

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

<b>Submission date</b> 09/09/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/09/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/10/2018	<b>Condition category</b> Surgery	<input type="checkbox"/> 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?  
Dr Xu Zhang  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

Shijiazhuang

China

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## Sponsor information

**Organisation**

Third Hospital of Hebei Medical University

**ROR**

<https://ror.org/004eknx63>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Third Hospital of Hebei Medical University

## Results and Publications

**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?
<a href="#">Basic results</a>		15/10/2018	15/10/2018	No	No