Extensor Tendon Randomised Controlled Trial

Appendix 2: Guidelines for study clinicians

Southern District Health Board

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1. Study Outline

Division of the digital extensor tendons (ET) on the back of the hand over the MCP joints and the metacarpals (zones V and VI) (Figure 1) is a common injury in working-age people which usually requires 6-12 weeks of restricted work duties (Bulstrode 2005, *Bűhler 2010). Dunedin Hospital currently uses a widely accepted method of rehabilitation following extensor tendon repair 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 static extension 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 ET 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 the effectiveness of RME and dynamic splinting for ET repair in zones V and VI in terms of functional outcomes and cost-effective analysis.

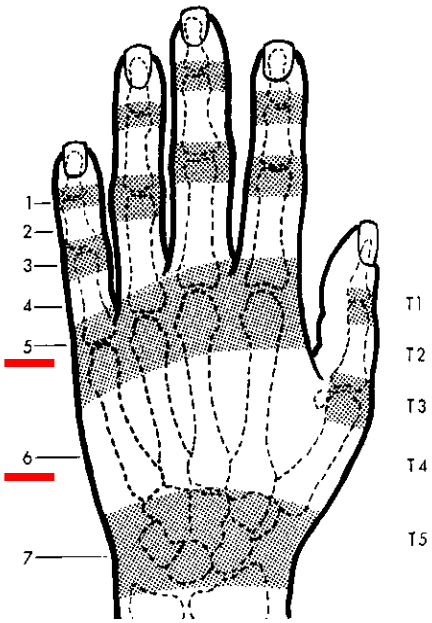

Figure 1 Extensor tendon zones in the hand

Participants will be recruited through the Dunedin Hospital Emergency Department following an ethically approved recruitment and consent process, and randomised to either Dynamic Extension group or RME group. Initial Hand Therapy and splint fabrication will in most cases occur at Dunedin Hospital, however due to distance may take place at a local Hand Therapy clinic. Ongoing Hand Therapy treatment should then continue as per normal, guided by the study protocols outlined in this document, depending on group allocation.

Ongoing rehabilitation will in most cases occur with the same Hand Therapist, or with a local Physiotherapist under the close supervision of a Hand Therapist. All participants will return to Dunedin Hospital at 6 and 12 weeks for assessment by an independent Hand Therapist

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 unless asked as part of the assessment. Participants will be provided with petrol vouchers towards the cost of travelling to and from the two follow-up assessments, at the rate of $20 for each follow-up for participants who live 20 km or less from Dunedin Hospital and at the rate of 50c per km for participants who travel more than 40 km in total to attend the follow-up session(s).

Training will be provided to all therapists involved in study participants' care. Training of the OT and PT Hand Therapists who will fabricate splints and initiate the interventions will occur during a one hour session. Training of all OT and PT Therapists involved in participant care will consist of provision of these written treatment guidelines, and a 30 min telephone or face-to-face session.

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. 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.

As far as practical, **please do not reveal the study hypothesis to participants.**

If participants have questions regarding the study, please refer them to the study Principal Investigator or Co-investigator (contact details at the end of this document).

Thank you for your participation in this study. Please do not hesitate to contact us if you have any further questions or concerns at any time.

<u>Overview of treatment:</u>

During the first Hand Therapy appointment participants in both groups are educated about their injury and the rehabilitation process. Participants will be informed about risks and contraindications, and their consent gained to proceed with the early mobilisation programme they are allocated to. Instruction will be given regarding skin cares and splint hygiene, and safe methods of removing the splints for hygiene purposes only and donning and doffing splints. Wound care and oedema management will also be undertaken.

The early mobilization programmes are outlined in sections 2 and 3 of these guidelines. Adjunct treatments described in section 4. will commonly form part of the treatment plan. It is recommended that patients attend for therapy appointments weekly for the first three weeks, then weekly or fortnightly as indicated, until discharged.

If any concerns arise, the treating Orthopaedic Surgeon should be consulted.

1) Early identification of any complications
   a. The most significant complication is re-rupture of the extensor tendon and this should be brought to the attention of the treating Orthopaedic Surgeon as soon as possible, or if the Surgeon cannot be contacted the patient should be directed to the Emergency Department.
   b. The most common complication following extensor tendon repair is limitation of composite finger flexion usually as a result of scar adhesion, MCP capsular tightening, and/or swelling.

c. Extensor lag may also be detected – in this case the duration of dynamic extension or RME splinting should be extended by 1 – 2 weeks. Note that in some cases extensor lag is caused by scar adhesion which would benefit from greater and more frequent composite flexion ROM.

