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TRAUMA

Acute plate fixation of displaced midshaft clavicular fractures is not associated with earlier return of normal shoulder function when union is achieved

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Aims

It is unclear whether acute plate fixation facilitates earlier return of normal shoulder function following a displaced mid-shaft clavicular fracture compared with nonoperative management when union occurs. The primary aim of this study was to establish whether acute plate fixation was associated with a greater return of normal shoulder function when compared with nonoperative management in patients who unite their fractures. The secondary aim was to investigate whether there were identifiable predictors associated with return of normal shoulder function in patients who achieve union with nonoperative management.

Methods

Patient data from a randomized controlled trial were used to compare acute plate fixation with nonoperative management of united fractures. Return of shoulder function was based on the age- and sex-matched Disabilities of the Arm, Shoulder and Hand (DASH) scores for the cohort. Independent predictors of an early recovery of normal shoulder function were investigated using a separate prospective series of consecutive nonoperative displaced mid-shaft clavicular fractures recruited over a two-year period (aged ≥ 16 years). Patient demographics and functional recovery were assessed over the six months post-injury using a standardized protocol.

Results

Data from the randomized controlled trial consisted of 86 patients who underwent operative fixation compared with 76 patients that united with nonoperative treatment. The recovery of normal shoulder function, as defined by a DASH score within the predicted 95% confidence interval for each respective patient, was similar between each group at six weeks (operative 26.7% vs nonoperative 25.0%, p = 0.800), three months (52.3% vs 44.2%, p = 0.768), and six months post-injury (86.0% vs 90.8%, p = 0.349). The mean DASH score and return to work were also comparable at each timepoint. In the prospective cohort, 86.5% (n = 173/200) achieved union by six months post-injury (follow-up rate 88.5%, n = 200/226). Regression analysis found that no specific patient, injury, or fracture predictor was associated with an early return of function at six or 12 weeks.

Conclusion

Return of normal shoulder function was comparable between acute plate fixation and nonoperative management when union was achieved. One in two patients will have recovery of normal shoulder function at three months, increasing to nine out of ten patients at six months following injury when union occurs, irrespective of initial treatment.

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Introduction

Acute plate fixation of mid-shaft clavicular fractures reduces the incidence of nonunion following injury from approximately 15% with nonoperative treatment to less than 2% with surgery.[1] Recent randomized trials have all concluded that acute fixation facilitates earlier recovery of shoulder function in the first three months following injury when compared with nonoperative management.[2-4] However, this may be influenced by the greater prevalence of nonunion following nonoperative management which is associated with a worse functional recovery.[5] This may adversely affect the functional outcome of nonoperative management unless the influence of nonunion is accounted for.

Recovery following an upper limb fracture should be evaluated in the context of the patient demographic that sustain the injury. For the clavicle, the Disabilities of the Arm, Shoulder and Hand (DASH) score is commonly used to assess upper limb recovery following injury but this can be affected by both the sex and age of the patient.[6] When considering return of 'normal' shoulder function following a clavicular fracture, it is unclear if all patients have a predictable recovery following nonoperative management when union occurs. Patient, injury, and fracture demographics have been extensively investigated for the risk of fracture nonunion[7-11] but, to the authors' knowledge, no study has prospectively evaluated the predictors associated with functional recovery. An improved understanding of functional recovery following clavicular fracture management may be useful for patients and surgeons in aiding decision making.

The primary aim of this study was to establish whether acute plate fixation was associated with a greater return of normal shoulder function when compared with nonoperative management in patients that unite their fractures. The secondary aim was to investigate whether there were identifiable predictors associated with return of normal shoulder function in patients who achieve union with nonoperative management.

