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

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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. Low-profile dorsal plates have shown stable fracture fixation and decreased rates of extensor tendon complications. During the last decades, there has been a shift away from dorsal plating toward low-profile volar locking plates. 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.

Thus, alternative fixation constructs have emerged. One such implant is the dorsal locking nail-plate, which was
introduced in 2005\(^1\). 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\(^2\)-\(^14\), 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 \(\geq 55\) 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.
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.

**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.
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, 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). The PRWE score has a proposed minimum clinically important difference (MCID) of 11.5. 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]). 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%. We did not adjust for hand dominance. A senior radiologist (H.B.), who was blinded to patient outcome, conducted all radiographic measurements with use of a standardized protocol. 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. With a standard deviation of 15 points 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%. 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. 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, 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
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, 25.5 points [95% CI, 9.9 to 1.2]; \( p = 0.014 \)). At no time interval did the PRWE score reach the

| 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.

**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) |
| Left | 26 (46%) | 30 (51%) |
| Right | 34 (56%) | 36 (63%) |
| **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.
### 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) | 0.84 (0.62 to 1.14) | 0.017 |
| Operation performed by single surgeon (no. of patients) | 38 (63%) | 32 (53%) | — | — | 0.36 |
| Converted to different fixation type perioperatively (no. of patients) | 0 (0%) | 2 (3%) | — | — | 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‡ | 42.1 ± 17.3 (n = 60) | 47.9 ± 17.3 (n = 59) | −5.8 (−12.1 to 0.5) | — | 0.972 |
| 2 weeks | | | | | |
| 6 weeks | | | | | |
| 3 months | | | | | |
| 6 months | | | | | |
| 1 year | | | | | |
| PRWE score‡ | 39.4 ± 12.3 (n = 60) | 44.5 ± 11.1 (n = 59) | −5.1 (−9.4 to −0.8) | — | 0.019 |
| 2 weeks | | | | | |
| 6 weeks | | | | | |
| 3 months | | | | | |
| 6 months | | | | | |
| 1 year | | | | | |
| EQ-5D index score‡ | 0.69 ± 0.18 (n = 60) | 0.67 ± 0.19 (n = 59) | 0.023 (−0.047 to 0.085) | — | 0.57 |
| 2 weeks | | | | | |
| 6 weeks | | | | | |
| 3 months | | | | | |
| 6 months | | | | | |
| 1 year | | | | | |
| EQ-5D VAS score‡ | 73 ± 17.0 (n = 60) | 76 ± 16.0 (n = 59) | −2.3 (−8.3 to 3.6) | — | 0.44 |
| 2 weeks | | | | | |
| 6 weeks | | | | | |
| 3 months | | | | | |
| 6 months | | | | | |
| 1 year | | | | | |

*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.
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 [36]. 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 [38]. 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 [39]. 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 [40]. One meta-analysis of RCTs of all surgical interventions included 38 trials, but only 2 of the trials...
### 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    |
| **Ulnar 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    |
| **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.
included intramedullary implants. 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. 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. 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. Next, associated soft-tissue injuries are more frequent in non-osseoprotic patients, who more often sustain more complex fractures caused by high-energy trauma. 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.” 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. These 2 definitions are still the most used definitions in the literature. Although a comprehensive article was published on this subject in 2006, 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), and Cho et al. reported that a flexor tendon rupture may occur after a long symptom-free interval.

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

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**TABLE VI Radiographic Results According to Allocated Treatment**

| Volar Locking Plate (N = 60) | Dorsal Locking Nail-Plate (N = 58) | Mean Difference Between Groups* | P Value |
|-----------------------------|-----------------------------------|---------------------------------|---------|
| **Mean and Standard Deviation** | **Mean and Standard Deviation** | **Mean Difference** | **P Value** |
| Volar tilt (deg) | Postop. | 4.5 ± 3.8 | 2.4 | 0.046 (1.0 to 2.0) | 0.547 |
| | 1 year | 4.2 ± 4.2 | 2.4 | 0.046 (1.0 to 2.0) | 0.547 |
| Radial inclination (deg) | Preop. | 14.9 ± 4.6 | 7.0 | 0.012 (0.97 to 1.0) | 0.981 |
| | Postop. | 21.3 ± 2.4 | 0.6 | 0.012 (0.97 to 1.0) | 0.981 |
| | 1 year | 21.7 ± 2.2 | 0.2 | 0.012 (0.97 to 1.0) | 0.981 |
| Ulnar variance (mm) | Preop. | 3.0 ± 2.5 | 2.9 | 0.55 (0.40 to 1.5) | 0.256 |
| | Postop. | −0.73 ± 1.8 | 0.8 | 0.55 (0.40 to 1.5) | 0.256 |
| | 1 year | 0.07 ± 1.9 | 0.02 | 0.55 (0.40 to 1.5) | 0.256 |

*The 95% CI is shown in parentheses.*
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.

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