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Rehabilitation following surgery for flexor tendon injuries of the hand.
Cochrane Database of Systematic Reviews 2017, Issue 1. Art. No.: CD012479.
DOI: 10.1002/14651858.CD012479.

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TABLE OF CONTENTS

HEADER 1
ABSTRACT 1
BACKGROUND 1
OBJECTIVES 4
METHODS 4
ACKNOWLEDGEMENTS 7
REFERENCES 8
APPENDICES 9
CONTRIBUTIONS OF AUTHORS 11
DECLARATIONS OF INTEREST 11
SOURCES OF SUPPORT 11

[Intervention Protocol]

Rehabilitation following surgery for flexor tendon injuries of the hand

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Editorial group: Cochrane Bone, Joint and Muscle Trauma Group.
Publication status and date: New, published in Issue 1, 2017.

Citation: Peters SE, Jha B, Ross M. Rehabilitation following surgery for flexor tendon injuries of the hand. *Cochrane Database of Systematic Reviews* 2017, Issue 1. Art. No.: CD012479. DOI: 10.1002/14651858.CD012479.

ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects (benefits and harms) of different rehabilitation interventions after surgery for flexor tendon injuries of the hand.

BACKGROUND

Description of the condition

Tendons connect muscles to bones and enable movement at joints. The flexor tendons of the hand, which connect various flexor muscles in the forearm and hand to the bones (phalanges) in the fingers and thumb, act to bend (flex) the fingers or thumb. They are essential for complex hand function including pinch, grip and motor dexterity. There are two flexor tendons in each finger; these connect with the flexor digitorum profundus (FDP) and the flexor digitorum superficialis (FDS) muscles. The two flexor tendons in the thumb connect with the flexor pollicis longus (FPL) and flexor pollicis brevis (FPB). For much of the finger, flexor tendons move within fibro-osseous tunnels called flexor sheaths. These are synovium-lined tunnels that hold the tendons close to the bones, ensuring mechanical efficiency and preventing the tendons from 'bowstringing' across the joints. Sections of the sheaths are thickened into five fibrous bands called annular pulleys (A1-A5) and the three flexible compressible sections called cruciate pulleys (C1-C3).

Flexor tendon injuries can be caused by open cuts (such as by broken glass) to the hand, crush injuries and degloving injuries. They can also be caused by sudden forced extension of the fingers or thumb resulting in an avulsion injury where the tendon is, or tendons are, pulled away from the bone. Flexor tendon injuries of the hand are relatively common. The incidence of tendon injuries is higher in males and in people aged 20 to 29 years (De Jong 2014). The FDP tendon of the fifth (little) finger is the most commonly injured tendon in isolation (Rosberg 2003).

Five anatomical zones (zones I to V) are commonly used to categorise the level of tendon injury in the fingers, hand and forearm (Verdan 1960). Zone I includes the FDP tendons from the insertion of the FDP on the distal phalanx bone to the insertions of

the FDS tendons. Zone II extends between the FDS insertions to the proximal edges of the A1 pulleys. Zone III is the area in the palm of the hand between the A1 pulleys and the distal edge of the transverse carpal ligament in the wrist. Zone IV includes the tendons passing in the carpal tunnel. Zone V is proximal to the carpal tunnel in the forearm to the origin of the tendons at their respective muscle bellies. Injuries in zone II, where the tendons are contained within the flexor sheaths, are the most common (De Jong 2014). Often, the associated pulleys are damaged during the flexor tendon injury in this zone. The clinical issues related to an inefficient pulley system can include bowstringing, reduced composite flexion, stiffness and reduced grip strength (Lilly 2006).

