Clavicle and proximal humeral fractures: what is the evidence?

The age of evidence-based medicine is truly upon us, and the past few years have seen an explosion of randomized controlled trials (RCTs) in orthopaedic trauma. However, unpicking a consensus from the multiple – and often apparently conflicting – studies that have been published can be somewhat tricky.

The Cochrane Collaboration, along with other evidence synthesis groups, do an excellent job of keeping the meta-analysis up to date, and this work is supplemented by systematic reviews. Yet there is often a delay to establishing a conclusive answer. A recent study in *The BMJ* suggested that using traditional evidence synthesis methods takes an average of 23 years.[1] The authors make a compelling argument for using living network meta-analysis to shorten this to 19 years. Most treatments in orthopaedic surgery, however, are superseded within five years. As such, the evidence is lagging significantly behind.

Keeping up with contemporary evidence-based practice has increasingly relied on reading primary RCTs. With more and more registered ongoing RCTs currently being undertaken in orthopaedics, this can be a daunting task. This article aims to summarize some of the most important trials of recent years giving treatment guidance in upper limb trauma without waiting 23 years for the definitive meta-analysis.

THE CLAVICLE

Since the publication of the Canadian Orthopaedic Trauma Society (COTS) RCT on clavicle fracture fixation,[2] there has been not only a renaissance in the development of clavicle fixation solutions, but also renewed interest in trials surrounding treatment of the clavicle itself.

Middle third clavicle: to fix or not?

There are no fewer than nine RCTs, all of which are relatively well-conducted, that have reported the outcomes of surgical *versus* non-surgical treatments for the clavicle (Table I). The first of the modern studies to evaluate this question was the aforementioned COTS trial.[2] The COTS group have an enviable record for collaboration across Canada, and for delivering on their trials. In 2007, they published an RCT of 132 patients, all with middle third clavicle fractures, randomized from centres across Canada. Patients with a shortened, off-ended clavicle fracture in the middle third were included. Treatment was pragmatic and the authors selected the Constant and the Disabilities of the Arm, Shoulder and Hand (DASH) scores for functional outcome assessment. Both scores favoured the operative group at all timepoints. Furthermore, radiographic union was observed more quickly in the operative group (16.4 weeks *vs* 28.4 weeks). Perhaps the least surprising finding of this study was the higher rate of nonunion in the nonoperative group (7 *vs* 2) and the higher complication rates seen in the operative group (five patients had local irritation and/or prominence of the hardware, three had a wound infection, and one had mechanical failure). The authors concluded, in light of the better functional outcomes and lower nonunion rate, that clavicle fixation was a preferable option in these patients.

Two years following the COTS study, a further operative *versus* nonoperative study was

A. Das
Nottingham University Hospital, Nottingham, UK
email: avidas17@doctors.org.uk

J. Giddie
Nottingham University Hospital, Nottingham, UK

B. Ollivere
Nottingham University Hospital, Nottingham, UK

Table I. Study characteristics

Author (year)	No. of patients	Injury	Age range, yrs	Interventions	Follow-up	Outcome measures
COTS[2]	132	DMCF	16 to 60	Plate fixation *vs* sling	Intervals to 1 yr	Constant Shoulder and DASH scores, union
Smekal et al[3]	60	DMCF	18 to 65	Elastic stable IM nailing *vs* sling	Intervals to 2 yrs	Constant Shoulder and DASH scores, union, complications
Virtanen et al[4]	60	DMCF	18 to 70	Plate fixation *vs* sling	Intervals to 1 yr	Constant Shoulder and DASH scores, union, complications, pain
Mirzatolooei[5]	60	DMCF	18 to 65	Plate fixation *vs* sling	Intervals to 1 yr	Constant Shoulder and DASH scores, union, satisfaction, clavicular shortening
Robinson et al[6]	200	DMCF	16 to 60	Plate fixation *vs* collar and cuff	Intervals to 1 yr	Constant Shoulder and DASH scores, union on CT, complications
Woltz et al[7]	160	DMCF	18 to 60	Plate fixation *vs* sling	Intervals to 1 yr	Constant Shoulder and DASH scores, union, pain, cosmesis
Ahrens et al[8]	301	DMCF	Adult patients	Plate fixation *vs* sling	Intervals to 9 mths	Radiographic nonunion, Constant and DASH scores, patient satisfaction
Tamaoki et al[9]	117	DMCF	Adult patients	Figure-of-8 harness *vs* anterior plating	Intervals to 1 yr	DASH, radiographic findings, pain, satisfaction, complications, return to work and previous activities
Melean et al[10]	76	DMCF	>18	Plate *vs* conservative	Intervals to 1 yr	Constant score, x-ray and CT for union, return to work

