Can Relative Motion Extension Splinting (RMES) Provide an Earlier Return to Function than a Controlled Active Motion (CAM) Protocol?

A Randomised Clinical Trial

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MHSc

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Faculty of Environmental and Health Sciences

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Abstract

Various active mobilisation protocols are used after repair of extensor tendons in zone V and VI. These include relative motion extension splinting (RMES) and controlled active motion (CAM) protocols. Similar outcomes are reported for most early active mobilisation protocols, however reports on RMES protocols suggest a possible earlier return to work and functional use of the affected hand. To date no published prospective trials have compared the RMES to other early active mobilisation protocols. This randomised clinical trial prospectively investigated whether patients with extensor tendon repairs in zone V and VI managed with an RMES protocol would return to functional use of the hand sooner than those managed with an extensor CAM protocol.

Between January 2015 and February 2016, 42 participants who had undergone extensor tendon repair in zone V and/or VI were recruited to the study. They were randomised into two groups: one group was treated using a CAM protocol, the other an RMES protocol. Participants were reviewed at four and eight weeks post-operatively. The primary outcome was the Sollerman Hand Function Test (SHFT) score. Secondary outcomes included: days to return to work, total active motion (TAM), grip strength the QuickDASH (Disabilities of Arm, Shoulder and Hand) questionnaire and participant satisfaction. Complications were recorded.

The RMES group demonstrated significantly better results than the CAM group at four weeks with regard to the SHFT mean score (p=0.0073), the QuickDASH score (p=0.77) and TAM (p=0.008). At eight weeks the RMES group continued to show better results than the CAM group for TAM (p=0.030), but there was no difference between groups for the SHFT and QuickDASH scores. Median days to return to work were similar between groups with RMES group 20 days (Interquartile range [IQR]: 12, 57) and CAM 18 days (IQR: 6, 55), (p=0.77). There was no significant difference between groups with regard to grip strength at eight weeks. RMES participants reported a significantly higher level of satisfaction with the splint than the CAM group (p<0.0001). No tendon ruptures occurred in either group. One RMES participant underwent tenolysis surgery and there was no significant difference in complication rates between groups.

This is the first randomised clinical trial to prospectively compare an RMES protocol to a CAM protocol. Participants treated with an RMES protocol demonstrated better early return to functional use of the hand than those treated with a CAM protocol, and RMES participants continued to show better range of motion than CAM participants at eight weeks. RMES participants were also more satisfied with splinting than CAM participants. There was no difference in return to work timeframes, possibly due to factors outside the control of the study. No ruptures occurred in either group, complication rates were low and not significantly different between groups. This study has demonstrated that an RMES protocol provides an earlier return to hand function than a CAM protocol for patients who have undergone extensor tendon repair in zone V and VI.

Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

09/06/2017

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Ethical approval for the study was obtained from the Southern Health and Disability Ethics Committee (14/STH/164) on 5 November 2014 and from Auckland University of Technology Ethics Committee (14/377) on 18 November 2014.

Chapter 1 Introduction & Background

1.1 Introduction

1.1.1 Statement of the problem

Tendons are the mechanism by which muscles act on the bones of the hand to produce complex, co-ordinated patterns of motion, enabling hand function (Van Kampen & Amadio, 2012). Tendon lacerations are common; the current study was carried out at Counties Manukau Health (CMH), the tertiary regional centre for hand injuries in Auckland, New Zealand. At this centre approximately 3000 acute hand/upper limb surgeries are performed annually, and over 800 of these involve injuries to tendons (CMH, 2016).

Significant lacerations to tendons are usually repaired surgically and the repair needs to be strong enough to prevent failure and rupture (Tang & Xie, 2012). The biological process by which tendons heal may result in the formation of adhesions of tendon to the surrounding tissue; this restricts the ability to glide relative to the neighbouring tissues (Amadio, 2012) and may require surgical release by means of tenolysis. The ability of the tendon to glide relative to the surrounding structures must be restored in order to regain normal function of the hand (Pettengill & Van Strien, 2011). The restoration of tendon glide by controlling the formation of restrictive adhesions, while avoiding tendon rupture, is the primary goal of rehabilitation after tendon repair (Evans, 2011).

Extrinsic tendons of the hand consist of flexor tendons which enable grip and extensor tendons which enable release (N. Pratt, 2011). Extensor tendons are situated close to the skin and are therefore easily lacerated (Amirtharajah & Lattanza, 2015). An epidemiological study of patients with extensor tendon injuries found that laceration was the most common mechanism of injury, with the metacarpophalangeal (MCP) joints the most common location of injury (Patillo & Rayan, 2012). In their study 83% of those who sustained injuries were male, the average age was 34.2 years and the dominant hand was most commonly injured (Patillo & Rayan, 2012). The young, predominantly male patients who sustain these injuries are frequently manual workers

(Hall, Lee, Page, Rosenwax, & Lee, 2010; Hirth et al., 2011; Patil & Koul, 2012; Svens, Ames, Burford, & Caplash, 2015).

The primary role of extensor muscles, of which the extensor tendons provide the distal attachment, is opening of the hand and positioning of the digits in space (N. Pratt, 2011). The extensor muscles are relatively small muscles, when compared to the flexor muscles, and are able to exert approximately half of the strength of flexor muscles (Sammer & Chung, 2009). Poor management of extensor tendon injuries can lead to a loss of the ability to extend the digits, however it may also lead to a loss of flexion of the injured digits thereby affecting the ability to form a fist and powerful grip (Newport & Tucker, 2005). The loss of the ability to form a strong grip with the dominant hand has significant implications for return to work and other activities; optimal management of these injuries is therefore important for these patients and their communities.

Extensor tendons tend to act on individual joints and are anchored along their course (N. Pratt, 2011). They are divided into zones from zone I at the fingertip to zone VII at the wrist; the tendon anatomy changes significantly over these zones which leads to the need for different rehabilitation protocols depending on the location of the tendon laceration (Kleinert & Verdan, 1983). Rehabilitation protocols designed for extensor tendon repairs should take into account the unique structure and function of these tendons; they also need to be specific to the zone of the repair. The focus of the current study was on tendon repairs in zones V and VI, over the MCPs and dorsum of the hand, where extensor tendons are most commonly lacerated (Patillo & Rayan, 2012).

Most authors currently advocate the use of early controlled mobilisation within the first three to six weeks after extensor tendon repair in zones V and VI to achieve the goals of protecting the repair and controlling formation of adhesions (Canham & Hammert, 2013; Evans, 2012; Howell & Peck, 2013; Newport & Tucker, 2005). Early controlled mobilisation protocols make use of splints to protect the repaired tendon while allowing some motion of the hand to promote tendon glide (Howell & Peck, 2013). These protocols can be grouped into those that allow early active motion (EAM) of the repaired tendon and those that allow early passive motion (EPM) of the repaired

tendon (Hammond, Starr, Katz, & Seiler, 2012; Ng et al., 2012; Pettengill, 2005; Talsma, de Haart, Beelen, & Nollet, 2008). Systematic reviews of rehabilitation after extensor tendon repair (Ng et al., 2012; Sameem, Wood, Ignacy, Thoma, & Strumas, 2011; Talsma et al., 2008) have concluded that there is insufficient evidence to determine whether EAM or EPM protocols provide superior outcomes. However some authors advocate for the use of EAM protocols due to possible lower complication rates (Hammond et al., 2012) and simplicity of fabrication (Chester, Beale, Beveridge, Nancarrow, & Titley, 2002; Hall et al., 2010; Khandwala, Webb, Harris, Foster, & Elliot, 2000). There is currently no consensus regarding the optimal rehabilitation protocol for rehabilitation after extensor tendon repairs in zones V and VI (Ng et al., 2012; Sameem et al., 2011; Talsma et al., 2008). At the commencement of the current study, CMH used an EAM protocol known as a controlled active motion (CAM) protocol for rehabilitation of patients with repairs of extensor tendon tendons in zone V and VI. An audit conducted in 2009 had shown that patients treated with a CAM protocol at CMH had achieved comparable results to those reported in literature, with 100% of patients achieving good or excellent ROM (Edwards, 2009). However the results of some studies (Hirth et al., 2011; Howell et al., 2005) suggest that another type of EAM protocol, relative motion extension splinting (RMES), may provide an earlier return to functional use of the hand.

1.1.2 Purpose and aims

The purpose of this research was to compare two EAM protocols for participants who had undergone extensor tendon repairs in zone V and/or VI. The design was a randomised clinical trial. The protocols compared were a CAM protocol and an RMES protocol.

Primary aim:

To compare activity limitations between the two groups of participants, those treated with a CAM protocol compared to those treated with an RMES protocol, measured by the Sollerman Hand Function Test (SHFT) score at four and eight weeks post-operatively.

Secondary aims:

1. To compare the two groups of participants (CAM versus RMES protocol) with respect to:
    a. Participation restrictions assessed by
        i. The Quick Disability of Arm, Shoulder and Hand (DASH) questionnaire at four and eight weeks post-operatively.
        ii. Days to return to work (RTW) post-operatively.
    b. Components of hand function assessed by:
        i. Range of motion (ROM) of injured and contralateral digits and wrist at four and eight weeks post-operatively.
        ii. Grip strength of injured and contralateral hand at eight weeks post-operatively.
    c. Adherence to splinting at four weeks post-operatively.
    d. Satisfaction with splinting, treatment and outcome at eight weeks post-operatively as measured by the modified Patient Evaluation Measure (PEM).
    e. Incidence and type of post-operative complications.

2. To correlate objective assessment of hand function with subjective assessment of hand function and components of hand function in the total sample.

1.1.3 Hypotheses

The hypotheses of this research were as follows:

1. Participants treated with an RMES protocol would achieve a greater SHFT score at four weeks and a similar SHFT score at eight weeks post-operatively compared to those treated with a CAM protocol.
2. Participants treated with an RMES protocol would report superior subjective functional performance as measured by the QuickDASH score at four weeks, and similar scores at eight weeks, compared to those treated with a CAM protocol.
3. Participants treated with an RMES protocol would return to work in a fewer number of days post-operatively compared to those treated with a CAM protocol.
4. Participants treated with an RMES protocol would demonstrate a greater ROM at four weeks and no difference in ROM or grip strength at eight weeks compared to those treated with a CAM protocol.

5. Participants treated with an RMES protocol would report better adherence and similar satisfaction measured by the modified PEM score compared to those treated with a CAM protocol.
6. Participants treated with an RMES protocol would have no difference in complication rate compared to those treated with a CAM protocol.
7. There would be a significant correlation between the SHFT score and the QuickDASH score and between the SHFT score and ROM and grip strength.

1.1.4 Significance of the study

The results of this study will add to the body of evidence on the outcomes of early active mobilisation after extensor tendon repair in zones V and VI. With the acceptance of the research hypotheses, the RMES protocol will conclusively demonstrate better outcomes than the CAM protocol. This finding could be instrumental in shaping a change of practice at the institution where the research was conducted; it could also be likely to influence other similar hand rehabilitation protocols used in hospitals and clinics in New Zealand and internationally. The results of this research will be disseminated through presentation at local and international conferences and publication.

1.2 Background

The remainder of this chapter will review extensor tendon anatomy, tendon healing and theory of rehabilitation of extensor tendon injuries relevant to the study purpose. It will conclude with a discussion of early mobilisation protocols.

1.2.1 Anatomy

Extrinsic extensor tendon anatomy

The extrinsic extensor muscles consist of a superficial and a deep layer (Lee, 2008; Wehbé, 1995). Extrinsic extensor tendons to the fingers arise from three muscles (Figure 1): extensor digitorum, also known as extensor digitorum communis (EDC) and extensor digiti minimi (EDM) muscles in the superficial layer, and extensor indicis (EI) muscle in the deep layer (Lee, 2008; Wehbé, 1995). This study included repairs of one or more of these tendons.

EDC originates from the lateral epicondyle of the humerus as part of the common extensor origin (Lee, 2008) and then divides distally into a variable number of tendons (Rosenthal & Elhassan, 2011; Wehbé, 1995). EDC consistently provides a tendon slip to the index, middle and ring fingers, but not always to the little finger (Earp & Blazar, 2012; Rosenthal & Elhassan, 2011; Van Kampen & Amadio, 2012). Blood supply to EDC is from the recurrent radial artery for the proximal third, branches from the posterior interosseous artery for the distal two thirds and a perforating artery from the anterior interosseous artery for the most distal part (Lee, 2008). The nerve supply to EDC is from the posterior interosseous nerve (Lee, 2008).

EDM originates distal to the elbow from the common extensor tendon and intermuscular septum; it is situated towards the ulnar aspect relative to the EDC and usually provides two slips to the little finger (Lee, 2008; Wehbé, 1995). The EDM tendon lies ulnar to the EDC tendon to the little finger and has the same blood supply and innervation as EDC (Lee, 2008).

EI has its origin from the dorsal ulna and interosseous membrane and provides a tendon to the index finger (Lee, 2008). Blood supply to EI is from branches of the posterior and anterior interosseous arteries; its nerve supply is the same as EDC (Lee, 2008).

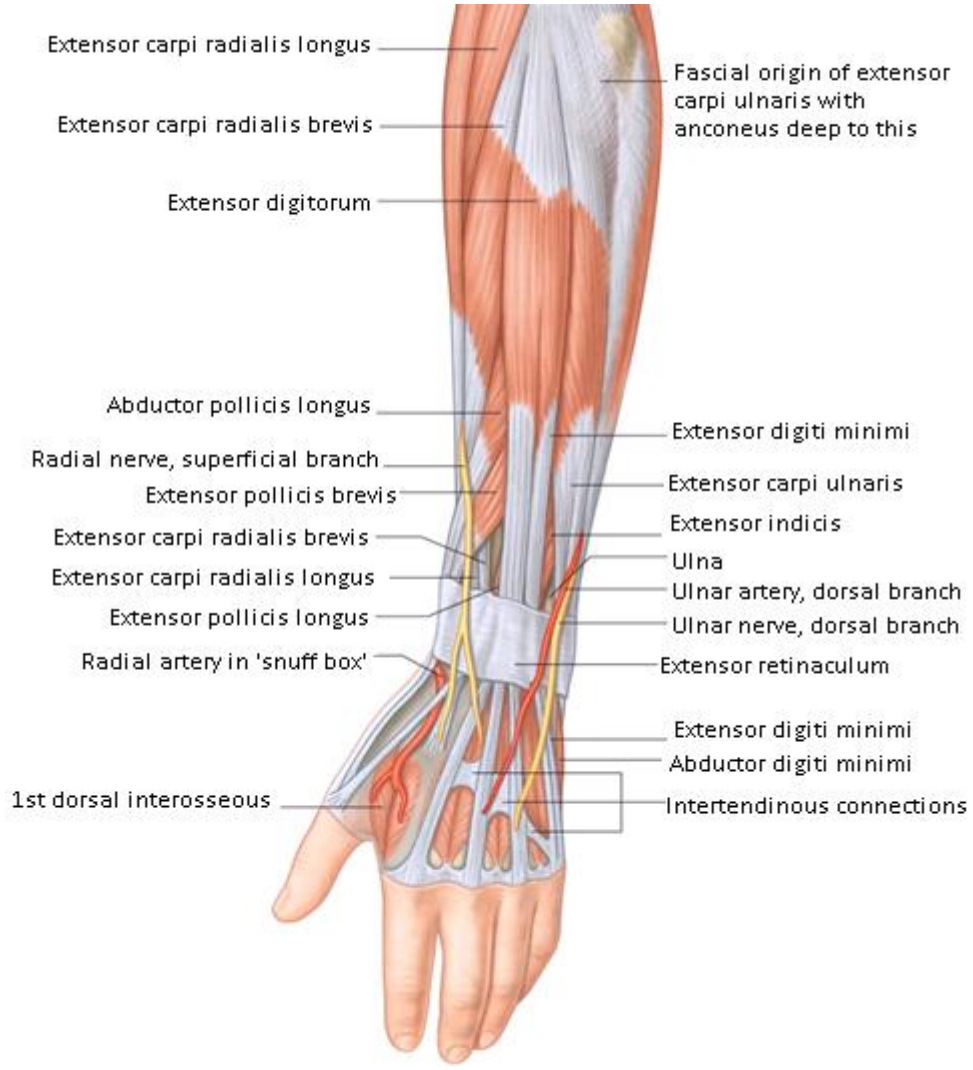

Figure 1. Extensor muscles of the forearm. From "Pectoral Girdle and Upper Limb: Forearm," by J. Lee, 2008, in S. Standring (Ed.), *Gray's Anatomy* (40th ed), p.848., London, England. Copyright 2008 by Churchill Livingstone Elsevier. Reprinted with permission.

Extensor tendon zones

The extensor mechanism is divided into seven zones (Figure 2), numbered from I to VII, distal to proximal (Kleinert & Verdan, 1983). The odd zones I, III , V and VII are located across the joints, and the even zones across the bones in between (Rosenthal & Elhassan, 2011; Wehbé, 1995). These zones are significant because there are differences in structure, function and attachments of the tendons in each zone which influence the choice of rehabilitation protocol and amount of protection required post-operatively (Evans, 2011).

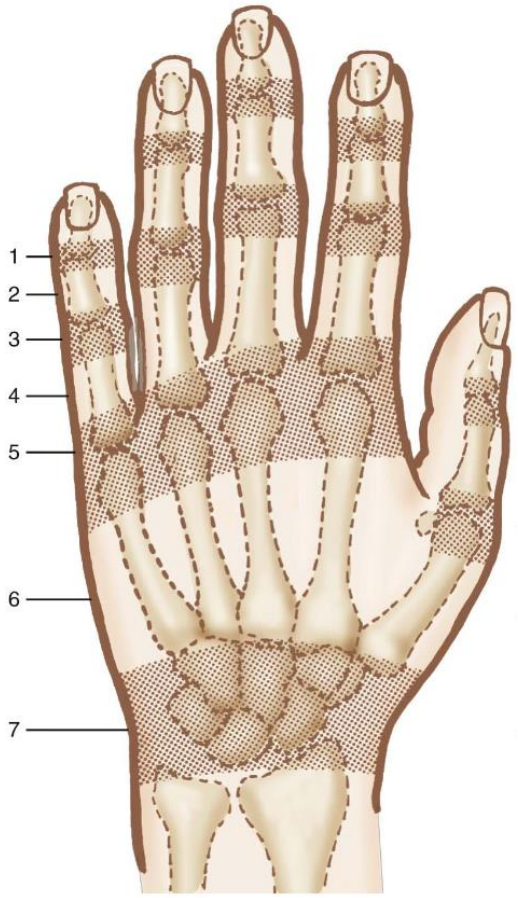

Figure 2. Extensor tendon zones as defined by the Committee on Tendon Injuries for the International Federation of the Society for Surgery of the Hand. From "Clinical Management of Extensor Tendon Injuries," by R. Evans, 2011, in T. Skirven, A. Osterman, J. Fedorczyk & P. Amadio (Eds.), *Rehabilitation of the Hand and Upper Extremity* (6th ed., Vol. 1), p. 523, Philadelphia, PA. Copyright 2011 by Mosby Inc. Reprinted with permission.

Zone VII

At the wrist, in zone VII, the extensor tendons pass across the dorsum of the radius through six compartments created by the extensor retinaculum (Figure 3) (Evans, 2014; Van Kampen & Amadio, 2012; Wehbé, 1995). The extensor retinaculum creates fibro-osseous tunnels through which the extensor tendons run within synovial sheaths, with the retinaculum functioning as a pulley, preventing bowstringing of the extensor tendons across the wrist (Rosenthal & Elhassan, 2011). The EDC tendon runs together with and superficial to the EI tendon in the fourth compartment and the tendon of EDM runs alone through the fifth compartment (Lee, 2008).

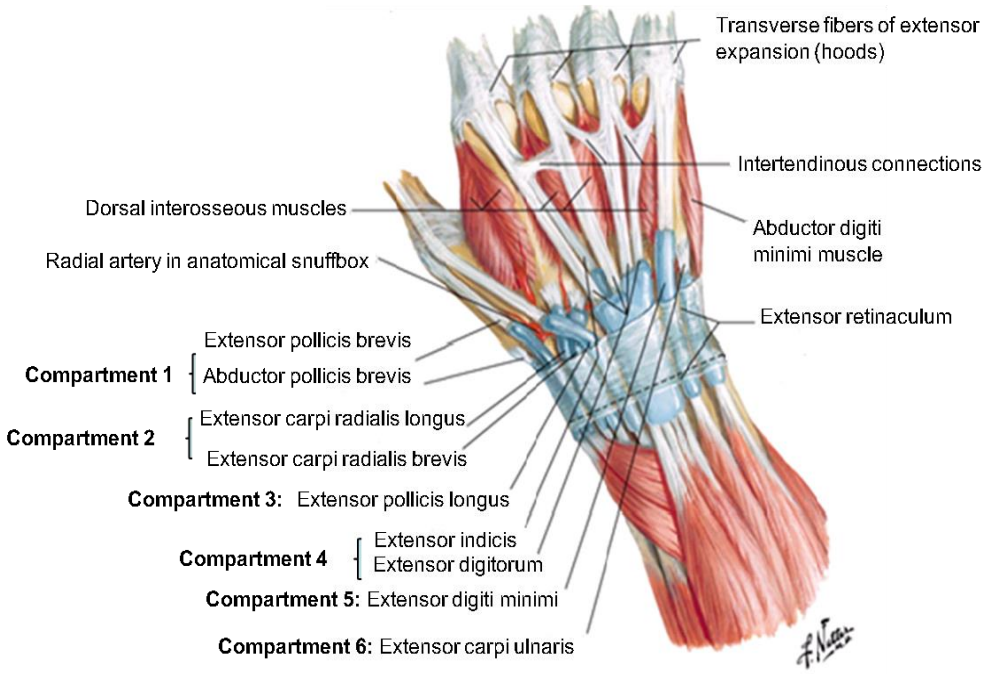

Figure 3. Extensor tendon compartments. From "Extensor Tendons at Wrist," by R. Evans, 2014, in F. Netter (Ed.), *Atlas of Human Anatomy* (6 ed.), pp. 431 to 506, Philadelphia, PA. Copyright 2014 by Elsevier - Health Sciences Division.

Zone V and VI

Zone VI is across the dorsum of the hand (Wehbé, 1995). In this zone the extensor tendons are flat in shape and run between two layers of deep fascia, the supratendinous and infratendinous layers; tendons are surrounded by thin peritendinous tissue known as the paratenon which allows the tendon to glide between these layers (Rosenthal & Elhassan, 2011). Synovial sheaths around the tendons continue in zone VI until approximately the mid-metacarpal level (Zbrodowski, Gajisin, & Grodecki, 1980). Intertendinous connections known as juncturae tendinae are located in zone VI (Figure 3) (Rosenthal & Elhassan, 2011; Wehbé, 1992). The juncturae tendinae run distally from the EDC tendon of the ring finger and connect the EDC tendons of the little, ring, middle and index fingers (Rosenthal & Elhassan, 2011; Van Kampen & Amadio, 2012). During finger extension the juncturae tendinae help the tendons to work together, and during finger flexion help to create stability, transmitting force through the sagittal bands (Rosenthal & Elhassan, 2011). If a middle or little finger extensor tendon laceration occurs proximal to the juncturae tendinae it may be disguised by the action of the juncturae tendinae on the adjacent intact tendons during finger extension; the injured tendon will be pulled proximally enabling

extension of the finger despite the injury (Earp & Blazar, 2012; Rosenthal & Elhassan, 2011).

Zone V is over the dorsum of the MCPs. The structure of the extrinsic tendons changes as they reach this zone, becoming part of a thin sheet of fibres which cover the dorsum of the MCP and proximal phalanx (Rosenthal & Elhassan, 2011). These fibres are orientated in various planes to transmit forces to the digits and include extrinsic and intrinsic tendons, forming a dorsal hood (Megerle & Germann, 2013; Rosenthal & Elhassan, 2011; Tubiana, 1997) (Figure 4). The main function of the extrinsic extensor tendons is extension of the MCP joints. The tendons attach to the fibrous sagittal bands which insert into both sides of the MCP volar plate and the proximal phalanx (Rosenthal & Elhassan, 2011; Wehbé, 1995). MCP extension is achieved through this attachment (Rosenthal & Elhassan, 2011). The sagittal bands help to centralise the extensor tendons over the MCP joints during digital flexion, and injury to the radial sagittal bands may result in ulnar displacement of the tendon during flexion (Rosenthal & Elhassan, 2011). After injury to the tendons in zones V and VI the paratenon has a tendency to develop extensive scar tissue and controlled early mobilisation in these zones is usually recommended to limit adhesion formation (Evans, 2011, 2012; Howell & Peck, 2013; Newport & Tucker, 2005).

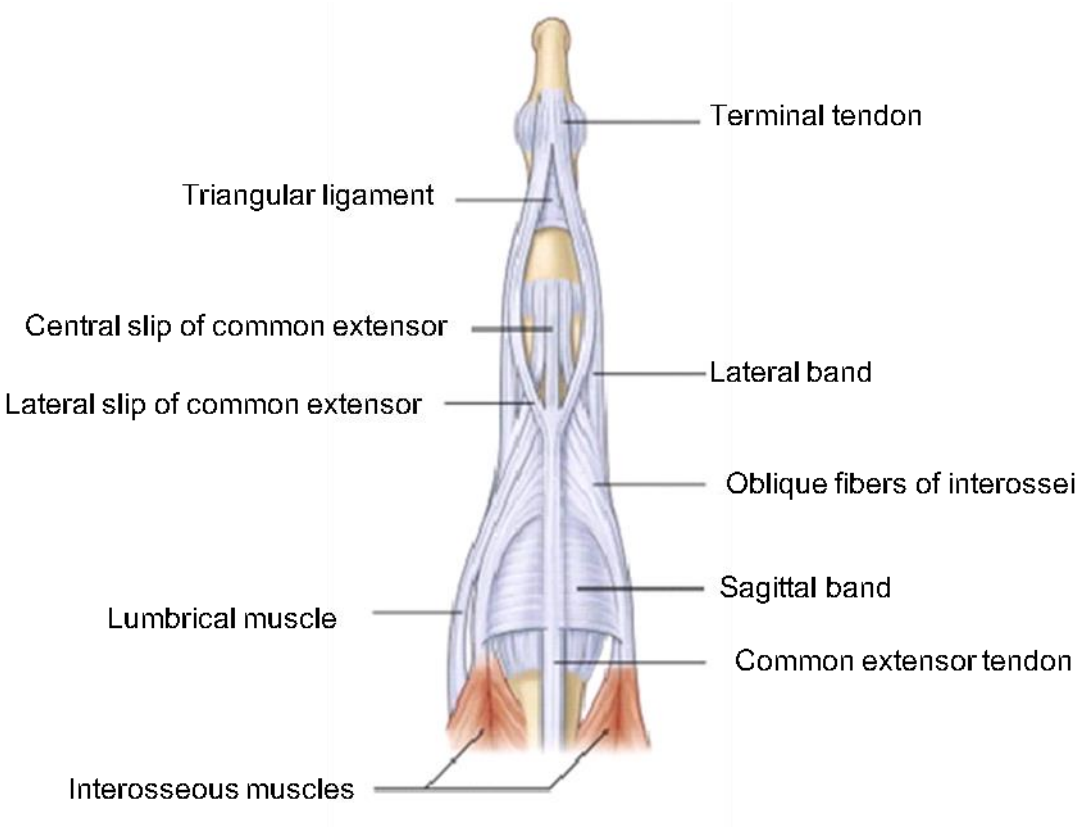

Figure 4. Extensor apparatus. From "Extensor Tendon Injuries," by K. Megerle & G. Germann, 2013, in P. Neligan (Ed.), *Plastic Surgery* (Vol. 6). p. 211, London, England. Copyright 2013 by Elsevier. Reprinted with permission.

Distal zones: I to IV

In zone IV, beyond the sagittal bands, lumbrical and interosseous muscles provide contributions to the dorsal extensor apparatus (Figure 4). As the extrinsic extensor tendons pass the MCP they divide into three slips: a central portion and two lateral slips (Wehbé, 1995). The central slip inserts at the base of the middle phalanx (Tubiana, 1997; Wehbé, 1995) and is responsible for proximal interphalangeal (PIP) joint extension (Rosenthal & Elhassan, 2011; Tubiana, 1997). The lateral slips receive contributions from the lumbricals and the interossei, to form lateral bands (Wehbé, 1995); these join to form the terminal tendon which inserts at the base of the distal phalanx where it is responsible for distal interphalangeal (DIP) joint extension (Rosenthal & Elhassan, 2011; Tubiana, 1997; Wehbé, 1995).

Blood supply to extensor tendons in zone V and VI

Blood supply to the extensor tendons within the synovial sheath in zone VII is from a combination of mesotendons (30%) and synovial diffusion (70%) (Rosenthal & Elhassan, 2011; Zbrodowski et al., 1980). Mesotendons are small vessels contained in

the fascia that connect the tendons to their sheath (Rosenthal & Elhassan, 2011). From the mid-metacarpal level to the MCP joints, the paratenon provides the vascular supply for the tendon (Rosenthal & Elhassan, 2011).

Animal studies have demonstrated that immobilisation after injury leads to decreased vascularity of the tendon and blood vessels that are orientated transverse to the tendon axis, while mobilisation results in blood vessels that are similar in structure to those of uninjured tendons and are aligned to the long axis of the tendons (Gelberman, Menon, Gonsalves, & Akeson, 1980). Mobilisation after tendon repair is therefore advised because of these positive effects on vascularity (Evans, 2011).

1.2.2 Tendon injury and healing

After surgical repair of an injured tendon, healing is required to restore strength and the ability to transmit force. The process of tendon healing following repair influences the design of rehabilitation protocols and will be discussed in more detail.

Tendon healing is achieved by the action of undifferentiated epitenon cells as they are stimulated by growth factors to proliferate and migrate to the lacerated tendon ends (Amadio, 2011, 2012; Joyce, Lou, & Manske, 1997). However if these growth factors stimulate epitenon cells to move away from the injured tendon, towards the tendon sheath (Amadio, 2012), they may also produce problematic tendon adhesions between the tendon, its sheath and surrounding structures (Joyce et al., 1997). It was previously thought that repaired tendons relied on adhesions to the surrounding tissue in order for healing to take place (Pettengill, 2005). However it has been shown that tendons have an inherent healing capability due to nutrition obtained from the surrounding synovial sheath and presence of vascular structures (Amadio, 2012; Matsui & Hunter, 1997).

A predictable sequence of healing events follows tendon injury: Firstly, inflammation during which cells proliferate and migrate to the injury site over the first 48 to 72 hours (Strickland, 1986); secondly fibroplasia which involves synthesis of new extracellular matrix, usually commencing around day five and continuing until three to four weeks (Strickland, 1986), and finally remodelling of the extracellular matrix (Joyce et al., 1997) which commences at around four weeks. By eight weeks the collagen has

reached maturity (Strickland, 1986), however remodelling can continue for months or even years (Joyce et al., 1997).

Research on chicken tendons has shown a period of 'no-gain' in strength in the repaired tendons during the first three to four weeks after repair (Tang et al., 2012), which corresponds to the fibroplastic period. Between weeks four and five a rapid increase in strength occurs followed by a slower increase in strength until eight weeks after repair (Tang et al., 2012). The initial 'no-gain' period followed by gradual increase in strength, together with the belief that tendons healed only by means of adhesions, led to repaired tendons historically being immobilised for three to six weeks post-operatively (Amadio, 2011; Pettengill, 2005). However it has been shown that early mobilisation of the repaired tendons during the fibroplastic period can prevent 'softening' of the tendon ends (Pettengill & Van Strien, 2011), promote healing through the synovial route (Amadio, 2012), promote normal vascularity (Gelberman et al., 1980), speed up the process of maturation and increase the tensile strength of the tendon so that it provides increased resistance to rupture and improved excursion (Amadio, 2011; Gelberman, Woo, Lothringer, Akeson, & Amiel, 1982; Kubota, Manske, Aoki, Pruitt, & Larson, 1996; Mason & Allen, 1941).

Negative effects are associated with immobilisation following tendon repair, even of healthy connective tissue. After one week of immobilisation collagen fibres may be laid down in a disorganised pattern and normally flexible tissues contract and limit motion (Cyr & Ross, 1998). This effect is greatly increased in injured tissue and can result in permanent loss of motion (Cyr & Ross, 1998). In this way tendons which are immobilised are more likely to develop adhesions to the surrounding tissue (Amadio, 2012), with resultant poorer outcomes (Amadio, 2011).

1.2.3 Rehabilitation after extensor tendon repairs in zone V and VI

The benefits of early mobilisation of repaired tendons are clear and it has been said that 'one of the most important concepts in orthopaedics in the past century is the understanding that loading accelerates healing of bone, fibrous tissue, and skeletal muscle' (Evans, 2012, p.174). However, an understanding of the effect of early mobilisation on healing tissues is important. Early *unrestricted* mobilisation of repaired tendons in animal models has been shown to result in gapping and rupture of the

repair with increased reaction at the repair site, which increases the risk of adhesion formation (Boyer, Goldfarb, & Gelberman, 2005; Gelberman et al., 1982; Mason & Allen, 1941). In a human population unrestricted mobilisation of repaired extensor tendons has been shown to result in the development of an extensor lag (Stuart, 1965).

Early mobilisation should therefore be in a controlled manner to optimise the benefits of mobilisation while avoiding the risks related to unrestricted motion (Amadio, 2012; Gelberman et al., 1982; Howell & Peck, 2013). This requirement to balance motion with protection has led to the development of early controlled mobilisation protocols where, during the first three to four weeks post-operatively, motion is allowed while being controlled by a splint (Evans, 2011, 2012; Howell & Peck, 2013; Newport & Tucker, 2005; Pettengill, 2005; Talsma et al., 2008).

The choice of rehabilitation protocol after extensor tendon repair should be based on an understanding of tendon healing (Evans, 2012; Howell & Peck, 2013). Loading of the repaired tendon, biomechanics of extensor tendon excursion and timing of mobilisation all affect the repaired tendon during the early post-operative period and therefore need to be considered when choosing a rehabilitation protocol (Evans, 2012; Howell & Peck, 2013). These factors will be discussed in further detail.

Biomechanics of the repaired tendon: Loading and excursion

During rehabilitation, in order for mobilisation to occur, a certain amount of mechanical load must be applied to the repaired tendon to induce motion. Load is applied to the extrinsic extensor tendons actively through contraction of the extensor muscles or passively through wrist and/or finger flexion (Newport & Tucker, 2005). Resistance to motion is created by a number of factors: friction between the tendon and surrounding structures, oedema, the weight of the digit, joint stiffness, the force of the antagonist muscle and shortening due to the repair technique (Amadio, 2005; Evans, 2012; Newport & Tucker, 2005). If the load is too small, it will not overcome this resistance (Amadio, 2005). If the load is too great it will exceed the strength of the repair at that stage of healing, resulting in gapping or rupture of the repair (Amadio, 2005). The range of loading which is sufficient to produce tendon motion, but not so great as to result in gapping or rupture of the tendon repair, is termed the ‘safe zone’

of loading for mobilisation (Figure 5). The safe zone increases over time after repair as healing occurs and tendon strength increases.

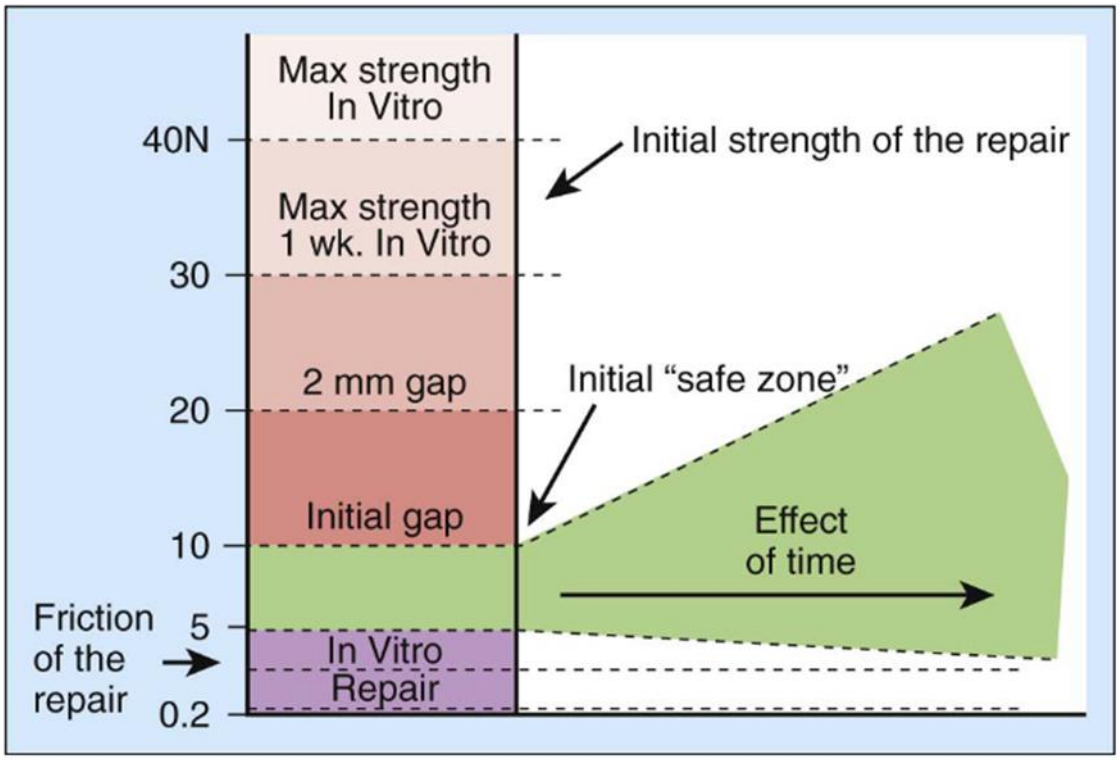

Figure 5. The safe zone for mobilisation of tendon repairs. From "Tendon Nutrition and Healing," by P. Amadio, 2012, in J. Tang, P. Amadio, J. Guimberteau, J. Chang, D. Elliot & J. Colditz (Eds.), *Tendon Surgery of the Hand* (1st ed.), p. 19, Philadelphia, PA. Copyright 2012 by Saunders. Reprinted with permission.

Tendon excursion is thought to prevent adherence of the tendon to surrounding tissue and it has been suggested that 3 to 5mm of tendon excursion during early mobilisation protocols is required to prevent adherence (Amadio, 2012; Boyer et al., 2005; Duran & Houser, 1975; Evans, 2012; Newport & Tucker, 2005; Pettengill, 2005). Cadaver studies, mathematical calculations and intra-operative measurements have shown that approximately 30° of passive MCP motion may result in 5mm of extensor tendon glide (Evans & Burkhalter, 1986). This finding, that 30° of MCP motion is required, initially led to the development of early passive mobilisation protocols which allowed early active MCP flexion from 0° to 30° (Bruner, Wittemann, Jester, Blumenthal, & Germann, 2003; Chow, Dovelle, Thomes, Ho, & Saldana, 1989; Mowlavi, Burns, & Brown, 2005). A study on flexor tendon excursion has however shown that the actual tendon excursion only achieves the predicted excursion if more than 300 grams of force is applied to the tendon (Horii, Lin, Cooney, Linscheid, & An, 1992); this may be the same for extensor

tendons. It has therefore been suggested that active tendon motion may be required to achieve the desired tendon excursion (Evans, 2012; Pettengill, 2005). Additionally, active mobilisation 'pulls' the tendon by muscle contraction whereas passive mobilisation may result in 'buckling' of the tendon rather than true excursion as the tendon is 'pushed' (Amadio, 2012; Pettengill, 2005) so that active mobilisation may be preferable. Far greater excursion of the extrinsic extensor tendons takes place with wrist flexion and extension than with MCP motion alone so that allowing wrist motion during rehabilitation promotes greater excursion of the repaired tendon (Evans, 2011).

Mobilisation therefore incorporates mechanical loading and excursion of the repaired tendon, and active mobilisation may be required to obtain effective tendon excursion. Load and excursion together produce better results than load or excursion alone (Evans, 2012; Kubota et al., 1996), however it has been demonstrated that excursion is more important than motion for the final result. Once sufficient load has been applied to the tendon to create motion, there is no benefit to additional loading of the tendon with regard to the final tendon strength and range of motion obtained (Amadio, 2005, 2011; Boyer et al., 2005; Evans, 2012). The available evidence therefore suggests that a safe and effective rehabilitation protocol should incorporate both loading and excursion, ensuring loading remains within the safe zone while optimising tendon excursion.