Laceration or avulsion injury to the flexor tendons is generally managed with surgery. However, there is variability between the type of possible surgical repairs. New techniques continue to evolve, ultimately aiming to promote tendon glide, limit postoperative complications and restore normal hand function (Taras 1999). Acute injuries tend to be managed with primary surgical repair of the tendon. This is done by direct end-to-end tendon repair with multistrand sutures (2, 4, 6 or 8 strand) of the core of the tendon and additional peripheral sutures around the sides of the tendon. The pattern and strength of the suture repairs prevent gapping and contribute to the strength of the repair. When primary repair of the tendon has failed (that is, a tendon rupture) or when primary repair is not feasible due to concurrent injuries (e.g. nerve, blood vessel, bony injury or infection) or loss of tendon length, secondary surgical intervention may be advised. Secondary surgery involves either secondary repair of the failed primary tendon repair or a two-stage reconstructive surgical process using a donor tendon graft (Smith 2004). Additionally, zone II injury is typically considered to be more difficult both to repair surgically and to rehabilitate. Repair of zone II tendons often require more additional procedures (e.g. excising one slip of the FDS tendon or part of the A2 or A4 pulleys) than other zones, often resulting in poorer mobility and functional outcomes (Tang 2013).

Description of the intervention

This review will examine the rehabilitation interventions that are prescribed after the surgical repair of both open and closed flexor tendon injuries. Rehabilitation interventions are usually provided by a physical therapist or an occupational therapist who specialises in providing hand therapy interventions. Therapists often prescribe a combination of interventions.

Early rehabilitation in the first six to eight weeks following surgery is focused on protecting the tendon repair (Evans 2012; Strickland 2005). Intervention in this early postoperative period can include patient education, prescription or fabrication of a type of orthosis, an exercise regimen, wound care (application of dressings or topical applications), swelling management (e.g. compression therapy, elevation or cryotherapy), scar management (e.g. massage treatments, topical applications, desensitisation programmes) and electrotherapy modalities (e.g. neuromuscular electrical stimulation) (Pettengill 2005; Villecio 2010).

A therapist may provide a pre-fabricated orthosis or fabricate one to purpose in order to protect the tendon repair. Orthoses restrict hand use and allow joints to move within a safe range of movement. They can be made from a variety of materials. Orthoses can also have different designs including hand-based designs (crossing only the finger or thumb joints), forearm-based designs (crossing multiple joints including the wrist, fingers and/or thumb), or they can have a dynamic component (often using an elastic traction system to mimic the action of the tendons, thus preventing strain on the repairs when moving the joints) (Evans 2012; Strickland 2005). Variations also exist with respect to the specific position of the wrist and digits within the orthosis.

Different exercise regimens are in use, often defined in terms of the types of exercise entailed. These include: immobilisation regimens, controlled passive motion (CPM) regimens, place and hold regimens, or controlled active movement (CAM) regimens (Clancy 2013; Gelbermann 1991; Hagberg 2000; Pettengill 2005). During immobilisation, therapists prescribe no exercise during a defined time period. A CPM regimen refers to bending the finger manually with assistance from either the patient's other hand, from another person (e.g. a physical therapist) or by means of a dynamic component (e.g. elastic component such as rubber bands). This movement mimics action in a way that does not place the flexor tendon under strain. The patient then actively straightens the finger into the orthosis using the muscle power of the uninjured extensor tendon. 'Place and hold' regimens are exercise programmes where the injured digit is manually flexed using either the patient's uninjured hand or by another person (e.g. a physical therapist); the patient then tries to hold the flexed position by actively using the muscle strength of the injured flexor tendon. A CAM regimen refers to bending and straightening the fingers using the patient's own muscle strength with no assistance. Exercise regimens may comprise combinations of these regimens (for example, passive movement exercises followed by place and hold and/or active exercises) or variations of these regimens (for example, active movement through a 'mid-range' or 'full-range', or synergistic movement of the wrist and hand using the tenodesis effect). The timing of the commencement of the exercise programme (for example, delaying the commencement of certain types of exercises following surgery), as well as duration and frequency of exercises may also vary (Evans 2012).

