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Scientific Article

Complex Regional Pain Syndrome Following Distal Radius Fracture: Does Surgical Method Matter?

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Abstract

Background The purpose of this study was to compare the risk of complex regional pain syndrome (CRPS) following surgical treatment of distal radius fractures (DRFs) with either a volar locking plate (VLP) or an external fixator (EF).

Methods Data from two randomized controlled trials (RCTs) were merged and analyzed. A logistic regression analysis was conducted to identify independent risk factors for the occurrence of CRPS.

Results A total of 322 patients were included from the two RCTs; 159 patients were operated upon with VLP and 163 patients with EF. CRPS was diagnosed in 6 patients treated with VLP (4%) and in 16 patients receiving EF (11%), overall 22 cases of CRPS (7%). None of the other independent risk factors had a significant influence on the risk for CRPS (all $p > 0.05$).

Conclusion Patients treated with an EF had a higher risk of developing CRPS compared to those treated with a VLP. We found no other independent variable predicting CRPS.

Level of evidence III.

Keywords
- complex regional pain syndrome
- distal radius fracture
- external fixator
- volar locking plate
- Budapest criteria

Complex regional pain syndrome (CRPS) is a poorly understood neuropathic clinical syndrome that involves both peripheral and central sensitization.[1] The most common cause of CRPS is a fracture of the distal radius (DRF).[2] CRPS is a challenging condition associated with negative outcomes for the patients, including functional, psychological, and psychosocial.[3] A key feature of CRPS is that the severity and duration of symptoms often are disproportionate to the severity of the trauma.[4] The condition exhibits several overlapping symptoms, such as excessive pain, hyperesthesia, temperature change, altering skin color, joint stiffness, edema, sweating, and trophic changes to hair, nails, and skin.[5] The upper extremities are most often affected, especially after surgery or fractures.[6] Recently, there has been an

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increase in surgical fixation of unstable DRFs.[7,8] Volar locking plate (VLP) has largely replaced the external fixator (EF) in the surgical treatment of displaced DRFs.[9] However, randomized controlled trials (RCTs) comparing EF to VLP find no difference in functional and patient-reported outcomes beyond 1 year postoperatively.[10–13] Accordingly, EF is still considered a valid and safe alternative to VLP for unstable DRFs. It is not clear whether either of the methods has a higher risk of developing CRPS. Some studies have identified EF as a possible risk factor for CRPS,[14,15] while others could not find such an association.[2,16] However, these studies were underpowered, not designed to answer this question, or lacked control groups.

Recently, two RCTs from Norway compared the clinical outcome after surgical treatment of DRF with either VLP or EF.[10,11] In both studies, the patients in the VLP group recovered quicker and returned to work earlier than patients treated with EF. Functional results after 1 year were no longer statistically different between the two groups. However, there was a tendency towards more CRPS among patients in the EF group (8 vs. 3) in both trials, but neither had the statistical power to detect a significant difference.

The purpose of this study was to pool data from these two RCTs, increasing the statistical power, and assessing risk factors for developing CRPS after DRFs.

Methods

Eligibility Criteria

This study is a secondary analysis of two RCTs conducted in different regions and hospitals in Norway between 2009 and 2017 (►**Fig. 1**). The inclusion criteria for both RCTs were identical, except for the type of fracture. RCT1 included only intra-articular fractures (Arbeitsgemeinshaft für

