The effect of night extension splinting following surgical release of Dupuytren's contracture

Julie Collis

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Faculty of Health and Environmental Science

Primary Supervisor: Dr Wayne Hing

Table of Contents

List of Figures

List of Tables

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."

Julie Collis

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Abstract

The application of splints following surgical release of Dupuytren's contracture has long been recommended for maintaining finger extension. Questions exist regarding the efficacy and potential detrimental effects of this treatment approach.

The literature pertaining to the effects of splints on finger range of motion and hand function following surgery was systematically reviewed. A search of electronic databases was conducted and a quality assessment was undertaken using the Downs and Black Quality Index. A comparison was made with findings from a 2008 systematic literature review. The results of the review suggested that the traditional practice of providing night extension splints was not effective and highlighted the need for further studies.

A single centre randomised trial was conducted to investigate the effect of night extension splinting on finger range of motion and hand function in the three months following surgical release of Dupuytren's contracture. Fifty six patients (males n=45, females n=11) between the ages of 48 and 86 were included in the study. Participants were randomised to receive a night extension splint plus hand therapy (n= 26) or hand therapy alone (n=30). The primary outcome was total active extension (TAE) of the little finger in degrees. Secondary outcomes were total active flexion (TAF) of the fingers in degrees, active distal palmar crease (ADPC) in cm, grip strength in kg, self-reported hand function using the Disabilities of the Arm shoulder and Hand (DASH) questionnaire (1-100 scale) and patient satisfaction. Primary analysis was by intention to treat.

There were no statistically significant differences between the no splint and splint groups for any of the outcomes measured. When compared with the splint group the no splint group showed adjusted mean differences of little finger TAE -9.8 (95%CI -20.19 to 0.59, p=0.07), little finger TAF 12.7 (95%CI -1.8 to 27.2, p= 0.08) and ADPC -0.21 (95%CI -0.74 to 0.32, p=0.44). Equally there were no statistical differences for DASH -1.1 (95%CI -5.41 to 3.21, p=0.59), left hand grip strength 2.6 (95%CI -1.52 to 6.72, p=0.22) or right hand grip strength 2.5 (95%CI -0.64 to 5.64, p=0.10). A secondary per protocol analysis was conducted which also showed no statistically significant

differences. Although statistical significance was not reached there was a consistent trend across all outcomes in favour of not splinting.

The data were also evaluated to identify how well finger extension was maintained overall between the first postoperative measure and three months postoperatively. Of all 40 little fingers 62.5% had the same or better TAE (13^{o} unadjusted mean improvement) and 37.5% had lost TAE (32^{o} unadjusted mean loss) over this period.

It was concluded that night extension splinting in combination with standard hand therapy has no greater effect on maintaining finger extension than hand therapy alone in the three months following surgical release of Dupuytren's contracture. The trend towards poorer outcomes in the splinted group also suggested that splinting is not a benign therapy. The results of this trial indicate that the practice of providing every patient with a night extension splint following surgical release of Dupuytren's contracture may no longer be justified.

Chapter 1. Introduction and Background

1.1 Introduction

Dupuytren's disease is a common disease of the palmar fascia of the hand. Collagen proliferation within the fascia leads to the development of tight cords and bands which pull the fingers into flexion and, without intervention, results in progressively disabling contractures of the fingers (Shaw, Chong, Zhang, Hentz, & Chang, 2007; Swartz & Lalonde, 2008). The mainstay of Dupuytren's contracture treatment is surgical excision of diseased tissue and release of the contracture in a procedure known as fasciectomy (Desai & Hentz, 2011). Following surgery the practice of placing the hand in a splint to hold the operated fingers in extension has long been advocated (Abbott, Denney, Burke, & McGrouther, 1987; Au-Yong, Wildin, Dias, & Page, 2005; McFarlane, 1997; Mullins, 1999). The splinting is thought to help in maintaining extension of the fingers during the scar maturation process and help correct residual contracture of the finger joints. These splints are traditionally worn at night for periods of up to six months.

Evidence for this treatment approach has been lacking and until 2011 no randomised controlled trial had been carried out to verify if splints assisted in maintaining finger extension or not. The current study was initiated in 2009 at the Hand Therapy Unit of Counties Manukau District Health Board (CMDHB) in Auckland, New Zealand, in response to this lack of evidence and following a clinical audit which demonstrated that 40% of patients lost some degree of finger extension regardless of wearing a night extension splint (Collis & Collocott, 2009).

The study aimed to provide information on whether splinting the fingers at night in the three months following fasciectomy was more effective than not splinting with respect to finger range of motion and function. The research will add valuable evidence to the body of knowledge on management of Dupuytren's Contracture following surgical release. If splinting is found to be ineffectual in maintaining finger extension, the current practice of splinting all patients would need revaluation. Patients could be spared the inconvenience and discomfort of splinting and financial savings could be made with regards to materials and therapist time.

With respect to nomenclature of splinting it is acknowledged that new guidelines disseminated by the American Hand Therapy Association (Coverdale, 2012) recommend the introduction of the term orthoses in preference to splinting. Although the new terminology is becoming more widely used in the literature it is not yet common clinical practice within New Zealand and for the purposes of this thesis the terminology pertaining to splinting will be used. Throughout this paper the term hand therapist refers to occupational therapists or physiotherapists who have gained registration with a certifying hand therapy body or therapists who are not registered but working in a hand therapy clinic.

The purpose of this thesis was to: (a) summarise the anatomy, pathology, epidemiology, functional implications and management of Dupuytren's disease; (b) conduct a systematic literature review on the evidence for splinting following surgical release of Dupuytren's contracture; (c) conduct and present the results of a randomised controlled trial investigating the effect of splinting following the surgical release of Dupuytren's contracture on finger range of motion and function.

1.2 Pathologic anatomy

Dupuytren's disease is a disorder of the palmar fascia of the hand causing flexion contractures of the fingers. The palmar fascia is a strong three dimensional aponeurotic sheet that lies beneath the dermis and superficial to the flexor tendons and interosseal muscles of the palm of the hand. It serves to tether the skin to the deeper structures while allowing free gliding of the flexor tendons and conformation of the hand to the shape of objects during grasp (Hayton & Gray, 2003; Rayan, 2007; Townley, Baker, Sheppard, & Grobbelaar, 2006). This fascial layer is fan shaped with its apex in the base of the hand (Figure 1). In the palm the fibres are orientated in longitudinal, transverse and vertical planes with the longitudinal fibres terminating as pretendinous and spiral bands in the digits (Figure 2). The transverse fibres form the natatory ligament in the distal palm (Saar & Grothaus, 2000; Townley, et al., 2006) (Figure 3 and Figure 4). As Dupuytren's disease progresses these normal fascial bands form into diseased cords which become nodular, shorten and lead to secondary joint and soft tissue contractures of the metacarpophalangeal (MCP) and interphalangeal (IP) joints (Hayton & Gray, 2003; Rayan, 2007) (Figure 3 and Figure 4).

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Figure 1: Palmar aponeurosis

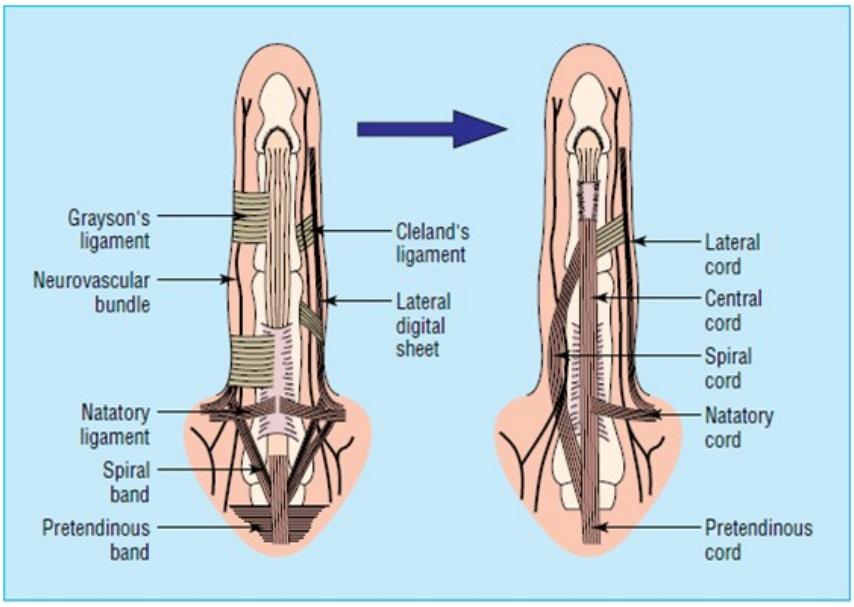

Figure 2: Normal elements of the digital fascia (left) and the diseased fascia (right) of Dupuytren's disease

From: "Dupuytren's contracture unfolded," by W. A. Townley, R. Baker and A. O. Grobbelaar, (2006), BMJ, 332, p. 398. Reprinted with permission from BMJ Publishing Group Ltd

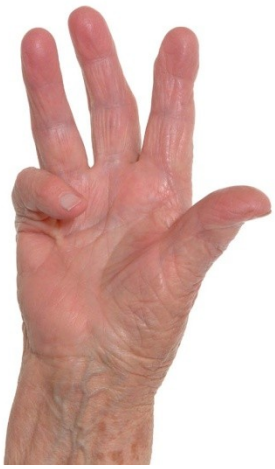

Figure 3: Dupuytren's contracture of little finger - volar view

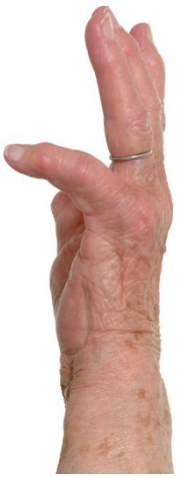

Figure 4: Dupuytren's contracture of little finger - lateral view

Three phases are described in the development of Dupuytren's disease: proliferative, involutional and residual (Hayton & Gray, 2003; Rayan, 2007; Thurston, 2003). The proliferative phase is characterised by early skin changes where thickening of the skin and underlying subcutaneous tissue forms skin pits or surface rippling and dimpling. The skin progressively adheres to the underlying fascia which causes loss of the normal architecture and mobility of the palm (Rayan, 2007; Shaw, Chong, Zhang, Hentz, & Chang, 2007). Random proliferation of immature fibroblasts in whorl patterns is the initial event in this phase (Swartz & Lalonde, 2008), but it is not yet well understood what triggers the onset of Dupuytren's disease. It is generally thought that fibroblastic and myofibroblastic proliferation causes strangulation of vascularity to the palmar fascia. This ischaemia then stimulates fibroblastic production and the generation of oxygen free radicals which in turn results in further ischaemia (Hayton & Gray, 2003; Swartz & Lalonde, 2008; Townley, et al., 2006).

Progression into the involutional phase is demonstrated by the development of characteristic nodules and cords firstly in the palm and later in the fingers. Nodules are firm elevated soft-tissue masses adherent to the skin and deep fascia and are usually sited in the palm adjacent to the distal palmar crease and in the fingers at the proximal interphalangeal (PIP) joint or base of the finger (Rayan, 2007; Shaw, et al., 2007). Initially well vascularised and abundant in myofibroblasts, nodules are soon replaced by collagen rich cords organised along lines of tension in the fascia. These

structures take on a rigid, raised, tendon-like appearance in the palm of the hand (Shaw, et al., 2007; Swartz & Lalonde, 2008; Thurston, 2003).

Finally, the residual phase is recognised by the formation of progressive finger flexion contractures. Cords take on a relatively acellular composition due to the deposition of dense Type I collagen and this inflexible scar like tissue pulls the fingers into flexion causing soft tissue shortening and inevitably the formation of contractures (Swartz & Lalonde, 2008). The ring finger is most commonly involved followed by the little, middle and index fingers with the thumb being least frequently affected (Thurston, 2003). The most commonly found cord is the pretendinous cord (Shaw, et al., 2007) (Figure 2) which causes a flexion contracture of the MCP joint. The vertical and natatory cords are also found in the hand which can cause triggering and web space contracture respectively leading to loss of finger abduction. Cords found in the digits are the central, spiral and lateral cords (Figure 2) and are implicated in the development of PIPJ contractures and displacement of the neurovascular bundle (Rayan, 2007; Shaw, et al., 2007).

1.3 Aetiology

Many factors have been implicated in the aetiology of Dupuytren's disease however debate continues to exist as to their relative contribution. The most frequently cited risk factors are genetics, repetitive trauma to the hand, alcohol consumption, smoking and diabetes (Hindocha, McGrouther, & Bayat, 2009; Thurston, 2003). Dupuytren's disease has long been cited as the 'Vikings' or 'Nordic' disease primarily due to the higher prevalence in Scandinavian and northern European countries and in those regions that have been settled by migrants from northern Europe such as Canada, New Zealand, Australia and the USA (Slattery, 2010). It is generally accepted that there is a strong familial link expressed by an autosomal dominant inheritance pattern however the actual gene has yet to be discovered (Hindocha, et al., 2009; Shaw, et al., 2007; Townley, et al., 2006). Much discussion exists as to whether Dupuytren's disease has a causal relationship with manual labour as was first purported by Guillaume Dupuytren in 1831 and reported by Descatha, Jauffret, Chastang, Roquelaure, & Leclerc (2011). Many authors have supported this theory on the basis that trauma to the palmar fascia causes fibril ruptures in the collagen (Shaw, et al., 2007). Thurston (2003) disputed this

premise on the basis that there is equal prevalence between manual and non-manual workers, however a recent meta-analysis concluded that high cumulative exposure to vibration and manual work did indeed increase the risk of developing Dupuytren's disease (Descatha, et al., 2011). High alcohol consumption, smoking, diabetes mellitus and hand injury all continue to be widely reported as risk factors associated with the onset of Dupuytren's disease although not all authors agree (Loos, Puschkin, & Horch, 2007). Many of these statistics are from older studies and it is recognised that societal changes such as changing work patterns, higher alcohol consumption, decrease in smoking, increasing age and disease incidence will have a bearing on the ability to identify definitive causal links (Hindocha, et al., 2009; Loos, et al., 2007).

1.4 Epidemiology

Dupuytren's disease is primarily a disease of older Caucasian males with prevalence increasing with advancing age. Men are affected at a rate of 5.9:1 women and tend to present for treatment in their fifth decade whereas women present on average a decade later and by the ninth decade there is equal distribution between genders. The disease is known in Asian, Hispanic, Native American and African populations but at much lower rates than in descendents of northern European peoples (Hindocha, et al., 2009; Shaw, et al., 2007; Slattery, 2010; Townley, et al., 2006). Prevalence is reported at between 0.2% to 56% depending on the ways in which data were collected and the groups in which it was studied. Such high variation in reported rates is attributed to the differing ways in which these studies are conducted and the experience of those in diagnosing Dupuytren's disease (Hindocha, et al., 2009). Most of the studies conducted are prevalence studies in discrete populations rather than incidence studies where the development of the disease is studied over a long period of time (Thurston, 2003). Comparison across studies therefore becomes difficult and the true rate of the disease is largely unknown. There are no known data on rates of Dupuytren's disease in New Zealand. An early Australian study conducted in 1960, as cited by Hindocha et al. (2009) showed a 23% prevalence rate in a cross-sectional study of 3,700 people in the community.

1.5 Functional implications

The disablement caused by flexion contractures of the fingers, loss of finger abduction, stiffness and loss of dexterity of the hand can be considerable (Pratt & Byrne, 2009).

Many tasks have been cited as being difficult for the Dupuytren's sufferer including poking oneself in the eye while washing the face, an inability to place the hand in a pocket, write, put on a glove, catching a ball and washing and grooming (Engstrand, Boren, & Liedberg, 2009; Hayton & Gray, 2003). Clinicians have noted other unique difficulties encountered by Dupuytren's' sufferers such as reluctance to shake hands, inability to clap hands, decrease in social activities due to embarrassment at hand disfigurement or worry about injuring the finger.

As the primary purpose for undertaking corrective Dupuytren's contracture surgery is functional improvement, any research should not only measure range of motion, but also the effect of that intervention on hand function. Currently there are no known outcome measures which were purposely designed to evaluate functional outcomes particular to Dupuytren's disease. Rather, previous surgical and therapeutic research has used generic hand function measures including the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) (Engstrand, et al., 2009; Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011; van Rijssen, Gerbrandy, Ter Linden, Klip, & Werker, 2006; Zyluk & Jagielski, 2007), the Michigan Hand Outcome Questionnaire (MHQ) (Herweijer, Dijkstra, Nicolai, & Van der Sluis, 2007) and the Sollerman hand function test (Draviaraj & Chakrabarti, 2004; Sinha, Cresswell, Mason, & Chakrabarti, 2002).

Underpinning this thesis is the premise that post-fasciectomy splinting may not only affect change on finger range of motion but also on hand function. For the individual, functional use of the hand has been noted by clinicians to have greater import than the particular degree of joint motion, and in many cases, is the primary and often only reason treatment was sought. It is important therefore within the context of this thesis to examine functional outcomes for individuals undergoing surgery and postoperative hand therapy.

1.6 Surgical intervention

Treatment for Dupuytren's disease is generally sought when function begins to be impeded (Pratt & Byrne, 2009). Surgical excision of diseased tissue known as fasciectomy or aponeurotomy has been described since the late 17th century and

remains the mainstay of surgical treatment (Desai & Hentz, 2011). More recently, collagenase injections have undergone clinical trials and are now being introduced into clinical settings as an alternative to more invasive surgery (Desai & Hentz, 2011). Surgery is generally recommended in the presence of an MCP joint contracture of ≥ 30 degrees and/or any PIP joint contracture that impedes function (Desai & Hentz, 2011; Rayan, 2007). Several techniques are widely used which are broadly classified according to the degree of tissue excised and these include percutaneous fasciotomy, regional fasciectomy and dermofasciectomy.

Fasciotomy is the simplest procedure, involving division of the cord(s) without any excision of diseased tissue and can be performed as an open procedure or percutaneously. Early recurrence is a complication with this technique and is consequently only performed on the very elderly or in high surgical risk patients (Shaw, et al., 2007; Townley, et al., 2006). Regional fasciectomy is the most widely recommended procedure whereby the skin is elevated and macroscopically diseased cords are identified and excised in a proximal and distal direction. Release of the PIP joint may need to be performed in conjunction with fasciectomy in the presence of intractable contracture (Desai & Hentz, 2011; Swartz & Lalonde, 2008). Radical fasciectomy or dermofasciectomy is performed less frequently and involves extensive excision of the palmar aponeurosis and palmar skin. It is thought, that as the diseased tissue extends into the skin, removal of the skin and fascia lowers the incidence of recurrence. In the presence of insufficient skin to effect wound closure following any procedure, Z-plasties or full thickness skin graft may need to be performed (Swartz & Lalonde, 2008; Townley, et al., 2006). Collagenase is a novel, non-invasive procedure showing promise in the treatment of Dupuytren's contracture. Derived from the enzyme clostridium histolyticum, collagenase is injected directly into the diseased cord. The collagenase is allowed to infuse into the diseased cord overnight promoting a breakdown and lysis of the collagen within the cord. The patient returns to the clinic on the following day where the finger is forcefully extended to rupture the previously weakened cord and restore extension to the finger (Desai & Hentz, 2011; Townley, et al., 2006).

1.7 Splinting following Dupuytren's contracture release

Following surgical release of Dupuytren's contracture there are a number of well-documented complications that can occur. These include excessive inflammation, infection, joint stiffness, complex regional pain syndrome, parasthesiae, persistent PIP joint flexion contracture and recurrence of Dupuytren's contracture (Bulstrode, Jemec, & Smith, 2005; Dias & Braybrooke, 2006; Prosser & Conolly, 1996). The failure to maintain the degree of finger extension achieved intra-operatively or the recurrence of joint contracture is a frequently reported problem and has been discussed widely in the literature (Au-Yong, et al., 2005; Dias & Braybrooke, 2006). A routine approach to minimise the risk of this occurrence is to apply a splint to the hand (Figure 5 and Figure 6), traditionally custom-made by a hand therapist, within the first two weeks following surgery (Au-Yong, et al., 2005; McFarlane, 1997; Mullins, 1999). The use of splinting is central to the investigation of this thesis and several points need to be addressed in order to understand the background to this treatment modality. These are with respect to the incidence and aetiology of finger extension loss, the rationale for splinting and the debate regarding the use of splinting.

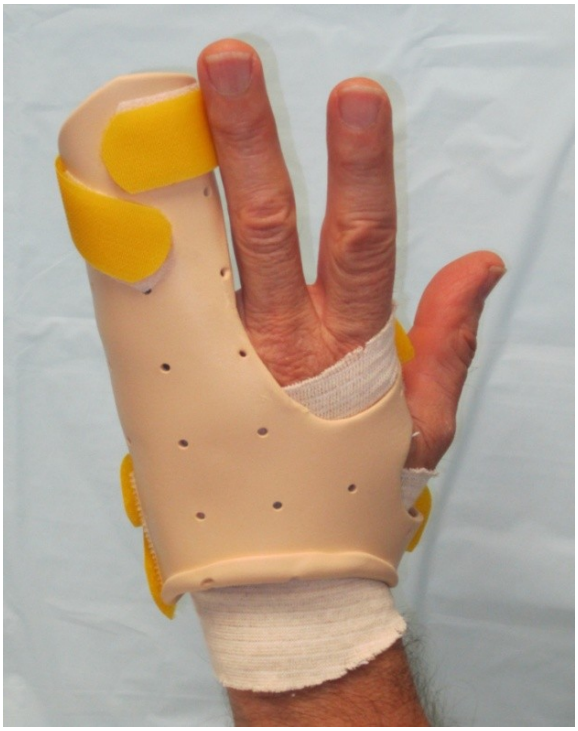

Figure 5: Thermoplastic finger extension splint - dorsal view

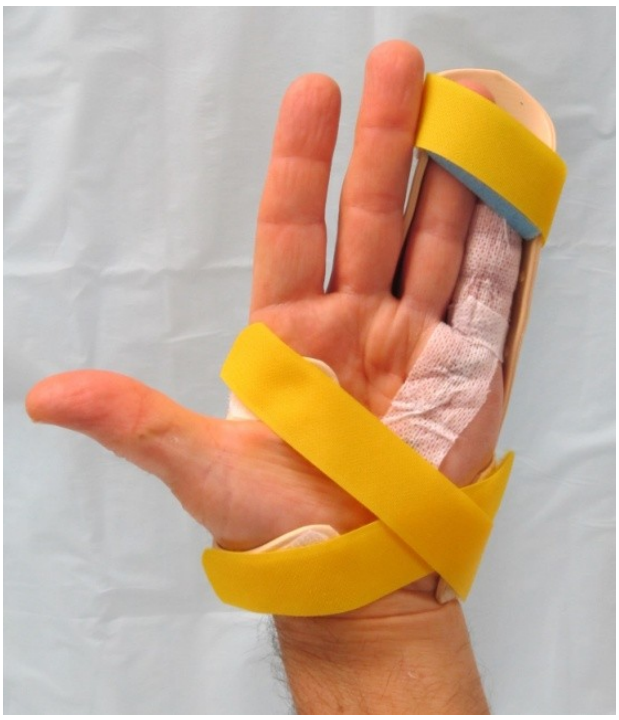

Figure 6: Thermoplastic finger extension splint - volar view

1.7.1 Incidence and aetiology of extension loss

Failure to maintain finger extension or contracture recurrence is a common problem following Dupuytren's fasciectomy with reports of up to 59% of patients experiencing loss of extension (Dias & Braybrooke, 2006; Donaldson, Pearson, Reynolds, & Bhatia, 2010; Ebskov, Boeckstyns, Sorensen, & Soe-Nielsen, 2000; Glassey, 2001). In a 2009 clinical audit of 45 patients having undergone surgery for Dupuytren's contracture, it was found that 40% of patients lost an average of 10 degrees of composite extension from the first postoperative appointment to three months (range 2^{o} - 24^{o}) (Collis & Collocott, 2009).