Rehabilitation generally progresses over time. Interventions recommended later in the rehabilitation process include grip strengthening, functional rehabilitation (that is, prescription of graduated hand function by introducing more strenuous self-care, domestic and work duties) and return-to-work interventions (for example, work hardening and work modifications). Work hardening programmes are graded exercises and activities to improve strength, endurance and co-ordination to facilitate a person's return to employment (Pettengill 2010).

The mode of delivery of the intervention is also an important consideration. People may receive early rehabilitation in a hospital or clinic setting. Later programmes may take place in the clinic setting, or alternatively the individual might perform them in the home or workplace. In each setting, the level of patient supervision differs. For example, a therapist may supervise rehabilitation in a clinic setting, whereas there will be no supervision for a home exercise programme.

How the intervention might work

Over the last few decades, knowledge of tendon structure and biomechanics has improved considerably (Osei 2014; Wu 2013). This includes tendon response to injury, repair and stress as well as the mechanical characteristics of the current surgical techniques (to improve the strength of the repair whilst allowing smooth excursion of the tendons through the tunnels of the flexor tendon sheaths) (Lutsky 2015). This knowledge has, in turn, influenced rehabilitation protocols and the types of treatments offered (Groth 2004).

Rehabilitation aims to protect the repaired tendons, promote intrinsic tendon healing, minimise extrinsic scar tissue formation, optimise tendon gliding and restore movement and functional use (Elliot 2007; Strickland 2005). The types of rehabilitation interventions recommended by healthcare providers are generally based on a number of factors that may include: the nature of the injury (e.g. traumatic open injury or closed avulsion injury), stage of the rehabilitation (e.g. immediately following the surgery versus longer term rehabilitation at three months or beyond), the strength of the repair (e.g. number of suture strands in the repair), associated injuries (e.g. concomitant nerve, bone, blood vessel or ligament damage), pre-injury medical history or ability to comply with rehabilitation (Evans 2012).

Education is considered very important for patient adherence following surgery (Evans 2012). Advice often focuses on the importance of adhering to treatment recommendations, the level of functional activity permitted and general care of the repaired tendon and wound (Pettengill 2010).

Orthoses are applied in the early postsurgical stage. The purpose of providing orthoses is to position the wrist and fingers so that the tendon repairs are not under any tension, but still allow movement within a safe range (Pettengill 2010). Careful positioning of the hand within the orthosis is necessary. Therefore, the joint angles within the orthosis have great significance. For example, experts consider that dynamic traction designs with the metacarpal joints in 70 degrees of flexion increase the risk of proximal interphalangeal (PIP) joint flexion contracture (Burge 1990).

Early designs of exercise regimens assumed that 3 mm to 5 mm of tendon excursion (i.e. the distance a tendon travels upon movement of a joint) decreased tendon adhesions that limit finger mobility (Duran 1975). Therapists often recommend protocol-based exercise regimens to improve the tendons' gliding function by minimising adhesions (Khanna 2009), preventing joint stiffness and improving range of movement. Practitioners believe these exercises to be essential in regaining long-term finger dexterity and hand function (Pettengill 2010). Moreover, research suggests that controlled stress on the tendons, created by either passive or active movement, facilitates healing, controls early collagen deposition and facilitates biochemical events that increase tensile strength (Buckwalter 1999; Evans 2012). However, excessive stress during motion may also pose a risk of gapping or rupture of the repaired tendon ends. The timing of the interventions, especially the commencement of an exercise regimen, may influence how an intervention works (Adolfsson 1996; Evans 2012). Various studies have found that periods of immobilisation immediately following repair can result in loss of tensile strength and glide (Evans 2012). However, other authors advocate delayed mobilisation for up to three to five days to allow inflammation and oedema to subside and minimise the strain on the flexor tendon (Halikis 1997; Zhao 2004).

