outcome measure for disorders in the upper limb evaluating the function of the arm, shoulder, and hand as one combined entity. Six domains are evaluated; daily activities, social function, work function, symptoms, sleep, and confidence. The DASH consists of 30 items (Appendix I). Each item has 5 response options available to calculate a total score ranging from 0 (no disability) to 100 (most severe disability). A DASH score cannot be calculated if more than 10 percent of the items are left blank by the patient. The DASH has been translated and validated (shown to measure the conditions according to its intended purpose) in Swedish (Atroshi et al. 2000). A short version, the QuickDASH (Appendix II), containing 11 of the 30 items was introduced (Beaton et al. 2005) and has also been translated into and validated in Swedish. A good correlation between the QuickDASH and the original 30 item DASH questionnaire was found (Gummesson et al. 2006). The DASH questionnaire was validated in patients with different chronic conditions in the upper extremity, before and after surgery (Gummesson et al. 2003; Sorensen et al. 2013). The initiators of the DASH instrument described two intentions for its use: 1) A descriptive measure – to compare the impact of upper-limb disorders among individuals or groups. 2) An evaluative measure – to assess change over time related to natural history or the effect of treatment interventions (Kennedy 2011). For longitudinal changes, i.e. changes over time in patient health and function, an MCID was found to be between 8 and 19 points for DASH or QuickDASH in a variety of upper extremity conditions (Schmitt and Di Fabio 2004; Mintken et al. 2009; Polson et al. 2010; Sorensen et al. 2013; Franchignoni et al. 2014). In evaluating the MCID, the values before and after treatment are compared, with hopefully large clinical differences achieved due to the intervention. With the lack of standardized methods how to calculate the MCID, problems of interpretation arise (Slutsky 2013). DASH was not intended and is too blunt for evaluating small differences between two types of treatment. Yet another aspect to consider, comparing two treatments, is the risk of a ceiling effect of the chosen outcome instrument, when >15-20% of the cohort reaches the best outcome (Kim et al. 2015). The DASH has a risk of a ceiling effect and therefore possibly a lack of sensitivity. Since DASH is skewed and approximately 20% of patients with a distal radius fracture (Figure 1, Paper III) reach a score of 0 at 12 months, a difference between two groups may be interpreted falsely as absent when actually present, i.e. a type II error.

#### Other regional patient-reported outcome measures

The PRWE is a validated subjective outcome questionnaire, and was, in contrast to the DASH, designed to measure pain and disability specifically in the wrist (MacDermid et al. 1998). This questionnaire consists of five items regarding pain; six



**Figure 1.** DASH at 1 year in Paper III illustrating skewness of DASH score.

items regarding disability and four items regarding personal activities, household work, and recreational activities. The questionnaire has been translated twice into Swedish and validated, both validation showing that the PRWE correlates well to the DASH questionnaire (Wilcke et al. 2009; Navarro et al. 2011). The risk of a ceiling effect may be present with the PRWE as well (Kim et al. 2015). Other regional validated outcome instruments exist, for instance the Michigan Hand Outcomes Questionnaire (MHQ) (Chung et al. 1998). The Patient Evaluation Measure (PEM), has a hand health profile section and is a self-administered questionnaire. The PEM has been shown valid and comparable to both DASH and MHQ (Dias et al. 2008). The MHQ and PEM have not been translated to Swedish.

#### Generic outcome instruments

The Quality-of-Life (QoL) can be assessed in a population using generic outcome measures and can be used to compare between treatment cohorts as well as to compare a cohort to a normative population.

The 36-item Short Form health survey (SF-36) was used in **Paper I**, is a widely used and validated instrument consisting of 36 questions estimating the general health of a population (Brazier et al. 1992). The instrument evaluates the functional status, well-being, and overall evaluation of health by measuring on eight multi-item dimensions each resulting in scores from 0 (best status) to 100 (worst status). These can be expressed as the Physical Component Summary (PCS) and a Mental Component Summary (MCS) scores.

The 12-item Short Form (SF-12 used in **Paper II**), is more user friendly with only 12 questions (Ware Jr et al. 1996). Both SF-36 and SF-12 have been translated to Swedish and the PCS and MCS scores correlates well with each other.

The EuroQol five-dimensional (EQ-5D) questionnaire is also a generic measure of health status and quality of life. The instrument is widely used in many health care interventions, but has been used in few studies of distal radius fractures (Bartl et al. 2014; Navarro et al. 2016).

#### Comparison DASH and Short Form instruments

The regional specific outcome measure DASH and the generic measure SF-36 has been found to correlate well regarding pain, but the correlations between DASH and physical and mental function is only moderate (Aktekin et al. 2011).

## Complications

Complications are relatively frequent in the treatment of distal radius fractures and depend on type of treatment, whether non-surgical or surgical, as well as on how a complication is defined. The reported rate for complications vary widely from as low as 6% to as high as 80% (McKay et al. 2001).

Major complications cause significant morbidity. Complex Regional Pain Syndrome (CRPS) is a condition with autonomic dysfunction, pain and impaired function. CRPS can follow both non-surgical and surgical treatment with an incidence ranging from 1% to 37% (Mathews and Chung 2015). Treatment is complex, but in general early awareness of the risk, pain management, and anti-edema exercises are paramount as prevention and intensified physiotherapy the treatment once manifest. (Hove et al. 2014). Unplanned surgery can be regarded as a major complication. Carpal Tunnel Syndrome (CTS) can be either transient or manifest, the latter can be considered as a major complication and necessary to treat surgically. Tendon injuries, most often the long thumb extensor tendon (EPL) rupture can occur in non-surgically treated fractures but the incidence is low (0.3%) (Hove 1994). In surgically treated fractures tendon irritations are more frequent and synovitis could be considered as a minor complication while tendon rupture requiring tendon transfer as a major complication (Mathews and Chung 2015). With no uniform definition of complications, comparison between different reports on treatment techniques is difficult (McKay et al. 2001).

In closed reduction and external fixation of distal radius fractures, the overall complications rate ranges from 27 to 67% (Ahlborg and Josefsson 1999; Anderson et al. 2004). Superficial wound infection is the most frequent complication and varies from 11 to 43% (Ahlborg and Josefsson 1999; McKay et al. 2001; Krishnan et al. 2003; Margaliot et al. 2005; Hove et al. 2010) and in one study at a rate of 30% despite both perioperative and oral prophylactic antibiotics during the first postoperative week (Krishnan et al. 2003). Other complications include pin loosening in 3 to 11% (Ahlborg and Josefsson 1999; Margaliot et al. 2005).

In open reduction and internal fixation, the overall complication rates span from 10% to 27% using volar locking plates (Rozental and Blazar 2006; Arora et al. 2007; Soong et al. 2011; Johnson et al. 2014). Tendon synovitis is a known consequence as a result of malpositioned plates protruding volarly or screws crossing the dorsal cortex. In a systematic review of 56 studies (6278 patients) the incidence of tendon synovitis was 5% after volar locking plate and 8% after dorsal plating (Johnson et al. 2014). Tendon rupture was rare with an incidence of 2% in volar plates and 2% in dorsal plates (Johnson et al. 2014), similar to earlier volar locking plate publications (Arora et al. 2007; Soong et al. 2011). The incidence of CRPS has been reported to be 4%, CTS 3%, screw loosening 2%, and intra-articular screw displacement to be 1% (Arora et al. 2007).

### Malunion

Malunion is a general concept of a fracture that has healed in an anatomically suboptimal position, which may lead to chronic pain and functional disability. The definition of malunion of a distal radius fracture is not evident. Several definitions have been proposed, but none is universal for understanding all effects for the outcome. Fourrier et al. suggested correlation to the increased risk to develop disability, suggesting worse outcome if a fracture healed in more than  $10-20^{\circ}$  dorsal angulation, >1-2 mm radial shortening, and <20-30° radial inclination (Fourrier et al. 1981). MacKenny et al. defined malunion as dorsal angulation  $\geq 0^{\circ}$  and an ulnar variance of 1-2 mm (Mackenney et al. 2006). Brogren et al. defined malunion as dorsal angulation >10° or ulnar variance  $\geq 1$  mm (Brogren et al. 2011b). In this study, patients scored a significantly higher DASH score (mean 11) at one year after the fracture in patients with either dorsal angulation >10° or ulnar variance >1 mm, and a mean DASH score of 17 if both dorsal angulation >10° and ulnar variance >1 mm was present.

Due to the lack of a global definition, the prevalence of malunion after distal radius fractures is thus not clear. Using the most strict definition of a dorsal angulation  $\geq 0^{\circ}$  and a ulnar variance of 1-2 mm, Mackenny et al. predicted malunion to occur in 27% of non-displaced fractures treated with cast, and 60% of displaced fractures treated with reduction and cast (Mackenney et al. 2006). Using the definition of malunion defined as a dorsal angulation >10° or ulnar variance  $\geq 1$  mm. Brogren et al. found 72% of their patients treated with closed reduction and cast, with closed reduction and external fixation, or percutaneous pinning to be malunited (Brogren et al. 2011b).

Malunion can turn out as either a minor or a major complication. When the malunion renders pain, weakness or dysfunction for the patient and is a symptomatic malunion, it is considered as a major complication. Non-surgically treated fractures tend to have a greater risk to malunite. In a randomized trial of closed reduction and cast versus open reduction and volar locking plate, a greater rate of symptomatic malunion was found in the closed reduction group at final (24 months) follow-up, 37% (DASH mean 14) and 0% (DASH mean 9) respectively (Sharma et al. 2014). Historically, the incidence of malunion was reported to be 24% after cast immobilization and 10% after surgical treatment (Haase and Chung 2012). In meta-analyses, malunion is reported at a rate of 2–4% after internal or external fixation (Margaliot et al. 2005; Zhang et al. 2016).

The most common symptoms of a malunion are related to an incongruency of the distal radio-ulnar joint (DRU-joint) and consist of pain at forearm rotation. In symptomatic patients with a malunion, a corrective osteotomy can be discussed with the patient (Haase and Chung 2012). Most often a radial osteotomy is performed, or an ulna osteotomy if the malunion is predominantly due to an axial shortening of the radius. In radius osteotomies, the fracture is cut and aligned at the previous fracture site and stabilized with screws and a plate. In a study of patients with symptomatic malunion (Abramo et al. 2008b), surgery resulted in a significant improvement in radiographic, functional, and subjective outome. The median DASH score improved from median 39 preoperatively to median 21 after one year.

## Patients and methods

All studies were conducted at the Department of Orthopedics, in Lund, Sweden. The primary hospital catchment area has 256,000 inhabitants (Statistics Sweden) and approximately 450 adult patients (hospital reimbursement data) are treated for a distal radius fracture annually. Figure 2 shows the timeline and an overview of the patients in the 4 studies.

