Outcomes after treatment of distal radius fractures with a volar locking plate or an external fixator

Trine Ludvigsen

Thesis for the degree of Philosophiae Doctor (PhD)
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Scientific environment

This study is based on data from patients operated at the Department of Orthopaedic Surgery at Haukeland University Hospital and Voss Hospital. The PhD training took place in the Department of Clinical Medicine, University of Bergen, Norway.

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Abbreviations

AAOS: American Academy of Orthopaedic Surgeons
AO: Arbeitsgemeinschaft fur Osteosynthesefragen
AP: Anterior-Posterior
CRPS: Complex Regional Pain Syndrome
CT: Computed Tomography
CTS: Carpal Tunnel Syndrome
DRF: Distal Radius Fracture
DRUJ: Distal Radio Ulnar Joint
EF: External Fixator
MCID: Minimal Clinical Important Difference
MD: Mean Difference
MRI: Magnetic Resonance Imaging
OR: Odds Ratio
PROM: Patient-Reported Outcome Measure
PRWHE: Patient-Rated Wrist and Hand Evaluation
PQ: Pronator Quadratus
Quick DASH: Quick Disabilities of the Arm, Shoulder and Hand
RCT: Randomized Controlled Trial
ROM: Range Of Motion
TFCC: Triangular Fibro Cartilage Complex
USF: Ulnar Styloid Fracture
VAS: Visual Analogue Scale
VLP: Volar Locking Plate

Abstract

Background/aims

The use of volar locking plates (VLPs) for unstable extra-articular distal radius fracture (DRF) has increased in recent decades while external fixation is correspondingly less frequently used. This change of surgical approach has only to some extent been evidence based.

The aim of Paper I was to determine whether an EF or VLP provides superior outcomes for treatment of displaced extra-articular DRF.

The correlation between the degree of radiographic deformity and functional outcome of the fracture is controversial.

The aim of Paper II was to test the hypothesis that precise restoration of distal radius fractures is correlated to better patient-reported outcome measures (PROMs).

Complex regional pain syndrome (CRPS) is a severe chronic pain condition that can lead to a vicious circle of pain and disability. The most common cause of CRPS is a fracture of the distal radius (DRF).

The aim of Paper III was to compare the risk of developing CRPS following surgical treatment of DRFs with a VLP or EF.

Methods

For Papers I and II the study included 156 patients, aged 18 to 70 years, in a multicentre, randomized controlled trial. Patients with displaced, extra-articular DRF, AO type A3, who attended Haukeland University Hospital or Voss Hospital, Norway between 2013 and 2017 were included. The patients were treated with a VLP or EF and examined at six weeks, three months and one year postoperatively. The primary outcome measure was the Patient-Rated Wrist and Hand Evaluation score (PRWHE). Secondary outcomes were Disabilities of the Arm, Shoulder and Hand scores (QuickDASH), pain (VAS), range of motion (ROM), grip strength, finger stiffness and radiological measurements. Complications and reoperations were also recorded.

In Paper II the correlation between radiographic results and functional outcome was assessed using a Pearson correlation analysis.

In Paper III the data from the same 156 patients were combined with data from another RCT on distal radius fractures conducted at Akershus University Hospital, Lørenskog, Norway. The primary outcome of this study was the diagnosis of CRPS according to the Budapest criteria. We conducted a logistic regression analysis to identify independent risk factors for the occurrence of CRPS, including age, gender, type of implant and fracture, energy of trauma, an additional fracture of the ulnar styloid, time to surgery and operation time.

Results

One hundred and forty-two patients (91%) completed one-year follow-up. Mean age was 56 years. At six weeks, the median PRWHE was significantly higher (worse) for EF than for VLP but at three months and one year, the difference was not significant. Median QuickDASH score was significantly higher for EF after six weeks and a significant difference persisted at three months. Pain during activity, wrist extension and ulnar and radial deviation were better with VLP after one year while the number of major complications was similar in the two groups.

In Paper II we found no correlation between radiographic parameters and the PRWHE at one-year follow-up within the whole group, regardless of which treatment was chosen.

Paper III included 322 patients from the two RCTs. A CRPS was diagnosed in six patients treated with VLPs (4%) and 16 patients receiving EFs (11%) ($p=0.032$). The risk of developing CRPS was higher for patients treated with EF compared to VLP (OR 2.78, 95% Confidence Interval 1.06-7.29). None of the other independent risk factors had a significant influence on the risk for CRPS (all $p>0.05$).

Conclusions

Paper I

Patients treated with a VLP had earlier recovery of function than those treated with an EF. One year postoperatively, we found no significant functional difference.

Paper II

We found no correlation between functional outcome (PRWHE) and radiographic findings after one year in patients with AO type A3 distal radius fractures operated with a VLP or EF. Patient specific factors were more important than radiographic measurements in this study group.

Paper III

We observed, when merging data from the two RCTs that patients treated with an EF had a higher risk of developing CRPS compared to those treated with a VLP. We found no other independent variable predicting CRPS.

Samandrag på norsk

Bakgrunn

Bruk av volare låseplater (VLP) i behandling av ustabile ekstra-artikulære distale radiusfrakturar (DRF) har auka dei siste tiåra samstundes som bruk av ekstern fiksasjon (EF) er mindre vanleg. Denne endringa i kirurgisk tilnærming er berre til ei viss grad basert på forsking.

Mål med Artikkel I var å avgjere om EF eller VLP gjer det beste resultatet i behandling av dislokerte distale ekstra-artikulære radiusfrakturar.

Samanhengen mellom grad av radiografisk feilstilling og funksjonelt resultat for pasienten er usikker og kontroversiell.

Mål med Artikkel II var å teste hypotesen at presis reponering av distale radiusfrakturar er korrelert med betre pasient rapporterte resultat (PROM).

Komplekst regionalt smertesyndrom (CRPS) er ein alvorleg kronisk smertetilstand som kan føre til uttalte plager med smerte og redusert funksjon. Den vanlegaste utløysande årsaken til CRPS er brot i distale radius (DRF).

I artikkel III såg ein på om det var auke risiko for å utvikle CRPS etter kirurgisk behandling for DRF med anten VLP eller EF.

Metode

Artikkel I og II er basert på 156 pasientar i alderen 18-70 år inkludert i ein randomisert klinisk studie. Pasientane hadde dislokerte, ekstra-artikulære DRF, AO type A3, som vart behandla på Haukeland Universitetssjukehus eller Voss sjukehus i perioden 2013-2017. Pasientane vart behandla med VLP eller EF og vart undersøkt 6 veker, 3 månader og 1 år etter operasjonen. Primært utfallsmål var Patient-Rated Wrist and Hand Evaluation-score (PRWHE). Sekundære utfall var Disabilities of the Arm, Shoulder and Hand-scores (QuickDASH), smerte (VAS), røyrsleutslag (ROM), gripestyrke, fingerstivheit og radiologiske målingar. Komplikasjonar og reoperasjonar vart også registrert.

I Artikkel II vart korrelasjonen mellom radiografisk funn og funksjonelt resultat undersøkt ved bruk av Pearson korrelasjosanalyse.

I Artikkel III vart data frå dei same 156 pasientane kopla saman med data frå ein annan RCT på distale radiusfrakturar utført ved Akershus Universitetsykehus. Det primære utfallsmålet for denne studien var CRPS diagnose basert på Budapest kriteria. Vi utførte ein logistisk regresjonsanalyse for å identifisere uavhengige risikofaktorar for å utvikle CRPS.

Resultat

142 pasientar (91%) fullførte 1-års oppfølging. Gjennomsnittsalder var 56 år. Etter 6 veker var median PRWHE signifikant høgare for pasientar operert med EF samanlikna med VLP, men etter 3 mnd og 1 år var skilnaden ikkje lengre signifikant. Median QuickDASH var signifikant høgare for EF etter 6 veker og framleis ved 3 mnd. Smerte ved aktivitet, ekstensjon i handleddet og ulnar- og radial deviasjon var i favør av VLP etter 1 år, medan tal på alvorlege komplikasjonar var lik i dei to gruppene.

I Artikkel II fann me ingen korrelasjon mellom radiografiske målingar og PRWHE etter 1 år i heile gruppa uavhengig av kva implantat som vart nytta.

Artikkel III inkluderte 322 pasientar frå dei to RCTane. CRPS vart diagnostisert hjå 6 pasientar behandla med VLP (4%) og 16 pasientar behandla med EF (11%) (p=0,032), i alt 22 tilfelle av CRPS (7%). Risikoen for å utvikle CRPS var høgare (95% CI 1,1-7,2) for pasientar behandla med EF samanlikna med VLP.

Konklusjon

Artikkel I
Pasientar operert med VLP kom seg raskare samanlikna med pasientar operert med EF. Eit år etter operasjonen fann me ingen skilnad i funksjonelt resultat.

Artikkel II
Me fann ingen korrelasjon mellom funksjonelt resultat (PRWHE) og radiologiske funn etter 1 år hjå pasientar med distale radiusfrakturar, AO type A3, operert med VLP eller EF. Andre faktorar var viktigare enn radiologiske målingar i denne pasientgruppa.

Artikkel III
Pasientar med distale radiusfrakturar operert med EF hadde høgare risiko for å utvikle CRPS samanlikna med dei som blei operert med VLP.

List of Publications

I. **Surgical treatment of distal radial fractures with external fixation versus volar locking plate. A multicenter randomized controlled trial.**
The Journal of Bone and Joint Surgery American volume 2021 mar 3; 103(5):405-14. Epub 2020/12/29

II. **Is there a correlation between functional results and radiographic findings in patients with distal radius fractures AO type A3 treated with volar locking plate or an external fixator?**
OTA International 2021 Vol.4 Issue 3 Pages e142

III. **Complex regional pain syndrome following distal radius fracture. Does surgical method matter?**
Submitted to The Journal of Hand Surgery (European Volume) 2022

The publications will be referred to by their corresponding Roman numbers, **Paper I, Paper II** and **Paper III**, as noted above**.**

Contents

1. Introduction

1.1 Historical review

The first reports on how to manage distal radius fractures date back 5000 years. Ancient Egyptian case reports describe manipulation and splinting of a fractured arm using wood and rolls of linen hardened with grease and honey to maintain the desired position.

«The father of western medicine», the Greek physician Hippocrates, described in 490 BC distal radius fracture and its mechanism of injury, although he described it as a dislocation of the wrist. This misconception withheld until the 18th century when the French surgeons Jean-Louis Petit and later Claude Poteau both theorized that the injury actually was a fracture of the distal radius.

In 1814, the Irish surgeon Abraham Colles published his landmark work on distal radius fractures which is still regarded as the definite description of the fracture. Apart from the injury pattern, he also described how to reduce the fracture and the importance of stabilization of the wrist. Colles described a technique using a wooden splint to prevent the wrist from dorsal dislocation.

Later, in 1850, the plaster of Paris brought to Europe from the Orient by British diplomats gained popularity in casting techniques. During the last half part of the 19th century, many articles were published based on anatomical dissections and cadaver experiments trying to enlighten injury mechanisms and fracture classification.

In 1895, Wilhelm Röntgen presented the use of X-rays and this new tool quickly became popular for developing a greater understanding of the fracture and diagnosis. Röntgen had also questioned the conservative management of distal radius fractures and in 1908 Joseph Lister was the first to describe the use of a percutaneous wire through the radial styloid to maintain reduction. New operative techniques developed during the 20th century. In 1944 the initial design of an external fixator was introduced and in 1958 the first two case reports using internal fixation were published. In the 1990s, dorsal plates became popular but due to frequent tendon irritation and subsequent rupture, they fell out of favour. During the last decades, after the introduction of volar locking plates, this operative method has become the method of choice.

1.2 Background

A displaced fracture of the distal radius is a common injury and may result in functional impairment for the patient. Accordingly, the successful management of such fractures is of great importance. The overall goals are to restore anatomy and function and to avoid late problems of instability, osteoarthritis and pain. Historically, radiographic deformity has been considered to correspond with a poor functional outcome[1].

Some studies have identified factors that predict the radiographic outcome for distal radius fractures[2-5]. However, the definition of fracture stability is not fully agreed upon[6]. There has been considerable research in an attempt to predict what makes a fracture unstable. Lately, age has been found to be the most important factor associated with an unstable fracture. Radiographically, a dorsal comminution and inability to re-establish volar cortical continuity indicate an unstable fracture[6-8]. There is still no clear consensus on what constitutes an acceptable radiological position before and after treatment. However, many will agree that a position that predicts good function in the majority of cases may be considered an acceptable position. A perfect anatomical reduction is not always achievable, nor is it always necessary for a satisfactory result[9]. In large clinical studies and meta-analyses, the correlation between final anatomy and wrist function is weak[1, 10-12]. The challenge remains to identify which fractures are best treated surgically and which are not[13]. Surgically, volar locked plating is a well-documented treatment for all age groups. It gives faster return to activity and better radiographic outcomes compared to cast immobilization, though at the cost of a higher complication rate[14-17]. Further, subjective outcome in elderly patients does not seem to be related to radiographic outcome, as some studies report satisfaction rates of up to 92% despite poor radiographic alignment[18-26]. Therefore, closed reduction should always be considered for elderly patients. Closed treatment slows recovery but is unlikely to alter it except in cases with significant intra-articular malalignment, which is associated with 38% poor outcome in the elderly. Further, restoration of intra-articular gaps positively affects outcome in elderly people[17, 27, 28].

The Norwegian Orthopaedic Association adheres to the American Association of Orthopaedic Surgeons (AAOS) guidelines[29]. According to these guidelines, operative treatment is recommended, with moderate strength, in the following cases: dorsal tilt ≥10°, radial shortening ≥3mm, articular step or gap ≥2mm, and dorsal comminution or incongruence of the distal radio-ulnar joint present after reduction.

Which surgical method should then be recommended?

Unfortunately, although the AAOS clinical practice guidelines had 29 recommendations, none of them have received a strong rating due to weak levels of evidence.

In 2012, while planning for this RCT, external fixation was recommended as the implant of choice for dislocated extra-articular fractures in younger patients in our hospital`s local guidelines. Still, from 2009-2014 there was a shift towards the use of volar locking plates from 53% to 81%[30]. This happened despite no evident change in the percentage of patients undergoing surgical treatment in Norway. A similar pattern was also seen in Sweden[31] and in the Unites States[32-34].

Several studies have implied that volar locked plating of distal radius fractures results in better range of motion, better grip strength and better anatomical reduction compared to external fixation[35-42]. However, only a few studies report better patient reported outcome[39, 43]. The conflicting messages in the literature are due to a wide range of injury patterns, interventions and methodologies and a large number of different outcome measures.

The current study was initiated hoping to provide stronger evidence on which to base the treatment guidelines.

1.3 Epidemiology

Distal radius fractures are the most common fractures of the upper extremity[44, 45]. In children, this fracture accounts for 25-30% and in adults 18% of all fractures in an orthopaedic trauma unit[31, 46-48]. It has a bimodal distribution and the two major patients groups are skeletally immature children and osteoporotic elderly people[45, 49-51]. Boys account for 60% of fractures in children, whereas 70% of adult fractures occur in women. After the age of 60, women have a three to five time's higher incidence than men due to osteoporosis[31, 45, 49, 50, 52, 53]. A low-energy fall on an outstretched arm is the most common mechanism of injury in elderly people[52-54]. In young adults, the fractures are more likely to be caused by high-energy trauma during sports and leisure activities[52, 54].

Epidemiological differences across Europe have been reported, with higher incidence rates of distal radius and other osteoporotic fractures in Scandinavia than in other European regions[55].

Increasing incidence of DRFs was reported in the last half of the 20th century in several studies. A study from Malmø, Sweden, conducted in 1955, found an annual incidence of 19/10.000[56], whereas a 1988 study from Bergen, Norway found the overall incidence of distal radius fractures to be 38/10.000[44].

A similar increase of DRFs has also been seen in other studies worldwide[54, 57, 58]. However, more recent studies have shown no further change, or even a decreased incidence, especially in young postmenopausal women[31, 59-61]. The reason for this recent plateau is unknown and probably multifactorial.

1.4 Classifications

Classification of distal radius fractures has used eponyms to a greater extent than any other area of skeletal injury and descriptions of fractures such as Colles, Smith, Barton and Chauffeur are still being used in clinical practice.

To describe fracture patterns more accurately, numerous classification systems such as AO/OTA, Frykman and Older have emerged during the last half of the 20th century. An ideal fracture classification should have satisfactory inter- and intra-observer reliability. It should describe severity of the injury, suggest appropriate methods of treatment and have prognostic value. The most detailed classification is the AO/OTA classification, which also has been found to be the most reliable for routine use[62]. This system is arranged in order of increasing severity of the osseous and articular lesions. The fractures are divided into extra-articular (type A), partial articular (type B), and complete articular (type C). According to location and comminution, each group is subdivided into three groups (1-3). Furthermore, these groups can be subdivided into subgroups (1-3) reflecting morphologic complexity, difficulty of treatment, and prognosis. The AO/OTA classification system was used in **Papers I-III,** but only the three main groups (A, B and C) and the first subdivision (A1, A2, A3…..C2,C3) were applied, due to better inter- and intra-observer agreement compared to using all subgroups[63].

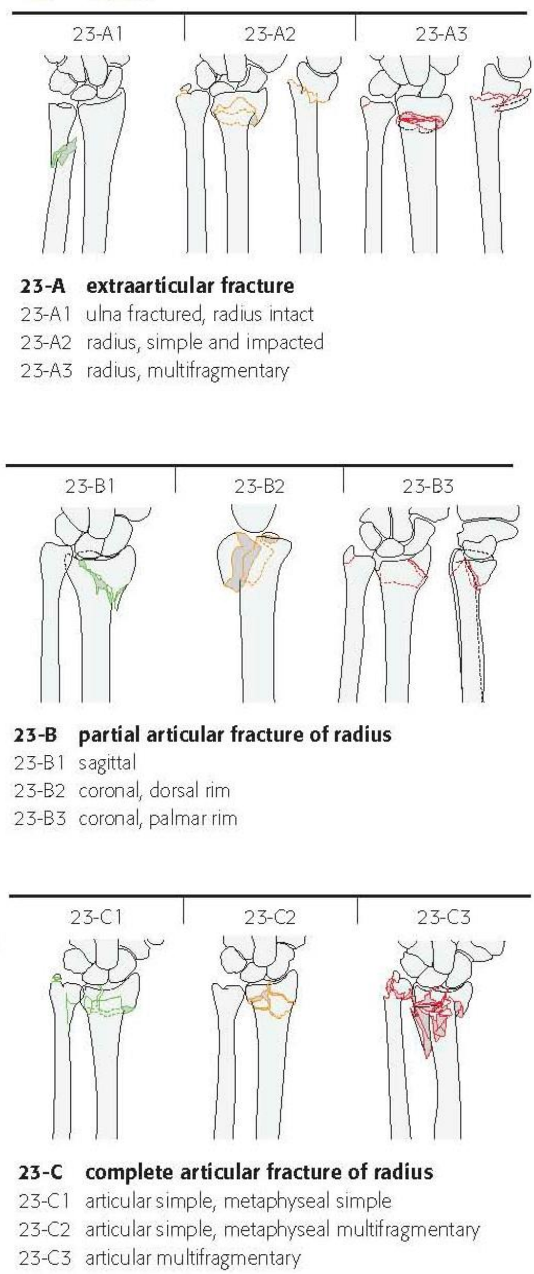


Figure 1: The AO/OTA fracture classification (Copyright by AO Foundation, Switzerland. Reprinted with permission). (Source: AO Surgery Reference, www.aosurgery.org)

1.5 Functional anatomy and biomechanics of the wrist

Knowledge of the anatomy and biomechanics of the wrist is important in order to understand normal wrist function and thus optimize treatment and outcome. The wrist is the link between the forearm and the hand and consists of the proximal and distal carpal row and the five metacarpal bases, and the distal radius and distal ulna. The radial metaphysis begins approximately 2-3 cm proximal to the radiocarpal joint. The volar surface of the distal radius consists of thick cortical bone while the dorsal cortex is thin, leading to fracture comminution and a high risk of dorsal tilt of the distal fragment. The dorsal surface of the distal radius is convex with Lister's tubercle protruding towards the lateral side. The volar side is slightly concave and covered by the pronator quadratus (PQ) muscle[64]. A slightly elevated ridge distal to the PQ called the "watershed line" is an important landmark, as it should not be crossed during volar plate fixation. In the distal radius there are three articulations. The radiocarpal joint is biconcave and divided into two articular facets, the lunate and scaphoid fossa. The joint surface is tilted 11° in volar direction and has a 20° radial inclination. In the sigmoid notch on the medial side, the surface is concave and contributes to the stability in the distal radio ulnar joint (DRUJ) when forearm rotation is performed. The triangular fibrocartilage complex (TFCC) is a structure that covers the DRUJ towards the radiocarpal joint creating rotational stability and allowing for simultaneous flexion and extension of the hand.

