JB&JS OPEN ACCESS

Volar Locking Plate Versus Dorsal Locking Nail-Plate Fixation for Dorsally Displaced Unstable Extra-Articular Distal Radial Fractures

Functional and Radiographic Results from a Randomized Controlled Trial

Morten Eikrem, MD, Hege Brannsten, MD, Dagfinn Bjørkøy, MD, Tom Lian, MD, Jan Erik Madsen, MD, PhD, and Wender Figved, MD, PhD

Investigation performed at Baerum Hospital, Vestre Viken Hospital Trust, Gjettum, Norway

Background: The use of low-profile dorsal and volar locking plates for distal radial fracture surgery has improved results and lowered the complication rate compared with older plate designs. The purpose of the present randomized controlled trial was to compare patient-reported outcomes as well as radiographic and functional results between patients who underwent stabilization with a volar locking plate or a dorsal locking nail-plate for the treatment of dorsally displaced unstable extra-articular distal radial fractures.

Methods: One hundred and twenty patients ≥55 years of age were randomized to surgery with either a volar locking plate or a dorsal locking nail-plate and were assessed at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year. The primary outcome was the abbreviated version of the Disabilities of the Arm, Shoulder and Hand (QuickDASH) score. Secondary outcomes were the Patient-Rated Wrist Evaluation (PRWE), EuroQol 5 Dimensions (EQ-5D) index and visual analog scale (VAS), range of motion, grip strength, radiographic measurements, and complication rate.

Results: The median age was 66 years (range, 55 to 88 years). The rate of follow-up was 97%. There was no clinically important difference between the groups at any point during follow-up. Patients in the volar locking plate group had better mean QuickDASH scores at 6 weeks, 6 months, and 1 year. However, the differences were small (5.8 vs. 11.3 points at 1 year; mean difference, −5.5 points [95% confidence interval (CI), −9.9 to 1.2]; p = 0.014), which is lower than any proposed minimum clinically important difference (MCID). The difference in PRWE scores was also lower than the MCID (1.0 vs. 3.5 at 1 year; mean difference, −2.5 [95% CI, −4.4 to 0.6]; p = 0.012). The dorsal locking nail-plate group had slightly better restoration of volar tilt (p = 0.011). EQ-5D index, EQ-5D VAS, range of motion, grip strength, and complication rates were similar.

Conclusions: We found no clinically relevant difference between the volar locking plate and dorsal locking nail-plate groups after 1 year or in the time period up to 1 year. A dorsal locking nail-plate can therefore be an alternative method for the treatment of these unstable fractures or in cases in which a dorsal approach is preferable over a volar approach.

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

Earlier designs of dorsal plates for distal radial fracture surgery were associated with a high complication rate[1-4]. Low-profile dorsal plates have shown stable fracture fixation and decreased rates of extensor tendon complications[5-7]. During the last decades, there has been a shift away from dorsal plating toward low-profile volar locking plates[8]. However, extensor tendon problems are still a concern in association with both dorsal and volar plates, and volar plating has added new complications that do not commonly occur following dorsal plating of these fractures[9].

Thus, alternative fixation constructs have emerged[10]. One such implant is the dorsal locking nail-plate, which was

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A322).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJSOA/A323).

JBJS Open Access • 2021:e21.00068.

introduced in 2005[11]. This device is a hybrid implant with a fixed-angle low-profile plate section distally, which supports the articular surface, and proximal intramedullary locking nail fixation. Both the dorsal locking nail-plate and the volar plate have shown much higher yield load than the load previously described during active wrist and finger motion in biomechanical studies[12-14], but few studies have compared treatment with a volar locking plate with intramedullary nailing[15,16].

The aim of the present study was to compare patient-reported outcomes, radiographic and functional results, and complications following the treatment of dorsally displaced unstable extra-articular distal radial fractures with a volar locking plate or a dorsal locking nail-plate.

Materials and Methods

This single-center randomized controlled trial (RCT) was conducted at Baerum Hospital, Vestre Viken Hospital Trust, Norway, a level-II trauma hospital with a catchment area population of 190,000 (2011).

Ethics

The study protocol was designed according to the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) initiative[17] and was approved by the Regional Ethics Committee of Eastern Norway (ref. S-0862b) and the local data protectorate (ref. 09-2008SAB). The trial was registered at ClinicalTrials.gov (NCT00848263).

Enrollment

We evaluated patients ≥55 years of age who had an unstable dorsally displaced fracture of the distal radius without articular involvement or extension into the diaphysis (AO/OTA type 2R3A2 or 2R3A3[18]). Instability was diagnosed on the basis of the criteria of Lafontaine et al.[19] (Fig. 1) or observed displacement following adequate reduction.

Exclusion criteria included previous fracture of the same wrist, >1 acute fracture (except of the ulnar styloid process), open fracture, fracture older than 14 days, and mental impairment or inability to understand and sign an informed consent form. One hundred and twenty patients were included between April 2009 and December 2012 (Fig. 2).

Randomization

After the patient provided informed consent, the assignment of the surgical method was drawn from a sealed, opaque envelope. Allocation to treatment with either a volar locking plate or a dorsal locking nail-plate was conducted by a computer-generated permuted block randomization, with blocks of 5. All operations were performed by the surgeon on call, either a senior resident or consultant. To avoid selection bias, surgeons were allocated prior to randomization.

Surgical Technique

Both implants had been in regular use at the study site for 12 months prior to the study start date, and participating surgeons were required to be familiar with both procedures.

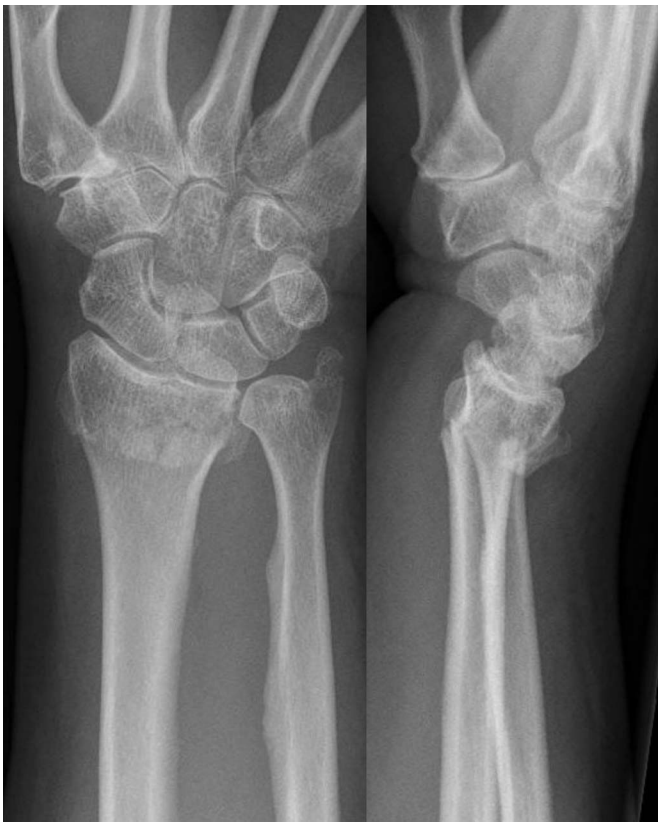

Fig. 1

Radiographs showing a characteristic dorsally displaced AO/OTA 2R3A fracture that met 4 of the 5 instability criteria according to Lafontaine et al.: a patient age of >60 years, dorsal angulation of >20°, dorsal comminution, and an associated ulnar fracture. The fifth criterion is intra-articular radiocarpal fracture. Fractures presenting with ≥3 criteria at the time of admission are considered unstable.