Paper II 50 patients

Paper III 50 patients

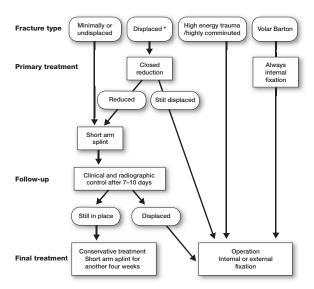
Paper III 3,666 patients

Paper IV 445 patients

2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014

**Figure 2.** Timeline of patients and study years, Paper I–IV

Patients with a distal radius fracture were treated according to a joint treatment protocol for southern Sweden (Figure 3, Abramo et al. 2008a). Non-displaced fractures were treated in a forearm cast for four to five weeks, and displaced fractures were reduced and casted. If the fracture was impossible to reduce primarily or if a secondary loss of reduction occurred at the 7–10-day follow-up, surgical treatment was recommended.



**Figure 3.** Treatment protocol for distal radius fractures at the hospitals in the southern Swedish region (Södra sjukvårdsregionen). <sup>a</sup>Displaced = dorsal angulation >10° and/or ulnar variance >2 mm and/or articulation step >1 mm or volar angulation >25°.

## Paper I and II – clinical studies

#### Study design and patient populations

**Paper I** was a long-term follow-up of a randomized study of 50 patients, included between May 2002 and December 2005, and treated with either fragment-specific or external fixation for a distal radius fracture. In that publication, the results 1 year after the fracture had been presented (Abramo et al. 2009) and in **Paper I** a mean 5 (3–7) years follow-up was performed. **Paper I** was approved by the local ethics committee (Lu 45/02). Inclusion and exclusion criteria are summarized in Table 2.

**Table 2.** Inclusion and exclusion criteria for Paper I

**Paper II** was a single-center, parallel group, prospective, randomized trial of 50 patients, included and surgically treated between December 2010 and December 2012 (Figure 4). The study was performed in accordance with the CONSORT criteria (Moher et al. 2010), registered in the ClinicalTrials.gov (ID No. NCT01311531), and monitored externally by a hospital-based independent organization (Clinical Study Support, R&D Centre, Lund, Skåne, Sweden). **Paper II** was approved by the local ethics committee (ETIK 2009/318). Inclusion and exclusion criteria are summarized in Table 3.

**Table 3.** Inclusion and exclusion criteria for Paper II

Inclusion criteria	Exclusion criteria
Age 18–70 Injury <14 days AO A or C Primary non-reducible or a secondarily redisplaced DRF One or more of the below:  >20° dorsal angulation of the distal radius articular surface >2 mm shortening of ulnar variance > 1 mm incongruence of the radio-carpal > 1 mm incongruence the distal radio-ulnar joint Informed consent	Previous ipsilateral wrist fracture Open fracture AO B Fracture extending to the diaphysis Fracture on the contralateral side Concomitant fractures in need of treatment Ongoing radiotherapy or chemotherapy Metabolic disease affecting the bone Medication affecting the bone Dementia, psychiatric disorder, or alcohol abuse Difficulty understanding Swedish

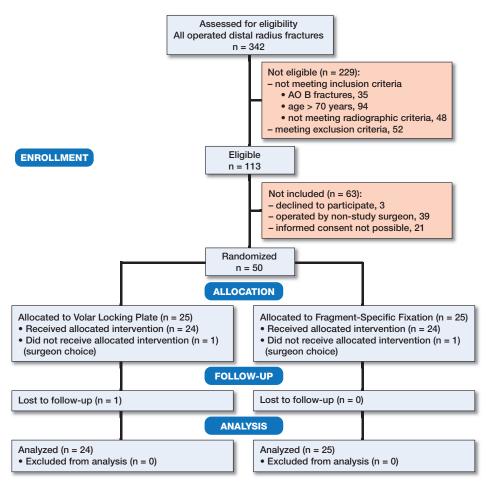


Figure 4. Flowchart Paper II.

#### **Recruitment and intervention**

In **Paper I**, in January 2009 participants in the previous randomized trial were invited to participate in a long-term follow-up study. Patients had been treated with either open reduction and internal fixation with fragment-specific wrist fixation (TriMed, Santa Clarita, CA, USA) or by closed reduction and bridging external fixation (Hoffmann, Stryker, Hopkinton, MA, USA/ Orthofix Srl, Bussolengo, Italy).

In **Paper II**, random numbers were generated (Research Randomizer, www.randomizer.org), blinded to examiners and placed in sealed envelopes by a secretary before commencing the study. Simple randomization was used with 25 patients in each group. The envelopes were opened in the operation theatre, immediately prior to the surgery. Patients were assigned to either fragment-specific wrist fixation or to

the volar locking plate group (TriMed, Santa Clarita, CA, USA). Surgical implants and instruments for both procedures were available in the common instrument tray. Three experienced hand surgeons performed all surgical procedures. Surgery was performed, in all patients using a tourniquet under brachial plexus block or general anesthesia. With the fragment-specific wrist fixation system (Konrath and Bahler 2002), an incision was made through the first extensor compartment. Reduction of the fracture was achieved with two pins and a pin-plate was applied onto the styloid pin and secured by screws. The fourth extensor compartment was opened and a buttress pin and/or ulnar pin-plate was applied for dorsal stability. If necessary, a volar buttress pin was introduced through a modified Henry's incision. In the volar locking plate group, the modified Henry's approach was used (Orbay and Fernandez 2002). A below-the-elbow plaster splint was applied for pain reduction. Patients postoperatively followed the standard rehabilitation for distal radius fractures. Finger motion was started immediately to reduce edema. At 2 weeks the sutures and plaster was removed and wrist motion initiated.

#### **Outcome measurement**

Primary outcome in **Paper I** and **Paper II** was grip strength, which formed the basis for the calculation of the sample size.

Grip strength was examined in a standardized fashion, with the elbow flexed at 90 degrees, holding the wrist in neutral rotation and the wrist held between 0 and 30 degrees dorsal extension, as recommended by the American Society of Hand Therapists (ASHT) (Fess 1992). Three consecutive attempts were performed and the mean value calculated, expressed as an absolute value as well as a percentage of the contralateral uninjured side (Ashford et al. 1996). For correction of hand dominance, a 10% correction in grip strength in **Paper II** was made in right-handed subjects, with no correction performed in left-handed subjects (Petersen et al. 1989). Patients in **Paper I** were assessed once in the outpatient clinic 3 to 7 years after primary surgery. Prior to the evaluation, an experienced physiotherapist had instructed the two orthopedic residents examining the patients in a standardized method to use the JAMAR, as well as the goniometer for range of motion (ROM). In **Paper II**, all patients were assessed clinically regarding grip strength and range of motion at 2 and 6 weeks, and at 3 and 12 months by one of two physiotherapists.

Pain at palpation, the presence of an obvious clinical wrist deformity in the frontal and/or lateral plane, and minor and major complications were recorded according to the predefined list in the protocol (Appendix III). In **Paper I**, patients were evaluated with the QuickDASH and SF-36 questionnaires. Patients not available for the clinical evaluation received a second letter and were asked to fill out the two questionnaires. Re-operations were identified using the medical records and radiographs. In **Paper II**, QuickDASH and the SF-12 were assessed at 6 weeks, 3 and 12 months.

#### Radiographic assessment

Radiographs in PA and lateral projections were obtained in the neutral position (Jedlinski et al. 1995). Measurements of radial inclination, ulnar variance and dorsal angulation (Mann et al. 1992) carried out using digital tools on the picture archiving and communication system (PACS) workstation, by one experienced radiologist. The radial inclination angle was measured on PA radiographs. Dorsal angulation was measured in the lateral projection and expressed as the angle of joint surface of the distal fragment relative to the long axis of the radius. Ulnar variance was measured from the distal radial joint surface to the distal ulnar surface, according to the method of perpendiculars on PA radiographs of the wrist. Apart from angles and shortenings, signs of secondary osteoarthritis were evaluated in the long-term follow-up, **Paper I**, evaluating the presence of reduced joint space width, subcortical sclerosis, subchondral cysts, and distal radio-ulnar joint (DRU-joint) incongruence (Kellgren and Lawrence 1957). In Paper II, radiographs were evaluated at inclusion (time of fracture), using perioperative fluoroscopy radiographs immediate after surgery, and radiographs at six weeks and twelve months. The presence of incongruence in the radio-carpal joint (RC-joint) and the DRU-joint was recorded as well as fracture union defined as osseous bridging across the fracture site on both PA and lateral projections.

## Paper III and IV – registry studies

## The wrist fracture register

Both Paper III and Paper IV were approved by the ethics committee ETIK 2009/318 and were based on data from the Lund Wrist Fracture Register, Department of Orthopedics at Skåne University Hospital, Lund, Sweden. The register started in 2001 with the intention to evaluate the subjective outcome after wrist fractures in a larger cohort. Since the start of the register, medical records from the emergency department were weekly scrutinized and patients 18 years or more with wrist fractures were prospectively and consecutively included. A patient reported outcome measurement (DASH) was distributed and collected three and twelve months after the fracture via regular mail. Non-responders received a reminder 2 weeks later. Results from the first 2 years, September 2001 to August 2003, have been reported (Abramo et al. 2008a). When established in 2001, the patients received the Swedish version of the 30-item DASH questionnaire (Atroshi et al. 2000). During the registry follow-up a shorter questionnaire, the 11-item QuickDASH questionnaire was developed, translated, and validated in Swedish (Gummesson et al. 2006). The original DASH questionnaire was replaced with the shorter QuickDASH in February 2008 to improve the reply rate.

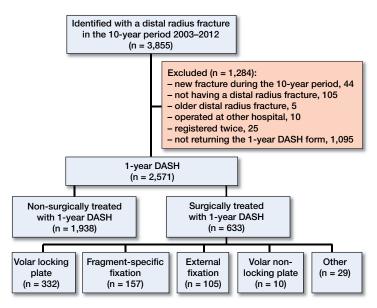
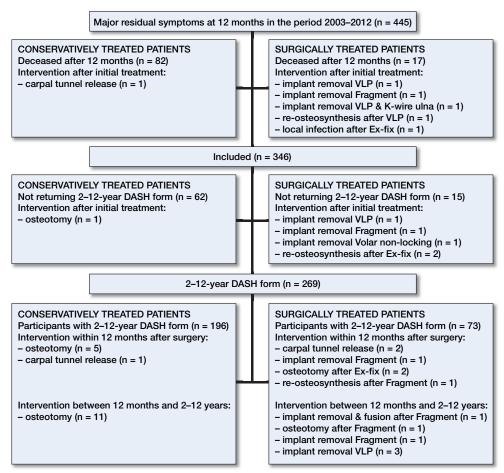


Figure 5. Flowchart Paper III.

#### Paper III – the 1-year subjective outcome in 3,666 patients

Between January 2003 and December 2012, 3,855 patients were coded as having a distal radius fractures at the Emergency Department at the Skåne University Hospital, Lund, Sweden (Figure 5). In total, 189 patients were excluded, of which 44 had a new distal radius fracture during the 10-year period. 105 had incorrect coding (distortions, fractures or dislocations of other parts of the arm), 5 patients came to the emergency department due to persisting pain from older fractures, 10 patients had recently been operated at other hospitals, and 25 patients had been incorrectly registered twice.

