Volar Plate Fixation Versus Plaster Immobilization in Acceptably Reduced Extra-Articular Distal Radial Fractures: A Multicenter Randomized Controlled Trial

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A commentary by Allan Peljovich, MD, MPH, is linked to the online version of this article at jbjs.org.

Volar Plate Fixation Versus Plaster Immobilization in Acceptably Reduced Extra-Articular Distal Radial Fractures

A Multicenter Randomized Controlled Trial

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Background: There is no consensus as to whether displaced extra-articular distal radial fractures should be treated operatively or nonoperatively. We compared the outcomes of open reduction and volar plate fixation with closed reduction and plaster immobilization in adults with an acceptably reduced extra-articular distal radial fracture.

Methods: In this multicenter randomized controlled trial, patients 18 to 75 years old with an acceptably reduced extra-articular distal radial fracture were randomly assigned to open reduction and volar plate fixation or plaster immobilization. The primary outcome was function as measured with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire after 12 months. Follow-up was conducted at 1, 3, and 6 weeks and at 3, 6, and 12 months. Analyses were performed according to the intention-to-treat principle.

Results: Ninety-two patients were randomized, 48 to open reduction and volar plate fixation and 44 to plaster immobilization; 1 patient in each group was excluded for withdrawing informed consent. At all follow-up time points, operatively treated patients had significantly better functional outcomes, as indicated by significantly lower DASH scores, than patients treated nonoperatively (all p values < 0.05). Twelve nonoperatively managed patients (28%) had fracture redisplacement within 6 weeks and underwent subsequent open reduction and internal fixation, and 6 patients (14%) had a symptomatic malunion treated with corrective osteotomy.

Conclusions: Patients with an acceptably reduced extra-articular distal radial fracture treated with open reduction and volar plate fixation have better functional outcomes after 12 months compared with nonoperatively managed patients. Additionally, 42% of nonoperatively managed patients had a subsequent surgical procedure. Open reduction and volar plate fixation should be considered for patients who experience this common injury.

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

The incidence of distal radial fracture is 20 to 32 per 10,000 person-years[1,2]; despite this high incidence, there is no unequivocal evidence regarding the optimal treatment. The recommended treatment for patients with acceptably reduced distal radial fracture is nonoperative by means of immobilization[3,4]. However, the evidence supporting this method of treatment is not convincing as it is based on studies that include both extra- and intra-articular fractures and that focused mainly on

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A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/F287).

elderly patients[5,6]. Moreover, fracture redisplacement after closed reduction has been observed in up to 60% of patients[7-9].

In 1814, Abraham Colles was the first to describe the dorsally displaced extra-articular distal radial fracture[10]. Although he stated that unreduced Colles fractures result in a pain-free malunion with a perfect range of motion, more recent studies have shown that malunion may result in pain and impaired function[11,12]. Moreover, subsequent surgical procedures for fracture redisplacement or symptomatic malunion have been reported in 37% of nonoperatively treated displaced extra-articular distal radial fractures[13], which has raised concerns about nonoperatively managing these patients[14-16]. Open reduction and internal fixation (ORIF) allows for early mobilization and therefore may lead to improved functional recovery[17].