Methods

Randomized trial of acute fixation versus nonoperative management. A trial cohort of displaced mid-shaft clavicular fracture patients who underwent acute plate fixation (n = 86) were compared against united patients following nonoperative management (n = 76). This provided a matched cohort of patients to compare return of normal shoulder function. They were recruited into a prospective randomized controlled trial (RCT) which has been previously published, including the specific details of their operative intervention.[12] All operations were undertaken within two weeks of injury and rehabilitation between the groups was identical. Only those patients followed up to one year with known fracture outcomes were included. The DASH score was collected prospectively and CT scanning was undertaken in all patients to confirm union at six months post-injury.

Nonoperative observational cohort. A separate prospective cohort of consecutive patients who presented to our trauma unit with a mid-shaft displaced clavicular fracture were recruited over a two-year period. Inclusion criteria included fully displaced mid-shaft clavicular fractures with no residual cortical contact, with or without comminution (Edinburgh Type 2 fractures),[13] age 16 years at time of injury, locally resident, and an isolated injury with no known pre-existing shoulder pathology. All patients who met inclusion criteria were referred to a single specialist clinic and were consulted on operative and nonoperative treatment options. The patients who opted for acute fixation were excluded. The decision to undertake acute fixation was based solely on patient request and only 3.7% of all eligible patients underwent acute operative management over the study period (n = 10/269). The nonoperative management protocol was a sling for three weeks post-injury followed by a range of movement and strengthening exercises under the supervision of a physiotherapist.

Injuries were classified as high energy if they were sustained from a fall from > 2 metres, road traffic accidents including high-speed cycling accidents (> 20 mph), and pedestrian or cyclist versus automobile accidents. Low-energy injuries were classified as falls from standing height, sporting accidents, or low-speed cycling accidents. Occupation was considered to be manual if the employment had a significant physical daily component (e.g. construction, care work, fitness instructor); otherwise it was considered to be sedentary work.

Exclusion criteria are summarized in the flow diagram (Figure 1). A total of 226 patients undergoing nonoperative management were recruited into the study and 200 patients completed follow-up at six months (follow-up rate of 88.5%, 200/226). The median age was 36.0 years and 75% were male (149/200). The 26 patients lost to follow-up and ten patients who chose acute fixation showed no statistically significant difference in demographics (age, sex, smoking status) or fracture characteristics (overall displacement or comminution) compared with those who completed the study.

Patients underwent a standardized clinical review at six weeks, and at three and six months, by the lead or senior author. The shortened DASH questionnaire, QuickDASH,[14] and EuroQol five dimension summary index (EQ-5D, EuroQol Group, Rotterdam, The Netherlands)[15] were self-reported at each visit, along with a proforma of history and examination findings. The overall displacement of the fracture was estimated using an erect radiograph corrected for magnification, measuring the distance between the proximal and distal fragments from the centre of the medullary canal.[8] Patients who had bridging callus on radiograph with resolution of