Although the reasons for loss of finger extension are not fully understood, several factors have been put forward to explain the occurrence. These have included: insufficient surgical excision of diseased tissue, recurrence of disease, aggressive disease, attenuation and insufficiency of the extensor mechanism, joint stiffness, arthritis, infection, oedema or Complex Regional Pain Syndrome (CRPS) (Clare, Hazari, & Belcher, 2004; Dias & Braybrooke, 2006; Prosser & Conolly, 1996).

Another frequently cited cause of extension loss is contraction of the volar scar in the weeks and months following surgery due to the natural process of wound healing and

scar formation (Abbott, et al., 1987). Wound healing follows predictable phases, beginning with the early inflammatory phase, followed by an active proliferative phase and finally scar maturation. During the proliferative phase, which begins at day three and continues until approximately six weeks, collagen is rapidly being synthesised and laid down in the wound space (Davidson, 1998; Smith & Dean, 1998). By around six weeks, the wound enters the maturation phase where collagen synthesis declines and fibres begin to become organised and aligned along lines of stress. Over the subsequent weeks to months, these scars increase in tensile strength and become softer and more pliable. Initially however during the maturation phase, these newly forming scars shrink and contract due to the process of water being squeezed out of the extracellular spaces and collagen becoming more densely packed (Davidson, 1998). This contraction leads to the formation of a tight, shortened scar which, if situated over a joint, can cause progressive joint contracture. With respect to Dupuytren's fasciectomy, excision of diseased tissue can be widespread and can result in an extensive scar over the volar surface of the finger (Figure 7). As this scar inevitably crosses at least one and in many cases two joints, namely the MCP and/or the PIP joints, there is a risk that scarring will result in a contracture of either or both of these joints. It is therefore considered that one of the primary causes of postoperative finger extension loss is due to this process of scar tissue deposition and contraction of the scar over the joint surface (Abbott, et al., 1987).

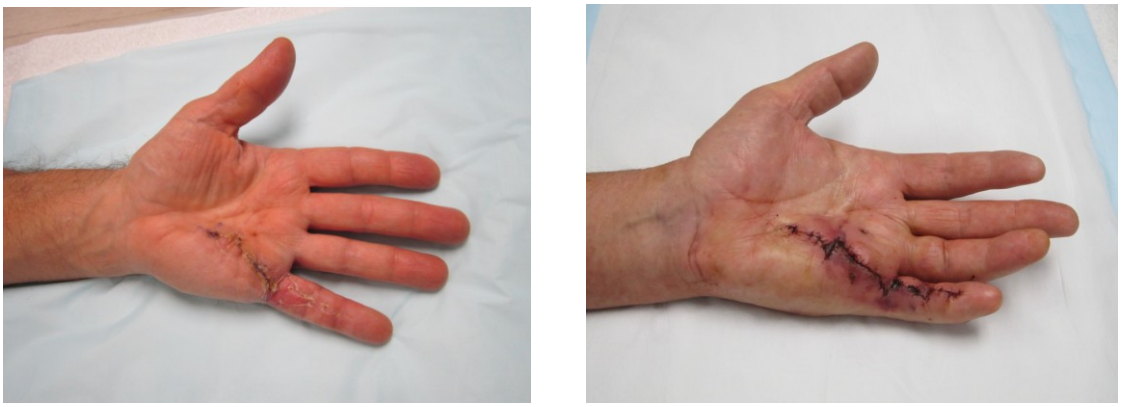

Figure 7: Scarring following surgical release of Dupuytren's contracture

1.7.2 Rationale for splinting

Following release of Dupuytren's contracture, splinting has long been advocated as a method of maintaining the extension achieved intra-operatively in both the MCP and PIP joints. Traditionally, a custom-made thermoplastic splint (Figure 5 and Figure 6) is made by a hand therapist within one to three weeks following surgery. Varying splinting techniques are described in the literature with respect to the amount of tension placed on the fingers, the type of splint, duration of wearing time and the volar or dorsal placement of splints (Au-Yong, et al., 2005; Ebskov, et al., 2000; Evans, Dell, & Fiolkowski, 2002; Herweijer, Dijkstra, Nicolai, & Van der Sluis, 2007). The primary principle however, of holding the operated fingers in extension, remains consistent regardless of the type or duration of splinting.

Despite the widespread use of splinting there is little attention given to discussing the mechanisms by which splinting is thought to maintain finger extension following fasciectomy. It is not widely thought that splinting can prevent the progression of Dupuytren's disease itself (Abbott, et al., 1987) although there are no known randomised controlled trials (RCTs) undertaken which can verify or refute this claim. Other rationales cited are correction of extensor insufficiency (Clare, et al., 2004) and most commonly, the effect of splinting on the remodelling of scar tissue (Au-Yong, et al., 2005; Jabaley, 1999; Mullins, 1999).

It has been claimed that splinting may assist in resolving contracture where there is attenuation of the extensor tendon mechanism, due to long-standing preoperative contracture (Clare, et al., 2004). This mechanism is not further described by Clare (2004) and is not reported by other authors. It is not a likely mechanism of action, as although passive correction of finger extension may be achieved with splinting, splints cannot act on the motor control of the muscle tendon unit. Active extension of the joint can only be achieved through muscular control, and if the central slip of extensor digitorum communis (EDC) is attenuated there will be ineffective pull on the PIP joint and consequently extensor lag at this joint.

The most frequently cited rationale for splinting is that holding the soft tissues in their end range during the maturation phase of wound healing, assists in preventing scar contraction and correction of residual joint contracture (Jabaley, 1999; Jerosch-Herold,

Shepstone, Chojnowski, & Larson, 2008; Mullins, 1999). It has been established that the application of prolonged low load stress to healing or contracted tissues, results in the reorganisation and growth of new soft tissue, and has long been used by hand therapists to effect resolution of joint contracture and prevention of scar contracture following injury and surgery (Brand, 1995; Fess & McCollum, 1998; Flowers & LaStayo, 1994; Glasgow, Wilton, & Tooth, 2003; Schultz-Johnson, 2002). The application of splints following Dupuytren's fasciectomy may therefore act by preventing the organisation of scar tissue into shortened positions, and promote the laying down of collagen in the regions of the excised tissue in the desired position of finger extension. This in turn will minimise contraction of the palmar scar and resultant finger flexion contracture.

1.7.3 Splinting debate

Although splinting is widely used there is ongoing debate in the literature as to whether splinting is indeed effective in preventing loss of finger extension (Abbott, et al., 1987; Ebskov, et al., 2000). Some authors have claimed that splinting may in fact cause further joint contracture due to the misapplication of force, leading to microscopic tearing of tissues and the deposition of further scar tissue, or due to mechanical stress causing acceleration in Dupuytren's disease fibroproliferation (Evans, et al., 2002). Questions regarding the efficacy of splinting are verified by the variability reported with regards to the routine use of splinting. In a survey of 141 UK surgeons (Au-Yong, et al., 2005) 89% recommended use of a night splint for up to six months and Abbot et al. (1987) found a 98% rate of postoperative splint usage. Other authors however recommend splinting only where marked deterioration is noted or only in the presence of severe disease (Herweijer, et al., 2007).

In clinical practice, a wide range of outcomes have been observed with respect to finger range of motion, despite the use of standard splinting protocols. In some cases it appears that splinting is effective in maintaining or increasing finger extension, whereas in other cases patients appear to lose extension regardless of being highly compliant with splint wear. Equally, variable outcomes are observed when splinting compliance has been low. It may also be that splinting has effect in some patients and not in others due to factors such as the presence of osteoarthritis, previous surgery,

age, type of surgery or the degree of preoperative contracture, and clinicians have suggested that splinting may be more beneficial if used selectively rather than routinely. This inequity of outcomes along with lack of empirical evidence has led clinicians to question postoperative splinting protocols.

In addition, splinting is not a benign modality and there may be other, unwanted effects which in turn may outweigh any benefit. Splinting may cause increased stiffness, pain and slow recovery of function following Dupuytren's surgery (Glassey, 2001; Larson & Jerosch-Herold, 2008; Pratt & Byrne, 2009). Splints can be cumbersome to wear and authors have noted that patients find wearing of splints difficult to manage and interruptive to function (Glassey, 2001; Pratt & Byrne, 2009). There has also been some discussion in the literature as to whether splinting and the application of inappropriate tension following fasciectomy could accelerate recurrence (Abbott, et al., 1987; Evans, et al., 2002).

In summary, splinting following surgical release of Dupuytren's contracture is thought to maintain finger extension through the action of preventing scar contracture. Recent questions regarding the efficacy of splinting, the variability with which it is used internationally and concerns over detrimental effects have suggested that routine use of splinting may not be as beneficial as traditionally thought. A systematic literature review was therefore undertaken to examine the current evidence as it relates to the effect of splinting on maintaining finger extension post Dupuytren's contracture release.

Chapter 2. The efficacy of splinting following surgical release of Dupuytren's contracture: a systematic review

2.1 Methodology

A systematic literature review was undertaken with the aim of identifying and evaluating the current evidence relating to the effect of splinting on finger range of motion and function following surgical release of Dupuytren's Contracture. Both the findings from the identified studies and an assessment of the quality of evidence will be presented.

2.1.1 Search strategy

A search of the literature was conducted to identify studies examining the effect of splinting on finger extension, finger flexion and hand function in the 12 months following fasciectomy for Dupuytren's contracture. The electronic databases searched were AMED via Ovid, Ovid MEDLINE(R) 1946 to Present with Daily Update, EBSCO Health Databases, Cochrane Library via Ovid and Wiley and Allied Health Evidence via PED*ro.* The terms searched were: splint* OR brace* OR orthot* AND Dupuytren*, B) "hand therapy" OR "occupational therapy" OR physiotherapy AND Dupuytren*. Once relevant studies were identified, a manual search of the reference lists was conducted to identify any further studies of interest. All abstracts were reviewed and articles were selected according to the following parameters:

Inclusion

- Literature from 1980 to 2011
- Studies which investigated splinting as the primary independent variable or as part of the intervention programme in the 12 months following surgery for Dupuytren's contracture
- All types of splinting including static, dynamic or serial static
- Studies reporting on one or more of the following dependent variables: composite or individual finger joint extension or flexion, hand function
- All studies including randomised controlled trials (RCTs), case control, cohort, retrospective chart reviews

Exclusion

- Non-research articles describing splinting protocols or rehabilitative approaches following Dupuytren's contracture release
- Non-research articles
- Studies examining splinting preoperatively
- Non-English articles
- Any articles investigating outcomes with respect to differing surgical interventions even where splinting was used postoperatively
- Studies reporting on surgical splinting

2.1.2 Quality assessment

The quality of the identified studies was evaluated using the validated Downs and Black Quality Index (Downs & Black, 1998). This tool was developed for the rating of both randomised and non-randomised health intervention studies, as an alternative to scales which focus primarily on randomised controlled trials. Many health care studies use study designs such as cohort observational or case series, and these papers need to undergo close scrutiny, to allow the reader to make an informed opinion as to the clinical relevance and strength of the findings. The Downs and Black critiques the quality of reporting, validity and power of each study as summarised in Table 1. A previous systematic review of splinting after surgical release of Dupuytren's contracture (Larson & Jerosch-Herold, 2008) used a tool developed by MacDermid (2004) for critical appraisal of journal articles. It is a 24 point scale for the critiquing of reporting, study design, statistical analysis and validity with a total possible score of 48.

The Downs and Black was selected for this review for the following reasons: due to the high ratio of non-randomised trials, to allow for comparison with the Larson and Jerosch-Herold (2008) systematic review and to use a validated tool. The Downs and Black Quality Index can be viewed in full in Appendix A. Question 27, which deals with statistical power, was modified from the original version to a two point scale, where 1 (yes) was scored if a power or sample size calculation was carried out a priori and 0 (no) if there was no power analysis. The final score was then grouped to indicate a level of quality of evidence for each paper: excellent (26 to 28), good (20 to 25), fair (15 to 19), and poor (less than 14). This grading was based on groupings used in

previous health intervention studies (Jutai, Strong, & Russell-Minda, 2009; Russell-Minda, et al., 2009; Samoocha, Bruinvels, Elbers, Anema, & van der Beek, 2010). All the studies were reviewed and rated independently by three scorers (JC, WH and EK). Where disagreement occurred between raters, a consensus was reached through discussion and review of the debated question.

Table 1: Summary of Downs and Black Quality Index

A 27-item checklist with five sub-scales to rate the quality of randomised and non-randomised health studies with a total possible score of 28.
Reporting (10 items) Assesses whether the information provided in the paper is sufficient to allow a reader to make an unbiased assessment of the findings of the study
External validity (3 items) Addresses the extent to which the findings from the study can be generalised to the population from which the participants were derived
Internal validity—bias (7 items) Addresses biases in the measurement of the intervention and the outcome
Internal validity—confounding (6 items) Addresses bias in the selection of study participants
Power (1 item) Assesses whether the negative findings from a study could be due to chance

2.2 Results

Full details of the search results are found in Figure 8. A total of six studies were finally selected for review, only one of which was a RCT, the remaining studies being observational or non-RCTs. All studies were identified through the Ovid MEDLINE and EBSCO Health databases. Review of the reference lists did not reveal further studies of interest. Types of splints investigated were either static or dynamic, worn for periods of up to six months postoperatively, with sample sizes ranging from 20 to 268. The study characteristics and methodology are summarised in Table 2 and the major results in Table 3.

Final scores ranged from 11 to 26 out of a total possible of 28 with only the Jerosch-Herold et al. (2011) study being allocated an excellent score of 26. One study attained a good score of 20 and the remaining four scored fair or poor. The full results are presented in Table 4. It is important to note that although a grading of 'good' was allocated to the Herweijer et al. (2007) study, due to the higher standard of reporting and handling of the data, this study was not a controlled trial and splinting was not investigated as an independent variable. This study was not included in the Larson & Jerosch-Herold (2008) review but was included in the current review, as it met the inclusion criteria of investigating splinting as part of the intervention programme in the 12 months following surgery for Dupuytren's contracture. The scores of both the current review and the Larson & Jerosch-Herold (2008) systematic review were then converted to percentages to allow for comparison as shown in Table 5. Similar percentages were achieved in the four studies critiqued in both reviews; Ebskov et al. (2000) and Evans et al. (2002) scored 40% in the current review compared with 44% and 35% respectively by Larson & Jerosch-Herold (2008); Glassey (2001) scored 57% compared with 46% and Rives 46% and 44%.

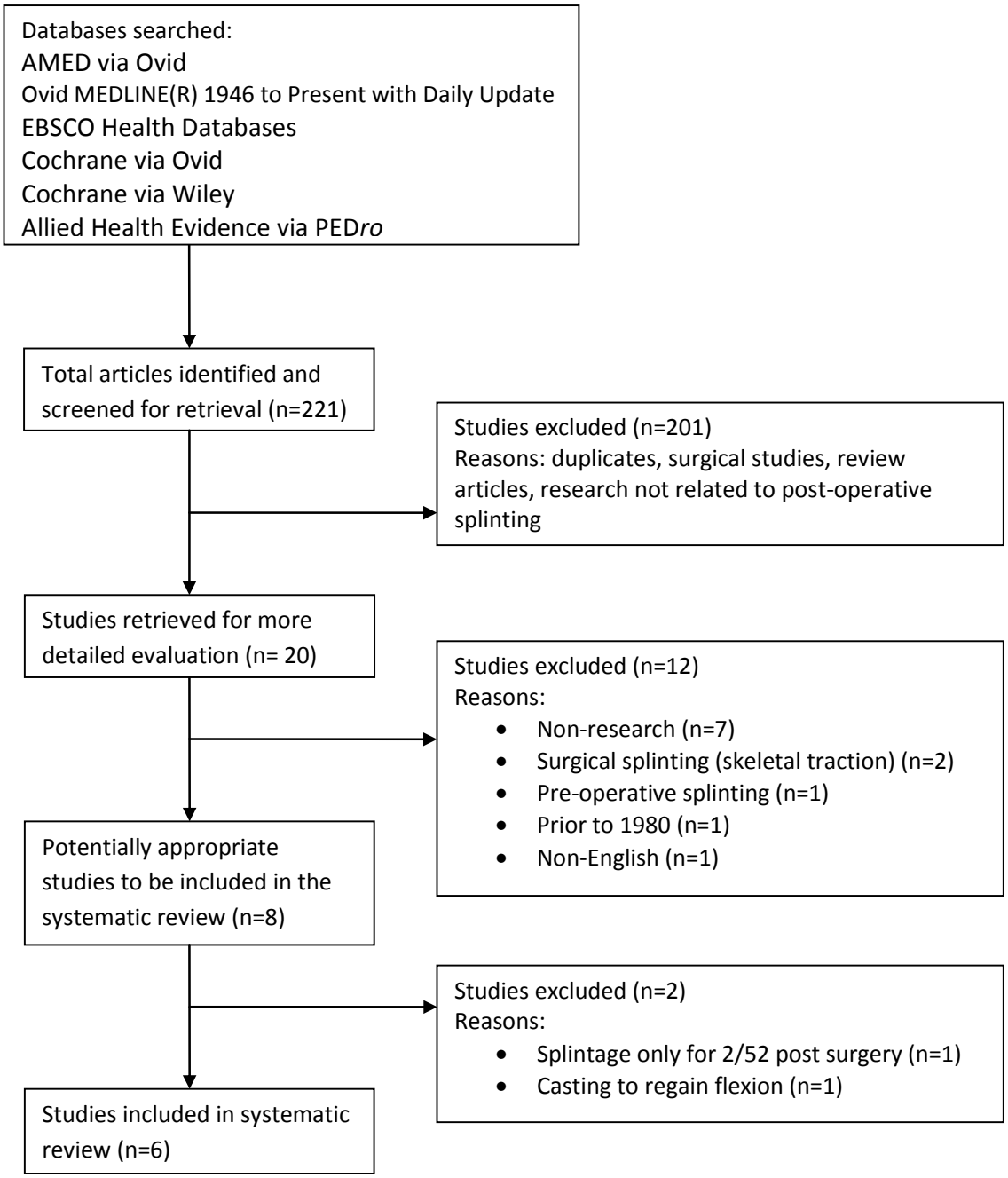

Figure 8: Quorum diagram for literature search

Table 2: Characteristics and methodology of the included studies

Author Year	Purpose	Study Design	Participants and group allocation	Splinting protocol – design and joint position	Splinting protocol – frequency and duration	Timing of Assessments
Ebskov, Boeckstyns, Sorensen, & Soe-Nielsen (2000)	To study the effect of dynamic extension splinting on recurrence of PIP and MCPJ joint contracture	Prospective, non-randomised controlled trial	n =69 Age and gender not reported Inclusions: >25° joint contracture or rapid recurrence of contracture Group allocation: splint compliance 1. Adequate use (n=15) 2. Inadequate use (n=15) 3. No splint (n=24)	Dorsal dynamic extension splint with extension force of approximately 200g to MCP and PIP joints	From 2-3/52[+] postoperatively until six months at night	Preoperatively, 3/52 and 9/12[++] postoperatively
Evans, Dell & Fiolkowski (2002)	To examine the effect of stress as applied by splinting on finger ROM, scarring and flare of Dupuytren's Disease in the immediate postoperative period	Retrospective chart review & prospective observational	n=268 Group allocation: extension force to finger in first 3/52 Tension applied group (TA): n=103, mean age 67.15, male:76, female:27 No tension applied group (NTA): n=165, mean age 69.33, male:128, female:37	TA: static splint with MCP and PIP in 0^o-20^o extension NTA: static extension splint with MCP 40^o-45^o flexion & IP extension first 2-3 weeks, then replaced by volar static splint with MCP and IP joints extended	TA: intermittent day and overnight splinting for first 2-3/52 NTA: 24 hour splinting first 2-3/52. From 3/52 splint worn only at night Duration of splinting unknown	TA: 68 days NTA: 36 days

Author Year	Purpose	Study Design	Participants and group allocation	Splinting protocol – design and joint position	Splinting protocol – frequency and duration	Timing of Assessments
Glassey (2001)	To investigate the effectiveness of splinting on finger range of motion, grip strength, pain and function	Retrospective observational	n=31 Group allocation: surgeon preference, two surgeons splinted all patients, others splinted only when extension lost Splint group: n=21, mean age 68.8, male:18, female:3 No splint group: n=10, mean age 58.5, male:7, female:3	Static volar extension splint in comfortable extension	Worn at night for 3/12	≤2/52 and 3/12 postoperatively
Herweijer, Dijkstra, Nicolai, & Van der Sluid (2007)	To evaluate the effect of hand therapy post-Dupuytren's Contracture release in more severe disease	Prospective observational	n= 46 Male:38, female:8 Mean age 62 Group allocation: referred for hand therapy according to referral criteria or not (recurrent disease, MCP or PIP preoperative contracture of >40^{o}, extended surgical scar, loss of > 15^{o} postoperatively) 1. Correctly referred (n=21) 2. Incorrectly not referred (n=17)	Static dorsal extension followed by static volar extension splint	Dorsal splint worn 24/24^{+++} until wound healed Volar splint worn at night and 3x 1.5 hour periods during the day Daytime splinting gradually reduced, night splinting continued until 6/12	Preoperatively, 10/12 postoperatively
Jerosch-Herold et al. (2011)	To investigate the effect of postoperative night-time static splinting on function, digital range of motion and patient satisfaction	Randomised controlled trial	n=154 Group allocation: random assignment Splint group: n=77, mean age 67.2, male:61, female:16 No splint group: n=77, mean age 67.5, male:59, female:18	Static extension splint with fingers under no tension for first 3/52 then greater extension force applied after 3/52 Volar or dorsal not stated	At night for 6/12	Preoperatively, and postoperatively at 3, 6 and 12/12