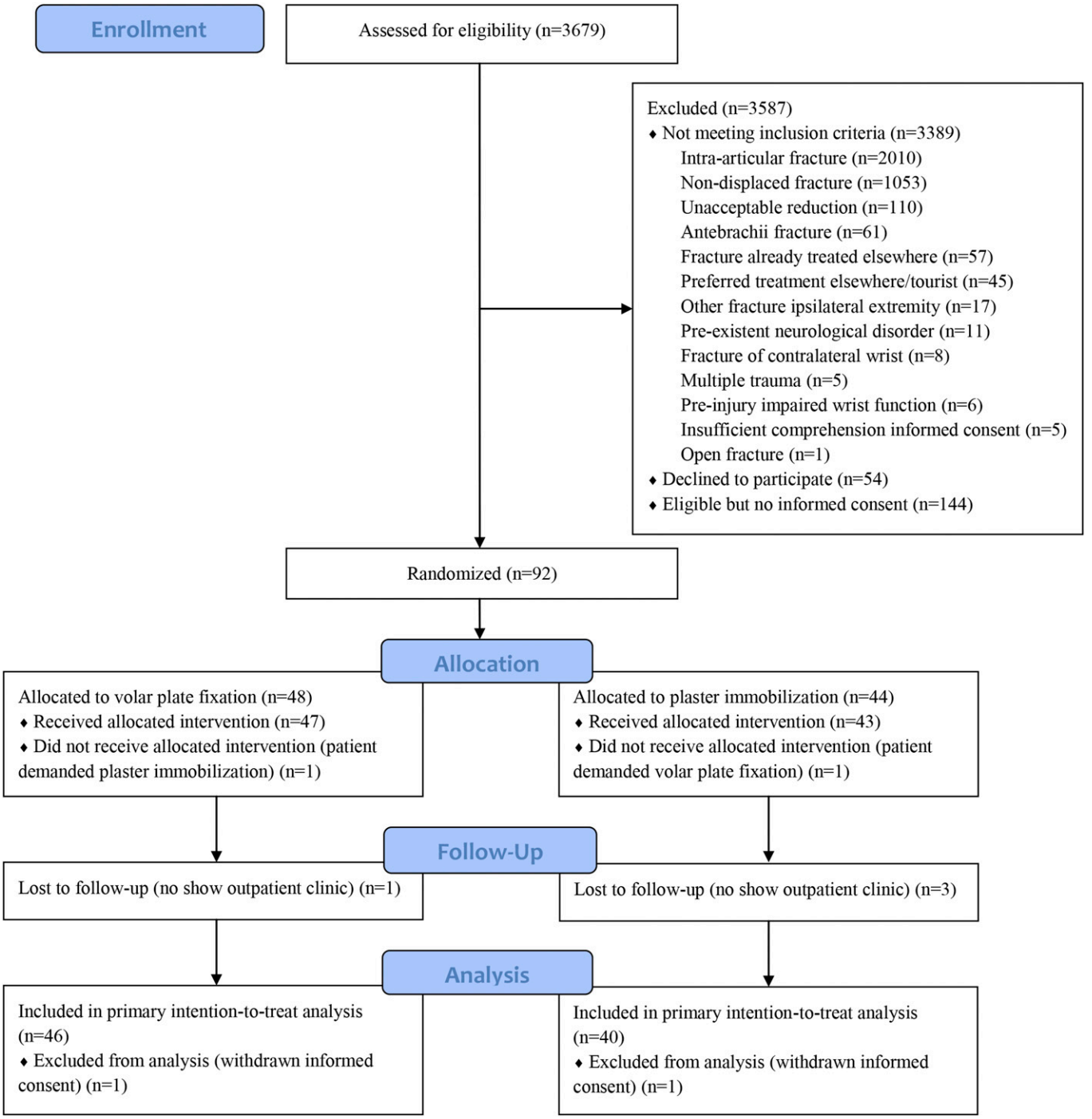

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the VIPER Trial.

TABLE I Baseline Characteristics*

	Operative Group (N = 47)	Nonoperative Group (N = 43)
Age *(yr)*	59 [42.0-66.0]	60 [52.0-65.0]
Sex		
Female	31 (66%)	36 (84%)
Male	16 (34%)	7 (16%)
Fracture of dominant side	30 (64%)	23 (54%)
AO/OTA classification		
A2	10 (21%)	13 (30%)
A3	37 (79%)	30 (70%)
Ulnar styloid fracture		
Yes	19 (40%)	28 (65%)
No	28 (60%)	15 (35%)
Diabetes mellitus		
Yes	1 (2%)	4 (9%)
No	46 (98%)	39 (91%)
Previous corticosteroid use		
Yes	3 (6%)	6 (14%)
No	44 (94%)	37 (86%)
Smoking		
Yes	10 (21%)	11 (26%)
No	37 (79%)	32 (74%)

*Values are given as the number of patients with the percentage of patients in the cohort in parentheses, except for age, which is given as the median with the IQR in brackets. There were no significant differences between the 2 groups in baseline characteristics, except for a fracture of the ulnar styloid (p = 0.019).

The aim of this randomized controlled trial was to compare the functional outcomes of open reduction and volar plate fixation with plaster immobilization in adults with acceptably reduced extra-articular distal radial fractures. We hypothesize that volar plate fixation will result in better functional outcomes at 1 year after trauma, as measured with use of the Disability of the Arm, Shoulder and Hand (DASH) questionnaire.

Materials and Methods

Study Design and Eligibility Criteria

The VIPER Trial was a multicenter prospective randomized controlled trial conducted at 14 hospitals in the Netherlands from January 2013 to March 2016. The hospitals ranged from level-I trauma centers to non-teaching or community hospitals. Approval was obtained from the ethics committee and institutional review board, as well as the boards of directors of all participating centers. All patients provided written informed consent prior to randomization. The trial protocol has previously been published[18].

All patients 18 to 75 years old with an acceptably reduced extra-articular distal radial fracture (AO/OTA types A2 and A3), as confirmed on radiographs, were eligible for inclusion. All fractures were initially reduced at an emergency department (ED) under hematoma-block local anesthesia and immobilized with a below-the-elbow dorsal splint (see Appendix Figs. 1-A and 1-B). Acceptable reduction was confirmed on lateral and posteroanterior radiographs by an experienced radiologist or orthopaedic trauma surgeon. In accordance with Dutch guidelines, fracture reduction was considered acceptable with the following conditions: radial inclination ≥15°, loss of radial height ≤5 mm, dorsal angulation ≤15°, and palmar angulation ≤20°[3]. A description of all exclusion criteria is provided in Appendix 1. A log of patients who were screened for eligibility was kept for each participating center.