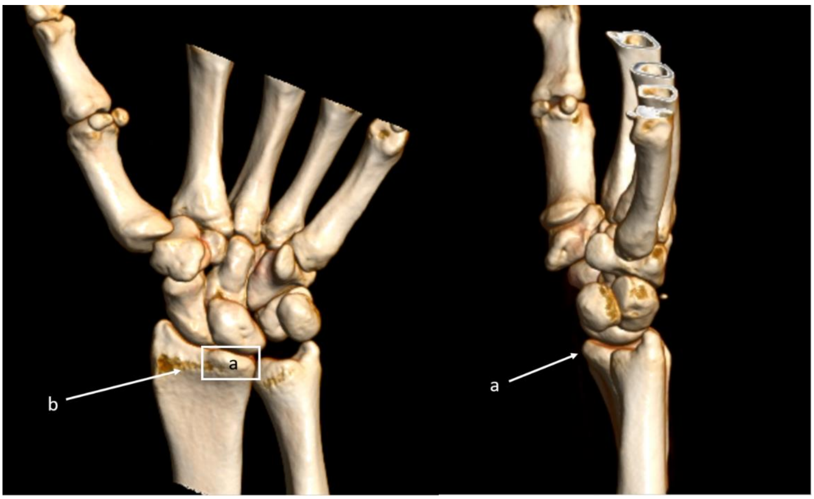


Figure 2: CT scan demonstrating the volar lip (a) and the watershed line (b). Picture from a local patient, with permission.

Biomechanically, the distal forearm has three columns[65, 66].

1. The radial column is the lateral half of the radius with the radial styloid process and the scaphoid facet extending to the base of Lister's tubercle. The radial column serves as an osseous buttress and the origin of the radiocarpal extrinsic ligaments.
2. The intermediate column is the ulnar border of the distal radius including the lunate facet and the sigmoid notch. With the volar lip of the lunate facet acting as a volar buttress for the carpus, its main task is load transmission and it is called the critical corner. Most of the lunate facet rests directly on the underlying distal radius but 16% of the facet forms a volar lip and is particularly vulnerable to shearing forces[67]. Failure to secure the volar lip in an intra-articular fracture may lead to volar dislocation of the entire carpus with this fragment.
3. The ulnar column consists of the distal ulna, the TFCC and the DRUJ. A similar amount of load as in the intermediate column is transmitted here.

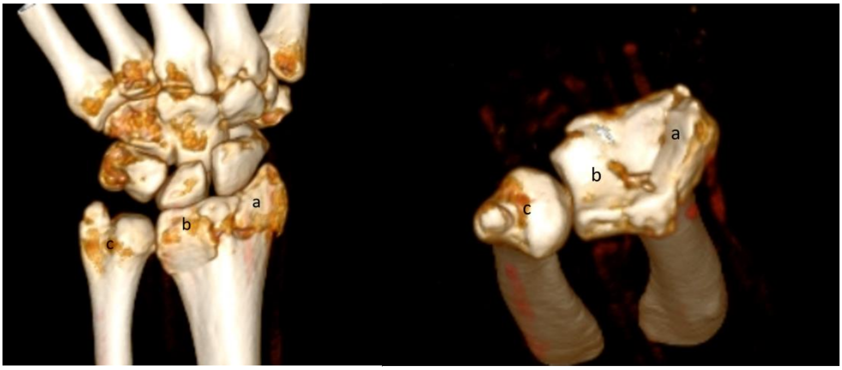


Figure 3: CT scan showing the radial column (a), the intermediate column (b) and the ulnar column (c). Picture from a local patient, with permission,

The DRUJ is complex, with the head of the ulna as the stable, non-rotating and weight-bearing structure around which the carpus and radius rotate. The DRUJ has different anatomical variations and this might explain why some patients have limited range of motion after minor mal-unions while others may develop instability[68].

The axial load on the ulna in neutral position is about 18% of the load applied on the carpus. Around 40% of the total load on the radius is carried by the lunate facet and 60% by the scaphoid facet[69-72]. The load distribution shifts with different wrist and forearm positions. With daily activities such as holding objects, the wrist is positioned slightly extended and ulnar deviated, leading to a load shift towards the lunate fossa[70, 73]. Fractures that heal with mal-union resulting in lengthening of the ulna and dorsal angulation of the distal joint surface will lead to a load shift towards the distal ulna. The remaining load will be concentrated on the scaphoid fossa and may result in reduced grip strength and pain. Dysfunction of the DRUJ may result in reduced rotation of the forearm and impingement of the radius and ulna[1].

1.6 Treatment

Abraham Colles concluded in 1814 in his famous article “On the fracture of the carpal extremity of the radius”: *“….the limb will at some remote period again enjoy perfect freedom in all its motions, and be completely exempt of pain”*[74]. He would probably have been surprised to learn that the optimal treatment for distal radius fractures is still a matter of discussion and a variety of non-surgical and surgical treatments are used.

For adults with distal radius fractures, non-surgical treatment is the preferred treatment for three-quarters of patients[75]. Closed reduction and cast immobilization remains the standard treatment for displaced distal radius fractures. The procedure is a longitudinal traction, combining volar flexion, ulnar deviation and pronation of the wrist before a cast is applied. This will provide an acceptable outcome for about 2/3 of these patients[76].

Figure 4: Cast immobilization (private photo)

For unstable and non-reducible fractures surgical treatment is recommended. For decades pinning and external fixation has been the method of choice. The method is based on indirect reduction of the fracture using ligamentotaxis to maintain proper reduction[77]. In our **Papers I-III** the Hoffmann II compact T2 bridging external fixator was used.

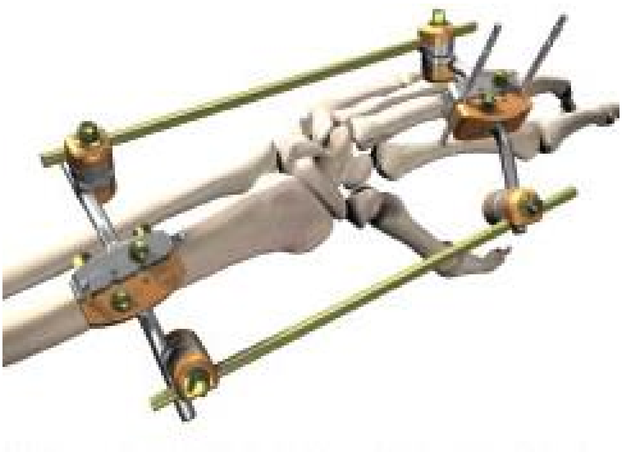


Figure 5: Hoffman Compact T2 external fixator

Based on findings with 30% of the patients with dissatisfactory results[78], there was a search for new treatment concepts. Open reduction and internal fixation focusing on anatomical reduction, stable fixation and early mobilization were developed**.** After the introduction of the volar locking plate in 2002[79], this became the preferred surgical treatment for many orthopaedic surgeons. **In Papers I-III** the Volar Locking Plate (DVR, DePuy) was used.

Figure 6: DePuy Volar Locking Plate

1.7 Outcome assessments after distal radius fractures

Patient outcomes after DRFs are multifaceted and we believe these are best evaluated using both subjective and objective outcome measures.

1.7.1 Patient-based outcome measures

Historically, the evaluation of functional impairment, clinical symptoms and treatment satisfaction from the patient's perspective has been underestimated. Potential misconceptions were held by clinicians regarding the reliability of an "objective" approach partly due to traditions favouring clinician-assessed outcome measures[80]. A patient-reported outcome measure (PROM) is used to measure the patient's own experience with function, pain and quality of life without the involvement of a researcher or clinician[81].

The PROMs used in this thesis are described below.

PRWHE

The Patient-Rated Wrist and Hand Evaluation score (PRWHE), is designed to measure wrist function in two (equally weighted) sections in terms of the patient's experience of pain and limitations in everyday activities. It consists of 15 items, with five in the pain domain and ten in the function domain (six regarding disability and four regarding personal activities, household work and recreational activities). This gives a score of 0-100, with 100 being the worst score[82]. The PRWHE questionnaire has been cross-culturally validated for the Norwegian population[83].

QuickDASH

The Quick Disabilities of the Arm, Shoulder and Hand score (QuickDASH) consists of eleven questions to measure function and disabilities in persons with musculoskeletal disorders of the upper limb, resulting in a score of 0-100, with 100 indicating greater disability[84, 85]. The QuickDASH questionnaire has been cross-culturally validated for the Norwegian context[86].

VAS

Pain at rest and during activity was measured using a Visual Analog Scale (VAS) ranging from 0-100, with 100 being the worst result[87].

1.7.2 Physical examination

Range of motion

Clinical examination includes measurements of the three axes of rotation in the wrist. Range of motion (ROM) in the radio-carpal joint is flexion/extension, radial and ulnar deviation, and supination/pronation. ROM is measured in degrees using a goniometer. Measurements of the uninjured side serve as preinjury (baseline) values. An estimate for good patient function after DRF is when 95% of the ROM of the contralateral side is achieved[88].

Finger stiffness and grip strength

Fingertips to palm distance, when attempting to make a fist, addresses finger stiffness. Grip strength can be measured quantitatively and commonly using a dynamometer (Jamar). Normal values of grip strength depend on gender and age. Since grip strength varies considerably between individuals, the patient's uninjured side often serves as a control and the strength is often given as a ratio in comparison to the uninjured hand. Grip strength as an objective outcome parameter is one of the most significant factors related to patient satisfaction and is assessed in most recent studies[89].

1.7.3 Radiographic assessment

Imaging plays a central role in the diagnosis, treatment and evaluation of distal radius fractures. Conventional radiography in two planes is still considered first choice imaging for wrist injuries. In cases of uncertain radiographic findings, and in more complex intra-articular fractures, a supplementary CT scan is recommended[90-93]. In cases with suspicion of soft tissue injuries or occult fractures, MRI can be a useful supplement[94]. Soft tissue injuries associated with distal radius fractures are very common and almost always hidden. Fortunately, most of them resolve over the course of time[95-102].

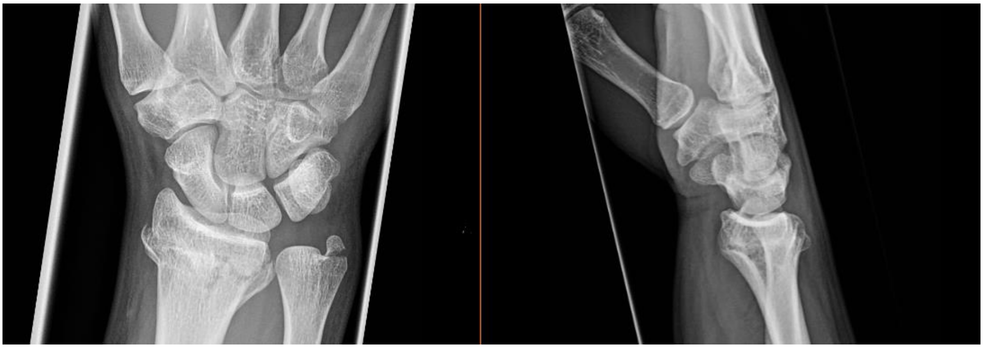


Figure 7: Standard radiographs of a fractured wrist (local patient, with permission)

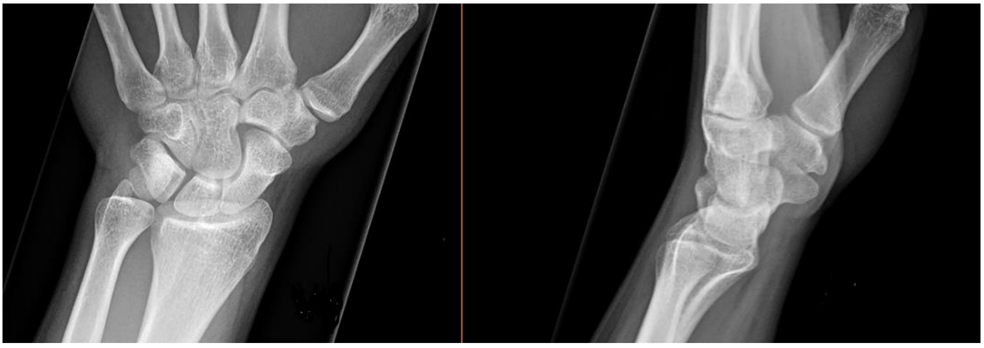


Figure 8: Radiographs of the contralateral uninjured side of the same patient for comparison

1.8 Complications

An important factor when assessing successful outcome of any treatment is the rate of complications. Complications are relatively frequent after distal radius fractures and the rate and type of complications are related to the method of treatment[103, 104]. Complications are defined as minor if they are transient or do not affect the patient's final outcome, such as superficial wound infections and scar tissue problems. Complications leading to a reoperation, permanent nerve injury or a persistently reduced function are classified as major complications. Major complications may cause significant morbidity. After closed reduction and external fixation of DRFs, the overall complication rate ranges from 27%[105] to 67%[106], while open reduction and internal fixation using volar locking plates have overall complication rates of between 10% and 27%[107-110]

Some complications like Carpal Tunnel Syndrome (CTS) can either be transient or manifest. A persisting CTS may need surgical decompression and will then be regarded as a major complication. Another example is tendon irritation occurring in Extensor Pollicis Longus (EPL). While synovitis will be considered a minor complication, a secondary rupture of the tendon requiring surgical treatment with tendon transfer will be considered a major complication.

Complex regional pain syndrome may be the most serious complication of a distal radius fracture and is associated with negative outcomes, which may be functional, psychological (e.g. increased depression and anxiety) and psychosocial (e.g. reduced quality of life, impaired occupational functioning)[111, 112]. CRPS is sympathetic activity in a perpetuated reflex arc characterized by pain out of proportion to physical examination findings.

One of the earliest descriptions of CRPS dates back to 1864, by a physician named Mitchell during the American Civil War. He described a specific type of pain resulting from gunshot wounds[113]. His patients complained of severe burning pain associated with shiny red skin and the condition was coined causalgia[114]. Later, in 1946, a similar condition was described by Evans, another American physician. He had made observations of patients who experienced intense suffering associated with abnormalities of the sympathetic nervous system, a condition he named reflex sympathetic dystrophy[115]. In Orlando in 1994 the International Association for the Study of Pain (IASP) decided on a standard set of criteria for making a diagnosis that is now called complex regional pain syndrome [116]. CRPS was further subdivided into Type 1, previously known as reflex sympathetic dystrophy and Type 2, previously known as causalgia. Both types are believed to be caused by trauma, but with the absence of nerve injury in Type 1, which accounts for the majority of cases[117-119], and the presence of nerve injury in Type 2[120]. The diagnostic criteria unfortunately had low specificity, often leading to misdiagnosis[121]. In 2003, the diagnostic criteria were revised and are now known as the Budapest criteria. The new criteria maintained the high sensitivity of CRPS (0.99) and improved the specificity (0.41-0.79)[122]. The Budapest criteria are considered the current standard in diagnosing CRPS[121, 122].

The pathophysiology of CRPS is still unclear and it is equally uncertain whether all cases of CRPS share the same underlying pathophysiology. The condition is most likely multifactorial with a combination of different factors starting at the time of the initial injury, including autonomic dysfunction, nervous system sensation and inflammatory changes[123-129]. Genetic predisposition to the syndrome[130-134] and psychological factors have also been postulated to influence the occurrence[121, 135-137].

The most common injury associated with developing CRPS is a fracture of the distal radius, which accounts for more than 40% of patients diagnosed with CRPS[138]. Other common inciting injuries or events include contusions, sprains, crush injuries and surgery. CPRS has even been reported to arise after seemingly innocuous interventions such as intravenous line placement.

The diagnosis of CRPS is based solely on clinical signs and symptoms, and by excluding other forms of chronic pain. No specific laboratory or radiological marker has yet been identified. Normally, pain levels for patients treated for DRFs should start decreasing after six weeks. If a patient reports a higher level of pain at rest at six weeks follow-up than expected, the diagnosis of CRPS should be considered[139].

The treatment of CRPS may be very challenging. Evidence of the effectiveness of the various treatment modalities for CRPS often lacks strength[112, 140]. However, there is growing support for multidisciplinary approaches including physical therapy, psychological therapy, neuropathic pain medication, anti-inflammatories and interventional procedures[121, 136, 141].

2 Aims of the thesis

Specific aims of the three papers included in the thesis were:

I. To determine whether an external fixator or a volar locking plate for displaced extra-articular distal radius fractures provides a superior patient outcome.

II. To assess whether there is a correlation between radiological findings and functional outcome after surgical treatment of displaced extra-articular distal radius fractures.

III. To evaluate the risk of developing a complex regional pain syndrome related to the surgical method after distal radius fractures.

3 Materials and methods

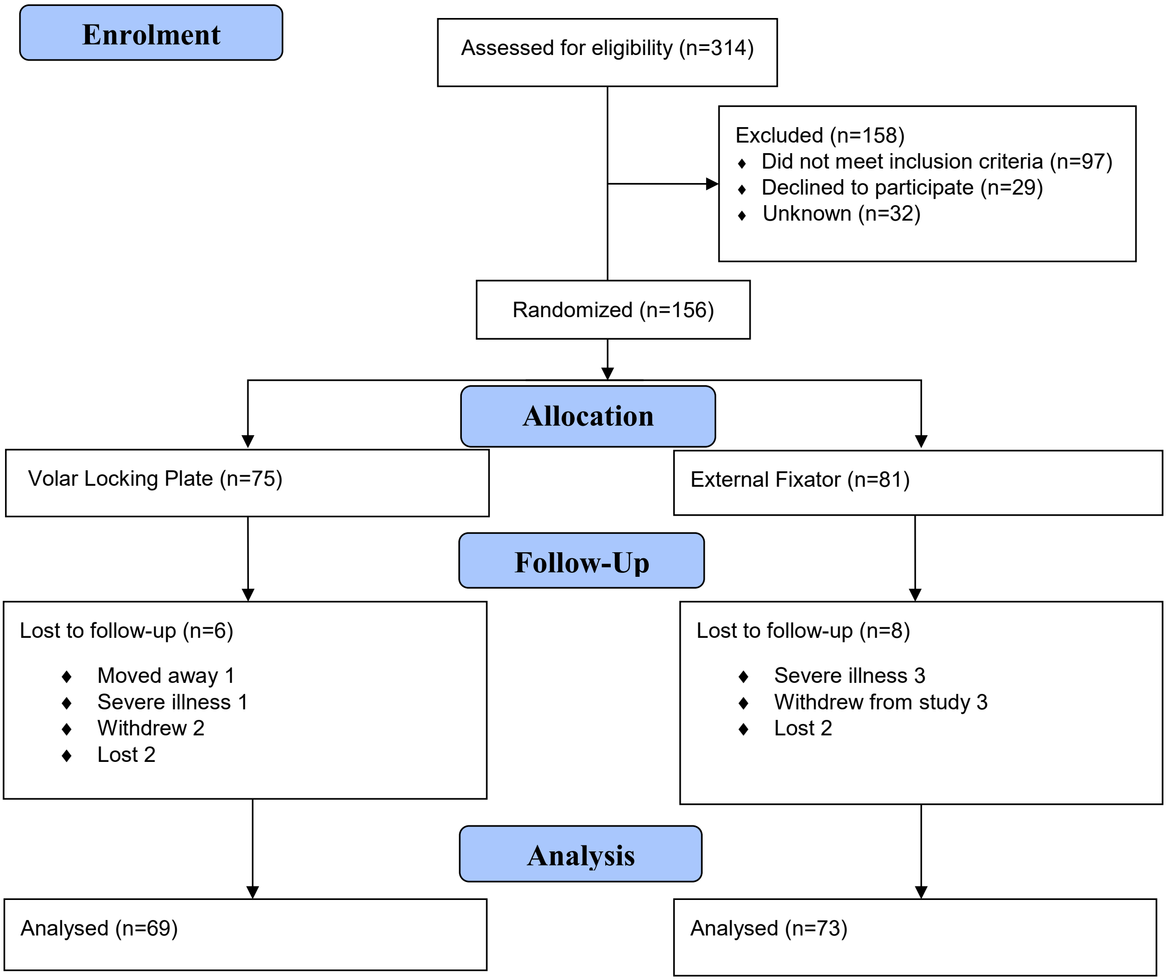
The patients presented in **Papers I-II** were recruited from the Department of Orthopaedics, Haukeland University Hospital and the Department of Surgery, Voss Hospital, Norway. The primary catchment area has 450 000 inhabitants and approximately 320 adult patients are treated surgically for distal radius fractures annually. During the period 2013-2017, all patients aged 18 to 70 years presenting to the orthopaedic department with an isolated unilateral displaced extra-articular fracture of the distal radius (AO type A3) were eligible for inclusion in the trial. Only patients with fewer than 16 days between injury and intervention were included. We excluded patients with previous fractures in the contra- or ipsilateral wrist, patients with open fractures, mental illness, dementia and severe drug abuse (Table 1).