Loading of the extensor tendon in zone V and VI during active extension of the MCPs is influenced by wrist position (Evans, 2012). Some authors suggest that it is safest to maintain the wrist in extension, due to the finding that when the wrist is flexed it is possible to exert greater active force through the extrinsic extensors (Newport & Tucker, 2005). However, allowing flexion of the wrist during active MCP extension reduces load on the extensor tendon because it reduces passive tension in the extrinsic flexor tendons (Savage, 1988); this phenomenon is referred to as the tenodesis effect (Sakellariou, Sawada, & Tsubota, 2006; Thompson & Wehbe, 1995). The activity of EDC during active MCP extension, measured electromyographically, has been found to be reduced when the wrist is in 20° flexion compared to a neutral or extended position (Sakellariou et al., 2006). Similarly, the load transmitted through the EDC tendon during active extension has been calculated mathematically to be lowest if the wrist is in 20°of flexion and highest with the wrist in extension (Evans & Thompson,

1993). As a result of these findings it has been suggested that flexing the wrist to approximately 20° during active extension of the MCPs after extensor tendon repair in zone V and VI provides protection for the repair (Evans & Thompson, 1993; Sakellariou et al., 2006). A synergistic type rehabilitation protocol incorporating wrist tenodesis with wrist flexion/finger extension and wrist extension/finger flexion promotes high tendon excursion with low load (Amadio, 2005). Some authors have incorporated early tenodesis exercises into rehabilitation protocols for extensor tendon repairs in zone V and VI (Berry & Neumeister, 2008; Chinchalkar & Yong, 2004; Eissens, Schut, & van der Sluis, 2007; Evans, 1995; Hirth et al., 2011; Svens et al., 2015; Thomas, Moutet, & Guinard, 1996).

Passive loading of the extensor tendons in zone V and VI during wrist and finger motion has been investigated to determine how much wrist and finger flexion can safely be allowed. The question of how splinting protects a repaired extensor tendon from rupture during finger or wrist flexion has been investigated, with conflicting results. One cadaver study analysed the effect of relative motion extension splinting (RMES) on repaired extensor tendons (J. V. Sharma, Liang, Owen, Wayne, & Isaacs, 2006). They found that simulating full active finger flexion while the wrist was held in 25° of extension resulted in gapping of a repaired digital extensor tendon. Gapping of the tendon was effectively prevented after the authors added an RMES yoke splint to position the affected MCP in 15° of relative extension to the other fingers. Sharma et al. (2006) therefore recommended the use of the RMES protocol using a wrist and yoke splint as it was effective in protecting the extensor tendon. Similarly, another study reviewed participants intra-operatively (Howell et al., 2005). They reported that an RMES yoke splint positioning the affected MCP in 15-20° greater extension than the other digits, was combined with a splint holding the wrist at 20° extension, they observed no tension through the repair during finger flexion and extension. A cadaver study investigated tendon excursion and tension with the wrist in different positions (Minamikawa et al., 1992). In contrast to the study by Sharma et al. (2006), Minamikawa et al. (1992) found that if the wrist was held in more than 22° of extension, extensor tendons in zone V and VI moved from full passive finger extension to full active finger flexion with little or no tension; Minamikawa et al. (1992) therefore

recommended that full finger flexion be allowed in a passive early motion protocol provided the wrist was held in greater than 22° of extension.

The biomechanical evidence reviewed in this section agrees that a mobilisation protocol needs to include mechanical loading and excursion of repaired tendons; tendons should not be overloaded during the first few weeks post-operatively and excursion should be promoted. Active extension of the MCPs is preferred, and a synergistic protocol which allows tenodesis may be an appropriate choice; full composite passive wrist and finger flexion should be prevented. The current biomechanical evidence does not provide consensus as to how many degrees of wrist and/or finger flexion is safe. This uncertainty is reflected in the wide variation of protocols currently in use after extensor tendon repair in zone V and VI. Protocols differ with regard to the amount and type of motion allowed and will be discussed in detail in Chapter 1.2.4.

Timing of mobilisation

Significant benefits of increased tensile strength and excursion have been found in flexor tendons mobilised immediately post-repair compared to those mobilised at three weeks (Gelberman et al., 1982). Current recommendations are that early mobilisation of repaired tendons should commence within a few days post-operatively, and no more than ten days at the latest (Evans, 2012; Howell & Peck, 2013; Pettengill, 2005). By ten days there may be a reduction in tendon glide, and by two weeks a reduction in tensile strength in immobilised tendons (Evans, 2011).

However it has been suggested that mobilising too early, during the first three days of the acute inflammatory response, may be harmful to the tendon by causing new bleeding, potentially increasing the risk of adhesion formation (Amadio, 2005). A study which examined repaired canine flexor tendons demonstrated that the optimal timing for mobilisation was at day five post-operatively, as the load required to overcome resistance of the glide of the tendon due to the effects of oedema, friction of the repair and joint stiffness was the lowest at this point in time (Zhao et al., 2004).

The above studies therefore suggest that it may be ideal to mobilise the repaired tendon at three to five days, however in the clinical situation due to high pressure on

hand therapy appointments it may not always be possible for rehabilitation to commence at exactly three to five days post-operatively. For the purpose of the current study, early mobilisation was therefore defined as mobilisation at any time within the first seven days post-operatively.

1.2.4 Protocols for rehabilitation after extensor tendon repairs in zone V and VI

Recent systematic reviews have found strong evidence that early mobilisation for rehabilitation after hand/wrist extensor tendon repair provides better ROM outcomes sooner than immobilisation (Ng et al., 2012; Sameem et al., 2011; Talsma et al., 2008). As discussed in section 1.2.2, the advantages of early mobilisation over immobilisation for tendon rehabilitation are clear. Early mobilisation protocols for extensor tendon repairs in zone V and VI are usually divided into EPM and EAM protocols (Hammond et al., 2012; Ng et al., 2012; Talsma et al., 2008).

Early passive mobilisation

The benefits of early motion after flexor tendon repair were recognised and reported as early as the 1960s (Pettengill, 2005), however tendon repairs were initially not thought to be of sufficient strength to withstand the force of active motion (Evans & Thompson, 1993). This meant that early mobilisation protocols initially allowed only passive motion of repaired tendons (Evans, 2011).

The defining feature of EPM protocols is that they allow early *passive* mobilisation of the repaired tendon via passive MCP extension, combined with active flexion of the MCP joints during the first three to six weeks post-operatively (Ng et al., 2012; Talsma et al., 2008). This controlled motion is achieved by means of a custom-made splint which uses rubber band dynamic traction to hold the MCP joints passively in extension by means of digital slings (Figure 6) (Bruner et al., 2003; Chester et al., 2002; Chow et al., 1989; Crosby & Wehbe, 1999; Evans, 1995; Hung, Chan, Chang, Tsang, & Leung, 1990; Ip & Chow, 1997; Kerr & Burczak, 1989; Khandwala et al., 2000; Kitis, Ozcan, Bagdatli, Buker, & Kara, 2012; Mowlavi et al., 2005; Neuhaus, Wong, Russo, & Mudgal, 2012).

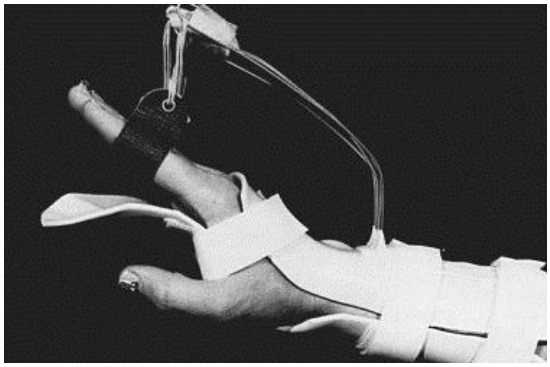

Figure 6. Dynamic extension splint used in early passive mobilisation protocol. From "Clinical Management of Extensor Tendon Injuries," by R. Evans, 2011, in T. Skirven, A. Osterman, J. Fedorczyk & P. Amadio (Eds.), *Rehabilitation of the Hand and Upper Extremity* (6th ed., Vol. 1), p.545, Philadelphia, PA. Copyright 2011 by Mosby, Inc. Reprinted with permission.

Randomised controlled trials (RCTs) involving EPM protocols have reported good/excellent range of motion outcomes in 95% to 100% of participants (Chester et al., 2002; Khandwala et al., 2000; Kitis et al., 2012; Mowlavi et al., 2005). Ruptures have been uncommon (Crosby & Wehbe, 1999; Evans, 1995; Khandwala et al., 2000) and tenolysis surgery to free tendon adhesions has infrequently been required (Bruner et al., 2003; Mowlavi et al., 2005).

Early active mobilisation

Improvements in suture technique and strength led to tendon repairs that were better able to withstand the greater force of active motion, and consequently to the development of EAM protocols (Pettengill, 2005). In contrast to EPM protocols, EAM protocols encourage *active* mobilisation of the repaired tendon via active extension of the MCP joints during the early post-operative phase (Ng et al., 2012; Talsma et al., 2008).

In an EAM protocol controlled motion is usually achieved by the use of a static splint which allows active extension and active flexion, while restricting end-range flexion of the affected digits (Bulstrode, Burr, Pratt, & Grobbelaar, 2005; Chester et al., 2002; Howell et al., 2005; Khandwala et al., 2000; Patil & Koul, 2012; Saini, Sharma, Sharma, & Patni, 2008; Sylaidis, Youatt, & Logan, 1997). Splinting is usually for three to six weeks after which time the splint is weaned and progressive mobilisation of the repaired tendon, strengthening and return to activities is commenced (Bulstrode et al., 2005; Chester et al., 2002; Howell et al., 2005; Khandwala et al., 2000; Patil & Koul, 2012; Saini et al., 2008; Sylaidis et al., 1997). Some splint designs include only the

MCPs of the injured digits (Berry & Neumeister, 2008; Hirth et al., 2011; Izadpanah, Hayakawa, Murray, & Islur, 2014; Svens et al., 2015). These include RMES protocols which make use of a yoke splint (Figure 7) which holds the MCP joint of the injured digit in relatively greater extension than the other MCP joints (Altobelli, Conneely, Haufler, Walsh, & Ruchelsman, 2013; Burns, Derby, & Neumeister, 2013; Hirth et al., 2011; Howell et al., 2005). The yoke splint reduces tension on the repair and harnesses the intertendinous connections to assist active extension (Howell et al., 2005) (Figure 10). Other splints include the wrist and MCPs (Altobelli et al., 2013; Hall et al., 2010; Howell et al., 2005; Khandwala et al., 2000) (Figure 8) while others include wrist, MCPs and IP joints (Bulstrode et al., 2005; Chester et al., 2002; Saini et al., 2008; Sylaidis et al., 1997) (Figure 9).

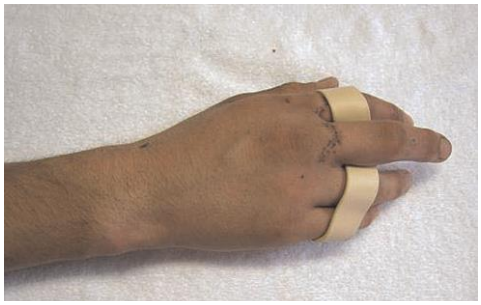

Figure 7. Splint for early active mobilisation including only the metacarpophalangeal joint of the injured digit. From "Early Return to Work and Improved Range of Motion with Modified Relative Motion Splinting: A Retrospective Comparison with Immobilization Splinting for Zones V and VI Extensor Tendon Repairs," by M. Hirth, K. Bennett, E. Mah, H. Farrow, A. Cavallo, M. Ritz, & M.Findlay, 2011, *Hand Therapy, 16(4)*. p. 90. Copyright 2011 by SAGE publications. Reprinted with permission

Figure 8. Active mobilisation in splint including the wrist and metacarpophalangeal joints. From "Extensor controlled active motion protocol [pamphlet]," by Hand Therapy Manukau Superclinic, 2004, Auckland, New Zealand. Copyright 2004 by Hand Therapy Manukau SuperClinic. Reprinted with permission.

Figure 9. Active mobilisation in splint including the wrist, metacarpophalangeal and interphalangeal joints. From "Norwich protocol for extensor tendon repairs [pamphlet]," by Hand Therapy Manukau Superclinic, 2010, Auckland, New Zealand. Copyright 2010 by Hand Therapy Manukau SuperClinic. Reprinted with permission.

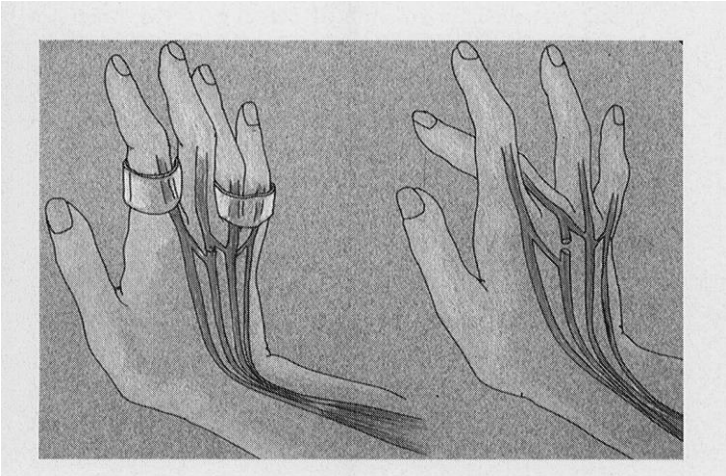

Figure 10. Relative motion extension splint. From "Immediate Controlled Active Motion Following Zone 4-7 Extensor Tendon Repair," by J. Howell, W. Merritt & S. Robinson, 2005, *Journal of Hand Therapy, 18(2),* p. 187. Copyright 2005 by Elsevier. Reprinted with permission.

Similar to reports on EPM protocols, studies using EAM protocols have reported a high percentage of good/excellent results for range of motion, with RCTs showing good/excellent outcomes for 93% to 100% of participants (Bulstrode et al., 2005; Chester et al., 2002; Khandwala et al., 2000). Again, low complication rates have been reported with two patients requiring tenolysis in one study (Berry & Neumeister, 2008) and two studies reporting a small proportion (2% to 4%) of tendon ruptures (Evans, 1995; Khandwala et al., 2000).

Which early mobilisation protocol? EAM versus EPM

Two randomised controlled trials (Chester et al., 2002; Khandwala et al., 2000) have investigated the question of whether EAM or EPM protocols provide superior

outcomes. One study (Chester et al., 2002) found significantly better ROM in the early passive group at four weeks. Neither Chester et al. (2002) nor Khandwala et al. (2000) found any significant difference in ROM by 8 to 12 weeks post-operatively. More recently a pilot study (Hall et al., 2010) found better ROM in a group managed with an EAM protocol compared to those managed with an EPM protocol. Systematic reviews on extensor tendon repair (Ng et al., 2012; Sameem et al., 2011; Talsma et al., 2008) concluded that there was insufficient evidence to determine whether EAM or EPM protocols provide superior outcomes; however an additional recent systematic review (Hammond et al., 2012) suggested that EAM protocols may have lower complication rates.

Newport and Shukla (1992) performed an electrophysiological study which found that within a splint designed to allow passive extension and active flexion, participants were in fact actively contracting the extensor muscle. This means that the use of passive protocols most likely inadvertently includes a component of active extension; similar results between active and passive protocols may be because tendons are in fact moving *actively* within the so-called 'passive' protocols (Evans, 2011). The biomechanical studies discussed in Chapter 1.2.3 support early active mobilisation as it may provide a biomechanical advantage, particularly when tenodesis is incorporated. There are practical disadvantages involved in the use of passive mobilisation protocols, namely the cost and labour-intensive nature of fabricating a dynamic splint (Chester et al., 2002; Hung et al., 1990; Khandwala et al., 2000), the intensive frequency of therapy required to make regular adjustments to splints (Hung et al., 1990) and the inconvenience of wearing a bulky splint for the patient (Khandwala et al., 2000). In comparison, the low-profile static splints usually employed in EAM protocols are said to be cheaper and quicker to make, and easier for the patient and therapist to manage (Chester et al., 2002; Hall et al., 2010; Khandwala et al., 2000). It is also thought that these EAM splint designs may promote adherence to splint wear, particularly if they allow more easy early functional use of the hand (Hirth et al., 2011; Howell et al., 2005).

Therefore, although the two types of mobilisation protocols show similar outcomes, EAM protocols may be preferable as they may result in fewer complications, demonstrate a biomechanical advantage, are more cost-efficient and provide a

reduced burden to the patient. It is the opinion of this author that the use of an EAM protocol, with the use of tenodesis, is an evidence-based and pragmatic choice for rehabilitation after extensor tendon repairs in zone V and VI. The following chapter will investigate the current evidence for the use of EAM protocols after extensor tendon repair in zone V and VI in greater detail.

Chapter 2 Literature Review

A systematic review of the literature was undertaken to investigate the evidence for the use of different EAM protocols after extensor tendon repair in zones V and VI.

2.1 Purpose of Review

The literature reviewed in Chapter 1 suggests that an EAM protocol is an evidence-based and pragmatic choice for rehabilitation after extensor tendon repair in zone V and VI. EAM protocols demonstrate a biomechanical advantage, are more cost-efficient and provide a reduced burden to the patient. EAM protocols may also result in fewer complications compared to passive mobilisation.

A number of different EAM protocols have been described for the management of extensor tendon repairs in zone V and VI. However no published trials have investigated the relative benefits of different active mobilisation protocols for extensor tendon repairs in zone V and VI to determine whether any one provides superior outcomes to any other. Therefore the objective of this systematic review of literature was to investigate the evidence for the use of EAM protocols after extensor tendon repairs in zone V and VI to determine whether any protocol provided superior outcomes. Literature included in the review was full length articles including randomised controlled trials, cohort studies and case series describing the outcomes of participants with extensor tendon repairs in zone V and/or VI treated with an EAM protocol. This review was structured according to the PRISMA guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009).

2.2 Methods

2.2.1 Search strategy

The databases that were searched for this review were: AMED (Allied and Complementary Medicine) 1985 to June 2016 via Ovid, Embase via Ovid 1974 to June 2016, Medline (R) In- Process & Other Non-Indexed Citations, Medline (R) Daily and Medline (R) 1946 to June 2016 via Ovid, Cochrane via Wiley, Cochrane via Ovid and Cinahl. Limits were date from 1980 until the current date (6 June 2016) and ‘English’.

The terms used for this search are presented in Table 1. Once articles had been identified the reference lists were screened to identify additional articles which might meet the inclusion criteria.

Table 1. Search Terms

Item number	Keywords used
1	'extensor tendon injur$' OR 'extensor tendon repair$' OR 'extensor tenorrhaphy' AND 'early motion' OR 'relative motion' OR 'active motion' OR 'splint$' OR 'orthos$' OR 'rehabilitation'

Inclusion criteria:

- Studies involving participants with repairs to extensor tendon lacerations of EDC, EI or EDM injuries zone V and VI in digits 2-5.
- Post-operative rehabilitation regimes allowing active extension of the affected MCP joints within the first week post-operatively, while controlling motion by means of a splint.
- RCTs, prospective and retrospective observational studies, cohort studies or case series.
- Full text articles.

Exclusion criteria:

- Studies including thumb extensor tendon repairs only.
- Extensor tendon transfers.
- Studies describing protocols involving only passive mobilisation or immobilisation of the MCP joints of digits with repaired tendons, or only early active motion of interphalangeal (IP) joints from the first week post-operatively.
- Studies including only extensor tendon repairs in zones other than V or VI.
- Description of rehabilitation protocol or splint without description of outcomes of patients treated with this protocol or splint.
- Studies involving the lower limb extensor tendons, lateral epicondylitis, tendinopathies or fractures.
- Closed injuries to extensor tendons.

- Review articles.
- Non-English articles.
- Case studies.

2.2.2 Data extraction

A data extraction form was used with the following data extracted from each study by the first author (SC): author and date of publication or presentation, type of study, inclusion criteria, zones of injury, intervention groups, sample size, baseline characteristics of participants, results including timing, ROM, grip strength, RTW, complications, subjective outcomes and amount of hand therapy input.

2.2.3 Assessment of methodological quality

MacDermid's Evaluation Guidelines for Rating the Quality of an Intervention Study (MacDermid, 2004) was used to assess the quality of the included studies. This tool, also known as the SEQES (Structured Effectiveness Quality Evaluation Scale) has been used widely in recent years in the assessment of hand therapy and musculoskeletal literature (Brudvig, Kulkarni, & Shah, 2011; Larson & Jerosch-Herold, 2008; Marks, Herren, Vlieland, Simmen, & Angst, 2011; L. Miller, Chester, & Jerosch-Herold, 2012; Raja & Dewan, 2011) and has been shown to have high inter-rater reliability with regard to scoring of studies (Brudvig et al., 2011). The advantages of the SEQES are that it was designed to evaluate a variety of intervention study designs including RCTs, cohort and retrospective studies (MacDermid, 2004) and that it provides a numerical score that allows a quantitative assessment of research methodology and the subsequent comparison of research quality across included studies.

The SEQES tool consists of 24 items (see Appendix A); items are scored 2 if completely fulfilled, 1 if partially fulfilled and 0 if not fulfilled or not addressed at all. The maximum score obtainable is 48, and the minimum is 0. The items are grouped into seven sections which evaluate: the study question (question 1), study design (questions 2 - 8), subjects included (questions 9 - 12), intervention (questions 13 - 15), appropriateness of outcomes (questions 16 - 18), analysis of results (questions 19 - 23) and recommendations (question 24).

The author of the SEQES (MacDermid, 2004) has not provided a classification for quantitative interpretation of scores obtained using this tool. However previous studies using this tool have classified articles as being of 'low' methodological quality if they scored 1 to 16 (Raja & Dewan, 2011) or 1 to 20 (L. Miller et al., 2012) 'moderate' if scores were between 17 to 32 (Raja & Dewan, 2011) or 21 to 34 (L. Miller et al., 2012) and 'high' if they were 33 to 48 (L. Miller et al., 2012) or 35 to 48 (Raja & Dewan, 2011). For the purpose of this review, studies scoring 0 to 20 were regarded as being of 'low' methodological quality, 21 to 32 as 'moderate' methodological quality, and 33 to 48 as 'good' methodological quality. Scoring was carried out by two authors (SC and EK) independently. Recommendations for multiple reviewers provided in the original description of the tool (MacDermid, 2004) were applied. Differences in scoring were discussed; consensus was obtained to within one point of difference in all cases. In the small number of cases where one point of difference remained, the lower score was assigned. A third reviewer was not required as there were no cases where there was a difference of more than one point or where more than three items were assigned the lower score arbitrarily.

2.2.4 Levels of evidence

The level of evidence was considered during the evaluation of the included studies. These were derived from the "The Oxford 2011 Levels of Evidence 2" (Oxford Centre for Evidence-based Medicine, 2011).

Level 1: Systematic review of randomised trials or n-of-1 trials

Level 2: Randomised trial or observational study with dramatic effect

Level 3: Non-randomised controlled cohort/follow-up study

Level 4: Case-series, case-control studies, or historically controlled studies

Level 5: Mechanism-based reasoning

2.3 Literature Review Results

One hundred and sixty six articles were identified through the database search; an additional five articles were identified through review of reference lists of included articles. After inclusion and exclusion criteria had been applied, 12 full text articles were selected for the review (Figure 11). Four of the included studies were RCTs, one

was a pilot study with a randomised design, three were cohort studies comparing two or more groups and four were cohort studies reporting outcomes of a single group.

2.3.1 Methodological quality of included studies

The scores for methodological quality of each study according to the SEQES are presented in Table 2. Of the 12 studies which were included in this review, four (Bulstrode et al., 2005; Chester et al., 2002; Khandwala et al., 2000; Patil & Koul, 2012) were RCTs. The SEQES scores for these studies ranged from 31 (Chester et al., 2002) to 36 (Patil & Koul, 2012). Two of the studies achieved a score of 'good' (Bulstrode et al., 2005; Patil & Koul, 2012) and two achieved a score of 'moderate' methodological quality (Chester et al., 2002; Khandwala et al., 2000).

With regard to study design of the included RCTs, the randomisation process was not always clearly described (Khandwala et al., 2000) or was not truly random (Patil & Koul, 2012) due to consecutive participants being allocated to each group alternately. Blinding of the treatment provider and participants was not possible in any of the studies, although two studies (Bulstrode et al., 2005; Khandwala et al., 2000) attempted to reduce potential for bias by using a blinded assessor. None of the included RCTs reported a sample size calculation and two studies suffered from a high loss to follow-up of 33% (Chester et al., 2002) and 35% (Bulstrode et al., 2005). Neither of these two studies reported an intention-to-treat analysis, however one (Bulstrode et al., 2005) reported attempting to contact those lost to follow-up by phone to assess their outcome. The analysis section was hampered in two RCTs by data being reported without means or *p*-values (Khandwala et al., 2000) and without an effect size (Chester et al., 2002; Khandwala et al., 2000).

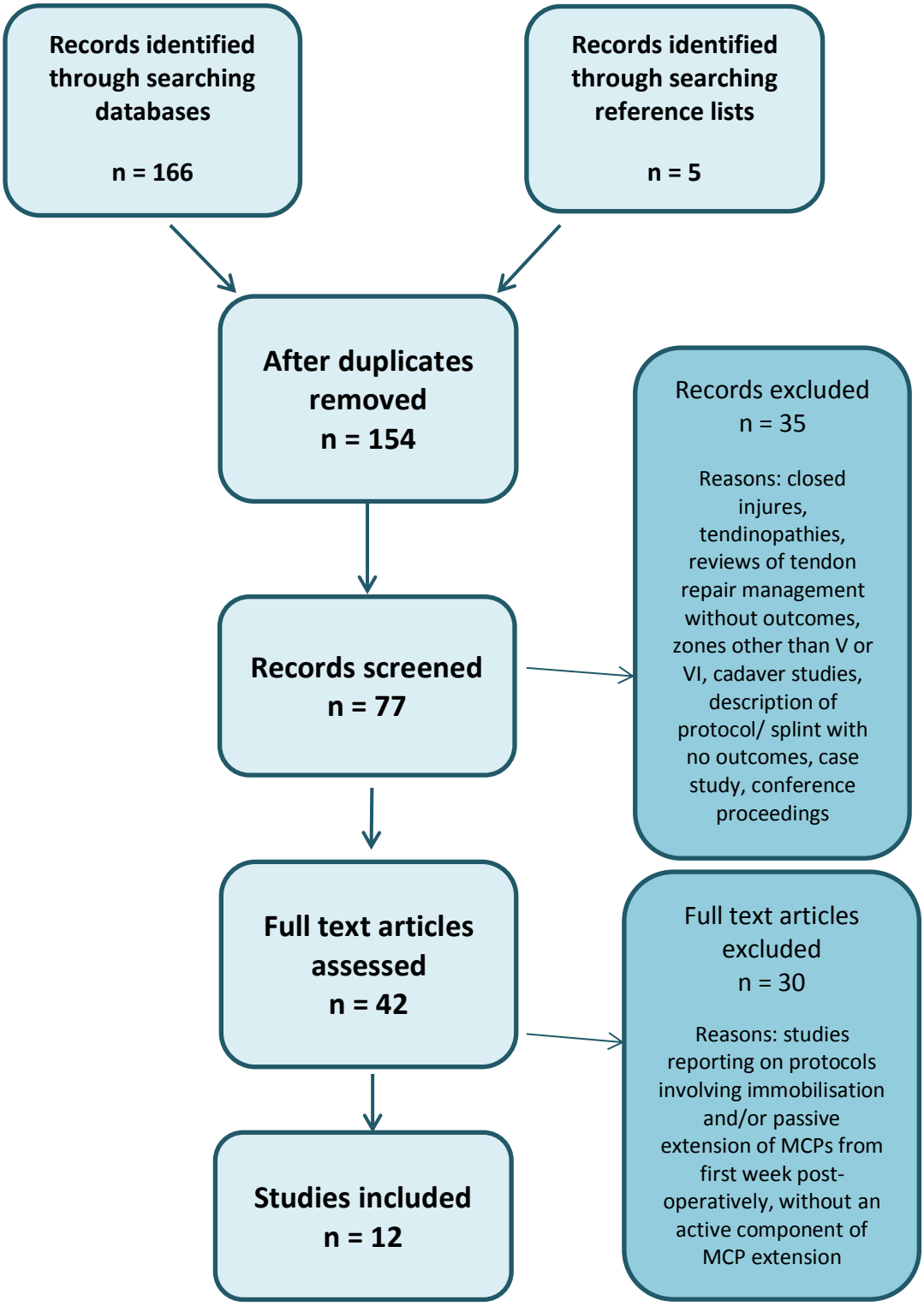

Figure 11. PRISMA flow diagram. From "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement," by D. Moher, A. Liberati, J. Tetzlaff & D. Altman, The PRISMA Group, 2009, *PLoS Med 6(6): e1000097*. Copyright 2009 by Moher et al.

Of the 12 studies included in this review, one was a pilot study with a randomised design (Hall et al., 2010). This study was rated as having 'good' methodological quality and achieved a score of 34 on the SEQES. This study was notable for its development of a training manual for therapists to reduce treatment provider bias. A sample size calculation was performed but unfortunately there was a high loss to follow-up of 33%; there was no mention of an intention-to-treat analysis, although the mean age of those who dropped out was reported.

Of the 12 studies included in this review, three were cohort studies where two or more cohorts were compared. Two studies used a prospective design including two or more cohorts (Evans, 1995; Hall et al., 2010; Svens et al., 2015) and one a retrospective design of two cohorts (Hirth et al., 2011). The SEQES scores for these cohort studies ranged from 22 (Evans, 1995) to 33 (Svens et al., 2015), with one study rated as having 'good' (Svens et al., 2015) and two rated as having 'moderate' methodological quality (Evans, 1995; Hirth et al., 2011).

Blinding of participants and therapists was not possible in any of the cohort studies however Svens et al. (2015) made use of assessor blinding. Each of the three groups in one study (Evans, 1995) were recruited during different time periods over 15 years which increased the risk of confounding variables such as change in suture material or technique which could have influenced the outcome. The two groups investigated in the study by Svens et al. (2015) were treated at two different centres which may have introduced a risk of selection bias and/or treatment bias. A sample size calculation was utilised in one study (Svens et al., 2015) but unfortunately these authors reported a high loss to follow-up of 30%. The study by Evans (1995) stated one group demonstrated 'significant' improvement but neglected to indicate whether statistical testing had been carried out.

Four of the 12 included studies were single cohort studies with no comparison group (Altobelli et al., 2013; Howell et al., 2005; Saini et al., 2008; Sylaidis et al., 1997). Two were prospective (Saini et al., 2008; Sylaidis et al., 1997) and two retrospective (Altobelli et al., 2013; Howell et al., 2005). Scores ranged from 16 (Saini et al., 2008) to 19 (Howell et al., 2005) with all four studies rated as having 'low' methodological quality.

The study design scored poorly in all four single cohort studies due to the absence of a comparison group and because there was no therapist blinding. Loss to follow-up was moderately high in two studies at 27% (Howell et al., 2005) and 15% (Sylaidis et al., 1997). Howell et al. (2005) did not mention an intention-to-treat analysis, however Sylaidis et al. (1997) reported on the early outcomes of those lost to follow-up. The study by Howell et al. (2005) included a high number of participants (140), however they were recruited over a 10 year period and it is unclear whether the mobilisation protocol was consistently applied over this time. Statistical analysis was limited in all four studies with results for the primary outcome only reported categorically by numbers of excellent, good, fair or poor results rather than with mean scores, *p*-values and confidence intervals.

Table 2. Quality assessment of included articles using the Structured Effectiveness Quality Evaluation Scale (SEQES)

Evaluation Guidelines	Question	Study Design							Subjects				Intervention			Outcomes			Analysis					Recommendations	Score	Rank
Author + Date	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**Total**	
Randomised controlled trials																										
Bulstrode, Burr, Pratt & Grobbelaar (2005)	1	2	1	2	2	1	1	2	2	1	0	0	2	1	2	2	2	2	2	1	2	1	2	2	**36**	Good
Chester, Beale, Beveridge, Nancarrow & Titley (2002)	2	2	1	2	2	1	1	0	1	2	0	0	2	1	2	2	1	2	2	1	1	0	2	1	**31**	Moderate
Khandwala, Webb, Harris, Foster & Elliot (2000)	2	2	1	1	1	1	1	0	2	2	0	2	2	1	2	2	1	1	1	1	0	2	2	2	**32**	Moderate
Patil & Koul (2012)	1	1	1	2	1	1	1	2	2	2	0	2	2	1	2	2	2	2	1	1	2	1	2	2	**36**	Good
Pilot study																										
Hall, Lee, Page, Rosenwax & Lee (2010)	2	2	1	2	1	1	1	0	1	1	1	0	2	2	2	2	2	2	2	0	2	1	2	2	**34**	Good

Evaluation Guidelines	Question	Study Design							Subjects				Intervention			Outcomes			Analysis						Recommendations	Score	Rank
Cohort studies: more than one group																										
Evans (1995)	2	1	0	1	0	1	1	0	0	1	0	1	2	0	2	2	0	1	0	1	0	1	2	2	**21**	Moderate
Hirth et al. (2011)	2	2	1	0	0	1	1	0	1	2	0	2	2	1	2	2	2	2	2	0	1	2	2	2	**32**	Moderate
Svens, Ames, Burford & Caplash (2015)	2	2	1	2	0	1	1	1	0	2	1	1	2	1	2	2	2	2	2	1	2	0	2	1	**33**	Good
Cohort studies: single group																										
Altobelli, Conneely, Haufler, Walsh & Ruchelsman (2013)	2	0	0	0	0	0	0	0	2	2	0	2	2	0	0	2	0	1	0	0	0	1	2	2	**18**	Low
Howell, Merritt & Robinson (2005)	2	0	0	0	0	0	0	0	2	2	0	1	2	0	0	2	2	1	0	1	0	0	2	2	**19**	Low
Saini, Sharma & Patni (2008)	1	0	1	1	0	0	0	0	1	1	0	2	2	0	0	1	0	1	0	0	0	2	2	1	**16**	Low
Sylaidis, Youatt & Logan (1997)	1	0	1	2	0	0	0	0	1	2	0	1	2	0	0	1	2	1	0	0	0	1	1	2	**18**	Low

2.3.2 Characteristics of included studies

The characteristics of the included studies are detailed in Table 3. All studies included tendon repair within zone V and the majority included zone VI extensor tendon repairs (Bulstrode et al., 2005; Chester et al., 2002; Evans, 1995; Hall et al., 2010; Hirth et al., 2011; Howell et al., 2005; Khandwala et al., 2000; Patil & Koul, 2012; Saini et al., 2008; Svens et al., 2015; Sylaidis et al., 1997). By definition of the inclusion criteria, the protocols included in the review all allowed active extension of the MCP joint(s) of the injured digit(s) within the first week post-operatively.

In general, all protocols required the wearing of a splint post-operatively to limit flexion of the digit(s) with repaired tendons. The splint was usually worn full time for four to six weeks, whereafter it was weaned, while being worn for another two weeks at night and for risk periods. During the first four to six weeks all protocols, except that described by Hirth et al. (2011), described an exercise regime to promote tendon glide. Interventions to address limited ROM and strengthening were gradually introduced after the full time splinting was discontinued (Altobelli et al., 2013; Bulstrode et al., 2005; Chester et al., 2002; Hirth et al., 2011; Khandwala et al., 2000; Saini et al., 2008; Svens et al., 2015). Comparative studies compared EAM protocols to immobilisation (Bulstrode et al., 2005; Evans, 1995; Hall et al., 2010; Hirth et al., 2011; Patil & Koul, 2012), EPM protocols (Chester et al., 2002; Evans, 1995; Hall et al., 2010; Khandwala et al., 2000) or an alternative EAM protocol (Svens et al., 2015).

Although all protocols used in the studies were classified as EAM, on closer review it was found that the EAM protocols could be divided into one of two groups. Eight studies could be classified as investigating ‘controlled active motion’ (CAM) protocols (Bulstrode et al., 2005; Chester et al., 2002; Evans, 1995; Hall et al., 2010; Khandwala et al., 2000; Patil & Koul, 2012; Saini et al., 2008; Sylaidis et al., 1997) and four as investigating ‘relative motion extension splinting’ (RMES) protocols (Altobelli et al., 2013; Hirth et al., 2011; Howell et al., 2005; Svens et al., 2015). None of the included studies directly compared the outcomes of participants treated with CAM and RMES protocols. Most of the studies investigating CAM protocols were more than 10 years old with only three published after 2005 (Hall et al., 2010; Patil & Koul, 2012; Saini et al., 2008), while those investigating RMES protocols were more recent, with no studies

published prior to 2005. The methodological quality and level of evidence of studies describing CAM protocols differed from those describing RMES protocols. Studies on CAM protocols included six studies of good/moderate methodological quality (level 2 and 3 evidence) while those on RMES protocols included two studies of good/moderate methodological quality (level 3 and 4 evidence).

In CAM protocols the wrist and MCPs were included in a one-piece forearm-based splint (Bulstrode et al., 2005; Evans, 1995; Hall et al., 2010; Khandwala et al., 2000; Patil & Koul, 2012; Saini et al., 2008; Sylaidis et al., 1997) as in Figure 12; this design may have enabled some restricted use of the hand in a hook or lateral pinch grasp. Some CAM protocols additionally included the IP joints in the splint (Chester et al., 2002; Evans, 1995; Patil & Koul, 2012; Saini et al., 2008; Sylaidis et al., 1997) which is likely to have prevented any functional use of the hand. In contrast, the RMES protocols made use of a small 'yoke' splint which positioned the MCPs of the injured digit(s) in relative extension to those of the non-injured digits (Altobelli et al., 2013; Hirth et al., 2011; Howell et al., 2005; Svens et al., 2015) as in Figure 13; the non-injured digits were left free, enabling grasp. Some RMES protocols included the wrist in a separate splint (Altobelli et al., 2013; Howell et al., 2005; Svens et al., 2015).

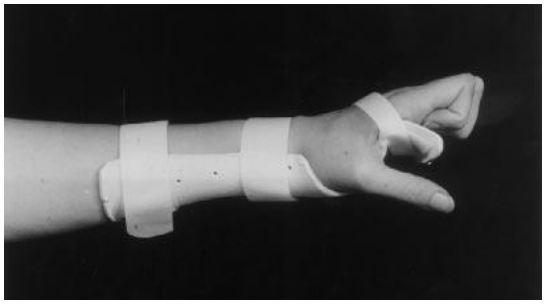

Figure 12. Splint used in controlled active motion (CAM) protocol. From "A Comparison of Dynamic Extension Splinting and Controlled Active Mobilization of Complete Divisions of Extensor Tendons in Zones 5 and 6," by A. Khandwala, J. Webb, S. Harris, A. Foster & D. Elliot, 2000, *Journal of Hand Surgery, 25 B(2)*, p. 143. Copyright 2000 by Elsevier.

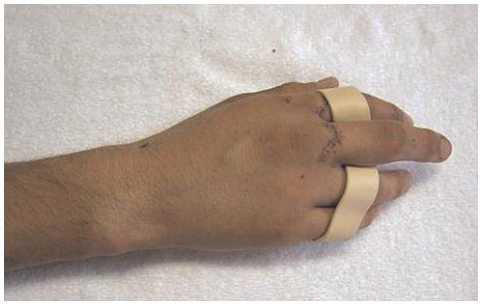

Figure 13. Splint used in relative motion extension splinting (RMES) protocol. From "Early Return to Work and Improved Range of Motion with Modified Relative Motion Splinting: A Retrospective Comparison with Immobilization Splinting for Zones V and VI Extensor Tendon Repairs," by M. Hirth, K. Bennett, E. Mah, H. Farrow, A. Cavallo, M. Ritz, & M.Findlay, 2011, *Hand Therapy, 16(4)*. p. 90. Copyright 2011 by SAGE publications. Reprinted with permission.

An important difference was found between RMES and CAM protocols in included studies regarding advice to participants on when to resume functional use of the injured hand. Participants treated with CAM protocols were advised to commence use of the hand for light activities at four or six weeks after daytime splinting was discontinued (Chester et al., 2002; Hall et al., 2010; Khandwala et al., 2000; Patil & Koul, 2012). Some functional use of the hand may have been possible while wearing the CAM splint with the IP-free design, however one group (Bulstrode et al., 2005) specifically stated that this was a negative aspect of the design because it might encourage early use of the hand. Participants treated with CAM protocols were advised to return to work at six to 10 weeks (Chester et al., 2002; Hall et al., 2010) and full heavy duties from 12 weeks (Chester et al., 2002; Khandwala et al., 2000).

