A pilot randomized controlled trial comparing the effect of a percutaneous and lipofilling technique in patients with a secondary Dupuytren*s contracture with standard fasciectomy surgery on convalenscence, contracture correction and recurrence rate.

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To compare treatment of secondary Dupuytren*s contracture by standard limited (dermo)fasciectomy and by the modified percutaneous release combined with fat grafting. We focus specifically on return to function and if applicable to return to work (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON34920

Source
ToetsingOnline

Brief title
RCT comparing two surgical techniques for secondary Dupuytren contracture

Condition

- Connective tissue disorders (excl congenital)
- Skin and subcutaneous tissue therapeutic procedures

Synonym

hand diseases, Secondary Dupuytren's contracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds Nuts Ohra

Intervention

Keyword: Hand, new technique, Secondary Dupuytren's contracture, surgery

Outcome measures

Primary outcome

- Convalescence: return to function and return to work

- VAS score: standardized list of questions about pain and well-being of the

patient; to register the pain of the hand and donor site.

- Contracture reductions:

1) Total passive extension deficity (TPED): the sum of the passive extension

deficits of the metacarpophalangeal, proximal interphalangeal, and distal

interphalangeal joints.

2) Boyes measure: measuring the distance from pulp to distal palmar crease with

the hand in a maximum fist position. Flexion is defined as reduced if the

distance is more than 1.5 cm.

Secondary outcome

Intervention:

o Register the anaesthetics drugs administered and vital signs during surgery.

o Register of arthrolysis (if it is used)

Hand sensibility and complications due to intervention:

o Semmes Weinstein testo Swelling measured following hand volume

o DASH score: standardized list of questions about hand and arm function of the

patient

o CISS-score: cold-intollerance

o Esthetic and contracture correction: Kodak photos

o EQ-5D: cost-effectiveness

o MRI: fat monitoring

o cord: investigate the new intervention technique

Patients satisfaction:

o To determine the patient satisfaction, a questionaire with VAS-scale was

made.

Study description

Background summary

Dupuytren*s disease (DD) is a benign, progressive, fibroproliferative disorder that results in the development of abnormal scar-like tissue in the palmar fascia of the hand. Extension to the digits causes progressive digital flexion contracture. The cause of Dupuytren*s contracture is unknown, but the pathogenic cord is the result of myofibroblast-mediated nodules and collagen deposits.

Dupuytren*s disease predominantly affects older men of northern European

descent. Disease prevalence varies from 2 to 42 percent, and a genetic predilection is generally agreed upon. In literature, there is no consensus on aetiologic factors of DD. Multiple factors (positive family history, bilateral DD, ectopic lesions, male gender, age at onset of younger than 50 years) contribute to the diathesis of DD. A French group published a study on the economic and surgical burden of treating DD, indicating a considerable financial burden to the state of treating this condition. These financial numbers are unknown with resepect to the Netherlands. In 2006, Dupuytren*s disease was diagnosed 7048 times in the Netherlands. In total, 5843 DD operations were performed that year (Prismant Informatie Expertise).