Thus, 3666 patients presented with a distal radius fracture during the 10-year period. All medical records were analyzed retrospectively to verify the diagnosis, the type of treatment, and the classification according to the International Classification of Disease (ICD) 10 system for distal radius fractures (S52.50, S52.51, S52.60, and S52.61). The operated patients were analyzed for the AO type, high or low energy injury, and time from fracture to surgery. The non-responders were analyzed regarding age, sex, treatment, AO-type, high vs. low energy.



**Figure 6.** Flowchart Paper IV, from injury to the long-term follow-up with information regarding presence of an intervention after the initial treatment. VLP = volar locking plate. Fragment = Fragment-specific. Ex-fix = External fixation.

#### Paper IV – long-term follow-up of patients with inferior outcome

Between January 2003 and December 2012, 445 patients (17%) with distal radius fractures had a DASH score >35 at one year implying major residual symptoms.

In December 2014, 346 patients were still alive and received a new DASH outcome from for long-term evaluation of their wrist (Figure 6). After three weeks a reminder was sent to the non-responders. The non-responders were analyzed regarding age, sex, treatment, and re-operations.

#### Statistical analyses

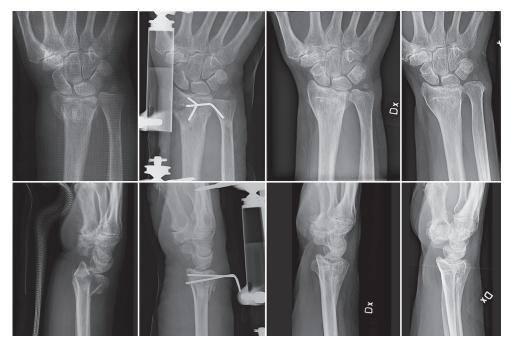
- **Paper I:** Student's t-test was used for continuous variables, such as range of motion (ROM) and grip strength. A two-sided p-value < 0.05 was considered statistically significant. The radiographic results regarding DRU-joint incongruence and the presence of osteoarthritis and reoperations were evaluated by Fischer's exact test. The Wilcoxon rank sum test was used for QuickDASH score and SF-36.
- **Paper II:** Data are presented as mean or median according to type of data and distribution. The primary outcome was tested by Student's t-test and a two-sided p-value < 0.05 was considered statistically significant. Statistical tests were made also for pre-determined secondary outcomes and post-hoc complication rate between the groups using the Wilcoxon rank sum test for the QuickDASH and Fischer's exact test for complications. Our sample size calculation, based on a previous study (Kopylov et al. 1999), showed that 17 patients were needed two show a 20% difference in grip strength between the two groups with a power of 85% in a 2-sided test at the level of significance of 5%.
- **Paper III:** DASH outcome data is ordinal with a skewed distribution, thus non-parametric tests were used with medians and interquartile range (IQR) to report the central tendency and variation. In the tables, also mean and standard deviations are presented to enable comparisons with previously published studies. For group comparisons, the Wilcoxon rank sum test was used. A two-sided p-value < 0.05 was considered statistically significant. For multiple group comparisons, the Kruskal-Wallis test was used. Cutoff values for the DASH score were arbitrarily set and the patients divided into 3 groups to reflect the severity of residual symptoms; minor (0–10), moderate (11–35) and major (36–100). The inter-observer reliability of AO type classification was assessed with unweighted Cohen's kappa. A Spearman's rank-order correlation was run to determine the relationship between age and DASH,
- Paper IV: Demographic data were described using frequency and percentage. Continuous variables with normal distribution were presented using mean and standard deviation (SD). Since DASH data are skewed and ordinal, non-parametric tests were used. Median and interquartile range (IQR) was used to describe the central tendency and variation. For paired data, the Wilcoxon signed rank test and for comparisons between groups the Mann-Whitney U test were used. The Chi-square method was used for between-group comparisons and the Kruskal-Wallis test was used for multiple group comparisons. A two-sided p-value < 0.05 was considered statistically significant.

# Results

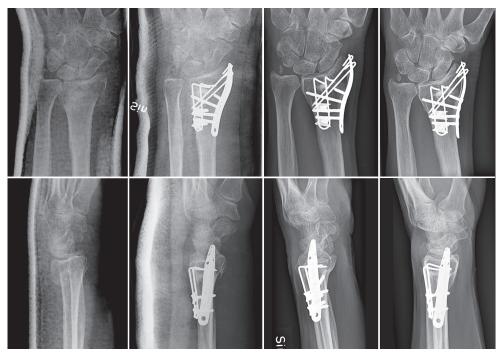
#### Paper I – external versus internal fixation?

#### **Outcome**

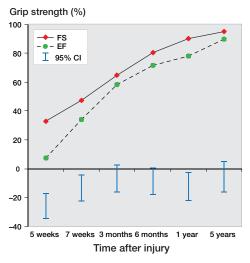
45 of 50 patients attended the clinical examination. The mean follow-up time was 5 years (range 3–7), (radiographs illustrating the development from injury to 5-year follow-up, Figure 7 and 8). The mean grip strength was; 95% (SD 12) of the uninjured side in the fragment-specific group and 90% (SD 13) in the external fixation group (p = 0.3), (Figure 9). Range of motion reached normal values in both groups and was similar between the groups (Figure 10).



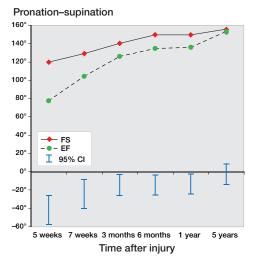
**Figure 7.** 64-year-old woman in Paper I randomized to external fixation. From left to right; at injury, immediate postoperative, 1 year and 5 years postoperative.



**Figure 8.** 65-year-old woman in Paper I randomized to fragment specific fixation. From left to right; at injury, immediate postoperative, 1 year and 5 years postoperative.

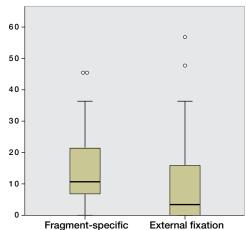


**Figure 9.** Grip strength and the gradual improvement from injury to 5 years. Error bars represent the 95% confidence interval (CI) of the difference between groups.



**Figure 10.** Pronation-supination and the gradual improvement from injury to 5 years. Error bars represent the 95% CI of the difference between groups.

#### QuickDASH at 5 years



**Figure 11.** Similar median QuickDASH in both groups at 5 years. Fragment-specific (n = 24) and external fixation (n = 26), (p = 0.3). Lower whiskers represent min, upper whiskers represent Q3 +  $1.5 \times IQR$ .

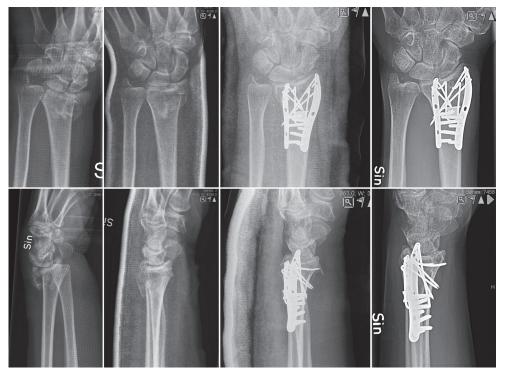
The median QuickDASH score was 9 (0–57) in the 45 patients participating in the clinical examination and 10 (0–34) in the 5 patients who did not attend the clinical examination. Median QuickDASH score was 11 (0–46) in the fragment-specific fixation group and 3 (0–57) in the external fixation group (Figure 11). Of the 50 patients, 27 (54%) patients had none or minor disability, i.e. DASH 0–10, 17 (34%) had moderate disability, and 6 (12%) hade major disability. In the fragment-specific group, 3 patients had major disability with DASH scores of 36, 45, and 45 respectively. In the external fixation group, 3 patients had major disability with DASH scores of 36, 48, and 57 respectively. SF-36 was similar between the 2 groups.

The groups were similar regarding osteoarthritis, radial inclination, ulnar variance, dorsal angulation or radial compression. No patients in the fragment-specific group had distal radio-ulnar joint incongruency compared with 4 patients in the external fixation group (p = 0.05, DASH 0, 0, 0, and 2 respectively).

#### **Complications and reoperations**

In the fragment-specific group 1 patient was reoperated due to symptomatic malunion and 12 patients had pins and/or plates removed after fracture healing, due to nerve irritation or tenosynovitis. In the external fixation group 5 patients were reoperated due to symptomatic malunion, 3 had been operated for carpal tunnel release and 2 for pin tract skin adherence. Thus, no difference was found between groups regarding the total number of reoperations 10 compared with 14 (p = 0.4).

#### Paper II – fragment-specific versus volar locking plates?

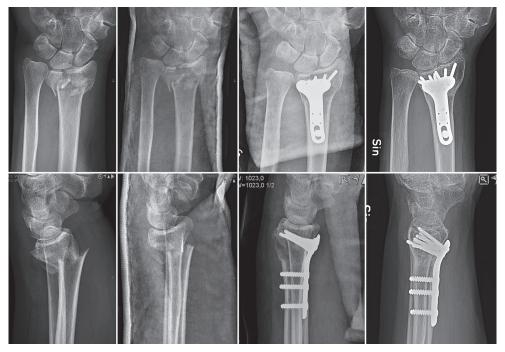


**Figure 12.** 55-year-old woman randomized to fragment-specific fixation. From left to right; before reduction, after reduction, immediate postoperative, and 1 year postoperative.

#### **Outcomes**

No significant difference between the two groups was found, radiographs of one patient from each group illustrating the types of implants used (Figure 12 and 13). The mean grip strength at 12 months, which was the primary outcome, approached normal values in both groups with the mean grip strength 90% (SD 16) of the uninjured side in the volar locking plate group and 87% (SD 13) in the fragment-specific group (p = 0.62). The range of motion approached normal values and was similar between the groups.

The median QuickDASH score normalized in both groups and was similar; 5 (0–68) in the volar plate group and 5 (0–32) in the fragment-specific group at 12 months (Figure 14). In the fragment-specific group none of the patients had major disability with DASH scores above 35. In the in the volar plate group, 2 patients had

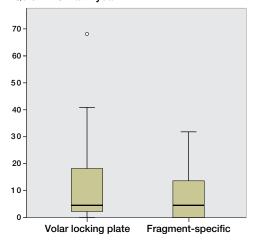


**Figure 13.** 61-year-old woman randomized to volar locking plate. From left to right; before reduction, after reduction, immediate postoperative, and 1 year postoperative.

major disability with DASH scores of 41 and 68 respectively. The generic SF-12 was similar between the 2 groups.

The dorsal angulation was  $-2^{\circ}$  (SD 6) in the volar locking plate group compared with  $5^{\circ}$  (SD 5) in the fragment-specific group, measured on perioperative fluoroscopic radiographs, but the difference was not found at later follow-ups. No other differences were found between groups regarding dislocation, shortening, joint incongruence or rate of healing.

#### QuickDASH at 1 year



**Figure 14.** Similar median QuickDASH in both groups at 1 year (p = 0.4). Volar locking plate (n = 24) and fragment-specific (n = 25). Boxes represent IQR and whiskers min-max. In the boxplot with an outlier (circle), the upper whisker represents  $Q3 + 1.5 \times IQR$ .

