

Percutaneous flexor tenotomy with toe deformity in diabetic patients.

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To demonstrate that percutaneous flexor tenotomy is an effective way to treat poorly healing ulcers in diabetic patients with hammertoes. We want to measure this effect by determining the healing time, percentage healed wounds and decrease in size...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON39421

Source

ToetsingOnline

Brief title

Percutaneous flexor tenotomy.

Condition

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

Synonym

Hamertoe. Diabetic foot wound

Research involving

Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum

Source(s) of monetary or material Support: Geen van boven! Moet zijn: Eigen zorgverzekering (reguliere zorg)

Intervention

Keyword: Diabetic Foot, Footdeformity, Hammer-clawtoes, Percutaneous tenotomy

Outcome measures

Primary outcome

Primary outcome measure:

- Cure rate of the existing wound on the treated toe.

This is defined as the number of healed wounds on the treated toe, if complete epithelialization occurred, after a year and is measured in the absolute number that is healed.

The cure is determined by the classification pedis.

The pedis scale consists of 5 items with the following corresponding classification:

- * Perfusion: 1) absence of PAD, 2) symptoms of PAD, however, no critical ischemia, 3) existence of critical ischaemia.
- * Scope: The size of the ulcer measured in mm x mm after wound debridement has taken place.
- * Depth: 1) surface, 2) the ulcer penetrates to the subcutaneous structures such as fascia, muscle or tendon, 3) all underlying layers are involved including bone and / or joint.
- * Infection: 1) absence of infection, 2) the case of infection of the skin, and the subcutaneous tissue, 3) erythema greater than 2 cm or deeper than the skin or subcutis but without systemic inflammatory symptoms, 4) clear systemic symptoms of infection.

* Sensation: 1) no loss of protective sensation, 2) loss of protective sensation

- Healing Trend existing wound:

This is defined as the degree of healing, reduction of scale / size wound.

Is determined by the classification pedis.

- Healing Time existing wound to the treated toe.

This is defined by the Nurse practitioner as the time from the intervention date until the day the wound is cured

, measured in number of days. This is also determined by the classification pedis.

Secondary outcome

Secondary outcome measure:

- New wound to the treated toe.

This is defined as a wound other than the existing wound at the time of the intervention, as it may be in the same place as in any other place but in the same toe.

Is determined by the classification Pedis.

- Caused infection of the treated toe

This is defined as: There must be at least one of the following clinical symptoms: redness, local swelling or heat to the treated toe. This is measured in temperature (fever), skin temperature, blood values **Leukocytes +

C-reactive protein (CRP) and also through the Pedis classification.

Fever: At temperature > 38.50 C (ear thermometer).

Skin temperature: Infection > 20C difference with the other foot (skin thermometer).

Leukocytes > 10 E9 / L infection.

CRP > 10mg / L infection.

- Wound size of the existing wound.

This is defined as the extent of the wound and is measured in millimeters x millimeters, with a wound centimeter measurer, and is also classified by the pedis classification .

- Wound Classification

This is defined on the causes and characteristics of a diabetic foot ulcer and is measured according to the classification pedis

- Complication lingering toe (grasping toe)

Study description

Background summary

The treatment that is now handled in the diabetic foot clinic in the Atrium MC is mainly conservative and focused on relief through Orthopaedic Footwear (OS), callus removal, foam, felt, orthosis or Total Contact Cast (TCC) (Van Schie, 2005). In contrast, in other countries and in several Dutch hospitals often surgical intervention (Kearney, Hunt, & Lavery, 2010; Kim, 2008; Roukis, 2009; Roukis & Damage, 2009; Van Schie, 2005) is used. There are several surgical

techniques that have been described, such as resection of PIP or DIP, arthrodesis of the PIP joint or lengthening of the extensor tendon. A recently described surgical technique is the subcutaneous flexor tenotomy, which means the subcutaneous cleavage of the flexor digitorum longus. This is a minimally-invasive procedure that is carried out with a "Admix needle" (page 6,7,18 protocol), and can be used for hammer toes and claw positions (Kearney, et al, 2010). By cleaving this tendon, the toe backs into its anatomical position allowing optimal pressure relief and the wound can heal. Moreover, the chance of a new wound will be equal to the probability of a wound in a toe in anatomical position. It is known that the wound healing time without this surgery is an average of 2 to 5 months (Diabetic Foot, 2006).

Research has shown that after the percutaneous flexor tenotomy 98.3% to 100% of the wounds healed completely within a period of 40-52 days (Kearney, et al, 2010; Laborde, 2007, page 3-4 Protocol). The importance of the research is therefore primarily to demonstrate that percutaneous flexor tenotomy is an effective way to treat poorly healing ulcers in diabetic patients with hammertoes. We want to measure this effect by determining the healing time, percentage healed wounds and decrease in size of the wound.

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Study objective

To demonstrate that percutaneous flexor tenotomy is an effective way to treat poorly healing ulcers in diabetic patients with hammertoes. We want to measure this effect by determining the healing time, percentage healed wounds and decrease in size of the wound.

Study design

Quasi experimental

Intervention

Under local anesthesia, the flexor digitorum longus of the corresponding toe is percutaneously cleaved using a small knife of about 2mm in width (Admix non-coring needle). The wound that is made on the underside of the toe is therefore limited to 2mm.

The surgery will be performed by a trained Nurse practitioner or assistant physician at the outpatient surgery.

As said before use will be made of an Admix needle , this is a needle with a cutter at the end.

At the height of the spot a prick will be made with the Admix needle, where the toe will be moved manually untill the flexor is cut, after which the needle is removed.

Then, the wound will be treated with betadine gauze and a bandage. The patient can immediately be discharged and will have to come for a checkup 1 week after surgery. During the first 24 hours, the patient is not allowed to put weight on the leg. The day after the operation, the bandage may be removed and the prescribed anti-infection material can be put on the old existing wound and fixated with a bandage

The next day the patient can put weight on the foot and walk normally, provided the Pullman shoe is worn.

Study burden and risks

By cleaving the flexor digitorum longus, the toe regains its normal anatomical stand. This may take several days to weeks. The effect of a normal position of the toe on wound healing is expected to become noticeable after 2 weeks. The chance that the wound, after pursuing optimal wound healing, is therefore expected to be large. The risk of amputation will thereby decrease. The signs that may indicate an infection during the study will be closely monitored and, if necessary, blood will be pinned.

Some people experience the ability to no longer bend the toe at their own desire as disturbing.

The intervention itself is minimally invasive and complications are not expected.

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

- Patients older than 18 years of age (female and male)
- Patients with hamertoe and existing wounds on the concerning toe.
- Wound exists longer than 3 months and is treated at the diabetic foot clinic
- Patients with diabetes mellitus and treated by the general practitioner or by the Internal medicine physician
- Osteomyelitis (patients with osteomyelitis on the toe due to a non-healing wound caused by a hammer toe, are also included). Osteomyelitis is diagnosed using radiographic photography (an obvious cortical disruption can be seen here). This x-ray is requested by the diabetic foot

clinic and belongs to the standard care (covered by regular health insurance).

Exclusion criteria

- Halluxpressure lower than 40mmHg, measured at the vascular laboratory in accordance with regular care
- Last new orthopedic footwear less than 26weeks old
- Antibiotic use 2 weeks prior to operation
- Antibiotic use for other indications than use for the affected foot, and 3 weeks after surgery
- Note: Amputation of another toe in the past is no reason for exclusion

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Will not start

Enrollment: 60

Type: Anticipated

Ethics review

Approved WMO

Date: 08-04-2013

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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	NL38898.096.12