COMPARISON OF TWO CARPOMETACARPAL STABILIZING SPLINTS FOR INDIVIDUALS WITH THUMB OSTEOARTHRITIS

by

HELIA SUZANNE SILLEM

B.Sc.OT., The University of Alberta, 1993

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

in

THE FACULTY OF GRADUATE STUDIES

(Rehabilitation Sciences)

THE UNIVERSITY OF BRITISH COLUMBIA

(Vancouver)

July 2009

ABSTRACT

OBJECTIVE: To compare the effect of two different splints on hand function, pain and hand strength in adults with carpometacarpal osteoarthritis (CMC OA): the prefabricated neoprene Comfort Cool^{TM} a long opponens design, and a custom-made thermoplastic and neoprene splint, the Hybrid, a short opponens design.

STUDY DESIGN: Equivalence trial, 2 phase crossover design.

METHODS AND MEASURES: Participants with CMC OA from 3 out-patient clinics were assigned randomly to splint order in a 2 phase crossover trial. Each splint was worn for 4 weeks separated by a 1 week wash-out period. Hand function, the primary outcome, was assessed using the Australian Canadian Hand Osteoarthritis Index (AUSCAN) numerical rating scale (NRS) version. Secondary outcomes included pain (AUSCAN pain subscale), and grip and lateral pinch strength measured with dynamometers. Participants were assessed at baseline, after each splint phase and after the 1 week washout period. AUSCAN alone was administered at 3 months. Data were analysed using descriptive statistics, paired t-tests and chi-square tests.

RESULTS: Fifty-four participants (91% women, mean age = 64 years, time since diagnosis = 2.99 years) were randomized and completed the study. They wore the assigned splints for an average of 8 hrs/day. Differences between the effect of Comfort Cool™ and Hybrid splints were not statistically significant for hand function, grip and pinch strength. However, the Hybrid resulted in a greater average reduction in pain scores compared to the Comfort Cool™ (3.72 points, p = 0.02). No carryover or order effects were present. Compared to the baseline measures, modest improvements were noted for all outcomes after 4 weeks with both splints. At the 3 month follow-up, both hand function and pain had improved significantly over baseline.

CONCLUSION: The splints demonstrated similar, modest improvement in hand function and similar to previous published studies, neither thumb splint had a significant effect on grip or pinch strength. The findings of equivalence for both splints allow therapists to use a client centred approach to splinting. This study supports exisiting evidence that splinting benefits individuals with CMC OA by providing pain relief. Thumb splinting may have a continued effect on CMC OA pain and function with longer term intervention.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACKNOWLEDGEMENTS

I would like to express my thanks to my thesis supervisor, Dr. Catherine Backman for her invaluable support and encouragement throughout this research project. Her very patient guidance and kindness over the past three years enabled me to complete this thesis. Her depth of knowledge and ability to connect the theoretical research to practical therapy situations helped to ground this thesis in clinical practice and hopefully make it useful for my fellow Occupational therapists and Physiotherapists.

I would also like to acknowledge my thesis committee members, Dr. Bill Miller and Dr. Linda Li for sharing their wealth of knowledge and continually stimulating my thinking.

In addition, I would like to thank the three treating therapists, Susan Ogilvie (Occupational Therapist), Clare Faulkener (Physiotherapist) and Julia Rogers (Occupational Therapist) from each site who enthusiastically participated in this research project and donated their own valuable time.

Finally, I would like to acknowledge Dr. Jonathan Berkowitz for assisting with the statistical analyses.

CO-AUTHORSHIP STATEMENT

This research project was initiated by discussions between Dr. Catherine Backman (supervisor) and Helia Sillem. Dr. Bill Miller and Dr. Linda Li contributed to the final details of the research design and protocol. The research was performed by Helia Sillem. Data analysis was also decided on collaboratively by Dr. Catherine Backman and Helia Sillem. Helia Sillem wrote the manuscript which was revised primarily by Dr. Catherine Backman. Dr. Bill Miller and Dr. Linda Li provided feedback in the final revisions of the manuscript.

CHAPTER I
BACKGROUND TO THE STUDY

This thesis is organized following the instructions for a manuscript-based thesis at the University of British Columbia. Chapter 1 presents an overview of literature relevant to the study; Chapter 2 presents the study in the form of a manuscript that will be submitted for publication; and Chapter 3 discusses the implications of the study and what was learned in the research process.

Introduction

Osteoarthritis (OA) is a common joint disease, especially among older adults. Autopsy studies demonstrated almost universal cartilage damage in people over the age of 65 (Cooper, 1994). In radiographic studies, 44% to 70% of people over the age 55, and 80% to 85% of those over the age 75, showed signs of OA in one or more joints (Cooper, 1994; Grant, 2005). It is well known that OA is strongly associated with aging, and to a lesser amount with obesity, occupation and previous trauma, but it is also found in 10 to 20% of adults in their forties (Cooper, 1994).

Hand OA, although less prevalent than hip and knee OA, is present radiographically in 41 to 54% of the population over the age of 55 (Chaisson et al., 1997; Dahaghin et al., 2004; Wilder, Barrett, & Farina, 2006). Joint pain is the main symptom of hand OA and its clinical prevalence ranges from 6% to 26%, depending on the population studied (Mannoni et al., 2000; Hirsch, Guralnik, Ling, Fried, & Hochberg, 2000; Glickel & Home, 2001; Zhang et al., 2002). Hand OA particularly affects the base of the thumb: the carpometacarpal (CMC) joint. In a community-based longitudinal study of 3327 individuals, Wilder et al. (2006) found that 18% of males and 21% of females aged 40 or older had radiographic CMC OA. In another population-based longitudinal study, the Framingham Study of 5209 adults aged 29 – 62 years, (Zhang et al., 2002) 2.2 – 3% of males and 5% of females had symptomatic CMC OA. Thus, the thumb CMC joint is a frequently involved site in patients with OA.

CMC OA can lead to pain and stiffness that subsequently limits a person's ability to perform grasping and pinching motions necessary to everyday activities. Everyday tasks like opening jars, turning taps, handwriting and wringing out cloths can be difficult for a person with CMC

OA. A survey of over 10,000 patients with OA found 74% with hand OA reported difficulties with activities of daily living (ADL) (Fautrel et al., 2005). In a study examining the functional impact of hand OA in 87 females aged 50 to 70 years, grip strength was reduced to 60% of age norms and participants reported difficulties with activities that require a fair amount of grip strength, like wringing out washcloths and opening jars (Kjeken et al., 2005). In Kjeken`s study, decreased 3-point (thumb, index and middle finger) pinch strength was found to be associated with lower function. The amount of pinch force required to open a pill bottle, dual safety squeeze bottle and to operate a trigger pump spray bottle or aerosol can were found to be between 2.19 and 9.76 pounds in a study of 42 women and 9 men over the age of 60 (Rahman, Thomas & Rice, 2002). It is not known exactly what degree of weakness would limit ability to open these containers on a daily basis, however it is known that people with CMC OA experience muscle atrophy and losses in pinch and grip strength (Baron, Dutil, Berkson, Lander & Becker, 1987; Dominick, Jordn, Renner & Kraus, 2005; Kjeken et al., 2005). This in turn limits their ability to open containers. One of 4 risk factors, associated with the independence of older people is decreased upper extremity strength (Tinetti, Inouye, Gill & Doucette, 1995). Being able to open containers, cut up food and use one's arms to rise from sitting to standing can make the difference between independent living or assisted living.

Radiographic OA has been associated with reduced hand function in several studies. In the Rotterdam Study (Dahaghin et al., 2005), radiographic (X-ray) assessments of 3906 participants over the age of 55 years showed a significant association between X-ray evidence of thumb OA and hand disability – those with thumb OA visible on X-ray were 50% more likely to be disabled (as measured by the Stanford Health Assessment Questionnaire) than those without X-ray changes. The Framingham study (Zhang et al., 2002) examined X-rays and function in 1041 adults over the age of 70. Adults with hand OA had at least 10% lower grip strength and 3 times more difficulty in writing and handling small objects, compared to those without hand OA. It has been suggested that the thumb is responsible for up to 45 - 60% of hand function (Dickson & Morrison, 1979). Given the limitation in hand function that occurs in the presence of degenerative changes, it is reasonable to expect that people with hand OA will seek rehabilitation services.

Patients with thumb OA are commonly seen in outpatient occupational therapy and physiotherapy departments. Riley (1998) lists thumb OA as the most common joint complaint referred to occupational therapy. In a survey of occupational therapists in the United Kingdom (UK), the primary reason for occupational therapy referral for patients with hand OA was difficulty with everyday activities (Grant, 2005). Typically, people with thumb OA are referred to therapy by their family physicians or rheumatologists for "conservative treatment." Conservative treatment of thumb OA consists of splinting, exercises, education in joint protection techniques and physical modalities (such as heat) to decrease pain. No adverse side effects have been reported with conservative treatment and it is relatively inexpensive. If individuals do not respond to conservative treatment, and their disability persists, they eventually have surgery to reconstruct the anterior oblique ligament and remove part or all of the trapezium (a bone at the junction of the thumb and wrist), depending on the amount of cartilage and bone degeneration. Three previous studies have evaluated the results of conservative treatment in patients with CMC OA (Swigart, Eaton, Glickel & Johnson, 1999; Berggren, Joost-Davidsson, Lindstrans, Nylander & Povlsen, 2001; Day et al., 2001). All three studies showed long-term (18 months to 7 years) pain relief where the majority of patients did not go on to have surgery. Therefore, ensuring the best possible conservative management may help delay or avoid the need for reconstructive joint surgery and its associated costs.

Rationale for Thumb Splints in Osteoarthritis

Theoretically the goal of splinting the CMC joint is to increase stability at the joint. The instability of the CMC joint can be caused by weakening of the ligaments or stretching of the joint capsule. As osteoarthritis progresses, the joint surfaces become rough and incongruent, leading to localized stress or high loading to a small region of the joint. Splinting applies external support to the joint. During the application of the splint, the CMC joint is positioned as close to a neutral position as possible to increase joint congruity. Splinting the CMC joint also limits the amount of movement at the joint. The premise is that if there is less movement at the joint there will be less shearing and friction on the articular surfaces and this may prevent joint space narrowing and reduce pain (Poole & Pellegrini, 2000).

Controversy exists over how restrictive the splint should be in order to stabilize the CMC joint and achieve desirable functional outcomes. The splint design is based on the need of a specific joint to be immobilized. In order to immobilize the CMC joint from a biomechanical perspective, one needs to use a long thumb splint that includes the adjacent joints of the wrist and thumb metacarpal bone. It is also necessary to cross the palm to stabilize the first metacarpal against the other metacarpals. Because this type of splint immobilizes a number of joints and limits hand function, adherence to the use of the splint can be low (Colditz, 2000).

Previous cadaver studies have attempted to specify the location of degeneration at the CMC joint in osteoarthritis (Koff et al., 2003; Kovler, Lundon, McKee, & Agur, 2004; Moulton et al., 2001). It was thought that by determining the cartilage wear patterns, this would influence treatment, particularly preventing further joint degeneration through ideal positioning of the joint. All 3 studies found that degeneration primarily occurred at the dorsal radial surface of the trapezium. Contact stress between the first metacarpal and the trapezium was found to be greatest during lateral pinch. Using a specially designed pinch measuring device, Cooney and Chao (1977) measured 12 kg of compressive force at the thumb CMC joint during lateral pinch exerting a force of 1 kg. This implies that the functional task of lateral pinch when starting the car or handwriting produces 12 times the force through the CMC joint. It is likely that forceful pinch during daily activities will aggravate pain, and possibly contribute to progression of CMC OA.

In addition to the excessive force found at the CMC joint during pinch, other movements including thumb metacarpal pronation, adduction and flexion have been found to concentrate joint contact stress on the dorsal area of the trapezium (Koff et al. 2003). Hence, restricting these movements may alter the contact stress on the unhealthy cartilage and preserve the CMC joint. There is also evidence supporting the association between occupations involving repetitive thumb use (tasks requiring repeated thumb flexion and extension more than once per minute) with an increased risk for CMC OA (Fontana, Neel, Claise, Ughetto, & Catilina, 2007). Splinting the thumb in the recommended position of thumb palmar abduction, so that the index and thumb can oppose, (Colditz, 2000) can restrict repetitive thumb movement. The question remains how to restrict some movements at the thumb but allow some freedom to perform every day

activities. For patients to be able to perform gripping and pinching movements a smaller, less restrictive splint is required – yet this type may not provide enough joint stability to effectively reduce pain. It is impossible to completely immobilize the thumb CMC joint, however by restricting the movement at the joint, pain relief is anticipated.

In view of the preceding theoretical foundation for thumb splints, it is not surprising that many different splints exist. There are prefabricated ("off-the-shelf") and custommade splints, of various materials including fabric, plastic, and leather, using different designs, such as short (thumb only) and long (thumb and wrist). In an overview of the use of splinting for individuals with upper extremity OA (Yonclass, Nadler, Moran, Kepler & Napolitano, 2006), the authors state that there is good theory to support the effectiveness of splinting in hand OA, however there have been few empirical studies to support the selection of any one type of splint.

In discussion with several hand clinics in BC, occupational therapists and hand therapists stated that the decision to use a certain type of splint is based on patient and therapist preference; this concurs with my clinical experience. Therapists typically develop an individualized treatment plan depending on the patient's symptoms together with their knowledge of biomechanical theory. It was through this discussion that two hand clinics within Vancouver Island Health Authority and one private hand clinic agreed to compare two commonly used splints in an attempt to gather evidence to guide treatment decisions. Therefore, the proposed study arises directly from the health care providers and end-users of the study results.

Evidence based recommendations for the management of hand OA have been developed by European League Against Rheumatism (EULAR) in 2006 (Zhang et al., 2007). EULAR reports level 4 evidence (expert opinion) exists to support the use of thumb splints in CMC OA, but there have not been any randomized controlled trials (RCT) with placebo (sham treatment) or no splint as the comparator in CMC OA. Even though EULAR reports only level 4 evidence exists, several quasi-experimental studies have examined the effects of splinting the thumb in CMC OA. The existing evidence, systematically reviewed by Pasterno-Sluga and Stieger (2004) as well as by Egan and Brosseau (2007), suggests that thumb splints reduce pain, but their effect on function is not fully known because few splinting studies have included functional outcome

measures. It is unknown whether splinting has an effect on the ability to perform tasks such as opening containers and writing or whether there is an effect on pinch strength.

Literature Review

The literature review is organized in two sections: a review of CMC splinting studies, and a discussion of clinical trial issues relevant to the proposed study.

Splinting effectiveness in CMC OA. Only a few studies have evaluated the effect of thumb splints in adults with thumb OA, with varied results. In a narrative review on the effectiveness of hand splinting, Paternostro-Sluga and Steiger (2004) point out that even though the clinical use of splinting is widespread, there is little scientific evidence to support its effectiveness. Egan and Brousseau (2007) conducted a systematic review that examined the effect of splinting for CMC OA. They found 16 published studies, up to 2006, of which 7 met their inclusion criteria and 9 were theoretical discussions, case studies and an earlier systematic review from 2004 (which included 4 of the 7 studies reviewed by Egan & Brousseau). A summary of these clinical trials as well as an additional RCT and 2 observational trials is presented in Table 1.1. Pedro scores were used to rate the methodological quality of the RCT's (http://www.pedro.org.au/scale_item.html).

