Distal Radius Fractures:
On the Cutting Edge of Improving Outcomes and Preventing Complications

Caroline A. Selles

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Distale radius fracturen:
Verbeteren van uitkomsten en voorkomen van complicaties op het scherpst van de snede

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Promotoren:	Prof.dr. M.H.J. Verhofstad Prof.dr. J.C. Goslings
Overige leden:	Prof.dr. I.M.J. Mathijssen dr. P.F.W. Hannemann Prof.dr. R. Arora
Copromotor:	dr. N.W.L. Schep

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Chapter 1

GENERAL INTRODUCTION AND OUTLINE OF THIS THESIS

Distal radius fractures are one of the most common fractures, with an incidence of approximately 200-400 per 100,000 persons [1,2]. Annually, 1 million patients are treated in the Dutch Emergency Departments, of which 29% constitute patients with wrist injuries[3]. These fractures have a bimodal distribution, with a peak among young patients (predominantly male) with high-energy traumas and with a peak among elderly with low-energy falls (predominantly female)[4,5].

Due to the high incidence of distal radius fractures, these fractures are among the most expensive injuries of the upper extremity and have a great impact on society[6]. These fractures have both high health-care and productivity costs. Together with hand injuries, distal radius fractures account for $740 million annually, and rank higher than knee and lower limb fractures ($562 million), and hip fractures ($532million)[7].

Many aspects of distal radius fracture management remain a subject of debate. Guidelines advise nonoperative treatment in the form of plaster cast immobilization for patients with adequately reduced distal radius fractures[8]. The golden standard for displaced distal radius fractures used to be reduction and plaster cast immobilization[9]. However, the use of volar locking plates has become more popular, as they improve the stability of the fracture allowing for early postoperative mobilization and in return possible quicker return to work[10,11]. The Dutch guidelines recommend surgical treatment for inadequately reduced fractures in patients below the age of 65 years. For patients older than 65 years operative versus nonoperative treatment should individually be assessed. The evidence on which these guidelines is based on, are studies predominantly regarding an elderly population and makes no distinction between extra-articular and intra-articular fractures[12,13].

Multiple outcome measures have been described to determine the success of the treatment of distal radius fractures. Radiological measurements are used in the assessment of distal radius fractures. However, there is no consensus on acceptable radiological parameters as these correlate poorly with functional outcome[14,15]. Patient reported outcome measures have gained importance in clinical trials concerning fracture treatment, and guidelines are more often based on studies that use these outcomes[16-18]. The Patient-Rated Wrist Evaluation (PRWE) and Disabilities of the Arm, Shoulder and Hand (DASH) are two specific PROMs related to wrist function, and are valid and reliable outcome measures in assessing function and disability in patients with distal radius fractures[19-21].

This thesis aims to improve the prognosis of distal radius fractures by studying various treatment modalities in various types of patients. The first part of this thesis analyzes current distal radius fracture treatment, and the functional outcomes of these treatment methods. The main question we aim to answer in part one is: what is the optimal treatment of patients

with intra-articular distal radius factures? The second part of this thesis describes procedures to prevent and treat complications following distal radius fractures. Here we aim to better understand fracture anatomy and implant positioning in relation to complications. Additionally, operative treatment of malunion and triangular fibrocartilage complex (TFCC) lesions will be addressed.

PART 1 OUTCOME OF INTRA-ARTICULAR DISTAL RADIUS FRACTURE TREATMENT

Despite the high incidence of intra-articular distal radius fractures, the evidence for the treatment of patients with these fractures remains inconclusive. Some guidelines advise plaster cast immobilization for adequately reduced displaced distal radius fractures[17]. However, due to the high rate of fracture displacement, other guidelines also recommend surgery for those fractures presumed unstable[17,22].
In **chapter 2,** we describe the results of a multicenter randomized controlled trial comparing the functional outcomes of plaster cast immobilization and volar plate fixation in patients with an acceptably reduced intra-articular distal radius fracture.

There is an increasing tendency to treat patients with distal radius fractures with open reduction and internal fixation (ORIF)[23,24]. However, the direct costs of operative treatment are two to three times higher than those of non-operative treatment[17,25]. **Chapter 3** describes the health economic evaluation of the multicenter randomized controlled trial of plaster cast immobilization and volar plate fixation in patients with acceptably reduced intra-articular distal radius fractures.

Arthroscopy of the wrist has proven instrumental in identifying associated ligament and chondral lesions accompanying distal radius fractures[26]. Arthroscopically assisted removal of intra-articular fracture hematoma and debris may improve the functional outcomes following operative treatment of intra-articular distal radius fractures due to improvement of the synovial joint mobility[27-29]. However, there is still no consensus on the benefit of arthroscopically assisted treatment of intra-articular distal radius fractures. **Chapter 4** describes the design of a multicenter randomized controlled trial comparing functional outcomes of open reduction and internal fixation (ORIF) with and without arthroscopic debridement in adult patients with displaced intra-articular distal radius fractures. **Chapter 5** presents the results of this multicenter randomized controlled trial.

PART 2 PREVENTION AND TREATMENT OF COMPLICATIONS FOLLOWING DISTAL RADIUS FRACTURES

Conventional radiologic parameters have been described to correlate with functional outcome in patients with distal radius fractures. However, this correlation is only weak [30-32]. Most frequently used parameters are: radial inclination, ulnar variance, radial length, dorsal and volar tilt. Carpal alignment is a radiological parameter used less frequently, but has been shown to be an important predictor of functional outcome[33,34]. **Chapter 6** describes a new method, called the perpendicular method, for quantitative assessment of carpal alignment.

Since volar plate fixation has become an increasingly accepted operative technique for the treatment of distal radius fractures, the possible complications should also be properly addressed[35]. Improper plate position or malpositioned or prominent screws may cause tendon injuries or damage joint surfaces[36]. Plate prominence at the watershed line, categorized according to the Soong classification, is a contributing factor to this complication[37]. **Chapter 7** assesses the relationship between volar plate removal and Soong classification.

Operative treatment of distal radius fractures requires thorough planning. New technologies such as three-dimensional (3D) fluoroscopy have become increasingly popular[38]. This technique may be able to help visualize the quality of fracture reduction and implant position that routine two-dimensional fluoroscopy may not reveal[39]. The randomized controlled trial described in **chapter 8** assesses the clinical effectiveness of the intraoperative use of 3D fluoroscopy, compared to conventional 2D fluoroscopy, in patients with a distal radius fracture.

Soft tissue injuries, in particular those of the triangular fibrocartilage complex (TFCC) are very common associated injuries of distal radius fractures, occurring in up to 63 to 82% of these fractures[26,40]. **Chapter 9** describes the functional outcome of patients with symptomatic TFCC injuries treated with arthroscopic debridement or suture repair.

Fractures of the wrist account for 25% of all pediatric fractures[41]. Displaced fractures of the distal radius in children are usually managed by closed reduction and cast immobilization, whereas unstable fractures are mostly fixed with K-wires. Redisplacement requiring further intervention is found in up to 39% of the nonoperatively treated pediatric patients. Volar plate fixation, although less popular in pediatric patients, enhances anatomical reduction and allows for functional postoperative treatment. **Chapter 10** presents the functional outcomes of a cohort of pediatric patients with distal radius fractures treated with volar plate fixation.

In children with distal radius fractures, K-wire fixation and plaster cast immobilization may lead to secondary displacement, which in turn may lead to a symptomatic malunion of the distal radius. A symptomatic malunion of the distal radius causes pain, weakness or functional impairment of the wrist joint[42,43]. A corrective osteotomy can be performed to improve pain and function of the wrist joint. Therefore, in **chapter 11** we evaluate the functional outcomes of children who underwent a corrective osteotomy due to symptomatic malunion of the distal radius.

Chapter 12 presents a general discussion and future perspectives on the research in this field of distal radius fracture management. **Chapter 13** summarizes the findings of this thesis.

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Part 1

OUTCOME OF DISTAL RADIUS FRACTURE TREATMENT

Chapter 2

VOLAR PLATE FIXATION VERSUS CAST IMMOBILIZATION IN ACCEPTABLY REDUCED INTRA-ARTICULAR DISTAL RADIAL FRACTURES. A RANDOMIZED CONTROLLED TRIAL

C.A. Selles, M.A.M. Mulders, J. Winkelhagen,
P.V. van Eerten, J.C. Goslings MD, N.W.L. Schep,
on behalf of the VIPAR collaborators*

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**VIPAR trial collaborators:*
R.J. Derksen, T. Schepers, R.N. van Veen, B.I. Cleffken, P. Joosse,
A.H. van der Veen, J.P.M. Frölke, B.A. van Dijkman, B.A. Twigt,
M.R. de Vries, M. van Heijl, M. Schouten, R.W. Poolman

ABSTRACT

Background: The evidence for the treatment of acceptably reduced intra-articular distal radial fractures remains inconclusive. We therefore compared the functional outcomes of cast immobilization (nonoperative) and volar plate fixation (operative) for patients with these fractures.

Methods: This multicenter randomized controlled trial enrolled patients between 18 and 75 years old with an acceptably reduced intra-articular distal radial fracture. Patients were randomized to nonoperative treatment or to operative treatment. The primary outcome measure was the Patient-Rated Wrist Evaluation (PRWE) score after 12 months. Secondary outcome measures were the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire; the Short Form-36 (SF-36) questionnaire; a visual analog scale for pain; range of motion; grip strength; radiographic parameters; and complications. Analyses followed the intention-to-treat principle.

Results: A total of 96 patients were randomized, and 90 (46 in the nonoperative group and 44 in the operative group) were included in the analysis. Patients treated in the operative group had significantly better functional outcomes measured with the PRWE at 6 weeks, 3 months, 6 months, and 1 year. Additionally, a 28% rate of subsequent surgery was identified in the nonoperative group.

Conclusions: Adult patients with an acceptably reduced intra-articular distal radial fracture have better functional outcomes for 12 months when treated operatively instead of nonoperatively. We therefore recommend surgical treatment for patients with these fractures.

INTRODUCTION

Intra-articular distal radial fractures have an overall incidence of 20 per 10,000 persons per year[1]. Despite this high incidence, the evidence for the treatment of these fractures remains inconclusive. Some guidelines advise cast immobilization for adequately reduced displaced distal radial fractures but also recommend close follow-up for these patients and possibly surgery for presumed unstable fractures[2-4].

There is an increasing tendency to treat patients with a distal radial fracture with open reduction and internal fixation (ORIF)[5,6]. Volar locking plates improve the stability of the fracture, allowing for early postoperative mobilization[7]. This results in patients treated operatively having a quicker return of function during the first 3 to 6 months compared with those treated nonoperatively[8]. A recent randomized study found that patients between 18 and 75 years old with a displaced extra-articular fracture treated with ORIF had better patient-related outcomes, compared with those who underwent cast immobilization, at a 12-month follow-up[9].

The aim of this randomized controlled trial was to compare functional outcomes between volar plate fixation and cast immobilization in a series of adult patients with a displaced and acceptably reduced intra-articular distal radial fracture. We hypothesized that patients treated operatively would have better functional outcomes than those treated nonoperatively.

MATERIALS AND METHODS

Study design

The VIPAR (Internal Plate Fixation versus Plaster in Complete Articular Distal Radius Fractures) trial was a multicenter randomized controlled trial in which adult patients with an acceptably reduced intra-articular distal radial fracture were randomized between volar plate fixation and cast immobilization.
Institutional board and ethics committee approval was obtained. The trial protocol has been published[10]. The results were reported according to the Consolidated Standards of Reporting Trials (CONSORT). The study was registered at ClinicalTrials.gov (NCT02651779).

Patients and Participating Centers

The study was conducted in 13 hospitals in the Netherlands. The participating hospitals ranged from level-1 trauma centers to non-teaching or community hospitals. Patients were between 18 and 75 years of age and had a displaced intra-articular distal radial fracture

(complete articular type C) with acceptable closed reduction. Fracture reduction was considered acceptable according to the Dutch guidelines. These parameters and exclusion criteria are provided in Appendix 1.

Randomization

After providing informed consent, patients were randomized to plaster cast immobilization or to volar plate fixation in a 1:1 ratio. To ensure concealment of allocation, randomization was performed using a secure computer randomization procedure, with the use of mixed blocks. The randomization process stratified according to age, into 3 strata: 18 to 30, 31 to 65, and 66 to 75 years.

Trial Intervention

A detailed description of the trial interventions has previously been published[10]. After acceptable closed reduction all patients were initially treated with cast immobilization. The patients randomized to the nonoperative group continued the cast immobilization for 4 to 5 weeks whereas those randomized to volar plate fixation were operated on within 2 weeks after the injury. Volar plate fixation (no adjunct procedures) was performed by a certified (orthopaedic) trauma surgeon or a surgical resident under supervision of a certified surgeon.

Identical instructions on moving the wrist were given to both groups. Immediate postoperative mobilization of the wrist was allowed in the operative group. During the first 6 weeks, weight-bearing exercises were not allowed. Physiotherapy was prescribed at the discretion of the treating physician. Follow-up was conducted at 1, 3, and 6 weeks and at 3, 6, and 12 months.

Outcome Measures

The primary outcome measure was the functional outcome measured with the Patient-Rated Wrist Evaluation (PRWE) questionnaire, a validated tool for assessing functional outcome in patients with a distal radial fracture[11]. The score ranges from 0 to 100, with 0 indicating no impairment[12]. The minimal clinically important difference (MCID) is the minimal change in score that is considered meaningful to the patient. The MCID of the PRWE questionnaire has been reported to be 14, which is the value on which this study was powered[13]. Secondary outcome measures were the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire; quality of life measured with the Short-Form-36 (SF-36) questionnaire; postoperative pain as indicated on a visual analog scale (VAS); range of motion; grip strength; radiographic parameters; and complications during the 1-year follow-up.

The DASH score ranges from 0 to 100, with 0 indicating no disability[14]. The SF-36 is a validated multipurpose health questionnaire consisting of a physical component summary (PCS) subscale and a mental component summary (MCS) subscale. The score ranges from 0 to 100, with higher scores indicating better quality of life[15]. Pain was indicated on a VAS on which 0 indicated no pain and 10, the worst possible pain. Range of motion included active wrist flexion and extension, radial and ulnar deviation, and pronation and supination. Grip strength (in kilograms) was measured as a mean of 3 measurements with a hydraulic hand dynamometer. Range of motion and grip strength on the injured side were compared with those on the uninjured side, not taking into account hand dominance.
Radiographic parameters included radial inclination, radial height, ulnar variance, dorsal or volar angulation, and an intra-articular gap or step.

A complication was defined as any adverse event for which additional treatment was required. Complications included wound infection, carpal tunnel syndrome, tenosynovitis, tendon rupture, complex regional pain syndrome (CRPS type 1), and plate-related complications for which plate removal was necessary.

Secondary displacement was defined as fracture displacement that was no longer acceptable according to the Dutch guidelines (see Appendix 1). Subsequent surgery was defined as ORIF that was necessary due to fracture displacement or corrective osteotomy due to symptomatic malunion. We defined fracture redisplacement as loss of acceptable reduction as described above. Symptomatic malunion was defined as a malunited fracture with pain and/or functional impairment.

Statistical Analysis
The sample size was calculated based on the primary outcome, the PRWE score at the 1-year follow-up. With $\alpha = 0.05\%$ and a power of 90%, a sample size of 64 patients was required to detect a difference of 14 points in the PRWE score. With an expected loss to follow-up of 10%, 45 patients were included in each arm.
All analyses were based on the intention-to-treat principle. A Mann-Whitney U test was used to compare continuous non-normally distributed data, and a chi-square test was used for categorical data.

Differences between the 2 groups in the PRWE, DASH, and SF-36 scores were analyzed with an analysis of covariance (ANCOVA) test. Range of motion, grip strength, VAS scores, and radiographic parameters at the follow-up intervals were analyzed using a linear mixed model. The best covariance structure for each linear mixed model was determined using the smallest Akaike information criterion (AIC)[16]. In both the ANCOVA and the linear mixed model, the data were ranked by follow-up time point if they were not normally distributed.

To confirm the normality of the ranked data, the histograms of the residuals were visually inspected. All outcome measures were corrected for age because this was a stratification factor in the design of the study.
An additional subgroup analysis was performed to compare patients primarily treated operatively with those treated only with cast immobilization, thus excluding those who underwent subsequent surgery. Patients with subsequent surgery were also compared with those primarily treated operatively.

The baseline characteristics of patients who were eligible for inclusion but did not give informed consent were compared with the characteristics of the included patients in order to evaluate potential selection bias.
Two-sided p values of ≤0.05 were considered significant for all statistical tests.

Ethics Committee Approval
Institutional review board approval was obtained from the ethics committee and institutional review board of our hospital and the board of directors of all participating centers.

Funding
An AO Netherlands start-up grant was received for this study.

RESULTS

Randomization and Baseline Characteristics
Between June 2015 and February 2018, 3,171 patients were screened for eligibility and 96 of them provided written informed consent (Fig. 1). After randomization, 4 patients withdrew consent and 2 patients were excluded because they met exclusion criteria. Patients were randomized at a median of 5 days (interquartile range [IQR] = 2 to 8) after closed reduction. A total of 90 patients were included for analysis, 46 in the nonoperative group and 44 in the operative group. All patients received the treatment to which they had been allocated. In each group, 1 patient did not complete the final 12-month follow-up.

The median age of the study participants was 61 years (IQR = 51 to 66), and 84% were female. Baseline characteristics were similar between the 2 groups (Table I). The baseline characteristics of the included patients did not differ from those of the eligible but not included patients (see Appendix 2).

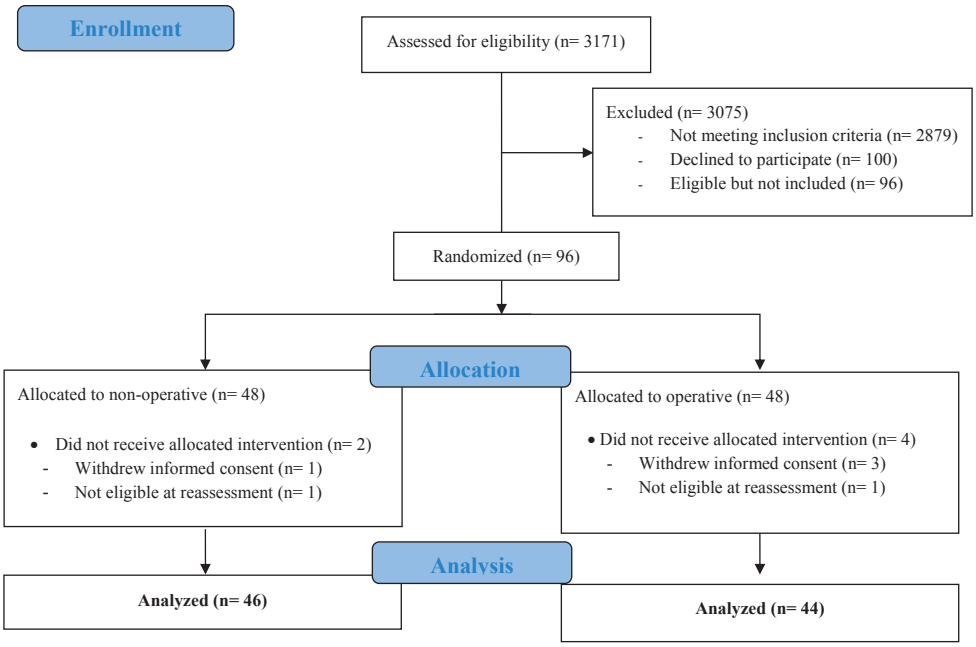

Figure 1: CONSORT Flow diagram of included patients

Primary Outcome

The operative group had significantly better functional outcomes measured with the PRWE at 6 weeks (median [and IQR] = 39 [22 to 60] versus 58 [49 to 76]), at 3 months (21 [7 to 49] versus 40 [15 to 62]), at 6 months (9 [3 to 18] versus 24 [9 to 51]), and at 1 year (5 [0 to 12] versus 12 [3 to 28]) (Table II) than those treated nonoperatively.

Secondary Outcomes

The median DASH scores [IQR] for the operative group were significantly better at 6 weeks (23 [13 to 47] versus 50 [36 to 61]), at 3 months (12 [4 to 29] versus 24 [9 to 44]), and at 6 months (5 [3 to 10] versus 15 [4 to 33]). At 1 year, DASH scores were significantly higher for the operative group compared with the nonoperative group (Table II).

Operatively treated patients had significantly better physical quality of life (PCS) at 3 months (median [IQR] = 49 [44 to 55] versus 46 [38 to 50], p = 0.02) and at 12 months (55 [50 to 59] versus 51 [41 to 56], p = 0.04). At the other time points, no significant difference was found. There was also no significant difference in the mental quality of health (MCS) between the operatively and nonoperatively treated patients at any time point (Table II).

Patients treated operatively had a better range of motion and grip strength at 6 weeks. At 1-year follow-up, all range-of-motion parameters and grip strength were similar between

Table 1: Patient Characteristics

	Nonoperative (N = 46)	**Operative (N = 44)**
Median age [IQR] *(yr)*	59 [53-67]	62 [49-66]
Sex *(no.)*		
Female	40	36
Male	6	8
Fracture of dominant side (no.)	20	15
Diabetes mellitus *(no.)*		
Yes	4	2
No	42	42
Smoking *(no.)*		
Yes	6	8
No	40	36
Radiographic parameters (mean ± std. dev.)		
Radial inclination *(°)*	24 ± 3	25 ± 3
Radial height *(mm)*	11 ± 2	11 ± 2
Volar angulation* *(°)*	4 ± 2	5 ± 3
Dorsal angulation* *(°)*	6 ± 2	5 ± 3
Intra-articular gap *(mm)*	0.3 ± 0.4	0.5 ± 0.6
Intra-articular step *(mm)*	0.2 ± 0.3	0.1 ± 0.2

*The total range in angulation was 9° volar to 9.6° dorsal.

the 2 groups (Table III). Pain measured with the VAS did not differ between the groups at any point during the follow-up period (p = 0.2).

At randomization, the mean radiographic parameters of the reduced distal radial fractures were: radial inclination of 24° ± 3°, radial height of 11 ± 2 mm, volar angulation of 5° ± 3° or dorsal angulation of 6° ± 2°, intra-articular gap of 0.4 ± 0.5 mm, and intra-articular step of 0.1 ± 0.5 mm. During the follow-up period, operatively treated patients had better radiographic parameters than nonoperatively treated patients (see Appendix 3).

In the nonoperative group, 24 complications occurred in 19 patients, compared with 21 complications in 17 patients in the operative group (p = 0.83) (Table IV). In the nonoperative group, 11 patients had secondary displacement during cast immobilization and underwent subsequent ORIF. Subsequent ORIF was performed at a median of 15 days (IQR = 12 to 20). Six patients had a symptomatic malunion, and 2 of them underwent a corrective osteotomy at 6 and 8 months. The other 4 patients chose not to undergo subsequent surgery during the follow-up period. In total, 13 patients (28%) treated nonoperatively had subsequent surgery due to secondary displacement or a symptomatic malunion. Two patients had an additional surgical triangular fibrocartilaginous complex (TFCC) repair due to persistent ulnar pain resulting in loss of range of motion caused by the TFCC lesion. Plate removal

Table 2: Functional (PRWE and DASH) and Quality-of-Life (SF-36 PCS and MCS) Outcomes in Nonoperative Versus Operative Groups

	Median [IQR]		
	Nonoperative (N = 46)	**Operative (N = 44)**	**P Value**
6 weeks			
PRWE	58 [49-76]	39 [22-60]	**<0.001**
DASH	50 [36-61]	23 [13-47]	**<0.001**
PCS	41 [36-45]	45 [37-49]	0.05
MCS	46 [38-55]	54 [38-58]	0.3
3 months			
PRWE	40 [15-62]	21 [7-49]	**0.002**
DASH	24 [9-44]	12 [4-29]	**0.004**
PCS	46 [38-50]	49 [44-55]	**0.02**
MCS	53 [41-57]	55 [48-58]	0.4
6 months			
PRWE	24 [9-51]	9 [3-18]	**0.002**
DASH	15 [4-33]	5 [3-10]	**0.001**
PCS	49 [42-55]	54 [47-57]	0.1
MCS	52 [48-58]	55 [49-57]	0.7
12 months			
PRWE	12 [3-28]	5 [0-12]	**0.01**
DASH	8 [2-17]	3 [1-11]	**0.04**
PCS	51 [41-56]	55 [50-59]	**0.04**
MCS	53 [48-58]	55 [51-57]	0.9

was performed in 2 patients because of plate-related symptoms. All of the patients with subsequent surgery were analyzed in the nonoperative group due to the intention-to-treat analysis.

In the operative group, 12 patients had plate removal due to plate-related symptoms such as pain, tendinitis, and carpal tunnel syndrome. Six cases of carpal tunnel syndrome were treated with carpal tunnel release during the follow-up period. The plate was also removed in 4 of these patients. One patient had loss of flexor pollicis longus (FPL) function due to fibrosis, for which an FPL release was performed.

In the nonoperative group, 39 patients (85%) were satisfied with the treatment that they received but only 22 (48%) stated that they would recommend the treatment to others. Reasons for not recommending nonoperative treatment were ultimately undergoing subsequent surgery (n = 15), wanting to mobilize the wrist immediately (n = 8), and experiencing symptoms due to the cast (n = 1). All 44 patients in the operative group were satisfied with the treatment that they received. However, 4 patients stated that they would recommend nonoperative treatment as they believed that this treatment option should be given a chance first.

Table 3: Clinical Outcomes Measured with Range of Motion and Grip Strength in Nonoperative Versus Operative Groups

	Median [IQR] (Percentage Compared with Uninjured Side)							
Clinical Outcome	**6 Weeks**		**3 Months**		**6 Months**		**12 Months**	
	Nonoperative	**Operative**	**Nonoperative**	**Operative**	**Nonoperative**	**Operative**	**Nonoperative**	**Operative**
Range of motion (°)								
Radial deviation	5 [4-9] (33%)	*10 [10-15] (75%)*	10 [10-15] (100%)	*15 [10-20] (100%)*	15 [10-15] (100%)	15 [10-15] (100%)	15 [10-20] (96%)	15 [10-15] (98%)
Ulnar deviation	9 [5-15] (40%)	*20 [15-20] (80%)*	20 [15-20] (94%)	20 [20-25] (100%)	20 [20-25] (100%)	20 [20-25] (100%)	20 [20-22] (94%)	20 [20-25] (95%)
Pronation	70 [60-80] (87%)	*85 [80-85] (100%)*	85 [80-85] (100%)	85 [85-85] (100%)	85 [80-85] (100%)	85 [85-85] (100%)	85 [85-85] (100%)	85 [85-85] (99%)
Supination	30 [20-45] (35%)	*60 [50-75] (74%)*	65 [50-75] (79%)	*80 [67-85] (94%)*	75 [65-80] (92%)	85 [80-85] (100%)	81 [75-85] (96%)	83 [80-85] (94%)
Dorsiflexion	20 [10-30] (31%)	*53 [40-69] (69%)*	60 [50-71] (82%)	70 [61-80] (93%)	70 [60-75] (88%)	78 [70-85] (100%)	77 [70-77] (96%)	75 [70-80] (97%)
Palmar flexion	28 [20-35] (36%)	*48 [31-60] (60%)*	55 [45-61] (75%)	60 [50-70] (83%)	65 [65-70] (82%)	*70 [65-80] (94%)*	70 [60-80] (91%)	75 [70-80] (93%)
Grip strength *(kg)*	3 [0-8] (16%)	*12 [7-18] (46%)*	12 [6-18] (48%)	*18 [12-26] (68%)*	15 [13-22] (67%)	22 [16-29] (80%)	21 [18-28] (89%)	22 [16-28] (92%)

Italicized values are statistically significant values.

Table 4: Complications in Nonoperative Versus Operative Groups

Complication	Nonoperative	Operative	P Value
Implant removal	2	12	
Secondary displacement requiring ORIF	11	0	
Carpal tunnel syndrome	0	6	
Symptomatic malunion	6	0	
Superficial infection	0	2	
TFCC repair	2	0	
Quervain syndrome	1	0	
CRPS	1	0	
FPL release	0	1	
Total	**24**	**21**	**0.83**

Table 5: Functional Outcomes Measured with PRWE in Subgroups at Different Time Points

	Median [IQR]			Median [IQR]		
	Operative (N = 44)	Nonoperative Only (N = 33)	P Value	Operative (N = 44)	Nonoperative with Subsequent Surgery (N = 13)	P Value
6 weeks	39 [22-60]	57 [45-73]	**0.001**	39 [22-60]	75 [57-82]	**<0.001**
3 months	21 [7-49]	32 [12-62]	**0.03**	21 [7-49]	42 [34-56]	**0.02**
6 months	9 [3-18]	25 [8-50]	**0.007**	9 [3-18]	22 [11-51]	**0.02**
12 months	5 [0-12]	11 [4-30]	**0.02**	5 [0-12]	15 [0-38]	**0.2**

Subgroup Analysis

When we excluded the patients who had been treated with subsequent surgery from the nonoperative group, we found that the operative group still had better functional outcomes than the nonoperative group throughout the entire follow-up period (Table V). Patients treated operatively primarily also had better functional outcomes than those treated non-operatively with subsequent surgery. At the 1-year follow-up, the functional outcomes were similar between those 2 groups.

DISCUSSION

In this multicenter randomized trial, we found that patients with a displaced and adequately reduced intra-articular distal radial fracture treated operatively had better patient-related functional outcomes during 12 months of follow-up than those treated nonoperatively. During the first 6 months, the difference in functional outcomes was also clinically relevant. Additionally, subsequent surgery due to secondary displacement or symptomatic malunion was performed in 28% of the patients treated nonoperatively.

Previous studies have compared outcomes of nonoperative and operative treatment of distal radial fractures. Arora et al. found that patients with an unstable distal radial fracture treated operatively had better DASH and PRWE scores during up to 12 weeks of follow-up, but they found no significant difference at 6 and 12 months. That study, however, analyzed both extra-articular and intra-articular fractures in a population that was older than ours[8]. Other studies analyzing displaced intra-articular distal radial fractures in patients 65 years and older found a trend toward better DASH scores and significantly better PRWE scores for the operative group compared with the nonoperative group[17,18]. Studies concerning a younger population with intra-articular distal radial fractures have, to our knowledge, not yet been performed. Our findings for intra-articular fractures are in line with the results of Mulders et al., who found that operatively treated patients with an acceptably reduced extra-articular distal radial fracture had significantly better functional outcomes than patients treated nonoperatively[9].