Wound care treatments are essential in preventing infection and facilitating wound healing (Von der Heyde 2010). As therapists often prescribe early exercise, the dressings should not impede motion or place extra stress on the tendon repairs when the finger is moved.

Oedema management helps to reduce the amount of swelling in the digit and hand. Oedema in the subcutaneous tissue adds significantly to the gliding resistance, whereas pulleys may add to the resistance of the swollen repaired tendon (Wu 2013).

Scar management treatments may be advisable to promote optimal scar formation and prevent skin and tendon adhesions or reduce scar hypersensitivity. Evidence for this is limited, and recommendations draw primarily from anecdotal and clinical experience (Jones 2005).

Electrotherapy modalities, such as neuromuscular electrical stimulation, provoke stronger muscle contractions. Practice guidelines have recommended therapeutic ultrasound for promoting healing while minimising the formation of soft-tissue and skin adhesions (Pettengill 2010).

Therapists also utilise strengthening and work hardening treatments to facilitate early return-to-work, leisure and sporting activities (Pettengill 2010).

Why it is important to do this review

Flexor tendon injuries of the hand can result in loss of finger and thumb motion, reduced functional hand use and quality of life. The management of these injuries has evolved over several decades. At present, there is no gold standard rehabilitation programme used for rehabilitation following surgery for flexor tendon injuries. As a result, centres across the globe use a wide range of rehabilitation treatments. Clinical practice is often influenced by the results of biomechanical studies (Osei 2014; Wu 2013). Instead we need to examine the high-quality clinical evidence to establish the ef-

fectiveness and safety of rehabilitation interventions for managing flexor tendon injuries of the hand and thus identify those that are most effective at restoring digital motion and function whilst minimising the risk of complications and adverse events.

Recent non-Cochrane systematic reviews have examined rehabilitation protocols in zone II flexor tendon injuries and rehabilitation for all flexor zones of the digits (Chesney 2011; Starr 2013). Both reviews included all types of study design and specifically focused on comparisons of different types of exercise programmes. Our review will include only randomised and quasi-randomised trials and will include all types of rehabilitation interventions.

OBJECTIVES

To assess the effects (benefits and harms) of different rehabilitation interventions after surgery for flexor tendon injuries of the hand.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised and quasi-randomised (i.e. not strictly random method of treatment allocation, such as by hospital number) controlled trials evaluating rehabilitation interventions after surgery for flexor tendon injuries of the hand.

Types of participants

We will include trials of individuals who have undergone post-surgical rehabilitation following primary and secondary repair, or reconstruction of partial or total lacerations or rupture of one or more flexor tendons in any of the five zones in the hand. We will exclude studies examining the effectiveness of tendon transfers for people with neurological conditions.

Types of interventions

We will include all types of rehabilitation following surgery for flexor tendon injury of the hand. Primary interventions will include orthoses to protect the repair/reconstruction, exercise protocols, scar management and hand strengthening. We will also consider interventions for reducing or controlling oedema, for work hardening and desensitisation programmes. We will also consider the timing of the interventions' commencement (e.g. early active movement protocols). We will exclude wound care, oral pharmacological interventions and topical pain relief ointments.

The main comparisons might include:

- different types of orthoses; e.g. dynamic orthosis versus static orthosis; comparisons of different finger and wrist positioning within the orthosis;
- different orthosis wearing regimens, including duration; e.g. six weeks or shorter versus longer than six weeks;
- different exercise protocols; e.g. controlled passive mobilisation versus controlled active mobilisation;
- different timings for commencing mobilisation; e.g. started within the first three days versus after three days;
- different types of scar management; e.g. massage versus topical applications such as silicone gel sheets;
- different timings for commencing strengthening; e.g. 6 to 10 weeks versus after 10 weeks.

For interventions in which a control or sham group is appropriate (such as scar management or strengthening and work hardening), we will compare the active intervention versus the control or sham group. For the exercise protocols, we will select the least aggressive protocol as the control group.

