A biomechanical study on functional outcome after a midshaft clavicular fracture with a 3D- Electromagnetic Motion Tracking Device

Published: 10-10-2011
Last updated: 29-04-2024

Objective: The primary objective of this study is to assess the influence of clavicular shortening after fracture consolidation of a midshaft clavicular fracture, on the Active Range of Motion of the arm/shoulder. Measurements are performed with a…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON35922

Source
ToetsingOnline

Brief title
Biomechanics Clavicle Study (BMCS)

Condition

- Fractures

Synonym
clavicular fractures, collar bone fractures

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Anna Fonds (aangevraagd)

Intervention

Keyword: 3D-Electromagnetic Motion Tracking Device, biomechanics, clavicle, Range of Motion

Outcome measures

Primary outcome

• Range of Motion (RoM)

Secondary outcome

• Length of the clavicle: on a conventional X-ray and measured with the

3D-Electromagnetic Motion Tracking Device.

• DASH Outcome Measure

Study description

Background summary

Rationale: Fractures of the clavicle are common (2.6-10% of all fractures). Until recently, (dislocated) midshaft clavicular fractures are considered to heal with a good prognosis, with few residual symptoms and a low non-union rate. More recent studies suggest that the percentage of non-union or mal-union after a dislocated midshaft clavicular fracture is higher than previously presumed. The influence of different degrees of shortening of the clavicle on scapular rotation is still unknown. Cadaveric and in vivo studies have revealed that more than twenty millimetres shortening may cause functional complaints. However, none of these findings have been objectified by use of Electromagnetic Motion Tracking devices.

Study objective

Objective: The primary objective of this study is to assess the influence of clavicular shortening after fracture consolidation of a midshaft clavicular fracture, on the Active Range of Motion of the arm/shoulder. Measurements are performed with a 3D-Electromagnetic Motion Tracking Device at one and five years after the fracture. Secondly, length measurement of the clavicle with the 3D-Electromagnetic Motion Tracking Device is compared to the 2-D X-ray, to

validate accuracy of length measurement with the conventional X-ray.

Study design

Study design: A multiple case series.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Selected patients will participate on a voluntary base. An X-ray of both shoulders is taken for length measurements of the clavicles, involving a negligible extra radiation dose. A questionnaire (DASH-score) on the function of the arm will be filled out. Force of both arms will be measured with a handheld dynamometer (MicroFET2). The patients will have to perform movements with both arms, attached to sensors, which will be recorded with the 3D-Electromagnetic Motion Tracking Device. The study participants will not gain any personal benefit from this project. The study may be of value for future patients with a dislocated and shortened midshaft clavicular fracture however, because in the study results may support decision making between available treatment options.

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

• A (dislocated) midshaft clavicular fracture 1 or 5 years ago.
• Age at time of fracture between 18 and 60 years.
• Clavicular shortening of respectively, <10 mm, 10 - 20 mm and >20 mm.
• Willingness to undergo functional tests with both arms.

Exclusion criteria

• Current or previous fracture in the proximal or distal third of the clavicle, or acromio-clavicular injury.
• Prior surgery to the shoulder or prior shoulder complaints before fracture.
• Neurovascular injury with objectified neurological findings after fracture or developed due to other illnesses.
• Pathologic fracture.
• New fractures of ipsilateral or contralateral shoulders/arm that could influence the Active Range of Motion.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2011

Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	31-01-2012
Application type:	Amendment
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	NL37126.058.11

Study results

Date completed:	30-04-2012
Actual enrolment:	33