In our study, we found a subsequent surgery rate of 28% in the nonoperatively treated group due to secondary displacement or a symptomatic malunion. Secondary displacement has been reported in up to 43% to 60% of patients following closed reduction of distal radial fractures, which is slightly higher than the 24% found in our study[19,20]. One could argue that this is not a complication of nonoperative treatment but a complication of the injury itself. Predicting which fractures will remain stable and in which ones secondary displacement will occur remains a point of discussion. Not all popular predictors of instability that are persistently used in the literature have been identified as significantly associated with secondary displacement[21]. Because the power calculations were based on only 2 groups, our study may not have had sufficient power to detect differences between the secondary surgery subgroup and the other subgroups. However, the patients who required subsequent surgery in our study were initially worse off than those treated with primary operative treatment. During the first 6 months of follow-up, they did not obtain the functional outcomes of those with primary operative treatment. This finding is supported by other studies that showed that patients who underwent subsequent surgery for secondary displacement had worse functional outcomes up to 12 months compared with patients who were primarily treated operatively[9,22]. These high subsequent surgery rates may further justify choosing primary operative treatment of initially displaced intra-articular distal radial fractures.

In our study, plate removal was performed in 27% of the patients treated primarily with volar plate fixation. This percentage is considerably higher than the 3% to 17% reported in the literature[23-25]. Patients may have become more aware of their wrist function and possible stiffness during follow-up. With the increase in use of volar plate fixation, possible complications should be assessed at follow-up intervals and discussed when formulating treatment recommendations. Improper plate position or malpositioned or prominent screws may

cause tendon or joint injuries[26,27]. The patients in this study had routine follow-up and were assessed for plate-related symptoms. This may account for the higher rate of plate removal in our population.

This study has several limitations. Patients and physicians were not blinded to the treatment group assignment, as treatment was visible to both. The patients completed the questionnaires about their functional outcomes before their visit to the outpatient clinic, decreasing the bias of the clinical assessment. The functional outcomes were evaluated during a 1-year follow-up period, but whether the patient returned to the same function as before the fracture is unknown. We could, however, compare the injured side with the uninjured side and assume that, due to randomization, the difference between the 2 sides before injury was distributed equally in the 2 groups. A total of 96 eligible patients were not included in this study, which might have allowed for selection bias. The baseline characteristics of these patients, however, did not differ from those of the included patients. Furthermore, the majority (94%) of the 96 patients were treated nonoperatively, but they were found to have a similar subsequent surgery rate of 27%.

In summary, we found that adult patients with an acceptably reduced intra-articular distal radial fracture had better functional outcomes during 12 months when treated operatively instead of nonoperatively. Additionally, a subsequent surgery rate of 28% in the nonoperative group was found. Due to rising health-care costs, it has become increasingly important to provide effective care with good functional outcomes. We therefore recommend surgery for patients with these fractures.

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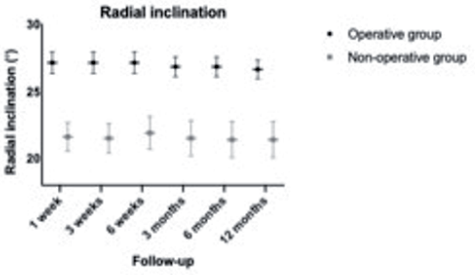
APPENDIX 1:
DUTCH GUIDELINES FOR ACCEPTABLE CLOSED REDUCTION AND EXCLUSION CRITERIA

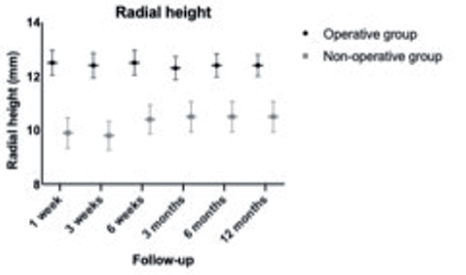
Acceptable closed reduction was defined by a radial inclination ≥ 15^0, radial height ≥ 5 mm **compared to the ulna**, dorsal angulation ≤ 15^0, palmar angulation ≤ 20^0, and gap or step-off < 2 mm. Patients with open distal radius fractures or other fractures of the affected extremity, with a fracture of the contralateral wrist, with impaired wrist function prior to trauma, and multi-trauma patients (Injury Severity Score ≥16) were excluded. Patients unable to understand the study information and informed consent forms, as judged by the treating physician, were also excluded.

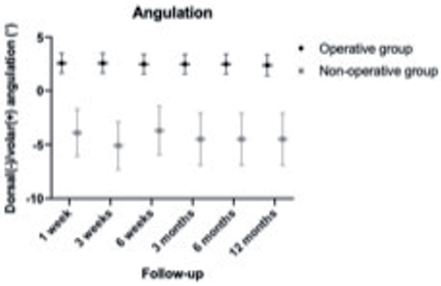
APPENDIX 2:
PATIENT CHARACTERISTICS OF ELIGIBLE PATIENTS, BUT WHO DECLINED TO PARTICIPATE

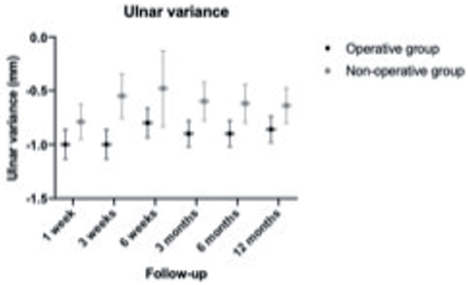
Patient characteristics	N (%)
Age, median [IQR]	62 [50-69]
Gender	
Female	80 (83)
Male	16 (17)
Treatment	
Conservative	90 (94)
Subsequent surgery	24/90 (27)
Operative	6 (6)

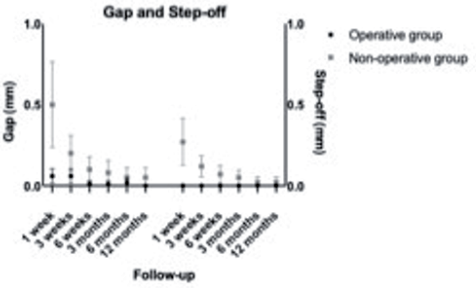
APPENDIX 3:
RADIOLOGICAL PARAMETERS, MEAN WITH 95% CI











Chapter 3

COST ANALYSIS OF VOLAR PLATE FIXATION VERSUS PLASTER CAST IMMOBILIZATION FOR INTRA-ARTICULAR DISTAL RADIAL FRACTURES

C.A. Selles, M.A.M. Mulders, S. van Dieren, J.C. Goslings, N.W.L. Schep on behalf of the VIPAR collaborators*

In Press JBJS

**VIPAR trial collaborators:*
R.J. Derksen, T. Schepers, R.N. van Veen, B.I. Cleffken, P. Joosse, A.H. van der Veen, J.P.M. Frölke, B.A. van Dijkman, B.A. Twigt, M.R. de Vries, M. van Heijl, M. Schouten, R.W. Poolman

ABSTRACT

Background: The aim of this study was to compare the cost-effectiveness and cost-utility between plaster cast immobilization and volar plate fixation for acceptably reduced intra-articular distal radial fractures.

Methods: A cost-effectiveness analysis was conducted as part of a randomized controlled trial comparing operative (volar plate fixation) with nonoperative (plaster cast immobilization) treatment in patients between 18 and 75 years old with an acceptably reduced intra-articular distal radial fracture. Health-care utilization and use of resources per patient were documented prospectively and included direct medical costs, direct non-medical costs, and indirect costs. All analyses were performed according to the intention-to-treat principle.

Results: The mean total cost per patient was $291 (95% bias-corrected and accelerated confidence interval [bcaCI] = $−1,286 to $1,572) higher in the operative group compared with the nonoperative group. The mean total number of quality-adjusted life-years (QALYs) gained at 12 months was significantly higher in the operative group than in the nonoperative group (mean difference = 0.15; 95% bcaCI = 0.056 to 0.243). The difference in the cost per QALY (incremental cost-effectiveness ratio [ICER]) was $2,008 (95% bcaCI = $−9,608 to $18,222) for the operative group compared with the nonoperative group, which means that operative treatment is more effective but also more expensive. Subgroup analysis including only patients with a paid job showed that the ICER was $−3,500 per QALY for the operative group with a paid job compared with the nonoperative group with a paid job, meaning that operative treatment is more effective and less expensive for patients with a paid job.

Conclusions: The difference in QALYs gained for the operatively treated group was equivalent to an additional 55 days of perfect health per year. In adult patients with an acceptably reduced intra-articular distal radial fracture, operative treatment is a cost-effective intervention, especially in patients with paid employment. Operative treatment is slightly more expensive than nonoperative treatment but provides better functional results and a better quality of life.

INTRODUCTION

Intra-articular distal radial fractures have an overall incidence of 20 per 10,000 person-years[1]. Not only do these injuries have a large impact on physical and mental health, they also lead to high health-care costs of $740 million annually in the Netherlands[2].

Operative treatment for extra- and intra-articular distal radial fractures has become increasingly popular[3,4]. Several studies have shown favorable outcomes in patients treated operatively with volar plate fixation compared with patients treated nonoperatively with plaster cast immobilization[5-7]. Operative treatment may also allow for a quicker return to work.
Costs as a result of loss of productivity account for approximately 56% to 67% of total health-care costs[2,8]. Operative treatment may allow for a quicker return to work and independence, decreasing total costs. However, the costs of operative treatment are 2 to 3 times higher than those of nonoperative treatment[9,10]. Due to rising health-care costs, it has become increasingly important to provide cost-effective care with good functional outcomes.

The aim of this economic analysis was to compare the cost-effectiveness and cost-utility between volar plate fixation and plaster cast immobilization for adults with an acceptably reduced intra-articular distal radial fracture. We posed the hypothesis that volar plate fixation was cost-effective.

MATERIALS AND METHODS

This economic evaluation was conducted as part of a randomized controlled trial comparing volar plate fixation (operative treatment) with plaster cast immobilization (nonoperative treatment) in adults with a displaced intra-articular distal radial fracture (VIPAR [Internal Plate Fixation versus Plaster in Complete Articular Distal Radius Fractures] trial). Institutional review board approval was obtained from the ethics committee and institutional board of our hospital, and the board of directors of all participating centers. The study was registered at ClinicalTrials.gov (NCT02651779).

Patients between 18 and 75 years of age with an adequately reduced intra-articular distal radial fracture were included and randomized to volar plate fixation or plaster cast immobilization. Adequate reduction was defined as described by the Dutch guidelines as radial inclination of ≥15°, radial height of ≥5 mm compared to the ulna, dorsal angulation of ≤15°, palmar angulation of ≤20°, and a gap or step-off of <2 mm[10]. The primary outcome was the functional outcome, measured with the Patient-Rated Wrist Evaluation (PRWE) questionnaire. The design of the study has been reported previously[11]. In summary, the VIPAR trial

found that patients treated operatively had significantly better PRWE scores compared with those treated nonoperatively (median [interquartile range] = 5 [0 to 12] versus 12 [3 to 28], p = 0.02) after 1 year of follow-up. Additionally, a subsequent surgery rate in the nonoperative group of 28% was found.
The data required for the economic evaluation, both costs and health benefits, was collected alongside the randomized controlled trial.

Economic Evaluation
The economic evaluation analyzed the costs, cost-effectiveness, and cost-utility of operative treatment and nonoperative treatment from a societal perspective in the Netherlands with a time horizon of 12 months following randomization. The effectiveness of treatment was defined as a change of 14 points in the PRWE score at 12 months. The PRWE is a validated tool for assessing functional outcomes in patients with a distal radial fracture. The highest score, indicating severe impairment, is 100 and the best score, indicating no impairment, is 0[12]. The effectiveness in terms of utilities was determined using the EuroQol-5 Dimension-3 Level (EQ-5D-3L) health index. This standardized questionnaire is a validated generic instrument to measure quality of life. The mean costs and mean health outcomes were used to calculate the cost per quality-adjusted life-year (QALY) at 6 weeks and at 3, 6, and 12 months. One QALY represents 1 year of perfect health.

Incremental cost-effectiveness ratios (ICERs) were analyzed from a societal perspective for a 12-month time-period. The ICER is calculated as the incremental change in costs divided by the incremental change in health outcome. The ICER represents the additional costs per QALY or PRWE score gained, and indicates the cost per life-year of perfect health gained, described as the trade-off between costs and effectiveness for the treatment methods.
The mean difference in costs between the 2 groups was divided by the mean difference in QALYs and PRWE scores. An intervention that costs less than €30,000 in the Netherlands or $50,000 in the U.S. per QALY is considered to be cost-effective[13,14]. This is called the "willingness-to-pay threshold."

At the time of randomization or during follow-up, not all patients were employed in a paid occupation. Therefore, an additional subgroup analysis was performed comparing patients with a paid job with those without one, in order to analyze the total costs of absence from paid work.

Resource Utilization and Unit Costs
Data regarding the use of heath-care resources was assessed using 4 questionnaires, which patients were asked to fill out at 6 weeks and at 3, 6, and 12 months[15].

Direct medical costs, direct non-medical costs, and indirect costs due to the distal radial fracture were assessed. Direct medical costs included those for treatment, follow-up visits at the outpatient clinic, treatment of possible complications, other visits to health-care professionals such as general practitioners, and professional home care. The direct medical costs were estimated by means of the Dutch National Health Care Institute's costing manual and the hospital cost ledgers from 1 academic and 1 non-academic hospital, in order to have a representative cost index in the Netherlands[16]. The costs were indexed to the year 2017 using the consumer price index for the Netherlands (see Appendix 1). Direct non-medical costs included those for travel to and from the hospital, over the counter medication, care provided by family or paid help, and assistive devices.

Indirect costs referred to the value of production lost or to lowered productivity due to injury-related absence. Lowered productivity while at work was determined using the Short Form-Health and Labor Questionnaire (SF-HLQ) at 6 and 12 months[17,18]. This questionnaire was designed to collect quantitative data on the relationship between illness/treatment and work performance. The data permit the estimation of production loss of paid and unpaid labor[17]. The human-capital approach was used to estimate the duration of loss of productivity[19]. This approach counts the expected loss of production of an individual during 1 year. The net income declared by each patient in the cost diaries was used to calculate the loss of productivity. When data for wages were missing, the age-adjusted hourly wage according to the SF-HLQ was used and extrapolated to 2017 using the consumer price index[16]. Return-to-work decisions were not protocolized as these are made by an independent health and safety doctor.

Statistical Analysis

As most volumes of resource utilization follow a skewed distribution, 95% confidence intervals (CIs) around the differences in mean costs were calculated using bias-corrected and accelerated bootstrapping (bcaCI). Bootstrapping generates multiple replications of the statistic of interest by sampling (1,000 samples) with replacement of the original data[20]. A cost-effectiveness plane was constructed to illustrate the difference in costs and effects between the 2 treatments[21].

A cost-effectiveness acceptability curve was graphed to determine the probability of cost-effectiveness at different willingness-to-pay ceiling ratios.

Robustness of the results to uncertainty in the assumptions and estimates was evaluated in sensitivity analyses, by varying unit costs for pertinent volumes of health-care utilization.

All analyses were performed for the randomized groups according to the intention-to-treat principle. Analyses were done using SPSS version-22.0 software (IBM) and R version 2.13.1 (R Foundation for Statistical Computing).

Table 1: Baseline Characteristics and Outcomes of VIPAR Trial*

	Nonoperative (N = 46)	**Operative (N = 44)**
Age (median [IQR]) *(yr)*	59 [53-67]	62 [49-66]
Sex *(no.)*		
Female	40	36
Male	6	8
PRWE score at 12 months (median [IQR])	12 [3-28]	5 [0-12]

*IQR = interquartile range.

Funding
There was no outside funding for this study.

Ethics Committee Approval
Institutional board approval was obtained by the ethics committee and institutional review board of our hospital, and the board of directors of all participating centers.

RESULTS

Between June 2015 and February 2018, 90 patients were randomized between operative (n = 44) and nonoperative (n = 46) treatment. Baseline characteristics and PRWE scores at 12 months are presented in Table I.

The mean number of QALYs gained at 12 months was significantly higher in the operative group (0.748; 95% bcaCI = 0.678 to 0.813) than in the nonoperative group (0.603; 95% bcaCI = 0.5470 to 0.813), with a mean difference of 0.15 (95% bcaCI = 0.056 to 0.243). The difference in QALYs gained for the operatively treated group, compared with the nonoperative group, was equivalent to an extra 55 days of perfect health per year.

Resource utilization per treatment group is shown in Table II. The mean total direct medical cost during the 12 months of follow-up was higher in the operative group than in the nonoperative group ($180,365 versus $123,185 [$4,099 versus $2,678 per patient]). However, the mean direct non-medical cost ($88 versus $196 per patient) and indirect cost ($1,278 versus $2,300 per patient) were lower in the operative group than the nonoperative group. Patients treated operatively missed a mean of 53 hours of work whereas patients treated nonoperatively missed a mean of 79 hours of work. This resulted in a mean total cost per patient during the 12-month follow-up period of $5,465 (95% bcaCI = $4,879 to $6,198) for operatively treated patients and $5,174 (95% bcaCI = $4,173 to $6,635) for nonoperatively treated patients, resulting in $291 (95% bcaCI = –$1,286 to $1,572) lower costs for nonoperative treatment.

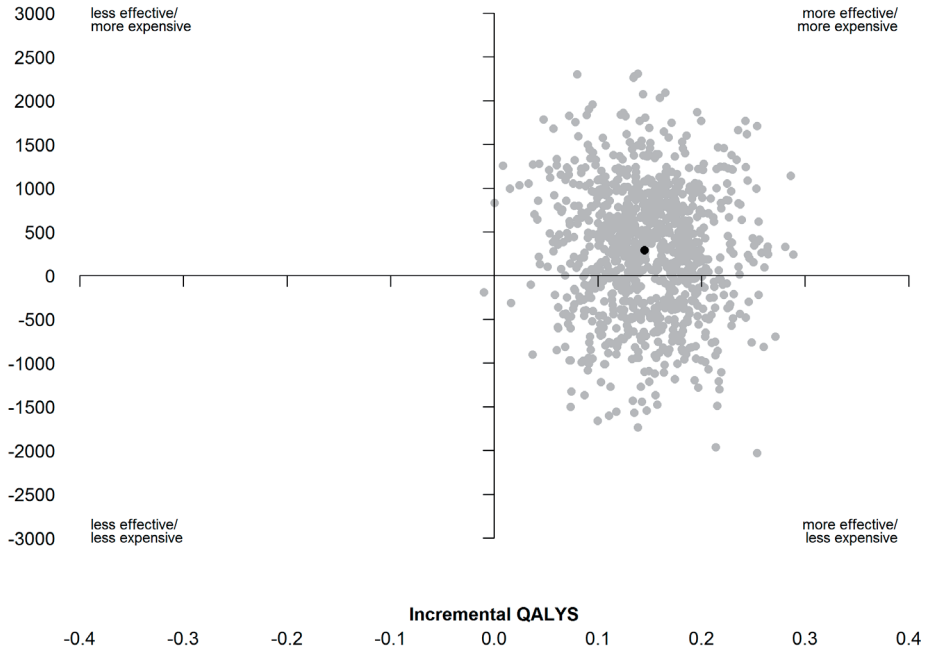


Figure 1: Cost-effectiveness between operative and non-operative treatment versus difference in QALYS over 12 months

Cost-Effectiveness Analysis

The difference in costs of operative and nonoperative treatment versus the difference in QALYs during 12 months is depicted in Figure 1. It costs $291 more to treat a patient operatively instead of nonoperatively, but an operatively treated patient gains 0.15 QALY more compared with a nonoperatively treated patient. The ICER was $2,008 (95% bcaCI = –$9,608 to $18,222) per QALY for the operative group compared with the nonoperative group, which means that operative treatment is more effective but also more expensive. The cost-effectiveness acceptability curve depicted in Figure 2 shows that, at a willingness-to-pay threshold of $50,000 per QALY, the probability of operative treatment being cost-effective was 99.4%.

The cost of operative and nonoperative treatment versus the PRWE score during 12 months showed that operative treatment is more effective but also more expensive. The ICER was $26.57 (95% bcaCI = –$112.6 to $312.64), indicating that operative treatment costs $26.57 more per 1 point of PRWE score decrease.

Subgroup Analysis

In the analysis of only patients with a paid job, the total costs were $663 lower in the operative group (Table III). The mean difference in total costs for patients without a paid job was

Table 2: Resource Utilization and Costs (in US Dollars) for Both Treatments

		Nonoperative		Operative	
	Price ($)	**Volume**	**Cost for Group**	**Volume**	**Cost for Group**
Direct medical costs					
Initial treatment					
ORIF	1,964	0		44	86,415
Plaster cast	244	46	11,247	0	
Additional treatment					
ORIF	1,964	11	21,604	0	
Corrective osteotomy	1,904	2	3,809	0	
Wrist arthroscopy	1,584	2	3,167	0	
Implant removal	185	2	371	12	2,225
Tendon release	576	0		1	576
Carpal tunnel release	402	0		6	2,412
Diagnostic imaging					
Radiograph: wrist	62	343	21,226	325	20,052
Ultrasound with injection: wrist	612	1	612	0	
CT scan: wrist	164	27	4,420	21	3,438
MRI scan: wrist	261	6	1,566	1	261
Electromyography	136	0		3	407
Bone densitometry (DXA)	42	11	460	10	418
Outpatient and inpatient care					
Emergency department visits	297	1	297	1	297
Outpatient appointments		331	22,578	291	22,317
Surgical ward admission		16	7,115	57	24,478
Primary and personal care					
Primary care appointments			14,134		16,545
Home and personal care			10,643		524
Total direct medical costs			**123,185**		**180,365**
Direct non-medical costs					
Travel expenses			2,539		2,447
Out-of-pocket expenses			6,455		1,425
Total direct non-medical costs			**8,994**		**3,872**
Indirect costs					
Loss of productivity			33,873		36,399
Lowered productivity			71,953		19,829
Total indirect costs			**105,826**		**56,228**
Total costs†			**238,004**		**240,467**

*ORIF = open reduction and internal fixation, CT = computed tomography, MRI = magnetic resonance imaging, EMG = electromyography, and DXA = dual x-ray absorptiometry. †The mean total cost per patient (and 95% bcaCI) was $5,174 ($4,173 to $6,635) for the nonoperative group and $5,465 ($4,879 to $6,198) for the operative group, with a difference between groups of $291 ($–1,286 to $1,572).

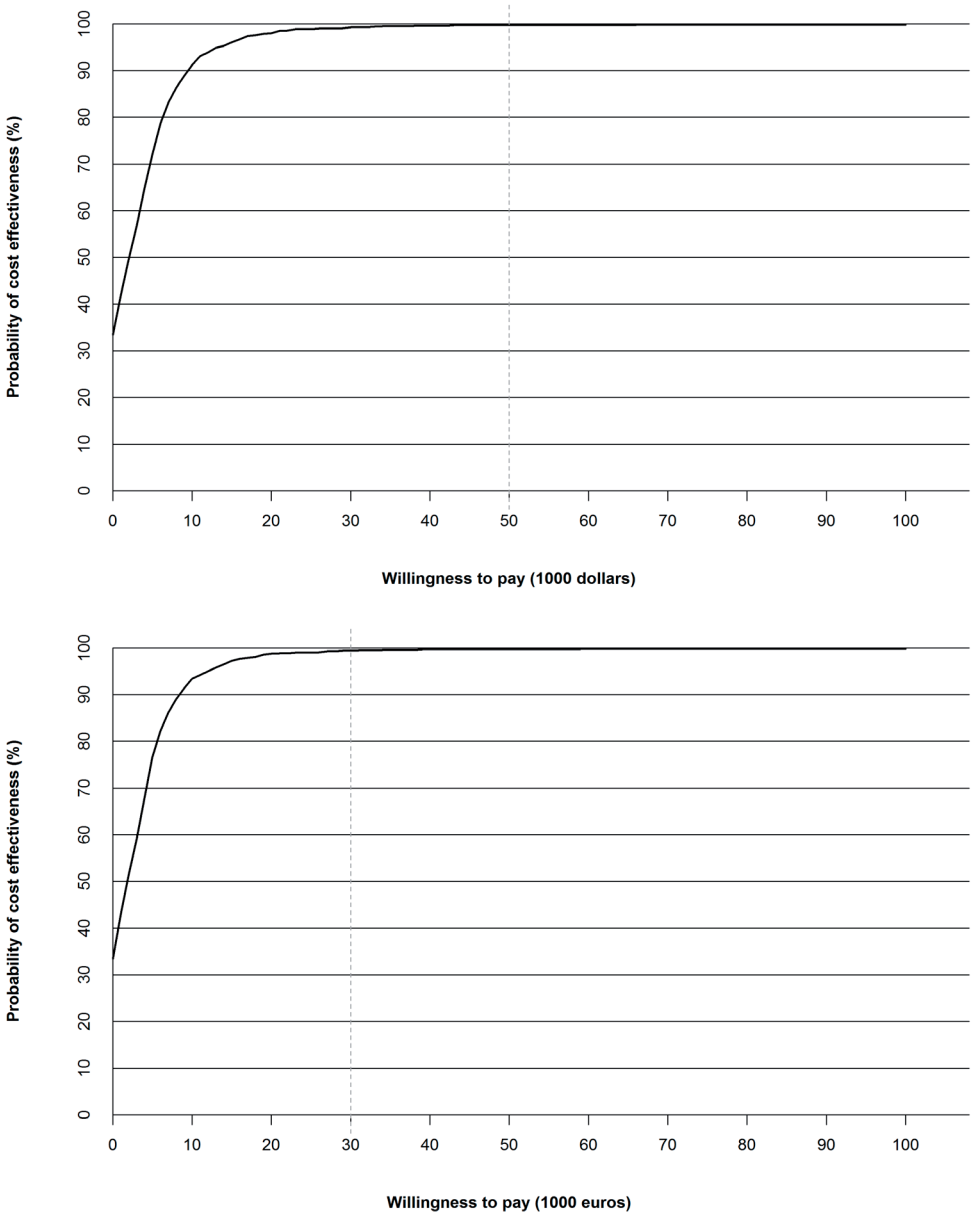


Figure 2: Probability of cost-effectiveness per QALY gained at 12 months versus several willingness to pay threshold

Table 3: Subgroup Analysis: No Paid Versus Paid Work*

	No Paid Work (N = 40)			Paid Work (N = 50)		
	Nonoperative	**Operative**	**Difference**	**Nonoperative**	**Operative**	**Difference**
Costs *($)*	2,492 (1,876 to 3,880)	4,136 (3,893 to 4,447)	1,643 (280 to 2,328)	7,238 (5,862 to 9,047)	6,573 (5,678 to 7,722)	−663 (−2,566 to 1,090)
QALY	0.643 (0.546 to 0.750)	0.731 (0.625 to 0.836)	0.088 (−0.058 to 0.2300)	0.573 (0.492 to 0.671)	0.763 (0.675 to 0.848)	0.190 (0.071 to 0.322)
ICER *($)*			18,592 (−26,088 to 983,163)			−3,500 (−21,301 to 7,094)
PRWE	18.70 (10.20 to 31.77)	12.50 (6.74 to 21.94)	-6.20 (-19.27 to 4.74).	23.08 (14.81 to 32.83)	8.31 (4.74 to 14.67)	−14.76 (−5.32 to 24.61)
ICER *($)*			266 (−433 to 17,387)			−45 (−1,478 to 232)

*The values are given as the mean (95% bcaCI).

$1,643 lower for the nonoperative treatment. The QALYs at 12 months were higher for the operative group than the nonoperative group in the analyses of both patients with a paid job (mean difference = 0.19; 95% bcaCI = 0.071 to 0.322) and patients without a paid job (mean difference = 0.088; 95% bcaCI = −0.058 to 0.23). The ICER was $−3,500 per QALY in the operative group compared with the nonoperative group in the analysis of patients with a paid job. This means that gaining 1 QALY for patients with a paid job costs $3,500 less with operative treatment than with nonoperative treatment. For patients without a paid job, the ICER was $18,592 per QALY in the nonoperative group compared with the operative group. The mean PRWE score was lower for the operative group in the analyses of both patients with a paid job and those without a paid job. The ICER per 1-point decrease in PRWE score was −$44.96 for operatively treated patients with a paid job and $266 for nonoperatively treated patients without a paid job.

DISCUSSION

Operative treatment in patients between 18 and 75 years of age with an acceptably reduced intra-articular distal radial fracture results in a higher number of QALYs gained and better functional outcomes, measured with the PRWE questionnaire, compared with nonoperative treatment. However, operative treatment has a slightly higher total mean cost per patient, resulting in an ICER of $2,008.

In the past years, a significant increase in hospital admissions due to wrist fractures has been noted as a result of a shift in treatment from nonoperative to operative[22]. Volar locking plates improve the stability of the fracture, allowing for early postoperative mobilization[23]. Patients treated operatively, compared with those treated nonoperatively, have a quicker return of function during the first 3 to 6 months and better functional outcomes after 1 year[5,6]. Mulders et al. found that volar plate fixation for adults with an acceptably reduced extra-articular distal radial fractures is cost-effective, with a difference in cost per QALY of −$1,838 in favor of volar plate fixation[24]. Furthermore, in agreement with the current study, they found that, for patients who had paid employment, volar plate fixation was even more cost-effective, with an ICER of −$7,459. Other studies have shown that medical costs due to operative treatment are higher than those due to nonoperative treatment[9,25]. Shauver et al. analyzed the Medicare data set for annual distal radial fracture-attributable spending in 2007[9]. For operative treatment, 61% of the costs were due to procedure-related costs; however, procedure-related costs made up only 22% of the costs for nonoperative treatment. In this study, we found that direct medical costs were $57,180 higher in the operative group compared with the nonoperative group ($180,357 versus 123,185. In the operative group, 48% of all direct medical costs was caused by the surgical procedure.

Operative treatment was $291 more expensive per patient than nonoperative treatment. However, the patients treated operatively in this study had a high prevalence of plate removal (27%). This contributes to a large portion of costs, due to additional operative treatment and hospital admissions. More remarkable is the $28,951 in costs due to additional surgical procedures in the nonoperative group, which accounts for 24% of all direct costs in this group.

Distal radial fractures have a large economic burden on society, with costs due to loss of productivity of €1.44 billion ($1.9 billion) per year in the Netherlands[2]. In this study, we found $49,597 higher indirect costs due to loss or lowered productivity in the nonoperative group compared with the operative group. The indirect costs in the operative group were approximately half (53%) of the indirect costs in the nonoperative group. The source of this difference in indirect costs lies in the lowered productivity, suggesting that patients treated operatively are able to fully resume their activities sooner than those treated nonoperatively. We found that indirect costs were almost 45% of the total costs in the nonoperative group compared with 23% in the operative group. Swart et al. found similar results in a prospective observational cohort of 82 patients, in which indirect costs made up 36% of total costs in the nonoperatively treated group compared with 28% in the operatively treated group[25]. In our subgroup analysis of patients with a paid job, the ICER indicated that it cost $3,500 less (and thus was cost-saving) for operatively treated patients to gain 1 QALY compared with those treated nonoperatively. This means that gaining 1 year of perfect health for patients with a paid job costs $3,500 less with operative treatment than with nonoperative treatment. Earlier return to work is often cited as a potential benefit of surgical intervention. This study supports the advantages of operative treatment for patients with a distal radial fracture especially when they have a paid job.