Twenty-six different surgeons were registered as being primary surgeons. Surgery was performed according to manufacturer guidelines. The carpal tunnel was not routinely decompressed.

Volar Locking Plate

The DVR (DePuy Synthes) is a volar locking plate with cortical screws in the radial shaft and locking pegs or screws in the distal fragment of the radius (Fig. 3). We used a standard volar approach[20]. Reduction and plate fixation were conducted under fluoroscopic surveillance. If possible, the pronator quadratus muscle was sutured back to cover the distal part of the plate.

Dorsal Locking Nail-Plate

The dorsal locking nail-plate (DePuy Synthes) is a hybrid implant with a distal fixed-angle plate section and a proximal intramedullary locking nail section (Fig. 4). After closed reduction and temporary Kirschner wire fixation, a 3 to 4-cm longitudinal incision overlying the Lister tubercle was used for exposure. The extensor pollicis longus (EPL) was released, and

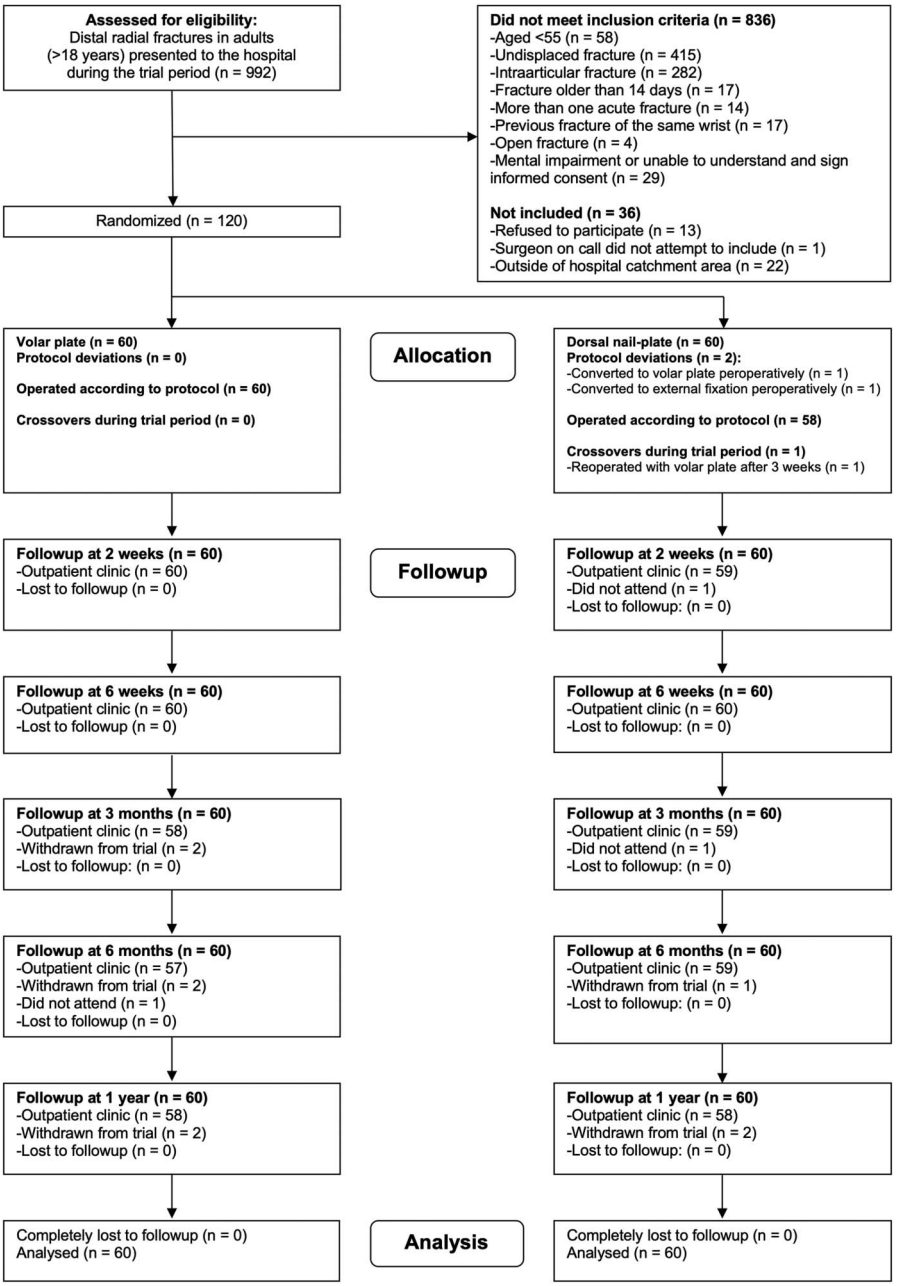

Fig. 2

CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the recruitment and flow of patients with distal radial fractures through the study.

the Lister tubercle was removed with a rongeur, creating a flat surface for seating the head of the implant between the tendons of the second and fourth extensor compartments. The medullary canal was opened with an awl, and the implant was introduced retrograde through the fracture site. The implant head was seated on the distal fragment, and 4 pegs or screws were placed distally under fluoroscopic guidance. Unicortical proximal locking screws were then placed. According to the preference of the operating surgeon, the remnants of the Lister tubercle could be grafted back into the fracture site before the EPL was replaced over the repaired extensor retinaculum, avoiding tendon impingement[11].

Perioperative Care

Cephalothin (2 g) was administered intravenously 15 to 30 minutes preoperatively. Patients in both groups received the same wound dressing and a wrist orthosis postoperatively. The orthosis was removed after 2 weeks but could be used intermittently until then if desired. Participants were instructed in basic exercises and received illustrated written instructions.

Fig. 3
Radiographs and photograph showing a volar locking plate.

Primary Outcome

Patients were assessed in the outpatient clinic at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year, unblinded, by a trained study nurse and a physiotherapist who were not involved in enrollment or perioperative treatment. The primary outcome measure was the abbreviated version of the Disabilities of the Arm, Shoulder and Hand (QuickDASH) outcome measure[21-23], which measures upper-limb function and has a possible range of 0 (excellent result) to 100 (worst possible result).