Randomization and Blinding

Patients were randomized in a 1:1 ratio to open reduction and volar plate fixation or plaster immobilization. Randomization was performed by means of a secured online computerized randomization procedure, using mixed block sizes of 2, 4, 6, and 8. Randomization was stratified according to age into 3 strata (18 to 30, 31 to 60, and 61 to 75 years old). Because the assignment involved a surgical procedure, neither participants nor treating physicians were blinded to the treatment allocation.

Interventions

A detailed description of the interventions has previously been published[18]. Open reduction and volar plate fixation was performed by a certified orthopaedic trauma surgeon or by a surgical resident under the supervision of a certified orthopaedic trauma surgeon. In participants randomized to plaster immobilization, the dorsal splint was changed under traction after a minimum of 1 week and a circular plaster of Paris was applied for another 4 to 5 weeks. If loss of reduction occurred during plaster immobilization, ORIF was carried out at the discretion of the treating physician and the patient.

Identical instructions on moving the wrist were given to both operatively and nonoperatively managed patients. These instructions included flexion and extension of the wrist, radial and ulnar deviation, and pronation and supination. Patients were also instructed to exercise their fingers or squeeze a ball. Operatively managed patients were instructed to use the wrist after the operation as pain allowed; however, for the first 6 weeks only non-weight-bearing exercises were allowed. Rehabilitation with a physiotherapist was at the discretion of the patient and treating physician.

Outcomes

Patients were assessed at the outpatient clinic at 1, 3, and 6 weeks, and at 3, 6, and 12 months postoperatively. Clinical assessment was performed by an independent examiner who was not blinded to the allocated treatment because the scars on the palmar side of the wrist in the operative group could easily be observed.

The primary outcome was the DASH score at 12 months of follow-up. The DASH score ranges from 0 to 100, with 0 indicating no disability[19]. The smallest change that patients perceive as beneficial, also known as the minimal clinically important difference (MCID), in the DASH score for nontraumatic conditions of the wrist is 10[20,21]. However, the MCID of the DASH for traumatic conditions is unknown.

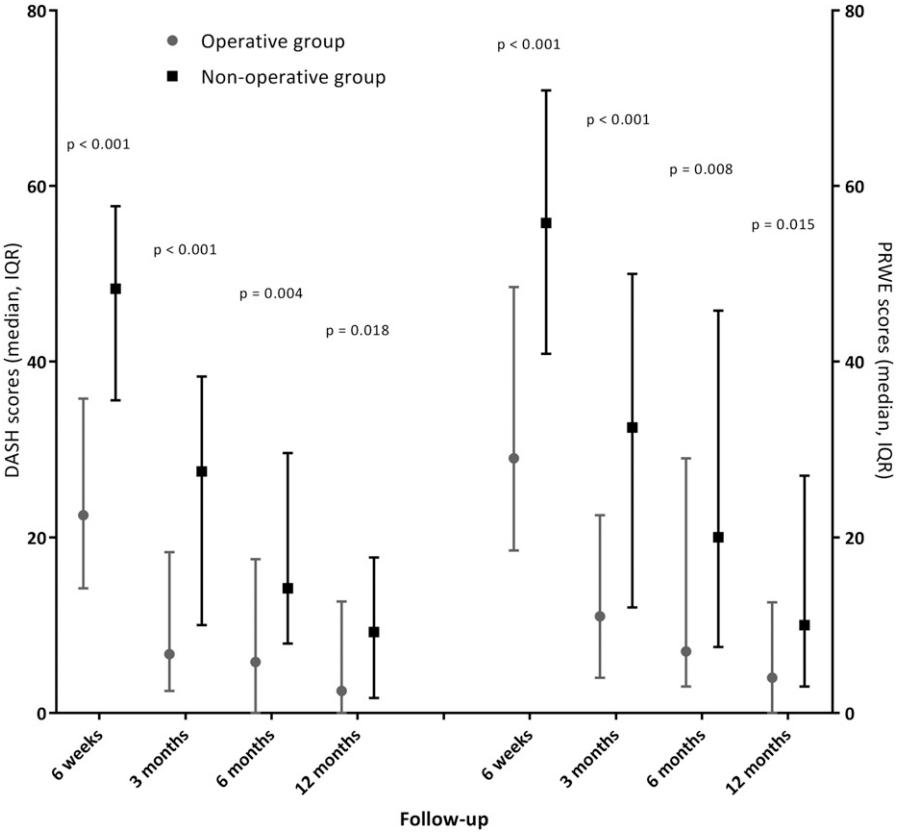

Fig. 2
Median DASH and PRWE scores with IQR, corrected for age.