Beginning with the highest level of evidence, two small randomized crossover trials were reported, comparing different splint designs. In the first crossover trial, 26 participants wore 2 different thermoplastic thumb splints (a short, less restrictive versus a long, more restrictive splint) for 1 week each (Weiss, LaStayo, Mills & Bramlet, 2000). The authors reported that both long and short splints significantly decreased thumb pain, and they did not observe a significant difference between the two splints. ADL were reportedly improved with the use of the short thumb splint compared to the long thumb splint. The short thumb splint was the preferred splint for 73% of patients.

Another crossover trial led by the same primary author (Weiss et al., 2004) compared the same custom-made short thumb splint based on biomechanical principles (Colditz, 2000) with a prefabricated long neoprene (Comfort Cool) splint on 25 participants. They found a significant

decrease in pain with both splints, however it was significantly greater with the prefabricated Comfort Cool™ splint (mean change scores of 3.59 and 2.29, respectively, using VAS; p = 0.02). Pinch strength was stronger with the Comfort Cool™ and it was preferred by patients. The results showed a trend of greater improvement in ADL with the use of the Comfort Cool™. On radiological examination both splints significantly reduced the CMC joint subluxation, however, the custom-made splint provided better reduction than the Comfort Cool™. Both studies (Weiss et al. 2000, 2004) used a non-validated measure of ADL function, the "Self-rated Scale of Activities of Daily Living". Additional limitations of both studies are the small sample sizes, very short treatment intervention period of 1 week and no washout periods in between splints.

The third crossover trial compared 3 different splints worn for 4 weeks each: a semi-rigid polyethylene hand-based splint, a firm elastic splint with a rigid strip along the back of the thumb, and a soft elastic wrist splint, in 10 women with thumb OA (Buurke, Grady, de Vries & Baten, 1999). No significant improvements were found in pain for any of the splints. The soft elastic wrist splint was preferred by 6/10 patients for comfort and function, and this splint also demonstrated a statistically significant improvement in function measured by a timed test of 3 different hand grips. More appropriate hand function measures would be useful in future studies as these patients reportedly found the more rigid splints interfered with use of the hand. Also, the small sample size increased the likelihood of a Type 2 error.

In an RCT designed to assess the effect of conservative treatment on preventing thumb surgery, Berggren and colleagues randomly assigned 33 women on a thumb surgery waitlist to a long prefabricated thumb splint (n = 11), a short custom-made leather splint (n = 11) and ADL training (n = 11), using surgery as the primary outcome to assess the success of these conservative treatments. Participants were followed by a hand surgeon on two occasions, at 7 months and at 7 years. The results showed that 23 participants (70%) did not require surgery at 7 months, irrespective of splint group. By 7 years, 4 had died and only 2 of the remaining 19 participants had surgery. The main purpose of this study was to measure the effect of splinting on the need for CMC arthroplasty surgery, which although important, neglects to measure the effect of the thumb splint on function, which is critical to addressing the issue of everyday disability. There appeared to be no difference with regard to splint type or ADL training, but

there was inadequate statistical power to detect differences between the groups as only 11 women were in each treatment group and approximately 2/3 of each group did not require surgery.

Quasi-experimental studies may also offer some insight to guide practice decisions. Two observational studies were found on the effect of thumb splints in people with OA. A pretest-posttest study of 13 women treated with a short thumb splint demonstrated significant decreases in pain measured at 1 week, 1 month and 1 year after having the splint, suggesting the splint may relieve pain (Bongi, Guidi, Cencetti & Zoppi, 1991). Six ADL tasks such as turning a key and driving a car were performed at each follow up, and performance improved significantly on 5 of the 6 ADL tasks at all 3 times. The authors postulated that their specific splint design was small and light and therefore enhanced function.

In a follow-up study, 114 patients with severe or moderate radiographic OA were provided with long thumb splints, including the wrist and thumb metacarpal joint (Swigart et al., 1999). Pain, the only outcome, was measured by a postal questionnaire six months after receiving the splint. Among those with moderate OA, 76% described an improvement in symptoms, whereas only 54% with severe OA reported an improvement. Unfortunately there was a 35% attrition rate in this study and only 7 patients at the 6 month follow-up reported still wearing their splints, seriously challenging the credibility of the results.

More recently, a prospective pretest–posttest study (McKee & Eason-Klatt, 2006) compared the use of two short thumb splints for a 4-week period: one that left the thumb metacarpal-phalangeal (MCP) joint free (N = 9), while the other restricted MCP motion (N = 11). Compared to the baseline measures, statistically significant improvement was observed in pain, functional ability on the Patient Rated Wrist/Hand Evaluation, and lateral pinch strength, with no significant difference between the two groups. This suggests that, contrary to biomechanical theory, a minimalist splint that does not immobilize the MCP joint may be just as effective as the more traditional splint design. Unfortunately, the small sample size as well as non-random allocation to treatment group limits causal inference.

The preceding studies each assessed the effect of splinting alone, which is consistent with the purpose of the systematic review by Egan and Brousseau (2007). Several other trials were found that combined splinting with exercise, anti-inflammatory drugs and steroid injections.

In 2005, Wajon and Ada compared two different splints, a thumb strap and a short thumb splint combined with an exercise regime for 40 patients. Initially, both groups wore each splint for a period of 2 weeks, before the different exercise regimes were introduced. At the 2 week assessment both groups improved significantly in pain, pinch strength and on the Sollerman Test of Hand Function however there was no significant difference between groups. The authors attributed this to possible lack of statistical power.

One other prospective study using a single group pretest-posttest design followed 30 participants who had a corticosteroid injection combined with 3 weeks of wearing a prefabricated fabric thumb splint (Day et al., 2004). The primary purpose of this study was to evaluate the effect of non-surgical treatment for CMC OA. At 6 weeks only 13 participants experienced improvement in their pain level and twelve of the participants still had pain relief at 18 months. Measurement of function was administered using the Disabilities of the Arm, Shoulder, and Hand (DASH) a self-report questionnaire. The DASH scores were reported to correspond with the patient's symptom improvement. Sub-group analysis was performed based on the Eaton-Littler staging method of OA, where stage 1 has normal articular surfaces with subluxation or joint space widening, stage 2 shows joint space narrowing with ostephytes less than 2mm in diameter, stage 3 shows significant joint space narrowing, subchondral sclerosis and osteophytes greater than 2mm in diameter and stage 4 is the most severe stage of OA involving the scaphoid trapezium joint as well as the carpometacarpal joint (Eaton & Littler, 1987). Their findings suggested that 83% of those with stage 1 thumb OA, 41% with stage 2 and 3 OA and 14% with stage 4 OA had long-term pain relief. This study is relevant to the present review of CMC splinting because it mimics clinical practice where patients often receive cortisone injections concurrently with a splint. Many hand surgeons base their practices on a combination of corticosteroid injections and splinting (Siegel et al.,1991,Van Heest & Kallemeier, 2008). Because the study combined steroid injection with splinting, and because the splint was

prescribed for only the 3 weeks following the injection, a conclusion cannot be drawn regarding splint effects solely.

In summary, there is some evidence that splints provide pain relief in thumb OA, however, there is even less empirical evidence regarding performance of everyday activities. Of the 10 studies summarized above, only 3 used a standardized hand function test, and only 4 measured pinch strength. No one splint design appears consistently superior, however, Weiss et al. (2004) found the prefabricated neoprene Comfort Cool™ splint was preferred by patients for pain relief and comfort, and it also demonstrated greater pinch strength compared to the custom-made splint, even though CMC joint stabilization appeared better on x-ray with the custom-made splint. Combining the comfort of neoprene with the stabilizing property of a custom-made thermoplastic splint may achieve both objectives of enhancing hand function and reducing pain symptoms. Such a "hybrid" splint, designed by Pat McKee (presentation at an Orthotics Workshop, Vancouver, BC Sept 15, 2007), has generated considerable clinical interest and warrants further study.

The above literature review concurs with Egan and Brousseau's (2007) conclusion. They recommended further studies be undertaken comparing different splints and taking into account the stage of OA disease. There is a clinical need for more knowledge regarding the effectiveness of specific types of thumb splints. Given that thumb OA is so common and the potential for conservative treatment like splinting to delay surgery and potentially preserve function, there is a clear need to systematically gather evidence in support of the most appropriate splints, using validated outcome measures. Therefore, the present study was designed to compare two thumb splints that are used in everyday practice in occupational therapy on Vancouver Island: the prefabricated Comfort Cool™ thumb splint and McKee's custom-designed Hybrid splint.

Clinical trials: Equivalence vs. superiority designs. In planning the present study, current issues in the design of clinical trials were reviewed. The standard clinical trial sets out to demonstrate that a new treatment is superior to an existing treatment or placebo (Daya, 2001) – superiority is demonstrated in rejecting a null hypothesis of no difference between the new treatment and placebo, and accepting an alternative hypothesis that favours the new treatment.

However, there are clinical situations where a placebo-controlled trial is not possible or unethical, and comparing two treatments is more acceptable. The nuances of treatment comparators is more rigorous in drug trials or other interventions with higher risk of potential harm than most rehabilitation interventions, nevertheless, issues in assessing therapeutic equivalence gleaned from drug trials may be applied to more conservative treatment. In the case of splinting, where a placebo or sham treatment is almost impossible, equivalence trials may be appropriate.

Evidence exists to support the use of thumb splints in people with thumb OA to reduce pain, yet only one prior study has shown a superior effect of one splint design over another (Weiss et al., 2004). Equivalence studies are generally used to compare a new treatment to an existing treatment that has already been proven to be effective. In this case, the prefabricated neoprene, Comfort Cool™ splint was found to be effective in pain reduction, improved function and improved pinch strength (Weiss et al., 2004), and the Hybrid splint is a new treatment.

The design of equivalence trials is more complex than that of superiority trials and, it has been argued that it requires a high standard of conduct (Pater, 2004; Jones, Jarvis, Lewis, & Ebbutt, 1996). The equivalence trial seeks smaller treatment effect than the superiority trial, therefore a larger sample size is required. In the superiority trial, a difference in treatment effect is the desired outcome. This necessitates efforts to ensure that the treatment effect found is accurate and unbiased, by strict inclusion and exclusion criteria, randomization of treatment allocation, standardized treatments and measurements. These approaches tend to minimize bias and blur the results to show no treatment differences (Jones et al., 1996). For equivalence trials, these approaches make it more likely for a trial to show equivalence. Jones et al. recommends rigorous methods in the design, conduct and analysis of the equivalence trial to minimize the possibility of a Type I error, incorrectly concluding equivalence.

These rigorous methods include calculating the sample size based on a null hypothesis of non-equivalence, specifying the appropriate equivalence margin or confidence interval *a priori*, using both intention-to-treat and per protocol analyses. It is impossible to show absolute equivalence of both treatments in equivalence trials (Pater, 2004). Statistically, there will always be uncertainty,

regardless of how large the sample size is, it can only be shown that two treatments are close in performance (Lesaffre et al., 2001). This amount is called the equivalence margin and is typically based on the minimally clinically important difference (MCID) found in a previous superiority trial (Kaul & Diamond, 2006). The equivalence margin is determined before the beginning of a trial and should be substantially smaller than the MCID.

Our trial, comparing the effects of two different CMC OA thumb splints, attempts to follow those recommendations. The research aim is to show that both thumb splints are equally effective in improving hand function, reducing pain, and increasing hand strength. If the observed differences between the two splints fall within the specified equivalence margin for each outcome, we conclude the Hybrid thumb splint is equivalent to the standard Comfort Cool™. The practical implication of this is that the new splint is just as effective as the existing treatment, and clinicians can select either splint, using other factors to guide the decision, such as availability, patient preference or cost.

Ideally, the existing or standard treatment should have been proven to be superior in a placebo-controlled trial. The Comfort Cool™ has not been compared in a placebo-controlled trial; it is selected as the 'standard treatment' based on widespread use. It should be noted that the recent EULAR guidelines have recommended splinting for the management of thumb osteoarthritis, but no preference was given to any specific type of splints (Zhang et al., 2007). For these reasons, we argue that the active control, the Comfort Cool™ splint, will maintain its treatment effect in this clinical trial. The underlying assumption to an equivalence trial is that the active control is effective. This alleviates any doubt that both the control and the new splints may be equally ineffective.

The present study meets the requirements of an equivalence trial, to compare the two splints that are assumed to be equally effective on pain reduction and hand function. It must also meet two ethical principles (Djulbegovic & Clarke, 2001): (a) that the use of a new splint is justified (the less restrictive design and custom-fit is appealing) and (b) that the control or comparative treatment is appropriate (the Comfort Cool™ has evidence to suggest this is the case). Occupational therapists continually strive to improve the design of existing splints. Splint

modifications generally occur through practice and therapist's experience, as new materials become available or changes in splint length or shape are considered. This study selected a short custom-made splint designed by McKee et al., (2006), incorporating a neoprene thumb web space, thereby making it less bulky. This smaller splint may provide the same effect as the prefabricated Comfort Cool. Therapists in British Columbia are currently using both splints in their practice and this equivalence trial is justified to compare the benefits of both splints and guide practice.

Merits of using a crossover design. Clinical equivalence trials are often conducted using a crossover design (Zhang, 2003). By using repeated measures of different treatments, on one group of participants who act as their own control, all subject variables remain constant throughout the trial. This removes the between subject variation that is present in a parallel group design. It is believed the variability of measures taken on different participants, as is the case in parallel groups designs, exceeds the variability of repeated measures taken on the same subject (Jones & Kenward, 2003).

Statistically, crossover designs can reduce the variance of the estimated treatment difference because there is usually a positive correlation between the within-subject's responses to two treatments (Piantadosi, 2005) as they come from the same subject. In parallel group designs, there is no correlation of responses between treatment groups. Thus, the treatment difference is estimated with greater precision, resulting to a reduction in the sample size.

The greatest advantage of crossover trials is the smaller sample size required. All participants receive all treatments, therefore the same number of observations are made with half the number of participants as in a parallel group design. Patients may also be more willing to participate as they know they will receive both treatments eventually compared to the parallel group design where they may be in the group that receives the less beneficial treatment; crossover trials may generate better compliance (Piantadosi, 2005).

The simplest crossover trial is the 2 treatment/2 phase design, which is used in the present study. We compare two different thumb splints worn for 4 weeks each. The treatment order is

randomized to minimize treatment-by-period interaction and carry-over effect. An example of treatment-by-period interaction may occur if a subject's condition (osteoarthritis) changes during one treatment period as compared to the other. Carry-over effects arise when the treatment effect from one thumb splint is still present during the next treatment period. To allow time for the active effect of the treatment to wear off, a wash-out period of 1 week was put in place. Measurements are repeated at the end this wash-out to demonstrate return to baseline. Jones and Kenward (2003) state that if a trial is well designed, there is only a small chance of treatments interacting with periods.

There is some controversy over whether or not statistical analyses should test for carryover. As, stated above, Piantadosi (2005) also states that the careful design of a trial should control for carryover, then preliminary testing for carryover is not necessary. It has been suggested that by testing for carryover, there is room for error, possibly stating that carryover is present erroneously. This in turn biases the data to accept a positive treatment effect when in actuality there was not any (Wang & Hung, 1997).