Author Year	Purpose	Study Design	Participants and group allocation	Splinting protocol – design and joint position	Splinting protocol – frequency and duration	Timing of Assessments
Rives, Gelberman, Smith, & Carney (1992)	To examine the effect of postoperative dynamic splinting on PIPJ contracture	Prospective observational	n=20 (23 digits), mean age 60, male:15, female:5 Group allocation: splint compliance (wore splint for > or <50% of recommended time) (only patients with PIPJ > 45° preoperatively included) Compliant group (n=13) Non-compliant group (n=7)	Dynamic extension splint; MCPJ 70^{o}, PIPJ complete extension Static volar extension splint with wrist in 25^{o} extension, MCP and PIP joints in neutral	Dynamic splint worn 24/24^{+++} until 4/52^{+} and then during the day only until 8-12/52 and then 6 hours during the day until 3-6/12^{++} Static splint at night from 4/52 until 3-6/12	Preoperatively, and postoperatively at 3 month intervals for first year then 6 monthly thereafter Mean follow-up at 2 years (1- 3.5)

$^{+}$ weeks/weeks
$^{++}$ months/months
$^{+++}$ hours/hours

Table 3: Outcomes of included studies

Author Year	Outcome Measures	Results	Effect
Ebskov, Boeckstyns, Sorensen, & Soe-Nielsen (2000)	MCP and PIP joint contracture: change of ≤ 10°, ± 10-40°, >40° Compliance: self-report questionnaire 1. adequate splint wear = daily use 2. inadequate splint wear = worn less often than daily 3. no splint	No significant difference between the three groups in either joint % of participants with MCPJ loss of > 10° extension in three groups: 36%, 27%, 13% % of participants with PIPJ loss of >10° extension in three groups: 80%, 60%, 45%	No, but tendency for better extension with no splint
Evans, Dell & Fiolkowski (2002)	No. of therapy visits	TA^{+}: 20 NTA^{++}: 13 ($p<0.01$)	Yes, fewer visits in NTA group
	Days of therapy	TA: 67.73 NTA: 36.49 ($p<0.01$)	Yes, fewer days of therapy in NTA group
	Flare: nil, mild, severe	NTA: fewer flare-ups ($p < 0.01$)	Yes, fewer flare-ups
	Scar: nil, mild, severe	NTA: fewer scar complications ($p < 0.01$)	Yes, fewer scar complications
	MCP/PIP flexion: goniometry	PIP Flexion significantly greater flexion in NTA group ($p<0.05$)	Yes, better flexion but only at the PIPJ, no effect at MCPJ
	MCP/PIP extension: goniometry	PIPJ extension deficit significantly lower deficit in NTA group ($p<0.05$)	Yes, less extension deficit but only in the PIPJ, no effect at MCPJ
Glassey (2001)	Finger ROM: total active flexion (TAF)	Splint group: 42.62°(30.88) No splint group: 62.25°(32.48) (p=0.11)	No, but tendency for better flexion in no splint group
	Finger ROM: total lack of active extension (TLAE)	Splint group: loss of 4.76° (21.33) extension No splint group: gain of 13.75° extension (2.12) (p=0.04)	Yes, better extension in no splint group
	Finger ROM: total active motion (TAM)	Splint group: 35.95(39.98) No splint group: 74.50(35.99) (p=0.02)	Yes, better total finger range of motion in no splint group
	Pain: 10cm visual analogue scale (VAS)	No statistical difference	No

Author Year	Outcome Measures	Results	Effect
	Grip strength: dynamometry	No statistical difference	No
	Hand function: Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire	Gain of 13.75° in no splint group (p=0.01)	Yes, better function in no splint group
Herweijer, Dijkstra, Nicolai, & Van der Sluid (2007)	Finger ROM: TAM	Correctly referred: 50° (40) Incorrectly not referred: 29° (27) -43.9 to 2.4 95%CI (p=0.08)	No, but tendency for greater TAM in correctly referred group
	Finger ROM: Total passive motion (TPM)	Correctly referred: 29° (52) Incorrectly not referred: 22° (28) -33.5 to 20.6 95%CI	No
	Sensibility: 2 point discrimination	No difference	No
	Pinch Grip: pinch meter	No difference	No
	Function: DASH and Michigan Hand Outcomes Questionnaire (MHQ)	No difference	No
Jerosch-Herold et al. (2011)	Function: DASH	Splint group at 3/12: 9.6(12.8) No splint group at 3/12: 10.8(12.5) (95% CI -1.48, p=0.403) Splint group at 12/12: 7.0(14.6) No splint group at 12/12: 6.0(9.2) (95% CI 0.66, p=0.703)	No
	Finger ROM: TAF (MCP+PIP+DIP)	Splint group at 3/12: 213.0(26.5) No splint group at 3/12: 217.6(22.5) (95% CI -3.49, p=0.326) Splint group at 12/12: 223.8(25.7) No splint group at 12/12: 227.3(19.5) (95% CI -2.02, p=0.493)	No

Author Year	Outcome Measures	Results	Effect
	Finger ROM: TAE (MCP+PIP+DIP)	Splint group at 3/12: -32.9(19.6) No splint group at 3/12: -30.9(20.7) (95% CI 3.30, p=0.209) Splint group at 12/12: -32.9(27.4) No splint group at 12/12: -29.6(23.3) (95% CI 5.11, p=0.172)	No
	Patient satisfaction	Not measured at 3/12 At 12/12 (95% CI-0.35, p=0.315)	No
Rives, Gelberman, Smith, & Carney (1992)	PIP joint contracture: % of improvement, technique not further described Splint compliance: patient verbal self report	Compliant group; improvement = 59%. 11/14 digits maintained 75% improvement in PIPJ extension at 2 years Non-compliant group; 25% improvement in PIPJ extension over preoperative contracture at 2 years ($p<0.05$)	Yes, compliance only factor associated with improvement, outcome not affected by contracture severity, involved digit or surgical technique Greatest improvement in the first month

[+] Tension applied

[++] No tension applied

Table 4: Quality index score: consensus of three raters

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	Total
Ebskov et al. (2000)	1	1	0	1	0	1	0	0	0	0	1	0	0	0	0	1	1	1	1	0	1	1	0	0	0	0	0	11
Evans et al. (2002)	1	1	1	1	1	1	1	0	0	1	0	0	0	0	0	1	0	1	0	0	1	0	0	0	0	0	0	11
Glassey (2001)	1	1	1	1	2	1	1	0	0	1	0	0	0	0	0	1	1	1	0	1	1	1	0	0	1	0	0	16
Jerosch-Herold et al. (2011)	1	1	1	1	2	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	26
Herweijer et al. (2007)	1	1	1	1	2	1	1	0	1	1	1	1	1	0	0	1	1	1	0	1	1	1	0	0	0	1	0	20
Rives (1992)	0	1	1	1	1	0	0	0	1	0	0	0	1	0	0	1	1	1	1	0	1	1	0	0	0	1	0	13

Table 5: Quality scores of included studies

	Reporting Questions 1 – 10	**External Validity** Questions 11 - 13	**Internal Validity – bias** Questions 14 - 20	**Internal Validity – confounding** Questions 21-26	**Power** Question 27	**Quality Score, Downs & Black Total**	**Quality Score, Downs & Black Grade[+]**	**Quality Score, Larson & Jerosch-Herold (2008)**
Ebskov et al. (2000)	4	1	4	2	0	11/28 (40%)	poor	21/48 (44%)
Evans et al. (2002)	8	0	2	1	0	11/28 (40%)	poor	17 (35%)
Glassey (2001)	9	0	4	3	0	16/28 (57%)	fair	22 (46%)
Jerosch-Herold et al. (2011)	11	3	5	6	1	26 (92%)	excellent	n/a
Herweijer et al. (2007)	10	3	4	3	0	20 (71%)	good	n/a
Rives (1992)	5	1	4	3	0	13 (46%)	poor	21 (44%)

[+] Excellent (26-28); good (20-25); fair (15-19); poor (<14)

2.3 Discussion

The literature review identified four key themes within the identified studies which will be discussed in the following section. These relate to the type of interventions, length of follow up, frequency of measures, the outcomes that were measured and the effectiveness of the splint wear regimes on finger range of motion and hand function.

2.3.1 Type of interventions

Four studies evaluated the use of static hand splints which were worn by participants for periods between five weeks and six months primarily at night (Evans, et al., 2002; Glassey, 2001; Herweijer, et al., 2007; Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011). Ebskov et al. (2000) examined the effect of a dynamic extension splint which was worn for six months and the Rives et al. (1992) protocol involved a complicated combination of dynamic and static splints which were worn for up to six months including day-time use. The paucity of studies on dynamic splints may reflect the fact that fabrication of custom-made dynamic splints is considerably more time-consuming and requires greater splint making skill by therapists and therefore less likely to be used routinely.

There were varying descriptions of the position of the fingers within the splints and the degree of force applied to the wound and scar. Questions have repeatedly been raised in the literature regarding potentially detrimental effects of excessive force to wounds following the surgical excision of Dupuytren's tissue (Evans, et al., 2002; Glassey, 2001; Larson & Jerosch-Herold, 2008). It is therefore important that authors report on the amount of tension being applied by splints to the wound and later the scar. Two authors (Evans, et al., 2002; Rives, et al., 1992) described the actual degrees at the MCP and PIP joints, and the level of force was measured by way of a rubber band tension device in two of the studies (Ebskov, et al., 2000; Rives, et al., 1992). In one further study it was clearly stated that tension to the wound was avoided in the initial three weeks (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011) and the remaining authors did not discuss the degree of force applied to the fingers at all.

Questions regarding the effect of varying degrees of tension to the healing wound remain unanswered with only one study evaluating this variable in isolation. Evans et al. (2002) examined the effect of stress on healing tissue as applied by splints with the

premise that excessive force in the first few weeks postoperatively may result in greater hypertrophic scar formation. Comparisons were made between groups placed in a splint under tension or with no tension to the wound. There was no randomisation in this study, and group allocation was by way of a retrospective chart review and prospective observation of a group following a change to a 'no-tension' practice thereby limiting the strength of the findings. Although many clinicians have adopted the 'no-tension' principal there are no known subsequent studies that have directly examined this variable.

The interventions therefore varied between dynamic and static splints with inconsistent reporting of the degree of force applied to the fingers. This is an important factor to report in future studies due to questions raised by Glassey (2001), Evans et al. (2002) and Larson & Jerosch-Herold (2008) regarding the potentially detrimental effect of excessive force.

2.3.2 Length of follow-up

Final follow-up ranged from five weeks to two years, with splints being worn for periods between five weeks to six months. The two year follow-up of Rives et al. (1992) may not be an appropriate time frame if splints are only being worn for up to six months and not during the intervening 18 months. At two years it may be difficult to differentiate between the effects of splinting and natural recurrence of the disease which is known to be high. The effects of splinting are most likely to be seen while splints are being worn which would justify a shorter follow-up of three or six months as suggested by Larson and Jerosch-Herold (2008).

2.3.3 Frequency of measures

Frequency of measures and the inclusion of preoperative measures must also be considered. The ability to observe change in finger range of motion over time is important in identifying whether splinting has benefit at differing time points postoperatively. The inclusion of preoperative range of motion enables analysis of the effect of contracture severity on final outcomes and ensures homogeneity in any comparative groups. In addition, if comparisons are only made between preoperative and final measurement, it is not possible to isolate the effect of splinting distinct from the surgical correction of contracture. Three authors took preoperative measures

(Herweijer, et al., 2007; Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011; Rives, et al., 1992) however only two took repeated measures following surgery (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011; Rives, et al., 1992) and no studies reported measurements taken at the first postoperative hand therapy appointment which would enable comparisons to be made against final outcomes. In order to determine the effect of splinting at varying time points, it is suggested that measures taken at the first postoperative appointment should consistently be included in future studies.

2.3.4 Outcomes assessed

The primary outcome of interest for this review was finger range of motion and this was included as one of the main measures in all six studies. The method in which both finger flexion and extension were recorded varied greatly between individual joint motion (MCP, PIP), summation of joint motion for flexion and extension (MCP+PIP+DIP), total finger motion, deficits of total range of motion and percentages of change. Summative scores of total active flexion and extension (TAF and TAE: MCP+PIP+DIP) were used by Glassey (2001) and Jerosch-Herold et al. (2011) and is perhaps the most transparent and easily reproducible method of reporting composite finger range of motion. The main drawback of this method is that it does not allow for the differentiation in individual joint motion and it may be that splinting has greater effect on one or other of the MCP or PIP joints. PIP joint contractures can be more problematic to resolve than contractures of the MCP and also Dupuytren's disease can cause contracture of the MCP, PIP or both. The recording of summative data therefore does not allow for analysis of change in individual joints or the pairing of data with preoperative joint contracture. Reporting of actual degrees of motion at each joint (MCP and PIP) would enable closer scrutiny of the outcomes observed.

Finger goniometry is a reliable and valid method of measuring joint range of motion with error rates of up to five degrees being considered acceptable. Assessment by a single rater is preferred due to the higher intra-rater reliability with error rates of less than five degrees (Ellis & Bruton, 2002; Lewis, Fors, & Tharion, 2010) compared with five to nine degrees for inter-rater reliability (Burr, Pratt, & Stott, 2003; Ellis & Bruton, 2002; Lewis, et al., 2010). Other factors associated with the reliability of finger goniometry are the type of goniometer used, lateral or dorsal placement of the

goniometer, experience of the rater, which finger joint is measured, position of adjacent joints and presence of oedema in the finger (Burr, et al., 2003; Groth, VanDeven, Phillips, & Ehretsman, 2001; Kato, et al., 2007). Due to these factors it is essential that studies report on the method and tool used and the number of persons taking the measures. The technique of measuring joint range of motion is only described well by Herweijer et al. (2007) and Jerosch-Herold et al. (2011) who describe the goniometry techniques according to a standard protocol. Due to higher inter-rater error rates it is preferable that all the measures are taken by a single assessor. In only one study was a single assessor used (Glassey, 2001). Jerosch-Herold et al. (2011) used two assessors, however training took place at regular intervals to maximise accuracy of measurement and in all other studies it was not possible to determine the number of assessors. Lack of clear reporting in regards to measurement of finger motion is an important omission in the majority of these studies.

The other outcome of interest was hand function and this was measured by three authors using the self report DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire (Glassey, 2001; Herweijer, et al., 2007; Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011), and one paper using the Michigan Hand Questionnaire (MHQ) (Herweijer, et al., 2007). Grip strength, which is often considered a useful measure of hand function (Cox, Spaulding, & Kramer, 2006; Michener, et al., 2001) was measured in only one of the six studies (Glassey, 2001). The inclusion of grip strength in more studies would have greatly added to data on hand function, as would the use of a specific hand function test such as the Sollerman which has been used in previous surgical outcome studies in a Dupuytren's population (Draviaraj & Chakrabarti, 2004; Sinha, et al., 2002).

With regards to the reporting of outcomes this review identified several inadequacies which, if addressed in future studies, would provide useful information and add robustness to findings. Firstly, it is suggested that authors not only report summative range of motion measures but also actual degrees at the MCP and PIP joints respectively. Secondly, the goniometry or joint measurement technique should be clearly described according to a standard protocol, along with the way in which error rates were mitigated. Lastly, further studies should consider the inclusion of grip

strength and a greater variation in the measurement of functional outcomes in order to determine the usefulness of interventions to the individual.

2.3.5 Splinting effectiveness

2.3.5.1 Beneficial effects of splinting on finger range of motion

Gains in finger extension following a postoperative period of extension splinting were reported by only two authors at significance level of $p<0.05$ (Evans, et al., 2002; Rives, et al., 1992) and in neither of these studies were participants randomised into a treatment and control group. Herweijer et al. (2007) noted a slight trend of greater finger range of motion in a correctly referred and splinted group without reaching statistical significance, however extension was not measured separately from composite finger range of motion, so it is not possible to determine whether the gains were due to increases in flexion, extension or both. Also, in this study, splinting was not isolated as an independent variable and was examined as part of overall hand therapy postoperatively. Rives et al. (1992) compared 13 patients who were compliant with wearing splints against seven patients who were deemed non-compliant having worn the splint less than 50% of the recommended time. The splinting protocol used by Rives et al.(1992) involved the greatest splint duration of all the studies with participants (n=20) being required to wear a splint at least some part of every day and all night for six months. It is not surprising therefore that one third of the participants did not tolerate this regime. In the group that wore the splints for greater than 50% of the recommended time, improvements of 59% were found in PIPJ extension compared with 25% in the noncompliant group. The actual degrees are not given, nor the method for calculating percentages. Evans et al. (2002) reported statistical improvement ($p>0.05$) in PIPJ extension in a group splinted under a "no tension" protocol of MCPJ 30^{o} flexion and IPJ extension for two to three weeks to take force off the healing wound. Comparisons were made against a primarily retrospective chart review group who had been splinted under tension. Evans et al. (2002) concluded that although there was statistically greater finger extension in the no tension group, these gains were not sufficiently great to be deemed clinically significant. Follow-up varied between five and ten weeks in the Evans et al. (2002) study, to two years in the Rives et al. (1992) study; however Evans et al.'s (2002) sample of 268 was much greater than Rives et al.(1992) who only included 20 participants. Evidence for splinting being effective in the maintaining of finger extension is weak with only Rives et al. (1992)

showing any real gains in finger extension and this in a very demanding splint regime which is unlikely to be tolerated by a large number of patients and in a study with a very small sample and without a control group.

2.3.5.2 Detrimental or no effect of splinting on finger range of motion

Detrimental or no effect of splinting on finger extension was reported in three of the six studies (Ebskov, et al., 2000; Glassey, 2001; Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011). In the Jerosch-Herold et al. (2011) RCT no significant differences were found on finger extension (p=0.172) between groups that did or did not receive a night extension splint at three, six or twelve months. Ebskov et al. (2000) found that 45% of participants in a group who did not receive a splint lost >10 degrees in the PIP joint between two to three weeks postoperatively and nine months whereas in a group who wore the splint adequately there was an 80% loss of >10 degrees in the PIP joint. At the MCPJ the differences were similar with a >10 degrees extension loss of only 13% in the no splint group compared with 36% in the adequate wear splint group. These groups were not homogenous, as only patients with a rapid recurrence of contracture or a postoperative contracture of >25 degrees were given a splint whereas those in the no splint group had less severe disease. The differences between the adequate and not adequate splint wear are difficult to compare as there is no reporting of why compliance differed and what motivated those in the adequate splint wear group to comply with splinting. It may be that these patients had worse contracture and felt that splinting would give them the best chance of regaining lost extension. Glassey (2001) reported an average loss of 4.76 degrees of extension in a splinted group compared with 13.75 degrees increase in finger extension in the no splint group. This was a retrospective study and group allocation was according to surgeon preference. The strongest findings are from Jerosch-Herold et al. (2011) where the groups were homogenous in nature including the severity of preoperative contracture. This inclusion of a wide range of contracture severity makes the findings of this study more robust as it is possible to conclude that contracture severity is not an indicator in itself of the need to splint. External validity in this study is also high as participants were recruited from five different hospitals and were operated on by 16 different surgeons with a range of therapists treating patients. This removes the bias of the effect of one particular surgeon or therapist having a unique approach which may influence outcomes.

With regards to finger flexion similar results were found with both Glassey (2001) and Jerosch-Herold et al. (2011) reporting no differences in flexion between splinted and non-splinted groups (p=0.11 and p=0.326 at three months respectively). Evans et al. (2002) reported significantly improved flexion in the no-tension group at the PIPJ (<0.05).

Studies published prior to 2011 found conflicting outcomes with regards to the effect of extension splinting on finger range of motion particularly that of maintaining finger extension over time. With the publication of the Jerosch-Herold et al. (2011) RCT there is now convincing evidence for the lack of benefit of night extension splinting on finger range of motion following Dupuytren's contracture release.

2.3.5.3 Effects of splinting on hand function

Half of the studies measured hand function and none found outcomes in favour of splint use. Two studies (Herweijer, et al., 2007; Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011) showed no difference in self-reported hand function between groups receiving or not receiving a splint and one study (Glassey, 2001) demonstrated a detrimental effect of splint wear on hand function. Findings from two of the studies (Glassey, 2001; Herweijer, et al., 2007) are limited, due to lack of randomisation and the way in which inequitable group allocation occurred, by way of surgeon preference, in one study (Glassey, 2001). Findings from Herweijer et al. (2007) are also weak as splint wear was examined as part of a total hand therapy programme rather than as an independent variable. Both Herweijer et al. (2007) and Glassey (2001) do concur with Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., (2011) where no differences were found in hand function as measured by the DASH questionnaire at three, six or twelve months (p = 0.403, 0.892 and 0.703 respectively) between groups who did or did not receive a splint. With respect to hand function, it appears there is no discernible effect in favour of wearing a splint at night following surgical release of Dupuytren's contracture.

2.4 Conclusions

This systematic review identified six studies conducted between 1992 and 2011. With the exception of the Jerosch-Herold et al. (2011) study, the overall quality of these studies was low, with methodological and reporting inadequacies. Only one study included random allocation to intervention and non-intervention groups (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011). The designs in the remaining studies were not able to properly control for confounding factors thereby limiting the validity and strength of the findings. The key methodological inadequacy was lack of random assignment of participants to intervention and control groups. In addition, there was a wide range in the studies with regard to the type of splints, duration of wear, the way in which joint range of motion was reported and measured, frequency of measures and final follow-up, making comparisons between studies difficult.

With respect to the effect of splinting post Dupuytren's fasciectomy, the literature preceding 2011 was inconclusive and conflicting. The publication of the 2011 Jerosch-Herold et al. RCT however has now given strong evidence that night extension splinting has no effect on finger extension, finger flexion or hand function in the 12 months following surgery. The long-held tenet that splinting at night for up to six months following Dupuytren's fasciectomy prevents loss of finger extension has now been challenged and appears to no longer hold true.

Several suggestions have been put forward in this review for future studies evaluating the outcomes of Dupuytren's fasciectomy. Firstly, it is suggested that authors not only report summative range of motion measures but also actual degrees of the MCP and PIP joints. This will allow for analysis of the relative efficacy of any intervention on differing joints. Secondly, the goniometry or joint measurement technique should be clearly described, according to a standard protocol along with the way in which error rates are mitigated. Lastly, further studies should consider the inclusion of grip strength and a greater variation in the measurement of functional outcomes in order to determine the usefulness of interventions to the individual.

Future studies with proper randomisation and control groups including a range of outcomes measures would add further evidence to the growing body of knowledge on therapeutic management following surgical release of Dupuytren's contracture.

Chapter 3. Study aims and hypotheses

3.1 Introduction

Prior to 2011, and at the inception of this study, there was inconclusive and conflicting evidence regarding the effect of splinting on finger range of motion and function following surgical release of Dupuytren's contracture. The ability of splinting to maintain finger extension after surgery had not been clearly established and further evidence was required to enable therapists to implement therapies based on robust research findings. A study was therefore designed to further investigate the effect of night extension splints in a New Zealand population. To the author's knowledge no such study had previously been undertaken in this geographic region.