TABLE 1 Inclusion and Exclusion Criteria	
Inclusion criteria	Exclusion criteria
18<age>70	Dementia
Displaced unstable extra-articular distal radius fracture	Severe mental illness
	Drug abuse
Substantial initial displacement, inadequate initial reduction, or loss of reduction within two weeks of injury as defined by one or more of the following:	Congenital bone disease
	Previous wrist fracture of either side
	Open fracture
♦ ≥10 degrees dorsal angulation of the joint line	Pathological fracture
♦ Ulnar variance ≥2mm	
♦ Dorsal comminution of the fracture area/loss of intact dorsal cortex	Patients living outside the Helse-Bergen area (catchment area)

To be included, patients also had to be able to understand the meaning of the trial and its consequences. Written informed consent was obtained from each patient prior to participation (mandatory for trial inclusion).

After having agreed to trial participation, patients were randomized by the responsible surgeon to one of the two treatment arms: VLP or EF. Randomization was performed using sealed envelopes based on block randomization designed by a biostatistician. The block size varied randomly and the allocation sequence was hidden from those performing the randomization.

Figure 9: Flow diagram, Papers I and II



3.1 Intervention

Surgical training manuals were developed for each procedure. All surgeons involved (n=40) had experience of both procedures. They had performed at least five procedures, of each techniques, independently or with experienced supervision, before participating in the study. Operations were standardized regarding implants and surgical techniques. All surgeries were performed under regional or general anaesthesia and with fluoroscopic guidance.

External fixator: One proximal 4 cm dorso-radial incision 3-4 cm from the fracture or at least 6 cm from the wrist joint, and two stab incisions on the second metacarpal were used to insert the four apex pins. Rods and blocks were mounted, traction was applied and the fracture reduced. Placing the rods close to the skin increases stability against bending loads. Massive distraction force should be avoided as the EF should work as a neutralization device, not a traction device. Ligamentotaxis is used to obtain reduction of the larger fracture fragments. There is no exact way to assess the right amount of traction but the patient should be able to make a fist. No supplementary K-wires were used. The skin was closed between the two proximal apex pins and a cotton dressing applied. The dressing around the pins was left in place for three days. The incisions were cleaned using tap water, air dried and a dressing was applied. At six weeks the EF was removed at the outpatient clinic without anaesthesia.

Volar locking plate: With the patient positioned on the operating table a volar approach (Henry's)[142] was performed along the flexor carpi radialis tendon (FCR). To improve exposure distally a short oblique incision over the flexor crease was applied. The sheath of the FCR was split and the FCR was retracted in ulnar direction. The flexor pollicis longus was retracted and the pronator quadratus, if intact, was lifted off subperiosteally. The fracture was reduced using a volar and ulnar directed force with traction being applied. Reduction was verified by fluoroscopy and, if needed, temporarily fixated with K-wires. An appropriately sized VLP was added. After plate fixation, the pronator quadratus was re-attached if possible and the DRUJ was tested. The skin was closed and a dorsal splint was applied and removed within few days.

Postoperative care: In both groups, postoperative radiographs were taken in three projections: anterio-posterior, lateral and tilted lateral. Patients were advised to mobilize the injured limb as tolerated, but without weight bearing, for six weeks. When the fracture was considered healed after six weeks all patients were instructed to begin independent exercises. The need for further physiotherapy was individually assessed. Plate removal was not routinely recommended, except in cases with verified malposition of the plate and screws.

3.2 Outcome measures

Primary outcome

The Patient-Rated Wrist and Hand Evaluation (PRWHE) scores measured at six weeks, three months and one year postoperatively were the primary outcomes. For patients with distal radius fractures, the minimum clinically important difference (MCID) for this score is 11.5 points[143]. We defined patients reporting a postoperative PRWHE with a difference of less than 11.5 points compared to the preoperative score as fully recovered.

Secondary outcome

Disabilities of the Arm, Shoulder and Hand scores (QuickDASH).

Pain at rest and during activity was measured using a visual analogue scale (VAS) ranging from 0-100, with 100 being the worst result.

Range of motion (ROM)

ROM in the radio-carpal joint is supination/pronation, flexion/extension and radial/ulnar deviation. ROM is measured in degrees using a goniometer. Measurements of the uninjured side serve as preinjury (baseline) values. The measurements were conducted with the patient positioned as follows:

Pronation/supination: The elbow positioned next to the waist with 90° of flexion and the forearm in a neutral position.

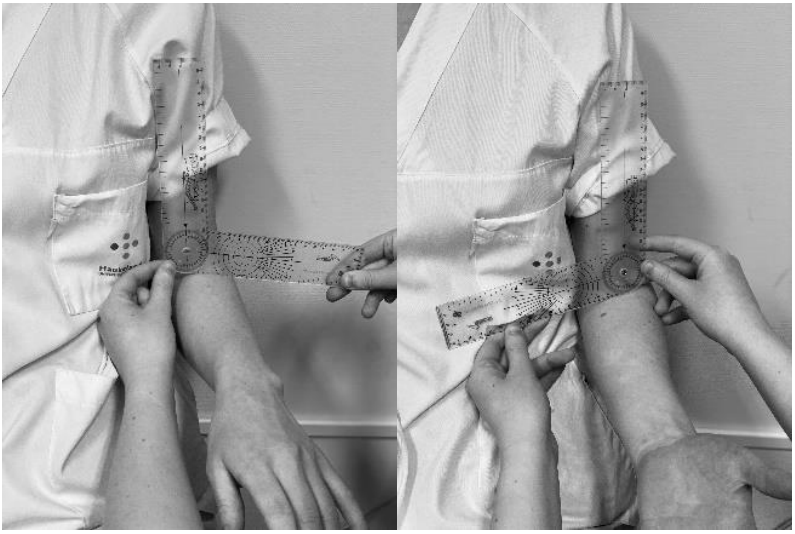


Figure 10: Forearm rotation (private photos)

Flexion/extension: The elbow flexed, the forearm in a neutral position and relaxed fingers.

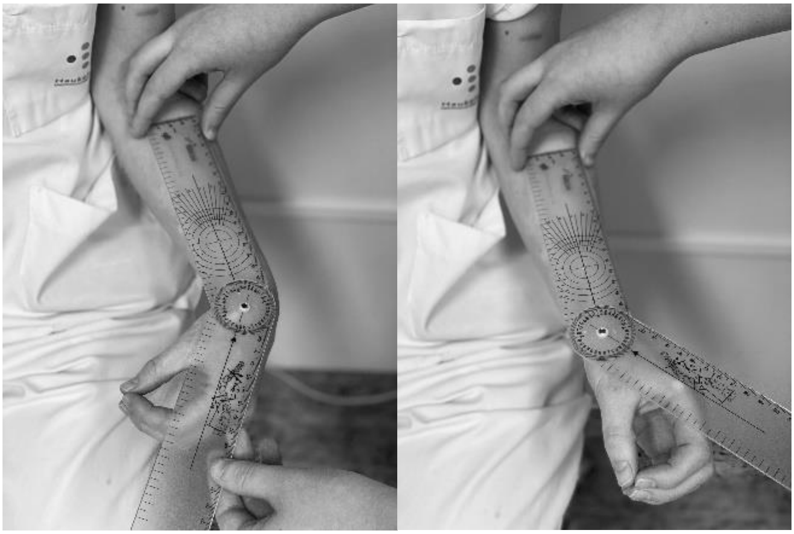


Figure 11: Measurement of flexion/extension of the wrist (private photos)

Radial/ulnar deviation: The forearm resting pronated on a surface, the wrist in 0° extension/flexion.

Figure 12: Measurement of radial and ulnar deviation of the wrist (private photos)

Finger stiffness

Fingertips to palm distance, when attempting to make a fist, addresses finger stiffness. The distance is measured in mm and 0 mm means full flexion. Measurements are conducted with the forearm and the wrist in a neutral position.

- Normal = fingertips touch the palm
- Moderate stiffness = 0-20 mm
- Severe stiffness = >20 mm between fingertips and palm

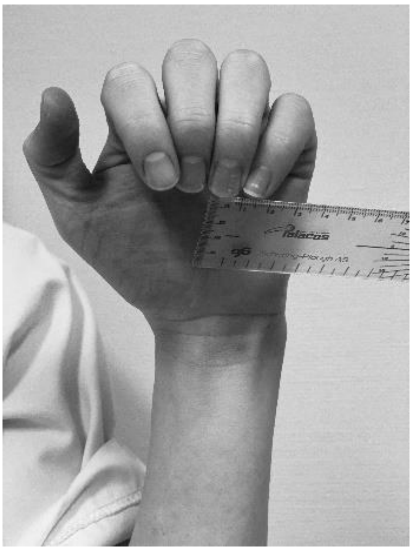


Figure 13: Measurement of fingertip to palm distance (private photo)

Grip strength

Grip strength was measured with the patient in sitting position with the shoulder adducted and neutrally rotated. The elbow joint was kept in approximately 90° flexion, and the forearm and wrist in neutral position. The grip handle was in the second position. The unaffected hand was measured first. The patient was instructed to squeeze the handle as hard as possible. The result was measured in kg. The grip strength of the non-dominant side was adjusted down by 10% for right-handed patients[144], while left-handed patients were assumed to have equal grip strength on both sides[145, 146]. The MCID for grip strength has been found to be a decrease of 6.5 kg (19.5%)[147].

Figure 14: Measurement of grip strength (private photo)

The measurements of ROM, finger stiffness and grip strength were assessed according to the Swedish national quality register for hand surgery, HAKIR.

[Manual-for-rorelse-styrka-Version-1-2016_Eng.pdf (hakir.se)]

Method of radiographic measurement

Radiographs of the wrist were obtained according to standardized clinical procedures: anterior- posterior (AP) views with the shoulder in 90 degrees abduction, elbow in 90 degrees flexion and wrist in neutral position, and lateral views with the shoulder in adducted position, elbow in 90 degrees flexion and wrist in neutral position. If necessary the beam can be angled to visualize the radiocarpal joint. The AP view is used for measuring radial height, radial inclination, intra-articular joint step-off and ulnar variance. The lateral view is used to determine dorsal angulation.

Radiographic findings were assessed as follows:

The long axis of the radius was defined as the line between the midpoint of the radius at 3 and 6 cm proximal to the radiocarpal joint.

The volar tilt was defined as the angle between lines drawn perpendicular to the long axis of the radius and the distal joint surface of the radius using the lateral view. A positive angle denotes volar angulation and a negative angle dorsal angulation.

The ulnar variance was defined on the AP view as the distance between two parallel lines drawn along the distal ulnar aspects of the radius and the distal cortical rim of the ulna, perpendicular to the long axis of the radius.

Radial height was measured on the AP view as the distance between two parallel lines drawn along the tip of the radial styloid and the distal cortical rim of the ulna, perpendicular to the long axis of radius.

Radial inclination was defined as the angle between a line drawn from the tip of the radial styloid to the medial edge of the articular corner of the radius and a line perpendicular to the long axis of the radius.

Any additional ulnar styloid fracture was also recorded.
All values for the involved side were compared with those for the contralateral side.

All radiographs from ten randomly selected patients were reviewed independently by three radiologists and one orthopaedic surgeon. The results were compared to check for understanding of the process and the accuracy of measurements. The radiographs for the remaining patients were split into four equally sized groups and reviewed by one of the same four professionals.

Sample size was guided by a previous study on inter- and intra-observer reliability of assessment of distal radial fractures[148]. A power analysis was not performed.

Figure 15: Measurements of radial height and ulnar variance

Figure 16: Measurements of volar tilt
and radial inclination (local patient, with permission)

Complications

We classified as major complications those which led to reoperations, permanent nerve injury or persistently reduced function such as chronic regional pain syndrome (CRPS). Complications were defined as minor if they were transient or did not affect the patient's final outcome, such as superficial wound infections, scar tissue problems and transient neuropathy. Based on the 2003 "Budapest clinical diagnostic criteria", patients with CRPS were identified by the criteria listed in Table 2[122]. These patients were treated by a dedicated team, and the treatment included physiotherapy and pain management.

Table 2 Budapest Clinical Diagnostic Criteria for Complex Regional Pain Syndrome

To make the clinical diagnosis of CRPS, the following criteria must be met:

1. Continuing pain, which is disproportionate to any inciting event
2. Must report at least one symptom in three of the four following categories:
    - Sensory: Reports of hyperesthesia and/or allodynia.
    - Vasomotor: Reports of temperature asymmetry and/or skin colour changes and/or skin colour asymmetry.
    - Sudomotor/Oedema: Reports of oedema and/or sweating changes and/or sweating asymmetry.
    - Motor/Trophic: Reports of decreased range of motor and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).
3. Must display at least one sign at time of evaluation in two or more of the following categories:
    - Sensory: Evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or temperature sensation and/or deep somatic pressure and/or joint movement).
    - Vasomotor: Evidence of temperature asymmetry (>1°C) and/or skin colour changes and/or asymmetry.
    - Sudomotor/Oedema: Evidence of oedema and/or sweating changes and/or sweating asymmetry.
    - Motor/Trophic: Evidence of decreasing range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).
4. There is no other diagnosis that better explains the signs and symptoms.

Evaluation and follow-up

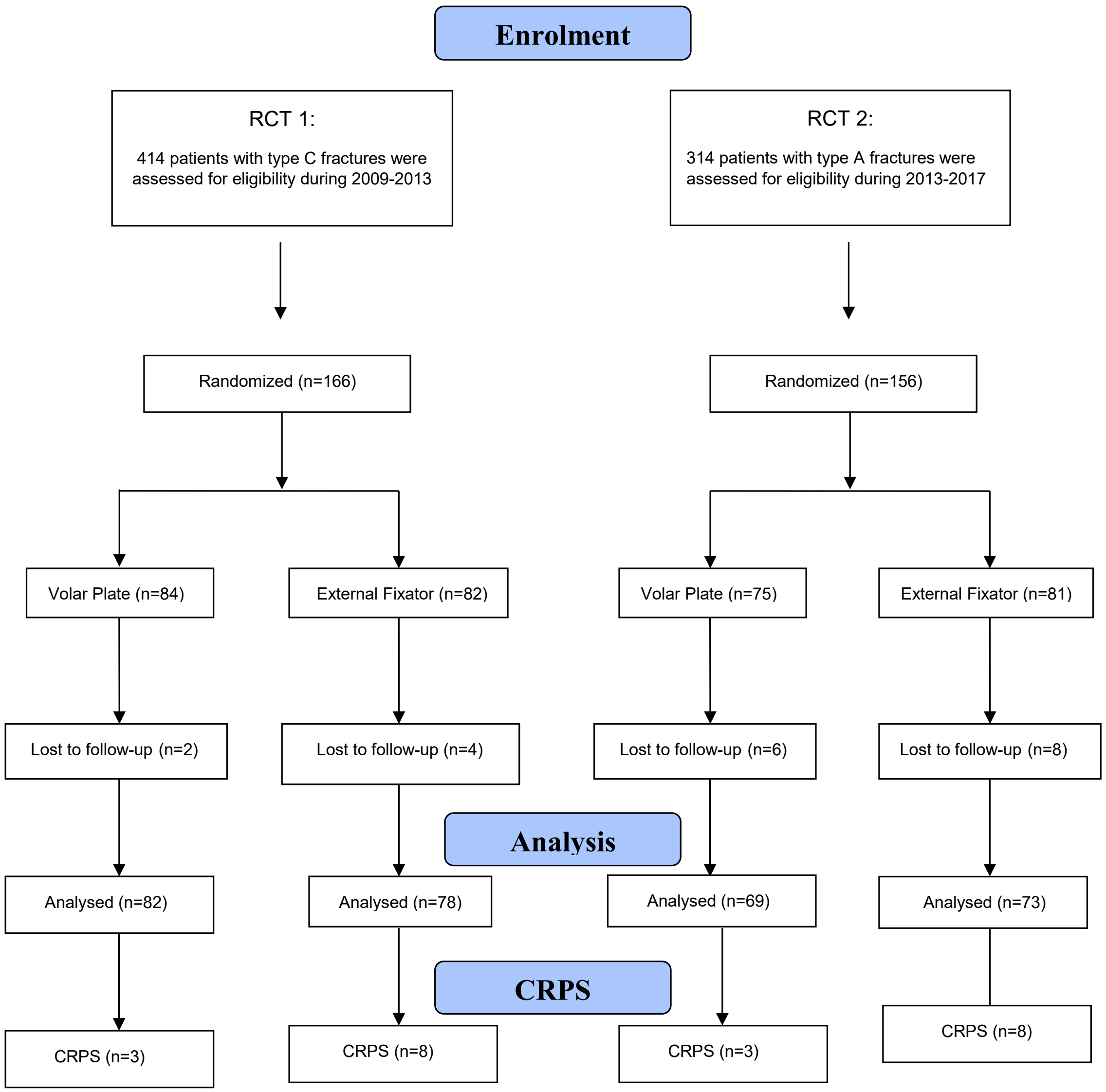
Clinical evaluation and trial documentation were performed during five visits: at baseline, time of intervention, and at six weeks, three months and one year postoperatively. One hundred and forty-two patients (91%) completed the one-year follow-up, while 14 were lost to follow-up.

In **Paper III** our data (RCT2)[149] were pooled with data from another independent RCT conducted at Akershus University Hospital, Norway (RCT1)[150] during 2009-2013. The data were combined to increase the size of the study population to enable the study of an infrequent complication. The aim was to evaluate the risk of developing a CRPS after treatment with a VLP or EF in patients with distal radius fractures. The inclusion criteria for both RCTs were identical, except that RCT1 included intra-articular fractures (AO type C2 and C3) while RCT2 included exclusively extra-articular fractures (AO type A3).

The primary outcome in this study was the number of patients with CRPS during follow-up. Both RCTs adhered to the Budapest clinical diagnostic criteria for CRPS.

All patients were clinically assessed at six weeks, three months and one year postoperatively.

Figure 17: Flow chart, Paper III



3.3 Statistical analysis

Paper I

A block randomization with two equally sized blocks was performed by a biostatistician.

Functional results in terms of the PRWHE score three months and one year postoperatively were the primary outcomes.

The significance level (α) was set to 0.05. With a test strength (1-β) of 80% and standard deviation of 21, 70 patients were needed in each group to show a clinically significant difference of 11.5 points. Assuming a follow-up rate of 90%, we had to include 160 patients.

The non-parametric, independent sample Mann-Whitney U-test was used to identify differences in PROM data (PRWHE, QuickDASH and VAS), as PROMs are often not normally distributed. Other continuous variables were analysed using the Student t-test, and for categorical variables the Chi-square test.

All analyses were based on the intention-to-treat principle, and SPSS version 26 (IBM) was used.

Paper II

Data from all the outcome measures were summarized using means and standard deviations. A Pearson's correlation was calculated for radiological parameters and patient-reported outcomes (PRWHE). The strength of the correlations was interpreted as follows: negligible (r=0.00 to 0.3), weak (r=0.31 to 0.5), moderate (r=0.51 to 0.70), strong (r=0.71 to 0.90) and almost perfect (r=0.91 to 1.00)[12, 151]. A paired *t*-test was used to assess differences in the radiological parameters between the uninjured side and one-year follow-up. To compare fully recovered patients with those not recovered after one year, continuous variables were analysed using the t-test and categorical variables using the chi-square test. P-values less than 0.05 were considered statistically significant. The statistical analyses were performed in the IBM SPSS Statistics 26.0 software (IBM Corp., Armonk, NY, USA) and the R software package (http://CRAN.R-project.org).

Paper III

Variables available in both RCTs were used in the analysis. Continuous variables are presented as mean and with standard deviation (SD), and categorical variables are presented as frequencies and percentages. A Pearson chi-square test was performed to examine the relation between type of implant and CRPS. To identify possible independent risk factors for the development of CRPS, logistic regression analyses were performed. Baseline (pre-operative) variables included in the analyses were selected based on a combination of known risk factors from the literature and clinical experience. The demographic variables included were sex and age at the time of surgery. Surgical risk factors were intra-articular fracture (yes/no), ulnar styloid fracture (yes/no), trauma energy (low/high), time from injury to surgery, and duration of surgery (operation time). In addition, we included implant type (VLP or EF) in the analyses. The results are presented as odds ratios (OR), with 95 % confidence intervals (CI) and p-values. Lastly, due to few patients with CRPS and low statistical power, we performed stepwise regression to identify possible statistically significant variables. P-values less than 0.05 were considered statistically significant. Statistical analyses were performed with SPSS for Windows version 26 (IBM Corp, Armonk, NY, USA).

4 Results

4.1 Paper I

Primary outcome

At six weeks there was a significant difference in PRWHE scores ($p<0.001$) in favour of the VLP. At three months ($p=0.069$) and one year ($p=0.233$) postoperatively, the differences were not statistically significant (Figure 16).

At six weeks, 23% of the VLP group and 6% of the EF group had full recovery. At three months, 58% in the VLP group and 47% in the EF group had fully recovered. At final follow-up, the figures were 81% in the VLP and 79% in the EF group. However, we found ten EF patients with PRWHE scores above 25 points (25-68), indicating a major disability. Only three VLP patients had such high scores.

Secondary outcomes

The QuickDASH scores were in favour of the VLP at six weeks ($p<0.001$) and three months ($p=0.023$). We found no significant difference at one year ($p=0.45$).

