STUDY PROTOCOL

Short title: Extensor tendon randomised controlled trial

Full title: Is relative motion extension splinting non-inferior and more cost-effective compared to dynamic extension splinting for extensor tendon repair in zone V and VI: A randomised controlled trial.

Principal Investigator: Miranda Bűhler (MB), Senior Hand Therapist and Physiotherapist, Physiotherapy Outpatient Department, Dunedin Hospital, Southern DHB. Role will be in coordinating the research programme, and in research design, recruitment, data collection, analysis and cost evaluation, in collaboration with HA, DGJ, MC and JW. Time commitment 0.08 FTE.

Co-investigators:

A/P Haxby Abbott (HA), Research Associate Professor, Orthopaedic Section, Dept of Surgical Sciences, Dunedin School of Medicine, University of Otago; Sir Charles Hercus Fellow. A/P Abbott has extensive research experience in clinical epidemiology, clinical trials, health services research - economic evaluation alongside clinical intervention trials, diagnostic validity studies, prognostic studies, validity and psychometrics of outcome measures. Time commitment 0.02 FTE.

A/P David Gwynne Jones (DGJ), Consultant Orthopaedic Surgeon, Southern DHB; Associate Professor Orthopaedic Surgery Dunedin School of Medicine, University of Otago. A/P Gwynne Jones has research experience in epidemiology, aetiology and outcomes of upper limb orthopaedic conditions, orthopaedic pathway development and enhanced recovery protocols, and tendon injury outcomes. Time commitment 0.02 FTE.

Mr Michael Chin (MC), Consultant Orthopaedic Surgeon, Southern DHB; Senior Lecturer, Dunedin School of Medicine, University of Otago. Mr Chin has extensive clinical experience and research interest in surgery and rehabilitation of hand and upper limb conditions. Time commitment 0.01 FTE.

Joshua Woodside (JW), is a Senior Hand Therapist at Southern DHB with a special interest in extensor tendon injuries. Time commitment 0.01 FTE.

Funding:

This study is funded by a Healthcare Otago (HCO) Trust award, and a New Zealand Association of Hand Therapists (NZAHT) research grant.

Abstract:

Background

Relative motion extension (RME) splinting is a new method of rehabilitation for extensor tendon repair that is simpler and easier than the current well-established early mobilisation treatment of dynamic extension splinting, however to date no studies have directly compared the two.

Purpose

This study aims to compare range of motion and functional outcomes, patient adherence and satisfaction, and complication rates between groups at 6 and 12 weeks after surgery, and to compare the cost-effectiveness of the two treatment methods.

Method

Up to 38 consenting participants with extensor tendon repair in zones V and VI (on the back of the hand) involving up to three fingers will be recruited from the Dunedin Hospital Orthopaedic service and randomised to either RME or dynamic splinting. Participants will be partially-blinded by not revealing to them the study hypothesis in full; independent hand therapists blinded to group allocation will assess outcomes at 6- and 12 weeks. Differences in mean values between groups will be compared using regression analysis carried out at the 5% level of significance, following the intention to treat principle. Cost analysis will be on a health utility basis.

Discussion

A finding of significantly better outcomes and/or cost-effectiveness with RME will result in practise change locally and internationally. Information from this study will help to avoid unnecessary time off work and the associated loss of wages and productivity, minimise the cost and burden of splinting, and improve outcomes. The incidence of extensor tendon injury in zones V and VI of the hand appears to be higher in Māori and Pacific people and therefore findings of this study are likely to be of particular significance to this population.

Trial Registration:

It is intended to register this trial with the Australian New Zealand Clinical Trials Registry (ANZCTR)

Key words:

Extensor tendon injury

Splinting

Orthosis

Hand therapy

Randomised controlled trial

Cost utility

Background:

Division of the digital extensor tendons on the back of the hand over the MCP joints and the metacarpals (zones V and VI) is a common injury in working-age people which usually requires 6-12 weeks of restricted work duties (Bulstrode 2005, *Bűhler 2010). The most widely established method of rehabilitation following surgical repair is dynamic extension splinting (used at Dunedin Hospital) whereby a dynamic forearm based orthosis allows early motion while protecting the repaired extensor tendons. While this method of rehabilitation produces good outcomes, it is costly to implement, significantly limits function for the

duration of splint wear (ca. 6 weeks) and has low acceptability to patients. Other methods of rehabilitation have therefore been developed.