The costs of operative treatment in the Netherlands are 8 times higher than those of nonoperative treatment. The difference between operative and nonoperative treatment is smaller in the U.S., $350 versus $800 according to Medicare data[26]. The costs charged by U.S. physicians, however, vary substantially, from $280 to $450 for nonoperative treatment and from $660 to $1,030 for operative treatment. These costs do not include facility/anesthesia fees or implant costs. Furthermore, in the U.S. Medicare system, a patient with a distal radial fracture initially treated nonoperatively and subsequently requiring surgical treatment may be charged for both nonoperative and operative treatment. If Medicare data were to be used, the difference between treatments would lead to a higher ICER and operative treatment would be possibly more cost-effective.

This study has several limitations. Unit costs may differ between hospitals and countries. In this study, the unit costs of 1 academic and 1 non-academic teaching hospital were used to

generalize the costs. Furthermore, this study only performed a cost-analysis over a period of 12 months. The long-term effects of distal radial fractures on outcome and on the potential costs were therefore not addressed. However, most guidelines advise a follow-up of 12 months for patients with a distal radial fracture, which suggests that possible future treatments would not contribute a significant amount to the total costs. The choice to perform additional surgery such as corrective osteotomy or implant removal was at the discretion of the surgeon. The choice to perform these procedures may also have taken place after the 12-month follow-up.

Operatively treated patients with an acceptably reduced intra-articular distal radial fracture have a better quality of life and better functional outcomes at 12 months than patients treated nonoperatively, especially when they have a paid job. Although operative treatment is marginally more expensive than nonoperative treatment, the ICER of operative treatment is lower than the willingness-to-pay threshold and it can therefore be considered cost-effective. We recommend that current treatment guidelines take into account the cost-effective aspect of volar plate fixation for acceptably reduced intra-articular distal radial fractures.

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Chapter 4

OPERATIVE TREATMENT OF INTRA-ARTICULAR DISTAL RADIUS FRACTURES WITH VERSUS WITHOUT ARTHROSCOPY: STUDY PROTOCOL FOR A RANDOMISED CONTROLLED TRIAL

M.A.M. Mulders, C.A. Selles, J.W. Colaris, R.W. Peters, M. van Heijl, B.I. Cleffken, N.W.L. Schep

Trials. 2018 Feb

ABSTRACT

Background

In the past several years, an increase in open reduction and internal fixation (ORIF) for intra-articular distal radius fractures has been observed. This technique leads to a quicker recovery of function compared to non-operative treatment. However, some patients continue to have a painful and stiff wrist postoperatively. Arthroscopically assisted removal of intra-articular fracture haematoma and debris may improve the functional outcomes following operative treatment of intra-articular distal radius fractures. The purpose of this randomised controlled trial is to determine the difference in functional outcome, assessed with the Patient-Rated Wrist Evaluation (PRWE) score, after ORIF with and without an additional wrist arthroscopy in adult patients with displaced complete articular distal radius fractures.

Methods

In this multicentre trial, adult patients with a displaced complete articular distal radius fracture are randomised between ORIF with an additional wrist arthroscopy to remove fracture hematoma and debris (intervention group) and conventional fluoroscopic-assisted ORIF (control group). The primary outcome is functional outcome assessed with the PRWE score after three months. Secondary outcomes are wrist function assessed with the Disability of the Arm, Shoulder and Hand (DASH) score, postoperative pain, and range of motion, grip strength, complications and cost-effectiveness. Additionally, in the intervention group, the quality of reduction, associated ligamentous injuries and cartilage damage will be assessed. A total of 50 patients will be included in this study.

Discussion

Although ORIF of intra-articular distal radius fractures leads to a quicker resume of function compared to non-operative treatment, some patients continue to have a painful and stiff wrist postoperatively. We hypothesize that, due to the removal of fracture hematoma and debris by an additional arthroscopy, functional outcomes will be better compared to the non-arthroscopically treated group.

BACKGROUND

In the last decade, an increase in open reduction and internal fixation (ORIF) for distal radius fractures has been observed[1-3]. In particular, intra-articular distal radius fractures, which comprise almost 50% of all fractures, are increasingly being treated operatively[4]. This technique leads to a quicker resume of function in the first three to six months compared to non-operative treatment[5,6]. However, some patients continue to have a painful and stiff wrist postoperatively. Arthroscopically assisted removal of intra-articular fracture hematoma and debris may improve the functional outcomes following operative treatment of intra-articular distal radius fractures[7,8]. Moreover, during arthroscopy the quality of the reduction and the presence of associated ligamentous injuries can be assessed[7,9-14].

Lindau et al. already examined the frequency of associated chondral and ligament lesions with arthroscopy in 50 patients in 1997[14]. They described 35 subchondral hematomas in 16 cases, and an incidence of chondral lesions of approximately 33%. These lesions may lead to the development of osteoarthritis in the long term[15]. Additionally, 98% of the patients had a ligamentous injury. However, they found no major instability in these patients and it is uncertain if these injuries will be clinically relevant in the long term[16].

Although, no advantage of arthroscopically guided reduction over conventional fluoroscopic-assisted reduction in regard to functional and radiographic outcomes was found, to our knowledge no studies have been carried out to further examine the use of arthroscopy after ORIF to remove fracture hematoma and debris on functional outcomes[17]. We hypothesise that, due to the removal of fracture hematoma and debris, functional outcomes will be better compared to the no arthroscopically treated group. Therefore, the purpose of this randomised controlled trial (RCT) is to determine the difference in functional outcome, assessed with the Patient-Rated Wrist Evaluation (PRWE) score, after ORIF with and without an additional wrist arthroscopy in adult patients with displaced complete articular distal radius fractures. Furthermore, we aim to determine the difference in functional outcomes with the Disability of the Arm, Shoulder and Hand (DASH) score, postoperative pain, range of motion (ROM), grip strength, complications, and cost-effectiveness. Additionally, the quality of reduction, associated ligamentous injuries and cartilage damage will be assessed by arthroscopy

METHODS/DESIGN

Study objectives

The primary objective is to determine the difference in functional outcome of ORIF with or without an additional arthroscopy to remove the fracture hematoma and debris in adult patients with displaced complete articular distal radius fractures (AO/OTA type C).

The secondary objectives are to assess if additional wrist arthroscopy leads to less post-operative pain, a better ROM and grip strength, and fewer complications. Additionally, cost-effectiveness for both treatments is determined. Moreover, for patients undergoing additional wrist arthroscopy, the quality of reduction, associated ligamentous injuries and cartilage damage will be assessed.

Study design

The RADAR (Operative Treatment of Intra-Articular Distal Radius Fractures With versus Without Arthroscopy) trial is designed as a multicentre RCT, with a 1:1 allocation ratio and a superiority framework. Patients are randomised between ORIF with an additional wrist arthroscopy to remove fracture hematoma and debris (intervention group) and conventional fluoroscopic-assisted ORIF (control group). A total of three centres in the Netherlands are involved in recruiting patients (Additional file 1).
The design of the trial is compliant with the Standard Protocol Items: Recommendations for Interventional Trials[18] (Additional file 2).

Study population

The study population will consist of all adult patients who are diagnosed with a complete articular distal radius fracture (AO/OTA type C) where the treating surgeon deems ORIF necessary. Independent radiologists will assess and classify complete articular distal radius fracture based on radiography according to the AO/OTA classification of fractures. All patients undergo a computed tomography (CT) scan of the wrist. This is standard care in decision-making and planning for surgery[19].

Inclusion criteria

- Patients aged 18 years and older
- Displaced complete articular distal radius fracture (AO/OTA type C) as classified on lateral, posterior-anterior, and lateral carporadial radiographs by a radiologist or trauma surgeon, requiring ORIF. An additional dorsal approach is allowed only when the dorsal capsule is not opened and thus leaving the radiocarpal joint untreated.
- Inacceptable alignment on radiograph defined, according to the Dutch National Guidelines[19], as:

- radial inclination < 15°;
- radial length (distance between lateral most radial tip and ulnar surface) ≤ 5 mm;
- volar angulation ≥ 20° or dorsal angulation ≥ 15°;
- articular step-off or gap ≥ 2 mm. A gap is defined as loss of articular congruity of the distal radius parallel to the articular surface and a step-off perpendicular to the articular surface[20].

Exclusion criteria

- Dorsal plate fixation in case the radiocarpal joint needs to be opened
- Multiple trauma patients (Injury Severity Score (ISS) ≥ 16)
- Open distal radius fractures
- Other fractures in the ipsilateral extremity (except for a fracture of the ulnar styloid process)
- Fracture of the contralateral wrist (distal radius, distal ulna or one of the carpal bones)
- Patients with impaired wrist function before injury due to arthrosis, rheumatoid arthritis, neurological disorders or malunion of the upper limb or patients suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget's disease, renal osteodystrophy, osteomalacia) or connective tissue disease or (joint) hyper-flexibility disorders such as Marfan's or Ehler Danlos
- Patients with insufficient comprehension of the Dutch language to understand the study information and informed consent process, the rehabilitation program and other treatment information as judged by the attending physician

Interventions

All patients will be treated by a certified (orthopaedic) trauma surgeon with experience in ORIF of distal radius fractures and wrist arthroscopy. In both groups, ORIF of the distal radius fracture will be similar. The intervention group will be treated with wrist arthroscopy following ORIF. A delay of at least five days before performing arthroscopy is mandatory to enable visualisation due to the organisation of the hematoma. The operation has to be performed within three weeks after the initial trauma.

Antibiotic prophylaxis (Cefazolin, 1000 mg i.v.) is given preoperatively, according to the current standard. The volar approach according to Henry will be used[21]. This entails an incision between the radial artery and the tendon of the flexor carpi radialis. The pronator quadratus muscle from will be detached from its distal and lateral side and lifted for optimal exposure to the fracture site. After the fracture site is revealed, the fracture will be debrided, reduced and fixated with an appropriate volar locking plate. The type and brand of the plate are at the discretion of the treating surgeon. When a dorsal approach is deemed necessary the

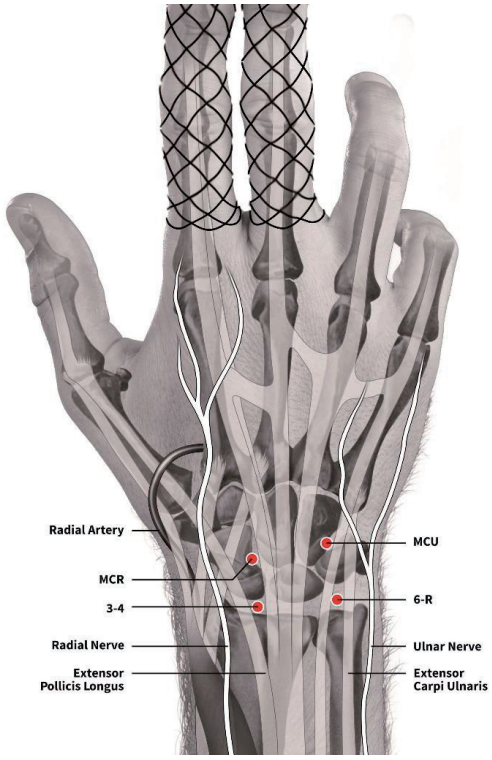

Figure 1: View of arthroscopy portals

distal radius will be approached through the third dorsal extensor tendon compartment, without opening the dorsal capsule. Fluoroscopic images are obtained to evaluate the quality of articular reduction. Wrist arthroscopy will be performed when the treating surgeon is satisfied with the result of the ORIF.

During wrist arthroscopy, the forearm will be positioned upright and in neutral position, the elbow flexed by 90° and axial traction of 4-6 kg will be performed. Four portals are created dorsally by superficial stab incisions and blunt preparation through the joint capsule; one midcarpal radial (MCR) and ulnar (MCU) portal and one radiocarpal 3-4 and 6-R portal (Fig. 1). Portals may be changed to improve visualisation. A shaver or mini grasper is used for removal of fracture haematoma and osteocartilaginous debris. Cartilage damage will be graded using the Outerbridge classification system[22] (Additional file 3). With the 1-mm hook probe, assessment of the quality of reduction and ligamentous injuries will be performed. Step-off and gaps will be measured with a calibrated 1-mm probe at the point of maximum displacement and recorded. The trampoline and hook test are performed to demonstrate a triangular fibrocartilage complex (TFCC) tear. TFCC tears will be classified according to Palmer[23] (Additional file 4). All scapholunate ligament injuries will be noted and

graded according to the Geissler classification[11] (Additional file 5). The same classification will be applied for lunotriquetral injuries. Wound closure will be performed using standard techniques. All patients will receive a pressure bandage for 24–48 h.

For both the intervention and the control group, patients are allowed to start exercising immediately after the operation. Exercises include pronation and supination, flexion and extension, and ulnar and radial deviation of the wrist. Patients are instructed to use the affected extremity as far as pain allows. However, only non-weight-bearing practice is allowed for the first six weeks. Rehabilitation with the assistance of a physiotherapist is recommended at the discretion of the patient and treating surgeon.

All interventions are performed according to predefined Standard Operating Procedures (SOPs). Individuals can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a participant from the study for urgent medical reasons.

OUTCOMES

Primary outcome

The primary outcome of this study is wrist pain and disability expressed as change on the PRWE score after three months. In addition, the PRWE questionnaire will be completed after three and six weeks, and six and 12 months of follow-up (Fig. 2). The PRWE is a validated tool for assessing functional outcome in patients with distal radius fractures[24,25]. The PRWE is a 15-item questionnaire which measures wrist pain and disability in activities of daily living on a scale of 0–10. Although the PRWE consists of three subscales (pain, function and cosmetics), the PRWE results in a single score[26]. The highest score, indicating severe impairment, is 100 and the best score, indicating no impairment, is zero. The Dutch version has been structurally validated[26]. The PRWE score will be expressed as a final value at each of the follow-up moments.

Secondary outcomes

Wrist function, disability and pain as measured with the DASH score, at three and six weeks and three, six and 12 months of follow-up (Fig. 2). The DASH questionnaire is a 30-item, self-report questionnaire which measures physical function and symptoms in patients with any or several musculoskeletal disorders of the upper limb, including the distal radius[27-29]. The DASH questionnaire tests the degree of difficulty in performing a variety of physical activities because of arm, shoulder or hand problems (six items), the severity of pain, tingling (two items), as well as the effect of the upper limb problem on social activities, work

			STUDY PERIOD							
	Enrolment	Allocation		Post-allocation						
TIMEPOINT	$-t_1$	0	Baseline	*Day 1*	*Week 1*	*Week 3*	*Week 6*	*Month 3*	*Month 6*	*Month 12*
ENROLMENT:										
Eligibility screen	X									
Informed consent	X									
Allocation		X								
INTERVENTIONS:										
ORIF + wrist arthroscopy			X							
ORIF			X							
ASSESSMENTS:										
Baseline variables		X								
PRWE						X	X	X	X	X
DASH						X	X	X	X	X
VAS				X	X	X	X	X		
Range of motion						X	X	X		
Grip strength						X	X	X		

Figure 2: Follow-up visits

and sleep (three items). The highest score is 100, indicating severe disability and pain; the lowest score is zero, indicating no disability and pain. The Dutch version of the DASH questionnaire has been validated and has shown to be a reliable and valid instrument[30]. The DASH score will be expressed as a final value at each of the follow-up moments.

Postoperative pain as indicated on a Visual Analogue Scale (VAS), where zero means no pain and ten the worst pain possible. Patients will be asked to give an estimation of their pain and the type and quantity of pain medication taken postoperatively at one day, one week, three weeks, six weeks and three months (Fig. 2). The VAS pain score will be expressed as the final value at each of the follow-up moments.

Table 1: Costs included in the economic evaluation

Direct health care costs
Open reduction and internal fixation
Additional costs wrist arthroscopy
Follow-up visits medical specialist
Additional visits to health care professional
Prescribed medication
Professional home care
Treatment and follow-up of complications
Physical therapy
Direct non-health care costs
Travel expenses to and from the hospital
Over the counter medication
Care provided by family or paid help
Assistive devices
Indirect costs
Absenteeism from paid labour (per day)
Absenteeism from unpaid labour

ROM of the wrist measured on both the injured as well as the uninjured wrist with a hand-held goniometer. Measurements of ROM include ulnar and radial deviation, pronation and supination, and flexion and extension of the wrist. ROM is measured at three weeks, six weeks and three months, and will be expressed as both a final value and as a percentage of the uninjured side (Fig. 2).

Prehensile grip strength as a percentage of the uninjured wrist. Grip strength will be measured on both sides with a Baseline dynamometer (White Plains, NY, USA) with the arm of the patient to the side and the elbow at 90° flexion. Grip strength will be calculated as the mean of three measurements and expressed as a final value and as a percentage of the uninjured side. Grip strength is measured at three weeks, six weeks and three months (Fig. 2).

Complications, such as superficial or deep infection divided by the criteria of the US Centers for Disease Control and Prevention, tendinitis or rupture of one of the flexor or extensor tendons, carpal tunnel syndrome, compartment syndrome, complex regional pain syndrome (CRPS) type 1 according to the Veldman and the Budapest criteria, and hardware-related complications will be recorded[31-34].

Cost-effectiveness and cost-utility of ORIF with and without an arthroscopic-assisted procedure from a societal perspective, measured with an economic evaluation questionnaire at three weeks, six weeks and three months follow-up. The economic evaluation questionnaire is based on the EQ-5D and the Standard Form Health and Labour questionnaire. The EQ-5D will be used to measure quality-adjusted life years (QALY). Since this analysis is from a societal perspective, direct healthcare costs, direct non-healthcare costs and indirect costs due

to the operative treated distal radius fracture will be considered (Table 1). A more detailed description of the economic analysis can be found in the protocol of the VIPAR trial[35]. The cost-effectiveness is determined at three weeks, six weeks and three months (Fig. 2).

In the intervention group the quality of reduction, associated ligamentous injuries and cartilage damage will be assessed. Ligamentous injuries are divided in TFCC injuries, classified according to the Palmer classification, and scapholunate ligament and lunotriquetral injuries, graded according to the Geissler classification[11,23].

Randomisation

All consecutive adult patients who are diagnosed with a displaced complete articular distal radius fracture (AO/OTA type C) and scheduled for ORIF will be invited to participate in this study if they meet the inclusion and exclusion criteria. Informed consent will be obtained at the outpatient clinic before the operation. Randomisation will be performed by means of a computerised randomisation procedure, using Castor®, which is an online secure randomisation service. Allocation concealment will be ensured until patients have been randomised, which takes place after baseline characteristics have been obtained. The sequence of allocation is concealed until trial completion. To avoid imbalances between treatment groups, patients will be randomised in two strata according to age: 18–65 years and ≥ 65 years using a mixed block randomisation with blocks of four, six and eight patients. The order of the block sizes is unknown to the researchers, who therefore remain blinded to the allocation of the next individual throughout the whole study.

Blinding

Since the treatment allocation involves a surgical procedure and therefore the surgical incision and portal entrees will be visible for both physician and patient, randomisation status will not be blinded.

Sample size calculation

The sample size calculation is based on our primary outcome, the PRWE score. We choose the PRWE score at three months as our primary outcome, since we expect patients to profit most from additional wrist arthroscopy within three months after the initial trauma. After this point, the haematoma has dissolved without intervention. The mean PRWE score after a distal radius fracture after three months of follow-up in adult patients is 28 with a standard deviation of 21.3[36]. This PRWE score was measured in a population in which 38% of patients suffered from a complete articular distal radius fracture (AO/OTA type C fracture). Although this cohort of patients is not fully comparable to our cohort of patients, it is the data which most closely resembles our study population. We chose an effect size of 18 points on the PRWE score at three months, since we expect the greatest difference in PRWE score between

both groups at three months of follow-up. The minimally clinically important difference is set at 11.5, therefore every difference > 11.5 is clinically meaningful[37]. Therefore, at $\alpha = 0.05\%$ and a power of 80%, we would require 46 patients in total and 23 per treatment arm. For safety measures and with an expected loss to follow-up of 5%, 25 patients in each arm will be included. In a separate study conducted in the Netherlands by our research group, a prevalence of AO/OTA type C distal radius fractures of approximately 25% was found[4]. Therefore, we estimate to include and follow-up all 50 patients in a maximum of 1.5 years.

Data analysis

All patients will be analysed according to the intention-to-treat protocol. General descriptive statistics on patient characteristic at baseline will be performed including factors such as gender and age, and presented as percentages (categorical variables) or means and standard deviation (SD) (continuous variables), whichever is applicable. Normality will be determined by visually inspecting the plotted data distribution in a histogram. Differences between the two groups in the primary outcome, the PRWE score, will be analysed using an analysis of covariance (ANCOVA), corrected for age. The same applies for the DASH score at the different follow-up moments. The secondary outcomes—pain (VAS), ROM and grip strength—will be analysed using a linear mixed model. The best covariance structure for each linear mixed model is determined using the smallest Akaike information criterion (AIC). The VAS pain score will be corrected for painkiller use. Differences in complication rates between the two treatment groups will be analysed using the Chi-square test or Fisher's exact test (in case the expected incidence is less than five). Subgroup analyses will be performed on gender and age. Multiple imputation will be used in case of > 10% missing data.

Data management and monitoring

All follow-up moments are part of the regular outpatient clinic appointments. Data of patients lost to follow-up will be analysed until the last follow-up appointment. Data will be stored in two separate files. One dataset will contain coded patient information, based on an unambiguous identification code, and a second set of medical history linked to these codes. The coordinating investigator safeguards the key to the code. The same applies for all screened patients. Data are entered in Castor®. All entered data and changes are saved; a list is maintained of all individuals who are authorised to make data changes. A reason is always indicated when changes are made to the data. All data are adequately backed up and can be retrieved form the archive. All researchers involved in the study will have access to all data collected. Data will be stored and kept for 15 years according standard guidelines. The Institutional Review Board waived the need for a data monitoring committee, since both treatment modalities are part of standard care. An audit is performed half way during the trial.

Protocol amendments

For any modifications of the study protocol (29 December 2016; version 6) that may impact the study, approval will be obtained from the Institutional Review Board before implementation. Protocol modifications are communicated to relevant parties by letter.

Adverse events

All adverse events will be described in the patient file during consult at any of the follow-up visits or any other moment if indicated or requested by the patient. This includes wound infection, complex regional pain syndrome, compartment syndrome and any neurovascular or tendon damage. Complex regional pain syndrome will be classified according to the 'Budapest Criteria' created and validated by the Budapest consensus group[33,34].

All serious adverse events (SAE) are reported to the accredited medical ethics board that approved the protocol, within 15 days after the sponsor has first knowledge of the serious adverse reactions. Arthroscopic-related complications which require a readmission or reoperation are listed in a periodic overview.

SAEs that result in death or are life-threatening should be reported expeditiously. The expedited reporting will occur not later than seven days after the responsible investigator has first knowledge of the adverse reaction. This is for a preliminary report with another eight days for completion of the report.

All adverse events will be followed until they have abated or until a stable situation has been reached. Depending on the event, follow-up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.

Ethics

This study will be conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO) and 'Good Clinical Practice' guidelines. Insurance was set up for compensation for the study participants who suffer from potential harm.

Dissemination policy

The results of this study will be submitted for publication in a peer-reviewed journal. The criteria for authorship will follow the guidelines established by the International Committee of Medical Journal Editors.

DISCUSSION

Randomisation status will not be blinded, since the treatment allocation involves a surgical procedure and therefore the surgical incision and the portal entrees are visible for both physician and patient.

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Chapter 5

ARTHROSCOPIC DEBRIDEMENT DOES NOT ENHANCE SURGICAL TREATMENT OF INTRA-ARTICULAR DISTAL RADIUS FRACTURES: A RANDOMIZED CONTROLLED TRIAL

C. A. Selles, M.A.M. Mulders, J.W. Colaris,
M. van Heijl, B.I. Cleffken, N.W.L. Schep

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ABSTRACT

The aim of this study was to determine the difference in functional outcomes after open reduction and internal fixation (ORIF) with and without arthroscopic debridement in adults with displaced intra-articular distal radius fractures. In this multicenter trial, 50 patients were randomized between ORIF with or without arthroscopic debridement. The primary outcome measure was the Patient-Rated Wrist Evaluation (PRWE) score. Secondary outcome measures were Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, pain scores, range of wrist motion, grip strength, and complications. Median PRWE was worse for the intervention group at 3 months and was equal for both groups at 12 months. The secondary outcome measures did not show consistent patterns of differences at different time-points of follow-up. We conclude that patients treated with additional arthroscopy to remove intra-articular hematoma and debris did not have better outcomes than those treated with ORIF alone. We therefore do not recommend arthroscopy for removal of hematoma and debris when surgically fixing distal radius fractures.

INTRODUCTION

Arthroscopy of the wrist has proven instrumental in identifying associated ligament and chondral lesions after distal radius fractures[1]. However, there is still no consensus on the benefit of arthroscopically assisted treatment of intraarticular distal radius fractures. Patients treated with arthroscopically assisted reduction appear to have a greater range of motion (ROM) [2]. With regard to functional outcomes or radiographic parameters, however, arthroscopic reduction does not appear advantageous[3]. Hemarthrosis may lead to inflammation, damage of articular cartilage and eventually to destruction of the entire joint[4]. We hypothesized that arthroscopically assisted removal of intra-articular fracture hematoma and debris may improve the functional outcomes after operative treatment of intra-articular distal radius fractures due to improvement of the synovial joint mobility[2,5-7]. Moreover, during arthroscopy, the quality of the reduction and the presence of associated ligament injuries can be assessed[8,9]. The purpose of this randomized controlled trial was to determine the difference in functional outcome, assessed with the Patient-Rated Wrist Evaluation (PRWE) score with a follow-up of 12 months, after open reduction internal fixation (ORIF) with and without arthroscopy in adults with displaced intra-articular distal radius fractures.

METHODS

Study design and patient randomization

This study was a multicenter randomized controlled trial in which adult patients with displaced intra-articular distal radius fractures were randomized between ORIF with wrist arthroscopy to remove fracture hematoma and debris (intervention group) and conventional ORIF (control group). Study approval was obtained from the ethics committee and institutional board of our hospital and the boards of directors of all participating centers. All patients provided written informed consent before randomization. The results were reported according to the Consolidated Standards for Reporting Trials (CONSORT). The study protocol has been published[10].

The study was conducted in three centers in the Netherlands. Two are academic hospitals and one is a regional teaching hospital. All consecutive patients aged 18 years with displaced intra-articular distal radius fractures (AO/OTA type C) where ORIF was deemed necessary were included in the study. The decision for ORIF was based on the Dutch guidelines for unacceptable alignment of the distal radius: radial inclination ≤ 15^0, loss of radial height ≥ 5 mm, dorsal angulation ≥15^0, palmar angulation ≥20^0, and gap or step-off > 2 mm[11]. Patients with open distal radius fractures or other fractures of the affected extremity (except for a fracture of the ulnar styloid process), patients with impaired wrist

function before the recent fracture and multiply injured patients (Injury Severity Score 16) were excluded. Patients unable to understand the study information and informed consent forms, as judged by the treating physician, were also excluded.

After obtaining informed consent, patients were randomized 1:1 to ORIF with arthroscopy: ORIF without arthroscopy. Randomization was performed using a secured online computer randomization procedure, with the use of permuted blocks of four, six and eight patients. We stratified randomization according to age into two strata: 18–64 years; and 65 years and older.

Surgical techniques

Open reduction and plate fixation, as well as wrist arthroscopy were performed by a certified (orthopedic) trauma surgeon of at least Level 3 expertise, according to criteria of Tang and Giddins in both ORIF of distal radius fractures and wrist arthroscopy[12]. An additional dorsal approach was allowed only when the dorsal capsule was not opened and thus leaving the radiocarpal joint closed to facilitate comparison between patients. The approach was at the discretion of the treating surgeon.

The intervention group was treated with wrist arthroscopy directly after ORIF. Arthroscopic debridement of hematoma and debris was performed. A detailed description of the arthroscopic procedure has previously been described[10]. No corrections of reduction were allowed and all additional soft-tissue injuries were left untreated according to study protocol. A delay of at least 5 days before performing arthroscopy was mandatory to enable visualization due to the organization of the hematoma[13]. The operation was performed within 3 weeks after the initial trauma. For both the intervention and control groups, patients started exercise immediately after the operation. For the first 6 weeks, only non-weight-bearing exercises were allowed. Physiotherapy was recommended at the discretion of the surgeon, as this was the nearest reflection of daily practice.

Outcome assessment

The primary outcome measure was the PRWE score at 3 months. In addition, the PRWE questionnaire was completed after 3 and 6 weeks, and 6 and 12 months of follow-up. The PRWE is a validated tool for assessing functional outcome in patients with distal radius fractures. The highest score, indicating severe impairment, is 100; the best score, indicating no impairment, is zero. In the intervention group, the quality of reduction, associated ligament injuries and cartilage damage was assessed. Ligament injuries were divided into triangular fibrocartilage complex (TFCC) injuries, classified according to the Palmer classification, and scapholunate (SL) ligament and lunotriquetral (LT) injuries, graded according to the Geissler classification.

Secondary outcome measures were the arthroscopic findings, the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, postoperative pain as indicated on the visual analogue scale (VAS), ROM, grip strength and complications during 1-year follow-up. ROM included active wrist flexion and extension, radial and ulnar deviation, and pronation and supination, measured with a handheld goniometer. Grip strength was measured with a hydraulic hand dynamometer (Baseline, Fabrication Enterprises, White Plains, NY, USA). ROM and grip strength of the injured side were compared to the uninjured side. A complication was defined as any adverse event for which additional treatment was required.

Statistical analysis

The sample size was calculated based on the primary outcome, the PRWE at 3 months. With an a ¼ 0.05%, a sample size of 46 was required to provide 80% power to detect a difference of 18 points in the PRWE score. For safety measures and with an expected lost-to-follow-up of 5%, 25 patients in each arm were included.

All analyses were based on the intention-to-treat principle. General descriptive statistics on patient characteristic at baseline were performed including factors such as sex and age. Normality was determined by visually inspecting the plotted data distribution in a histogram and boxplot. Normally distributed data were reported as mean and standard deviation (SD) and non-normally distributed data were reported as median with interquartile range (IQR). To compare continuous non-normally distributed baseline characteristics such as age and operation duration, the Mann–Whitney U-test was used. For the analysis of the categorical baseline characteristics, the chi-square test was used.

Differences between the two groups in PRWE and DASH scores, VAS pain sores, ROM and grip strength at the follow-up intervals were analyzed using a linear mixed model. The best covariance structure for each linear mixed model was determined using the smallest Akaike information criterion[14]. All outcome measures were corrected for age, because this was a stratification factor in the design of the study. Differences in complication rates between the two treatment groups were analyzed using the chi-square test. An additional per-protocol analysis was performed.

