# The Clavicle Trial

## A Multicenter Randomized Controlled Trial Comparing Operative with Nonoperative Treatment of Displaced Midshaft Clavicle Fractures

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**Background:** The treatment of displaced midshaft clavicle fractures remains controversial.

**Methods:** We undertook a multicenter randomized controlled trial to compare effectiveness and safety between nonoperative management and ORIF (open reduction and internal fixation) for displaced midshaft clavicle fractures in adults. Three hundred and one eligible adult patients were randomized to 1 of the 2 treatment groups and followed at 6 weeks, 3 months, and 9 months after recruitment. The primary outcome was the rate of radiographically evident nonunion at 3 months following treatment. Secondary outcomes were the rate of radiographically evident nonunion at 9 months, limb function measured using the Constant-Murley Score and DASH (Disabilities of the Arm, Shoulder and Hand) score, and patient satisfaction.

**Results:** There was no difference in the proportion of patients with radiographic evidence of nonunion at 3 months between the operative (28%) and nonoperative (27%) groups, whereas at 9 months the proportion with nonunion was significantly lower ($p < 0.001$) in the operative group (0.8%) than in the nonoperative group (11%). The DASH and Constant-Murley scores and patient satisfaction were all significantly better in the operative group than in the nonoperative group at 6 weeks and 3 months.

**Conclusions:** Although at 3 months there was no evidence that surgery had reduced the rate of nonunion of displaced midshaft clavicle fractures, at 9 months nonoperative treatment had led to a significantly higher nonunion rate (11% compared with <1%). The rate of secondary surgical intervention during the trial period was 12 (11%) of the 147 patients in the nonoperative group. ORIF is a safe and reliable intervention with superior early functional outcomes and should be considered for patients who sustain this common injury.

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

Clavicle fractures account for approximately 4% of all fractures[1] and up to 44% of fractures of the shoulder girdle[2,3]. Fractures of the middle third (midshaft fractures) account for approximately 80% of all clavicle fractures[2,3]. It is not clear whether surgery produces better outcomes than nonsurgical management, which has been the traditional method for midshaft clavicular fractures even when they are substantially displaced[4]. Previous literature has highlighted the high nonunion rate (up to 15%) after nonoperative treatment of displaced midshaft clavicular fractures[5-7]. Furthermore, there is some evidence that nonoperative management affects the outcome in terms of upper-limb function[8-10], although this is not a universal finding[11], and that treatment of nonunions results in inferior outcomes compared with those of primary fracture treatment[12,13]. There have been few studies comparing operative with nonoperative treatment for midshaft clavicle fractures, and contradictory results have been obtained[1,14-16].

In two large multicenter prospective clinical trials, 132 and 200 patients with a displaced midshaft fracture of the clavicle were randomized to either operative treatment or nonoperative treatment[17,18]. At 1 year, the patients treated with operative fixation had a better functional outcome and lower rates of malunion and radiographic evidence of nonunion than those who had had nonoperative treatment. Interestingly, the authors of these 2 studies made conflicting recommendations regarding the indication for surgery. A subsequent smaller randomized study of displaced midshaft fractures of the

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clavicle in a Workers' Compensation population[19] was supportive of plate fixation.

Two recently updated Cochrane reviews indicated that there is insufficient evidence from randomized controlled trials to determine which methods of nonoperative[12] and operative[20] treatment are the most appropriate for middle-third clavicle fractures. The authors of another Cochrane review[1] comparing nonoperative and operative interventions concluded that little evidence was available and treatment should be selected on an individual patient basis.

## Materials and Methods

### *Study Design*

Nonoperative management was compared with ORIF (open reduction and internal fixation) for displaced midshaft clavicle fractures in a multicenter randomized controlled trial. As the full trial protocol was published previously[21], only the core methodological features and any variation of the original trial protocol and analysis during the trial period will be presented in this paper. All variations of the trial protocol were approved by the trial's ethics committee.

### *Setting*

Patients were recruited from 20 acute-care hospitals in England between 2008 and 2014.

### *Outcomes*

The primary outcome was the rate of nonunion identified radiographically at 3 months following fracture. Nonunion was defined as a lack of radiographic evidence of bridging callus between the proximal and distal fragments, and/or tenderness and mobility at the fracture site[17,22].