Secondary Outcomes

The Patient-Rated Wrist Evaluation (PRWE) score was used to measure wrist pain and disability subjectively during activities of daily living, with a possible range of 0 (representing an excellent result) to 100 (representing the worst possible result)[24,25]. The PRWE score has a proposed minimum clinically important difference (MCID) of 11.5[26]. Health-related quality of life was measured with use of the 3-level version of the EuroQol 5 Dimensions (EQ-5D), including both the EQ-5D index (ranging from −0.59 [worst] to 1.00 [best]) and the EQ-5D visual analog scale (VAS) score (ranging from 0 [worst] to 100 [best])[27]. Grip strength was measured in kilograms with use of a hand-held dynamometer (Hydraulic Hand Dynamometer; MSD Europe). Participants performed 3 maximal attempts for each measurement, and the average value was recorded. The MCID was considered to be 19.5%[28]. We did not adjust for hand dominance[29]. A senior radiologist (H.B.), who was blinded to patient outcome, conducted all radiographic measurements with use of a standardized protocol[30,31]. Range of motion was measured with a goniometer. Patients underwent clinical examination for the detection of complications (Table I). Range of motion and complication outcomes were not among the prespecified outcomes registered at Clinicaltrials.gov.

Sample Size Calculation

Normative data for the QuickDASH score were used for sample size calculation[32]. With a standard deviation of 15 points[32] and an MCID of 13 points as proposed on the QuickDASH website at the time of study design, we determined that 36 patients would be needed in each group to achieve a statistical power of 95% with a significance level of 5%[33]. The sample size calculation was then sufficient for conducting equivalence analyses if no significant difference between the groups was found. To allow for loss of follow-up and an uncertain MCID, we included 60 patients in each group.

Statistical Methods

For equivalence analyses, we used the 2-sided confidence interval (CI) approach[33]. We used the 2-tailed Fisher exact test for dichotomous variables, and t tests for numerical variables. All analyses were conducted on a per-protocol basis in order to minimize the risk of falsely concluding equivalence[33], supplemented with intention-to-treat analyses. Baseline characteristics were analyzed with normality tests. The nonparametric Mann-Whitney U test was used where there was a significant difference in variance or if equivalence was not found.

Source of Funding

The trial was funded by the study site, with no external funding.

Results

Of the 156 patients who met the inclusion criteria, 120 were included (Fig. 2). Forty-five patients (38%) were included

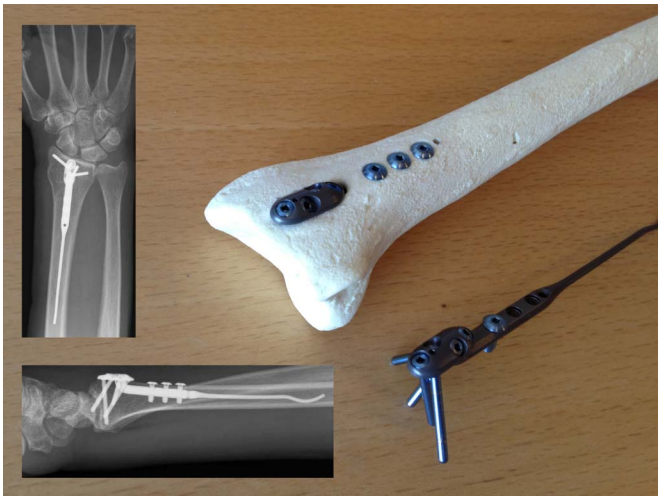

Fig. 4
Radiographs and photograph showing a dorsal locking nail-plate.

JBJS Open Access • 2021:e21.00068. openaccess.jbjs.org

TABLE I Complications at 1-Year Follow-up

	Volar Plate (N = 60)*	Dorsal Nail-Plate (N = 60)*	Relative Risk (95% CI)	P Value
Reoperations				
Carpal tunnel syndrome	3 (5%)†	3 (5%)		
Secondary osteosynthesis due to redisplacement	0 (0%)	1 (2%)		
Implant removal due to local pain	2 (3%)†	0 (0%)		
Removal of screws/pegs due to misplacement	1 (2%)	2 (3%)		
Total number of reoperations	5 (8%)	6 (10%)	1.1 (0.62 to 1.95)	0.75
Other complications				
Complex regional pain syndrome	0 (0%)	2 (3%)		
Scapholunate dissociation (untreated)	1 (2%)	1 (2%)		
Reactivated small-joint arthritis	1 (2%)	0 (0%)		
Radioulnar instability (untreated)	0 (0%)	1 (2%)		
Retained suture material	0 (0%)	1 (2%)		
Extensor carpi ulnaris tendinopathy	1 (2%)	1 (2%)		
Trigger finger	1 (2%)	0 (0%)		
Scar adhesion	1 (2%)	0 (0%)		
Dupuytren contracture	1 (2%)	0 (0%)		
Total number of other complications	6 (10%)	6 (10%)	1.0	1.0

*The values are expressed as the number of patients, with the percentage in parentheses. There were no cases of infection, tendon ruptures, or delayed union. †One patient had the volar plate removed during carpal tunnel release, making the total number of reoperations in that group 5. The other removal in that group was due to a dorsally protruding screw causing local pain/tendon irritation.

after failed nonoperative treatment and underwent operative treatment within 2 weeks after the injury. Baseline and demographic characteristics were similar between the groups after randomization (Table II). The median age was 66 years (range, 55 to 88 years). There were 3 protocol violations, all in the dorsal locking nail-plate group (Table III), but this did not cause the intention-to-treat analyses to differ from the reported per-protocol results in terms of significance. The rate of follow-up at 1 year was 97%.

Clinical Outcomes

The mean difference in QuickDASH scores between the groups did not reach the MCID of 13 points during follow-up (Table IV). The volar locking plate group had significantly better scores at 6 weeks, 6 months, and 1 year. The scores were equivalent at 2 weeks and 3 months (Fig. 5). Although significant, the difference at 1 year was small (5.8 compared with 11.3 points) (mean difference, −5.5 points [95% CI, −9.9 to 1.2]; p = 0.014). At no time interval did the PRWE score reach the

TABLE II Baseline and Demographic Characteristics of Patients According to Treatment*

	Volar Plate (N = 60)	Dorsal Nail-Plate (N = 60)
Age at time of fracture* *(yr)*	66.5 ± 7.8	66.9 ± 6.29
Female sex *(no. of patients)*	53 (88%)	56 (93%)
Side of injury *(no. of patients)*		
Left	35 (58%)	29 (48%)
Right	25 (42%)	31 (52%)
Handedness of patient† *(no. of patients)*		
Left	6 (11%)	5 (9%)
Right	51 (89%)	54 (92%)
Injury of dominant hand† *(no. of patients)*	26 (46%)	30 (51%)
Included after prior nonoperative treatment *(no. of patients)*	21 (35%)	24 (40%)

*The values are expressed as the mean and the standard deviation. †Data were missing for some patients, so the percentages are based on the number of patients with available data.

