Surgical interventions for treating acute fractures or non-union of the middle third of the clavicle

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ABSTRACT

Background
This review covers two conditions. These are acute fractures and non-union resulting from failed fracture healing. Clavicle or collarbone fractures account for around 4% of all fractures. While treatment of these fractures is usually non-operative, some types of fractures, as well as non-union of the middle third of the clavicle, are often treated surgically.

Objectives
To evaluate the effectiveness of different methods of surgical treatment for acute fracture or non-union of the middle third of the clavicle.

Search strategy
We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to December 2008), Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2008, Issue 4), MEDLINE (1966 to December 2008), EMBASE (1988 to December 2008), LILACS (1982 to December 2008), trial registries and reference lists of articles. No language or publication restrictions were applied.

Selection criteria
Randomised and quasi-randomised controlled trials evaluating any surgical intervention for treating people with fractures or non-union of the middle third of the clavicle were considered. The primary outcomes were pain, treatment failure and health-related quality of life or shoulder function.

Data collection and analysis
Two authors independently selected eligible trials and three authors assessed methodological quality and cross-checked data extraction. There was no pooling of data.

Main results
Data from three small trials, each testing a different comparison, were included. Two trials had design features that carry a high risk of bias, limiting the strength of their findings. Low-contact dynamic compression plates appeared to be associated with significantly
better upper-limb function throughout the year following surgery; earlier fracture union and return to work, and a reduced incidence of implant-associated symptoms when compared with a standard dynamic compression plate in 36 adults with symptomatic non-union of the middle third of the clavicle. One study (69 participants) compared the Knowles pin versus a plate for treating middle third clavicle fractures or non-union. Knowles pins appeared to be associated with lower pain levels and use of post-operative analgesics; reduced incidence of implant-associated symptoms, and shorter operation time and hospital stay. One study (133 participants) found that a three-dimensional technique for fixation with a reconstruction plate was associated with a significantly lower incidence of symptomatic delayed union than a standard superior position surgical approach.

Authors’ conclusions

There is limited evidence, from single trials only, regarding the effectiveness of different methods of surgical fixation of fractures and non-union of the middle third of the clavicle.

**PLAIN LANGUAGE SUMMARY**

**Surgical interventions for treating fractures and non-union of the collarbone**

Collarbone or middle third of the clavicle fractures are a very common injury and account for up to 4% of all fractures. Although the majority of acute fractures can be treated conservatively, such as using a sling, there are some types of fracture that need to be surgically treated. Non-union of the collarbone, which results from failed fracture healing, is usually treated surgically when associated with pain and functional impairment.

This review set out to evaluate the effects, primarily on pain and long-term function, of different methods for surgically treating collarbone fractures and non-union.

Three small studies, two of which had methodological limitations that may affect the reliability of their findings, were included in this review. One poor quality trial that involved 36 participants compared two types of plates for treating non-union of fractures of the middle third of the clavicle. The trial found that participants treated with a low-contact dynamic compression plate reported a better quality of life in the year after surgery and returned to work earlier than those patients treated with a standard dynamic compression plate. The second trial, which was also of poor quality, concluded that there were advantages in using intramedullary nail fixation compared with plate fixation in 69 people with either acute fractures or non-union. The third trial, involving 133 participants, was well conducted but did not include enough participants to be conclusive. It compared two different techniques for placement of plates to fix displaced clavicle fractures. This trial found that a technique in which the plate is contoured in three dimensions before fixation to the clavicle gave better results than placing the plate along the upper surface of the clavicle.

Evidence regarding the effectiveness of different methods of surgical interventions for treating fracture and non-union of the collarbone is limited and further studies are justified.

**BACKGROUND**

The clavicle or collarbone has several important functions. It acts as a bridge connecting the upper limb to the thoracic cage, which helps to stabilise the shoulder girdle, while allowing the arm to perform a full range of movement. In addition, it functions as an attachment for muscles, provides protection to vital neurovascular structures, supports respiratory function, and has a significant aesthetic role in a person’s physical appearance. These functions can be damaged by the occurrence of fractures and non-union (Kotelnicki 2006; Lazarus 2001).

This review deals with two conditions. Those are acute fractures and non-union resulting from failed fracture healing.