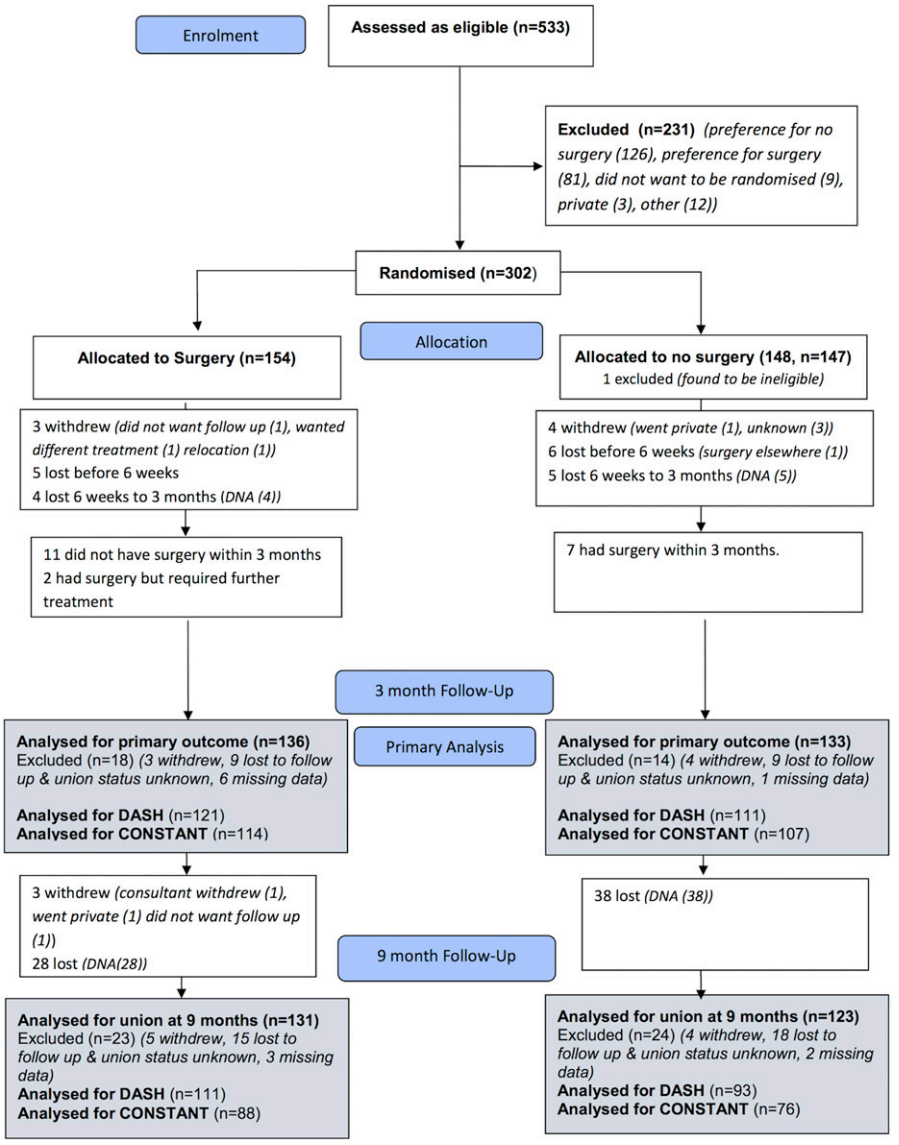


Fig. 1

CONSORT flow diagram. DNA = did not attend follow-up appointment.

Secondary outcomes were the rate of nonunion identified radiographically at 9 months and limb function measured using the Constant-Murley Score[23] and Disabilities of the Arm, Shoulder and Hand (DASH) score[24] at 6 weeks, 3 months, and 9 months post-randomization. The 6-week clinical assessment was added early in the trial period to improve the longitudinal assessment of clinical recovery.

### *Ethical Considerations*

Ethical approval was obtained from the U.K. National Research Ethics Service, Charing Cross Hospital Ethics Committee (for multicenter trials), reference number 06/Q0411/82, prior to commencement of this study. Local ethics committee approval for each center involved in the trial was also obtained. Lay advice was obtained from the non-medical members of the steering committee and the patient representative members of the Ethics Committee. The protocol includes the requirement for patient feedback.

### *Consent and Recruitment Procedures*

Patients were identified from accident and emergency department referrals and attendance at fracture clinics. Informed consent was obtained from all patients prior to randomization, with written patient information and a reflective period as defined by the protocol.