JBJS Open Access • 2021:e21.00068. **openaccess.jbjs.org**

TABLE III Perioperative Details

Perioperative Details	Volar Plate (N = 60)	Dorsal Nail-Plate (N = 60)	Mean Difference*	Relative Risk*	P Value
Duration of surgery *(min)*	68.8 ± 17.7†	60.8 ± 18.4†	8.0 (1.5 to 14.5)		0.017
Operation performed by single surgeon *(no. of patients)*	38 (63%)	32 (53%)	—	0.84 (0.62 to 1.14)	0.36
Converted to different fixation type perioperatively *(no. of patients)*	0 (0%)	2 (3%)	—	0.97 (0.92 to 1.01)	0.50
Intact pronator quadratus muscle‡ *(no. of patients)*	28 (50%) of 56	—	—	—	—
Pronator quadratus muscle reattached‡ *(no. of patients)*	44 (76%) of 58	—	—	—	—

*The 95% CI is shown in parentheses. †The values are given as the mean and the standard deviation. ‡Data were missing for some patients.

TABLE IV Functional Outcomes According to Allocated Treatment*

	Volar Plate	Dorsal Nail-Plate	Mean Difference†	Relative Risk†	P Value
QuickDASH score‡					
2 weeks	42.1 ± 17.3 (n = 60)	47.9 ± 17.3 (n = 59)	−5.8 (−12.1 to 0.5)	—	0.072
6 weeks	27.7 ± 17.0 (n = 60)	34.5 ± 17.5 (n = 60)	−6.8 (−13.0 to 0.5)	—	0.034
3 months	14.6 ± 12.3 (n = 58)	18.4 ± 15.3 (n = 58)	−3.8 (−8.9 to 1.3)	—	0.14
6 months	7.9 ± 9.2 (n = 57)	13.1 ± 13.5 (n = 59)	−5.3 (−9.5 to 1.0)	—	0.016
1 year	5.8 ± 8.1 (n = 58)	11.3 ± 14.7 (n = 58)	−5.5 (−9.9 to 1.2)	—	0.014
PRWE score‡					
2 weeks	39.4 ± 12.3 (n = 60)	44.5 ± 11.1 (n = 59)	−5.1 (−9.4 to −0.8)	—	0.019
6 weeks	17.0 ± 10.3 (n = 60)	21.6 ± 14.6 (n = 60)	−4.6 (−9.2 to −0.02)	—	0.049
3 months	7.9 ± 8.0 (n = 58)	11.0 ± 13.8 (n = 59)	−3.1 (−7.2 to 1.0)	—	0.14
6 months	3.3 ± 6.0 (n = 57)	5.5 ± 7.7 (n = 59)	−2.2 (−4.8 to 0.3)	—	0.084
1 year	1.0 ± 2.3 (n = 58)	3.5 ± 7.0 (n = 58)	−2.5 (−4.4 to −0.6)	—	0.012
EQ-5D index score‡					
2 weeks	0.69 ± 0.18 (n = 60)	0.67 ± 0.19 (n = 59)	0.023 (−0.047 to 0.085)	—	0.57
6 weeks	0.73 ± 0.20 (n = 60)	0.74 ± 0.14 (n = 60)	−0.014 (−0.077 to 0.048)	—	0.65
3 months	0.85 ± 0.17 (n = 58)	0.82 ± 0.16 (n = 58)	0.025 (−0.035 to 0.085)	—	0.42
6 months	0.86 ± 0.18 (n = 57)	0.83 ± 0.16 (n = 59)	0.030 (−0.032 to 0.093)	—	0.33
1 year	0.90 ± 0.15 (n = 58)	0.88 ± 0.14 (n = 57)	0.013 (−0.040 to 0.066)	—	0.64
EQ-5D VAS score‡					
2 weeks	73 ± 17.0 (n = 60)	76 ± 16.0 (n = 59)	−2.3 (−8.3 to 3.6)	—	0.44
6 weeks	78 ± 16.5 (n = 60)	80 ± 12.6 (n = 60)	−1.9 (−7.2 to 3.4)	—	0.47
3 months	84 ± 14.1 (n = 58)	80 ± 14.6 (n = 58)	3.2 (−2.1 to 8.5)	—	0.23
6 months	86 ± 13.4 (n = 56)	83 ± 17.3 (n = 59)	3.2 (−2.5 to 8.9)	—	0.27
1 year	86 ± 15.4 (n = 58)	86 ± 13.6 (n = 58)	0.2 (−5.2 to 5.5)	—	0.95
No pain medication needed *(no. of patients)*					
2 weeks	48 (80%) of 60	30 (51%) of 59	—	2.46 (1.39 to 4.34)	0.001
6 weeks	58 (97%) of 60	47 (78%) of 60	—	6.50 (1.53 to 27.6)	0.004
3 months	57 (98%) of 58	55 (93%) of 59	—	3.93 (0.45 to 34.1)	0.36
6 months	55 (96%) of 57	59 (100%) of 59	—	1.03 (0.99 to 1.09)	0.24
1 year	57 (98%) of 58	58 (100%) of 58	—	1.02 (0.98 to 1.05)	1.00

*Data were missing for some patients. †The 95% CI is shown in parentheses. ‡The values in the treatment groups are expressed as the mean and the standard deviation.

JBJS Open Access • 2021:e21.00068.

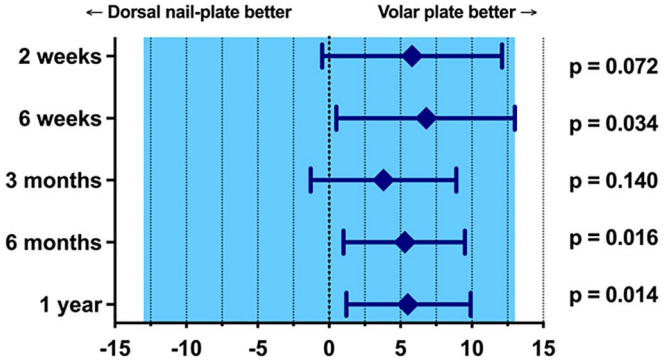

Fig. 5

Graph of the mean difference in QuickDASH score between the groups, showing that the volar plate was superior at 6 weeks, 6 months, and 1 year (with superiority being indicated when the 95% CI [shown by the whiskers] lies entirely above 0 points). Although significant, the difference between the 2 groups lies well within the minimum clinically important difference of the QuickDASH score. The treatments were equivalent at 2 weeks and 3 months, indicated when the 95% CI lies entirely within the margins of ±13 points.

proposed MCID of 11.5 points. The PRWE score showed significantly better scores in the volar locking plate group at 2 weeks, 6 weeks, and 1 year, but the difference at 1 year was small (1.0 compared with 3.5) (mean difference, −2.5 [95% CI, -4.4 to 0.6]; p = 0.012). The EQ-5D index and VAS score showed no differences between the groups. Range of motion did not differ between the groups. More patients in the dorsal locking nail-plate group needed pain medication, but this difference only lasted up to 6 weeks (Table IV). The volar locking plate group regained 94% of grip strength, and the dorsal locking nail-plate group regained 99% (Table V).