Other disadvantages to the crossover design include the inconvenience to the patients, requiring more time to complete both treatments. However, in this case it may be advantageous for patients with thumb OA to try two treatments and determine which thumb splint may benefit them the most.

The crossover trial compares the subject's response to treatment A (the Comfort Cool™) to his/her response to treatment B (the Hybrid splint). By removing the subject variation, this type of clinical trial is considered more powerful than a parallel group trial (Feng, 2004). Using a crossover design is appropriate with our population of CMC OA as this is a constant condition that does not fluctuate a great deal. Also, our chosen treatment, splinting, has a short term outcome that is unlikely to have a carryover effect after the splint is withdrawn.

Research Questions and Hypothesis
The purpose of this study was to compare the effect of the Hybrid thumb splint with the Comfort Cool™ thumb splint on hand function, pain and hand strength. The goal was to provide more

evidence for clinical practice, to assist therapists and patients to make decisions about selecting splints to treat thumb OA.

There were two main research questions:

1. Is the effect of the new Hybrid splint equivalent to the Comfort Cool™ thumb splint in adults with CMC OA, on self-reported hand function, pain, and hand strength, after 4 weeks of use?
2. What is the effect of CMC splints on perceived hand function, pain & strength?

Given the results of the literature review, which showed limited evidence for the effect of splints on hand function, the primary outcome for the study was hand function. That is, the study sample size was calculated with regard to detecting differences in hand function. Pain, grip strength and pinch strength were selected as secondary outcome measures.

Because therapists are interested in the client's perspective, and whether or not a therapeutic effect is maintained over time, additional research questions were posed:

3. After trying each splint for 4 weeks, which of the two splints did participants prefer?
4. What was the effect of a thumb splint on hand function and pain at 3 months?

Chapter 2 presents the method and findings in the form of a manuscript for publication. Chapter 3 discusses what was learned in the research process and explores the implications of this study in greater depth.

Table 1.1 Summary of the Evidence for Splinting in CMC OA

AUTHORS (sample size)	TYPE OF SPLINT	OUTCOMES			EFFECT SIZES	PEDRO	CONCLUSION
		Pain	Self-report Function	Performance based Function			
COMPARISON STUDIES							
Weiss et al., 2000 Randomized Crossover (n=26)	**CM[1] short –** thermoplastic	Decreased	42% activities easier	No change in pinch	NA[3]	6	No significant difference between splints Short splint preferred by 73%
	CM long – thermoplastic	Decreased	16% activities easier	No change in pinch			
Weiss et al, 2004 Randomized Crossover (n=25)	**CM short –** thermoplastic	Decreased	26% activities easier	No change in pinch	NA[3]	6	PF long splint significantly less pain and greater pinch strength
	PF[2] long - neoprene	Decreased, significantly less pain than CM short	48% activities easier	No change in pinch Pinch strength: PF > CM (p=.012)			
Buurke et al., 1999 Randomized Crossover (n=10)	**PF long –** thin thermoplastic			Pinch inconclusive as patients complained of too much pain	Pain = 0.03, 0.21, 0.23 Green Test of Function = 0.09, -0.32, -0.43	5	Most flexible splint was the preferred
	PF long – semi-rigid elastic						
	PF long – elastic	Performed the best on VAS pain decrease, but not significant	Green test of function score was best (p=.09)				

16

AUTHORS (sample size)	TYPE OF SPLINT	OUTCOMES			EFFECT SIZES	PEDRO	CONCLUSION
		Pain	Self-report Function	Performance based Function			
Berggren et al., 2001 Randomized Controlled Trial (n=33)	**CM short -** leather **PF long –** semi-stable textile No splint	Symptoms improved, no significant difference between groups			NA[3]	4	Only outcome was desire to have surgery 23/33 opted not to have surgery after 7 mos.
SINGLE CONTROLLED STUDIES							
Bongi et al., 1991 Pretest-posttest (n=13)	**CM short –** thermoplastic	VAS pain decreased		5/6 ADL tasks improved	NA	4	Splinting is useful for pain relief and performance improvement in CMC OA
Swigart et al., 1999 Retrospective (n=74)	**CM long –** thermoplastic	76% stages 1 & 2 OA symptoms improved, 54% stages 3 & 4 OA symptoms improved			NA	2	Splinting is an effective conservative treatment for symptomatic CMC OA
UNPUBLISHED STUDY							
McKee et al., 2006 Pretest-posttest (n=20)	**CM short –** thin thermoplastic	Pain decreased	PRWHE function scores improved	Pinch improved, no change in grip from baseline to f/u	Pain = -0.17 PRWHE[4] function = -0.42	4	No significant differences between splints, except grip strength was less

AUTHORS (sample size)	TYPE OF SPLINT	OUTCOMES			EFFECT SIZES	PEDRO	CONCLUSION
		Pain	Self-report Function	Performance based Function			
	CM short – thin thermoplastic	Pain decreased	PRWHE function scores improved	Pinch improved, no change in grip from baseline to f/u	Lateral pinch = 0.22		with the thumb MCP incl.
COMBINATION STUDIES							
Wajon & Ada, 2005 Randomized Controlled Trial (n=40)	CM short – thermoplastic	VAS pain decreased		Sollerman test of hand function improved, pinch improved	Pain = 0.17 Tip pinch = 0.24 Sollerman Test = 0.07	8	No significant differences between each splint after 2 wks.
	CM short – thermoplastic	VAS pain decreased		Sollerman improved, tip pinch improved 0.6kg			
Day et al., 2004 Prospective (n= 30)	PF long - cloth	Pain decreased in 13/30 (5/6 Stage 1 OA, 7/17 Stage 2 & 3 , 1/7 Stage 4)	DASH corresponded with symptom improvement		NA	3	Splinting combined with corticosteroid injection may provide relief of CMC OA symptoms

Abbreviations: [1] CM = custom-made; [2] PF = pre-fabricated; [3] NA = not available; [4] PRWHE = Patient Rated Wrist Hand Evaluation

References

Baron, M., Dutil, E., Berkson, L., Lander, P., & Becker,R. (1987). Hand function in the elderly: relation to osteoarthritis. *Journal of Rheumatology, 14*, 815-819.

Berggren, M., Joost-Davidsson, A., Lindstrans, J., Nylander, G., & Povlsen, B. (2001). Reduction for the need for operation after conservative treatment of osteoarthritis of the first carpometacarpal joint: A seven year prospective study. *Scandinavian Journal of Reconstructive Hand Surgery, 35,* 415-17.

Bongi, M.S., Guidi, G., Cencetti, A., & Zoppi, M. (1991). Treatment to carpometacarpal joint osteoarthritis by means of a personalized splint. *Pain Clinic, 4,* 119-123.

Buurke, J.H., Grady, J.H., de Vries, J., & Baten, C.T.M. (1999). *Clinical Rehabilitation, 13*, 288-94.

Colditz, J. (2000). The biomechanics of a thumb carpometacarpal immobilization splint: Design and fitting. *Journal of Hand Therapy, 13*, 228-235.

Cooney, W. & Chao, E. (1977). Biomechanical analysis of static forces in the thumb during hand function. *The Journal of Bone and Joint Surgery American Edition, 59*, 27-36.

Cooper, C. (1994). Osteoarthritis epidemiology. In J. Klippel & P. Dieppe, (Eds), *Rheumatology*, pp. 7.3.1 – 7.3.4. London: Mosby.

Chaisson, C., Zhang, Y., McAlindon, T., Hanan, M., Aliabadi, P., Naimark, A., et al. (1997). Radiographic hand osteoarthritis; incidence, patterns and influence of pre-existing disease in a population based sample. *Journal of Rheumatology, 24*, 1337-1343

Dahaghin, S., Bierma-Zeinstra, S.M., Ginai, A., Pols, H.A., Hazes, J.M., & Koes, B.W. (2005). Prevalence and pattern of radiographic hand osteoarthritis and association with pain and disability (the Rotterdam study). *Annals of the Rheumatic Diseases, 64*, 682-687.

Day, C., Gelberman, R., Patel, A., Vogt, M., Ditsios, K., & Boyer, M. (2004). Basal joint osteoarthritis of the thumb: A prospective trial of steroid injection and splinting. *The Journal of Hand Surgery, 29A,* 247-251.

Daya, S. (2001). Issues in assessing therapeutic equivalence. *Evidence-based Obstetrics and gynecology, 3,* 167-168.

Dickson, R.A., & Morrison, J.D. (1979). The pattern of joint involvement in hands with arthritis at the base of the thumb. *Hand, 11,*249-255.

Djulbegovic, B. & Clarke, M (2001). Scientific and ethical issues in equivalence trials. *Journal of the American Medical Association, 285*, 1206-1208.

Dominick, K., Jordn, J., Renner, J. & Kraus, V. (2005). Relationship of radiographic and clinical variables to pinch and grip strength among individual with osteoarthritis. *Arthritis & Rheumatism, 52*, 1424-1430.

Eaton, R. & Glickel, S. (1987). Trapeziometacarpal osteoarthritis. Staging as a rationale for treatment. *Hand Clinics,* 3: 455-471.

Egan, M. & Brosseau, L. (2007). Splinting for osteoarthritis of the carpometacarpal joint: A review of the evidence. *American Journal of Occupational Therapy, 61,* 70-8.

Fautrel B., Hilliquin, P., Rozenberg, S., Allaert, F.A., Coste, P., Leclerc, A., & Rossignol, M. (2005). Impact of osteoarthritis: Results of a nationwide survey of 10,000 patients consulting for OA. *Joint Bone Spine, 72*, 235-40.

Feng, W. SAS application in 2 X 2 crossover clinical trial. Paper SP02. Medfocus inc. Available at: http://www.lexjansen.com/pharmasug/2004/statisticspharmacokinetics/sp02.pdf. Accessed January 16, 2009.

Fontana, L., Neel, S., Claise, J., Ughetto, S. & Catilina, P. (2007). Osteoarthritis of the thumb carpometacarpal joint in women and occupational risk factors: A case-control study. *The Journal of Hand Surgery, 32A,* 4, 459-465.

Glickel, S.Z., & Home L.T. (2001). Basal joint arthroplasty: Indications and treatment. *Current Opinion in Orthopedics, 12*, 1290-294.

Grant, M. (2005). Occupational therapy for people with osteoarthritis: Scope of practice and evidence base. *International Journal of Therapy and Rehabilitation, 12*, 7-12.

Hwang, I. & Morikawa, T. (1999). Design issues in noninferiority/equivalence trials. *Drug Information Journal, 33*, 1205-1218.

Hirsch, R., Guralnik, J.M., Ling, S.M., Fried, L.P., & Hochberg, M.C. (2000). The patterns and prevalence of hand osteoarthritis in a population of disabled older women: The Women's Health and Aging Study. *Osteoarthritis and Cartilage, 8* Suppl A:S16-21.

Kaul, S. & Diamond, G. (2006). Good enough: A primer on the analysis and interpretation of noninferiority trials. *Annals of Internal Medicine, 145,* 62-69.

Kjeken, I., Dagfinrud, H., Slatkowsky-Christensen, B., Mowinckel, P., Uhlig, T., Kvien, T.K., & Finset, A. (2005). Activity limitations and participation restrictions in women and hand osteoarthritis: Patient's descriptions and associations between dimensions of functioning. *Annals of the Rheumatic Diseases, 64*, 1633-38.

Koff, M., Ugwonali, O., Strauch, R., Rosenwasser, M., Ateshian, G. & Mow, V. (2003). Sequential wear patterns of the articular cartilage of the thumb carpometacarpal joint in osteoarthritis. *Journal of Hand Surgery, 28*, 597-604.

Kovler, M., Lundon, K., McKee, N. & Agur, A. (2004). The human first carpometacarpal joint: Osteoarthritic degeneration and 3-dimensional modeling. *Journal of Hand Therapy, 17,* 393-400.

Jones, B., Jarvis, P., Lewis, J., & Ebbutt, A. (1996). Trials to assess equivalence: the importance of rigorous methods. *British Medical Journal, 313*, 36-39.

Jones, B., & Kenward, M. (2003). What is a crossover trial? In E. Chapman & W. Hall (Ed.), *Design and analysis of cross-over trials* (pp. 1-29) CRC Press.

Lesaffre, E., Bluhmki, E., Wang-Clow, F., Danays, T., Fox, N. & Van der Werf, F. (2001). The general concepts of an equivalence trial, applied to ASSENT -2, a large-scale mortality study comparing two fibrinolytic agents in acute myocardial infarction. *European Heart Journal,* 22, 898-902.

Mannoni, A., Briganti, M.P., Di Bari, M., Ferrucci, L., Serni, U., Masotti, G. & Marchionni, N. (2000). Prevalence of symptomatic hand osteoarthritis in community-dwelling older persons: the ICARe Dicomano study. *Osteoarthritis & Cartilage, 8* Suppl A:S11-13.

McKee, P., & Eason-Klatt, M. (2006, September). *A multi-center study comparing two styles of orthoses for individuals with thumb carpometacarpal osteoarthritis – less is more.* Paper presented at the meeting of the American Society of Hand Therapists, Atlanta, GA.

McKee, P. Intermediate/Advanced Upper Extremity Orthotics, Presented at Orthotics Workshop, Vancouver, BC, September15, 2007.

Moulton, M., Parentis, M., Kelly, M., Jacobs, C., Naidu, S., & Pellegrini, V. (2001). Influence of metacarpalphalangeal joint position on basal joint-loading in the thumb. *Journal of Bone and Joint Surgery,* 83A, 5, 709-716.

Pasternostro-Sluga, T. & Stieger, M. (2004). Hand splints in rehabilitation. *Critical Reviews in Physical and Rehabilitation Medicine, 16,* 233-256.

Pater, C. (2004). Equivalence and noninferiority trials – are they viable alternatives for registration of new drugs? (III) *Current Controlled Trials in Cardiovascular Medicine* [On-line serial], 5 (8). Available FTP: *http://cvm.controlled-trials.com/content/5/1/8*

Piantadosi, S. (2005). Crossover designs. In R. Chappell (Ed.), *Clinical trials: A methodological perspective* (pp.515-527). Baltimore, MD: A John Wiley & Sons Inc.

Poole, J. & Pellegrini,V. (2000). Arthritis of the thumb basal joint complex. *Journal of Hand Therapy, 13*, 91-107.

Rahman, N., Thomas, J., and Rice, M. (2002). The relationship between hand strength and the forces used to access containers by well elderly persons. *American Journal of Occupational Therapy, 56*, 78-85.

Riley, M. (1998). The effects of medical conditions and aging on hand function. *OT Practice, 3* (6), 24-27.

Siegel, D.B., Gelberman, R.H., Smith, R. (1991). Osteoarthritis of the hand and the wrist. In R.H. Gelberman, (Ed.), *Operative nerve repair and reconstruction,* Philadelphia: Lippincott.

Swigart, C., Eaton, R., Glickel, S., & Johnson, C. (1999). Splinting in the treatment of arthritis of the first carpometacarpal joint. *Journal of Hand Surgery, 24,* 86-91.

Tinetti, M., Inouye, S., Gill, T., & Doucette, J. (1995). Shared risk factors for falls, incontinence, and functional dependence: Unifying the approach to geriatric syndromes. *Journal of American Medical Association, 237,* 1348-1353.