Types of outcome measures

We will include studies if the protocol includes the measurement of at least one clinical outcome related to function, range of movement or adverse event reporting. We will assess all outcomes as short-term (defined as three months or less), and long-term (over three months).

Primary outcomes

1. Functional assessment using a patient reported outcome measure (such as Patient Rated Wrist and Hand Evaluation; Michigan Hand Questionnaire)
2. Active finger range of motion using goniometric measurement
3. Adverse events including revision surgery, rupture, scar adhesion, delayed wound healing, loss of mobility or function, joint contracture, triggering of the digit, pulley failure, persistent pain and sensory deficits. We will report the total number of participants with adverse events and for each of these events.

Secondary outcomes

1. Passive finger range of motion using goniometric measurement
2. Hand strength (including grip strength, pinch strength)
3. Return to previous activity (including return to work, education, musical instrument or sport). Return to work will be reported separately if available (including same, modified or alternate duties) for individuals working at the time of injury
4. Functional assessment using an objective measure (including Jebsen hand test)

5. Quality of life using a self-report measure (such as EuroQOL, SF-36)

6. Satisfaction with the result of the surgery at three months or longer

Where available, we will collect resource and cost data such as health care utilisation, and insurance data related to work absence. However, these data will not be the focus of the review.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL; current issue in the Cochrane Library), MEDLINE (1946 to present), Embase (1980 to present), AMED (1985 to present) and CINAHL Plus (1937 to present). We will also search the WHO International Clinical Trials Registry Platform (ICTRP) search portal, and ClinicalTrials.gov (the US National Institute of Health Clinical Trials search portal) for ongoing and recently completed trials.

In MEDLINE, we will combine subject-specific terms with the sensitivity-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised trials (Lefebvre 2011). Search strategies for MEDLINE, CENTRAL and Embase are shown in Appendix 1. We will develop other search strategies at a later stage.

There will be no language or date restrictions.

Searching other resources

We will search the reference lists of included studies, relevant articles on flexor tendon rehabilitation and any known systematic reviews on the topic for information on additional trials, including unpublished or ongoing studies.

Data collection and analysis

Selection of studies

Two review authors (BJ and SP) will independently screen the titles and abstracts of all retrieved references. We will seek full-text articles of all studies that appear to meet the eligibility criteria. The same two authors will independently screen the full-text articles against the eligibility criteria and document their decisions. A third author (MR) will resolve any disagreement. Where identification is possible, we will collate multiple reports of the same study and place these under the same study ID. We will include a PRISMA flow chart to illustrate the study selection process (Moher 2009).

We will attempt to contact trial authors for clarification of study methods and characteristics, if necessary, to establish trial eligibility.

Data extraction and management

Two review authors (BJ and SP) will independently extract data using a standard pre-defined data extraction form.

We will extract the following study characteristics.

- Methods: study design, date of study, duration of study, study setting, randomisation procedure, allocation, blinding and unit of analysis.
- Participants: number of participants, number of involved digits, number of injured flexor tendons, age (mean, standard deviation, range), sex, type of flexor tendon injury, baseline characteristics, time between injury and surgery, inclusion criteria, exclusion criteria, type of surgery, diabetes and smoking status.
- Interventions: intervention, comparison (e.g. control or sham), co-interventions, and care programmes provided to all participants.
- Outcomes: primary outcomes, secondary outcomes specific and collected, time points of evaluation, and resource use.
- Notes: funding for trial, relevant conflicts of interest related to the study of trial authors, and any unit of analysis issues.

Two review authors (SP and BJ) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' tables if trial authors did not report outcome data in a usable way. We will resolve disagreements by discussion. Two review authors (SP or BJ) will transfer data into Cochrane's statistical software, Review Manager 5 (RevMan 2014), and a third (MR) will cross-check the entries.

