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Reconstruction of finger pulp defects using the distally based cross-digital flap harvested from the dorsum of the thumb

Submission date
09/09/2018

Recruitment status
No longer recruiting

Registration date
19/09/2018

Overall study status
Completed

Last Edited
15/10/2018

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
The finger pulp (flesh) plays an important role in tactile (touch) sensation. Restoring sensation to the finger pulp is essential for daily activities. Currently, sensory reconstruction of finger pulp defects remains a challenging task for plastic and hand surgeons. Some random-pattern skin flaps, such as thenar flap, conventional cross-finger flap, and abdominal flap, have been used for finger pulp reconstruction. Those flaps are easy to perform, but the flap transfer is not innervated (no nerve supply) and sensory recovery of the finger pulp is poor. The dorsal island pedicle flaps taken from the dorsum (back) of the adjacent finger are also used for finger pulp reconstruction. However, scar formation in the donor site is the major concern. Transfer of a free flap, such as free partial toe transfer, can achieve coverage with good texture match, but the procedures are cumbersome to perform, require small vessel anastomosis (cross-connection), and carry the risk of anastomosis failure. The aim of this study is to assess the use of a new cross-digital flap harvested from the dorsum of the thumb for reconstruction of finger pulp defects.

Who can participate?
Patients with finger pulp defects and exposed tendon or bone who require thumb pulp reconstruction for sensation

What does the study involve?
The cross-digital flap with nerve repair is performed on 36 patients. The sensitivity of the flap and the donor site, the degree of scarring, and the disability of the hand are assessed at 20 months after surgery.

What are the possible benefits and risks of participating?
Possible benefits include sensory reconstruction of the finger pulp defects which result in a better finger pulp function. Possible risks included flap loss and wound infection.

Where is the study run from?
Third Hospital of Hebei Medical University (China)

When is the study starting and how long is it expected to run for?
December 2014 to September 2017

Who is funding the study?
Third Hospital of Hebei Medical University (China)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
THHMU20181548

Study information

Scientific Title
Reconstruction of finger pulp defects using the distally based cross-digital flap harvested from the dorsum of the thumb

Acronym
DBCDF

Study objectives
Reconstruction of finger pulp defects using the novel cross-digital flap harvested from the dorsum of the thumb results in 2PD less than 7 mm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of the Third Hospital of Hebei Medical University, 08/01/2015, THHMC20150364

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Reconstruction of finger pulp defects

Interventions
The cross-digital flap with nerve repair was performed on 36 thumbs in 36 patients. The flap was a distally based neurovascular pedicle flap. The sensitivity of the flap and the donor site were tested using static 2-point discrimination. Scars were assessed the degree of scarring using the Vancouver scar scale. The Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire was used to assess the subjective disability of the hand.

Intervention Type
Procedure/Surgery

Primary outcome measure
Sensitivity of the flap and the donor site tested using static 2-point discrimination at 20 months after surgery

Secondary outcome measures
Subjective disability of the hand assessed using Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire at 20 months after surgery

Overall study start date

15/12/2014

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. A finger pulp defect
2. Necessity of thumb pulp reconstruction for sensation
3. Exposed tendon or bone

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Injury to the dorsum of the thumb
2. Injury to the radial proper digital artery of the thumb or its dorsal branches

Date of first enrolment
30/01/2015

Date of final enrolment
15/07/2016

Locations

Countries of recruitment
China

Study participating centre
Third Hospital of Hebei Medical University
Ziqiang Road, Shijiazhuang, Hebei
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Sponsor information

Organisation
Third Hospital of Hebei Medical University

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Sponsor type
University/education

ROR
https://ror.org/004eknx63

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Third Hospital of Hebei Medical University

Results and Publications

Publication and dissemination plan
Planned publication in a plastic or hand surgery journal.

Intention to publish date
10/08/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		15/10/2018	15/10/2018	No	No