The relative motion extension (RME) technique is a new method which employs two components; a volar wrist cock-up orthosis, and a digital orthosis in the manner of a 'yoke'. Relative motion extension has been shown to be a safe and low-cost method of rehabilitation which appears to allow earlier return to function following extensor tendon repair in zones V and VI (Hirth 2011, Howell 2005). However no controlled comparison between RME and dynamic splinting has been conducted. This study proposes to compare effectiveness of RME and dynamic splinting for extensor tendon repair in zones V and VI in terms of functional outcomes and cost-effective analysis

Study objective

The primary objective of this study is to determine whether total active motion (TAM) using RME is non-inferior to that using dynamic splinting at 6 weeks post-surgery. Secondary objectives are to compare ROM between groups at 12 weeks, compare function and satisfaction between groups at 6 and 12 weeks, and compare strength, complications and cost utility between groups at 12 weeks.

Methods:

Study development

This study has been designed by a group of researchers with backgrounds as Physiotherapists/Hand Therapists, Orthopaedic Surgeons and Clinical Researchers with experience in treating extensor tendon injuries in the hand and in performing clinical trials.

Study design

This study has been designed as a pragmatic, assessor blinded and partial participant blinded parallel-group RCT with equal randomisation to assess the non-inferiority of a RME rehabilitation protocol versus a dynamic extensor protocol at the 6-week follow up. Measurements are collected at baseline, and at 6- and 12 weeks post-surgery. The protocol adheres to the SPIRIT 2013 Statement (Chan 2013), which defines standard protocol items for clinical trials, and the CONSORT guidelines for non-pharmacological interventions (Altman 2001, Boutron 2008). The study is designed to conform to the principles of the Declaration of Helsinki.

Setting

The study is being conducted in the Physiotherapy Outpatient Department Hand Clinic of a single small tertiary hospital in the South Island of New Zealand, at Dunedin Hospital in Dunedin. Four Hand Therapists with more than 3 years' specialist Hand Therapy experience will fabricate the splints and initiate the interventions. Ongoing rehabilitation will in most cases occur with one of the same four Hand Therapists. Some participants who reside in an outlying area will continue rehabilitation with a local Hand Therapist, or with a local Physiotherapist under the close supervision of a Hand Therapist, but will all return to Dunedin Hospital for study follow-up. Training will be provided to all therapists involved in study participants' care. Two independent, contracted Hand Therapists will be conducting the 6- and 12-week assessments at Dunedin Hospital. Training will be provided for the assessors.

Participants

We aim to recruit 38 participants who have undergone surgical repair of one or more of their extensor tendons in zone V or zone VI of either hand at Dunedin Hospital between March 2014 and September 2016, according to the inclusion and exclusion criteria (Table 1). Potential participants will be given a 'Patient information sheet and consent form' (Appendix 1) by their surgeon and invited to participate in the study. The recruitment and consent process is outlined in Figure 1. Participants will be consented to the study at an initial interview by the Principal Investigator or a Co-investigator.

In order to optimise retention and adherence to intervention protocols, participants will be provided with petrol vouchers in recognition of the costs of attending the two follow-up assessments. Petrol vouchers will be provided at the rate of $20 for each assessment attended. In addition, for participants who live more than 20 km from Dunedin Hospital and the follow-up assessment does not coincide with a follow-up Hand Therapy or Surgical appointment (and the participant is not eligible for ACC travel costs), petrol vouchers will be provided at the rate of 50c per km travelled.