Secondary outcomes included functional outcome measured with use of the Patient-Rated Wrist Evaluation (PRWE) questionnaire, quality of life measured with use of the Short Form-36 (SF-36) questionnaire, range of motion, grip strength, radiographic parameters, and complications. The PRWE ranges from 0 to 100, with 0 indicating no pain or functional impairment[20]. The MCID for the PRWE is 11.5[22,23]. The SF-36 is divided into 2 subscales, the physical component summary and the mental component summary, and the score ranges from 0 to 100, with higher scores indicating a better state of health[22]. Patients completed the questionnaires either online before the outpatient clinic appointment or on paper at the outpatient clinic before they were seen by their surgeon.

Range of motion was measured with a handheld goniometer. Grip strength was measured as the mean of 3 measurements taken with a hydraulic hand dynamometer. Both range of motion and grip strength on the injured side were compared with the uninjured side and expressed as a percentage.

A complication was defined as any adverse event for which any additional treatment was required. Subsequent surgical intervention was defined as either ORIF for fracture redisplacement or corrective osteotomy for symptomatic malunion. We defined fracture redisplacement as loss of acceptable reduction as described above. Symptomatic malunion was defined as a malunited fracture with pain and/or functional impairment. Standard lateral and posteroanterior radiographs were made at all follow-up appointments and evaluated for radial inclination, radial height, ulnar variance, and dorsal and palmar angulation. Evaluation was performed by an examiner other than the treating surgeon.

Statistical Analysis

With $\alpha = 0.05\%$, a sample size of 66 patients was required to provide 90% power to detect a difference of 15 points for DASH score, with a standard deviation of 18. Because the MCID of the DASH score for patients with distal radial fractures is unknown, we considered a difference of 15 points to be clinically relevant. To correct for patients lost to follow-up, 90 patients had to be included. Because the trial compared 2 interventions routinely used in clinical practice, an interim analysis was not performed.

All analyses were performed according to the intention-to-treat principle. A Mann-Whitney U test was used to compare the 1 continuous, non-normally distributed baseline characteristic (patient age). Other baseline characteristics were analyzed with use of a chi-square test. An analysis of covariance (ANCOVA) was used to test for differences between the groups in DASH, PRWE, and SF-36 scores at each follow-up time point. A linear mixed model was applied to the secondary outcomes (range of motion, grip strength, and radiographic parameters). The best

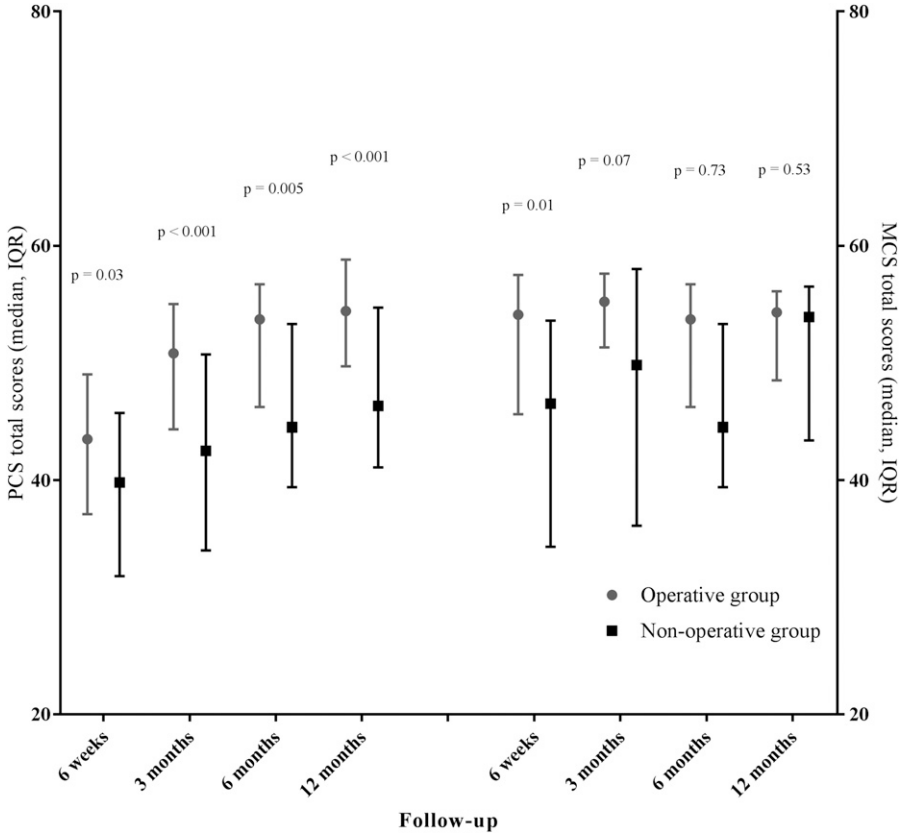

Fig. 3

Median SF-36 physical component summary (PCS) and mental component summary (MCS) subscores with IQR, corrected for age.

covariance structure for each linear mixed model was determined with use of the smallest Akaike information criterion. In both the ANCOVA and the linear mixed model, data were ranked by follow-up time point if they were non-normally distributed[24]. To verify the normality of the ranked data, histograms of the residuals were visually inspected. All outcome measures were corrected for age, as this was a stratification factor in the design of the study[25]. Single imputations were used for radiographic outcomes, applying predictive mean matching, with treatment and the other follow-up measurements used as predictors.