#### **Complications and reoperations**

The overall complication rate was greater in the fragment-specific group (52%, n = 13) compared with the volar locking plate group (21%, n = 5) (p < 0.05). Minor complications were registered in both groups. In the fragment-specific group, 3 major complications were registered; 1 complex regional pain syndrome (CRPS), 1 hardware loosening, and 1 extensor pollicis longus (EPL) tendon rupture. The latter was related to plate loosening and was treated with hardware removal and tendon transfer. In the volar locking plate group, the patient that crossed over and was treated with fragment-specific fixation had hardware loosening, which was considered as a major complication and the implant was extracted.

# Paper III – the 1-year subjective outcome in 3,666 patients

Totally 3,666 patients (2,833 women) with a distal radius fracture were included in the register in the period between January 2003 and December 2012. Patients were treated either non-surgically (78%) or surgically (22%). The overall mean age was 62 years (18–98). In the 2,571/3,666 (70%) patients who returned the DASH questionnaire at 1 year, the overall median DASH score was 9 (IQR 2–25, mean 17). Higher median DASH scores were found for women than for men and for patients in the older age group 65–98 years than patients aged 18–64 years old (Table 4). A weak correlation was found between age and DASH ( $r_s = 0.24$ , p < 0.001).

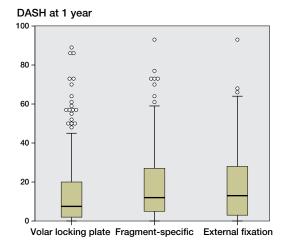
**Table 4.**Demographic data showing the DASH scores 1 year after fracture of the distal radius

	1-yearDASH score			
	n	median (IQR) a	mean (95% CI)	p-value <sup>b</sup>
Sex				
Female c	2,051	11 (2-27)	18 (17-19)	
Male °	520	5 (0–18)	13 (11–14)	< 0.001
Age (years)		, ,	, ,	
18–64	1,323	7 (1–20)	14 (13-15)	
≥ 65	1,248	14 (3-32)	20 (19-21)	< 0.001
Treatment group				
Surgical	633	9 (3-25)	17 (15–18)	
Non-surgical	1,938	9 (2–27)	17 (16–18)	0.5

<sup>&</sup>lt;sup>a</sup> Interquartile range

<sup>&</sup>lt;sup>b</sup> Independent samples Wilcoxon rank sum test between group comparison

<sup>°</sup> Female mean age 64 and male mean age 53



**Figure 15.** Boxplot showing median DASH and IQR in patients treated with the three main types of implants; Volar locking plate (n = 332), fragment-specific (n = 157), and external fixation (n = 105). Upper whiskers represent Q3 +  $1.5 \times$  IQR. Circles represent outliers.

#### Non-surgical versus surgical treatment and outcome

In the non-surgically treated group, the median DASH score was 9 (IQR 2–27), and was 9 (IQR 3–25) also in the surgically treated group (Table 4). Patients operated with the volar locking plate had a better DASH (8 IQR 2–20) compared with fragment-specific fixation or external fixator (12, IQR 5–27 and 13, IQR 3–30; p < 0.004, Figure 15).

The severity of the fracture did influence the outcome and a worse median DASH score was found for patients with AO type C fractures (n = 188) (DASH 11, IQR 4–27), vs. AO type B (n = 36) (DASH 5, IQR 0–13), vs. AO type A (n = 405) (7, IQR 2–18) (p < 0.001). Examples of AO type A, B, and C are illustrated in Figures 16 to 18. No difference was found when dividing the trauma mechanism into high-vs. low-energy fractures.

In the patients with a distal forearm fracture, involving both the distal radius and the distal ulna (Figure 19), a substantially worse outcome of DASH, 23 (IQR 5–41) was found post-hoc.

#### Surgeons experience and outcome

According the local treatment tradition and organization, 4 hand surgeons operated the majority, 500/805 (62%) of the patients, who at one year had a lower median DASH score of 8 (IQR 2–23) compared to DASH 13 (IQR 5–34) in 164 patients operated by 25 general orthopedic surgeons or DASH 13 (IQR 3–32) in 66 patients operated by 17 orthopedic residents.



**Figure 16.** 36-year-old woman in 2003 with an AO type A fracture.



**Figure 17.** 46-year-old man in 2008 with an AO type B fracture.



**Figure 18.** 45-year-old man in 2012 with an AO type C fracture.



**Figure 19.** 60-year-old woman with a distal radius ulna fracture.

#### Outcome and residual symptoms at 1 year

The total cohort of 2,571 patients was divided into 3 groups reflecting the severity of residual symptoms at 1 year. 1,338/2,571 (52%) had no or minor residual symptoms (DASH 0–10), 788/2,571 (31%) moderate (DASH 11–35) and 445/2,571 (17%) major disabilities (DASH 36–100; Figure 20).

Also in the 633 surgically treated patients, a similar distribution of residual symptoms was found at 1 year with 334/633 (53%) having no or minor residual symptoms, 194/633 (30%) moderate, and 105/633 (17%) major disabilities (Figure 21).

# Distribution (%) of all patients in the cohort 100 90 80 70 60 40 30 20 Major 10 Moderate Minor 0 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012

**Figure 20.** All patients in the cohort divided into 3 groups of severity based on the DASH score 1 year after fracture (n = 2,571). Minor residual symptoms (DASH 0–10), moderate (DASH 11–35) and major (DASH 36–100).

#### 

**Figure 21.** All surgically treated patients divided into 3 groups of severity based on the DASH score 1 year after fracture (n = 633). The volar locking plate was in routine use from 2006.

#### Non-responder analysis

In total, 1,095 (30%) patients did not return a correct DASH questionnaire 1 year after the fracture. A non-responder analysis was made and showed that the non-responder group peaked both in the younger and the very old age groups, contained a higher proportion of men, and consisted of larger proportion of non-surgically treated patients. Similar response rates were found in the surgically treated patients regarding AO-type, however high-energy fractures had more non-responders than low-energy fractures.

# Paper IV – long-term follow-up of patients with inferior outcome

The long-term follow-up questionnaire of patients scoring DASH >35 at 1 year was returned by 269 (77%) of the 346 invited patients. Patients received the questionnaire 2–12 years after the fracture with a mean follow-up time of 5.5 years.

DASH score

100
90
80
70
60
50
40
30
20
10 Improved
Not improved
12 months
2-12 years

**Figure 22.** Median and IQR DASH at 12 months for the group that later improved and the group that did not improve. At the 2–12 year follow-up, 127 (47%) improved to DASH ≤35, while 142 (53%) continued to have high DASH scores >35. Whiskers represent min–max. In the boxplots with outliers (circles), upper whiskers represent Q3 + 1.5 × IQR.

73 patients (27%) had been treated surgically and 196 (73%) non-surgically. The mean age was 55 for men (range 18–83) and 66 for women (range 22–93).

#### Did the patients improve over time?

A significant improvement was found for the whole cohort, improving from a median DASH score of 50 (IQR 43–61) to 36 (IQR 20–55), from 12 months to long-term follow-up (p < 0.001). Men improved more than women, from median 52 at 12 months to 25, compared with women who improved from median 50 to 39 (p = 0.002).

In 127 of 269 (47%) patients, the DASH score was better at the follow-up than the cut off limit of  $\leq$ 35 used to indicate severe disability (Figure 22). Only 34 of these 127 patients reached a DASH score between 0 and 10 indicating minor disability and more than half, 142/269 patients (53%), still had a DASH score exceeding 35. The mean age was similar for patients that improved or continued to have high DASH scores >35.

#### Non-responder analysis

77 of the 346 patients did not return the DASH questionnaire at the follow-up. 39 of these patients or their relatives declined participation due to dementia, severe illness or old age. 38 patients did not reply. The mean age at follow-up was similar for the responders and non-responders, 70 (range 26–97; SD 14) and 72 years (range 22–96; SD 18) respectively.

# Discussion

#### Overall perspective

In the short perspective the outcome after a distal radius fracture (DRF) can be considered to be good. The median DRF patient has a DASH score of 18 (Abramo et al. 2008a) at 3 months, indicating intermediate disability according to our definition. At 6 months, 63% of the patients have no or minimal pain (MacDermid et al. 2003). After 12 months, the DRF patients as a group is considered to have minimal pain and good function with minor restrictions in their activities of daily living (MacDermid et al. 2003), and a median DASH of 7.5 at 12 months (Abramo et al. 2008a). As a group, however, the patients still have not reached the level of an age- and sex matched group of uninjured patients (median DASH 2.5) (Abramo et al. 2008a) and when approximately 17–21% reported moderate to major disability as long as 12 months after the injury, it could be argued that the outcome of a DRF is not as favorable as commonly anticipated (**Paper III**)(MacDermid et al. 2003). Especially, as shown in **Paper IV**, it appears that only a small proportion of the patients with major disability after one year will ever reach pre-fracture status even in the long-term.

The incidence of DRF in Scandinavia appears to have decreased slightly after the turn of the 20th century (Brogren et al. 2007; Sigurdardottir et al. 2011; Rosengren et al. 2015). The reason is unknown, but the trend is promising. With the life expectancy increasing in Sweden, for both women and men, (Statistics Sweden, Demographic reports, The future population of Sweden 2006-2050), the total number of fractures, however can be expected to increase and the burden on society to increase. The treatment of a DRF has changed in the last decades with new techniques, and with a larger proportion of patients being treated surgically (Chung et al. 2009; Mattila et al. 2011; Wilcke et al. 2013; Mellstrand-Navarro et al. 2014). One would have hoped that the outcome would have improved, at least for the surgically treated group, but the proportion of patients with an unfavorable outcome in the register study in Paper III remained unchanged. There may be several explanations to why the median DASH or the proportion of patients with high DASH scores remained unchanged over the decade. The instrument might not be sensitive enough or designed to minor changes, the DASH score for patients with poor outcome has already reached the ceiling, and finally these patients would maybe have ended up with poor outcome regardless of treatment due to comorbidities or psychological reasons. Or, the change in treatment simply has no effect on a population level.

#### Surgical treatment of unstable DRF

A fracture can be unstable depending on age, the initial displacement, metaphysal comminution, intra-articular involvement, angulation or axial compression (Abbaszadegan et al. 1989; Lafontaine et al. 1989; Mackenney et al. 2006; Wadsten et al. 2014; Walenkamp et al. 2015). Due to the properties of the fractured bone, a cast only provides relative stability (Mackenney et al. 2006). In fractures reduced and treated with cast in acceptable anatomical position; (<10° and <5 mm radial shortening), only 50% will remain within an acceptable position at 1 week and not more than 30% at 5 weeks (Earnshaw et al. 2002). In a more recent publication, with acceptable position; (<10° dorsal tilt, <20° volar tilt, >10° radial tilt, <2 mm ulnar variance, and <2 mm intra-articular step off), 31% of fractures in acceptable alignment at 10 to 14 days continue to displace and 64% of all fractures will have displaced at the 3-month follow-up (Wadsten et al. 2014).