Randomisation and allocation concealment

The randomisation schedule is prepared by Co-investigator (HA) and concealed in opaque envelopes opened in sequence. Following the consent process, the PI (MB) or Co-investigator (JW) will reveal group allocation according to the randomisation schedule, and will notify the treating Hand Therapy clinician via written notification to the Physiotherapy Outpatient office administration staff – who will place a notification on patients' files for the first appointment.

Blinding

It will not be possible to fully blind participants or treating clinicians to group allocation due to the nature of the study interventions – they differ significantly in appearance. However partial blinding of participants can be undertaken by not revealing to them the study hypothesis in

Table 1 Table of inclusion and exclusion

Inclusion criteria	Exclusion criteria
• Patients undergoing primary repair of the extensor tendon in zones V and/or VI of one or more digits at Dunedin Hospital.	• Complex multi-tissue injury e.g. unstable fracture; significant skin loss; concurrent flexor tendon repair; replantation or revascularisation.
• Simple division of 50% to 100% of the tendon as determined intra-operatively by the surgeon	• Extensor tendon repair to more than three digits
• Surgical repair suitable for early mobilisation.	• Extensor tendon repair to the thumb
• Able to provide written informed consent.	• Age under 16 years
	• Co-existing rheumatologic illness
	• Individual factors such as inability to adhere to the intervention or significant co-morbidity.

full. Information provided to participants will therefore be modified, and instruction given to the treating therapists and all health professionals and administration staff involved in participants care.

Outcome assessors will not be involved in participant care, and will be blinded to group allocation. Participants' splints will be removed prior to assessment and participants will be instructed not to volunteer information about their rehabilitation including splinting.

Training of research occupational therapists and physiotherapists

Training of the Occupational Therapist (OT) and Physiotherapist (PT) Hand Therapists who will fabricate splints and initiate the interventions will occur during a one hour session. Training of all OT and PT involved in participant care will consist of provision of written treatment guidelines (Appendix 2), and a 30 min telephone or face-to-face session.

Training of the two independent OT and PT Hand Therapists who will conduct follow-up outcome assessment will occur during a one hour session. During this session, assessors will be instructed to screen every completed questionnaire (QuickDASH, satisfaction survey, adherence and cost questionnaires, general health status questionnaire) for missing items while the participant is still present.

All training sessions will be repeated at yearly intervals until the study ends.

Intervention

NB the terms 'orthosis' and 'splint' are used interchangeably.

The interventions are summarised in the 'Flow diagramme of the study protocol' (Figure 1), and further detailed and illustrated in sections 2 and 3 of the 'Guidelines for treating clinicians' (Appendix 2).

Group one will undergo dynamic extensor splinting and rehabilitation, which is the current usual care delivered at Dunedin Hospital. Dynamic extensor splinting comprises a dorsal forearm based orthosis that positions the wrist in 30 degrees extension; the injured and adjacent fingers rest in MCP extension (0 degrees) in dynamic slings. For comfort patients are placed in a static volar extension orthosis for use at nighttime whilst sleeping. Treatment usually begins by Day 5 day after surgery; by Day 10 at the latest.

During Weeks 1 – 3 participants in Group one are instructed to actively flex the fingers at the MCP joints 30-40 degrees, allowing the extensor outrigger to passively return the MCP joints to 0 degrees. The participant is also instructed to actively flex and extend the IP joints as far as comfortable within the confines of the splint. The patient is instructed to perform these exercises 10 – 20 times each waking hour. During Weeks 3 – 6 MCP flexion is progressed by 10-20 degrees per week, unless an extensor lag appears. The patient is instructed to remove the dynamic orthosis to actively flex and extend the IP joints. The participant is also instructed to remove the dynamic splint and mobilise the wrist from neutral to extension in a tenodesis pattern 10 times every two hours. The dynamic orthosis is gradually weaned off for light activity from Week 4 and discontinued by Week 6. The static volar extension orthosis is continued at night for a further 2 weeks.