In contrast, participants treated with RMES protocols were encouraged to commence light functional use of the hand immediately from the time of splint application and were advised to return to heavier tasks earlier. One group (Howell et al., 2005) explained that advantages of the RMES splint were that it enabled 'immediate active motion and function' and allowed the participant to resume 'normal activities.' Hirth et al. (2011) specifically encouraged participants to use their hands functionally within the RMES splint. Participants in an RMES group in one included study (Svens et al., 2015) were encouraged to commence light activities of daily living and return to work on light duties within the first three weeks. Participants in another included study treated with an RMES protocol (Howell et al., 2005) were allowed to return to heavy tasks from three weeks while wearing the splint. Participants treated with an RMES protocol described by Hirth et al. (2011) were allowed to return to heavy duties provided they wore the yoke until 8 to 10 weeks.

Table 3. Study Characteristics

Authors	Type of study	Inclusion	Interventions	n= participants (fingers)	Characteristics
Randomised controlled trials					
Bulstrode, Burr, Pratt & Grobbelaar (2005)	Prospective randomised trial: Immobilisation vs EAM (CAM) vs MCP immobilisation with free IPs	Zone V or VI Complete divisions, simple	(a) Immobilisation: splint: wrist 30° extension, MCP and IP extension (b) CAM: splint: wrist 45° extension, MCP 50° flexion, IP neutral; exercises: actively extend MCP and IP joints, then actively extend MCP joints and flex and extend IP joints (c) Immobilisation with free IPs: splint: wrist 30° extension, MCP extension, IP free; exercises: IP flexion/extension (a), (b), (c): splint for 4wks fulltime, then only at risk; scar massage when wound healed; from 4wks full active motion + passive extension; passive and resisted flexion from 8wks	n = 42 (46 tendon divisions) (a) 17 (17 tendons) (b) 10 (13 tendons) (c) 15 (16 tendons) Loss to follow-up: (a) 10, (b) 3, (c) 2	Male: 90% RHD: n = 32 Age: 35yrs
Chester, Beale, Beveridge, Nancarrow & Titley (2002)	Prospective randomised controlled trial: EAM (CAM) vs EPM	Zone IV to VIII Simple tendon divisions > 50%; no thumb injuries, no associated fracture or palmar injuries, no < 10yr olds	(a) CAM: splint: wrist 30° ext, MCP 30° flexion, IP full extension; exercises: remove splint, MCP flexion/extension with IP extension, IP flexion/ extension with MCPs extended; (b) EPM: day splint: wrist 30° extension, MCP neutral, IP free; night splint: wrist ° extension, MCP neutral, IP free; night splint: wrist 30° extension, MCP neutral, IP extension; exercises: MCP active flexion/ passive extension, IP flexion/extension in splint (a)+ (b) 2wks: wrist extension/flexion; 3wks fist formation, active extension exercises' scar management; 4wks: discontinue splint except night; 4-6wks passive flexion MCP, 6-8wks: strengthening	n = 54 (a) 30 (b) 24 Loss to follow-up: (a) 11 (b) 7	Male: (a) 75% (b) 89% Age: (a) 31yrs (b) 33yrs Dominant injured (a) 72% (b) 55%

Authors	Type of study	Inclusion	Interventions	n= participants (fingers)	Characteristics
Randomised controlled trials continued					
Khandwala, Webb, Harris, Foster & Elliot (2000)	Prospective randomised trial: EPM vs EAM (CAM)	Zone V and VI, complete divisions; simple injuries only; exclude 1 tendon repaired IF/ LF	(a) EPM: splint : wrist neutral, rubber bands holding MCPs in neutral extension; IPs free; exercises: IP flexion/extension, MCP active flexion/ passive extension; splint until 4wks; passive flexion/ultrasound after 5wks (b) CAM: splint: wrist 30° extension, MCPs 45° flexion, IPs free; exercises: active flexion/extension IP and MCP in splint; MCP extension to neutral; from 2wks 70° MCP flexion allowed + hyperextension of MCP with IPs flexed; splint until 4wks; passive flexion/ultrasound after 5wks	Total: 100 (a) 50(78) (b) 50(84) Zone V (a) 39 (b) 52 Zone VI (a) 39) (b) 32 Loss to follow-up: excluded: 6pts disappeared after hospital discharge; 19 pts did not attend follow-up; 5 pts ruptured before 1st hand therapy appt	Male (a) 96% (b)98% Age: (a) 30yrs (b) 28yrs
Patil & Koul (2012)	Prospective randomised trial: EAM (CAM) vs immobilisation	Zone V –VII; simple lacerations; exclude complex injuries and IF/ LF if only 1 tendon injured, incomplete injuries	(a) Immobilisation: static splint; wrist 30° extension, finger joints in extension; after 4wks IPs free and graded MCP flexion allowed; splint till 6wks; splint night until 8wks (b) CAM: Splint (only injured fingers); wrist 30° extension, MCPs + IPs in extension; removable wedge to allow 30° flexion/ extension of MCPs for exercise, gradually increased MCP flexion allowed; from 2wks IPs free; wedge removed from 4wks; splint until 6 wks	45 (119 tendons) (a) 22 (58 tendons) (b) 23 (61 tendons) Loss to follow-up: 0 until 12wks, 3 at 6 mths	'Majority manual workers'

Authors	Type of study	Inclusion	Interventions	n= participants (fingers)	Characteristics
Pilot study					
Hall, Lee, Page, Rosenwax & Lee (2010)	Pilot randomised controlled study: Immobilisation vs EPM vs EAM (CAM)	Zone V + VI repairs; exclude if unable to comply or if only 1 tendon repaired in IF or LF; include joint capsule damage + infection of interosseous muscle and finger joints	(a) Immobilisation: splint 3/52, wrist 40-45° extension, MCP 0-20°, IP 0°, then graded mobilisation, discontinue splint 6 wks; (b) EPM: splint: wrist 40-45° extension, MCP 0°, palmar block to allow MCP active flexion to 30-40°, passive extension; exercises: active MCP flexion, passive MCP extension with IP extended; therapist-supervised passive wrist tenodesis + IP motion; palmar block removed 3wks, splint discontinued 5 wks (c) CAM: splint: wrist 30° extension, MCP 45° flexion, IP free; exercises: MCP flexion/extension with IPs extended; composite active flexion/extension in splint; after 3 wks splint allows 70° MCP flexion, start active hook fists; splint discontinued 5wks	n = 27 Results given for n= 18 (24) (a) 4 (b) 5 (c) 9 Loss to follow-up: 9 of 27 prior to 12wks	Male (a)n= 4, (b)n= 4, (c)n= 9 Manual occupation (a)n= 3, (b)n= 3, (c)n= 4 Multiple digits (a)n= 1, (b)n= 3, (c)n= 2
Cohort studies: more than one group					
Evans (1995)	Prospective cohort study: Immobilisation vs EPM vs EAM (CAM)	Zone V – VII and thumb IV and V; simple and complex	(a) Immobilisation: splint: wrist 40° extension, MCP 0°: 3-6wks (b) EPM: splint: wrist extension 40°, dynamic slings MCP + IP in neutral; palmar block prevent > 30-40° MCP flexion; exercises: active MCP flexion, then allow passive extension; passive hyper-extension MCP and passive flexion PIP 70-80°; therapist-supervised wrist tenodesis; 3wks: volar block removed; 5-6wks discontinue splint; 'standard protocols' in wk 3-6 (c) CAM: splint and exercises as for EPM; addition: therapist supervised exercises: wrist placed 20° flexion, and IP held in extension, active MCP flexion/ extension 0-30°	n = 147 (271) (a) 24 (46 tendons) (b) 100 (184 tendons) (c) 23 (41 tendons) Zone V/VI (a) 14 (24 tendons) (b) 84 (151 tendons) (c) 18 (31 tendons) Loss to follow-up: not noted	Zone V/VI complex (a) 80% (b) 67% (c) 44% No demographics

Authors	Type of study	Inclusion	Interventions	n= participants (fingers)	Characteristics
Cohort studies: more than one group continued					
Hirth et al. (2011)	Retrospective cohort: EAM (RMES) vs immobilisation	Zone V and VI, single finger, exclude associated fractures, incomplete data set, under 17 years, failure to attend follow-up	(a) Immobilisation: splint: wrist 30° extension, MCP 30° flexion, IP extension; fulltime 4wks, then discontinue completely; commence home exercise programme for joint stiffness, tendon lag or scar adherence; avoid 'heavy' tasks 8-10wks (b) RMES: daytime: yoke only; MCP of injured digit in 15-20° relative extension to other MCP; all 4 fingers included; no wrist immobilisation; night time: splint as for immobilisation group; splint for 4wks, thereafter splint for 'heavy' tasks until 8-10wks; no specific exercises until 4 wks, then home exercise programme for joint stiffness, tendon lag or scar adherence	n = 39 (a) 16 (b) 23 Loss to follow-up: excluded by definition	Male: (a) 81.3% (b) 95.7% Age: (a) 39.4yrs (b) 37.2yrs Zone V: (a) 81.3% (b) 91.3% Manual workers: (a) (37.8%) (b) (47.8%)
Svens, Ames, Burford & Caplash (2015)	Prospective cohort two groups EAM (RMES – compare two versions)	Zones IV, V, VI Simple laceration 80-100%	(a) Immediate relative active motion (IRAM) – orthosis: wrist 20-25° extension, MCP 15-20° relative extension. Finger flexion/extension exercises, wrist exercises from 3wks Wrist splint weaned after 3wks, yoke weaned at 6 wks; strengthening from 5-6wks (b) Modified Immediate relative active motion (mIRAM) – zone IV/V yoke only, zone VI or EDM repaired yoke + wrist splint (as for (a)), exercises as per (a); Wrist orthosis weaned after 3wks; yoke orthosis weaned 4wks; strengthening from 4 weeks	(a) 45(48) (b) 18 (19) Total=63 Loss to follow-up: 4wks: (a) 9 (b) 4 6wks: (a) 12 (b) 4 8wks: (a) 13 (b) 6	Male: (a) 89% (b) 78% Age: (a) 35yrs (b) 35yrs Dominant hand injured: (a) 49% (b) 44% Manual work: (a) 58% (b) 33%

Authors	Type of study	Inclusion	Interventions	n= participants (fingers)	Characteristics
Cohort studies: single group					
Altobelli et al. (2013)	Retrospective review one cohort: EAM (RMES)	IV and V and thumb zone TII,III, IV; complete injury, simple.	Daytime splint: wrist 20-25° ext, MCP 15-20° relative ext; full time; full active motion in splint; wrist splint weaned 3-5wks, start wrist exercises; yoke weaned 5-7wks; strengthening from 8 weeks Night-time splint: wrist neutral, all finger joints extended; worn 6wks	8 (9) Fingers: 5 (6) Loss to follow-up: 0	Age: 31yrs Male: 88%
Howell, Merritt & Robinson (2005)	Retrospective review: EAM (RMES)	Zone IV - VII tendon repairs – at least one but not all; simple and complex; complex incl complete laceration with no tenorrhaphy	RMES: Splint: wrist 20-25° extension, separate yoke positions affected MCP in 15-20° relative extension to other digits; exercises: until 3wks both splints worn fulltime, full active flexion/extension of fingers to be obtained within splint; scar massage; 3wks – 5wks: wear yoke fulltime, start wrist extension/flexion exercises, combine wrist flexion + fist, wrist + finger extension if no lag ; wean out of wrist splint for light actv once wrist moves freely; from 5wks start weaning from yoke, wean fully once full composite wrist + finger motion obtained	n = 140 Zone IV: 14 Zone V: 112 pts Zone VI: 9 Zone VII: 5 Loss to follow-up: 27%	Male: 87% Dominant injured: 86% Age: 34yrs Simple: n= 89 Complex: n= 51
Saini, Sharma, Sharma & Patni (2008)	Prospective observational single cohort: EAM (CAM)	Zone V- VIII; simple and complex injuries , include flexor tendon injuries	Splint: wrist 45° extension, MCP 50° flexion, IP extended; exercises: MCP + IP extension and MCP extension with IP flexion; splint till 4 wks if extensor lag <30°, 6 wks if lag >30°; continue splint at night another 2wks; from 4wks increase composite flexion; strengthening from 6wks; scar massage if adherence	Total: 26 Zone V: 4 Zone VI: 11 Zone VII-VIII: 11 EPL: 31% Loss to follow-up: 0	Male: 73% 20 patients <30yrs old Dominant injured: 62% Multiple tendon involvement: 85%

Authors	Type of study	Inclusion	Interventions	n= participants (fingers)	Characteristics
Cohort studies: single group continued					
Sylaidis, Youatt & Logan (1997)	Prospective observational study: EAM (CAM)	Zone IV to VII, complete Primary extensor tendon repair; simple and complex	CAM: Splint: wrist 45° extension, MCP 50° flexion, IP extension; exercises: MCP and IP extension; MCP extension with IP flexion; 4wks: discontinue splint, wear only at night; start gentle fist formation unless lag, then delay by 2 weeks; 6wks: discontinue night splint	n = 27 Simple = 23 (26 tendons) Complex = 10 (15 tendons) Loss to follow-up: not noted	Male: 100% Age: 28yrs

Note. actv = activities; CAM = controlled active mobilisation protocol; EAM = early active mobilisation protocol; EPL = extensor pollicus longus; EPM = early passive mobilisation protocol; excl = exclude; IF = index finger; incl = include; IP = interphalangeal joint; LF = little finger; MCP = metacarpophalangeal joint; n = number; RMES = relative motion extension splinting protocol; wks = weeks; yrs = years

2.3.3 Outcomes of included studies

Outcomes of included studies are presented in Table 8.

Range of motion (ROM)

ROM was the most frequently reported outcome in all 12 studies. ROM was reported in various ways with total active motion (TAM) the most common method. TAM is the sum of degrees of active flexion of the MCP + PIP + DIP joints of the affected digit, minus the sum of the extensor lag of MCP + PIP + DIP joints of that digit (Kleinert & Verdan, 1983). TAM was reported as degrees of motion (Bulstrode et al., 2005; Evans, 1995; Hall et al., 2010; Patil & Koul, 2012; Svens et al., 2015), and/or categorised as a percentage of the TAM of the contralateral uninjured digit as per Kleinert and Verdan (1983) (Table 4) (Bulstrode et al., 2005; Chester et al., 2002; Evans, 1995; Hirth et al., 2011; Khandwala et al., 2000; Svens et al., 2015).

Table 4. TAM Classification

TAM classification	Percentage of contralateral digit TAM
Excellent	Normal
Good	>75%
Fair	>50%
Poor	<50%
Worse	Worse than before surgery

Note. From "Report of the Committee on Tendon Injuries," by H. Kleinert & C. Verdan, 1983, *The Journal of Hand Surgery*, *8(5)*. p. 797. Copyright 1983 by American Society for Surgery of the Hand.

An alternative method for reporting ROM was Miller's criteria (H. Miller, 1942) reported as flexion and extension lag (Howell et al., 2005; Svens et al., 2015) (Table 5) or as a combined score (Altobelli et al., 2013; Khandwala et al., 2000).

Table 5. Miller's Criteria

Miller's criteria	Excellent	Good	Fair	Poor
Active extension lag	None	5-10°	11-45°	>45°
Terminal flexion loss	None	<20°	21-45°	>45°

Note. From "Immediate Controlled Active Motion Following Zone 4-7 Extensor Tendon Repair," by J. Howell, W. Merritt & S. Robinson, 2005, *Journal of Hand Therapy, 18(2),* p. 187. Copyright 2005 by Elsevier. Reprinted with permission.

Two groups (Saini et al., 2008; Sylaidis et al., 1997) reported ROM using Dargan's criteria (Dargan & Woolf, 1969) (Table 6). This tool has been strongly criticised as not being sufficiently stringent with regard to the measurement of flexion, and as having poor intra-rater reliability (Khandwala et al., 2000).

Table 6. Dargan's Criteria

Dargan's criteria	Range of motion
Excellent	Full extension (0°) and flexion to the mid-palmar line
Good	Extensor lag <15° and flexion of pulps to mid-palmar line
Fair	Extensor lag 15-45° OR pulp to mid-palmar line distance of <2cm
Poor	Extensor lag >45° OR pulp to palm distance of >2cm

Note. From "Management of Extensor Tendon Injuries of the Hand," by E. Dargan & R. Woolf, 1969, *Plastic and Reconstructive Surgery, 44(6),* p. 609. Copyright 1969 by American Society of Plastic Surgeons.

ROM outcomes per study at final follow-up are compared in Table 7. High degrees of TAM and high percentages of good and excellent ROM outcomes were reported in all studies in participants treated with both CAM and RMES protocols.

In three comparative studies (Bulstrode et al., 2005; Hirth et al., 2011; Patil & Koul, 2012), EAM protocols showed significantly better ROM results than immobilisation protocols at early time-points but no differences in final ROM outcome. Chester et al. (2002) reported significantly poorer ROM in an EAM group compared to an EPM group at four weeks (p=0.02) but no difference at 12 weeks. Hall et al. (2010) reported significantly better TAM in their EAM group at three weeks (p=0.002), six weeks (p=0.003) and 12 weeks (p=0.004) when compared to EPM and immobilisation protocols, however the results of their study need to be interpreted with caution due to post-hoc testing on a small sample size (n=18) after a high loss to follow-up (33%).

Table 7. Range of Motion (ROM) Outcomes for Included Studies

Range of motion (ROM) at final follow-up						
	TAM Degrees	**TAM** % good & excellent	**Miller's extensor lag %** good & excellent	**Miller's flexor lag** % good & excellent	**Miller's combined** % good & excellent	**Dargan** % good & excellent
RMES protocols						
Altobelli, Conneely, Haufler, Walsh & Ruchelsman (2013)					100	
Hirth et al. (2011)		100				
Howell, Merritt & Robinson (2005)			96	94		
Svens, Ames, Burford & Caplash (2015) mIRAM/IRAM	256/253	100/94	83/72	100/79		
CAM protocols						
Bulstrode, Burr, Pratt & Grobbelaar (2005)		100				
Chester, Beale, Beveridge, Nancarrow & Titley (2002)		100				
Evans (1995)	248					
Hall, Lee, Page, Rosenwax & Lee (2010)	266.2					
Khandwala, Webb, Harris, Foster & Elliot (2000)		95			93	
Patil & Koul (2012)	269					
Saini, Sharma & Patni (2008)						92
Sylaidis, Youatt & Logan (1997) Simple/complex						92/85

Note. IRAM = Immediate Relative Active Motion; mIRAM = Modified Immediate Relative Active Motion

Grip strength

Grip strength was the second-equal most frequently measured outcome (Bulstrode et al., 2005; Hall et al., 2010; Howell et al., 2005; Patil & Koul, 2012; Svens et al., 2015). Mean grip strength at final follow-up was similar for participants treated with a CAM protocol compared to those treated with an RMES protocol. Mean strength measured using a dynamometer was 38.9kg in one CAM group (Hall et al., 2010) and 36kg to 39kg (Svens et al., 2015) or 80% to 94% of the strength of the contralateral hand (Howell et al., 2005; Svens et al., 2015) in RMES groups. The grip strength of participants treated with a CAM protocol in the study by Patil and Koul (2012), measured with a dynamometer, stood out with a reported 77kg at 12 weeks. This high strength is likely because the majority of their population were manual workers which would mean that their usual grip strength may have been greater at baseline, and may therefore not be representative of the populations included in the other studies. Confounders such as the measuring tool or system used for measuring grip strength can influence the results (Roberts et al., 2011). The first author of the current review therefore considers that reporting grip strength as a percentage of the contralateral hand allows for more reliable comparison between studies. No significant differences in grip strength were found between injured and contralateral hands in EAM protocols (Bulstrode et al., 2005) or between EAM, EPM and immobilisation protocols at final follow-up in comparative studies (Hall et al., 2010).

Return to work (RTW)

The time taken for participants to RTW post-operatively was the second-equal most frequently measured outcome (Hirth et al., 2011; Howell et al., 2005; Patil & Koul, 2012; Svens et al., 2015; Sylaidis et al., 1997). There was a wide range of average time to RTW ranging between 2.6 to 10 weeks (Table 3). There were differences in reported RTW times between CAM and RMES groups. Participants treated with CAM protocols RTW between 6.5 to 10 weeks (Patil & Koul, 2012; Sylaidis et al., 1997) while those treated with RMES protocols RTW at 2.6 to 6.7 weeks (Hirth et al., 2011; Howell et al.,

2005; Svens et al., 2015). Participants treated with an RMES protocol RTW significantly faster when compared to an immobilised group (p=0.0062) (Hirth et al., 2011).

Subjective outcomes

Few authors reported on subjective outcomes whilst one (Svens et al., 2015) made use of a validated tool. Svens et al. (2015) made use of the Hand Health section of the PEM, a subjective assessment which has been found to have good internal consistency, internal and external validity for scoring (Dias, Bhowal, Wildin, & Thompson, 2001). Mean scores for the Hand Health section at 12 weeks were from 87% to 93% (100% indicates no problems with hand health). Hall et al. (2010) used a non-validated visual analogue scale to report on overall perceived function. Patil and Koul (2012) assessed pain subjectively using a 0 to 10 scale (with 0 = no pain and 10 = severe pain). Interestingly, no authors in any of the included studies recorded participant adherence, although lack of adherence was recognised as a potential issue with patients who undergo extensor tendon repair in zone V and VI (Hirth et al., 2011; Khandwala et al., 2000).

Hand therapy intervention

The amount of hand therapy intervention is a reflection of the total financial cost of a protocol. Hand therapy intervention was reported in five of the included studies as number of sessions or in total therapy time. One study (Saini et al., 2008) reported that no hand therapy input was required. Total therapy time ranged between 300 minutes and 409 minutes (Bulstrode et al., 2005; Hall et al., 2010). The number of therapy sessions ranged between 3.6 and 9 (Chester et al., 2002; Howell et al., 2005; Svens et al., 2015). Comparative studies showed no significant difference in overall mean therapy time between EAM and immobilisation groups (Bulstrode et al., 2005; Hall et al., 2010) and EPM groups (Hall et al., 2010), or number of therapy sessions between EAM and EPM groups (Chester et al., 2002).

Complications

Tendon rupture is a potential risk of early motion protocols, but was an uncommon reporting from the included studies. The majority of studies (Altobelli et al., 2013; Bulstrode et al., 2005; Chester et al., 2002; Hirth et al., 2011; Howell et al., 2005; Patil & Koul, 2012; Saini et al., 2008; Svens et al., 2015) reported that there were no

ruptures in their populations. Two ruptures occurred in the CAM group in the study by Khandwala et al. (2000). Evans (1995) reported on three ruptures but did not specify in which group they occurred; all three occurred in participants who removed their splints prior to three weeks. No ruptures were reported in any RMES groups. Two studies (Hall et al., 2010; Sylaidis et al., 1997) did not report on whether their participants had any ruptures.

Six of the twelve studies included reported on the rate of infection. Infection rates ranged from 3% to 11.5% in two studies that included CAM groups (Chester et al., 2002; Saini et al., 2008). Three studies that included RMES groups reported an infection rate of zero (Altobelli et al., 2013; Hirth et al., 2011; Howell et al., 2005) and one study of an RMES protocol reported an infection rate of 4% (Svens et al., 2015). One study that included a CAM group (Saini et al., 2008) and two studies that included an RMES group (Altobelli et al., 2013; Howell et al., 2005) reported on the need for tenolysis; no participants in these three studies required tenolysis. One study (Khandwala et al., 2000) reported the development of reflex sympathetic dystrophy in one participant but did not specify whether this was in the CAM or EPM group.

Table 8. Study Results

Authors	Intervention groups	Range of motion (ROM)	Grip strength	Return to work or other functional assessment	Therapy sessions	Complications
Randomised controlled trials						
Bulstrode, Burr, Pratt & Grobbelaar (2005)	(a) Immobilisation (b) CAM ('Norwich') (c) MCP immobilisation with free IPs	**TAM in degrees** 4wks: (a) 79°, (b) 165° (c) 160°** ** (b) and (c) significantly better than (a) 4wks + 6wks: Injured hand TAM significantly poorer than contralateral hand **TAM Kleinert and Verdan % excellent/good** 12wks: 100	**Kg vs contralateral hand** 12wks: (a) 23 vs 45* (b) and (c) no difference *significantly lower than contralateral hand (p<0.01)	-	**Overall mean time** 5hrs (300min), no difference between groups	No ruptures; flexion/extension deficits in 2 patients resolved after 12 weeks.
Chester, Beale, Beveridge, Nancarrow & Titley (2002)	(a) CAM (b) EPM	**TAM % of other hand** 4wks: (a) 77 (b) 87** 3mths: (a) 100, (b) 98 **(b) significantly greater TAM at 4wks (p=0.02) **TAM Kleinert and Verdan % excellent/good** 12wks: (a)100, (b) 100 **Extension lag in degrees** 4 wks (a) 15, (b) 10 12wks: (a) 0, (b) 0 **Flexion deficit in degrees** 4wks (a) 45, (b) 25** 12wks (a) 0, (b) 0 **(b) significantly better flexion lag 4wks	-	-	**Median therapy sessions** (a) 9, (b) 10	No ruptures One patient in each group developed cellulitis

Authors	Intervention groups	Range of motion (ROM)	Grip strength	Return to work or other functional assessment	Therapy sessions	Complications
Randomised controlled trials continued						
Khandwala, Webb, Harris, Foster & Elliot (2000)	(a) EPM (b) CAM	**TAM Kleinert & Verdan % excellent/good** 8wks: (a)98, (b)95 **Miller % excellent/good** 8wks: (a) 95, (b) 93	-	-	-	3 ruptures: 2 ruptures group (b), 1 while riding motorcycle with splint on; 1 rupture group (a); 1 reflex sympathetic dystrophy, resolved
Patil &Koul (2012)	(a) Immobilisation (b) CAM	**TAM in degrees** 4wks: (a) 142, (b) 200** 6wks: (a) 186, (b) 224** 8wks: (a) 212, (b) 246** 12wks: (a) 233, (b) 261** 6mths: (a) 264, (b)269 **Significant difference between the groups at 4 and 6wks (p<0.0001), 8wks (p=0.0001) and 12wks (p=0.0003); but not at 6 mths (p=0.67)	**Kg** 8wks: (a) 51, (b) 58** 12wks:(a) 66, (b) 77** **Significant difference between groups at 8 and 12wks (p<0.01)	**Weeks to return to work** (a) 11wks, (b) 10wks **Pain** (a) Pain wk1, then 4-12wks (b) Pain wk1-2	-	No rupture No need for re-exploration **Oedema** (a) Until 10 weeks post-op (b) First 3-4 weeks
Pilot study						
Hall, Lee, Page, Rosenwax & Lee (2010)	(a) Immobilisation (b) EPM (c) CAM	**TAM in degrees:** 3wk:(a) 109.8, (b) 133.3, (c) 187.9** 6wk: (a) 178.4, (b) 197.7, (c) 248.8** 12wk: (a) 239.9, (b) 247.8, (c) 266.2** **all pairwise differences significant except immobilisation vs EPM **Extensor lag in degrees:** 12wks: (a) 14.6, (b) 14.3, (c) 7.87	**Kg** 12wks: (a) 34.9, (b) 35.6, (c) 38.9	**VAS function improvement** (0-10 scale) (a) 2.78, (b) 3.15, (c) 3.45	**Mean total contact time** 409min, no difference between groups Clinic visits per week 1.75, no difference between groups	-

Authors	Intervention groups	Range of motion (ROM)	Grip strength	Return to work or other functional assessment	Therapy sessions	Complications
Cohort studies: more than one group						
Evans (1995)	(a) Immobilisation (b) EPM (c) CAM	**TAM in degrees** (Timeframe not stated) (a) 189, (b) 235, (c) 248** **(c) Significantly better than (a)	-	-	-	3 ruptures in patients who removed splints prior to 3 weeks
Hirth et al. (2011)	(a) Immobilisation (b) RMES (yoke only)	**TAM Kleinert an Verdan %excellent/good** 6wks (a) 62.5, (b) 78.3** 12wks: (a) 93.85, (b) 100** **significant difference at 6wks, with 12° difference in mean TAM (p=0.0076); use of RMES and increased time after surgical repair = significant improvement in TAM (p=0.014, p<0.0001)	-	**Return to work in weeks** (a) 9.4 (b) 3.3 ** **significant difference (p=0.0062) **Return to work in weeks manual workers** (a) 11.7, (b)7.7** **significant difference (p=0.0071)	-	No infection, no rupture

Authors	Intervention groups	Range of motion (ROM)	Grip strength	Return to work or other functional assessment	Therapy sessions	Complications
Cohort studies: more than one group continued						
Svens, Ames, Burford & Caplash (2015)	RMES (a) Immediate relative active motion (IRAM) (b) Modified Immediate relative active motion (mIRAM)	**TAM in degrees (mean % of contralateral)** 4wks: (a) 205(78), (b) 211(84) 6wks: (a) 236(89), (b) 244 (94)* 8wks: (a) 253(94), (b) 256(99)* **Kleinert & Verdan % excellent and good** 4wks: (a) 72, (b) 86 6wks: (a) 91, (b) 100 8wks: (a) 94, (b) 100 **Miller % excellent/ good extension lag** 4wks: (a) 25 (b) 64 6wks: (a) 48, (b)65 8wks: (a) 72, (b) 83 **Miller % excellent/ good flexion lag** 4wks: (a) 28, (b) 36 6wks:(a) 66, (b) 86 8wks: (a) 79, (b) 100 *TAM significantly better at 6wk and 8wk than 4wk (p<0.0001), 8wk TAM significantly better than 6wk TAM (p=0.0005) No significant difference IRAM vs mIRAM for any outcomes (p≥0.09)	**Kg (% of contralateral)** 6wks: (a) 30 (69), (b) 34 (83) 8wks: (a) 36 (80), (b) 39 (94)* *Grip strength increased significantly from 6 to 8wks (p<0.0001)	**Modified work (wks)** (a) 3.9 (b) 3.2 **Full work** (a) 6.7, (b) 3.7** **Return to full work significantly faster mIRAM group **PEM** Baseline (a) 45%, (b)46% 6wks: (a) 75%, (b) 82% 12wks: (a) 87%, (b) 93%* *PEM 12 wk scores significantly better than 6wk (p<0.0001)	**Mean nr sessions attended** (a) 5.2 (b) 3.6	No ruptures (a) 4% infection, 13% persistent oedema, 1 patient ongoing stiffness + oedema >8/52 (b) No complications

Authors	Intervention groups	Range of motion (ROM)	Grip strength	Return to work or other functional assessment	Therapy sessions	Complications
Cohort studies: single group						
Altobelli, Conneely, Haufler, Walsh & Ruchelsman (2013)	RMES single cohort (with RIHM repair technique)	**Miller % excellent/good** Timeframe not stated 100	-	-	-	No ruptures, no wound infections, no extensor tenolysis surgery required
Howell, Merritt & Robinson (2005)	RMES single cohort	**Miller extension lag % excellent/good** 7wks: 96 **Miller flexion loss % excellent/good** 7wks: 94	**% of contralateral hand:** 7wks: 85	**Days to return to work** 18	**Mean number of sessions** 8.1	No ruptures, no infections, no pain syndromes; no need for tenolysis or capsulotomies
Saini, Sharma, Sharma & Patni (2008)	CAM ('Norwich') single cohort	**Dargan criteria % excellent/good:** 6wks: 92 12mths: 92	-	-	No hand therapy input	No rupture, no tenolysis surgery needed, no re-repairs Scar adherence: 31%; joint stiffness 8%; superficial infection 11.5%, 4% deep infection
Sylaidis, Youatt & Logan (1997)	CAM ('Norwich') single cohort	**Dargan % excellent/ good** 4wks: Simple: 69, Complex: 47 6wks: Simple: 92, Complex: 85	-	**Return to work in weeks** Simple: 6.5 Complex: 8.5	-	-

Note. CAM = controlled active motion protocol; EPM = early passive motion protocol; hrs = hours; IPs =interphalangeal joints; kg= kilograms; MCP = metacarpophalangeal joint; min = minutes; PEM = patient evaluation measure; RIHM = running interlocking horizontal mattress technique; RMES = relative motion extension splinting; TAM = total active motion; VAS = visual analogue scale; wks = weeks

2.4 Discussion of Literature Review

This systematic review was undertaken to investigate the evidence for the use of EAM protocols after extensor tendon repairs in zone V and VI. The aim was to identify whether any one protocol provided superior outcomes. Only full text, English articles were included which may have led to some bias in the results obtained. From a total of 166 articles identified, 12 studies were selected which met the inclusion and exclusion criteria. All studies reported on the outcomes of participants treated with an EAM protocol.

A mix of study designs was included in these 12 studies: three RCTs, one pilot study, three cohort studies including more than one cohort, and four studies reporting the outcomes of one cohort. Following the rating of methodological quality via the SEQES, scores ranged from 16 to 36. Four studies achieved a score of 'good' methodological quality, four a score of 'moderate' methodological quality and four a score of 'low' methodological quality. Common limitations in the 12 included studies were high loss to follow-up, statistical reporting which did not include *p*-values and effect sizes, and in some cases, risk of bias due to non-blinding of assessors or recruitment over extended periods of time. High percentages of excellent and good results were reported in all studies for the primary outcome of ROM; low complication rates were reported. Comparative studies showed significantly better short term outcomes for EAM protocols compared to immobilisation, and variable outcomes for EAM protocols when compared to EPM protocols.

This systematic review found level 2 evidence, i.e. an RCT or observational study with dramatic effect (Oxford Centre for Evidence-based Medicine, 2011), to support the use of EAM protocols after the repair of extensor tendons in zone V and VI. This supports the results of previous reviews which concluded that EAM protocols provide good outcomes after extensor tendon repair in zone V and VI (Hammond et al., 2012; Ng et al., 2012; Sameem et al., 2011; Talsma et al., 2008).

With regard to identifying a superior protocol the studies included revealed two main groups of protocols, CAM and RMES. Studies describing CAM protocols were older and demonstrated a higher level and better methodological quality of evidence than those describing RMES protocols. No studies compared a CAM to an RMES protocol. RMES

protocols had a less restrictive splint design and participants in these studies were advised to return to functional use of the injured hand earlier than those treated with the CAM protocols.

Similar satisfactory ROM and grip strength outcomes were reported for participants treated with CAM and RMES protocols. However there was a notable difference with regard to reported time to return to work post-operatively: participants treated with an RMES protocol returned to work earlier than those treated with a CAM protocol. This earlier return to work in RMES groups may have been influenced by the less restrictive splint design and the advice provided to participants regarding functional use of their hand.

The main concern relating to any tendon rehabilitation protocol is the risk of rupture of the repaired tendon. It is possible that the combination of EAM with less restrictive splinting and advice to return to functional use of the hand earlier could have increased the risk of tendon rupture in participants treated with RMES protocols. Despite this theoretical increased risk, no ruptures were reported in any participants treated with an RMES protocol while small numbers of ruptures were reported in participants treated with a CAM protocol. A number of factors may have influenced the difference in rupture rate in reported for the CAM and RMES groups in the reviewed studies including adherence to splinting, splint design and the strength of the repair.

Adherence to splint wear was not measured in any of the studies, but the reason for rupture in CAM groups was often removal of splints in the early stages (Evans, 1995). The less restrictive RMES splints and the ability to use the hand functionally may have reduced the temptation to remove the splint during the first few weeks for participants treated with RMES protocols. This may have reduced the risk of rupture in the RMES groups.

The design of the splints used in the RMES groups may further have reduced the risk of rupture in these studies. Splinting the affected MCP in relative extension to the other digits may harness the supportive effect of the connection provided by the juncturae tendinae (Howell et al., 2005). Allowing the wrist to be free, as in some RMES

protocols, promotes a tenodesis action which reduces tension on the repaired tendon during active digital extension (Evans, 2012; Sakellariou et al., 2006); this may in fact reduce the risk of rupture, providing patients are cautioned to avoid composite wrist and finger flexion (Hirth et al., 2011).

Studies reporting on outcomes of participants treated with RMES protocols included in this review were more recent than those reporting on CAM protocols. This means that the ability to allow more tendon excursion and active motion without increased risk of rupture may additionally be due to recent improvements in suture technique and materials for tendon repair (Starr, Snoddy, Hammond, & Seiler, 2013).

Heterogeneity of outcome measures made it difficult to compare outcomes in some cases. Future studies would be more comparable if they reported ROM in degrees of TAM and categorisation according to Miller's and Kleinert and Verdan's criteria and reported on grip strength in kilograms and as a percentage of the contralateral side. There was minimal use of subjective patient-rated outcomes in the studies reviewed. A number of validated, standardised tools have been developed to measure subjective outcomes and future studies should employ these tools. Adherence is an important parameter which should be recorded in future studies.

2.5 Conclusion of Literature Review

The past 40 years has involved a gradual progression of rehabilitation after extensor tendon repair in zone V and VI from immobilisation to EPM and more recently EAM. This systematic review of literature has confirmed that there is good evidence for the use of EAM protocols after extensor tendon repair in zone V and VI. Two subcategories of EAM protocols were identified: CAM and RMES. The evidence reviewed suggests that there may be some benefits of RMES protocols over CAM protocols with regard to earlier return to work and decreased incidence of tendon rupture. It is possible that the RMES protocols safely allow easier, earlier functional use of the hand. However CAM and RMES protocols have not been compared. Studies describing RMES protocols are of a lower level of evidence and poorer methodological quality than those describing CAM protocols. In light of the possibly superior outcomes of participants treated with the RMES protocols, and the absence of high level, good quality research

comparing RMES and CAM protocols, it would be appropriate to conduct a well-designed prospective trial comparing the two protocols.

The RMES protocol takes into account all that has been learnt about tendon rehabilitation over the past 40 years and acknowledges the unique function and biomechanics of zone V and VI extensor tendons in its design. The splint is low-profile and appears to be minimally restrictive to tendon glide and function of the hand, while providing sufficient protection for the repaired tendon. The results of a prospective randomised clinical trial may demonstrate an RMES protocol to be the optimal choice for extensor tendon rehabilitation in zone V and VI.

Chapter 3 Methodology

An interventional study was designed to compare the outcomes of participants treated with two different EAM protocols after repair to extensor tendon lacerations in zone V and/or VI. The study was entitled: "Can relative motion extension splinting (RMES) provide an earlier return to function than a controlled active motion (CAM) protocol?"

3.1 Study Design

The study design was a prospective randomised clinical trial with two groups of patients. One group was managed with an extensor CAM protocol and the other with an RMES protocol. Refer to Chapters 1.1.2 and 1.1.3 for the objectives and hypotheses, respectively, for this study.

3.2 Participants

The study sample was recruited from patients under the care of CMH. CMH is the district health board responsible for the tertiary management of hand conditions in the Auckland region. The hospital for CMH, where hand surgery takes place, is called Middlemore Hospital (MMH). Participants were recruited from patients who underwent extensor tendon repair in zone V and/or VI between 26 January 2015 and 28 February 2016 at MMH. Inclusion and exclusion criteria are presented in Table 9.

Table 9. Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Extensor tendon repairs to at least one digit in zone V and/or VI at Middlemore Hospital.	Patients under 16 years old.
Simple tendon lacerations of 50-100% of the tendon substance as assessed intra-operatively by surgeon.	Complex injuries involving unstable fractures or concurrent flexor tendon or other significant injury.
Tendon repair judged suitable for an early controlled active motion protocol by the operating surgeon.	Extensor tendon repairs to more than two digits.
Attendance at first post-operative hand therapy appointment to commence rehabilitation no more than seven days post-operatively.	Lacerations which could not be primarily repaired due to infection.
	Thumb extensor tendon repair
	Any factor which would make the patient unsuitable for inclusion in the view of the treating surgeon or investigator such as a tenuous tendon repair.

3.3 Ethical Considerations

The main risk considered in this study was that there was a small possibility that participants in the RMES group might have a higher risk of rupture of the repaired extensor tendon as they were allowed freer movement of the hand at an earlier time. It was determined that this risk was acceptably low as no previous studies making use of this protocol had reported any ruptures (See Chapter 2.3.3). Plastic and hand surgeons who would be operating on these patients were consulted during the design phase of the trial and were satisfied with the protocol and the low risk of rupture. Ethical approval for the study was obtained from the Southern Health and Disability Ethics Committee (14/STH/164) on 5 November 2014 (Appendix B) and from Auckland University of Technology Ethics Committee (14/377) on 18 November 2014 (Appendix C). This research was approved by the Ko Awatea Research Office at CMH (1843) on 11 December 2014 (Appendix D). The trial was registered with the Australia New Zealand Clinical Trials Registry (ACTRN12615000043538).