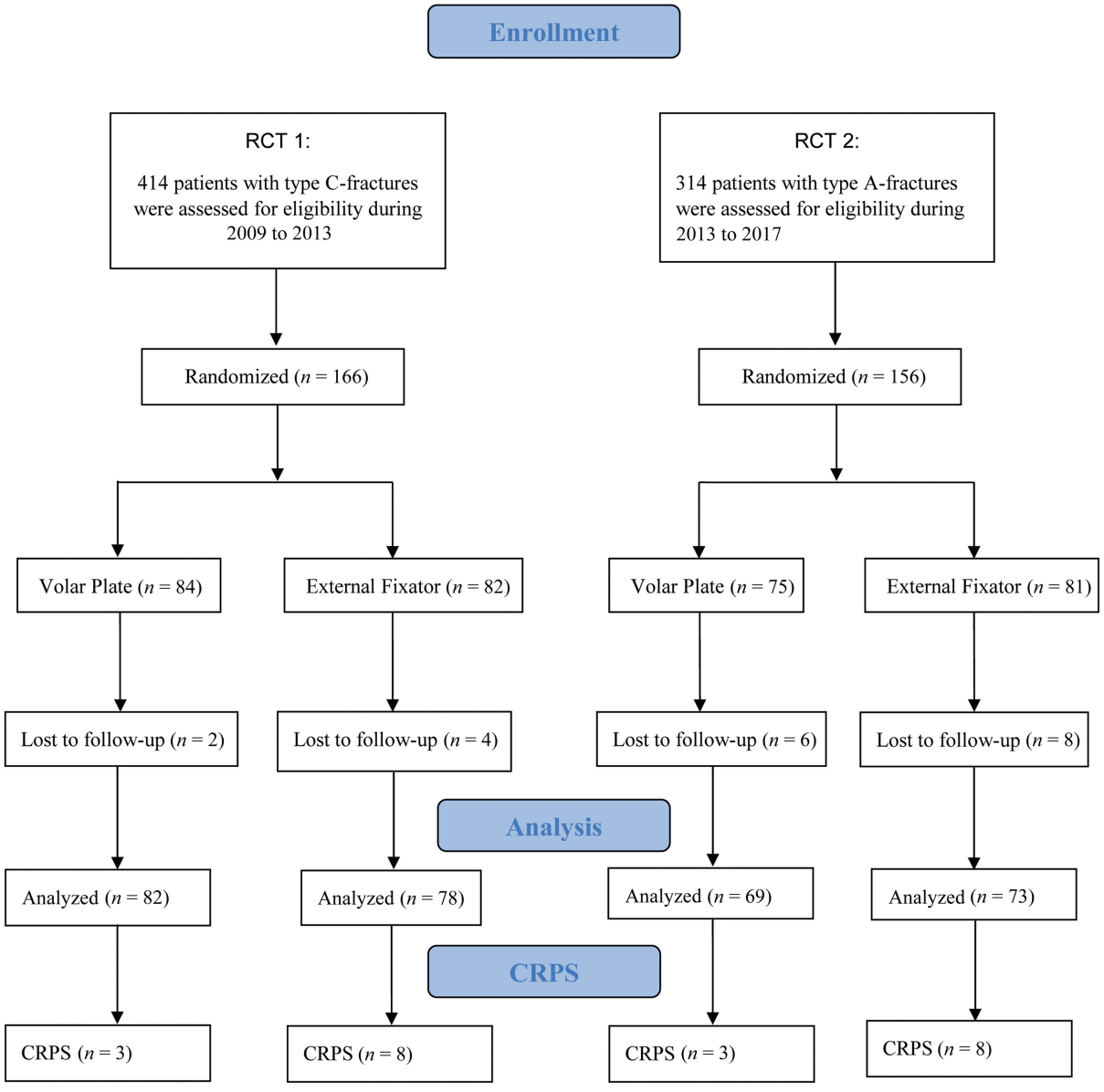

Fig. 1 Consort flow chart of included patients. CRPS, complex regional pain syndrome; RCT, randomized controlled trial.

Osteosyntesefragen/Orthopaedic Trauma Association [AO/OTA] type C2 and C3), while RCT2 included only extra-articular fractures (AO/OTA type A3). Both trials included patients aged 18 to 70 years, and all fractures were considered unstable, requiring surgical fixation (►**Table 1**). Patients with previous fractures in the contralateral or ipsilateral wrist were excluded, as were patients with open fractures, mental illness, dementia, or severe drug abuse. In both trials, the patients were randomized to either VLP or EF. In RCT1, EF was augmented with Kirschner wires. Neither of the RCTs were originally designed to evaluate the risk of CRPS. The surgical techniques and overall clinical results are described in the two articles.[10,11]

All patients were clinically assessed at 6 weeks, 3 months, and 1 year postoperatively.

Postoperative Care

The postoperative care was similar in both trials. The EFs were removed after 6 weeks in the outpatient clinic. Patients operated with volar plates had a dorsal splint for pain relief 2 or 3 days postoperatively. Free range of motion was permitted and encouraged, but no weight-bearing or heavy lifting was allowed for 6 weeks. Thereafter, the patients followed a defined protocol and were instructed to begin independent exercises.[17] Physiotherapy was prescribed according to the surgeon's discretion or patient's request. Patients with CRPS were treated by a dedicated team following a standardized protocol, including physiotherapy and pain assessment.

Outcome Measure

The primary outcome in the present study was the risk of developing CRPS during follow-up. The diagnosis of CRPS was based solely on clinical signs and symptoms, and by excluding other forms of chronic pain. No specific laboratory or radiological marker has yet been identified to make this diagnosis. Both RCTs adhered to the Budapest clinical diagnostic criteria for CRPS[18] (►**Table 2**).