RESULTS

Patient demographics

Between February 2016 and October 2017, 93 patients were screened for eligibility. Patients were excluded if they did not meet inclusion criteria (n=23), declined to participate (n = 10) or because no arthroscopy set was available (n= 9). In the period that the arthroscopy set

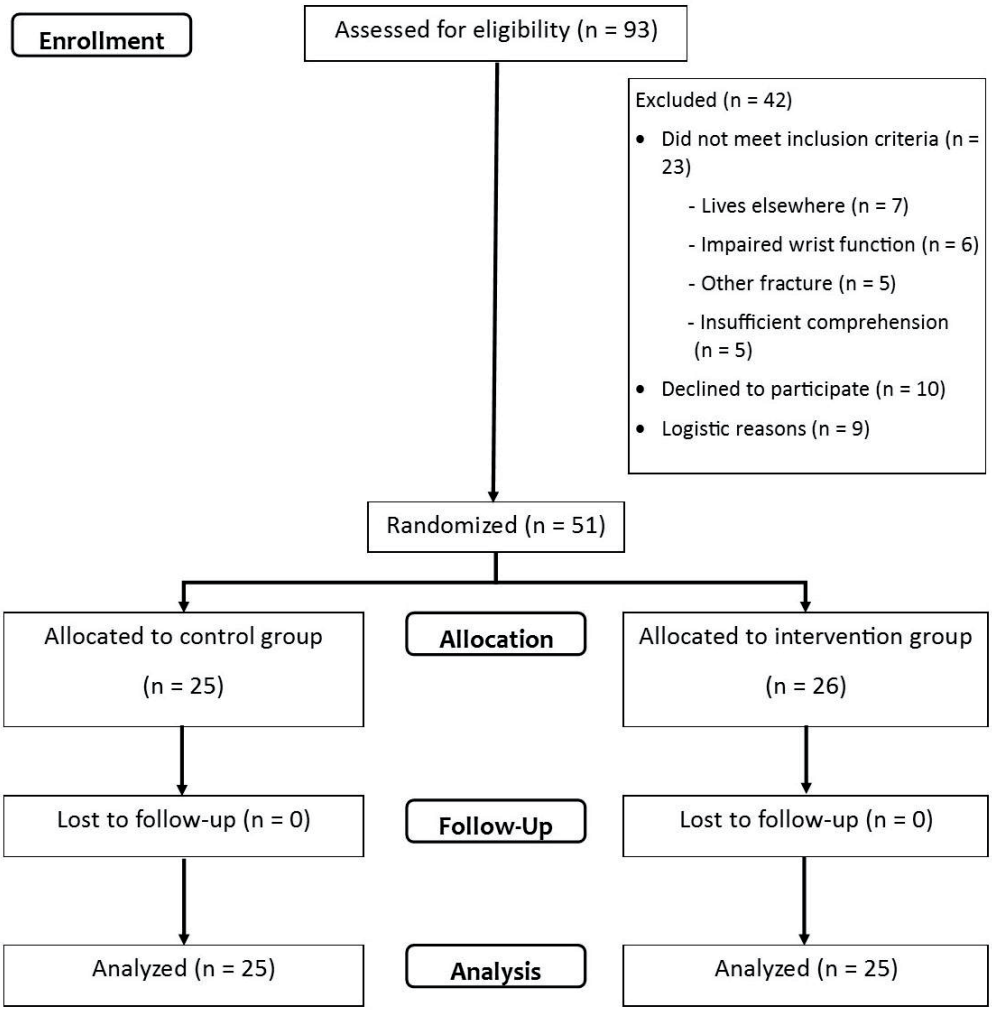

Figure 1: CONSORT flow diagram of this study

was not available, patients were not included in the study. In total, 25 patients were assigned to the intervention group and 26 patients were assigned to the control group. One patient in the intervention group was excluded after randomization because this patient did not meet the inclusion criteria. In each group, 25 patients were analyzed for the primary outcome (Figure 1).

The median age of the 50 study participants was 59 years (IQR 44-66) and 33 (66%) participants were women. Baseline characteristics were evenly distributed between the two treatment groups (Table 1). The baseline characteristics of the included patients did not differ from the eligible but not included patients. Patients were operated within a mean of

Table 1: Patient characteristics

Patient information	ORIF alone (N = 25)	ORIF with arthroscopy (N = 25)
Age (years), median [IQR]	58 [47-65]	60 [36-66]
Gender		
Female	17	16
Male	9	9
Fracture of dominant side	11	8
Operation duration (minutes), mean ± SD	64 ± 37	98 ± 30

1.5 weeks (SD 0.4). Operation duration was significantly longer for the intervention group than the control group, 98 minutes vs. 64 minutes (p ¼ 0.002).

Three patients in the intervention group did not receive arthroscopy. This was because the dorsal joint capsule had already been opened during surgery before the intervention could take place.

Primary outcome

The PRWE scores were not significantly different for the arthroscopy group at 3 weeks or at 6 weeks. The PRWE scores were significantly worse for the arthroscopy group at 3 months (p = 0.008) and at 6 months (p = 0.01). In the mixed-model analysis used for this study, these scores were statically different at the two time-points, due to the large spread in range. However, the mean differences are none or too small; therefore, they are not clinically significant (Table 2). The median PRWE score at 12 months was equal for both groups (Table 2).

Secondary outcomes

All 22 patients who underwent arthroscopy had a hematoma that was removed; 11 patients had a loose piece of cartilage or bone floating freely in the joint. Anatomic reduction (no gap or step-off) was obtained in 13 patients (Table 3). All patients had additional ligament or chondral injuries. Twenty patients had TFFC injuries. SL injury and LT injury were present in half of the patients in the arthroscopy group (Table 4). No patients received postoperative plaster cast immobilization.

The DASH scores were significantly better for the arthroscopy group at 3 weeks (p = 0.01) (Table 2). At 3 months, the arthroscopy group had a significantly worse DASH score (p = 0.046). At the other follow-up time-points, no significant differences were found between the two groups. Patients treated with arthroscopy had slightly lower VAS scores overall compared to those treated with only ORIF from 1 day to 2 months (Table 2). ROM did not differ significantly between the groups. Grip strength was overall significantly better for the group with ORIF alone (p = 0.003), though the mean difference was small (15 kg vs 18 kg, at 3 months after surgery) (Online supplementary Table S1).

Table 2: Functional outcomes in PRWE,DASH, and VAS scores expressed as median [IQR]

Postoperative time-points	ORIF alone	ORIF with arthroscopy	p-value
1 day			
VAS	7 [5-8]	5 [3-7]	**0.001**
1 week			
VAS	4 [3-6]	3 [2-4]	0.11
3 weeks			
PRWE	58 [44-73]	48 [26-67]	0.07
DASH	45 [34-60]	34 [20-49]	**0.01**
VAS	3 [2-3]	2 [0-3]	**0.02**
6 weeks			
PRWE	39 [19-53]	37 [18-63]	0.65
DASH	23 [17-36]	27 [15-40]	0.87
VAS	2 [1-4]	1 [0-3]	0.31
3 months			
PRWE	13 [5-21]	23 [9-44]	**0.008**
DASH	9 [4-15]	19 [5-30]	**0.046**
VAS	2 [0-2]	0 [0-2]	0.13
6 months			
PRWE	10 [3-17]	10 [1-47]	**0.01**
DASH	8 [3-18]	6 [0-15]	0.75
12 months			
PRWE	7 [1-15]	7 [0-20]	0.26
DASH	6 [1-18]	8 [0-21]	0.16

Table 3: Quality of reduction

Quality of reduction	N = 22
Step-off	
None	16
1-2mm	4
≥ 2mm	2
Gap	
None	16
1-2mm	5
≥ 2mm	1

Complications

Complications occurred in five patients in the group without arthroscopy (Table 5). Four patients had implant removal due to tendonitis, of which one developed a superficial wound infection that was treated with oral antibiotics, which resolved the infection. Another patient had a superficial wound infection after ORIF that was treated with oral antibiotics. This same patient later had a flexor pollicus longus tendon rupture, which was reconstructed. In the arthroscopy group, six patients had complications. In five, the implant was removed due to tendonitis. One patient had extensor carpi ulnaris tendinitis. There is no significant difference in complication rate between the two groups (Table 5).

Table 4: Arthroscopic findings

Arthroscopic findings	**N = 22**
Triangular fibrocartilage complex injury (Palmer)	
none	2
A	8
B	10
C	1
D	1
Scapholunate injury (Geissler)	
none	11
grade 1	2
grade 2	1
grade 3	5
grade 4	3
Lunotriquetral injury (Geissler)	
none	11
grade 1	4
grade 2	4
grade 3	3
grade 4	0
Cartilage damage lunate fossa (Outerbridge)	
grade 0	7
grade 1	2
grade 2	6
grade 3	4
grade 4	3
Cartilage damage scaphoid fossa (Outerbridge)	
grade 0	10
grade 1	4
grade 2	6
grade 3	1
grade 4	1

Table 5: Complications

Complication	**ORIF alone**	**ORIF with arthroscopy**	**p-value**
Hardware related complaints	4	6	
Superficial wound infection	2	0	
ECU tendonitis	1	0	
FPL rupture	0	1	
Total	**7**	**7**	1.0

DISCUSSION

In this multicenter randomized trial, we found that patients with displaced intra-articular distal radius fractures treated with ORIF and additional arthroscopy to remove hematoma and debris did not have better clinically relevant functional outcomes than patients treated with ORIF alone. The differences in median scores of each outcome measure were small, though some show statistical differences. We therefore do not recommend performing additional arthroscopy with removal of hematoma and debris in patients with displaced intra-articular distal radius fractures.

Previous studies have explored the role of arthroscopy in the treatment of distal radius fractures. A study by Varitimidis et al. found that patients who underwent arthroscopically assisted reduction had better supination, extension and flexion[15]. Functional outcomes measured with the DASH score were similar in the two groups. This study was, however, underpowered, so no definitive conclusions could be drawn. Another retrospective study of 30 patients showed a better ROM for patients who underwent arthroscopic reduction compared to those treated with fluoroscopic reduction[2]. Patients in this study were, however, treated with external fixation and not with ORIF. Yamazaki et al. compared functional and radiographic outcomes of fluoroscopically and arthroscopically guided reduction of unstable intraarticular distal radius fractures and found no significant differences between the two techniques with regard to functional and radiographic outcomes[3].

In this study, we found soft-tissue injuries in all patients where arthroscopy was performed. This included different degrees of TFCC injuries in 90% of patients, SL ligament injuries in 50% of patients and LT ligament injuries in 50% of patients. Lindau et al. reported soft-tissue injuries in all patients[1]. This percentage of soft-tissue injuries is comparable to that in other studies reporting TFCC lesions in up to 63% to 82%[1,16] (Abe et al., 2013; Lindau et al., 1997), and SL and LT ligament lesions in up to 88% and 61%, respectively[1,16,17]. In contrast to our study, Yamazaki et al. treated soft-tissue injuries and found significantly better functional results[3]. However, we find that most of these soft-tissue injuries do not require treatment. This recommendation is further supported by two studies that show that patients with untreated SL injuries and TFCC injuries, except one, had good functional outcomes measured with the DASH score at a follow-up of 13–15 years[18,19]. In our study, additional lesions were left untreated and these patients had good functional outcomes at 6-month and 12-month follow-ups with PRWE scores of 10 and 7. The long-term functional results of these patients are still unknown.

This study has several limitations. Patients and physicians were not blinded to the treatment group assignment. Being aware of the additional injuries sustained may have influenced the self-reported functional outcomes. The functional outcomes were evaluated during a 1-year follow-up period, but whether the patient returned to the same function as before the fracture is unknown. We can, however, compare the injured side to the uninjured side and assume that due to randomization this difference is divided equally in both groups.

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Online supplementary Table: Clinical outcomes in range of motion (degrees) and grip strength (kg), expressed as median [IQR] and (percentage of uninjured side)

	3 weeks		6 weeks		3 months		
Clinical outcome	**ORIF alone**	**ORIF with arthroscopy**	**ORIF alone**	**ORIF with arthroscopy**	**ORIF alone**	**ORIF with arthroscopy**	**p-value**
Radial deviation	*5 [5-10] (44%)*	*10 [5-13] (59%)*	10 [5-15] (74%)	10 [10-15] (77%)	10 [9-15] (86%)	15 [10-15] (90%)	0.13
Ulnar deviation	*10 [8-15] (49%)*	*15 [10-18] (63%)*	15 [10-20] (71%)	15 [11-20] (72%)	20 [18-20] (98%)	20 [18-25] (90%)	0.05
Pronation	*80 [70-83] (86%)*	*80 [75-85] (93%)*	80 [78-85] (92%)	85 [83-85] (98%)	85 [80-85] (97%)	85 [85-85] (100%)	0.16
Supination	40 [20-63] (49%)	50 [25-65] (52%)	65 [60-73] (77%)	65 [58-80] (76%)	75 [70-80] (87%)	85 [78-85] (92%)	0.71
Dorsoflexion	*25 [10-40] (37%)*	*40 [20-50] (49%)*	50 [30-64] (65%)	55 [43-70] (68%)	60 [60-73] (85%)	70 [60-80] (89%)	0.10
Palmarflexion	30 [30-43] (43%)	30 [25-39] (43%)	40 [35-60] (58%)	40 [35-58] (56%)	65 [50-70] (79%)	65 [50-75] (80%)	0.90
Grip strength	3 [1-7] (18%)	7 [2-12] (28%)	12 [6-19] (45%)	10 [2-17] (41%)	18 [12-28] (72%)	15 [11-25] (62%)	**0.003**

Part 2

PREVENTING AND TREATING POST-TRAUMATIC COMPLICATIONS

Chapter 6

CARPAL ALIGNMENT: A NEW METHOD FOR ASSESSMENT

C.A. Selles, L. Ras, M.M.J. Walenkamp,
M. Maas, J.C. Goslings, N.W.L. Schep

J Wrist Surg. 2019 Apr

ABSTRACT

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Background Carpal alignment may be used as a tool to evaluate fracture reduction in patients with distal radius fractures. However, there is little consensus on how to measure and quantify carpal alignment. Purpose The aim of this study was to compare the inter- and intraobserver variability of a new perpendicular method with the existing method in fractured and unfractured wrists. Additionally, the normal distribution of carpal alignment in unfractured wrists was investigated.

Patients and Methods Carpal alignment was assessed on lateral plain radiographs using two different methods, one described by Ng and McQueen and another newly proposed method, the perpendicular method. Using the perpendicular method, the observer draws one line along the inner rim of the volar cortex of the radius and one perpendicular line to the center of the capitate. The carpus is aligned when the line along the inner rim transects the center of the capitate. Three examiners measured the carpal alignment in 50 patients with nonfractured and 50 patients with fractured distal radius. Intra- and interobserver variability for both methods were determined.

Results The interobserver coefficient for the perpendicular method was 0.98 and that for the Ng method was 0.86. The intraobserver coefficients for three examiners were 0.89, 0.62, and 0.63, respectively, for the Ng method. For the perpendicular method, the intraobserver variability was 0.96, 0.89, and 0.72, respectively. In patients with unfractured wrists, the mean perpendicular to the center of the capitate was 0.25 mm dorsally.

Conclusion The new proposed method is a reproducible method for measuring carpal alignment with a high inter- and intraclass coefficient.

Clinical Relevance This method of measurement allows for a reproducible technique for measuring carpal alignment.

INTRODCTUION

Conventional radiological parameters such as radial inclination, radial length, ulnar variance, and dorsal or volar angulation have been described to correlate with functional outcome in patients with distal radius fractures[1-4]. However, there are also numerous studies that show no or only a weak correlation between these same parameters and functional outcome[3,5,6]. Previous studies have shown the clinical importance of carpal alignment. The incidence of carpal malalignment is correlated with poor functional outcome[7]. McQueen et al noted that carpal alignment was the main predictor of functional outcome[8].

Carpal alignment is not commonly used, maybe because doctors are unsure about how to measure and quantify this parameter[9,10]. Carpal alignment entails that the hand should be in line with the forearm[4,11]. Carpal malalignment has been described as early as in 1919 as the "dorsal luxation of the capitate"[12]. In malunited distal radius, fractures compensatory movement at the midcarpal or radiocarpal level takes place to realign the hand. This mechanism may correlate with poor functional outcome[4,8,11,13,14]. Therefore, carpal alignment may be used as a tool to predict patient-related outcome in patients with distal radius fractures. Ng and McQueen defined carpal alignment as a line along the long axis of the capitate and a line along the long axis of the radius. If these lines intersect within the carpus, the carpus and the radius are aligned.

Several radiographic additional indices have been described to assess carpal alignment. The effective radiolunate flexion measures the relationship between the axes of the displaced distal radius and the lunate and classifies carpal alignment into two patterns: midcarpal and radiocarpal alignment[9,10]. Despite these methods, there is still no gold standard to measure carpal alignment radiographically. Moreover, none of these methods is able to quantify carpal alignment and discriminate between volar and dorsal translation of the carpus. We proposed a new and simple method, the perpendicular method, to assess and to quantify carpal alignment

The aim of this study was to compare the inter- and intraobserver variability for the new perpendicular method with the standard Ng method in fractured and unfractured wrists and to determine the normal distribution of carpal alignment in unfractured wrists. Additionally, the agreement between the two methods was analyzed.

PATIENTS AND METHODS

Patient Selection

Between 2011 and 2014, a prospective database was established for patients with wrist trauma in an academic hospital. All patients had a protocolized physical examination and a radiographic measurement of the wrist[15]. This database contains information about patients with and without fractures of the distal radius. For this retrospective observational study, consecutive adult patients with nonoperatively treated distal radius fractures (AO [Arbeitsgemeinschaft für Osteosynthesefragen] classification type A and C) and with unfractured wrists were included. Radiographs were available at presentation and at 6 weeks follow-up. Patients with pathological fractures, and a previous distal radius fracture in the same arm, were excluded.

Sample Size Calculation

To express the degree of inter- and intraobserver agreement, the intraclass correlation coefficient (ICC) was used. To be able to detect a difference between an ICC of an excellent correlation (0.8) and a good correlation (0.7) with an $\alpha = 0.05$ and a power of 0.80, a total 100 patients were needed to be assessed. The calculations were performed with Power Analysis and Sample Size Software (PASS, NCSS Statistical Software, Kaysville, UT).

Radiographic Measurements

In the unfractured wrists, the lateral radiographic parameters at presentation were measured. In the fractured wrists, the lateral radiographic parameters at presentation and at 6 weeks follow-up were measured. Carpal alignment was measured using two different methods. The Ng method uses a line along the long axis of the capitate and a line along the long axis of the radius. Carpal alignment was defined as when both lines intersected within the carpus. Consequently, malalignment was defined as displacement of the longitudinal axis of the capitate either dorsal or volar to the longitudinal axis of the radius on a lateral view (Fig. 1A)[16].

However, this method only provides a dichotomous variable: aligned versus nonaligned. Therefore, we proposed a new method, the perpendicular method. This method uses one line along the inner rim of the volar cortex of the radius, also known as the line of Lewis, and one perpendicular line to the center of the capitate[17]. The carpus was defined as aligned when the line along the inner rim transected the center of the capitate. The center of the capitate is at the center of a circle drawn around the base of the capitate. The carpus was defined as aligned when the line along the inner rim transected the center of the capitate. By measuring the perpendicular distance to the center of the capitate, the degree of carpal malalignment and direction volar versus dorsal can be quantified (Fig. 1B).

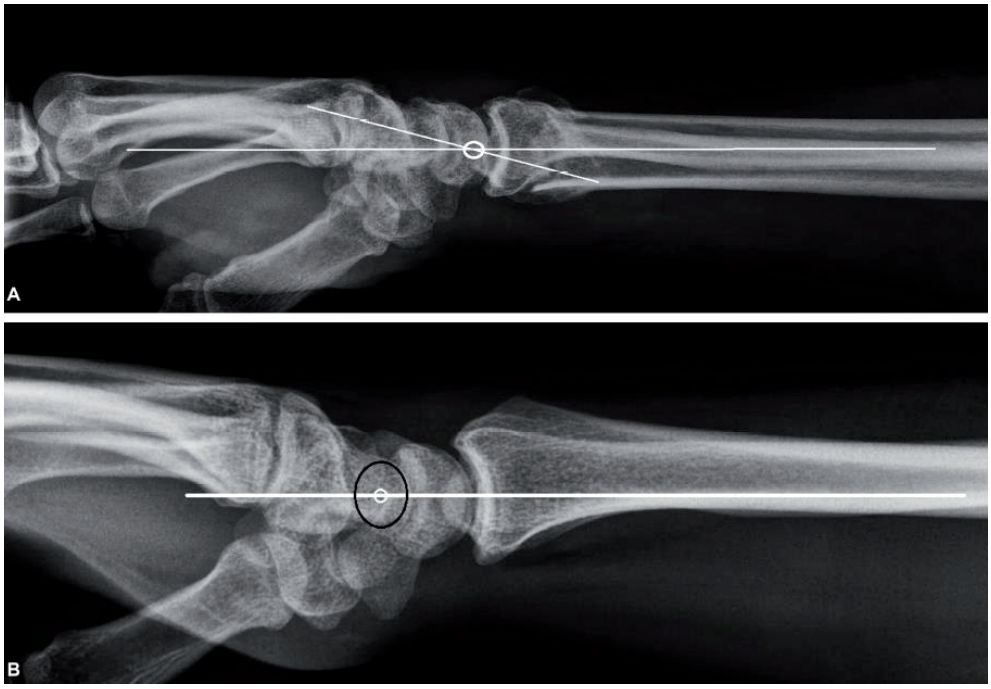

Figure 1: (A) Carpal alignment measured using the Ng method. (B) Carpal alignment measured using the perpendicular method

These radiographic parameters were measured independently by three authors (C. A. S., L. R., and N. W. L. S.) on all radiographs using a digital radiographic system (IMPAX). A calibration session was performed prior to the measurements were performed. The inter- and intraobserver variability as determined for carpal alignment and perpendicular line measurement was determined. To determine the intraobserver variability, the measurements were reassessed by the same researchers with a 1-month increment. With three observers performingmeasurements twice on 100 patients, a total of 600 measurements were performed. Additionally, the correlation between the two methods was analyzed. Moreover, the normal distribution of carpal alignment in unfractured wrists was determined for both methods.

Statistical Analysis

Descriptive analyses were performed to assess baseline characteristics. For continuous data, mean (standard error of the mean) and standard deviation (SD) (parametric data) or medians and percentiles (nonparametric data) were calculated. For categorical data, frequencies and percentages were calculated.

Table 1: Patient demographics

	Unfractured N, (%)	Fractured N, (%)
Gender		
Male	21 (42%)	14 (28%)
Female	29 (58%)	36 (72%)
Age, median [IQR]	32 [23-54]	63 [56-75]

Table 2: Intraobserver variability for the Ng and perpendicular methods

	Intraclass coefficient (95% CI)		
	Observer 1	**Observer 2**	**Observer 3**
Ng method	0.89 (0.83-0.93)	0.62 (0.44-0.75)	0.62 (0.46-0.75)
Perpendicular method	0.96 (0.84-0.97)	0.88 (0.82-0.92)	0.72 (0.58-0.81)

The ICC for inter- and intraobserver agreement was calculated for each study parameter. Based on its value, the ICC is summarized, according to Hallgren, as an excellent correlation (0.75),3 a good correlation (0.6–0.74), a fair correlation (0.4–0.59), and a poor correlation (<0.4)[18]. For this study, an ICC of 0.6 or above was considered acceptable.

Normality was determined by using the Shapiro–Wilk test and a visual check by plotting the data distribution on a histogram. Data analysis was performed with the Statistical Package for Social Sciences (SPSS version 24, SPSS Inc., Chicago, IL).

RESULTS

Patient Demographics

This study comprised 100 patients, 50 with unfractured distal radius and 50 with displaced distal radius fractures. Patient demographics are shown in Table 1.

Intraclass Correlation Coefficient

The interobserver agreement to determine carpal alignment was 0.95 (95% confidence interval [CI]: 0.93–0.96) for the perpendicular method and 0.86 (95% CI: 0.82–0.90) for the Ng method. The intraobserver variability for measuring carpal alignment according to the Ng method and the perpendicular method is depicted in Table 2.

Perpendicular line measurement to the center of the capitate (measured in millimeters) had an interobserver agreement of 0.98 (95% CI: 0.976–0.987).

Agreement between the Two Methods

Carpal alignment was identified with the Ng method in 356 of the total 600 measurements. In 53% of these measurements (n = 187), the carpus was aligned using the perpendicular

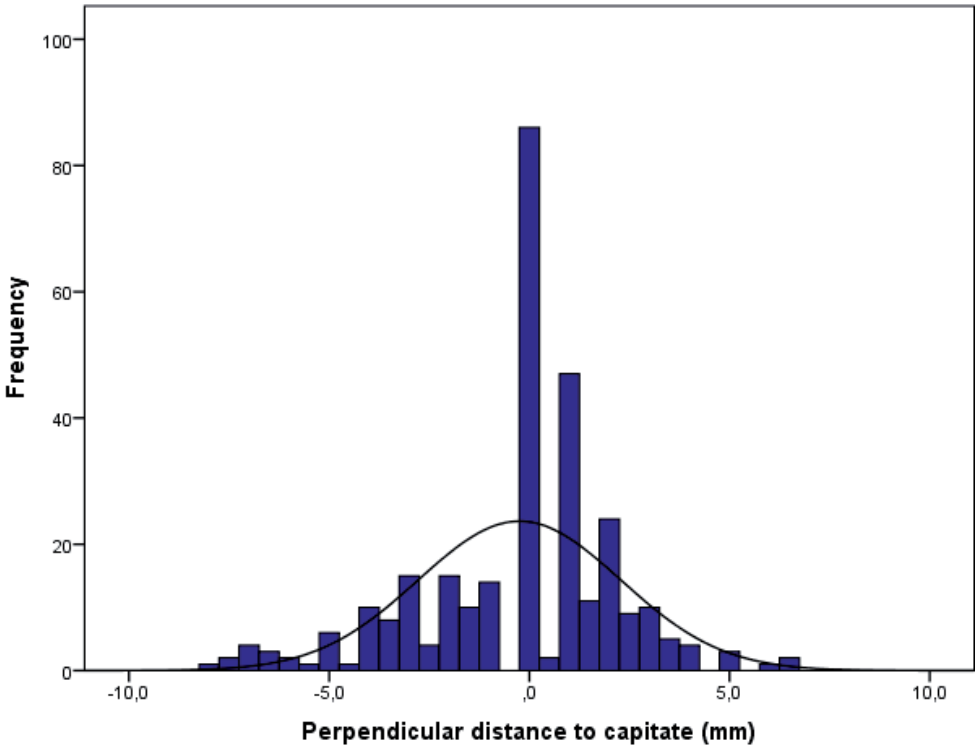

Figure 2: Distribution of the perpendicular distance from the line of Lewis to the capitate in unfractured wrists

method (rs = 0.03; p = 0.4). When both methods found the carpus to be aligned, the mean translation of the center of the capitate was 0.75 mm (SD: 1.9) dorsally. In the other 47% of the measurements in which the carpus was found malaligned according to the perpendicular method, the mean translation of the capitate was 2.9 mm (SD: 3.2) dorsally, with a range of –12 to 7 mm.

Carpal Alignment in Unfractured Wrists

In the unfractured wrists, the mean of the perpendicular line along the line of Lewis to the center of the capitate was 0.25 mm dorsally (SD: 2.52; 95% CI –0.53 to 0.41). Fig. 2 depicts the distribution of the length of the perpendicular for unfractured wrists. There was carpal alignment in 79% (236/300) of the unfractured wrists when using the perpendicular method compared with 59% (177/300) carpal alignment in the unfractured wrists using the Ng method. For the considered malaligned unfractured wrists (n = 66), the median perpendicular to the center of the capitate was –2.4 (interquartile range: –4.5 to 1. 1).

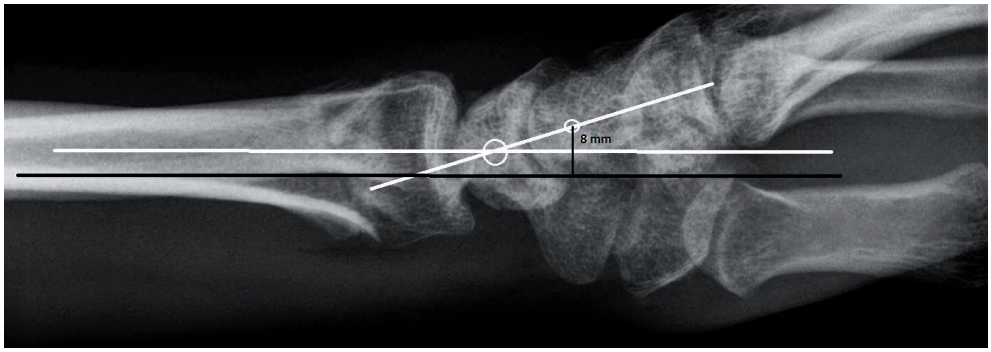

Figure 3: Discrepancy between the two methods: alignment with the Ng method (white) but malalignment with the perpendicular method (black)

DISCUSSION

The perpendicular method is a reproducible method to determine carpal alignment with a high inter- and intraobserver variability. Furthermore, it is possible to quantify carpal malalignment, with an intraobserver variability for the perpendicular line measurement to the center of the capitate of 0.98. In 79% of unfractured wrists, the carpus was found to be aligned using the perpendicular method, whereas, in only 59% of these wrists, carpal alignment was identified using the Ng method.

In only 53% of measurements using the Ng method, we correspondingly found carpal alignment using the perpendicular method. There was a mean translation of the capitate of 3 mm dorsally when the Ng method defined the carpus to be aligned and the perpendicular method did not. Moreover, the measurements ranged up to –12 mm, indicating that the center of the capitate was more than 1 cm dorsal to the line of Lewis, clearly demonstrating malalignment. Consequently, when using the Ng method, carpal malalignment may not always be recognized. Fig. 3 illustrates a case in which, according to the Ng method, the carpus is aligned, but where both optically and with the perpendicular method a noteworthy malalignment is measured. The clinical implications of this finding are a field for further research.

An additional feature of the perpendicular method compared with the Ng method is the quantification of the amount of translation by measuring the distance of the perpendicular. This makes it possible to quantify the amount and direction of carpal malalignment. An evident learning curve was observed in measuring carpal alignment. This was more apparent when the Ng method was used. The least experienced member of the team had a lower intraobserver agreement compared with the more experienced member.

