Perioperative Lipofilling in Operative Treatment of Proximal Phalanx Fractures and Related Tenolysis: Improving Range of Motion

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The aim of the two separate studies is as follows: 1. To evaluate the effect of perioperative micronised lipofilling in patients with ORIF of P1 fractures on postoperative range of motion2. To evaluate the effect of perioperative micronised…

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON57006

Source
ToetsingOnline

Brief title
Lipofilling in Surgery of Proximal Phalanx Fractures and Related Tenolysis

Condition

- Tendon, ligament and cartilage disorders
- Soft tissue therapeutic procedures

Synonym
Adhesions, Stiffness

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Geen specifieke subsidie voor deze studie.

Intervention

Keyword: Fracture, Lipofilling, Surgery, Tenolysis

Outcome measures

Primary outcome

1. In case of an indication for ORIF of P1 fractures the following parameters

will be assessed:

• Preoperative

- Total active motion (TAM) of the contralateral unaffected digit.

• 6 weeks, 3 months and 6 months postoperative

- TAM of the operated digit and the contralateral unaffected digit.

2. In case of tenolysis after operative treatment of P1 fractures the following

parameters will be assessed:

• Preoperative

- TAM of the affected digit and the contralateral unaffected digit;

• 6 weeks, 3 months and 6 months postoperative

- TAM of the operated digit and the contralateral unaffected digit;

Secondary outcome

1. In case of an indication for ORIF of P1 fractures the following parameters will be assessed:

• Preoperative

- Active range of motion (AROM) and passive range of motion (PROM) of the metacarpophalangeal, proximal interphalangeal and distal interphalangeal (MCP-, PIP- and DIP) joint of the contralateral unaffected digit.

• 2 weeks, 6 weeks, 3 months and 6 months postoperative

- NRS-score of the abdominal donor site.

• 6 weeks, 3 months and 6 months postoperative

- AROM and PROM of the MCP-, PIP- and DIP-joint of the operated digit and the contralateral unaffected digit;

- MHQ-score.

• During the 6 months postoperative period

- Postoperative complications, including infection, wound-related problems, malunion/arthritis, non-union and stiffness;

- Number of secondary procedures, including tenolysis.

2. In case of tenolysis after operative treatment of P1 fractures the following

parameters will be assessed:

• Preoperative

- AROM and PROM of the MCP-, PIP- and DIP-joint of the affected digit and the contralateral unaffected digit;

- MHQ-score.

• 2 weeks, 6 weeks, 3 months and 6 months postoperative

- NRS-score of the abdominal donor site.

• 6 weeks, 3 months and 6 months postoperative

- AROM and PROM of the MCP-, PIP- and DIP-joint of the operated digit and the contralateral unaffected digit;

- MHQ-score.

• During the 6 months postoperative period

- Postoperative complications, including infection, wound-related problems and stiffness.

Study description

Background summary

Hand fractures are a common clinical problem worldwide and account for a substantial economic burden and workload for experienced hand surgeons. With regard to metacarpal and phalangeal fractures, surgery might be indicated in case of dislocation and/or instability to restore functionality through closed

or open reduction and adequate stabilization by fixation. Unfortunately, tendon adhesions after operative treatment of these hand fractures remain a common complication; especially after open reposition and internal fixation (ORIF) of proximal phalanx (P1) fractures. This results in postoperative stiffness and thus decreased digital function. In case of insufficient digital function, tenolysis of the flexor and/or extensor tendons could be considered once the fracture is consolidated and competent hand therapy for at least 3 months seems ineffective. Several studies have focused on perioperative measures to prevent tendon adhesions and related stiffness after operative treatment of hand fractures avoiding tenolysis. These prophylactic measures include for example adhesion barriers, anti-adhesion membranes and adipofascial flaps, which could possibly improve the postoperative range of motion if further research is conducted. Only one of these studies, using an adipofascial flap as a tendon-gliding system after ORIF of P1 fractures, found a significant difference regarding postoperative range of motion. Related to the use of adipose tissue, lipofilling has been proven to be a promising technique in the treatment of scars/adhesions, especially in burn wounds. Recent studies even demonstrated the role of fat grafting in hand surgery, including scar management and tenolysis. Despite these promising results, no previous research has evaluated the use of perioperative lipofilling during surgical treatment of hand fractures or related tenolysis. Therefore, it might be that lipofilling could result in an improvement of postoperative motion and prevent and/or improve tenolysis due to providing a gliding surface for tendons.