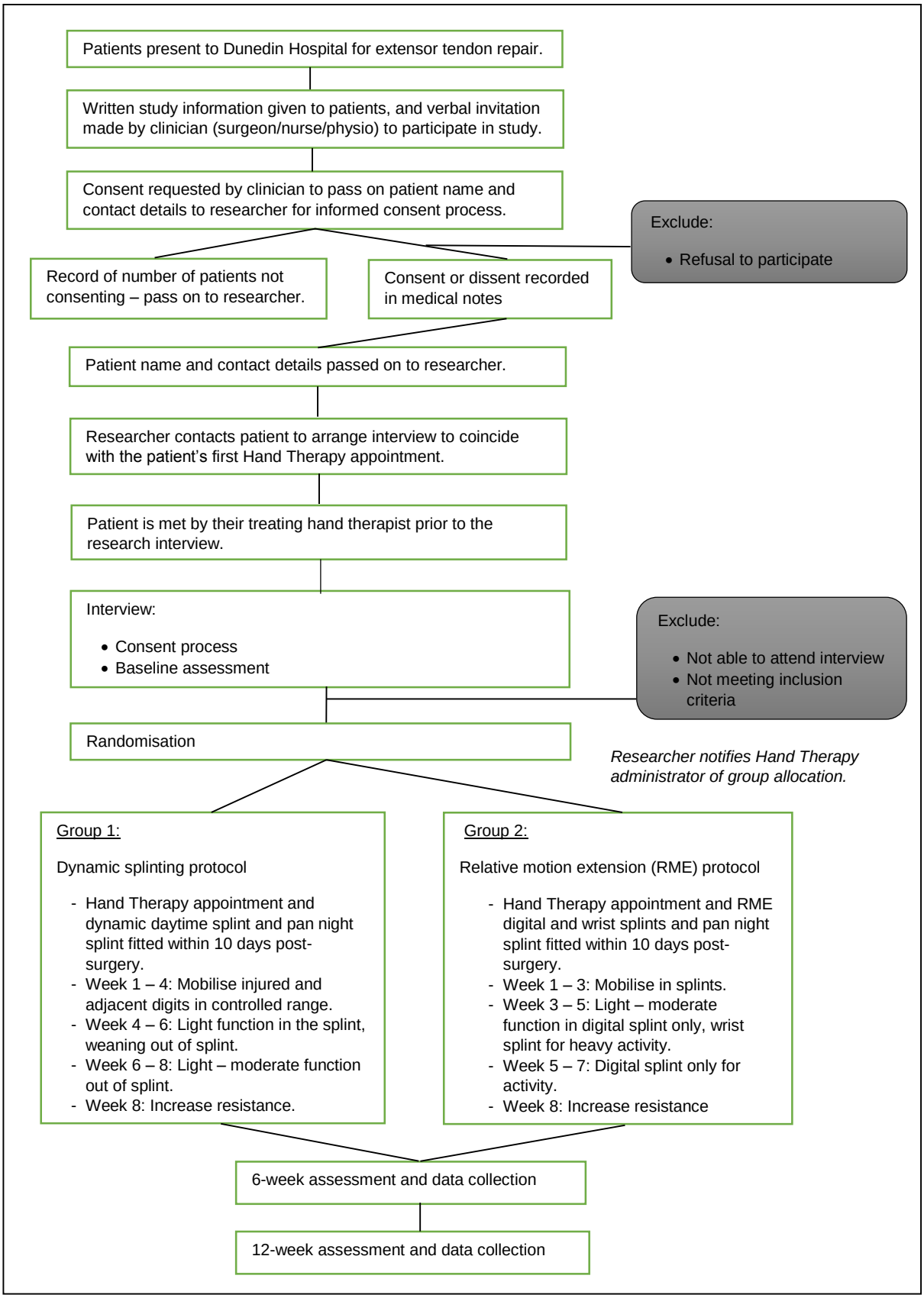

Figure 1 Flow diagramme of the study protocol

Group two will be treated with relative motion extension (RME) splinting and rehabilitation comprising a static finger-based orthosis and a static wrist orthosis. The finger-based orthosis places the injured digit(s) in 15 degrees relative extension, and is initially worn with the wrist orthosis which places the wrist in 10 – 15 degrees extension to further protect the repaired extensor tendon(s) and to control for the 'Yahoo Factor'. Patients mobilise in the splint(s) usually by 5 days post-surgery, by Day 10 at the latest, and can be functional with the splint(s) on. A volar static extension orthosis is fitted for nighttime.

