ISRCTN10458465 https://doi.org/10.1186/ISRCTN10458465

How cost-effective is a Touch® prosthesis for the treatment of thumb osteoarthritis compared to the removal of the damaged bone?

Submission date
10/12/2020

Recruitment status
No longer recruiting

Registration date
12/01/2021

Overall study status
Completed

Last Edited
16/02/2026

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Thumb osteoarthritis is the most common form of arthritis that affects the hands and results from the breakdown of joint cartilage and the underlying bone.
In recent years, economic evaluations have become more important because of the growing emphasis on cost containment. The evaluation of both costs and benefits allows better consideration of the value of a particular intervention. In cost-utility studies, benefits are measured in a way that health states which are less preferable than full health can be given numerical values too. These year equivalents are also known as quality-adjusted life-years (QALYs). Benefits can also be measured by dividing the difference in costs between two interventions by the difference in their effect (expressed in QALYs). This calculation is called an incremental cost-effectiveness ratio (ICER).
There is no explicit threshold defining a cost-effective intervention. Thresholds have been suggested being below 50,000 USD – 150,000 USD for high-income countries. Besides direct healthcare expenses, the costs associated with loss of productivity at work also lead to substantial economic consequences for the patient, the employer, and society. Studies have shown that costs associated with loss of productivity are much higher than the direct medical costs.
This is where the researchers of this study see a great potential for the Touch® implant. A first analysis of their data showed that in average patients return to work 20 days after surgery. In contrast, data from a previous study investigating loss of productivity in patients undergoing the formerly most common operation showed a considerably longer absence from work of 54 days. During this standard operation, the damaged/arthritic bone was removed, and a piece of a tendon was used as a filler material (resection-suspension-interposition [RSI] arthroplasty). The difference in the return to work is also confirmed by other studies that even showed considerably longer absences from work after surgery on the thumb joint, with the time of sick leave also being shorter for patients with a prosthesis compared to the patients who underwent the standard procedure without an implant (RSI arthroplasty; 4.7 vs. 8.9 months). Also, the clinical and patient-reported outcomes in the short-term seem to be
favorable for patients with a Touch® implant, once again emphasising the potential of this specific implant. Lastly, there is a risk that health insurances will not pay for the Touch® implant

because it is more expensive. However, if other associated costs, such as loss of productivity, are significantly lower with the Touch® implant, there will be strong arguments against such decisions.

Who can participate?
Patients with thumb osteoarthritis who will be implanted with a Touch® prosthesis and who are working in Switzerland.

What does the study involve?
The study duration for a participant is about 1 year. Surgery with the Touch® prosthesis will not be affected by the study and will be performed in the same way as would have been the case without the study. Routine follow-up examinations at the surgeon's office take place at the Schulthess Klinik after 6 weeks, 3 months and 1 year. This means that participants do not have to come specifically because of the study. At the pre-examination and at each follow-up examination, as well as 6 months after surgery, patients will be asked to complete an additional study-specific questionnaire electronically (upon invitation by e-mail) or on paper. This takes about 30 minutes.

What are the possible benefits and risks of participating?
Participants receive no direct benefit from participating in this study as it does not affect surgery or follow-up. By participating, the participants help future patients. The cost-benefit analysis is of great importance for the Schulthess Klinik, the Swiss health system and the general population. Participation can lead to an improvement in the cost-effective treatment of other patients with thumb arthrosis. Participation in this health economic study is not expected to involve any study-specific risks for the participants.

Where is the study run from?
Schulthess Klinik (Switzerland)

When is the study starting and how long is it expected to run for?
October 2019 to July 2024

Who is funding the study?
1. KeriMedical (Switzerland)
2. Schulthess Klinik (Switzerland)

Who is the main contact?
1. Dr Daniel Herren (for medical questions)
2. Dr Miriam Marks (for study-specific questions)
Miriam.Marks@kws.ch

Contact information

Type(s)
Scientific

Contact name
Dr Miriam Marks

ORCID ID
https://orcid.org/0000-0002-0623-2465

Contact details
Lengghalde 6
Zurich
Switzerland
8008
+41 (0)385 75 81
Miriam.Marks@kws.ch

Type(s)
Scientific

Contact name
Mr Michael Oyewale

Contact details
Lengghalde 6
Zurich
Switzerland
8008
+41 (0)385 79 83
michael.oyewale@kws.ch

Additional identifiers

Protocol serial number
OE-0137

Study information

Scientific Title
Cost-utility analysis of Touch® Dual mobility trapeziometacarpal prosthesis versus resection-suspension-interposition arthroplasty

Acronym
CUA Touch

Study objectives
H0: Null hypothesis
The thumb carpometacarpal (CMC I) arthroplasty using the Touch® implant is not more cost-effective compared to the resection-suspension-interposition (RSI) arthroplasty in terms of an acceptable incremental cost-effectiveness ratio (ICER).