The first clinical manifestations of DD are pitting and thickening of the palmar skin and moreover, the presence of a (sometimes painful) nodule. Classically, a nodule precedes development of a cord. Over time, which may be months or several years, the cord gradually contracts, reeling in the MCP joint and the PIP joint and leading to progressive digital flexion deformity. Contracture, causing loss of hand function, is the common complaint. Over the years many non-surgical treatments of DD (splinting, radiation, physical therapy, ultrasonic therapy, continuous slow skeletal traction, steroid injection, enzymatic fasciotomy) have been investigated. Only recent studies on enzymatic fasciotomy using collagenase have shown encouraging results. Treatment of DD is mainly surgically. Accepted options for managing diseased skin and fascia are (1) limited fasciectomy, (2) segmental fasciectomy (3) fasciotomy (4) dermofasciectomy. Limited fasciectomy and if necessary limited dermofasciectomy are the most standard techniques used. In general, full recovery of hand function takes 2-3 months. Percutaneous release of fibrotic cord at multiple levels (on average two palmar levels and two digital levels) is un upcoming treatment for DD. Its non-invasive character promotes fast post operative recovery. Variable publications mention iatrogenic neurovascular and tendon injury. Moreover, a higher recurrence rate is reported using the percutaneous technique without additional techniques such as subdermal fat grafting.
The clinical presentation of DD may also involve fat atrophy in the palmar area. Autologous fat grafting is a well known procedure where fat stores of the body are utilized to fill soft tissue contour defects in order to augment, rejuvenate or correct. Recently, fat grafting has proven to be more than just a filler. Clinical evidence exist for treatment of radiation damage, breast capsular contracture, and chronic ulcerations. Furthermore, subdermal fat grafting improves quality of the skin.In collaboration with the Miami Hand Center (Roger K. Khouri, MD), we developed a technique in which percutaneous release of fibrotic cords is refined in combination with subdermal fat grafting. Subdermal dissection of the cord is performed by making multiple superficial nicks along the entire cord. (This differs from the old percutaneous release method, which only 2 to 3 superficial nicks in the cord are created)The cord then chops, disintegrates and separates from the dermis. This space is filled with fat grafts. This technique differs from standard percutaneous release in two main major points: (1) separation and

disintegration of the cord along the entire length of the cord, and (2) subdermal fat grafting providing padding of the palmar surface and possibly preventing scar tissue.

A combined preliminary study of the Miami Hand Center and the department of Plastic and Reconstructive Surgery of the Erasmus MC Rotterdam was conducted over the last 14 months. In this period 21 patients were treated as described above, making a total of 23 hands. We treated the complete spectrum of DD (primary, recurrence, strong and weak diathesis, mcp and pip contractures). The maximal follow up at this moment is 12 months. We managed to get full extension of the joints except for residual joint contracture, with only 2 recurrence cases. Patients were satisfied and impressed by their fast recovery. We encountered 2 transient neuropraxias and one reflex sympathetic dystrophy reaction in a young woman, which is not uncommon in DD treatment.

At this point a (already by the same METC committee approved) RCT for primary Dupuytren's contracture patients is running in our Medical Centre. The reason we want to start a RCT for secondary Dupuytren's contracture is because almost all patients suffer from recurrent Dupuytren's disease. We want to prove that the new minimal invasive surgery is also for this patient population a good surgical treatment with less time to recover.

Study objective

To compare treatment of secondary Dupuytren*s contracture by standard limited (dermo)fasciectomy and by the modified percutaneous release combined with fat grafting. We focus specifically on return to function and if applicable to return to work (convalescence). We will also study the contracture correction, recurrence rates and cost-effectiveness.

Study design

Interventions will be compared in a randomized controlled trail. 80 patients with secondary Dupuytren*s contracture will be randomly assigned to the intervention group and controlled group using a computer generation random sequence.

Outcomes will be recorded at the first intake visit from the study, two weeks, three weeks, six months and one-year post-operatively. Outcomes will be measured at the Erasmus Medical Center by an structured interview, hand range of motion measurements (TPED and boyes), sensibility (Semmes Weinstein test) and hand swelling (hand volume) and grip. These tests will be conducted by physical therapist of the department of Rehabilitation that are not involved in the study and are not aware of the details of the study. There will also be a registration about the complications due to surgery of the hand and donor site (healing of the wound, infection, dystrophic characteristics (according to

Bruell), sensibility disorders).
There will be taken some Kodak pictures of the hand (pre- and post-operatively).
In the interview we will ask the patient to identify on what day, following surgery, they first returned to daily activity and work (normal hand function).
We also ask the patient to fill in the average intensity of pain on the visual analog scale (VAS) 0-100 and questions about the hand function (DASH), pre-operatively, and at 2 weeks, three weeks, six months and one-year post-operatively.
We also ask the patients to fill in the CISS and the EQ-5D questionaires.

