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Outcomes of repeated surgery at the thumb base joint

Submission date
17/05/2019

Recruitment status
No longer recruiting

Registration date
28/05/2019

Overall study status
Completed

Last Edited
16/11/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Surgery for osteoarthritis of the thumb joint, such as trapeziectomy (removal of a small bone in the wrist at the base of the thumb), leads to good results and high patient satisfaction. However, in some cases, repeated surgery is required due to persistent pain and restricted hand function. We aim to study the outcomes of this repeated surgery and to analyse the reasons for this surgery.

Who can participate?
All patients, who had a revision surgery at our center in the last 10 years will be invited for a follow-up consultation consisting of a clinical examination, radiographs and a questionnaire.

What does the study involve?
All patients who had a revision surgery of the CMC I joint between April 2009 and at least one year prior to examination will be eligible for participation and will be invited to a follow-up consultation. This consultation consists of a clinical examination, radiographs and a patient questionnaire.

What are the possible benefits and risks of participating?
Benefits: There is no compensation for participation. The increased scientific knowledge generated by this project will be primarily a gain for other patients seeking treatment for the same condition and will assist the surgeon in the decision-making process prior to surgery_
Risks: As patients will be invited for a follow-up examination, there is no intervention. The clinical examination and the completion of a patient subjective outcome questionnaire represent no more than minimum risk for project participants. At the follow-up examination, three radiographs of the thumb will be taken which are associated with low level of radiation of about 0.001 mSv (comparable to normal background radiation from less than a day according to www.webmd.com).

Where is the study run from?
Schulthess Klinik, Zurich, Switzerland.

When is the study starting and how long is it expected to run for?
June 2019 to October 2019

Who is funding the study?
Schulthess Klinik, Zurich, Switzerland.

Who is the main contact?
Dr Miriam Marks,
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
OE-0112

Study information

Scientific Title
Outcomes of revision of thumb carpometacarpal joint (CMC I) arthroplasty

Study objectives
Patients after CMC I revision surgery are in an acceptable pain state shown by a NRS score of ≤ 2.5 during daily activities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/05/2019, Kantonale Ethikkommission Zürich (Cantonal ethics committee Zurich, Stampfenbachstrasse 121, 8090, Zürich, Switzerland; +41 (0) 43 259 79 70; Info.KEK@kek.zh.ch), ref: 2019-00569

Study design
Ambidirectional monocenter research project consisting of a retrospective chart review and a prospective case series

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the CMC I joint

Interventions
This study solely consists of one consultation with a duration of approx. 45 min. After the patient provided written informed consent, the patient will undergo a clinical examination including radiographs. The clinical examination includes measures of range of motion (ROM), grip and pinch strength and radiographs. Afterwards, the patient will complete a questionnaire on a tablet PC, which data will be stored in a REDCap database. All data from the clinical measures will be entered directly into the REDCap project database by the doctor.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Level of pain. If patients are in a Patient Acceptable Symptom State (PASS) regarding pain during activities measured on a Numeric Rating Scale (NRS; 0 = no pain, 10 = worst pain). The PASS is defined as an NRS score of ≤ 2.5.

Key secondary outcome(s))
1. Range of Motion measured using flexion and extension of the MCP and thumb Interphalangeal (IP) joint will be measured with a goniometer. The evaluation of active thumb opposition is based on the Kapandji index, ranging from 1 to 1026. Patients try to touch their fingers with the tip of the thumb. The score is 1 when patients are able to touch only the lateral side of the index finger and 10 when they can reach the volar crease of the hand.
2. Grip strength measured using a JAMAR dynamometer.
3. Key pinch measured using a pinch gauge.
4. Radiographs. If radiographs of before primary surgery are available, OA severity will be graded from stage I (normal articular contours with joint widening due to ligament laxity) to stage IV (complete thumb CMC joint deterioration and narrowed, sclerotic scaphotrapezial joint) based on the Eaton classification. At follow-up, three radiographic views of the affected hand (anterior-posterior, lateral and oblique) to assess the trapezial space ratio will be taken and the trapezial space ratio will be calculated.
5. Hand function measured using the Brief Michigan Hand Outcomes Questionnaire (MHQ).
6. Satisfaction measured using two additional questions about satisfaction in the consultation.
7. Sociodemographic and disease-related data which will be extracted from the medical records:

Age, gender, diagnosis, date and type of primary and revision surgery/surgeries, indication for primary and revision surgery/surgeries, affected side, date of diagnosis, complications after primary and revision surgery/surgeries, other surgeries performed in the same session (e.g. carpal tunnel release), clinical data (range of motion, strength).
8. Adverse events that had been occurred during or after primary and revision surgery will be extracted out of the medical records and patients will be asked about additional events not documented in the medical records.

Completion date
13/11/2019

Eligibility

Key inclusion criteria
1. Patient with any type of revision surgery at the CMC I join
2. Revision surgery between 1 and 10 years before the follow-up examination
3. Primary surgery consisted of any type of resection arthroplasty or implant arthroplasty
4. Informed consent as documented by signature

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
27

Key exclusion criteria
1. Major surgery at another joint at the same hand (e.g. PIP arthroplasty, DIP arthrodesis) less than 6 months before the examination
2. Legal incompetence
3. Cannot read or write German language to complete the questionnaires

Date of first enrolment
01/06/2019

Date of final enrolment
13/11/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
Schulthess Klinik
Lengghalde 2
Zurich
Switzerland
8008

Sponsor information

Organisation
Schulthess Klinik

ROR
https://ror.org/01xm3qq33

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Schulthess Klinik

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/10/2021	16/11/2021	Yes	No