The anatomy can be restored with surgery but the surgical methods differ regarding the capacity to *maintain* the reduced fracture's position during healing. With closed or limited open reduction plus pinning, a good position can be achieved, but secondary loss of position may occur (Cooney et al. 1980). The stability using external fixators with or without pinning is achieved only by indirect fixation, and the reduced position less likely to be maintained than in open fixation and internal fixation (Karantana et al. 2013). Using open reduction and plate fixation, an anatomic position can be achieved and maintained also in patients with poorer bone quality (FitzPatrick et al. 2012), but with an increased morbidity due to the open surgery and specific complications (Mathews and Chung 2015). In the last decades new theories and new technology have made it possible to design surgical implants allowing for stable durable anatomic fixation (Konrath and Bahler 2002; Orbay and Fernandez 2002). No evidence exists, however, that these improved techniques matter for the subjective outcome for the patients.

#### Fragment-specific versus external fixation

Almost simultaneously two implants based on the three-column theory came to market (Medoff and Kopylov 1998; Rikli and Regazzoni 1996; Konrath and Bahler 2002; Rikli et al. 2003). The implants were intended for minimal invasive technique and made it possible to address the individual fragments of a comminuted fracture. Pins, wire-forms, and small plates held the distal fragments and were attached to the intact radius proximally. Implants were designed specifically for the volar and dorsal lip fragments as well as for the radial styloid, and allowed open surgery also for the shattered comminuted fracture. These fractures had previously been treated

by closed reduction and external fixation or pinning. In choosing an open technique the risk of surgical complications increased but, on the other hand, the chances of achieving better reduction, and in particular maintained fixation during healing, were better. To evaluate whether the new technique not only would improve the radiographic outcome, but also the subjective outcome, a randomized trial was designed comparing the open fragment-specific fixation and the traditional closed external fixation technique (Abramo et al. 2009). The primary outcome variable, grip strength, was shown to be better in the fragment-specific group, as late as 12 months after the fracture (90% versus 78% of contralateral, p = 0.03). Also secondary variables as pronation-supination were found to be better using the fragment-specific fixation ( $149^{\circ}$  versus  $136^{\circ}$ , p = 0.03), as was a tendency of more malunions in the external fixation group. The subjective outcome, as measured with median DASH was 5 for the fragment specific versus 6 in the external fixation group (p = 0.2). In **Paper I**, we investigated at long-term, mean 5 (3–7) years after the fracture, whether internal fixation remained superior over time. At the long-term follow-up, grip strength and pronation-supination had improved in both groups, and a difference, if still existing, was not significant anymore. Other authors have found similar gradual improvement in grip strength after the first year (Brogren et al. 2011a). Seemingly, due to the prolonged immobilization and initial stiffness after an external fixation of the wrist, it takes long time for grip strength and forearm rotation to normalize. Further, even though 3-5 years had passed since the fracture, the median DASH score (fragment-specific group 11 (range 0-46); external fixation group 3 (range 0-57)) had not reached the median pre-injury measured level of DASH, which in the fragment-specific group was 0 (range 0-26) and the external fixation group 0 (range 0–44), respectively.

#### Internal or external fixation

Several studies imply that internal fixation of distal radius fractures results in better grip strength (Abramo et al. 2009; Jeudy et al. 2012; Karantana et al. 2013), better range of motion (Egol et al. 2008; Abramo et al. 2009; Wilcke et al. 2011; Williksen et al. 2013; Navarro et al. 2016), and better anatomical reduction (Wei et al. 2009; Wilcke et al. 2011; Karantana et al. 2013; Williksen et al. 2013; Roh et al. 2015; Navarro et al. 2016), but only few report better patient reported outcomes (Wei et al. 2009; Wilcke et al. 2011) when compared to external fixation or percutaneous pinning. Although no differences in patient reported outcome were shown in the individual series, an improvement is seen when the data is pooled as in recently published meta-analyses, in which internal fixation has been compared with external fixation. The improvement in patient reported outcome was significant up to a year after fracture, also better range of motion and better anatomic restoration were

found (Cui et al. 2011; Wei et al. 2012; Esposito et al. 2013; Walenkamp et al. 2013; Wang et al. 2013; Xie et al. 2013; Li-hai et al. 2015).

Only few randomized studies comparing external fixation to internal fixation have longer follow-up than one or two years, probably due to the difficulty in keeping patients in the trials for a longer time. In Paper I, 45/50 (90%) of the randomized patients attended the long-term follow-up and all 50 patients returned the outcome questionnaire. In an older randomized study on 90 patients with a displaced distal radius fracture, the mean follow-up was 4 years, comparing three treatment methods; closed reduction and cast, external fixation, and open reduction and internal fixation with small non-locking T-plates and percutaneous K-wire. The authors' main results were better radiological position, good functional outcome and better grip strength in the external and internal fixation groups (Kapoor et al. 2000). The group treated with reduction and cast scored lower functional scores, poorer radiographic outcome as well as lower grip strength. Only one randomized long-term follow-up has compared closed reduction and external fixation with adjuvant K-wires with open reduction and volar locking plates (Williksen et al. 2015). 104/114 (91%) patients attended the 1 year and 91/113 (77%) the 5-year follow-up. The volar locking plate group had better range of motion (supination) at 1-year, but no difference was found at 5 years. Both treatment methods achieved good subjective, objective and radiographic outcome.

## The volar locking plate

Towards the end of the recruitment period during the first randomized, prospective trial between the fragment-specific fixation and external fixation (Abramo et al. 2009), a new type of fixation of wrist fractures appeared. The volar locking plate was introduced in 2002 (Orbay and Fernandez 2002) and quickly became popular both in Sweden and internationally. The concept was introduced without any evidence or comparing studies (Orbay and Fernandez 2004; Margaliot et al. 2005). The first study to compare the volar locking plate to the fragment-specific fixation was a biomechanical cadaver study, which found stability to be equivalent between the two (Taylor et al. 2006). In a prospective but non-randomized clinical study, the volar locking plate was compared to the fragment-specific fixation and the authors found the volar locking plate to be more stable (better dorsal angulation and retained radial length), provide better objective and subjective outcomes in the early postoperative period and having have less complications (Sammer et al. 2008). The volar locking plate has never been compared to fragment-specific fixation in a randomized clinical trial (RCT). An RCT is considered to be best practice in evidence-based medicine, but is resource consuming (Moher et al. 2010).

In **Paper II**, an RCT was designed and performed with grip strength as primary outcome to evaluate if the results of the fragment-specific fixation could be further improved, which had been proven superior to external fixator in the previous series (Abramo et al. 2009). However, at the 1-year follow-up, no difference was found, but instead the results were very similar and both groups presented with excellent grip strength approaching normal values.

In the volar locking plate group the grip strength was 90% of the contralateral side versus 87% in the fragment-specific group. The grip strength ratios in both groups thus were similar to the 90% found in the fragment-specific group at 1 year, in the first randomized study (Abramo et al. 2009). And as comparison, the group of patients in the external fixator group had 78% grip strength after 1 year and reached 90% first at the late follow-up in **Paper I** 3–7 years after the fracture.

All other secondary measurements also showed similar results for the two groups, in **Paper II**. There were no significant differences in the objective, subjective or radiographic outcome at 1 year. Both groups had similar and good subjective outcome, with median DASH scores of 5 in both groups, ranging from 0 to 68 in the volar locking plate group and from 0 to 32 in the fragment specific group.

In the fragment-specific group none of the patients had DASH scores above 35, the cutoff for major disability. In the volar locking plate group 2 patients had DASH exceeding the cutoff. One patient had a DASH score of 41 after 1 year and was the only patient involved in a true high-energy injury, a motorcycle accident. The other patient had a DASH score of 68 and was the only patient with multiple comorbidities, known to correlate with higher DASH scores (FitzPatrick et al. 2012).

Although, DASH in both randomized studies in this thesis failed to show a difference between the groups, the DASH still can be useful. With similar, almost identical results of two implants, like in **Paper II**, the rate of complications becomes increasingly important. By using DASH we find the individuals in which our treatment fail. We can analyze the causes and identify measurement to avoid the complications causing the high score in our future patients. We can adjust the rehabilitation protocol or identify early problems like pain or swelling. The rate and type of complications found using a particular technique can also help us to judge which treatment method is the best for a certain fracture or patient group.

## Complications and reoperations

In the report preceding **Paper I** (Abramo et al. 2009), the complications were classified as minor (transient), moderate (transient after intervention) and major (chronic) complications. At 12 months more major complications with external fixation was noted (5 symptomatic malunion, 1 fractured metacarpal bone, 2 CRPS) compared with fragment-specific fixation (1 symptomatic malunion and 1 CRPS, p = 0.04).

While the total number of complications appeared higher in the external fixation group (n = 29 vs. n = 21, p = 0.3), no significant difference was found. In **Paper I**, reoperations were reevaluated beyond the 12 months reported in the original study. In the external fixation group, 8 reoperations occurred during the first year (5 osteotomies and 3 carpal tunnel releases) and in addition, 2 operations were carried out after the first year for skin adherence caused by the external fixation pins. In the fragment-specific group 5 reoperations occurred during the first year (1 osteotomy, 1 tenosynovectomy, 3 extractions of osteosynthesis materials) and another 9 hardware extractions after the first year. In total, during the entire period there were 14/26 (54%) reoperations in the fragment-specific group compared with 10/24 (42%) in the external fixation group, both rather high numbers. To our knowledge only one other long-term follow-up of a randomized study has reported reoperation rates for as long after primary surgery as in Paper I. In a randomized study comparing open reduction and volar locking plate to closed reduction and external fixation in unstable distal radius fractures the outcome from the 1-year follow-up (Williksen et al. 2013) was further studied at a 5-year follow-up (Williksen et al. 2015). Comparisons between studies are difficult, but at the 5-year follow-up, 16/52 (31%) reoperations had occurred in the internal fixation group and 10/59 (17%) in the external fixation group respectively. Hardware extraction was the most frequent reason for reoperation.

In the internal fixation group (n = 16) of Williksens report, 11 volar locking plates (VLP) were removed due to surgical technical complications (6 at 1-year follow-up and 5 at the long-term follow-up) and 4 volar locking plates were removed due to patient request (2 at one year and 2 at the long-term follow-up) and finally, 1 patient had early secondary surgery with reconstruction of the ulnar styloid process. Of the patients with hardware removal in the volar locking plate group, 2 also had EPL ruptures due to prominent screws. In the external fixation group (n = 10); 5 patients had minor surgery due to scar contractures, 2 had CTS release, 1 had early fixation-failure with external fixation and were reoperated with a volar locking plate. One patient was reoperated due to incomplete reduction and 1 patient in the external fixation group also had been treated with a dorsal plate and the dorsal plate removed due to loosening. Thus, results were similar compared to our long-term follow up regarding repeat surgery.

Patients treated with external fixation will need pin treatment, and are more prone to superficial wound infections, as found at 1-year (3/24 compared with 0/26 (Abramo et al. 2009). The high frequency of pin track infections in external fixation has also been shown in other studies (Ahlborg and Josefsson 1999; McKay et al. 2001; Anderson et al. 2004; Margaliot et al. 2005; Mathews and Chung 2015). All patients treated with external fixations need removal of pins, which can be painful. However, pin removal can be made without analgesia, correction of scars or adherence loosening in local anesthesia, whereas plate removals, have to be performed as a full operation with anesthesia or a block.