Radiographic Results

The dorsal locking nail-plate group had significantly better restoration of volar tilt (mean difference, 2.1° [95% CI, 0.47° to 3.6°]; p = 0.011) (Table VI), but the difference was small and probably not clinically relevant.

Complications

There were no differences in the reoperation or complication rates (Table I). In the dorsal locking nail-plate group, there were 2 conversions during surgery because of intra-articular fracture patterns that were not consistent with inclusion criteria, with 1 patient having conversion to external fixation and 1 having conversion to a volar locking plate. One dorsal locking nail-plate was revised with a long volar locking plate after 3 weeks because of an unaddressed diaphyseal fracture that extended proximally. Three patients in each group were later diagnosed with carpal tunnel syndrome and had subsequent carpal tunnel release. Two patients in the volar locking plate group had the plate removed during a reoperation after 2 months because of dorsal pain caused by a long protruding screw (1 patient) and carpal tunnel syndrome (1 patient). Symptoms resolved in both patients. There were no cases of infection, tendon rupture, or delayed union.

Discussion

In this trial comparing the use of a volar locking plate and a dorsal locking nail-plate for the treatment of dorsally displaced extra-articular distal radial fractures, the main finding was that patient-reported outcomes showed no clinically important differences between the treatment groups at 1 year. The secondary outcomes support this finding as we did not find any significant differences in terms of pain, range of motion, or grip strength. The complication rate was the same in both groups. Throughout the trial, both implants maintained the fracture position that had been achieved during surgery. The dorsal locking nail-plate group had a small but significantly better reduction of volar tilt. We found a significantly different QuickDASH score in favor of the volar locking plate, but the difference was smaller than any published MCID, suggesting that the difference was clinically irrelevant. Although 13 points may seem a generous estimate for an MCID, our results are also well within a more conservative value of 10 points, which has been used in similar trials[34,35]. The type of result seen in this study is described as "unusual" by the Extension of the CONSORT Statement on Reporting of Noninferiority and Equivalence Randomized Trials[33]. The 95% CI lies wholly above zero but, at the same time, below the MCID margin (Fig. 5). In theory, this type of result may be due to a very large sample size, which was not the case in the present trial, or a too-wide MCID margin. Different MCIDs for the QuickDASH have been reported, ranging from 8 to 20[34,36,37]. It may be debated whether a QuickDASH MCID of 13 is too large but also whether a significant difference between the groups as low as 5.5 points in the QuickDASH and 2.5 points in the PRWE is clinically relevant, with both scores using a 0-to-100 scale. One explanation for these small but significant differences that is not mentioned in the CONSORT statement could be very consistent scores in both groups, expressed by our very narrow CIs.

Clinical trials involving dorsal locking nail-plate or similar intramedullary devices are scarce and relatively small. One retrospective study of 48 patients comparing dorsal locking nail-plate with Kirschner wire fixation demonstrated better range of motion for the dorsal locking nail-plate but similar DASH scores[15]. One RCT of 31 patients who were managed with the same 2 implants as in our trial showed similar DASH scores but better Mayo Clinic scores in the volar locking plate group[16]. Contrary to our findings, that study demonstrated better range of motion toward extension and better recovery of grip strength in the volar locking plate group at the time of the latest follow-up at 6 months. We found no extension-flexion limitations after 6 months or 1 year, and grip strength was not different between the groups.

One problem with comparing different trials is the heterogeneity of implants that are often classified as belonging to the same group of intramedullary devices; one meta-analysis attempting to define the role of intramedullary nailing in the treatment of distal radial fractures included 5 different intramedullary implants that were inserted with different surgical approaches and techniques[38]. One meta-analysis of RCTs of all surgical interventions included 38 trials, but only 2 of the trials

JBJS Open Access • 2021:e21.00068. **openaccess.jbjs.org**

TABLE V Wrist Range of Motion from Neutral Position and Grip Strength According to Allocated Treatment*

