The evaluation of treatment after zone II flexor tendon repair: modified Kleinert versus controlled early active mobilisation, a pilot study

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The aim of this pilot study is to analyse the effects of two different hand therapy treatments after flexor tendon repair. These two hand therapy treatments concern the active mobilization protocol of the Belfast regime and the passive mobilization...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31646

Source
ToetsingOnline

Brief title
rehabilitation of flexor tendon injury

Condition

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

Synonym
flexor tendon injuries, tendon injury

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: early active mobilisation, flexor tendon injury, modified Kleinert, zone II

Outcome measures

Primary outcome

- Joint mobility: Total Active Motion (TAM) and Total Passive Motion (TPM)

measured with digital goniometry

- Strength measured with the digital dynamometer

- Michigan Hand Outcomes Questionnaire (MHQ). A questionnaire of the hand

function in general, activities of daily living, quality of life, working

performance, pain, aesthetics and the satisfaction with the hand.

- The (Quick) DASH (Disabilities of the Arm, Shoulder and Hand); a

questionnaire the ability to perform daily activities with the upper limb,

based on the condition at that moment.

- The Perdue Pegboard test; ability test of the fine motor control.

- Number of tendon ruptures and other complications like infection, bleeding,

wound dehiscence.

- Moment of the return to work (in days).

- Duration of the therapy and the number of therapy sessions. This will be

recorded by the hand therapist.

- The total costs of treatment. This calculation is based on working hours and

material costs.

Secondary outcome

Not applicable.

Study description

Background summary

The post-operative treatment of flexor-tendon injuries is based on the knowledge of the nutrition and healing of the tendons. Until the late 70ties people where convinced that the main part of the healing was extrinsic, therefore they prescribed total immobilization.
Later on more knowledge became available on the intrinsic healing of the tendon. At that moment Kleinert and Duran & Houser developed the passive mobilisation protocols, which provides a better sliding capability of the tendon. They used a dynamic splint with the fingers hold in a flexion position by elastic cords and made active extension only possible when allowed. The results of this treatment where better than the results of the total immobilization.
Over the last years the treatment according to Kleinert is improved in many different ways (the modified Kleinert protocols) with alterations in the position of the joints in the splint. Furthermore, several protocols concerning early active mobilization were developed (Chow, Belfast, Elliot). These protocols differ on details. Beside the active extension in a post-operative early stage, active flexion is allowed as well. The profit of the active treatment is that by active contraction of the muscle, a better sliding capability of the tendon is achieved. In active treatment the tendon is drawn through the tendon sheath instead of pushing the oedematous tendon through the sheath as is the case in the passive treatment protocol. The disadvantage of the active mobilization procedure is the higher risk of a rupture of the sutured tendon

Different study analyses of the effectiveness of the methods described above were made, but the literature can*t give a clear preference between the active or passive treatment after flexor tendon repair. Accurate randomised controlled trials are, up till now, not accomplished.

Study objective

The aim of this pilot study is to analyse the effects of two different hand therapy treatments after flexor tendon repair. These two hand therapy treatments concern the active mobilization protocol of the Belfast regime and the passive mobilization treatment by the modified Kleinert protocol.

Study design

Randomized controlled trial

Study burden and risks

Not applicable

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

the patient is 18 years of age or older
the patient has an isolated Zone II flexor tendon injury of the FDP and/or FDS (Flexor

Digitorum Profundus and/or Superficialis)
The patient is able to execute instructions of the hand therapist or the researcher.
The patient has a sufficient command of the Dutch language

Exclusion criteria

-comorbidity interfering with hand function
-phalangeal fractures
-psychological-, alcohol-, and/or drug induced problems
-extensive soft tissue (skin) lesions

Study design

Design

Study type:	Observational non invasive
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):	01-09-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL19142.042.08