Van Heest, A., & Kallemeier, P. (2008). Thumb carpalmetacarpal arthritis. *Journal of the American Academy of Orthopaedic Surgeons, 16,* 140-151.

Wajon, A., & Ada, L. (2005). No difference between two splint and exercise regimes for people with osteoarthritis of the thumb: A randomized controlled trial. *Australian Journal of Physiotherapy, 51,* 245-249.

Wang, S., & Hung, H. (1997). Use of a two-stage test statistic in the two-period crossover trials. *Biometrics, 53,* 1081-1091.

Weiss, S., LaStayo, P., Mills, A., & Bramlet, D. (2000). Prospective analysis of splinting and the first carpometacarpal joint: An objective, subjective and radiographic assessment. *Journal of Hand Therapy, 13,* 218-226.

Weiss, S., LaStayo, P., Mills, A., & Bramlet, D. (2004). Splinting the degenerative basal joint: Custom-made or prefabricated neoprene? *Journal of Hand Therapy, 17,* 401-406.

Wilder, F., Barrett, J., & Farina E. (2006). Brief report: Joint specific prevalence of osteoarthritis of the hand. *Osteoarthritis and Cartilage, 14,* 953-957.

Yonclass, P.P., Nadler, R.R., Moran, M.E., Kepler, K.L. & Napolitano, E. (2006). Orthotics and assistive devices in the treatment of upper and lower limb osteoarthritis. *American Journal of Physical Medicine & Rehabilitation, 85* Suppl:S82-S97.

Zhang, P. (2003) A simple formula for sample size calculation in equivalence studies. *Journal of Biopharmaceutical Statistics,* 13, 3, 229-538.

Zhang, W., Doherty, M., Leeb, B., Alekseeva, L., Arden, J., Bijlsma, J., Dincer, F., Dziedzic, K., Hauselmann, H., Herrero-Beaumont, G., Kaklamanis, P., Lohmander, S., Verbruggen, G. and Zimmermann-Gorska, I. (2007). EULAR evidence based recommendations for the management of hand osteoarthritis: Report of a task force of the EULAR standing

committee for International Clinical Studies Including Therapeutics (ESCISIT). *Annals of the Rheumatic Diseases, 66*, 377-388.

Zhang, Y., Niu, J., Kelly-Hayes, M., Chaisson, C., Aliabadi, P., & Felson, D. (2002). Prevalence of symptomatic hand osteoarthritis and its impact on functional status among the elderly. *American Journal of Epidemiology, 156,* 1021-1027.

CHAPTER 2

A CROSSOVER TRIAL COMPARING A PREFABRICATED NEOPRENE THUMB SPLINT AND A CUSTOMMADE THUMB SPLINT FOR CARPOMETACARPAL OSTEOARTHRITIS[1]

Background

Osteoarthritis (OA) of the thumb carpometacarpal (CMC) joint is a common disorder, affecting up to 20% of men and women over the age of 40 (Wilder, Barrett, & Farina, 2006). As people age, the incidence of CMC OA increases. Prevalence rates of radiographic CMC OA have been cited as high as 42% in males and 57% in females over the age of 75 (Van Saase, Van Rommunde, Cats, Vandenbrouke & Valkenburg, 1989). Symptomatic hand OA is less prevalent than radiographic hand OA, yet it has still been found to be present in 37% of the population over the age of 60 (Dillon, Hirsch, Rasch & Gu, 2007).

Symptomatic CMC OA manifests itself through pain, joint stiffness and weakness of the thumb. When individuals with symptomatic hand OA were compared with asymptomatic individuals, they reported two to three times as many functional limitations with dressing, eating and carrying a 10 pound load (Dillon et al., 2007). Symptomatic hand OA has been associated with difficulties performing activities of daily living (ADL) and work tasks (Fautrel et al., 2004) and with weak grip and pinch strength (Dominick, Jordan, Renner, & Kraus, 2005). In the Framingham study (Zhang et al., 2002) participants with symptomatic hand OA had 2 to 3 kg (10%) less grip strength (measured with a hand-held dynamometer) compared to those without symptomatic hand OA.

There is a significant association between radiographic CMC OA and hand pain, compared to other hand joints (Dahaghin et al., 2004). Furthermore, CMC OA of the dominant hand was found significantly associated with hand disability. Radiographic hand OA has been found to have a significant association with grip and pinch strength (Dominick et al. 2005; Kjeken et al., 2005), suggesting that hand strength decreases in the presence of OA. Kjeken and colleagues reported that women with OA had only 60% of the expected grip strength norms for their age.

---

[1] A version of this chapter will be submitted for publication: Sillem, H., Backman, C.L., Miller, W.C. & Li, L.C. A crossover trial comparing prefabricated neoprene and custommade thumb splints for carpometacarpal osteoarthritis.

The exact etiology of CMC OA remains unclear; however, several mechanisms have been proposed. Pellegrini (1992) has demonstrated an association between ligamentous laxity, generalized joint hypermobility and cartilage degeneration at the CMC joint. Joint impingement theory (Kovler, Lundon, McKee & Agur, 2004) suggests that during pinch there is reduced contact between the trapezium and the metacarpal, increasing contact stress. This increase in damaging force can subsequently result in joint degeneration. Biomechanical theory supports stabilizing the CMC joint to reduce any deforming forces. This can be accomplished through splinting the CMC joint.

Given the prevalence of CMC OA, it is a frequent clinical diagnosis seen by occupational therapists, physiotherapists and hand therapists. The first line of conservative treatment is splinting. The intention of splinting is to provide support to the CMC joint while permitting functional movement of the hand. A variety of thumb splints are available, both prefabricated and custom-made, and in different types of material. Unfortunately, there are no guidelines specifying the type of splint suitable for CMC OA and only a few well-designed studies are available on the effectiveness of splinting the CMC joint.

Recently, a systematic review (Egan & Brousseau, 2007) of the evidence for splinting in CMC OA concluded that there was fair evidence to support using thumb splints for pain reduction. The authors used the American Occupational Therapy Association's Evidence-Based Practice Project schema (Lieberman & Scheer, 2002) to rate the levels of evidence of each splinting study. In their review, 7 studies met inclusion criteria. Statistically significant improvement in pain was found in 3 of the 7 studies with the use of thumb splints (Bongi, Guidi, Cencetti, & Zoppi, 1991; Weiss, LaStayo, Mills, & Bramlet, 2000, 2004). Of the 4 comparative trials, only 1 (Weiss et al., 2004) showed a significant difference between the two thumb splint's effects on pain. However, most of the included studies were limited by small sample sizes, short treatment times, and other methodological flaws, hence the evidence to support splinting the thumb in CMC OA for pain relief is considered limited. Of the 3 studies that considered the effects of splinting on muscle strength, no improvement was observed in objective measures such as pinch and grip strength.

ADL performance showed a statistically significant improvement in only 2 of the 4 studies that measured it (Bongi et al., 1991; Buurke, Grady, de Vries, & Baten, 1999).

In addition to the above mentioned studies, 3 other CMC splinting studies were located. McKee and Eason-Klatt's (2006) unpublished study compared the effects of 2 short CMC stabilizing splints, one that included the thumb metacarpalphalangeal (MCP) joint and one that left the MCP joint free. They found both splints had a statistically significant improvement in pain, hand function and pinch strength compared to the baseline measure, however no difference in these outcome measures was observed between the two splints. The effect size for splinting and pain relief was -0.17, for function it was -0.42 and for pinch strength it was 0.22, favoring the thumb splint which included the MCP joint. This is the first study to show an increase in lateral pinch strength after a splinting intervention for CMC OA.

The remaining 2 trials studied the combined effects of exercise and cortisone injections with splinting. In one of these trials (Wajon & Ada, 2005) the effects of 2 different thumb splints were measured after 2 weeks, before introducing the exercise routines. Pain, hand function and tip pinch improved significantly with both thumb splints. In the trial that combined the cortisone injection with 3 weeks of a long thumb splint (Day et al., 2004), there was a clinical improvement in pain relief, of more than 4 points on a VAS (0-10) with those patients who had earlier stages of CMC OA. Unfortunately the combination of a cortisone injection with splinting confounds any conclusion about the effects of CMC splinting.

The purpose of the present study was to compare the effectiveness of two different splints. Because the trend in splinting the thumb in CMC OA has moved towards a minimalist approach, one design is the short custom-made CMC stabilizing splint used in Weiss et al.'s studies (2000, 2004), as modified by McKee, using a thinner thermoplastic and incorporating neoprene to make the splint more flexible for grip and pinch, and improve comfort (personal communication, P. McKee, September 15, 2007). We labeled this modified design the Hybrid splint. The second splint is the prefabricated, neoprene, Comfort Cool™, the preferred splint for comfort, function and strength in Weiss et al's 2004 study (from North Coast Medical®). There were 4 research questions:

1. Is the effect of the new Hybrid splint equivalent to the Comfort Cool thumb splint in adults with CMC OA, on self-reported hand function, pain, and hand strength, after 4 weeks of use?
2. What is the effect of CMC splints on perceived hand function, pain & strength at 4 weeks?
3. After trying each splint for 4 weeks, which of the two splints do clients prefer?
4. What is the effect of a thumb splint on hand function and pain at 3 months?

Methods

     Participant Recruitment. Participants were recruited from 3 outpatient hand therapy departments on Vancouver Island, British Columbia. Two hand therapy departments (Nanaimo Regional General Hospital and Campbell River Hospital) are part of the public healthcare system, Vancouver Island Health Authority, and the third was a private hand clinic (Victoria Island Hand Clinic). Participants were referred by their family physicians, hand surgeons or rheumatologists for splinting intervention. Participants were enrolled in the study if they had a doctor's diagnosis of CMC OA. Additional inclusion criteria were: 1) adults aged 45 or older (the target population for thumb OA); and 2) ability to speak, read and write English. Even though 48 participants had x-rays within the last 2 years, these were undertaken at various private and public centres making it impossible for one radiologist to read them; fortunately, diagnosis of CMC OA based solely on symptoms and clinical examination is considered accurate (Mannoni et al., 2000). Participants were excluded from the study if they had 1) previous thumb surgery such as a trapezium arthroplasty; 2) concomitant neurological diagnoses, such as peripheral nerve injury, Parkinson's, or similar conditions (these conditions affect measures of daily function); and 3) diagnosed OA of the wrist, since this would require a different splint design that might subsequently affect the outcome.

Participants with bilateral CMC OA were included in the study if they had been referred for the fabrication of only one thumb splint or if they were willing to wait 9 weeks before having the second thumb splinted. In these cases, the most symptomatic thumb, based on the subjective report of pain was studied. The risks and benefits were explained to all participants and written consent was obtained.

The study protocol was approved by the Clinical Research Ethics Board at the University of British Columbia and the Clinical Research Ethics Board at Vancouver Island Health Authority. The study was registered at ClinicalTrials.gov (NCT00705146).

Research Design. An equivalence trial using a two period crossover design was conducted with consecutively referred patients randomly assigned to different treatment order. The two 4-week treatment periods were separated by a 1 week washout period. A table of random numbers was used to develop treatment order assignments. Numbers were inserted into opaque envelopes and divided into 3 groups for each site, initially allocating 8 to Campbell River, 16 to Nanaimo and 24 to Victoria, based on referral numbers. As recruitment lagged at Campbell River and Victoria, an additional 12 envelopes were provided to Nanaimo. Even numbers denoted the participant receiving the Hybrid splint first and odd numbers the Comfort Cool first. Envelopes were assigned to participants in consecutive order at each site as they arrived for their initial appointment.

This was designed as an equivalence trial anticipating both splints to have a similar effect on hand function, thumb pain and strength. The hypothesis for this equivalence trial states that a small (clinically irrelevant) difference exists between the Comfort Cool™ and Hybrid splints (i.e., falls within an acceptable equivalence margin). The predefined equivalence margin for this study was set at 8 points on the Australian Canadian Osteoarthritis Hand Index version 3.1 (AUSCAN) (Bellamy, Campbell, Haraoui, Buchbinder et al., 2002) function subscale; that is, a difference of 8 points or less on the AUSCAN function subscores after wearing each splint would allow us to reject the null hypothesis and consider the thumb splints equivalent.

Interventions. The prefabricated neoprene Comfort Cool™ splint (Figure 2.1), was fit according to size (S, M, M+, L). The custom-made Hybrid splint (Figure 2.2) was fabricated out of neoprene and 1.6 mm Colors™ by Orfit. Two therapists at each site were trained to provide the splints (a primary therapist and an alternate in case of vacation or other absence). Participants were instructed to contact the therapists as necessary for adjustments if the splints were uncomfortable. Participants were instructed to wear the splints when symptomatic, during

heavier manual tasks, and at nighttime if they desired. Therapists did not provide exercises or education regarding joint protection until the final outcome measurement session at 9 weeks. During the one-week washout period, participants were required to leave their first splint at their respective hand clinics. This ensured they would not be able to wear that splint at home and contaminate the second intervention period.

All participants were asked to keep a daily log reporting how many hours per day they wore their splint. Splints were provided free of charge and at the end of the study participants were given both splints. Participants were given a $10 gift card at each appointment as a token recognition of time given to the study. The total duration of the study was 9 weeks plus 1 follow-up phone call at 3 months.

Originally one therapist was trained at the Campbell River site, however she relocated midway through the study and the second therapist was trained at that site. Both therapists at Campbell River Hospital had little splinting experience. Two therapists were trained at the Victoria site because it was anticipated that this site would have the highest volume of participants with CMC OA. Both therapists from Victoria were experienced (greater than 5 years) in splinting. Two therapists were trained at the Nanaimo site in order to replace one therapist because of a preplanned summer vacation absence. Both therapists in Nanaimo were experienced in splinting. The treating therapists were not blinded to the splinting intervention.

To ensure standardized treatment protocols, therapists at each of the 3 sites attended a 2 hour orientation session detailing instructions on splint fabrication and study protocol, including standardized outcome measures. All occupational therapists were provided with video instructions as well as written instructions on splint fabrication. Therapists were able to practice splint fabrication at these orientation sessions. The study therapist was available for questions throughout the study.

Baseline and Outcome Measures. Data collection occurred at the initial visit (baseline, week 0), after the first splint (week 4), after the washout period (week 5) and after the second splint (week 9). Table 2.1 outlines the schedule of study visits and measures. The treating

therapists provided the participants with their splints and collected data at baseline and outcome sessions. Evaluation at baseline included demographic information, current medication use, hand dominance and occupation.

The primary outcome was hand function measured by the functional subscale of the AUSCAN. The AUSCAN is a self-report tool designed for people with hand OA. It consists of 15 questions with three subscales to rate pain, function and joint stiffness, measured using either a Likert (0 to 4) scale, visual analog scale (VAS) (choosing a point on a 10 cm line) and/or an 11 point (0-10) numerical rating scale (NRS). According to Bellamy (personal communication, October 22, 2006), the AUSCAN – NRS version is just as responsive as the VAS and simpler to use. The NRS version of the AUSCAN scale was chosen for this study. The AUSCAN function subscale consists of 9 questions regarding the level of difficulty to perform daily tasks such as opening a jar, holding a full pot with one hand, turning a doorknob, wringing out a washcloth and fastening jewelry or watches (Appendix C). Possible scores range from 0 to 90, with higher scores indicating worse function.