**TABLE I Comparison of Baseline Characteristics Between Eligible Patients Who Declined Randomization and Those Who Were Randomized**

| Baseline Characteristics | Declined Randomization* (N = 231) | Randomized*† (N = 301) |
|---|---|---|
| Age at injury‡ *(yr)* | 34.4 ± 11.5 (n = 227) | 36.2 ± 12.0 |
| Sex | N = 230 | |
| Male | 199 (87%) | 262 (87%) |
| Female | 31 (13%) | 39 (13%) |
| Smoking | N = 205 | N = 297 |
| Yes | 35 (17%) | 69 (23%) |
| No | 170 (83%) | 228 (77%) |
| Occupation | N = 202 | N = 295 |
| Manual | 104 (51%) | 121 (41%) |
| Non-manual | 98 (49%) | 174 (59%) |
| Type of center | | |
| Major trauma center | 78 (34%) | 116 (39%) |
| Teaching hospital | 92 (40%) | 117 (39%) |
| District general hospital | 61 (26%) | 68 (23%) |
| Side of injury | N = 225 | N = 300 |
| Left | 102 (45%) | 146 (49%) |
| Right | 123 (55%) | 154 (51%) |
| Injury on dominant side | N = 220 | N = 300 |
| Yes | 119 (54%) | 153 (51%) |
| No | 101 (46%) | 147 (49%) |
| Mechanism of injury | N = 225 | N = 300 |
| Bicycle | 73 (32%) | 117 (39%) |
| Motorcycle | 38 (17%) | 42 (14%) |
| Automobile | 11 (5%) | 9 (3%) |
| Sport (non-wheeled) | 47 (21%) | 73 (24%) |
| Fall | 36 (16%) | 42 (14%) |
| Other | 20 (9%) | 17 (6%) |
| ASA grade | N = 211 | N = 289 |
| I | 202 (96%) | 267 (92%) |
| II | 8 (4%) | 20 (7%) |
| III | 1 (<1%) | 2 (<1%) |
| Fracture class | N = 213 | N = 299 |
| 2B1 | 112 (53%) | 168 (56%) |
| 2B2 | 101 (47%) | 131 (44%) |

*The data are given as the number of patients with the percentage in parentheses unless otherwise stated. †One randomized patient was later found to be ineligible and is excluded from this table. ‡The data are given as the mean and standard deviation.

**TABLE II Baseline Characteristics of Patients by Treatment Group**

| Baseline Characteristics | Operative* (N = 154) | Nonoperative*† (N = 147) |
|---|---|---|
| Age at injury‡ *(yr)* | 36.1 ± 12.3 | 36.4 ± 11.8 |
| Sex | | |
| Male | 132 (86%) | 130 (88%) |
| Female | 22 (14%) | 17 (12%) |
| Smoking | N = 152 | N = 145 |
| Yes | 36 (24%) | 33 (23%) |
| No | 116 (76%) | 112 (77%) |
| Occupation | N = 150 | N = 145 |
| Manual | 63 (42%) | 58 (40%) |
| Non-manual | 87 (58%) | 87 (60%) |
| Dominance | N = 153 | |
| Left | 17 (11%) | 22 (15%) |
| Right | 136 (89%) | 125 (85%) |
| Type of center | | |
| Major trauma center | 61 (40%) | 55 (37%) |
| Teaching hospital | 59 (38%) | 58 (39%) |
| District general hospital | 34 (22%) | 34 (23%) |
| Side of injury | N = 153 | |
| Left | 78 (51%) | 68 (46%) |
| Right | 75 (49%) | 79 (54%) |
| Injury on dominant side | N = 153 | |
| Yes | 76 (50%) | 77 (52%) |
| No | 77 (50%) | 70 (48%) |
| Mechanism of injury | N = 153 | |
| Bicycle | 58 (38%) | 59 (40%) |
| Motorcycle | 22 (14%) | 20 (14%) |
| Automobile | 4 (3%) | 5 (3%) |
| Simple fall | 15 (10%) | 17 (12%) |
| High-energy fall | 6 (4%) | 4 (3%) |
| Football | 20 (13%) | 14 (10%) |
| Contact sport | 7 (5%) | 7 (5%) |
| Horseback riding | 6 (4%) | 6 (4%) |
| Winter sport | 6 (4%) | 7 (5%) |
| Other | 9 (6%) | 8 (5%) |
| ASA grade | N = 147 | N = 142 |
| I | 136 (93%) | 131 (92%) |
| II | 9 (6%) | 11 (8%) |
| III | 2 (1%) | 0 |
| Fracture class | | N = 145 |
| 2B1 | 87 (56%) | 81 (56%) |
| 2B2 | 67 (44%) | 64 (44%) |
| Comminution seen on radiographs | N = 143 | N = 138 |
| No | 37 (26%) | 30 (22%) |
| Yes | 106 (74%) | 108 (78%) |

*The data are given as the number of patients with the percentage in parentheses unless otherwise stated. †One randomized patient was later found to be ineligible and is excluded from this table. ‡The data are given as the mean and standard deviation.