COTS, Canadian Orthopaedic Trauma Society; DMCF, displaced midshaft clavicle fractures; DASH, Disabilities of the Arm, Shoulder and Hand; IM, intramedullary; CT, computed tomography

reported by Smekal et al,[3] and this remains the only study to report conservative management *versus* intramedullary (IM) nail – in this case, an elastic stable intramedullary nail (ESIN). This study is a relatively small RCT of 60 patients, all of whom were working-age adults (between 18 and 65 years old). Clinically, the authors selected the DASH score reported at six months and two years to evaluate function. Again, the DASH score favoured operative management over nonoperative management at both reported timepoints. Although this was a small study, there were differences again in the union rates, with no reported nonunion in the ESIN group and a 10% nonunion in the nonoperative group, of which, perhaps more importantly, two were symptomatic and required subsequent surgery. Not unreasonably, the authors conclude that there are better functional outcomes and lower rates of nonunion seen with ESIN over nonoperative management.

Another small trial, reported by Virtanen et al[4] in 2012, looked further at operative fixation with a plate *versus* nonoperative treatment, and the authors were unable to establish any statistical differences in terms of pain, Constant, or DASH score at one year following a clavicle fracture. In this group, however, the nonunion rates were markedly higher in the nonoperative group at 24% (n=6), with all operative-treated fractures healing. These first three studies set the scene for the subsequent six trials, with either no-difference outcomes favouring operative fixation or the nonoperative group suffering a higher nonunion rate. Mirzatolooei[5] reported another small study of 60 patients, again with similar inclusion and exclusion criteria. In this study, there was just a single nonunion in each group, but there were significant differences in malunion. Nearly a third of patients in the nonoperative group suffered malunion (4 *vs* 19), and superior Constant and DASH scores were reported in the operative group.

Our understanding of the benefits (or otherwise) of clavicle fixation was quite significantly furthered by Robinson et al,[6] who reported a multicentre RCT in 2013 in which 200 patients, all aged between 16 and 60 and presenting with an acute displaced midshaft clavicle fracture, were randomized to either operative fixation with a plate or nonoperative management. Outcomes were again assessed with the Constant and DASH scores at six weeks, three months, six months, and one year. In addition to the clinical outcomes, the investigators included a CT scan to show union. In this trial, the rate of nonunion was significantly reduced after open reduction internal fixation (ORIF) (relative risk (RR) 0.07, p=0.007) and the Constant and DASH scores were significantly better at one year. These investigators undertook a more refined analysis than previous trials, and also reported outcomes when nonunions from nonoperative management were excluded, which removed the beneficial effect of operative treatment. The take-home message from this trial is that the improved outcomes in the operative arm appear to be due to prevention of nonunion, rather than due to improved outcomes following union. This, of course, is achieved at the usual rate of implant-related complications.

The surgical complications are further examined in a trial from Woltz et al[7] published in 2017. In a similar design to the other studies, the authors report a multicentre RCT of adults aged between 18 and 60 years old, all with displaced midshaft clavicle fractures. The participants were randomly allocated to either operative plate fixation or nonoperative treatment. Their trial reports the outcomes of 160 patients, and again reports the rate of nonunion to be

Table II. Study characteristics

Author (year)	No. of patients	Injury	Age range, yrs	Interventions	Follow-up	Outcome measures
Fuglesang et al[11]	123	DMCF	16 to 60	Elastic stable IM nailing *vs* plate	Intervals to 1 yr	Constant and DASH scores, radiographs, complications, operative time
Andrade-Silva et al[12]	59	DMCF	16 to 65	Elastic stable IM nailing *vs* plate	Intervals to 1 yr	Constant and DASH scores, union, shortening, pain, satisfaction, complications
Assobhi[13]	38	DMCF	16 to 60	Retrograde titanium elastic nailing *vs* plate	Intervals to 1 yr	Constant score, union, perioperative data, complications
Ferran et al[14]	32	DMCF	13 to 53	Rockwood pin *vs* plate	Intervals to 1 yr	Constant and Oxford Shoulder scores, union, complications
Van der Meijden et al[15]	120	DMCF	18 to 65	IM nailing *vs* plate fixation	Intervals to 1 yr	Constant and DASH scores, complications

DMCF, displaced midshaft clavicle fractures; DASH, Disabilities of the Arm, Shoulder and Hand; IM, intramedullary

significantly higher in the nonoperative group (23.1% *vs* 2.4%) with no difference in Constant and DASH scores at all reported timepoints (six weeks, three months, and one year). This trial, however, pays special attention to operative complication rates and reports a high rate of second operation in the ORIF group (27.4%).