Potential participants were informed about the study while they were inpatients at MMH and were provided with a participant information sheet (Appendix E). The details of the study were explained by the treating therapist at the first hand therapy appointment and potential participants were provided the opportunity to ask questions. If they agreed to be included in the study they signed a consent form (Appendix F) prior to the commencement of any study procedures.

In order to further minimise risk of rupture the Primary Investigator (PI) (SC) held training sessions with hand therapists in Auckland involved in treating the participants to ensure they understood the precautions related to the protocol. Therapists were provided with exercise hand-outs (Appendix G), therapist guidelines (Appendix H), a list of ‘do’s and don’ts’ (Appendix I) and the PI’s contact details. The Accident Compensation Corporation (ACC) and participants’ general practitioners (GPs) were informed of their involvement in the study.

Participants were requested to attend two hour long research appointments post-operatively at Manukau SuperClinic (MSC), the outpatient clinic for patients who have

surgery at MMH. It was recognised that this could be an added burden due to travel expenses and time involved. To minimise the burden participants were provided with fuel vouchers of $30 when they attended the research appointments.

3.4 Outcome Measures

The purpose of this study was to determine whether one protocol allowed participants to return to functional use of their hand earlier than the other protocol. One way in which to conceptualise function is by means of The International Classification of Functioning, Disability and Health (ICF) model (Steiner et al., 2002) (Figure 14). According to this model, function consists of the domains of “activity”, “participation”, and “body function and structure” (Metcalf, Adams, Burridge, Yule, & Chappell, 2007). The outcome measures for this study were chosen to incorporate these three domains. The primary outcome “activity” was assessed by the Sollerman Hand Function Test (SHFT) (3.4.2). “Participation” was assessed by the QuickDASH questionnaire and questions regarding return to work timeframes (Chapter 3.4.3). “Body function and structure” were assessed by joint ROM and grip strength (Chapter 3.4.4). Personal factors including adherence to splinting, satisfaction and demographic data, and environmental factors such as type of occupation were also recorded (Chapters 3.4.5 and 3.4.6).

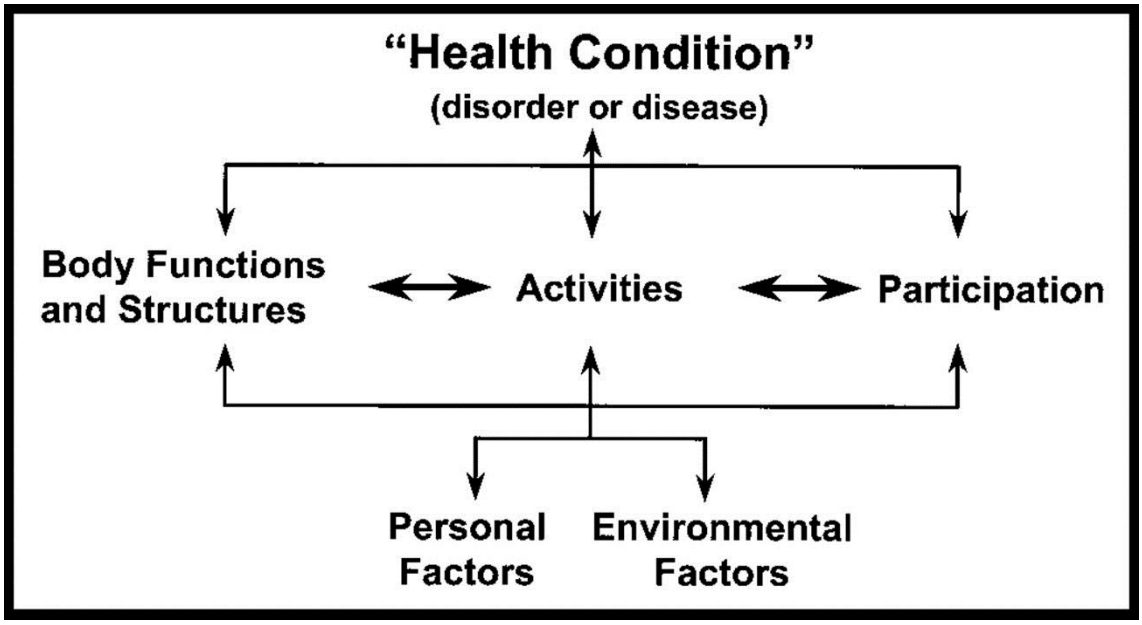

Figure 14. Illustration of the ICF model created by the World Health Organization. From "Use of the ICF Model as a Clinical Problem-Solving Tool in Physical Therapy and Rehabilitation Medicine," by W. Steiner, L. Ryser, E. Huber, D. Uebelhart, A. Aeschlimann & G. Stucki, 2002, *Physical Therapy, 82(11)*, p. 1101. Copyright 2002 by the American Physical Therapy Association.

3.4.1 Timing of outcome measures

Outcomes were measured at four and eight weeks post-operatively. The four week mark was chosen to provide early post-operative outcomes. It was anticipated that at this time participants would be accustomed to using the hand with the splint on functionally, and would be able to report on their functional performance over the early post-operative period. Four weeks was the time-point when full-time splinting was discontinued. Eight weeks was chosen to provide medium to longer term outcomes. It was the time at which participants were discharged from the surgical clinic if there were no concerns and were advised to return to all activities except very heavy tasks.

These assessment time-points made the current study comparable to a recent RMES study which reported outcomes at four, six and eight weeks post-operatively (Svens et al., 2015). Longer follow-up was not deemed necessary as most previous studies reviewing the outcomes of rehabilitation after extensor tendon repair have not found long term differences between rehabilitation protocols (Ng et al., 2012; Sameem et al., 2011; Talsma et al., 2008) and previous studies on rehabilitation involving participants with extensor tendon repair in zone V and VI have reported a high loss to follow-up at later stages of rehabilitation (Khandwala et al., 2000; Svens et al., 2015).

3.4.2 "Activity": Sollerman Hand Function Test (SHFT)

Background of the SHFT

A variety of standardised performance measures have been described for the assessment of hand function (Van Alphen, Oepkes, & Bos, 1996) and were considered during the planning phase of the current study. The SHFT was chosen as it provided a comprehensive assessment of functional performance by incorporating both objective and subjective scoring (Singh, Dias, & Thompson, 2015; Sollerman & Ejeskär, 1995; Weng et al., 2010), and assessing a range of grip patterns (Sollerman & Ejeskär, 1995). In addition the SHFT was quick to administer (20 minutes) (Sollerman & Ejeskär, 1995) and incorporated tasks with which it was felt that most participants in the sample population would be familiar.

The SHFT was designed in 1980 with the full description published in 1995 (Sollerman & Ejeskär, 1995). The SHFT is a standardised performance measure of hand function which makes use of a standardised kit (Figure 15 and Figure 16) and requires the participant to complete 20 everyday tasks (Sollerman & Ejeskär, 1995) (Table 11). Each task has a maximum possible score of four, and a minimum score of zero; a score of 80 is expected for a dominant hand with no functional impairment and a score of 77 to 80 for a non-dominant hand with no functional impairment (Sollerman & Ejeskär, 1995). Scoring for the SHFT (Table 10) is based on: time taken to complete the task, difficulty with which the task is completed and whether or not the prescribed grip pattern is used to complete the task (Sollerman & Ejeskär, 1995).

Figure 15. SHFT view 1

Figure 16. SHFT view 2

In the current study the SHFT was completed for the injured hand at four weeks post-operatively with the splint in situ so that the participant's function while wearing the splint could be assessed. The author is not aware of other studies using the SHFT to assess participants while wearing a splint and this may therefore be a novel application of the SHFT.

Table 10. Scoring of Sollerman Hand Function Test

Score	Description
4	Task completed without any difficulty within 20sec *and* with prescribed hand-grip of normal quality
3	Task completed with slight difficulty *or* • Not completed within 20sec but 40sec *or* • Completed with prescribed hand-grip with slight divergence
2	Task completed but with great difficulty *or* • Not completed within 40sec but within 60sec *or* • Not performed with prescribed hand-grip
1	Task only partially performed within 60sec
0	Task cannot be performed at all

Note. From "Sollerman Hand Function Test: A Standardised Method and its Use in Tetraplegic Patients," by C. Sollerman & A. Ejeskär, 1995, *Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery, 29(2)*, p. 167-176. Copyright 1995 by Taylor & Francis. Reprinted with permission.

Table 11. Sollerman Tasks

No.	Description	No.	Description
1.	Put key into Yale lock, turn 90°	11.	Cut putty with knife and fork
2.	Pick coins up from flat surface, put into purses mounted on wall	12.	Put on Tubigrip stocking on the other hand
3.	Open and close zip	13.	Write with pen
4.	Pick up coins from purses	14.	Fold paper, put into envelope
5.	Lift wooden cubes over edge 5cm in height	15.	Put paper-clip on envelope
6.	Lift iron over edge 5cm in height	16.	Lift telephone receiver, put to ear
7.	Turn screw with screwdriver	17.	Turn door-handle 30°
8.	Pick up nuts	18.	Pour water from Pure-pak
9.	Unscrew lid of jars	19.	Pour water from jug
10.	Do up buttons	20.	Pour water from cup

Note. From "Sollerman Hand Function Test: A Standardised Method and its Use in Tetraplegic Patients," by C. Sollerman & A. Ejeskär, 1995, *Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery, 29(2)*, p. 167-176. Copyright 1995 by Taylor & Francis. Reprinted with permission.

A recent study which used the SHFT to assess participants after a distal radius fracture (Porter, 2013) excluded task 6, lifting a cast-iron iron weighing 2.7kg, at their early assessment due to a risk of injury. In the current study, the same conclusion was made in regard risk of injury for task 6, at the early four week assessment. It was considered that the combination of the weight and the position of composite wrist and finger flexion required to perform the task may overload the tendon, placing it at risk of rupture. Task 6 was therefore excluded at the four week assessment, which meant that the total obtainable score at four weeks was 76 points rather than 80, as was the case in the previously mentioned study by Porter (2013). Task 6 was included at the eight week assessment as the tendon would be in the remodelling phase of healing and strong enough to withstand the weight of the iron without risk of rupture. A minor alteration was made to task 13 'write with a pen'. The original test suggested that the participant should write their name; in the current study the participant was requested to write 'New Zealand' instead. The CMH catchment area includes a wide variety of ethnicities, and it was anticipated that some participants may have much longer names than others due to their ethnicity. The choice of a uniform phrase was an attempt to

standardise this task for the sample population. At eight weeks both hands were tested without the splint. The contralateral hand was assessed to provide a control for each participant. In order to reduce any learning effect, the injured hand was always assessed prior to the contralateral hand at eight weeks.

Psychometric properties of the SHFT

Initial validation of the SHFT was conducted on 40 patients with conditions including rheumatoid arthritis, finger amputations, nerve injuries and impaired ROM due to Dupuytren contracture, shoulder-hand-finger syndrome, burns and fractures (Sollerman & Ejeskär, 1995). The SHFT was correlated with a subjective estimation of function using a 10cm visual analogue scale (r=0.68) and a Swedish disability rating scale used by Swedish insurance companies (r=0.88) (Sollerman & Ejeskär, 1995).

A subsequent study of 43 participants, which included finger tendon lacerations, reported a significant correlation (p<0.05) between the SHFT and the QuickDASH (Akkaya et al., 2013). Other studies involving traumatic hand/wrist injuries have further demonstrated the validity of the SHFT. A study which assessed recovery after distal radius fracture found a significant correlation between the SHFT and the validated DASH score (r_s=-0.53, p<0.011) and patient-rated wrist evaluation questionnaires (r_s=-0.48, p<0.024) (Porter, 2013). In a study of patients with burned hands the SHFT correlated significantly (Intraclass correlation coefficient [ICC]=0.52, p=0.017) with grip strength (Weng et al., 2010). Studies of acquired conditions affecting the hand/upper limb, such as gout and stroke, have also found the SHFT to correlate significantly with previously validated assessments of hand function including grip strength and the QuickDASH (Dalbeth et al., 2007; Eriksson & Lindberg, 2012; Limaye, Frankham, Disney, & Pile, 2001).

Test-retest reliability and inter-rater reliability with regard to scoring was shown to be high (r=0.98) in the initial report for testing of the SHFT (Sollerman & Ejeskär, 1995). In subsequent studies inter-rater reliability for scoring of the SHFT has also been found to be high, in populations with burned hands (ICC=0.98) (Weng et al., 2010), rheumatoid arthritis (r=0.98) (O'Connor et al., 1999) and in a stroke population (r=0.96) (Brogårdh, Persson, & Sjölund, 2007). Intra-rater reliability for the scoring of the SHFT was found to be high in a population with burned hands (r=0.98) (Weng et al., 2010), in a

population with sporadic inclusion body myositis (*r*=0.99) (Eriksson & Lindberg, 2012) and in a stroke population (*r*=0.96) (Brogårdh et al., 2007). A minimal detectable change (MDC) for the SHFT was determined as 7 points in patients with burned hands (Weng et al., 2010) however the author is not aware of an MDC or a minimal clinically important difference (MCID) for the SHFT after tendon repair.

Strengths and limitations of the SHFT

Aside from the strong psychometric properties, another strength of the SHFT is that it assesses the quality and difficulty of the grip used, in addition to the time taken for task completion (Limaye et al., 2001; Sinha, Cresswell, Mason, & Chakrabarti, 2002; Sollerman & Ejeskär, 1995; Weng et al., 2010). This may make it a more thorough assessment of hand function than the commonly used Jebsen Hand Function Test (Jebsen, Taylor, Trieschmann, Trotter, & Howard, 1969) which records only the time taken to complete tasks (Limaye et al., 2001; Sinha et al., 2002; Sollerman & Ejeskär, 1995; Weng et al., 2010). Some functional performance assessments such as the Nine-hole Peg Test or Box and Block Test, only assess fine dexterity whereas the SHFT assesses a variety of grips (Sollerman & Ejeskär, 1995). Other strengths of the SHFT are that it is not limited for use with a specific diagnostic group (Sinha et al., 2002; Sollerman & Ejeskär, 1995) and that it assesses the type of grasp used which means that it accounts for compensatory movements in the score (Eriksson & Lindberg, 2012).

A limitation of the SHFT is that it has been found to have a ceiling effect, where scores tend to cluster around the upper values (Singh et al., 2015). The study by Singh et al. (2015) found that time taken to complete the SHFT was influenced by age, gender and hand dominance; for example, women who were between 30 and 40 years of age took a shorter amount of time to complete the SHFT than other age and gender groups. In the current study the total time taken to complete the SHFT was therefore recorded in addition to the total score; this was to identify subtle differences which may have been masked by the total score and to compare scores to those of a normal population (Singh et al., 2015). Other limitations of the SHFT are that it incorporates only light tasks (Eriksson & Lindberg, 2012) and does not include tasks such as using a keyboard or smart-phone which have become common everyday activities since the development of the tool in 1980. In the current study it was anticipated that the

QuickDASH questionnaire would provide an adjunct to assist in identifying occupational performance issues, such as taking force through the hand when hammering or the ability to carry a bag of shopping, and effect on work or social activities not assessed by the SHFT.

Finally, an important limitation of the SHFT is a possibility of bias due to the subjective nature of some aspects of scoring (Porter, 2013); this possibility was anticipated and managed in the current study. See the following sections: “Pilot testing of the SHFT” and “Validation of the standardised SHFT” for a discussion of this limitation and the management strategies for this limitation for the current study.

Pilot testing of the SHFT

At the commencement of this study, the SHFT was not commercially available. The CMH clinical engineering department constructed the SHFT for this study by copying an existing SHFT on loan, using details from the original description (Sollerman & Ejeskär, 1995) and additional information supplied by a Swedish Occupational Therapist, Birgitte Rosén (personal communication). Ms Rosén has made extensive use of the SHFT in her research on peripheral nerve injuries (Rosen, 1996; Rosén & Lundborg, 2003) and was provided details for the SHFT by one of the original authors, Christer Sollerman.

As mentioned earlier, some concerns have been raised in regard to the subjectivity of scoring of the SHFT (Porter, 2013). Although the instructions for use of the SHFT (Sollerman & Ejeskär, 1995) provide guidance on how to administer the test, it was felt that some instructions were open to interpretation which could reduce inter-rater reliability. Early pilot testing was carried out by the PI and research assistants by assessing other therapists in the MSC hand therapy department while these therapists completed the SHFT and discussing the scoring of the test. During this early stage it was found that calculating the score for each task while simultaneously observing a participant was difficult and could lead to errors. A scoring sheet was therefore developed (Appendix J) based on the instructions provided by the published SHFT instructions (Sollerman & Ejeskär, 1995). It was noted that the different assessors had recorded different timing when observing the same tasks being completed. It was therefore decided that a standardised timing sequence would be used where

participants would start each task with their hand on their lap, when timing would begin, and return their hand to their lap at completion of the task, when timing would end.

Validation of standardised SHFT

Using the scoring sheet and the new timing sequence, as described above, the SHFT was then used to assess four hand therapy patients who were not part of the study. The PI and the two research assistants simultaneously observed each participant perform the SHFT and then compared scoring. The four patients had varying pathologies including tendon repair, nerve repair, spinal cord injury and arthritis, and were identified by their treating therapist as patients who would benefit from assessment with the SHFT; they provided informed consent for their participation.

After the first patient was assessed in this manner, the PI and research assistants found two areas of uncertainty from the scoring of the SHFT, which could potentially lead to discrepancies in the scoring. Interestingly, these same two areas of uncertainty were identified by a previous researcher who examined the validity and reliability of the SHFT (Doehr, 1985). The study by Doehr (1985) did not provide a solution for these areas of uncertainty but reported that they did not appear to affect the overall reliability of the total score.

The first area of uncertainty was deciding how to score a task when a patient demonstrated difficulty completing it. According to the scoring system, 'slight' difficulty scores 3, while 'great' difficulty scores 2. The researchers felt that this distinction was subjective and were unsure how to score a task which they perceived as being completed with 'moderate' difficulty. As a solution, it was decided that if the assessor was unsure how to grade the degree of difficulty, then the timing should be the deciding factor, as a longer time to completion implied a greater degree of difficulty; the task would be scored 3 if completed between 20 and 40 seconds or 2 if it took 40 or more seconds, as per the scoring instructions (Table 10).

The second area of uncertainty was the interpretation of 'slight divergence' from the expected grip pattern, which would score 3 points, and use of a different grasp altogether, which would score 2 points. It was decided that if a similar grip pattern to

that described was used - for example if a lateral pinch was to the middle rather than the index finger - then this was a 'slight divergence' and scored 3, but if a different type of grip - such as transverse volar grip instead of a tripod grip was used - then this would score 2.

The remaining three test patients were assessed using these more defined standards. The scores for the four patients are displayed in Table 12. Results will be described as the numbers were too small for quantitative analysis. As can be seen, the total scores for the last three patients were similar, with the greatest difference between scores being three points and two assessors scoring the same in each case. The standardisation and scoring was applied as described in the current study.

Table 12. Sollerman Hand Function Test Preliminary Assessment Scoring

Assessor	Patient 1	Patient 2	Patient 3	Patient 4
1	36	68	53	64
2	38	68	56	64
3	35	66	53	62

3.4.3 "Participation": QuickDASH questionnaire and return to work

QuickDASH (Disabilities of Arm, Shoulder and Hand) questionnaire

The QuickDASH was developed from the well-validated 30 item DASH questionnaire (Beaton et al., 2005; Hudak, Amadio, & Bombardier, 1996) to provide a briefer version of the DASH while still retaining its measurement properties (Beaton et al., 2005). The QuickDASH (Appendix K) is a patient-rated subjective assessment of upper limb function (Beaton et al., 2005; Gummesson, Ward, & Atroshi, 2006). It consists of 11 questions asking a patient to rate function/symptoms over the past week and makes use of a Likert scale of 1 to 5 for rating, with 1 being the best outcome for each item and 5 being the poorest. For each section a calculation is used to derive a score which provides a total out of 100. Zero indicates no problem or functional difficulty and 100 indicates complete disability. Participants completed the QuickDASH assessment at four and eight weeks post-operatively.

The author is not aware of the use of the QuickDASH in any studies focussed specifically on extensor tendon zone V/VI repairs. However the QuickDASH has been found to be valid in a population which included extensor and flexor tendon injuries (Franchignoni et al., 2014) and has been shown to correlate significantly (p<0.05) with the SHFT in a population which included finger tendon lacerations (Akkaya et al., 2013). The QuickDASH has been found to be valid in a variety of other upper limb conditions including amputation (Resnik & Borgia, 2015), distal radius fractures (Niekel, Lindenhovius, Watson, Vranceanu, & Ring, 2009) and hand burns (Wu, Edgar, & Wood, 2007). High test-retest reliability of scoring was determined in a population of people which included tendon injuries (ICC=0.92) (Franchignoni et al., 2014) and in a population of people with burn injuries (ICC=0.93) (Wu et al., 2007). Using the calculation of effect sizes, the QuickDASH has been found to be responsive to change, with an MDC of 11 points, which means that a change of 11 points in the QuickDASH score detects an actual change in functional ability (Polson, Reid, McNair, & Larmer, 2010; Wu et al., 2007). Furthermore, in a population which included tendon injuries, the QuickDASH has shown an MCID of 15.91 points; this is the smallest change in score that represents a change that is clinically important to the patient (Franchignoni et al., 2014).

Some authors have however criticised the QuickDASH as being poorly responsive due to low correlations with 'global estimates of change' (Kennedy et al., 2013). It has been suggested that the QuickDASH is best suited for conditions which have a significant impact on upper extremity function (Badalamente et al., 2013). Extensor tendon injuries can cause significant disability of the upper extremity (Patillo & Rayan, 2012) and the QuickDASH is therefore considered to be an appropriate tool for assessment in this type of injury.

In addition to the psychometric properties of the QuickDASH, other strengths are that it is specific to the upper limb (Beaton et al., 2005; Wu et al., 2007) and is quicker to complete than the original DASH (Beaton et al., 2005; Kennedy et al., 2013; Polson et al., 2010).

Return to work (RTW)

Previous studies on extensor tendon repairs in zone V and VI using EAM protocols have reported time to return to work in different ways. Some studies reported days or weeks to return to work, without defining whether this was to full or restricted duties (Howell et al., 2005; Sylaidis et al., 1997). One study distinguished between days to return to restricted and full duties (Svens et al., 2015) and another reported return to work for manual workers separately (Hirth et al., 2011). RTW in the current study was recorded in two ways: firstly as days to return to work in any capacity and secondly days to return to full duties post-operatively. If a participant was unable to RTW then the reasons were recorded. Information on RTW was obtained directly from participants, their treating therapists and ACC.

Guidelines for the classification of participants' usual work (Table 13) were derived from the classification used by ACC in their Return to Work guide ACC14191 (ACC, 2006). Participants' usual work was classified as light, moderate or heavy depending on the amount of weight they were usually required to handle in their job and was determined through interview of the participant at the four week assessment.

Table 13. Work classification.

Classification	Description
Light work	Sedentary work or work requiring lifting up to 9kg occasionally and 4.5kg frequently
Moderate work	Lifting up to 22.5kg occasionally, 9kg frequently and 4.5kg constantly
Heavy work	Lifting up to or over 45kg occasionally, up to or over 22.5kg frequently, and up to 9kg constantly.

Adapted from "ACC14191 Return to work guide May 2006," by Accident Compensation Corporation, 2006. Retrieved from www.acc.co.nz

3.4.4 "Body function and structure": Range of motion and grip strength

Range of motion (ROM)

ROM of the injured and contralateral non-injured digits(s) was measured at four and eight weeks using a goniometer (Burr, Pratt, & Stott, 2003; Ellis & Bruton, 2002; Rose, Nduka, Pereira, Pickford, & Belcher, 2002). A Baseline metal finger goniometer was used to measure MCP flexion (Figure 17), PIP flexion, PIP extension (Figure 18) and DIP

extension. A Sammons Preston plastic hyperextension goniometer was used to measure DIP flexion in a composite fist (Figure 19) and to measure hyperextension (Figure 20) (Engstrand, Krevers, & Kvist, 2012). A standardised protocol was used to optimise accuracy of ROM measurement (A. L. Pratt, Burr, & Stott, 2004): the wrist was maintained in neutral (A. L. Pratt et al., 2004), extension was measured with the digits in composite extension and flexion with the digits in composite flexion (Lewis, Fors, & Tharion, 2010). The goniometer was placed dorsally with the axis of the goniometer over the dorsum of the joint, the fixed arm of the goniometer over the proximal bone and the movable arm over the distal bone (Groth, VanDeven, Phillips, & Ehretsman, 2001).

Figure 17. Measuring metacarpophalangeal joint flexion

Figure 18. Measuring proximal interphalangeal joint extension

Figure 19. Measuring distal interphalangeal joint flexion

Figure 20. Measuring metacarpophalangeal joint hyperextension

The PI took all the ROM measurements at each assessment to optimise reliability (Burr et al., 2003; Ellis & Bruton, 2002; Lewis et al., 2010) and remained blinded to the intervention group allocation of the participants to prevent bias while assessing ROM (Hartzell et al., 2013). Active flexion and extension were measured at four and eight weeks.

ROM was reported using Total Active Motion (TAM) and Miller's criteria. This made ROM outcomes comparable to previously published studies which have examined outcomes of extensor tendon repairs in zone V and VI (Altobelli et al., 2013; Hall et al., 2010; Hirth et al., 2011; Howell et al., 2005; Svens et al., 2015). TAM is defined as the sum of degrees of active flexion of the MCP + PIP + DIP of the affected digit, minus the sum of the extensor lag of MCP + PIP + DIP of that digit (Kleinert & Verdan, 1983). In the current study it was recorded as the actual degrees of TAM and categorised as excellent, good, fair or poor when compared to TAM of the contralateral digit as per the recommendation of Kleinert and Verdan (1983) (Table 14).

Table 14. TAM Classification

TAM classification	Percentage of contralateral digit TAM
Excellent	Normal
Good	>75%
Fair	>50%
Poor	<50%

Miller's criteria (Howell et al., 2005) was used to report on extension and flexion lag (Table 15). The lag was determined by comparing the ROM of the injured digit to the contralateral uninjured digit, and combining any lag at the MCP, PIP and DIP joints. As can be seen in Table 15 an extensor lag of between 1 and 4° was not specified in Miller's criteria; for the purpose of this study, an extensor lag of 1° to 4° was included in the 'excellent' category.

Table 15. Miller's Criteria

Miller's criteria	Excellent	Good	Fair	Poor
Active extension lag	None	5-10°	11-45°	>45°
Terminal flexion loss	None	<20°	21-45°	>45°

From "Immediate Controlled Active Motion Following Zone 4-7 Extensor Tendon Repair," by J. Howell, W. Merritt & S. Robinson, 2005, *Journal of Hand Therapy, 18(2),* p. 187. Copyright 2005 by Elsevier. Reprinted with permission.

Few studies report on the reliability of the measurement of hyperextension and the goniometer used in the current study did not measure greater than -30° hyperextension. For this study, it was decided that for the TAM and Miller's criteria calculations, extension which was equal to or greater than 0° (hyperextension) at any joint would be documented as 0° and considered to be full extension; a lack of extension would be documented if the joint was unable to extend to 0°.

Active extension and flexion of the injured and uninjured wrists was measured at four and eight weeks. At eight weeks passive wrist flexion was measured with the fingers in a composite fist to assess for shortening or adherence of the extensor musculotendinous unit. A flexible transparent Jamar goniometer was used to measure wrist range of motion (Figure 21 and Figure 22). Wrist flexion was measured dorsally and wrist extension was measured volarly, with the fixed arm along the midline of the forearm and the movable arm along the third metacarpal as this has been shown to be the most reliable method (LaStayo & Wheeler, 1994). Active flexion and extension were added to calculate an active arc of motion, and was reported as a percentage of the active arc of motion of the uninjured side.

Figure 21. Measuring wrist extension

Figure 22. Measuring wrist flexion

Grip strength

Grip strength was measured in kilograms at eight weeks post-operatively using a Jamar dynamometer (Figure 23). Grip strength was not measured at four weeks as protocols do not generally recommend commencement of strength training prior to four to eight weeks at the earliest, likely due to risk of tendon rupture (Altobelli et al., 2013; Chester et al., 2002; Saini et al., 2008; Svens et al., 2015). In the current study strengthening was commenced after eight weeks. The Jamar dynamometer is the most frequently utilised tool for the assessment of grip strength and has good inter and intra-rater reliability as well as test-retest reliability for this assessment (Roberts et al., 2011).

A standardised protocol was used for measuring grip strength (Mathiowetz et al., 1985). Participants were advised to sit up straight with their feet flat on the ground, arm adducted, the elbow at 90° of flexion and the forearm in neutral rotation and wrist in slight extension. The dynamometer handle was at the second setting (Figure 24). Participants were asked to squeeze as hard as they could until the investigator saw that the needle had stopped rising, and then release the handle.

Figure 23. Jamar goniometer

Figure 24. Jamar testing position

A meta-analysis of studies in the United States of America, United Kingdom, Canada, Australia and Sweden has provided normative grip strength values assessed using a Jamar dynamometer (Bohannon, Peolsson, Massy-Westropp, Desrosiers, & Bear-Lehman, 2006). It is possible that normative grip strength for a New Zealand population may be similar to that of the populations included in the meta-analysis. However, as discussed in Chapter 2.3.3, the specific tool or system used for measuring grip strength could have a confounding effect on the outcome, making comparison in kilograms unreliable. In addition we anticipated a high proportion of manual workers would be included in the current study; manual workers might have a greater grip strength than the general population, making comparisons unreliable. In the current study the grip strength of both hands was therefore measured so that the uninjured hand provided a control for the injured hand, and an average of the three measures was calculated (Mathiowetz et al., 1985). Grip strength was documented in kilograms and as a percentage of the uninjured side regardless of dominance.

3.4.5 "Personal and environmental factors": Adherence and satisfaction

Adherence to splinting

In the current study it was considered important to obtain an indication of the degree of participant adherence to the prescribed protocol as previous studies had found 55% to 67% of participants to be non-adherent to therapists' instructions and/or splinting

after tendon repair (Kaskutas & Powell, 2013; Sandford, Barlow, & Lewis, 2008). Participants were advised that they would be asked about splinting and adherence to splinting as this was an important aspect of the study. Adherence was assessed at the four week assessment by means of a questionnaire (see Appendix L) modified from a questionnaire previously developed to assess patient adherence to wearing thermoplastic splints after tendon repair (Sandford et al., 2008).

At the initial hand therapy appointment the treating therapist provided splint-wear instructions to the participant. The daytime splint was to be worn full time during the day, and removed only for hand hygiene, for wound/scar care and at therapy appointments. The night-time splint was to be worn while sleeping. Participants were advised not to use the hand without the splint on and not to drive until six weeks post-operatively. Accordingly, participants were rated as fully adherent if they removed the daytime splint for less than an hour per day, did not use the hand without the splint on and wore the night splint every night for the first four weeks.

Satisfaction

Participant satisfaction was assessed at eight weeks by administration of a questionnaire developed from the Patient Evaluation Measure (PEM) (Dias et al., 2001; Macey & Burke, 1995). The questionnaire used in the current study (Appendix M) consisted of three sections, with a rating of each item on a Likert scale from one to seven, with one being the best outcome, and seven being the poorest. The first section consisted of 11 questions relating to 'Hand Health', and included items which asked about symptoms such as pain and psychological response to the hand. The second part of the questionnaire 'Splint Satisfaction' was designed for the current study, and consisted of three questions on satisfaction with the splint. The third section 'Overall Assessment' consisted of three questions addressing satisfaction with the hand and the treatment received.

The three sections of the modified PEM were scored separately. It has been suggested that the scores can be added and expressed as a percentage of the total score (Dias et al., 2001) however the results can be confusing to interpret. The biostatistician involved in the current study (IZ) developed a formula by which the raw summed scores of each section could be converted into a percentage of satisfaction so that

100% would indicate that the participant had scored the best outcome for each question.

The PEM score has been found to have high internal consistency and external validity (Dias et al., 2001) and better reproducibility than other outcome questionnaires (R. Sharma & Dias, 2000). The Hand Health section of the PEM score has been found to correlate significantly with grip strength (Dias et al., 2001) and was used as an outcome measure in a recent RMES study on extensor tendon repairs in zone V and VI (Svens et al., 2015).

3.4.6 Participant characteristics

In addition to the outcome measures described above, variables which could potentially confound the outcome were also recorded. These were divided into baseline demographics and injury characteristics

Baseline demographics

- Gender
- Age
- Hand dominance
- Ethnicity
- Smoker (yes or no)
- Occupation type (heavy, moderate or light) as reported by participant defined according to criteria described in Chapter 3.4.3
- Presence of co-morbidities (specifically diabetes or osteoarthritis in the hand)

Injury characteristics

- Number of digits injured
- Whether the dominant hand was injured
- Zone of injury
- Which digit was injured
- Previous injury to injured hand
- Whether or not the joint capsule was involved
- Whether other structures in the same hand were injured simultaneously

- Mechanism of injury
- Delay to surgery

3.4.7 Complications

Tendon rupture, infection and need for tenolysis were considered the most important complications by the research team, after discussion with the MMH surgeons and therapists. These complications were recorded, together with the date they were noted, and the outcome. Rupture was of primary importance as it was considered to be a potential risk with the use of the less restrictive splint used in the RMES protocol. Treating therapists were requested to inform the PI immediately if they had any concerns regarding potential tendon rupture. Infection was recorded from the surgeons' clinic notes. Due to the relatively short follow-up period of the study, it was unlikely that surgery for tenolysis would be performed during the participants' enrolment in the trial, however surgeons' clinic notes were reviewed after the completion of the eight week follow up visit to note any need for tenolysis surgery. Therapists were asked to indicate any complications on the checklist which they returned to the primary investigator.

3.4.8 Therapist checklist

A therapist checklist was developed (Appendix N). Therapists treating participants in the study were requested to complete the checklist at eight weeks post-operatively or once they discharged the patient from their care, and return it to the PI. Therapists were provided with participant hand-outs, exercise sheets and therapist guidelines, and were requested to adhere to them as far as possible but to describe any additional exercises or interventions they used and to contact the PI if they had any concerns. The checklist provided information on concerns, complications, dates of RTW and discharge from hand therapy, number of appointments attended, cancelled and missed by the participant. The checklist included tick-boxes for therapists to indicate which hand therapy interventions had been provided in each week and space to document any additional intervention provided.

3.5 Procedures

3.5.1 Randomisation and blinding

Participants were randomised at their first post-operative hand therapy appointment after providing written informed consent. Randomisation was by means of a sealed envelope with a piece of paper indicating 'RMES' or 'CAM' to provide the group allocation. At the start of the study there were equal numbers of envelopes for each group. Blinding of participants and the treating therapists was not possible, however in order to reduce bias, the PI did not participate in consenting, randomisation or treatment for any of the participants. A research assistant kept a record of participant group allocation which was revealed to the PI at the completion of data collection. To maintain blinding of the PI, two research assistants performed the SHFT at four and eight weeks; the PI assessed the remaining outcomes once the research assistant had ensured that the splint was hidden from view, so that the participant group allocation remained unknown.

3.5.2 Study process

Potential participants were identified while they were inpatients at MMH by the treating surgeon or the inpatient physiotherapists and provided with information on the study. All potential participants had a first post-operative hand therapy appointment arranged within seven days at MSC, the location of the hand therapy outpatient clinic. The hand therapy clinic is staffed by registered hand therapists, occupational therapists and physiotherapists. At the first appointment, the treating therapist explained the participant information sheet, and if the patient consented they were randomised into one of two treatment protocols (CAM or RMES) and commenced on the relevant treatment protocol. Participants who lived in the CMH catchment continued with hand therapy follow-up appointments at MSC, while those living elsewhere in Auckland were referred to a local registered hand therapist for follow-up. The study process is demonstrated in Figure 25.

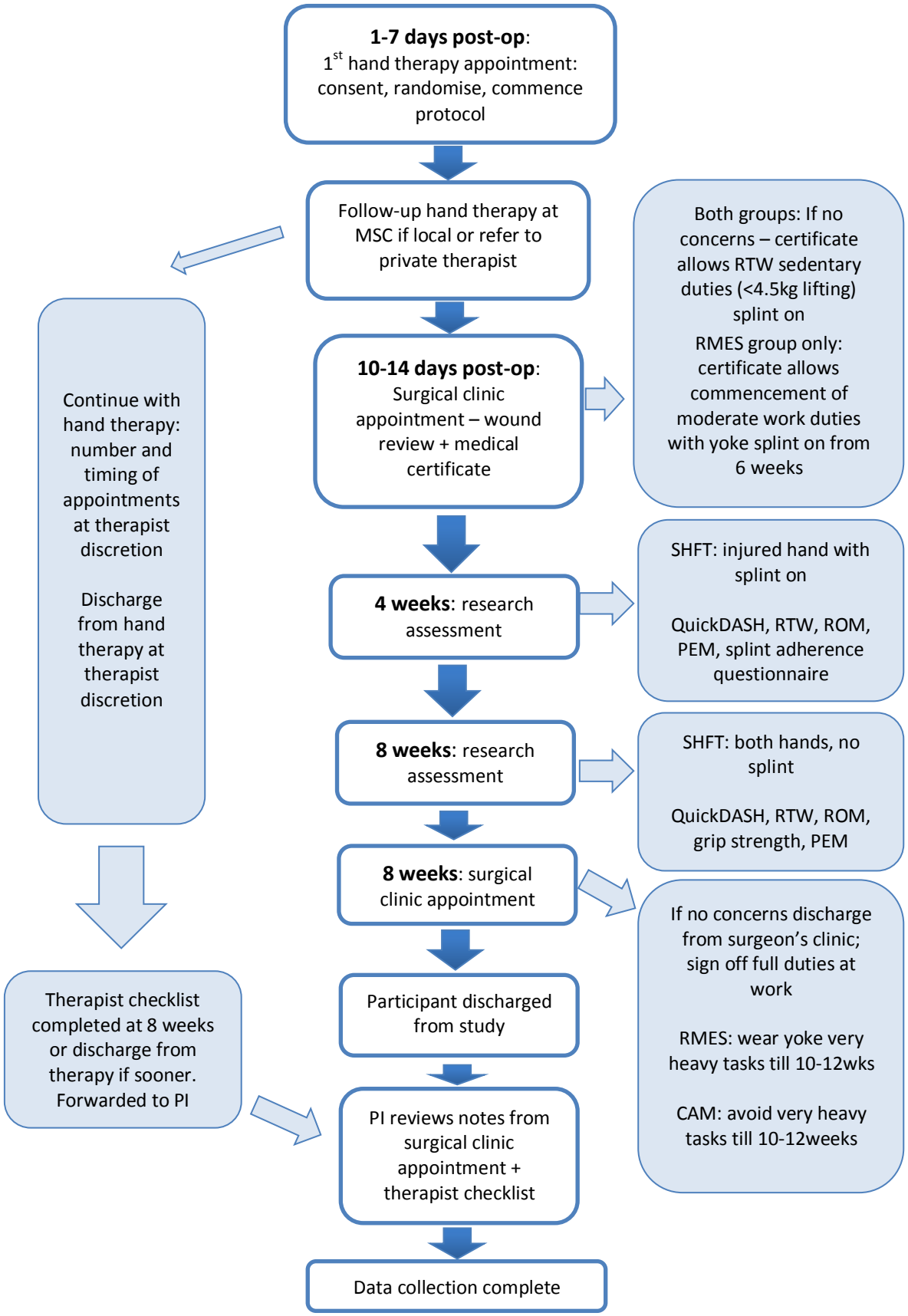

Figure 25. Study process. Note. CAM = controlled active motion; kg = kilograms; MSC = Manukau SuperClinic; PEM = modified Patient Evaluation Measure; PI = primary investigator; QuickDASH = Quick Disabilities of Arm, Shoulder and Hand questionnaire; RMES = relative motion extension splinting; ROM = range of motion; RTW = return to work

3.5.3 Protocols

The main difference between the two protocols was the type of splint used (Table 16).