Statistical Analysis

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

Results

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

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

In the logistic regression analyses, none of the independent risk factors were found to be statistically significant related to

Table 1 Inclusion criteria

Inclusion criteria
Age 18–70 years
Dislocated unstable intra- and extra-articular distal radius fracture
No history of previous surgery or fracture to the wrist
Unilateral injury
Ability to read and understand Norwegian
Ability to comply to required follow-up
Substantial initial displacement, inadequate initial reduction, or loss of reduction within 2 weeks after injury as defined by one or more of the following: • ≥ 10 degrees dorsal angulation of the joint line • Ulnar variance ≥2 mm • Dorsal comminution of the fracture/loss of intact dorsal cortex • Intra-articular stepoff ≥2 mm

Table 2 Budapest clinical diagnostic criteria for complex regional pain syndrome

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

Table 3 Combined patient demographic and baseline data for all patients included in the two randomized controlled trials

	Volar plate	External fixation	*p*-Value
	(*N* = 159)	(*N* = 163)	
Age, years ± SD	55.8 ± 11.1	55.5 ± 11.0	0.8
Sex, *n* (%)			
Female	126 (79.2%)	128 (78.5%)	
Male	33 (20.8%)	35 (21.5%)	0.9
Dominant side, *n* (%)			
Right	147 (92.5%)	135 (82.8%)	
Left	12 (7.5%)	28 (17.2%)	0.01
Injured side, *n* (%)			
Right	68 (42.8%)	59 (36.2%)	
Left	91 (57.2%)	104 (63.8%)	0.3
Dominant side injured, *n* (%)			
Yes	66 (41.5%)	49 (30.1%)	
No	93 (58.5%)	114 (69.9%)	0.04
AO/OTA classification, *n* (%)			
A3	75 (47.2%)	81 (49.7%)	
C1	5 (3.1%)	3 (1.8%)	
C2	49 (30.8%)	51 (31.3%)	
C3	30 (18.9%)	28 (17.2%)	0.9
Ulna fracture, *n* (%)			
Yes	88 (55.3%)	79 (48.5%)	
No	71 (44.7%)	84 (51.5%)	0.2
Mechanism of injury, *n* (%)			
Low-energy trauma	134 (84.3%)	132 (81.0%)	
High-energy trauma	25 (15.7%)	31 (19.0%)	0.5

CRPS; this was also the case for the stepwise regression. The OR for CRPS after EF compared to VLP in the adjusted logistic regression increased slightly to 3.4 (95% CI 1.10–10.37, $p = 0.043$; ►**Table 4**).

Table 3 (*Continued*)

	Volar plate ($N = 159$)	External fixation ($N = 163$)	*p*-Value
Occupation, *n* (%)			
Office work	51 (32.1%)	47 (28.8%)	
Light manual labor	37 (23.3%)	50 (30.7%)	
Heavy manual labor	15 (9.4%)	15 (9.2%)	
Retired	34 (21.4%)	32 (19.6%)	
Unemployed	5 (3.1%)	7 (4.3%)	
Disabled	12 (7.5%)	11 (6.7%)	
Student	5 (3.1%)	1 (0.6%)	0.6
QuickDASH preinjury ± SD	2.5 ± 6.7	2.0 ± 5.3	0.5

Abbreviations: AO/OTA, Arbeitsgemeinshaft für Osteosyntesefragen/Orthopaedic Trauma Association; n, number; QuickDASH, Disabilities of the Arm, Shoulder and Hand; SD, standard deviation.

Table 4 Logistic regression analyses

	OR for CRPS	95% CI for OR	*p*-Value
External fixation (vs. VLP)	3.243	1.036–10.156	**0.043**
Age (in years)	0.985	0.945–1.028	0.490
Sex (ref: female)	1.235	0.391–3.894	0.719
Trauma energy (low vs. high)	0.807	0.250–2.609	0.721
Intra-articular fracture	1.278	0.478–3.418	0.624
Ulnar styloid fracture	0.943	0.379–2.348	0.899
Time to surgery (days)	1.067	0.969–1.174	0.188
Operation time (minutes)	1.011	0.987–1.036	0.370

Abbreviations: CI, confidence interval; CRPS, complex regional pain syndrome; OR, odds ratio; VLP, volar locking plate.
The effect of external fixation compared to VLP (reference) on the risk of developing CRPS after surgery for a displaced distal radius fracture. Estimates adjusted for age, sex, trauma (ref; high), intra-articular fracture (ref: no), ulnar styloid fracture (ref: no), time to surgery, and operation time. Significant values ($p < 0.05$) are listed in bold.