**Description of the condition**

The clavicle is one of the most commonly fractured bones, accounting for 2.6% to 4% of all fractures (Nordquist 1994; Postacchini 2002). The incidence of clavicle fractures in adults is 71 per 100,000 men and 30 per 100,000 women (Neer 1984). Court-Brown 2006, in an epidemiological study of fractures in people over 12 years of age, observed a bimodal distribution curve for the incidence of clavicle fractures in males and a peak incidence in younger males and, to a lesser extent, in older males. The curve was unimodal in females with a high incidence in older women.
There are two mechanisms of injury that most typically result in clavicle fractures. The most common occurs after a fall directly onto the outer side of the shoulder and corresponds to around 90% of the cases. The other mechanism of clavicle injury is indirect trauma, which happens after a fall onto an outstretched arm. The force of the fall is transmitted through the upper extremity to the clavicle, producing the fracture. Although this was previously believed to be the most frequent cause of injury, it represents only 2% to 5% of fractures (Nowak 2000). Sporting activities such as bicycling and skiing are common causes of falls resulting in a fracture (Nowak 2000).

Allman 1967 proposed a classification for clavicle fractures, by dividing them into three groups according to their location along the bone. Group I fractures are in the middle third of the bone; group II are fractures in the outer or lateral third of the bone; and group III are fractures in the inner or medial third of the bone. In a large epidemiological study, Nordqvist 1994 classified 76% of all fractures as group I fractures; a median age of 13 years was found for patients in this group. Recently, due to the absence of a single system that has both prognostic and therapeutic value, Robinson 1998 proposed his own classification. It is based on Allman’s categories but includes prognostically important variables, such as the degree of displacement and comminution (fragmentation of the bone). A possible complication of middle third clavicle fractures is non-union. In 1986, the American Food and Drug Administration (FDA) defined non-union to be “established when a minimum of nine months has elapsed since injury and the fracture shows no visible progressive signs of healing for three months”. However, these criteria cannot be applied to every fracture (LaVelle 2003). Even though non-union of the clavicle has not been definitively defined in the literature so far, many investigators agree that a diagnosis can be made if consolidation does not happen within six months after the injury (Joffay 2007; Manske 1985; Pyper 1978; Wilkins 1983). The verification of the non-union is made when there is clinical or radiographic evidence showing that healing has ceased and that union is highly improbable.

Description of the intervention
Indications for operative treatment of middle third clavicle fractures include: open fracture, severe displacement caused by comminution, an open lesion of the skin by a sharp edge of the clavicle, and neurovascular injuries. The relative (not absolute) indications for surgery are: multiple trauma, floating shoulder, painful malunion, and painful non-union. More recently other relative indications have been adopted, including high energy fractures such as clavicle shortening greater than 20 mm, complete displacement, and severe comminution. When the surgical approach is chosen to treat these fractures there are several techniques of fixation that can be implemented (Bradbury 1996; Ebrahim 1997; Jupiter 1987; Mullaji 1994). These include internal fixation with screws, pins, wire loops, or plates; and external fixation with external fixators. Bone grafting may also be used.

The primary indications for treatment of an established non-union are pain and functional impairment. Usually there is no indication for treating an asymptomatic non-union. Surgical treatment of clavicle non-union includes a bone graft with or without fixation, clavicle excision, and more rarely a free-limb vascularized graft. The latter involves the use of a bone graft from the fibula (one of the two bones of the lower leg) which includes blood vessels that can be connected to the blood vessels in the locality of the clavicle. Each treatment has documented advantages and disadvantages (Lazarus 2001).

How the intervention might work
Whilst studies show incidences of non-union ranging from 0.03% to 5.9% (Nordqvist 1998; Robinson 2004; Złowodziński 2005) for undisplaced fractures, studies of displaced fractures reveal non-union rates up to 15% (Canadian 2007; Feli 1997; McKee 2006). Etiological factors that predispose to the development of non-union include open fracture, associated poly-traumatic lesions, re-fracture, initial fracture displacement, comminution, shortening, older age, and an inadequate period of immobilisation (Jupiter 1987; Marti 2003). Robinson 2004 observed that intrinsic factors, such as advanced age and female gender, are more likely to be predisposing factors for non-union. These findings have recently prompted an increase in preference for operative treatments by surgeons: through the usual techniques of open reduction and internal fixation (using a plate and screw) or intramedullary fixation (either approaching the focus of the fracture or not) (Canadian 2007; Meier 2006). The comparison between surgical and conservative (non-operative) management is the subject of a separate Cochrane Review, which is in preparation (Cheung 2008).