Table 16. Splints

	RMES	CAM
Day	• Yoke splint, strip of 3.2mm ezeform the width of the little finger proximal phalanx • Holds affected MCP in 15-20° more extension than other digits • If only one peripheral digit involved, e.g. index finger then include the other peripheral digit (i.e. little finger) at 15-20° relative extension even if uninjured so that it is balanced.	• Volar forearm based splint extending to mid-proximal phalanx; 3.2mm ezeform • Wrist 40° extension • MCP 30° flexion • IPs free
		
Night	• Resting splint, 3.2mm ezeform • Wrist 30° extension, MCPs 30° flexion, IPs extended	• Same as above but add night piece • Night piece attaches onto volar splint and maintains MCPs and IPs in 0° extension
		

Note. CAM protocol images from "Extensor controlled active motion protocol [pamphlet]," by Hand Therapy Manukau Superclinic, 2004, Auckland, New Zealand. Copyright 2004 by Hand Therapy Manukau SuperClinic. Reprinted with permission. CAM = controlled active motion; IPs = interphalangeal joints; MCP(s) = metacarpophalangeal joint(s); RMES = relative motion extension splinting

There were also differences between protocols regarding exercises and RTW (Table 17). The RMES group had no specific exercises taught before four weeks post-operatively and thereafter were only taught exercises if there was a loss of finger ROM. A previous study using the RMES (Hirth et al., 2011) found that their participants achieved satisfactory results without specific exercises being required in the first four

weeks, and it was felt that the ability of the participant to use their hand functionally within the yoke splint might allow for sufficient tendon glide to prevent joint stiffness and tendon adherence. There were two differences between protocols with regard to advice regarding RTW. At six weeks post-op the RMES group was advised that they could return to moderate duties (up to 20kg) provided they wore their yoke splint, whereas the CAM group was advised to avoid moderate tasks until eight weeks post-operatively. Participants in the RMES group were advised to continue to wear the yoke splint for very heavy tasks requiring lifting of over 45kg (ACC, 2006) at work until 10-12 weeks, while those in the CAM group had to wait until 10-12 weeks to resume very heavy tasks.

Table 17. Protocols

	RMES	CAM
Stage I: First hand therapy appointment until end of week 4		
Splint	Full time; remove only for hygiene	Full time; remove only for hygiene
Exercises	None	5x per day, 10 repetitions: IP hook and actively extend within splint, place and hold MCPs into hyperextension keeping IPs relaxed
Therapy	Education on injury and precautions, manage oedema, wound care, scar management	Education on injury and precautions, manage oedema, wound care, scar management
Work	At 10 days can return on light duties (less than 4.5kg) with splint on	At 10 days can return on light duties (less than 4.5kg) with splint on
Advice	Use hand for light activities with splint on; less than 4.5kg, avoid composite wrist and finger flexion, no driving	Use hand for light activities with splint on; less than 4.5kg, no driving
Stage II: End of week 4 until end of week 6		
Splint	Day splint off for light activities <4.5kg, continue night splint	Day splint off for light activities <4.5kg, continue night splint
Exercises	Only if limitation of ROM 10 repetitions, 5 x per day : finger extension, table-top, hook, place and hold of MCPs in hyperextension	10 repetitions, 5 x per day: Finger extension, table-top, hook, wrist tenodesis, continue place and hold of MCPs in hyperextension if lag exists
Therapy	Education, oedema management, scar management, use of heat prior to exercise	Education, oedema management, scar management, use of heat prior to exercise
Work	Light duties (<4.5kg) with splint off If needing to do anything heavier with this hand then do not RTW	Light duties (<4.5kg) with splint off If needing to do anything heavier with this hand then do not RTW
Advice	Avoid a forceful fist or forcing the fingers down into flexion, avoid combined wrist and finger flexion No driving	Avoid a forceful fist or forcing the fingers down into flexion, avoid combined wrist and finger flexion No driving
Stage III: End of week 6 until end of week 8		
Splint	Yoke splint heavy tasks only Discontinue night splint	Day splint at risk times only Discontinue night splint
Exercises	Only if stiffness, lag or tendon adherence 10 repetitions, 5 x per day: Finger extension, flat fist, full fist, IP extension with MCPs blocked in flexion, continue previous exercises if not yet fully achieved, gentle passive flexion of isolated joints	10 repetitions, 5 x per day: Finger extension, flat fist, full fist, continue previous exercises if not yet fully achieved, gentle passive flexion of isolated joints
Therapy	Commence passive flexion stretch of isolated joints if necessary	Commence passive flexion stretch of isolated joints if necessary
Work	Commence moderate duties (up to 20kg) with yoke splint on	Continue with light duties only
Advice	Heavy tasks with (over 20kg) yoke splint on; commence driving	Avoid heavy tasks; commence driving

	RMES	CAM
Week 8 onwards		
Exercises	Continue previous exercises until full ROM obtained	Continue previous exercises until full ROM obtained
	Commence composite passive flexion if required	Commence composite passive flexion if required
Therapy	Commence strengthening if necessary	Commence strengthening if necessary
Work	Return to work full duties at 8-10 weeks without splint; wear yoke if very heavy (over 45kg)	Return to work full duties at 8-10 weeks unless very heavy (over 45kg)
Advice	Gradually return to all activities by week 10-12	Gradually return to all activities; very heavy work by week 10-12

Note. CAM = Controlled Active Motion; IP = interphalangeal joint; MCP = metacarpophalangeal joint; RMES = Relative Motion Extension Splinting; ROM = range of motion; RTW = return to work

3.6 Sample Size Calculation

Calculation of sample size was undertaken with the assistance of a CMH biostatistician (IZ). No previous data had been published using the SHFT as the primary outcome for patients with zone V/VI extensor tendon repairs. A recent study had used the SHFT to evaluate patients recovering from a distal radius fracture (Porter, 2013). This provided an estimation of data variability in a patient population that had sustained a traumatic injury to an upper limb, albeit an alternative diagnosis.

Data from this study were used to calculate a coefficient of variation. In addition, preliminary testing of the SHFT was carried out with a group of healthy volunteers from the CMH hand therapy department wearing the splints from the two protocols to determine a likely difference in scores between groups. Using the coefficient of variation derived from the distal radius study (13.3%), and the difference in mean scores calculated from the healthy volunteers (10 points), a proposed sample size was derived. With equivalent group sizes, 90% statistical power, 5% type I error and a derived standard deviation of 8.5 and 7.2 respectively for the RMES and extensor CAM groups, it was estimated that each group required 13 participants to detect a 10 points difference. Expected drop-out rate was 30% (Hall et al., 2010) which indicated that 40 patients were required for the total sample.

Over the year from June 2012 to May 2013 over 50 patients who would have met the inclusion criteria for the current study underwent surgery at MMH. The sample size of 40 participants was therefore considered achievable for the proposed study duration

of one year. CMH research office management staff reviewing the funding application for this study advised that it would be prudent to allow for an extension of the recruitment period in order to ensure sufficient numbers were obtained; it was therefore decided that an attempt would be made to recruit the required number of participants within one year, but if this was not achieved then recruitment could be extended to the end of May 2016 (an addition of a possible three months).

3.7 Data Analysis

The mean differences in objective and subjective measures of hand function, grip strength, ROM, satisfaction and adherence between the CAM and RMES groups at four and at eight weeks were assessed by using analysis of covariates, adjusted by covariates (ANCOVA) that are selected from sets of ANCOVA including all pre-specified variables except for the treatment group indicator. Differences in number of days to RTW in any capacity or full capacity between the two treatment groups were analysed by quantile regressions due to the skewed distribution, and adjusted for significant covariates. Adjustments were not made for multiple comparisons.

The frequency distribution of complications and categorical outcomes in both groups was compared by a Chi-square test of association or Fisher exact test. Correlations between the objective and subjective measures of hand function were investigated using either Pearson correlation coefficient or a Spearman's rank order correlation.

3.8 Funding

Funding for this study was obtained from the New Zealand Association of Occupational Therapists (NZAOT), the New Zealand Association of Hand Therapists (NZAHT) and a research grant from the Ko Awatea Tupu fund, which is affiliated to CMH.

Chapter 4 Results

This chapter presents the results of the randomised clinical trial which was designed to answer the question: Can relative motion extension splinting provide an earlier return to hand function than a controlled active motion protocol? The chapter describes the recruitment and follow-up rates of participants to the study, the characteristics of participants, the results of the hypothesis testing, complications and correlations between outcome measures.

4.1 Recruitment and Follow-up

Patients who underwent surgery to repair extensor tendons in zone V and/or VI between 26 January 2015 and 28 February 2016 were invited to participate in the study. See the CONSORT flow diagram (Altman, Moher, & Schulz, 2010) (Figure 26) for details. Over the study period 76 patients were assessed for eligibility. Of these, 24 patients were excluded as they did not meet the inclusion/exclusion criteria and 10 patients declined to participate. Three of the patients excluded were for reasons of co-morbidity which the investigators felt would have negatively influenced their outcomes: one had a pre-existing inability to extend the injured MCP, one had spina bifida and required a crutch to ambulate using the injured hand and a third had an aortic aneurysm and was transferred to another hospital. Two of the patients who were excluded did not attend hand therapy within the first seven days due to referrals not being sent to the department in time.

Twenty one participants were randomised to each group; all participants received the allocated intervention. One participant in each group did not attend the first four-week assessment; the participant from the CAM group withdrew from the study, while the participant from the RMES group was lost to follow-up and became uncontactable. The drop-out rate at four weeks was therefore 4.7%. At eight weeks, one additional participant from the CAM group and two additional participants from the RMES group were lost to follow-up and could not be contacted. This meant that the total loss to follow-up by the final assessment was 5 participants or 11.9%. At eight weeks, 18 RMES and 19 CAM participants were assessed. Numerous attempts were made to

contact those who dropped out, by telephone, text message and letter, however it was not possible to contact them.

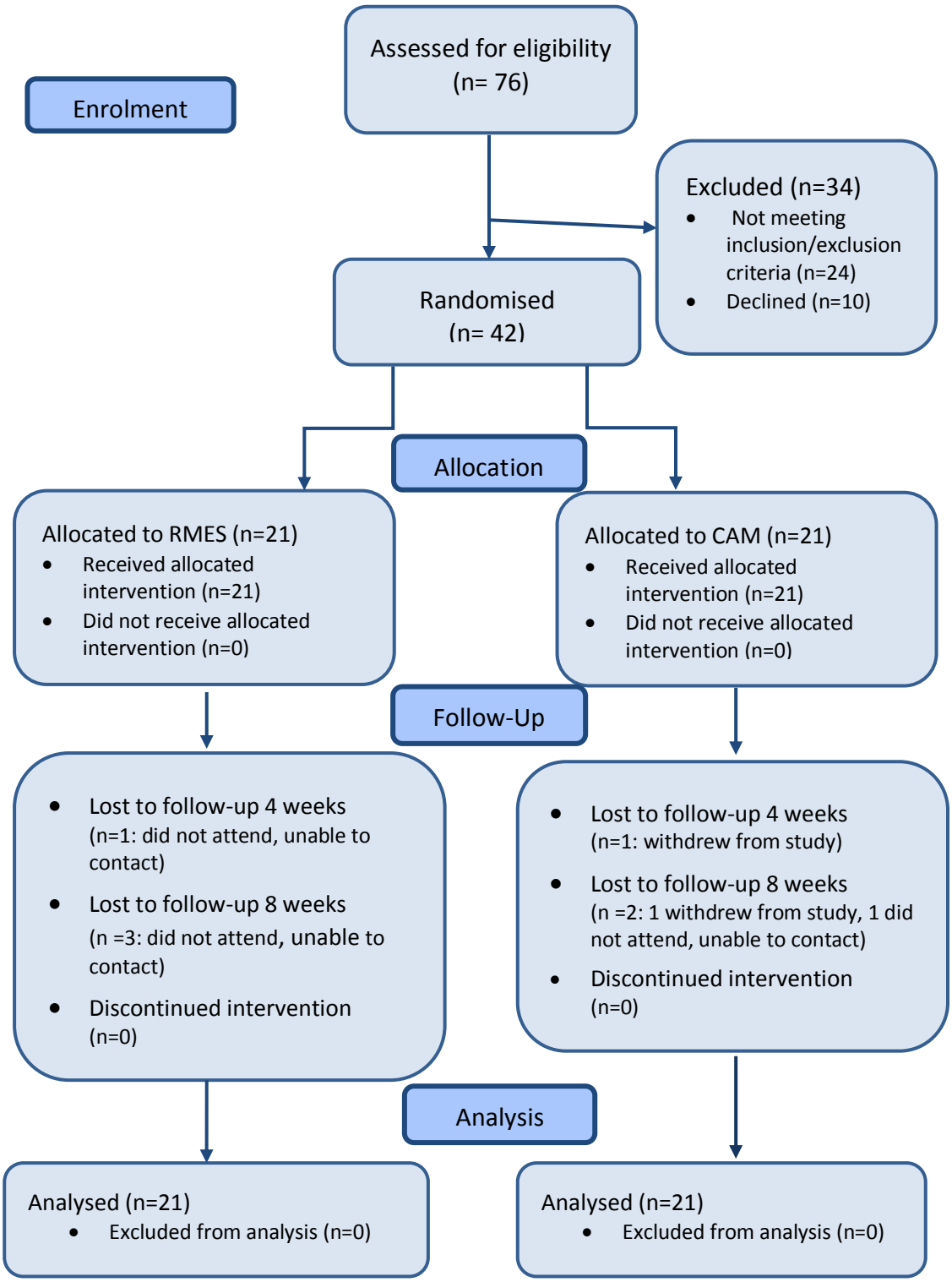

Figure 26. CONSORT flow diagram. From "CONSORT 2010 Flow Diagram," by D. Altman, M. Moher & K. Schulz, The CONSORT group, 2010. Retrieved from http://www.consort-statement.org/consort-statement/flow-diagram. Note. CAM = controlled active motion; n = number; RMES = relative motion extension splinting

4.2 Participant Characteristics

The baseline demographics and injury characteristics of the two groups are displayed in Table 18 and Table 19 respectively. The two groups were similar with regard to most baseline demographics. Both groups had one female participant and 20 male participants. The mean age was similar at 35 and 36 years for CAM and RMES groups respectively. All participants were right hand dominant apart from one in the RMES group. There was some variation in ethnicity between groups (see Figure 27 and Figure 28), with a higher proportion of European (57.1% RMES vs 38.1% CAM) and lower proportion of Maori and Pacific Island participants (19.1% RMES vs 57.2% CAM) in the RMES group compared to the CAM group.

There was a higher proportion of smokers (50%) in the RMES group compared to the CAM group (23%). A higher proportion of CAM participants (40%) than RMES participants (10%) reported co-morbidities. Prior to the commencement of the study it had been considered that diabetes and arthritis would be the co-morbidities that could have an effect on outcome; however none of the participants in either group reported either of these conditions. The reported co-morbidities were high cholesterol, hypertension, hypotension, gout not affecting the hands, stroke with no functional deficit of the injured hand, angina and gastritis. A similar number of participants in each group reported having had a previous injury to the injured hand (CAM: 23.8%, RMES: 28.5%).

The majority of participants worked in moderate or heavy occupations: 76.2% of CAM participants and 80.9% of RMES participants. As per the definition used in this trial this meant that the majority of participants would be required to lift at least up to 22.5kg occasionally, 9kg frequently and 4.5kg constantly.

Participants who dropped out or withdrew were younger, at a mean of 22.3 years, but the remaining demographics were similar, with all being male, right hand dominant, European or Pacific Islander ethnicity and four of the five working in moderate or heavy occupations. Those participants who dropped out also failed to attend their follow-up hand therapy and surgical clinic appointments, however their electronic records were reviewed and none represented to hospital due to rupture, infection or other complications.

Table 18. Baseline Demographics

Baseline demographics			
		CAM	**RMES**
n =		21	21
Gender, n (%)	Male	20 (95.2%)	20 (95.2%)
	Female	1 (4.8%)	1 (4.8%)
Age in years, mean *(SD)*		35 (16)	36 (16)
Dominance, % R:L		100: 0	95.2: 4.8
Ethnicity, n (%)	European	8 (38.1%)	12 (57.1%)
	NZ Maori	3 (14.3%)	0 (0%)
	Pacific Islander	9 (42.9%)	4 (19.1%)
	Indian	1 (4.8%)	4 (19.1%)
	Other	0 (0%)	1 (4.8%)
Smoker, n (%)	Current	5 (23%)	10 (50%)
	Ex or no	15 (81%)	10 (50%)
Presence of comorbidities, n (%)		8 (40%)	2 (10.0%)
Previous injury to injured hand, n (%)		5 (23.8%)	6 (28.5%)
Occupation, n (%)	Heavy	12 (57.1%)	7 (33.3%)
	Moderate	4 (19.1%)	10 (47.6%)
	Light	4 (19.1%)	3 (14.3%)

Note. CAM = Controlled Active Motion; L = left; n = number; R = right; RMES = Relative Motion Extension Splinting; *SD* = standard deviation

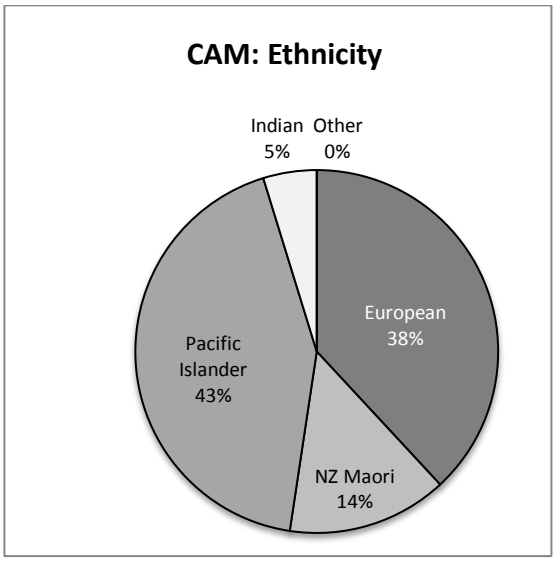

***Figure 27*. Ethnicity distribution controlled active motion (CAM) group**

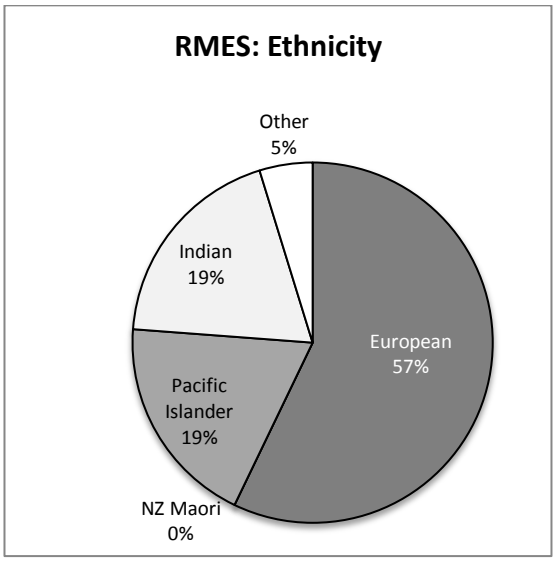

***Figure 28*. Ethnicity distribution relative motion extension splinting (RMES) group**

Injury characteristics were similar between groups Table 19, with 24 and 22 digits injured in the CAM and RMES groups respectively. The majority of participants in both groups injured their dominant hand at 66.7% for the CAM group and 57.1% for the RMES group. Zone V was the most commonly injured in both groups at 58.3% for the CAM group and 63.7% for the RMES group. There was a reasonably even spread of injuries across the digits, however the most commonly injured digits in both groups were index and little fingers. In the CAM group index and little finger injuries accounted for 25% and 38% of the injuries respectively, while in the RMES group the proportions were 36% and 27% respectively. The joint capsule was injured in the same number of digits in both groups, however a higher percentage of additional structures were injured in the CAM group (43%) compared to the RMES group (19%). Additional structures injured included bone, periosteum, sagittal band, cartilage, juncturae tendinae, muscle belly (superficial, not requiring repair) and sensory nerves.

The mechanism of injury was similarly distributed between the two groups with the most common cause of laceration being glass, for 38% of the CAM group and 40% of the RMES group (see Figure 29 and Figure 30). The delay to surgery was minimal and the same in both groups, with a median of one day.

The data were assessed for any significant interactions between participant characteristics and outcome. Adjustments were made when significant interactions were found to eliminate the effect of potentially confounding variables. The variables for which *p*-values were adjusted differed between different outcomes and are noted with the results for each outcome in the following sections.

Table 19. Injury Characteristics

Injury characteristics			
		CAM	**RMES**
Number of digits injured		24	22
Dominant hand injured, n (%)		14 (66.7%)	12 (57.1%)
Zone of injury, n (%)	V	14 (58.3%)	14 (63.7%)
	VI	9 (37.5%)	6 (27.3%)
	V/VI	1 (4.2%)	2 (9.1%)
Digit injured, n (%)	IF	6 (25%)	8 (36%)
	MF	4 (17%)	5 (23%)
	RF	5 (21%)	3 (14%)
	LF	9 (38%)	6 (27%)
Joint capsule involved, n (%)		7 (29%)	7 (32%)
Other structures injured, n (%)		9(43%)	4 (19%)
Mechanism of injury, n (%)	Knife	3 (14%)	4 (20%)
	Metal	5 (24%)	3 (15%)
	Glass	8 (38%)	8 (40%)
	Machine/Tools	4 (19%)	3 (15%)
	Other	1 (5%)	2 (10%)
Delay to surgery, median days *(SD)*		1 (1 ,1)	1 (1, 1)

Note. CAM = Controlled Active Motion; IF = index finger; LF = little finger; MF = middle finger; n = number; RF = ring finger; RMES = Relative Motion Extension Splinting; *SD* = standard deviation

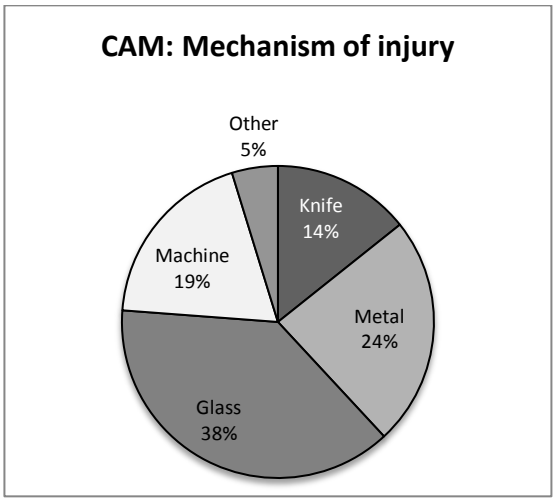

Figure 29. Mechanism of injury in controlled active motion (CAM) group

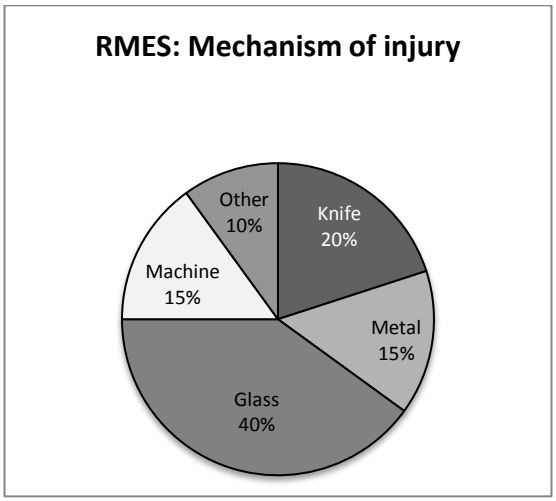

Figure 30. Mechanism of injury in relative motion extension splinting (RMES) group

4.3 "Activity": Sollerman Hand Function Test

The results of the primary outcome, the SHFT, are presented in Table 20. This outcome assessed activity limitations and provided a measure of functional performance. At four weeks post-operatively, the SHFT was performed while participants were wearing their splints; at eight weeks they did not wear a splint to perform the test and the contralateral hand was assessed to provide a control. As described in Chapter 3.4.2, a higher score indicates a better result; at four weeks the maximum attainable score was 76, due to the exclusion of one task, while at eight weeks it was 80. The SHFT score was adjusted for gender and mechanism of injury.

Table 20. Sollerman Hand Function Test (SHFT)

Sollerman Hand Function Test (SHFT)				
	CAM	**RMES**	***P* value**	***P* value adjusted**
SHFT Mean score *(SD)*				
4 weeks	59 *(10)*	66 *(7)*	0.017	0.0073
8 weeks injured hand	75 *(5)*	76 *(2)*	0.48	0.63
8 weeks contralateral hand	75 *(3)*	76 *(2)*	0.63	
SHFT time Mean seconds *(SD)*				
4 weeks	399 *(149)*	276 *(66)*	0.0018	0.0009
8 weeks injured hand	224 *(40)*	236 *(50)*	0.44	0.75
8 weeks contralateral hand	238 *(45)*	218 *(42)*	0.19	

Note. CAM = Controlled Active Motion; RMES = Relative Motion Extension Splinting; *SD* = standard deviation

The SHFT score is presented as a mean score followed by the standard deviation (*SD*), i.e. (mean; *SD*). At the four week assessment the RMES group (66; *7*) had a significantly better SHFT score (*adjusted p*=0.0073) compared to the CAM group (59; *10*). At eight weeks, there was no significant difference (*adjusted p*=0.63) for the SHFT score between the CAM (75; *5*) and RMES (76; *2*) CAM groups. At eight weeks the mean score for the contralateral hands matched the score for the injured hands with no significant difference (*p*=0.63) between the CAM (75; *3*) and RMES (76; *2*) groups. Results for the SHFT score for the injured hand are presented graphically in Figure 31.

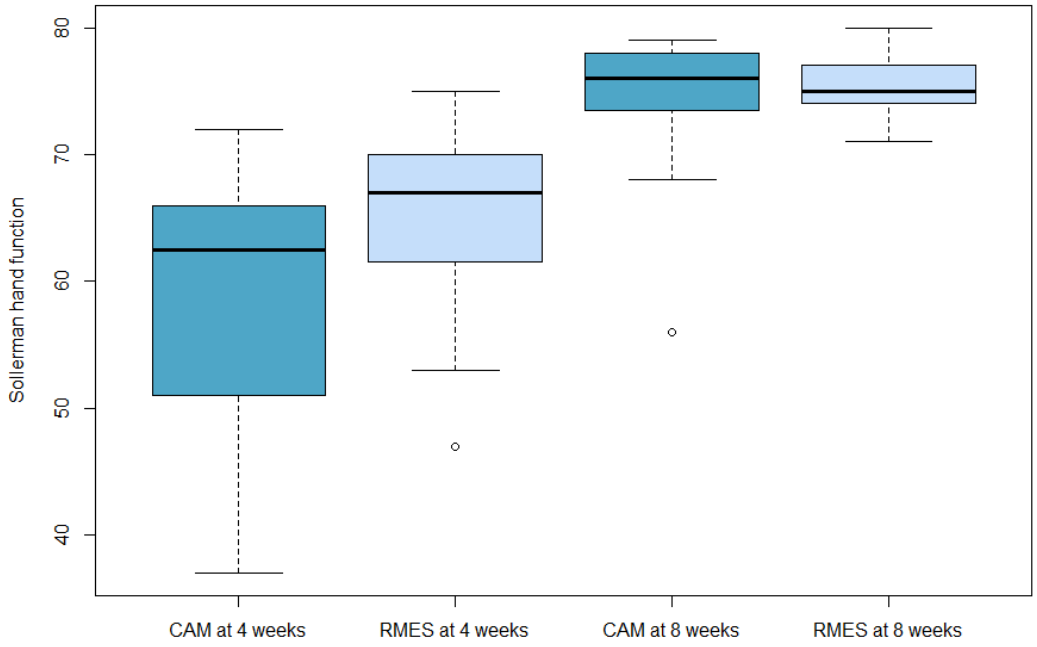

Figure 31. Sollerman Hand Function Test score box-plot. Note. The boxes indicate the 25th and 75th percentiles, the dark line the median value and the whisker 1.5 times the median. The small circles indicate outliers. CAM = controlled active motion; RMES = relative motion extension splinting.

The total time taken for completion of the SHFT with the injured hand was recorded in mean seconds at four and eight weeks. At eight weeks the time taken to complete the SHFT with the contralateral hand was also recorded to provide a control. A shorter time indicates a better result. SHFT time was adjusted for gender, hand dominance and ethnicity. Results for SHFT time are presented as mean seconds, followed by *SD*, i.e. (mean; *SD*). At four weeks the RMES group (276; *66*) took a significantly lower number of seconds (*adjusted p*=0.0009) to complete the SHFT than the CAM group (399; *149*) At eight weeks the times were similar (*adjusted p*=0.75) between RMES (236; *50*) and CAM (224; *40*) groups. The contralateral hands in the CAM group (238; *45*) took a similar number of seconds (*p*=0.19) to complete the SHFT, to those in the RMES group (218; *42*).

The time taken to complete the SHFT with the injured hand is presented graphically in Figure 32.

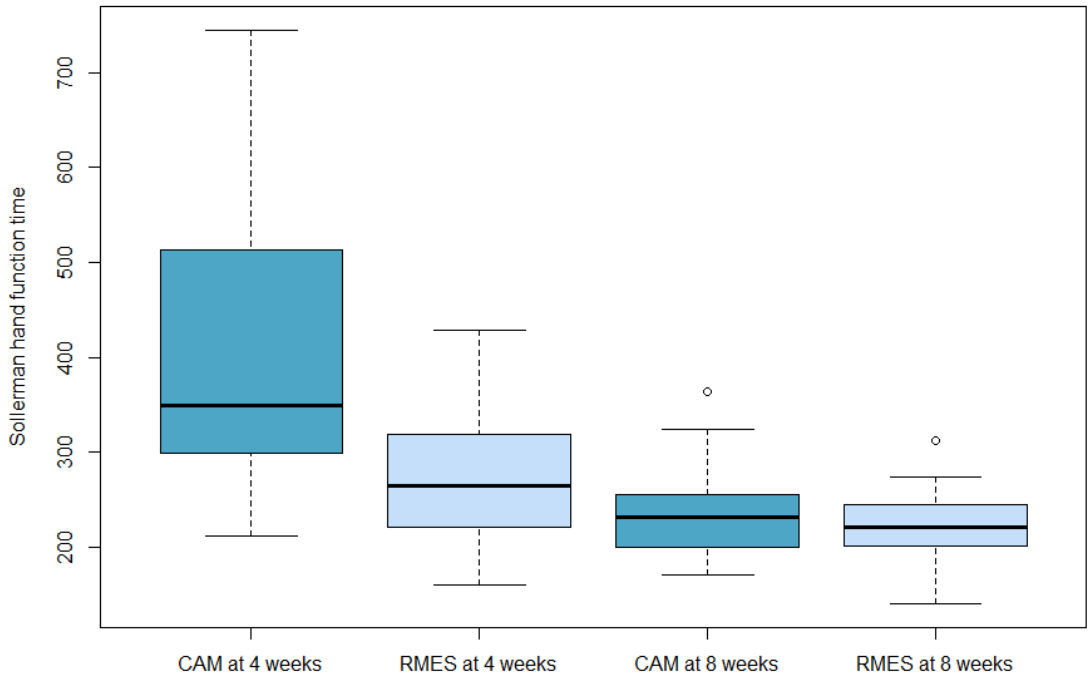

Figure 32. Sollerman Hand Function Test time box-plot. Note. The boxes represent the 25th and 75th percentile, the dark line the median seconds, and the whiskers 1.5 of the median. Outliers are indicated by the small circles. CAM = controlled active motion; RMES = relative motion extension splinting.

4.4 "Participation": QuickDASH Questionnaire and Return to Work

Participation restrictions were measured by the completion of the QuickDASH questionnaire and days to RTW. Results are displayed in Table 21.

Table 21. QuickDASH Questionnaire and Return to Work

QuickDASH questionnaire and return to work				
	CAM	**RMES**	***P* value**	***P* value adjusted**
QuickDASH mean score *(SD)*				
4 weeks	40.7 *(18.0)*	28.4 *(14.5)*	0.023	0.05
8 weeks	14.0 *(13.1)*	11.0 *(11.0)*	0.45	0.35
Return to work median days *(IQR)*				
In any capacity	18 *(6-55)*	20 *(12-57)*	0.90	0.80
Full duties	50 *(39-60)*	49 *(14-64)*	0.77	0.59

Note. CAM = Controlled Active Motion; *IQR* = interquartile range; QuickDASH = Quick Disabilities of Arm, Shoulder and Hand questionnaire; RMES = Relative Motion Extension Splinting; *SD* = standard deviation;

4.4.1 QuickDASH (Disabilities of Arm, Shoulder and Hand) questionnaire

The QuickDASH questionnaire was administered at four and eight weeks post-operatively. As described in Chapter 3.4.3, the best score obtainable is 0 and the poorest score obtainable is 100; a lower score therefore denotes a better outcome. The QuickDASH score was adjusted for ethnicity and whether the dominant hand was operated. Scores are presented as mean score followed by the *SD*, i.e. (mean; *SD*). At four weeks the RMES group (28.4; *14.5*) achieved a significantly better QuickDASH score (*adjusted p*=0.05) than the CAM group (40.7; *18*) At eight weeks the QuickDASH score was not significantly different (*adjusted p*=0.35) between the RMES (11; *11*) and CAM (14; *13.1*) groups. The QuickDASH scores at four and eight weeks are represented in Figure 33.

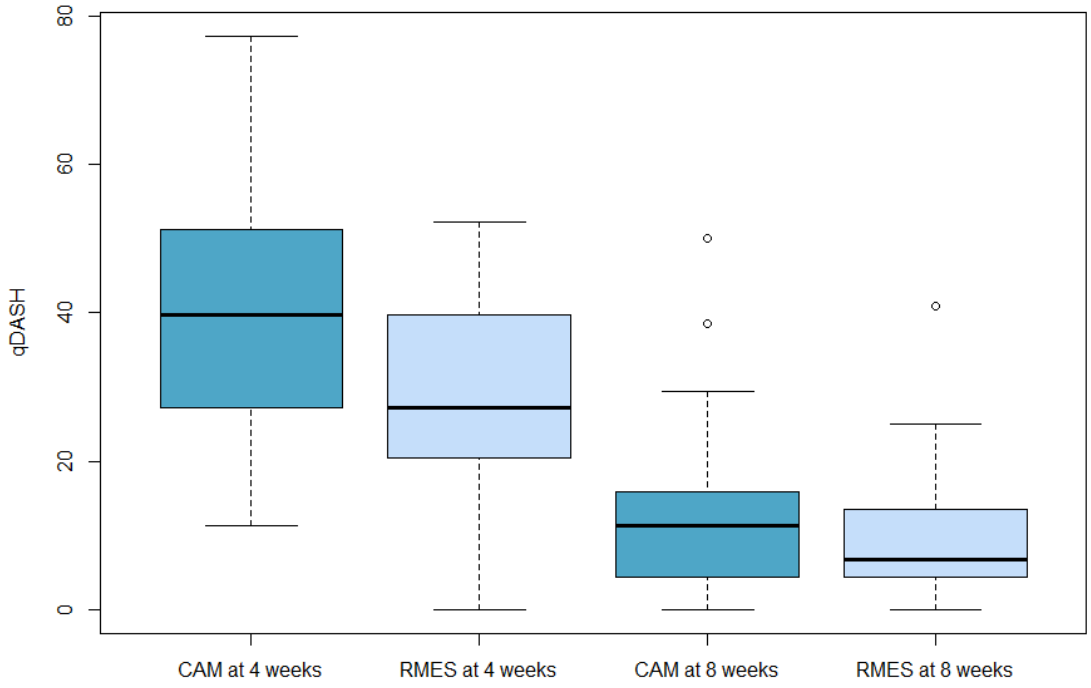

Figure 33. QuickDASH (Disabilities of Arm, Shoulder and Hand) questionnaire scores. Note. The boxes show the 75th and 25th percentiles, the dark lines the median values and the whiskers 1.5 times the median; the small circles indicate outliers. CAM = controlled active motion; RMES = relative motion extension splinting.

4.4.2 Return to work (RTW)

RTW was recorded as the days taken RTW in any capacity, whether that was light or usual duties, and days to RTW on full duties. The results were adjusted for gender, smoking status, ethnicity, mechanism of injury, digit injured, and zone of injury.

RTW outcomes will be presented as the median days followed by the interquartile range (*IQR*), i.e. (median; *IQR*). Days to RTW in any capacity was not significantly different (*adjusted p*=0.80) between the CAM (18; *6-55*) and RMES (20; *12-57*) groups. Days to RTW on full duties was also not statistically significant (adjusted *p*=0.59) between CAM (50; *39-60*) and RMES (49; *14-64*) groups. Figure 34 shows the days to RTW in any capacity, and Figure 35 shows days to RTW on full duties.

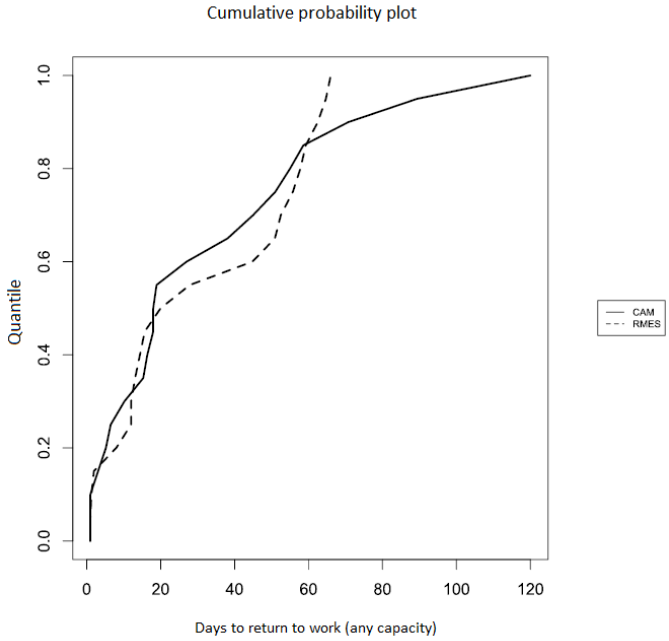

Figure 34. Days to return to work (RTW) in any capacity. The X-axis shows the days to RTW, and the Y-axis the proportion of participants that had returned. The overlap between the CAM and RMES groups in all quartiles demonstrates the lack of significant difference between the two groups.

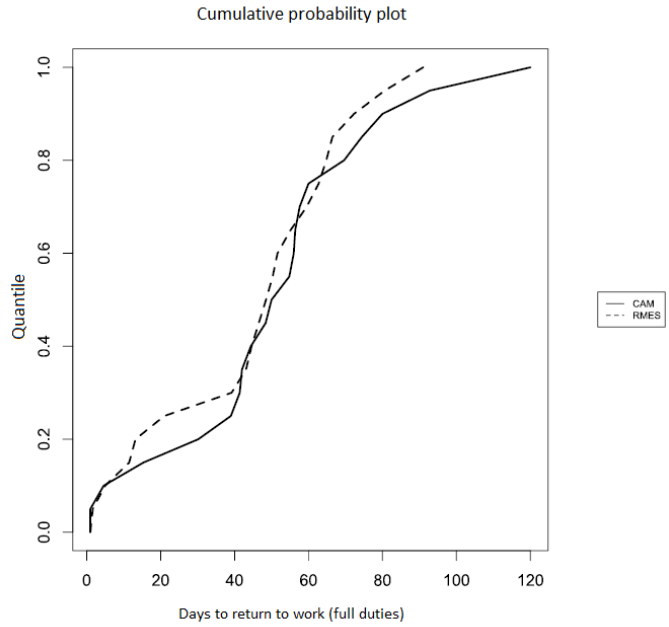

Figure 35. Days to return to work (RTW) on full duties. The X-axis shows the days to RTW, and the Y-axis the proportion of participants that had returned. The overlap between the CAM and RMES groups in all quartiles demonstrates the lack of significant difference between the two groups.

4.5 "Body Function and Structure": Range of Motion and Grip Strength

4.5.1 Range of motion (ROM)

Active range of motion (ROM) of the affected and contralateral uninjured digit was measured at four and eight weeks post-operatively. The degrees of motion were used to calculate TAM. This is presented as degrees of TAM, where a higher number indicates a better result, and classified into excellent, good, fair or poor as per Kleinert and Verdan's classification described in Chapter 3.4.4 (Table 22). In addition, degrees of extension lag and flexion deficit were calculated compared to the contralateral digit, where a lower number indicates a better result, and classified according to Miller's criteria, also described in Chapter 3.4.4 (Table 23). Continuous ROM variables were adjusted for hand dominance, gender and ethnicity. Adjusted modelling was not performed for the categorical ROM variables due to small counts in the combination of group and hand dominance, gender, ethnicity.