This study was undertaken due to the following reasons:

1. Outcomes from an audit conducted at CMDHB Hand Therapy in 2009 indicated that 40% of patients lost finger extension regardless of night extension splinting (Collis & Collocott, 2009)
2. Clinical concerns that splinting may increase stiffness and delay return of finger flexion and function
3. Uncertainty as to the relationship between splinting compliance and final finger range of motion
4. Debate in the literature as to the efficacy of splinting in maintaining finger extension
5. Wide variability in the recommended use of splinting internationally

3.2 Hypotheses

1. Splinting following Dupuytren's contracture release will result in greater finger extension by three months than not splinting
2. Not splinting following Dupuytren's contracture release will result in greater finger flexion and function by three months than splinting
3. Not splinting will result in fewer hand therapy appointments by three months than splinting.
4. Not splinting will result in greater grip strength by three months than splinting

3.3 Significance of the study

Dupuytren's contracture is a pathological condition of the hand not related to injury. For this reason, surgery for Dupuytren's contracture in New Zealand is not covered by ACC (Accident Compensation Corporation), a government funded accident insurance scheme, but is provided through local District Health Board funding. Much of this surgery in the Auckland region is provided by the CMDHB Regional Hand Service. Hand therapy for patients undergoing surgery through CMDHB is also not funded through ACC. Patients therefore typically attend hand therapy at the Manukau Super Clinic, unless they choose to fund private hand therapy or the cost is covered by health insurance. Consequently, CMDHB carries much of the cost of postoperative hand therapy for patients undergoing this surgery.

Currently, CMDHB hand therapists are using a splinting protocol whereby all patients are placed in a night extension splint for three months postoperatively. This is based on physiological principles and common international practice rather than robust evidence. It is currently unknown whether it is overall more beneficial for patients to be splinted or not after surgery for Dupuytren's contracture release. The current practice means expensive resources, including thermoplastic splinting materials and therapist time are required to construct an individualised splint, with further appointments being required to monitor the splint and make adjustments as needed.

The findings from this study may show that splinting is effective in maintaining extension following Dupuytren's contracture release surgery without deleterious effects on finger flexion and hand function. Conversely, results may show that splinting adds no benefit to outcomes regarding finger extension. If this is demonstrated then patients will not need to undergo the intrusion and inconvenience of splinting which may result in less finger stiffness and thereby decrease the need for hand therapy to treat this problem. Additionally, patients may be able to return to work, leisure occupations and usual daily activities much sooner, resulting in less time off work and/or less dependence on health services such as home help. Importantly, financial savings may be made for CMDHB with regards to splinting materials and the therapy time required for splint construction and subsequent monitoring of this therapeutic modality.

The findings from this study will therefore add important knowledge to the body of evidence on postoperative rehabilitation of fasciectomy for Dupuytren's contracture. This will enable hand therapists to make decisions based on scientific evidence with regards to whether splinting following Dupuytren's contracture release is beneficial or not.

Chapter 4. Research Methods

4.1 Design and subjects

4.1.1 Design

A randomised, prospective, parallel group comparative study was conducted to evaluate the effect of extension splints worn for three months at night on finger range of motion, hand function and patient satisfaction. Between September 2010 and June 2011, 136 patients were placed on the Counties Manukau District Health Board (CMDHB) Hand Service waiting list for surgical release of Dupuytren's contracture. A total of 56 patients were randomised at their first postoperative hand therapy appointment into a group who received or did not receive a night extension splint. Both groups received a standard hand therapy programme delivered by a hand therapist. Data collection was undertaken at the hand therapy unit of CMDHB, an outpatient clinic co-located with the hand surgical service.

4.1.2 Ethics

A national ethics application was submitted to the Northern X Regional Ethics committee and approved on 20th August 2010 (Appendix B). A 12 month extension was granted on the 27th October 2011 (Appendix C). Approval was granted by the Auckland University of Technology Ethics Committee (AUTEC) on the 22 November 2011 (Appendix D). All participants received a participant information sheet (Appendix E) explaining the study. The study was also explained by the investigator(s) via a telephone call or at the pre-admit appointment and participants were given the opportunity to ask questions and clarify requirements of the study. Signed consent (Appendix F) was gained prior to surgery, however patients were free to withdraw from the study at the first hand therapy appointment if they wished.

The main ethical consideration was the risk of participants in the no splint group losing finger extension. The following clause, based on the protocol by Jerosch-Herold et al. (2008) and in consultation with the CMDHB hand surgeons, was developed to ensure no harm to potential participants: participants in the no splinting group will be provided with a splint if they show a loss of extension greater than 20 degrees in a PIP joint or greater than 30 degrees in an MCP joint compared to the baseline measurement.

The treating therapist took weekly range of motion measures and if any loss of extension was noted then the primary assessor was called to check measures and a splint was provided if the above threshold was reached.

4.1.3 Participants and setting

The following criteria were defined to identify eligible participants:
Inclusion criteria

- Male and female patients included
- Age range from 18-95 years
- Dupuytren's contracture release on one or more fingers
- Attended hand therapy within 14 days of surgery
- Can keep follow up appointments
- Ability to understand instructions for exercise and splinting programme
- Fasciectomy or dermofasciectomy with or without skin grafting, providing the aforementioned criteria were met
- Ability to provide written, informed consent

Exclusion criteria

- Impaired comprehension as a result of dementia or intellectual disability
- K-wiring of PIP joint intra-operatively
- Any other factor which in the opinion of the investigators or surgeon made the patient unsuitable for inclusion in the study
- Refusal to provide written, informed consent

Participants were recruited from the CMDHB waiting list for surgical release of Dupuytren's contracture. It was estimated that 49 patients would be recruited over a time period of nine months based on previous surgical rates determined from the Hand Service database. All patients who met the entry criteria for the study were invited to participate at the time they were placed on the surgical waiting list. The patient information sheet was given to potential participants at their clinic appointment at CMDHB or was subsequently posted to them. Once a surgical date was appointed a follow-up phone call was made to further explain the study, obtain interest in participation and arrange a hand therapy appointment to take preoperative

measures. At this appointment the consent form was signed by those patients willing to participate. The study was conducted in the CMDHB outpatient hand therapy clinic which provides hand therapy for a wide range of hand injuries, pathologies and surgeries. This clinic is part of the CMDHB Plastic Reconstructive and Hand Surgery Service which is one of the four regional plastic surgery centres in New Zealand.

4.2 Measurements

The primary outcome was total active extension (TAE) of the little finger which was a sum of active MCP, PIP and DIP joint extension.

Secondary outcomes were:

- Total active flexion (TAF) of the little finger: (MCP+PIP+DIP joint flexion)
- TAE and TAF of the middle and ring fingers
- Composite finger flexion (ADPC)
- Grip strength as measured by a Jamar dynamometer
- Hand function as measured by the self report DASH questionnaire
- Number of hand therapy appointments attended within three months
- Patient satisfaction as measured by the Likert Scale (part three of the standardised Patient Evaluation Measure (PEM) questionnaire)
- Splint adherence; calculated as a percentage of the total number of nights the splint was worn over three months

Measures were taken at differing time frames as shown in Table 6. It was not considered reasonable to take grip strength and hand function measures at the first postoperative appointment due to the early stage of wound healing. All range of motion measurements were taken at the first postoperative appointment, at six weeks and at three months. Measures were taken by one named therapist in order to increase the reliability of measures. In isolated cases where that assessor was unavailable to take measures one of two allocated therapists took measures. Training sessions were held with all three assessors to standardise measurement technique and minimise inter-rater error.

Three months was selected as a suitable follow-up period as the study was particularly interested in the effect of splinting during the phase the splints were worn, and when

loss of finger range of motion is likely to be most evident i.e., in the three months following surgery. This relatively short follow-up was also supported as being appropriate by Larson and Jerosch-Herold in a 2008 systematic review.

Table 6: Data collection timeline

	Preoperatively	1st postoperative visit	6 weeks	3 months
TAE and TAF	✓	✓	✓	✓
MCP, PIP, DIP flexion and extension	✓	✓	✓	✓
ADPC	✓	✓	✓	✓
Grip strength	✓		✓	✓
Hand function	✓		✓	✓
Number of hand therapy appointments				✓
Patient satisfaction				✓
Splint adherence		✓	✓	✓

4.2.1 Range of motion

Goniometry was used to measure finger range of motion of the MCP, PIP and DIP joints according to a standard protocol. The finger was measured in composite active finger extension (Figure 9) for all extension measures, and composite finger flexion (Figure 10) for all flexion measures with the goniometer placed on the dorsal aspect of the finger, according to the procedure described by the American Society of Hand Therapists (ASHT) (1992). Flexion and extension of the fingers was measured with a standard metal finger goniometer for the MCP and PIP joints, and with a plastic finger goniometer with a short mobile arm for the DIP joints (Figure 11). Joint range was recorded in degrees for each joint respectively. Extension and flexion of the MCP, PIP and DIP was summed to give a total active extension (TAE) and flexion (TAF) measure as used by Jerosch-Herold et al. (2011). In addition, a measure of composite finger flexion was taken in centimetres using a plastic goniometer, from the distal palmar crease of the palm to the distal corner of nail bed as described by Ellis and Bruton (2002) (Figure 12) and is referred to as ADPC (active distal palmar crease). ADPC has been shown to be a useful measure of total finger flexion and with good reliability where a single rater is used (Ellis & Bruton, 2002).

Figure 9: Measuring finger extension with a standard finger goniometer

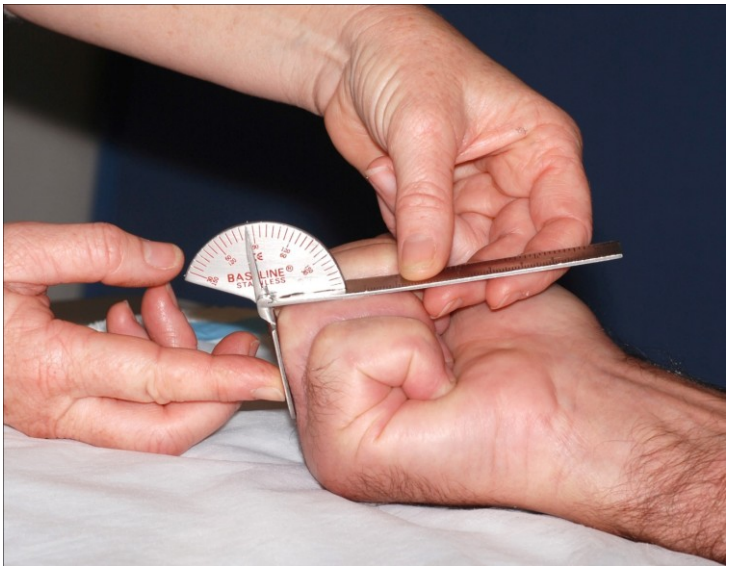

Figure 10: Measuring finger flexion with a standard metal finger goniometer

Figure 11: Measuring the DIPJ with a plastic goniometer

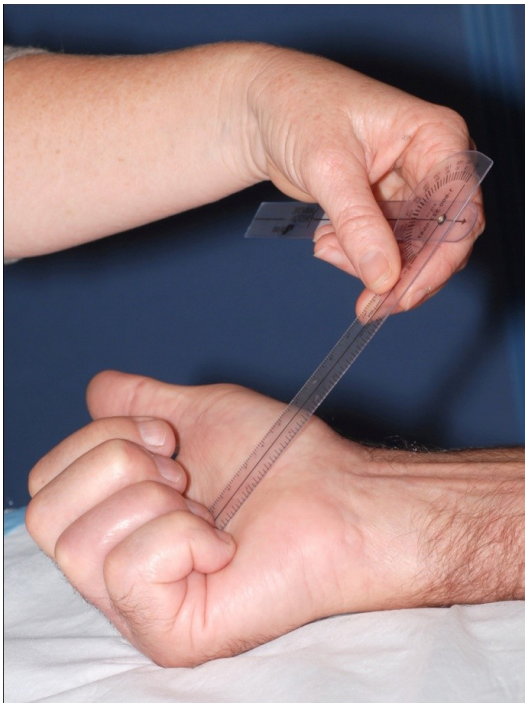

Figure 12: Measurement of composite finger flexion in cm (ADPC)

4.2.2 Grip strength

Grip strength was measured in kilograms with a Jamar dynamometer (Figure 13). Testing was conducted according to the procedure described by Seftchick et al. (2011) whereby the patient is seated, the forearm is in neutral rotation and the elbow is flexed to 90 degrees. The dynamometer was set at the second spacing and the patient was asked to grip maximally. The test was repeated three times alternately for each hand at a rate paced to eliminate fatigue. The average of three measures was taken

for the final score. Grip strength has been claimed to correlate well with hand function (Cox, et al., 2006; Marmon, Pascoe, Schwartz, & Enoka, 2011) but has also been criticised as being an overly simplistic measure of hand function, which may not adequately represent the complexity of hand function (Tyler, Adams, & Ellis, 2005). Grip strength has been used in previous Dupuytren's studies to evaluate therapeutic and surgical outcomes (Glassey, 2001; Zyluk & Jagielski, 2007) and may add useful information in determining any differences between patients who do or do not receive a splint postoperatively.

Figure 13: Jamar dynamometer for measurement of grip strength

4.2.3 Hand function

The Disabilities of the Arm, Shoulder and Hand (DASH) was used to measure hand function. The DASH is a 30-item self-report questionnaire with scores ranging from 0 to 100 where lower scores represent better hand function (Gummesson, Atroshi, & Ekdahl, 2003) (Appendix G). The DASH is used widely in Dupuytren's research making it useful in comparing outcomes with other studies and has been validated in the Dupuytren's population (Wong, Fung, Chu, & Chan, 2007). A 10-point difference is considered as a minimal important change. Construct validity has been established with the DASH correlating strongly with the Sollerman Hand Function test (r_s = -0.887)

(Dalbeth, et al., 2007), the Upper Limb Functional Index (r = 0.78) (Gabel, Michener, Burkett, & Neller, 2006) and the Michigan Hand Outcome Measure (r = 0.82) (Dias, Rajan, & Thompson, 2008). It has been criticised as being insufficiently sensitive to detect small changes in hand function and may be limited by recall bias (Gummesson, et al., 2003), however the DASH is quick to administer, does not require assessor training and has acceptable validity (Pratt & Byrne, 2009; Prosser & Conolly, 1996). The DASH was used as the primary outcome measure in a 2011 RCT investigating the effects of splinting following Dupuytren's fasciectomy (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al.). It was therefore considered to be an appropriate measure of hand function which is easy to administer in the clinical setting and would allow comparison of findings with similar studies.

4.2.4 Number of hand therapy appointments

The total number of hand therapy appointments attended within three months was recorded. Any non attendance was also recorded for each participant.

4.2.5 Patient satisfaction

Outcomes of therapeutic interventions should not only evaluate the effects of the interventions but the degree to which the patient was satisfied with that outcome. Patient satisfaction was measured by part three of the Patient Evaluation Measure (PEM) questionnaire (Dias, Bhowal, Wildin, & Thompson, 2001). This is a three part validated self-report questionnaire developed to measure severity of symptoms, disability and overall patient satisfaction in hand disorders (Dias, et al., 2001; Dias, et al., 2008) (Appendix H). Part one deals with satisfaction of the medical treatment received and part two with symptoms and functional aspects. Part three relates particularly to satisfaction with final outcomes. It has been used in previous Dupuytren's outcomes research (Dias & Braybrooke, 2006) and it was considered that the PEM (part three) may identify any differences in patient perceptions of outcome satisfaction between the no splint and splint groups.

4.2.6 Splint compliance

In order to evaluate the effect of any splinting intervention it is important to determine whether the splints are actually worn by participants as instructed and the effect that adherence has on the final outcomes. Studies have demonstrated

variability in rates with which splints are worn as recommended (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011; Sandford, Barlow, & Lewis, 2008) and may be influenced by splint comfort, lack of understanding the reasons for needing a splint and intrusion into daily activities (Pratt & Byrne, 2009; Sandford, et al., 2008). No known standardised means of measuring compliance has been described in the literature, however various methods are discussed including: subjective report, interview, daily diaries, questionnaires and ordinal scales (Jerosch-Herold, et al., 2008; Rannou, et al., 2009; Rives, et al., 1992; Sandford, et al., 2008). Splint adherence was measured in this study by asking patients to complete a daily diary indicating the number of nights the splint was worn each week (Appendix I). The number of nights the splint was worn over three months was then converted to a percentage to give a final score of compliance.

4.3 Procedures

4.3.1 Randomisation

Participants were allocated to one of two treatment groups at the first postoperative hand therapy appointment which occurred within the first two weeks following surgery:

Group A: Night extension splinting plus standard hand therapy

Group B: Standard hand therapy

Randomisation occurred by the participant selecting a tag from an envelope with group allocation concealed. Participants followed the therapy programme as per group allocation.

4.3.2 Intervention

Patients were allocated to a hand therapist once a postoperative referral was received from the operating surgeon. There was no attempt to randomise therapist allocation or to assign to any particular therapist preferentially. Therapist allocation was based on availability of appointments or to the therapist assigned to the clinic on the day of referral. The therapist was either a New Zealand registered hand therapist or an occupational or physiotherapist working under the supervision of a registered hand therapist. Participants in the splint group received a splint custom-fabricated by a therapist at the first postoperative appointment. The splint was moulded on the

dorsal surface of the hand holding the operated finger(s) in maximal comfortable extension without placing undue tension on the wound(s) and held in place by velcro straps (Figure 5 and Figure 6). The degree of finger extension differed for each patient depending on the surgical correction gained. The patients were instructed to apply the splint while sleeping and remove it during the daytime. The splint was adjusted at each appointment for comfort if necessary. Once wound healing occurred, the splint was adjusted to apply greater extension force to the operated finger(s) if the therapist deemed this necessary, in an attempt to gain greater finger extension. This practice was in accordance with the treatment protocol at the CMDHB hand therapy unit.

Extension of the finger was measured at each hand therapy appointment. With respect to the no splint group, if a loss of greater than 20 degrees in a PIP joint or 30 degrees in an MCP joint compared to the baseline measurement was found, the patient was provided with a night extension splint.

Both groups were followed up in the Hand Therapy Clinic and all participants received standard hand therapy which included any or all of the following treatments:

- Active tendon gliding range of motion exercises from the first hand therapy appointment. Patients were instructed to carry out five to ten repetitions every one to two hours during waking hours (Appendix J) (all patients)
- Education regarding the rehabilitation programme
- Wound care
- Oedema management
- Scar management
- Functional goal setting
- Passive stretch with or without heat to increase finger extension and/or flexion
- Intermittent use of daytime dynamic finger extension splint
- Grip and upper limb strengthening
- Graded return to normal daily activities

4.4 Statistical analysis

4.4.1 Sample size justification

An audit (Collis & Collocott, 2009) was conducted on a cohort of patients who all received splinting following surgical release of Dupuytren's contracture and of whom 75% had surgery on the little finger. Finger extension was measured at three months using a composite finger extension scale (MCP + PIP joint degrees of extension). The mean and standard deviation of little finger extension in degrees was 23(16).

A power analysis was undertaken based on this audit whereby the same standard deviation was assumed for groups receiving and not receiving a splint. It was established that a minimum of 21 patients would be needed in a splint and 21 in a no splint group to detect a clinically significant difference of 20 degrees (taking the known measurement error of five degrees for each joint into account) (Ellis & Bruton, 2002) at a 0.05 significance level with 90% power. Based on clinical experience it was estimated that up to 25% of patients may lose extension after surgery and would need to be provided with a splint. This would only be known following randomisation. It was therefore determined that 28 patients would be recruited to the no splint group to account for any group allocation swapping. Sample sizes were adjusted for a possible 10% dropout rate.

4.4.2 Data management

All data were entered by two investigators to account for entry error. A 100% completeness of data collection was achieved during the study for both baseline data and all postoperative measures despite one death and two losses to follow-up.

4.4.3 Data analysis

The distribution of patients' characteristics and preoperative clinical measurements between groups are presented in tabulated format, as recommended by the most recent CONSORT (Consolidated Standards of Reporting Trials) statement for reporting of parallel group RCTs (Moher, et al., 2010).

Two sample t test or Mann Whitney U test was used to assess if there were significant differences in finger range of motion, grip strength, hand function and patient satisfaction between the two treatment groups at three months postoperatively.

A mixed effect repeated measure analysis of variance (ANOVA) was applied to assess if there were significant differences in the main outcomes between groups from the first postoperative visit to three months and was adjusted for preoperative measurements and clinical factors (age, sex, type of surgery, dominance, skin graft). Mixed effect repeated measure analyses were used to account for the dependency in the outcome data from multiple postoperative visits, where random intercept of each patient was used in the models (Laird & Ware, 1982; McLean, Sanders, & Stroup, 1991). Treatment allocation and clinical factors were treated as fixed effects in the model. The interactions between visit and treatment were also evaluated in the mixed effect model.

The primary analysis was based on the intention-to-treat (ITT) principle whereby patients were analysed according to the group they were randomly allocated. No imputations were applied in the analysis. A secondary per protocol analysis was performed based on the treatment that patients actually received and only including those with a splint compliance rate of greater than 50%. This included patients from the no splint group who met the threshold for requiring a splint subsequent to randomisation.

All tests were two tailed and the statistical significance level was set at 0.05. All analyses were conducted by SAS 9.3 released by the SAS institute Inc. Cary, NC, USA.

Chapter 5. Results

5.1 Patients

Figure 14 outlines the flow of patients through the study. A total of 136 patients were placed on the surgical waiting list for Dupuytren's contracture release during the recruiting period between September 2010 and June 2011 and were invited to participate. Of these patients, 56 were included in the study and 80 were excluded. Reasons for exclusion are detailed in Figure 14. Of the 56 patients who were enrolled, 26 were allocated to the splint group and 30 to the no splint group. The intervention phase of the study took place between September 2010 and December 2011. Measurements were taken prior to surgery (mean 21 days), at the first postoperative hand therapy visit (mean 7 days), six weeks postoperatively (mean 44 days), and three months postoperatively (mean 89 days). A total of 12 different surgeons performed either fasciectomy or dermofasciectomy.

Baseline demographics and clinical characteristics of the participants are presented in Table 7 demonstrating a relatively equal spread of patient characteristics. Of note, all the left hand dominant patients were in the no splint group (n=5) and the no splint group had a higher proportion of the left hand operated than the splint group (60% and 46% respectively). Both groups had similar proportions in surgical types and skin graft. The no splint group had fewer patients with middle fingers operated than the splint group (17% and 31% respectively). Preoperative range of motion, grip strength and hand function are shown in Table 8. Both groups had similar measurements prior to surgery except for the LF and MF which had greater preoperative extension deficit in the no splint group.