Complications of surgical treatments include wound infection or dehiscence, deep infection, and problems with the hardware used for fixation. The rate of infection ranges from 0% to 18% (Böstman 1997; Poiger-Fürst 1992; Verborg 2005; Wu 1998) and the rate of hardware irritation that requires part or total hardware removal ranges from 50% to 100% (Ali Khan 1978; Böstman 1997; Canadian 2007). Other potential drawbacks of surgical interventions include scarring, complex regional pain syndrome, transient brachial plexus symptoms, non-union and re-fracture after hardware removal, and hardware migration (Lazarus 2001).

Why it is important to do this review
Middle third fracture of the clavicle is one of the most common fractures of the body. It frequently results in short-term disability and pain and can result in long-term deformity and disability. Although the majority of acute fractures can be treated conservatively, there are some types of fracture that need to be treated surgically.
Surgically. Surgical treatment for symptomatic non-union is also performed. Hence, it is important to systematically review the available evidence in the literature on surgical interventions in order to inform management decisions for these injuries.

**OBJECTIVES**

The objective of this review was to evaluate the effectiveness of different methods of surgical treatment for fractures and non-unions of the middle third of the clavicle.

**METHODS**

**Criteria for considering studies for this review**

**Types of studies**

Any randomised or quasi-randomised (method of allocating participants to a treatment which is not strictly random, for example by date of birth, hospital record number, or alternation) controlled trials comparing surgical interventions for treating middle third clavicle fractures or non-union were considered.

**Types of participants**

Trials with adolescents or adults diagnosed with an acute middle third clavicle fracture or non-union were included. Any trials that exclusively included young children (age less than 10 years) were excluded. Trials that involved some young children were included provided the proportion of young children was clearly under 10%, or separate data were available. People with other shoulder injuries or disorders were excluded.

**Types of interventions**

All surgical interventions for treating middle third clavicle fractures or non-union. Examples include internal fixation using a plate, Kirschner wires, titantium nails, Knowles pins, and external fixation with an external fixator. All possible comparisons between these surgical strategies (applied either singly or combined) together with the use of bone grafting were considered.

**Types of outcome measures**

**Primary outcomes**

- Pain, treatment failure (a systematic non-union, unresolved non-union, or re-operation), and health-related quality of life or shoulder function.

Examples of validated patient-assessed instruments for measuring these outcomes are:

- VAS (visual analogue scale) (Revill 1976) for pain.
- Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) (Hudak 1996) for upper-limb function.
- Short Form-36 (SF-36) (Ware 1992) for health-related quality of life.

A commonly used instrument for assessing shoulder function is the Constant score (Constant 1987). This is a composite score for shoulder function that includes subjectively rated pain and activities of daily living, and objectively rated range of movement and strength.

**Secondary outcomes**

**Functional impairment and clinical outcomes**

- Shoulder range of motion.
- Shoulder strength.
- Cosmetic appearance.
- Patient satisfaction with treatment.
- Time of rehabilitation.
- Time to return to previous activities (sport, manual labour, etc).

**Radiographic outcomes**

- Time to consolidation.
- Clavicular length or shortening and shift.
- Step off or gap deformity of shaft of clavicular bone.
- Composite measures including malunion and total radiological deformity.
- Non-union.

**Adverse outcomes**

- Early complications (wound infection or dehiscence, paraesthesia in upper limbs, pain, etc).
- Short-term complications (skin problems, stiffness, hardware irritation requiring removal, wire migration, etc).
- Late complications (asymmetric shoulder, sensitive or painful fracture site, hardware irritation and/or prominence, etc).

**Economic data**

- Hospital admission, number of outpatient attendances, and other costs with treatment.
- Time off work or education.
Search methods for identification of studies

Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to December 2008), the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2008, issue 4), MEDLINE (1966 to December 2008), EMBASE (1988 to December 2008), and Latin American and Caribbean Health Sciences (LILACS) (1982 to December 2008). We also searched Current Controlled Trials, the UK National Research Register Archive (for records up to September 2007), and the WHO International Clinical Trial Registry for ongoing and recently completed trials. There were no restrictions based on language or publication status.

In MEDLINE (PubMed) the first two phases of the optimal trial search strategy (Higgins 2006) were combined with the subject-specific search (see Appendix 1). Search strategies are also shown for The Cochrane Library (Wiley Interscience), EMBASE (Ovid Web), and LILACS in Appendix 1.