The largest of the RCTs to date, reported last year from the United Kingdom, is the Clavicle trial.[8] The authors here report a multicentre randomized trial, again of nonoperative *versus* plate fixation in adults for displaced midshaft. This trial reports the outcomes of 301 patients at six weeks, three months, and nine months, using radiological evidence of nonunion at three and nine months, along with the functional Constant and DASH scores. Due in part to the greater power and larger numbers, this trial report focuses in a little more detail on what happens during the early and mid-term outcomes. The authors report no difference in nonunion rates at three months, but nonunion was significantly less likely in the ORIF group at nine months (0.8% *vs* 11%). There were also better scores at six weeks and three months in the ORIF group, with improved early satisfaction rates, which equilibrated at time went on.

There does not seem much need for any further study into the midshaft clavicle fracture, and, although these trials appear to be in conflict at first glance, the results are all remarkably similar. The trial outcomes are all dominated by the incidence of nonunion, which varies within the studies. This is probably explained by variable trial populations. It is well known that gender, age, smoking status, energy of injury, fracture pattern, and diabetes, among other covariates, are geographically different and drive nonunions. The different rates of nonunions are likely explained by population differences here, which, in turn, go on to drive the differences in the outcome of the trial. It appears that, if you don't have a complication, operative and nonoperative management are equivalent.

However, there are still a couple of unturned stones, and two smaller studies are worth considering here. The operative fixation method of choice used in these studies was superior plating, and the world has (especially in North America) moved more towards an anterior operative approach. The rationale often cited for this is the biomechanical superiority of anterior plates in the clavicle, which, while proven in biomechanical dry-bone studies, has little in the way of clinical evidence to support it. The low rates of surgical failure in the randomized trials discussed here suggest this may be a spurious argument. Anterior metalwork placement may, however, have a benefit in terms of managing the need for metalwork removal and complications from prominent metalwork. In a moderate-sized randomized trial, Tamaoki et al[9] undertook a trial of figure-of-eight *versus* anterior plating in 117 patients. Follow-up was to one year, and the results look remarkably similar to many of the previous studies. There were no differences in DASH score, visual analogue scale (VAS) pain score, or time to return to previous activities at any reported timepoint (six weeks, six months, one year), although surgical treatment did decrease the likelihood of nonunion.

The final significant trial on the topic concerns that of patients seeking workers' compensation.[10] These investigators tackled the thorny topic of treatment of patients who were going through the workers' compensation programme in the United States, a group who are known to have notoriously poor outcomes, probably due to the ongoing compensation process. The authors were able to recruit 76 patients, all members of the working population who were seeking injury compensation. Patients were randomized to either nonoperative or operative fixation with a plate. Outcomes were assessed as bony union on CT scanning at six and 12 weeks. In this sub-population there was a significant advantage towards fixing the clavicle. The group who underwent ORIF reported shorter time to return to work, earlier bone union, and fewer nonunions.

If we are fixing, how should we do it?

The early attempts at fixation of the clavicle suffered from high rates of metalwork failure. Use of a pelvic reconstruction plate contoured to the superior aspect of the clavicle resulted in high rates of fatigue failure due to excessive torsional forces. The subsequent development of anatomically contoured plates and locking head screw technology has contributed to the success of plate fixation, reported low nonunion and metalwork failure rates. There are now a number of different options for treatment – superior plating, anterior plating, or intramedullary nailing – and a surprisingly large number of trials to support the use of one treatment or another (Table II).

Elastic stable intramedullary nailing (ESIN)

There are multiple randomized trials comparing ESIN to traditional plating. The potential advantages of ESIN are a small incision with minimal risk of infection, but the technique is challenging, may not be suitable for length-unstable fractures, and runs the risk of damage to surrounding structures while trying to pass the nail.

