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Correlation of the degree of clavicle shortening after non-surgical treatment of midshaft fractures with upper limb function

Submission date
16/04/2014

Recruitment status
No longer recruiting

Registration date
12/05/2014

Overall study status
Completed

Last Edited
05/02/2016

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fractures of the clavicle (broken collarbone) are very common. They represent approximately 2.6% of all skeletal injuries (fracture of the middle third of the clavicle responsible for 80% to 85% of all clavicle fractures). Very often this type of fracture is associated with some deviation caused by muscle insertions. Nonsurgical treatment of clavicle fractures with a figure-of-eight bandage or sling has been used for years with excellent results and low complication rates. However, some recent studies have questioned these results especially in cases of fracture with some bone displacement and shortening. Shortening of the clavicle is linked to decreased strength and range of motion. Some studies have demonstrated a relationship between shortening and loss of strength and worse functional outcomes and recommend surgical treatment in case where shortening is greater than 2 cms. Other studies report good functional outcome and low complication rates in patients that have undergone conservative treatment (figure-of-eight bandage or sling) even when the clavicle is shortened.
It is not clear whether clavicle shortening affects upper limb function. The aim of this study is to assess the relationship between shortening of the clavicle after conservative treatment with figure-of-eight bandage and upper limb function by observing a number of patients.

Who can participate?
Patients aged 18 and over, with a fracture of the middle third of the clavicle.

What does the study involve?
We looked at 59 patients with clavicle fractures (recruited sequentially) from the Discipline of Hand and Upper Limb Surgery at São Paulo Federal University (UNIFESP). All patients were treated with a non-surgical standard care figure-of-eight bandage for a minimum of six weeks until clinical and radiological healing of the fracture was observed. In the first evaluation, the length of both clavicles was measured on a single anteroposterior radiograph. The degree of shortening was calculated as the difference between the lengths of the two clavicles. During treatment with a figure-of-eight bandage, the function of the affected upper limb was released as tolerated. Each patient underwent rehabilitation from the sixth week onward, and the rehabilitation was similar to that for any patient undergoing physiotherapeutic rehabilitation,

with exercises to increase range of motion and passive, active, and progressive strength. Participants answered 30 questions concerning the level of difficulty in completing everyday tasks, and pain during and after the treatment.

What are the possible benefits and risks of participating?
All patients receive standard care. There is no benefit in participating. Risks are related to the treatment and the type of fracture such as non-union (fracture area has not healed), malunion (fracture heals out of position it was set) in and cosmetic deformity in the shoulder by the consolidation.

Where is the study run from?
Discipline of Hand and Upper Limb Surgery at São Paulo Federal University (UNIFESP).

When is the study starting and how long is it expected to run for?
January 2010 to June 2012

Who is funding the study?
UNIFESP (São Paulo Federal University), Brazil

Who is the main contact?
Dr Gustavo Santiago de Lima Figueiredo

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Correlation of the degree of clavicle shortening after non-surgical treatment of midshaft fractures with upper limb function: a prospective cohort single-centre study

Study objectives
We developed this study to assess the relationship between shortening of the clavicle after conservative treatment with figure-of-eight bandage and upper limb function, hypothesising that there is no relationship between shortening and functional deficit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CEP UNIFESP - Plataforma Brasil (Center for Ethics in Research of the Federal University of São Paulo - Brazil platform), 08/02/2013, approval number 192248, protocol number 11376613.2.0000.5505.

Study design
Prospective cohort single-centre study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Clavicle fracture

Interventions
At the time of diagnosis all patients were treated with a non-surgically standard care figure-of-eight bandage (a type of immobilization to this kind of fracture), for a minimum of 6 weeks until clinical and radiological healing of the fracture was observed. During treatment with a figure-of-eight bandage, the function of the affected upper limb was released as tolerated. Each patient underwent rehabilitation from the sixth week onward, and the rehabilitation was similar for all with physiotherapeutic rehabilitation, starting with exercises to increase range of motion and passive, active and progressive strength gain.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
The primary clinical outcome was measured using the Disability of Arm, Hand and Shoulder (DASH) score revalidated for Portuguese language, consisting of 30 questions concerning the level of difficulty in completing everyday tasks, and the visual analogue scale (VAS), score (0 = no pain, 10 = unbearable pain), both applied in the 6 weeks and 1 year consultations, and compared to the clavicle shortening in the first evaluation (the length of both clavicles was measured on a single anteroposterior radiograph from the centre of the sternoclavicular joint to the centre of the acromioclavicular joint; the degree of shortening was calculated as the difference between the lengths of the two clavicles)

Secondary outcome measures
As secondary outcomes we examined the association of the objective variables age, sex (male /female), and affected limb (right/left) with the dichotomous, subjective variables of occupation, cause of trauma (high/low energy), aesthetic satisfaction (satisfied/not satisfied), and occurrence of complications (type of complication and frequency)

Overall study start date
20/01/2010

Completion date
01/05/2012

Eligibility

Key inclusion criteria
Patients aged 18 and older diagnosed with a fracture of the middle third of the clavicle

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
65

Key exclusion criteria
1. Neurological and vascular deficits
2. Open fractures
3. Associated fracture in the upper limb
4. Bilateral fractures
5. Clavicle fractures with bone contact

6. Passage of more than 14 days since fracture
7. Previous surgery
8. Chronic disease in the affected limb

Date of first enrolment
20/01/2010

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
Brazil

Study participating centre
Avenida Doutor Altino Arantes n. 895
São Paulo
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04042-034

Sponsor information

Organisation
São Paulo Federal University (Brazil)

Sponsor details
Rua Borges Lagoa n. 778
São Paulo
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04042-034

Sponsor type
University/education

Website
https://www.unifesp.br/

ROR
https://ror.org/02k5swt12

Funder(s)

Funder type
University/education

Funder Name
São Paulo Federal University (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/06/2015		Yes	No