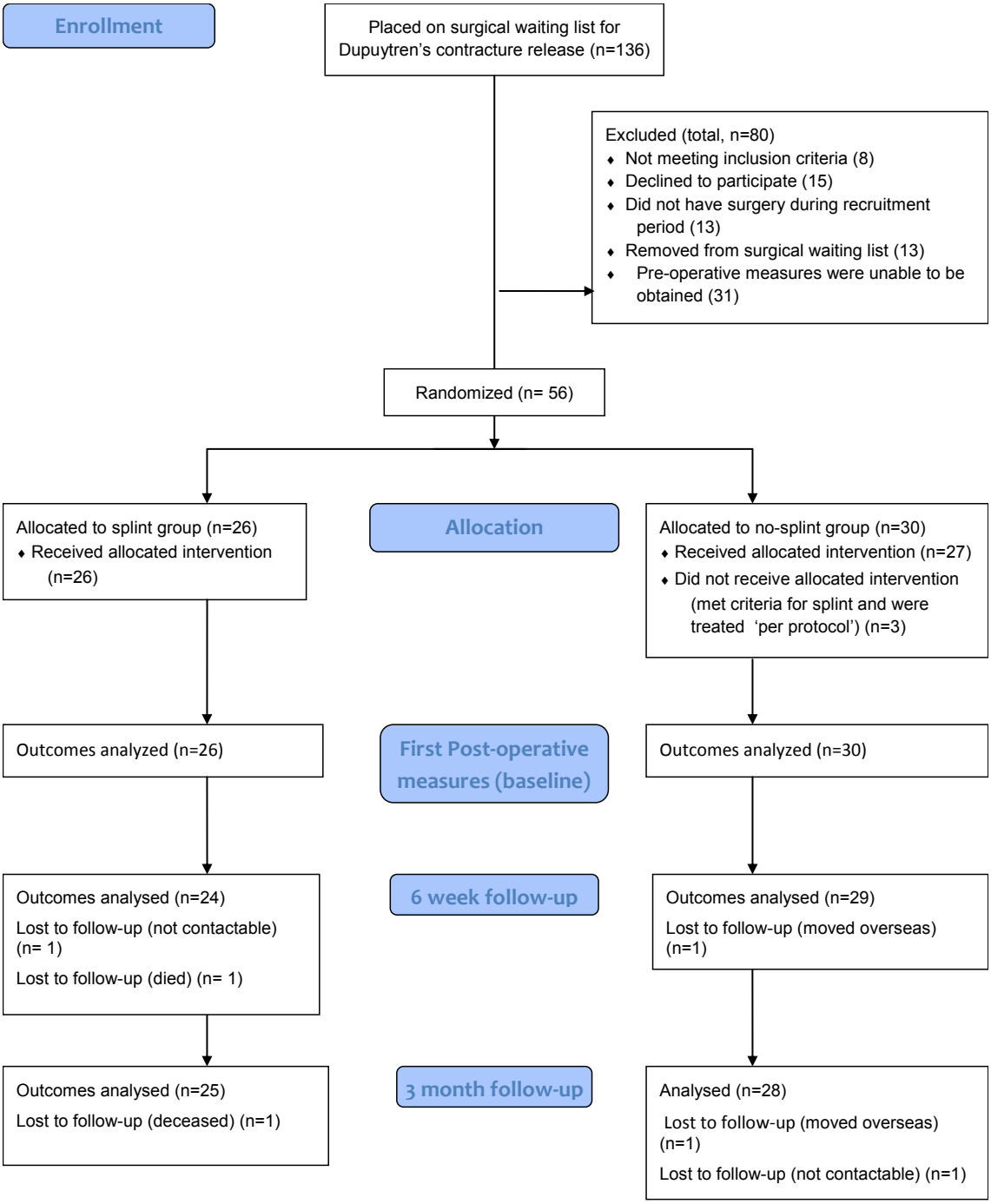

Figure 14: Flowchart of study

Table 7: Baseline characteristics

		No splint (n=30)	Splint (n=26)
Age	Mean (SD)	67(9)	68(8)
Gender	Ratio male:female	23:7	22:4
Ethnicity	NZ European: number(percentage)	23 (77%)	18 (69%)
	Other European	6(20%)	7(27%)
	Fijian	0(0%)	1(4%)
	Indian	1(3%)	0(0%)
Operated hand	Left	18(60%)	12(46%)
	Right	12(40%)	14(54%)
Operated digits	Little fingers (LF)	22 (73%)	21 (81%)
	Ring fingers (RF)	11(37%)	11 (42%)
	Middle fingers (MF)	5 (17%)	8 (31%)
No. of operated digits	One	22(73%)	17(65%)
	Two	8(27%)	5(19%)
	Three	0(0%)	4(15%)
Dominance	Left	5(18%)	0(0%)
	Right	23(82%)	26(100%)
Surgery type	Dermofasciectomy	3(10%)	3(12%)
	Fasciectomy	27(90%)	23(88%)
Skin graft	Full thickness skin graft	4(13%)	3(12%)

Table 8: Preoperative measures: mean (SD)

	No splint	Splint
Little finger	n=22	n=21
TAE (degrees)	92.1(44.0)	80.0(30.4)
TAF (degrees)	233.3(24.6)	241.8(14.6)
ADPC (cm)	1.4(1.0)	1.3(0.9)
Ring finger	n=11	n=11
TAE	64.1(29.7)	73.3(42.2)
TAF	240.9(16.1)	230.0(11.3)
ADPC	1.4(0.7)	2.0(0.9)
Middle finger	n=5	n=8
TAE	70.6(15.3)	58.9(24.0)
TAF	248.2(18.1)	242.4(11.2)
ADPC	0.8(0.8)	1.8(0.4)
	n=30	n=26
Grip strength left	32.3(10.9)	31.2(7.9)
Grip strength right	33.2(13.6)	31.2(10.3)
DASH	13.2(14.4)	14.0(12.4)

5.2 Operational outcomes

The data presented in Table 9 to Table 12 show the results for range of motion, grip strength and hand function from the primary analysis. Outcomes of the two groups were compared for each finger separately: 43 patients had operations on their little fingers, 22 on the ring finger and 13 on the middle finger. The range of motion outcomes (TAE, TAF and ADPC) were measured preoperatively and postoperatively and are related to the fingers that had surgery. Grip strength, DASH and patient satisfaction were measured for all patients. There were no statistically significant differences between the no splint and splint groups in any of the outcomes in the primary analysis. It was observed however that the no splint group showed slightly superior results across all measures in both the ITT and per protocol analyses.

Table 9 presents the results of finger range of motion from the primary analysis (ITT). The differences in the unadjusted means between groups are shown for each postoperative visit. There was no statistically significant difference in the primary outcome of LF TAE at three months. Equally there were no statistically significant differences in any of the range of motion measures for the ring and middle fingers. The unadjusted mean difference for LF TAE at three months was -4.6(35.9), p=0.68 (Figure 15) and for LF TAF was 9.6(29.4), p=0.68 (Figure 16). For LF ADPC the difference was -0.2(1.0), p=0.49) (Figure 17).

Table 10 presents the difference in the means, adjusted for preoperative measurements and clinical factors, averaged across the three postoperative visits. The results from this mixed effect model also showed no statistically significant differences in any of the LF range of motion outcomes. The adjusted mean difference between groups for LF TAE was -9.8^{o} (se: 5.3, p=0.07); for LF TAF was 12.7 ^{o} (se: 7.4, p=0.08) and -0.21 cm (se: 0.27, p=0.44) for LF ADPC. For patients who had ring finger surgery, the two groups also did not show statistically significant differences in their TAE, TAF and ADPC. The adjusted mean differences were 0.7^{o} (se: 6.3, p=0.92), 12.1^{o} (se:11.3, p=0.29), and -0.21cm (se: 0.56, p=0.71) respectively.

Table 9: Comparison of range of motion between groups at each postoperative visit (ITT)

Data presented are unadjusted means(SD)	No splint	Splint	Difference	p value
1st postoperative visit				
	n=22	n=21		
LF TAE (degrees)	31.4(18.0)	33.1(19.9)	-1.7(19.0)	0.77
LF TAF (degrees)	125.2(32.9)	114.5(32.2)	10.7(32.6)	0.29
LF ADPC (cm)	5.3(1.6)	5.5(1.2)	-0.2(1.4)	0.72
	n=11	n=11		
RF TAE	37.5(10.3)	34.4(25.3)	3.1(19.3)	0.71
RF TAF	127.1(31.0)	124.5(35.5)	2.6(33.3)	0.85
RF ADPC	6.2(1.6)	6.0(2.0)	0.2(1.8)	0.84
	n=5	n=8		
MF TAE	33.6(17.9)	36.3(12.0)	-2.7(14.5)	0.75
MF TAF	120.6(21.7)	135.5(24.8)	-14.9(23.8)	0.29
MF ADPC	7.8(0.1)	6.4(1.4)	1.4(1.1)	0.03
6 weeks				
	n=21	n=19		
LF TAE	31.2(28.0)	31.8(23.3)	-0.60(25.9)	0.94
LF TAF	221.5(19.5)	206.5(34.5)	15.0(27.7)	0.11
LF ADPC	1.9(0.8)	2.2(1.2)	-0.2(1.0)	0.46
	n=11	n=10		
RF TAE	31.2(21.8)	32.9(15.3)	-1.7(19.0)	0.84
RF TAF	224.9(24.3)	197.5(36.3)	27.4(30.6)	0.05
RF ADPC	2.0(1.2)	2.6(1.7)	-0.6(1.5)	0.39
	n=5	n=7		
MF TAE	29.0(18.5)	32.6(22.8)	-3.6(21.1)	0.78
MF TAF	230.8(21.8)	214.7(19.6)	16.1(20.5)	0.21
MF ADPC	2.0(1.0)	2.5(0.8)	-0.5(0.9)	0.40
3 months				
	n=20	n=20		
LF TAE	33.3(34.2)	37.9(37.5)	-4.6(35.9)	0.68
LF TAF	229.3(22.1)	219.7(35.2)	9.6(29.4)	0.68
LF ADPC	1.7(0.8)	1.9(1.1)	-0.2(1.0)	0.49
	n=11	n=11		
RF TAE	23.5(23.5)	28.3(22.4)	-4.7(23.0)	0.63
RF TAF	232.0(18.2)	208.2(35.9)	23.8(28.5)	0.07
RF ADPC	1.6(1.0)	2.5(1.8)	-0.82(1.4)	0.20
	n=5	n=7		
MF TAE	29.6(35.5)	25.7(17.5)	3.9(26.3)	0.80
MF TAF	245.0(15.9)	216.4(27.7)	28.6(23.7)	0.07
MF ADPC	1.3(0.5)	2.4(1.6)	-1.1(1.2)	0.13

Table 10: Range of motion from mixed effect model averaged across postoperative visits (ITT)

data presented are least square means (adjusted by covariates)	Difference no splint vs. splint groups	se	lower of 95% confidence interval	upper of 95% confidence interval	p value
LF TAE (degrees)	-9.8	5.3	-20.19	0.59	0.07
LF TAF (degrees)	12.7	7.4	-1.8	27.2	0.08
LF ADPC (cm)	-0.21	0.27	-0.74	0.32	0.44
RF TAE	0.7	6.3	-11.67	13.01	0.92
RF TAF	12.1	11.3	-10.05	34.25	0.29
RF ADPC	-0.21	0.56	-1.31	0.9	0.71
MF TAE	-9.62	7.15	-23.69	6.88	0.23
MF TAF	4.51	9.3	-13.7	22.73	0.63
MF ADPC	0.04	0.69	-1.31	1.39	0.95

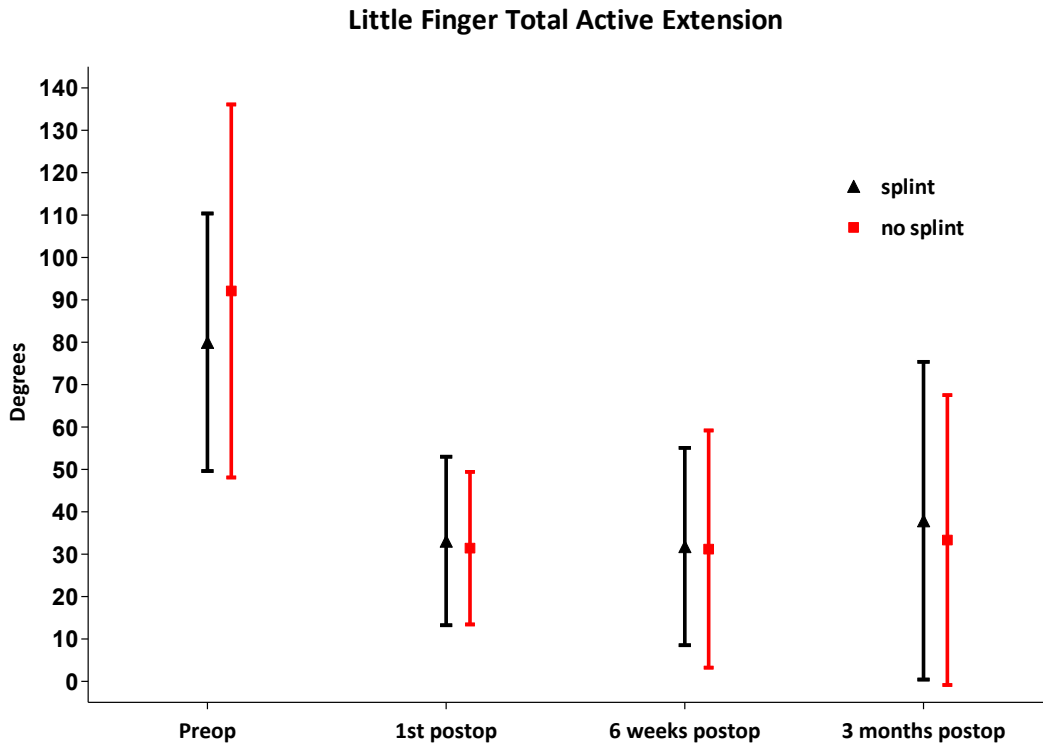

Figure 15: Comparison of LF TAE between groups at each visit (ITT): unadjusted means and 95% confidence intervals

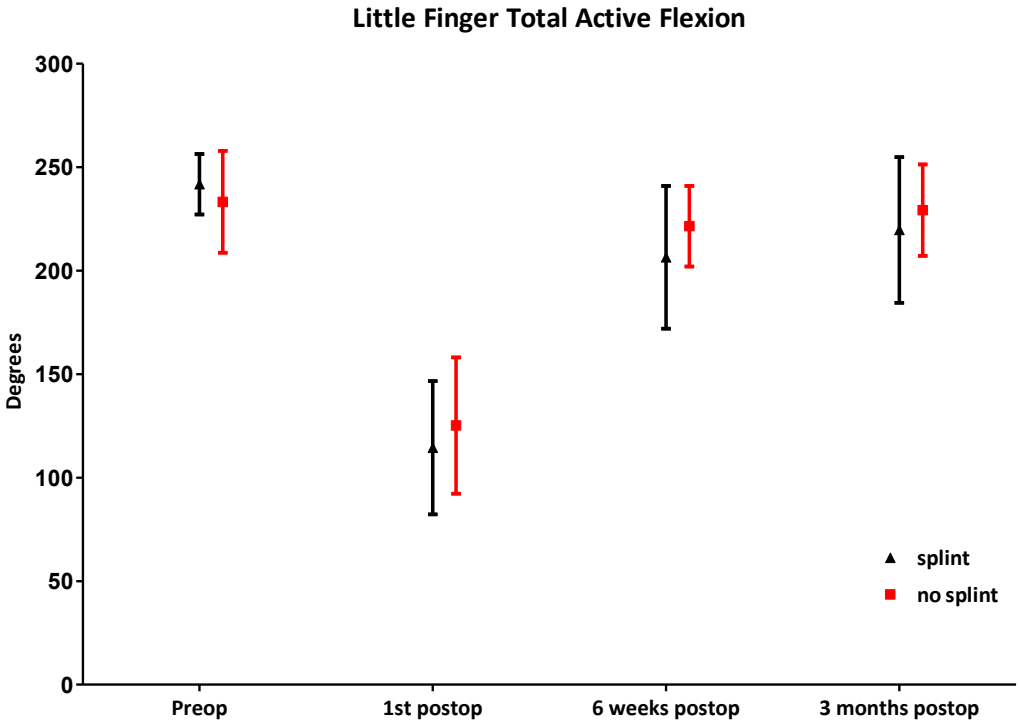

Figure 16: Comparison of LF TAF between groups at each visit (ITT): unadjusted means and 95% confidence intervals

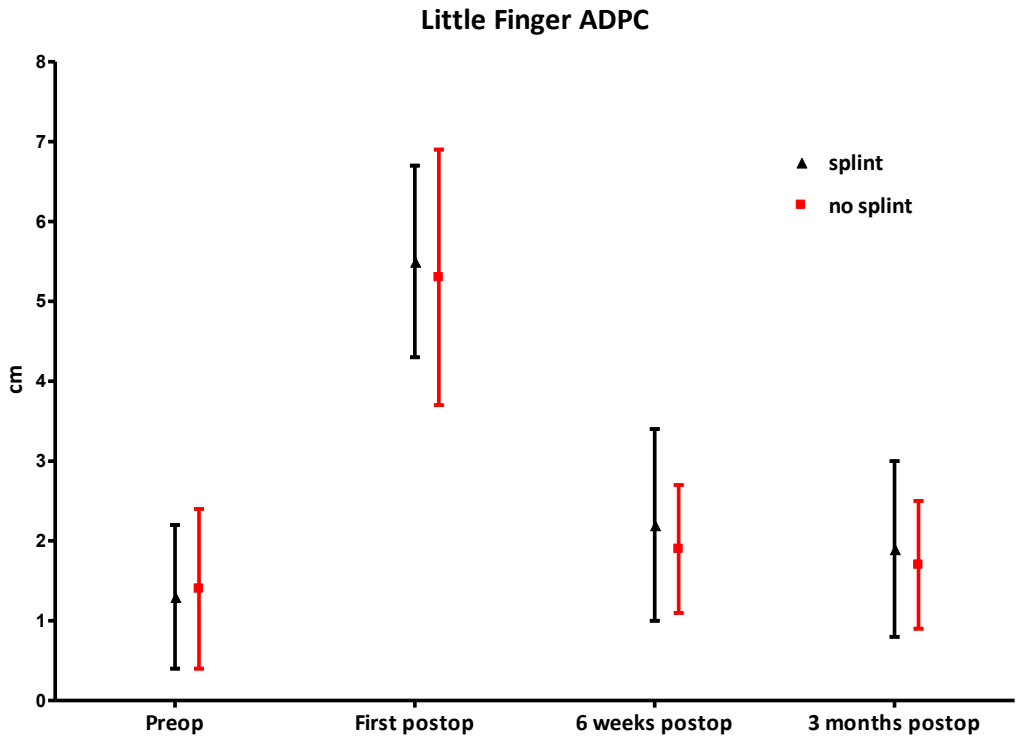

Figure 17: Comparison of LF ADPC between groups at each visit (ITT): unadjusted means and 95% confidence intervals

Table 11 and Table 12 show the results of grip strength and hand function. There was no statistically significant difference between the no splint and splint group for either of these outcomes. The unadjusted means for each postoperative visit are shown in Table 11 and the adjusted mean differences averaged across the three postoperative visits in Table 12. Figure 18 and Figure 19 represent the unadjusted mean differences between the groups of left and right hand grip strength.

Table 11: Comparison of grip strength and hand function between groups at each postoperative visit (ITT)

Data presented are unadjusted means(SD)	No splint	Splint	Difference	p value
6 weeks	n=29	n=24		
Grip strength left (kg)	27.3(12.9)	23.7(12.1)	3.5(12.6)	0.31
Grip strength right (kg)	29.9(11.0)	26.5(13.0)	3.4(11.9)	0.30
DASH (0-100)	12.2(9.0)	16.0(10.7)	-3.8(9.8)	0.16
3 months	n=28	n=25		
Grip strength left (kg)	29.6(12.7)	25.4(10.5)	4.2(11.7)	0.19
Grip strength right (kg)	32.7(12.5)	27.2(11.7)	5.5(12.1)	0.11
DASH (0-100)	10.8(16.2)	9.6(8.8)	1.1(13.3)	0.75

Table 12: Grip strength and hand function from mixed effect model averaged across postoperative visits (ITT)

data presented are least square means (adjusted by covariates)	Difference no splint vs. splint groups	se	lower of 95% confidence interval	upper of 95% confidence interval	p value
Grip strength left (kg)	2.6	2.1	-1.52	6.72	0.22
Grip strength right (kg)	2.5	1.6	-0.64	5.64	0.10
DASH (0-100)	-1.1	2.2	-5.41	3.21	0.59

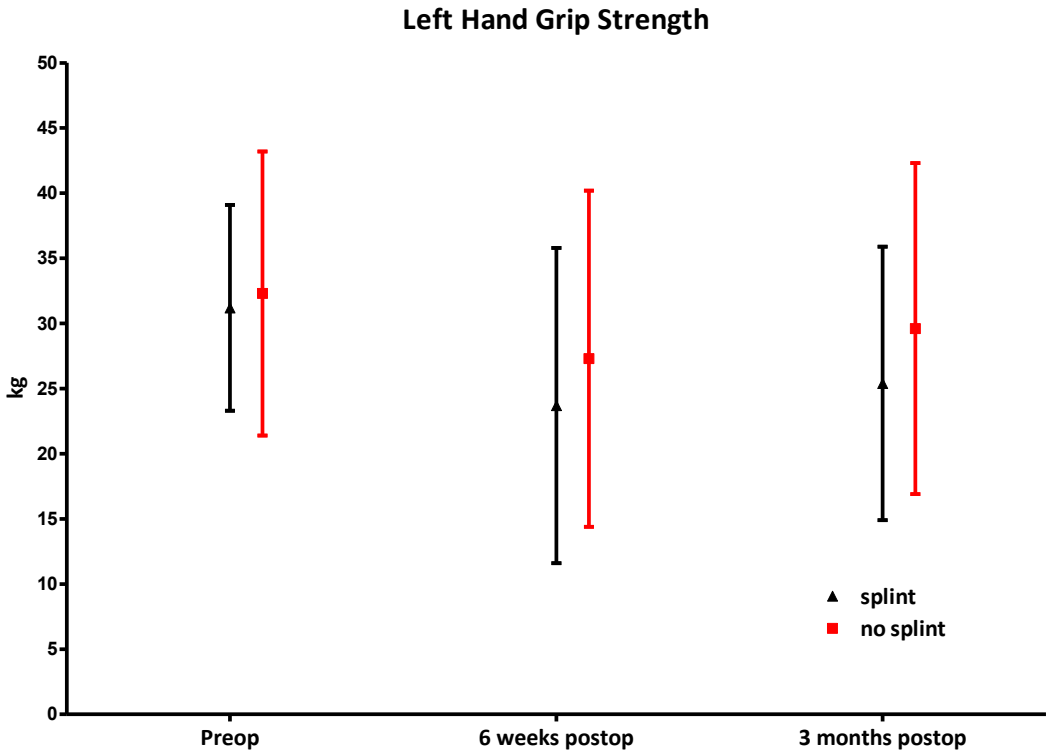

Figure 18: Comparison of left hand grip strength between groups at each visit (ITT): unadjusted means and 95% confidence intervals

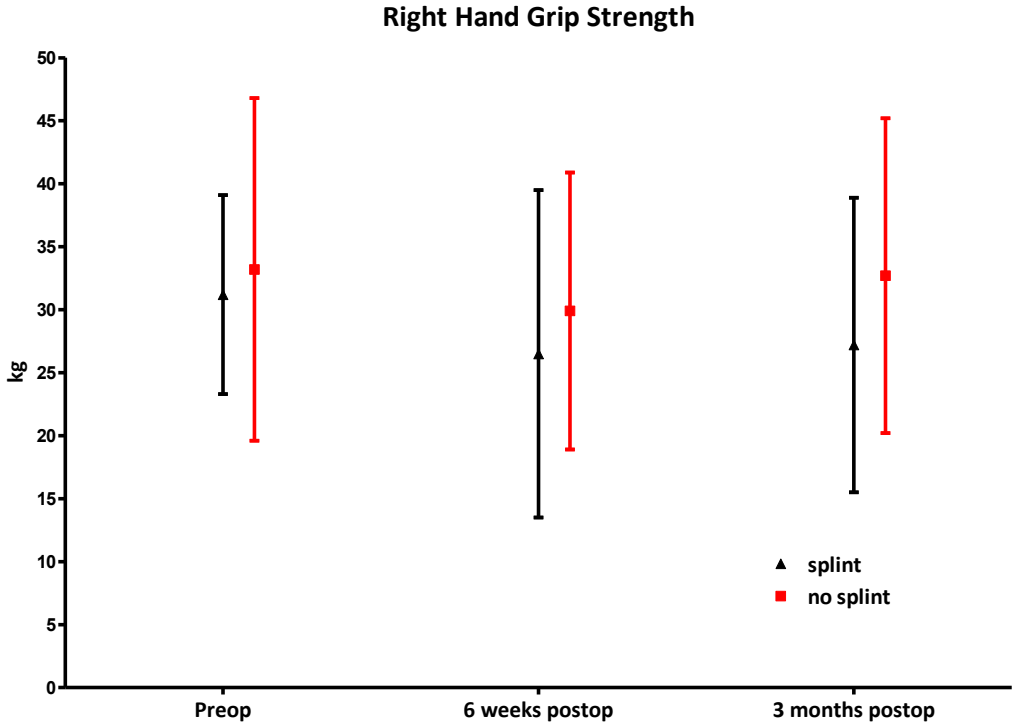

Figure 19: Comparison of right hand grip strength between groups at each visit (ITT): unadjusted means and 95% confidence intervals

There were also no statistically significant differences in the number of hand therapy visits between the two groups. The median number of hand therapy appointments was 7(IQR:6,9) for the splint group and 7(IQR:6,8) for the no splint group.