	Volar Plate†	Dorsal Nail-Plate†	Mean Difference‡	P Value
Dorsal range of motion *(deg)*				
2 weeks	31 ± 14 (n = 60)	34 ± 13 (n = 58)	−3.0 (−7.9 to 2.0)	0.24
6 weeks	46 ± 14 (n = 60)	48 ± 16 (n = 60)	−2.7 (−8.2 to 2.7)	0.33
3 months	56 ± 10 (n = 58)	56 ± 12 (n = 59)	−0.7 (−4.8 to 3.4)	0.74
6 months	61 ± 11 (n = 57)	63 ± 13 (n = 59)	−2.1 (−6.5 to 2.2)	0.33
1 year	65 ± 12 (n = 58)	63 ± 11 (n = 58)	1.8 (−2.4 to 6.0)	0.40
Volar range of motion *(deg)*				
2 weeks	36 ± 11 (n = 60)	35 ± 11 (n = 58)	1.5 (−2.5 to 5.5)	0.47
6 weeks	46 ± 11 (n = 60)	43 ± 13 (n = 60)	2.5 (−1.9 to 6.9)	0.26
3 months	51 ± 11 (n = 58)	49 ± 11 (n = 59)	1.7 (−2.3 to 5.7)	0.40
6 months	56 ± 10 (n = 57)	55 ± 13 (n = 59)	0.6 (−3.7 to 4.9)	0.78
1 year	59 ± 12 (n = 58)	55 ± 11 (n = 58)	3.5 (−0.8 to 7.9)	0.11
Ulnar range of motion *(deg)*				
2 weeks	23 ± 9 (n = 60)	22 ± 9 (n = 58)	0.9 (−2.4 to 4.2)	0.59
6 weeks	26 ± 10 (n = 60)	25 ± 9 (n = 60)	0.5 (−3.0 to 3.9)	0.79
3 months	29 ± 8 (n = 58)	28 ± 10 (n = 59)	1.4 (−2.0 to 4.8)	0.41
6 months	30 ± 9 (n = 57)	32 ± 9 (n = 59)	−2.0 (−5.3 to 1.4)	0.25
1 year	32 ± 10 (n = 58)	31 ± 9 (n = 58)	0.9 (−2.5 to 4.3)	0.60
Radial range of motion *(deg)*				
2 weeks	17 ± 6 (n = 60)	19 ± 7 (n = 58)	−2.3 (−4.8 to 0.2)	0.07
6 weeks	22 ± 7 (n = 60)	23 ± 8 (n = 60)	−1.9 (−4.6 to 0.9)	0.19
3 months	23 ± 8 (n = 58)	25 ± 9 (n = 59)	−1.6 (−4.6 to 1.4)	0.30
6 months	24 ± 8 (n = 57)	28 ± 8 (n = 59)	−3.4 (−6.4 to −0.4)	0.028
1 year	26 ± 8 (n = 58)	26 ± 8 (n = 58)	0.07 (−2.9 to 3.0)	0.96
Pronation range of motion *(deg)*				
2 weeks	79 ± 15 (n = 60)	80 ± 10 (n = 58)	−0.6 (−5.2 to 4.1)	0.81
6 weeks	82 ± 13 (n = 60)	84 ± 4 (n = 60)	−2.8 (−6.3 to 0.8)	0.13
3 months	86 ± 4 (n = 58)	84 ± 12 (n = 59)	2.1 (−1.2 to 5.4)	0.21
6 months	87 ± 5 (n = 57)	88 ± 6 (n = 59)	−1.2 (−3.2 to 0.8)	0.24
1 year	87 ± 10 (n = 58)	87 ± 3 (n = 58)	−0.14 (−2.9 to 2.6)	0.92
Supination range of motion *(deg)*				
2 weeks	51 ± 18 (n = 60)	51 ± 18 (n = 58)	0.3 (−6.2 to 6.9)	0.92
6 weeks	61 ± 17 (n = 60)	62 ± 17 (n = 60)	−1.6 (−7.8 to 4.5)	0.60
3 months	70 ± 12 (n = 58)	68 ± 12 (n = 59)	1.8 (−2.5 to 6.1)	0.40
6 months	71 ± 11 (n = 57)	72 ± 12 (n = 59)	−0.6 (−4.8 to 3.5)	0.76
1 year	71 ± 12 (n = 58)	71 ± 9 (n = 58)	−0.14 (−4.1 to 3.8)	0.95
Grip strength *(kg)*				
6 weeks	11.7 ± 6.3 (n = 58)	8.4 ± 5.1 (n = 59)	3.3 (1.2 to 5.4)	0.002
3 months	16.9 ± 6.4 (n = 58)	15.1 ± 6.7 (n = 58)	1.8 (−0.6 to 4.2)	0.14
6 months	20.6 ± 5.5 (n = 57)	19.8 ± 7.1 (n = 57)	0.8 (−1.6 to 3.1)	0.51
1 year	22.3 ± 6.7 (n = 58)	21.7 ± 7.1 (n = 58)	0.6 (−2.0 to 3.1)	0.66
Grip strength as percentage of uninjured side *(%)*				
6 weeks	51 ± 25 (n = 58)	39 ± 29 (n = 59)	11 (0.9 to 21)	0.032
3 months	70 ± 21 (n = 58)	66 ± 22 (n = 58)	4.2 (−4 to 12)	0.29
6 months	84 ± 17 (n = 57)	90 ± 24 (n = 57)	−6 (−14 to 2)	0.12
1 year	94 ± 18 (n = 58)	99 ± 22 (n = 58)	−5 (−13 to 2)	0.16

*Data were missing for some patients. †The values are expressed as the mean and the standard deviation. ‡The 95% CI is shown in parentheses.

TABLE VI Radiographic Results According to Allocated Treatment

	Volar Locking Plate (N = 60)		Dorsal Locking Nail-Plate (N = 58)			
	Mean and Standard Deviation	Mean Difference from Uninjured Wrist	Mean and Standard Deviation	Mean Difference from Uninjured Wrist	Mean Difference Between Groups*	P Value
Volar tilt *(deg)*						
Preop.	−25.2 ± 12.0	31.8	−22.7 ± 1.2	30.0	2.5 (−1.8 to 6.8)	0.256
Postop.	4.5 ± 3.8	2.1	4.9 ± 4.3	2.4	0.46 (−1.0 to 2.0)	0.547
1 year	4.2 ± 4.2	2.4	6.3 ± 4.2	1.0	2.1 (0.47 to 3.6)	0.011
Radial inclination *(deg)*						
Preop.	14.9 ± 4.6	7.0	14.9 ± 5.2	7.7	−0.024 (−1.8 to 1.8)	0.979
Postop.	21.3 ± 2.4	0.6	21.3 ± 3.0	1.3	0.012 (−0.97 to 1.0)	0.981
1 year	21.7 ± 2.2	0.2	21.9 ± 3.1	0.7	−0.25 (−1.2 to 0.76)	0.627
Ulnar variance *(mm)*						
Preop.	3.0 ± 2.5	2.9	2.4 ± 2.7	2.5	0.55 (−0.40 to 1.5)	0.256
Postop.	−0.73 ± 1.8	0.8	−0.62 ± 1.8	−0.74	−0.12 (−0.79 to 0.56)	0.735
1 year	0.07 ± 1.9	0.02	0.58 ± 1.9	0.7	−0.52 (−1.2 to 0.2)	0.160

*The 95% CI is shown in parentheses.

included intramedullary implants[39]. The authors of that study concluded that plate fixation offers the best results but could not make any conclusions regarding surgical approach or plate design.

There is no consensus on the best choice for primary outcome in trials comparing 2 types of implants for distal radial fracture surgery. The QuickDASH is a validated tool for the assessment of patients with distal radial fractures[40]. The PRWE is preferred over the QuickDASH by some authors, who have argued that the QuickDASH is neither side nor joint-specific and thus measures the ability of the upper limb to adapt rather than to recover natural function[25]. Those same authors have underlined the importance of including objective assessment, including functional tests to provide information for comparison between patients undergoing a specific treatment.

We excluded intra-articular fractures and younger patients. These narrow inclusion criteria were intentional for 2 reasons. First, normative data for our primary outcome, the QuickDASH, as well as those for the PRWE, differ between age groups[41,42]. Next, associated soft-tissue injuries are more frequent in non-osteoporotic patients, who more often sustain more complex fractures caused by high-energy trauma[43]. We wanted to confine the trial on the basis of age and fracture type to better assess whether these 2 implants would perform similarly for these fractures.

Forty-five patients were not diagnosed with an unstable distal radial fracture initially but rather were diagnosed at the time of their first outpatient clinic visit. Walenkamp et al., in a systematic review from 2015, found that there is no general consensus for the definition of "unstable."[44] Those authors reported that a definition for an unstable distal radial fracture was provided in only half of the studies, with a total of 143 different definitions being used. We defined instability according to the criteria described by Lafontaine et al. as well as on the basis of displacement following adequate reduction[19]. These 2 definitions are still the most used definitions in the literature[44]. Although a comprehensive article was published on this subject in 2006[45], the 2 former definitions were still used in our institutions practice at the time of inclusion. A general consensus definition is important in order to standardize future research.

