

Deltoid splitting approach for surgical osteosynthesis in displaced proximal humerus fractures

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| Submission date 14/07/2017 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/07/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 17/08/2018 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The humerus is the long bone that connects the shoulder to the elbow. When it is fractured, it is usually fixed using a less invasive surgical procedure called deltoid muscle splitting. However, this procedure has concerns about its effectiveness in aging people and complex fractures. The efficacy of the using a 'locking plate' needs to be evaluated using the anterolateral (located in front and to one side) deltoid splitting approach and specially examine the effect depending on the patient's age, gender and fracture type. The aim of this study is to evaluate the efficacy of a humeral locking plate using the anterolateral deltoid splitting approach and to specifically examine the effect of patient age, gender and fracture pattern on surgical outcomes.

Who can participate?

Adults aged 36 to 77 years old who have humerus fractures.

What does the study involve?

This is a case review study of proximal humerus fractures that are treated surgically with the Locking compression plate from 2009 to 2011. The researchers gathered data about the surgery, reviewed record and radiographs, as well as gender, age, fracture type and their follow up. This is done to assess the surgical outcomes to this procedure.

What are the possible benefits and risks of participating?

There are no benefits or risks with participating.

Where is the study run from?

Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?

December 2008 to June 2017

Who is funding the study?

Chang Gung Medical Foundation (Taiwan)

Who is the main contact?

Dr Alvin Chao-Yu Chen
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Contact information

Type(s)

Scientific

Contact name

Dr Alvin Chao-Yu Chen

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

No. 201700826B0

Study information

Scientific Title

Influence of age, gender, and radiographic features on the deltoid splitting approach for surgical osteosynthesis in displaced proximal humerus fractures

Study objectives

Examining the influence of the surgical approach for management of displaced proximal humerus fractures and to specifically examine the impact of patient age and fracture pattern on the outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Chang Gung Memorial Hospital, 07/06/2017, ref: No. 201700826B0

Study design

Observational case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

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

Examining the influence of patient demographics on the influence of surgical approach in displaced proximal humerus fractures

Interventions

This study retrospectively evaluated cases of unilateral proximal humerus fractures that were treated surgically with the Locking Compression Plate (LCP), as per the Neer classification criteria at our institute between 2009 and 2011.

Institutional review board approval was obtained to perform a review of patients' records and radiographs; informed consent was obtained from 132 patients with displaced proximal humerus fractures. All these cases of proximal humerus fractures either met the indications for operative treatment outlined by Neer or were considered unstable when tested for passive motion with an image intensifier.

Those with pathological fractures, head split fractures, open fractures, fractures with primary neurovascular damage, multiple fractures, and cases lost to follow-up are excluded from the study. Forty-two patients, who underwent anterolateral deltoid splitting surgery, are selected for a retrospective matched pairs analysis according to their age (younger than 60 years vs. older than 60 years), gender, and fracture type with a minimum follow-up of 24 months.

Intervention Type

Procedure/Surgery

Primary outcome measure

Fracture healing is measured using the data from the cases.

Secondary outcome measures

1. Functional outcomes are measured using the data from the cases
2. Radio is measured using the data from the cases

Overall study start date

01/12/2008

Completion date

30/06/2017

Eligibility

Key inclusion criteria

1. Displaced proximal humerus fractures. All these cases of proximal humerus fractures either met the indications for operative treatment outlined by Neer or were considered unstable when tested for passive motion with an image intensifier.
2. Aged 36 to 77 years old

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Patients with pathological fractures
2. Head split fractures
3. Open fractures
4. Fractures with primary neurovascular damage
5. Multiple fractures
6. Cases lost to follow-up were excluded from the study

Date of first enrolment

01/01/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Taiwan

Study participating centre
Chang Gung Memorial Hospital
5th
Fu-Hsin Street
Kweishan District
Taoyuan
Taiwan
333

Sponsor information

Organisation
Chang Gung Memorial Hospital

Sponsor details
5th
Fu-Hsin Street
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+886 3281200 3882
alvinchen@cgmh.org.tw

Sponsor type
Hospital/treatment centre

Website
www.cgmh.org.tw

ROR
<https://ror.org/02verss31>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Medical Foundation

Results and Publications

Publication and dissemination plan

Plans to publish our reports in peer-reviewed journals this year.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Alvin Chao-Yu Chen, MD at alvinchen@cgmh.org.tw

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/12/2017 | | Yes | No |