The AUSCAN demonstrates concurrent validity with more expensive observational assessments and other self-report outcome measures of hand function (Massy-Westropp, Krishnan, & Ahern, 2004) and grip and pinch strength (Allen, Jordan, Renner & Kraus, 2006: Jones, Cooley & Bellamy, 2001). It also demonstrates high construct validity with grip strength among older adults, similar to those recruited in the present study, (Jones et al.), and high test-retest reliability (Bellamy, Campbell, Haraoui, Gerecz-Simon et al., 2002).

Secondary outcomes were pain, measured with the AUSCAN hand pain subscale (possible score range 0-50), and hand strength as measured by grip and lateral pinch. Grip and pinch strength, were assessed using the Jamar dynamometer and Preston pinch gauge, respectively, in kg. We followed the protocol of the American Society of Hand Therapists (1992), which has well-established reliability and is widely used in therapy clinics in North America. The mean of 3 trials was recorded for both grip and pinch measurements of the splinted hand. Grip and pinch strength measurements at baseline and at week 5 (return to baseline) were taken without splints, and at weeks 4 and 9 with the splints on. Patient preference with respect to the splints was

assessed by asking participants to rate their satisfaction with comfort (fit), appearance, convenience and durability, using a 5-point Likert scale (Table 2.2).

Sample size and data analysis. The primary outcome of hand function was used to estimate sample size. An *a priori* power calculation indicated that 48 participants were required to test the null hypothesis of a small difference in hand function between the Hybrid and Comfort Cool splints. Up to this date there had been no published studies to determine the minimum clinically important difference (MCID) for the AUSCAN NRS version. Based on a review of the literature using the AUSCAN Likert and VAS versions, various estimates were calculated (Appendix D). These included standard deviations of the differences in AUSCAN VAS function scores of 15.91 (Bellamy, Campbell, Haraoui, Gerecz-Simon et al., 2002) and minimal meaningful change (MMC) scores of 5.8 to 8.97. To allow for possible attrition of 15%, a total of 56 participants were recruited.

Descriptive statistics (range, means and standard deviations), for the study sample were tabulated. The AUSCAN function subscale score, pain subscale score, grip strength and lateral pinch strength were evaluated for potential carryover and order effects using paired t-tests. Paired t-tests were used to compare the effects of the two splints with regard to changes from baseline to 4 weeks for AUSCAN function and pain scores, grip strength and lateral pinch strength (between groups comparisons). Paired t-tests were also used to assess the effect of each splint on AUSCAN function, pain, grip strength and pinch strength (within group comparisons). Chi square tests were used for the assessment of splint satisfaction questions and splint preference. An intention to treat analysis was used as well as per protocol analysis. A post hoc analysis examined outcomes based on hand dominance (compared participants whose dominant versus non-dominant hand was splinted). Statistical analysis was performed using SPSS Statistics Grad Pack version 17.0. Significance was accepted at a probability value of p <0.05.

Results

Participants. Fifty-nine patients with CMC OA were invited to the trial between April 1, 2008 and March 31, 2009 (Figure 2.3). Three declined to participate due to travel and time commitment. Fifty-six participants were randomized to splint order, either Hybrid first, Comfort

Cool second (HY-CC group, n= 24), Comfort Cool first, Hybrid second (CC-HY group, n=32). Participant characteristics are in Table 2.3. Participants were 45-84 years of age, with a mean age of 64 years (SD = 8.61). Bilateral CMC OA was present in 32 participants (57%), but those participants only had one thumb splinted for the duration of the study. In the HY-CC group, 1 participant withdrew without a given reason. In the CC-HY group, 1 participant withdrew due to illness (Figure 2.3). Both drop-outs were retained in the analysis and a last observation carried forward analysis was used for missing data.

Of the 54 participants who completed the study, 43 (80%) returned their daily logs for both splints and an additional 3 participants only returned their daily logs after wearing the Comfort Cool. Participants reported wearing the Comfort Cool splints for an average of 7.71 (SD = 5.18) hours per day and the Hybrid splints for 8.20 (SD = 5.42) hours per day. There was no significant difference between wearing times. One participant reported not wearing her second splint (Hybrid) at all because her symptoms had completely resolved.

When analyzing for treatment order effect, no significant differences were found in any of the outcomes (AUSCAN function and pain, grip and pinch strength) between those who received the Comfort Cool™ first and those who received the Hybrid first. There were no significant differences in any of the four outcome measures after the one-week washout period compared to baseline, indicating no carryover effect was present (Table 2.4).

Table 2.5 presents the mean baseline and 4 week scores for all four outcomes for each of the Comfort Cool™ and the Hybrid. The between splints comparison is presented in Table 2.6.

Hand function (primary outcome). The change scores for self-reported hand function using the AUSCAN did not differ significantly between the two splints (Table 2.6). The AUSCAN function subscores improved with both the Hybrid and the Comfort Cool™ splints, by 5.54 and 2.69 points respectively, however, paired t-tests showed that this improvement over baseline was statistically significant only for the Hybrid (Table 2.5). Overall, after wearing the Comfort Cool for 4 weeks, 28 participants had a measureable improvement in AUSCAN

function subscore compared to 29 participants after wearing the Hybrid for 4 weeks. The overlap in participants who improved after wearing either splint is 13 participants.

Pain. Participants who wore the Hybrid had a significantly greater reduction in pain symptoms than those wearing the Comfort Cool (Table 2.5). Pain improved after wearing both the Hybrid and the Comfort Cool splints for 4 weeks, but only the Hybrid had a statistically significant effect, as measured by the AUSCAN pain subscale. Thirty-two participants demonstrated an improvement in AUSCAN pain subscores after wearing the Comfort Cool for 4 weeks and 36 after wearing the Hybrid for 4 weeks.

Strength. Both grip and lateral pinch strength improved slightly, but not significantly, after wearing the splints for 4 weeks (Table 2.5).

Splint satisfaction rating. The Comfort Cool was rated as the preferred splint by 63% of the participants and the Hybrid by the remaining 37%. In chi square analyses, an association was found between those who preferred the Hybrid and high comfort ratings. For those who preferred the Comfort Cool, there was an association with high ratings for durability. No other ratings of splint characteristics were significantly associated with splint preference.

Hand dominance and duration of symptoms. To explore the characteristics of participants more likely to benefit from splints, post hoc analyses were conducted based on hand dominance and duration of CMC OA. (There were insufficient male participants to conduct a post hoc analysis based on gender.) When comparing results by hand dominance, a statistically significant improvement in function (9.24 points, SD = 20.27, p = 0.05) and pain (9.62 points, SD = 12.42, p < 0.01) was reported by those participants whose dominant hand was splinted with the Hybrid, but not for the Comfort Cool™. In contrast, no significant changes were found for any of the outcomes for participants whose non-dominant was splinted. There were no significant differences in outcomes between those participants who had recent CMC OA (symptoms for less than a year) and those who reported their onset of thumb pain more than a year ago.

Three month follow-up. At the end of the 9-week crossover trial, participants received both splints. At three months after initial baseline assessment, a follow-up phone call was made, and 44 participants (81%) were contacted. Four of those participants (9%) indicated that they were no longer wearing either splint: 3 because their symptoms had improved to the point that they no longer needed the splints and the fourth reported that both splints fell apart. Seven (13%) participants reported that they were still using both splints. The Hybrid splint was preferred for nighttime and gardening whereas the Comfort Cool™ was preferred for activities during the day such as going to the gym, golfing and driving.

The AUSCAN was administered over the phone. The results are presented in Table 2.7. Three month scores for the AUSCAN function and pain subscales were not significantly different from the scores after the initial splinting period (4 weeks) for either splint. When compared to baseline scores both the function and pain subscores improved significantly.

Additional treatments. In spite of efforts to control for concurrent treatments, 2 participants underwent cortisone injections during one of the treatment periods (1 in each splint order group) (Figure 2.3). It was also discovered after enrollment in the study that an additional 2 participants (also 1 in each splint order group) had received cortisone injections 1 to 3 weeks prior to beginning the study. The reported results include these participants. When the analysis was repeated excluding these participants it did not change the findings.

Discussion

The main purpose of this study was to compare the effect of two CMC splints on hand function. In the current head-to-head comparison of the Comfort Cool™ and the Hybrid, we failed to detect even a small difference between the 2 splints' effects on hand function, hence both splints appear to have similar effects on function.

The primary outcome of function was selected to focus on disability and the real-life impact of CMC OA on everyday activities rather than pain alone. Three measures of function were chosen, including the self-report AUSCAN questionnaire as well as grip and pinch strength measurements. In hand OA, grip strength has been strongly correlated with hand function

(Kjeken et al., 2005). The authors found that hand strength was the main contributing factor to hand related activity limitations. However, it has also been suggested that patient reported outcome may be superior to observational performance based tests (Stamm et al., 2007). By combining perceived functional ability with the performance based indicators of function, it was intended that actual functional improvement (or impairment) would be better captured.

In this study, the AUSCAN function subscores improved by a mean of 5.54 points after wearing the Hybrid for 4 weeks, however this improvement was not significantly different from the 2.69 mean improvement with the Comfort Cool, although it was better than participants' mean baseline function scores. The reported Minimally Clinically Important Improvement (MCII) for the AUSCAN NRS function subscale was determined to be 3.47 in a group undergoing 4 weeks of NSAID treatment (Bellamy & Wilson, 2007). They defined the MCII as the 75th percentile of change scores where patients reported slightly to moderately important improvement. The Hybrid and the Comfort Cool did not differ more than the MCII on their effect on hand function, nor did they differ more than our predefined equivalence margin of 8 points on the AUSCAN function subscale. (The MCII reported by Bellamy & Wilson was not known at the time the present study was conceived.) Based on this finding we reject our null hypothesis of non-equivalence.

After 4 weeks of wearing the Hybrid, the AUSCAN pain subscore improved by a mean of 5.69 points (on a scale of 0 to 50) compared to the Comfort Cool™ mean improvement of 2.05 points. The improvement in pain scores was significantly greater, though small in magnitude, for the Hybrid splint compared to the Comfort Cool™.   The MCII for the AUSCAN NRS pain subscale is reported to be 7.46 points (Bellamy & Wilson, 2007). The effect of the Hybrid on the AUSCAN pain subscale came close to a 7 point improvement. It is possible that a longer duration of splint use would improve pain even further, but this is not supported by our 3 month follow up: the mean improvement in the pain subscale from baseline to 3 months was 4.25 points, showing that some of the improvement in pain gained immediately after 4 weeks of splint use had been lost by 3 months. Because not all participants could be contacted at 3 months, several had stopped using their splints, and splint use was not obtained for the rest, our follow up

phone call is not evidence of long term effects. Further research would be required to evaluate the longer term effects of splinting.

Interestingly, when the results were considered in the context of hand dominance, those participants who had their dominant hand splinted had a significantly larger improvement with the Hybrid than the Comfort Cool™ for both function (12.43) and pain reduction (10.62). This difference is not only statistically significant, but exceeds the MCII and our *a priori* equivalence margin, indicating an important clinical improvement. This could be attributed to the larger role the dominant hand has in daily functional activities. CMC OA of the dominant hand has been found to have a significant association with hand disability (Dahaghin et al., 2004). Improvements in symptoms maybe more noticeable in the more frequently used dominant hand. There have been reports that unilateral CMC OA tends to be more prevalent in the non-dominant hand (Wilder et al., 2006), which may explain why more of our participants were referred for splints for the non-dominant hand, however another prevalence study showed that radiological CMC OA and thumb pain are not associated with hand dominance (Armstrong, Hunter, & Davis, 1994). Future studies should be stratified for hand dominance to better evaluate whether or not the beneficial effect of thumb splints differs according to hand dominance.

The AUSCAN asks about performance of both unilateral and bilateral daily tasks. Most daily tasks are bilateral, however when CMC OA is present in one hand, there maybe value in separate evaluation of each hand. Unilateral tasks may not be problematic if the non-dominant hand is affected with CMC OA. The AUSCAN HI User Guide (Bellamy, 2006) states that having hand OA in the dominant hand can have a higher impact on hand function and influence AUSCAN scores more. This could limit the ability of the AUSCAN function subscale to measure true change in function after treatment in the non-dominant hand.

Overall, participants reported that they found the splints beneficial for tasks such as driving, handwriting, gardening, golfing, reading and housework. At the 3 month follow-up, participants made comments to the effect that the splints are supportive, provide immediate relief, assist with grip, and even allow some to reduce their pain medication. The fact that 40 out of 44 participants

reported still wearing one of their splints, 3 months later, suggests that they found the splints beneficial.

Performance of everyday activities has only been measured in 6 previous studies of splinting effects in CMC OA. The measures used included non-validated and non-standardized questionnaires. Our findings of improved function with the Hybrid splint support similar findings for short thumb splints (Weiss et al., 2000, 2004, Bongi et al., 1991, Wajon & Ada, 2005). Our findings for the Comfort Cool™ differed from those of previous studies of long splints, some of which used shorter treatment periods (Weiss et al. 2000, 2004, Buurke et al, 1999, Day et al., 2004). In this study, the duration each splint was worn was set at 4 weeks, assuming that this would be ample time to become accustomed to the splints. Nevertheless, it may take even longer to achieve the full effect of splints on function, given the continued improvement noted at the 3 month follow-up call.

Our results differ slightly from previous studies in regard to the effect of thumb splinting on pain. Pain was significantly reduced with both splints in both comparative trials by Weiss et al. (2000, 2004). In McKee et al.'s unpublished comparative study (2006), pain was also found to be significantly better after wearing both splints. One explanation for the difference may be the measures used, although our study had double the participants of Weiss's, so the findings may be more reliable.

The increases in grip strength and pinch strength were very small for the Comfort Cool™ (0.37 and 0.33 kg respectively) and the Hybrid (0.83 and 0.21 kg respectively), not statistically significant, and it is difficult to assess their clinical relevance. Rahman, Thomas, and Rice (2002) showed the mean forces required to open various containers such as medicine bottles and trigger pumps were between 0.91 and 4.5 kg.   They also found a fair relationship between lateral pinch strength and the ability to open three different containers (r = 0.42-0.44). If the strength improvement resulting after wearing a thumb splint helps an individual over the necessary threshold of 0.9 kg to open a container, this would be a meaningful improvement. The mean improvement in grip strength after wearing the Hybrid for 4 weeks was 0.83 kg. Some participants may have made strength gains larger than this thereby achieving a meaningful

clinical improvement but this effect is lost in group research designs. In contrast to our findings, several studies have reported increases in pinch strength after splinting the CMC joint (McKee et al., 2006; Wajon & Ada, 2005). McKee et al. (2006) reported a significant improvement in pinch from baseline to follow-up with and without the splints. However, when comparing the amount of pinch force generated with the splints on it was still less than follow-up scores without the splint on. This suggests that splints actually hinder pinch. Wajon and Ada (2005) found an increase of 0.6 Kg in tip to tip pinch after 2 weeks of splinting. Our results for pinch strength were similar to Weiss et al. (2004) where there were no significant differences in pinch strength generated in either splint compared to baseline without a splint. Weiss et al. did find that participants were able to generate more pinch strength in the Comfort Cool compared to the custom-made CMC splint.