A select couple of patients from the intervention group will undergo two MRI scans to monitor the fat. The cords that will be taken out during standard surgery will be used for further investigation of the new technique. We will stretch the cords and will nick the cords with the same needles that are used during the minimal invasive surgery. This will be monitored by film/photos.

The patients are ask to fill in five questions during the one year follow-up.
1. When could you first make a full fist? (with the operated fingers)
2. When was the pain at the operated hand <=3 on the visual analog scale of 10 for the first time?
3. When were you pain free (VAS = 0)?
4. When could you use your operated hand for daily activity for the first time?
5. When did you return to work and hobbies for the first time since the operation?

Intervention

Anti-coagulants should be stopped before the surgical procedures.

1) Limited fasciectomy and limited dermofasciectomy
- Commonly used technique the participating clinic
- Use of tourniquet
- Limited fasciectomy is performed and extended to limited dermofasciectomy only if overlying skin is pathologically involved.
- Standard z-plasty or bruner*s incision are used. Skin flaps are raised in plane between involved fascia and subcutaneous fat. After identification of the neurovascular bundles, all pathologic tissue is excised from proximal to distal. Dermofasciectomy is performed by excising involved skin and closing the defect with full thickness skin grafts.
- When, after release of the cord, an extension defecit persists based on joint stifness, we will perform a arthrolysis of the joint.
- Postoperative treatment consists of plaster immobilisation for 1 week. If wound healing permits, hand therapy is started. If the wound or skin graft has not healed sufficiently, the hand is immobilised another week. A night extension splint is used for 3 months

2) Extensive percutaneous release in combination with subdermal fat grafting
- Technique is recently introduced in the participating clinic
- Use of tourniquet
-Subdermal dissection of the cord by multiple superficial nicks while maintaining strong extension force (lead hand is of extreme importance to maintain constant extension force). The cord is only superficially released by using the bevel of a 18 gauge needle as a depth gauge. The cord is released from proximal to distal through numerous puncture wounds. By doing this at multiple levels along the entire cord, the cord chops and separates from the dermis. This space is than filled with fat grafts.
- Standard liposuction is performed to harvest the fat using the Coleman lipofilling technique.
- Fat is grafted subdermally between the divided end of the cord and between the cord and the dermis after opening the skin withe a 14 gauge needle proximally and distally. Per complete ray approximately 5-10 cc fat is injected using a 2 mm blunt tip spatulated cannula.
- Postoperative extension splint for 1 week. Full use is allowed at 2 Weeks. A night extension splint is used for 3 months.

Study burden and risks

The risks of the standard surgical procedure are well known: neurovascular injury, CRPS symptoms, wound healing problems, stifness of the hand. The risks of the experimental technique are similar, although we expect to encounter less wound healing problems and decreased stifness of the hand. The risks of standard liposuction are known and are minimal and recovery is usually fast. There are few long-term adverse clinical effects. After a standard liposuction, the following effects can be expected: edema and redness of the liposuction areas for a few days, moderate contusion of the liposuction areas for a few months. Less common complications may include: persistent edema, persistent bleeding, hematoma, visible puncture sites. Rare complications may include: local and systemic infection.

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

-males and females
- patients of 18 years and older
- secondary Dupuytren's contracture
- PIP > 30 degrees / MCP > 20 degrees
- one or more affected rays
- severe or less severe diatheses
- ASA criteria I, II, and III

Exclusion criteria

- Primary Dupuytren*s contracture
- Amputation of 1 or more fingers of the affected hand.
- More than 2 times hand surgery in the affected ray.
- disorder (trauma/congenital) in the past that affects the affected finger (0-situation is unknown).
- Dystrophic characteristics in the past.
- use of anticoagulants that can not be stopped for surgery
- ASA IV and V

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2010
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	20-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL29979.078.09