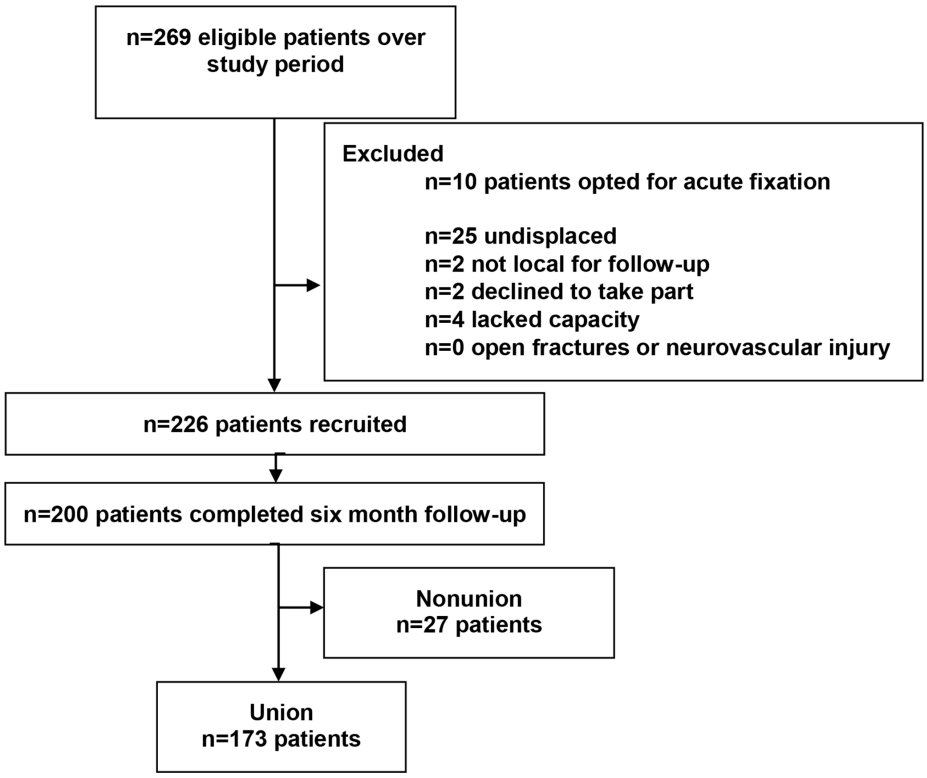

Fig. 1
Flow diagram of patient recruitment and outcome.

pain were considered united. All patients who had pain, movement of fracture, or absent bridging callus on radiograph at six months underwent a CT scan. Union on CT was defined as bridging callus of more than 50% of the diameter between fracture fragments on 3D reconstruction.[16] Of the final cohort, 24.5% of patients (n = 49/200) underwent a CT (n = 27 nonunion and n = 22 united).

Statistical analysis and sample size. Statistical analysis was performed using SPSS version 24 (IBM, USA). Data were tested for normal distribution with the D'Agostino-Pearson test. Linear variables were assessed using the independent-samples *t*-test for parametric data or the Mann-Whitney U test for non-parametric data. Differences between dichotomous data were assessed by using the chi-squared test. A p-value of < 0.05 was defined as statistically significant.

Recovery of shoulder function was considered to be achieved if the DASH or QuickDASH score was below or equal to the upper limit of the 95% confidence interval (CI) of a 'normalized score' for each respective patient matched to the relevant sex and age.[6] For example, a 20-year-old male would have a predicted mean QuickDASH score of 5 with a 95% CI of 2 to 7, if his six-week QuickDASH score was 7, he would be considered to have recovery of shoulder function. This was considered at six weeks, and at three and six months for each patient, respectively, in the cohort. Predictors of return of function were evaluated using logistic stepwise regression with 'forward' and 'backward' conditional entry. A single unadjusted model was used, including findings on univariate analysis trending towards significance (p < 0.2) or clinically relevant predictors.

The minimal clinical significant difference of the DASH score is considered to be 10.83.[17] Using the trial data, the six-week SD of the cohort was 18.0. To power the study to detect a minimal clinical difference of 10.8, with 80% power and Type I (α) of 0.05, 44 patients in each treatment arm were required.

Ethics and source of funding. The study had ethical approval and was registered with the NHS Institute for Health Research with the unique code REC 16/SS/0026. No formal funding was received. The previous randomized trial was registered with the unique code N0256199069.

Results

Primary aim – operative versus nonoperative recovery. The two patient groups that underwent operative and nonoperative management in the trial were matched with no significant differences in patient demographics (Table I). There was no difference in the rate of recovery between the two treatment groups at any timepoint over the first six months (Table I). At six weeks, 26.7% of the acute plate fixation group (n = 23/86) had a return of normal shoulder function

Table I. Acute plate fixation (open reduction and internal fixation) compared with nonoperative management. Patient demographics and functional recovery.