In **Paper II**, the study protocol included a predefined list of complications (Appendix III) to be filled out at follow-up visits. Such a list should be part of the basic protocol before launching a RCT. Minor complications were defined as transient problems, considering not to affect the final outcome, while major were severe complications considered to influence the final outcome.

Minor complications, such as carpal tunnel syndrome, were diagnosed with two patients in each group and both resolved spontaneously without operative treatment. A transient radial neurapraxia was the most common minor complication in the fragment-specific group (6 patients) compared with the volar locking plate group (1 patients), and all cases resolved within the year. 1 patient had mild tendinitis and 1 patient had skin adherence in the fragment-specific group and all mentioned cases were considered as minor complications.

Major complications were few. One patient in the fragment-specific group developed a CRPS, which resolved with intense exercise during the first year. In the volar locking plate group one plate loosened and was removed. This patient was actually treated with fragment-specific fixation instead of the allocated treatment, since it became clear intra-operatively that the fracture was distal to the watershed line and not able to fix with a volar locking plate. Alternatives to the techniques in **Paper II**, using newer treatment options addressing the volar rim fractures with volar hook plates might be a better method (O'Shaughnessy et al. 2015). In the fragment-specific group, 2 patients had hardware loosening, but only 1 patient had the radial pin plate removed and at the same time as a concomitant EPL rupture was treated by tendon transfer. All 3 patients had good grip strength, (range 88% to 95%), similar to the other patients and a 1-year DASH score of 14–23.

The overall complication rate in **Paper II**, however, differed between 21% in the volar locking plate group and 52% in the fragment-specific group. Due to a lack of a unanimously accepted definition of minor, major or overall complications, comparisons between studies are difficult, but similar 1-year complication rates have been reported in other studies. Karantana et al. found no statistically significant difference; 24% overall complications in the volar locking plate group and 42% in the external fixation group (Karantana et al. 2013). Williksen et al. found no difference; 29% overall complications in the volar locking plate group and 31% in the external fixation group (Williksen et al. 2013). Navarro et al. found a 51% overall complication rate in the volar locking plate group compared with to 45% in the external fixation group, without no statistical difference (Navarro et al. 2016).

#### Evaluating outcome – a multifaceted aspect

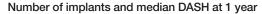
The patient outcome after a DRF is multifaceted. We still believe that the outcome is best evaluated using both objective and subjective outcome measures (Karnezis

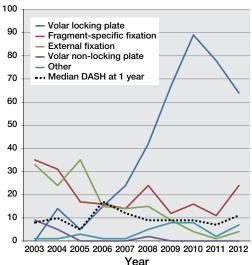
et al. 2005; Földhazy et al. 2007; Wilcke et al. 2007; Changulani et al. 2008). However, the patient reported outcome instruments of today may be able to discriminate between the outcome after a DRF after 3 versus 12 months or between before and after an osteotomy, but these instruments are too blunt to tell the difference between two implants which already result in good but maybe not excellent results. Grip strength was used as the primary outcome parameter forming the basis for the sample size estimation in previous studies (Kopylov et al. 1999; Abramo et al. 2009) as well as in Paper I and Paper II. Grip strength was found to be a consistent and reliable outcome measure and seemingly a good surrogate variable for pain. But it appears that the result of the surgery has reached a level that is going to be difficult to surpass. If one has the intention to show another new method to be even better and alternative designs probably then has to be chosen. Using the data from **Paper II** resulting in a 3% difference in grip strength, a study on 420 patients in each treatment arm would be needed to show an incremental 3% improvement with 85% power. Maybe the limit has been reached for one small size single-center randomized study to show a significant difference in subjective or objective data, and meta-analyses are needed instead, or registers consisting of several thousand patients as in the hip and knee arthroplasty communities. Maybe we need to focus on minimizing the number of patients with poor results instead of trying to improve the mean and median values of subjective and objective measurements. Maybe other methods are needed, using wearable and automated measurements system to collect data and using artificial intelligence and mathematical algorithms to find the patterns.

## The distal radius fracture – outcome over 10-years

In the clinical randomized studies, grip strength was used as primary outcome measure, and found normalizing at 1 year. The DASH scores were low in the patients treated with internal fixation. Patients treated with external fixation also reached normal grip strength, but later. These conclusions are all based on the result of the median patient and in this next chapter we try to use our hospital-based distal radius fracture register to give a broader view of all the DRF patients during a 10-year period. The 1-year DASH score of patients included in the register between January 2003 and December 2012 was used. During the 10-year period a shift in the choice of surgical implant occurred, as reflected by the two previously reported randomized studies (Abramo et al. 2009; **Paper II**). No longitudinal registry study has evaluated if and how the subjective outcome of distal radius fractures during this shift.

In **Paper III**, 2571/3666 (70%) patients with a distal radius fracture returned a correctly filled out DASH questionnaire at 1 year. The median DASH was low with a score of 9 (IQR 2–25, mean 17). This is similar to the median DASH score of 7.5

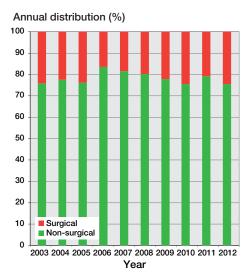




**Figure 23.** The 1 year DASH and types of implant used during the study period (n = 805). A randomized study between external fixator and fragment-specific fixation was conducted 2002–2005 and between fragment specific fixation and volar locking plate 2010–2012.

(IQR 1.7–25) (mean 16) reported in the first report of the patients included between September 2001 and August 2003 (Abramo et al. 2008a), evaluating the treatment protocol used for distal radius fractures. Normative data exist for DASH in a population without a DRF. In a representative US population of 1800 patients, older than 18 years (Hunsaker et al. 2002), the normative values were median 4 (IQR 1–13) and mean 10.1 (SD 14.7) for DASH and median 4.5 (IQR 1–14) and mean 10.9 (SD 15.3) for QuickDASH (The DASH and QuickDASH - Outcome measures e-bulletin fall 2012). The developers of the DASH, the American Academy of Orthopedic Surgeons and the Institute for Work and Health in Toronto, Canada, suggested that a DASH score of less than 10 should be aimed for when evaluating outcome. In **Paper III**, 1,338 patients (52%) reported DASH-values between 0–10, which could be considered as a good result 1 year after a distal radius fracture and a return to pre-fracture status.

In **Paper III**, low and almost identical DASH scores were found for both non-surgically (median 9, IQR 3–25) and surgically (median 9, IQR 2–27) treated patients. The result supports that the treatment protocol (Abramo et al. 2008a) still is valid and that most patients reach an acceptable or good outcome at one year after a distal radius fracture. The non-surgical treatment has largely been unchanged during the period. In contrast, the surgical technique and the choice of implants at the operating hospital has changed during this period, from external fixators (42%) and fragment-specific plates (45%) in 2003, to predominantly volar locking plates (65%) in 2012 (Figure 23). There was no radical improvement in the 1-year median DASH.



**Figure 24.** Relative proportions of nonsurgical treatment (n = 2,861) and surgical treatment (n = 805) in the period 2003 to 2012.

The change in choice of implants appears to be ubiquitous during this period and other centers have noted a similar shift from external to internal fixation, on a regional level (Stockholm 2004 to 2010; Wilcke 2013), on a national level (Sweden 2005 to 2010; Mellstrand-Navarro 2014), on a Scandinavian level (Finland 2003 to 2008; Mattila 2011) and internationally (USA 2000 to 2004; Chung 2009). The shifts occurred without any support from randomized studies, and although with somewhat conflicting results, the recent meta-analyses appear to provide some evidence for a better outcome of unstable distal radius fractures treated with internal fixation instead of external fixation. In a systematic review of the published meta-analyses of the volar locking plate, it is even concluded that a significant lower DASH, a better volar tilt and radial inclination, and a lower infection rate is found at one year with the internal fixation compared with the external fixation (Zhang et al. 2016).

In **Paper III**, the mean rate of surgical treatment was 22%, which remained unchanged over the 10-year time period (Figure 24). In a Swedish national perspective, the rate of surgical treatment of distal radius fractures increased from 16% in 2005 to 20% in 2010 (Mellstrand-Navarro et al. 2014)

Even if the change of implants did not change the outcome and even if surgically and non-surgically treated patients achieved the same outcome, a difference in outcome was found, related to the experience of the surgeons. Thus, with a small group of dedicated surgeons with special interest in wrist fractures treating a large volume of patients a better subjective outcome in a cohort can be expected, and by speculation thereby reducing complications.

To better understand the outliers and not only analyze the median patient outcome, we divided the whole cohort of 2571 patients into three groups regarding residual symptoms and outcome; "the good, the bad and the ugly". We chose DASH 0-10 as a level of minor, 11 to 35 as moderate, and 36 to 100 as major residual

symptoms. The level 0 to 10 was based on the normative values for DASH and the level >35 was based on two studies of radial osteotomies due to malunion, in which the median DASH score was 39 (range 2–63) (Abramo et al. 2008b) and median 35 (range 22-61) (Abramo et al. 2010). The assumptions have some support from the founders of the DASH questionnaire who have not fully established cutoff limits for DASH, but suggested some tentative levels (DASH/QuickDASH e-Bulletin Summer 2013). Patients with a DASH score 10–29 are "aware of their upper-limb limitations but do not consider them a problem" and patients with a DASH score 40–69 are patients "having a lot of difficulty".

Approximately half of the patients, both surgically (52%) and non-surgically (53%) treated patients, ended up with a DASH between 0-10, i.e. with minor disabilities and on par with the normative values of an unfractured population. The proportions of patients with moderate disability (DASH 11–35) were similar (30%). Major disabilities (DASH 36–100) were found in 17% in non-surgically or surgically treated patients. In another cohort study of 129 patients (56% non-surgically and 44% surgically treated), 21% had moderate to severe disability, evaluated with PRWE, 1 year after a distal radius fracture (MacDermid et al. 2003). So even if the vast majority of the fractured wrist, regardless if surgically or non-surgically treated, at some remote period again will enjoy an almost perfect freedom in all its motions, and be exempt from pain, a rather large proportion (17–21%) still have major disabilities as late as 1 year after a distal radius fracture.

The selected cutoff levels of DASH into minor, moderate, and major residual disability after a distal radius fracture in **Paper III**, are presumably both valid and helpful to clinicians in evaluating patient related outcome and predicting patient outcome. The PRWE questionnaire has been shown to be more responsive than the DASH questionnaire in a study over a 6-month period in recovery after distal radius fractures (MacDermid et al. 2000) and slightly more responsive in another study over a six-month period in patients with hand and wrist problems (MacDermid and Tottenham 2004). However, both the DASH and PRWE can be used as a screening tool to find patients with poor outcomes in the months after a distal radius fracture. Especially if a patient continues to report a high DASH score over months the patient should be summoned for an outpatient visit to identify any complication of the non-surgical or surgical treatment, like CRPS, tendinitis, CTS or tendon rupture.