There was no significant difference in pain at rest between subjects who received a VLP versus an EF at any time point. Pain during activity was similar at six weeks, but at three months ($p=0.022$) and one year ($p=0.034$), EF patients had significantly more pain.

VLP patients had better ROM and grip strength at six weeks and three months. At one year, they still had better wrist extension ($p=0.013$), but no longer a statistically significant difference in grip strength ($p=0.085$). Patients treated with an EF had more finger stiffness six weeks and three months postoperatively, while at one year there was no difference.

Radiographic measurements were similar prior to reduction, but more patients in the VLP group had an additional ulnar styloid fracture (58% compared to 47% of EF patients). Correspondingly, we found 37% non-unions of the ulnar styloid in the VLP group compared to 25% in the EF group at one year. We found no significant differences in volar tilt, radial inclination or radial height. However, ulnar variance was still smaller in the VLP group ($MD=-0.80$ mm, $p=0.007$), indicating better length restoration.

Complications and reoperations

The number of major complications was 16 (23%) in the VLP group and 18 (25%) in the EF group, while 17 (25%) and 23 (32%) minor complications were recorded in the VLP and EF groups respectively. A transient carpal tunnel syndrome was observed in five VLP patients and three EF patients. Three patients in the VLP group developed a type-1 CRPS versus eight in the EF group. Six of the patients, one in the VLP group and five in the EF group, had CRPS symptoms one year postoperatively.

There were four reoperations in the EF group. Three were early crossovers due to insufficient fracture reductions. According to the intention-to-treat principle, these three patients were analysed in the EF group. One late reoperation was an arthroscopic TFCC repair. We had six reoperations in the VLP group, including five late plate removals due to local pain.

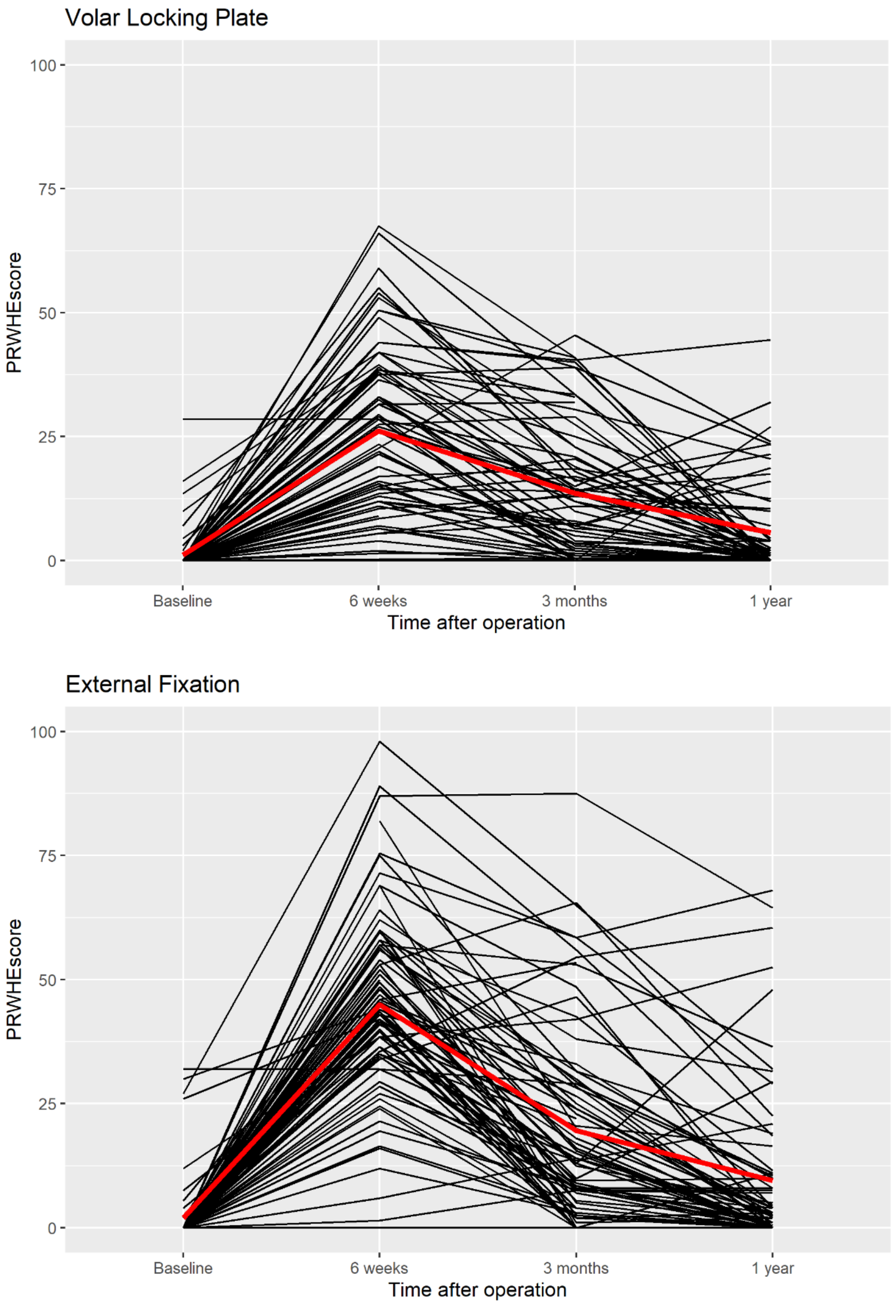


Figure 18: Results for volar locking plate and external fixator. Change in PRWHE score over time for each patient. The red line indicates the mean.

4.2 Paper II

The mean patient-reported PRWHE score prior to injury was 1.4±5, while after one year it was 7.6±13.5. Radiographic results after one year differed significantly from the uninjured side. At the time of injury 53% (n=80) had sustained an additional fracture of the styloid ulna. After one year the fracture was still radiographically present in 31% (n=43) of the patients.

Overall, we found no correlation between radiographic parameters and the PRWHE at one-year follow-up in the entire sample, regardless of which treatment was chosen (volar tilt r=-0.005, p=0.95, radial inclination r=-0.083 p=0.34, radial height r=-0.043, p=0.62 and ulnar variance r=0.068 p=0.43). No correlation between PRWHE score and the presence of an ulnar styloid fracture at one-year follow-up (MD=2.24, p=0.37) was found.

We found no significant difference in radiographic findings between the two surgical methods in terms of volar tilt (MD =0.908, p=0.34), radial inclination (MD=-0.97, p=0.10) and radial height (MD=0.468, p=0.30). However, ulnar variance was significantly smaller in the VLP group (MD=-0.819, p=0.01).

At one year, we found that 80% had made a full recovery. However, we also noted that 20% had PRWHE scores higher than 11.5 points compared to their preoperative score, indicating a persisting major disability. When comparing the two groups we found no difference in results in relation to age, gender, injury of dominant hand, injury energy level or manual work. Further, type of implant, time until surgery, type of anaesthesia, duration of surgery and duration of postoperative stay had no influence on results at one year in either group. However, we found that patients with high PRWHE scores at one year were more likely to have had an injury indoors, be unemployed or be receiving disability benefits. Radiologically, we found that the patients with a high PRWHE score at one year had significantly larger initial displacement after injury in terms of radial inclination (p=0.004) and radial height (p=0.047), but this was not found in relation to volar tilt, ulnar variance and the presence of an ulnar styloid fracture. At one year, no radiological difference was found affecting the functional results. Neither a dorsal displacement >10° (p=0.975) nor an ulnar variance >2 mm (p=0.838) compared to the uninjured side after one year were found to affect the functional outcome.

4.3 Paper III

Overall, 322 patients were included in the present study. 159 were operated with a VLP and 163 with an EF. All patients received the intended method of treatment according to the randomization. Twenty patients (6 %) were lost to follow-up, leaving 302 patients available for analysis (Figure 1). The mean age at the time of surgery was 55.7 years (SD 11.0), and 254 patients were female (79%). The patient characteristics are presented in Table 3.

A CRPS was diagnosed in 22 patients (7%), including 6 patients (4%) in the VLP group and 16 patients (11%) in the EF group. Patients operated with an EF were more likely to be diagnosed with CRPS compared to patients treated with a VLP (p=0.032). The Odds Ratio for developing CRPS after EF was 2.78 (95 % Confidence Interval (CI) 1.06 - 7.29) compared to VLP.

In the logistic regression analyses none of the independent risk factors were found to be statistical significant related to CRPS, this was also the case for the stepwise regression. The Odds Ratio for CRPS after EF compared to VLP in the adjusted logistic regression increased slightly to 3.4 (95% CI 1.10-10.37, p=0.043).

5 Discussion

5.1 Methodological considerations

Paper I is based on a RCT and the evidence level is set to level 1. The study design enables us to decide the inclusion criteria, procedures, outcome measures and analysis suitable to address the research question. The gold standard of study design to find a causal relationship between exposure and outcome is the randomized controlled trial (RCT)[152, 153]. Unlike a retrospective study where conclusions have to be drawn from assumptions instead of calculations, a prospective study has the advantage of controlling for all biasing and confounding factors. A confounder, a variable other than the one studied, can cause or prevent the outcome of interest[154]. Randomization minimizes potential confounding by distributing all confounders evenly between groups and breaking any link between the type of intervention and confounders. The patients are randomly assigned to treatment groups, and the risk of bias and confounding factors is low. With two treatment arms, randomization assigns each patient to one of the treatment groups with 50% probability. Several consecutive patients allocated to the same treatment could lead to logistic challenges with the supply of implants and sterile operating instruments. This was solved by block randomization to ensure a balance in sample size across groups over time. By randomly varying block size the probability of correctly guessing the next allocation compared to other methods was ruled out. Selection bias was also reduced by hiding the allocation sequence from those performing the randomization. A systematic review from 2011 found that control group patients in non-randomized controlled trials were frequently found to have a worse prognosis than patients in the study group, underlining randomization as a protection against selection bias[155].

There is a possibility of recall bias, which means that some patients are unable to recall their preoperative state at the time of inclusion. In our study, the relatively short duration between injury and operation (<16 days) makes this less probable. It is well known that patients enrolled in a study self-report more positively in response to being observed[156]. This phenomenon limits the external validity of the results. Missing data and patients lost to follow-up are always a challenge in medical research. In our study 9% were lost to follow-up, which is acceptable and to be expected based on our sample size and power calculations.
For two main reasons, neither double nor simple blinding was deemed feasible in the current study. The postoperative rehabilitation protocol differed between the groups in the

intervention and the very nature of the surgical procedures and the implants made blinding impossible.
An important limitation of RCTs is that the study often includes a limited subgroup of patients, as in our study where only patients between 18-70 years of age with extra-articular fractures were included. In that case, external validity is lower than in larger studies that include a more diverse patient group and the results cannot be extrapolated to older patients and patients with intra-articular fractures. The same can be said for studies where patients receive treatment in clinics with close follow-up by highly engaged doctors. However, this was not the case in our study. To ensure an appropriate level of experience, all surgeons involved needed to have performed a minimum of five procedures with each technique following a standard protocol. With 40 different surgeons performing the procedures, treatment of this common fracture is almost an everyday occurrence in most hospitals, thus providing external validity.

PROMs provide measurements based on the patient's perspective, without amendment or interpretation of the patient's response by a clinician or other observer[81]. Different types of PROM have been available since they were introduced in the 1970s. Over the years, PROMs have become the primary choice for evaluating the effect of a treatment[157]. The most common wrist functional assessments are The Patient-Rated Wrist and Hand Evaluation (PRWHE) and The Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) scoring systems. Although they are widely used, the PRWHE and QuickDASH scoring systems have not been validated for different ages or for different outcomes and functional abilities.

The PRWHE is the most sensitive PROM for patients sustaining distal radius fractures[82] and is the primary outcome in our study. This study was designed to find differences in PRWHE between the two treatment arms. The Minimal Clinical Important Difference (MCID) defines that change in an outcome score that would correspond to a change in clinical status appreciated by the patient[158]. The MCID of the PRWHW is found to be 11.5 points for patients with distal radius fractures[143]. It is crucial to recognize that the MCID cannot be used directly to compare mean group differences following different treatments. It should be applied to changes in individual subjects, not to group changes[159]. We defined patients as fully recovered if they reported a difference in PRWHE score below 11.5 points, compared to their preoperative score. Instead of knowing the mean improvement on a PROM score, knowledge of the probability of being substantially cured would be more relevant to the patient and physician.

When a PROM is used to compare two treatments there is a risk of a ceiling effect possibly involving a lack of sensitivity when more than 15-20% of patients achieve the best outcome. PROMs are often skewed, particularly after a successful operation, at which time many patients cluster toward the highest functional ability of the scale. The t-test is appropriate for normally distributed data, but PROMs are often not normally distributed even in relatively large samples.

A difference between two groups may then be interpreted falsely as absent when actually present (type II error)[160]. A non-parametric assessment of the results could be a better option as used in Paper I.

An RCT with a sample size of 156 patients as in our study is insufficient to uncover rare complications. A larger register study could, in theory, have sufficient power to do so. Another alternative would be a multi-centre, prospective RCT.
Despite their many advantages, RCTs are extremely time-consuming and tend to take longer than planned. In our study, the time from inclusion of the first patient until publication of Paper I was seven years.

Paper II is based on a prospective cohort study to assess the relationship between radiological findings and functional outcome. The study was conducted based on findings from the RCT in Paper I. Cohort studies are appropriate to evaluate associations between exposures and outcomes. A prospective cohort study has the advantage of being designed to collect specific data, but they can be very expensive and time-consuming and patients lost to follow-up can introduce bias. Its evidence level is lower than that of an RCT, set to level 2.
A weakness of this study might be the small range of variations in radiological results. All patients were operated with no conservatively treated control group. Then again, the fracture type was homogenous, where only extra-articular fractures were included. The radiological measurements were performed very accurately. PROMs were available to assess the relationship between radiological findings and functional outcome.

Paper III is based on pooled data from two separate RCTs. Both trials recorded complications as secondary outcome. More cases of CRPS in the EF group were found in both trials, but neither had the power to detect a statistically significant difference. The purpose was to pool the data from the two RCTs to increase the statistical power to assess the risk of developing CRPS. The strength is the similarity between the two large RCTs conducted in two separate regions in Norway. Both RCTs had identical inclusion criteria except for the fracture classification. The RCTs were comparable in sample size, implants, PROMs and objective outcomes recorded as well as complications. The CRPS diagnosis was based on the Budapest clinical diagnostic criteria. A statistically significant difference was found between the two groups treated with either a VLP or an EF. Although the RCTs were not designed to analyse complications as primary outcome, the pooled data found a significantly higher risk of developing CRPS following treatment with an EF than with a VLP. A post-hoc power analysis demonstrated that our result reached 58% power with a 5% significance level. To reach 80% power the number of patients included would have had to be in total at least 444. This indicates that this study is underpowered. Still, in light of the severity of this chronic pain condition, the results are important for decision making in treating these fractures. The evidence level was level 2.

5.2 Discussion of results

Subjective measurements

As stated earlier in this thesis, VLP has become the method of choice during the last decades when treating displaced distal radius fractures. This trend developed despite lack of evidence that VLP would provide better functional results compared with an EF at the time. Previous AAOS guidelines[29] were inconclusive regarding surgical fixation method and were unable to recommend any specific method. The aim of this study was to determine whether VLP or EF provides superior outcomes for displaced extra-articular DRFs and contribute to new information to the abundant literature on the topic. Due to the frequency of the fracture and the uncertainty about the best treatment, this is important to both the patients and the society.

In 2013, a few months after the inclusion of our first patient, Walenkamp el al.[161] published a meta-analysis comparing functional outcome in patients with DRF treated with either VLP or EF. They found a statistically significant and clinically relevant better DASH score at 3 months in favour of VLP but the difference was no longer clinically relevant at one year. At that time, only 3 RCTs were found eligible and they included only a total of 174 patients[38, 39, 43]. Since then, several RCTs [36, 37, 40-42, 150, 162-164] comparing these two surgical treatment methods have been published giving rise to new meta-analyses on the topic. Li-Hai et al.[165] published in 2015 a meta-analysis based on 6 RCTs[36, 38, 39, 43, 161, 163] with the same result as

Walenkamp et al.[161], VLP had superior DASH scores at all follow-up points but the difference was no longer clinically relevant after 3 months. In 2018 the same results were confirmed in two meta-analyses published by Fu et al.[166] (9 RCTs 2008-2014[36-40, 42, 43, 163, 164]) and Gouk et al.[167] (9 RCTs 2008-2016[36, 38-43, 163, 164]). Lastly, in 2021 Gou et al [168] could add two RCTs by Chung et al[162] and Hammer et al.[150], and now presenting a total of 12 RCTs, including 1205 patients to their meta-analysis. Again, one of the significant differences in the outcome of VLP and EF was the DASH score at 3 months suggesting that patients treated with VLP might obtain a better functional outcome at early stages but no difference in long term results.

Our study is in line with these findings. VLP resulted in a much faster recovery than EF, with superior results related to PROM score at 3 months while no clinically relevant difference was found for long-term results.

AAOS published updated clinical practice guidelines in 2022[169]. The new guidelines now provide strong evidence that there is no difference in long term reported outcomes between the different fixation techniques for unstable distal radius fractures in patients younger than 65 years old with the following post reduction displacement: radial shortening < 3mm, dorsal tilt <10°, intra-articular displacement or step-off < 2mm, although VLP leads to early recovery of function in the short term (3 months).

The results indicate that patients treated with VLP might obtain a better functional outcome at earlier stages. With this in mind, one might argue that long rehabilitation periods are not desired or acceptable for younger patients with high demands.

In our study, patients was either included based on the initial displacement of the fracture or secondary displacement at the first follow-up after 7-10 days. In 2019, two studies reported outcomes from primary surgery vs delayed primary surgery. Mulder et al.[170] found in a RCT that patients treated with early primary surgery had significantly better PROM score up to 12 months compared to patients who received delayed primary surgery. Sirnö et al.[171] found that delayed surgery in case of secondary displacement was not beneficial in terms of function as early operation with a VLP resulted in better 2-year outcomes for patients≥50 years. By reducing the number of patients with delayed primary surgery prolonged immobilization could have been avoided, potentially speed up the return to work and most important result in better final functional outcome. In our study we conducted no sub analysis based on early vs delayed surgery, consequently we do not know if delayed surgery influenced the outcome in our patients.

From a societal perspective, Hammer et al.[172] conducted a cost-utility analysis alongside their RCT. They found longer duration of sick leave (3.7 weeks) in the EF group resulting in greater costs due to lost productivity.

This might also be an important aspect when it comes to favour VLP as the treatment of choice.

VAS

Few studies report specifically on pain, apart from questions included in standard PROMs. Only 4 out of 12 studies in the meta-analysis by Gou el al[168] provided data on VAS [38, 43, 150, 163]. These studies included a general question about pain and found no heterogeneity for the scores. At 6 months follow-up VLP had an overall better VAS than the EF but this was not found at 3 and 12 months. In our study, we distinguished between pain at rest and during activity. We found no difference in pain at rest, but patients with EF reported statistically more pain during activity at three months and one year. It is important to separate the question about pain into these two categories, pain at rest and pain during activity. Although patients no longer suffers from pain during rest and sleep, pain during leisure activities and work may give the patients limitations and reduced quality of life.

Objective measurements

Differences in ROM, grip strength and finger stiffness were especially found in the short term follow-up. In our study, patients treated with a VLP had better recovery of wrist flexion and extension, forearm supination, ulnar and radial deviation of the wrist, finger stiffness and grip strength at three months. After one year, they still had better extension, ulnar and radial deviation, but grip strength, wrist flexion, supination and finger stiffness no longer varied between the groups, in line with other studies[36-40, 42, 43, 150, 173]. The difference in grip strength was both statistically and clinically important at 3 months as MICD has been found to be a decrease of 6.5 kg (19.5%)[147]. The MICD for ROM is not established making it difficult to assess at what time during follow-up the difference was no longer of interest. The VLP group had an advantage as wrist movements could start immediately postoperatively. Patients in the EF group could not start full functional rehabilitation before removal of the EF six weeks postoperatively. For this group, initial weakness and stiffness gradually improved after removing the EF. The immobilization of the wrist with an external fixator for six weeks postoperatively may explain these early functional differences.