When papers or unpublished reports require translation, the translator may either extract data directly using a data extraction form or provide a translation. Where possible, a review author (SP) will check the numerical results data in the data extraction form or translation against the original study report.

Assessment of risk of bias in included studies

Two review authors (BJ and SP) will use Cochrane's tool for assessing risk of bias to independently evaluate the risk of bias for each trial in the following seven domains (Higgins 2011).

1. Sequence generation (selection bias).
2. Allocation concealment (selection bias).
3. Blinding of participants and personnel (performance bias).
4. Blinding of outcome assessment (detection bias).
5. Incomplete outcome data (attrition bias).
6. Selective outcome reporting (reporting bias).
7. Other risk of bias (we will consider whether the unit of analysis was appropriate, check for premature stopping of the

trial and the basis for this; and for extreme baseline differences between comparison groups).

We will assess risk of bias of self-reported and objective outcome measurements separately for the two blinding and incomplete outcome data domains. For each domain, we will assign a judgement of high, low or unclear risk of bias based on the criteria in Table 8.5.d of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The review authors will resolve disagreement by discussion and consensus. Where information on risk of bias relates to unpublished data or correspondence with trialists, we will note this in the 'Risk of bias' tables.

Measures of treatment effect

For dichotomous data we will use risk ratios (RRs) with 95% confidence intervals (CIs).

For continuous data measured with the same scale we will use mean differences (MDs) and 95% CIs. If trials use different scoring systems to measure the same underlying concept (for example, different measures of function), we will use the standardised mean differences (SMDs) and 95% CIs. We will use final scores in preference to change scores.

Where reported in trial reports, we will present non-parametric data such as medians and interquartile ranges in the text, tables or both.

Unit of analysis issues

We will clarify the unit of analysis; thus, whether the number reported represents participants, hands, digits or flexor tendons. Unit of analysis issues may arise if multiple fingers on the same hand have had separate flexor tendon injuries. Bilateral involvement may be possible. We will seek information about the unit of randomisation (that is, hands, involved fingers or participants) for studies that included participants with multiple-digit involvement in the same hand or bilateral injury. We will examine the study reports to see whether analyses were conducted using methods that take into account the dependency of observations. If trials do not report appropriate analyses, we will contact the authors for further information and data. If such data are not available, we will conduct sensitivity analyses that take into account the number of randomised participants with bilateral or multiple digit involvement. We will also avoid unit of analysis issues related to repeated observations of the same outcome, such as by presenting separate data for different periods of follow-up (section 9.3.1; Higgins 2011). Where a single trial reports on multiple trial arms, we will include only the relevant groups of the trial. If the same meta-analysis combines two comparisons from the trial, we will split the control group to avoid double-counting.

Dealing with missing data

Intention-to-treat (ITT) analysis will be our first choice when data are available. If data for key study characteristics or primary outcomes are missing or incomplete, we will contact the trial authors to obtain these. We will consider conducting sensitivity analyses when missing data are not obtainable and their absence is considered likely to introduce bias. Sensitivity analyses are likely to include worst- and best-case analyses and explore the effects of excluding such studies from the analyses. We will calculate missing data where possible; for example, calculating standard deviations from other available data such as standard errors (section 16.1.3.1; Higgins 2011), but we will not impute these from other sources. We will also consider extraction of data presented graphically only.

Assessment of heterogeneity

We will assess clinical heterogeneity (i.e. study populations, interventions and outcomes) between studies qualitatively. We will assess statistical heterogeneity by visual inspection of the overlap of CIs on the forest plots, along with consideration of the Chi^2 tests for heterogeneity and I^2 statistic (Higgins 2011). We will base our interpretation of the I^2 value in Higgins 2011: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% may represent very substantial heterogeneity.

Assessment of reporting biases

To reduce reporting bias, we plan to search for published and unpublished studies without language restrictions. When possible, we will try to obtain the protocol of the clinical registration documents for all trials and will contact the authors of unpublished trials to ask for unpublished results. Selective outcome reporting biases will be appraised as part of the risk of bias assessment of each trial. To investigate the likelihood of publication bias, we will generate funnel plots providing there are pooled data from at least 10 trials.