Variable	Parameter		ORIF (n = 86)	Nonoperative (n = 76)	p-value
Demographic	Mean age, yrs (95% CI)		32.7 (30.3 to 35.1)	31.9 (29.1 to 34.6)	0.556*
	Sex, % (n)	Male	86.0 (74)	86.8 (66)	0.883†
		Female	14.0 (12)	13.2 (10)	
	Smoking status, % (n)	Smoker	16.3 (14)	17.1 (13)	0.962†
		Non-smoker	83.7 (72)	82.9 (63)	
	Hand dominance, % (n)	Dominant	55.8 (48)	68.4 (52)	0.099.†
		Non-dominant	44.2 (38)	31.6 (24)	
	Employment type, % (n)	Sedentary	58.1 (43)	58.5 (38)	0.966†
		Manual	41.9 (31)	41.5 (27)	
Injury mechanism	Energy, % (n)	High-energy	22.1 (19)	23.7 (18)	0.810†
		Low-energy	77.9 (67)	76.3 (58)	
Fracture findings	Fracture (Edinburgh classification), % (n)	Comminution (2B2)	48.8 (42)	36.8 (28)	0.124†
		Simple (2B1)	51.2 (44)	63.2 (48)	
	Mean overall fracture displacement, mm (95% CI)		27.8 (26.5 to 29.0)	26.5 (24.9 to 28.0)	0.196*
Patient recovery		6 weeks	22.9 (19.0 to 26.9)	25.5 (21.2 to 29.9)	0.385*
	Mean QuickDASH (95% CI)	12 weeks	10.4 (7.7 to 13.1)	11.8 (8.2 to 15.3)	0.532*
		24 weeks	5.2 (3.4 to 7.1)	5.8 (3.0 to 8.6)	0.701*
	Return of normality, % (n)	6 weeks	26.7 (23)	25.0 (19)	0.800*
		12 weeks	52.3 (45)	44.2 (38)	0.768*
		24 weeks	86.0 (74)	90.8 (69)	0.349*
	Mean return to work, days (95% CI)		21.6 (14.7 to 28.5)	22.8 (15.3 to 30.2)	0.820*

*Independent-samples *t*-test.
†Chi-squared test.
CI, confidence interval; ORIF, open reduction and internal fixation; QuickDASH, Quick Disabilities of the Arm, Shoulder and Hand questionnaire.