Kirsch wire fixation versus VLP

Our study confirms the trend of choosing VLP as the preferred surgical technique over EF. But what about other treatment modalities? Aside from VLP and EF, Kirschner wire fixation is the most common form of fixation. While Kirschner wires historically used to be the operative treatment of choice it gradually fell out of favour after the introduction of the VLP. Kirschner wire fixation is a quicker and cheaper method but the potential benefits from a VLP fixation and subsequently facilitating a quicker rehabilitation has justified the higher costs of VLP[174]. Several smaller single centre trials comparing the two methods indicated that the VLP provided superior functional and radiological outcome[37, 175-177]. However, Costa et al.[178] in 2015 presented their results from a multicentre RCT including 461 patients (UK DRAFFT). Adult patients with a dorsally displaced fracture that could be reduced with indirect technique were randomized to either Kirschner wire technique or VLP. In contradiction to previous studies they could not find any clinically important differences in PRWHE scores between the treatment groups at any time during the 12 month follow-up. A five year follow-up study by the same authors continued to show no evidence of a difference in long-term clinical outcome[179]. This contributeed to a change in clinical practice in the UK. A report by Costa et al.[180] from 2016 documented that during the 5 years before the DRAFFT, 75% of the operatively treated patients received a VLP versus only 12% Kirschner wires. After the publication of the results from DRAFFT the picture changed, and VLP had dropped to 48% while 42% now received Kirschner wires. Tubeuf et al.[181] did a detailed cost analysis of DRAFFT and found that the total costs were significantly higher in the VLP group. When British Orthopaedic Association and British Society of the Hand updated their guidelines on management of distal radial fractures in 2018 this was taken into account[182]. The group agreed "*that when surgery is needed for dorsally displaced distal radial fractures that can be reduced, closed, K-wire fixation and cast immobilization should be offered*", indicating that only fractures that need an open reduction should be treated with a VLP.

Conservative treatment versus VLP

Some fractures usually need surgical treatment in all age groups. Among these are fractures with subluxation of the carpus, fractures with volar displacement, open fractures, intra-articular comminute fractures, and fractures with impacted lunate facet fragments. However, the majority of DRFs are dorsally displaced fractures with more or less displacement.

The latest meta-analysis on the topic by Lawson et al.[183] from 2021 included 8 RCTs with 391 patients allocated to VLP and 401 allocated to conservative treatment[17, 22, 170, 171, 184-187]. Five studies specifically recruited older patients[17, 22, 171, 184, 185]. At 3 months PRWHE favoured VLP while the difference in DASH score was small and unlikely to be clinically meaningful. At 12 months no meaningful difference between the two treatments was found. Also no clinically important differences in ROM and grip-strength were found.

Focusing on dorsally displaced fractures in elderly >65 years old, a recently published RCT from Norway in 2021 by Hassellund et al.[188] comparing cast immobilization with VLP found cast immobilization to be non-inferior as measured by QuickDASH. They also conducted a cost –analysis and found surgical fixation not to be cost-effective in this age group. This is despite a worse radiographic outcome for conservatively treated fractures indicating that radiographic outcome does not correlate as well with functional outcome in elderly patients, a result previously supported by other studies[22, 189]. The updated guidelines by AAOS from 2022[169] recommend surgical treatment for patients younger than 65 years of fractures with post reduction radial shortening>3mm, dorsal tilt >10° or intra-articular displacement or step-off >2mm. The recommendation is given with moderate strength.

While cut off age previously was set to older than 55 years, the updated guidelines now define elderly patients 65 years and older. The same guidelines now report strong evidence that surgical treatment of older patients does not lead to improved long-term outcome compared with nonsurgical treatment.

Still, the elderly patient group is heterogeneous ranging from active high demanding individuals to those living in nursing homes. In light of this it is important not only to focus on age but to also take into consideration the patient's preferences and functional demands before deciding on which treatment to choose.

Radiographic evaluation

Our radiographic evaluation demonstrated no significant difference in radiographic parameters between the groups after one year, with the exception of the failure of EF to maintain ulnar variance to the same extent as VLP, a result also found in other studies[37, 39, 41, 42, 150, 190]. The finding of different ulnar variance between postoperative and later follow-ups, even in the VLP group, is unexpected, as studies have generally shown no reduction with VLP. This is probably a result of posterior-anterior views taken in slight supination due to postoperative pain, compared to neutral rotation at later follow-ups, resulting in negative ulnar variance[191, 192].

Historically, anatomical and radiographic outcomes were considered to correlate with functional outcome. The possible correlation between radiological findings and the PRWHE score has been evaluated in 3 prior studies. Karnezis et al.[193] demonstrated a moderate correlation with the degree of radial shortening at 12 months post injury while Plant et al.[10].found overall poor correlation between the radiographic parameters and PRWHE except from palmar tilt at 3 months. In older patients, Synn et al.[194] found no association between radiographic assessments and PRWHE at six months. In our study, we found no correlation between radiographic measurements and wrist function (PRWHE) at one-year follow-up in patients with extra-articular (A0 type A3) distal radius factures operated with a VLP or EF.

Previous studies have indicated that radiographic and functional outcomes are more closely correlated in younger patients[2, 195]. This was not supported by our study, where all patients were under the age of 70.

Some studies have reported that more than 40% of distal radius fractures have an associated ulnar styloid fracture[196-198]. This is similar to our findings of 53%.

The frequency of ulnar styloid non-union has previously been found to be between 26%[199] and 63%[196], and functional outcome scores for such patients were not worse than for patients with healed fractures[196, 200-202]. In our study, there were 31% non-unions and we found no correlation with the PRWHE score after one year, consistent with the recent meta-analysis by Mulders et al.[203].

At one year, most patients had good PRWHE scores and there was no statistically significant difference at group level although 20% reported persisting disability. However, a comparison of patients with poor results to those who had achieved full recovery revealed that the former were more likely to be unemployed or disabled, and to have sustained a low-energy indoor trauma. These patients also had greater loss of radial inclination and radial height. This may indicate that patients with poorer functional results have other health issues, including osteoporosis. Earlier correlation studies found that a dorsal angulation >10° and radial shortening >2 mm were associated with a worse functional outcome than that of patients with a satisfactory radiological outcome[1]. In our study, the function of patients with a difference in dorsal tilt >10° or radial shortening >2 mm at one year, compared with the uninjured side, were compared with patients with satisfactory radiological outcome. However, in our study no correlation was found and we found no difference in PROM.

Our study included more patients than previous studies, which makes it less probable that our failure to detect a correlation between radiographic findings and functional outcomes is due to an underpowered study.

The AAOS recommendations are in general based on the age of the patient and fracture type assessed from radiographs of the wrist. The use of radiological parameters alone to predict successful treatment outcome was not supported by our study. Other patient-specific factors were found to be more important than radiographic measurements in this study group.

The lack of radiological variation in our study makes it difficult to draw decisive conclusions about possible associations between the various radiological parameters and clinical outcome. Such variation might have been expected if a third, conservative arm was added to the study.

Reoperations

There were six reoperations in the VLP group compared to four in the EF group. Early reoperations were found in three out of the four in the EF group and in one out of six in the VLP group, all due to mal-reduction. One late reoperation was reported in the EF group due to a TFCC rupture and five implant removals were performed in the VLP group due to persistent pain. Previous studies have reported a plate removal rate of 6-21% [42, 150], with our results of 7% comparable to this. When included in the trial, the patients in the present study were informed that plate removal is usually unnecessary. This might explain our relatively low removal rate.

Complications

There was a relatively high rate of complications in our study (VLP 48%, EF 57%). This was almost identical to the complications reported by Hammer et al.[150] (VLP 44.1%, EF 54.9%). This was also consistent with the study by Mellstrand-Navarro et al.[41] who reported 50.7% overall complications in the VLP group and 44.6% in the EF group. We found a tendency towards more CRPS in the EF group (8 versus 3), but this was not a statistically significant difference (p=0.14). However, for this infrequent complication, the power of the study may have been insufficient to detect a possible difference. Interestingly, Hammer et al. found the same tendency of CRPS related to EF (8 versus 3)[150]. Based on these numbers, the two study groups decided to pool the data from these two RCTs.

When analysing the combined data, we found ten more cases of CRPS among patients treated with an EF compared to those treated with a VLP (16 versus 6) and the difference in CRPS between EF and VLP was statistically significant (p=0.032). One could thus argue that more cases of CRPS could have been avoided by treating all our patients with a VLP. In addition to the obvious patient benefit of avoiding CRPS, this would also reduce the institutional and societal healthcare costs, related to CRPS, substantially[172].

In our study, 7% of the patients were diagnosed with CRPS. This is comparable to other studies of fracture patients[204, 205]. In population studies, the incidence has been reported to be less than 1%[138, 206], indicating that a distal radius fracture is a substantial risk factor for CRPS. A Korean population-based study from 2019 concluded that the incidence of CRPS was lower after an EF than after plate fixation[138], which directly contradicts our findings. That study, however, used a national health insurance database to identify patients diagnosed with CRPS after a surgically treated DRF. Their incidence of CRPS after surgery for DRF of less than 1% is very low, and contrasts with the much higher incidence of CRPS reported in our and other clinical studies[204]. As CRPS is a clinical diagnosis, the variability in these studies highlights the challenges of the CRPS diagnosis. The Korean study utilized the Persistent Disability and Assessment Guidelines of the American Medical Association, which focus more on objective findings than subjective symptoms. Other epidemiologic studies by Ott and Maihofner[118] and Sandroni et al.[119] used more clinical criteria. How well these studies reflect the “true” incidence in the general population is difficult to know and probably depends on the diagnostic criteria employed. Prospective clinical studies will probably be the best study design to include a representative patient cohort for analysis.

The results of the Korean study also contradicts our study with regards to our finding of a higher risk of developing CRPS following an EF compared to a VLP. Ortiz-Romero et al. [207], on the other hand, published a case-control study of 249 patients with a DRF. They did not find any correlation between type of surgical treatment and development of CRPS. However, their study was underpowered with only ten cases of CRPS, and the patients were not randomized to treatment groups, introducing a substantial selection bias. Similarly, Zollinger et al.[208] could not find an increased risk of CRPS following EF, but this study was also underpowered with only 29 patients in the EF group. Furthermore, the patients were not randomized by surgical method.

Our results are supported by previous reports of a high incidence of CRPS after an EF. An early report on EF reported that over 60% of patients experienced symptoms of CRPS, although that study was conducted before the Budapest criteria were established[209]. Hegeman and co-workers found CRPS in 19% of patients treated with an EF for a displaced and unstable DRF[210]. Some authors have suggested that excessive distraction of the radiocarpal and midcarpal joints, resulting in reduced microcirculation with fibrosis and increased stiffness, might be an explanation for this, but the pathophysiology behind this complication is not fully understood[211, 212]. However, our study indicates that even modern EF techniques increase the risk of CRPS considerably.

Some studies have suggested that CRPS correlates with old age[205-207]. We did not find such a correlation, but patients older than 70 years were not included in our study.

Several studies have found a higher rate of women developing CRPS after DRF[138, 205, 206, 213], but this is confounded by the fact that more women also sustain a DRF[44]. An association of CRPS with female gender was not supported by the combined results from our two RCTs, which is in line with other reports[207, 208].

According to some authors, high-energy injuries[205, 207], and concomitant ulnar styloid fracture[138, 206, 207] lead to higher incidence of CRPS following DRF. This was not supported by our study. Neither an ulnar fracture nor intra-articular affection of the fracture was associated with the risk of developing CRPS.

More research on this topic is called for. If additional research confirms an association between an EF and CRPS, this could be a reason to favour VLP.

The study population included patients from one country, perhaps affecting the external validity of the results.

CRPS is still an enigmatic condition with an unclear pathophysiology. The Budapest criteria for CRPS have been widely used in previous research and are increasingly used in clinical practice. As the Budapest criteria are based on consensus and expert opinion without a specific test or a imaging technique capable of confirming or excluding the diagnosis, this represents a weakness to the reliability of the diagnosis itself[140, 205, 214]. As evidence-based recommendations are lacking, the treatment for CRPS is generally still driven by clinical experience. Although studies are frequently being published, larger RCTs are needed in this field.

6 Conclusion

Paper I

Treating displaced extra-articular distal radius fractures, AO type A3, with a VLP resulted in faster recovery compared to an EF. Even though one-year results were similar between the groups, more patients operated with a VLP had less pain and better function during activity after one year.

Paper II

In extra-articular distal radius fractures, the functional outcome was not correlated to any significant degree, with radiographic alignment. Other patient factors, such as being unemployed or disabled, or having sustained an indoor low energy trauma, were found to be more important predictors of outcome.

Paper III

We found that being operated with EF was an independent risk factor for CRPS after treatment for a displaced DRF.

Thesis

In conclusion, we think that the quality and validity of this thesis is sufficient to conclude that patients treated for distal radius fractures with VLP regain good function earlier than those treated with EF. Furthermore, the VLP treated patients have less activity related pain at one year postoperatively, than the EF group. Also in favour of the VLP is the finding of less risk of CRPS after VLP treatment compared to EF. Based on our findings we support the trend towards increasing use of VLP which is likely to benefit the patients.

However, we found that the correlation between radiologic findings and functional results was low, raising questions regarding the use of the current radiologic criteria as basis for indications for surgical treatment.

7 Future perspectives

- Treating an increasing number of distal radius fractures, safely, predictably, and at a reasonable cost remains a challenge also in the future. Selecting the best treatment for individual patients, with particular attention to avoiding surgical and other complications, should be the main goal. More studies, focusing on who would benefit from an operation and who should be treated conservatively, are needed.

- There is a lack of evidence of using radiographic deviations to decide when to operate distal radius fractures. Future studies should be designed to identify cut-off for misalignment affecting the outcome.

- Appropriate PROM and relevant questions is important to evaluate the effect of the treatment and more studies should focus on this.

- Further, relatively small single-centre RCTs may not be able to show significant differences in subjective or objective data. There is a need for meta-analyses including large numbers of patients to give us new insights. The quality of the aggregated evidence depends on the amount of analysable data available for meta-analysis. It is problematic that reporting of PROMs and follow-up time differs across publications and endpoints are presented using incompatible parameters. A greater consensus on data recording methods would enable us to incorporate more available data in meta-analyses. This would help us to record less frequent complications and identify patients at risk.

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9 Appendices

Appendix I: Information for patients
Appendix II: Written informed consent
Appendix III: PRWHE questionnaire (in Norwegian)
Appendix IV: QuickDASH questionnaire (in Norwegian)

I

Førespurnad om deltaking i forskningsprosjektet

"Volar plate versus eksternfiksasjon"

Bakgrunn og hensikt
Dette er eit spørsmål til deg om å delta i ein forskingsstudie for å finne best mogleg behandling for ei gruppe særs kompliserte handleddsbrudd. Vi har valt ut deg fordi du har pådratt deg eit slikt brudd. Studien vert utført ved Voss sjukehus og Haukeland Universitetssjukehus.

Kva inneberer studien?
Behandlinga av handleddsbrudd har dei siste åra endra seg.
Den dominerande behandlinga har til no vore å sette på ei ytre metallramme som ved hjelp av skruer gjennom huden vert festa til underarmen og handa.
Dei siste åra har ei ny type metallplate blitt stadig meir brukt i staden. Ved denne behandlinga opnar ein huda på undersida av nedre del av underarmen. Deretter opererer ein seg inn til bruddet. Etter å ha dradd bruddet på plass legger ein ei metallplate direkte på beinet og fester denne med skruer.

Begge inngrepa blir utført anten i narkose eller ved at ein bedøver heile armen, og stort sett reiser ein heim frå sjukehuset dagen etter.

Kva som er best behandling veit ein enno ikkje. Det er gjort få undersøkingar som samanliknar dei to typane operasjon, og ut frå desse kan ein ikkje seie sikkert kva type behandling som bør bli "standardbehandling".

I vår studie vil pasientar som deg med denne typen kompliserte handleddsbrudd bli tilfeldig trekt ut til ein av de to behandlingane. Begge gruppene med pasientar vil så bli følgt tett med jamlege kontrollar etter skaden.
Vi vil samle inn opplysningar om kva som skjedde da du skada deg, kva jobb du har, om du er høgre- eller venstrehendt og om du har andre sjukdommar. For å kunne sjå på dei økonomiske følgjene av ein slik skade kjem vi og til å sjå på kor lenge du blir sjukemeldt. Undervegs gjer vi fleire røntgenundersøkingar og testar styrken og bevegelegheit i armen din. Du vil også bli beden om å fylle ut spørjeskjema som fortel oss korleis du synes armen din fungerer og korleis livskvaliteten din er etter skaden.

Du vil bli kalla inn til kontroller 6 veker, 3 månader og 1 år etter skaden.

Utanom dei faste kontrollane vil du ha mogelegheit for å kontakte oss dersom du har spørsmål.

Dersom du vel å ikkje delta i studien vil operasjonsmetode oftast bli vald av den enkelte kirurg. Hos pasientar som ikkje deltek i studien vil oppfølginga normalt bli avslutta etter 6 veker.

Moglege fordeler og ulemper
Operasjonsmetodane brukt i studien vår er dei vanlegaste ved kompliserte handleddsbrudd av din type. Den største fordelen ved å delta i studien er at du får ein mykje tettare oppfølging etter operasjonen. Ulempa med dette er at kvar kontroll med testar og røntgen tar noko tid og du må fylle ut nokre skjema.

Tidlegare studiar har vist at begge operasjonsmetodane har sine fordeler og ulemper.
Dei som får operert inn ei metallplate får kanskje raskare betra bevegeligheit. Ein mogleg ulempe med plata er at den nokon gonger irriterer senene i handa og nokon gonger må bli fjerna etter at bruddet har grodd.
Ein mogleg fordel med å sette på ei ytre metallramme er at ein ikkje opnar opp huda i bruddområdet og såleis får mindre arr. Ulemper kan være at metallramma er utan på huda og noko "upraktisk". Ein kan få lokal hudinfeksjon der skruene blir satt inn i armen, og disse skruene kan også irritere musklar og sener.

Kva skjer med informasjonen om deg?
All informasjon om deg vert lagra streng konfidensielt og resultata vil bli presentert i anonymisert form.

Informasjonen som blir registrert om deg skal kun bli nytta slik som beskrevet i hensikta med studien. Alle opplysningane vil bli handsama utan namn og fødselsnummer eller andre direkte gjenkjennande opplysningar. Ein kode knytter deg til dine opplysningar og prøver gjennom ei namneliste.

Det er kun autorisert personell knytt til prosjektet som har tilgang til namnelista og som kan finne tilbake til deg. Vi ønskjer å ha mogelegheit til å kontakte din fastlege for å finne ut kor lenge du eventuelt har vore sjukemeldt. Vi kjem til å lagre resultata når denne studien er avslutta og det er mogleg vi kontaktar deg også seinare etter 1 år for få meir informasjon om korleis du har det.

Det vil ikkje være mogleg å identifisere deg i resultata av studien når desse vert publisert i eit vitenskapeleg tidsskrift.

Frivillig deltaking
Det er frivillig å delta i studien. Du kan når som helst og utan å gje nokon grunn trekke samtykket ditt til å delta i studien. Dette vil ikkje få konsekvensar for din vidare behandling. Det er likevel viktig at flest mogleg pasientar følgjer opplegget i studien for at den skal bli best mogleg. Dersom du ynskjer å delta, skriv du under på samtykkeerklæringa på siste side. Om du no sier ja til å delta, kan du seinare trekke tilbake samtykket ditt utan at det påverkar din øvrige behandling. Dersom du seinare ynskjer å trekke deg eller har spørsmål til studien, kan du kontakte leiaren av studien dr. Trine Ludvigsen på Voss sjukehus, tlf. 56533500. Dersom dr Ludvigsen ikkje er til stades kan du kontakte "vakthavande ortoped", som er til stades på sjukehuset.

Informasjon om utfallet av studien
Deltakarane i studien vil bli informert om funna ein gjer når desse er gjennomarbeida og publisert. Dersom ein skulle gjere funn som fører til at ein må revurdere behandlinga undervegs vil pasientane få beskjed om dette.

Rett til innsyn og sletting av opplysningar om deg og sletting av prøver
Om du sier ja til å delta i studien, har du rett til å få innsyn i kva opplysningar som er registrert om deg. Du har vidare rett til å få korrigert eventuelle feil i dei opplysningane vi har registrert. Dersom du trekkjer deg frå studien, kan du krevje å få sletta innsamla prøver og opplysningar, med mindre opplysningane allereie er gått i analyser eller brukt i vitenskapelege publikasjonar.

Samtykke til deltaking Ex.fix/plate-studien

Eg er villig til å delta i studien

(Signert av prosjektdeltakar, dato)

Stadfortredande samtykke når berettiga, anten i tillegg til personen sjølv eller istadenfor

____

(Signert av nærstående, dato)

Eg stadfester å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Dato ………..
Navn ……………………………….