H1: Alternative hypothesis
The thumb carpometacarpal (CMC I) arthroplasty using the Touch® implant is more cost-effective than the resection-suspension-interposition (RSI) arthroplasty in terms of an acceptable incremental cost-effectiveness ratio (ICER).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/02/2021, Kantonale Ethikkommission Zürich (Stampfenbachstrasse 121, 8090 Zürich, Switzerland; +41 (0)43 259 79 70; admin.kek@kek.zh.ch), ref: 2020-02982

Primary study design
Observational

Study design
Prospective observational single-center clinical cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with a carpometacarpal (CMC) I arthroplasty vs a resection-suspension-interposition (RSI) arthroplasty

Interventions
Questionnaires and medical costs will be analysed to evaluate the cost-utility of the Touch implant in patients compared to a RSI arthroplasty. As comparison group, the researchers will use outcome data of a previous cohort of patients who had a RSI arthroplasty and were working (n=42), (KEK-ZH Nr. 2013-0381). This outcome data is already available and will not have to be collected. The cost data will be derived from patients undergoing a RSI arthroplasty during the timeframe of this study and retrospectively matched and assigned to the control group.
The prosthesis will be implanted according to the instruction manual and the technique under investigation is a well-recognized and accepted surgical procedure using a CE-marked implant that can be classified as safe, if correctly applied. This study will only observe surgical procedures that would have been done in the same manner independently from the present study. The study neither interferes with the treatment nor with the usual clinical follow-up procedures. The study will evaluate the radiological, subjective and objective outcome over a 1-year follow-up period. Questionnaires will be sent to the patients at baseline and 6 weeks, 3 months, 6 months and 1 year after surgery. The patients will undergo clinical examinations at the same timepoints except for the 6-month follow-up appointment at which they will only fill out the questionnaires.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Touch® Dual mobility trapeziometacarpal prosthesis (KeriMedical, Geneva, Switzerland)

Primary outcome(s)
The cost-utility of the Touch® compared to the RSI arthroplasty in terms of an acceptable incremental cost-effectiveness ratio (ICER):
1. Costs will comprise of direct medical costs that have accrued due to the operation until 1 year after surgery, taken from the clinic's billing system
2. Indirect costs associated with loss of productivity measured with the Work Productivity and Activity Impairment Questionnaire (WPAI) at baseline, 6 weeks, 3 months, 6 months and 1 year

after surgery
3. Utilities (quality-adjusted life years) will be derived from the EuroQol EQ-5D five-level (EQ-5D-5L) questionnaire at baseline, 6 weeks, 3 months, 6 months and 1 year after surgery

Key secondary outcome(s)
Measured at baseline, 6 weeks, 3 months and 1 year after surgery:
1. Range of motion (flexion-extension of the MCP and thumb interphalangeal joint) measured using a goniometer
2. Thumb opposition measured using the Kapandji scoring system
2. Grip strength measured with a JAMAR dynamometer and key pinch strength measured with a pinch gauge
3. Hand function measured using the Brief Michigan Hand Outcomes Questionnaire (brief MHQ)
4. Pain scores at rest and during daily activities measured using a Numeric Rating Scale (NRS, o = no pain, 10 = worst pain)
5. Satisfaction measured using a questionnaire (e.g. How is your operated thumb in general compared to before the surgery?)
6. Physical work demands measured using a questionnaire (e.g. Do you have to use your hands a lot during your regular work?)

Completion date
22/07/2024

Eligibility

Key inclusion criteria
1. Informed consent as documented by signature
2. Patient is diagnosed with primary osteoarthritis (OA) at the thumb carpometacarpal (CMC I) joint and will be operated with a Touch® prosthesis (typically on average 62.9 [±8] years old)
3. Patient is working in Switzerland and intends to continue doing so for at least the duration of their study participation (1 year, i.e. no retirement, sabbatical)
4. Comparison group: Patients who received a resection arthroplasty in a previous study (KEK-ZH Nr. 2013-0381) and had an occupation at that time

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
80

Key exclusion criteria

1. Patient with any type of revision surgery at the CMC I joint
2. Patient with rheumatoid arthritis
3. Patient has an additional surgery in the same session (except for simultaneous trigger finger release at the thumb)
4. Non-working patients
5. Legal incompetence
6. German or English language barrier which prevents the participant from completing the questionnaires

Date of first enrolment
01/03/2021

Date of final enrolment
04/08/2023

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
Industry

Funder Name

Investigator initiated and funded

Funder Name
KeriMedical

Funder Name
Schulthess Klinik

Results and Publications

Individual participant data (IPD) sharing plan
Although able to do so, there is no intention as of yet to share the individual patient data available with other researchers outside the current study protocol. However, all requests would be considered. Data exported from the database for the analyses are saved into a dedicated server only accessible to designated researchers. Data security and confidentiality rules of the Schulthess Klinik applies to all involved personnel. The IT department of the Schulthess Klinik is responsible and performs back-up procedures of all collected and transformed data according to internal rules.
Type of data: Individual participant data that underlie the results, after deidentification (text, tables, figures, and appendices).
When will data be available: Immediately after publication and ending 36 months following article publication.
Share with whom: With investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.
For what: To achieve the aims in the approved proposal.
How it will be made available: Proposals should be directed to marm@kws.ch.
To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/01/2026	16/02/2026	Yes	No
Protocol file	version v4.0	12/02/2021	16/03/2021	No	No