With respect to patient satisfaction 100% in the no splint group were satisfied with the treatment they received compared with 96% in the splint group. When considering satisfaction with the current state of their hand, results were 89% and 80% for the no splint and splint groups respectively. The results for question three regarding patient expectations showed that 82% in the no splint group compared with 72% in the splint group felt their hand was better than expected.

The mixed model analysis was also conducted to determine any effect of gender, age, surgery type, hand dominance and skin graft on LF range of motion, grip strength and DASH. Those patients who underwent dermofasciectomy (n=6, 11% of total sample) showed poorer little finger flexion in both measures of TAF and ADPC than those who underwent fasciectomy. This difference was statistically significant (p=0.006 and p=0.008).

A secondary per protocol analysis was conducted on all patients who had more than 50% compliance rate in the wearing of their splint. Compliance with splint wear was high with 94% of participants wearing the splint greater than 50% of the recommended time and only one patient wearing the splint for <50% of the recommended time. Three patients who had been allocated to the no splint group but were subsequently given a splint and whose compliance was >50% were included in the splint group analysis. Patients with compliance <50% were excluded from the analysis.

Table 13 and Table 14 present the results of the per protocol analysis for primary and secondary range of motion outcomes. Per protocol analysis revealed a similar result to the primary analysis in that there was no statistically significant difference in either the unadjusted or adjusted means for LF TAE between the no splint and splint groups. The adjusted mean difference for LF TAE between the groups was -9.78 (se: 5.66, p=0.09) (Table 14). No other outcomes were significantly different excepting LF TAE at visits two and three and these were in favour of the no splint group -17.6(24.7), p=0.03 and -22.2(33.9), p=0.03 respectively (Table 13).

Table 13: Comparison of range of motion between groups at each postoperative visit (per protocol)

Data presented are unadjusted means(SD)	No splint	Splint	Difference	p value
1st postoperative visit				
	n=18	n=22		
LF TAE (degrees)	28.0(16.3)	34.9(21.3)	-6.9(19.3)	0.27
LF TAF (degrees)	125.3(35.7)	115.1(31.8)	10.2(33.6)	0.34
LF ADPC (cm)	5.5(1.7)	5.4(1.2)	0.007(1.4)	0.99
	n=9	n=13		
RF TAE	35.7(10.3)	36.1(23.6)	-0.4(19.4)	0.96
RF TAF	117.4(24.8)	131.5(36.8)	-14.1(32.6)	0.33
RF ADPC	6.7(1.2)	5.7(2.0)	1.0(1.7)	0.18
	n=5	n=7		
MF TAE	33.6(17.9)	35.7(12.9)	-2.1(15.1)	0.82
MF TAF	120.6(21.7)	133.4(26.1)	-12.8(24.4)	0.39
MF ADPC	7.8(0.1)	6.4(1.5)	1.4(1.2)	0.05
6 weeks				
	n=17	n=21		
LF TAE	21.1(15.2)	38.8(30.2)	-17.6(24.7)	0.03
LF TAF	224.2(17.3)	206.3(33.7)	17.9(27.6)	0.05
LF ADPC	1.8(0.8)	2.2(1.2)	-0.4(1.0)	0.29
	n=9	n=12		
RF TAE	22.9(12.5)	38.8(19.9)	-15.9(17.1)	0.05
RF TAF	225.6(27.0)	201.6(34.3)	24.0(31.4)	0.10
RF ADPC	2.0(1.3)	2.5(1.6)	-0.5(1.5)	0.44
	n=5	n=7		
MF TAE	29.0(18.5)	32.6(22.8)	-3.6(21.1)	0.78
MF TAF	230.8(21.8)	214.7(19.6)	16.1(20.5)	0.21
MF ADPC	2.0(1.0)	2.5(0.8)	-0.5(0.9)	0.40
3 months				
	n=16	n=23		
LF TAE	21.4(15.7)	43.6(42.1)	-22.2(33.9)	0.03
LF TAF	231.4(22.3)	218.3(34.1)	13.1(29.7)	0.19
LF ADPC	1.6(0.8)	1.9(1.1)	-0.4(1.0)	0.29
	n=9	n=13		
RF TAE	15.9(16.1)	32.8(24.3)	-17.0(21.4)	0.08
RF TAF	232.9(20.0)	211.2(33.7)	21.7(29.0)	0.10
RF ADPC	1.6(1.0)	2.4(1.7)	-0.8(1.4)	0.24
	n=5	n=7		
MF TAE	29.6(35.5)	25.7(17.5)	3.9(26.3)	0.81
MF TAF	245.0(15.9)	216.4(27.7)	28.6(23.7)	0.07
MF ADPC	1.3(0.5)	2.4(1.6)	-1.1(1.2)	0.13

Table 14: Range of motion from mixed effect model averaged across postoperative visits (per protocol)

data presented are least square means (adjusted by covariates)	Difference no splint vs. splint groups	se	lower of 95% confidence interval	upper of 95% confidence interval	P value
LF TAE (degrees)	-9.78	5.66	-20.87	1.31	0.09
LF TAF (degrees)	11.83	7.73	-3.32	26.97	0.13
LF ADPC (cm)	-0.17	0.29	-0.73	0.39	0.56
RF TAE	1.18	6.28	-11.14	13.50	0.85
RF TAF	12.10	11.30	-10.05	34.25	0.29
RF ADPC	-0.21	0.56	-1.31	0.90	0.71
MF TAE	-11.74	8.23	-27.87	4.39	0.17
MF TAF	5.85	9.67	-13.10	24.80	0.55
MF ADPC	-0.02	0.73	-1.45	1.42	0.98

The results of grip strength and hand function are shown in Table 15 and Table 16. There was no statistically significant difference between the groups. The adjusted mean difference for grip strength of the left hand was 1.84kg (se 2.09, p=0.38) and for the right hand was 2.23kg (se 1.7, p=0.19). For the DASH, the score was -0.46(se: 2.19, p=0.83).

Table 15: Comparison of grip strength and hand function between groups at each postoperative visit (per protocol)

Data presented are unadjusted means(SD)	No splint	Splint	Difference	p value
6 weeks				
Grip strength left (kg)	27.3(13.2)	23.8(12.4)	3.5(12.8)	0.33
Grip strength right (kg)	30.1(11.1)	25.6(12.5)	4.5(11.7)	0.18
DASH (0-100)	11.9(9.0)	15.8(10.9)	-3.9(9.9)	0.17
3 months				
Grip strength left	29.8(12.8)	25.5(10.7)	4.3(11.9)	0.20
Grip strength right	33.0(12.6)	26.4(11.3)	6.5(12.0)	0.06
DASH	11.0(16.5)	9.7(9.0)	1.3(13.5)	0.72

Table 16: Grip strength and hand function from mixed effect model averaged across postoperative visits (per protocol)

data presented are least square means (adjusted by covariates)	Difference no splint vs. splint groups	se	lower of 95% confidence interval	upper of 95% confidence interval	P value
Grip strength left (kg)	1.84	2.09	-2.25	5.94	0.38
Grip strength right (kg)	2.23	1.69	-1.09	5.54	0.19
DASH (0-100)	-0.46	2.19	-4.76	3.84	0.83

The data were also evaluated to identify the overall number of little fingers that maintained extension between the first postoperative measure and three months postoperatively. Figure 20 illustrates the progression of finger extension between the first postoperative appointment and three months for all patients who had surgery to the little finger. The first measures were taken at a mean of 7 days (range 0-14 days) and the three month measures at a mean of 89 days (range 67-188), postoperatively. Of the 40 little fingers, 62.5% (25/40) had the same or better total finger extension at three months compared with the first postoperative appointment (mean 13°, range 0-39°). Loss of extension occurred in 37.5% 15/40 little fingers (mean 32°, range 5-96°). Figure 21 shows the progression of extension for the MCP joint and Figure 22 for the PIPJ. Of the 40 little finger MCP joints 72.5% (29/40) were the same or better (mean 6°, range 0-38°) compared with 52.5% (21/40) in the PIP joint (mean 7°, range 0-22°).

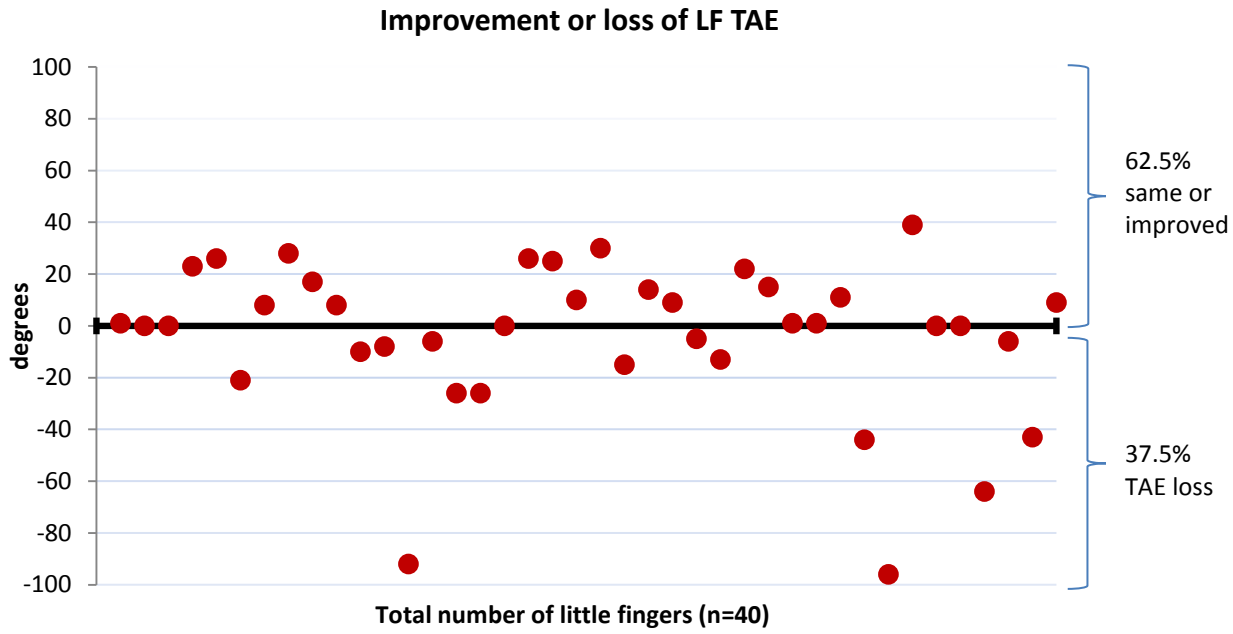

Figure 20: Difference in total active extension in degrees between the first postoperative visit and three months across all little fingers

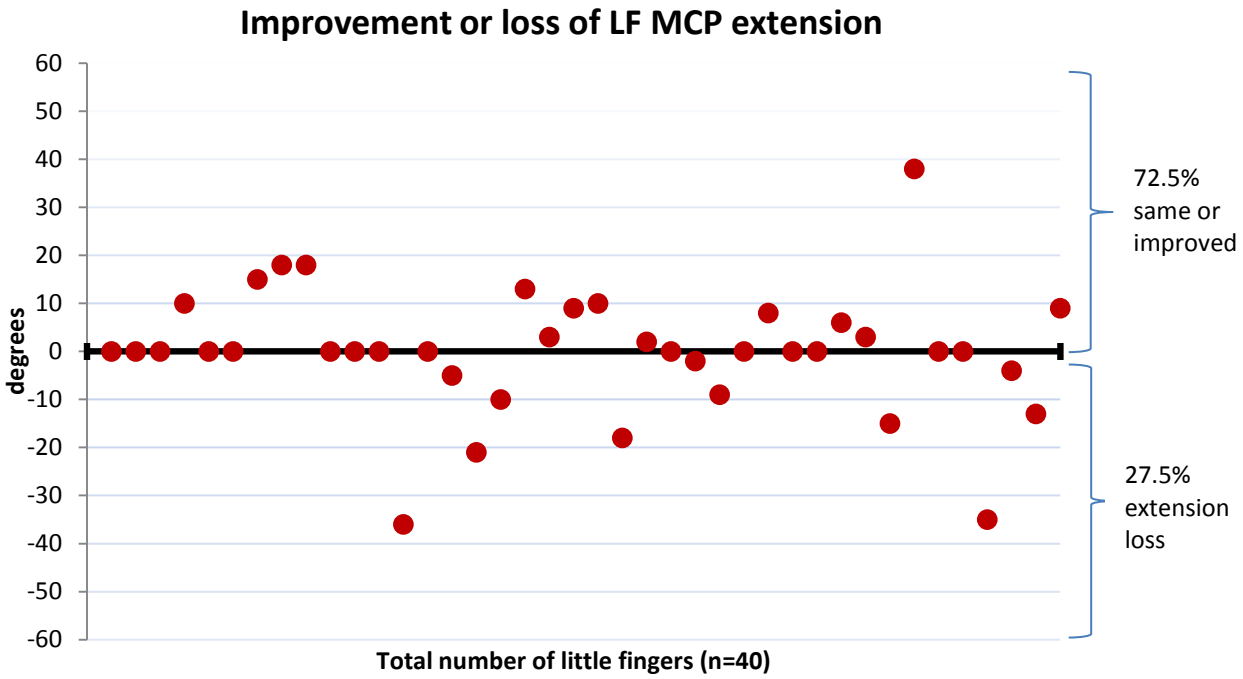

Figure 21: Difference in MCP extension in degrees between the first postoperative visit and three months across all little fingers

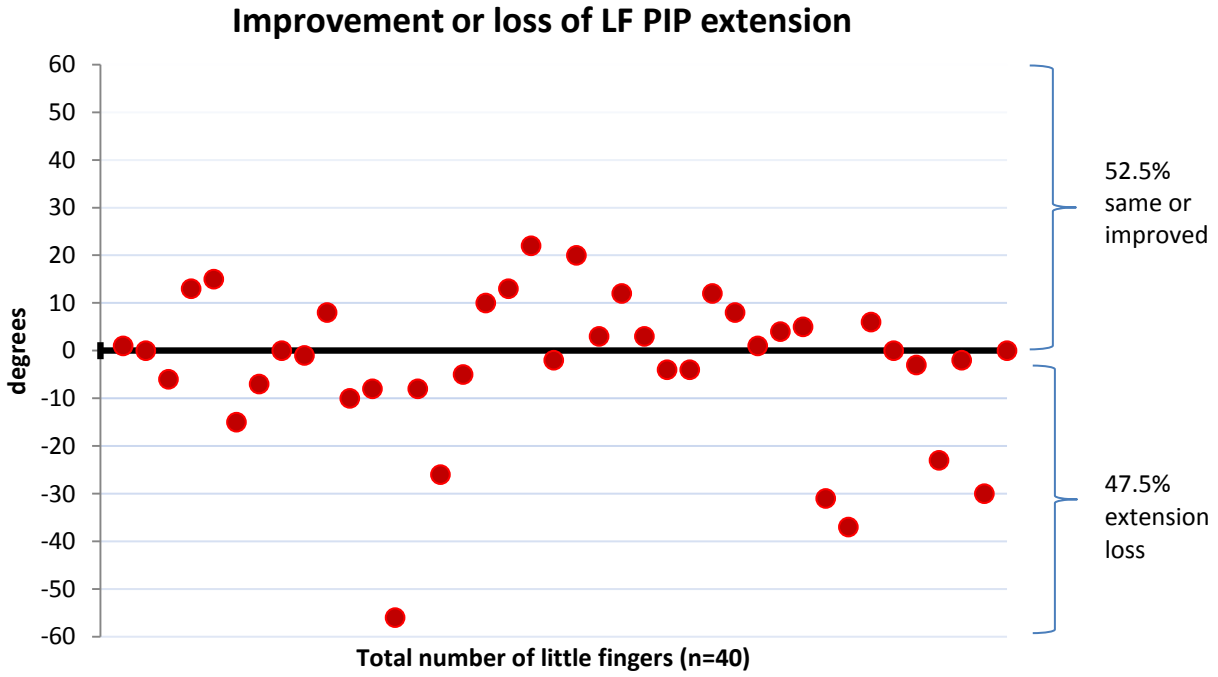

Figure 22: Difference in PIP extension in degrees between the first postoperative visit and three months across all little fingers

5.3 Subgroup analysis

Table 17 presents the results of a subgroup analysis based on only those patients with a preoperative contracture of the little finger MCP or PIP joint. Hypothesis testing could not be conducted on these data as the study was not sufficiently powered for subgroup analysis. Unadjusted mean difference from preoperative to three months for the MCP joint was -49.5(95% C.I.-39.0, 60.1) in the no splint group, and -34.0(95% C.I.-24.8, -43.2) for the splint group. Unadjusted mean difference from preoperative to three months for the PIP joint was -18.4(95% C.I. -10.7, 26.2) in the no splint group, and -13.6(95% C.I.-6.1, -21.1) for the splint group. The confidence intervals overlap between the no splint and splint groups in both MCP and PIP joints which indicates a non significant difference in the two treatments based on the current samples.

Table 17: Improvement in LF degrees of extension preoperatively to 3 months: MCP and PIP in both groups

Data presented are unadjusted means(SD)	**n**	**Preoperative**	**n**	**3 month**	**Difference**
MCP					
No splint	16	57.7(20.4)	15	10.3(19.5)	-49.5(95%C.I-39.0, -60.1)
splint	16	45.9(22.7)	15	14.7(13.4)	-34.0 (95% C.I.-24.8, -43.2)
PIP					
No splint	21	37.3(26.3)	19	23.8(20.6)	-18.4(95% C.I -10.7, -26.2)
splint	20	37.2(20.1)	19	22.3(18.3)	-13.6 (95% C.I.-6.1, -21.1)

Chapter 6. Discussion

This randomised controlled trial investigated the effects of night extension splinting over the three months following surgical release of Dupuytren's contracture. Outcome measures included finger extension, finger flexion, grip strength, self-reported hand function, patient satisfaction and number of hand therapy appointments. The intention to treat (ITT) results showed no statistically significant differences for any of the outcomes measured, although there was a trend of more favourable results in the no splint group in all outcomes. Our study demonstrates that night extension splinting in combination with hand therapy has no greater effect in maintaining finger extension than hand therapy alone. The trend towards better finger flexion, grip strength and self-reported hand function in the group that did not receive a splint may also indicate that splinting is not a benign modality. Our study confirms the findings of two recent RCTs (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011; Kemler, Houpt, & van der Horst, 2012) in that there is no discernible benefit in splinting at night in a finger extension splint following surgical release of Dupuytren's contracture.

6.1 Finger extension

Our study challenges long-held assumptions that splinting the fingers at night in extension is effective in maintaining extension postoperatively and adds evidence to the growing body of knowledge on splinting following surgical release of Dupuytren's contracture. Our results showed no significant difference in finger extension between patients in the splint or no splint group with an adjusted mean difference between the groups of 9.8 degrees in favour of the no splint group. This lack of difference demonstrates that splinting at night for three months does not maintain finger extension any better than receiving an individualised hand therapy programme that includes active and passive finger exercises, wound and scar care, strengthening and education.

The results from our study concur with findings from both Kemler et al. (2012) and Jerosch-Herold, Shepstone, Chojnowski, Larson, et al. (2011) in that night splinting does not result in greater finger extension than not splinting. Sample sizes in these studies were 54 and 154 respectively and both studies randomised participants to a no splint and splint group. The three month LF TAE unadjusted mean and SD in our study

of 33.3^{o}(34.2) and 37.9(37.5) in the no splint and splint groups respectively are similar to those of Jerosch-Herold et al. (2011) who reported a TAE of 30.9(20.7) and 32.9(19.6). The outcome measures are not identical in that Jerosch-Herold et al. (2011) used an aggregate TAE of all operated fingers whereas our study reported on each finger separately. Direct comparisons could not be made with Kemler et al. (2012) as range of motion was reported separately for each joint rather than as a composite measure. It is also interesting to note that although the preoperative TAE was substantially lower in the Jerosch-Herold et al. (2011) study, similar finger extension was found at three months in both studies.

There were three patients from the no splint group who subsequently met the criteria for needing a splint due to postoperative loss of finger extension (see section 4.1.2, page 39). This represented 10% of the no splint group sample which was lower than the 17% reported in the Jerosch-Herold et al. (2011) study. Of interest, was that the three patients never regained the degree of finger extension as measured at the first postoperative appointment, despite being compliant with splint wear. Comparisons were unable to be made with Jerosch-Herold et al. (2011) as the progression of finger extension in their patients once they received a splint was not documented.