PRWHE

Egen vurdering av hånd-/håndleddsfunksjon

*Spørsmålene nedenfor vil hjelpe oss med å forstå hvor mye problemer du har hatt med hånden/håndleddet. Beskriv dine **gjennomsnittlige** plager **den siste uken**, på en skala fra 0 til10. **Vær snill å svare på alle spørsmål.** Dersom det er en aktivitet du ikke har utført den siste uken, angi den graden av smerter eller problemer som **du ville ha forventet** om du hadde utført aktiviteten. Dersom du **aldri** har utført aktiviteten, kan du la spørsmålet stå åpent.*

1. Smerter

*Angi **gjennomsnittlig** hånd/håndleddssmerter **den siste uken**, ved å sette en ring rundt tallet som best beskriver dine smerter på en skala fra 0 til 10. **0** betyr at du ikke hadde noen smerter. **10** betyr at du hadde de verst tenkelige smerter, eller at du ikke greide å utføre en aktivitet pga. smerter.*

Beskriv din hånd/ håndleddssmerte

	ingen smerter										verst tenkelige smerter
I hvile	0	1	2	3	4	5	6	7	8	9	10
Når du utfører en aktivitet med gjentatte bevegelser i håndleddet	0	1	2	3	4	5	6	7	8	9	10
Når du løfter en tung gjenstand	0	1	2	3	4	5	6	7	8	9	10
Når smertene er på det mest intense	0	1	2	3	4	5	6	7	8	9	10
	aldri										alltid
Hvor ofte har du smerter?	0	1	2	3	4	5	6	7	8	9	10

SNU ARKET

2. Funksjon

a) spesifikke aktiviteter
*Angi **hvor vanskelig det har vært** å utføre aktivitetene som er beskrevet under **den siste uken**.*
*Sett en ring rundt tallet som best beskriver vanskelighetsgraden på en skala fra 0 til 10. **0** betyr at du ikke har hatt noen problemer og **10** betyr så store problemer at det har vært umulig å utføre aktiviteten.*

Hvor vanskelig har det vært å bruke hånden du har/har hatt problemer med til å

	ingen vansker										greier ikke å utføre
Vri om en nøkkel	0	1	2	3	4	5	6	7	8	9	10
Holde i kniven når du skjærer kjøtt	0	1	2	3	4	5	6	7	8	9	10
Kneppe skjorteknapper	0	1	2	3	4	5	6	7	8	9	10
Skyve fra når du reiser deg fra en stol	0	1	2	3	4	5	6	7	8	9	10
Bære en gjenstand på 5 kg	0	1	2	3	4	5	6	7	8	9	10
Bruke toalettpapir	0	1	2	3	4	5	6	7	8	9	10

b) generelle aktiviteter
*Angi **hvor vanskelig det har vært for deg** å utføre dine vanlige aktiviteter innenfor hvert av områdene beskrevet nedenfor i løpet av **den siste uken**. Med "vanlige aktiviteter" mener vi aktiviteter du vanligvis utførte **før** du fikk problemer med hånden. Sett en ring rundt tallet som best beskriver dine problemer på en skala fra 0-10. **0** betyr at du ikke hadde noen problemer, **10** betyr at du ikke greide å utføre dine vanlige aktiviteter.*

	ingen vansker										greier ikke å utføre
Personlig pleie (påkledning, vask/stell)	0	1	2	3	4	5	6	7	8	9	10
Husarbeid (renhold/vedlikehold)	0	1	2	3	4	5	6	7	8	9	10
Arbeid (ditt yrke eller annet daglig arbeid)	0	1	2	3	4	5	6	7	8	9	10
Fritidsaktiviteter	0	1	2	3	4	5	6	7	8	9	10

3. Utseende (valgfritt)

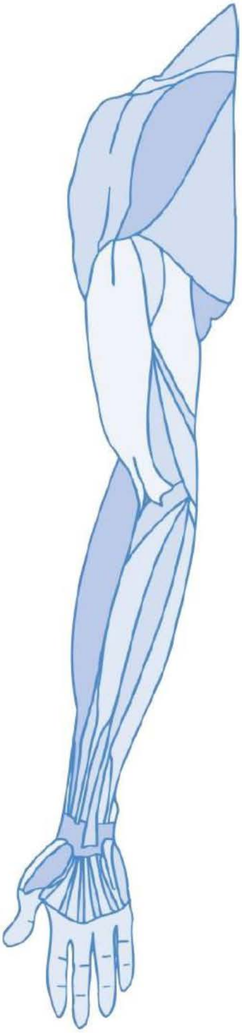
Hvor viktig er håndens utseende for deg? ☐ svært viktig ☐ nokså viktig ☐ ikke viktig

	svært tilfreds										svært utilfreds
Hvor tilfreds har du vært med håndens utseende den siste uken?	0	1	2	3	4	5	6	7	8	9	10

Kommentarer: ....

Quick DASH

Norsk versjon



Instruksjon

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

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

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

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

Vennligst sett kryss for ett svaralternativ for hvert spørsmål.

Norweigan translation courtesy of Professor Vilhjalmur Finsen,
Norwegian University of Science and Technology, Faculty of Medicine, Trondheim, Norway.

Quick DASH

Navn: født: Dato: ☐☐☐☐☐☐

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

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

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

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

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

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

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

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

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

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

Arbeider du? ☐ Ja ☐ Nei

Dersom svaret er nei, kan du hoppe over de fire følgende spørsmålene

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

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

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

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

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

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

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

Hvilket instrument eller idrett er viktigst for deg: ____________________________

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

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

Poengberegning

Dysfunksjon i arm, skulder og hånd

Dysfunksjon/symptom (De første 11 spørsmålene)

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

Beregning av DASH score:

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

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

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

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

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

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

Musikk/idrett

Samme regler som for "Arbeid"

Skjemaet kan lastes ned fra DASH offisielle nettside http://dash.iwh.on.ca/

Vennligst henvis til: *Finsen V. Tidsskr Nor Laegeforen 2008; 128: 1070*, hvis den norske utgaven av skjemaet brukes i en publikasjon.

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16.11.2016 vilh.finsen@ntnu.no

Papers I-III

II

Surgical Treatment of Distal Radial Fractures with External Fixation Versus Volar Locking Plate

A Multicenter Randomized Controlled Trial

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Investigation performed at Haukeland University Hospital, Bergen, and Voss Hospital, Voss, Norway

Background: The use of volar locking plate fixation (VLP) for unstable extra-articular distal radial fractures has increased in the last decades. External fixation (EF) is less frequently used. This change of surgical approach has only to some extent been evidence-based.

Methods: In this multicenter, randomized controlled trial, we compared VLP and EF in patients between 18 and 70 years of age who had a displaced extra-articular distal radial fracture (OTA/AO type A3). The patients were examined at 6 weeks, 3 months, and 1 year postoperatively. The primary outcome measure was the Patient-Rated Wrist/Hand Evaluation score (PRWHE). Secondary outcomes were the shortened version of the Disabilities of the Arm, Shoulder and Hand (QuickDASH), pain score on a visual analog scale (VAS), and radiographic measurements. Range of motion, grip strength, finger stiffness, complications, and reoperations were also recorded.

Results: One hundred and fifty-six patients were included. One hundred and forty-two (91%)—127 women (89%) and 15 men (11%)—completed 1 year of follow-up. Sixty-nine patients were treated with VLP and 73, with EF. The mean age was 56 years. At 6 weeks, the median PRWHE score was significantly higher in the EF group (44) compared with the VLP group (27) ($p < 0.001$). At 3 months and 1 year, the difference between groups was not significant. The median QuickDASH score was 27 in the VLP group and 43 in the EF group at 6 weeks ($p < 0.001$), and a significant difference persisted at 3 months ($p = 0.023$). The VLP group had superior results in terms pain during activity, wrist extension, and ulnar and radial deviation at 1 year, whereas the number of major complications was similar in the 2 groups.

Conclusions: Patients treated with VLP had earlier recovery of function compared with patients treated with EF. One year postoperatively, we found no significant functional difference.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Distal radial fractures are the most common fractures of the upper extremity[1,2]. Surgical treatment is recommended for unstable fractures[3] and has undergone major changes in recent years[4-6]. External fixation (EF) and percutaneous pinning used to be the treatments of choice, but the use of volar locking plate fixation (VLP) has increased dramatically since its introduction. Several studies, including some randomized controlled trials (RCTs), have suggested that VLP is associated with faster functional recovery compared with EF, but long-term results seem to be similar for the 2 methods[7-17]. However, most RCTs have been based on a small number of patients and have included both intra-articular and extra-articular fractures. The results of several meta-analyses are not conclusive regarding which treatment should be recommended[18-23]. Differences in patient cohorts, fracture types, implants, and surgical methods as well as

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A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/G261).

TABLE I Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age 18-70 yr	Dementia
Displaced unstable extra-articular distal radial fracture	Severe mental illness
Substantial initial displacement, inadequate initial reduction, or loss of reduction within 2 wk after injury as defined by ≥1 of the following:	Drug abuse
• ≥10° dorsal angulation of the joint line	Congenital bone disease
• Ulnar variance of ≥2 mm	Previous wrist fracture on either side
• Dorsal comminution of the fracture area/loss of intact dorsal cortex	Open fracture
	Pathological fracture
	Patients living outside the Helse-Bergen area (catchment area)

limitations in follow-up may have contributed to this lack of conclusions. The aim of this large and carefully designed RCT was to determine whether EF or VLP provides superior outcomes for treatment of displaced extra-articular distal radial fractures.

Materials and Methods

Design

This was a multicenter RCT with 2 parallel treatment arms.

Ethics

The study was conducted according to the Declaration of Helsinki. It was registered in ClinicalTrials.gov (ID: NCT01904084).

Eligibility Criteria

Consecutive patients between 18 and 70 years of age presenting to Haukeland University Hospital and Voss Hospital from 2013 to 2017 with an isolated unilateral displaced extra-articular fracture of the distal part of the radius (OA/AO type A3)[24] were eligible for inclusion into the trial. Criteria for exclusion were

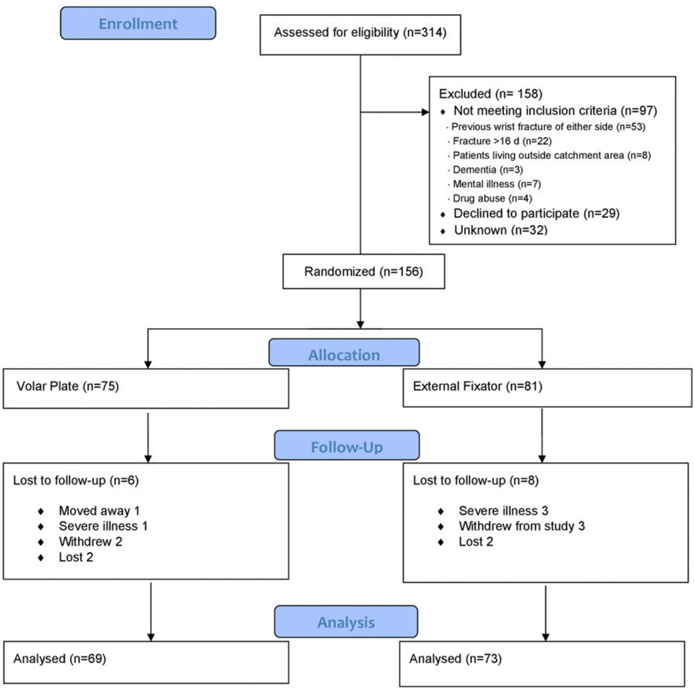

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the study.

TABLE II Demographic Characteristics

	VLP	EF
No. of patients	75	81
Age* *(yr)*	56 (20-70)	57 (20-70)
Sex†		
Female	67 (43%)	73 (47%)
Male	8 (5%)	8 (5%)
Dominant side†		
Right	70 (46%)	68 (44%)
Left	4 (3%)	11 (7%)
Injured side†		
Right	33 (25%)	29 (22%)
Left	26 (19%)	46 (34%)
Dominant side injured†		
Yes	38 (24%)	30 (19%)
No	37 (24%)	51 (33%)
Pre-injury PROM‡		
PRWHE	0.85 ± 2.9	1.95 ± 6.4
QuickDASH	2.5 ± 5.6	2.7 ± 6.6

*The values are given as the mean and range. †The values are given as the number and the percentage of the total number in both groups combined with data on the variable. ‡The values are given as the mean and the standard deviation.

>16 days between the intervention and the injury, a previous fracture in the contralateral or ipsilateral wrist, an open fracture, mental illness, dementia, and severe drug abuse (Table I). Informed consent was obtained from all patients.

Randomization

The surgeon on call randomized the patients using sealed envelopes and block randomization designed by a statistician (Fig. 1). There was no significant difference in the demographics between the groups, or between patients who completed follow-up and those who did not (Tables II and III).

Interventions

All 40 surgeons involved had performed at least 5 procedures with each technique, either independently or with experienced supervision, before participating in the study. Operations were standardized regarding anesthesia, implants, surgical techniques, and fluoroscopic guidance.

In the EF group, 1 proximal dorsoradial incision and 2 incisions on the second metacarpal were used to insert the 4 apex pins of a Hoffmann Compact T2 external fixator (Stryker). Rods and blocks were mounted, and the fracture was reduced. Supplementary Kirschner wires were not used. At 6 weeks, the EF was removed at the outpatient clinic.

The VLP (DVR; DePuy) was inserted through the Henry distal volar approach. To improve exposure distally, a short oblique incision was made over the flexor crease. The pronator quadratus was lifted subperiosteally and was reattached after plate fixation; the distal radioulnar joint was then tested. A dorsal splint was applied and was removed within a few days.

Patients were advised to mobilize the wrist as tolerated, with no weight-bearing for 6 weeks.

Outcome Measures

Primary Outcomes

The Patient-Rated Wrist/Hand Evaluation (PRWHE) scores at 6 weeks, 3 months, and 1 year postoperatively were primary outcomes[25]. This patient-reported score rates wrist function in 2 equally weighted sections addressing pain and limitations in the activities of daily living. The score ranges from 0 to 100, with 100 being the worst score[25]. The minimum clinically important difference (MCID) in this score for patients with a distal radial fracture is 11.5 points[26]. We defined full recovery as a difference in the PRWHE score of <11.5 points compared with the preoperative score.

Secondary Outcomes

Secondary outcomes were the scores on the shortened version of the Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire, pain as measured with a visual analog scale (VAS), and radiographic measurements.

The QuickDASH is a standardized self-administered questionnaire using 11 items to measure function and disabilities in persons with musculoskeletal disorders of the upper limb; the score ranges from 0 to 100, with 100 indicating greater disability[27,28]. The PRWHE and QuickDASH questionnaires are cross-culturally validated to Norwegian[29,30].

Pain at rest and during activity was measured using a VAS ranging from 0 to 100, with 100 being the worst result[31].

Radiographs of the wrist were standardized. Posteroanterior views were obtained with the shoulder in 90° of abduction, the elbow in 90° of flexion, and the wrist in neutral. Lateral views were obtained with the shoulder in an adducted position, the elbow in

TABLE III Demographic Characteristics of Patients Who Did and Did Not Complete 1-Year Follow-up

	Completed 1-Year Follow-up	
	Yes	No
No. of patients	142	14
Mean age *(yr)*	56.2	57.7
Female sex*	128 (90%)	12 (86%)
Currently employed*	95 (67%)	9 (64%)
Pre-injury PROM†		
PRWHE	1.2 ± 4.6	5.2 ± 10.2
QuickDASH	2.5 ± 5.6	3.7 ± 10

*The values are given as the number and the percentage of the total number in the “yes” or “no” group. †The values are given as the mean and the standard deviation.

TABLE IV PROMs at Follow-up

	Median (Interquartile Range)		
	VLP	EF	P Value*
PRWHE			
6 wk (n = 148)	27 (12-38.5)	43.5 (34.5-56.6)	**<0.001**
3 mo (n = 148)	11.5 (1.6-20.9)	13.8 (4.8-29.1)	0.069
1 yr (n = 142)	1.3 (0-6.8)	2.3 (0-10.8)	0.233
QuickDASH			
6 wk (n = 148)	27.3 (15.9-38.6)	43.2 (33.0-53.4)	**<0.001**
3 mo (n = 148)	11.4 (2.3-20.5)	15.9 (4.5-29.6)	**0.023**
1 yr (n = 142)	2.3 (0-9.1)	2.3 (0-11.4)	0.357
Pain at rest			
6 wk (n = 148)	0 (0-11.3)	0 (0-20)	0.498
3 mo (n = 148)	0 (0-7.5)	0 (0-5)	0.868
1 yr (n = 142)	0 (0-0)	0 (0-0)	0.201
Pain during daily activity			
6 wk (n = 148)	22.5 (10-40)	30 (10-50)	0.449
3 mo (n = 148)	10 (0-27.5)	20 (10-30)	**0.022**
1 yr (n = 142)	0 (0-7.5)	0 (0-10)	**0.034**

*Significant values ($p < 0.05$) are in bold.

90° of flexion, and the wrist in neutral; if necessary, the beam was angled to visualize the radiocarpal joint. All values for the involved side were compared with those for the contralateral side.

We assessed volar tilt, radial inclination, radial height, ulnar variance, and the presence of an ulnar styloid fracture[32]. Initially, radiographs of 10 randomly selected patients were reviewed independently by 3 experienced radiologists and 1 orthopaedic surgeon. The results were assessed to check for comparability of the accuracy of measurements by calculating the intraclass correlation coefficient (ICC) according to guidelines given by Koo and Li[33]. The other radiographs were divided into 4 equal groups, each assessed by 1 of the same 4 interpreters.

Range of Motion, Grip Strength, Finger Stiffness, Complications, and Reoperations

Range of motion, grip strength, finger stiffness, complications, and reoperations were also recorded.

We measured range of motion with a goniometer and grip strength with a dynamometer (Jamar). Measurements on the uninjured side served as preinjury (baseline) values. The grip strength on the nondominant side was adjusted down by 10% for right-handed patients[34], whereas left-handed patients were assumed to have equal grip strength on both sides[35,36].

Finger stiffness was assessed according to the fingertips-to-palm distance when the patient attempted to make a fist (normal = fingertips touch the palm, moderate stiffness = 0 to 2 cm between the fingertips and palm, and severe stiffness = more than 2 cm between the fingertips and palm).

We classified complications leading to a reoperation, permanent nerve injury, or persistently reduced function such as chronic regional pain syndrome (CRPS) (Budapest criteria[37]) as major complications. We defined complications as minor if they were transient or not affecting the patient's final result. Patients with CRPS were treated by a dedicated team, and the treatment included advanced physical therapy and pain management.

Evaluation and Follow-up

Clinical evaluation and trial documentation were carried out at 5 visits: baseline; the time of intervention; and 6 weeks, 3 months, and 1 year postoperatively. One hundred and forty-two patients (91%) completed the 1-year follow-up; 14 were lost to follow-up (Fig. 1).

Statistical Analysis

Sample Size and Power Calculation

A block randomization was performed by a biostatistician.

Functional results based on the PRWHE score at 6 weeks, 3 months, and 1 year postoperatively were the primary outcomes.

The significance level (α) was set at 0.05. With a test strength ($1 - \beta$) of 80% and a standard deviation of 21, 70 patients were needed in each group to show a clinically relevant difference of 11.5 points[38]. Assuming a follow-up rate of 90%, we intended to include 160 patients.

The nonparametric independent-samples Mann-Whitney U test was used to identify differences in patient-reported outcomes

TABLE V Functional Outcomes at Follow-up

	Mean ± Standard Deviation (% of Value for Uninjured Side)		
	VLP	EF	P Value*
Wrist flexion *(°)*			
6 wk (n = 148)	49 ± 15 (68.6%)	39 ± 17 (54.8%)	**<0.001**
3 mo (n = 148)	62 ± 11 (87.4%)	57 ± 12 (80.6%)	**0.009**
1 yr (n = 142)	69 ± 9 (97.0%)	66 ± 9 (94.0%)	0.66
Wrist extension *(°)*			
6 wk (n = 148)	43 ± 16 (62.0%)	3 ± 24 (3.8%)	**<0.001**
3 mo (n = 148)	58 ± 15 (83.4%)	51 ± 16 (78.2%)	**0.004**
1 yr (n = 142)	64 ± 13 (93.2%)	59 ± 11 (91.0%)	**0.013**
Supination *(°)*			
6 wk (n = 148)	63 ± 23 (74.1%)	37 ± 27 (42.5%)	**<0.001**
3 mo (n = 148)	75 ± 15 (89.4%)	69 ± 18 (80.7%)	**0.034**
1 yr (n = 142)	83 ± 8 (99.4%)	79 ± 13 (92%)	0.18
Pronation *(°)*			
6 wk (n = 148)	74 ± 11 (87.7%)	61 ± 18 (14.3%)	**<0.001**
3 mo (n = 148)	81 ± 8 (96.0%)	78 ± 12 (92.5%)	0.070
1 yr (n = 142)	84 ± 6 (98.9%)	82 ± 9 (97.5%)	0.318
Ulnar deviation *(°)*			
6 wk (n = 148)	30 ± 10 (70.6%)	23 ± 9 (60.0%)	**<0.001**
3 mo (n = 148)	36 ± 9 (87.4%)	31 ± 9 (81.7%)	**0.001**
1 yr (n = 142)	40 ± 9 (97.0%)	37 ± 9 (95.5%)	**0.017**
Radial deviation *(°)*			
6 wk (n = 148)	16 ± 10 (65.5%)	−1.9 ± 11 (−11.7%)	**<0.001**
3 mo (n = 148)	21 ± 8 (90.0%)	14 ± 8 (73.7%)	**<0.001**
1 yr (n = 142)	23 ± 7 (98.7%)	20 ± 8 (103.8%)	**0.037**
Grip strength *(kg)*			
6 wk (n = 148)	10.9 ± 6.5 (41.7%)	1.01 ± 2.37 (3.8%)	**<0.001**
3 mo (n = 148)	19 ± 7.3 (72.9%)	12 ± 8.2 (46.8%)	**<0.001**
1 yr (n = 142)	24.8 ± 7.6 (95.4%)	21.8 ± 8.1 (88.4%)	0.085

*Significant values ($p < 0.05$) are in bold.

measure (PROM) data (PRWHE, QuickDASH, and VAS scores). Other continuous variables were analyzed using the Student t test. We used the chi-square test for categorical variables.

