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ORIGINAL ARTICLE

Surgery for the fractured clavicle: factors predicting nonunion

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Background: This study identifies the reasons for failure after plate osteosynthesis of midshaft clavicle fractures, complication rates, and time to radiographic union.
Methods: A retrospective review of 84 consecutive patients who had undergone surgical fixation for a midshaft clavicle fracture was performed.
Results: There were 82 patients who were included for analysis and operated on by 11 different surgeons using a mixture of locking (63%) and nonlocking (37%) plates. The rate of osteosynthesis failure was 12.2%. A logistical regression analysis found that failure of osteosynthesis had no relationship to type of plate used ($P = .82$), gender ($P = .42$), number of proximal ($P = .96$) or distal ($P = .63$) screws to the fracture, or length of plate ($P = .42$). Smoking was found to be the only risk factor ($P = .02$) that increased failure rates after midshaft clavicle osteosynthesis.
Conclusion: Smoking was the only identifiable risk factor to increase failure rates in clavicle osteosynthesis. Preoperative counseling can identify those at increased risk of implant failure and can help improve clinical results by implementing a smoking cessation plan.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Clavicle; fracture; midshaft; osteosynthesis; plate; failure; smoking

Clavicle fractures are common, accounting for 5%-10% of all fractures, at an incidence of 50 per 100,000 people per year.[15] Following early reports by Rowe[17] of conservative management, indicating good range of motion and high rates of union, treatment has previously been mostly conservative. Studies then began filtering through suggesting that patients complained of pain, loss of strength, distal paresthesia, and issues of cosmesis after shortened malunion of midshaft clavicle fractures.[7] More recent reports have shown that restoration of clavicle length after failed conservative management ending in malunion improves functional outcomes and patient satisfaction.[8,20] The restoration of clavicle length is thought to improve glenoid orientation and scapular position, reducing abnormal forces through the sternoclavicular and acromioclavicular joints, and to improve muscle strength around the shoulder.[11] In active or semiprofessional athletes, osteosynthesis has been shown to allow quick return to sports and early pain relief.[21] A randomized controlled trial published by the Canadian Orthopaedic Trauma Society in 2007[3] changed surgeons' outlook regarding clavicular osteosynthesis. It reported on functional and radiologic results of midshaft clavicle fractures managed conservatively or with osteosynthesis; the investigators recommended osteosynthesis in displaced or shortened midshaft clavicle fractures.

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An improvement in our understanding of the mechanics of the clavicle and our ability to identify fracture patterns such as shortened, severely comminuted, or displaced that will lead to an inferior clinical result have led to an increase in the number of clavicle osteosyntheses. The aim of our study was to assess the complication rates, the time to union, and the reasons for failure of osteosynthesis in midshaft clavicle fractures.

Materials and methods

A retrospective review of 84 patients who had undergone surgery for a shortened or displaced fracture of the midshaft clavicle (AO type 15-B) at the Wrightington, Wigan and Leigh NHS Foundation Trust and The Arm Clinic, Manchester, in the period of January 2008–February 2012 was conducted. Patients were identified on the hospital's electronic patient records system. For each case, the age of the patient at time of injury, gender, smoking status, and number of days from injury to primary operation (and, if applicable, secondary operation) were recorded. The mechanism of injury was also noted. The time until radiologic union was assessed by calculating the number of days from the date of operation to the date that union was confirmed either in the notes or as observed on radiographs through the hospital picture archiving and communication system. Operation notes were accessed through electronic patient records and used to record the American Society of Anesthesiologists grade of each patient, type of plate used, quality of reduction, and number of proximal and distal screws.

Complications were defined as any adverse event in the patient's notes and compared according to comorbidity status of the patient, age of the patient, time between injury and osteosynthesis, smoking status, and number of proximal and distal screws. Reoperation was defined as any operation as a consequence of the initial osteosynthesis. Major complications were classified as any complication that required further operation, and minor complications were classified as any deviation from a normal postoperative course not requiring further operation or altering the final outcome.