Searching other resources

We checked the reference lists of articles, reviews and textbooks for possible relevant studies. We handsearched abstracts for the annual meetings of the British Elbow and Shoulder Society (2001 to December 2008), the American Orthopaedic Association (1996 to November 2008), American Academy of Orthopaedic Surgeons, and the British Trauma Society.

Data collection and analysis

Selection of studies

Two authors (JB and ML) independently selected and assessed, using a piloted form, potentially eligible studies for inclusion in the review. Any disagreements were resolved by discussion and, when necessary, adjudication by a third author (JG).

Data extraction and management

Two review authors (JB and ML) used a piloted data extraction form to independently collect data including methods, participants, interventions and outcomes. Disagreements were resolved by a third review author (JG). Two review authors (JB and ML) entered data into Review Manager. When necessary, we sent requests to trial authors for additional information or data.

Assessment of risk of bias in included studies

Three authors (JB, JG and ML) independently assessed, without masking the source or authorship of trial reports, various aspects of methodological quality of the included studies. We used a modified version of the Cochrane Bone, Joint and Muscle Trauma Group's former quality assessment tool (Table 1). An impression of the overall risk of bias was also made based on allocation concealment, blinding, and the potential effects of incomplete outcome data of the individual studies. Disagreements were resolved by a fourth review author (MM).

Table 1. Methodological quality assessment scheme

<table>
<thead>
<tr>
<th>Items</th>
<th>Scores</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Was the assigned treatment adequately concealed prior to allocation?</td>
<td>Yes = method did not allow disclosure of assignment. Uncl = small but possible chance of disclosure of assignment or uncl. No = quasi-randomised, or open list or tables.</td>
<td>Cochrane code (see Handbook): Clearly yes = A: Not sure = B: Clearly no = C.</td>
</tr>
</tbody>
</table>
| (2) Were the outcomes of participants who withdrew described and included in the analysis (intention-to-treat)? | Yes = withdrawals well described and accounted for in analysis. Uncl = withdrawals described and analysis not possible, or probably no withdrawals. No = no mention, inadequate mention, or obvious differences and no adjustment. | }
Table 1. Methodological quality assessment scheme (Continued)

| (3) Were the outcome assessors blinded to treatment status? | Yes = effective action taken to blind assessors. Unclear = small or moderate chance of unblinding of assessors, or some blinding of outcomes attempted. No = not mentioned or not possible. | Although many characteristics including hand dominance are important, the principal confounders are considered to be age, gender, type of fracture or non-union. |
|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| (4) Were important baseline characteristics reported and comparable? | Yes = good comparability of groups, or confounding adjusted for in analysis. Unclear = confounding small, mentioned but not adjusted for, or comparability reported in text without confirmatory data. No = large potential for confounding, or not discussed. | |
| (5) Were the trial participants blind to assignment status after allocation? | Yes = effective action taken to blind participants. Unclear = small or moderate chance of unblinding of participants. No = not possible or not mentioned (unless double-blind), or possible but not done. | |
| (6) Were the treatment providers blind to assignment status? | Yes = effective action taken to blind treatment providers. Unclear = small or moderate chance of unblinding of treatment providers. No = not possible, or not mentioned (unless double-blind), or possible but not done. | |
| (7) Were care programmes, other than the trial options, identical? | Yes = care programmes clearly identical. Unclear = clear but trivial differences, or some evidence of comparability. No = not mentioned or clear and important differences in care programmes. | Examples of clinically important differences in other interventions are: method of anaesthesia, experience of surgeons, time of intervention, duration of intervention, difference in rehabilitation. |
| (8) Were the inclusion and exclusion criteria for entry clearly defined? | Yes = clearly defined (including type of fracture). Unclear = inadequately defined. No = not defined | |
| (9) Were the outcome measures used clearly defined? | Yes = clearly defined. Unclear = inadequately defined. No = not defined. | |
Table 1. Methodological quality assessment scheme (Continued)

| (10) Were the accuracy and precision, with consideration of observer variation, of the outcome measures adequate and were these clinically useful and did they include active follow-up? | Yes = optimal. Unclear = adequate. No = not defined, not adequate. |
| (11) Was the timing (e.g. duration of surveillance) clinically appropriate? | Yes = optimal (> 1 year) Unclear = adequate (6 months - 1 year) No = not defined, not adequate (< 6 months) |

Measures of treatment effect

Quantitative data, both dichotomous and continuous, were reported in the text and in the analyses. Dichotomous outcome data were considered as risk ratios with 95% confidence intervals. When appropriate, we expressed estimate effects as numbers needed to treat (NNTs). The NNT corresponds mathematically to the inverse of the risk difference and clinically to the number of patients to be treated to avoid one undesired event and was calculated using the pooled risk ratio. Continuous outcome data were expressed as mean differences with 95% confidence intervals (CI). We intended to pool the data as a mean difference (MD) if two or more studies presented data derived from the same validated instrument of evaluation (with the same units of measure). If primary studies measured the same variables through different instruments (and different units of measure) we intended to use the standardised mean difference (SMD).