**TABLE III Results of Analysis of Primary Outcome: Radiographic Evidence of Union at 3 Months (N = 269*)**

| | Rate or Estimate | 95% CI | P Value |
|---|---|---|---|
| Union rate† | | | |
| Operative (n = 136) | 98 (72%) | | |
| Nonoperative (n = 133) | 97 (73%) | | |
| Nonunion rate† | | | |
| Operative (n = 136) | 38 (28%) | | |
| Nonoperative (n = 133) | 36 (27%) | | |
| Unadjusted analysis (n = 269) | | | 0.87 |
| Difference in proportions | 0.009 | −0.098 to 0.115 | |
| Odds ratio (of nonunion) | 1.04 | 0.61 to 1.78 | |
| Adjusted analysis | | | |
| Odds ratio adjusted for random center effect (n = 269) | 1.04 | 0.61 to 1.78 | 0.87 |
| Odds ratio adjusted for random center effect, age at injury, sex, fracture classification, & ASA grade (n = 261) | 1.10 | 0.63 to 1.92 | 0.73 |

*The primary outcome was missing for 18 patients (12%) in the operative group and 14 (9.5%) in the nonoperative group. The baseline characteristics of the patients with missing data were similar to those for whom the outcome was recorded except that they were more likely to be smokers (43% versus 21%). Adjusting for this difference in the regression analysis made little difference with respect to the results (odds ratio = 1.11 [95% CI = 0.64 to 1.95]). †The data are given as the number of patients with the percentage in parentheses.

### *Inclusion and Exclusion Criteria*

Inclusion criteria were an age of 18 to 65 years, a displaced midshaft fracture of the clavicle seen within 2 weeks after the injury, a Robinson classification of 2B1 or 2B2[25], and being medically fit to undergo surgery (American Society of Anesthesiologists [ASA] grade I, II, or III). The exclusion criteria were a patient's refusal to participate, being medically unfit to undergo surgery (ASA grade IV or V), any other type of clavicle fracture, established nonunion from a previous fracture, a previous fracture around the clavicle, a previous operation on the shoulder or clavicle, metabolic bone disease, and substantial neuromuscular upper-limb disability.

### *Operative Treatment*

All patients in the surgical group were administered prophylactic antibiotics according to local protocols in each center. General anesthesia, with or without supplementary interscalene blockade, was used for all patients. All surgical procedures were performed by 1 of the orthopaedic consultants named in the protocol or by their specialist registrar/research fellow under their supervision. All of the patients enrolled in the study were treated in a standardized way. An infraclavicular incision was used, and a myoperiosteal flap was elevated from the fracture segments. Fixation was performed using the Acumed clavicle fixation system, consisting of a precontoured titanium plate. Following wound closure, the affected arm was placed in an arm sling. Pendulum and elbow

**TABLE IV Results of Analysis of Radiographic Evidence of Union at 9 Months (N = 254*)**

| | Rate or Estimate | 95% CI | P Value |
|---|---|---|---|
| Union rate† | | | |
| Operative (n = 131) | 130 (99.2%) | | |
| Nonoperative (n = 123) | 110 (89%) | | |
| Nonunion rate† | | | |
| Operative (n = 131) | 1 (0.8%) | | |
| Nonoperative (n = 123) | 13 (11%) | | |
| Unadjusted analysis‡ | | | <0.001§ |
| Difference in proportions | −0.098 | −0.163 to −0.042# | |
| Odds ratio (of nonunion) | 0.065 | 0.002 to 0.450§ | |

*The 9-month union information was missing for 23 patients (15%) in the operative group and 24 (16%) in the nonoperative group. Missingness of this outcome was related to dominance and smoking, with more of those with missing data being left-handed (23% versus 11%) and smokers (43% versus 20%). †The data are given as the number of patients with the percentage in parentheses. ‡Adjusted analyses were not performed because of the small numbers of events. §Fisher exact test and exact 95% CIs. #Wallenstein CI calculation[28].