Discussion

The main finding in this study was that EF increases the risk of developing CRPS threefold compared to VLP. Accordingly, our results indicate that some cases of CRPS could have been avoided by treating all our patients with a VLP. In addition to the obvious patient benefit of avoiding CRPS, this would also reduce institutional and societal health care costs substantially.[19]

We found that 7% of the patients were diagnosed with CRPS. This is comparable to other studies of patients with DRF.[20,21] In population-based studies, the incidence of CRPS has been reported to be less than 1%,[2,22] indicating that surgical treatment of a DRF is a substantial risk factor for CRPS. A Korean study from 2019 concluded that the incidence of CRPS was lower after EF than after plate fixation[2] contradicting our findings. This study, however, used a national health insurance database to identify patients diagnosed with CRPS after a surgically treated DRF. Their incidence of less than 1% CRPS is very low and in contrast to a much higher incidence of CRPS reported in our and other clinical studies.[20,23] As CRPS is a clinical diagnosis, a prospective clinical study is probably the best study design to identify patients at risk.

In contrast to our study, a Brazilian case–control study including 249 patients with a DRF did not find any correlation between the type of surgical treatment and CRPS.[24] That study, however, was underpowered including only 10 cases of CRPS. Further, the patients were not randomized to treatment groups, introducing a substantial selection bias. Similarly, a Dutch study could not find an increased risk of CRPS following EF, but this study included only 29 patients in the EF group.[25] Furthermore, the surgical method and implant selection were not based on randomization.

Our results are supported by previous reports of high incidence of CRPS after EF. An early report on EF found that over 60% of the patients experienced symptoms of CRPS, but this was before the Budapest criteria were established.[15] Hegeman and coworkers found CRPS in 19% of the patients treated with EF for a displaced and unstable DRF.[14]

It remains unclear why EF, as a minimally invasive procedure, increases the risk of developing CRPS compared to VLP. It has been suggested that excessive distraction of the EF

might explain the increased risk of CRPS[26,27] but the mechanisms are not well understood. We have not been able to quantify the force of distraction applied to the patients in our cohorts, but in both RCTs, the surgeons ensured that full metacarpophalangeal flexion could easily be achieved, which has been suggested to indicate adequate distraction.[28] Further, immobilizing of the wrist for 6 weeks, even without overdistraction might influence the outcomes and the rate of CRPS negatively. Early mobilization is an established principle in orthopaedic rehabilitation, and VLP allows early free movement of the wrist postoperatively.

Some studies have suggested that CRPS is associated with old age.[21,22,24] We did not find such an association but patients older than 70 years were not included in our study.

Several studies have found a higher rate of women with CRPS after DRF,[2,21,22,29] but this could simply be explained by the fact that more women also sustain a DRF.[30] An association of CRPS with female gender was not supported by our study, which is also in-line with other reports.[24,25]

Some studies have found that high-energy injuries[21,24] and DRFs including an ulnar styloid fracture[2,22,24] may lead to a higher incidence of CRPS. In the present study, neither an ulnar styloid fracture nor an intra-articular extension of the fracture was associated with the risk of developing CRPS in a multivariable regression analysis.

There are some limitations to our study. Data from two separate RCTs were combined, but neither was originally designed to evaluate the risk for CRPS. Most inclusion criteria for our RCTs were identical, but the fracture type was not. Due to the different nature of the surgical procedures, blinding was not possible. Only surgically treated DRFs were included, so the result cannot be generalized to conservatively treated DRFs. Although this was a multicenter study, the study derived from one country, perhaps affecting the external validity of the results. The Budapest criteria are based on consensus and expert opinion without a specific test or imaging technique capable of confirming or excluding the diagnosis, a weakness to the reliability of the diagnosis itself.[5,21,31] However, the Budapest criteria for CRPS have been widely used in previous research, and are increasingly used in clinical practice.

The major strength of this study is the large number of patients included by randomization and the low number of patients lost to follow-up. To our knowledge, this is the largest prospective study on CRPS after operative treatment of unstable DRFs.

Finally, a better understanding of CRPS, its trigger mechanisms, and pathophysiology, is a prerequisite to be able to prevent and treat this complex condition in the future. Accordingly, this should also be the focus of future research.

Ethical Approval and Consent to Participate

Both RCTs were conducted according to the Declaration of Helsinki and approved by the local data protection officers. RCT1 was approved by the Regional Ethics Committee of Eastern Norway (ref. 2009/1517) and registered at www.ClinicalTrials.gov (NCT01062997). RCT2 was approved by the Regional Ethics Committee of Western Norway (ref 2013/555) and registered at ClinicalTrials.gov (NCT01904084). Written informed consent was obtained from all the patients.

Availability of Data and Materials

The datasets generated and analyzed during the current study are not publicly available due to sensitive information but are available from the corresponding author upon reasonable request.

Authors' Contributions

T.L. and O-L.H. collected and analyzed the data. T.L. and P-H.R. contributed to the study design, statistical analysis, and writing the manuscript. E.H.D. contributed to statistical analysis. J.M.F. and K.M. supervised and critically revised the manuscript. All authors approved the final manuscript.

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Conflict of Interest

None declared.

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