ROM results are presented as mean degrees followed by *SD*; i.e.(mean; *SD*).At four weeks post-operatively, TAM for the RMES group (185.9; *48.3*)was significantly better (*adjusted p*=0.008) than TAM for the CAM group (147.9; *41.7*). At eight weeks TAM for the RMES group (236.4; *28.3*) remained significantly better (*adjusted p*=0.03) than TAM for the CAM group (209.1; *37.6*).

Table 22. Range of Motion per Digit: Total Active Motion

Range of motion (ROM) per digit: Total active motion (TAM)											
	CAM				**RMES**				**Mean difference (95% CI)**	***P* value**	**Adjusted *p* value**
TAM mean degrees, *(SD)*											
4 weeks	147.9 *(41.7)*				185.9 *(48.3)*				-38.0 (-65.4, -10.6)	0.0077	0.008
8 weeks	209.1 *(37.6)*				236.4 *(28.3)*				-27.2 (-48.7, -5.8)	0.014	0.030
Kleinert & Verdan score n (% of group)											
	Excellent	**Good**	**Fair**	**Poor**	**Excellent**	**Good**	**Fair**	**Poor**			
4 weeks	0 (0)	2 (8.7)	15 (65.2)	6 (26.1)	1 (4.8)	11 (52.4)	5 (23.8)	4 (19.1)	NA	0.003	
8 weeks	4 (19.1)	14 (66.7)	3 (14.3)	0 (0)	5 (26.3)	13 (68.4)	1 (5.3)	0 (0)	NA	0.78	

Note. CAM = Controlled Active Motion; CI = confidence interval; n = number; RMES = Relative Motion Extension Splinting; *SD* = standard deviation

Table 23. Range of Motion per Digit: Extensor Lag, Flexion Deficit

Range of motion (ROM) per digit: Extension lag, flexion deficit										
	CAM				**RMES**				**Mean difference (95% CI)**	***P* value**	**Adjusted *p* value**
Extension lag, mean degrees, *(SD)*										
4 weeks	10.0 *(13.5)*				9.0 *(14.2)*				0.7 (-8.3, 9.7)	0.88	0.82
8 weeks	2.6 *(8.7)*				3.1 *(7.8)*				-0.3 (-6.1, 5.4)	0.91	0.78
Flexion deficit, mean degrees, *(SD)*										
4 weeks	84.3 *(34.0)*				53.3 *(38.9)*				34.3 (10.3, 58.2)	0.007	0.011
8 weeks	30.7 *(27.0)*				15.2 *(22.6)*				14.3 (-2.5, 31.0)	0.058	0.13
Miller criteria extension lag n (% of group)										
	Excellent	**Good**	**Fair**	**Poor**	**Excellent**	**Good**	**Fair**	**Poor**		
4 weeks	10 (43.5)	5 (21.7)	8 (34.8)	0 (0)	12 (57.1)	2 (9.5)	6 (28.6)	1 (4.8)	NA	0.48	
8 weeks	17 (81)	2 (9.5)	2 (9.5)	0 (0)	17 (89.5)	0 (0)	2 (10.5)	0 (0)	NA	0.54	
Miller criteria flexion n (% of group)										
	Excellent	**Good**	**Fair**	**Poor**	**Excellent**	**Good**	**Fair**	**Poor**		
4 weeks	0 (0)	1 (4.4)	3 (13)	19 (82.6)	0 (0)	5 (23.8)	5 (23.8)	11 (52.4)	NA	0.08	
8 weeks	3 (14.3)	5 (23.8)	6 (28.6)	7 (33.3)	4 (21.1)	10 (52.6)	2 (10.5)	3 (15.8)	NA	0.17	

Note. CAM = Controlled Active Motion; CI = confidence interval; n = number; RMES = Relative Motion Extension Splinting; *SD* = standard deviation;

Categorisation of the TAM scores compared to the contralateral side using Kleinert and Verdan's classification system showed a significant difference in distribution of excellent, good, fair and poor results between groups at four weeks (p=0.003) (Table 22). The RMES group had 57.2% good/excellent results by four weeks while the CAM group had only 8.7% good/excellent results (Figure 36).

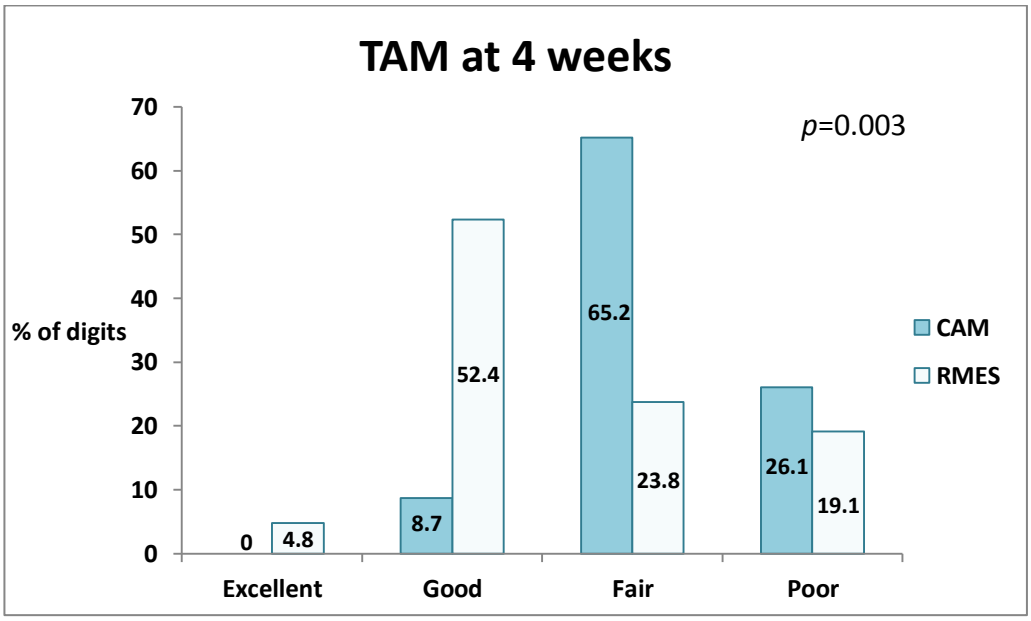

Figure 36. Kleinert & Verdan classification of total active motion (TAM) at four weeks

By eight weeks post-operatively the distribution across categories using Kleinert and Verdan's classification was similar between groups (p=0.78), with 85.8% of the CAM group and 94.7% of the RMES group having good/excellent ROM according to these criteria (Figure 37).

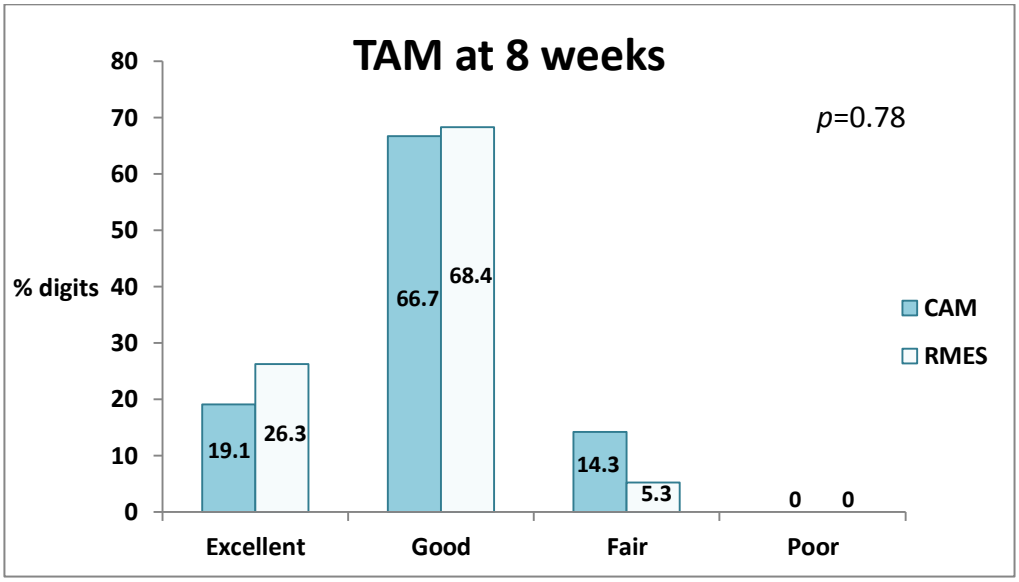

Figure 37. Kleinert & Verdan classification of total active motion (TAM) at eight weeks

Extension lag in degrees was similar between the RMES (9; *14.2*) and CAM (10; *13.5*) groups at four weeks (*adjusted p*=0.82). At eight weeks there was also no significant difference in extension lag (*adjusted p*=0.78) between the RMES (3.1; *7.8*) and CAM (2.6; *8.7*) groups. Similarly, categorisation of the extensor lag results into excellent, good, fair and poor using Miller's criteria showed no significant difference at four weeks (*p*=0.48) (Figure 38) or eight weeks (*p*=0.54) (Figure 39). At eight weeks 90.5% of CAM participants and 89.5% of RMES participants had good or excellent results for extension lag.

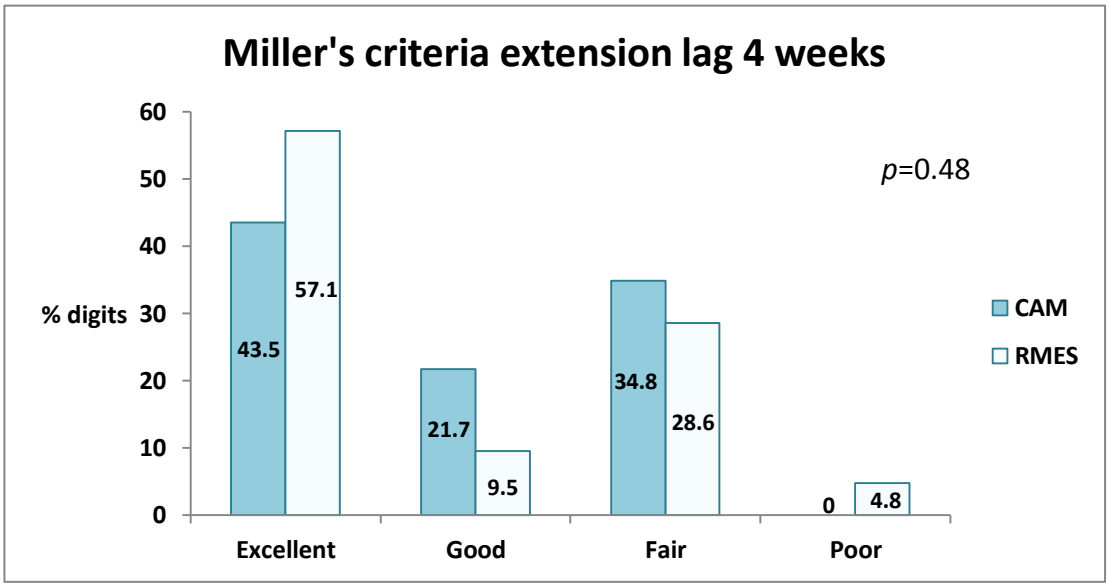

Figure 38. Classification of extension lag using Miller's criteria at four weeks

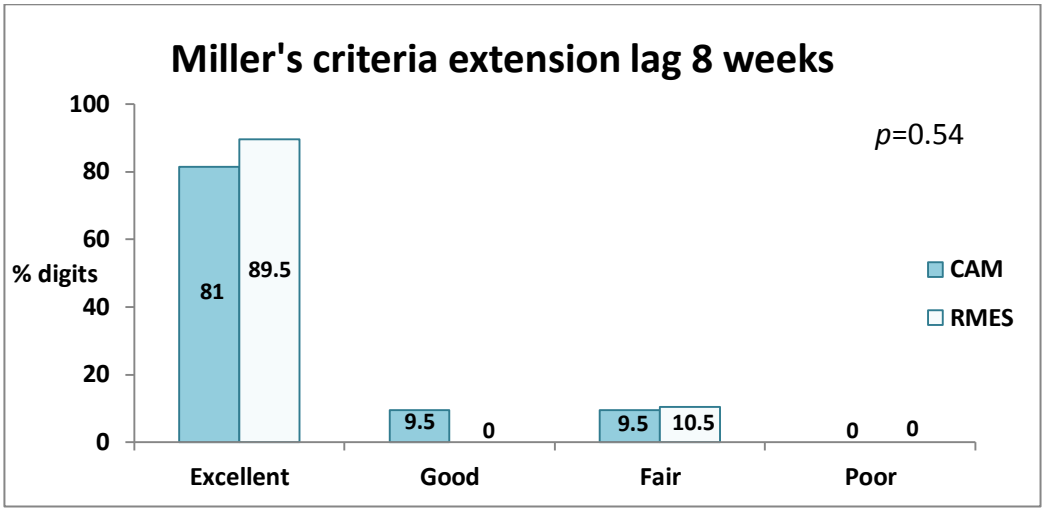

Figure 39. Classification of extension lag using Miller's criteria at eight weeks

Flexion deficit was however significantly different between the groups at four weeks (*adjusted p*=0.011) in favour of the RMES group (53.3; *38.9*) compared to the CAM group (84.3; *34*). The mean difference in flexion deficit between groups at eight weeks was smaller and not significant (*adjusted p*=0.13) between the RMES (15.2; *22.6*) and CAM group (30.7; *27*). Categorisation of the flexion deficit using Miller's criteria showed no significant difference at four weeks (*p*=0.08) (Figure 40) or eight weeks (*p*=0.17) (Figure 41). By eight weeks, 38.1% of digits in the CAM group and 73.7% of digits in the RMES group scored good or excellent according to Miller's criteria for flexion deficit.

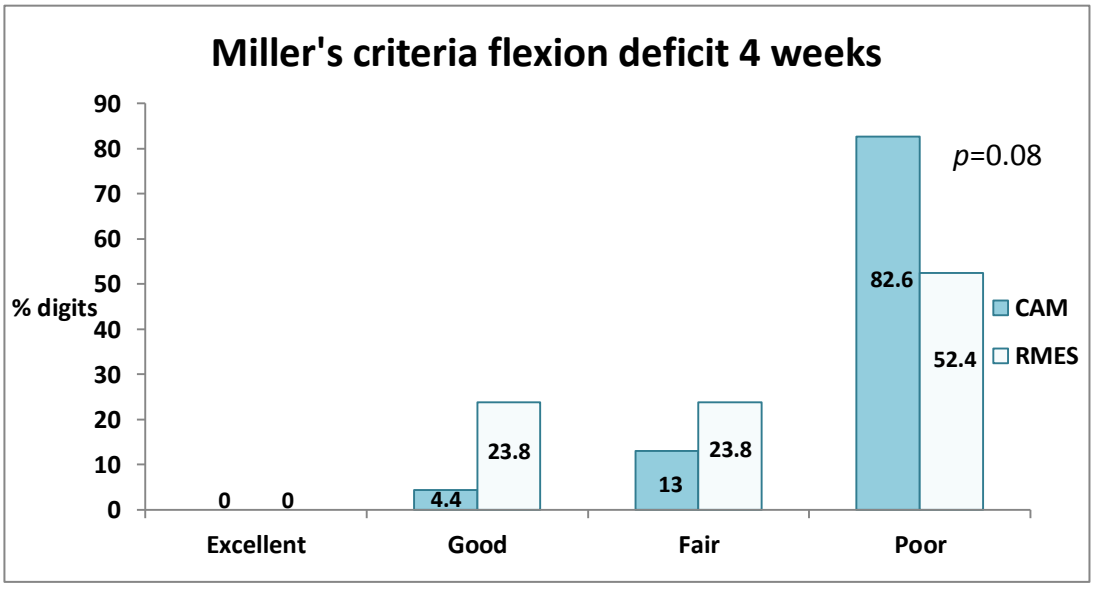

Figure 40. Classification of flexion deficit using Miller's criteria at four weeks

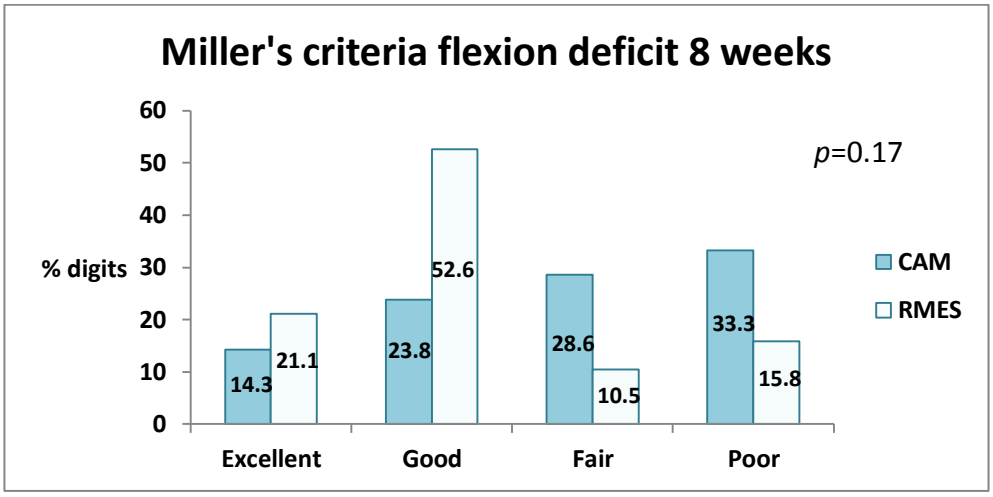

Figure 41. Classification of flexion deficit using Miller's criteria at eight weeks

Active extension and flexion of the wrist ROM was measured at four and eight weeks post-operatively. Degrees of flexion and extension were added to calculate an active wrist arc of motion and the same measure was carried out for the contralateral wrist to provide comparison. The affected wrist active arc was expressed as a percentage of the contralateral wrist active arc In addition, at eight weeks post-operatively passive wrist flexion was measured while the hand was held in a fist and compared to the contralateral side to assess for extrinsic extensor musculotendinous unit shortening. Wrist ROM results were adjusted for hand dominance, gender and ethnicity and results are presented in Table 24.

Table 24. Wrist Range of Motion

Wrist range of motion					
	CAM	**RMES**	**Mean difference** (95% CI)	***P* value**	**Adjusted *p* value**
Active wrist arc mean % of contralateral *(SD)*					
4 weeks	80.1 (15.4)	95.7 (8.8)	-15.6 (-23.9, -7.2)	0.0006	0.002
8 weeks	97.4 (9.9)	97.2 (11.1)	0.2 (-6.9, 7.3)	0.95	0.33
Passive wrist flexion with a fist mean % of contralateral *(SD)*					
8 weeks	88.9 (16.7)	93.5 (27.3)	-4.6 (-19.6, 10.5)	0.54	0.98

Note. CAM = Controlled Active Motion; CI = confidence interval; RMES = Relative Motion Extension Splinting; *SD* = standard deviation;

Wrist ROM is presented as a percentage of the contralateral side, followed by the *SD*, i.e.(% of contralateral side; *SD*). At four weeks the RMES group (95.7; *8.8*) had a

significantly better (*adjusted p*=0.002) wrist arc of motion than the CAM group (80.1; *15.4*). At eight weeks the difference in active wrist arc between groups was not significantly different (*adjusted p*=0.33) between the RMES (97.2; *11.1*) and CAM (97.4; *9.9*) groups. Passive wrist flexion with the hand held in a fist at eight weeks was not significantly different (*adjusted p*=0.98) between the RMES (93.5; *27.3*) and CAM (88.9; *16.7*) groups.

4.5.2 Grip strength

Grip strength of the injured and contralateral hands was measured at eight weeks post-operatively. It is reported as kilograms of strength and as a percentage of the contralateral side, presented in Table 25, adjusted for gender, hand dominance and ethnicity.

At eight weeks the mean grip strength in the CAM group was 31.6kg (*SD*: 14) compared to 35.2kg (*SD*: 16) in the RMES group. This difference was not significantly different between groups (*adjusted p*=0.66). Similarly there was no significant difference between groups for percentage of grip strength of the contralateral side (adjusted *p*=0.47) with the CAM group at 73.8% (*SD*: 22.1) and the RMES group at 82.8% (*SD*: 23.7).

Table 25. Grip Strength

Grip strength					
	CAM	**RMES**	**Mean difference** (95% CI)	***P* value**	**Adjusted *p* value**
Mean % of contralateral side *(SD)*	73.8 (22.1)	82.8 (23.7)	-9.1 (-24.3, 6.2)	0.24	0.47
Mean kg *(SD)*	31.6 (14.0)	35.2 (16.0)	-3.6 (-13.6, 6.4)	0.47	0.66

Note. CAM = Controlled Active Motion; CI = confidence interval; RMES = Relative Motion Extension Splinting; *SD* = standard deviation;

4.6 "Personal and Environmental factors": Adherence and Satisfaction

Adherence to the protocol was measured by means of a questionnaire at four weeks post-operatively. Satisfaction was measured at eight weeks post-operatively using a modification of the PEM.

4.6.1 Adherence to protocol

The questionnaire on adherence included questions on whether the participant had driven a vehicle during the first four weeks post-operatively, frequency, duration and reasons for splint removal, whether they had used their hand without the splint on, and whether they had worn the night splint. Participants were considered to be fully adherent to the protocol if they removed the splint for no more than an hour, did not use their hand with the splint off, and wore the night splint every night. Driving was assessed as a separate component. Frequency of splint removal was recorded, but did not count towards adherence as participants had been advised that they could remove their splint to wash their hands, which may have been a few times a day. Results of adherence are presented in Table 26.

Table 26. Adherence to Protocol

Adherence to protocol			
	CAM	**RMES**	***P* value**
Drove a vehicle in the first four weeks, n (%)	15 (75)	17 (85)	-
Not fully adherent with splint wear in first 4 weeks, n (%)	11 (55)	15 (75)	0.18
Removed splint >1hour, n (%)	3 (15)	3 (15)	-
Used hand without the splint on, n (%)	11 (55)	15 (75)	-
Did not wear night splint every night, n (%)	0 (0)	5 (15)	-

Note. CAM = Controlled Active Motion; n = number; RMES = Relative Motion Extension Splinting;

Although participants had been advised not to drive a vehicle for the first six weeks post-operatively, 75% of CAM participants and 85% of RMES participants reported that they had driven within the first four weeks post-operatively. One participant in each group reported removing the splint to drive, while the remainder who had driven had worn their splint to drive.

Forty-five percent of CAM participants and 25% of RMES participants were fully adherent with splinting; this difference was not statistically significant (p=0.18). Most participants removed their splints for less than one hour per day, with only three in each group (15%) reporting that they removed their splint for more than an hour per day. All participants who were not fully adherent with splinting reported having used their hands for activities without the splint on. Figure 42 displays the reasons the non-adherent participants reported removing their splints. The most common reasons CAM participants removed their splints were inability to do their job, embarrassment, inability to use their hand, discomfort and to look at their hand. The most common reason RMES participants removed their splints was for self-care tasks. Only one participant reported engaging in moderate to heavy activities (moving house) without the splint on during the first four weeks.

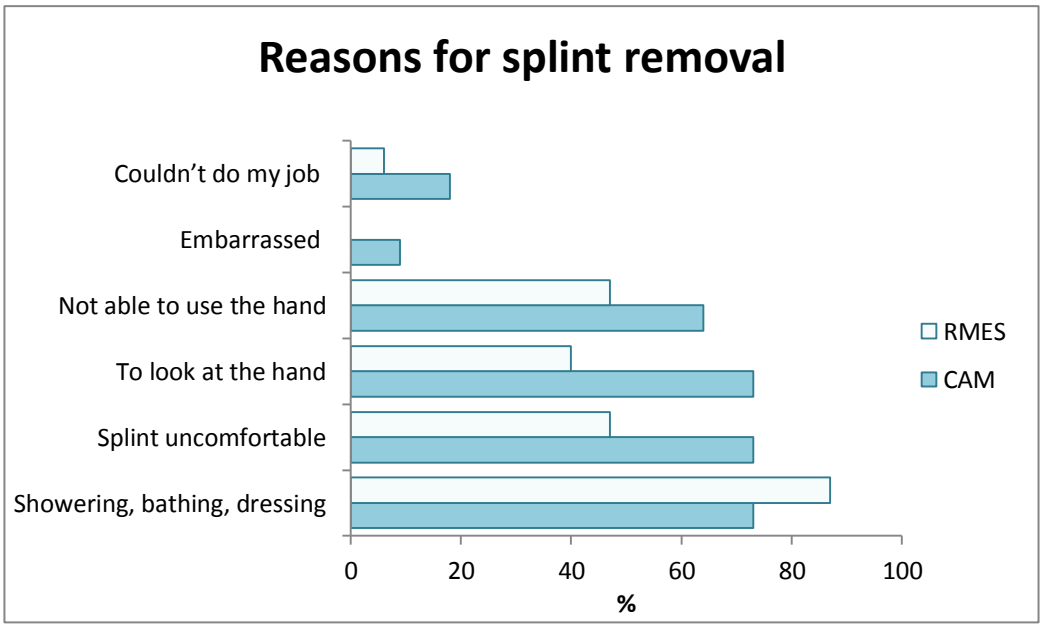

Figure 42. Reasons for splint removal

All CAM participants and 75% of RMES participants wore the prescribed night splint overnight. CAM participants did however report that the night piece fell off (25%) or that the splint was uncomfortable (40%). The 25% of RMES participants who did not wear the prescribed night splint preferred to wear the yoke splint overnight as the full forearm based splint was too awkward or uncomfortable or they felt it was unnecessary.

4.6.2 Satisfaction: Modified Patient Evaluation Measure (PEM)

The modified PEM used in this study consisted of three sections; section one was 'Hand Health', section two was 'Splint Satisfaction' and section three was 'Overall Assessment'. For the raw scores, a lower score indicates a better outcome; the raw scores were transformed into percentages; a higher percentage indicates a higher level of satisfaction. Results were adjusted for gender and are displayed in Table 27.

Table 27. Satisfaction: Modified Patient Evaluation Measure (PEM)

Modified Patient Evaluation Measure (PEM)				
	CAM	**RMES**	***P* value**	***P value adjusted*** [†]
Modified PEM mean score (SD), *% (SD)*				
Hand Health	24.9 (10.0), *78.9 (15.1)*	22.1 (10.7), *83.2 (16.2)*	0.41	0.32
Splint Satisfaction	13.3 (4.0), *43.0 (22.2)*	7.3 (3.1), *75.9 (17.3)*	<0.0001	<0.0001
Overall Assessment	5.8 (2.5), *84.2 (13.8)*	5.2 (2.9), *87.9 (15.9)*	0.45	0.39

Note. CAM = Controlled Active Motion; RMES = Relative Motion Extension Splinting; *SD* = standard deviation

PEM scores are presented as percentage, followed by SD, i.e. (%; *SD*). For the 'Hand Health' section, scores were similar (*adjusted p*=0.32) between the CAM (78.9; *15.1*) and RMES (83.2; *16.2*) groups. For the 'Splint Satisfaction' section however the RMES group (75.9; *17.3*) scored significantly better (*adjusted p*<0.0001) than the CAM group (43; *22.2*). The 'Overall Assessment' score showed no significant difference (*adjusted p*=0.39), between RMES (87.9; *15.9*) and CAM (84.2; 13.8) groups. Modified PEM results are presented graphically in Figure 43.

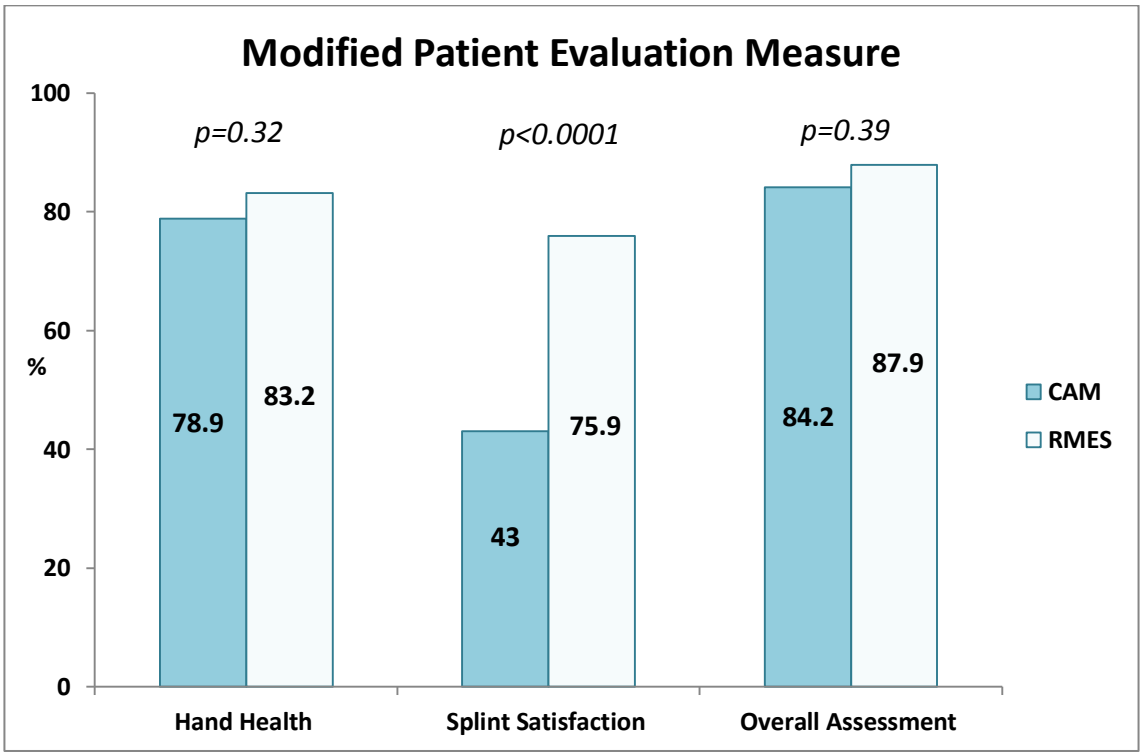

Figure 43. Modified Patient Evaluation Measure (PEM)

4.7 Complications

No tendon ruptures occurred in either group. There were no complications in the CAM group and three in the RMES group; this difference was not significant (p=0.23). It was the opinion of the surgeon involved in the current study (MF) that none of the three complications in the RMES group could be directly attributed to the protocol.

In the RMES group one participant underwent tenolysis surgery at seven months post-operatively to maximise ROM, and another had a retained suture which became infected, requiring surgical excision at four months post-operatively; a third developed irritation of the ulnar nerve. The two participants who underwent secondary surgery were both discharged at two weeks after the secondary surgery with no concerns. The participant who developed ulnar nerve irritation was lost to follow-up and her final outcome is unknown.

Table 28. Complications

Number of complications			
	CAM	**RMES**	***P* value**
Rupture	0	0	
Infection	0	1	
Tenolysis	0	1	
Other	0	1	
TOTAL	0	3	0.23*

Note. CAM = Controlled Active Motion; RMES = Relative Motion Extension Splinting; **Fisher exact test*

4.8 Therapist Checklist

Therapist checklists were returned for 20 participants in each group. The checklists provided information on the number of hand therapy appointments attended and duration of hand therapy intervention for each participant; it also provided information about concerns therapists may have had or any minor variations they had made to the treatment protocol. Results are displayed in Table 29. No statistical testing of these outcomes was performed as they were considered to be covariates or potentially confounding variables.

Table 29. Therapist Checklist Outcomes

Therapist checklist		
	CAM	**RMES**
Total number of hand therapy appointments attended		
Mean number *(SD)*	6.3 *(3.0)*	5.6 *(4.4)*
Total number of hand therapy appointments not attended		
Mean number *(SD)*	1 *(1.2)*	1 *(1.1)*
Total duration of hand therapy intervention		
Mean weeks *(SD)*	8.8 *(4.7)*	9.5 *(8.2)*
Therapist concerns regarding protocol		
n (%)	0 (0)	1 (5)
Therapist concerns regarding participants n (%)		
No concerns	13 (65)	11 (55)
Non-attendance	0 (0)	4 (20)
Adherence of scar/tendon	5 (25)	2 (10)
Limited ROM	4 (20)	2 (10)
Pain/hypersensitivity	2 (10)	1 (5)
Delayed healing	0 (0)	1 (5)
Firm scar	0 (0)	1 (5)
Poor adherence to instructions	2 (10)	0 (0)

Note. CAM = Controlled Active Motion; n = number; RMES = Relative Motion Extension Splinting; *SD* = standard deviation

Participants attended a similar number of appointments, with a mean of 6.3 (*SD*: 3) for the CAM group and 5.6 (*SD*: 4.4) for the RMES group. The duration of hand therapy intervention was a mean of 8.8 weeks (*SD*: 4.7) for the CAM group and 9.5 weeks (*SD*: 8.2) for the RMES group.

Only one therapist noted a concern with the protocol, where she thought that perhaps the increased MCP motion allowed in the RMES splint may have contributed to a delayed healing time for one participant's wound. At three weeks post-operatively the therapist advised this participant to wear his night splint full time for four days to allow the wound to settle. The participant's wound had healed fully by the following week when he resumed wearing the yoke splint during the day; no concerns were identified by the PI at this participant's eight week assessment.

Other concerns raised by therapists were related to participants rather than the protocol: non-attendance at appointments, poor adherence to splinting/instructions,

limited ROM, adherence of scar and/or tendon, pain, hypersensitivity and a thickened scar. A higher proportion of therapists in treating participants in the RMES group reported concerns relating to non-attendance (20% vs 0%), while a higher proportion of therapists treating CAM participants reported concerns relating to scar/tendon adherence (25% vs 10%) and limited ROM (20% vs 10%).

Minor reported alterations to the protocol were as follows:

- RMES group: one therapist advised the participant to gently flex the uninjured digits at week one, two participants were advised to hook the IP joints over the splint at week two or three, two participants were taught stage 2 exercises at week three.
- CAM group: one participant who was reluctant to wean out of the splint was provided with a yoke splint at four weeks as an interim splint, one participant was advised to continue night splinting an extra week due to an extensor lag at six weeks.

4.9 Correlations

Correlations between selected outcomes were investigated for the four and eight week results and are presented in Table 31 and Table 32. Within each cell the first line is the correlation coefficient and the second line is the *p* value. Spearman correlations were carried out as a number of the outcomes were non-normally distributed. The correlation coefficient, Rho, is denoted by "ρ". The strength of the correlation is graded according to its value. For the purpose of this study Munro's description (Domholdt, 2005) was used, as displayed in Table 30.

Table 30. Interpretation of Correlation Coefficients

Value	Interpretation
0.00 – 0.25	Negligible; little, if any correlation
0.26 – 0.49	Low correlation
0.50 – 0.69	Moderate correlation
0.70 – 0.89	High correlation
0.90 – 1.00	Very high correlation

Note. From "Statistical Analysis of Relationships: The Basics," by E. Domholdt, 2005, in M. Waldman & M. Fraser (Eds.), *Rehabilitation Research*, p.358. St Louis, Missouri. Copyright 2005 by Elsevier Saunders. Reprinted with permission.

At four weeks post-operatively (Table 31) there was a significant (p<0.0001), high correlation (ρ=-0.86) between the SHFT score and SHFT time. The SHFT time showed significant (p=0.0002) and moderate (ρ=-0.55) correlation with QuickDASH score. In addition the SHFT score showed significant but low correlations with the QuickDASH score (p=0.0023; ρ=-0.47) and the mean degrees of TAM (p=0.0013; ρ=0.49). The SHFT time showed significant (p=0.02) and low (ρ=-0.37) correlation with mean degrees of TAM. The QuickDASH score and mean degrees of TAM showed a significant (p=0.0103; ρ=-0.40) low correlation.

Table 31. Correlation at Four Weeks

Correlation of outcomes at four weeks				
Spearman Correlation Coefficients Prob > |r| under H0: Rho=0				
	SHFT Score	**SHFT Time**	**QuickDASH**	**TAM in degrees injured digit**
SHFT Score	1.00 -			
SHFT Time	-0.86 <.0001	1.00 -		
QuickDASH	-0.47 0.0023	0.55 0.0002	1.00 -	
TAM in degrees injured digit	0.49 0.0013	-0.37 0.02	-0.40 0.0103	1.00 -

Note. QuickDASH = Quick Disabilities of Arm, Shoulder and Hand questionnaire; SHFT= Sollerman Hand Function Test; TAM = Total Active Motion. Within each cell the top row is the correlation coefficient and the bottom row is the *p* value. Significant low correlations are coloured light grey, significant moderate correlations medium grey and significant high correlations black.

At eight weeks (Table 32) the only significant (p<0.0001) correlation for the SHFT score and SHFT time was their high correlation (ρ=-0.77) with each other. Other significant high correlations were between the QuickDASH and the Hand Health section of the PEM (p<0.0001; ρ=-0.80) and between the Hand Health and Overall Assessment sections of the PEM (p<0.0001; ρ=0.74). Significant moderate correlations were found between three outcomes: the QuickDASH and mean degrees of TAM (p<0.0001; ρ=-0.63), the QuickDASH and Overall Assessment section of the PEM (p<0.0001; ρ=-0.67) and mean degrees of TAM and the Hand Health section of the PEM (p<0.0001; ρ=0.64).

At eight weeks there were significant low correlations between grip strength and four other outcomes: QuickDASH (p=0.0206; ρ=-0.38), mean degrees of TAM (p=0.0050; ρ=0.45), the Hand Health section of the PEM (p=0.0025; ρ=0.48) and the Overall Assessment section of the PEM (p=0.0044; ρ=0.46). There was also a significant low correlation between mean degrees of TAM and the Overall Assessment section of the PEM (p=0.0060; ρ=0.44).

Table 32. Correlation at Eight Weeks

Correlation of outcomes at eight weeks							
Spearman Correlation Coefficients Prob > |r| under H0: Rho=0							
	SHFT Score	**SHFT Time**	**QuickDASH**	**TAM in degrees injured digit**	**Grip Strength**	**PEM: Hand Health**	**PEM: Overall Assessment**
SHFT Score	1.00 -						
SHFT Time	-0.77 <.0001	1.00 -					
QuickDASH	-0.26 0.1322	0.24 0.1616	1.00 -				
TAM in degrees injured digit	0.28 0.0922	-0.19 0.2565	-0.63 <.0001	1.00 -			
Grip Strength	0.25 0.1423	-0.30 0.0726	-0.38 0.0206	0.45 0.0050	1.00 -		
PEM: Hand Health	0.05 0.7527	-0.04 0.8350	-0.80 <.0001	0.64 <.0001	0.48 0.0025	1.00 -	
PEM: Overall Assessment	0.06 0.7288	-0.02 0.8888	-0.67 <.0001	0.44 0.0060	0.46 0.0044	0.74 <.0001	1.00 -

Note. PEM = Patient Evaluation Measure; QuickDASH = Quick Disabilities of Arm, Shoulder and Hand questionnaire; SHFT= Sollerman Hand Function Test; TAM = Total Active Motion. Within each cell the top row is the correlation coefficient and the bottom row is the *p* value. Significant low correlations are coloured light grey, significant moderate correlations medium grey and significant high correlations black.

Chapter 5 Discussion

In our study the use of an RMES protocol after extensor tendon repair in zone V and VI enabled significantly better early functional outcomes post-operatively than a CAM protocol. Results were significantly better for outcome measures from all three domains of function defined by the ICF: activity limitation, participation restriction and body function and structure. In addition to significantly better functional outcomes, the RMES group was significantly more satisfied with their splint than the CAM group. Both groups returned to work relatively early, within a similar number of days. At the medium term follow-up of eight weeks the RMES group continued to demonstrate significantly better ROM, as measured with TAM, than the CAM group, while other functional outcomes were similar between groups. There were no ruptures and few complications with no difference in complication rate between groups. This chapter will interpret these findings and discuss them in the light of previous research on extensor tendon repairs.

5.1 Participant Follow-up

The loss to follow-up of 11.9% of participants by the final assessment was better than expected. Previous studies involving patients who have undergone extensor tendon repairs have reported loss to follow-up of up to 30% (Bulstrode et al., 2005; Chester et al., 2002; Hall et al., 2010; Svens et al., 2015). Our high follow-up rates may be as a result of negotiation of suitable appointment times with participants, text reminders and the provision of fuel vouchers to reduce the burden on participant attendance.