We ask that you inform the Principal Investigator (MB) or Co-investigator (JW) (see contact details in section 5) 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 yearly as part of a data monitoring process alongside the 12-week 'complications and further surgery' data, and the 6- and 12-week data sets for all study outcomes.

2. Dynamic extension protocol

The SDHB dynamic extension protocol is modified from Evans 2002. It is designed to deliver 5 mm of tendon excursion at the repair site which is considered necessary to gain the benefits of early mobilization. The primary goals of a dynamic protocol are: 1) to control early collagen deposition, 2) facilitate biochemical events that strengthen the repair site, and 3) avoid complications associated with adhesion formation, gapping or re-rupture of the repair site (Evans, 2012).

With the wrist and MP joints fully extended, IP joint motion effects minimal extensor tendon excursion, and the IP joints can be moved through a complete range of motion without creating excessive stress or gapping.

A dynamic extensor orthosis positions the wrist in 30 degrees extension to relieve stress at the repair site. The fingers rest in MCP extension in dynamic slings. For comfort patients are placed in a static volar extension splint for use at nighttime whilst sleeping. Treatment usually begins by Day 5 after surgery; by Day 10 at the latest.

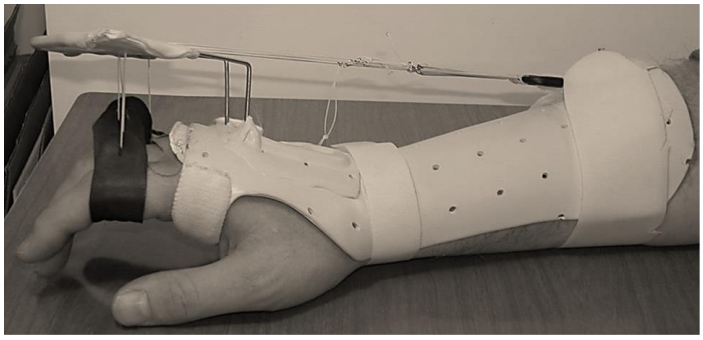

Figure 2 Dynamic extension orthosis

<u>Exercises Week 1 – 3:</u>

1. The patient is instructed to actively flex the finger at the MCP joints 30-40 degrees, allowing the extensor outrigger to passively return the MCP joints to 0 degrees. The patient is instructed to perform this exercise 10 – 20 times each waking hour.

2. The patient is 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 this exercise 10 – 20 times each waking hour.

<u>Exercises Week 3 – 6:</u>

1. Exercise 1. above is progressed by 10-20 degrees per week, unless an extensor lag appears.

2. The patient is instructed to remove the dynamic orthosis to actively flex and extend the IP joints as far as comfortable (Figure 3).

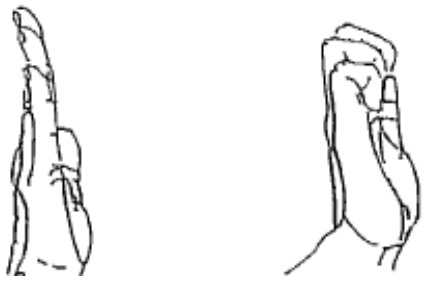

Figure 3 Active IP joint flexion and extension performed out of the dynamic orthosis

3. The patient is instructed to remove the dynamic splint and mobilise the wrist from neutral to extension in a tenodesis pattern. The patient is instructed to perform this exercise 10 times every two hours.

Figure 4 Tenodesis pattern

2.ii SDHB **Dynamic Extension Protocol**

Stage		Considerations
Week 1 – 3		• Patient compliance • Strength of repair • Skeletal stability • Concomitant injuries • Loss of tendon length • Zone of injury • Wound • Bulky dressings • Oedema • Pain • Pulley status • Scar • Sensibility • Early mover or prolific scarring? • Work demands • Adhesions
	Post-op dressings reduced Dynamic extension orthosis fabricated Night resting pan orthosis fabricated Active MCP flexion to 30 - 40 degrees; assisted extension Full active IP ROM within the confines of the splint Splint worn at all times	
Week 3 – 4		
	Remove dynamic orthosis for wrist ROM exercises Resume light functional activities in the dynamic orthosis	
Week 4 – 6		
	Dynamic orthosis gradually weaned off Aim for composite finger flexion	
Week 6 – 8		
	Dynamic orthosis is discontinued Night resting pan orthosis is continued further 2 weeks Aim for full composite wrist and finger flexion Return to light – moderate work duties	
Week 8 – 12 (max 4 months)		
	Increase resistance Prepare for return to full work/sport loading requirements	