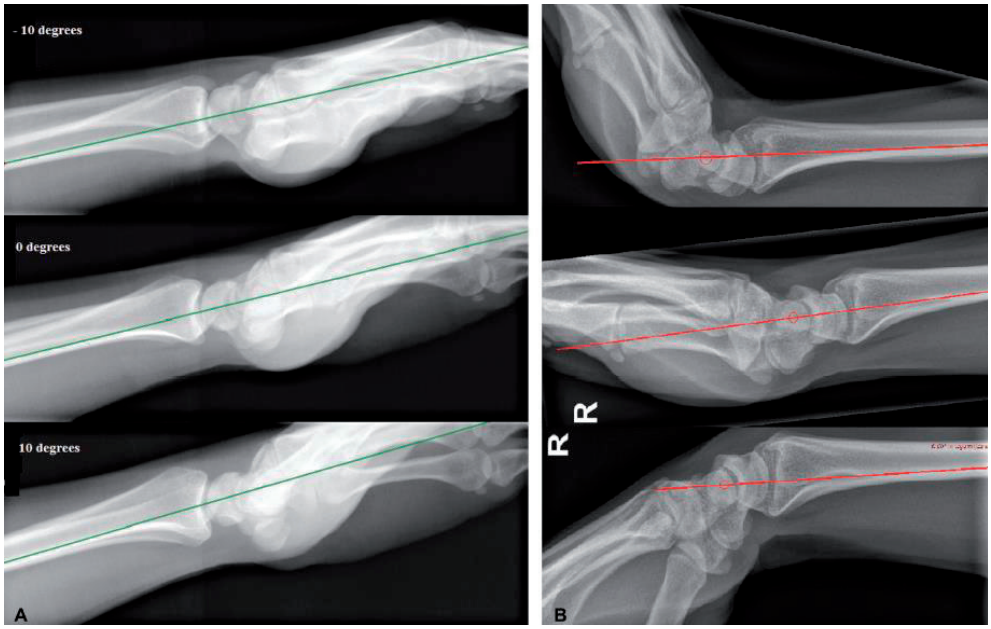

Figure 4: (A) Carpal alignment measured using the perpendicular method in the same wrist in different rotational positions: –10, 0, and 10 degrees. (B) Carpal alignment measured using the perpendicular method in the same wrist in flexed and extended positions

A noteworthy, but contradictory, result in our study is that in 20% of unfractured wrists, the carpus seems maligned using the perpendicular method, and using the Ng method, this is 40%. This may indicate that in some patients, the carpus is physiologically not aligned with the radius. The distribution of carpal alignment in the general population has not yet been investigated. These variations in alignment in unfractured wrists may be an area for future research. Measurements were performed with no margin, and perhaps an acceptable range of distance from the perpendicular to the center of the capitate should be accepted. Based on the CI of – 0.53 to 0.41, we would argue that a margin of 0.5 cm of dorsal and 0.5 cm of volar displacement would be within the range of aligned. This would need to be validated in further studies.

Limitations of this study should be addressed. Wrist positioning on radiographs may influence the carpal alignment indices[19]. Although radiographs of the wrist are taken according to protocols, there remains variability in wrist positioning leading to off-axis films. When using the perpendicular method, alignment might be less influenced by wrist position due to the line along the inner cortex of the volar rim being in proportion to the capitate. Fig. 4 depicts a wrist in various rotational positions (A) and in extended and flexed positions (B), but the carpal alignment remains. This is consistent with clinical practice but may limit the precision of our measurements. Furthermore, the line of Lewis may not always be obvious,

especially in pathological cases such as Paget's disease. A reasonable length of radial shaft needs to be visible on the radiograph to be accurate. Moreover, the distribution of normal carpal alignment was determined in a significantly younger population than those with fractured wrists. Midcarpal instability could, for example, play a role in the distribution of carpal alignment in unfractured wrists. Patients may have experienced a previous distal radius fracture. In these patients, two forms of malalignment may have occurred: "adaptive" midcarpal malalignment and pathological radiocarpal malalignment.16 "Adaptive" midcarpal malalignment is the adaptation to the malunion at the midcarpal level. Pathological radiocarpal malalignment causes a radiocarpal dorsal imbalance, resulting in dorsal subluxation of the radiolunate joint. These changes in alignment are more often the result of biomechanical changes than of ligament injury[20]. Last, there is no gold standard for carpal alignment, making it impossible to calculate the sensitivity and specificity of our new method.

The newly proposed method, the perpendicular method, is a reproducible method for measuring carpal alignment with a high inter- and intraclass coefficient. The amount of translation can be reliably measured, allowing quantification of carpal malalignment rather than a binary outcome (alignment or malalignment). A considerable carpal malalignment may be missed when using the Ng method. Now that we have this method for measuring carpal alignment, future validation studies should be performed. Moreover, the effect of this radiological parameter on the functional outcome is still to be determined.

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Chapter 7

RELATIONSHIP BETWEEN PLATE REMOVAL AND SOONG GRADING FOLLOWING SURGERY FOR FRACTURED DISTAL RADIUS

C.A. Selles, S.T.H. Reerds, G. Roukema,
C.H. van der Vlies, B.I. Cleffken, N.W.L. Schep

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ABSTRACT

The aim of this study was to determine the relationship between volar plate removal and the Soong classification following fixation for fractured distal radius. In this retrospective cohort study, all consecutive patients who had volar plate fixation for a distal radius fracture in 2011–2015 were reviewed. Differences in Soong classification between patients who had plate removal and those who did not were analyzed. The total incidence of plate removal was calculated and the indications analyzed. A total of 323 patients were included. The incidence of plate removal in all patients was 17%. Soong classification was significantly higher in patients who had plate removal compared with those who did not. For patients with plate placement classified as Soong grade 2, the incidence of plate removal was almost six times higher than those classified as Soong grade 0. The relationship between volar plate removal and a higher Soong grading stresses the importance of accurate plate positioning.

INTRODUCTION

Open reduction and internal plate fixation is an increasingly accepted method of treatment for displaced distal radius fractures, offering biomechanically stable fixation and thus allowing for early rehabilitation[1-6]. The reported incidence of volar plate removal for distal radius fractures is in the range of 3–10%[7,8]. Indications for removal vary from factors such as pain and stiffness, to tendonitis or tendon rupture, hardware prominence and hardware failure[7,9]. Improper plate position or malpositioned or prominent screws may cause tendon injuries or damage joint surfaces[10]. Flexor tendonitis or rupture is a recognized complication of volar plate fixation of distal radius fractures. Plate prominence at the watershed line, where the flexor tendons lie closest, is a contributing factor to this complication[11]. Soong et al. developed a classification system to determine plate prominence in relation to the watershed line. Plates that do not extend volar to the critical line are classified as Grade 0, those volar to the line but proximal to the volar rim as Grade 1 and plates directly on or distal to the volar rim as Grade 2. In a group of patients where Grade 2 volar prominence was present, the increased incidence of flexor tendon ruptures approached statistical significance[11]. The authors therefore suggested that plate placement volar to the critical line and distal to the volar rim could increase the risk of flexor tendon rupture.

The primary aim of this study is to determine the relationship between volar plate removal and the Soong classification system. We hypothesize that a higher Soong grade will be associated with plate related complaints and thus be more common in the group of patients where plate removal has taken place. Secondary outcome measures are incidence and indications for volar plate removal following distal radius fracture treatment.

METHODS

In this retrospective cohort study, all consecutive patients who had volar plate fixation for a distal radius fracture between 2011 and 2015 were reviewed. Inclusion criteria were adult patients with volar plate fixation who were operated in our hospital, with or without subsequent plate removal. Patients had to have at least one year of follow-up after initial plate fixation to be included.

The primary outcome measure was the relationship between volar plate removal and Soong classification. Secondary outcome measures were the incidence of plate removal, calculated as the number of patients with plate removal divided by patients who had plate fixation of the distal radius, and indications for plate removal.

Plate prominence was graded according to the Soong classification. This was done on post-operative radiographs. The volar rim was defined as the most volar extent of the volar cortex on the lateral radiographs. On the postoperative radiographs, a line was drawn tangential to the volar rim, parallel to the diaphyseal bone of the radial shaft. Plates that do not extend volar to this line were recorded as Grade 0. Plates volar to the line but proximal to the volar rim were recorded as Grade 1. Plates directly on or distal to the volar rim were recorded as Grade 2[11].

A variety of plates were used in the course of the study. All were supplied by Synthes (DePuy Synthes Companies, Zuchwil, Switzerland). The plates were classified as extra-articular or volar column plates (designed for use proximal to the watershed line) and juxta-articular and volar rim plates (designed to lie exactly on or distal to the watershed line) (Figure 1).

Statistics

General descriptive statistics on patient gender and age at baseline were gathered and presented as percentages (categorical variables) or mean and standard deviation (normal data) or median and interquartile range (IQR; non-normal data), as applicable. Differences between groups were analyzed using the unpaired T-test (in case of normal distribution) or the Mann–Whitney U test (where distribution was not normal). Normality was determined using the Shapiro–Wilk test and a visual check by plotting the data distribution in a histogram.

Differences in Soong classification, plate placement and AO fracture type were analyzed with a Chi-squared test or Fisher's exact test in case of $N < 5$ in a group. A logistical regression was performed to determine the relation between plate removal and various covariates. In the regression analysis, the plates were grouped as those designed for use proximal to the watershed line and those designed for designed to lie on or distal to the watershed line.

RESULTS

A total of 323 patients were included. The median age of the total population was 61 years (IQR 48–70) and 76% were women. The median age in the group without plate removal was 63 years (IQR 52–71) and in the plate removal group this was 54 years (IQR 39–61) ($p = < 0.001$). Patient characteristics and AO fracture type are shown in Table 1.

Soong grades were reviewed for all patients with a volar plate. In the group in whom the plate was not removed, the percentage of patients for each Soong grade was 31% grade 0,

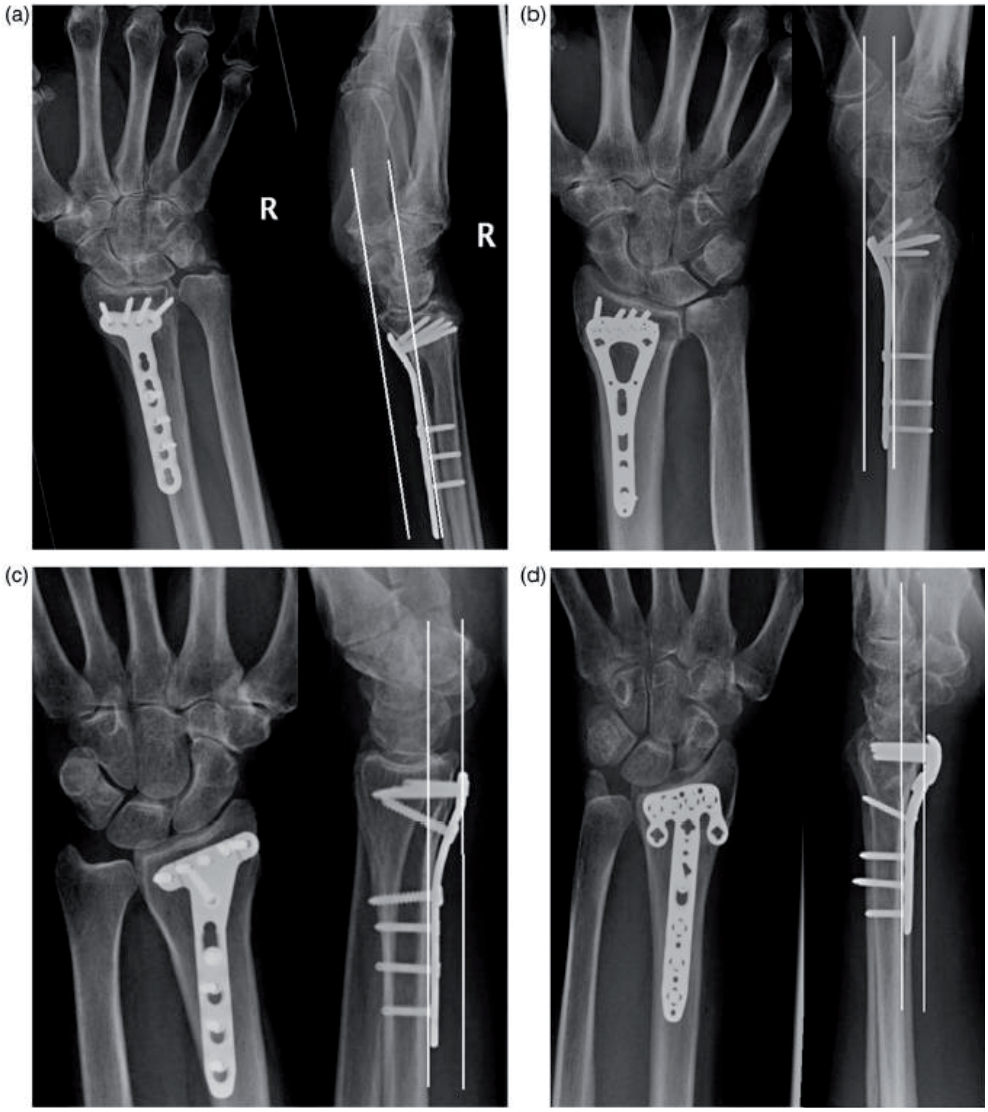

Figure 1: Ideal placement of plates relative to the watershed line. (a) Extra-articular plate, Soong 0. (b) Volar column plate, Soong 0. (c) Juxta-articular plate, Soong 1. (d) Volar rim plate, Soong 2

56% grade 1 and 13% grade 2. For the plate removal group, this was 19% grade 0, 37% grade 1 and 44% grade 2. There was a significant difference in Soong grades between groups ($p < 0.001$). Type of plates also differed significantly in relation to Soong grade. Juxta-articular plates and volar rim plates are more often classified as Soong grade 2 (Table 2). Fifteen of the 39 extraarticular plates and four of the 13 volar column plates were graded as Soong 2. The incidence of plate removal for extra-articular, volar column, juxta-articular and volar rim plates was 15%, 31%, 16% and 100%, respectively.

Table 1: Patient characteristics

Patient characteristics	Total (N = 323)	No plate removal (N = 269)	Plate removal (N = 54)	p-value
Age (median, [IQR])	61 [48 – 70]	63 [52 – 71]	54 [39 – 61]	**<0.001**
AO fracture type*				0.50
A	125 (39)	108 (40)	17 (32)	
B	20 (6)	16 (6)	4 (7)	
C	178 (55)	145 (54)	33 (61)	

IQR: interquartile range
* Expressed as N (%)

Table 2: Soong grade in relation to plate removal and plate type

		Soong classification			
	Total	**Grade 0**	**Grade 1**	**Grade 2**	**p-value**
No plate removal	269	82 (31)	150 (56)	37 (13)	**<0.001**
Plate removal	54	10 (19)	20 (37)	24 (44)	
Plate type					**<0.001**
Extra-articular	256	86 (34)	134 (52)	36 (14)	
Volar colum	13	4 (31)	4 (31)	5 (38)	
Juxta-articular	51	2 (4)	32 (63)	17 (33)	
Volar rim	3	0 (0)	0 (0)	3 (100)	

Results expressed as N (%)

Table 3: Odds ratio of variables in regression analysis

Variable	Odds ratio	p-value, (95% CI)
Age	0.96	**0.001** (0.94-0.99)
Gender	0.83	0.64 (0.39-1.78)
AO type		
A	(ref)	
B	1.40	0.62 (0.37-5.20)
C	1.43	0.32 (0.71-2.84)
Soong grade		
0	(ref)	
1	1.41	0.42 (0.60-3.32)
2	6.2	**<0.001** (2.47-15.64)
Plate type (on or past watershed line	0.81	0.61 (0.35-1.84)

Regression analysis showed a positive correlation of a higher Soong classification with the need for volar plate removal ($p < 0.001$). Moreover, it showed a negative correlation for age ($p = 0.001$) and a trend for negative correlation for plate type ($p = 0.61$). Table 3 presents the odds ratios of the variables in the regression analysis.

The overall incidence of volar plate removal was 17% (n = 54). Indications for plate removal were identified from medical records (Table 4). The majority were for pain or 'stiffness'. In one patient, the volar plate was removed following a penetrating injury from a dogbite.

Table 4: Indications for volar plate removal

Indication	**N, (%)**
Pain	34 (63)
Stiffness	8 (15)
Carpal tunnel syndrome	3 (5)
Malpositioned screws	3 (5)
Extensor tendon rupture (1x EPL & 1x EPL, EIP, EDC dig 2)	2 (4)
Corrective osteotomy	2 (4)
Extensor tendon irritation	1 (2)
Penetrating injury	1 (2)
Total	**54**

Two cases of plate removal were indicated due to extensor tendon rupture. In the first case, a rupture of extensor pollicus longus (EPL) was treated with an extensor indicis proprius (EIP) transfer. In the second, EPL, EIP and the common extensor of the index finger were ruptured but no reconstruction was performed due to patient's wishes. No flexor tendon ruptures were observed.

In the follow-up of patients after plate removal surgery, 89% (48 patients) experienced no complications. Complications observed were painful scarring requiring additional treatment in two patients, and plate removal in a patient who at the time of plate removal appeared to have a nonunion (n = 1). This patient received an arthrodesis of the wrist. An additional three patients were lost to follow-up.

DISCUSSION

Our results show that greater plate prominence after volar plate fixation for distal radius fractures is associated with an increased incidence of eventual hardware removal. For patients with plate placement classified as Soong grade 2 the incidence of plate removal is almost six times higher than those classified as Soong 0. In addition, patient's age at plate fixation surgery showed a negative correlation to plate removal surgery. A higher age at surgery makes it less likely that hardware removal will be necessary. This could be due to the fact that younger patients are more aware of their wrist function and demand more of it compared to older patients.

Removal of plates is not routinely performed in our institution. However, we found a relatively high incidence of 17% for plate removal. In previous studies, incidences of 10% or less were found[7,8]. We routinely have a follow-up of one year to assess whether patients have plate-related problems which may account for the higher incidence of plate removal in our

population. Furthermore, the reasons for hardware removals in our study are mostly pain or stiffness. In the case of volar rim plates especially designed to be placed distally, the plate always exceeds the watershed line. Consequently, plate placement will always be graded as Soong 2. One may suggest that plate removal in these patients should be performed routinely.

Soong et al. designed a classification system to determine plate prominence and compared this in two groups treated with different types of volar plates[11]. This study suggests that plate designs should take into account their prominence at the watershed line. In the group where the plate was more prominent at the watershed line of the distal part of the radius, the incidence of flexor tendon rupture was 4%, while this was 0% in the group with a lower profile of the plate ($p = 0.08$). The authors therefore advise surgeons to take steps to avoid improper plate position. Some plates, however, are specifically designed to achieve distal fixation and these do not fit within the watershed line. Although not used often, all volar rim plates in our study had to be removed. Also, juxta-articular plates were more often classified as Soong grade 1 and 2. In 67% of volar plates (volar column and extra-articular plates), these were placed exactly on or distal to the watershed line despite being designed to lie proximal to the watershed line. Our regression analysis demonstrated a statistically significant correlation between plate removal and Soong grade, but a negative correlation between plate removal and plate type. The number of distally positioned plates may be too small for statistical significance which could explain this finding. It is, however, possible that these results indicate that plate position is more important than plate type. Surgeons should be aware of the correct placement and type of plate and its possible relationship to postoperative complaints.

Snoddy et al. also investigated the relationship between Soong grade and tendonitis and plate removal[8]. They also used a logistic regression model to assess covariates associated with plate removal but did not find a significant relationship between Soong grade and plate removal. We have no sound explanation for the discrepancy between our study and Snoddy's. Possibly the smaller number of patients with hardware removal, 33 compared to 54 in our population, may have led to an underpowered statistical analysis.

We have not observed a single case of flexor tendon rupture. Flexor tendon tendinitis, especially of the flexor pollicus longus, may be underestimated in the population and recorded as pain. We did, however, observe two cases of extensor tendon ruptures. In both cases the EPL was ruptured and in one the EIP and the common extensor to the index finger were also ruptured. Both patients had volar plates and the extensor tendon ruptures were likely a result of screw protrusion on the dorsal side in one patient and of ischemia in the other. In cases such as these, plate removal may be unrelated to the plate position.

There are several limitations to this study. Due to its retrospective nature, unknown and known bias may be of influence. Specific reasons for plate removal, despite usually detailed medical records, may not be underlined. Furthermore, the possibility remains that patients have undergone hardware removal elsewhere after the initial one year of follow-up.

The Soong classification system is a useful method to describe the position of volar plates, with high inter- and intra-observer reliability of 78% and 0.80–0.94%, respectively[7]. Our results emphasize the value of the Soong grading system as a predictor of plate removal. We would suggest that the grading system be implemented in standard peri- and postoperative assessment to ensure best possible plate localization.

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Chapter 8

THE VALUE OF INTRAOPERATIVE 3D FLUOROSCOPY IN THE TREATMENT OF DISTAL RADIUS FRACTURES: A RANDOMIZED CLINICAL TRIAL

C.A. Selles, R.J.O. de Muinck Keizer, M.S.H. Beerekamp, P.A. Leenhouts, M. Maas, J.C. Goslings, N.W.L. Schep, on behalf of the EF3X-studygroup*

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** EF3X-studygroup*
R.J.O. de Muinck Keizer, D.T. Ubbink, T.J. Blokhuis, P. Kloen, R. van den Berg, B.A. van Dijkman, J.S.K. Luitse, M. Maas, R.W. Peters, B. Twigt, J. Winkelhagen

ABSTRACT

Purpose: The purpose of this trial was to determine the clinical effectiveness of the intraoperative use of 3D fluoroscopy, compared to the conventional 2D fluoroscopy in patients with distal radius fractures.

Methods: We performed a multicenter randomized clinical trial in which 206 fractures were randomized between the use of 3D fluoroscopy or not during operative treatment of their distal radius fracture. The primary outcome was quality of fracture reduction and fixation assessed on a post-operative CT-scan with a dichotomous outcome: indication for revision yes or no.

Results: There was no significant difference in whether the fracture required revision surgery; 31% (2D group) versus 24% (3D group). In 11% of operated distal radius fractures allocated to the 3D group, additional intraoperative corrections, namely screw replacements, were performed.

Conclusion: Compared to 2D fluoroscopy, the use of intraoperative 3D fluoroscopy does not appear to improve quality of reduction and fixation in the management of patients with a distal radius fracture. However, the use of 3D fluoroscopy does appear to have advantages such as more intra-operative revisions and less revision surgeries that this study could not clearly demonstrate.

INTRODUCTION

In patients treated operatively for distal radius fractures, intraoperative evaluation of fracture reduction and implant positioning is usually based on 2D fluoroscopy. However, incorrect positioning of screws and the quality of reduction of the articular surface is difficult to evaluate using this imaging technique.

The use of intraoperative 3D fluoroscopy has become increasingly popular [1]. 3D fluoroscopy comprises a mobile C-arm unit, modified to provide a motorized rotational movement combined with a workstation. This system provides multiplanar 3D reconstructions of the radiocarpal joint in addition to 2D fluoroscopic images. 3D fluoroscopy creates an enhanced representation of the articular surface and may possibly improve assessment of fracture reduction and fixation [2].

The use of intraoperative 3D fluoroscopy has led to intraoperative corrections for malpositioned screws in 12-29% [3,4], and fewer revision procedures in 21-39% of the patients [5,6]. However, the quality of these alterations and their effect on functional outcome has not yet been assessed.

Just adding and comparing 3D fluoroscopy to the standard 2D fluoroscopy to study its additional value would be prone to performance bias and it would be unclear on which information intraoperative corrections would be conducted, if required. Therefore, we conducted a randomized clinical (RCT) trial to determine the clinical effectiveness of the intraoperative use of 3D fluoroscopy, compared to the conventional 2D fluoroscopy, in patients with a distal radius fracture.

METHODS

Study Design

The EF3X trial was a multicenter RCT conducted from December 2010 until July 2015 [7]. Institutional board approval was obtained from the ethics committee of our hospital, and the board of directors of all the participating centers. All patients provided written informed consent before randomization.
The study was registered in the Dutch Trial Register as NTR 1902.

Patients and Participating Centers

Patients were recruited from two academic level 1 trauma centers and one regional teaching hospital. All surgeries were performed by a board certified trauma or orthopedic surgeon together with a surgical resident in training.

All patients aged above 17 years old with a distal radius fracture, AO-classification A2-C3, requiring open reduction and internal fixation were eligible to participate. Distal radius type A2-C3 fractures were chosen because the additional value of intra-operative 3D imaging was expected in these types of fractures. A2-3 type fractures were also included in order to assess the congruence of the distal radioulnar joint. The decision for ORIF was based on the national guidelines for unacceptable alignment of the distal radius: radial inclination ≤ 15^0, loss of radial height ≥ 5 mm, dorsal angulation ≥15^0, palmar angulation ≥20^0, and gap or step-off > 2 mm[8].
Patients with a pathological fractures, rheumatoid arthritis, pregnant patients, and patients unable to provide informed consent were excluded.

Randomization
Patient randomization was performed by means of a secured online computerized randomization procedure to ensure allocation concealment. Block randomization was used, and patients were stratified for participating centers. During the surgery, initially only 2D fluoroscopy was used for the intraoperative imaging as part of the usual procedure. The views used during 2D fluoroscopy were at the discretion of the surgeon. Once the surgeon was satisfied with the results, an additional 3D-RX scan was performed. Randomization then took place and in half of the patients the surgeon was blinded to the results of the 3D-RX scan and in the other half the surgeon was able to use the 3D-RX results to further optimize fracture reduction and implant positioning during the same surgical procedure, if deemed necessary (Figure 1). If the surgeon was satisfied with the operative result, conclusive 2D-fluoroscopic images and a 3D-scan were performed.

Trial Intervention
In all participating centers, a BV Pulsera 3D-RX (Philips Healthcare, Best, the Netherlands) was used. The BV Pulsera 3D-RX is a mobile C-arm unit calibrated for 2D and 3D use, and is equipped with a motorized rotational movement for volumetric acquisition and a Philips 3D-RA workstation for visualization of the 3D data set [7]. A series of 225 projection images is acquired over a period of 30 seconds during a 200° rotation of the C-arm. The projection images are used to reconstruct a 3D data set. Both volume rendering and multiplanar reformations (MPR) in axial, coronal and sagittal planes were available for evaluation. The image visualization was enhanced by coloring the implant (Titanview©).

Radiation dose
Patients with a distal radius fracture received an expected maximum of two 3D-RX scans during surgery. The maximum equivalent dosage of a 3D-RX-scan of the extremities is 17 µSv. Therefore, the additional dosage during surgery of the two exams was in the order of 34 µSv., and together with the radiographs performed postoperatively, the radiation

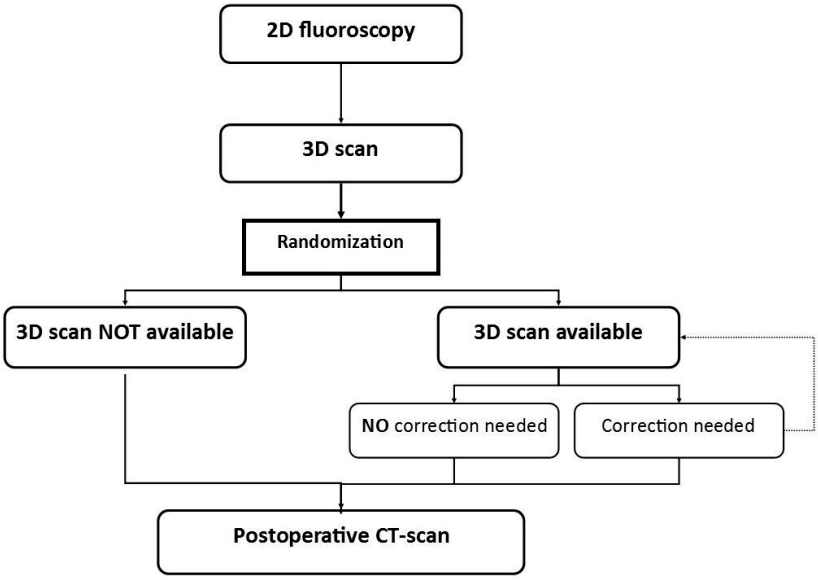

Figure 1: Flowchart of the EF3X-trial

dose was approximately 50 µSv. The effective dose of the postoperative CT-exam (120 kV, 150 mAs) did not exceed 0.2 mSv. The total dosage for all imaging performed as part of this trial were therefore less than 0.25 mSv. The institutional radiation board classified the study as category IIa (0.1-1 mSv) of the International Commission on Radiological Protection (report ICRP62), which qualifies as a minor risk.

Outcome Measures

The primary outcome measure was quality of fracture reduction and fixation assessed on a post-operative CT-scan with a dichotomous outcome: indication for revision yes or no, determined by three independent reviewers. The indication for revision was based on sub-optimal reduction, according to the national guidelines, and/or suboptimal fixation consisting of intra-articular or excessively long screws[8].

Secondary outcome measures were the number and type of corrections conducted when the surgeon was allowed to see the results of the 3D fluoroscopy, the number of revision procedures within one year after the index operation, the number of complications after one year of follow-up, and functional outcome as measured with the Patient-Rated Wrist Evaluation (PRWE) questionnaire. The PRWE score ranges from zero (no pain or functional impairment) to 100 (worst pain and severe impairment) [9].

A complication was defined as any adverse event that required additional treatment. Complications included wound dehiscence, wound infection, compartment syndrome, tendon irritation or rupture, complex regional pain syndrome (CRPS), and hardware removal. Hardware removal was only performed if the patient had hardware related complaints. If hardware removal was performed due to inadequate fixation (i.e. intra-articular screw) this was categorized as a revision procedure.

Clinical and Radiological Assessment

Each patient received a postoperative CT scan within seven days. Postoperative CT scans were collected, anonymized, and systematically evaluated according to a standard scoring protocol. The reduction and fixation was classified as revision necessary or not, based on the following factors: intra-articular screws, too long screws, gap > 2mm, step-off > 2mm, volar angulation > 20 degrees, and dorsal angulation > 15 degrees. Revision was deemed as required if at least two of the three reviewers judged a revision was necessary. This was regarded as suboptimal fracture reduction and/or fixation. All CT scans were evaluated in a blinded fashion by three reviewers the trauma surgery department. These reviewers had a level of expertise of I, IV and V according to Tang [10].

All patients underwent clinical assessments, at baseline, after 6 weeks, 12 weeks, and one year. Clinical examination included range of motion and grip strength, and assessment of potential complications. This assessment was no different from any other patient who was operated for a distal radius fracture. Patients completed the questionnaires on paper before or at the outpatient clinic visit before they were seen by their surgeon.

Statistical Analysis

Analysis of our institution's data showed a 17% sub-optimal fracture reduction and fixation of intra-articular fractures. We hypothesized a suboptimal fracture reduction and or fixation would occur in 5% of the patients when using the 3D-RX system, resulting in an absolute reduction of 12% of unacceptable fracture reductions [11]. Using a two-sided $\alpha = 0.05$ and a power of 0.80, 122 fractures per group were necessary to demonstrate this difference. To account for an approximately 3% dropout by technical or logistic failures of the 3D-RX-system, we calculated a sample size of 250 fractures to be included.

All analyses were performed according to the intention-to-treat principle, i.e. all patients were analyzed in the groups to which they were randomly assigned.

The primary dichotomous outcomes, indication for revision yes/no, as well as the number of intraoperative corrections were described as percentages.