All analyses were based on the intention-to-treat principle.

SPSS version 26.0 (IBM) was used for all statistical analyses.

Results

The outcomes are presented in Tables IV, V, VI, and VII.

Primary Outcome

At 6 weeks postoperatively, there was a significant difference in PRWHE scores ($p < 0.001$) in favor of VLP. The differences were not significant at 3 months ($p = 0.069$) or 1 year ($p = 0.233$) (Fig. 2).

At 6 weeks, 23% of the patients in the VLP group and 6% in the EF group had full recovery. At 3 months, 58% in the VLP group and 47% in the EF group had full recovery. At the time of final follow-up, the percentages were 81% in the VLP group and 79% in the EF group. However, 10 patients in the EF group had a PRWHE score of ≥25 (range, 25 to 68), indicating a major disability. Only 3 patients in the VLP group had such a high score.

Secondary Outcomes

The QuickDASH scores were better in the VLP group than in the EF group at 6 weeks ($p < 0.001$) and 3 months ($p = 0.023$). We found no significant difference between groups at 1 year ($p = 0.36$).

There was no significant difference in pain at rest between the VLP and EF groups at any time point. Pain during activity was similar between groups at 6 weeks, but patients

TABLE VI Radiographic Results

	VLP	EF	P Value; ICC (95% CI)*
Volar tilt† *(°)*			
Prior to reduction	−22 ± 11.4	−20.4 ± 11	0.400; 0.95 (0.87-0.98)
Postoperative	6.3 ± 5.6	3.6 ± 5.5	**0.004**; 0.93 (0.83-0.97)
6 wk	6.1 ± 5.2	3.7 ± 5.5	**0.006**; 0.94 (0.86-0.98)
1 yr	5.5 ± 5.7 (4.8%)	4.6 ± 5.5 (5.7%)	0.342; 0.98 (0.95-0.99)
Radial inclination† *(°)*			
Prior to reduction	18 ± 6.2	18.5 ± 5.5	0.622; 0.93 (0.83-0.97)
Postoperative	22.5 ± 3.7	24.4 ± 3.6	**0.001**; 0.83 (0.62-0.93)
6 wk	23 ± 3.4	24 ± 3.3	0.062; 0.60 (0.31-0.83)
1 yr	23.2 ± 3.3 (2.9%)	24.2 ± 3.6 (1.8%)	0.102; 0.66 (0.37-0.87)
Radial height† *(mm)*			
Prior to reduction	6.7 ± 4.5	7 ± 3.8	0.701; 0.90 (0.76-0.96)
Postoperative	11 ± 2.6	11 ± 2.3	0.992; 0.88 (0.72-0.95)
6 wk	10.5 ± 2.4	10.3 ± 2.7	0.709; 0.88 (0.71-0.95)
1 yr	10.3 ± 2.6 (1.3%)	10.1 ± 2.7 (1.4%)	0.296; 0.89 (0.74-0.96)
Ulnar variance† *(mm)*			
Prior to reduction	2.5 ± 2.2	2.6 ± 2.6	0.911; 0.93 (0.84-0.98)
Postoperative	−0.2 ± 1.7	0.6 ± 1.6	**0.004**; 0.81 (0.60-0.93)
6 wk	0.7 ± 3.0	1.2 ± 1.8	0.278; 0.72 (0.45-0.88)
1 yr	0.8 ± 1.6 (−0.09%)	1.6 ± 1.9 (−0.8%)	**0.007**; 0.86 (0.68-0.95)
Ulnar styloid fracture prior to reduction‡	43 (58%)	37 (47%)	
Ulnar styloid nonunion at 1 yr‡	25 (37%)	18 (25%)	

*Significant values (p < 0.05) are in bold. ICC (95% CI) = intraclass correlation coefficient (95% confidence interval). With regard to the ICC, <0.50 = poor, between 0.50 and 0.75 = moderate, between 0.75 and 0.90 = good, and >0.90 = excellent. †The values are given as the mean and the standard deviation, with the percentage of the value for the uninjured side in parentheses in the "1 yr" row. ‡The values are given as the number and the percentage of the total number in the VLP or EF group.

with EF had significantly more pain at 3 months (p = 0.022) and 1 year (p = 0.034) (Table IV).

Radiographic measurements were similar between groups prior to reduction, but a higher percentage of patients in the VLP group had an ulnar styloid fracture (58% compared with 47% in the EF group). Correspondingly, we found nonunion of the ulnar styloid process in 37% of the VLP group compared with 25% of the EF group at 1 year. We found no significant difference regarding volar tilt, radial inclination, or radial height at 1 year. However, the ulnar variance was still smaller in the VLP group at 1 year (mean difference = −0.8 mm, p = 0.007), indicating a better length restoration (Table VI).

Range of Motion, Grip Strength, and Finger Stiffness

Patients treated with VLP had a better range of motion and grip strength at 6 weeks and 3 months than those in the EF group. At 1 year, they still had better wrist extension (p = 0.013), but they no longer had a statistically significant or clinically relevant difference in grip strength (p = 0.085). Patients treated with EF had more finger stiffness than the VLP group at 6 weeks and 3 months postoperatively; at 1 year, there was no difference between groups.

Complications and Reoperations

The number of major complications was 16 (23%) in the VLP group and 18 (25%) in the EF group, whereas 17 (25%) and 23 (32%) minor complications were recorded in the VLP and EF groups, respectively. A transient carpal tunnel syndrome was observed in 5 patients in the VLP group and 3 in the EF group. Three patients in the VLP group developed type-1 CRPS compared with 8 in the EF group. Six of these patients—1 in the VLP group and 5 in the EF group—had CRPS symptoms 1 year postoperatively (Table VII).

There were 4 reoperations in the EF group. Three were early crossovers due to insufficient fracture reduction. According to the intention-to-treat principle, these 3 patients were analyzed in the EF group. The remaining (late) reoperation was an arthroscopic repair of the triangular fibrocartilage complex (TFCC). There were 6 reoperations in the VLP group, including 5 late plate removals due to local pain (Table VII).

TABLE VII Complications at 1-Year Follow-up

	No. (%) of Patients		
	VLP (N = 69)	EF (N = 73)	P Value
Major complications*			
CRPS	3 (4%)	8 (11%)	0.14
CTS	5 (7%)	3 (4%)	0.49
Prolonged pain in wrist/hand	2 (3%)	2 (3%)	1.0
Deep infection		1 (1%)	1.0
Suboptimal osteosynthesis leading to secondary surgery	1 (1%)	3 (4%)	0.62
Plate removal	5 (7%)		0.025
Arthroscopic TFCC repair		1 (1%)	1.0
Total	16 (23%)	18 (25%)	0.83
Minor complications			
Superficial infection	1 (1%)	7 (10%)	0.063
Scar tissue problems	5 (7%)	6 (8%)	0.83
Paresthesia	4 (6%)	5 (7%)	1.0
Neuropathy	2 (3%)	2 (3%)	1.0
Other	5 (7%)	3 (4%)	0.49
Total	17 (25%)	23 (32%)	0.36

*CRPS = complex regional pain syndrome, CTS = carpal tunnel syndrome, and TFCC = triangular fibrocartilage complex.

Discussion

The PRWHE is the most sensitive outcome measure for patients with a wrist injury[25]. In our study, VLP resulted in a quicker recovery, with a better PRWHE score compared with EF at 6 weeks, but at 3 months and 1 year postoperatively we found no significant difference between groups. The difference in the percentage with full recovery in favor of the VLP group declined from 17% at 6 weeks to 11% at 3 months and

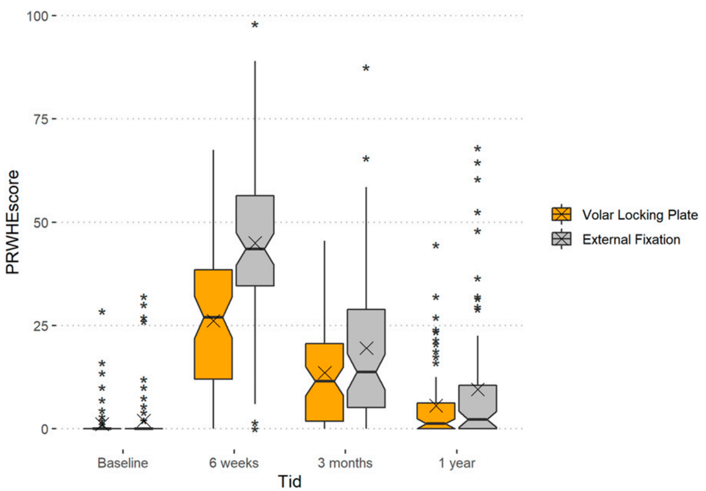

Fig. 2

The change in PRWHE score over time for patients with VLP (orange) and EF (grey). The top and bottom of each box denotes the interquartile range, the horizontal line within the box denotes the median, X denotes the mean, and * denotes outliers. An approximation of the 95% confidence interval is also included, represented by the notches around the median. Tid = Time.

finally to 2% at 1 year. This result resembles that of Wilcke et al.[15], who compared EF with VLP in 63 patients with an unstable extra-articular fracture and found that VLP was advantageous in terms of early rehabilitation but the outcomes were similar at 1 year.

The QuickDASH score was better in the VLP group than in the EF group at 6 weeks and 3 months but no longer at 1 year. Several studies support these findings[8,14,15]. Hammer et al. compared VLP with EF and additional Kirschner wires in 166 patients with an OTA/AO type-C fracture and came to the same conclusion[8]. Wilcke et al.[15] and Wei et al.[14] included fewer patients (63 and 46, respectively) than we did, but their results at 3 months were similar to ours. However, Karantana et al.[10], who compared VLP with conventional percutaneous methods in 130 patients, and Egol et al.[7], who compared VLP with EF with supplementary Kirschner wire fixation in 88 patients, found no difference between groups at 3 months. At 1 year, no difference between the groups was found in any of these studies[7,8,10,14,15].

Interestingly, few investigators have reported specifically about pain apart from questions included in PROMs. Hammer et al. included a general question about pain and found no statistical difference between treatment methods[8]. In our study, we distinguished between pain at rest and pain during activity. We found no difference in pain at rest between groups, but patients with EF reported significantly more pain during activity at 3 months and 1 year.

Our evaluation demonstrated no significant difference in radiographic parameters between the groups at 1 year, with the exception of the failure of EF to maintain ulnar variance to the same extent as VLP, a result also found in other studies[8,10,11,15-17]. The difference between ulnar variance immediately postoperatively and at the later follow-up intervals even in the VLP group was an unexpected finding as studies[18-21,39,40] have shown generally no loss of reduction with VLP. Most likely, this is a result of posteroanterior radiographs made in slight supination at the immediate postoperative visit, due to postoperative pain, resulting in a negative ulnar variance, and in neutral rotation at the later follow-up examinations[41,42].

Patients treated with VLP had better recovery of wrist flexion and extension, forearm supination, wrist ulnar and radial deviation, grip strength, and finger stiffness at 3 months in our study. At 1 year, they still had better extension as well as ulnar and radial deviation, but wrist flexion, supination, grip strength, and finger stiffness no longer differed between the groups. The immobilization of the wrist with an external fixator may explain these early functional differences.

Early mobilization is a sound principle in orthopaedic rehabilitation, and the VLP group had an obvious advantage with regard to adhering to this principle as wrist movements could start immediately postoperatively. Patients in the EF group could not start full functional rehabilitation before removal of the EF 6 weeks postoperatively. In this group, initial weakness and stiffness gradually improved after removal of the EF. In line with other studies, our EF group still had poorer outcomes 1 year postoperatively with respect to extension as well as ulnar and radial deviation[7-10,12-16]. These results confirm the hypothesis that VLP fixation results in less loss of function and a better range of motion both short and long-term. However, this was not reflected in patient-rated scores 1 year postoperatively.

The total number of complications was similar in the 2 groups. We found a tendency toward more CRPS in the EF group (8 versus 3), but this was not a significant difference ($p = 0.14$). However, the power of the study may have been insufficient to detect a significant difference in the occurrence of this infrequent complication. Interestingly, Hammer et al. found the same tendency of CRPS to be related to EF (8 versus 3)[8]. Overdistraction using EF, resulting in reduced microcirculation with fibrosis and increased stiffness, might be an explanation for this, but the pathophysiology behind this complication is not fully understood. More research on this topic is called for. If additional research confirms an association between EF and CRPS, this could be a reason to favor VLP.

There were 6 reoperations in the VLP group compared with 4 in the EF group. Three of the 4 in the EF group and 1 of the 6 in the VLP group were early reoperations due to malreduction. One late reoperation, due to a TFCC rupture, was reported in the EF group and 5 late reoperations, all for implant removal due to persistent pain, were reported in the VLP group. Previous studies have demonstrated a plate removal rate between 6% and 21%[8,16], comparable with our rate of 7%. The patients in the present study were informed, when included in the trial, that plate removal usually is unnecessary. This might explain our relatively low removal rate.

The major strengths of this study are the large sample size and low number of patients lost to follow-up as well as the uniform type of fractures and surgical methods.

We recruited the patients from 2 hospitals and a large number of surgeons were involved in the primary treatment, yielding external validity of the results.

There are some limitations to our study. It was not blinded, and patients older than 70 years were not included. Also, because we only selected patients with an extra-articular fracture, the results cannot be generalized to distal radial fracture management overall. Follow-up was limited to 1 year.

Conclusions

Treating displaced extra-articular distal radial fractures (OTA/AO type A3) with VLP resulted in faster recovery compared with EF. Even though 1-year results were more similar between the groups, there may be a tendency toward a lower rate of CRPS, less pain during activity, and a better range of motion 1 year after VLP. Accordingly, our data support VLP as the first choice of treatment when an early return of wrist function is of major importance. ■

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III

Clinical/Basic Science Research Article

OPEN

Is there a correlation between functional results and radiographic findings in patients with distal radius fracture A0 type A3 treated with volar locking plate or external fixator?

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Purpose: The aim of this study was to test the hypothesis that precise restoration of distal radius fractures is correlated to better patient-reported outcome.

Methods: The correlation between radiographic results and functional outcome was explored in 156 patients with extra-articular distal radius fractures included in a multicenter, randomized controlled trial comparing 2 surgical interventions, Volar Locking Plate or External Fixator. The primary functional outcome was the Patient Rated Wrist and Hand Evaluation score (PRWHE). Radiographically we assessed volar tilt, radial inclination, radial height, ulnar variance, and the presence of ulnar styloid fracture. The Pearson correlation analysis was used to estimate correlations between parameters.

Results: At 1-year follow-up the mean difference in radiographic findings compared with the uninjured side (min, max) was: reduced volar tilt 5.3° (−15°, 25°), reduced radial inclination 2.3° (−6°, 12°), radial height 1.3 mm (−4 mm, 7 mm), and ulnar variance −0.5 mm (−6 mm, 3 mm). Overall, we found no correlation between radiographic parameters and the PRWHE at 1-year follow-up within the whole group, regardless of which treatment was chosen. At the time of injury 53% (N = 80) had sustained an additional ulnar styloid fracture. After 1 year this fracture was still radiographically present in 31% (N = 43) of the patients. No correlation between PRWHE score and the presence of an ulnar styloid fracture at 1-year follow-up was found.

Conclusions: We found no correlation between functional outcome (PRWHE) and radiographic findings after 1 year in patients operated on with a Volar Locking Plate or External Fixator. Patient-specific factors were more important than radiographic measurements in this study group.

Level of evidence: Therapeutic Level 2
Trial registration: Norway: National Committee for Medical and Health Research Ethics 213/555
ClinicalTrials.gov ID: NCT01904084
Randomization of first patient: 02.09.2013

Keywords: displaced extra-articular fracture, distal radius fracture, external fixation, PRWHE, radiographic measurements, volar locking plate

1. Introduction

A fracture of the distal radius (DRF) is the most common fracture in adults.[1,2] Surgical fixation is recommended in severely displaced fractures.[3] Volar locking plate (VLP) and external fixation (EF) are 2 of the most commonly used methods for treating DRF.[4–8] The goal of the operation is to restore the normal anatomy and a mobile, pain-free wrist without functional limitations. The correlation between the degree of radiographic deformity and functional outcome of the fracture however is controversial.[3,9–13] We therefore conducted a study alongside a RCT to assess the relationship between radiological findings and functional outcome.[14]

2. Methods and design

2.1. Design

This was a prospective follow-up study. The patients included participated in a RCT comparing 2 surgical interventions in

The study received research funds from the public health system (Helse-vest, Norway).

The authors have no conflicts of interest to disclose.

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patients who had sustained an extra-articular distal radius fracture. Consecutive patients aged 18 to 70 years presenting to the orthopedic department with an isolated unilateral dorsally displaced unstable extra-articular fracture of the distal radius (OTA/AO 23 A3), according to the judgement of the surgeon on call, were eligible for inclusion into the trial.[15] Patients were included in the study if they received treatment within 16 days of their injury. Patients had the meaning of the trial and the consequences explained to them, and all patients signed a consent form prior to inclusion.

Exclusion criteria were previously fractured contra- or ipsilateral hand, open fractures, mental illness, dementia, and severe drug abuse.

During the inclusion period, 314 patients with A3 fractures between the age 18 and 70 years were assessed for eligibility. Out of these, 158 patients were excluded because of the following:

- Not meeting inclusion criteria (n=97)
  - Previous wrist fracture of either side (inclusive childhood fractures) (n=53)
  - Fracture >16 days (n=22)
  - Patients living outside catchment area (n=8)
  - Dementia (n=3)
  - Mental illness (n=7)
  - Drug abuse (n=4)
- Declined to participate (n=29)
- Unknown (n=32)

Of 156 primary included patients, 142 (91%) completed 1-year follow-up, among whom 73 were allocated to external fixator and 69 to volar plate. Patient characteristics are shown in Table 1. Forty different doctors were involved as primary surgeons, while the 1-year follow-up visit was performed by the authors. We analyzed the follow-up data 1 year after inclusion of the last patient.

2.2. Ethics

The study was conducted according to the Declaration of Helsinki and approved by the Regional Ethics Committee of Western Norway (ref 2013/555) and the local data protection officer. The trial was registered at ClinicalTrials.gov (NCT01904084). Written informed consent was obtained from all patients.

Table 1

Patient characteristics

Number of patients included	156
Mean age (min–max)	56 (20–70)
Sex	
Female	140 (90%)
Dominant side	
Right	138 (88%)
Dominant side injured	
Yes	68 (43%)
Implant	
External fixator	81 (52%)
Volar locking plate	75 (48%)
PRWHE preinjury†	1.4±5.0
Radiology*	
Volar tilt (°)†	−21±11
Radial inclination (°)†	18±5.8
Radial height (mm)†	6.8±4.2
Ulnar variance (mm)†	2.6±2.4
Ulna fracture (N)	80 (52.2%)

PRWHE=Patient Rated Wrist and Hand Evaluation score (0–100).
* Radiographic measurements of injured side prior to reduction.
† The values are given as the mean with standard deviation.

2.3. Intervention

Implants were standardized to either Hoffman Compact T2 external fixator or DVR/DePuy volar locking plate. All the surgeons involved (n=40) had experience with both procedures. They should have performed a minimum of 5 procedures of both techniques, independently or with experienced supervision, before participating in the study. All operations were performed with brachial plexus block or general anesthesia and fluoroscopic guidance. Operating techniques were standardized and all patients were admitted and treated as inpatients. The external fixator was removed after 6 weeks at the out-patient clinic. In the VLP group, a dorsal splint was applied until the patient had regained control of the arm after having the plexus block. The splint was removed before being discharged from the hospital. The patient was advised to move the wrist with a free range of motion but not to apply any weight for the first 6 weeks.

2.4. Outcome measures

2.4.1. Functional outcome measures. The PRWHE (The Patient-Rated Wrist and Hand Evaluation), is a patient-reported outcome measuring wrist function in 2 (equally weighted) sections concerning the patients experience of pain and limitations in daily life activities, to give a score out of 100 (with 100 being the worst score).[16]

The PRWHE questionnaire has been cross-cultural validated to the Norwegian population.[17] The minimum clinically important difference for this score, in patients with distal radius fractures, is 11.5 points.[18] We defined patients reporting a difference in PRWHE score less than 11.5 points, compared with their preoperative score, as fully recovered.