An additional post-hoc subgroup analysis was performed in which the DASH and PRWE scores of patients treated operatively were compared with those of patients who were initially treated nonoperatively but who underwent a subsequent surgical procedure. Additional comparison was made between patients treated operatively and patients treated nonoperatively without a subsequent surgical procedure.

To evaluate potential selection bias, baseline characteristics of patients eligible for inclusion but without informed consent were compared with those of included patients.

Two-sided p values of <0.05 were considered significant. All analyses were performed with SPSS software (version 24; IBM). This trial was registered with ClinicalTrials.gov (NCT02030496).

Results

A total of 3,679 patients were screened for eligibility between January 2013 and March 2016, of whom 92 provided written informed consent (Fig. 1). Forty-eight patients were randomly assigned to open reduction and volar plate fixation and 44 to plaster immobilization; 1 patient in each group was excluded for withdrawing informed consent. The median age was 59 years (interquartile range [IQR]: 45.8 to 65.3 years), and 74% of patients were female. Baseline characteristics were well-balanced, except for the proportions of patients with fracture of the ulnar styloid process (Table I). The baseline characteristics of the included patients did not differ from those of eligible patients who were not included (see Appendix 2). At the time of randomization, all patients had an acceptable reduction, with a mean radial inclination (and standard deviation [SD]) of 23.3° ± 25.2°, radial height of 9.9 ± 1.6 mm, ulnar variance of −0.7 ± 1.7 mm, and dorsal angulation of 1.4° ± 5.3°. One patient assigned to open reduction and volar plate fixation and 3 patients assigned to plaster immobilization were lost to follow-up. Of all randomized patients, 96% had a complete follow-up of 12 months for the primary outcome (DASH score). Open reduction and volar plate fixation was performed at a median of 6 days (IQR: 4.5 to 6.0 days) after randomization and 11 days (IQR: 7.0 to 13.5 days) after trauma.

At all follow-up time points, operatively treated patients had significantly better functional outcomes, as indicated by

TABLE II Clinical Outcomes*

	6 Weeks		3 Months	
	Operative Group	Nonoperative Group	Operative Group	Nonoperative Group
Radial deviation *(°)*	15 [10-20] (86%)†	10 [5-15] (58%)†	15 [10-24] (93%)	15 [10-20] (90%)
Ulnar deviation *(°)*	25 [20-35] (89%)†	20 [10-30] (55%)†	30 [20-35] (95%)	25 [19-31] (77%)
Pronation *(°)*	85 [75-90] (93%)†	75 [55-85] (80%)†	90 [80-90] (97%)	88 [70-90] (91%)
Supination *(°)*	70 [60-80] (82%)†	50 [30-70] (57%)†	75 [70-88] (90%)	70 [64-80] (83%)
Extension *(°)*	60 [42-75] (74%)†	35 [20-55] (47%)†	75 [60-88] (87%)	63 [50-85] (82%)
Flexion *(°)*	55 [45-70] (72%)†	40 [25-55] (52%)†	65 [60-80] (85%)†	55 [45-70] (74%)†
Grip strength *(kg)*	17 [9.1-21.3] (58%)†	5 [1.3-8.3] (25%)†	23 [14.8-28.4] (75%)†	15 [10.5-19.5] (57%)†

*Values are given as the median with the IQR in brackets and the percentage of the uninjured side in parentheses. Range of motion and grip strength are corrected for age. †Values are significantly different at the corresponding follow-up time point. ‡Significant.

significantly lower DASH and PRWE scores, than patients treated nonoperatively (Fig. 2; see Appendix 3).

Operatively treated patients had significantly higher SF-36 physical component subscores, indicating a better physical quality of life up to 12 months. SF-36 mental component subscores were only significantly different between groups at 6 weeks (Fig. 3).

At 6 weeks, operatively managed patients had significantly better range of motion compared with nonoperatively