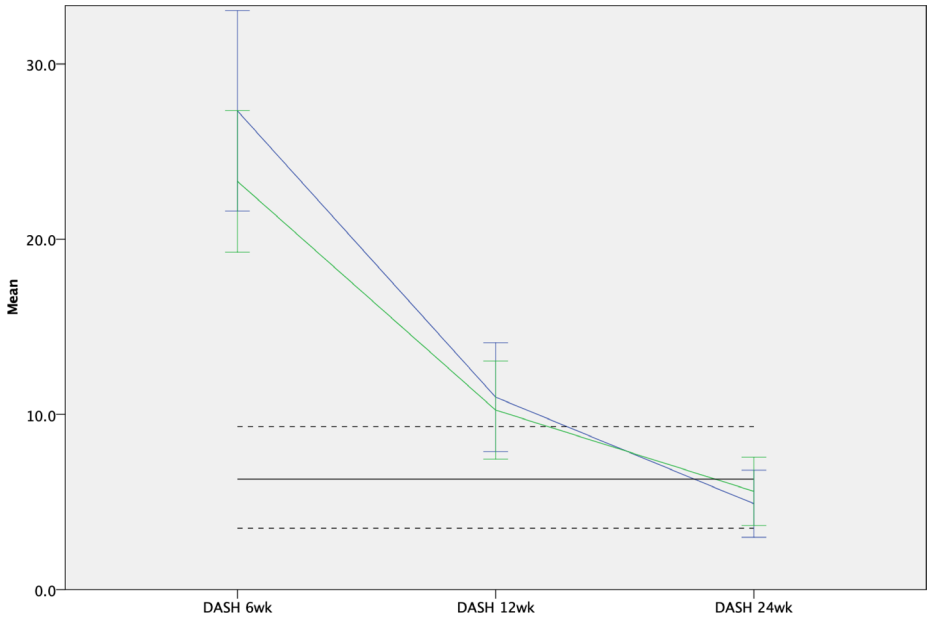

Fig. 2

Disabilities of the Arm, Shoulder and Hand (DASH) score at six, 12, and 24 weeks post-injury comparing acute plate fixation cohort (green) against united patients following nonoperative management (blue). The horizontal solid and dotted lines are the estimated normal mean DASH score (6.3) and respective 95% confidence interval (3.5 to 9.3) for the study cohort.

compared with 25.0% of those which united with nonoperative management (n = 19/76) (p = 0.800). This remained comparable at three and six months. There was also no difference in the mean DASH score (Figure 2) or return to work (Table I) in either treatment arm at any timepoint.

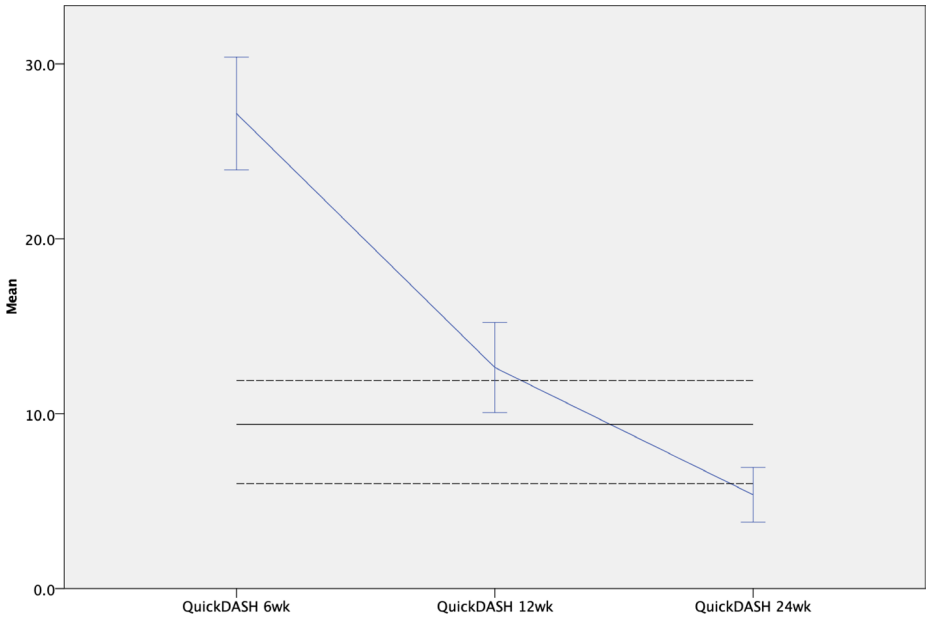

Fig. 3

The QuickDisabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH) score at six, 12, and 24 weeks post-injury following nonoperative management in those patients that unite. The horizontal solid and dotted lines are the estimated normal mean QuickDASH score (9.4) and respective 95% confidence interval (6.0 to 11.9) for the study cohort.

Table II. Functional recovery following nonoperative management of united fractures (n = 173). Standard deviation in brackets (SD).