Data synthesis

When considered appropriate, we will pool results of comparable groups of trials using both the fixed-effect and the random-effects models. Our choice of the model to report will be guided by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors, such as the number and size of included studies. We will use 95% CIs throughout. We will consider not pooling data where there is considerable heterogeneity ($I^2 > 75\%$) that cannot be explained by the diversity of methodological or clinical features among trials. Where it is inappropriate to pool data, we will still present trial data in the analyses or tables for illustrative purposes and will report these in the text.

Subgroup analysis and investigation of heterogeneity

If sufficient studies are available, we will consider performing subgroup analyses selected from the following list. The selection of the subgroups for individual treatment comparisons will depend on an a priori assessment of whether a substantial difference in treatment effect (either size or direction) would be anticipated for the subgroups under comparison. We will state our expectations for difference in treatment effect when conducting any subgroup analysis.

1. Zone of the tendon repair (zone 1, 2, 3, 4, 5).
2. Two-strand, four-strand, six-strand repairs.
3. Primary repair, secondary repair (i.e. repair following rupture of a primary repaired tendon) versus secondary tendon reconstruction.
4. Timing of the start of the intervention (e.g. immediate (within the first three days), three days to 6 weeks, 6 to 10 weeks, after 10 weeks).
5. Thumb versus fingers.
6. Partial lacerations, complete lacerations and avulsion injuries (ruptures).
7. Workers' compensation insurance versus privately insured.

These subgroups were selected as these groups may influence the outcome. Repair of flexor tendons in different zones are thought to have different outcomes because of the biomechanics of the flexor tendons (Rigo 2016; Stone 1989). The strength of the repair is thought to increase together with the number of strands, which in turn may influence outcomes (Lee 2015; Myer 2016). Primary and secondary repair and secondary reconstruction may have different outcomes due to the length of time after the initial injury and different method used (Freilich 2007).

We will investigate whether the results of subgroups are significantly different by inspecting the overlap of confidence intervals and performing the test for subgroup differences available in RevMan (RevMan 2014).

Sensitivity analysis

If sufficient studies are available, we will conduct sensitivity analyses on various aspects of trial and review methodology and the robustness of the results. These will include sensitivity analyses to explore the effects of the following.

- Exclusion of trials at high or unclear risk of selection bias from inadequate concealment of allocation.
- Exclusion of trials at high or unclear risk of attrition bias from incomplete outcome data.
- Exclusion of trials reported only in conference proceedings and other short reports.
- The choice of statistical model for pooling (fixed-effect versus random-effects).
- Exclusion of trials at risk of unit of analysis issues, relating either to body parts or outcome reporting (e.g. total complications where it is unclear whether participants had more than one reported complication).

Assessing the quality of the evidence and *'Summary of Findings' tables*

We will use the GRADE approach to assess the quality of evidence related to individual outcomes (Schünemann 2011).

The quality rating 'high' is reserved for a body of evidence based on randomised controlled trials. We may downgrade the quality rating to 'moderate', 'low' or 'very low' depending on the presence and extent of five factors: study limitations, inconsistency of effect, imprecision, indirectness or publication bias. We will prepare 'Summary of Findings' tables for the main comparisons if there is sufficient evidence. We will include the following outcomes: functional ability using a self-reported outcome at three months or longer; active range of movement at three months or longer; adverse events (rupture; revision surgery); return to previous activity (or work); and self-reported quality of life at three months or longer.

ACKNOWLEDGEMENTS

We are grateful to Megan Blakeway and Helen Handoll for helpful comments on drafts of the protocol. We also thank Joanne Elliott for her help with the search strategy and the editorial support of the Cochrane Bone, Joint and Muscle Trauma Group. We would also like to acknowledge the support of the Brisbane Hand and Upper Limb Research Institute.