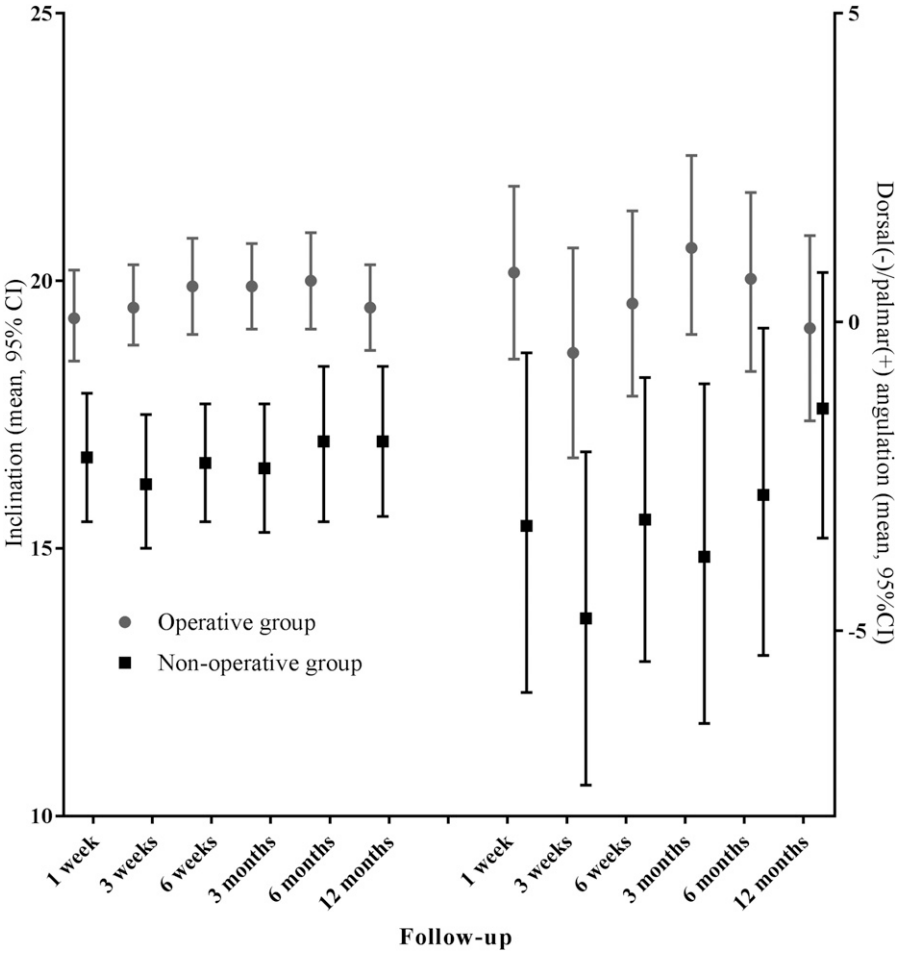

Fig. 4-A

Mean radial inclination and dorsal/palmar angulation in degrees with 95% confidence interval (CI), corrected for age.

TABLE II (*continued*)

6 Months		12 Months		
Operative Group	Nonoperative Group	Operative Group	Nonoperative Group	P Value
15 [10-20] (97%)	15 [10-20] (99%)	15 [10-20] (97%)	15 [10-15] (101%)	0.001‡
25 [25-40] (98%)	25 [20-32] (91%)	25 [25-31] (97%)	25 [20-30] (94%)	0.113
90 [80-90] (98%)	85 [75-90] (94%)	90 [80-90] (99%)	85 [75-90] (95%)	0.001‡
80 [75-90] (94%)†	78 [65-85] (92%)†	85 [75-90] (97%)†	75 [70-85] (91%)†	<0.001‡
80 [75-90] (93%)	80 [70-89] (92%)	85 [80-90] (98%)†	80 [70-90] (93%)†	<0.001‡
75 [65-85] (93%)†	68 [56-80] (87%)†	80 [70-86] (95%)†	70 [60-80] (89%)†	0.001‡
27 [16.7-34.0] (86%)†	21 [14.8-24.1] (75%)†	26 [19.3-35.3] (93%)†	20 [17.3-28.7] (83%)†	<0.001‡

managed patients. At 12 months, only flexion, extension, and supination of the wrist were significantly better in operatively managed patients than in nonoperatively managed patients. Moreover, when measured as a percentage of the uninjured side, grip strength was significantly higher in operatively managed patients up to 12 months of follow-up (Table II).

During the entire follow-up period, operatively managed patients had significantly better radiographic parameters than nonoperatively managed patients (Figs. 4-A and 4-B).

Significantly more patients in the nonoperative group had a complication than in the operative group (25 patients and 16 patients, respectively; p = 0.02) (Table III). Twelve nonoperatively managed patients (28%) had fracture redisplacement within 6 weeks of the trauma and were managed with open reduction and volar plate fixation. A total of 17 nonoperatively managed patients (40%) developed a malunion, 6 of whom were symptomatic and were managed with a corrective osteotomy at a median of 6 months (IQR: 3.5 to 7.5 months) after the trauma.