Unit of analysis issues

The unit of randomisation for all the included trials was the individual participants. There were no unit of analysis issues in the analysis of studies such as with cluster-randomised trials or for people with bilateral fractures, where data could have been presented for fractures or limbs instead of individual patients.

Dealing with missing data

We performed an intention-to-treat analysis with the purpose of including all available data from patients randomised to any intervention. When there was insufficient information relative to estimate effects, such as number of participants, means, measures of uncertainty (standard deviation or standard error), or number of events and participants, we contacted the main authors of the included trials. When it was impossible to acquire adequate data for the forest plot (for example means and standard deviations), we have presented the data in the text or Appendices.

Assessment of heterogeneity

The heterogeneity of estimate effects between the included studies was assessed by visual inspection of the forest plot (analysis) along with consideration of the Chi² test for heterogeneity and the I² statistic.

Data synthesis

When considered appropriate, we planned to pool results of comparable groups of trials using the fixed-effect model and 95% confidence intervals. We also planned to use the random-effects model where there was diversity in clinical or methodological characteristics between the studies included in a meta-analysis.

Subgroup analysis and investigation of heterogeneity

We investigated surgical management of both acute clavicle fractures and non-union of clavicle fractures. We planned, where possible, to carry out subgroup analyses by: age (adolescent, adult, and elderly), type of fracture (two fragments and more than two fragments), type of non-union (hypervascular or avascular), mechanism of injury, and surgical experience. We would have tested whether subgroups were statistically significantly different from one another using the test for interaction outlined in Altman 2003.

Sensitivity analysis

We also planned, where possible, to conduct sensitivity analyses exploring aspects of trial and review methodology, including the effects of missing data and study quality (specifically allocation concealment and outcome assessor blinding).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.
Results of the search
The search strategy found 159 references (Figure 1), of which 152 were excluded through initial screening of reference titles and abstracts by JB and ML. Of those excluded, 115 were duplicates or not relevant, 20 were excluded as they were not randomised controlled trials, and 17 did not meet the inclusion criteria for participants and interventions. Of the seven remaining potentially relevant studies, for which full reports were obtained, three were included and four were excluded. One further study, subsequently excluded, was identified via PubMed related articles.
Figure 1. Search strategy

Algorithm of search strategy results

Total number of references = 159 studies

- MEDLINE (PubMed) = 57 references
- CENTRAL (Wiley) = 24 references
- EMBASE (OVID) = 59 references
- LILACS (Bireme) = 4 references
- Specialised register (BJMT) = 15 references

References excluded = 152 studies

Reasons:
- Duplicate references: 49 studies
- Other issues or not adult or adolescent participants: 56 studies
- Not randomised or quasi-randomised controlled trials: 20 studies
- Studies of conservative interventions or surgical versus conservatives interventions: 13 studies
- Studies of medial or lateral clavicle fractures (not middle third clavicle fractures): 4 studies

Potentially relevant references retrieved

for detailed evaluation = 7

Randomised or quasi-randomised clinical trials with usable information by outcomes = 3

Kabak 2004; Lee 2007; Shen 2008
Included studies

Further details of the three included studies (Kabak 2004; Lee 2007; Shen 2008) can be found in the Characteristics of included studies. All three trials were located in MEDLINE; we also located Kabak 2004 and Lee 2007 in The Cochrane Library. All trials were reported in English.

Design of the studies

Two studies were randomised controlled trials (Kabak 2004; Shen 2008) and one was a quasi-randomised controlled trial (Lee 2007). All three single-centre trials randomised individual patients into one of two intervention groups.

Sample sizes

The three trials enrolled a total of 238 participants: outcome data allowing analysis by the trial authors were available for 212 participants. Participant flow diagrams for the three trials are presented in Figure 2 (Kabak 2004), Figure 3 (Lee 2007) and Figure 4 (Shen 2008) respectively.