In order to provide rationale for the lack of splinting effect found in our study a number of factors should be considered. Firstly, the condition of the soft tissues surrounding the PIP joint must be taken into account. Restoring extension to the PIP joint is generally considered to be more challenging than at the MCP joint (Dias & Braybrooke, 2006). Extensor lag and flexion contracture of the PIP joint is a biomechanically complex problem with alterations to both the anatomy and physiology of the tissues resulting from long-term flexion forces on the joint. One of the primary changes that occurs at the PIP joint is attenuation of the central slip of EDC (Smith & Breed, 1994) particularly with PIPJ contracture greater than 60 degrees (Bulstrode, et al., 2005). This thinning and elongation of the central slip results in inefficiency of the extensor tendon in effecting active PIPJ extension. Another change that may occur is volar migration of the lateral bands of the extensor mechanism resulting in the lateral bands ultimately becoming flexors rather than extensors of the PIP joint (Andrew, 1991). Other contributors to flexion deformity of the PIPJ are

contraction of the volar plate, joint capsule and the collateral ligaments (Tonkin, Burke, & Varian, 1985).

These complex changes at the PIP joint present challenges in restoring extension that night extension splinting may not be able to address adequately. Where central slip attenuation has occurred, static splints are unlikely to correct this problem. Such splints may position the PIP joint in passive end range extension but this intermittent immobilisation is unlikely to result in shortening of the central slip and correct any tendon length to tension imbalance. Night extension splints are also unlikely to correct lateral band displacement and are not designed to improve the strength or effectiveness of the extensor tendon mechanism. None of the participants in our study underwent surgical correction of the central slip, and the possibility exists that a lengthened and weakened central slip is a factor in the inability to regain full PIPJ extension, and one which is unlikely to be mitigated by night extension splinting.

Conversely, it is conceivable that normal hand use and hand therapy is sufficient to positively affect normal scar remodelling and prevent scar contracture without the addition of passive extension force as applied by a night splint. It has been shown that active motion promotes normal remodelling of scar tissue by directing the alignment of collagen along the desired lines of stress (Buckwalter, 1996; Cyr & Ross, 1998). Additionally, movement promotes strengthening of the finger extensors which may have some effect on offsetting the forces of scar contraction. All patients in our study were encouraged to mobilise and use their hand for light functional tasks within comfort levels from the first postoperative hand therapy visit (1-14 days). The addition of a splint did not result in any better finger extension so it is reasonable to consider that active motion along with individualised hand therapy provides sufficient force on the newly forming scar to prevent any undue contraction.

Duration of splinting is another factor that needs to be considered, in light of the lack of splinting effect. It is possible that splinting only at night for three months may be insufficient to influence the orientation and length of the newly forming scar and to prevent the development of a tight shortened scar. It is conceivable that if splinting was of a longer duration then greater finger extension could be found in patients wearing splints. Previous studies investigating the effect of splinting on joint contracture have demonstrated that the degree of contracture resolution is directly

proportional to the total splinting duration (hours per day and number of days) (Flowers & LaStayo, 1994; Glasgow, et al., 2003). Also, a recent study evaluating the effect of dynamic splints on PIP extension deficit suggested that greater than four months splinting duration may be required to achieve improvement (Glasgow, Fleming, Tooth, & Hockey, 2012). Although none of these studies were directly examining the effect of splinting on scar formation they do demonstrate that short, tight tissues often require prolonged splinting to effect change in tissue length. In Dupuytren's studies where splinting was used for longer periods of time, variable results have been reported. One non-randomised study did demonstrate improved extension in patients who wore a combination of dynamic and static splints all night and some part of every day for six months (Rives, et al., 1992). Conversely, in two randomised trials where patients wore splints for greater durations than in our study: six months at night (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011) and continuously for four weeks and then at night for three months (Kemler, et al., 2012), no significant difference in finger extension was found between groups.

Optimal duration of splinting in preventing scar contraction is unknown and will likely vary according to the individual's response to wound healing and scar maturation. Also, there is considerable risk in losing the ability to regain finger flexion with prolonged splinting, and any potential gains in finger extension from such splinting may be outweighed by this risk. The effect of splinting for periods of time greater than overnight for up to six months is therefore largely unknown and future studies may need to investigate this premise further.

Another factor to consider when evaluating why greater extension was not seen in the splint group is the relative effect of night extension splints on the MCP and PIP joints. The primary outcome measure of TAE is a composite measure of finger extension which does not take into account whether splinting may have acted preferentially on the MCP or PIP joint. A subgroup analysis was conducted based on those patients with a preoperative contracture of the LF MCP (n=32, 57% of total sample) or PIP (n=41, 73% of total sample). Improvement in finger extension from preoperative to three months was compared for each joint and in both groups (Table 17). Unadjusted means showed that MCP extension improved at a greater magnitude (34.0 and 49.5 degrees in the no splint and splint groups) than the PIP joint (18.4 and 13.6 degrees). With

respect to the relative effect of splinting on each joint there was no difference observed between the groups in either joint. These results are similar to those of Kemler et al. (2012) who reported an MCP improvement of 34 and 30 degrees in the no splint and splint groups and 18 and 10 degrees in the PIP joint. Our study was not powered for subgroup analysis and therefore caution must be taken when making inferences about these results. They do however indicate that the MCPJ has a greater propensity for improvement than the PIPJ regardless of three month night extension splinting.

When considering the greater magnitude of improvement in MCP than PIP extension it is necessary to consider the type of splint used in our study. It is possible that the splint design was not optimal for acting on the PIPJ and that alternate splint designs could result in greater PIPJ extension. Two previous RCTs (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011; Kemler, et al., 2012) which showed no difference in finger extension at three months used splints similar to those in our study (i.e., splints which position the MCPJ and PIP joints in maximal extension). Biomechanically, this may not be the most advantageous position for an extension force on the PIPJ as adequate leverage is difficult to achieve with the MCP joints in extension. When the MCP joints are flexed, tension is taken off the extrinsic flexor tendons, reducing the tendency of the flexors to pull the PIP into flexion. Additionally, due to the biomechanics of the lumbrical muscles, PIP extension is easier to achieve when the MCP joint is flexed. It is suggested that alternate splint designs, such as a volar splint which positions the MCPJ in flexion and the PIP in extension, could be more effective in gaining PIP extension. A 1992 observational study by Rives et al. (1992) used a dynamic splint with the MCP joints in 70 degrees of flexion and the PIP in complete extension. The findings from this study did show greater extension in the splint group which may indicate that a better leverage is achieved from positioning the MCP in flexion. The conclusions from the Rives et al. (1992) study are limited by the lack of randomisation or a control group and additionally, a dynamic force differs considerably from that applied by a static splint. Greater consideration however, may need to be given to splints that would act more advantageously on PIP joint extension. Concurrently, any detrimental effect of losing MCP joint extension would need to be closely examined if such splints were investigated.

6.2 Progression of finger extension

It is generally considered, that the goal of splinting following surgical release of Dupuytren's contracture is to maintain finger extension, and our study has now established that such splints do not result in any better extension at three months, than hand therapy alone. What these findings do not define, is how well extension was maintained, across the total sample, from surgery to follow up at three months. Previous splinting studies have not reported early postoperative finger extension and it is not well established the degree to which finger extension is actually maintained or lost in the first three postoperative months. Our study identified that of 40 little fingers, only 62.5% had the same or better total finger extension at three months compared with the first postoperative measures, and 37.5% had lost a mean of 32 degrees. When observed per joint, 73% of the LF MCP joints were the same or better compared with 53% of the PIP joint. Of the eleven MCP joints that lost extension, 82% (9/11) lost less than 20 degrees, with the exception of two outliers. In the PIP joints, 68% (13/19) lost less than 20 degrees and 32% (6/19) lost over 20 degrees. These observational data are important as they indicate that over one third of patients lost some finger extension after the first postoperative appointment and that the rate of loss was greater in the PIP joint than the MCP. These results are similar to an earlier audit from our hand therapy clinic (Collis & Collocott, 2009), where it was found that extension deficit worsened in 40% of fingers between three weeks and three months postoperatively.

If the goal of hand therapy is to maintain intra-operative correction, then it could be argued that comparisons should be made with measures taken at the time of surgery rather than with immediate postoperative range of motion. Finger extension measured in the first 14 days following surgery will be influenced by pain, oedema, wound healing, patient effort and how many days postoperatively the measures were taken. This first postoperative measure of finger extension is thus unlikely to equal that taken during surgery. Conversely, the value of intra-operative measurement may be limited by the fact that it is a measure of passive extension attained under anaesthesia and may vary substantially from what can be achieved actively by a patient. Its accuracy will also be influenced by the experience of the surgeon in goniometry and the degree of passive force applied during measurement. It is suggested therefore that using early postoperative measures as a baseline may be a

more pragmatic way of evaluating how well extension is maintained after surgery than comparisons with intra-operative correction.

Caution must be applied with the interpretation of these observational results as they are unadjusted means from a small sample. The postoperative measurements were not taken at identical time frames and measurements taken on day one may vary considerably from those were they taken on the same patient at day 10-14 following surgery. Additionally, the follow-up in our study was relatively short and it is unknown how extension deficit would progress over the ensuing months. Regardless, our results will allow for comparison with future studies and also enable clinicians to inform patients about likely outcomes of finger extension. They should also challenge therapists to research alternative splint designs or treatments in an attempt to find ways of maintaining or improving finger extension in more patients and most particularly in the PIP joint.

6.3 Finger flexion

One of the aims of our study was to investigate the effects of splinting on finger flexion. This arose from clinical concerns that immobilising the fingers overnight in extension may result in joint stiffness and delay the return of flexion. There are known detrimental effects of immobilisation (Buckwalter, 1996; Cyr & Ross, 1998) and although patients in our splint group were instructed to only wear the splint at night it was thought that this may be of sufficient duration to adversely affect joint motion. Previous authors have suggested that splinting may cause stiffness, pain and slow recovery of function following Dupuytren's surgery (Glassey, 2001; Larson & Jerosch-Herold, 2008; Pratt & Byrne, 2009). Additionally, wearing of splints has been reported as being difficult to manage and interruptive to function (Glassey, 2001; Pratt & Byrne, 2009). Findings from our study showed that there were no statistically significant differences in TAF or ADPC of the LF at three months. This demonstrates that the wearing of splints only at night does not appear to have a significantly detrimental effect on finger flexion following surgery. Similar results were reported by two recent RCTs (Jerosch-Herold, Shepstone, Chojnowski, & Larson, 2011; Kemler, et al., 2012) who also found no significant difference in finger flexion in groups who did or did not wear a splint at night.

A subgroup analysis was conducted to determine any effect of gender, age, surgery type, hand dominance and skin graft on LF flexion. It was found that patients who underwent dermofasciectomy showed poorer little finger flexion in both measures of finger flexion (TAF and ADPC) than those who underwent fasciectomy. This difference was statistically significant (p=0.006 and p=0.008), however, the number who underwent dermofasciectomy (n=6) was small and this result should be interpreted with caution. Also, this is not an unexpected finding as dermofasciectomy is a more extensive surgical procedure requiring excision of both skin and diseased fascia. This is likely to result in greater postoperative oedema, pain and stiffness which can have a detrimental effect on finger flexion.

6.4 Hand function and grip strength

The effect of splinting on hand function was investigated due to concerns that the immobilisation from splinting may have detrimental effects on the return of hand function and grip strength. It was considered that the absence of a splint may promote greater functional use of the hand over a 24 hour period and this in turn could facilitate sooner return of hand function and grip strength. No statistically significant differences were found between the groups on self-reported hand function or grip strength scores however.

Of interest, was that grip strength equivalent to preoperative measures had not been achieved by three months in either group. It was expected that grip strength would improve over time with ongoing hand therapy and normal functional use of the operated hand.

One concern was that the use of the self-reported DASH may not be sensitive enough to detect change in the Dupuytren's population. Although it has been used in Dupuytren's research, a recent study (Jerosch-Herold, Shepstone, Chojnowski, & Larson, 2011) showed a very weak association between hand function as measured by the DASH scores and flexion contracture in Dupuytren's disease. The DASH may therefore not be the most appropriate choice of hand function measures, and future studies should consider alternative tests such as the Sollerman Hand Function Test (Sollerman & Ejeskar, 1995), or self-report measures of hand function including the Upper Limb Functional Index (Gabel, et al., 2006), or the Patient Rated Wrist and Hand Evaluation (PRWHE) (MacDermid, 1996; MacDermid, Turgeon, Richards, Beadle, &

Roth, 1998). The PRWHE is widely used in hand therapy practice and has been validated on a population which included patients having undergone surgery for Dupuytren's contracture. It has been shown to be slightly more responsive in determining change after hand therapy and has a higher rate of therapist acceptability than the DASH (MacDermid & Tottenham, 2004). It is therefore likely to be a suitable alternative or adjunct to the DASH in Dupuytren's studies. With increasing emphasis on measuring functional outcomes from therapeutic interventions it may also be necessary to consider the development of a Dupuytren's specific outcome measure to give researchers a more sensitive tool.

The trend towards better flexion in the no splint group, along with slightly better grip strength and DASH scores in our study, supports previous reported trends of greater flexion deficit in groups of patients who wore a splint compared with groups who did not wear a splint (Glassey, 2001; Kemler, et al., 2012). As with our study, neither of these findings was statistically significant but together must raise concerns about unwanted effects of splinting. It is put forward that splinting is not entirely benign and that there are some small, but undesirable, effects of flexion stiffness and delayed return of grip strength and hand function in patients who wear a night extension splint following fasciectomy.

One possible explanation for the trend in improved outcomes in the no splint group is that the absence of a splint may promote the concept of quicker recovery. There is less focus on solely maintaining extension and greater effort directed towards reengaging in usual everyday occupations. It is conceivable that patients may feel less concerned about their recovery or hindered by the wearing of a splint. These patients may be more inclined to use their hand earlier for everyday function than those patients receiving a splint thereby improving the strength, range of motion and function of the operated fingers.

6.5 Number of hand therapy appointments

Another hypothesis was that not splinting would result in fewer hand therapy appointments by three months than splinting. It was considered that if patients did not receive a splint then fewer hand therapy visits may be needed as there would be no requirement to adjust splints over time for comfort and changes in finger extension.

No such difference was found with a mean of seven hand therapy treatment sessions in both groups.

It may be that differences were not observed as regular appointments were still required in order to provide the hand therapy needed for each patient following surgery. Also, as not providing a splint represented a substantial change in usual practice, it is likely that therapists were careful to regularly monitor for loss of finger extension. In future, if changes to postoperative protocols are changed, there may well be a reduction in the average number of appointments required as therapists become accustomed to not needing to splint all patients.

6.6 Indications for splinting

Although our study confirms the results of two other RCTs (Jerosch-Herold, Shepstone, Chojnowski, Larson, et al., 2011; Kemler, et al., 2012) in that there is no discernible effect of splinting on maintaining finger extension, the question remains as to whether splinting should be used selectively. It may be that splinting has benefits in certain circumstances and identification of any associations would be useful in establishing clinical guidelines. Despite mixed model and subgroup analyses our study was unable to identify any factors which influenced the effect of splinting. Factors which did not affect the difference between groups were gender, age, surgery type, hand dominance and skin graft. Splinting may have benefit where there is early and rapid loss of extension as suggested by Jerosch-Herold et al. (2011), or where there are risk factors for loss of extension such as delayed wound healing, excessive scar formation, PIPJ release or revision surgery. Future studies would need to be undertaken however, to determine whether splinting is indeed effective in these circumstances and furthermore, what types of splints are most efficacious. In the clinical setting, therapists and surgeons will continue to have concerns about patients who show a loss of extension, or where the risk for extension loss is considered to be high. In these cases clinicians will need to evaluate the causative factors of postoperative extension loss and consider all available treatment options to restore extension to the finger(s).

Suggested clinical guidelines for splinting following fasciectomy include:

- Night extension splinting for all patients following surgical release of Dupuytren's contracture is not recommended
- Consider providing a splint in the presence of
    - early and rapid loss of extension
    - delayed wound healing
    - extensive surgical fasciectomy
    - PIP joint release
    - revision surgery
    - excessive scar formation
- Consider alternative splint designs which act preferentially on the PIPJ

6.7 Trial limitations

Our study had a number of limitations which may have influenced the strength of the findings. Firstly, our study was conducted in a single centre which may limit the ability to generalise the findings to other populations. We considered however that the surgery and hand therapy received by patients in our study and the demography of Dupuytren's disease is comparable to that reported internationally. Secondly, the final follow-up at three months may be considered to be too short as similar studies had a final follow-up of at least six to twelve months. As previously discussed (Chapter 4.2, page 41) this was deemed to be appropriate as the splinting intervention was confined to three months and our study was particularly concerned with evaluating the effects of a splinting intervention.

The sample size of 56 may be considered to be underpowered and raises the possibility of a type II error. We did conduct a power analysis based on a previous clinical audit using a standard deviation derived from a clinical audit where the cohort of patients all received a night extension splint. This was done as no standard deviation from a previous RCT was available at the time.

Another limitation of our study was the lack of blinding. Due to the nature of the intervention it was not possible to blind either the participants or the treating therapist which may have resulted in a bias. Jerosch-Herold et al. (2011) claimed that

this bias would be in favour of splinting as patients with an active intervention (i.e., splinting) would be more likely to report favourable results. In our study, we considered that the bias was more likely in favour of not splinting. Although there was a varied response from patients with respect to the group they were randomised to, it was generally observed that there was a preference for not receiving a splint. As the patients in the no splint group were aware they were participating in an experimental treatment they may have wished to demonstrate the benefits of not needing a splint. The assessor was also not blinded to the group assignment and this could have introduced a bias in favour of splinting, as our original hypothesis was that splinting would result in greater extension at three months. This bias would have been mitigated by the fact that our findings refuted this hypothesis.

Another potential weakness is the lack of reporting of intra-operative contracture correction. As the aim of splinting is to maintain the degree of finger extension achieved intra-operatively these data may allow for more accurate evaluation of the effect of splinting and the progression of extension loss or gain following surgery. It was not possible to obtain these data as intra-operative extension was not routinely documented by the operating surgeons. It has been suggested that the first postoperative measure may be an appropriate baseline from which to measure progression of finger extension.

6.8 Future directions

The results of our study have highlighted the need for ongoing research regarding the therapeutic management following surgical release of Dupuytren's contracture. In particular, the establishment of clinical guidelines for splinting is imperative. Growing evidence clearly demonstrates that night extension splints are not necessary for all patients postoperatively, however it is not yet known in what circumstances splinting may be of benefit. Future studies need to be of sufficient magnitude to conduct subgroup analyses, or target particular clinical factors such as MCP vs. PIP joint contracture, to identify if splinting is helpful in specified populations. Factors not investigated in our study but which could influence the effect of splinting include duration of contracture and presence of osteoarthritis.

There are now three studies investigating the effect of night extension splinting following surgical release of Dupuytren's contracture, however no known RCTs have

been conducted evaluating the effect of differing types of splints such as dynamic extension splints or serial casts. Such studies would add valuable knowledge regarding the effect of alternative splints.

Observational data showed that 37.5% of all little fingers lost some total finger extension following surgery and at a greater rate in the PIP than the MCP joint. Future research should focus on investigating ways to maintain or improve postoperative extension in a greater number of fingers and most particularly in the PIP joint. Suggestions for further research would be trialling alternate splint designs which act preferentially on the PIPJ and evaluating the way the PIP joint is positioned and splinted in the immediate postoperative period. A power calculation was carried out to identify what sample size would be required to undertake a study looking at extension of the PIP joint. Based on data obtained in our study of a standard deviation of 19 degrees PIP LF extension in a splint group and 21 degrees in a no splint group, it is estimated that a minimum of 85 patients with a preoperative PIPJ contracture would be needed in a splint group and 85 in a no splint group, to detect a clinically significant difference of 10 degrees at a 0.05 significance level with 90% power.

One of the identified limitations of our study was a relatively short follow-up time frame. It was considered that it would be useful to obtain measures on this cohort of patients at 12 to 24 months in order to determine if there were any effects that were not apparent at three months. Currently, ethics approval is being sought to recall participants of our study to obtain further follow up measures.

The lack of intra-operative correction reporting has been identified as a potential limitation in our study. It has been suggested that using the first postoperative measure of finger extension as a baseline, may be a more pragmatic way of evaluating the progression of finger range of motion, rather than comparisons with intra-operative measures. In future studies, if this approach is adopted, then the robustness of the study would be enhanced if this measure were taken within a more homogenous timeframe.

Lastly, it is suggested that future studies examine the effect of differing hand therapy interventions. Our study has shown that splinting in addition to hand therapy was no more effective than hand therapy alone in maintaining finger extension

postoperatively. Both groups received a wide variety of hand therapy interventions and it is not established which of these have beneficial effects following surgery. Investigations into the effect of hand therapy interventions such as scar management, passive stretch and strengthening exercises would assist therapists in determining the most efficacious therapies following surgery.

6.9 Conclusion

This paper has systematically reviewed the existing literature pertaining to splinting following surgical release of Dupuytren's contracture. The results of a randomised controlled trial are presented evaluating the effects of postoperative night time splinting. The results showed that night extension splinting, in combination with standard hand therapy, has no greater effect on maintaining finger extension than hand therapy alone in the three months following surgical release of Dupuytren's contracture. Equally, results showed no statistically significant effect of splinting on finger flexion, self-reported hand function, grip strength, patient satisfaction or number of hand therapy appointments. There was an overall trend of better outcomes in the no splint group across all measures without reaching statistical significance. This suggests that splinting is not a totally benign therapy and that there may be some small, but undesirable, effects of flexion stiffness and delayed return of grip strength and hand function in patients who wear a night extension splint following fasciectomy.

Limitations of the study have been discussed and suggestions put forward for further research. These include evaluating the effects of different splint designs that act preferentially on the PIP joints, establishing factors that indicate the selective use of splinting and identifying therapies or splints which would increase the rate of maintaining extension in more fingers.

This is the third known randomised trial to evaluate the effects of night extension splinting following surgical release of Dupuytren's contracture. There is agreement in all three studies that splinting the finger/s at night in extension does not result in greater finger extension than not splinting. It is concluded that routinely splinting the fingers in extension at night following surgical release of Dupuytren's contracture is no longer justified and that the current protocol at CMDHB of providing all patients with such splints postoperatively should be reviewed.

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Appendices

Appendix A: Downs and Black, Quality Index

Study title:
Author:
Year:

Scored by:
Date:

Total Score:

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

Yes	1
No	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
   If the main outcomes are first mentioned in the Results section, the question should be answered no.

Yes	1
No	0

3. *Are the characteristics of the patients included in the study clearly described?*
   In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

Yes	1
No	0

4. *Are the interventions of interest clearly described?*
   Treatments and placebo (where relevant) that are to be compared should be clearly described.