**TABLE V Results of Analysis of DASH and Constant-Murley Scores**

| | 6 Weeks | 3 Months | 9 Months |
|---|---|---|---|
| DASH score* | | | |
| Median (interquartile range) | | | |
| Operative | 15.83 (9.17 to 32.61) (n = 112) | 5.00 (1.67 to 13.33) (n = 121) | 1.67 (0 to 5) (n = 111) |
| Nonoperative | 28.75 (20.00 to 48.33) (n = 106) | 8.33 (2.50 to 23.33) (n = 111) | 2.5 (0 to 7.5) (n = 93) |
| Treatment effect (95% CI), p value† | | | |
| Unadjusted | −13.33 (−19.60 to −7.07), <0.001 (n = 218) | −3.33 (−6.86 to 0.198), 0.064 (n = 232) | −0.83 (−2.20 to 0.54), 0.231 (n = 204) |
| Adjusted for clustering by center | −13.33 (−17.97 to −8.69), <0.001 (n = 218) | −3.33 (−6.05 to −0.62), 0.016 (n = 232) | −0.83 (−1.94 to 0.28), 0.141 (n = 204) |
| Adjusted for center clustering, age, sex, fracture class, & ASA grade | −14.32 (−19.21 to −9.43), <0.001 (n = 213) | −3.55 (−5.65 to −1.45), 0.001 (n = 226) | −0.83 (−1.89 to 0.23), 0.123 (n = 198) |
| Constant-Murley score* | | | |
| Median (interquartile range) | | | |
| Operative | 76.50 (58.55 to 86.30) (n = 104) | 85.20 (76.87 to 91.03) (n = 114) | 91.97 (85.32 to 96.50) (n = 88) |
| Nonoperative | 63.97 (53.03 to 73.57) (n = 105) | 81.67 (72.77 to 89.93) (n = 107) | 89.88 (83.55 to 94.10) (n = 76) |
| Treatment effect (95% CI), p value† | | | |
| Unadjusted | 12.37 (6.59 to 18.14), <0.001 (n = 209) | 3.43 (−0.37 to 7.24), 0.077 (n = 221) | 2.13 (−1.12 to 5.38), 0.197 (n = 164) |
| Adjusted for clustering by center | 12.37 (6.32 to 18.41), <0.001 (n = 209) | 3.43 (0.47 to 6.40), 0.023 (n = 221) | 2.13 (−0.65 to 4.92), 0.133 (n = 164) |
| Adjusted for center clustering, age, sex, fracture class, & ASA grade | 13.42 (6.99 to 19.84), <0.001 (n = 204) | 3.20 (−0.16 to 6.55), 0.062 (n = 216) | 1.65 (−1.14 to 4.43), 0.245 (n = 161) |

*Interactions between treatment group and follow-up time were significant in models allowing for repeated measurements over time (p = 0.0001 for DASH scores and p = 0.002 for Constant-Murley scores). †Treatment effect estimates are differences in medians estimated using quantile regression.

exercises were allowed on the first day postoperatively, and the subsequent mobilization and rehabilitation protocol was the same as that for the nonoperative group (see below).

### *Nonoperative Treatment*

The patient wore a sling that immobilized the arm at the side with the shoulder in internal rotation for up to 6 weeks or until there was clinical and/or radiographic evidence of union. Patients were allowed to remove the sling for short periods to wash, dress, write, eat, and use a keyboard as soon as comfort allowed. Active-assisted range of motion was permitted starting at 2 weeks as comfort allowed. Full active mobilization, resistance exercises, and cross-arm adduction commenced after 6 weeks.

### *Allocation to Groups*

Computer-generated randomization lists, stratified by center, were produced using random permuted blocks and equal allocation to the operative and nonoperative groups. To conceal allocation, each center was provided with a set of sequentially numbered sealed envelopes, which were opened with the patient after recruitment.

### *Assessment*

Patients were assessed in the clinic at baseline (at the first orthopaedic consultation) and then at 6 weeks, at 3 months, and between 9 and 12 months after randomization at routine outpatient consultations.

Baseline data were collected for all eligible patients before they consented to randomization. If they did not consent, their reasons for declining were recorded when possible.

Radiographs were made for all subjects at the 6-week and 3-month follow-up visits. Radiographic evidence of union was assessed by the principal investigator at each site. Clinical data regarding union, including fracture mobility, tenderness, and pain, were also obtained at the 3-month follow-up visit. The radiographs of the first 40 subjects were reviewed by an independent, blinded radiologist once the principal investigator had judged the fracture to have united or be ununited. There was a discrepancy of opinion with regard to >2% of these patients (1 patient); therefore, per the trial protocol, the Chief Investigator reviewed the radiographs of all patients in the trial. When there was a discrepancy of opinion between the Chief Investigator and the principal investigator at the treating center, the case was reviewed by 2 additional principal investigators and a musculoskeletal radiologist who were blinded to the previous opinions and a majority consensus opinion was obtained.

The Constant-Murley questionnaire[23] and DASH questionnaire (including the Work and Sport and Music modules)[24] were administered at the 6-week, 3-month, and 9-month reviews by an independent research-trained health practitioner not involved in the patient's surgical care or rehabilitation program. At those visits, the patients were also asked, with a single-item question, to rate their satisfaction with treatment as excellent, good, satisfactory, or poor.