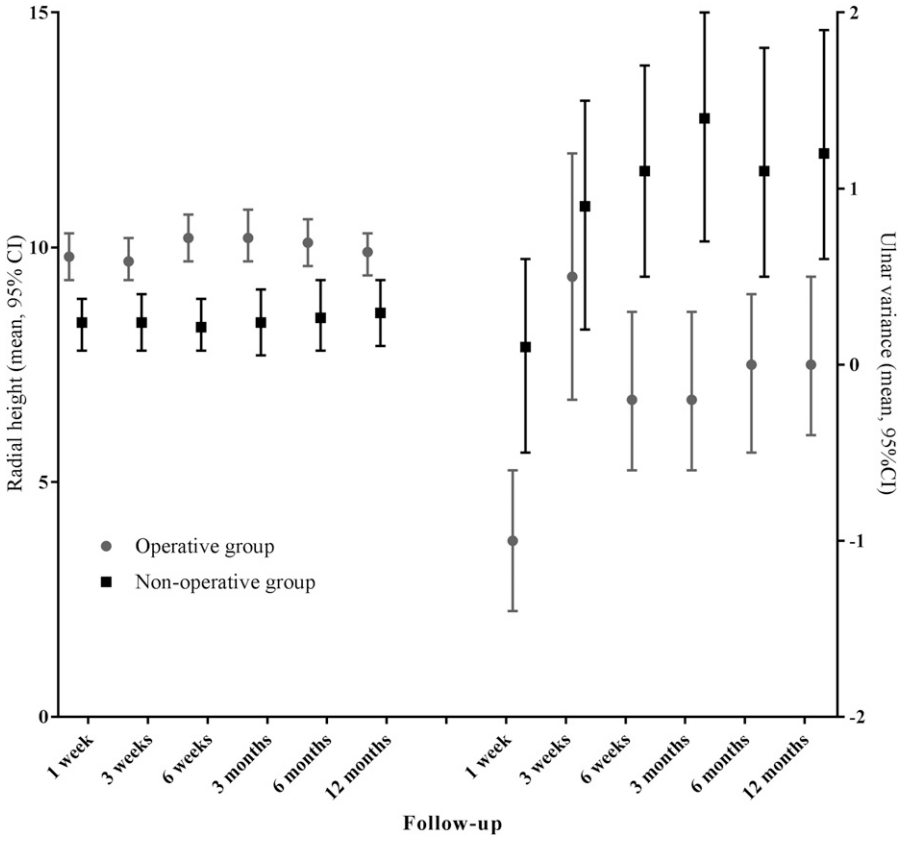

Fig. 4-B

Mean radial height and ulnar variance in mm with 95% confidence interval (CI), corrected for age.

TABLE III Complications*

	Operative Group	Nonoperative Group
Superficial wound infection	3	1
CRPS type 1	1	4
CTS	–	3
de Quervain tenosynovitis	–	2
Tendinitis	2	2
EPL rupture†	3	1
Implant removal	9	1
Screw breakage	1	1
Fracture redisplacement	–	12
Symptomatic malunion	–	6
Pseudarthrosis	1	–
Total	20	33

*Complications are presented according to the intention-to-treat principle. CRPS = complex regional pain syndrome; CTS = carpal tunnel syndrome; EPL = extensor pollicis longus. †The rupture in the nonoperative group was an attritional rupture; 2 of 3 ruptures in the operative group were hardware-related.

TABLE IV Difference in Patient-Reported Outcome Measures Between Patients Primarily Managed Operatively (N = 47) and Those Who Underwent Subsequent Surgery (N = 18)*

	Operative Group	Subsequent Surgical Procedure	P Value
6 wk			
DASH	22.5 [14.2-35.8]	50.4 [37.7-56.7]	<0.001†
PRWE	29.0 [18.5-48.5]	54.5 [42.4-73.9]	0.001†
3 mo			
DASH	6.7 [2.5-18.3]	27.1 [11.0-42.2]	0.001†
PRWE	11.0 [4.0-22.5]	38.5 [11.0-59.1]	0.002†
6 mo			
DASH	5.8 [0.0-17.5]	15.8 [6.5-43.5]	0.015†
PRWE	7.0 [3.0-29.0]	20.8 [4.8-51.9]	0.041†
12 mo			
DASH	2.5 [0.0-12.7]	9.2 [3.5-22.9]	0.019†
PRWE	4.0 [0.0-12.6]	12.8 [2.3-31.4]	0.035†

*Values are given as the median with the IQR in brackets. All patient-reported outcome measures are corrected for age. †Significant.

In a subgroup analysis, operatively managed patients had significantly better DASH and PRWE scores up to 12 months compared with patients who were initially treated nonoperatively but who underwent a subsequent surgical procedure (Table IV). Moreover, nonoperatively managed patients who had no subsequent surgical procedure had significantly worse DASH and PRWE scores up to 6 months than patients in the operative group (see Appendix 4).

Discussion

This multicenter randomized trial showed that adequately reduced extra-articular distal radial fractures demonstrated better functional outcomes after 12 months when treated with open reduction and volar plate fixation compared with nonoperative treatment. In addition, 42% of patients initially managed nonoperatively underwent a subsequent surgical procedure for fracture redisplacement or symptomatic malunion. Moreover, subgroup analyses showed that patients who required a subsequent surgical procedure had worse functional outcomes up to 12 months compared with patients primarily treated operatively.