The present study had several limitations. The patients, study nurse, and physiotherapist were not blinded to the allocation. At the time of inclusion, most patients who were not included in the study received volar plates, and a dorsal scar can bias the perception of the given treatment and its outcome.

One can argue that a 1-year follow-up is too short. Asadollahi and Keith, in a systematic review, reported that the median interval between surgery with a volar plate and a reported flexor tendon rupture was 9 months (range, 6 to 26 months)[46], and Cho et al. reported that a flexor tendon rupture may occur after a long symptom-free interval[47].

The present study also had several strengths. The small number of crossovers (n = 3) improves the reliability of the study, and the follow-up rate was high. The radiologist, study nurse, and physiotherapist were not otherwise involved in the study. The results are representative of an everyday setting, with procedures performed by a large number of surgeons. Participating surgeons, especially those familiar with dorsal approaches as well as intramedullary fixation principles, found the learning curve for the dorsal locking nail-plate implant to be short.

In conclusion, the present study shows that both a dorsal locking nail-plate and a volar locking plate may be used for fixation and early mobilization for dorsally displaced unstable extra-articular distal radial fractures, with similar outcomes. A

dorsal nail-plate construct such as the dorsal locking nail-plate may be preferred in situations in which a dorsal approach is desirable (for example, cases in which the volar cortical angle does not fit the volar plate design, cases in which intercarpal ligament injury or distal radioulnar joint instability must be concurrently addressed, or cases involving volar soft-tissue problems). The present study should encourage further development of dorsal plate designs, as we have seen with volar plates. ■

NOTE: The authors would like to thank orthopaedic surgeons at Baerum Hospital, Vestre Viken, who randomized and operated on the patients; Merete Finjarn, who scored the patients and helped keep track of patients during follow-up; Merete Fahs, who conducted testing of patients during follow-up; and Asbjørn Hjall, who contributed to the initiation of the study.

Morten Eikrem, MD[1,2,3]
Hege Brannsten, MD[4]
Dagfinn Bjørkøy, MD[1]
Tom Lian, MD[1,3]
Jan Erik Madsen, MD, PhD[3,5]
Wender Figved, MD, PhD[1,3]

[1]Orthopaedic Department, Baerum Hospital, Vestre Viken Hospital Trust, Gjettum, Norway

[2]Orthopaedic Department, Aalesund Hospital, Moere and Romsdal Hospital Trust, Aalesund, Norway

[3]Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

[4]Department of Radiology, Baerum Hospital, Vestre Viken Hospital Trust, Gjettum, Norway

[5]Division of Orthopaedic Surgery, Oslo University Hospital, Oslo, Norway

Email for corresponding author: Morten.Eikrem@helse-mr.no

References

1. Rozental TD, Beredjiklian PK, Bozentka DJ. Functional outcome and complications following two types of dorsal plating for unstable fractures of the distal part of the radius. J Bone Joint Surg Am. 2003 Oct;85(10):1956-60.

2. Tavakolian JD, Jupiter JB. Dorsal plating for distal radius fractures. Hand Clin. 2005 Aug;21(3):341-6.

3. Jakob M, Rikli DA, Regazzoni P. Fractures of the distal radius treated by internal fixation and early function. A prospective study of 73 consecutive patients. J Bone Joint Surg Br. 2000 Apr;82(3):340-4.

4. Lowry KJ, Gainor BJ, Hoskins JS. Extensor tendon rupture secondary to the AO/ASIF titanium distal radius plate without associated plate failure: a case report. Am J Orthop. 2000 Oct;29(10):789-91.

5. Yu YR, Makhni MC, Tabrizi S, Rozental TD, Mundanthanam G, Day CS. Complications of low-profile dorsal versus volar locking plates in the distal radius: a comparative study. J Hand Surg Am. 2011 Jul;36(7):1135-41.

6. Day CS, Franko OI. Low-profile dorsal plating for dorsally angulated distal radius fractures. Tech Hand Up Extrem Surg. 2007 Jun;11(2):142-8.

7. Kamath AF, Zurakowski D, Day CS. Low-profile dorsal plating for dorsally angulated distal radius fractures: an outcomes study. J Hand Surg Am. 2006 Sep;31(7):1061-7.

8. Koval KJ, Harrast JJ, Anglen JO, Weinstein JN. Fractures of the distal part of the radius. The evolution of practice over time. Where's the evidence? J Bone Joint Surg Am. 2008 Sep;90(9):1855-61.

9. Alter TH, Ilyas AM. Complications Associated with Volar Locking Plate Fixation of Distal Radial Fractures. JBJS Rev. 2018 Oct;6(10):e7.

10. Bachoura A, Shin EK. Emerging Technologies in Distal Radius Fracture Fixation. Curr Rev Musculoskelet Med. 2019 Jun 22;12(3):369-78.

11. Orbay JL, Touhami A, Orbay C. Fixed angle fixation of distal radius fractures through a minimally invasive approach. Tech Hand Up Extrem Surg. 2005 Sep;9(3):142-8.

12. McCall TA, Conrad B, Badman B, Wright T. Volar versus dorsal fixed-angle fixation of dorsally unstable extra-articular distal radius fractures: a biomechanic study. J Hand Surg Am. 2007 Jul-Aug;32(6):806-12.

13. Klitscher D, Mehling I, Nowak L, Nowak T, Rommens PM, Müller LP. Biomechanical comparison of dorsal nail plate versus screw and K-wire construct for extra-articular distal radius fractures in a cadaver bone model. J Hand Surg Am. 2010 Apr;35(4):611-8.

14. Capo JT, Kinchelow T, Brooks K, Tan V, Manigrasso M, Francisco K. Biomechanical stability of four fixation constructs for distal radius fractures. Hand (N Y). 2009 Sep;4(3):272-8.

15. Karatoprak O, Karaca S, Erdem MN, Kirac F, Enercan M, Tuncer S. Dorsal nail plate versus percutaneous k-wire fixation in the treatment of displaced distal radius fractures. Acta Orthop Belg. 2015 Mar;81(1):65-71.

16. Chappuis J, Bouté P, Putz P. Dorsally displaced extra-articular distal radius fractures fixation: Dorsal IM nailing versus volar plating. A randomized controlled trial. Orthop Traumatol Surg Res. 2011 Sep;97(5):471-8.

17. Schulz KF, Altman DG, Moher D. CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. PLoS Med. 2010 Mar 24;7(3):e1000251-7.

18. Meinberg EG, Agel J, Roberts CS, Karam MD, Kellam JF. Introduction: fracture and dislocation classification compendium-2018. J Orthop Trauma. 2018 Jan;32(Suppl 1):S1-170.