Scores of functional outcomes were expressed as means and standard deviations (SD) in case of normal distribution; non-normally distributed data were expressed as medians with

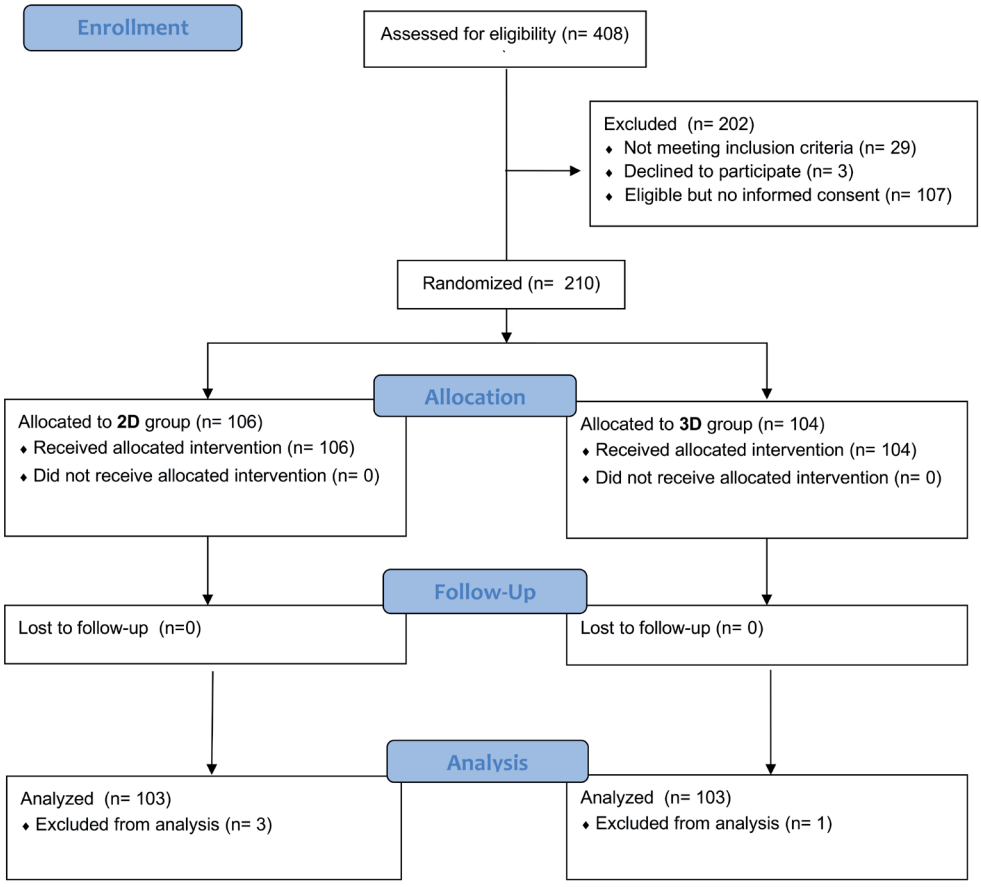

Figure 2: CONSORT Flow diagram

interquartile range [IQR]). Differences in primary outcome and revisions and complications within one year were analyzed with a Chi-squared test or Fisher's exact test in case of N<5 in a group. Differences in continuous parameters were analyzed using the Mann-Whitney U-test (non-parametric data). Two sided p-values of <0.05 were considered statistically significant for all statistical tests.

RESULTS

Randomization and Baseline Characteristics

Between December 2010 and July 2015, a total of 206 patients were analyzed in the study. Inclusion had to be terminated prior to reaching the expected 250 inclusions due to a lower accrual rate and budgetary restrictions. A total of 103 fractures were randomized to the

Table 1: Patient characteristics

	2D group N = 103	**3D group N = 103**
Gender, female	58 (56%)	58 (56%)
Age, mean ± SD	52.5 ± 13.6	52.0 ± 14.6
Smoking	14	19
Diabetes Mellitus	6	5
AO fracture type		
A	11	9
B	20	19
C	72	75
Operation duration (minutes), mean ± SD	126	125

Table 2: Reasons for surgical revisions based on postoperative CT-scan

Radiological outcome	**2D group**	**3D group**	**p-value**
Intra-articular screw	10	6	
Gap + Step > 2mm	11	4	
Step > 2mm	8	5	
Screw too long	7	4	
Gap > 2mm	1	6	
Angulation (volar)	0	1	
Angulation (dorsal)	2	0	
Total revisions	**39**	**26**	**0.07**

availability of 3D fluoroscopy and 103 to conventional 2D fluoroscopy alone (Figure 2). The mean age of the patients was 52 years (± SD 14) and 56% (n= 116) were female. Baseline characteristics of the patients included for analysis did not differ significantly between the two treatment groups (Table 1).

Primary outcome

Postoperative CT-scan images were not available for three patients in the 2D group and one patient in the 3D group. Based on the postoperative CT-scans, the decision on whether the fracture required revision surgery was 31% (n=32) in the 2D group versus 24% (n=25) in the 3D group (p=0.30, 95% CI 0.37-1.28). Reasons for the revisions deemed necessary are displayed in Table 2.

Secondary outcomes

In 11 of the 103 (11%) operated distal radius fractures allocated to the 3D group, additional intraoperative corrections were performed. Changes made intraoperatively were: replacement of too long screws (n=6), replacement of intra-articular screws (n=4), and replacement of a too short screw (n=1). Figure 3 shows an example of an intraoperative 2D and corresponding 3D image.

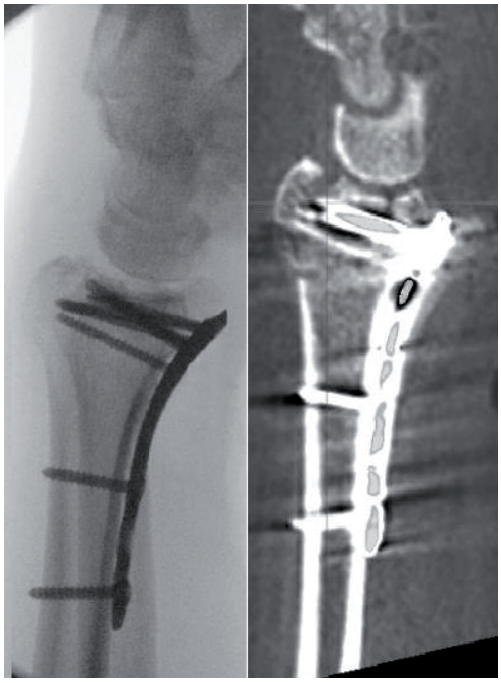

Figure 3: Intraoperative 2D and corresponding 3D image

Table 3: Reasons for revision surgery performed within one year follow-up

Indication	2D group	3D group
Dislocation volar fragment	3	1
Delayed union	2	0
Intra-articular screw	2	0
Malunion	1	1
Step-off	1	0
Synostosis distal radio-ulnar joint (DRUJ)	1	0
Dislocation dorsal fragment	0	1
Scapho-lunate (SL) instability	0	1
Total	**10**	**4**

A total of 4 revision surgeries were performed in the 3D group compared to 10 revision surgeries in the 2D group ($p = 0.16$) during the one year follow-up. Reasons for revision surgery performed within one year are displayed in Table 3.

There were no significant differences in complications between the study arms, 23 patients with complications in the 2D group vs. 21 patients with complications in the 3D group ($p=0.73$). Hardware removal was the most common complication, followed by wound infec-

Table 4: Types of complications during 1 year

Complication	2D group	3D group	p-value
Hardware removal	16	11	
Wound infection	1	4	
CTS	3	1	
Wound dehiscence	2	3	
CRPS	1	3	
Other	3	1	
Tendon injury	1	0	
Total	**27**	**23**	**0.41**

tion, carpal tunnel syndrome (CTS), wound dehiscence, CRPS type I, and tendon injury (partial flexor pollicus longus rupture) (Table 4).

The median PRWE score at 12 weeks follow-up (response rate 67%) for patients in the 3D group was 26 [IQR 12-42] compared to 27 [IQR 10-40] for patients in the 2D group (p=0.9). At one year follow-up the median PRWE score (response rate = 65%) was the same in both groups (3D group 8 [IQR 2-26] vs. 8 [2-26] 2D group (p=0.80)).

DISCUSSION

This multicenter randomized trial shows that the use of intraoperative 3D fluoroscopy, compared to 2D fluoroscopy does not appear to improve the quality of reduction and fixation in the management of distal radius fractures. However, because this study was slightly underpowered there may be a difference that this study could not show completely. Though not significant, more intraoperative changes were made in the 3D group and less revision surgeries were performed, indicating possible the advantages of this technique.

The indication for revision based on the postoperative CT-scans was lower after 3D than after 2D fluoroscopy. Atesok et al. identified an unacceptable reduction or fixation in 11% of the cases and Richter et al. described a need for revision in up to 39% with the use of 3D fluoroscopy [4,12]. Similar to a previous study by Hufner et al., reporting direct revision of fracture reduction in 10.5% of the cases, we performed direct revisions intraoperatively in 10% of the cases[3]. Our study showed post-operative revisions in 4-10% of the cases, indicating that even though revision may be deemed necessary in a larger percentage of cases, the step to performing the revision surgery is high.

Intra-articular penetration of screws is a well-known complication of volar plate fixation for distal radius fractures. Even though there was no significant difference in revisions deemed

necessary, the difference in intra-articular screw positioning was nearly 50%. An additional 11% of changes were made due to the 3D fluoroscopy, which may explain the difference in postoperative intra-articular screws. This is in accordance with previous studies showing an intra-articular screw replacement percentage of 5-20% with 3D fluoroscopy [6,12-14]. These authors vary in their conclusions about the use of 3D fluoroscopy in daily practice. In one study 3D fluoroscopic scanning was not implemented due to the technical demands and the time and costs involved, despite the additional detection of intra-articular screws [14]. Because 3D scans were performed in both groups in this study, we were not able to make definitive conclusions about the extra time added to operation duration. Another study, however, argues that intraoperative 3D fluoroscopy provides extra information, and the extra surgery time and radiation is justified by the added precision and potential decrease in revision surgery rate [13].

With the frequent occurrence of intraoperative corrections, and 7% difference in whether revision surgery appears necessary or not, it is likely that 3D fluoroscopy has some advantage. Furthermore, a nearly significant difference was found in the amount of revisions deemed necessary. Although not statistically significant in our study, a reduction of 60% in revision surgeries performed within one year, is certainly clinically relevant. Using 3D intra-operatively could help reduce the number of intra-articular screws and improve corrections of intra-articular gaps and steps. Future studies should further elucidate and specify these advantages, as the numbers in this study are not large enough, potentially by narrowing down the indications for use of this technique.

This study has several limitations. This study was slightly underpowered, although it did have a large study population. Differences between the 2D and 3D group were not statistically significant, but these differences have clinical implications. Full recruitment may have led to more prominent differences between the treatment groups. . After the completion of this study, the image quality of 3D fluoroscopy has improved with the introduction of newer software and hardware systems. In this study it was often difficult to interpret the images due to the amount of scattering caused by the implants. Improved imaging quality may lead to better recognition of reduction and fixation during the operation. However, it is unclear whether an increased visibility and number of intraoperative corrections will affect the patients' functional outcome, as these were already very good. There was a large difference between revisions performed intraoperatively and those deemed necessary. The higher rates of revision deemed necessary may be partially explained by the Hawthorne effect. This is effect is used to explain change due to an awareness of being observed, or in this case that the reviewers were excessively vigilant for "sub-optimal" fracture reduction and fixation[15].The threshold to perform a revision postoperatively based on a postoperative CT-scan may be high and surgeons prefer to observe functional outcomes postoperatively before performing revisions surgery based solely on a CT-scan.

The decision on whether post-operative revision was necessary, despite being based on several criteria, may be interpreted differently by reviewers.

Our primary outcome, the quality of fracture reduction and fixation, as measured on a post-operative CT-scan, did not appear to show a significant difference in both groups. However, in the 3D group additional changes were made in 11% of the patients, less intra-articular screws were placed, and less revision surgeries were performed. The clinical consequences of these findings should be further analyzed.

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Chapter 9

PATIENT-REPORTED OUTCOMES FOLLOWING ARTHROSCOPIC TRIANGULAR FIBROCARTILAGE COMPLEX REPAIR

C.A. Selles, P.N. d'Ailly, N.W.L Schep.

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ABSTRACT

Background Triangular fibrocartilage complex (TFCC) injury is a common cause of ulnar-sided wrist pain, which may lead to serious physical impairments. Arthroscopic repair has benefits such as less soft tissue damage, greater surgical accuracy, and may lead to faster recovery than open repair.

Objective The purpose of this study was to determine the functional outcome of patients with symptomatic TFCC injuries treated with arthroscopic debridement or repair.

Patients and Methods A retrospective study of all consecutive patients with a TFCC injury treated arthroscopically was conducted. The primary outcome was the patient rated wrist evaluation (PRWE) score. Secondary outcomes were, pain, operative findings, complications, and additional treatment.

Results A total of 51 patients with a median follow-up of 16.5 months (interquartile range [IQR]: 13–25) were included. Injuries were treated with TFCC debridement (n = 25), TFCC ligament to capsule suturing (n = 10), TFCC debridement and ligament to capsule suturing (n = 7), TFCC debridement and synovectomy (n = 5), and TFCC foveal reinsertion with a suture anchor (n = 4). The median PRWE was 19.5 (IQR: 6–49). Complications occurred in three patients and in nine patients additional surgery was performed.

Conclusion Arthroscopic treatment of TFCC lesions leads to satisfactory functional outcomes.

INTRODCUTION

Triangular fibrocartilage complex (TFCC) injury is a common cause of ulnar-sided wrist pain, which may lead to serious physical impairments[1]. Since Palmer first described and categorized TFCC injuries in 1981, many different surgical techniques have been described to treat these injuries[2,3].

Open repair of TFCC injuries was one of the first described operations[4]. In more recent studies, arthroscopic TFCC repair has shown to have comparable outcomes compared with open repair[5]. Ulnar peripheral lesions of the TFCC can be treated with arthroscopic ligament to capsule suturing[6,7]. TFCC foveal loosening can be repaired with arthroscopic fixation with a suture anchor whereas central lesions are usually treated by arthroscopic debridement[3,8]. Arthroscopic repair has benefits such as less soft tissue damage, greater surgical accuracy, and may lead to faster recovery than open repair[9,10].

Few studies have described the functional outcomes, measured with patient rated outcome measures, of patients following arthroscopic treatment of TFCC injuries[8,11]. These studies are usually pertaining to a specific type of arthroscopic technique or specific type of lesion. Therefore, the aim of this study was to determine the functional outcome of patients with symptomatic TFCC injuries treated with arthroscopic
debridement or suture repair.

PATIENTS AND METHODS

In this single center retrospective cohort study all consecutive patients with a TFCC injury treated arthroscopically in a single hospital between March 2015 and January 2018 were reviewed. All surgeries were performed by a single surgeon with an experience level V according to Tang[12].

All patients with arthroscopically confirmed and treated TFCC injuries were included. Minimum follow-up was 6 months and was determined as the time between the arthroscopy and completion of the patient related outcome.

The primary outcome was the patient-rated wrist evaluation (PRWE) score. The PRWE is a 15-item questionnaire that measures wrist pain and disability in activities of daily living. The highest score, indicating severe impairment, is 100 and the best score, indicating no impairment, is zero[13]. Secondary outcomes were, pain as indicated on the visual analogue scale (VAS), operative findings, complications, and additional treatment.

Table 1: Palmer classification for TFCC acute and degenerative traumatic tears

Type lesion	Description
Type 1	Acute traumatic tear
1A	Central perforation
1B	Ulnar avulsion with or withouth distal ulnar fracture
1C	Distal avulsion
1D	Radial avulsion with or without sigmoid notch fracture
Type 2	Degenerative
2A	TFCC wear
2B	TFCC wear with lunate and/or ulnar chondromalacia
2C	TFCC perforation with lunate and/or ulnar chondromalacia
2D	TFCC perforation with lunate and/or ulnar chondromalacia with lunotriquetral ligament perforation
2E	TFCC perforation with lunate and/or ulnar chondromalacia with lunotriquetral ligament perforation and ulnocarpal/radioulnar arthritis

Patient characteristics were collected using the clinical records. All patients were contacted by phone and asked to complete the PRWE questionnaire and to verify patient characteristics missing from their medical record. Types of arthroscopic interventions performed were debridement of central TFCC tears with or without additional synovectomy, ligament to capsule suture repair or TFCC reinsertion in the fovea with a suture anchor. Occupation was categorized by type: desk-based, manual labor, domestic, retired, unemployed or unknown. Students were grouped under desk-based occupation as well.

Classification of TFCC Tears

Palmer classified TFCC injuries. This classification categorizes TFCC lesions as traumatic (type 1) or degenerative (type 2). Traumatic lesions are classified according to the location of the injury (Table 1). Degenerative lesions are classified according to the extent of degeneration[14].

The "iceberg concept" according to Atzei presents a visual representation of the TFCC. The tip of the iceberg represents the TFCC part that functions as the shock absorber. The two base points represent the foveal insertion of the TFCC functioning as the stabilizer of the DRUJ (distal radioulnar joint) and the ulnar carpus[15]. An intact TFCC is soft and compliant, producing a "trampoline effect" when pressure is applied with a probe; this indicates a positive trampoline test[1]. This effect is gone when there is a peripheral TFCC tear. The hook test is performed by applying traction with the probe onto the free edge of the TFCC[6]. The test is considered positive when the TFCC can be lifted from the foveal area toward the center of the radiocarpal joint, indicating a proximal TFCC tear and thus foveal loosening. Both trampoline and hook test are considered reliable in diagnosing and classifying peripheral TFCC tears.

Operative Technique

During wrist arthroscopy the forearm was in an upright and neutral position and was held in an arc wrist tower (Acumed, Hampshire, United Kingdom). The elbow was flexed at 90 degrees and axial traction of 4 kg was applied. Four portal entries were created by superficial stab incisions and blunt preparation through the joint capsule; the 3-4, 6-R one midcarpal radial and one midcarpal ulnar portal. The 3-4 portal was used for visualization and the 6-R portal for instrumentation. With the 1mm hook probe assessment of the TFCC was performed. Type 1A, 2A, 2B, 2C, and 2D TFCC injuries were treated with debridement of the TFCC lesion and an additional synovectomy with a small duckbill or shaver.

Type 1B injuries were treated with either a simple ligament to capsule suture or a reinsertion of the TFCC at the fovea with a suture anchor (Mitek Mini QUICKANCHOR, DePuy Synthes Companies, Zuchwil, Switzerland) when the hook test was considered positive. The fovea was identified through a direct fovea incision just volar of the distal ulna. Next the fovea was debrided with a small rongeur. A Mitek anchor was inserted. At this stage both the sutures of the anchor were on the outside. The ends of the sutures were positioned in a needle, one by one and aimed through the TFCC inside the joint. Subsequently, both suture ends were brought outside through the 6R portal and were tightened in that manner that the knot was positioned inside on the TFCC.

Postoperatively, all patients had an above the elbow cast for 4 weeks followed by 2 weeks a short arm cast. Patients with a grossly unstable distal radioulnar joints were not treated arthroscopically but scheduled for open repair. The elbow was positioned in 90 degrees of flexion. The examiner fixed the radius with one hand. With the other hand the distal ulna was pushed volarly and dorsally with the wrist in neutral position. When the distal ulna balotted out of the sigmoid noth during balottement test, it was defined as grossly unstable. All patients were offered hand therapy postoperatively.

Statistical Analysis

General descriptive statistics on patient characteristics at baseline were performed including factors such as gender and age and presented as percentages (categorical variables), means and standard deviation (continuous variables, normally distributed) or median and interquartile range (continuous variables, not normally distributed), whichever applicable.
The difference in PRWE scores between groups was analyzed with the Mann-Whitney U test (not normally distributed data). Values of $p< 0.05$ were considered significant.

Table 2: MRI conclusion vs. arthroscopic findings

Arthroscopic finding	MRI conclusion		
	TFCC tear	**No TFCC tear**	**Inconclusive**
TFCC tear	12	10	2

Table 3: Patient characteristics (N=51)

	Number
Gender	
Male	26
Female	25
Age, median [IQR]	33 [21-45]
Dominant hand affected	23
Occupation	
Manual labor	26
Desk labor	17
Unemployed	6
Domestic	1
Missing	1
Previous trauma	45
with distal radius fracture	10

RESULTS

A total of 51 patients with a median follow-up of 16.5months (IQR 13–25) were included in this cohort study, of which 12 patients had a follow-up of 24 months or more. The median age was 33 years (IQR 21–45) and 51%were females. Patients were seen after visiting our Emergency Room (n = 24), referred by other specialists (n = 23) or by the general practitioner (n = 4). All patients presented with wrist pain, of which 41 had specific ulnar-sided wrist pain and a positive fovea sign. Forty-five patients had a previous trauma of the wrist, of which 10 had a concomitant fracture of the distal radius. Preoperative MRI imaging was performed in 24 patients, of which 12 showed a TFCC tear (Table 2). Patient characteristics are displayed in Table 3.

A total of 39 patients suffered traumatic TFCC injuries and 12 patients had a degenerative TFCC injury (Table 4). The 22 patients with 1B lesions when classified according to Atzei were 11 class 1 lesions, 6 class 2 lesions, and 5 class 3 lesions. Additional SL (scapholunate) lesions were found in 10 patients and additional LT lesions in 8 patients. Classification of the lesions is presented in Table 5.

Out of the 51 patients invited to complete the PRWE questionnaire, 44 patients responded. The median PRWE was 19.5 (IQR 6–49). Median VAS at follow-up was 0 (IQR 0–2).

Table 4: TFCC classification of patients (N=51)

TFCC	Number
1A	13
1B	22
1C	1
1A + 1B	1
1A + 1C	1
1B + 1C	1
2A	4
2B	3
2C	4
2D	1

Table 5: Geissler classification of additonal lesions

	Number
SL lesions	
None	39
Grade 1	1
Grade 2	4
Grade 3	6
Grade 4	1
LT lesions	
None	43
Grade 1	4
Grade 2	1
Grade 3	1
Grade 4	2

Injuries were treated with TFCC debridement (n = 25), TFCC ligament to capsule suturing (n = 10), TFCC debridement and ligament to capsule suturing (n = 7), TFCC debridement and synovectomy (n = 5), and TFCC foveal reinsertion with a suture anchor (n = 4). Median PRWE did not differ significantly between patients treated for Palmer type A lesions (17 [IQR 6–49]) and Palmer type B lesions (23 [IQR 3–50]; p = 0.9). There was also no significant difference in median PRWE scores between type 1 and type 2 Palmer lesions (21 [8–51] vs. 12 [2–43], p = 0.30).

Three patients had pain due to the polydioxanone suture. After removal of the suture knot these complaints disappeared. No other complications were found.

In nine patients additional surgery was performed. These nine patients had a median PRWE score of 51 (7–80). An ulna shortening osteotomy was performed in three patients. These were all patients with Palmer2C lesions in which debridement of the central TFCC perfora-

tion provided insufficient pain relief. Two patients had an additional arthroscopy, one for an additional debridement of the same TFCC lesion, and another for a new 1B TFCC lesion. Due to persistent pain caused by midcarpal and radiocarpal osteoarthritis a wrist denervation was performed in two patients. One patient with a 1B lesion had an open repair 6 months after arthroscopic ligament to capsule suturing of the lesion. One patient had a proximal row carpectomy followed by a radioscapholunate arthrodesis due to complaints caused by osteoarthritis in the 1 year following initial arthroscopy. Patients who had additional procedures performed had clinically worse PRWE scores, a median of 51 (IQR 7–80) versus a median of 19 (IQR 5–43), but this difference was not statistically different ($p = 0.18$).

DISCUSSION

The results of this study show that arthroscopic treatment of TFCC lesions leads to satisfactory functional outcomes. The median PRWE after 16.5 months follow-up was 19.5.

It must also be taken into account that arthroscopic treatment of a TFCC lesion may not always provide sufficient results. Our study showed that nine patients (18%) needed additional treatment such as ulnar shortening osteotomies, additional arthroscopy, or open TFCC repair. These findings are similar to the additional surgical procedures in 17 to 29% of cases reported in the literature[16,17].

Magnetic resonance imaging (MRI) is frequently used to detect TFCC tears[18]. The wide variety in quality of MRI and interpretation of MRI results in a range of sensitivity from 0.76 to 1.0 and specificity from 0.41 to 1.0[19]. MRI was performed in half of our patients. MRI, in this series, was only able to detect a TFCC in half of the patients with an arthroscopically confirmed TFCC lesion. Persistent ulnar-sided wrist pain, without abnormalities on MRI, may therefore not always exclude a TFCC lesion.

There are several limitations to this study. Due to its retrospective nature, no presurgical data were available to compare the functional outcomes with the postoperative ones. Despite the usually detailed medical records, more subtle complications such as sensory nerve damage may not have been documented. Functional outcomes were, however, collected prospectively. Furthermore, patients with all types of TFCC lesions were assessed in this study resulting in a heterogeneous group. The results, however, do provide a general overview of the functional outcomes of arthroscopic treatment and no difference was found between Palmer type A and type B lesions.

Time to follow-up ranged from 7 to 75 months. All patients did not have the same amount of time to recover and some had additional procedures performed during this time period. Although not statistically different, patients with additional procedures had clinically worse PRWE scores, with a difference of 32 points. The minimal clinical important difference for the PRWE score is 11.5 points[20]. This difference in follow-up affected the range in PRWE score.

The effect of arthroscopic treatment of TFCC lesions, measured with patient-rated outcomes, has been described by several studies. Studies addressing central lesions have shown that arthroscopic debridement efficiently reduces wrist pain and yields mean PRWE scores of 17[8]. Regarding arthroscopic treatment of peripheral tears, PRWE scores ranging from 19 to 33 with a follow-up range of 11.5 to 17.5 months have been reported[11,21]. These PRWE scores described are comparable to our median PRWE of 19.5, concluding that arthroscopic treatment of TFCC lesions leads to acceptable functional outcomes.

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Chapter 10

PLATE FIXATION FOR UNSTABLE DISPLACED DISTAL RADIUS FRACTURES IN CHILDREN

J.C. van Egmond*, C.A. Selles*, G.R. Roukema,
C.H. van der Vlies, B.I. Cleffken, N.W.L. Schep.

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**contributed equally*

ABSTRACT

Background Distal radius fractures in children are normally treated by plaster immobilization. For displaced unstable distal radius fractures, closed reduction and Kirschner wire (k-wire) fixation can be performed. Disadvantages of k-wire fixation are the need for postoperative plaster treatment for several weeks, which may induce stiffness, and the risks of complications such as tendon irritation and pin-track infections. More invasive volar plate fixation is less popular, although this allows for direct mobilization and enhances anatomical reduction.

Purpose To present the functional outcomes of pediatric patients treated with volar plate fixation for unstable displaced distal radius fractures.

Patients and Methods A retrospective cohort study of all consecutive pediatric patients between September 2010 and July 2017 was performed. A total of 26 patients with a median age of 12.5 years were included. The primary objective was functional outcome determined by the Patient-Rated Wrist Evaluation (PRWE) questionnaire. Secondary objectives were range of motion, grip strength, radiological parameters, complications, and incidence of plate removal.

Results Median PRWE score was 3 after a median follow-up of 29 months. Range of motion and grip strength did not differ significantly between the injured and uninjured wrists. No wound infections were found. Plate removal was performed in 15 patients (58%).

Conclusion Volar plate fixation for unstable displaced distal radius fractures in children provides good functional and radiological outcomes with minor complications.

INTRODUCTION

Fractures of the wrist account for 25 to 36% of all pediatric fractures[1-5]. Displaced distal radius fractures are treated by closed reduction and a plaster cast or splint with satisfying results[6]. However, redisplacement requiring further intervention is described in up to 39% of pediatric patients treated with closed reduction and casting[7,8].

Although pediatric patients have remodeling potential, unstable fractures and fractures with a rotational deformity require reduction and fixation[9]. Kirschner wire (k-wire) fixation is frequently used for distal radius fractures, and elastic stable intramedullary nailing (ESIN) is mostly used for distal forearm fractures[10-13]. A disadvantage of k-wire fixation is the need for postoperative plaster treatment resulting in stiffness of the hand and wrist. Moreover, complications such as pin track infection, tendon irritation, and migration of k-wires are found in up to 38% of cases[8,11].

More invasive volar plate fixation is less popular in pediatric patients. However, volar plate fixation enhances anatomical reduction and allows for functional postoperative treatment. This may lead to less redisplacement, malunions, and improved functional outcome. To the best of our knowledge, only one case study is available that describes volar plate fixation for a displaced distal radius fracture in a 13-year-old child[14].

The purpose of this study is to present a cohort of pediatric patients treated by volar plate fixation for unstable displaced distal radius fractures. Primary objective was patient-related outcome determined by the Patient-Rated Wrist Evaluation (PRWE) after at least 12 months of follow-up. Secondary objectives were range of motion and grip strength compared to the uninjured wrist, postoperative radiological parameters, complications, and incidence of plate removal.

PATIENTS AND METHODS

This retrospective observational study was conducted according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement guidelines. The setting was a level 2 trauma center specialized in hand and wrist fractures. Data collection was performed after approval from the institutional review board. Through a database search, all consecutive pediatric patients surgically treated for a distal radius fracture (type AO 23r-M/3.1 and 3.2) between September 2010 and July 2017 were screened for inclusion. Pediatric patients were defined as patients between 4 and 17 years of age. The indication for surgery was redisplacement following closed reduction, complete cortical displacement,

or the inability to reach an acceptable closed reduction. An acceptable closed reduction was defined as follows: for children younger than 12 years, acceptable angles were volar or dorsal tilt < 25 degrees and ulnar or radial angulation < 10 degrees. For children older than 12 years, acceptable angles were volar or dorsal tilt < 10 degrees and ulnar or radial angulation < 10 degrees. Patients treated with ESIN, k-wire, and closed reduction were excluded, and only patients treated with volar plate fixation were included. Some patients were scheduled for k-wire fixation, but when an acceptable closed reduction could not be reached, open reduction and volar plate fixation was performed. These patients were also included in the study. Medical records were screened for complications.

The primary objective was the PRWE questionnaire after at least 12 months of follow-up. The PRWE score ranges from 0 to 100, with 0 indicating no pain and no functional impairment[15]. Secondary objectives were range of motion and grip strength compared to the uninjured wrist, postoperative radiological parameters, complications, and incidence of plate removal.

Patients or their parents were contacted by telephone to visit the outpatient clinic to fill out the questionnaires and for physical examination. When the patient was not reached by three separate attempts, they were considered as lost to follow-up. When patients were not able to visit the outpatient clinic, the PRWE questionnaire was sent by mail. Missing scores were due to impossibility to reach the patient or inability of the patient to visit the outpatient clinic. Clinical Evaluation Range of motion was measured using a goniometer. The parameters included radial and ulnar deviation, pronation and supination, and dorsal and palmar flexion. Grip strength was measured using a Baseline Hydraulic Hand dynamometer (Fabrications Enterprises Incorporated, White Plains, NY). This was performed three times, and an average of these measurements was used. Both range of motion and grip strength were measured for the injured and uninjured sides.