Over the last 2 decades, open reduction and volar plate fixation has been increasingly utilized[26,27]. Although the true reasons for this increase are unknown, it has been suggested that functional outcomes are positively correlated with adequate reduction, especially in young patients[12,28,29]. Furthermore, reduced fractures require at least 4 weeks of immobilization, which can lead to stiffness[17]. Nonoperative treatment may avoid complications such as hardware-related tendon problems and wound infections, but this benefit is outweighed by the relatively high proportion of nonoperatively managed patients who require a subsequent surgical procedure (42%) and the worse functional outcomes overall. In 2 previous randomized controlled trials, Arora et al. and Bartl et al. compared ORIF with plaster immobilization in 73 and 149 patients aged 65 years and older, respectively[6,30]. Arora et al. included both extra-articular (AO/OTA types A2 and A3) and intra-articular (AO/OTA types C1, C2, and C3) fractures, whereas Bartl et al. only included intra-articular fractures (AO/OTA types C1, C2, and C3). Neither study showed any difference in wrist function between the 2 treatment groups at 6 or 12 months. These results are consistent with 2 previous retrospective studies[5,31]. However, all of these studies were conducted in an elderly population and included both extra- and intra-articular fractures. In 2009, Koenig et al. evaluated whether ORIF was preferable to nonoperative treatment for acceptably reduced distal radial fractures[32]. The authors concluded that ORIF was the preferred treatment, especially in young patients, and reported a long-term gain in quality-adjusted life years. These conclusions are consistent with those of the present study, in which we found significantly better functional outcomes and a significantly better physical quality of life for operatively managed patients up to 12 months. These differences were clinically significant up to 6 months as indicated by PRWE scores. At 12 months, the difference in PRWE score between groups was 6 points, which is lower than the MCID (11.5) for distal radial fractures[23]. DASH scores showed a significant difference of 8.4 points at 6 months and 6.7 points at 12 months, yet to our knowledge the MCID for DASH scores has only been determined for patients with chronic wrist conditions[21]; therefore, we cannot conclude if these differences

were clinically relevant or not. Although significant, the differences in flexion, extension, supination, and grip strength at 12 months were small and therefore unlikely to be of clinical importance.

Currently, the initial management with closed reduction and plaster immobilization is evaluated with use of radiographic examination, and surgical treatment is only instituted if reduced fractures redisplace[3,4]. However, we found that if nonoperatively managed patients undergo a subsequent surgical procedure, they have worse functional outcomes at up to 12 months of follow-up compared with patients who were primarily treated operatively. It could be argued that patients who underwent a subsequent surgical procedure had less time to functionally recover, especially those patients who had a corrective osteotomy; however, the median follow-up time of patients who had a subsequent surgical procedure was 48 weeks (IQR: 39.3 to 52.8 weeks), compared with 51 weeks (IQR: 50.0 to 54.0 weeks) for those primarily managed operatively. Nevertheless, we plan to assess the long-term functional results of this cohort of patients in the future.

This trial has several limitations. First, our randomization was slightly unbalanced because of the mixed-block randomization. Moreover, although baseline characteristics were equally distributed, more patients in the nonoperative group had a fracture of the ulnar styloid process. However, the literature shows that an associated ulnar styloid process fracture does not result in worse functional outcomes or an increased risk of secondary displacement[8,33]. Second, since the treatment allocation involved a surgical procedure, assessment was not blinded. Covering the wrist after 6 weeks could have kept the assessors blinded to the treatment group. However, this would have been applicable for blind assessment of range of motion and grip strength only. The questionnaires were completed by the patient before they were seen by a treating physician and without involvement of the examiner, thus avoiding biased assessments of these outcomes. Third, the decisions for management of loss of reduction in the nonoperative group were at discretion of the treating physician and patient, and therefore could have been subject to treatment bias. Lastly, although 198 eligible patients were not included in this study, the baseline characteristics of these patients did not differ from the included patients. In this way, we were able to rule out selection bias. Moreover, the participation of a large number of hospitals strengthens the external validity and applicability of the results of this study.

Patients 18 to 75 years old with an acceptably reduced extra-articular distal radial fracture managed with open reduction and volar plate fixation had clinically relevant better functional outcomes at up to 6 months compared with nonoperatively managed patients. At 12 months, functional outcomes in operatively managed patients are still better, although it is doubtful if these differences are also clinically relevant. In addition, 42% of nonoperatively managed patients required a subsequent surgical procedure for fracture redisplacement or symptomatic malunion. These findings suggest that operative treatment is the preferred treatment for displaced extra-articular distal radial fractures. However, we should also await the long-term functional outcomes of this cohort of patients. Moreover, an economic evaluation determining the costs, cost-effectiveness, and cost-utility of operative treatment versus nonoperative treatment should be conducted to assess whether operative treatment is also a cost-effective intervention.

Appendix

(eA) Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/F218). ■

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