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Minimally invasive plating of fractures of the upper aspect of the upper arm and its implication to muscle insertions and shoulder function

Submission date
25/05/2023

Recruitment status
No longer recruiting

Registration date
26/05/2023

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
A bridging plate can be surgically introduced to stabilise a humerus (upper arm bone) fracture. However, the deltoid muscle insertion may be penetrated when the plate is advanced downward to the bone to its final position. The aim of this study is to investigate whether this manoeuvre causes functional deficits and alterations of the deltoid muscle itself.

Who can participate?
Patients aged over 18 years undergoing surgery for a humerus fracture at Cantonal Hospital Winterthur

What does the study involve?
Participants undergo further tests at least 1 year after surgery, including functional testing (muscle strength) and MRI scans of both the affected and uninjured shoulder and upper arm. Patient-related outcome measurements are also obtained.

What are the possible benefits and risks of participating?
The study does not alter the outcome of the participants as it does not influence their treatment in any way. Besides the usual risks of MRI scans, no risks are involved.

Where is the study run from?
Cantonal Hospital Winterthur (Switzerland)

When is the study starting and how long is it expected to run for?
February 2021 to December 2021

Who is funding the study?
Cantonal Hospital Winterthur (Switzerland)

Who is the main contact?
Prof. Dr med. Christoph Meier, christoph.meier@ksw.ch

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BASEC Nr.: 2021-00811

Study information

Scientific Title
Minimally invasive lateral plating for diaphyseal fractures with extension into the proximal humerus and its implications for the deltoid muscle and its distal insertion: functional analysis and MR imaging

Study objectives
In minimally invasive lateral plate osteosynthesis of the humerus (MILPOH) the plate is introduced through a deltoid split proximally and advanced through the central portion of the deltoid insertion and between bone and brachial muscle to the distal aspect of the humerus. The fracture is then indirectly reduced and bridged by the plate. It was the aim of this study to evaluate the implications of this maneuver on the integrity of the deltoid insertion and muscle function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/11/2022, Kantonale Ethikkommission Kanton Zürich (Stampfenbachstrasse, 121 Postfach, 8090 Zurich, Switzerland; +41 (0)43 259 79 70; admin.kek@kek.zh.ch), ref: 2021-00811

Study design
Observational case series

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Potential damage to the deltoid muscle insertion caused by blunt advancement of a minimally invasive plate along the lateral aspect of the humerus to bridge a fracture

Interventions

The charts of all patients with MILPOH for diaphyseal fractures of the humerus with extension into the proximal metaphysis, operated at our institution between 03/2017 and 08/2020 were reviewed. Only patients with normal function of the affected extremity and the contralateral side before trauma were eligible for this study. Subjects with previous shoulder or upper arm surgery on either side were excluded. The remaining candidates were contacted and informed about the study. Only volunteers >18 years of age agreeing to undergo functional testing and MRI imaging of both shoulders and upper arm at least 12 months following surgery were included.

At least 1 year after surgery, patient-reported outcome measures (PROMs), functional results and MR imaging of both shoulders down to the deltoid tuberosity were obtained and compared to the contralateral uninjured side.

Intervention Type
Procedure/Surgery

Primary outcome(s)
All measured at least 1 year postoperatively, time range 12-48 months:
1. Abduction and flexion strength of the deltoid muscle at 30°, 60°, 90° of the affected and uninjured side, measured using an electronic isometric strength dynamometer (IsoForceControl EVO2; Medical Device Solutions AG, Oberburg, Switzerland).
2. Imaging of the deltoid muscle and its distal insertion performed by MR imaging (1.5T MRI scanner [Ingenia, Philips Healthcare, Best, the Netherlands])

Key secondary outcome(s))
All measured at least 1 year postoperatively, time range 12-48 months:
1. Overall shoulder function measured using the Constant-Murley Score (CMS) and gender- and age-adapted CMS
2. Shoulder pain and function measured using the Oxford Shoulder Score (OSS)
3. Upper-extremity disability and symptoms measured using the Disabilities for the Arm, Shoulder, and Hand (DASH) outcome measure
4. Patient's self-rated health measured using EQ-5D-5L visual analogue score (VAS)
5. Mobility, self-care, usual activities, pain and anxiety/depression measured using EQ-5D-5L

Completion date
10/12/2021

Eligibility

Key inclusion criteria
1. Patients with MILPOH for diaphyseal fractures of the humerus with extension into the proximal metaphysis, operated on at Cantonal Hospital Winterthur between 03/2017 and 08/2020
2. Patients with normal function of the affected extremity and the contralateral side before trauma
3. >18 years of age

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
6

Key exclusion criteria
1. Previous humerus fracture to either side
2. Impaired shoulder function prior to trauma
3. Claustrophobia (not suitable for MRI)
4. Previous shoulder or upper arm surgery on either side

Date of first enrolment
01/03/2017

Date of final enrolment
30/08/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
Cantonal Hospital Winterthur
Brauerstrasse 15
Winterthur
Switzerland
8302

Sponsor information

Organisation
Kantonsspital Winterthur

ROR
https://ror.org/014gb2s11

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cantonal Hospital Winterthur

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Christoph Meier (christoph.meier@ksw.ch). Complete datasets will be available upon publication of the study. Informed consent was obtained from all patients. The authors had access to information that could identify individual participants during or after data collection. However, the two senior radiologists who analysed the MR images had no access to any clinical data concerning the shoulder function of the participating patients.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/11/2023	08/11/2023	Yes	No