Radiographic Outcome

Standard radiographs were performed during emergency department visit, intraoperative by fluoroscopy and at 6 weeks postoperative follow-up. Further radiographs were performed on indication. Postoperative x-rays of the wrist were assessed independently by J. E. and C. S. for radiological outcome. A mean score was calculated for each radiological parameter. When the measured angels were in excess of 5 degrees, N. S. was contacted to assess the radiograph as well. The following radiographic parameters were determined: radial inclination, radial height, ulnar variance, carpal alignment, palmar tilt, and dorsal tilt. As the wrist was incompletely ossified, ulnar variance was measured according to that described by Hafner et al[16]. The distance between the most distal point of the ulnar metaphysis to the most distal point of the radial metaphysis was determined. Carpal alignment was determined using the perpendicular method in which one line along the inner rim of the volar

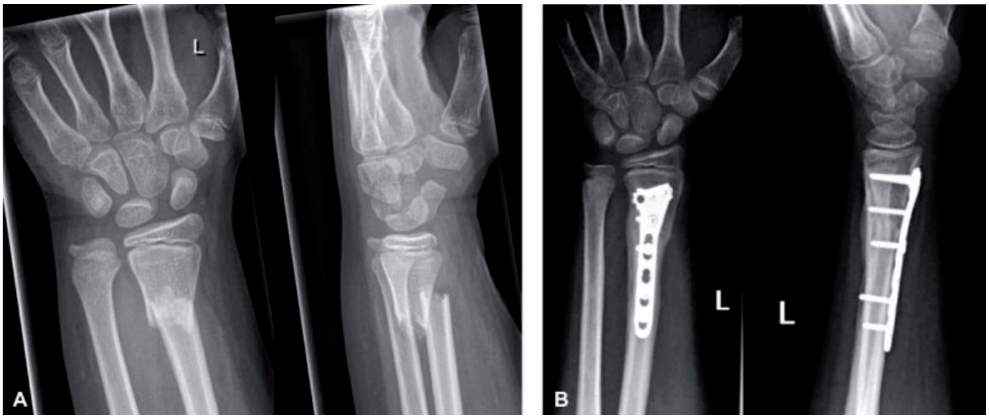

Figure 1: X-ray of (A) preoperative and (B) postoperative volar plate fixation.

cortex of the radius and one perpendicular line to the center of the capitate. The carpus is aligned when the line along the inner rim transects the center of the capitate[17].

Operative Technique

Before surgery, informed consent was obtained from caregivers of all patients. All patients received general anesthesia and antibiotic prophylaxis with cefazolin (50 mg/kg, maximal 2 g). A tourniquet was inflated. The arm was extended in a supinated position on a fluoroscopically translucent table. The surgical approach was performed through a modified Henry approach[18,19]. Next, the pronator quadratus muscle was detached in an L-shaped pattern, remaining attached on the ulnar side, and released subperiosteally from the radius. Following anatomical reduction of the fracture, a locking compression distal radius plate (DePuy Synthes, Zuchwil, Switzerland) was used. When the radius had a small diameter, mostly the T- and L-shaped dorsal plates were used for volar fixation. (Fig. 1) The positioning of the most distal screws proximal from the epiphysis was verified with fluoroscopy. The pronator quadratus muscle was not repaired to the radius. The skin was closed with soluble subcutaneous stitches. A pressure bandage was applied for 48 hours, and patients were allowed immediate postoperative mobilization.

Statistical Analysis

Descriptive statistics were performed to show patient characteristics and surgical details. Normally distributed data were reported as mean and standard deviation (SD), and nonnormally distributed data were reported as median with interquartile range (IQR). Normality was analyzed by plotting the data distribution in a histogram. Categorical data were presented as absolute frequency and percentage. Paired Student's t-test was used to compare range of motion and grip strength of the injured side compared to the uninjured side.

RESULTS

Between September 2010 and July 2017, a total of 123 pediatric patients were surgically treated for unstable distal radius fractures; 91 were treated by k-wire fixation and 6 were treated by ESIN.
A total of 26 pediatric patients were treated by volar plate fixation. Median age was 12.5 (IQR: 9–15) years at the time of surgery. Eight patients were female. Median follow-up was 29 months (IQR: 18–38). A total of 19 (73%) patients completed the PRWE questionnaire and 16 patients (62%) visited the outpatient clinic for physical examination. In total, 7 (27%) patients were lost to follow-up, and for 10 (48%) patients, no physical examination was possible.

Outcome
Median PRWE score was 3 (IQR: 0–10). Range of motion and grip strength are presented in (Table 1). Postoperative mean radiological parameters were a radial inclination of 21 degrees (SD 4), radial height of 9 mm (SD: 2), and an ulnar variance of negative 2 mm (SD: 2). Twelve patients had palmar tilt (mean: 7 degrees; SD: 4) and fourteen patients had dorsal tilt (mean: 5 degrees; SD: 3). Carpal alignment was achieved in 22 patients, with a median of 0 mm (IQR: –1 to 0.3).

Two patients had a complication involving postoperative stiffness of the wrist. Both were successfully treated with physical therapy. No wound infections were found after plate fixation and plate removal. Plate removal was performed in 15 patients, mostly due to routine removal (n = 9). Routine removal was performed at the discretion of the surgeon after 6 months to prevent possible future plate-related problems. In the remaining six patients, plate removal was performed because of pain or the patient's wish for removal. Median time to plate removal was 8 months (IQR: 5–8).

DISCUSSION

Surgical treatment of distal radius fractures in children is mostly performed by closed reduction and k-wire fixation. Disadvantages of k-wire fixation include the need for postoperative plaster treatment for several weeks, which may induce stiffness, tendon irritation, or rupture, and pin-track infections. Unfortunately, no exact rates of tendon rupture after k-wire fixation have been reported.8 More invasive volar plate fixation is less popular, although this allows for direct mobilization and enhances anatomical reduction. This may lead to less redisplacement, malunion, and improved functional outcome.

Table 1: Clinical outcome – range of motion and grip strength
All values are presented as mean (standard deviation)

Range of motion	Injured side	Uninjured side	Difference	p-value
Radial deviation	18 (5)	18 (5)	-	-
Ulnar deviation	28 (5)	32 (16)	4.3 (15)	0.3
Pronation	85 (0)	85 (0)	-	-
Supination	84 (3)	84 (2)	0 (2)	1
Dorsal flexion	79 (5)	78 (5)	0.6 (3)	0.4
Volar flexion	81 (5)	81 (4)	0.7 (2)	0.1
Grip strength (kg)	26 (9)	27 (10)	0.6 (4)	0.5

This cohort of 26 pediatric patients with displaced unstable distal radius fracture treated with a volar plate fixation was analyzed for postoperative functional outcomes. A good functional outcome, determined by the PRWE, was found. Moreover, no wound infections were found. Radiological outcome was determined on postoperative radiographs, which showed good results.

A disadvantage of volar plate fixation is the possible need for hardware removal. Fifteen (58%) patients underwent plate removal. No complications occurred following removal. In 23% of the patients (n = 6), plate removal was performed because of plate-related complaints. Complaints were pain (n = 5) and stiffness (n = 1). All other procedures (n = 9) were performed on routine basis. However, there is no evidence for the need for routine plate removal, and the optimal timing for plate removal is not known. Some authors even advise not to remove plates on routine basis since the advantages of removal and interference of growth are largely theoretical[20]. As concluded by Schmittenbecher, implant removal should be individually assessed since this is a more extensive procedure and there is a lack of evidence to support routine removal[21].
In contrast to the high complication rate of 16 to 38% for k-wire fixation (superficial infection, skin irritation, and migration of wires), only two complications of temporary stiffness (n = 2; 8%) were found in our cohort following volar plate fixation[8,11].

Since volar plate fixation of pediatric distal radius fractures is rare, no appropriate plate is available. Therefore, we noticed variable adjustments of plates to get these to match the radius. Further development of plates may be needed when plate fixation in pediatrics is performed more frequently.

The strength of this cohort study is its relatively long median follow-up of 29 months, providing valuable data on outcome, complications, and plate removal. However, this study also has some limitations. First, this is a retrospective cohort study with all its known and unknown forms of bias. Therefore, the registration of complications can be an underesti-

mation. However, all medical records were extensively screened, and all patients followed a strict follow-up protocol postoperatively. Secondly, although the PRWE score is not validated for children, this score was used to determine functional outcome since no other validated pediatric score in trauma is available. We presume this outcome is accurate since the questionnaire was completed with the help of one of the parents when necessary.

In conclusion, volar plate fixation for displaced distal radius fractures in pediatric patients provides good functional and radiological outcomes with minor complications.

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Chapter 11

FUNCTIONAL OUTCOMES AFTER CORRECTIVE OSTEOTOMY OF SYMPTOMATIC DISTAL RADIUS MALUNIONS IN CHILDREN

C.A. Selles, M.A.M. Mulders, B.I. Cleffken,
G.R. Roukema, C.H. van der Vlies, N.W.L. Schep.

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ABSTRACT

Background Closed reduction and cast immobilization of displaced distal radius fractures carries the risk of secondary displacement, which could result in a symptomatic malunion. In patients with a symptomatic malunion, a corrective osteotomy can be performed to improve pain and functional impairment of the wrist joint.

Objective The aim of this study was to assess the functional outcomes of children who underwent a corrective osteotomy due to a symptomatic malunion of the distal radius.

Patients and Methods Between 2009 and 2016, all consecutive corrective osteotomies of the distal radius of patients younger than 18 years were reviewed. The primary outcome was functional outcome assessed with the ABILHAND-Kids score. Secondary outcomes were QuickDASH (Quick Disabilities of Arm, Shoulder, and Hand) score, range of motion, complications, and radiological outcomes.

Results A total of 13 patients with a median age of 13 years (interquartile range [IQR]: 12.5–16) were included. The median time to follow-up was 31 months (IQR: 26–51). The median ABILHAND-Kids score was 42 (range: 37–42), and the median QuickDASH was 0 (range: 0–39). Range of motion did not differ significantly between the injured and the uninjured sides for all parameters. One patient had a nonunion requiring additional operative treatment. The postoperative radiological parameters showed an improvement of radial inclination, radial height, ulnar variance, dorsal tilt, and dorsal tilt.

Conclusion Corrective osteotomy for children is an effective method for treating symptomatic malunions of the distal radius.

INTRODUCTION

Displaced fractures of the distal radius in children are usually managed by closed reduction and cast immobilization, whereas unstable fractures are mostly fixed with Kirschner wires (K–wires). However, these treatment modalities may lead to secondary displacement, which, in turn, may lead to a symptomatic malunion of the distal radius. A malunion of the distal radius can become symptomatic causing pain, weakness, or functional impairment of the wrist joint[1,2].

Various types of corrective osteotomies have been developed for treating distal radius malunions. An open wedge osteotomy is a technique that can be performed to correct radial length, radial inclination, and rotation[3]. Open wedge osteotomy is an established technique in adult patients[4]. A fixed-angle plate can be used as a lever device to correct the deformity[5]. When there is only radial shortening, simple radius lengthening will suffice.

Functional outcomes measured with patient-rated outcome measures have been performed for adult patients undergoing a corrective osteotomy[4]. However, a few studies have been performed on corrective osteotomies in children. The existing studies usually report on radiological parameters and not on functional outcomes of these patients[6,7]. Functional outcomes may help clinicians in their decision-making as well as in informing patients and their parents about the outcomes prior to surgery. Therefore, the aim of this study is to assess the functional outcomes in children who underwent a corrective osteotomy due to a symptomatic malunion of the distal radius.

PATIENTS AND METHODS

In this retrospective cohort study, all consecutive pediatric (under 18 years of age) patients who underwent a corrective osteotomy for a symptomatic distal radius malunion between 2009 and 2016 were evaluated. Patients undergoing a corrective osteotomy due to a malunion of the distal radius for any other reason than a previous trauma, such as Kienbock's disease, were excluded.

Malunion, as measured on plain radiographs, for full-grown patients or those 16 years and older was defined as radial inclination $\leq 15^0$, loss of radial height $\geq$ 5 mm, dorsal angulation $\geq 15^0$ and palmar angulation $\geq 20^0$[8]. For patients between 6 and 16 years of age, dorsal angulation of more than 20 degrees and palmar angulation of more than 25 degrees was considered a malunion.

In patients up to 6 years of age, any degree of angulation was accepted unless this was symptomatic. Moreover, malunion was also defined as more than 2-mm positive ulnar variance, one-third shaft displacement, malrotation, and DRUJ incongruency. All patients had to have symptomatic malunions.

The primary outcome was the ABILHAND-Kids score. This questionnaire, filled in by parents with their children, is a measure of the manual ability for children with upper limb impairments. The scale is validated for children with cerebral palsy. The scale ranges from 0 to 42, with 42 indicating a maximum score in a child's ability to manage daily activities that require the use of the upper limb[9]. Secondary outcomes were the Quick Disability of the Arm, Shoulder, and Hand (QuickDASH) score, range of motion, and grip strength compared with the injured wrist, pain as indicated on the visual analog scale (VAS), radiological parameters, time to union, and complications. The QuickDASH is an eleven item questionnaire designed to measure physical function and symptoms in people with a musculoskeletal disorder of the upper limb, valid for older children and adolescents[10]. The QuickDASH ranges from 0 to 100, with 0 indicating no pain and no functional impairment[11,12].

Surgical Technique

All corrective osteotomies were performed by two highly experienced surgeons as classified by Tang[13]. Antibiotic prophylaxis (cefazolin 30mg/kg) was given preoperatively. The Henry volar approach was used in all patients. The radius was exposed and the appropriate level of the osteotomy was determined, after which an open wedge or lengthening osteotomy was performed. A graft was used if more than 1 cm of lengthening was necessary. The grafts consisted of demineralized bone matrix (DBM), autogenic grafts, and allogenic hipbone grafts. Ulnar epiphysiodesis was performed to prevent progressive ulnar growth after radial lengthening of a radius with closed physis was performed. Finally, the fracture was fixated with an angular stable volar plate.

Functional and Radiographic Evaluation

Institutional Review Board approval was obtained by the ethics committee and institutional board of our hospital. All patients who had undergone a corrective osteotomy at least 1 year ago were invited to visit the outpatient clinic to fill out the questionnaires and undergo physical examination. The patients, with their parents when necessary, filled out the ABILHANDKids and QuickDASH questionnaire. The ABILHAND-Kids questionnaire is a measure of the manual ability for children with upper limb impairments. The scale is validated for cerebral palsy children and measures a child's ability to manage daily activities that require the use of the upper limbs. Children and their parents are provided 21 questions on the perceived difficulty of various activities on a three-level scale: impossible, difficult, and easy. The maximum score is 42, indicating no difficulty in managing daily activities[9]. The Quick-

DASH is a shortened version of the DASH with 11 items. The score ranges from 0 to 100, with 0 indicating no disability[14]. In addition, patients were asked to indicate their pain as on a VAS score pre- and postoperatively and were asked if their symptoms improved after the corrective osteotomy.

Range of motion was measured using a goniometer and included radial and ulnar deviation, pronation and supination, and dorsal and palmar flexion. Grip strength was measured using a Baseline Hydraulic Hand Dynamometer (Fabrications Enterprises Inc., White Plains, NY). This was performed three times, and an average of these measurements was used. Both range of motion and grip strength were measured for both the injured and uninjured sides.

Radiographic evaluation was performed pre- and postoperatively on standard lateral and posteroanterior radiographs and included radial inclination, radial height, ulnar variance, and dorsal and palmar angulation. Time to union was defined as the time between the corrective osteotomy and bridging of the fracture site by callus.

Statistical Analysis

General descriptive statistics on patient characteristics at baseline were performed, including factors such as gender and age, and presented as percentages (categorical variables), means, and standard deviation (continuous variables, normally distributed), or median and interquartile range (continuous variables, not normally distributed), whichever applicable. The difference in range of motion, grip strength, radiological parameters, and pain pre- and postoperatively was analyzed using a paired Student's t-test. Values of $p<0.05$ were considered significant.

RESULTS

A total of 13 patients with a corrective osteotomy were included in this cohort. In this period, a total of 2,027 pediatric patients were treated for a distal radius fracture in our institution. Patients had a median age of 13 (interquartile range [IQR]: 12.5–16), and 11 were males. The median time to follow-up was 31 months (IQR: 26–51). Corrective osteotomy was performed within a median of 18 weeks (IQR: 2–62) after initial trauma. Initial treatment consisted of plaster cast immobilization (n=9), K-wire fixation (n=3), and volar plate fixation (n=1). Patient characteristics are presented in Table 1.

An open wedge osteotomy was performed in 11 patients (Fig. 1). In two patients, a radius lengthening with an additional ulnar epiphysiodesis was performed (Fig. 2). Grafts were used in six patients, of which two were allogenic hip grafts, two were autogenic grafts (one greater trochanter and one ulna graft), and two were DBM.

Table 1: Patient characteristics

	Number (%)
Age at corrective osteotomy, median [IQR]	13 [12.5-16]
Number of males	11 (85)
Fracture of dominant wrist	3 (23)
Trauma mechanism	
Fall from standing height	2 (15)
Sports related	11 (85)

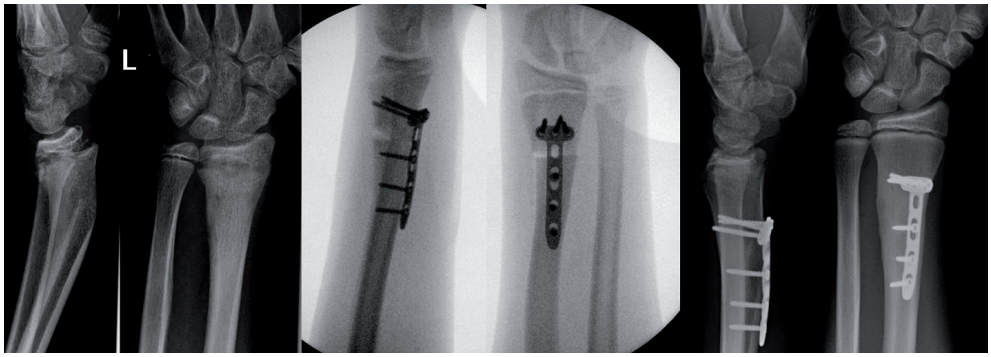

Figure 1: Open wedge osteotomy: pre- and postoperative radiographs. L, left

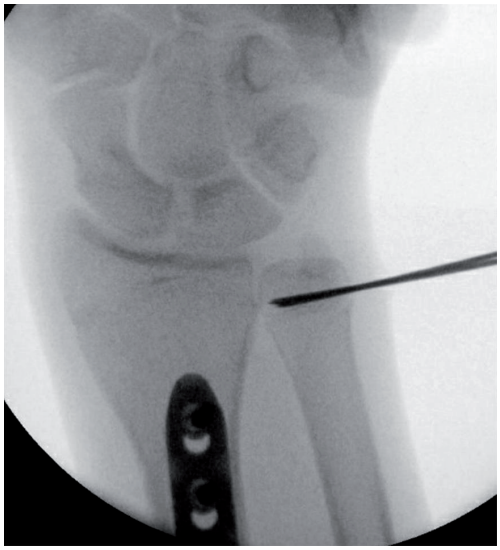

Figure 2: Ulna epiphysiodesis

Out of the 13 patients invited for follow-up, 11 completed the questionnaires and the clinical evaluation, and 1 patient completed only the questionnaires. One patient was lost to follow-up. The median ABILHAND-Kids score was 42 (IQR: 42–42), with a range of 37 to 42, and

Table 2: Range of motion and grip strength at follow up

Range of motion, grip strength, mean (SD)	**Injured side**	**Uninjured side**	**Difference**	**p-value**
Radial deviation	16 (4)	17 (3)	0.5 (2)	0.34
Ulnar deviation	22 (3)	21 (3)	0	-
Pronation	87 (4)	88 (3)	0.5 (2)	0.34
Supination	87 (3)	87 (3)	0	-
Dorsal flexion	84 (6)	84 (4)	0	-
Volar flexion	84 (5)	84 (4)	0.5 (2)	0.34
Grip strength (kg)	27 (8)	31 (11)	3 (5)	**0.04**

Table 3: Radiological evaluation

Radiological parameter, mean (SD)	**Preoperative**	**Postoperative**	**Difference**	**p-value**
Radial inclination	18 (4)	21 (3)	3 (3)	**0.003**
Radial height	8 (2)	9 (2)	1 (2)	**0.046**
Ulnar variance	0.5 (3)	-2 (1)	2 (2)	**0.006**
Dorsal tilt	17 (16)	2 (3)	15 (16)	**0.004**
Volar tilt	6 (9)	4 (4)	2 (7)	0.37

median the QuickDASH was 0 (IQR: 0–7), with a range of 0 to 39. The median preoperative VAS score was 6 (IQR: 2.3–7), which improved significantly to 0 postoperatively (IQR: 0–0) (p=0.003). Preoperative complaints were pain (n=9), pain and loss of function (n=2), and loss of function (n¼1).All but one patient had an improvement in their complaints after the corrective osteotomy. One patient complained of persistent pain, which was due to the plate. The patient was planned for plate removal, after which his pain improved from a VAS score of 3 to 0, measured 2 weeks postoperatively.

Range of motion did not differ significantly between the injured and the uninjured sides for all parameters (Table 2). Grip strength in the injured side was significantly lower (87% of the uninjured side) (p=0.04).

One patient, a 13-year-old girl, required additional surgery due to a nonunion following open wedge osteotomy. She was successfully treated with an autograft 8 months later. Nine patients had their plate removed due to symptomatic hardware.

The radiological parameters after corrective osteotomy compared with those before corrective osteotomy showed an improvement of the radial inclination, radial height, ulnar variance, and dorsal tilt (Table 3). The median time to union was 3 months (IQR: 1–5.5).

DISCUSSION

Our results show that corrective osteotomy of the distal radius for a symptomatic malunion in children provides good functional outcomes. Range of motion of the injured wrist is comparable to that of the uninjured wrist. Furthermore, pain scores decreased and radiographic parameters improved significantly after the corrective osteotomy.

Satisfactory results for corrective osteotomies for malunited fractures of the forearm in children have previously been reported[15]. This study did not, however, focus specifically on distal radius malunions but also analyzed fractures of both the radius and ulna, as well as distal and midshaft fractures. In our study, we found a median ABILHAND-Kids score of 42 and a median QuickDASH of 0. These patient-rated functional outcomes cannot be compared with results in the existing literature, as no functional outcomes for children have yet been described. Previous studies showed a DASH score of 10 to 16 after corrective osteotomy in adult patients[4,16]. Another study reported satisfactory outcomes after corrective osteotomy in young and middle-aged patients, with DASH scores ranging from 25 to 33 but these scores are arguably higher than the QuickDASH score found in our study[7].

Van Geenen and Besselaar reported a significant improvement of range of motion in a cohort of children with a malunion of the forearm. Patients included had fractures of either the radius or the radius and ulna, and location of the fracture varied from proximal and middle to the distal one-third of the bone[17]. The authors also suggest that the corrective osteotomy should be performed within 1 year, resulting in greater gain in range of motion. Hove and Engesaeter assessed the outcome of six pediatric patients with corrective osteotomies due to malunions of the distal radius[6]. The authors found complete postoperative pain relief, and a total range of motion that was 96% compared with the uninjured side.

One of the possible complications of an open wedge osteotomy is a nonunion[3]. We found one case of nonunion in this cohort. After 7 months, no bridging of the osteotomy site was visible. The patient had no complaints of the malunion and had a full range of motion. The defect was treated with an ulnar cancellous bone graft mixed with autograft from the iliac crest and Cerasorb (Curasan, Research Triangle Park, NC). Three months later, union was achieved. A previously published cohort of corrective osteotomies after injuries of the distal radial physis in children reported no complications, but this was a cohort of only six patients[6].

There are several limitations to this study. Due to its retrospective nature, no presurgical data were available to compare the functional outcomes with the postoperative ones. The range of motion and grip strength were evaluated at follow-up, but as preoperative data

were not available, the improvement could not be measured. These parameters were, however, compared with the uninjured side to give an indication of what the patient's baseline range of motion and grip strength would be. The preoperative VAS was also determined retrospectively, which might lead to recall bias. Future research should focus on collecting presurgical data prospectively to more thoroughly analyze the effect of corrective osteotomy on functional outcome. Furthermore, the use of functional outcomes has become increasingly popular. However, there are currently no validated questionnaires for children with upper limb trauma. The ABILDHAND-Kids questionnaire is a validated questionnaire for children with cerebral palsy and has been previously used as the next best available outcome measure[18]. The QuickDASH is a valid instrument for older children and adolescents with upper extremity pathology[10]. The questionnaires used in this study were the next best available for measuring functional outcomes in a pediatric population. The results provide an insight into the effect of corrective osteotomies for distal radius malunions and valuable information for shared decision-making. Time to union was determined on plain radiographs. The moment the radiograph was taken varied in time between patients. The union could have therefore been achieved earlier than the radiograph was taken.

CONCLUSION

Corrective osteotomy is an effective method to treat symptomatic malunions of the distal radius in children with good functional outcomes.

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Chapter 12

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

PART 1: OUTCOME OF INTRA-ARTICULAR DISTAL RADIUS FRACTURE TREATMENT

In **Part 1** we aimed to provide insights into the optimal treatment of patients with intra-articular distal radius fractures. We found that patients with acceptably reduced intra-articular distal radius fractures have better functional outcomes during a follow-up period of one year, measured with the PRWE and DASH scores, when treated operatively instead of non-operatively (Chapter 2). Furthermore, operative treatment is effective with a higher QALY but at a higher mean total cost than non-operative treatment. For patients with a paid job, operative treatment is more effective and less expensive, with a mean difference in costs per QALY of $2,008, than non-operative treatment. In the Netherlands, an intervention that costs more than $33,900 per QALY is not considered cost effective[1,2]. This is called the willingness-to-pay threshold. Total costs for operative treatment were $24,0467, and mean total QALY gained was 0.15, indicating that operative treatment for acceptably reduced intra-articular distal radius fractures is cost-effective (Chapter 3). New studies provide increasing evidence to support operative treatment for distal radius fractures [3,4]. Future guidelines should take into account these findings, which would increase the shift towards operative treatment for distal radius fractures. Current guidelines advise operative treatment for fractures with unacceptable reduction. Furthermore, our studies also advise operative treatment for fractures that are adequately reduced. A field for further research would be to analyze whether reduction for these fractures is even necessary, and operative treatment should be performed. This research provides information that can help in making a shared decision about treatment options. The question that remains is: how do we interpret these results for the individual patient?
Future research should focus on selecting the patient population that benefits most from operative treatment. A decision tool, based on data from various study groups could be created using patient and fracture characteristics to predict outcome of treatment modalities using an artificial intelligence algorithm.

Arthroscopy in distal radius fracture treatment has become more popular in the past years. Patients treated with arthroscopically assisted reduction appear to have a greater degree of range of motion [5]. With regard to functional outcomes or radiographic parameters, however, arthroscopic reduction does not appear advantageous [6]. In patients with intra-articular distal radius fractures requiring operative treatment, no role for arthroscopic debridement exists, as this does not lead to better functional outcome (Chapter 5). Arthroscopy of the wrist has, however, proven instrumental in identifying associated ligament and chondral lesions following distal radius fractures [7]. In our study we found accompanying ligament or chondral injuries all patients who have undergone arthroscopy after operative fixation of intra-articular distal radius fractures. Due to the study protocol, these injuries were left

untreated, and the majority of patients recovered fully. Other studies also showed that patients with untreated SL injuries and TFCC injuries, had good functional outcomes [8,9]. The next step would be to define which specific additional ligament injuries require treatment. The natural course of these untreated injuries occurring as part of a distal radius fracture is largely unknown. To determine which lesions need treatment we should examine the long-term functional outcomes of our study population.

PART 2: PREVENTION AND TREATMENT OF POSTTRAUMATIC COMPLICATIONS

In **part 2** we describe techniques and procedures to prevent and treat these complications. Carpal alignment is a significant radiological parameter related to functional outcome, but as it is a difficult method to reproduce, it is not often used[10]. The new perpendicular method (Chapter 6) is a valid and reproducible methodthat can be used to quantify carpal alignment. Another study also presented a similar technique to measure carpal alignment[11]. Both studies found a comparable variation in alignment in the unfractured wrist. The correlation between carpal alignment in both wrists would be useful to recognize for managing patients with complex fractures or for performing corrective osteotomies. Improving carpal alignment when treating patients with distal radius fractures or performing corrective osteotomies may improve functional outcomes. The correlation between carpal alignment and functional outcome, however, is an aspect that should further be analyzed by incorporating this measurement in studies measuring functional outcome.

Surgeons are advised to take steps to avoid suboptimal plate position, as this may lead to a higher risk of tendon complications[12]. Increased plate prominence following volar plate fixation for distal radius fractures is associated with an increased incidence of subsequent implant removal (Chapter 7). For patients with plate placement classified as Soong grade 2 the incidence of plate removal is almost six times higher than those classified as Soong 0. We suggest to implement the grading system in standard peri- and postoperative assessment to ensure best possible plate localization. This way the correct plate can be chosen for the fracture. Some plates, however, are specifically designed to achieve distal fixation and these do not fit within the watershed line. It should be considered to routinely remove these plates. Patients can also be properly counselled that they may need plate removal once the fracture has healed. With the increased use of 3D printing, in the future custom plates can be made to better suit the fracture and take into account the watershed line.

The use of intra-operative 3D fluoroscopy may enhance fracture reduction and fixation. Although not significant, in a study comparing intraoperative use of 2D fluoroscopy with

3D fluoroscopy, more intraoperative changes were made in the 3D group and less revision surgeries were performed, indicating possible the advantages of this technique (Chapter 8). Similar to a previous study reporting direct revision of fracture reduction in 11% of the cases, we performed revisions intraoperatively in 10% of the cases[13]. Even though there was no significant difference in revisions deemed necessary, the difference in intra-articular screw positioning was nearly 50%. An additional 11% of adjustments were made due to the 3D fluoroscopy, which may explain the difference in percentage of postoperative intra-articular screws. This shows the potential advantages of the use of 3D fluoroscopy intra-operatively. The addition of 3D fluoroscopy is time consuming, and before this is implemented into daily practice more research needs to be performed. The image quality of 3D fluoroscopy continuously improves with the introduction of newer software and hardware systems, leading to better resolution imaging and more user-friendly systems. This makes analyzing the benefits of 3D fluoroscopy in level 1 studies more difficult. Having the best possible imaging intra-operatively does allow for additional changes to be made. It is not clear if the intraoperative changes made also resulted in better functional outcomes, but they could possible lead to improvement of post-operative osteoarthritis. . Future studies should emphasize on functional outcomes and the continuously improved techniques.

