Biomechanics Clavicle Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29429

Source
Nationaal Trial Register

Brief title
BMCS

Health condition

clavicle, shortening, functional outcome, 3D-Electromagnetic Motion Tracking Device,

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

To assess the influence of clavicular shortening after fracture consolidatin of a midshaft clavicular fracture, on the Active Range of Motion of the shoulder, with help of a 3D-Electromagnetic Motion Tracking Device (Flock of Birds) after one and five years post-fracture.

Secondary outcome

The secondary objective will be to compare the clavicular length as measured on a conventional X-ray as usual care and estimated with the 3D-Electromagnetic Motion Tracking Device on the basis of the bony landmarks. Furthermore,force measurements of both arms will be accomplished with use of MicroFETs, a handheld dynamometer. Each participants is asked to fill out a questionnaire related to the function of arm, shoulder and Hand (Disabilities of Arm, Shoulder and Hand-Outcome Measure (DASH)).

Study description

Background summary

N/A

Study objective

From the literature it i likely that shortening of the clavicule >15mm leads to impairment of the shoulder function (especially regarding abduction). This association has not been scientifically proven, howeer, partially due to the fact that methods for a precise measurement of functional impairment of the shoulder are lacking. In this pilot study we want to study whether a new technique, 3D-Electromagnetic Motion Tracking Device (Flock of Birds), can provide more insight into this association. We assume that at most 10% of the patients with clavicular shortening <15 mm experience impairment in abduction. On anatomical grounds we expect that this percentage is at least 50% in the patients with a clavicular shortening> 15 mm.

Study design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. A (dislocated) midshaft clavicular fracture 1 or 5 years ago;

2. Age when fracture occured above 18 and below 60 years;

3. Clavicular shortening of respectively, <10mm, 10-20mm and >20 mm.

Exclusion criteria

1. Current or previous fracture in the proximal or distal third of the clavicule, or acromio-clavicular injury;

2. Prior surgery to the shoulder or prior shoulder complaints before fracture;

3. Neurovascular injury with objective neurological findings after fracture or developed due to other illnesses;

4. Pathologic fracture;

5. New fractures of ipsilateral or contralateral shoulders/arm that could influence the active Range of Motion.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-11-2011
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-11-2011
Application type:	First submission

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
NTR-new	NL3019
NTR-old	NTR3167
Other	METC LUMC : P11.101
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A