Displaced midshaft fractures of the clavicle: non-operative treatment versus Acumed ® plate fixation. A multi-centre randomised controlled trial in the Netherlands.

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Results of recent trials suggest that operative treatment with locking plate fixation results in better functional outcomes than non-operative treatment. Because more patients were lost to follow-up than anticipated in the main randomised trial,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON34752

Source
ToetsingOnline

Brief title
Non-operative treatment vs. locking plate for midshaft clavicle fractures

Condition

- Fractures

Synonym
clavicle fracture, collarbone fracture

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: aanvraag NutsOhra

Intervention

Keyword: clavicle fracture, conventional treatment, locking plate, randomized controlled trial

Outcome measures

Primary outcome

• Complete recovery of function of the shoulder to the level of mobility prior

to fracture.

Secondary outcome

• Complete radiological consolidation

• Complications

• Function of the shoulder compared to contra lateral using MicroFET2 ®

• Cosmetic aspects

• Quality of life, DASH and Constant score

Study description

Background summary

The traditional view that the vast majority of clavicular fractures heal with good functional outcomes following non-operative treatment is no longer valid. Recent studies have identi*ed a higher rate of non-union and speci*c de*cits of shoulder function in subgroups of patients with these injuries (7). Displaced or comminuted mid-clavicular fractures carry a risk of malunion with cosmetic deformity and recent studies have reported a rate of non-union of more than 15% (5;8).
While it is increasingly being accepted that the results of closed treatment for some clavicular fractures are inferior to operative treatment, as published in early reports, up until recently primary operative intervention for

dislocated fractures has not been shown superior. Numerous studies have examined the safety and efficacy of primary open reduction and internal fixation for completely displaced midshaft clavicle fractures and have noted a high union rate with a low complication rate. However, most of these studies were retrospective and only one recent study prospectively compared locking plate fixation with non-operative treatment (6).
Locking compression plates are fracture fixation devices, with threaded screw holes that allow screws to lock in the plate and function as a fixed-angle device. These plates may have a mixture of holes that allow placement of both locking and traditional non-locking screws (so-called combi plates). The locking plate fixation has been compared in one randomised controlled trial with non-operative treatment and showed favourable results for the locking plate fixation. Several other methods exist to operatively stabilize a clavicular fracture, such as K-wire and intramedullary fixation, but these types of fixation seem to be less solid and relate to more complications than plating or non-operative management. With improved implants, prophylactic antibiotics, and better soft-tissue handling, plate fixation has become an adequate, safe and reliable technique (6).
In a meta-analysis, non-randomized, non-comparative, pooled data across all studies showed that plating of 635 fractures resulted in a non-union rate of 2.5%, which was significantly lower compared with 5.9% for non-operative treatment (8). Looking at displaced fractures separately, plate fixation of 460 fractures resulted in a non-union rate of 2.2%, which was significantly lower compared with 15.1% for non-operative treatment. In a randomised clinical trial comparing plating and non-operative treatment of 100% displaced midshaft fractures, a non-union rate of 24% was reported for non-operative treatment and 0% for plating (8). In the non-operative group, 30% developed some symptoms of upper extremity neurologic complaints during overhead use of the arm compared to 6% in the operative group. In the non-operative group, 44% had complains about the cosmetic appearance of the shoulder. However, 30% of the patients in the plating group, requested hardware removal after healing of their fracture (8;9) In the Canadian trial, minor and major complications after surgery were frequently seen (37%), including wound infection, hardware irritation or premature hardware failure which required removal. Although operation may reduce the chance of developing pseudoarthrosis, the risk of complications has to be carefully considered when the need for operative treatment is not absolute (6;7).
A retrospective study of the non-operative treatment of displaced middle-third fractures of the clavicle showed that after at least four years only 69% of the patients were satisfied with the final result. Eight of the 52 fractures (15%) had developed nonunion. Thirteen patients had mild to moderate residual pain and 15 had some evidence of brachial plexus irritation. Of the 28 who had cosmetic complaints, only 11 would consider corrective surgery. None of the patients had significant impairment of range of movement or shoulder strength as a result of the injury. There was also a relatively high incidence of other problems including pain and nerve compression syndromes (10).
In the same study it was found that initial shortening at the fracture of more

than 20 mm had a highly significant association with non-union (P<0.001) and an unsatisfactory result. The authors recommend open reduction and internal fixation of severely displaced fractures of the middle third of the clavicle in adult patients(10).
Locking compression plates introduce the possibility for adequate and stable fixation of fragments with less regard to bone quality than traditional plates. Another advantage is the reduced impairment of periosteal blood supply due to the limited plate-bone contact. One of the most important features of the operative treatment is early and active mobilization of the shoulder. In the first two weeks pendulum exercises is started and more active exercise is initiated between two and four weeks postoperatively. After six weeks initial strengthening is started. The same method is followed for the standard non-operative treatment.

Study objective

Results of recent trials suggest that operative treatment with locking plate fixation results in better functional outcomes than non-operative treatment. Because more patients were lost to follow-up than anticipated in the main randomised trial, sample size criteria were not met. Therefore a multi-centre randomised clinical trial with sufficient power is needed to provide evidence for a favoured treatment of dislocated midshaft fractures of the clavicle. In this trial we will compare the locking compression plate of Acumed with the non-operative treatment with sling for dislocated midshaft fractures of the clavicle, analysing clinical results, complications, functional outcome and quality of life.

Study design

This study will be a randomised, multi-centre trial that compares treatment of fully displaced midshaft clavicular fractures with either non-operative treatment or locking compression plate fixation. Approximately 350 patients with clavicular fracture types 2B1 or 2B2 classified according to Robinson, will be included. Clinical function, radiographic consolidation, functional outcome, painscores, and quality of life will be monitored for each patient during the first postoperative year (i.e. 2 weeks, 6 weeks, 3 months and 1 year). The analysis will be performed on *an intention to treat* basis.

With a power of 80 percent and a significance of 5 percent, based on a 15 percent difference in scores between the two treatment groups, 156 patients in each of the treatment arms need to be included. After informed consent has been acquired, eligible patients will be selected and randomised in one of the two treatment arms during a period of two years or until the necessary amount of patients is reached. The follow-up period will be one year.

Intervention

nvt

Study burden and risks

nvt

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Completely displaced midshaft fracture of clavicle (Robinson class 2B1 or 2B2)
Age between 16 and 60 years
No medical contra indications to general anaesthesia
Signed informed consent

Exclusion criteria

Age less than 16 years or older than 60 years
A fracture in the proximal or distal third of the clavicle
A pathologic fracture (bony abnormalities at the side of the fracture)
An open fracture
Neurovascular injury with objective neurological findings on physical examination
An associated head injury (Glasgow Coma Scale <12)
An upper extremity fracture distal to the shoulder
A fracture seen more than 14 days after injury
Inability to give informed consent with the randomisation procedure
A medical contra-indication to surgery/ anaesthesia (such as a heart disease, kidney failure or active chemotherapy)
Inability to comply with follow-up
Prior surgery to the shoulder
Prior shoulder complaints

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2010
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31044.058.10