Variable	Parameter	6 wks	12 wks	24 wks
History	Night pain, % (n)	50.9 (88)	23.7 (41)	18.5 (32)
	Unable to dress normally, % (n)	17.9 (31)	11.6 (20)	5.8 (10)
	Sling still required, % (n)	10.4 (18)	2.3 (4)	1.2 (2)
	Returned to work, % (n)	72.1 (125)	89 (154)	91.3 (158)
	Returned to usual activities, % (n)	30.1 (52)	67.1 (116)	87.9 (152)
Examination	Fracture site tenderness, % (n)	22 (38)	12.7 (22)	9.2 (16)
	Inability to reach hand to head, % (n)	7.5 (13)	5.5 (10)	3.5 (6)
	Inability to reach hand to head and elbow to back, % (n)	10.4 (18)	4 (7)	4 (7)
	Movement at fracture, % (n)	9.8 (17)	5.2 (9)	0 (0)
	Inability to abduct shoulder beyond 90°, % (n)	13.9 (24)	4.6 (8)	2.3 (4)
Patient outcome scores	Mean QuickDASH score (SD)	27.2 (21.5)	12.6 (17.2)	5.4 (10.4)
	Return of normal QuickDASH score, % (n)	25.4 (44)	64.2 (111)	89 (154)
	Mean EQ-5D score (SD)	0.76 (0.20)	0.87 (0.18)	0.92 (0.12)

EQ-5D, EuroQol five-dimension questionnaire; QuickDASH, Quick Disabilities of the Arm, Shoulder and Hand questionnaire

Secondary aim – predictors of return of function following nonoperative management. In all, 200 patients who underwent nonoperative management completed the prospective cohort study; 27 patients did not unite at six months post-injury, giving an overall nonunion rate of 13.5% (n = 27/200). The majority of patients were employed (89.0%, n = 154/173), of whom 19.5% were in manual jobs (n = 30/154). At six weeks, 72.1% of patients had returned to work (n = 111/154), increasing to 89.0% by three months (n = 137/154).

At six weeks, 25.4% of patients (n = 44/173) had return of normal shoulder function defined by a QuickDASH score within their matched 95% CI range. This increased to 64.2% (n = 111/173) by three months, and 89% (n = 154/173) at six months (Figure 3, Table II). The recovery of the predicted QuickDASH score was strongly associated with the resumption of usual activities as reported by patients during follow-up (Table III).

On unadjusted univariate analysis there were no significant predictors associated with return of function at six or 12 weeks (Table IV). Regression analysis of clinically relevant predictors (age, sex, smoking, fracture displacement, and comminution, with 'forward and backward conditional' entry) did not change this finding. All patients managed nonoperatively (observation cohort and trial data) were combined into a single regression model to determine if this changed the overall

Table III. Return of predicted QuickDASH score and association with patient-reported resumption of usual activities.

Time	QuickDASH score returned and back to normal activities (Sensitivity)	QuickDASH score not returned and not back to normal activities (Specificity)	p-value
6 wks, % (n)	75 (33/44)	85.3 (110/129)	< 0.001*
12 wks, % (n)	85.6 (95/111)	66.1 (41/62)	< 0.001*
24 wks, % (n)	91.6 (141/154)	41.1 (8/19)	< 0.001*

*Chi-squared test.
QuickDASH, Quick Disabilities of the Arm, Shoulder and Hand questionnaire.

Table IV. Table evaluating predictors of return of normal QuickDASH function at six and 12 weeks in united fractures following nonoperative management (n = 173).