5.2 Function

5.2.1 Activity limitations

The first hypothesis of this study, namely that participants treated with an RMES protocol would achieve a greater SHFT score at four weeks and a similar SHFT score at eight weeks post-operatively than those treated with a CAM protocol was proven true. At the four week assessment, with both groups wearing their splints, the RMES group were able to perform the light everyday tasks of the SHFT with less difficulty and more quickly than those in the CAM group. This significantly superior functional performance of the RMES group at four weeks is thought to be due to the design of the RMES yoke

splint. The yoke splint allowed free wrist motion and only limited the last 15-20° of MCP flexion, and was therefore much less restrictive than the CAM splint.

The author is not aware of a score that represents a MCID for the SHFT, however a previous study in a population of burned hands (Weng et al., 2010) found a minimal detectable change in SHFT score to be 7 points. This finding suggests that the mean 7 point difference between CAM and RMES participants in our study at four weeks is likely to be a true difference and not due to measurement error.

There was no difference between groups for SHFT score at the medium term follow-up of eight weeks when participants were assessed without splints. In addition, by eight weeks participants in both groups had a level of function similar to that of the uninjured hand. These results suggest that by eight weeks the protocols have similar outcomes and choice of protocol does not have an effect on the ability to perform light tasks with the hand after extensor tendon repair.

A previous study used the SHFT to evaluate performance of participants with tendon repairs and reported a mean score of 76.1 ± 5.6 at final outcome (Akkaya et al., 2013). Their results are similar to the results of the current study which were 75 (*SD*: 5) and 76 (*SD:* 2) at eight weeks for the CAM and RMES groups respectively.

The time taken to complete the SHFT was recorded, as a previous study in a normal population showed that differences in SHFT completion time might identify subtle differences not evident in the SHFT score (Singh et al., 2015). In our study however, the SHFT completion time outcome mirrored the SHFT score with a significant difference at four weeks and no difference at eight weeks. The SHFT score and completion time were strongly and significantly correlated to each other.

The hypothesis our study, that in the sample as a whole there would be a significant correlation between the SHFT score and the QuickDASH score, and the SHFT score and ROM and grip strength, was proven true at four weeks and untrue at eight weeks. At four weeks the SHFT score showed low but significant correlations to subjective and objective measures of function, while at eight weeks there was no correlation to other outcomes. These findings suggest that the SHFT may be more representative of function when patients are experiencing a higher level of disability and less so once

disability reduces. The SHFT may therefore be a more suitable tool for use in populations where a high level of disability is expected. In contrast to the low significant correlation for the SHFT score with the QuickDASH score, the SHFT completion time at four weeks showed a moderate significant correlation to the QuickDASH score. This finding lends some support to the view that the time taken to complete the SHFT time may be more sensitive than SHFT score; it may be able to reveal subtle differences masked by the total score, but requires further investigation.

5.2.2 Participation restrictions

QuickDASH (Disabilities of Arm, Shoulder and Hand) questionnaire

The second hypothesis, that participants treated with an RMES protocol would achieve a higher QuickDASH score at four weeks, and similar scores at eight weeks, compared to those treated with a CAM protocol, was proved true. Participants treated with an RMES protocol reported a significantly lower level of disability when participating in their usual activities at four weeks post-operatively, as measured by the QuickDASH. This is thought to be because participants in the RMES group were able to use their hand more easily in the less restrictive design of the RMES yoke splint.

The change in the QuickDASH score between four and eight weeks in our study was 26.7 points for the CAM group and 17.4 points for the RMES group. A previous study which included participants with tendon injures found a MCID of 15.91 points for the QuickDASH (Franchignoni et al., 2014). This suggests that both groups in our study experienced a clinically important improvement between four and eight weeks, with a greater change experienced in the CAM group.

At eight weeks the QuickDASH scores were similar for both groups, showing that there was no medium term effect of the protocol on reported disability. A score of 0 for the QuickDASH indicates no disability. The QuickDASH scores of 14 (*SD*: 13.1) (CAM group) and 11 (*SD*: 11) (RMES group) at eight weeks in our study indicate that some disability was still present in the medium term for both groups. Our results are better than those of a previous study evaluating the outcome of hand tendon repairs who reported a mean QuickDASH result of 19.6 (*SD*: 15.2) at final outcome (Akkaya et al., 2013).

Return to work (RTW)

Hypothesis three, that participants treated with an RMES protocol RTW in a fewer number of days post-operatively compared to those treated with a CAM protocol, was proven to be untrue. There was no significant difference between groups with regard to the number of days to RTW. This finding was unexpected for two reasons: the first because previous studies which evaluated RMES protocols (Hirth et al., 2011; Howell et al., 2005; Svens et al., 2015) have reported an earlier RTW than those studies investigating the outcomes of studies evaluating CAM protocols (Patil & Koul, 2012; Sylaidis et al., 1997); the second reason because of the significantly better results for the RMES group in our study with regard to other functional outcomes.

The RTW timeframes in our study may not be a true reflection of functional ability. The similar timeframes for RTW for both groups may have been due to the effect of variables outside the control of the study, and not influenced by the treatment protocols themselves. A similar high proportion of participants in both groups worked in moderate or heavy occupations. If participants in these categories were to return to work prior to six weeks they would have had to carry out light duties only, as they had been advised to lift no more than 4.5kg with the injured hand during this timeframe. Some participants reported that there were no light duties available and others that their employers did not want them to work while wearing a splint because of potential health and safety risks. Participants whose work involved driving could not RTW prior to six weeks, as they had been advised not to drive until then. The above reasons are likely to have influenced return work timeframes to a greater degree than participants' ability to perform work tasks. This is likely to be the explanation for the observed lack of difference between groups.

The days to RTW in any capacity for the RMES group in the current study is similar to RTW results reported by previous studies evaluating RMES protocols, while the CAM RTW is earlier than for previous studies evaluating CAM protocols. Our RMES group returned to work at a median of 2.9 weeks compared to the 2.6 weeks to 3.9 weeks reported for RMES groups in previous studies (Hirth et al., 2011; Howell et al., 2005; Svens et al., 2015). However the CAM group in our study returned to work earlier than reports from previous studies. Our CAM group returned at 2.6 weeks where previous

studies evaluating CAM protocols reported return to work at 6.5 weeks (Sylaidis et al., 1997) or 10 weeks (Patil & Koul, 2012). As discussed in Chapter 2.3.2, participants treated with a CAM protocol in previous studies were advised to avoid using the injured hand during the period of full-time splinting (Chester et al., 2002; Hall et al., 2010; Khandwala et al., 2000; Patil & Koul, 2012). In contrast, the CAM group participants in our study were advised to use their hand for light activities immediately within the confines of the splint, and were allowed to return to work on light duties. It is likely that the advice to use the affected hand for light activities while in the splint is the reason for the better than expected return to work outcomes seen in our CAM group.

5.2.3 Body function and structure

Hypothesis four, that participants treated with an RMES protocol would demonstrate greater ROM at four weeks and no difference in ROM or grip strength at eight weeks compared to those treated with a CAM protocol, was proven partially true. Participants in the RMES group had greater wrist and finger ROM at four weeks, and continued to show greater TAM at eight weeks; there was no difference in grip strength at eight weeks.

Range of motion (ROM)

RMES participants demonstrated significantly greater degrees of TAM than the CAM participants at four weeks post-operatively; the majority of RMES participants had good or excellent TAM results at four weeks, while the majority of CAM participants were rated fair or poor. The difference in TAM at four weeks was due to significantly better flexion in the RMES group. There was no difference between groups for extension lag at four or eight weeks. By eight weeks TAM was still significantly greater in the RMES group, but the difference in TAM between groups had reduced and the distribution of good/excellent results was similar. Although there was no statistically significant difference between groups for flexion deficit at eight weeks, 74% of RMES participants had good/excellent results for flexion deficit compared to only 38% of CAM participants; this may represent a clinically meaningful difference between groups.

The difference seen in ROM between groups is likely a result of the less restrictive design of the RMES yoke splint. The extensor tendons in the RMES group were allowed greater excursion during the first four weeks and wrist and MCP joints were allowed greater ROM; the greater motion during this early stage may have resulted in the development of fewer adhesions and less loss of joint motion, resulting in better ROM in this group.

Previous studies on extensor tendon repairs have shown no difference in long term ROM outcomes, regardless of protocol (Bulstrode et al., 2005; Chester et al., 2002; Hirth et al., 2011; Patil & Koul, 2012). It is therefore probable that, although the CAM protocol delayed recovery of ROM, longer term follow-up would have shown no difference in ultimate ROM outcomes.

Our CAM outcome of 86% good/excellent results is poorer than the 95% to 100% of good/excellent reported for previous CAM groups (Bulstrode et al., 2005; Chester et al., 2002; Khandwala et al., 2000). Using the combined Miller's criteria for flexion deficit and extension lag, our CAM group achieved 38% good/excellent results because of poor flexion; this compares very poorly to a previous CAM study that reported 93% good/excellent results using these criteria (Khandwala et al., 2000). Our RMES group had 95% good/excellent TAM results, comparable to previous RMES studies reporting 94% to 100% good/excellent results using the same criteria (Hirth et al., 2011; Svens et al., 2015). Our RMES extension lag also compares favourably to that of previous RMES studies, with 90% good/excellent results, similar to the 72% to 96% good/excellent results for previous RMES reports (Howell et al., 2005; Svens et al., 2015). Our RMES flexion deficit is slightly poorer than that reported by previous RMES studies. Seventy-four percent of our RMES participants had good/excellent results, compared to 79% to 100% of participants in previous RMES studies (Howell et al., 2005; Svens et al., 2015).

It is possible that the timing of our final outcome measures affected our ROM outcomes negatively. ROM is expected to improve naturally over time and some comparable studies took measures at 10 or 12 weeks in contrast to our eight weeks (Bulstrode et al., 2005; Chester et al., 2002; Hall et al., 2010; Hirth et al., 2011). The results for our CAM group are however markedly poorer than other studies that

reported outcomes at six to eight weeks post-operatively (Hall et al., 2010; Khandwala et al., 2000; Patil & Koul, 2012).

It is likely that the reason for poorer results seen in our CAM group was due to our relatively conservative CAM protocol. In our study, the MCP joints in the CAM group were allowed only 30° flexion in the splint, and a night piece was added to the splint to maintain IP extension; participants were advised not to attempt to make a full fist until six weeks post-operatively. In contrast, other CAM protocols positioned the MCPs in 45° to 50° in the splint (Bulstrode et al., 2005; Hall et al., 2010; Khandwala et al., 2000; Saini et al., 2008; Sylaidis et al., 1997), gradually increased MCP flexion over the first few weeks (Hall et al., 2010; Khandwala et al., 2000) and encouraged fist formation from three to four weeks (Chester et al., 2002; Saini et al., 2008). Our conservative approach is likely to have influenced the recovery of flexion in the CAM participants.

The slightly poorer flexion deficit seen in our RMES group when compared to previous studies may be because participants were not provided with exercises in the first four weeks post-operatively, and because of the full forearm based splint worn overnight. The lack of exercise and the provision of a night-time splint were as per the protocol described by Hirth et al. (2011). Protocols reporting better flexion outcomes than ours (Altobelli et al., 2013; Howell et al., 2005; Svens et al., 2015) included flexion/extension exercises for the digits within the yoke splint during the first four weeks post-operatively and did not use a full night splint. It is likely that the lack of exercises and the overnight splint contributed to our RMES group's slightly poorer results.

The significantly greater active arc of wrist motion at four weeks was expected due to the free wrist ROM allowed in the RMES group, compared to wrist immobilisation in the CAM group. By eight weeks there was no difference in wrist active ROM or combined passive wrist and finger flexion. The choice of protocol therefore has no lasting effect on wrist active ROM or extrinsic extensor tendon musculotendinous length.

Grip strength

The similarity between groups with regard to grip strength was expected. Both groups had been allowed to commence light use of their hand without the splint on from four weeks and return of grip strength had therefore likely progressed at a similar rate.

Grip strength at eight weeks was reduced compared to the contralateral hand. For the RMES group in our study the mean of 83% of the contralateral side is within the range of 80% to 90% reported by previous RMES studies (Howell et al., 2005; Svens et al., 2015). The mean of 31.6kg in the CAM group at eight weeks is somewhat less than the 38.9kg reported for a previous CAM study at 12 weeks (Hall et al., 2010); however it is likely that strength would have continued to increase between eight and 12 weeks and this difference is therefore not thought to be clinically meaningful.

5.3 Adherence and Satisfaction

Hypothesis five, that participants treated with an RMES protocol would report better adherence and similar satisfaction measured by the PEM score compared to those treated with a CAM protocol, was proven partially true for satisfaction and untrue for adherence.

Our non-adherence rate of 55% and 75% is similar to the findings of previous studies of 55% to 67% non-adherence after tendon repair (Kaskutas & Powell, 2013; Sandford et al., 2008). However the majority of participants in both groups did not remove their daytime splint for more than an hour and reported engaging only in self-care or light work tasks without the splint. Some participants reported that when they used their hand without the splint they avoided positions that caused a feeling of strain in the repaired tendon, such as excessive wrist and/or finger flexion. Despite the relatively poor adherence rates there was no incidence of tendon rupture. This suggests that the activities that participants engaged in without the splint did not load the tendons more than the tendon repair could tolerate.

A higher proportion of RMES participants drove their vehicles in the first four weeks than CAM participants. This may be because they could grip the steering wheel more easily and move the wrist while wearing the RMES yoke. Our study was not designed

to investigate whether it is safe to drive in either splint, however future studies could investigate the impact of splinting on ability to drive.

Participants in the RMES group reported a significantly higher level of satisfaction with the daytime splint; they provided higher ratings for the RMES yoke with regard to comfort and ability to use the hand when wearing the splint; CAM participants frequently complained of discomfort and stiffness in their wrists as a result of their daytime splint. Both groups found the night splint awkward and uncomfortable and as a result a quarter of the RMES group wore the yoke splint overnight instead of the prescribed forearm based splint. Participants in both groups reported similarly high levels of satisfaction with Hand Health and Overall Assessment; the protocol therefore did not have an effect on overall satisfaction with outcome by eight weeks.

A previous RMES study used the Hand Health section of the PEM to assess their participant outcomes at eight weeks and reported 87% to 93% satisfaction (Svens et al., 2015). This is similar to the 83% satisfaction with Hand Health in our RMES group, and slightly better than the 79% in our CAM group.

5.4 Complications

Hypothesis six, that participants treated with an RMES protocol would have no difference in complication rate compared to those treated with a CAM protocol was proven true. Although there were three complications in the RMES group and none in the CAM group, this difference was not significant. The complications were not considered to be related to the protocol and could potentially have occurred in either group.

A primary concern after tendon repair is rupture of the repair. There were no ruptures in either group in our study which confirms that both the RMES and CAM can be considered safe protocols for use after extensor tendon repair in zone V and VI. The absence of tendon rupture is similar to reports of most previous studies on both CAM and RMES protocols (Altobelli et al., 2013; Bulstrode et al., 2005; Chester et al., 2002; Hirth et al., 2011; Howell et al., 2005; Patil & Koul, 2012; Saini et al., 2008; Svens et al., 2015).

There were initial concerns that in the RMES group the yoke splint might allow too much motion, increasing the risk of rupture. However a potential risk of rupture also existed in the CAM group, because active finger extension was initiated with the wrist in extension. Previous studies have shown the position of wrist extension combined with active finger extension increases loading of the extensor tendon (Evans & Thompson, 1993; Sakellariou et al., 2006) and could therefore potentially increase the risk of rupture. Despite these potential risks, the absence of rupture in our study demonstrates that sufficient protection was provided by both protocols.

5.5 Hand Therapy Intervention

The number of appointments and total duration of hand therapy was similar between groups at a mean of six appointments for both groups. Previous studies on extensor tendon repairs in zones V and VI (Chester et al., 2002; Howell et al., 2005; Svens et al., 2015) have reported a mean number of appointments of between 3.6 and 9; our results are therefore within the range reported by previous similar studies. No major concerns relating to either protocol were reported by therapists and only minor adaptations to treatment protocols were described. The most common adaptation was in the RMES group where therapists taught exercises to participants within the first four weeks. This is likely because therapists felt that functional use of the hand would be insufficient to prevent tendon adhesions and limitations of ROM.

5.6 Summary

The superior early functional outcomes for the RMES group in our study appear to be due to the minimally restrictive design of the RMES yoke splint. The absence of rupture and lack of difference in complication rates between groups have demonstrated that the RMES protocol is safe despite the only minimal restrictions it places on motion. RMES participants' ability to use the hand earlier and their greater satisfaction with splinting are findings that have important implications for rehabilitation. The findings of our research will influence practice and lead to questions for future studies. The implications and limitations of our study will be explored in the final chapter.

Chapter 6 Conclusions

This chapter discusses the implications of our findings on clinical practice, the limitations of the study, recommendations for future research and final conclusions.

6.1 Implications for Practice

Our study compared two EAM protocols to investigate whether one provided superior results over another; no previous studies have investigated this question. Our study has shown that, after extensor tendon repair in zone V and VI, the use of an RMES protocol results in significantly better early return to function, with greater splint satisfaction, than a CAM protocol. Initial concerns that the RMES yoke splint allowed too much motion and could result in rupture of the repaired tendon were shown to be unfounded. The RMES protocol has therefore been shown to be safe, effective and superior to the CAM protocol. We concluded that the RMES protocol is the preferred protocol for use after extensor tendon repairs in zone V and VI. The findings of this study will change practice at the unit where the study was conducted, and should influence practice both nationally and internationally.

Although the RMES group had good ROM results, as discussed, we found that the flexion deficit was slightly poorer than reports from previous RMES studies. In order to address this deficit we suggest that, when using an RMES protocol, patients should be taught active wrist tenodesis exercises within the yoke splint in the first four weeks: finger flexion with wrist extension, and finger extension with wrist flexion. The aim will be to regain full active flexion and extension within the splint by four weeks post-operatively, and after four weeks commence making a full fist without the splint. These alterations to our protocol are likely to improve flexion results for RMES patients.

The intended purpose of the forearm-based night splint for the RMES group and the extra night-piece for the CAM group in our study was to prevent the development of an extensor lag and to prevent composite flexion. However extension lag was a not problem in either group, and both groups complained of discomfort in the night-time splint. We believe that splinting fingers in extension at night does not reduce extension lag. We therefore suggest that the full forearm-based splint is unnecessary in the RMES group; instead the yoke splint should be worn overnight, with an added wrist

splint in approximately 25° of extension to prevent composite flexion. For the CAM protocol, we believe that the additional night extension piece is unnecessary and could be discontinued. These changes to night splinting will result in greater comfort and may have the added benefit of improving flexion as the IP joints will not be immobilised in extension overnight.

Our study included tendon repairs in a maximum of two digits; the results are therefore not generalisable to patients who have tendon repairs to more than two digits. We included simple injuries; the results are therefore not generalisable to patients with complex injuries with associated unstable fractures or extensive skin loss requiring flap coverage. For injuries involving more than two digits and for complex injuries, the RMES may be appropriate; however in these cases we would also consider the CAM protocol to be an acceptable alternative to the RMES. Our study found the CAM protocol to be safe, and although early functional outcomes for CAM participants were poorer, most medium outcomes were similar to those of RMES participants. If a CAM protocol is to be used, alterations should be made to the protocol to improve on the poor flexion deficit outcomes found in our study. To address the poor recovery of flexion we would suggest that the MCP joints should be positioned in 45° to 50° of flexion in the splint, and that patients should be advised to practise making a full fist from four weeks post-operatively. It may be beneficial to allow some early wrist tenodesis exercises, either therapist-supervised as described by Evans (1995) or perhaps by means of a hinged splint as described by previous authors (Chinchalkar & Yong, 2004; Eissens et al., 2007). Allowing greater MCP joint ROM and greater tendon excursion may improve the recovery of flexion in patients who are treated with a CAM protocol in the future.

Despite therapist instructions, the majority of participants in our study removed their splints to perform light tasks, potentially placing the repaired tendon at risk. Our population was not unique in this regard as evidenced by the findings of previous studies on adherence after tendon repair. In the light of these findings we suggest that the education that therapists provide to patients on how to protect the tendon is an essential element of the therapy programme. Education should incorporate teaching about tendon healing, what hand and wrist positions to avoid, and how to monitor a sensation of strain in the tendon. Education has the ability to empower patients and

may be more beneficial than rigidly demanding that they wear their splints full time when we know they will not adhere to this instruction.

We believe that the combination of subjective and objective assessments used in our study provided a comprehensive assessment of function after extensor tendon repair in zone V and VI. The SHFT was found to be an appropriate and useful measure of functional performance of the hand, particularly in the early stage of recovery. Previous reports have not used the SHFT to compare the effect of different splints or protocols, and this study has shown that it is useful for this purpose. We found that using Miller's criteria, and not only TAM, to assess ROM revealed that flexion deficit was a problem. This enabled us to make specific recommendations to optimise outcomes and we would therefore recommend the use of Miller's criteria in future extensor tendon studies. The QuickDASH, which has been used in many previous studies in various populations, has again been shown to correlate significantly to other measures, and served as a useful adjunct to traditional objective measures of function. The PEM has only previously been used in one extensor tendon repair study. In our study PEM score correlated significantly with subjective and objective measures of function, demonstrating that it is an appropriate tool for this population. Although correlations between the various outcome measures used were significant, correlations were predominantly of low or moderate strength. Each measure alone therefore provides only part of the total picture of function. We recommend that outcome measures from all three domains of ICF function should be used in future assessments for patients after extensor tendon repair to provide a comprehensive assessment of function.

6.2 Limitations

It was not possible to blind participants or therapists in our study due to the obvious difference between the splints used in the protocols. It is possible that the RMES participants' higher satisfaction with splinting was due to their knowledge that it was the less restrictive experimental alternative; however the splinting satisfaction questions related specifically to comfort and ability to use the hand in the splint and we are satisfied that the answers reflected participant experience. We attempted to minimise risk of bias by blinding of the PI to the group allocation, and ensuring that

research assistants carried out the assessment of the primary outcome measure (SHFT) and that the PI did not treat any of the study participants. These strategies helped maintain the objectivity of the PI.

The final assessment of participants in our study was medium term at eight weeks. It is possible that longer follow-up would have shown no difference between groups for any functional outcomes. A later final assessment may also have demonstrated final results more comparable to those of some previous extensor tendon studies. The eight week point was chosen because of an expected high loss to follow-up of the sample, and because previous studies have not shown significant differences in long term outcomes, regardless of protocol used. We believe the eight week assessment point was appropriate, as evidenced by our excellent follow-up rate and the finding that almost all outcomes were similar for both groups at this time-point.

Our minor adaptations of the SHFT may have had a slight impact on the scoring of the test. The mean SHFT score for the contralateral uninjured hand in our study was 75 or 76 points which is lower than the 77 to 80 points suggested for a normal population (Sollerman & Ejeskär, 1995). The alteration of task 13, the writing task, did not appear to have an effect on the scoring as most participants completed this task within 20 seconds. However we found that participants in our study frequently took longer than 20 seconds to complete task 18 (pouring water from a Purepak), therefore losing a point for this task; a normal population in a previous SHFT study took a mean of only 10.1 seconds to complete this task (Singh et al., 2015). The small plastic nozzle on the Purepak we used may have made it more difficult to empty than the one pictured in the original article which had a large opening (Sollerman & Ejeskär, 1995). It is possible that our standardisation of scoring made the scoring criteria stricter and therefore made it more difficult to achieve a full score. Our pilot testing of the SHFT prior to the study found good consistency of scoring between raters, and participants in both groups completed exactly the same tasks using the same equipment. The minor adjustments to the SHFT therefore did not influence our hypothesis testing and we are confident that our results are a true reflection of the participants' performance.

6.3 Further Research

In our study RMES participants were advised to avoid composite wrist and finger flexion in the yoke splint and to wear a full night splint to prevent accidental composite flexion when sleeping. However we do not know whether they did in fact avoid composite flexion and we do know that at least 25% did not wear the night splint. Despite the potential risk to the repaired tendon during composite wrist and finger flexion there was no incidence of rupture. This suggests that the yoke splint alone may limit flexion sufficiently to prevent rupture of the repaired tendon even when the wrist and fingers are flexed. The author is not aware of any biomechanical studies investigating the effect of an RMES yoke splint on extensor tendon repairs when the wrist and fingers are flexed. Future studies should investigate the effect of the yoke splint on loading and excursion of extrinsic extensor tendons during finger and wrist flexion.

Previous research has shown that unrestricted use of the hand after extensor tendon repair may result in tendon rupture (Stuart, 1965); however the exact amount of restriction required to prevent rupture is unknown. In our study, to protect the tendon repair, we advised participants to perform light activities with the yoke splint on for the first four weeks; we also advised them to avoid heavier activities, including driving, until six weeks, even while wearing the splint. However we found that the majority of our RMES participants removed the yoke splint for some light self-care or work activities, and drove within the first four weeks while wearing the splint. Despite this non-adherence to instructions there were no tendon ruptures. Previous RMES studies have allowed patients to return to heavier tasks from as early as three to four weeks, provided they wore their splints (Hirth et al., 2011; Howell et al., 2005; Svens et al., 2015). The author is not aware of previous studies investigating the loading of extensor tendon repairs during activities with and without a yoke splint. It is possible that patients may be able to safely carry out some light activities without the splint, and heavier activities with the yoke splint during the early post-operative period. Future research should determine how much protection of the repaired tendon is required by loading healthy and repaired extensor tendons during a variety of activities with and without a yoke splint.

In our study, as in many previously published studies on extensor tendon rehabilitation, four weeks of full-time splinting was advised. This corresponds to the fibroplastic phase of healing. A previous study on extensor tendon repairs showed that the optimal duration of splinting is 10 days and that splinting for three weeks resulted in a loss of flexion (Stuart, 1965). It is conceivable that repaired tendons may not require protection in a splint for as long as four weeks, and that a shorter duration of splinting would prove safe and result in a quicker recovery of flexion. Future studies could investigate whether a shorter duration of splinting may be sufficient and might facilitate earlier and improved outcomes.

The SHFT proved to be a useful and appropriate assessment tool in our study. Further investigation with regard to SHFT time and scoring for patients with different conditions and levels of disability could provide information on its sensitivity and applicability. The SHFT was developed more than 30 years ago and does not include some light tasks relevant to modern day life such as use of a keyboard or smartphone. In addition, the tasks currently included in the SHFT are familiar to patients from a Western culture but may not be considered relevant to all cultures. Future research could investigate expanding and adapting the SHFT tasks to incorporate tasks relevant to modern day patients' everyday lives and a wider range of cultures.

6.4 Conclusion

EAM protocols for rehabilitation of extensor tendon repairs in zone V and VI developed as a result of increased understanding of tendon healing, biomechanics and the benefits of mobilisation as well as improved suture techniques. Our study has been the first to compare two EAM protocols and has shown conclusively that the RMES protocol allows significantly better function, with no greater risk, and greater splint satisfaction than a CAM protocol during the early post-operative period. A combination of validated assessments was used to provide a thorough assessment of our participants' function and we are confident that our findings reflect a true difference between protocols.

The RMES yoke splint design is low profile and minimally restrictive, and appears to therefore allow easier use of the hand. The RMES yoke splint allows greater tendon excursion and joint motion than the CAM splint, thereby potentially reducing stiffness and adhesion formation, resulting in greater ROM. Although the yoke splint only limits end-range MCP flexion, it appears to provide sufficient protection for the repaired tendon. The results of our study suggest that the yoke splint used in the RMES protocol may effectively balance loading and excursion of the repaired extensor tendon in zone V and VI to result in better early functional recovery.

Further research on extensor tendons in zone V and VI should investigate the effect of the yoke splint on extensor tendon loading during motion and activity and determine whether a shorter duration of splinting may be sufficient to protect the repaired extensor tendon. Further research could more clearly define when and for how long the splint should be worn and what restrictions should be advised regarding return to activity.

Our study has contributed to the growing body of evidence on the benefits of early active mobilisation. We have demonstrated that the RMES protocol is safe and effective and provides superior outcomes to a CAM protocol. We recommend it as the preferred protocol for rehabilitation of patients after extensor tendon repair in zone V and VI.

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Appendices

Appendix A: SEQES

The Structured Effectiveness Quality Evaluation Scale

Evaluation criteria	*Score* 2 1 0
Study question	
1. Was the relevant background work cited to establish a foundation for the research question?	
Study design	
2. Was a comparison group used?	
3. Was patient status at more than one time point considered?	
4. Was data collection performed prospectively?	
5. Were patients randomised to groups?	
6. Were patients blinded to the extent possible?	
7. Were treatment providers blinded to the extent possible?	
8. Was an independent evaluator used to administer outcome measures?	
Subjects	
9. Did sampling procedures minimize sample/selection biases?	
10. Were inclusion/exclusion criteria defined?	
11. Was an appropriate enrolment obtained?	
12. Was appropriate retention/follow-up obtained?	
Intervention	
13. Was the intervention applied according to established principles?	
14. Were biases due to the treatment provider minimised (i.e., attention, training)?	
15. Was the intervention compared with the appropriate comparator?	
Outcomes	
16. Was an appropriate primary outcome defined?	
17. Were appropriate secondary outcomes considered?	
18. Was an appropriate follow-up period incorporated?	
Analysis	
19. Was an appropriate statistical test(s) performed to indicate differences related to the intervention?	
20. Was it established that the study had significant power to identify treatment effects?	
21. Was the size and significance of the effects reported?	
22. Were missing data accounted for and considered in the analyses?	
23. Were clinical and practical significance considered in interpreting the results?	
Recommendations	
24. Were the conclusions/clinical recommendations supported by the study objectives, analysis and results?	

Total Quality Score (Sum of above / 48) =
Level of Evidence (Sackett) 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

Appendix B: HDEC Approval

Health and Disability Ethics Committees

Health and Disability Ethics Committees
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington

0800 4 ETHICS
hdecs@moh.govt.nz

05 November 2014

Mrs Shirley Collocott
Auckland Regional Centre for Plastic Reconstructive & Hand Surgery
Private Bag 93311
Otahuhu 1640

Dear Mrs Collocott

Re:	**Ethics ref:**	**14/STH/164**
	Study title:	Can relative motion extension splinting provide an earlier return to function than a standard controlled active motion protocol after extensor tendon repair in zone V and VI? A prospective randomised controlled trial

I am pleased to advise that this application has been *approved* by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

The main issues considered by the HDEC in giving approval were as follows.

- The Committee noted that on the information sheet P2 para 1 & 2 suggests that the RMES protocol is better than the CAM. The Committee stated this suggestion should not be made at this stage of the study as it implies a bias. It should be an alternative that is being used as a comparison. If the researchers truly believe that the RMES protocol is better than CAM, they should not be undertaking this study.

- The Committee stated the sentence "When you come to the appointment at 4 weeks and 8 weeks after the operation you will be given a $20 fuel voucher for attending." can be deleted from the section headed "How will these discomforts and risks be alleviated?" The Committee believes it may be necessary to warn patients to check with their insurers whether participating in this study may affect their insurance

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

4. Amend the patient information sheet and consent form.

Non-Standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to HDEC before commencing your study.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

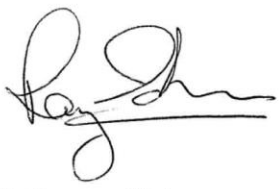
Your next progress report is due by 5 November 2015.

Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
Covering Letter: Cover letter	1	15 October 2014
CV for CI: Shirley Collocott CV	September 2014	20 September 2014
Evidence of scientific review: Approval of protocol via AUT PGR1 process	1	25 September 2014
PIS/CF: Participant information sheet	1.1	03 October 2014
PIS/CF: Consent form	1.1	03 October 2014
Protocol: Protocol for RMES vs CAM	1	17 September 2014
Survey/questionnaire: QuickDASH questionnaire	1	15 October 2014
Survey/questionnaire: Adapted patient evaluation measure and satisfaction questionnaire	1.1	06 October 2014
Survey/questionnaire: Splint adherence questionnaire	1.1	06 October 2014
CVs for other Investigators: CV for Mike Foster	2014	20 October 2014
CVs for other Investigators: Heidi Myhr CV	2014	21 October 2014
CVs for other Investigators: Amy Wang CV	2014	21 October 2014
CVs for other Investigators: Edel Kelly CV	2013	20 October 2014
CVs for other Investigators: Richard Ellis CV	2014	17 October 2014
CVs for other Investigators: Irene Zeng CV	2014	17 October 2014
Application	1	-
Evidence of scientific review	1	22 October 2014
Evidence of scientific review	1	22 October 2014

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Dr Sarah Gunningham	Non-lay (intervention studies)	01/07/2012	01/07/2015
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	01/09/2014	01/09/2015
Dr Fiona McCrimmon	Lay (the law)	01/09/2014	01/09/2015
Dr Nicola Swain	Non-lay (observational studies)	01/07/2012	01/07/2015
Dr Devonie Waaka	Non-lay (intervention studies)	01/07/2013	01/07/2016
Dr Mathew Zacharias	Non-lay (health/disability service provision)	01/07/2012	01/07/2015

http://www.ethics.health.govt.nz

Appendix C: AUTEC Approval

AUT UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

AUTEC SECRETARIAT

18 November 2014

Edel Kelly
Faculty of Health and Environmental Sciences

Dear Edel

Ethics Application: **14/377 Can relative motion extension splinting provide an earlier return to hand function that a controlled active motion protocol after extensor tendon repair in zone V and VI? A prospective randomised clinical trial.**

Short Title: RMES vs CAM

Thank you for submitting your application for ethical review to the Auckland University of Technology Ethics Committee (AUTEC). I am pleased to confirm that the Chair and I have approved your ethics application for three years until 18 November 2017.

As part of the ethics approval process, you are required to submit the following to AUTEC:

- A brief annual progress report using form EA2, which is available online through http://www.aut.ac.nz/researchethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 18 November 2017;
- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/researchethics. This report is to be submitted either when the approval expires on 18 November 2017 or on completion of the project;

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this.

To enable us to provide you with efficient service, we ask that you use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

Kate O'Connor
Executive Secretary
Auckland University of Technology Ethics Committee

Cc: Shirley Collocott shirley.collocptt@middlemore.co.nz

Appendix D: Counties Manukau Health Approval

Ko Awatea Research Office
Counties Manukau DHB
Clinical Support Building
Room 253, Level 2
Middlemore Hospital

11 December 2014

Dear Shirley

Thank you for the information you supplied to the Ko Awatea Research Office regarding your research proposal:

Research Registration Number: **1843**

Ethics Reference Number: **14/STH/164**

Research Project Title: **Can relative extension splinting provide an earlier return to function than a standard controlled active motion protocol after extenor tendon repair in zone V and VI? A prospective randomised controlled trial**

I am pleased to inform you that the CMDHB Research Committee and Director of Hospital Services have approved this research with you as the CMDHB Co-ordinating Investigator.

Your study is approved until 30 December 2016.

Amendments:

- All amendments to your study must be submitted to the Research Office for review.
- Any substantial amendment (as defined in the *Standard Operating Procedures for HDECs*, May 2012) must also be submitted to the Ethics Committee for approval.

All external reporting requirements must be adhered to.

Please note that failure to submit amendments and external reports may result in the withdrawal of Ethical and CMDHB Organisational approval.

We wish you well in your project. Please inform the Research Office when you have completed your study (including when a study is terminated early) and provide us with a brief final report (1-2 pages) which we will disseminate locally.

Yours sincerely

Alex Poor
Health Intelligence and Informatics Lead
Counties Manukau District Health Board
Under delegated authority from CMDHB Research Committee and Director of Hospital Services

Appendix E: Participant Information Sheet

Participant Information Sheet

Date Information Sheet Produced:

30 September 2014

Project Title

Can relative motion extension splinting provide an earlier return to hand function than a controlled active motion protocol after extensor tendon repair in zone V and VI? A prospective randomised clinical trial

Contact Person

Shirley Collocott, Hand Therapist, Counties Manukau District Health Board
Tel: 09 276 0044 x 8684
Email: shirley.collocott@middlemore.co.nz

An Invitation

We would like to invite you to participate in a research project. The reason you are being invited is because you have had an operation to repair tendon(s) in your hand. The research project is to find out if people who have had this type of operation can get back to using their hand sooner than they have in the past.

This research is taking place at Counties Manukau District Health Board (CMDHB) and will form part of a Master's of Health Science degree for the primary researcher, Shirley Collocott, through AUT University. Shirley is a Hand Therapist and Occupational Therapist working at CMDHB. Other researchers involved are Mr Mike Foster, Orthopaedic Hand Surgeon at CMDHB, Irene Zeng, Biostatistician at CMDHB and Heidi Myhr and Amy Wang, Hand Therapists at CMDHB. The project is being supervised by Edel Kelly and Dr Richard Ellis at AUT University.

Participating in this research is voluntary. This means that you do not have to take part in it if you do not want to. If you choose not to be part of this research you will still receive treatment for your hand injury and you will not be disadvantaged in any way. If you agree to participate in the research and then change your mind later you may tell us at any time and you can stop being part of it.

Please read through this information sheet carefully and ask your therapist or doctor if you have any questions. You may like discuss this with your family or friends before making the decision about whether you would like to take part in the project.

What is the purpose of this research?

When people have an operation to repair cut tendons on the back of their hand or knuckles their surgeons refer them to a Hand Therapist who makes them a plastic splint to protect their hand while the tendon is healing. The Hand Therapist may also give the person advice on how to use their hand safely, and teach them exercises to do at home. The splint, exercises and advice provided by the Hand Therapist is called a 'protocol' for managing repaired tendons. People who have this operation at CMDHB are usually treated with a protocol called an extensor controlled active motion (CAM) protocol.

Hand Therapists in some other countries, like Australia and America, have tried different protocols for treating people who have had this kind of operation. These protocols use different splints and exercises from the CAM. One of these different protocols is called a relative motion extension splinting (RMES) protocol.

The research project we are inviting you to join is one that will have two groups of people who have had their tendons repaired. One group will be treated with the CAM protocol and the other will be treated with the RMES protocol. There will be no change to the operation; the research is just looking at the Hand Therapy that people receive. We want to see if there is any difference between the two groups in how easily people can use their hands and when they are able to get back to work.

The research project will run for at least one year to make sure we have enough people in the study to make it worthwhile. At the end of the research we will write about what we have found in a full report for the university; we will report what we have found at conferences for surgeons and therapists who treat people with hand problems; we will also write a shorter report that will be published in journals that are read by surgeons and therapists who treat people with hand problems so that the information can be spread to people who will find it useful. We will write an easy-to-understand version of the report for people who have been part of the research and are interested in knowing the results but are not surgeons or therapists.

How was I identified and why am I being invited to participate in this research?

During the year that the study is running, everyone who has this type of tendon operation at CMDHB will be reviewed to see whether they will be suitable for the research project. If they are suitable then they will be invited to participate in the research. You were identified because you have had this type of operation and your surgeon is happy that it is safe for you to be part of the research. You are at least 16 years old and have had tendons to at least one finger but not more than two fingers repaired, and your injury does not involve other tendons or serious injuries.

What will happen in this research?

Everyone who has this type of operation will have a Hand Therapy appointment at the Manukau SuperClinic (MSC) Hand Therapy Department within 7 days after their operation, even if they are not part of the research project. If you choose to be part of the research project then at the first appointment you will be asked choose a closed envelope out of a box. Half the envelopes will have a piece of paper inside saying Group A, and half will have a paper inside saying Group B. No one will know which envelope has which piece of paper inside until it is opened. If the paper inside says Group A, you will be treated with the CAM protocol. If the piece of paper in your envelope says Group B then you will be treated with the RMES protocol. There will be equal numbers of people in each group, and you will not be able to choose which group you want to be in; it depends which envelope you choose and is entirely up to chance.

At this first Hand Therapy appointment your therapist will change your dressings and make you a plastic splint to protect your tendon; the type of splint will depend on which group you are in. Then she will give you advice on how to look after your hand, and you may be shown some exercises to do at home.

After this type of operation you need to see a Hand Therapist once a week, even if you are not part of the research project. If you live close to MSC then you will have follow-up hand therapy appointments there in about one week; if you live in a different suburb you will be referred to a hand therapist who is closer to your home.

The hand therapist you see will have had training about the research project so they will understand how to look after your hand. Your hand therapist will fill out a form to tell the researchers what appointments you have attended and what they have done in those appointments. Your treatment will be paid for by ACC and ACC will be informed that you are involved in the research project so that they understand this when they make plans for your return to work. Your GP will also be informed that you are involved in the research project.