During Weeks 1 – 3 participants in group two are instructed to actively flex and extend their fingers as far as they can within the confines of the orthoses. During Weeks 3 – 5 participants are instructed to remove the wrist component only and mobilise the wrist from extension to flexion in a tenodesis pattern 10 times every two hours. When full wrist range of motion is achieved, the wrist orthosis is discontinued for most of the time and only worn for heavy activity. During Weeks 5 – 7 participants are instructed to wear the finger orthosis only during activity and to remove the finger orthosis for active finger flexion and extension 10 times every hour. When full finger (active) range of motion is achieved, the finger orthosis is discontinued. The static volar extension orthosis is continued at night for a further 2 weeks.

At the first Hand Therapy appointment participants in both groups are educated about their injury and the rehabilitation process. Participants are informed about risks and precautions, and their consent gained to proceed with the early mobilization programme. Instruction is given regarding skin cares and splint hygiene, and safe methods of removing the splints for hygiene purposes. Wound care and oedema management are also undertaken. If any concerns or complications arise, the treating Orthopaedic Surgeon will be consulted.

Guidelines for OT and PT clinicians involved in participants' ongoing care are outlined in Appendix 2. Recommendations for the frequency and number of treatments are given, along with a list of considerations to be taken into account during the course of the interventions.

Adjunct treatments that may form part of standard management include oedema control, passive mobilisation, managing shoulder and neck posture, scar management, functional retraining, strengthening, and return to work/vocation are also described (see Appendix 2 section 4).

Outcome measures

The outcome measures consist of a combination of performance measures and self-reported instruments. Outcome measures are collected at 6- (primary endpoint) and 12 weeks post-surgery with the exception of patient adherence to splinting (measured at 6 weeks) and Grip strength (measured at 12 weeks) (Table 2). The number and type of complications are also collected at 12 weeks. Cost data is collected from participants at 6 and 12 weeks, and from clinical records at 12 weeks. Patient characteristic variables will be collected at baseline (Table 3). Data will be de-identified using a coding system and participants' information will remain confidential. Paper data will be stored securely in a locked file cabinet in an office in the Physiotherapy Outpatient Department, Dunedin Hospital. Digital data will be stored on a secure computer at the same location. All data will be kept for a minimum of 10 years. All investigators will have access to the final data set.

Table 2 Primary and secondary outcomes

Primary outcome measure:	**Measurement scale**	**Time***
Digital range of motion (Total Active Motion, TAM) (Kleinert 1983, Fess 2002)	Degrees *(mean of three measures);* category	6, 12
Secondary outcome measures:		
Patient-reported function (Quick Disabilities of the Arm, Shoulder and Hand, QuickDASH) (Beaton et al. 2005) (Appendix 3)	0-100	6, 12
Grip strength (JAMAR dynamometer)	Kilogram (best of three measures)	12
Return to *ordinary or modified* work (paid or un-paid) (Appendix 4)	Days post-surgery	6, 12
Patient-reported satisfaction (Satisfaction with Splinting, Treatment and Outcome) (Appendix 5)	0-5	6, 12
Patient adherence (Adherence to Splinting Questionnaire) (modified from Sandford et al. 2008) (Appendix 6)	Yes/No +/- frequency	6
Complications and further surgery (as recorded in medical records and reported by participant)	Type and number of events	12
Direct costs (Cost Questionnaire) (modified from Van den Brink 2005) ▪ Self-reported (Appendix 7): ○ Absence from work ○ Other health care utilisation e.g. visits to GP ○ Health insurer utilisation: visits to case manager, workplace assessment, gym programme. ○ Pharmacology use ○ Medical or technical equipment purchased to aid activities of daily living and/or work tasks ○ Costs for attending health appointments: distance travelled, transportation method, transportation costs, work absence, need for accompaniment ▪ From hospital records (Appendix 8) (costs based on current hospital fees for insured patients): ○ Orthosis fabrication ○ Hand Therapy / Physiotherapy / Occupational Therapy sessions ○ Review with surgeons ○ Additional surgical procedures ○ Investigations ○ Inpatient stay	 Number of days Number of visits (Type) Number of visits Self-reported Self-reported Self-reported Type and number of splints, total dollars Number of visits, total dollars Number of visits, total dollars Number of procedures, total dollars Number of procedures, total dollars Number of days, total dollars	 6, 12 12
Patient-reported health status (EuroQuol-5D-3L, EQ-5D-3L) (The EuroQol Group 1990) index value (Appendix 9)	0.0 – 1.0	6, 12