19. Lafontaine M, Hardy D, Delince P. Stability assessment of distal radius fractures. Injury. 1989 Jul;20(4):208-10.

20. Mauser NS, Benoit MY, Morrell NT, Shafritz AB. Treatment of Distal Radial Fractures by Open Reduction and Internal Fixation with a Volar Locking Plate. JBJS Essential Surg Tech. 2016 Sep 14;6(3):e31-2.

21. Finsen V. [Norwegian version of the DASH questionnaire for examination of the arm shoulders and hand]. Tidsskr Nor Laegeforen. 2008 May 1;128(9):1070.

22. Gummesson C, Ward MM, Atroshi I. The shortened Disabilities of the Arm, Shoulder and Hand questionnaire (Quick DASH): validity and reliability based on responses within the full-length DASH. BMC Musculoskelet Disord. 2006;7:44.

23. Hudak PL, Amadio PC, Bombardier C; The Upper Extremity Collaborative Group (UECG). Development of an upper extremity outcome measure: the DASH (Disabilities of the Arm, Shoulder and Hand) [corrected]. Am J Ind Med. 1996 Jun;29(6):602-8.

24. MacDermid JC, Turgeon T, Richards RS, Beadle M, Roth JH. Patient rating of wrist pain and disability: a reliable and valid measurement tool. J Orthop Trauma. 1998 Nov-Dec;12(8):577-86.

25. Barker SL, Rehman H, McCullough AL, Fielding S, Johnstone AJ. Assessment Following Distal Radius Fractures: A Comparison of 4 Scoring Systems, Visual Numerical Scales, and Objective Measurements. J Hand Surg Am. 2016 Feb;41(2):219-224.e1.

26. Walenkamp MMJ, de Muinck Keizer RJ, Goslings JC, Vos LM, Rosenwasser MP, Schep NWL. The Minimum Clinically Important Difference of the Patient-rated Wrist Evaluation Score for Patients With Distal Radius Fractures. Clin Orthop Relat Res. 2015 Oct;473(10):3235-41.

27. Rabin R, Gudex C, Selai C, Herdman M. From translation to version management: a history and review of methods for the cultural adaptation of the EuroQol five-dimensional questionnaire. Value Health. 2014 Jan-Feb;17(1):70-6.

28. Kim JK, Park MG, Shin SJ. What is the minimum clinically important difference in grip strength? Clin Orthop Relat Res. 2014 Aug;472(8):2536-41.

29. Mathiowetz V, Kashman N, Volland G, Weber K, Dowe M, Rogers S. Grip and pinch strength: normative data for adults. Arch Phys Med Rehabil. 1985 Feb;66(2):69-74.

30. Kreder HJ, Hanel DP, McKee M, Jupiter J, McGillivary G, Swiontkowski MF. X-ray film measurements for healed distal radius fractures. J Hand Surg Am. 1996 Jan;21(1):31-9.

31. Stirling E, Jeffery J, Johnson N, Dias J. Are radiographic measurements of the displacement of a distal radial fracture reliable and reproducible? Bone Joint J. 2016 Aug;98-B(8):1069-73.

32. Hunsaker FG, Cioffi DA, Amadio PC, Wright JG, Caughlin B. The American academy of orthopaedic surgeons outcomes instruments: normative values from the general population. J Bone Joint Surg Am. 2002 Feb;84(2):208-15.

33. Piaggio G, Elbourne DR, Pocock SJ, Evans SJW, Altman DG. CONSORT Group. Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. JAMA. 2012 Dec 26;308(24):2594-604.

34. Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the Disabilities of the Arm, Shoulder and Hand outcome measure (DASH) and its shortened version (QuickDASH). J Orthop Sports Phys Ther. 2014 Jan;44(1):30-9.

35. Hammer OL, Clementsen S, Hast J, Šaltytė Benth J, Madsen JE, Randsborg PH. Volar Locking Plates Versus Augmented External Fixation of Intra-Articular Distal

Radial Fractures: Functional Results from a Randomized Controlled Trial. J Bone Joint Surg Am. 2019 Feb 20;101(4):311-21.

36. Mintken PE, Glynn P, Cleland JA. Psychometric properties of the shortened Disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) and Numeric Pain Rating Scale in patients with shoulder pain. J Shoulder Elbow Surg. 2009 Nov-Dec;18(6):920-6.

37. Polson K, Reid D, McNair PJ, Larmer P. Responsiveness, minimal importance difference and minimal detectable change scores of the shortened Disability Arm Shoulder Hand (QuickDASH) questionnaire. Man Ther. 2010 Aug;15(4):404-7.

38. Jordan RW, Saithna A. Defining the role of intramedullary nailing for fractures of the distal radius: a systematic review. Bone Joint J. 2015 Oct;97-B(10):1370-6.

39. Vannabouathong C, Hussain N, Guerra-Farfan E, Bhandari M. Interventions for Distal Radius Fractures: A Network Meta-analysis of Randomized Trials. J Am Acad Orthop Surg. 2019 Jul 1;27(13):e596-605.

40. Tsang P, Walton D, Grewal R, MacDermid J. Validation of the QuickDASH and DASH in Patients With Distal Radius Fractures Through Agreement Analysis. Arch Phys Med Rehabil. 2017 Jun;98(6):1217-1222.e1.

41. Aasheim T, Finsen V. The DASH and the QuickDASH instruments. Normative values in the general population in Norway. J Hand Surg Eur Vol. 2014 Feb;39(2):140-4.

42. Mulders MAM, Kleipool SC, Dingemans SA, van Eerten PV, Schepers T, Goslings JC, Schep NWL. Normative data for the Patient-Rated Wrist Evaluation questionnaire. J Hand Ther. 2018 Jul - Sep;31(3):287-94.

43. Lindau T. Arthroscopic Evaluation of Associated Soft Tissue Injuries in Distal Radius Fractures. Hand Clin. 2017 Nov;33(4):651-8.

44. Walenkamp MMJ, Vos LM, Strackee SD, Goslings JC, Schep NWL. The Unstable Distal Radius Fracture-How Do We Define It? A Systematic Review. J Wrist Surg. 2015 Nov;4(4):307-16.

45. Mackenney PJ, McQueen MM, Elton R. Prediction of instability in distal radial fractures. J Bone Joint Surg Am. 2006 Sep;88(9):1944-51.

46. Asadollahi S, Keith PPA. Flexor tendon injuries following plate fixation of distal radius fractures: a systematic review of the literature. J Orthop Traumatol. 2013 Dec;14(4):227-34.

47. Cho CH, Lee KJ, Song KS, Bae KC. Delayed rupture of flexor pollicis longus after volar plating for a distal radius fracture. Clin Orthop Surg. 2012 Dec;4(4):325-8.