Complications were defined as any event that necessitated another operative procedure or additional medical treatment. Any radiographically evident

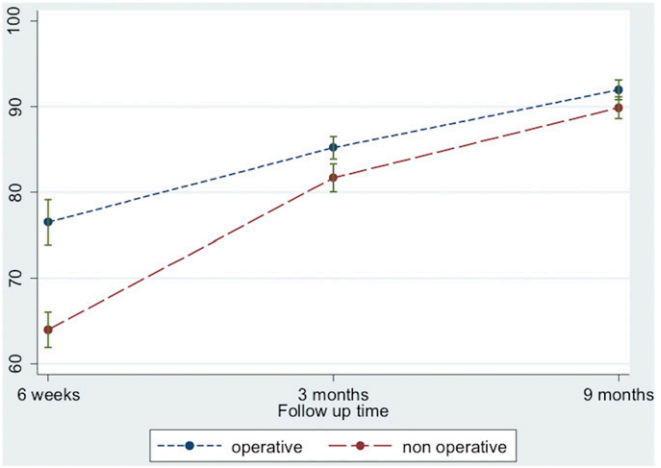


Fig. 2

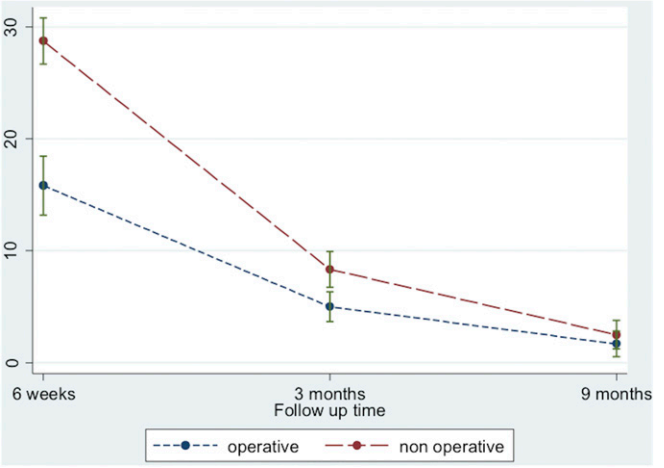


Fig. 3

**Fig. 2** Median Constant-Murley scores, with standard errors, over time by randomized group. **Fig. 3** Median DASH scores, with standard errors, over time by randomized group.

nonunions, symptomatic malunions, or cases of complex regional pain syndrome were recorded throughout the follow-up period.

Details about the surgery were recorded for the operative group, including perioperative complications and deviations from the standard technique. Also recorded were the level of surgeon training (consultant or trainee [registrar]), antibiotic use and dose, plate length, use of locking screws, number of cortices involved in the fixation, duration of the operation, use of radiographic control, and satisfaction with the reduction, .

When a patient withdrew or dropped out from the trial, the date and if possible the reason were obtained.

### *Sample Size*

It was estimated that, for the comparison of the nonunion rates at 3 months following treatment, 141 patients would be required in each treatment group to detect a reduction from 15% (the nonunion rate after nonoperative treatment in 1 study[6]) to 5% (used by us as the maximum acceptable clinical failure rate) with 80% power and a significance level of

**TABLE VI Patient Satisfaction**

| | Frequency (No. [%]) | | | | | Results of Ordered Logistic Regression (Odds Ratio [95% CI], P Value) | | |
|---|---|---|---|---|---|---|---|---|
| | Excellent | Good | Satisfactory | Poor | P Value* | Unadjusted | Adjusted for Clustering by Center† | Adjusted for Center Clustering, Age, Sex, Fracture Class, & ASA Grade† |
| 6 weeks | | | | | | 0.29 (0.17 to 0.52), <0.001 | 0.30 (0.17 to 0.53), <0.001 | 0.29 (0.16 to 0.53), <0.001 |
| Operative (n = 98) | 69 (70%) | 22 (22%) | 7 (7%) | 0 | <0.001 | | | |
| Nonoperative (n = 104) | 40 (38%) | 53 (51%) | 8 (8%) | 3 (3%) | <0.001† | | | |
| 3 months | | | | | | 0.34 (0.19 to 0.60), <0.001 | 0.33 (0.18 to 0.60), <0.001 | 0.46 (0.21 to 1.01), 0.05 |
| Operative (n = 106) | 82 (77%) | 22 (21%) | 2 (2%) | 0 | <0.001 | | | |
| Nonoperative (n = 105) | 57 (54%) | 38 (36%) | 8 (8%) | 2 (2%) | <0.001† | | | |
| 9 months | | | | | | 0.29 (0.16 to 0.53), <0.001 | 0.34 (0.18 to 0.63), 0.001 | 0.47 (0.21 to 1.07), 0.07 |
| Operative (n = 96) | 81 (84%) | 11 (11%) | 2 (2%) | 2 (2%) | 0.23 | | | |
| Nonoperative (n = 80) | 59 (74%) | 16 (20%) | 5 (6%) | 0 | 0.12 | | | |

*Test for trend. †Multilevel mixed-effects ordered logistic regression. ‡Poor and satisfactory scores were collapsed together because of small numbers.