	Parameter		Returned (n = 44)	Not returned (n = 129)	p-value	Returned (n = 111)	Not returned (n = 62)	p-value
Demographic	Median age, yrs (IQR)		37.5 (20.3 to 51.0)	34.0 (22.5 to 49.5)	0.570*	35.0 (21.0 to 50.0)	34.0 (24.8 to 53.5)	0.919*
	Sex, % (n)	Male	77.3 (34)	79.1 (102)	0.802‡	79.3 (88)	77.4 (48)	0.775‡
		Female	22.7 (10)	20.9 (27)		20.7 (23)	22.6 (14)	
	Smoking status, % (n)	Smoker	9.1 (4)	15.5 (20)	0.288‡	10.8 (12)	19.4 (12)	0.119‡
		Non-smoker	90.9 (40)	84.5 (109)		89.2 (99)	80.6 (50)	
	Hand dominance, % (n)	Dominant	45.5 (20)	46.5 (60)	0.903‡	44.1 (49)	50.0 (31)	0.459‡
		Non-dominant	54.5 (24)	53.5 (69)		55.9 (62)	50.0 (31)	
	Employment type, % (n)	Sedentary	81.6 (31)	72.1 (93)	0.849‡	84.2 (85)	73.6 (39)	0.115‡
		Manual	18.4 (7)	17.8 (23)		15.8 (16)	26.4 (14)	
Injury mechanism	Energy, % (n)	High-energy	9.1 (4)	17.8 (23)	0.168‡	12.6 (14)	21.0 (13)	0.146‡
		Low-energy	90.9 (40)	82.2 (106)		87.4 (97)	79.0 (49)	
Fracture findings	Fracture (Edinburgh classification), % (n)	Comminution (2B2)	18.2 (8)	14.7 (19)	0.586‡	18.0 (20)	11.3 (7)	0.242‡
		Simple (2B1)	81.8 (36)	85.3 (110)		82.0 (91)	88.7 (55)	
	Mean overall fracture displacement, mm (95% CI)		23.0 (20.6 to 25.3)	22.9 (21.7 to 24.1)	0.972†	22.5 (21.2 to 23.8)	23.7 (21.6 to 25.8)	0.308†
Patient-reported outcome	Mean QuickDASH (95% CI)		5.7 (4.2 to 7.1)	34.5 (31.0 to 38.0)	< 0.001†	3.6 (2.8 to 4.4)	28.8 (23.8 to 33.8)	< 0.001†
	Mean EQ-5D (95% CI)		0.90 (0.86 to 0.94)	0.71 (0.68 to 0.75)	< 0.001†	0.94 (0.92 to 0.96)	0.75 (0.69 to 0.80)	< 0.001†

*Mann-Whitney U test.
†Independent-samples *t*-test.
‡Chi-squared test.
CI, confidence interval; EQ-5D, EuroQol five-dimension questionnaire; IQR, interquartile range; QuickDASH, Quick Disabilities of the Arm, Shoulder and Hand questionnaire.

assumption of the results. The clinically relevant predictors and those trending towards significance (p < 0.2 from Table III; smoking, employment type, and energy) were examined by 'forward and backward conditional' entry in two independent models, however, there were no significant predictors at either six or 12 weeks.

Of the 19 patients who did not recover a normal QuickDASH function at six months, there were no significant patient, injury, or fracture demographic differences. One patient developed adhesive capsulitis and underwent a distension arthrogram at approximately four months post-injury. Another patient had a symptomatic bony prominence at the fracture site and underwent osseous prominence removal at nine months post-injury.

Discussion

This study has demonstrated that operative fixation of displaced mid-shaft clavicular fractures was not associated with an earlier return of normal shoulder function compared with nonoperative management when union occurs. Following nonoperative management, there were no specific patient, injury, or fracture findings associated with early return of normal function at six or 12 weeks. One in four patients achieved normal shoulder function at six weeks, increasing to one in two at 12 weeks post-injury. It takes six months following injury, however, for approximately nine out of every ten patients to have a return of normal shoulder function.

The outcome following acute plate fixation or nonoperative treatment is thought to be similar at one year post-injury when all of the published level 1 data are analyzed.[1,18] This is probably because malunion is thought to be largely well-tolerated in the majority of patients[19] and does not appear to directly correlate with shortening when assessed with CT imaging.[20] However, it is commonly believed in the orthopaedic community that plate fixation facilitates an earlier return of function with potential economic advantages.[21] This is despite the

paucity of level 1 evidence to support the idea that acute fixation results in a clinically meaningful earlier return to work. Of the three randomized trials which specifically report return to work,[12,22,23] only one found an advantage at 2.9 months with fixation versus 3.7 months with nonoperative management.