3. Relative motion extension (RME) protocol

3.i. Background

The relative motion extension (RME) orthosis, also known as the 'yoke' or ICAM' has been described for controlled motion following surgical repair of 'simple' division of the extensor tendon in zones IV to VI (Merritt & Howell 2005, Hirth 2011). Cadaver study shows that if the injured digit(s) are held in relative extension, there is no gapping at the repair site, even with no suture (Minamikawa 1992). It is thought that the RME orthosis harnesses the extension forces of the juncturae tendinae and adjacent uninjured digit(s), unloading the tendon repair (Howell 2005) (Figure 5).

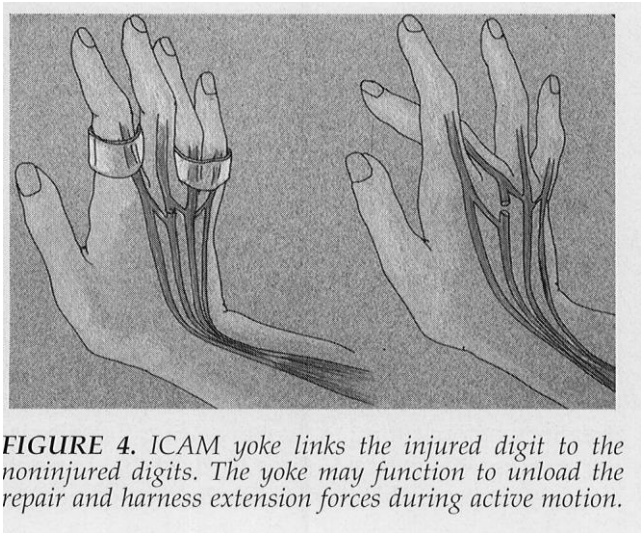

FIGURE 4. ICAM yoke links the injured digit to the noninjured digits. The yoke may function to unload the repair and harness extension forces during active motion.

Figure 5 From Howell (2005)

The finger based component places the injured digit(s) in 15 degrees relative extension and is initially worn with a wrist splint in 10 – 15 degrees extension to further protect the repaired extensor tendon(s) (Figure 6) and to control for the 'Yahoo Factor'. Patients mobilise in the splint(s) by 5 days post-surgery (by Day 10 at the latest) and can be functional with the splint(s) on.

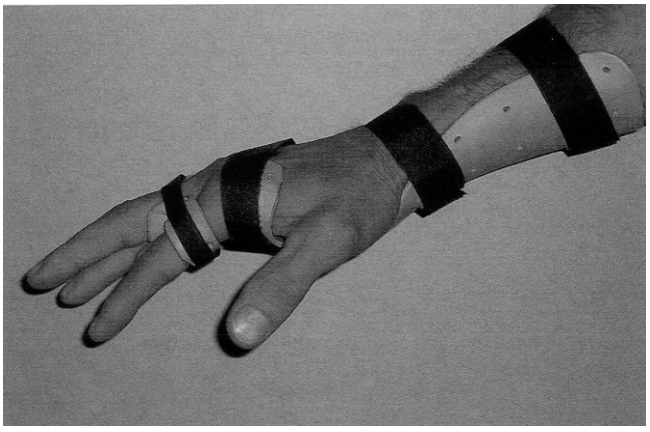

Figure 6 Relative motion extension (RME) splinting finger and wrist components for the right middle finger at Week 1 - 3. From Howell et al. (2005)

A volar static extension orthosis is worn at night until 7 weeks post-surgery.

Exercises Week 1 – 3:

1. Participants are instructed to actively flex and extend their fingers as far as they can within the confines of the orthosis.

Exercises Week 3 – 5:

1. 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.

Exercises Week 5 – 7:

1. Participants are instructed to wear the finger component only during activity, and to remove the 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.

In one long case series RME has been used following extensor tendon repairs for 33 years with no reported rupture or need for corrective surgery (Howell 2005). Patients were usually discharged following six or fewer visits. In the protocol reported by Howell (2005) the same splints are worn day and night, however our RME study protocol will include a volar static extension orthosis worn at night until 7 weeks post-surgery.

The RME protocol requires at least one finger with EDC intact. Therefore patients with extensor tendon repair to all four digits will be excluded from the study.