Only one previous study (McKee et al., 2006) has measured the effects of thumb splints on grip strength. They showed that participants wearing a thin thermoplastic splint that included the MCP joint actually had less grip strength than those wearing the splint that left the MCP joint free. McKee suggested that the hard thermoplastic through the thumb web space may make it difficult to optimize grasp or grip.

The preferred splint in this study was the Comfort Cool which was the same preferred splint in Weiss et al's trial (2004). Similar reasons for the preference were given, including ease of use, appearance, comfort and durability.

Limitations of the study. This was a multi-center study, where two therapists at each site were responsible for the treatment and carrying out the study protocol. The therapists were not blinded to the splinting intervention as they were required to fabricate and fit each splint. They were not blinded to the outcome measures as they measured grip and pinch strength. This raises the possibility of biasing the results if therapists had a strong preference for one splint. Since both splints were currently being used at all 3 sites, it is unlikely that there was a strong preference, and the findings show no significant improvement in hand strength for either splint. The primary outcome measure, the AUSCAN was a self-report outcome, therefore the therapists could not influence the score. No other study blinded their evaluators. To ensure standardized

protocol, treating therapists were provided with a 2 hour orientation that enabled them to practice fabrication of the custommade splint in accordance with study protocol. Three of the 6 therapists had already attended a splinting course where they became familiar with the Hybrid splint. All therapists were familiar with the Comfort Cool™.

The crossover design has an inherent weakness in the assumption that each treatment sequence group is identical because all participants receive both splints and serve as their own control. However, there is a possibility that participants were exposed to other interventions during one treatment period but not the other. This was the case with two participants who received cortisone injections near the end of the first splint period, before the second splint period. Exposure to other treatments and/or medication changes was not monitored, although the informed consent process asked that participants be on stable treatment regimes for the duration of the 9-week study.

The modest, less than expected improvements in AUSCAN function and pain subscores may have been due to a lack of sensitivity in the AUSCAN outcome measure. There was one instance of a ceiling effect, where one participant had minimal impairment at the onset of the trial making it impossible to capture measureable improvement after splinting, because there was no room for improvement on this scale. Massy-Westropp et al. (2004) found 12 out of 62 participants had floor effects on the AUSCAN function subscale indicating their scores could not get worse if their function deteriorated. Participants were also observed to struggle to answer several of the unilateral task questions such as carrying a full pot with one hand and one of the questions regarding turning a round doorknob as they reported they did not know of any round doorknobs.

With recent data from Dr. Bellamy's REFLECT study (2007), a MCII of 3.47 on the AUSCAN function subscale was suggested. A new power calculation using the standard deviation of the differences from the first treatment period of this study, 17.36, yields a sample size of 265 (two-tailed alpha = 0.05; 90% power given equivalence hypothesis). Because little is known about how much of a change is meaningful in everyday life, we used the MCII value and a range of values for the minimal meaningful change (MMC) in scores from 3.47 to 9 in order to propose a

sample size for future studies (Appendix 4). Based on our clinical experience, a change of one point on each of the 9 AUSCAN (NRS) function questions would be considered a minimal meaningful change (MMC). The lack of MCII data available for the AUSCAN NRS posed a limitation for our sample size estimation at the outset of this study.

The population in this study was a homogenous group with regard to their baseline characteristics, being predominantly females in their sixties. Severity of OA was not assessed in this study, even though there is some evidence to support the benefits of conservative splinting in the earlier stages of CMC OA (Swigart et al., 1999). There may have been a larger splinting effect if we had used radiological evidence of stages 1 and 2 CMC OA as inclusion criteria.

Strengths of the study. The crossover design of this study compared the effects of each splint on the same participant, reducing variability and strengthening internal validity. This design requires half as many participants as a parallel groups design (Piantadosi, 2005), thereby increasing the power of the study to detect even a small treatment effect between the splints, hence it is an efficient design for equivalence trials. Crossover designs are also appropriate for stable conditions such as CMC OA.

The 4 week splinting intervention improves on previous studies that used 1 and 2 weeks (Weiss et al., 2000, 2004, Wajon & Ada, 2005). This is the only crossover study that incorporated a 1 week washout period between splints. The 1 week washout period was deemed to be sufficient time to allow the effects of the first splint to disappear as splinting is thought to have an immediate effect when applied.

The effects of splinting for pain relief were already known, however there had been a lack of evidence regarding the use of splinting to enhance hand function. The primary outcome of hand function was measured using the AUSCAN-HI version 3.1, a standardized questionnaire specific to hand OA. The Osteoarthritis Research Society International (OARSI) has recommended that condition-specific clinical outcome measures be used in their guidelines on hand OA Clinical Trials (Maheu et al. 2006).

The sample size in this study was greater than any of the previous CMC OA splinting studies with one exception (Swigart et al., 1999). Our final group size (n=54) exceeded the minimum sample size requirement of 48 to have enough power to detect a small difference between splints based on the original assumptions regarding the AUSCAN tool.

Compliance to the study protocol by the participants was recorded with the use of daily logs. Forty-six participants (85%) returned their logs. Previous studies have measured adherence to splinting protocol by setting a specific amount of time, such as 10 hours per week (Haskett, Backman, Porter, Goyert, & Palejko, 2004) as the minimum expectation. A more recent study, (Rannou et al., 2009) rated adherence as high when participants wore their splints 5 to 7 nights a week. Considering these parameters, our participants reported wearing the splints an average of 8 hours per day. The daily logs that were returned had checks marked hourly increasing their accuracy. Aside from the two participants who had cortisone injections during the study, no other treatments were reported.

Clinical implications. Splinting is the first choice of conservative treatment of CMC OA, despite this there are no guidelines as to which splint design is most useful for which patients. This study considered subjective and objective outcomes in comparing two different splints for CMC OA. The results demonstrate that the Comfort Cool™ and Hybrid splint have an equivalent effect on hand function, grip and pinch strength. However, the Hybrid splint was statistically significantly better than the Comfort Cool™ at reducing pain.

The difference in pain relief between the two splints may be explained by the more rigid property of the thermoplastic used in the Hybrid fabrication. This may limit certain movements, types or amount of activities engaged in, thereby reducing pain. When participants were asked to choose their preferred splint, each participant had strong preferences for one or the other. None chose both splints or neither splint. Interestingly, the preferred splint for the majority of participants (63%) was the Comfort Cool™, and the reason usually given was because it was judged more comfortable even though the AUSCAN pain scores were significantly better after wearing the Hybrid. The post hoc analysis showed that the Hybrid improved both pain and function for participants whose dominant hand was splinted.

These findings may guide therapists and patients selecting splints to meet individual needs, but more research specific to participant characteristics may be required to provide greater direction in identifying which splints are most effective for whom.

Conclusion

In summary, the Hybrid and Comfort Cool™ splints had an equivalent therapeutic effect on hand function, grip and lateral pinch strength. The Hybrid had a greater effect on decreasing pain than the Comfort Cool™. Since a difference did exist between the two splints in this study, the choice of splint may be determined based on the patient's current symptoms as well as the patient's preference.

Given the variety of splint designs and splint materials for CMC OA, further research should compare different splints with a no splint control group and look at improved function over a longer term. The results of this study add to the knowledge base regarding the effect of thumb splints on function and pain in adults with CMC OA.

Table 2.1: Schedule of Outcome Measurements

Timeline	Outcome Measure	Intervention
Baseline	AUSCAN (pain & function) Grip & Pinch strength	Fit with first splint after baseline measures completed
Week 4 (outcome of first splint)	AUSCAN (pain & function) Grip & Pinch strength	First splint returned, commence 1 week washout
Week 5 (return to baseline measures)	AUSCAN (pain & function) Grip & Pinch strength	Fit with second splint
Week 9 (outcome of 2nd splint)	AUSCAN (pain & function) Grip & Pinch strength Splint preference questions	Both splints provided for patient's continued use
3 month follow up mailing	AUSCAN (pain & function)	Both/either splint used at patient's discretion

Table 2.2: Splint Preference Items

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
The fit of the splint is comfortable.	1	2	3	4	5
The splint's appearance is satisfactory.	1	2	3	4	5
The splint is easy to put on and remove.	1	2	3	4	5
The splint is durable.	1	2	3	4	5

Table 2.3: Participant Characteristics, n=56

Characteristic	Mean (SD)
Average age, years (SD)	64.05 (8.61)
Duration of CMC OA, years	2.99 (4.68)
	n (%)
Dominant hand splinted	23 (41%)
Bilateral CMC OA	32 (57%)
Sex	
Females	51 (91%)
Males	5 (9%)
Family History CMC OA	23 (41%)
Employment status	
Employed	20 (36%)
Retired	36 (64%)
Taking medication for symptoms	25 (45%)

Table 2.4: Assessment of Return to Baseline Between Splints (carryover effect)

Outcome Variable	Mean difference	SDD	t	p
AUSCAN function (possible score range = 0-90)	1.81	16.82	0.79	0.43
AUSCAN pain (possible score range = 0-50)	0.91	9.09	0.73	0.47
Grip Strength (Kg)	-0.72	4.61	-0.12	0.91
Lateral Pinch Strength (Kg)	0.11	1.28	0.65	0.52
Mean difference = Return to Baseline (week 5) minus Baseline (week 0), SDD =standard deviation of the difference.				

Table 2.5: Function, Pain and Strength Scores at Baseline and at 4 Weeks for Each Splint, n=56.

	Baseline	4 Weeks	Mean Difference (change)	SDD	t	p	95% CI
COMFORT COOL™							
AUSCAN function†	53.09	50.40	2.69	16.33	1.221	0.23	-1.73,7.11
AUSCAN pain‡	27.84	25.78	2.05	9.54	1.596	0.12	-0.53,4.63
Grip Strength	18.17	18.54	-0.37	4.14	-0.660	0.51	-1.50,0.76
Lateral Pinch Strength	4.40	4.72	-0.33	1.84	-1.299	0.20	-0.83,0.18
HYBRID							
AUSCAN function†	52.67	47.13	5.54	17.37	2.34	0.02	0.80,10.28
AUSCAN pain‡	27.67	21.98	5.69	11.08	3.772	<0.001	2.66,8.71
Grip Strength	18.43	19.25	-0.83	3.80	-1.584	0.12	-1.88,0.22
Lateral Pinch Strength	4.40	4.60	-0.21	1.14	-1.342	0.19	-0.52,0.10
SDD = standard deviation of the differences,† lower scores indicate better function, ‡ lower scores indicate less pain							

Table 2.6: Comparing Function, Pain and Strength Scores Between Comfort Cool & Hybrid Splints (after 4 weeks of use, n=56).

	Mean Difference	SDD	95% CI (lower, upper)	t	p
AUSCAN function	3.13	15.56	-1.12, 7.38	1.48	0.15
AUSCAN pain	3.72	11.13	0.68, 6.76	2.46	0.02
Grip Strength	-0.48	4.01	-1.58, 0.63	-0.87	0.39
Lateral Pinch Strength	0.12	1.68	-0.34, 0.58	0.51	0.61
SDD = standard deviation of the differences					

Table 2.7: AUSCAN Function and Pain Scores at 3 Months (n=44)

	AUSCAN Function				AUSCAN Pain			
	Mean difference	SDD	T	p	Mean difference	SDD	t	p
COMFORT COOL™ (4 wks – 3 mos)	3.25	15.53	1.39	0.17	1.50	9.67	1.03	0.31
HYBRID (4 wks – 3 mos)	1.32	14.32	0.61	0.55	-1.52	9.08	-1.11	0.27
BASELINE – 3 MONTH F/U	6.30	17.16	2.43	0.02	4.25	9.40	3.00	<0.01
SDD = standard deviation of the differences								

Figure 2.1: Comfort Cool Splint

Figure 2.2: Hybrid Splint

Figure 2.3: CONSORT Flow Chart
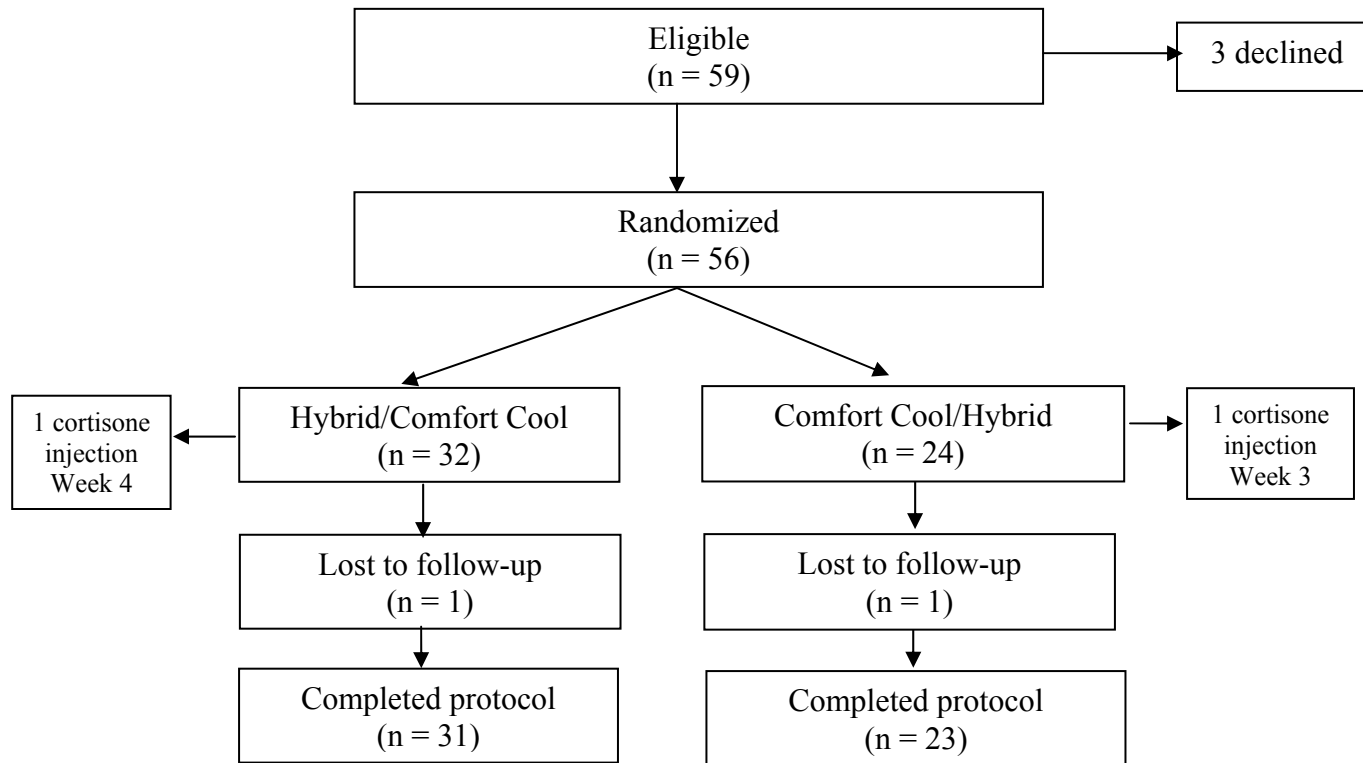
```
                    ┌─────────────────────┐
                    │      Eligible       │──────────►┌──────────────┐
                    │     (n = 59)        │           │  3 declined  │
                    └─────────────────────┘           └──────────────┘
                              │
                              ▼
                    ┌─────────────────────┐
                    │     Randomized      │
                    │     (n = 56)        │
                    └─────────────────────┘
                       ╱              ╲
                      ╱                ╲
                     ▼                  ▼
┌──────────────┐  ┌──────────────────┐  ┌──────────────────┐  ┌──────────────┐
│ 1 cortisone  │◄─│ Hybrid/Comfort   │  │ Comfort Cool/    │─►│ 1 cortisone  │
│ injection    │  │ Cool             │  │ Hybrid           │  │ injection    │
│ Week 4       │  │ (n = 32)         │  │ (n = 24)         │  │ Week 3       │
└──────────────┘  └──────────────────┘  └──────────────────┘  └──────────────┘
                           │                      │
                           ▼                      ▼
                  ┌──────────────────┐  ┌──────────────────┐
                  │ Lost to follow-up│  │ Lost to follow-up│
                  │ (n = 1)          │  │ (n = 1)          │
                  └──────────────────┘  └──────────────────┘
                           │                      │
                           ▼                      ▼
                  ┌──────────────────┐  ┌──────────────────┐
                  │ Completed protocol│  │ Completed protocol│
                  │ (n = 31)         │  │ (n = 23)         │
                  └──────────────────┘  └──────────────────┘
```

References

Allen, K.D., Jordan, J.M., Renner, J.B., & Kraus, V.B. (2006). Validity, factor structure, and clinical relevance of the AUSCAN osteoarthritis hand index. *Arthritis and Rheumatism, 54*, 551-556.