Fuglesang et al[11] reported a moderate-sized randomized trial last year with the intention of evaluating ESIN *versus* plate fixation. They

Table III. Study characteristics

Author (year)	No. of patients	Injury	Age range, yrs	Interventions	Follow-up	Outcome measures
Fjalestad et al[16]	50	Displaced 3- or 4-part FPH	>60	Angular stable plate fixation *vs* conservative	Intervals to 1 yr	Constant score, self-assessment, radiographic outcomes
Olerud et al[17]	60	Displaced 3-part FPH	>55	Anatomical locking plate *vs* conservative	Intervals to 2 yrs	Constant, DASH, HRQoL, and EQ-5D scores, ROM, complications
Rangan et al[18]	231	Displaced FPH	>16	Surgical (fixation or replacement) *vs* conservative	Intervals to 2 yrs	Oxford Shoulder and SF-12 scores, complications, mortality
Olerud et al[19]	55	Displaced 4-part FPH	>55	Global FX prosthesis *vs* non-surgical	Intervals to 2 yrs	Constant, DASH, HRQoL, and EQ-5D scores, ROM, additional surgery
Boons et al[20]	50	Displaced 4-part FPH	>65	Global FX prosthesis *vs* non-surgical	Intervals to 1 yr	Constant score, simple shoulder and abduction strength tests, pain
Cai et al[21]	32	Displaced 4-part FPH	67 to 86	Locking plate *vs* shoulder hemiarthroplasty	Intervals to 2 yrs	Constant, DASH, HRQoL. and EQ-5D scores, ROM
Sebastiá-Forcada et al[22]	62	Complex displaced 4-part FPH, head splits or 3-part fracture dislocations	>70	Hemiarthroplasty (SMR Trauma) *vs* reverse shoulder (SMR Reverse)	Minimum 2 yrs	Constant, DASH, and UCLA scores, ROM, complications

FPH, fracture of proximal humerus; DASH, Disabilities of the Arm, Shoulder and Hand; HRQoL, health-related quality of life; EQ-5D, EuroQol-5D; ROM, range of motion; SF-12, 12-Item Short-Form Health Survey; UCLA, University of California, Los Angeles

enrolled 123 patients with completely displaced midshaft clavicle fractures and randomized them to treatment with either ESIN or traditional open-plate fixation. The outcomes were reported for follow-up at six-week, three-month, six-month, and one-year radiographs. Outcomes were assessed using the Constant and DASH scores. The authors were able to make some recommendations based on subgroup analyses of their results. Plate fixation for comminuted fractures yielded quicker functional recovery at up to six months' follow-up, although there was no difference seen after one year. Overall, as perhaps one might surmise, there was a lower infection rate in the nail group. However, failure rates were higher in nail sizes greater than 2.5 mm. A smaller study of 59 patients reported similar outcomes in displaced midshaft clavicle fractures.[12] There were no major differences in complications between the plate reconstruction group and the ESIN in terms of clinical outcomes.

The outcomes of these two studies are confirmed by two smaller, and potentially biased, studies. Assobhi[13] reported 38 patients and, despite the methodological limitations of this study, the outcomes seem to suggest that earlier functional recovery and improved radiographic outcomes at six weeks are seen in the IM nail group. These, however, are equal by the 12 weeks point, and probably just reflect the smaller nature of the dissection. Supporting the findings of the previous study,[11] there was the suggestion of a lower complication with nail over plate. In a second small study,[14] 17 patients treated with a more complex locked IM nail were compared with 15 patients treated with open plate fixation. Although this was a pilot study, and is really only designed to estimate effect sizes, there were no differences observed in functional scores (Constant and Oxford scores). There was 100% union in both groups. There was, however, a marked difference in the incidence of re-intervention for metalwork removal. Eight patients needed metalwork removed in the plate group *versus* two in the IM Nail group.

The largest trial on the topic[15] is a multicentre study of 120 patients, all of whom had midshaft clavicle fractures and were randomized to either plating or nailing. The outcomes were assessed using the Constant and DASH scores. In terms of operative complications, this multicentre study is large enough to pay heed to the equivalent complication rates reported. The authors of this study looked at earlier outcomes as well, and reported less disability in the operative group.

With the evidence available at present, it would seem that a reasonable approach, and the current gold standard, remains plate fixation. However, there is some evidence that, in selected patients with length-stable fractures, IM nailing has an equivalent or possibly even lower complication rate.

FRACTURES OF THE SHOULDER

The recent publication of the Proximal Fracture of the Humerus Evaluation by Randomisation (PROFHER) study, the first large prospective RCT of its kind, has led to renewed interest in what evidence exists to support management of proximal humeral fractures (Table III).

Operative versus nonoperative treatment

We know that the majority of these fractures will heal, even with a reasonable amount of displacement. Consequently, shoulder surgeons have traditionally erred on the side of caution, with fixation reserved for the badly displaced fractures or those with multiple relative indications for fixation. The development of angular stable locking plates in the proximal humerus, however, allowed the indications for fixation to be pushed back with patients who would previously have been either managed with an arthroplasty or simply left in a sling and referred for a comprehensive rehabilitation package.