2.4.2. Method of radiographic measurements. Radiographs of the wrist were obtained according to standardized clinical procedures:

Posterior-anterior (PA) views with the shoulder in 90° abduction, elbow in 90° flexion, and wrist in neutral position. Lateral views with the shoulder in adducted position and elbow in 90° flexion, and wrist in neutral position, if necessary the beam angled to visualize the radiocarpal joint.

All values for the involved side were compared with those for the contralateral side.

Radiographic findings were assessed as follows.

The long axis of the radius was defined as the line between the midpoint of the radius at 3 and 6 cm proximal to the radiocarpal joint (Figs. 1 and 2).

The volar tilt was defined as the angle between lines drawn perpendicular to the long axis of the radius and the distal joint surface of the radius using the lateral view. A positive angle denotes volar angulation and a negative angle dorsal angulation (Fig. 2).

The ulnar variance was defined on the PA view as the distance between 2 parallel lines drawn along the distal ulnar aspects of the radius and the distal cortical rim of the ulna, perpendicular to the long axis of the radius (Fig. 1A).

Radial height was measured on the PA view as the distance between 2 parallel lines drawn along the tip of the radial styloid and the distal cortical rim of the ulna, perpendicular to the long axis of radius (Fig. 1A).

Figure 1. PA views of the wrist. PA=posterior-anterior.

Figure 2. Lateral views of the wrist.

Radial inclination was defined as the angle between a line drawn from the tip of the radial styloid to the medial edge of the articular corner of the radius and a line perpendicular to the long axis of the radius (Fig. 1B). An additional ulnar styloid fracture, if present, was registered (Fig. 1A).

All radiographs from 10 different randomly selected patients were reviewed independently by 3 radiologists and 1 orthopaedic surgeon. Previous studies have given a detailed description of these measurements.[3] The results were assessed to check for comparability of the accuracy of measurements by calculating the intraclass correlation coefficient (ICC) according to guidelines given by Koo and Li.[19] An ICC of 0 indicates no agreement and an ICC of 1 indicates perfect agreement. The ICC was interpreted as good or excellent (ICC 0.75–0.98) with the exception of radial inclination at 6 weeks and 1 year (moderate ICC 0.60–0.66). The radiographs for the remaining patients were split into 4 equally sized groups and reviewed by one of the same 4 interpreters.

Sample size was guided by a previous study on inter- and intra-observer reliability of assessment of distal radial fractures. However, no power analysis was undertaken.[20]

2.5. Evaluation and follow-up

PRWHE was reported at the first examination after the injury according to wrist function prior to the injury and at 1-year follow-up.

Radiographs of both the injured and uninjured wrist were obtained at the first consultation after injury and radiographs of the injured wrist were obtained at 1-year follow-up.

2.6. Blinding

The interpreters of the radiographs were not the treating surgeon and were blinded to functional outcome but not to the method of treatment (as it would show on the radiographs).

2.7. Statistical analysis

Data from all the outcome measures were summarized using means and standard deviations (given in parenthesis). A Pearson correlation was calculated for radiological parameters and patient reported outcome (PRWHE). The strength of the correlations was interpreted as: negligible ($r=0.00$–0.3), weak ($r=0.31$–0.5), moderate ($r=0.51$–0.70), strong ($r=0.71$–0.90), and almost perfect ($r=0.91$–1.00).[21,22] A paired *t* test was used to assess differences in the radiological parameters between uninjured side and 1-year follow-up. To compare the group of patients fully recovered with those not recovered after 1 year, continuous variables were analyzed using *t* test and categorical variables using chi-square test. *P* values less than 0.05 were considered statistically significant. The statistical analyses were performed in the statistical package IBM SPSS Statistics Version 26 (IBM Corp, Armonk, NY) and the statistical package R (http://CRAN.R-project.org).

3. Results

The mean patient reported PRWHE score prior to injury was 1.4 ± 5, while PRWHE score after 1 year was 7.6 ± 13.5. Radiographic results after 1 year differed significantly from the uninjured side. At the time of injury 53% (N=80) had sustained an additional fracture of the ulna styloid. After 1 year the fracture was still radiographically present in 31% (N=43) of the patients (Table 2).

Table 2

Radiographic outcomes 1 year

	Injured side	Uninjured side	*P* value†
Radiographic measurements			
*Volar tilt (°)	5±5.6	10.5±3.9	<**0.000**
*Radial inclination (°)	24±3.5	25.8±2.9	<**0.000**
*Radial height (mm)	10.3±2.6	11.6±2.1	<**0.000**
*Ulnar variance (mm)	1.2±1.8	0.7±1.6	**=0.001**
Ulna fracture (N)	43 (30.9%)	Nil	

* The values are given as the mean (standard deviation).
† *P* values derived from paired *t* tests given in bold.

Overall, we found no correlation between radiographic parameters and the PRWHE at 1-year follow-up within the whole group, regardless of which treatment was chosen (volar tilt r=−0.005, *P*=0.95, radial inclination r=−0.083 *P*=0.34, radial height r=−0.043, *P*=0.62, and ulnar variance r=0.068 *P*=0.43). No correlation between PRWHE score and the presence of an ulnar styloid fracture at 1-year follow-up (mean difference [MD]=2.24, *P*=0.37) was found (Figs. 3–6).

We found no significant difference in radiographic findings between the 2 surgical methods considering volar tilt (MD = 0.908, *P*=0.34), radial inclination (MD=−0.97, *P*=0.10) and radial height (MD=0.468, *P*=0.30). However, the ulnar variance was significantly smaller in the VLP group (MD=−0.819, *P*=0.01).

At 1 year, we found that 80% had regained full recovery. However, at the same time we found that 20% had PRWHE scores higher than 11.5 points compared with their preoperatively score, indicating persisting major disability (Table 3). When comparing the 2 groups we found no difference in results influenced by age, gender, injury of dominant hand, injury energy level, or manual work. Further, type of implant, time until surgery, type of anesthesia, operation time, and duration of postoperative stay had no influence on results at 1 year in either group. However, we found that patients with high PRWHE scores at 1 year were more likely to have had an injury indoor, being unemployed or receiving disability benefits. Radiologically, we found that the patients with high PRWHE score at 1 year had significantly larger initial displacement after injury considering radial inclination (*P*=0.004) and radial height (*P*=0.047), but this was not the findings regarding volar tilt, ulnar variance, and the presence of an ulnar styloid fracture. At 1 year, no radiological difference was found affecting the functional results. Neither a dorsal displacement >10° (*P*=0.975) nor an ulnar variance >2 mm (*P*=0.838) compared with the uninjured side after 1 year was found to affect the functional outcome.

4. Discussion

In our study, we found no correlation between radiographic measurements and wrist function at 1-year follow-up in patients with extra-articular (A0 type A3) distal radius factures operated with a VLP or EF. Furthermore, with the exception of significantly smaller ulnar variance in the VLP group no difference in radiographic findings was found between the 2 surgical methods. Still, there were 20% reporting persisting disability after 1 year, but no correlation to radiological outcomes were found.

The possible correlation between radiological findings and the PRWHE score has been studied previously. Synn et al,[11] in a study of 53 patients, demonstrated no associations between radiographic findings and the PRWHE score at 6 months postinjury in older patients above the age of 53. Among patients included in that study, 51% (n=27) received surgical treatment that included pin fixation or volar plating. Karnezis et al[23] demonstrated a moderate correlation (r=−0.53) with PRWHE and the degree of radial height 12 months postinjury. Their study

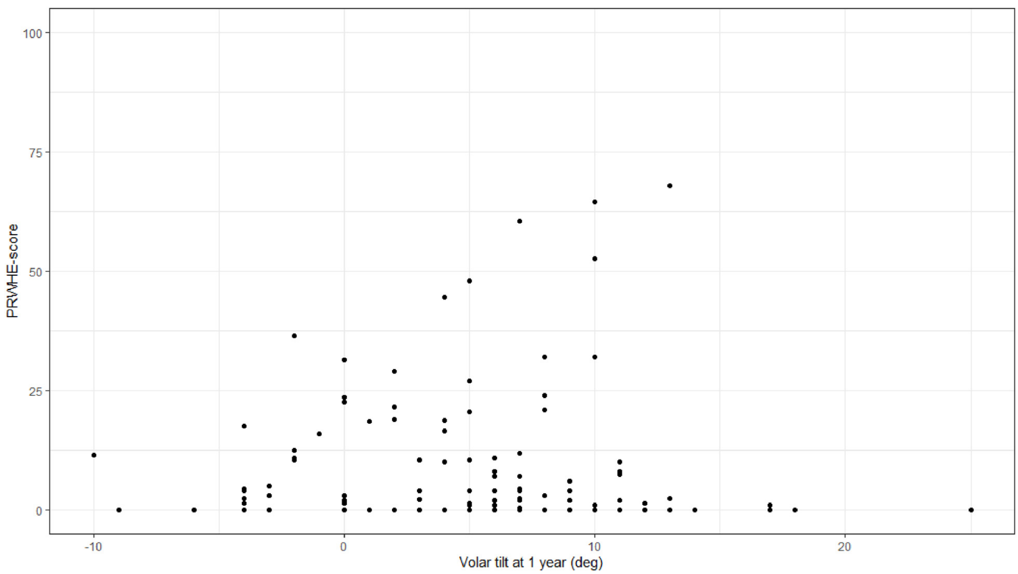

Figure 3. Result volar/dorsal tilt at 1 year.

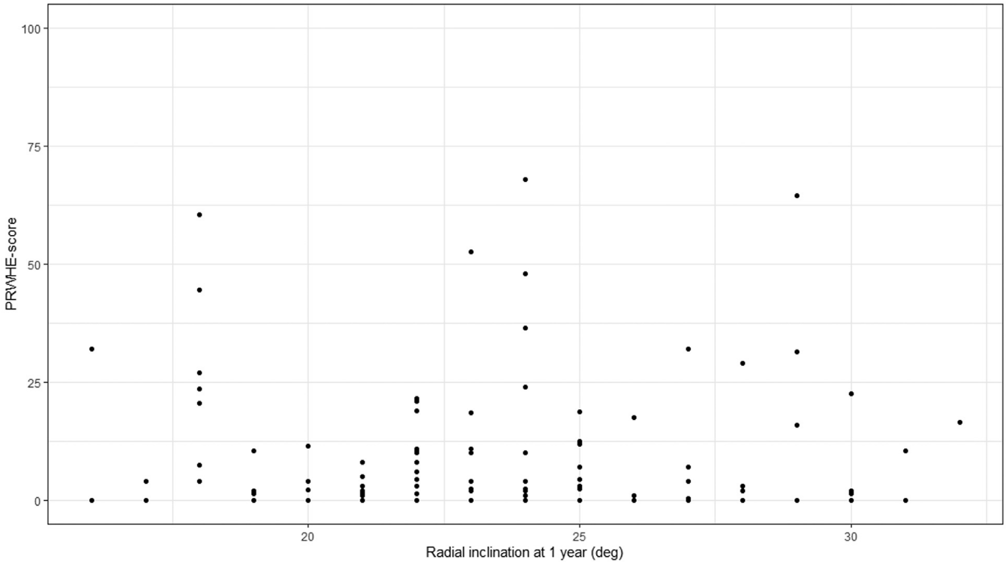

Figure 4. Result radial inclination at 1 year.

was smaller (n = 30) and the mean age was lower than of our study with mean age 46 versus 56 in our study. Furthermore, all included patients received surgical treatment with closed reduction and pin fixation, and the radial shortening was found to be 2.0 mm compared with our findings with radial shortening 1.6 mm. Plant et al[24] (n = 45) only presented radiological results according to volar tilt and ulnar variance, and the patients, which resembled ours in terms of mean age (56), all received surgical fixation with percutaneous pinning or volar plate. A weak correlation between volar tilt (r = 0.20), but no correlation

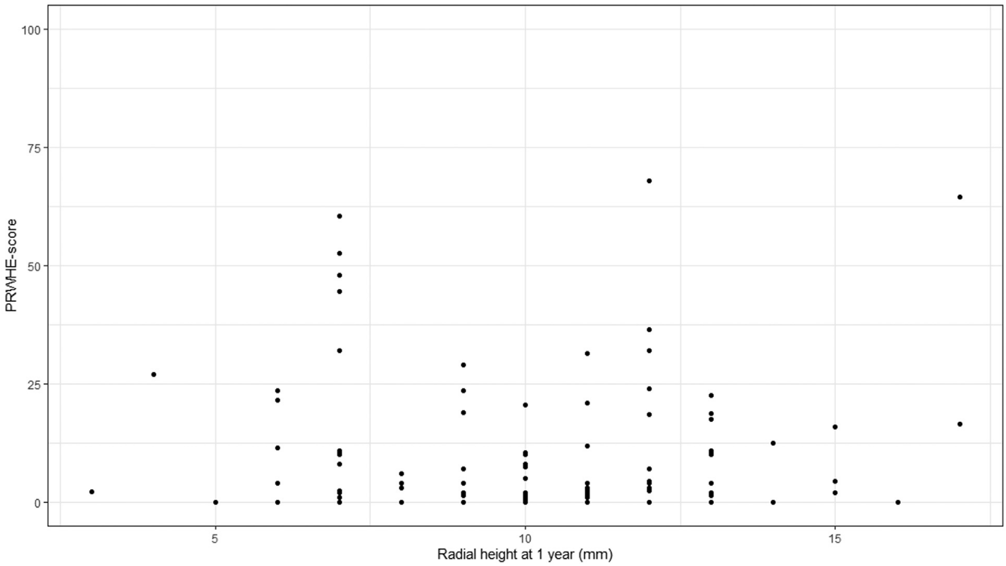

Figure 5. Result radial height at 1 year.

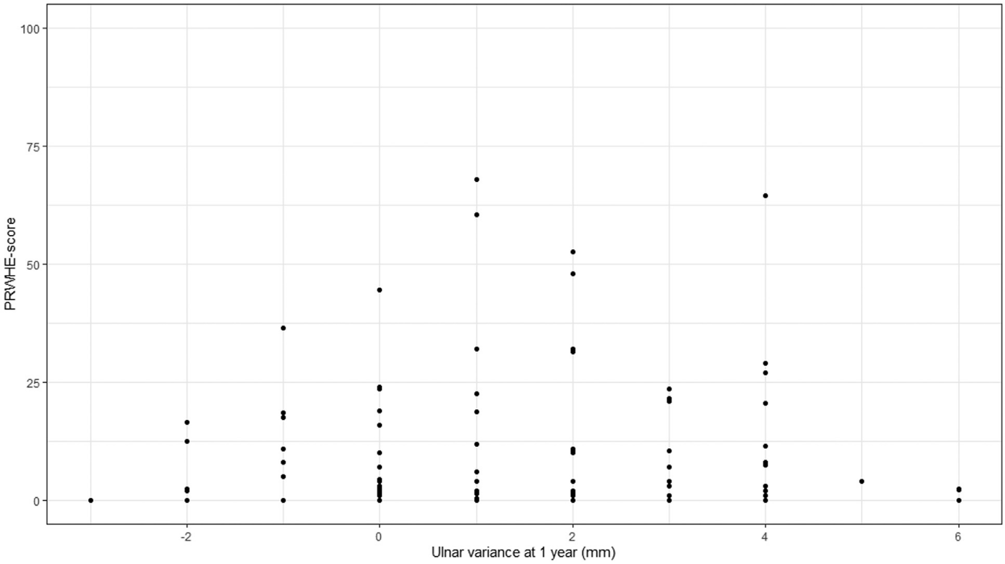

Figure 6. Ulnar variance at 1 year.

between ulnar variance (r=0.03) and the PRWHE score at 12 months, was reported in their study. Volar tilt was found to be 3.5° and ulnar variance 1.4 mm, which differed somewhat to our findings of 5° and 1.2 mm, respectively.

At 1 year, most patients had good scores and there was no statistically significant difference at a group level. When comparing the patients with poor results to those who had gained full recovery, they were more likely to be unemployed or disabled. This may indicate that patients with poorer functional results have other health issues. Roh et al[25] found that preoperative anxiety and catastrophic pain ideation were associated with delayed recovery after DRF and Yeoh et al[26] found depression to be the strongest predictor of worse functional score after 1 year. Our patients with poor outcome were also more likely to have sustained a low-energy indoor trauma and they had more loss of radial inclination and radial height, indicating osteoporosis. Fitzpatrick et al[27] found that postmenopausal osteoporotic women had worse functional outcomes than women without osteoporosis sustaining similar injuries at 1 year. No significant difference in ROM or radiographic data between the groups were found. Roh et al[28] also identified osteoporosis to be a risk factor delaying long-term functional recovery after DRF. This indicates that factors that can predict long-term results after surgical treatment of DRF are influenced by other issues than radiologic findings alone.

Our study included more patients than previous studies, which makes it less probable that our failure to detect a correlation between radiographic findings and functional outcomes is due to an underpowered study.

Previous studies have indicated that radiographic and functional outcomes are more closely correlated in younger patients.[29,30] This was not supported by our study, where all patients were under the age of 70.

With the exception of the failure of EF to maintain ulnar variance to the same extent as VLP, we found no significant difference in radiographic parameters between the 2 surgical treatments. Similar results have been found in other studies [31–36]

Some studies have reported that more than 40% of distal radius fractures have an associated ulnar styloid fracture.[37–39] This is consistent with our study (53% ulnar styloid fracture).

The frequency of ulnar styloid nonunion has previously been found to be between 26%[40] and 63%,[37] and functional outcome scores for such patients were not worse than for patients with healed fractures.[37,41–43] In our study, there were 31% nonunions and we found no correlation to the PRWHE score after 1 year.

The major strengths of our study were a large sample size (n=142), a uniform type of fractures and a high follow-up rate (91%). We used validated radiographic measurements, and the use of the PRWHE, the most sensitive outcome measure for patients sustaining wrist injuries, also strengthens our results.[16] The patients were recruited from the trauma unit in 2 hospitals, and a large number of surgeons were involved in the primary treatment. This renders external validity of the results although one could also argue that this also raise a concern regarding the level of experience the surgeons had with management of this type of injury.

However, the study was limited to patients having surgical fixation of their fractures. For this reason, the results cannot be extrapolated to patients treated conservatively, but should be interpreted in the context of the studied age group, type of fracture and the applied treatment methods. Further, our results do not translate into intra-articular deformity or severe degrees of extra-articular deformity, since no patients in this study had either of those 2 findings. Follow-up was limited to 1 year, thereby it is not possible to identify patients who will develop long-term symptoms and disability consequent to the injury.

Table 3

Patients fully recovered and patients not recovered after 1 year

	Fully recovered (N=113) PRWHE≤11.5	Not recovered (N=29) ΔPRWHE>11.5	*P* value
Gender			
Male	12	2	
Female	101	27	$P=0.549^{\dagger}$
Age (years)	56.2 (11.6)	56.1 (7.7)	$P=0.986^{*}$
Dominant hand injured	47	17	$P=0.100^{\dagger}$
Mechanism of injury			
Traffic	2	0	
Indoor	15	13	
Outdoor	67	13	
Work	7	2	
Sport	20	0	
Other	2	1	$\mathbf{P=0.005}^{\dagger}$
Energy of trauma			
Low-energy trauma	87	26	
High-energy trauma	26	3	$P=0.131^{\dagger}$
Work status			
Working, student, retired	104	20	
Disability, unemployed	9	9	$\mathbf{P=0.001}^{\dagger}$
Manual labor	43	13	$P=0.293^{\dagger}$
Radiology preop			
Volar tilt	−20.3 (10.6)	−24.1 (12.0)	$P=0.109^{*}$
Radial inclination	18.9 (5.7)	15.3 (6.4)	$\mathbf{P=0.004}^{*}$
Radial height	7.0 (4.3)	5.1 (4.0)	$\mathbf{P=0.047}^{*}$
Ulnar variance	2.6 (2.6)	2.4 (1.8)	$P=0.698^{*}$
Ulnar styloid fracture	57	16	$P=0.783^{\dagger}$
Δ dorsal tilt>10° at 1 year	26	6	$P=0.975^{\dagger}$
Δ ulna>2 mm at 1 year	27	6	$P=0.838^{\dagger}$
Implant			
Volar plate	56	13	
External fixator	57	16	$P=0.649^{\dagger}$
Anesthesia			
General anesthesia	23	4	
Brachial plexus block	90	25	$P=0.422^{\dagger}$
Time until surgery (days)	5.42 (4.1)	4.4 (3.7)	$P=0.219^{*}$
Duration of surgery (min)	52.5 (19.9)	57.2 (20.9)	$P=0.267^{*}$
Postoperative stay (days)	1.4 (0.9)	1.3 (0.8)	$P=0.787^{*}$

Low-energy trauma: fall from standing.
High-energy trauma: fall from greater than standing height, sporting, or traffic injury.
* Continuous variables are analyzed using Student *t* test and the values are given as the mean and standard deviation (SD) in parentheses.
† Categorical variables were analyzed using chi-square test.
Significant values ($P<0.05$) are listed in bold.

In conclusion, for extra-articular fractures, healing within a close range to normal values, there is little effect of radiographic alignment on functional outcome.

Future studies should focus on the limits of radiographic deviations, which might influence the patients' outcome.

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IV

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