The majority of randomized trials report that acute fixation facilitates an earlier return of shoulder function when compared with nonoperative management in the first three months following injury.[2-4] This treatment effect may be largely explained by the impaired recovery in those patients who develop a nonunion following nonoperative management. Nonunion occurs in approximately one in seven cases following nonoperative management of displaced mid-shaft clavicular fractures.[1] Although surgery reduces this risk, it is not cost-effective to routinely fix all displaced fractures in adults given that this results in over-intervention.[5]

Nicholson et al have recently shown that clavicular nonunion following nonoperative management can be estimated by a combination of the QuickDASH ≥ 40, fracture mobility on examination, and lack of callus on radiograph at six weeks.[24] This appears to be superior to estimations based on factors present at the time of injury alone, which include smoking, fracture displacement, and comminution.[24] Early identification of patients at increased risk of nonunion following nonoperative treatment for targeted fixation is an emerging strategy from recent evidence.[25-28]

Whether a predictable return of function can be expected for a given patient is an important aspect to consider in addition to the individual risk of nonunion. It is unknown if all patients recover in a similar fashion with nonoperative management when union occurs. This study found that the return of normal shoulder function varies substantially between patients over the first six months. However, patient demographics (e.g. age, sex, smoking status), injury (high- versus low-energy), and fracture findings (comminution and displacement) were not predictive of return of function at six or 12 weeks post-injury.

Age and sex will affect the DASH or QuickDASH score and unfortunately there were no pre-injury functional scores for the patients in this cohort. Although no patient had known pre-existing shoulder pathology prior to injury, increasing age and pre-clinical degenerative shoulder conditions (e.g. rotator cuff pathology) may well have a confounding effect.[6] Furthermore, normative values for one population may not be internationally transferable. There is currently no specific clavicle scoring tool to evaluate shoulder girdle recovery. The DASH and QuickDASH are thought to be comparable with regard to validity and reliability for upper limb disorders[29] but may have a ceiling effect in certain populations and could be a blunt tool to measure clavicular fracture outcome. Reassuringly, we did find that the patient's own assessment of return to usual activities was strongly associated with recovery of their normal predicted QuickDASH score.

The patients from the randomized trial were well-matched and sufficiently powered to detect a minimal clinical difference in the DASH score. A second large prospective cohort of consecutive displaced clavicular fractures undergoing nonoperative management was also used in this study. Union was confirmed with CT scanning using specific criteria when clinically in doubt and this is thought to have greater accuracy than radiological assessment alone.[16] This cohort was originally used to evaluate a nonunion prediction model at six weeks post-injury.[24]

The authors recognize that a power calculation was not formally undertaken for this study and neither cohort was recruited for the primary purpose of evaluating functional recovery. We did not use sophisticated clinical examination tools to measure range of motion, strength, or endurance capabilities which also limits our findings. Early recovery over the first six weeks could be influenced by the time spent in a sling and also the initial treatment but we are unable to comment further on this from our data. The population assessed may not be directly comparable with professional athletes with regard to a return to training and competition. Acute plate fixation is thought to be superior in such cases although the evidence base for this is limited.[30] The original randomized trial used for this study had approximately one-third of patients in each group involved in competitive sport. The original publication of this trial[12] reported no difference in return to sport but this may not directly represent high-level athletes and is beyond the scope of this paper.

Return of normal shoulder function was comparable between operative and nonoperative management of displaced mid-shaft clavicular fractures when union occurs. In this study, there were no identifiable patient, injury, or fracture demographics associated with an early return of function following a displaced mid-shaft clavicular fracture. Prospective studies comparing operative fixation with nonoperative management need to consider patients that unite as a separate analysis in order to evaluate accurately any benefit of fixation that is not mediated by the reduction of nonunion burden.

Take home message

- Following a displaced midshaft clavicle fracture it takes six months to recover normal predicted shoulder function in the majority of patients.
- If union occurs with nonoperative management, early functional recovery appears comparable to acute plate fixation.
- The association between acute plate fixation and faster recovery may result from a reduction of the nonunion burden associated with nonoperative managment.

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