Yes	1
No	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*
   A list of principal confounders is provided.

Yes	2
Partially	1
No	0

6. *Are the main findings of the study clearly described?*
   Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

Yes	1
No	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
   In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

Yes	1
No	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
   This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

Yes	1
No	0

9. *Have the characteristics of patients lost to follow-up been described?*
   This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

Yes	1
No	0

10. *Have actual probability values been reported (e.g. 0.03 rather than <0.0) for the main outcomes except where the probability value is less than 0.001?*

Yes	1
No	0

External validity

All the following criteria attempt to address the representatives of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
    The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample.

Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

Yes	1
No	0
Unable to determine	0

12. *Were those subjects who were prepared to participate, representative of the entire population from which they were recruited?*
    The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

Yes	1
No	0
Unable to determine	0

13. *Were the staff, places and facilities where the patients were treated, representative of the treatment the majority of patients receive?*
    For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

Yes	1
No	0
Unable to determine	0

Internal validity – bias

14. *Was an attempt made to blind study subjects to the intervention they have received?*
    For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

Yes	1
No	0
Unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

Yes	1
No	0
Unable to determine	0

16. *If any of the results of the study were based on "data dredging", was this made clear?*
    Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

Yes	1
No	0
Unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?*
    Where follow-up was the same for all study patients the answer should be yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

Yes	1
No	0
Unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*
    The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

Yes	1
No	0
Unable to determine	0

19. *Was compliance with the intervention/s reliable?*
    Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*
    For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

Internal validity – confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*
For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

Yes	1
No	0
Unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*
For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

Yes	1
No	0
Unable to determine	0

23. *Were study subjects randomised to intervention groups?*
Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

Yes	1
No	0
Unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*
All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

Yes	1
No	0
Unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*
This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

Yes	1
No	0
Unable to determine	0

26. *Were losses of patients to follow-up taken into account?*
    If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*
    Sample sizes have been calculated to detect a difference of *x% and y%*

Yes	1
No	0

Appendix B: Northern X Ethics Approval letter

Health and Disability Ethics Committees

Northern X Regional Ethics Committee
Ministry of Health
3rd Floor, Unisys Building
650 Great South Road, Penrose
Private Bag 92 522
Wellesley Street, Auckland
Phone (09) 580 9105
Fax (09) 580 9001

24 August 2010

Ms Shirley Collocott
Hand Therapy
Module 9
Manukau SuperClinic
901 Great South Rd, Manukau
Auckland

Dear Shirley-

Ethics ref:	**NTX/10/07/070** (please quote in all correspondence)
Study title:	The effect of splinting post Dupuytren's contracture release: Prot. V#1, 25/05/10: PIS/Cons V#2, 10/08/10
Principal Investigator:	Ms Shirley Collocott
Co-investigator:	Ms Julie Collis

This study has now been given ethical approval by the Northern X Regional Ethics Committee. A list of members of the Committee is attached.

Approved Documents

- Protocol Version # 1 dated 25 May 2010
- Information Sheet/Consent Form Version #2 dated 10 August 2010

This approval is valid until **24 August 2011.**

Access to ACC

For the purposes of section 32 of the Accident Compensation Act 2001, the Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out. Participants injured as a result of treatment received in this trial will therefore be eligible to be considered for compensation in respect of those injuries under the ACC scheme.

Amendments and Protocol Deviations

All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:

- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study

— the method of recruitment
— information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports

Should you wish to extend the study, a Progress Report for this study is due to the Committee by **24 August 2011**. The Annual Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A **Final Report** is also required at the conclusion of the study. The Final Report Form is also available at www.ethicscommittees.health.govt.nz.

Requirements for the Reporting of Serious Adverse Events (SAEs)

All SAEs occurring in patients located in New Zealand must be individually reported to the Committee within 7-15 days.

Please see www.ethicscommittees.health.govt.nz for more information on the reporting of SAEs, and to download the SAE Report Form.

We wish you all the best with your study.

Yours sincerely

Pat Chainey
Administrator
Northern X Regional Ethics Committee
Email: pat_chainey@moh.govt.nz

Cc: Alison Robertson, CMDHB Research Office # 928

Appendix C: Northern X Ethics Extension letter

Health and Disability Ethics Committees

Northern X Regional Ethics Committee
c/- Ministry of Health
650 Great South Rd
Penrose
Auckland
Phone: (09) 580 9105
Email: northernx_ethicscommittee@moh.govt.nz

27 October 2011

Ms Shirley Collocott
Counties Manukau District Health Board
Hand Therapy
Module 9
Manukau SuperClinic
901 Great South Rd, Manukau

Dear Shirley

Ethics ref:	**NTX/10/07/070** (please quote in all correspondence)
Study title:	The effect of splinting post Dupuytren's contracture release: Prot. V#1, 25/05/10: PIS/Cons V#2, 10/08/10
Principal investigator:	Shirley Collocott

Thank you for your progress report and presentation, received 26 October 2011.

The study has received ongoing ethical approval for the next ten months from the Deputy Chairperson of Northern X Regional Ethics Committee under delegated authority. The next progress report is due **24 August 2012.**

It should be noted that Ethics Committee ethical approval does not imply any resource commitment or administrative facilitation by any healthcare provider, within whose facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Please note that progress reports are the responsibility of the researcher and forms can be found on the website, www.ethicscommitttees.health.govt.nz. Please complete promptly to ensure ethical approval is continued.

It would be appreciated if we were advised when the study is completed and also that an End of Study Report is sent promptly after completion in order to close and archive the file.

Yours sincerely

Sabrina Young
Temp Administrator
Northern X Regional Ethics Committee

CC: CMDHB Research Office (CMDHB #928), alison.robertson@middlemore.co.nz

Appendix D: AUTEC Ethics Approval

MEMORANDUM

Auckland University of Technology Ethics Committee (AUTEC)

To: Wayne Hing
From: **Dr Rosemary Godbold** Executive Secretary, AUTEC
Date: 22 November 2011
Subject: Ethics Application Number 11/309 **Effectiveness of splinting post Dupuytren's contracture surgical release.**

Dear Wayne

Thank you for providing written evidence as requested. I am pleased to advise that it satisfies the points raised by a subcommittee of the Auckland University of Technology Ethics Committee (AUTEC) and I have approved your ethics application. This delegated approval is made in accordance with section 5.3.2.3 of AUTEC's *Applying for Ethics Approval: Guidelines and Procedures* and is subject to endorsement at AUTEC's meeting on 12 December 2011.

Your ethics application is approved for a period of three years until 22 November 2014.

I advise that 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/research/research-ethics/ethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 22 November 2014;
- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/research/research-ethics/ethics. This report is to be submitted either when the approval expires on 22 November 2014 or on completion of the project, whichever comes sooner;

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 reminded that, as applicant, you are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

Please note that AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to make the arrangements necessary to obtain this.

When communicating with us about this application, we ask that you use the application number and study title to enable us to provide you with prompt service. Should you have any further enquiries regarding this matter, you are welcome to contact me by email at ethics@aut.ac.nz or by telephone on 921 9999 at extension 6902.

On behalf of AUTEC and myself, I wish you success with your research and look forward to reading about it in your reports.

Yours sincerely

Dr Rosemary Godbold
Executive Secretary
Auckland University of Technology Ethics Committee

Cc: Julie Collis juliecollis@gmail.com

Appendix E: Participant Information Sheet

Participant Information Sheet

Investigators:
Shirley Collocott and Julie Collis
Occupational Therapists, Registered Hand Therapists (NZAHT)
Hand Therapy, Module 9, Manukau SuperClinic, 901 Great South Road, Manukau
Telephone: 09 250 8053

Title: Splinting after Dupuytren's contracture surgery.

Introduction:

You are invited to take part in a study looking at whether or not splinting is necessary after Dupuytren's contracture release surgery. Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part you will receive the standard treatment available. Think about whether you would like to be part of the study over the next few weeks, and let us know at your next appointment with the doctor; there will be a form for you to sign if you agree to be part of the study. If you do agree to take part in the study, you are free to withdraw from the study at any time, without having to give a reason, and this will in no way affect your future and ongoing health care. Participation in this study will be stopped should any harmful effects appear or if the hand therapist feels it is not in your best interests to continue.

About the study:

The aim of this study is to find out whether it is necessary to wear a splint at night after surgery for Dupuytren's Contracture. When you have had this surgery it is usual to have a splint made to hold the fingers as straight as possible. A splint is a plastic support which is moulded to your hand. This is worn at night for three months or longer. It is thought that wearing a splint is the best way to keep the fingers straight after surgery and to stop the new scar from pulling the fingers back into a bent position.

There is no research however to show that splints work and some surgeons and therapists are now thinking that they may be unnecessary, at least for some people. Splints can be cumbersome to wear and it is possible they could make it make it harder to get the bending and use of the fingers back again.

We want to find out for sure whether splints are needed and also if they help some people more than others.

People who take part in this study will either have a splint made or will receive no splint at all; the decision of who is provided with a splint and who is not will be made randomly to ensure the study is fair. At the first hand therapy session each participant will draw a slip of paper from an envelope; this will indicate whether or not they receive a splint. Participants will not be able to choose whether or not they want a splint as this will be decided in the random method described. All participants will receive usual hand therapy.

Who is included in the study?

We are asking all patients having Dupuytren's Contracture surgery at Counties Manukau District Health Board whether they would like to take part in this study.

Where and when will it take place?

It will be taking place at Hand Therapy in Module 9 at Manukau SuperClinic.

The study will take place over the period from August 2010 until June 2011; our aim is to recruit 49 participants over this period.

Your involvement in the study will be from just before surgery and during the course of your hand therapy treatment at the SuperClinic, and will run for 3 months. If you require ongoing treatment after 3 months, you will continue to receive treatment as necessary.

What does it involve?

If you take part in the study, before your surgery we will measure how strong your hand is, how well the joints move and how well you can use your hand. At your first hand therapy appointment after the operation, you will draw a piece of paper out of an envelope which will decide whether or not you will receive a splint. Group (a) will mean you receive a splint, Group (b) will mean you do not receive a splint.

Measurements of your joints' movement will be taken before surgery and at every hand therapy appointment. Before surgery, at 6 weeks after surgery and 3 months after surgery your grip strength will be measured and you will be asked to fill out a questionnaire regarding how well you can use your hand. As far as possible, we will try to co-ordinate your appointments so that they coincide with the surgeons' appointments. However a small number of participants may need to attend one extra hand therapy appointment before surgery so that measurements can be taken.

You will be asked to fill out a satisfaction survey at 3 months after surgery.

If you are provided with a splint you will need to wear it each night for 3 months after surgery. You will need to bring the splint in to each therapy appointment with you so that it can be checked and adjusted if needed.

Everybody will receive standard hand therapy which includes education, management of swelling and the surgical scar, teaching of exercises and stretches and advice regarding strengthening and using your hand.

If you choose not to take part in the study, you will receive hand therapy according to our usual treatment protocol; this means wearing a splint for 3 months at night and receiving standard hand therapy as described above. Your treatment will not be negatively affected in any way should you choose not to participate in the study.

Benefits, risks and safety:

Benefits

Nobody knows for sure whether splints are necessary or not after surgery for Dupuytren's contracture. This study will give therapists and surgeons direction as to whether splints are required and whether they are useful for everyone after this surgery, or only some people. This will be of benefit to people who have surgery for Dupuytren's contracture in the future.

Risks/ inconveniences

Splints can be uncomfortable and wearing a splint may slow down your ability to return to your usual activities. However it is possible that splints are necessary to ensure your fingers remain straight after surgery. Not wearing a splint may allow your fingers to become bent down again. If this happens during the therapy period, you will be provided with a splint.

Agreeing to join in the study means that you will need to come for an appointment to see the hand therapist before your surgery so that all the measurements can be taken then; this one visit is additional to what is usually required for hand therapy.

Who will be included?

- Male and female participants will be included.
- Age range from 18-95 years.
- Dupuytren's contracture surgery for one or more fingers.
- Attended first hand therapy appointment within 10 days of surgery
- Able to attend follow up appointments.
- Ability to understand instructions for exercise and splinting programme.
- All types of surgeries for Dupuytren's contracture will be included, including surgery where skin grafting is done, provided the aforementioned criteria are met.

Who will not be included?

- People who are unable to understand instructions as a result of intellectual disability or dementia.
- People who do not attend 2 or more hand therapy appointments in a row
- Pinning or wiring of a joint as part of surgery.
- Any other factor which in the opinion of the investigators or surgeon would make the person unsuitable for inclusion in the study.

Cost

Hand therapy is provided free of charge at Manukau SuperClinic. Parking is free. There will be no reimbursement for participants of this study.

General:

Please ask your nurse/ doctor if you have any questions right now. If they are unable to answer your question, then they will contact one of the hand therapists to speak to you.

If you have any further questions about the study you can contact either Shirley Collocott or Julie Collis at hand therapy. Our contact phone number is 250 8053.

An interpreter will be arranged if you require one. Please discuss this with your nurse so that she can let the hand therapists know.

You may have a friend, family or whaanau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

You will be issued a card to confirm your participation in a clinical trial. This card should be presented at the time of any treatment received during your participation in the trial.

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

Confidentiality:

No material that could personally identify you will be used in any reports on this study.

Records will be stored in your patient notes at hand therapy in a lockable cabinet. Data will be stored in a folder on the hand therapy computer drive; this is only accessible to hand therapists.

Results:

A report will be compiled detailing the outcomes of the study for internal purposes. Ultimately, the findings may be published in peer-reviewed literature. There is likely to be a delay which could be up to 9 months from the time when your therapy is completed to when the report is written. Please tick the box on the consent form if you would like a copy of the report. You may contact either Shirley or Julie to discuss the results or if you have any questions.

This study has received ethical approval from the Northern X Regional Ethics Committee.

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.

Appendix F: Consent Form

Consent Form

Investigators:
Shirley Collocott and Julie Collis
Occupational Therapists, Registered Hand Therapists (NZAHT)
Hand Therapy, Module 9, Manukau SuperClinic, 901 Great South Road, Manukau
Telephone: 09 250 8053

Title: Splinting after Dupuytren's contracture surgery.

Request for interpreter

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Maaori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Maaori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

	Please tick √ if you agree
I have read and I understand the information sheet Version #2 dated 10/08/10 for volunteers taking part in the study designed to investigate splinting following Dupuytren's Contracture surgery. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.	
I have had the opportunity to use whaanau support or a friend to help me ask questions and understand the study.	
I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my continuing health care.	
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 the treatment, or investigation, will be stopped if it should appear harmful to me.	
I have had time to consider whether to take part in the study.	
I know who to contact if I have any side effects from the study.	
I know who to contact if I have any questions about the hand therapy treatments used in this study or about the study in general.	

I would like to receive a copy of the study report once it has been completed.	Yes	No

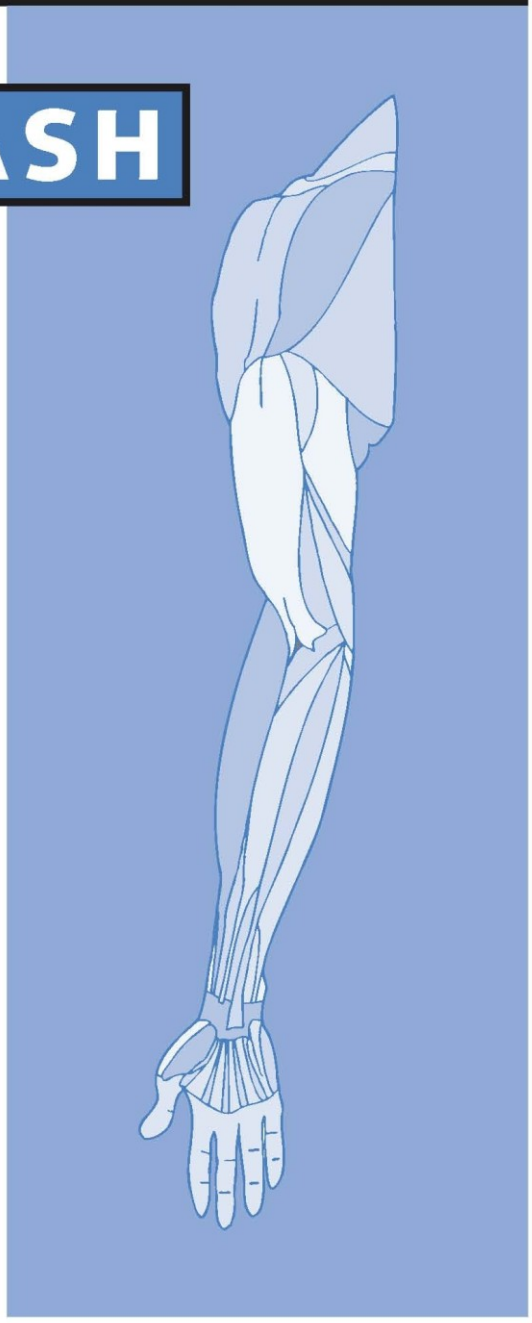
I ..... (*full name*) hereby consent to take part in this study.

Date:	
Signature:	
Full names of researchers:	Shirley Collocott Julie Collis
Contact phone number for researchers:	09 250 8053
Project explained by:	
Project role:	
Signature:	
Date:	

Appendix G: Disabilities of the Arm, Shoulder and Hand Questionnaire

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE **DASH**



INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

DISABILITIES OF THE ARM, SHOULDER AND HAND

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. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. 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
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. 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? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. 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? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness 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
29. 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

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH 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 DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is:_____

p I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*.
If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_

o I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may <u>not</u> be calculated if there are any missing items.

INSTITUTE FOR WORK & HEALTH
INSTITUT DE RECHERCHE SUR LE TRAVAIL ET LA SANTÉ

Appendix H: Patient Evaluation Measure

The PEM Questionnaire

Part three - overall assessment

1. Generally, my treatment at the hospital has been:

   1 2 3 4 5 6 7
   Very satisfactory Very unsatisfactory

2. Generally, my hand is now:

   1 2 3 4 5 6 7
   Very satisfactory Very unsatisfactory

3. Bearing in mind my original injury or condition, I feel my hand is now:

   1 2 3 4 5 6 7
   Better than I expected Worse than I expected

Appendix I: Splint Wear Diary

Please tick the box each night that you wear the splint; place a cross in the box if you did not wear the splint.

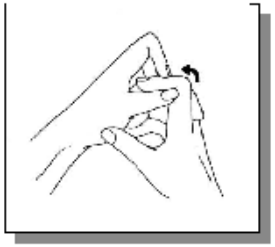
Weeks	Date	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								

Appendix J: Exercise Sheet

Passive Tip ☐

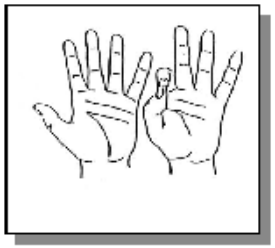
Support below the top finger joint and then bend the joint assisting with your other hand.
HOLD for 20 seconds.

Passive Middle ☐



Support below the middle finger joint and then bend the joint assisting with your other hand.
HOLD for 20 seconds.

Opposition ☐



Touch the tip of your thumb to the tip of each finger in turn. When you can touch your little finger roll your thumb down to its base.
HOLD 5 seconds.

Hand Therapy, Manukau SuperClinic, March 2008

COUNTIES MANUKAU DISTRICT HEALTH BOARD
A Community Partnership

Whare Whakaora o Manukau
Manukau Super Clinic
Phone (09) 250 8053

WHAKAORA RINGARINGA
HAND THERAPY

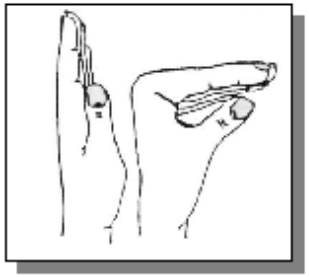
Koringa Matikara
Finger Exercises

Therapist: _____

Only do the exercises that your therapist suggests.

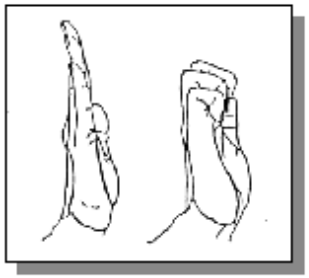
Relax and return to the starting position between each exercise.

Table Top ☑



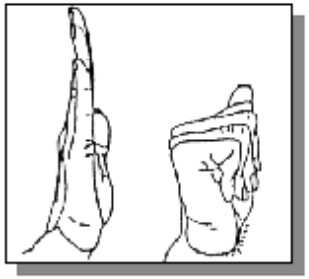
Bend down the knuckles keeping all your finger joints straight. **HOLD** for 5 seconds
Now straighten your fingers fully.

Hook Fist ☑



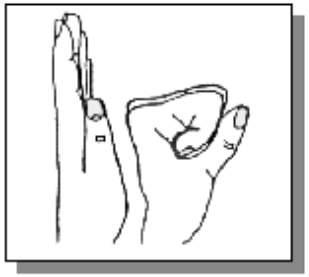
Keeping your knuckles straight, bend your fingers down to make a hook fist. **HOLD** for 5 seconds.
Now straighten your fingers fully.

Flat Fist ☑



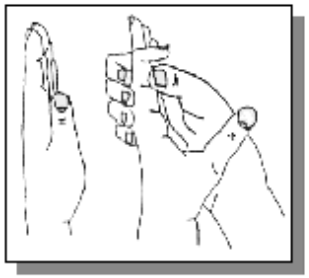
Bend all your fingers into palm keeping the tip joints straight. **HOLD** for 5 seconds.
Now straighten your fingers fully.

Full Fist ☑



Bend all your fingers around to make a tight fist. **HOLD** for 5 seconds.
Now straighten your fingers fully.

Blocked Flexion Tip ☐



With your other hand, block your finger and bend at the joint. **HOLD** for 5 seconds.
Repeat for all fingers.

Blocked Flexion Middle ☐

With your other hand, block your finger and bend at the joint. **HOLD** for 5 seconds.
Repeat for all fingers.

Appendix K: Copyright agreement

Copyright Clearance Center RightsLink® Home Account Info Help

BMJ

Title:	Dupuytren's contracture unfolded
Author:	W A Townley, R Baker, N Sheppard, A O Grobbelaar
Publication:	British Medical Journal
Publisher:	BMJ Publishing Group Ltd.
Date:	Feb 16, 2006

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Licensed content publication	British Medical Journal
Licensed content title	Dupuytren's contracture unfolded
Licensed content author	W A Townley, R Baker, N Sheppard, A O Grobbelaar
Licensed content date	Feb 16, 2006
Volume number	332
Type of Use	Thesis/Dissertation
Requestor type	Individual
Format	Print and electronic
Portion	Figure/table/extract
Number of figure/table/extracts	1
Will you be translating?	No
Circulation/distribution	1
Title of your thesis / dissertation	The effect of night extension splinting following surgical release of Dupuytren's contracture

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