5%. To allow for dropout, the aim was to randomize 300 patients (150 per group).

### *Data Analysis*

The proportions of patients with nonunion by 3 months were compared between the randomized groups using a chi-square test. We report an estimate of the difference in proportions and the odds ratio for nonunion, both with a 95% confidence interval (CI). In additional analyses, we allowed for a possible treatment-center effect using a random effects logistic regression model and also made adjustments for predefined baseline factors thought to be related to outcome (age at injury, sex, fracture classification, and ASA grade).

We carried out all analyses according to the intention-to-treat principle but excluded patients with missing information about radiographically evident union at 3 months. To consider the impact of the missing data on our conclusions, we examined characteristics of the patients with missing values and used logistic regression analysis to identify factors associated with missingness.

We applied similar approaches for analyses of the secondary outcomes. For the 9-month nonunion outcome, we used exact methods and carried out only unadjusted analyses because of small numbers. For the continuous Constant-Murley and DASH scores, we used quantile regression to estimate treatment effects as differences in medians with 95% CIs since both outcomes had highly skewed distributions. Robustified standard errors were used to allow for center clustering[26]. In addition we extended models to allow for the repeated measurements at 6 weeks, 3 months, and 9 months and to investigate interactions between treatment and follow-up time. For patient satisfaction outcomes, we used ordered logistic regression to estimate odds ratios with 95% CIs.

All statistical analyses followed a predefined analysis plan and were carried out using STATA version 14.

### *Trial Registry*

This study was registered in the United Kingdom Clinical Research Network (ID: 8665).

## Results

Figure 1 shows the recruitment and flow of participants in the trial. Of the 533 patients eligible for the study, 302 (57%) consented to take part; the remainder had a preference for surgery or no surgery, opted to be treated privately, or did not want to be randomized. One randomized patient was later found to be ineligible. Table I compares the known details of those who consented and those who did not and shows that the study sample had good external validity. Overall, 154 participants (51%) were randomized to the surgery group and 147 (49%), to no surgery. The randomized groups were well balanced for baseline characteristics (Table II).

In the operative group, 3 patients withdrew and 9 patients were lost to follow-up before 3 months. Eleven did not have surgery within 3 months (the study period defined by the trial protocol): 6 because they subsequently decided that they did not want surgical intervention, 2 because they were not medically fit for anesthesia, 1 because of a lack of pain, and 1 could not be contacted; in 1, the surgery was delayed for more than 3 months. Of the patients randomized to the nonoperative group, 4 withdrew and 11 were lost to follow-up. Seven additional patients in this group had surgery before the 3-month follow-up point, all because of a clinical choice based on excessive pain and/or deformity as judged by the surgeon or patient.

The proportions of patients who were not seen to have union on radiographs by 3 months were similar in the operative (28%) and nonoperative (27%) groups, with no statistically significant difference (difference in proportions = 0.9% [95% CI = −9.8% to 11.5%]; p = 0.87) (Table III). However, at 9 months, the proportion of patients with nonunion was 11% in the nonoperative group compared with 0.8% in the operative group, which was a significant difference (difference in proportions = −9.8% [95% CI = −16.3% to −4.2%]; p < 0.001) (Table IV).

The DASH and Constant-Murley scores measured at 6 weeks were significantly better in the operative group than in the nonoperative group in both the adjusted and unadjusted analyses (Table V and Figs. 2 and 3). Better scores in the operative group were also evident at 3 months. Patients with nonunion in the nonoperative group had worse clinical scores at 9 months even if they had subsequently undergone surgery, with average

**TABLE VII Complications by Treatment Group**

| Complication | No. |
|---|---|
| Operative group | |
| Serious, related to procedure | |
| Surgical failure; revision | 1 |
| Removal of plate | 1 |
| Serious, unrelated | |
| Additional surgery | 2* |
| Mallory-Weiss tear, costochondritis | 1 |
| Left scaphoid fracture | 1 |
| Not serious | |
| Planned removal of plate | 4 |
| Minor scar | 3 |
| Prominent plate | 2 |
| Frozen shoulder | 2† |
| Unrelated arrhythmia | 1 |
| Nonoperative group | |
| Serious, related to fracture | |
| Surgery within 3 months | 7 |
| Surgery after 3 months | 9 |
| Surgery planned after 9 months | 3 |
| Serious, unrelated | |
| Infected knee | 1 |
| Overdose | 1 |
| Pulmonary embolism | 1 |
| Respiratory tract infection | 1 |
| Not serious | |
| Frozen shoulder | 1 |

*One of these additional procedures, unrelated to the index procedure, was for a lateral clavicle fracture and the other was for disruption of the acromioclavicular joint. †One of these patients was treated with manipulation under anesthesia.