3.ii. SDHB **Relative Motion Extension** Extensor Tendon Protocol (Zones V & VI)

Stage		Considerations
Week 1 – 3		• Patient compliance • Strength of repair • Skeletal stability • Concomitant injuries • Loss of tendon length • Zone of injury • Wound • Bulky dressings • Oedema • Pain • Pulley status • Scar • Sensibility • Early mover or prolific scarring? • Work demands • Adhesions
	Post-op dressings reduced Finger and wrist RME orthoses fabricated Full active finger flexion and extension within the confines of the splint. Light functional activities in the splint Wear both components of the splint at all times	
Week 3 – 5		
	Wear the finger component at all times Remove wrist component for wrist ROM exercises When wrist is moving freely, discontinue the wrist component for light functional activities. Add wrist component for moderate – heavy activity Return to work light – moderate duties	
Week 5 – 7		
	Wrist splint is discarded Continue finger component for activity Remove finger component for ROM exercises Aim for full composite wrist and finger motion out of splints	
Week 8 – 12 (max 4 months)		
	Increase resistance Prepare for return to full work/sport loading requirements	

4. Adjunct treatments

2) Oedema control
   a. Oedema may be a problem in the hand, in the wrist or in the digits. Swelling usually disperses once gentle movement is started, however if swelling is significant and/or persistent it should be addressed early on.
   b. Key methods of oedema control are:
      i. Elevation of the hand above the heart, preferably with the elbow straight – e.g. resting the arm up on the back of the couch, on a pillow on the table, or on a pillow when lying down.
      ii. Repeatedly raising the arm up above the head – this creates a pumping effect on the lymphatic system, as well as conferring the benefits of elevation. Having the arm swing by the side while walking also aids normal lymphatic flow, but may only be tolerated for short periods.
      iii. Regular ROM exercises, per the protocols above (Sections 2 and 3), helps to pump swelling away.
   c. Additional methods of oedema management:
      i. Compression: Options included tubigrip, an 'isotoner' oedema glove (e.g. Surgical Synergies or Auckbritt), lycra or tubigrip finger sleeves (sewn - fabric from Spotlight) or a 'coban glove' – either for the whole hand or just single digits. Care should be taken to maintain wrist and finger extension when applying the compression.
      ii. Manual oedema massage (MEM): This is a light stroking effleurage type massage working proximal to distal including lymph node stimulation in order to 'clear' the limb. The patient can be taught to carry this out at home.
3) Passive mobilisation of digits
   a. This can be added to the patient's home exercise programme if AROM is not meeting the ranges described in the protocols above (Sections 2 and 3).
4) Monitor/manage posture to prevent shoulder and neck pain.
5) Scar management
   a. Desensitisation of hypersensitive scars
      i. Graded desensitisation – rubbing lightly beginning with soft texture or skin-to-skin, progressing to textures such as cotton fabric and towelling.
      ii. Sensory reintegration e.g. in bowl of rice
      iii. Mirror therapy or mental imagery
   b. Regular massage and moisturising to improve pliability
   c. Hypafix or Micropore tape is a useful first-line 'contact media' for hypersensitive or raised or thickened scars.
   d. Silicone gel products – contact the Dunedin Hospital Hand Therapy team.
6) Functional retraining
   a. Step down splint support per protocols above (Sections 2 and 3) – use intermittently for support and positioning
   b. Encourage normal movement patterns, include bimanual activities, as guided by protocols above (Sections 2 and 3)
      i. Picking up a handful of beads, putting down one at a time with thumb and index finger

ii. Using cutlery
iii. Lifting and pouring a half full jug, then full jug

7) Strengthening
   a. As guided by protocols above (Sections 2 and 3)
   b. Wrist extensors are key to power grip
   c. Aim for stability about the wrist – co-contraction of the forearm muscles while strengthening more proximally.
   d. General fitness & strength – lower limbs for lifting etc.
8) Return to work/vocation
   a. Recommended grip strength for return to work (RTW)/sport/vocation
      i. Do not test before 7 weeks post-tendon repair
      ii. Approximately 70% for return to heavy manual work
      iii. Approximately 50% for return to moderate tasks
      iv. Quality of movement patterns rather than grip strength is of greatest importance for return to light duties.
      v. 10 kgF is a good goal with regard to achieving light activities of daily living (ADLs).
      vi. Nb the dominant hand is often around 10%-20% stronger than the non-dominant hand, although this depends on the type of work usually undertaken. An educated 'guess' at normal should be made based on grip strength of the contra-lateral uninjured hand and patient's manual history.
      vii. Grip strength is tested with a dynamometer, setting usually on (2), held with the elbow at 90 degrees, shoulder slightly abducted. Record the best of up to three attempts.

5. Study contact details

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