***0 = baseline, 6 = 6 weeks, 12 = 12 weeks**

Primary outcome measure

The primary outcome measure is digital range of motion as measured using a metal finger goniometer and calculating ***total active motion (TAM)*** ([active flexion of MCP + PIP + DIP] – [extension lag of MCP + PIP + DIP]) (Kleinert 1983). The mean of three measurements will be recorded using the dorsal method. A clinically significant difference for TAM has not been established in the literature. A trial by Mowlavi et al (2005) found a statistically significant difference of 16% at 6 weeks between dynamic extension splinting (239 ± 22) and immobilization (206 ± 53). This is plausably a clinically significant difference as

Table 3 Participant characteristic variables

Participant characteristic variable:	Measurement scale	Time*
Age	Years	0
Gender	Male/Female	0
Ethnicity	European (Pakeha)/Māori/Pacific Island/Asian/Other European	0
Pre-injury work status	Working full time/working part time/not working/student/ working full-time in the home/unemployed or seeking work/ age retired/disability pension/sick leave	0
Hand dominance	Left/Right	0
Date of injury	Day/Month/Year	0
Mechanism of injury	Sharp/blunt/pugilent/crush	0
Involved digit(s)	Index/Middle/Ring/Little	0
Previous tendon or other injury on the involved or contralateral uninjured hand.	Yes/No, type, digit(s), hand	0
Other medical conditions (RA, OA, diabetes)	Type	0
Smoking status	Smoker/Non-smoker	0

***0 = baseline, 6 = 6 weeks, 12 = 12 weeks**

immobilization is assumed to be an inferior treatment compared with either splinting option, thus is appropriate for use as an inferiority boundary.

Secondary outcome measures

The 11-item ***Quick Disabilities of the Arm Hand and Shoulder (QuickDASH) questionnaire*** (not including the optional work or sports/performing arts modules) is a patient-rated instrument that asks participants to rate their symptoms and their ability to perform certain every-day activities on a 1 to 5 scale where 1 = no difficulty/symptoms, and 5 = unable/severe (Appendix 3). The QuickDASH is a shortened version of the original 30-item DASH and has been found to retain the measurement properties of the full DASH (Beaton 2005, Wong 2007). QuickDASH score has been found to correlate well that of the full DASH (Abramo et al. 2008, Aasheim 2013). Scores can range from 0 to 100 where 0 = no disability and 100 = maximum disability. Minimal clinically important difference (MCID) for the QuickDASH has been determined to be 14 points (Sorensen 2013).

Grip strength (kilograms of force [kgF]) is measured using a Jamar dynamometer set at the standard second setting (Mathiowetz 1985), and recording the best of three attempts (Buhler 2007).

The number of days until ***return to* ordinary *or* modified *work*** (paid or un-paid) is self-reported by participants by completing the 'Patient-reported days to return to work' questionnaire comprising two questions in two parts requiring yes/no and time-to-event responses (Appendix 4).

