ISRCTN75494532 https://doi.org/10.1186/ISRCTN75494532

Deltoid splitting approach for surgical osteosynthesis in displaced proximal humerus fractures

Submission date
14/07/2017

Recruitment status
No longer recruiting

Registration date
26/07/2017

Overall study status
Completed

Last Edited
17/08/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
alvinchen@cgmh.org.tw

Contact information

Type(s)
Scientific

Contact name
Dr Alvin Chao-Yu Chen

ORCID ID
http://orcid.org/0000-0003-0111-490X

Contact details
Chang Gung Memorial Hospital
5th Fu-Hsin Street
Kweishan District
Taoyuan
Taiwan
333
+886 3281200 3882
alvinchen@cgmh.org.tw

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
Keishan District
Taoyuan
Taiwan
333
+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