DASH scores of 11.3 (range, 4.1 to 56.2) compared with 1.6 (0 to 5.8) for patients who had union. At 9 months, there was no significant difference between the operative and nonoperative groups for either score. The scores for the DASH Work and Sport and Music supplementary modules were significantly better for the operative group at 6 weeks, but not at 3 or 9 months. There was greater patient satisfaction in the operative group than in the nonoperative group at 6 weeks and 3 months (Table VI).

Subgroup analyses of smokers and patients with fracture comminution showed no significant differences between the operatively and nonoperatively treated patients in these subgroups with regard to the rate of nonunion at 3 or 9 months. However, there was a nonsignificant trend for nonoperative treatment to be associated with higher nonunion rates at 9 months in smokers (25% in smokers versus 7% in nonsmokers) and patients with fracture comminution (13% in comminuted fractures versus 4% in noncomminuted fractures).

Complications are presented in Table VII. There was 1 reoperation for loss of fixation in the operative group, and the patient subsequently had union. There were no surgical site infections in this study. All patients in the operative group who received an operation subsequently went on to have union.

The operative technique protocol was followed in all cases. One patient received a plate from an alternative manufacturer because of nonavailability at the time of surgery. Both locking and nonlocking screws were utilized in 87% of the procedures, and only nonlocking screws were used in 13%. Six-cortex medial and lateral fixation was achieved in 92%. The median operative time was 60 minutes, and the median plate length was 8 holes.

## Discussion

The union rate of midshaft clavicle fractures at 3 months was low (approximately 70%) regardless of whether the treatment was operative or not. However, this rate did not correlate well with the clinical status of the patient, who generally demonstrated good functional recovery at this time point. Also, there was a significant difference between operative and nonoperative results at 9 months after the injury, with a very low rate of radiographically evident nonunion (<1%) in surgically treated patients but a persistently high rate (11%; 13 of 123) in nonsurgically treated patients. Including the 5 patients who had already been treated for nonunion by 9 months, the cumulative nonunion rate in the nonoperative group was 15% (18 of 123). In total, 12 patients had undergone or still required surgery for nonunion at the end of the trial period.

The objective and patient-reported scores were significantly better in the operative group at the early time points but were equivalent to those in the nonoperative group at 9 months. Patient satisfaction was also greater in the operative group at the early time points but approached equivalency with that in the nonoperative group by 9 months.

Importantly, the risk of complications in both treatment groups was low if one excludes treatment for nonunion. The clinical outcome was also good in both treatment groups when union had been achieved.

The strengths of this randomized controlled trial include the balance of representative demographics between the trial population and the patients who were screened but refused randomization as well as between the treatment arms. Patients were recruited from a range of hospital provider types, and there was a wide geographic distribution. A single implant and a standardized technique were used for the operatively treated patients, and the rehabilitation protocol was the same for both treatment groups. Follow-up was performed by independent assessors, and the follow-up rate for the primary outcome was high (89.4%) for a surgical randomized controlled trial.

Weaknesses of the study were that the assessors were not blinded to the treatment groups and the crossover between groups was higher than anticipated. The 9-month outcome-score data were also less complete than the union data, particularly for the Constant-Murley score.

Other randomized trials[17,18] have demonstrated similar results but were smaller and less controlled and the authors came to conflicting conclusions. One area of debate is the definition of nonunion as well as the timing and modality of its assessment. Computed tomography (CT) at 6 months was used in 1 study[18], but that is not usual clinical practice. Most other published randomized trials were comparisons of different surgical or nonsurgical techniques.

Our conclusion is that the outcome of a united midshaft clavicle fracture is good, regardless of whether the patient was treated operatively or nonoperatively. Both treatment modalities are safe, with few substantial complications demonstrated in this study population. The rate of radiographically evident nonunion at 9 months was significantly reduced by surgical intervention, and functional recovery and patient satisfaction were better at both 6 weeks and 3 months. There was also a high rate of secondary surgical intervention (11%) in nonoperatively treated patients. Overall, we think that surgical treatment for a displaced midshaft clavicle fracture should be offered to patients, and this paper can provide clear, robust data to help patients to make their choice.

Additional research is required to demonstrate the long-term outcomes for the patients who were awaiting treatment for nonunion at the completion of our trial. The relative safety and success of secondary surgical intervention for nonunion are not well documented and, as recently described, may be poorer than those of acute surgery[27]. A long-term longitudinal study is also required to clarify the rate of secondary surgical intervention for removal of metal implants. ■

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