Study objective

The aim of the two separate studies is as follows:
1. To evaluate the effect of perioperative micronised lipofilling in patients with ORIF of P1 fractures on postoperative range of motion
2. To evaluate the effect of perioperative micronised lipofilling in patients with tenolysis after operative treatment of P1 fractures on postoperative range of motion

Study design

A double-blinded randomized controlled trial

Intervention

Patients will either receive 1ml of subcutaneous micronised lipofilling or 1ml subcutaneous 0,9% NaCl around the operation site at the end of the ORIF or tenolysis

Study burden and risks

1. In case of ORIF, no additional procedures are added to the usual care.

In case of perioperative lipofilling, a minimal amount of autologous fat will be manually harvested perioperatively from the subdermal fat layer of the lower abdomen using very fine harvesting cannulas under additional tumescent anesthesia. The harvested autologous fat will be processed for injection by centrifugation and emulsification. The harvested and micronized autologous fat will be injected subcutaneous at the operation site after wound closure.
With regard to the control group, autologous fat of the lower abdomen will be harvested, but only 0,9% NaCl will be injected subcutaneous at the operation site after wound closure.
In addition to the regular postoperative follow-up including competent hand therapy, patients will complete the MHQ and rate their pain using a NRS-score (0-10 scale) of the abdominal donor site.

2. In case of tenolysis, patients will preoperatively complete the MHQ in addition to the usual care. The duration of this questionnaire is estimated at 15-30 minutes.
In case of perioperative lipofilling, a minimal amount of autologous fat will be manually harvested perioperatively from the subdermal fat layer of the lower abdomen using very fine harvesting cannulas under additional tumescent anesthesia. The harvested autologous fat will be processed for injection by centrifugation and emulsification. The harvested and micronized autologous fat will be injected subcutaneous at the operation site after wound closure.
With regard to the control group, autologous fat of the lower abdomen will be harvested, but only 0,9% NaCl will be injected subcutaneous at the operation site after wound closure.
In addition to the regular postoperative follow-up including competent hand therapy, patients will complete the MHQ and rate their pain using a NRS-score (0-10 scale) of the abdominal donor site.
Lipofilling is generally considered safe; however, like any surgical intervention, minor complications can occur with a low rate. Fortunately, the complication rate with lipofilling is extremely low when compared to most open surgical methods. Moreover, the likelihood of complications decreases significantly with the surgeon*s experience.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Aged 16-65 years
• Indication for one of the following surgical procedures:
o ORIF due to a single radiologically proven P1 fracture
o Secondary tenolysis due to limited digital function after former operative treatment of a P1 fracture
• Able to read and speak Dutch
• Mentally competent

Exclusion criteria

• Aged below 16 or above 65 years
• Concomitant tendinous or neurovascular injuries
• Prior surgical interventions of the affected digit; other than operative fracture fixation in case of tenolysis
• Prior pathology or surgical interventions of the contralateral digit
• Less than 3 months of competent hand therapy in case of secondary tenolysis
• A known psychiatric condition
• A known systemic disease that will impair wound healing (e.g. diabetes mellitus, known atherosclerosis with an event that required hospitalization, collagen diseases, diseases of the skin, HIV).
• Prednisone or other immunotherapy
• Smoking

• Pregnancy or active child wish

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	130
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	10-09-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85336.028.24