#### Limitations

A response rate of 70% in a patient-reported outcome after a distal radius fracture with no upper age limit was considered acceptable. The shift in 2008, replacing the 30-item DASH with the 11-item QuickDASH, increased the response rate from 66% to 73%. In comparison, 79% replied in a nationwide patient-reported outcome study of 4467 patients with displaced femoral neck fractures (Leonardsson et al. 2013). These patients were retrospectively identified and an outcome questionnaire was

mailed at mean 14 (7–22) months after the fracture. Patients included in the prospective wrist fracture register study (**Paper III** and **Paper IV**) received the DASH questionnaire at 3 and 12 months. In an attempt to analyze the non-responders, the patients were subdivided into three groups where an increased amount of both young (<40) and very old (>80) patients were found among the non-responders. Likely, some of these very old patients had died, although only 1 year had passed since their fracture. Further, more non-responders were found in the male cohort as well as in the non-surgically treated cohort.

#### The most dissatisfied patients – can they improve?

The overall outcome after a distal radius fracture is good, but still 17-21% will report a poor outcome at 1 year after the fracture. In **Paper IV**, the long-term overall improvement in patients with major disability was found to be significant. The median DASH decreased from 50 (IQR 43-61) at 12 months to 36 (IQR 20-55) at the 2–12 year follow-up, p <0.001), a quite substantial decrease. Seemingly, time from injury to follow-up can be a sole factor for improvement of subjective outcome. In a long-term retrospective study of 260 patients with non-surgically treated distal radius fractures (Finsen et al. 2012), the DASH score was higher in the group in which 2.5–4 years had passed since the fracture (DASH mean 17), as compared to the group in which 10-13 years had passed (DASH mean 8). Others authors have found spontaneous improvement in DASH over time. In a prospective population-based cohort study of 49 female patients aged 50-75 years with a non-surgically treated distal radius fracture (Brogren et al. 2011a), a trend was found of median DASH improving from 14 to 8, between 1 year and 2-4 years. Interestingly, a greater improvement was found in a subgroup of patients with moderate/severe malunion (defined as: radial shortening of ≥3 mm and/or dorsal angulation >15°), in which DASH was 20 at 1 year after fracture compared with 10 at 2-4 years after fracture.

Although, in **Paper IV**, 127/269 (47%) improved spontaneously after mean 5.5 years (2–12), to a level below the cutoff of major disability (DASH >35), more than half 142/269 (53%) of the patients continued to experience major disabilities. Of all the 269 patients with high DASH scores at 12 months only 13%, a surprisingly small proportion of the patients, returned to an estimated pre-injury level of DASH ≤10. Since the incidence of distal radius fractures is high, a considerable number of patients will suffer from pain and disability and not return to the level prior to the injury. The objective should be to prevent or minimize the number of patients with inferior outcome after a distal radius fracture as early as possible, thereby reducing the amount of avoiding post-operative complications such as swelling, pain, infection, malunions or other reasons.

#### Limitations

All adult patient ages were included. Very old patients tend to score higher DASH scores (Klum et al. 2012) as well as patients with osteoporosis and comorbidities (FitzPatrick et al. 2012). We found a high mortality rate in the patients with major disability. 22% (346/445) of patients with major residual symptoms died between the 12-month follow-up and the 2–12-year follow-up. If this is higher in patients with a high DASH value or not has not been evaluated. A high mortality rate in the years after a distal radius fracture, has been reported and an increased Standardized Mortality Ratio in women >70 year at 5 years after a distal radius fracture, but not in men (Øyen et al. 2014).

#### Strengths and weaknesses

#### Paper I

Long-term follow-up comparative studies of external fixation and internal fixation are scarce, but are important to understand the outcome in the longer perspective. Improvement in the clinical evaluation regarding blinding of scars could have minimized the risk of evaluation bias.

#### Paper II

Randomized controlled trials comprise the highest level of evidence. Despite this, only few randomized trials have compared two methods of internal fixation for treatment of DRF. By including both primarily non-reducible as well as secondary redisplaced DRF the results can be generalized. The patients did not undergo blinding at the follow-up clinical visit, which might have biased the clinical evaluation performed by four of the five authors. Little time to inform the first patient coming for surgery in the mornings resulted in eligible patients not being included in the study.

#### Paper III

The prospective register study is the largest and longest of its kind analyzing the subjective outcome in patients with distal radius fractures. In a decade of treatment shift, the treatment algorithm for wrist fractures is still valid; both non-surgically and surgically treated cohorts had similar low (good) median subjective outcome values over the period one year after fracture. Initially, almost one-third did not respond

to the 1-year DASH questionnaire, but by using the shorter form the non-response rate was reduced. Very old patients are likely to score higher due to co-morbidities.

#### Paper IV

Little is known regarding the subjective improvement over time in patients with a distal radius fracture, and even less in patients with major residual disability. Half of all patients improve after the first year, but still a large number of patients have persistent pain and disability after 2–12 years. More than one fifth of these patients were deceased at the long-term follow-up; another one fifth did not respond the questionnaire. Nevertheless, this group of patients with poor outcome needs to be drawn into focus.

# Conclusions

- **Paper I:** Grip strength and ROM continues to improve and approached normal values after mean 5 years, both in patients operated with closed reduction and external fixation or open reduction and internal fixation.
- **Paper II:** In 50 patients with a primarily non-reducible or secondarily redisplaced distal radius fractures the functional and subjective outcome after 1 year was good, regardless of being treated by volar locking plates or fragment-specific fixation both achieve.
- **Paper III:** The subjective outcome of the whole adult distal radius fracture cohort remained unchanged over a 10-year-period 2003–2012, using the data from the Lund Wrist Fracture Register. About half of the patients returned to a pre-fracture state (DASH 0–10) but up to one sixth reported severe residual disability (DASH >35). There was a radical shift in the choice of implant but the proportion of surgically treated fractures remained the same over the 10-years time period.
- **Paper IV:** In patients who reported severe residual disability (DASH >35) at 1 year, a modest improvement over time could be expected. Half of the patients continued to have major disability for the following 2–12 years and only 13% returned to pre-fracture status (DASH 0–10). Age at time of fracture and sex seemed to affect the outcome, with greater change of improvement if the patients were younger and male.

# Future perspectives

The distal radius fracture continues to challenge physicians and cause morbidity in a large number of patients every year.

#### Lessons learned from the thesis was:

- The DASH outcome questionnaire is a good and useful instrument in screening
  and identifying patients with poor outcome. It is not a very sensitive tool for a
  randomized study comparing two similar methods of treatment with already good
  results. We need sharper instruments to evaluate outcome.
- 17% of patients having major residual symptoms after a distal radius fracture is not acceptable. The future aim must be to prevent complications early to improve long-term patient satisfaction.
- A complication rate between 20–50% is a too high and a future aim must be to reduce the complications in both the surgically and non-surgically treated patients.
- 4% of the patients had a combined distal radius-ulna fracture. These patients had
  a significantly worse outcome, regardless if they were treated non-surgically or
  surgically. A future aim is to improve the treatment of this type fracture.
- A long-term follow-up is planned of the randomized trial in paper II comparing fragment-specific fixation with volar locking plates.

# Summary

#### Background

Most distal radius fractures are treated in a similar way as 200 years ago with reduction and cast splinting. To cite the "founding father" of the distal radius fracture treatment, Abraham Colles "...the limb will at some remote period again enjoy perfect freedom in all its motions, and be completely exempt from pain...". For most patients (in the register study at least half) this is true, but even after all these years, with hopefully improved treatment, there is a proportion of patients not satisfied with the end result. Since this fracture is one of the most common fractures, and with an ageing population, even a small percentage will add up to a substantial number of patients with poor outcome, and improvements will result in improved quality of life for a substantial number of patients on a yearly basis.

The main objective in the research and treatment of this common fracture must be to identify risk factors for poor outcome and prevent these before developing into complications. The purpose of this thesis was to analyze the result of the treatment at our hospital; both at a population level using a DRF register, as well as to contribute to the basis of evidence by evaluating the newest methods of surgical treatment.

#### Methods

In **Paper I**, a mean 5 years follow-up was performed of a randomized study between an external fixator and the fragment-specific open fixation in the treatment of unstable distal radius fractures. The initial 1-year follow-up had shown better grip strength and range of motion. The aim was to analyze whether or not the difference would persist over time.

In **Paper II**, the best method at 1 year in paper I was compared with the popular new volar plate in a randomized trial. Primarily non-reducible or secondary redisplaced distal radius fractures were included and outcome was measured using objective and subjective measures. The follow up time was 12 months. The aim was to find out if treatment could be further improved by the new method.

In **Paper III**, we conducted a retrospective epidemiological analysis of a 10-year period between 2003–2012 of our prospective and consecutive distal radius registry.

In the register, patients aged 18 years or more with a distal radius fracture, presenting at our hospital, were included in the database. The patients received a validated subjective outcome form (Disabilities of Arm Shoulder and Hand/DASH) at the time of injury and at three and twelve months after the fracture. The patients' records and radiographs were scrutinized, treatment recorded, and the fractures were classified according to the International Classification of Diseases (ICD-10), for type of surgery, AO fracture type, high or low energy, and time from fracture to surgery. The DASH scores at 12 months were analyzed over the 10-year-period. The aim was to find out if the subjective outcome changed over the 10-year-period.

In **Paper IV**, the group of patients with the highest (worst) DASH scores were followed up. Patients were sent a new DASH form 2–12 years after the fracture. The aim was to analyze if patients with elevated DASH-scores would normalize over time.

#### **Results and Discussion**

**Paper I**: Even if grip strength and pronation-supination was superior 1 year after surgical treatment in the cohort treated with fragment-specific fixation, the difference was no longer statistically significant at the 5-year follow-up. Both treatment groups improved and had almost normal grip strength and pronation-supination. In the fragment-specific group half of the patients had had the implant removed. In the external fixation group there was a tendency for radiographic malunion.

**Paper II:** Patients with primarily non-reducible or secondarily redisplaced distal radius fractures, treated with either volar locking plate or fragment-specific fixation both achieved good, almost identical subjective, objective, and radiographic outcome, although, more complications in the fragment-specific group was found.

**Paper III:** In the large prospective and consecutive cohort of patients with distal radius fracture, the 1-year outcome was good and basically unchanged over the 10-year period. About half the patients returned to a pre-fracture state (DASH 0-10) but up to one sixth reported severe residual disability (DASH >35). A marked shift in treatment was found in the 10-year period, but the overall and year-by-year subjective outcome remained the same.

**Paper IV:** In the one sixth of the patients reporting severe residual disability (DASH >35) at 1-year, only 13% returned to pre-fracture status (DASH 0-10), 2-12 years after the fracture. Half of the patients with major disability still reported DASH >35, 2–12 years after the fracture. Thus, even if improvement in both function and patient-reported outcome will occur also after the first year, the injury will for many continue to cause problems and restrictions in life.