A self-reported questionnaire 'Satisfaction with splinting, treatment and outcome' was developed to measure ***patient satisfaction*** (Appendix 5). The questionnaire comprises three questions requiring response on a 6-point Likert scale.

Patient adherence to splinting is measured using a self-reported questionnaire 'Adherence to splinting' which consists of five questions requiring yes/no and number of event responses (modified from Sandford et al. 2008) (Appendix 6).

Data regarding ***complications*** and further surgery are collected from Hand Therapy and Orthopaedic medical records.

Direct costs information will be collected from participants using a self-reported questionnaire modified from a previously tested patient-reported cost questionnaire (Van den Brink 2005) (Appendix 7). The questionnaire asks the participant about the number of sick leave days and absence from non-paid work, healthcare utilisation, any medication taken for the injury as well as any medical or technical devices bought to assist performance of activities of daily living or work tasks, and costs associated with attending appointments (i.e. distance travelled, transportation method, public transportation cost if applicable, work absence or travel escort). Cost data will also be collected from hospital records (medical and IPM records relevant to the extensor tendon injury) using a cost data collection form (Appendix 8).

Self-reported health status will be evaluated using the ***EuroQol-5D-3L (EQ-5D-3L)***, a widely-used standardised self-report questionnaire consisting of five multiple choice questions and a visual analogue scale that evaluate five dimensions of health status; mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (The EuroQol Group 1990) (Appendix 9).

Patient characteristic variables

Demographic variables including work history, injury details, and health status data will be collected from the participant at the initial interview prior to the participants first Hand Therapy appointment (baseline) (Table 3).

Statistical analysis

Data analysis

Participant characteristic variables will be presented to assess the baseline comparability of the two groups. Descriptive statistics will be presented for each group with the mean value (standard deviation, 95% confidence interval) for outcomes at each time point. As the outcome of multiple extensor tendon repairs in one hand cannot be considered as independent observations, the mean TAM scores for patients (rather than for individual digits) will be calculated and compared between the two groups. Differences in mean values between groups will be compared using regression analysis, carried out at the 5% level of significance. Primary analysis of the data will follow the intention to treat principle and will include all participants, including those who have missing data and who are not fully adherent to the protocol. The handling of missing data will be through the use of the multiple imputation method. Values for TAM will also be reported according to Miller's classification as 'Excellent', 'Good', 'Fair' or 'Poor' (Miller 1942) (Table 4).

Table 4 Millers classification for extensor tendon injuries

	Total extensor lag (degree)	Total flexor loss (degree)
Excellent	0	0
Good	10 ≥	20 ≥
Fair	11 – 45	21 – 45
Bad	> 45	> 45

Cost analysis

Cost analysis will include both health system and societal resource costs (Table 2). The primary economic evaluation will be a cost-utility analysis based on EQ-5D-3L score index value.

Sample size

A clinically significant difference for TAM has not been established in the literature. A trial by Mowlavi et al (2005) found a statistically significant difference of 16% at 6 weeks between dynamic extension splinting (239 ± 22) and immobilization (206 ± 53). This is plausably a clinically significant difference as immobilization is assumed to be an inferior treatment compared with either splinting option, thus is appropriate for use as an inferiority boundary. Assuming 16% difference in TAM is clinically significant, this requires a sample size of 17 participants per group to give 90% power using 1-sided p-values significant at the 5% level, appropriate for a primary non-inferiority and secondary superiority research question (Haynes 2006). This is a conservative estimate, as immobilization typically has greater variability (SD) than either splinting option. Allowing for a plausible drop-out of 20%, this equates to 19 participants in each group or a total of 38 participants.

Time schedule

Year 1: 1.1 Completed design, ethics, equipment and stationary. **Year 1/2/3:** 1.2 Completed recruitment and data collection. **Year 3:** 1.3 Completed analysis of data and cost-effectiveness evaluation, dissemination of results.