The primary outcome was failure of osteosynthesis for any reason (plate fracture, loosening, and atrophic nonunion). Secondary outcomes were complications (infection, numbness, secondary adhesive capsulitis) and removal of symptomatic hardware.

All operations were performed in the following manner. The patient was placed in the beach chair position, and preoperative intravenous antibiotic prophylaxis was administered. The unit's standard fixation of a midshaft clavicle fracture begins with an incision inferior to the clavicle, dissection of the clavipectoral fascia, reduction of the fracture, and temporary fixation with Kirschner pins or reduction clamps before definitive fixation. The construct is then washed out with saline, hemostasis is obtained, and the fascia and skin are closed separately. A sling is applied for comfort up to 6 weeks postoperatively, and active and passive physiotherapy is begun when comfort allows. For the first 2 weeks, movement is restricted to below 90° of abduction to reduce rotatory forces through the construct. Patients are then followed up at regular intervals postoperatively until radiologic union.

SPSS Statistics for Windows version 20.0 (IBM, Armonk, NY, USA) was used for statistical analysis. Non-normally distributed data were presented as median values and ranges, and binomial data were presented as proportions. A logistic regression was performed to ascertain the effects of number of proximal screws, number of distal screws, size of plate, age at fracture, gender, smoking status, use of fixation device, and time between injury and fixation on the likelihood of clavicular union after osteosynthesis.

A power analysis for multiple regression was conducted using the equation $N = [(Z\alpha + Z\beta)/C]\ 2 + 3$,[9] where N is the total sample size, $Z\alpha$ is the standard normal deviate for $\alpha = .05$, $Z\beta$ is the standard normal deviate for $\beta = .20$, and $C = 0.5 * \ln[(1 + r)/(1 - r)] = 0.310$ in which r is the expected correlation coefficient. An α of .05 was set as the threshold probability for rejecting the null hypothesis (type I error); β was set at .02 as the probability of failing to reject the null hypothesis under the alternative hypothesis (type II error). R value was set at 0.30 as the expected correlation coefficient. The result of the calculation is

$$N = [(Z\alpha + Z\beta)/C]2 + 3 = 85,$$

showing that the study was adequately powered.

Results

A total of 84 midshaft clavicle fractures were identified at the institutions. Two were lost to follow-up or had an incomplete data set, and 82 were included for analysis. All were closed injuries, and none had distal neurovascular deficit. Surgery was undertaken by 11 different surgeons, with junior surgeons being supervised by consultants. Fixation device was decided by surgeon. Three different fixation types were used: Dynamic Compression Plate (Synthes, Oberdorf, Switzerland), Acumed clavicle locking plate (Hillsboro, OR, USA), and AO Synthes Recon plate. A total of 52 locking plates (63%) and 30 nonlocking plates (Dynamic Compression Plate and Recon plates, 37%) were used. Patient demographics are shown in Table I, and the plate lengths and numbers of screws proximal and distal to the fracture are shown in Figures 1 and 2. The mechanism of injury is displayed as a pie chart in Figure 3. The overall complication rate was 20.7% (10 major and 7 minor complications), giving a major complication rate of 12.2% and a minor complication rate of 8.5% as detailed in Tables II and III. Of the major complications, which all required reoperation, 2 plates fractured after a fall and 1 while BMXing, and 4 became loose as a result of nonunion. One patient had a confirmed surgical site infection that

Table I Patient demographics, gender, age at time of injury, and time from injury to operation.

Total:	82
Male:	62
Female:	20
Mean age at time of injury (years):	31.02
Range:	*12-58*
Mean time until primary operation (days):	12
Range:	*0-32*
Mean time until secondary operation (days):	141
Range:	*13-360*
Mean in-patient stay (nights):	1
Range:	*0-5*