# Sammanfattning på svenska

Handledsbrott är den vanligaste frakturen på en akutmottagning. De yngre vuxna patienterna är jämnt fördelade mellan könen men de äldre har en övervikt av kvinnor. Hos de äldre uppstår frakturen företrädesvis i ett skelett med olika grad av benskörhet. Frakturen behandlas oftast med gips utan operation men drygt en femtedel opereras. Om felställningen är stor eller om frakturen inte bedöms kunna kvarstanna i ett gynnsamt läge rekommenderas en operation. Man väger in patientens funktionsnivå och ålder i den samlade bedömningen. Patienterna har under de första månaderna svårt att klara sina dagliga göromål och personliga hygien men de flesta patienter blir återställda ett år efter skadan. I vår studie har dock en femtedel av alla som bryter sin handled kvarvarande besvär ett år efter skadan såsom bestående svaghetskänsla och smärta vid belastning av handleden.

Syftet med denna avhandling är att analysera vår behandling under det senaste decenniet för att hitta sätt att förbättra behandlingen av handledsfrakturer. Avhandlingen baseras på fyra arbeten, två kliniska studier och två registerstudier.

Det första delarbetet är en fem-års uppföljning av en jämförande studie mellan två kirurgiska behandlingar för felställda handledsfrakturer. Med den nya metoden, intern fixation, fixerade man frakturfragmenten med små plattor och stift och vi jämförde mot den traditionella metoden med yttre stag, en så kallad extern fixation. Vid ett år sågs bättre greppstyrka i handen och rotation av underarmen hos patienter opererade med den nyare metoden och en tendens till färre större komplikationer. Vid fem år förelåg det inte längre någon skillnad i greppstyrka eller rörelseomfång utan nu hade även patienter opererade med extern fixation uppnått ett normalvärde avseende greppstyrka och underarmsrotation.

I det andra delarbetet, jämfördes två olika typer av intern fixation för felställda handledsfrakturer. Vi jämförde en ny operationsmetod som snabbt blivit populär (volar platta) med den som föll bäst ut i den förra studien (fragment-specifik). Vid ett år hade bägge grupper ett bra utfall och hade uppnått ett normalvärde i greppstyrka. Mellan grupperna fanns det ingen skillnad avseende rörelseomfång eller patientupplevd handfunktion men vi hittade fler komplikationer i gruppen som blivit opererade med fragment-specifik fixation än med volar platta.

Det tredje delarbetet är en genomgång av patienter i vår databas av patienter med handledsfraktur i vilken vi utvärderar den patientupplevda handfunktionen med en hälsoenkät (DASH). 3,666 patienter >18 år sökte akutmottagningen i Lund med en handledsfraktur 2003 till 2012 och ingick i studien. Patienterna blev behand-

lade enligt ett behandlingsprotokoll med ca 80 % gipsades och 20 % opererades. 2,571 patienter svarade på hälsoenkäten 12 månader efter frakturen. På gruppnivå var det patientupplevda resultatet bra och förblev oförändrad oavsett om man blev behandlad i början eller i slutet av 10-års perioden. Andelen patienter som blivit opererade var oförändrat, men en förändring av val av den kirurgiska behandlingsmetoden noterades. Extern fixation ersattes med intern fixation och den volara plattan blev den vanligaste metoden mot slutet av perioden. En subgruppsanalys visade att patienter opererade med extern fixation skattade sin handfunktion som sämre än de som opererats med volar platta.

Även det fjärde delarbetet baserades på registret och 445 av 2,571 (17 %) patienter med kraftiga kvarvarande besvär ett år efter sitt handledsbenbrott fick fylla i en ny hälsoenkät. 269 patienter svarade på enkäten två till 12 år efter fraktur. 127 av 269 (47 %) hade förbättrats till en nivå med minimala eller moderata besvär, men majoriteten 142 av 269 (53 %) hade fortfarande kraftiga kvarvarande besvär.

Vi konkluderar att det behandlingsprotokoll vi använder för handledsfrakturer är användbart, och att de flesta patienter får ett bra funktionellt slutresultat både avseende patienter som behandlas utan operation och för de som opereras. De nyare operationsmetoderna med intern fixation gav snabbare rehabilitering, en tidigare normalisering av både greppstyrka och rörelseomfång efter ett år men skillnaden var försvunnen efter fem år. Under en 10-års period upplevde medianpatienten sin handled som bra men inte helt normaliserad efter ett år. Den sjättedel som upplevde sin handfunktion som kraftigt försämrad efter ett år förbättrades i hälften av fallen men blev sällan helt återställda även mätt efter många år.

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# Appendices I–III

## DISABILITIES OF THE ARM, SHOULDER AND HAND

### Svenska **DASH**

#### INSTRUKTIONER

Denna enkät berör Dina symtom och Din förmåga att utföra vissa aktiviteter.

Svara på varje fråga, baserat på hur Du har mått den senaste veckan, genom att kryssa för ett svarsalternativ för varje fråga.

Om det är någon aktivitet Du inte har utfört den senaste veckan får Du kryssa för det svar som Du bedömer **stämmer bäst** om Du hade utfört aktiviteten.

Det har ingen betydelse vilken arm eller hand Du använder för att utföra aktiviteten. Svara baserat på Din förmåga oavsett hur Du utför uppgiften.

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Svenska DASH Isam Atroshi, Christina Gummesson Hässleholms sjukhus och Lunds Universitet Gradera Din förmåga att utföra följande aktiviteter under den senaste veckan genom att kryssa för ett svarsalternativ för varje fråga

	•	Ingen svårighet	Viss svårighet	Måttlig svårighet	Stor svårighet	Omöjligt att göra
1. Öppna en ny burk, eller hårt sittand	de lock					
2. Skriva						
3. Vrida om en nyckel						
4. Förbereda en måltid						
5. Öppna en tung dörr						
6. Lägga upp något på en hylla över I	Ditt huvud					
7. Utföra tunga hushållssysslor (t ex to och väggar, putsa fönster, hänga to						
8. Trädgårdsarbete						
9. Bädda sängen						
10. Bära matkassar eller portfölj						
11. Bära tunga saker (över fem kilo)						
12. Byta en glödlampa ovanför Ditt hu	vud					
13. Tvätta eller föna håret						
14. Tvätta Din rygg						
15. Ta på en tröja						
16. Använda en kniv för att skära upp	maten					
17. Fritidsaktiviteter som kräver liten a (t ex spela kort, sticka, boule)	nsträngning					
18. Fritidsaktiviteter som tar upp viss l genom arm, axel eller hand (t ex sp använda hammare, spela tennis, sk	oela golf,					
19. Fritidsaktiviteter där Du rör på am (t ex spela badminton, simma, gym						
20. Färdas från en plats till en annan						
21. Sexuella aktiviteter						

22.	. Under <b>de senaste sju dagarna</b> , i vilken utsträckning har Dina arm-, axel- eller handproblem stört Ditt vanliga umgänge med anhöriga, vänner, grannar eller andra?								
	□ Inte alls		Lite	□ Måttligt		lycket	□ Väldigt mycket		eket
23.	. Under <b>de senaste sju dagarna</b> , i vilken utsträckning har Dina arm-, axel- eller handproblem stört Ditt vanliga arbete eller andra dagliga aktiviteter?								
	☐ Inte alls		Lite	□ Måttligt		Mycket	□V	äldigt my	cket
	Ange svårighe	tsgraden på Di	na symton	n de senaste sju da	garna:				
					Ingen	Lätt	Måttlig	Svår	Mycket svår
24.	4. Värk/smärta i arm, axel eller hand								
25.	5. Värk/smärta i arm, axel eller hand i samband med aktivitet								
26.	5. Stickningar (sockerdrickskänsla) i arm, axel eller hand								
27.	Svaghet i arm	ı, axel eller han	d						
28.	Stelhet i arm,	axel eller hand							
29.	29. Har Du haft svårt att sova, under <b>de senaste sju dagarna</b> , på grund av värk/smärta i arm, axel eller hand?  □ Inte alls □ Viss svårighet □ Måttlig svårighet □ Stor svårighet □ Mycket stor svårighet								
30.	<ol> <li>Jag känner mig mindre kapabel, har sämre självförtroende eller känner mig mindre behövd på grund av mina arm-, axel- eller handproblem.</li> </ol>								
	☐ Instämmer absolut inte ☐ Instämmer inte ☐ Vet inte ☐ Instämmer ☐ Instämmer absolut								

#### Hälsoenkät (arm/axel/hand)

Denna enkät berör Dina symtom och Din förmåga att utföra vissa aktiviteter.

Svara på **varje fråga**, baserat på hur Du har mått **den senaste veckan**, genom att kryssa för ett svarsalternativ för varje fråga.

Om det är någon aktivitet Du inte har utfört den senaste veckan får Du kryssa för det svar som Du bedömer **stämmer bäst** om Du hade utfört aktiviteten.

Det har ingen betydelse vilken arm eller hand Du använder för att utföra aktiviteten. Svara baserat på Din förmåga

avsett nur Du utfor uppgiften.								
4 150	a nui Bu unor apparen.	Ingen svårighet		ss ighet		ttlig righet	Stor svårighet	Omöjligt att göra
1.	Öppna en ny burk eller hårt sittande lock				[			
2.	Utföra tunga hushållssysslor (t ex tvätta golv, putsa fönster, hänga tvätt)		[					
3.	Bära matkassar eller portfölj				[			
4.	Tvätta Din rygg				[			
5.	Använda en kniv för att skära upp maten				[			
6.	Fritidsaktiviteter som tar upp viss kraft eller stöt genom arm, axel eller hand (t ex spela golf, använda hammare, spela tennis, skytte, bowling)		С		[			
8.	Ditt vanliga umgänge med anhöriga, vänner, grannar eller andra?  ☐ Inte alls ☐ Lite ☐ Måttligt ☐ Mycket ☐ Väldigt mycket  8. Under den senaste veckan, i vilken utsträckning har Dina arm-, axel- eller handproblem stört Ditt vanliga arbete eller andra dagliga aktiviteter?							
☐ Inte alls ☐ Lite ☐ Måttligt ☐ Mycket ☐ Väldigt mycket  Ange svårighetsgraden på Dina symtom den senaste veckan:								
		In	gen	Lät	t	Måttlig	g Svår	Mycket svår
9.	Värk/smärta i arm, axel eller hand	[						
10.	10. Stickningar (sockerdrickskänsla) i arm, axel eller hand							
11.	11. Har Du haft svårt att sova, under <b>den senaste veckan</b> , på grund av värk/smärta i arm, axel eller hand?  □ Inte alls □ Viss svårighet □ Måttlig svårighet □ Stor svårighet □ Mycket stor svårighet							

Fragment-specific fixation versus volar locking plates in primarily non-reducible or secondarily redisplaced distal radius fractures: A randomized controlled study

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Appendix III: Paper II

Complication list from the clinical research file assessed at the 6-week, 3- and 12-month follow-ups

Type of complication	Yes	No
Trigger finger		
Pain		
Superficial infection		
Deep infection		
Carpal tunnel syndrome		
Radial neurapraxia		
Ulnar neurapraxia		
Tendinitis		
De Quervain syndrome		
Complex regional pain syndrome		
Compartment syndrome		
Skin adherence		
Tendon adherence		
Tendon rupture		
Posttraumatic arthritis/osteoarthritis		
Redisplacement		
Other		