American Society of Hand Therapists. (1992). *Clinical Assessment Recommendations*, 2nd edition, Chicago, IL: American Society of Hand Therapists.

Armstrong, A., Hubter, J., & Davis, T. (1994). The prevalence of degenerative arthritis of the base of the thumb in post-menopausal women. *Journal of Hand Surgery (British and European Volume), 19B,* 340-341.

Bellamy, N., Campbell, J., Haraoui, B., Buchbinder, R., Hobby, K., & MacDermid, J. (2002). Dimensionality and clinical importance of pain and disability in hand osteoarthritis: Development of the Australian/Canadian (AUSCAN) osteoarthritis hand index. *Osteoarthritis and Cartilage, 10*, 855-862.

Bellamy, N., Campbell, J., Haraoui, B., Gerecz-Simon, E., Buchbinder, R., Hobby, K., & MacDermid, J. (2002). Clinimetric properties of the AUSCAN osteoarthritis index: an evaluation of reliability, validity and responsiveness. *Osteoarthritis and Cartilage, 10,* 863-869.

Bellamy, N. (2006). AUSCAN Hand Osteoarthritis Index – User Guide III. 20 pp.

Bellamy, N., and Wilson, C. (2007). International estimation of minimally clinically important improvement (MCII75): The reflect study. *Internal Medicine Journal, (Suppl 2), 37,* A36.

Bongi, M.S., Guidi, G., Cencetti, A., & Zoppi, M. (1991). Treatment to carpometacarpal joint osteoarthritis by means of a personalized splint. *Pain Clinic, 4,* 119-123.

Buurke, J.H., Grady, J.H., de Vries, J., & Baten, C.T.M. (1999). *Clinical Rehabilitation, 13*, 288-94.

Day, C., Gelberman, R., Patel, A., Vogt, M., Ditsios, K., & Boyer, M. (2004). Basal joint osteoarthritis of the thumb: A prospective trial of steroid injection and splinting. *Journal of Hand Surgery, 29A,* 247-251.

Dahaghin, S., Bierma-Zeinstra, S.M., Ginai, A., Pols, H.A., Hazes, J.M., & Koes, B.W. (2005). Prevalence and pattern of radiographic hand osteoarthritis and association with pain and disability (the Rotterdam study). *Annals of the Rheumatic Diseases, 64*, 682-87.

Dillon, C., Hirsch, R., Rasch, E., and Gu, Q. (2007). Symptomatic hand osteoarthritis in the United States: Prevalence and functional impairment estimates from the third U.S. National

Health and Nutrition examination survey, 1991-1994. *American Journal of Physical Medicine and Rehabilitation, 86,* 12-21.

Dominick, K., Jordan, J., Renner, J., and Kraus, V. (2005). Relationship of radiographic and clinical variables to pinch and grip strength among individuals with osteoarthritis. *Arthritis & Rheumatism, 52,* 1424-1430.

Egan M. & Brosseau, L. (2007). Splinting for osteoarthritis of the carpometacarpal joint: A review of the evidence. *American Journal of Occupational Therapy, 61,* 70-78.

Fautrel, B., Hilliquin, P., Rozenberg, S., Allaert, F.A., Coste, P., Leclerc, A., & Rossignol, M. (2005). Impact of osteoarthritis: results of a nationwide survey of 10,000 patients consulting for OA. *Joint Bone Spine, 72,* 235-40.

Haskett, S., Backman, C., Porter, B., Goyert, J., & Palejko, G. (2004). A crossover trial of custom-made and commercially available wrist splints in adults with inflammatory arthritis. *Arthritis & Rheumatism* (*Arthritis Care and Research), 51,* 792-799.

Jones, G., Cooley, H.M., & Bellamy, N. (2001). A cross-sectional study of the association between heberden's nodes, radiographic osteoarthritis of the hands, grip strength, disability and pain. *Osteoarthritis and Cartilage, 9*, 606-611.

Kjeken, I., Dagfinrud, H., Slatkowsky-Christensen, B. et al. (2005). Activity limitations and participation restrictions in women and hand osteoarthritis: patients descriptions, and associations between dimensions of functioning. *Annals of the Rheumatic Diseases, 64*, 1633-38.

Kovler, M., Lundon, K., McKee, N., and Agur, A. (2004). The human first carpometacarpal joint: osteoarthritic degeneration and 3-dimensional modeling. *Journal of Hand Therapy, 17,* 393-400.

Lieberman, D. & Scheer, J. (2002). AOTA's evidence-based literature review project: An overview. *American Journal of Occupational Therapy, 56,* 344-349

Maheu E, Altman, R.D., Bloch, D. et al. (2006) Design and conduct of clinical trials in patients with osteoarthritis of the hand: Recommendations from a task force of the Osteoarthritis Research Society International. *Osteoarthritis and Cartilage, 14,* 303-322.

Mannoni, A., Briganti, M.P., Di Bari, M., Ferrucci, L., Serni, U., Masotti, G. & Marchionni, N. (2000). Prevalence of symptomatic hand osteoarthritis in community-dwelling older persons: the ICARe Dicomano study. *Osteoarthritis and Cartilage, 8,* Suppl A:S11-13.

Massy-Westropp, N., Krishnan, J., & Ahern, M. (2004). Comparing the AUSCAN osteoarthritis hand index, Michigan Hand Outcomes Questionnaire, and Sequential Occupational Dexterity Assessment for patients with rheumatoid arthritis. *Journal of Rheumatology, 31*, 1996-2001.

McKee, P., & Eason-Klatt, M. (2006, September). *A multi-center study comparing two styles of orthoses for individuals with thumb carpometacarpal osteoarthritis – less is more.* Paper presented at the meeting of the American Society of Hand Therapists, Atlanta, GA.

Piantadosi, S. (2005). Crossover designs. In R. Chappell (Ed.), *Clinical trials: A methodological perspective* (pp.515-527). Baltimore, MD: A John Wiley & Sons Inc.

Rannou, F., Dimet, J., Boutron, I., Baron, G., Fayad, F., Mace, Y., et al. (2009). Splint for base-of-thumb osteoarthritis: A randomized trial. *Annals of Internal Medicine, 150*, 661-669.

Stamm, T., Machold, K., Smolen, J., Fischer, S., Redlich, K., Graninger, W., Ebner, W., and Erlacher, L. (2002). Joint protection and home hand exercises improve hand function in patients with hand osteoarthritis: A randomized controlled trial. *Arthritis & Rheumatism (Arthritis Care and Research),* 47:44-49.

Swigart, C., Eaton, R., Glickel, S., & Johnson, C.(1999). Splinting in the treatment of arthritis of the first carpometacarpal joint. *Journal of Hand Surgery, 24,* 86-91.

Wajon, A., & Ada, L. (2005). No difference between two splint and exercise regimes for people with osteoarthritis of the thumb: A randomized controlled trial. *Australian Journal of Physiotherapy, 51,* 245-249.

Van Saase, J., Van Rommunde, L., Cats, A., Vandenbrouke, J., and Valkenburg, H. (1989). Epidemiology of osteoarthritis: Zoetermeer survey. Comparison of radiological osteoarthritis in a Dutch population with that in 10 other populations. *Annals of the Rheumatic Diseases, 48*, 271-280.

Weiss, S., LaStayo, P., Mills, A., & Bramlet, D. (2000). Prospective analysis of splinting and the first carpometacarpal joint: An objective, subjective and radiographic assessment. *Journal of Hand Therapy, 13*, 218-226.

Weiss, S., LaStayo, P., Mills, A., & Bramlet, D. (2004). Splinting the degenerative basal joint: Custom-made or prefabricated neoprene? *Journal of Hand Therapy, 17*, 401-406.

Wilder, F., Barrett, J., and Farina, E. (2006). Brief report: Joint specific prevalence of osteoarthritis of the hand. *Osteoarthritis and Cartilage, 14,* 953-957.

Zhang, Y., Niu, J., Kelly-Hayes, M., Chaisson, C., Aliabadi, P., and Felson, D. (2002). Prevalence of symptomatic hand osteoarthritis and its impact on functional status among the elderly. The Framingham Study. *American Journal of Epidemiology, 156,* 1021-1027.

CHAPTER 3

IMPLICATIONS OF THE STUDY

This study concluded that the two splints studied were essentially equivalent in their effects on hand function (a small, significant improvement over baseline) and grip and pinch strength (no significant difference over baseline), and that the Hybrid splint offered a greater reduction in pain than did the Comfort Cool,^{TM} in adults with CMC OA. Of particular interest was the post hoc analysis showing that the improvements were almost entirely observed in participants who had their dominant hand splinted. This chapter considers the implications of the study as a whole, and what was learned in the research process.

Osteoarthritis is a common musculoskeletal disorder. Chapter 1 established the high prevalence of CMC OA, especially in those over 65 and in women. It also discussed the substantial functional impact of CMC OA: symptomatic CMC OA has been associated with weaker grip strength and self-reported difficulty of activities of daily living (ADL). The exact etiology of CMC OA is still unknown. However the factors that lead to joint degeneration are understood to be abnormal stresses through the joint surfaces of the first metacarpal and the trapezium. Through 3-dimensional computer modeling and measurement of the joint surfaces, Kovler, Lundon, McKee, and Agur (2004) concluded that thumb metacarpal pronation could worsen CMC OA. They suggested that the thumb should be splinted in a neutral or a slightly adducted position to offload the trapezium. It is well known that splinting the thumb is the first line of conservative treatment for CMC OA, and it is understood that there are anatomic and biomechanical theories that support the use of splinting. Yet, there is uncertainty as to the exact splint design which would be the most beneficial and to how often the splint should be worn. These clinical questions precipitated the development of this study.

Previous studies of splinting effectiveness in CMC OA were summarized in the Literature Review of Chapter 1. Limited evidence exists to support the use of thumb splints for pain, and no good quality evidence related to hand function or the use of one specific type of splint being more effective than another. The decision to compare Pat McKee's Hybrid splint with the Comfort Cool^{TM} was based on findings from the previous studies as well as expert clinical

opinion. The objectives of splinting are to reduce pain as well as enhance hand function. Therefore a minimally restrictive splint that can stabilize the thumb CMC joint and provide comfort is considered beneficial. Both splints were considered minimally restrictive and comfortable. Both splints were being used frequently in hand clinics throughout British Columbia. The question of interest was whether the new Hybrid design would be as good as the more established Comfort Cool™ in improving function, reducing pain and improving strength. This question guided the crossover equivalency study described in Chapter 2.

Strengths and Weaknesses of Research

Improvements on previous splinting studies include the longer treatment phase of 4 weeks, the washout period of 1 week and the larger sample size of 54. Our sample size met the required minimum of 48 to be 90% confident in rejecting the null hypothesis of non-equivalence for the primary outcome of hand function.

The length of the intervention period of 4 weeks for each splint improved on the 1 week period in prior studies, and was considered adequate for participants to become accustomed to their splints in everyday tasks. However, results at the 3 month follow-up showed a significant improvement in AUSCAN function subscores compared to participants' final scores after the 9 week trial period. This suggests that longer than 4 weeks is needed to measure the full treatment effect. The continued improvement may have also been due to participants having the choice of wearing their preferred splint after completing both intervention periods.

Three previous cross-over studies were carried out and none of these had a washout period in between splints (Buurke, Grady, de Vries, & Baten, 1999; Weiss et al., 2000, 2004). In this study, the one week washout period was deemed adequate to eliminate any carryover effects. Testing for carryover effect confirmed that no carryover from either splint existed. The study took place over a full calendar year. Some participants completed the 12 week duration of the study in summer and some in winter. Higher pain in hand OA has been associated with rising barometric pressure (Wilder, Hall & Barrett, 2003), but it's unknown if a seasonal effect exists.

In previous splinting studies, the primary outcome measures were pain. This study's primary outcome was self-reported function as measured by the AUSCAN questionnaire. The AUSCAN is a disease specific health status measure that assesses patients' perceptions of their pain, joint stiffness and physical function. The Osteoarthritis Research Society International (OARSI) has recommended that condition-specific clinical outcome measures be used in their guidelines on hand OA Clinical Trials (Maheu, Altman, & Bloch, 2006), such as the AUSCAN hand index because it was developed for use with individuals with hand OA. The AUSCAN is considered highly responsive to change. In a prospective study (Allen, Jordan, Renner, & Kraus, 2006) participants completed several assessments of their OA symptoms on 2 occasions, an average of 4 years apart. It was found that a 1 point difference in the AUSCAN Likert version total score (75) corresponded to a 1 kg decrease in grip strength. The high sensitivity to change is important for an outcome measure used in an equivalence trial. Effort must be taken to search for a treatment difference in equivalence trials, to be confident in the event that the evidence shows no difference.

However, it does not differentiate between thumb CMC OA and digital interphalangeal (IP) OA. CMC OA has been found to have a larger impact on hand function than IP OA (Dahaghin et al., 2005). The AUSCAN was administered on 5 occasions in this study. Participants were observed to struggle to choose a number for certain tasks such as "turning a doorknob" and "carrying a full pot with one hand". They stated they either did not do this task with their non-dominant, affected hand or that they did not have round doorknobs or taps at home. The items "Opening a new jar" and "Peeling vegetables/fruits" posed problems for participants if they stated they used adaptive aids such as jar openers, large handled peelers or husbands. Bellamy (2006) in his AUSCAN User Guide acknowledges that the distribution of hand OA in the dominant hand may have an effect on index performance. Other outcome measures such as the PRWHE (Patient Rated Wrist/Hand Evaluation) or the DASH (Disabilities Arm, Shoulder and Hand) could have been considered, with their benefits being easier accessibility. However, asking participants to complete any outcome measure 5 times can lead to participants choosing the same answer repeatedly. Response biases will exist with all measurement scales, where some participants prefer the end position of responses and others prefer the middle. The small magnitude of improvement and equivalence between splints indicates a social desirability bias did not appear

to be present in this study, even though participants were not blinded to the splinting intervention and may have wanted to please the assessor by marking improved responses after wearing their splints.