At 10-14 days after your operation you will have an appointment to see a surgeon at MSC to check your wound and to have your stitches taken out; this is the same for everybody, even if you are not part of the research project. At this appointment, if the doctor is happy with how your wound is healing, they will talk to you about possibly being allowed to go back to work on light duties. You will only be able to go back to work if you can do light duties (lifting no more than 4.5kg) with your splint on or only use the other hand. If you are not able to do this then you will be unable to return to work until later.

At the end of 4 weeks after your operation you will have another appointment at Manukau SuperClinic which will be just for the research project. Because this is an extra appointment only for people who are in the research project you will be given a $20 petrol voucher to help you pay for fuel when you come to the appointment. This appointment will take approximately 1 hour. At the appointment you will be seen by Shirley Collocott and another Hand Therapist. You will be asked to do some everyday tasks such as turning a key in a door or putting coins in a purse. You will have measurements taken of how well your hand joints move and you will be asked questions about how easy or difficult it is for you to do things and how you are finding wearing the splint. You will also be asked how things are going at work if you have gone back to work. There will be time for you to ask questions too.

At the end of 8 weeks you will have another clinic appointment at Manukau SuperClinic where you will see a surgeon again. This is a normal clinic appointment that everyone who has this type of injury needs to go to even if they are not part of the research. If there are no problems with your hand the surgeon may sign you off to return to work on full duties from 8 -10 weeks after your operation. If there are no problems with your hand then this will be the last time you need to see the surgeon.

People who are part of this research project, will also see Shirley Collocott and the Hand Therapist for the second and final assessment on the same day as the 8 weeks clinic appointment. This extra assessment will take an hour, so it is important to be prepared. It will be similar to the 4 week research appointment and you will be asked to do the same tasks, have measurements taken of your hand and answer questions. You will also receive a $20 petrol voucher when you attend this appointment as we realise we are asking for more of your time.

What are the discomforts and risks?

1. The extra things you being asked to do if you agree to be part of the research project are:

- Attend an extra appointment with the researcher and a Hand Therapist at MSC for 1 hour at 4 weeks after your operation. (You will be provided with a $30 fuel voucher when you attend this appointment). At this appointment you will be asked to do some tasks, answer some questions and have measurements taken of your hand.

- Attend an extra appointment with the researcher and a Hand Therapist at MSC for 1 hour on the same day as your 8 week clinic appointment with the surgeon at MSC. (You will be provided with a $30 fuel voucher when you attend this appointment). At this appointment you will be asked to do some tasks, answer some questions and have measurements taken of your hand.

2. There is a very small chance that being in the research and using your hand more, earlier, could make it more likely that the repaired tendon could snap. However this has not happened in over 100 people who have used the RMES protocol after they have had the same operation as you, so the chance is extremely small.

How will these discomforts and risks be alleviated?

Your surgeon, the therapist who treats you and the researchers will advise you on how to take care of your hand and what you can do safely. They will discuss your work with you and if the surgeon does not think it is safe for you to go back to work, or if there are no light duties available, then you will not be signed off to return until later. If they are worried that there is a risk of you snapping the tendon that has been repaired then they may advise that you stop being part of the research project. The

research team will let ACC know that you are part of the study so that they will know how to plan for your to return to work.

What are the benefits?

Being in the research means that you may be able to use your hand more easily, earlier and you may be able to get back to work earlier. This depends on your type of job and which group you are in as part of the research.

Your help with the research means we will be able to find out whether the RMES protocol or the CAM protocol is better. Then in the future when we treat people who have the same kind of injury as you do, we will know which protocol to use and hopefully this will help people get back to using their hand sooner.

What compensation is available for injury or negligence?

In the unlikely event of a physical injury as a result of your participation in this study, rehabilitation and compensation for injury by accident may be available from the Accident Compensation Corporation, providing the incident details satisfy the requirements of the law and the Corporation's regulations.

How will my privacy be protected?

All your personal information will be kept confidential – this means that your personal details such as your name and address will not be reported on or given to anyone other than the therapist/ surgeon responsible for your care and the research team. When the study reports are written they will not contain any details that could identify you.

All the information related to the research will be kept in password-protected drives on the hospital network and the written information will be kept in an office with swipe-card access.

What are the costs of participating in this research?

It will not cost you anything to participate in the research project. You will be asked to attend 2 assessment appointments at MSC. They will be around 1hr long each. The first appointment will be an extra one which is just for the research, and the second one will be in addition to your last clinic visit to see the doctor. You will be provided with a $30 fuel voucher when you attend each of these appointments to pay for the cost of your getting to the appointment. Parking at MSC is free.

What opportunity do I have to consider this invitation?

You can think about this invitation between now and your first hand therapy appointment at MSC. Please feel free to talk it over with your friends or family and to ask any questions you may have.

How do I agree to participate in this research?

You will be provided with a consent form to sign at your first hand therapy appointment at MSC. Signing the form means that you agree to be part of the research. If you change you mind later after signing the form then you may let your therapist/ the researcher know that you no longer wish to be part of it.

Will I receive feedback on the results of this research?

A report will be written for people who have been part of the research and are interested to know the results. It will be mailed to you at the end of the project. If you would like to receive a copy of the report please tick the box on the consent form.

General

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:
Free phone: 0800 555 050
Free fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator. You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Edel Kelly, edelkelly@xtra.co.nz, 09 921 9999 x662. Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, *ethics@aut.ac.nz* , 921 9999 ext 6038.

Whom do I contact for further information about this research?

Researcher Contact Details:
Shirley Collocott
Primary Researcher
Registered Hand Therapist/ Occupational Therapist
Email: shirley.collocott@middlemore.co.nz
Phone: 09 - 276 0044 x8684.

Project Supervisor Contact Details:
Edel Kelly
AUT Supervisor
edelkelly@xtra.co.nz
09- 921 9999 x 6624

Is this research project approved?

The ethical aspects of this research project have been approved by the Southern Health and Disability Ethics committee, reference number 14/STH/164. It has also been approved by AUTEC, the ethics committee at AUT University, approval number 14/377. This project will be carried out according to ethical guidelines. It has been approved by the Counties Manukau District Health Board Research Office and will be carried out according to their guidelines.

Appendix F: Consent Form

Consent Form

Project title: *Can relative motion extension splinting provide an earlier return to hand function than a controlled active motion protocol after extensor tendon repair in zone V and VI? A prospective randomised clinical trial*

Project Supervisors: ***Edel Kelly, Richard Ellis***

Primary Researcher: ***Shirley Collocott***
Contact Details: ***09 276 0044 x8684 or email shirley.collocott@middlemore.co.nz***

- ○ I would like to have an interpreter: Yes ○ No ○
  Language _____
- ○ I have read and understood the information provided about this research project in the Information Sheet dated 30 Sept 2014.
- ○ I have had an opportunity to ask questions and to have them answered.
- ○ I understand that the treatment, or investigation, will be stopped if it should appear harmful to me.
- ○ I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.
- ○ I understand that ACC, my GP and my hand therapist will be informed that I am participating in this project
- ○ I understand that I may withdraw myself or any information that I have provided for this project at any time prior to completion of data collection, without being disadvantaged in any way.
- ○ I agree to take part in this research.
- ○ I wish to receive a copy of the report from the research (please tick one): Yes ○ No ○

Participant's signature: .....

Participant's name: .....

Participant's Contact Details :

.....

.....

Date:

Approved by the Auckland University of Technology Ethics Committee on 18 November 2014, AUTEC Reference number 14/377.
Approved by the Southern Health and Disability Ethics committee on 5 November 2014, reference number 14/STH/164.

Appendix G: Exercise Hand-outs

Additional Information

- Regular follow up with your therapist is important to prevent complications. Please try to keep all appointments. Contact your hand therapist if you cannot attend or have any problems.
- Follow the instructions from your therapist. Do not attempt variations - this puts your tendon at risk.
- The splint should be worn in the shower but can be removed 1 x day for hygiene but you should make sure your injured finger(s) is supported with your other hand or a towel or flat surface.
- The splint can be cleaned with soap and lukewarm water once a day. You need someone to help you do this; make sure it is properly dry before you put it back on.
- If a nurse, doctor or therapist removes your splint, support your hand keeping it in a straight position. Do not try to bend your wrist or fingers.
- You may be allowed to return to **light duties (no more than 4.5kg)** at work at 10 days after your operation **with your splint on**. Please discuss this with your doctor at your clinic appointment.
- You should not drive; if you need to drive to get to work, please contact your ACC case manager to discuss options.

COUNTIES MANUKAU HEALTH

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WHAKAORA RINGARINGA
HAND THERAPY

Controlled Active Motion (CAM)

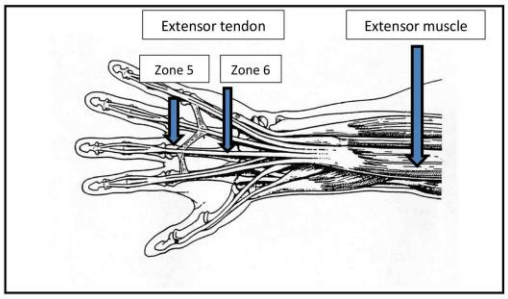
STAGE 1
Extensor Tendon
Zone 5 and 6

Weeks 1 - 4

Therapist: _____

Patient Advice

- The surgery you have had is to repair the tendon(s) that straighten your finger(s). **These tendons take 10 – 12 weeks to heal.**
- To protect the tendons your hand has been placed in a protective splint that should be worn **every day and night** for the next 4 weeks.
- If you remove this splint and try to move your hand you are likely to pull the repaired tendon apart.
- Normally these tendons glide through the tissues on the back of your hand. After injury and surgery these tendons can get stuck in scar tissue, these exercises are to help prevent that.

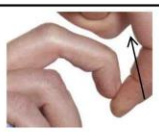


Splint

Day-time	Night-time
	

Exercises

Exercises should be repeated 10 times, 5 times each day

1 	With the splint on, bend and straighten your fingers as shown. Do not force your fingers down.
2a 	Keeping your fingers slightly bent lift your fingers up using your other hand. Take your hand away, try and hold in this position for a slow count of 3.
2b 	If at 2 weeks after surgery you can hold your finger(s) in this position you can then do this exercise without using your other hand to help.

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WHAKAORA RINGARINGA
HAND THERAPY

Controlled Active Motion (CAM)

STAGE 2
Extensor Tendon
Zone 5 and 6

Weeks 4 - 6

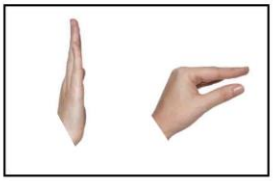
Therapist: _____

Patient Advice

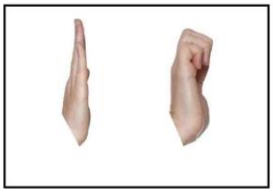
- Your repaired tendon is now strong enough to begin some gentle exercises out of your splint.
- It is safe for you to start using your hand for **light activities (no more than 4.5kg)** without the splint on.
- You should keep wearing your splint at risk periods and at night for the next two weeks.
- Do not try to make a tight fist until permitted by your therapist as this could damage your tendon.
- Regular follow up with your therapist is important to prevent complications. Please try to keep all appointments. Contact your therapist if you cannot attend or have any problems.
- Follow the instructions from your therapist. Do not attempt variations; this puts your tendon at risk.
- You may be allowed to start **light duties at work (no more than 4.5kg)** without the splint on. Please check your medical certificate and discuss with your therapist.
- You should still not be driving

Exercises

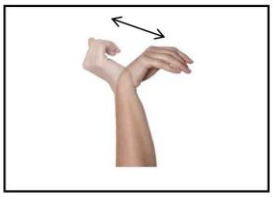
Exercises should be repeated 10 times, 5 times each day



Straighten your fingers fully, now bend down the knuckles keeping all your finger joints straight. **HOLD** for 5 seconds.



Straighten your fingers fully ,now keeping your knuckles straight, bend your fingers down to make a hook fist. **HOLD** for 5 Seconds.



Bend your wrist forward with your fingers relaxed. Do not force your wrist past the point of comfort, **HOLD** for 5 seconds.
Then bring your wrist back with your fingers gently curled up, **HOLD** for 5 seconds

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WHAKAORA RINGARINGA
HAND THERAPY

Controlled Active Motion (CAM)

STAGE 3
Extensor Tendon
Zone 5 and 6

Weeks 6 - 8

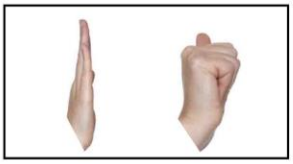
Therapist: _____

Patient Advice

- Your repaired tendon is now strong enough to further progress your exercises.
- You may now leave the splint off most of the time even when you are sleeping, *but* it is not yet safe to carry out heavy activities with your hand
- Continue to do the previous exercises you were given.
- Do not force your fingers down with your other hand as this could stretch your tendon
- Regular follow up with your therapist is important to prevent complications. Please try to keep all appointments. Contact your therapist if you cannot attend or have any problems.
- You will need to continue light duties at work until 8 weeks after your operation. Please check your medical certificate and discuss with your therapist.

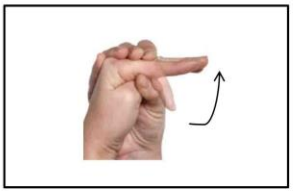
Exercises

Exercises should be repeated 10 times, 5 times each day



Straighten your fingers fully, now bend all your fingers into palm keeping the tip joints straight.
HOLD for 5 seconds.

Straighten your fingers fully, now bend all your fingers around to make a tight fist.
HOLD for 5 seconds.



Support your fingers holding them bent at the knuckles.
Straighten the fingers out until the middle and end joints are fully straight.
HOLD 5 seconds.

Additional Information

- Regular follow up with your therapist is important to prevent complications. Please try to keep all appointments. Contact your therapist if you cannot attend or have any problems.
- Follow the instructions from your therapist. Do not attempt variations - this puts your tendon at risk.
- The yoke splint should be worn in the shower but can be removed 1 x day for hygiene but you should make sure your injured finger(s) is supported with your other hand or a towel or flat surface.
- The splint can be cleaned with soap and lukewarm water once a day. You need someone to help you do this; make sure it is properly dry before you put it back on.
- If a nurse, doctor or therapist removes your splint, support your hand keeping it in a straight position. Do not try to bend your wrist or fingers.
- You may be allowed to return to **light duties** at work **(no more than 4.5kg)** at 10 days after your operation **with your splint on**. Please discuss this with your doctor at your clinic appointment.
- You should not drive; if you need to drive to get to work, please contact your ACC case manager to discuss options.

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WHAKAORA RINGARINGA
HAND THERAPY

Relative Motion Extension Splinting (RMES)

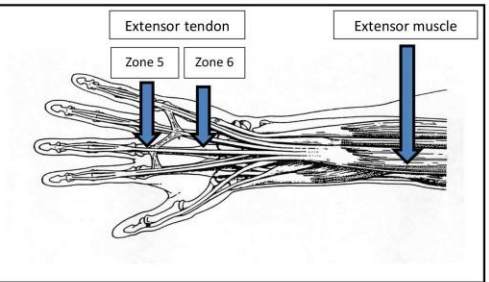
STAGE 1
Extensor Tendon
Zone 5 and 6

Weeks 1- 4

Therapist: _____

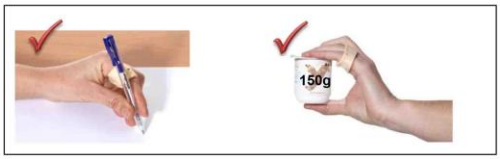
Patient Advice

- The surgery you have had is to repair the tendon(s) that straighten your finger(s). **These tendons take 10 – 12 weeks to heal.**
- To protect the tendons you have been provided with splints which need to be worn **all the time** for the next 4 weeks.
- Wear the yoke splint during the day and the resting splint at night or when you are sleeping.
- If you remove the splints and try to move your hand you are likely to pull the repaired tendon apart.
- Normally these tendons glide through the tissues on the back of your hand. After injury and surgery these tendons can get stuck in scar tissue, moving your fingers helps prevent this.



Day time: yoke splint

It is **safe** to use your hand for **light** activities (less than 4.5kg weight) with the yoke splint on



Do not bend your wrist forward while you are gripping something.

Do not lift anything heavier than 4.5kg

Night time: resting splint

Wear this splint when you go to sleep

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WHAKAORA RINGARINGA
HAND THERAPY

Relative Motion Extension Splinting (RMES)

STAGE 2
Extensor Tendon
Zone 5 and 6

Weeks 4 - 6

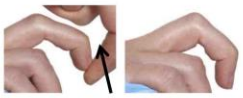
Therapist: _____

Patient Advice

- It is safe for you to start using your hand for **light activities (no more than 4.5kg)** without the splint on.
- You should keep wearing your yoke splint at risk periods and for heavy tasks and your resting splint at night for the next two weeks.
- **Do not try to make a tight fist** until permitted by your therapist as this could damage your tendon.
- Regular follow up with your therapist is important to prevent complications. Please try to keep all appointments. Contact your therapist if you cannot attend or have any problems.
- Follow the instructions from your therapist. Do not attempt variations; this puts your tendon at risk.
- You may be allowed to start **light duties at work (no more than 4.5kg)** without the yoke splint on. Please check your medical certificate and discuss with your therapist.
- You should still not be driving

Exercises

If you are having difficulty with moving your fingers your therapist may give you some exercises.
Exercises should be repeated ____ times ____ times each day



Keeping your fingers slightly bent lift your fingers up using your other hand. Take your hand away, try and **HOLD** in this position for a slow count of 3.

Straighten your fingers fully. Then bend down the knuckles keeping all your finger joints straight. **HOLD** for 5 seconds.

Straighten your fingers fully, now keeping your knuckles straight, bend your fingers down to make a hook fist. **HOLD** for 5 seconds.

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HAND THERAPY

Relative Motion Extension Splinting (RMES)

STAGE 3
Extensor Tendon
Zone 5 and 6

Weeks 6 - 8

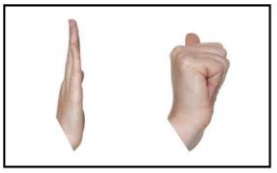
Therapist: _____

Patient Advice

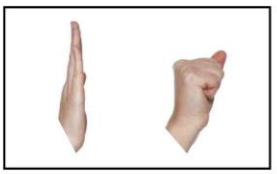
- You may now leave the splints off during the day and even when you are sleeping.
- **You should wear the yoke splint if you are doing heavy activities**
- Continue to do the previous exercises if you were given any.
- Do not force your fingers down with your other hand as this could stretch your tendon
- Regular follow up with your therapist is important to prevent complications. Please try to keep all appointments. Contact your therapist if you cannot attend or have any problems.
- You may be allowed to start full duties at work with your yoke splint on. Please check your medical certificate and discuss with your therapist.

Exercises

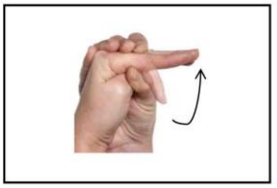
Your therapist may teach you some exercises
Exercises should be repeated ____ times ____ times per day



Straighten your fingers fully, now bend all your fingers into palm keeping the tip joints straight.
HOLD for 5 seconds.



Straighten your fingers fully, now bend all your fingers around to make a tight fist.
HOLD for 5 seconds.



Support your fingers holding them bent at the knuckles.
Straighten the fingers out until the middle and end joints are fully straight.
HOLD 5 seconds.

Appendix H: Therapist Guidelines

Therapist guidelines: Extensor CAM (controlled active motion)

Extensor tendons zone V and VI

Splint	
Daytime	• Volar forearm based splint extending to mid-proximal phalanx; 3.2mm ezeform • Wrist 40° extension • MCP 30° flexion • IPs free
Night time	• Same splint as above but add night piece • Night piece attaches onto volar splint and maintains MCPs and IPs in 0° extension
Stage I: Immediately post-op until end of week 4	
Splint wear	• All the time; remove only for hygiene or at appointments; protect tendons at all times
Exercises	• IP hook and actively extend within splint, 10 repetitions, 5 x per day • Place and hold MCPs into hyperextension keeping IPs relaxed • Note: If pt can hold MCP in hyperextension at 2 weeks then can hyperextend MCPs actively without 'placing' them
Therapy	• Education on injury and precautions • Manage oedema • Fabricate and monitor splint; adjust if necessary • Teach and monitor exercises • Wound care • Scar management by moisturising/ massaging
Work	• At 10 days can return on light duties (less than <4.5kg) if doctor happy with wound • Must wear splint at work; if unable to work with splint on then should not return to work
Advice	• Use hand for light activities with splint on; less than 4.5kg; no driving
Stage II: End of week 4 until end of week 6	
Splint wear	• Remove for exercises and light activities of <4.5kg • Continue to wear at night and risk periods
Exercises	• 10 repetitions, 5 x per day • Finger extension, table-top • Finger extension, hook • Wrist tenodesis • Continue with place and hold of MCPs in hyperextension if lag exists
Therapy	• Education on progress • Manage oedema if still present • Check splint, adjust if necessary • Teach and monitor exercises • Scar management by moisturising, massage, silicone gel if indicated, acupuncture/ ultrasound if this is what therapist usually would use • Use of heat prior to exercise if indicated – eg wax, wheat bag
Work	• Commence light duties (<4.5kg) with splint off • If needing to do anything heavier with this hand then should not return to work
Advice	• Start using hand for light activities (<4.5kg) with splint off • Do not make a forceful fist or force the fingers down into flexion • Avoid combined wrist and finger flexion

	• No driving
Stage III: End of week 6 until end of week 8	
Splint wear	• Discontinue splint day and night • Wear only at risk times
Exercises	• 10 repetitions, 5 x per day • Finger extension, flat fist • Finger extension, full fist • IP extension with MCPs blocked in flexion • May continue previous exercises if not yet fully achieved • Teach gentle passive flexion of isolated joints if required
Therapy	• As for previous stage • Commence passive flexion stretch of isolated joints if necessary to regain ROM
Work	• Continue with light duties at work with splint off
Advice	• Heavy tasks should be avoided
Week 8 onwards	
Exercises	• Commence composite passive flexion if required • Commence strengthening
Therapy	• As for previous stage • Teach strengthening if necessary
Work	• Return to work full duties at 8-10 weeks
Advice	• Gradually return to all activities by week 10

Therapist guidelines: RMES
(Relative motion extension splinting)
Extensor tendons zone V and VI

Splint	
Daytime	• Yoke splint • Holds affected MCP in 15-20° more extension than other digits • If only one peripheral digit involved, eg index finger then include the other peripheral digit at 15-20° relative extension even if uninjured (ie little finger) so that it is balanced • Use strip of 3.2mm ezeform the width of the little finger proximal phalanx
Night time	• Resting splint • 3.2mm ezeform • Wrist 30° extension • MCPs 30° flexion • IPs extended
Stage I: Immediately post-op until end of week 4	
Splint wear	• All the time; remove only for hygiene or at appointments; protect tendon at all times
Exercises	• None
Therapy	• Education on injury and precautions • Manage oedema • Fabricate and monitor splint; adjust if necessary • Wound care • Scar management by moisturising/ massaging
Work	• At 10 days can return on light duties (less than <4.5kg) if doctor happy with wound • Must wear splint at work; if unable to work with splint on then should not RTW
Advice	• Use hand for light activities with splint on; less than 4.5kg • NB! Avoid composite wrist and finger flexion; if unable to do this then should not RTW; no driving
Stage II: End of week 4 until end of week 6	
Splint wear	• Remove yoke splint for exercises and light activities of <4.5kg • Continue to wear night resting splint at night and yoke splint at risk periods
Exercises	• Only if limitation of ROM –stiffness, lag or tendon adherence • 10 repetitions, 5 x per day • Finger extension, table-top • Finger extension, hook • Place and hold of MCPs in hyperextension if lag exists
Therapy	• Education on progress • Manage oedema if still present • Check splint, adjust if necessary • Teach and monitor exercises • Scar management by moisturising, massage, silicone gel if indicated, acupuncture/ ultrasound if this is what therapist usually would use • Use of heat prior to exercise if indicated – eg wax, wheat bag
Work	• Commence light duties (<4.5kg) with splint off • If needing to do anything heavier with this hand then should not be at work

Advice	• Start using hand for light activities (<4.5kg) with splint off • Do not make a forceful fist or force the fingers down into flexion • Avoid combined wrist and finger flexion • No driving
Stage III: End of week 6 until end of week 8	
Splint wear	• Wear yoke splint only for heavy tasks • Discontinue night resting splint
Exercises	• Only if stiffness, lag or tendon adherence • 10 repetitions, 5 x per day • Finger extension, flat fist • Finger extension, full fist • IP extension with MCPs blocked in flexion • May continue previous exercises if not yet fully achieved • Teach gentle passive flexion of isolated joints if required
Therapy	• As for previous stage • Commence passive flexion stretch of isolated joints if necessary to regain ROM
Work	• Can commence heavier duties with yoke splint on • Continue to do light duties with yoke splint off
Advice	• Any heavy tasks must be done with the yoke splint on
Week 8 onwards	
Exercises	• Commence composite passive flexion if required • Commence strengthening
Therapy	• As for previous stage • Teach strengthening if necessary
Work	• Return to work full duties at 8-10 weeks without splint
Advice	• Gradually return to all activities by week 10

(Hirth et al., 2011; Howell, Merritt, & Robinson, 2005)

Hirth, M., Bennett, K., Mah, E., Farrow, H., Cavallo, A., Ritz, M., & Findlay, M. (2011). Early return to work and improved range of motion with modified relative motion splinting: a retrospective comparison with immobilization splinting for zones V and VI extensor tendon repairs. *Hand Therapy, 16*(4).

Howell, J. W., Merritt, W. H., & Robinson, S. J. (2005). Immediate controlled active motion following zone 4-7 extensor tendon repair. *Journal of Hand Therapy, 18*(2), 182-189.

Appendix I: "Do's and Don'ts"

Do's and don't

Weeks 1-6

(week 1-4 with splint on, week 5 and 6 without splint)

Do
Lift and hold small items
Use your hand for light activities as far as possible
Lift up items of clothing and dress yourself
Hold a cup of tea
Hold a plate or bowl to eat your meals
Write or type
Move a chair so you can sit down
Use eating utensils, toothbrush, hairbrush
Lift a shopping bag with a loaf of bread or one 2 litre bottle of milk
Exercises as recommended by your therapist
Go for walks to keep yourself fit
Use you other hand for toileting
Use your arm to 'scoop' up an infant, let them rest on your wrist rather than using just your hands
Don't
Drive
Lift or hold anything 4.5kg or more
Grip something and bend your wrist forwards at the same time
Lift a full washing basket with wet clothes
Lift a large jug full of water
Open a new tight jar with your injured hand
Write or type for more than an hour without a rest
Lift and transport a fridge/ other furniture
Wring out a wet cloth while gripping and twisting your wrist
Lift a shopping bag with 2 x 3 litre bottles of milk
Lift any weights at the gym
Fasten bra behind your back, pull it round to the front in stead
Lift a toddler with your hands or twist your hand to hold baby when breast-feeding
Grip a tool and twist your wrist around a corner or into a tight space

If your job involves using tools, please discuss with your therapist about what you need to be able to do to find out whether it will be safe or not.

ACC may be able to provide taxis to get to and from work – this can be discussed with your case manager.

Appendix J: SHFT Scoring Sheet

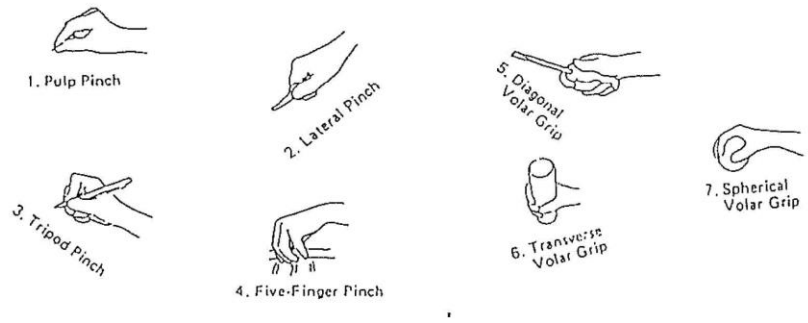
Patient label

Sollerman scoring

Score:

- 4 = Task completed without any difficulty within 20 sec and with prescribed hand- grip of normal quality
- 3 = Task completed with slight difficulty *or*
  - Not completed within 20 sec but 40 sec *or*
  - Completed with prescribed hand-grip with slight divergence
- 2 = Task completed but with great difficulty *or*
  - Not completed within 40 sec but within 60 sec *or*
  - Not performed with prescribed hand-grip
- 1 = Task only partially performed within 60 sec
- 0 = Task cannot be performed at all

Grips



Date:

Hand:

Dominance:

1. Pick up key, put into Yale-lock and turn 90°						
Pulp pinch Lateral pinch	Difficulty:	none slight great	Seconds:		Score:	
2. Pick up coins from surface, and put into purses (one at a time, 2 coins in each purse)						
Pulp pinch	Difficulty:	none slight great	Seconds:		Score:	
3. Close and open zippers (may help stabilise with other hand)						
Pulp pinch Lateral pinch	Difficulty:	none slight great	Seconds:		Score:	
4. Pick up coins from purses (one at a time, place at bottom of box)						
Pulp pinch	Difficulty:	none slight great	Seconds:		Score:	
5. Pick up wooden blocks from the inside of the box, lift over the edge and place on table in front of box						
Five-finger pinch	Difficulty:	none slight great	Seconds:		Score:	
6. Lift iron over edge – from inside of box, place on table in front of box						
Transverse volar grip, hand in pronation	Difficulty:	none slight great	Seconds:		Score:	
7. Pick up screwdriver and turn each screw one full revolution; the other hand can help stabilise the point of the screwdriver						
Diagonal volar grip	Difficulty:	none slight great	Seconds:		Score:	
8. Pick up nuts once at a time and put them on each bolt; just turn until it won't fall off, not all the way						
Pulp pinch, Lateral pinch Tripod pinch	Difficulty:	none slight great	Seconds:		Score:	
9. Unscrew lids from jars and place on the table						
Spherical volar grip	Difficulty:	none slight great	Seconds:		Score:	
10. Do up buttons with one hand; may stabilise material with other hand						
Pulp pinch Lateral pinch	Difficulty:	none slight great	Seconds:		Score:	

11. Pick up knife and fork and cut plasticine into four pieces (plasticine should be on the plate)						
Tripod pinch Diagonal volar grip	Difficulty:	none slight great	Seconds:		Score:	
12.Use tested hand to pull small tubigrip C onto non-tested hand; if unable then use large tubigrip F						
Lateral pinch Five-finger pinch	Difficulty:	none slight great	Seconds:		Score:	
13. Write 'New Zealand' with pen on a piece of paper						
Tripod pinch	Difficulty:	none slight great	Seconds:		Score:	
14. Fold paper twice, put into an envelope; using non-tested hand to help						
Five-finger pinch Lateral pinch	Difficulty:	none slight great	Seconds:		Score:	
15. Put 2 paperclips of different sizes onto the envelope						
Pulp pinch Lateral pinch	Difficulty:	none slight great	Seconds:		Score:	
16. Pick up telephone receiver and put it to ear						
Diagonal volar grip	Difficulty:	none slight great	Seconds:		Score:	
17. Turn door-handle 30° to stop in supination						
Transverse volar grip	Difficulty:	none slight great	Seconds:		Score:	
18. Pour full 1litre box of water into the jug; if unable to pour full box then empty half						
Five-finger pinch	Difficulty:	none slight great	Seconds:		Score:	
19. Lift jug and pour 100ml of water into cup; if unable to lift the jug then empty half the water						
Transverse volar grip	Difficulty:	none slight great	Seconds:		Score:	
20. Pour water from the cup back into the jug; if unable to manage this then empty half the water						
Pulp pinch Lateral pinch	Difficulty:	none slight great	Seconds:		Score:	

Appendix K: QuickDASH

QuickDASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

QuickDASH DISABILITY/SYMPTOM SCORE = $\left(\left[\frac{\text{sum of n responses}}{n}\right] - 1\right) \times 25$, where n is equal to the number of completed responses.

A QuickDASH score may not be calculated if there is greater than 1 missing item.

Appendix L: Splint Adherence Questionnaire

SPLINT QUESTIONNAIRE

Adapted from (Sandford, Barlow, & Lewis, 2008)

This questionnaire is part of the research study because it is important for us to know how you have managed wearing the splint during the day. Please answer honestly because that is the only way we will know if we need to change anything and will help us decide which splint is better. The information you provide will not change the treatment you receive.

Date:
Name and surname:
Dominant hand: ☐LEFT ☐RIGHT
Which hand do you wear your splint on? ☐ LEFT ☐ RIGHT
1. Have you driven a vehicle since you have been given the splint? ☐ YES ☐ NO
2. How often have you taken the day splint off? a) ☐ I have never taken it off b) ☐ Once c) ☐ Every few days d) ☐ Every day e) ☐ More than once a day
3. How long did you usually leave your splint off? a) ☐ I never took it off b) ☐ 5 minutes c) ☐ More than 5 minutes but less than an hour d) ☐ More than an hour e) ☐ More than half the day
4. Did you use your hand without the splint on? ☐ YES ☐ NO

5. Why or when did you take your splint off? (you may tick more than 1)

a) ☐ I never took it off
b) ☐ I only took it off at hand therapy or doctor's appointments
c) ☐ While I was showering or bathing or getting dressed
d) ☐ To wash my hand
e) ☐ The splint was too uncomfortable
f) ☐ I wanted to look at my hand
g) ☐ I became frustrated with not being able to use my hand properly
h) ☐ I didn't really know why it was so important to wear the splint all the time
i) ☐ I felt embarrassed about wearing the splint
j) ☐ I couldn't do my job with the splint on
k) ☐ Please write down any other reasons you took it off

6. Did you wear the night splint every night? If no, why not?

7. Thank you for taking the time to answer this questionnaire. Is there anything else you would like us to know about the splint?

_____

_____

Reference: Sandford, F. M. M., Barlow, N. B. M., & Lewis, J. P. M. M. (2008). A Study to Examine Patient Adherence to Wearing 24-Hour Forearm Thermoplastic Splints after Tendon Repairs. *Journal of Hand Therapy, 21*(1), 44-53.

Appendix M: Modified PEM

PATIENT SATISFACTION QUESTIONNAIRE

[adapted from Patient Evaluation Measure (Dias, Bhowal, Wildin, & Thompson, 2001)]

This is a questionnaire to find out how satisfied you are with the treatment you received for your injured hand. Please circle the number that shows how you feel about each question. Thank you for taking the time to answer these questions. Your answers will help us to make sure that patients are happy with the treatment they receive for this kind of injury.

Hand health

1. The feeling in my hand is now:							
	1	2	3	4	5	6	7
Normal							Absent
2. When my hand is cold and/or damp the pain is now:							
	1	2	3	4	5	6	7
Non-existent							Unbearable
3. Most of the time the pain in my hand is now:							
	1	2	3	4	5	6	7
Non-existent							Unbearable
4. The duration my pain is present is:							
	1	2	3	4	5	6	7
Never							All the time
5. When I try to use my hand for fiddly things it is now:							
	1	2	3	4	5	6	7
Skilful							Clumsy
6. Generally when I move my hand it is:							
	1	2	3	4	5	6	7
Flexible							Stiff
7. The grip in my hand is now:							
	1	2	3	4	5	6	7
Strong							Weak
8. For everyday activities, my hand is now:							
	1	2	3	4	5	6	7
No problem							Useless

9. For my work my hand is now:

1 2 3 4 5 6 7

No problem — Useless

10. When I look at the appearance of my hand now I feel

1 2 3 4 5 6 7

Unconcerned — Embarrassed and self-conscious

11. Generally, when I think about my hand I feel

1 2 3 4 5 6 7

Unconcerned — Very upset

Satisfaction:

1. I found wearing the splint during the day:

1 2 3 4 5 6 7

Very comfortable — Very uncomfortable

2. I found wearing the splint at night:

1 2 3 4 5 6 7

Very comfortable — Very uncomfortable

3. With the splint on, I found using my hand during the day:

1 2 3 4 5 6 7

Very easy, no problem — Very difficult, almost impossible

4. Overall the treatment for my hand has been

1 2 3 4 5 6 7

Very satisfactory — Very unsatisfactory

5. Generally my hand is now

1 2 3 4 5 6 7

Very satisfactory — Very unsatisfactory

6. Bearing in mind my original injury, I feel my hand is now

1 2 3 4 5 6 7

Better than I expected — Worse than I expected

Dias, J. J., Bhowal, B., Wildin, C. J., & Thompson, J. R. (2001). Assessing the outcome of disorders of the hand. Is the patient evaluation measure reliable, valid, responsive and without bias? *Journal of Bone and Joint Surgery - Series B, 83*(2), 235-240.

Appendix N: Therapist Checklist

Patient NHI and Name/ Surname

_____

Or sticker

RMES vs CAM

Therapist Checklist

Thank you for completing this form for each patient who is part of the research project. Please keep it until the patient has reached 8 weeks post-op or is discharged from your service. Then please forward it on to Shirley Collocott (contact details at the end of this form).

Any complications?					
Any concerns?					
Return to work light duties date:					
Return to work full duties date:					
Hand Therapy discharge date:					
Nr of appt attended		**Nr of appt cancelled**		**Nr of appt DNA**	

Please write in each date that you see the patient and tick which interventions you use with them at that appointment. The weeks indicate the number of weeks post-op, so if you saw the patient within 7 days post-op that would count as 'week 1'. If you saw them more than once in a week, write in both dates. If you did anything that is not provided as a tick-box or used different exercises from the hand-outs, please write in the details in the space provided.

Week 1 **Date:** _____	**Week 2** **Date:** _____	**Week 3** **Date:** _____	**Week 4** **Date:** _____
☐ Education ☐Exercises as per stage 1 ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Wound care ☐Scar management ☐Moisturising ☐Massage ☐Adjusted splint ☐Anything else? Please specify _____ _____ _____ _____	☐ Education ☐Exercises as per stage 1 ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Wound care ☐Scar management ☐Moisturising ☐Massage ☐Adjusted splint ☐Anything else? Please specify _____ _____ _____ _____	☐ Education ☐Exercises as per stage 1 ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Wound care ☐Scar management ☐Moisturising ☐Massage ☐Silicone gel ☐Adjusted splint ☐Anything else? Please specify _____ _____ _____	☐Education ☐Splint off for light actv ☐Exercises as per stage 1 ☐Exercises as per stage 2 ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Scar management ☐Moisturising ☐Massage ☐Silicone gel ☐Heat prior to exercise ☐Ultrasound ☐Acupuncture ☐Anything else? Please specify _____ _____

Week 5 **Date:** _____	**Week 6** **Date:** _____	**Week 7** **Date:** _____	**Week 8** **Date:** _____
☐Education ☐Splint off for light actv ☐Exercises as per stage 2 ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Scar management ☐Moisturising ☐Massage ☐Silicone gel ☐Heat prior to exercise ☐Ultrasound ☐Acupuncture ☐Anything else? Please specify _____ _____ _____ _____ _____	☐Education ☐Discontinue night splints ☐Yoke for heavy actv (RMES only) ☐Exercises as per stage 2 ☐Exercises stage 3 ☐Isolated passive stretches commenced ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Scar management ☐Moisturising ☐Massage ☐Silicone gel ☐Heat prior to exercise ☐Ultrasound ☐Acupuncture ☐Anything else? Please specify _____ _____	☐Education ☐Discontinue night splints ☐Yoke for heavy actv (RMES only) ☐Exercises stage 3 ☐Isolated passive stretches ☐Composite passive stretch ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Scar management ☐Moisturising ☐Massage ☐Silicone gel ☐Heat prior to exercise ☐Ultrasound ☐Acupuncture ☐Anything else? Please specify _____ _____	☐Education ☐Discontinue night splints ☐Yoke for heavy actv (RMES only) ☐Exercises stage 3 ☐Isolated passive stretches ☐Composite passive stretch ☐Oedema management ☐Tubigrip ☐Glove ☐Coban ☐Retrograde massage ☐Elevation ☐Scar management ☐Moisturising ☐Massage ☐Silicone gel ☐Heat prior to exercise ☐Ultrasound ☐Acupuncture ☐Anything else? Please specify _____ _____

Are there any other modalities you used or any other comments you would like to make?

_____

_____

_____

Please forward the completed form to

Shirley Collocott, Occupational Therapist/ Registered Hand Therapist
shirley.collocott@middlemore.co.nz or Hand Therapy Dept, Module 5, Manukau SuperClinic, Manukau.
If you have any questions or concerns please contact me: 021 975 107, or 276 0044 x 8684