Ethics

This study will be conducted according to good clinical practise, and is in compliance with the Declaration of Helsinki. The study is being submitted for approval to the Lower South Regional Ethics Committee and the Southern District Health Board Health Research office. Any important protocol modifications will be communicated to all relevant parties in writing. Specific ethical considerations of this study include ensuring that the patient's first point of

contact on attendance at the locality (Dunedin Hospital Physiotherapy Outpatient Department) is with the patient's treating clinician (Hand Therapist). The health organisation's (Southern DHB) duty of care can thus be established. A second consideration is the potential conflict of interest of the dual roles of researcher and treating clinician for MB and JW. This will be managed by ensuring that where MB is the treating clinician JW will conduct the informed consent process and baseline interview, and vice-versa. Any sense of obligation to participate in the study on the part of the patients will therefore be avoided.

Internal data monitoring committee

An internal data monitoring committee (DMC) comprising the Principal Investigator (MB) and two of the Co-investigators (HA and DGJ) will meet yearly to review trial data on safety, efficacy and trial conduct. These researchers have clinical and biostatistical experience in clinical trials, and DGJ is an Orthopaedic Surgeon.

An internal rather than an independent DMC is appropriate for this study because,

- The intervention is low-risk
- Previously published case series indicate good clinical safety with no concerns regarding potential serious adverse events.
- The study does not include vulnerable populations
- The study intervention is not carried out in the emergency setting

Criteria for terminating the study intervention:

Where data indicate differences in outcomes are more than twice the inferiority threshold (greater than 32%) or complication rates of a particular kind e.g. tendon re-rupture are more than twice those of the control group at 1 year or thereafter.

Notification of adverse events

In addition to information regarding complications collected from medical notes at 12-weeks, treating clinicians, as well as researchers and assessors, will be instructed to inform the Principal Investigator (MB) or Co-investigator (JW) immediately of any complications or adverse events that occur in relation to participants' injury or treatment. Notification of complications and adverse events will be recorded in a tabulated register, and reviewed alongside the 12-week 'complications and further surgery' data, and the 6- and 12-week data sets for all study outcomes.

Expected health outcomes and population benefits:

Extensor tendon injury in zones V and VI of the hand is a complex injury that occurs mainly in working-age people and uses a disproportionate amount of health and societal resource. This study protocol aims to compare the outcomes, effectiveness and cost-effectiveness of dynamic splinting and RME rehabilitation regimes for extensor tendon injury through controlled trial. These two regimes have not previously been directly compared, hence a high quality randomised trial is warranted.

A finding of significantly better outcomes and/or cost-effectiveness with RME will result in practise change with the RME regime being adopted by Dunedin Hospital. Findings may

also change practise nationally and internationally. Information from this study will help to avoid unnecessary time off work and the associated loss of wages and productivity, avoid the costs of fabricating and fitting splints that are unnecessarily complicated and functionally limiting, improve outcomes and reduce treatment burden for patients.

The incidence of ET injury in zones V and VI of the hand appears to be higher in Māori and Pacific people compared to New Zealanders of other ethnic origin (*Bűhler 2010). Extensor tendon injuries are likely to be of greater significance to Māori and Pacific people due to the impact these injuries have on work capacity especially for those in manual jobs.

Dissemination of research findings:

Research findings will be disseminated through oral presentation to NZAHT and NZOA conferences, and submission of article to Journal of Hand Therapy and/or Journal of Hand Surgery. Participants will be informed of the study findings by a short written report mailed out.

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List of Appendices:

Appendix 1: Participant information sheet and consent form

Appendix 2: Guidelines for study clinicians

Appendix 3: QuickDASH questionnaire

Appendix 4: Participant questionnaire – patient-reported days to return to work

Appendix 5: Participant questionnaire – satisfaction with splinting, treatment and outcome

Appendix 6: Participant questionnaire – adherence to splinting

Appendix 7: Data collection sheet – surgical management and complications

Appendix 8: Participant questionnaire – patient-reported cost

Appendix 9: Data collection sheet – hospital records cost

Appendix 10: EQ-5D-5L questionnaire

Appendix 11: Data collection sheet – baseline interview