This project was supported by the National Institute for Health Research via Cochrane Infrastructure funding to the Cochrane Bone, Joint and Muscle Trauma Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategies

CENTRAL (Wiley Online Library)

#1 MeSH descriptor: [Tendon Injuries] this term only
#2 MeSH descriptor: [Hand Injuries] 1 tree(s) exploded
#3 #1 or #2
#4 flexor*:ti,ab,kw (Word variations have been searched)
#5 #3 and #4
#6 MeSH descriptor: [Rupture] this term only
#7 MeSH descriptor: [Lacerations] this term only
#8 MeSH descriptor: [Wounds and Injuries] this term only
#9 Any MeSH descriptor with qualifier(s): [Injuries - IN]
#10 rupture* or lacerat* or injur* or repair*:ti,ab,kw (Word variations have been searched)
#11 #6 or #7 or #8 or #9 or #10
#12 flexor near/5 tendon*:ti,ab,kw (Word variations have been searched)
#13 flexor digitorum or flexor pollicis:ti,ab,kw (Word variations have been searched)
#14 #12 or #13
#15 #11 and #14
#16 #5 or #15 in Trials

MEDLINE (Ovid Online)

1 Tendon Injuries/ or Hand Injuries/ or Finger Injuries/
2 flexor*.ti,ab.
3 1 and 2
4 Rupture/ or Lacerations/ or "Wounds and Injuries"/
5 (rupture* or lacerat* or injur*).ti,ab.
6 in.fs.
7 4 or 5 or 6
8 (flexor adj5 tendon*).ti,ab.
9 (flexor digitorum or flexor pollicis).ti,ab.
10 8 or 9
11 7 and 10
12 3 or 11
13 Randomized controlled trial.pt.
14 Controlled clinical trial.pt.
15 randomized.ab.
16 placebo.ab.
17 Drug therapy.fs.
18 randomly.ab.
19 trial.ab.
20 groups.ab.
21 or/13-20
22 exp Animals/ not Humans/
23 21 not 22
24 12 and 23
.pt. denotes a Publication Type term;
.ab. denotes a word in the abstract;

.fs. denotes a 'floating' subheading;
/ denotes a Medical Subject Heading (MeSH) term;
.ti. denotes a word in the title.

Embase (Ovid Online)

1 Flexor Tendon Injury/
2 Tendon Injury/ or Tendon Rupture/ or Finger Injury/ or Hand Injury/
3 flexor*.ti,ab.
4 2 and 3
5 Rupture/ or Laceration/ or Injury/ or Avulsion Injury/
6 (rupture* or lacerat* or injur*).ti,ab.
7 5 or 6
8 Flexor Tendon/
9 (flexor adj5 tendon*).ti,ab.
10 (flexor digitorum or flexor pollicis).ti,ab.
11 8 or 9 or 10
12 7 and 11
13 1 or 4 or 12
14 exp Randomized Controlled Trial/ or exp Single Blind Procedure/ or exp Double Blind Procedure/ or Crossover Procedure/
15 (random* or RCT or placebo or allocat* or crossover* or 'cross over' or trial or (doubl* adj1 blind*) or (singl* adj1 blind*)).ti,ab.
16 14 or 15
17 (exp Animal/ or Animal.hw. or Nonhuman/) not (exp Human/ or Human Cell/ or (human or humans).ti.)
18 16 not 17
19 13 and 18

CONTRIBUTIONS OF AUTHORS

SP and BJ wrote the protocol. All authors contributed to, and approved, the final version of the protocol.

DECLARATIONS OF INTEREST

SP: none known.

BJ: none known.

MR: none known.

SOURCES OF SUPPORT

Internal sources

- Brisbane Hand and Upper Limb Research Institute, Australia.

Provided in-kind support to write the protocol

External sources

- No sources of support supplied