Volar plate fixation, although less popular in pediatric patients, enhances anatomical reduction and allows for functional postoperative treatment. In the pediatric population only one case study is available describing volar plate fixation for a displaced distal radius[14]. Pediatric patients with unstable displaced distal radius fractures have good functional outcomes after volar plate fixation (Chapter 10). Since volar plate fixation of pediatric distal radius fractures is rare, no appropriate plates are available. Therefore, we noticed variable adjustments of plates are required to get these to match the radius. Further development of plates may be needed when plate fixation in pediatrics is performed more frequently. Debate remains about whether to routinely remove the plates or to only remove these when complaints occur. Some authors advise not to remove plates on routine basis since the advantages of removal and interference of growth are largely theoretical[15]. Implant removal should be individually assessed since this is a more extensive procedure and there is a lack of evidence to support routine removal. Future studies should compare volar plate fixation in pediatric population to the more frequently used method of K-wire fixation. Furthermore, long-term effects of not routinely removing plates in these patients should be analyzed. Plate fixation for pediatric fractures can only be implemented in the guidelines after these questions have been researched on a larger scale.

Pediatric fractures of the distal radius have great remodeling potential[16,17]. However, some fractures with initial displacement lead to secondary displacement and in turn to a symptomatic malunion, causing pain, weakness or functional impairment of the wrist[18]. A corrective

osteotomy is an effective method for treating symptomatic malunions of the distal radius (Chapter 11). Due to remodeling of the pediatric distal radius, no guidelines exist as to what parameters are indicator for surgical intervention. Furthermore, we do not know the correct timing for an osteotomy. Is this when the patient has persistent complaints, or will these complaints improve over time with remodeling? As malunions in pediatric patients are not common, and corrective osteotomies performed even less so, it is of the utmost importance to collaborate and pool research.

This thesis produces new insights in the treatment of intra-articular distal radius fractures. The studies support a change towards operative treatment with better functional outcomes while being cost-effective. Furthermore, new techniques to treat and prevent posttraumatic complications are addressed that can further improve distal radius fracture treatment.
The clinical implications of this thesis are presented as a case example. A 55 year old female presents to the Emergency Department after a fall on her outstretched left hand. The radiograph shows she has a displaced intra-articular distal radius fracture. Following closed reduction the classic radiographic parameters show a dorsal tilt of 15°, a radial length of 5mm, radial inclination of 18 °and an ulnar variance of minus one. The fracture was reduced with traction and the control radiograph showed an anatomic position. Next the resident examines the radiograph for acceptable carpal alignment according to the perpendicular method (Chapter 6). As this method is reproducible, the attending trauma surgeon easily produces the same conclusion about carpal alignment, and judges that the carpus is aligned. The trauma surgeon suggests to treat the patient with plaster cast immobilization according to the national guideline. The resident, however, recalls the results of the VIPAR study in which operatively treated patients with adequately reduced intra-articular distal radius fractures have better functional outcomes than those treated nonoperatively (Chapter 1). The trauma surgeon is persuaded, and the patient is treated with volar plate fixation. Moreover, this patient has a payed job, and surgery is therefore cost-effective (Chapter 2). No additional arthroscopic debridement is performed during surgery as this does not improve functional outcome, and all associated soft tissue injuries are left untreated as well (Chapter 4). To improve fracture reduction and fixation 3D-fluoroscopy is used intra-operatively. Although this does not lead to significantly better outcomes per se, the resident and attending notice advantages regarding reduction of the intra-articular gap and/or step and plate and screw placement (Chapter 8). One screw is changed intra-operatively because it penetrated the dorsal cortex. The surgeon is cautious as to place the volar plate proximal to the watershed line, as placing it distal to this line causes a higher risk of plate removal and flexor tendon rupture (Chapter 7). Two years later the patient returns to the out-patient clinic with ulnar-sided wrist pain, caused by a TFCC lesion. The TFCC lesion is debrided arthroscopically with acceptable functional outcomes (Chapter 9).

At the same time a 13 year old boy and girl present to the Emergency Department after a fall while playing outside, both with a displaced distal radius fracture. The boy is treated with closed reduction and K-wire fixation. The girl is treated with a more novel technique, with volar plate fixation. This results in good functional outcomes (Chapter 5). Against the odds, the boy develops a symptomatic malunion of the distal radius with pain and functional impairment. He is treated with a corrective osteotomy, which has shown to be an effective method for treating symptomatic malunions of the immature distal radius (Chapter 11) and resumes all his activities two months later.

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Chapter 13

SUMMARY AND CONCLUSION

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SUMMARY AND CONCLUSION

Part 1: Outcome of distal radius fracture treatment

We conducted a multicenter randomized controlled trial for patients with acceptably reduced intra-articular distal radius fractures comparing operative and nonoperative treatment. In **chapter 2** we describe the results of this VIPAR trial. A total of 90 patients with acceptably reduced intra-articular distal radius fractures were randomized to plaster cast immobilization (nonoperative) or to volar plate fixation (operative). During 12 months follow-up, patients treated operatively had significantly better functional outcome measured with the PRWE score at six weeks (39 [22-60] vs 58 [49-76], $p < 0.001$), three months (21 [7-49] vs 40 [15-62], $p = 0.005$), six months (9 [3-18] vs 24 [9-51] $p = 0.002$) and at one year (5 [0-12] vs 12 [3-28], $p = 0.02$)). Additionally, a subsequent surgery rate due to secondary dislocation or symptomatic malunion in the nonoperative group of 28% was found. We concluded that operative treatment for acceptably reduced intra-articular distal radius fractures in patients between 18 and 75 years, is the superior treatment method. **Chapter 3** presented the results of an economic healthcare evaluation of operative versus nonoperative treatment. The mean total costs per patient were $291 higher in the operative group than in the nonoperative group. However, the operatively treated patient gains 0.15 QALY, equivalent to an extra 55 days in perfect health per year. The indirect costs were, lower in the operative group compared to the nonoperative group ($56,228 vs $105,825). In the subgroup analysis on patients with and without a paid job, the incremental cost-effectiveness ration was $3,500 per QALY in favor of the operative group for patients with a paid job. This means that $3,500 is gained per one year in perfect health when patients are treated operatively instead of nonoperatively. Operative treatment for acceptably reduced intra-articular distal radius fractures is effective, and also cost-effective with regards to indirect medical costs and especially in a population with a paid job.

Some patients continue to have a painful and stiff wrist postoperatively. Arthroscopically assisted removal of intra-articular fracture haematoma and debris may improve the functional outcomes following operative treatment of intra-articular distal radius fractures. To assess the role of arthroscopic debridement in intra-articular distal radius fracture treatment we conducted the RADAR trial, a multicenter randomized controlled trial described in **chapter 4.** In **chapter 5** we presented the result of the RADAR trial. A total of 50 patients were randomized to ORIF with or ORIF without additional arthroscopic debridement. The median PRWE was significantly worse for the intervention group at three months (23 [9-44] vs 13 [5-21]), but at 12 months this was equal for both groups, (7 [0-20] vs 7 [1-15]). All patients had additional ligament or chondral injuries. TFCC injury was found in 87% and, SL-injury and LT-injury were present in half of the patients in the intervention group. We concluded that patients treated with additional arthroscopy to remove intra-articular hematoma and

debris did not have better outcomes than those treated with ORIF alone. We therefore do not recommend routine arthroscopy for removal of hematoma and debris when performing surgical fixation of distal radius fractures.

Part 2: Prevention and treatment of posttraumatic complications

Carpal alignment may be used as a tool to evaluate fracture reduction in patients with distal radius fractures. However, there is little consensus on how to measure and quantify carpal alignment. In **chapter 6** we explained a new reproducible method for measuring carpal alignment with a high inter- and intraclass coefficient. Furthermore, the distribution of carpal alignment in unfractured wrists was determined with a mean perpendicular line along the line of Lewis to the center of the capitate of 0.25mm dorsally . The amount of translation can be reliably measured, allowing for quantification of carpal malalignment.

Plate placement has an important role in the development of complications. In **chapter 7** we found an incidence of plate removal in 17% in a cohort of 323 patients. Soong classification was significantly higher in patients who had plate removal compared to those who did not. For patients with plate placement classified as Soong grade 2, the incidence of plate removal was almost six times higher than those classified as Soong grade 0. The relationship between volar plate removal and a higher Soong grading stresses the importance of accurate plate positioning and suggests that some plates should be routinely removed.

In **chapter 8** we presented the results of a multicenter trial in which 206 patients were randomized between the use of 3D fluoroscopy or not during operative treatment of their distal radius fracture. No significant difference in whether the fracture required revision surgery was found: 31% (2D group) versus 24% (3D group). In 11% of operated distal radius fractures allocated to the 3D group, additional intraoperative corrections, namely screw replacements, were performed as a result of the 3D fluororscopy. However, because this study was slightly underpowered there may be a difference that this study could not show completely. Though not significant, more intraoperative changes were made in the 3D group and less revision surgeries were performed, indicating advantages of this technique.

In chapter 4 all soft-tissue injuries were left untreated. However, some patients following wrist trauma continue to have ulnar-sided wrist pain due to TFCC injuries. In **chapter 9** we analyzed 51 patients with TFCC injuries treated arthroscopically during a median follow-up of 16.5 months. Injuries were treated with TFCC debridement, TFCC ligament to capsule suturing, TFCC debridement and ligament to capsule suturing, TFCC debridement and synovectomy, and TFCC foveal reinsertion with a suture anchor. The median PRWE was 19.5 [IQR 6-49]. We concluded that arthroscopic treatment of TFCC lesions leads to satisfactory functional outcomes.

Although, pediatric patients have remodeling potential, unstable fractures and fractures with rotational deformity require reduction and fixation. In **chapter 10** we analyzed the functional outcomes of 26 pediatric patients with a distal radius fracture treated with volar plate fixation. At follow-up patients had a median PRWE score of three [IQR 0-10]. Range of motion and grip strength did not differ between the injured and uninjured side. Volar plate fixation for displaced distal radius fractures in pediatric patients provides good functional outcomes and is definitely a field for future research.

Functional outcomes measured with patient rated outcome measures have been performed for adult patients undergoing an extra-articular corrective osteotomy of the radius. However, few studies on corrective osteotomies in children have been performed. In **chapter 11** we therefore presented a cohort of 13 pediatric patients with a symptomatic malunion of the distal radius for which a corrective osteotomy was performed. The median ABILHAND-Kids score was 42 (range 37-42) and median Quick-DASH was zero (range 0-39). Range of motion did not differ significantly between the injured and the uninjured side for all parameters. The postoperative radiological parameters showed an improvement of radial inclination, radial height, ulnar variance, dorsal tilt, and volar tilt. Therefore, corrective osteotomy for children is an effective method for treating symptomatic malunions of the distal radius.

Conclusion

Patients with acceptably reduced intra-articular distal radius fractures should be treated operatively with plate fixation as this leads to better functional outcomes. Not only does operative treatment lead to better functional outcomes, but this treatment method is also cost-effective. Health insurance companies should take into account the reduction in indirect medical costs when evaluating reimbursement for distal radius fracture treatment. Furthermore, functional outcome in patients with intra-articular distal radius fractures is not improved by routine arthroscopy for removal of hematoma and debris when performing surgical fixation of distal radius fractures. To prevent post-traumatic complications factors such as carpal alignment and correct plate placement should be taken into account. To prevent malunions of the distal radius in pediatric patients, volar plate fixation can be considered when other minimal invasive options appear insufficient. If malunion does occur, a corrective osteotomy is an effective method for treating symptomatic malunions of the distal radius. These new insights in distal radius fracture treatment aim to further improve the prognosis of patients with distal radius fractures.

SAMENVATTING EN CONCLUSIE

Deel 1: Uitkomsten van distale radius fractuur behandeling

In **hoofdstuk 2** presenteerde wij de resultaten van de VIPAR studie, een multicenter studie waarbij operatieve behandeling met conservatieve behandeling wordt vergeleken in volwassen patiënten met een intra-articulaire distale radius fractuur. Na acceptabele reositie werden 90 volwassen patiënten tussen 18 en 75 jaar willekeurig toegewezen aan operatieve behandeling (volaire plaat fixatie) of conservatieve behandeling (gipsimmobilisatie). Gedurende 12 maanden follow-up waren de functionele uitkomsten significant beter in de operatieve groep dan in de conservatieve groep, weergegeven door lagere PRWE scores bij zes weken (39 [22-60] vs. 58 [49-76], $p < 0.001$), drie maanden (21 [7-49] vs. 40 [15-62], $p = 0.005$), zes maanden (9 [3-18] vs. 24 [9-51] $p = 0.002$) en 12 maanden (5 [0-12] vs. 12 [3-28], $p = 0.02$)). Tevens, werd 28% van de conservatief behandelde patiënten alsnog geopereerd als gevolg van secundaire dislocatie of een symptomatische malunion. Wij concludeerden dat patiënten van 18 tot en met 75 jaar met een acceptabel gereponeerde intra-articulaire distale radiusfractuur behandeld met volaire plaat fixatie betere functionele uitkomsten hebben bij 12 maanden dan conservatief behandelde patiënten.

Hoofdstuk 3 presenteerde de resultaten van de economische evaluatie van de VIPAR studie (operatieve versus conservatieve behandeling). De gemiddelde kosten per patiënt waren $291 hoger in de operatieve groep dan in de conservatieve groep. Daarentegen, heeft de operatief behandelde patiënt 0.15 quality adjusted life years (QALY) meer, wat gelijk staat aan een winst in perfecte gezondheid van 55 dagen per jaar.

De indirecte kosten waren lager in de operatieve groep dan in de conservatieve groep ($ 56.228 versus $ 105.825). In de subgroep analyse van patiënten met en zonder een betaalde baan was de incrementele kosteneffectiviteitsratio $ 3.500 per QALY ten gunste van de operatieve groep voor patiënten met een betaalde baan. Dit betekent dat er een winst van $ 3.500 per jaar in perfecte gezondheid is wanneer een patiënt met een betaalde baan operatief in plaats van conservatief behandeld wordt. Operatieve behandeling voor adequaat gereponeerde intra-articulaire distale radiusfracturen is effectief en ook kosteneffectief met betrekking tot indirecte medische kosten en vooral bij een populatie met een betaalde baan.

Sommige patiënten hebben postoperatief een pijnlijke en stijve pols. Het arthroscopisch verwijderden van intra-articulair fractuur hematoom en debris zou de functionele uitkomsten na operatieve behandeling van intra-articulaire distale radius fracturen verbeteren.
Hoofdstuk 4 beschreef de RADAR studie, een gerandomiseerde studie, waarin de rol van arthroscopisch debridement bij intra-articulaire distale radius fracturen wordt beoordeeld.

In **hoofdstuk 5** presenteerde wij de resultaten van de RADAR studie. Er werden 50 patiënten willekeurig toegewezen naar operatieve behandeling middels plaat fixatie of operatieve behandeling middels plaat fixatie met additionele arthroscopische debridement. De PRWE was significant slechter voor de groep waarbij additionele arthroscopische debridement werd verricht (23 [9-44] vs. 13 [5-21]), maar na 12 maanden was dit voor beide groepen gelijk (7 [0-20] vs. 7 [1-15]). Tijdens arthroscopie werd bij alle patiënten additioneel ligamentair of chondraal letsel gevonden. In 87% van deze patiënten werd een TFCC laesie gevonden en een SL-letsel en LT-letsel was aanwezig in 50%. Wij concludeerden dat patiënten die worden behandeld met aanvullende arthroscopie om intra-articulair hematoom en debris te verwijderen, geen betere functionele uitkomsten hadden dan degenen die alleen operatieve plaat fixatie worden behandeld. Daarom raden wij routinematige arthroscopie niet aan voor het verwijderen van hematoom en debris bij chirurgische fixatie van distale radiusfracturen.

Deel 2: Voorkomen en behandelen van posttraumatische complicaties

"Carpal alignment" is een radiologische parameter die beschrijft of de hand in lijn is met de onderarm en kan gebruikt worden om fractuur reductie in patiënten met distale radius fracturen te beoordelen. Er is echter weinig overeenstemming over hoe deze radiologische parameter moet worden gemeten en gekwantificeerd. In **hoofdstuk 6** hebben wij een nieuwe reproduceerbare methode met een hoge inter- en intraclass coëfficiënt voor het meten van 'carpal alignment' geïntroduceerd. De 'carpal alignment' werd bepaald met een loodrechte lijn langs de lijn van Lewis naar het midden van het capitatum. De verdeling van deze parameter in de populatie zonder een gebroken distale radius was een gemiddelde verplaatsing van 0.25mm naar dorsaal.
De hoeveelheid translatie kan op een betrouwbare manier worden gemeten, waardoor de mate van uitlijning gekwantificeerd kan worden.

Plaatsing van de volaire plaat speelt een belangrijke rol bij het ontstaan van complicaties. In **hoofdstuk 7** vonden wij een incidentie van verwijdering van het osteosynthese materiaal (VOSM) van 17% in een cohort van 323 patiënten. De Soong-classificatie was significant hoger bij patiënten waarbij de volaire plaat was verwijderd dan bij degenen die dat niet hadden. Voor patiënten met een volaire plaat geclassificeerd als Soong graad 2, was de incidentie van VOSM bijna zes keer hoger dan die geclassificeerd als Soong graad 0. De relatie tussen de verwijdering van de volaire plaat en een hogere Soong-beoordeling benadrukt het belang van nauwkeurige plaatpositionering en suggereert dat sommige platen routinematig moeten worden verwijderd.

In **hoofdstuk 8** presenteerden wij de resultaten van een multicenter studie waarin 206 fracturen werden gerandomiseerd tussen het wel of niet gebruik maken van 3D doorlichting

tijdens operatieve behandeling van de distale radiusfractuur. Er was geen significant verschil in de vraag of revisie chirurgie noodzakelijk werd geacht: 31% (2D-groep) versus 24% (3D-groep). In 11% van de groep die gebruik maakte van 3D doorlichting, werd aanvullende intra-operatieve correcties, namelijk schroefvervanging, uitgevoerd als gevolg van het verrichten van 3D doorlichting. Omdat deze studie echter enigszins te weinig patiënten had geïncludeerd, kan er een verschil zijn dat deze studie niet volledig kon laten zien. Hoewel niet significant, werden er meer intra-operatieve veranderingen aangebracht in de 3D-groep en werden er minder revisieoperaties uitgevoerd, hetgeen wijst op voordelen van deze techniek.

Het ligamentair en chondraal letsel werd in hoofdstuk 4 niet behandeld. Sommige patiënten blijven echter ulnaire pijn houden na een distale radius fractuur als gevolg van TFCC letsel. In **hoofdstuk 9** werden 51 patiënten (mediane follow-up 16.5 maanden) met TFCC letsel dat arthroscopisch behandeld werd geanalyseerd. TFCC letsel werd behandeld middels debridement, hechten van het TFCC ligament aan het kapsel, debridement en synovectomie, en TFCC fovea reinsertie met een hecht-anker. De mediane PRWE was 19.5 [IQR 6-49]. Wij concludeerden dat arthroscopische behandeling van TFCC letsel acceptabele functionele uitkomsten heeft.

Hoewel kinderen veel remodellerend potentieel hebben, vereisen instabiele fracturen en fracturen met een rotatie afwijking operatieve reductie en fixatie. In **hoofdstuk 10** analyseerden wij de functionele uitkomsten van 26 kinderen met een distale radiusfractuur behandeld met volaire plaatfixatie. Bij follow-up hadden patiënten een mediane PRWE-score van drie [IQR 0-10]. De functie en de grijpkracht verschilde niet tussen de aangedane en niet aangedane pols. Volaire plaatfixatie voor verplaatste distale radiusfracturen bij kinderen biedt goede functionele uitkomsten en is een veld voor toekomstig onderzoek.

De functionele uitkomsten, gemeten met patiënt gerapporteerde uitkomstmaten, zijn bekend voor volwassen patiënten die een extra-articulaire correctie osteotomie van de radius ondergaan. Er zijn echter weinig studies uitgevoerd naar correctie osteotomieën bij kinderen. In **hoofdstuk 11** presenteerden wij daarom een cohort van 13 kinderen met een symptomatische malunion van de distale radius waarvoor een correctie osteotomie werd uitgevoerd. De mediane ABILHAND-Kids-score was 42 (range 37-42) en de mediane QuickDASH was nul (range 0-39). De functie verschilde niet significant tussen de aangedane en de niet aangedane pols. De postoperatieve radiologische uitkomsten toonden een verbetering van radiaire inclinatie, radiaire hoogte, ulnaire variantie, dorsale kanteling en volaire kanteling. Een correctie osteotomie is een effectieve methode om kinderen met een symptomatische malunion van de distale radius te behandelen.

Conclusie

Patiënten met een acceptabel gereponeerde intra-articulaire distale radius fractuur zouden operatief behandeld moeten worden met plaat fixatie gezien dit tot betere functionele uitkomsten leidt. Operatieve behandeling leidt niet alleen tot betere functionele uitkomsten, maar is ook nog eens kosteneffectief. Ziektenkostenverzekeraars zouden vooral rekening moeten houden met de aanzienlijke verlaging van indirecte kosten in hun vergoeding voor de behandeling van distale radius fracturen. Het verrichten van routinematige arthroscopische debridement van het intra-articulair hematoom en debris bij intra-articulaire distale radius fracturen leidt niet tot betere functionele uitkomsten.

Om posttraumatische complicaties te voorkomen, moet rekening gehouden worden met factoren zoals "carpal alignment" en correcte plaatsing van de volaire plaat. Volaire plaat fixatie bij distale radius fracturen met dislocatie of rotatie fracturen bij kinderen kan overwogen worden wanneer minimaal invasieve behandelopties onvoldoende worden geacht. Mocht een symptomatische malunion van de distale radius optreden, dan is een correctie osteotomie een effectieve behandeling hiervan.

Deze nieuwe inzichten in de behandeling van distale radius fracturen hebben als doel de prognose van patiënten met distale radius fracturen verder te verbeteren.

Appendices

A

LIST OF PUBLICATIONS

PHD PORTFOLIO

ACKNOWLEDGEMENTS

CURRICULUM VITAE

LIST OF PUBLICATIONS

THIS THESIS

C.A. Selles, M.A.M. Mulders, J. Winkelhagen, P.V. van Eerten, J.C. Goslings, N.W.L. Schep. Volar Plate Fixation Versus Cast Immobilization in Acceptably Reduced Intra-Articular Distal Radial Fractures: A Randomized Controlled Trial. J Bone Joint Surg Am, *in press*.

C.A. Selles, M.A.M. Mulders, S. van Dieren, J.C. Goslings, N.W.L. Schep. Cost Analysis of Volar Plate Fixation Versus Plaster Cast Immobilization for Intra-Articular Distal Radial Fractures. J Bone Joint Surg Am, *in press*.

M.A.M. Mulders, **C.A. Selles**, J.W. Colaris, R.W. Peters, M. van Heijl, B.I. Cleffken, N.W.L. Schep. Operative Treatment of Intra-Articular Distal Radius Fractures With versus Without Arthroscopy: study protocol for a randomized controlled trial. Trials. 2018 Feb 2;19(1):84.

C.A. Selles, M.A.M. Mulders, J.C. Colaris, M. van Heijl, B.I. Cleffken, N.W.L. Schep, Arthroscopic debridement does not enhance surgical treatment of intra-articular distal radius fractures: a randomized controlled trial. J Hand Surg Eur Vol. 2019 Nov 5:1753193419866128.

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C.A. Selles, S.T.H. Reerds, G. Roukema, C.H. van der Vlies, B.I. Cleffken, N.W.L. Schep. Relationship between plate removal and Soong grading following surgery for fractured distal radius. J Hand Surg Eur Vol. 2018 Feb;43(2):137-141.

C.A. Selles, M.S.H. Beerekamp, M. J.M. Segers, P.A. Leenhouts, J.C. Goslings, N.W.L. Schep. The Value of Intraoperative 3-Dimensional Fluoroscopy in the Treatment of Distal Radius Fractures: A Randomized Clinical Trial. J Hand Surg Am. 2020 Mar;45(3):189-195.

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J.C. van Egmond, **C.A. Selles**, G. Roukema, C.H. van der Vlies, B.I. Cleffken, N.W.L. Schep. Plate fixation for unstable distal radius fractures in pediatrics. J Wrist Surg. 2019 Oct;8(5):384-387

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D.W.G. Langerhuizen, M. Bergsma, **C.A. Selles**, R.L. Jaarsma, J.C. Goslings, N.W.L. Schep, J.N. Doornberg. Diagnosis of dorsal screw penetration after volar plating of a distal radial fracture. Bone Joint J. 2020 Jul;102-B(7):874-880.

P.N. d'Ailly, J.E. Koopman, **C.A. Selles**, Z.O. Rahimtoola, N.W.L. Schep. Patient-Related Outcomes of Arthroscopic Resection of Ganglion Cysts of the Wrist. J Wrist Surg. 2021 Feb;10(1):31-35

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R.A. Klaassen, **C.A. Selles,** J.W. van den Berg, M.M. Poelman, E. van der Harst. Tranexamic acid therapy for postoperative bleeding after bariatric surgery. BMC Obes. 2018 Dec 3;5:36.

M.M.J. Walenkamp, M.A.M. Mulders, **C.A. Selles**, J.C. Goslings, G.P. Westert, N.W.L. Schep. Aanzienlijke variatie in chirurgische behandeling van distale radius fracturen. NTVG. 2017;161(0):D1042.

C.A. Selles and M.C.G. Tjong Joe Wai. Conscious Sedation in the Intensive Care Unit: the Future? Erasmus Journal of Medicine 2010; 1(1): 26-29.

J. Koolwijk, M. Fick, **C.A. Selles**, G. Turgut, J.I.M. Noordergraaf, F. S. Tukkers, G.J. Noordergraaf. Outpatient Cataract Surgery: Incident and Procedural Risk Analysis Do Not Support Current Clinical Ophthalmology Guidelines. Ophthalmology. 2015 Feb;122(2):281-7.

GENERAL COURSES

1. PhD training	Year	Workload (ECTS)
General courses		
BROK	2017	1
Practical Biostatistics	2017	1.1
Seminars and workshops		
Monthly research meetings	2016-2018	1.5
Value Based Healthcare (VBHC) Masterclass	2017	0.2
Oral presentations		
Relationship between plate removal and Soong grading following surgery for fractured distal radius.		
– Osteosynthese International Annual Meeting of the Gerhard Küntscher Society, Munich, Germany	2017	1
– Voorjaarscongres Nederlandse Vereniging voor Handchirurgie, St. Michielsgestel, The Netherlands	2017	1
– Traumadagen, Amsterdam, The Netherlands	2018	1
Symposium 3D Beeldvorming, 3D Printing en Augmented Reality in de klinische praktijk		
– Chirurgendagen, Veldhoven, The Netherlands	2017	1
The effectiveness of intraoperative 3D fluoroscopy in the treatment of distal radius fractures: a randomized controlled trial.		
– Chirurgendagen, Veldhoven, The Netherlands	2018	1
– European Congress for Trauma and Emergency Surgery, Valencia, Spain	2018	1
– Federation of European Societies for Surgery of the Hand (FESSH) Annual Meeting, Copenhagen, Denmark	2018	1
– Assistentensymposium Traumachirurgie, Amersfoort, The Netherlands	2018	1
Carpal alignment: A New Method for Assessment		
– Federation of European Societies for Surgery of the Hand (FESSH) Annual Meeting, Copenhagen, Denmark	2018	1
The effect of arthroscopic debridement as part of surgical treatment of intra-articular distal radius fractures: a randomized controlled trial		
– Traumaplatform Symposium, Davos, Switzerland	2018	1
– American Society for Surgery of the Hand (ASSH) Annual Meeting, Boston, USA	2018	1
– Orthopaedic Trauma Association (OTA) Annual Meeting, Orlando, USA	2018	1
– International Federation of Societies for Surgery of the Hand (IFSSH) Triennial Congress, Berlin, Germany	2019	1
Volar plate fixation for unstable distal radius fractures in pediatrics		
– International Federation of Societies for Surgery of the Hand (IFSSH) Triennial Congress, Berlin, Germany	2019	1
Functional outcomes after corrective osteotomy of distal radius malunions in children		
– International Federation of Societies for Surgery of the Hand (IFSSH) Triennial Congress, Berlin, Germany	2019	1

Volar plate fixation versus conservative treatment in displaced intra-articular distal radius fractures: a multicenter randomized controlled trial		
– Traumadagen, Amsterdam, The Netherlands	2019	1
Poster presentations		
Operative Treatment of Intra-Articular Distal Radius Fractures With versus Without Arthroscopy: study protocol for a randomized controlled trial Maasstad Wetenschapsdag, Rotterdam, The Netherlands	2016	0.5
(Inter)national conferences		
Traumadagen, Amsterdam, The Netherlands	2016, 2017, 2018, 2019	2
Chirurgendagen, Veldhoven, The Netherlands	2017, 2018	1
Voorjaarscongres Nederlandse Vereniging voor Handchirurgie, St. Michielsgestel, The Netherlands	2017	0.25
European Congress for Trauma and Emergency Surgery, Bucharest, Romania	2017	1
Osteosynthese International Annual Meeting of the Gerhard Küntscher Society, Munich, Germany	2017	0.75
Assistentensymposium Traumachirurgie, Amersfoort, The Netherlands	2018	0.25
Traumaplatform Symposium, Davos, Switzerland	2018	0.5
European Congress for Trauma and Emergency Surgery, Valencia, Spain	2018	1
Federation of European Societies for Surgery of the Hand (FESSH) Annual Meeting, Copenhagen, Denmark	2018	1
American Society for Surgery of the Hand (ASSH) Annual Meeting, Boston, USA	2018	1
Orthopaedic Trauma Association (OTA) Annual Meeting, Orlando, USA	2018	1
International Federation of Societies for Surgery of the Hand (IFSSH) Triennial Congress, Berlin, Germany	2019	1
Traumaplatform Symposium, Ameland, The Netherlands	2019	0.5
2. Teaching		
Bachelor Thesis	2018	1
Master Thesis	2019	2
3. Parameters of Esteem		
Best Abstracts European Congress for Trauma and Emergency Surgery	2018	
Best Oral Presentation Traumadagen	2018 & 2019	

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CURRICULUM VITAE

Caroline Andrea Selles was born on April 19th, 1990 in Rotterdam, the Netherlands. She grew up in Bulgaria, Burkina Faso, Slovakia, Israel, and Switzerland before graduating from high school (International Baccalearaute) in Athens, Greece.

She started medical school in 2007 at the Erasmus University Rotterdam. Throughout medical school and the regular internships, her interest in surgery grew into the ambition to become a surgeon.

After obtaining her medical degree in 2015, Caroline started as a surgical resident (ANIOS) at the Maasstad Hospital (dr. R.A. Klaassen). In 2016 she started as a PhD candidate at the Department of Surgery under de supervision of prof. dr. M.H.J. Verhofstad and prof. dr. J.C. Goslings. Her research focused on improving outcomes, and preventing complications of distal radius fractures. During this period she also worked as a surgical resident (ANIOS) at the Franciscus Gasthuis & Vlietland (T.M.L. Klem).

In July 2020, Caroline started her surgical residency training in Rotterdam (dr. B.P.L. Wijnhoven) at the Ikazia Hospital (dr. P.T. den Hoed).