The first high-quality studies on the treatment of proximal humeral fractures both reported the outcomes of internal fixation *versus* nonoperative treatment.[16,17] Olerud et al[17]

reported a 60-patient study, all of whom were elderly and had three-part proximal humeral fractures. Patients were treated with angular stable fixation or nonoperative conservative management. Although the results favoured improved outcomes at two years in the operative group, this was offset against a high (30%) re-operation rate. These results were similar to the other contemporaneous study,[16] which examined the outcomes of displaced three- or four-part proximal humeral fractures in patients aged 60 years and over. There were no significant differences in functional outcome scores at 12 months.

The most complete of the randomized studies evaluating proximal humerus is the PROFHER trial, which reported in 2015.[18] The study is a large multicentre RCT and includes 231 patients, all adults presenting with a displaced proximal humerus. The patients were randomized to nonoperative *versus* surgical management (the precise type of surgical management being the surgeon's choice). Outcomes were assessed using clinical scores, and there were no differences seen in Oxford Shoulder Score or 12-Item Short-Form Health Survey (SF-12) score over the two year follow-up period. Interestingly, there were also no differences in complication rates or mortality between the operative and nonoperative groups. In what remains the definitive trial on the topic, there is little evidence to support what is an increasing trend for surgery of displaced proximal humerus fracture.

Hemiarthroplasty in the proximal humerus

There have been two small but moderate-quality trials investigating the use of the humeral hemiarthroplasty in proximal humeral fractures. The first of the pair is a small study of 55 elderly patients, all with four-part proximal humeral fractures.[19] The patients were randomized to either conservative management or operative intervention, and follow-up was to two years using quality-of-life and functional scores. The study reports superior health-related quality of life (HRQoL) and EuroQol-5D (EQ-5D) scores in patients allocated to operative treatment. However, Constant, DASH, and VAS scores did not reach a significant difference between groups. From an objective outcomes perspective, there was no significant difference seen in range of motion achieved at two years between the groups.

The second trial on the topic again looks to compare displaced four-part proximal humeral fractures treated either nonoperatively or with hemiarthroplasty in patients aged 65 years and over.[20] The trial reports the outcomes of 50 patients randomized to one treatment allocation or the other. Outcomes were assessed using the Constant score and the Simple Shoulder Test. There were no between-group differences in Constant and Simple Shoulder Test scores at the reported three- and 12-month follow-ups. However, there was an improvement in abduction strength at three and 12 months in the nonoperatively treated group, although this was offset against higher pain scores at three months. These differences normalized and could not be detected at 12 months' follow-up.

Comparison of interventions

To make matters even more confusing, there are a small number of trials comparing fixation with hemiarthroplasty that should be considered in the proximal humerus. Cai et al[21] reported a small trial, which was essentially a pilot of 32 patients, all elderly and presenting with displaced four-part proximal humeral fractures. Patients were treated with locking plate or hemiarthroplasty, with patient-reported outcome measures and range of motion recorded. As perhaps would be expected with such a small study, although most scores favoured the replacement group, they did not reach significance.

There is a single trial in the literature that compares reverse shoulder arthroplasty (RSA) with hemiarthroplasty in complex proximal humeral fractures in patients over 70 years of age.[22] The authors enrolled 62 patients, all of whom underwent a randomly allocated treatment of hemiarthroplasty or RSA. Outcomes were assessed using the Constant, DASH, and University of California, Los Angeles (UCLA) scores, all of which significantly favoured the RSA group. In addition to improved outcome scores, the RSA group had significantly better improved forward elevation and abduction. The authors examined the link between outcomes and the tuberosity resorption (as a measure of surrogate function). In the hemiarthroplasty group, 30% of tuberosities failed and this subgroup of patients had poorer functional outcomes. In the RSA group, the authors reported that 13% of tuberosities resorbed, although this did not seem to affect the eventual functional outcome. In terms of complications, the two groups were equivalent. The authors conclude that RSA resulted in better pain and functional outcomes, as well as lower revision rates.

In the world of proximal humeral fractures, there is clearly more that we don't know than that which we do. There are a large number of ongoing trials, including PROFHER-2, ReShAPE, ProCon, and DELPHI, the majority of which will be reporting over the next few years.

CONCLUSION

There is now a considerable evidence base for making treatment decisions concerning fractures sustained around the shoulder girdle. As the majority of trials have been published since 2012, there has been a sharp increase in the number of trials available for both meta-analysis and clinical decision-making. Although there are a few major unknowns (like the role of the reverse arthroplasty in fracture) it seems likely that these will, at least in part, be answered by forthcoming, already registered, clinical randomized trials.

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