This was an active control study, where two different splints were compared to each other. The highest level of evidence is produced from randomized controlled trials where the control group receives a placebo or sham treatment, which is difficult in the case of splinting. As it is impossible to blind participants to the treatment of splinting and a satisfactory sham splint doesn't really exist, the participant would know when they were in the no treatment phase. Also, with existing practice favoring splinting, it may be considered unethical to subject participants to a no treatment phase. A wait-listed control group could be considered in future studies. However at all 3 sites in the present study, the waitlist is less than 3 weeks, whereas the length of the trial was 9 weeks, so a wait-listed control group would be withholding treatment.

The severity of radiographic CMC OA was not analyzed in our study due to lack of feasibility. Previous studies suggested that splinting the CMC joint in the earlier stages of OA has been most effective when symptoms are less severe (Swigart et al., 1999; Weiss et al., 2004). There is a strong association between severity of radiographic hand OA and hand pain (Dahaghin et al., 2005; Jones, Cooley, Bellamy, 2001,) as well as with hand function impairment (Dominick, Jordan, Renner, Kraus, 2005; Jones et al.). The general inclusion criteria of all doctor diagnosed referrals of CMC OA in this study may have biased the results to show little treatment effect, increasing the chance of a Type 1 error. By narrowing the inclusion criteria of this study to only stages 1 and 2 OA there may have been more significant treatment effects. Although the inability to assess the severity of CMC OA radiographically may diminish the generalizability of this study's results, in reality, therapists rarely have access to x-rays and the treatment objective to reduce pain remains the same regardless of the stage of CMC OA.

Compliance to the treatment protocol was measured using a daily splint wearing log. Splint wearing time has previously only been recorded by Weiss et al (2000). Eighty percent of participants returned the logs indicating good adherence to splinting protocol. No correlation was found between the reported duration the splint was worn and improved AUSCAN function and

pain outcomes. Each splint was worn a mean time of 8 hours per day, however the logs varied from 0 hours per day to 23 hours per day.

Significance of the Study

Regardless of medical diagnosis, further knowledge is required to determine whether specific splint designs can be more beneficial. Splinting is a practice that has existed since the early 1900's and has advanced subsequent to the introduction of thermoplastics in the 1960's. Over time, biomechanical theory has evolved to support mobilization and avoid joint movement restriction by immobilizing as few joints as possible. The theoretical background on which Colditz' short CMC splint (2000) is designed, describes the splint as a strut that limits the forward flexion motion of the first metacarpal. As the thumb moves to pinch, the strong thumb flexor muscles bulk up under the splint, pushing the distal metacarpal backwards. By maintaining normal joint mechanics, and preventing imbalance it is suggested that the splint can control CMC OA thumb pain. Colditz' splint design leaves the wrist and MCP joint free, encouraging hand function. By providing a scientific and anatomical basis for the rational of splinting, this further strengthens the evidence for the use of splinting in CMC OA.

To date, Colditz' short CMC splint design has been used in 2 published studies and 1 unpublished study (McKee et al., 2006; Weiss et al., 2000, 2004) with favorable results for pain relief, and increased self-report function. Colditz (2000) also provides anecdotal evidence that many of her patients have used her short CMC stabilizing splint to manage their symptoms and been able to avoid surgery for years.

This study used Colditz' (2000) short CMC stabilizing splint with McKee's (2006) modifications; the Hybrid splint design has been described in Chapter 1. All treating therapists were instructed in the fabrication of the splint, with emphasis on accurate molding of the thermoplastic over the proximal metacarpal, avoiding CMC adduction and flexion. Our results for the Hybrid support McKee's unpublished report (McKee et al., 2006) that a minimalist splint alleviates pain; whether or not it does so by providing sufficient immobilization of the CMC joint or serves as a reminder on how to use the hand in daily activity remains to be studied.

Interestingly, CMC OA in the dominant hand showed a significantly larger improvement in AUSCAN function and pain scores (a mean improvement of 9.24 and 9.62 points on function and pain subscales respectively), after wearing the Hybrid for 4 weeks. A strong association between radiographic CMC OA of the dominant hand and hand disability has been established (Dahaghin et al., 2005). Some tasks listed on the AUSCAN are primarily unilateral such as peeling vegetables, carrying a full pot with one hand and opening a jar. Therefore, people who have CMC OA in their dominant hand may notice greater difficulty performing daily tasks and consequently have a more noticeable improvement in function after splinting intervention.

A larger percentage of participants (68%) in this study preferred the Comfort Cool™ splint, as was the case in Weiss et al. (2004), yet, the Hybrid provided greater pain relief according to the AUSCAN pain subscale scores. Still, 20 of 54 participants had a definite preference for the Hybrid. Factors such as the kind of activities for which the splint is worn and when the splint is to be used may contribute to preference. The prefabricated Comfort Cool™ was reportedly more durable, however some of the participants' comments concerning the Hybrid indicated that it offered better pain relief.

By using an equivalence based trial design, it can be stated with confidence that these two specific splint designs have an equal effect on hand function, grip and pinch strength, however the Hybrid design was better than the Comfort Cool at reducing pain in CMC OA. If we had used a superiority based design with a null hypothesis stating that there would be no differences between the effects of both splints on function and pain, and then had accepted the null hypothesis, this would not have allowed us to state that both splints were equivalent in their treatment effect. "Absence of evidence of a difference is not evidence of absence of a difference" (Altman & Bland, 1995, p. 485).

By comparing one pre-fabricated splint with one custom-made splint, and determining that both splints are equivalent in their effects on hand function, grip and pinch strength, this enables the findings to apply to a wider audience. For instance, therapists who are living in rural areas do not necessarily have to be hand therapists or obtain expert splinting skills, as they can fit an

individual with CMC OA with a prefabricated small, medium or large splint that is equally effective to a custom-made splint. However, if cost of materials is an issue, a short custom-made CMC stabilizing splint can be easily fabricated. The cost of therapists' time was not factored into this trial, and it maybe that one splint is more expensive than the other if this was measured.

Potential Application of Research Findings

All participants in this study had definite splint preferences, no one was unable to choose a favorite splint. Patients with CMC OA should have the opportunity to choose or have both CMC splints. Participants who chose the Hybrid as their favorite gave the following reasons: "immediate relief", "instant relief", "gave more support", "immobilizes the thumb more" and "likes the support". The Comfort Cool™ as a favorite was given the following comments: "can grip better with it", "more comfortable", "like the wrist included", and "easier to wear".

Patient input is an important part of determining the most beneficial splint. As this study shows, splint preference and compliance with wearing the splint is very individual. Taking the patient's needs and occupational demands into consideration is done through a client-centred approach. McKee and Rivard (2004) recommend 6 essential considerations when selecting splints for patients. These are client centredness, comfort, cosmesis, convenience, less is more and follow-up. These authors recommend collaboration with the patients in choosing the optimal splint. This includes providing the patient with enough information regarding splint properties to select the most suitable splint design. In some cases, both splints may provide benefit. The more restrictive Hybrid could be worn at night or when symptoms are flared and the more flexible Comfort Cool™ could be used for activities requiring more dexterity, for example. Therapists can be confident in using either the Comfort Cool™ or the Hybrid for patients with CMC OA. The Comfort Cool™ has been previously found to be the preferred splint in reducing pain and improving daily hand function (Weiss et al., 2004). This study showed the Hybrid as having the largest effect on pain reduction but the Comfort Cool™ as being the preferred splint.

Future Research Directions

There are very few level 1 studies in regard to splinting for patients with CMC OA. This study is the largest randomized crossover trial, with 54 participants. The results did not show complete

equivalence of both splints in their effects on pain, though they had similar effects on hand function, grip and pinch strength. This still leaves the question of whether one specific thumb splint design can provide more benefit for patients with CMC OA. This topic should be examined further: in order to establish a therapeutic effect of a particular splint design, it should be compared to a non-splint control group. This could be done by using a waitlist control group, ideally for a treatment duration exceeding 4 weeks. This would be considered ethical in clinics with waiting times of that length or greater, as one would not be withholding an effective treatment.

The main outcome for this study was hand function. The functional impact for individuals with CMC OA is very individual and can be difficult to measure. For those individuals who participate in activities that require great hand dexterity such as knitting, embroidery, fine crafts and or gardening, the impact can be huge. The ability of one outcome measure, such as the AUSCAN, to measure individual functional impact is arguable. Perhaps another hand function outcome such as the DASH or PRWHE should be used in future studies. Both of these assessments easily accessible and have more questions pertaining to daily function.

Since several authors (Berggren, Joost-Davidsson, Lindstrans, Nylander, & Povlsen, 2001; Dell, Brushart, & Smith, 1978; Swigart et al., 1999) have suggested that the conservative treatment of splinting the thumb in CMC OA can delay the need for reconstructive surgery, a longitudinal study with longer term follow-up is recommended to assess whether splinting has an effect on the progression of OA.

Personal Reflection

Pursuing a Master of Science in Occupational Therapy has been a personal goal for over 10 years. Being able to combine my passion for hand therapy, personal academic goal and paid employment seemed like the perfect opportunity. I was very excited to be a co-investigator of a clinical study with the academic gurus of Occupational Therapy and Physical Therapy, Dr.'s Catherine Backman, Bill Miller and Linda Li. My major thesis project compared two CMC stabilizing splints with people with CMC OA. Initially, I had misguided ideas of how easy it would be to carry out a clinical trial and how important my clinical findings would be. The

patience involved in writing a grant application, developing a thesis proposal, waiting for ethics approval from several institutions, and implementing the project was trying to say the least. Several times, I questioned the benefits of continuing with this project.

My research question seemed to call for an equivalence designed trial. As my knowledge of equivalence trials has increased, I may have reconsidered a superiority designed trial in hindsight. I had expected a medium treatment effect from the use of thumb splints for 4 weeks with CMC OA. This would have made it easier to draw a conclusion of equivalence or non-equivalence for the splints. Also, having 4 separate outcome measures posed problems in interpreting the results. The challenges never stopped: supervising the project over 3 different clinical sites was painfully time consuming, one study therapist quit, summer vacations almost halted the project completely, referrals dried up, and 3 month follow-up phone calls required many attempts at contact. My inexperience with data collection did not help either. Data were input by treatment periods and not by treatment intervention. This entailed several extra steps to be taken before data analysis could begin and that subsequent data analysis was extremely difficult.

The results were a little disappointing because there was a very small treatment effect on all of the outcomes except one. This posed challenges in drawing a clear conclusion about splinting the thumb in CMC OA. In spite of this, it was fascinating to observe how interested the participants were in the study and how they all reported informally that the splints had been helpful, but then the measured outcome measures did not reflect the reported improvement. I understand the contribution that high level research studies have on clinical practice, however I think anecdotal evidence and participant's subjective reports have value as well.

My Master's experience has been enhanced by my thesis supervisor, Dr. Catherine Backman who has so patiently guided me through the stages of the thesis. I would not have completed this project without her generous and gently delivered feedback. I feel such a sense of personal achievement at having completed this research project from start to almost finish.

References

Allen, K.D., Jordan, J.M., Renner, J.B., & Kraus, V.B. (2006). Validity, factor structure, and clinical relevance of the AUSCAN osteoarthritis hand index. *Arthritis & Rheumatism, 54*, 551-556.

Altman, D., & Bland, M. (1995). Absence of evidence is not evidence of absence. *BMJ, 311*, 485.

Bellamy, N. (2006). AUSCAN Hand Osteoarthritis Index – User Guide III. 20 pp.

Berggren, M., Joost-Davidsson, A., Lindstrans, J., Nylander, G., & Povlsen, B. (2001). Reduction for the need for operation after conservative treatment of osteoarthritis of the first carpometacarpal joint: A seven year prospective study. *Scandinavian Journal of Reconstructive Hand Surgery, 35,* 415-17.

Bongi, M.S., Guidi, G., Cencetti, A., & Zoppi, M. (1991). Treatment to carpometacarpal joint osteoarthritis by means of a personalized splint. *Pain Clinic, 4,* 119-123.

Buurke, J.H., Grady, J.H., de Vries, J., & Baten, C.T.M. (1999). *Clinical Rehabilitation, 13*, 288-294.

Colditz, J. (2000). The biomechanics of a thumb carpometacarpal immobilization splint: Design and fitting. *Journal of Hand Therapy, 13*, 228-235.

Dahaghin, S., Bierma-Zeinstra, S.M., Ginai, A., Pols, H.A., Hazes, J.M., & Koes, B.W. (2005). Prevalence and pattern of radiographic hand osteoarthritis and association with pain and disability (the Rotterdam study). *Annals of the Rheumatic Diseases, 64*, 682-87.

Dell, P., Brushart, T., & Smith, M. (1978). Treatment of trapeziometacarpal arthritis: Results of resection arthroplasty. *Journal of Hand Surgery, 3,* 243-249.

Dillon, C., Hirsch, R., Rasch, E., and Gu, Q. (2007). Symptomatic hand osteoarthritis in the United States: Prevalence and functional impairment estimates from the third U.S. National Health and Nutrition examination survey, 1991-1994. *American Journal of Physical Medicine and Rehabilitation, 86,* 12-21.

Dominick, K., Jordan, J., Renner, J., and Kraus, V. (2005). Relationship of radiographic and clinical variables to pinch and grip strength among individuals with osteoarthritis. *Arthritis and Rheumatism, 52,* 1424-1430.

Jones, G., Cooley, H.M., & Bellamy, N. (2001). A cross-sectional study of the association between heberden's nodes, radiographic osteoarthritis of the hands, grip strength, disability and pain. *Osteoarthritis and Cartilage,* 9, 606-611.

Kovler, M., Lundon, K., McKee, N., and Agur, A. (2004). The human first carpometacarpal joint: osteoarthritic degeneration and 3-dimensional modeling. *Journal of Hand Therapy, 17,* 393-400.

Maheu E, Altman, R.D., Bloch, D. et al. (2006) Design and conduct of clinical trials in patients with osteoarthritis of the hand: Recommendations from a task force of the Osteoarthritis Research Society International. *Osteoarthritis and Cartilage, 14,* 303-322.

McKee, P., & Eason-Klatt, M. (2006, September). *A multi-center study comparing two styles of orthoses for individuals with thumb carpometacarpal osteoarthritis – less is more.* Paper presented at the meeting of the American Society of Hand Therapists, Atlanta, GA.

McKee, P., & Rivard, A. (2004). Orthoses as enablers of occupation: Client-centred splinting for better outcomes. *Canadian Journal of Occupational Therapy, 71,* 306-314.

Swigart, C., Eaton, R., Glickel, S., & Johnson, C.(1999). Splinting in the treatment of arthritis of the first carpometacarpal joint. *Journal of Hand Surgery, 24,* 86-91.

Van Saase, J., Van Rommunde, L., Cats, A., Vandenbrouke, J., and Valkenburg, H. (1989). Epidemiology of osteoarthritis: Zoetermeer survey. Comparison of radiological osteoarthritis in a Dutch population with that in 10 other populations. *Annals of the Rheumatic Diseases, 48,* 271-280.

Wajon, A., & Ada, L. (2005). No difference between two splint and exercise regimes for people with osteoarthritis of the thumb: A randomized controlled trial. *Australian Journal of Physiotherapy, 51,* 245-249.

Weiss, S., LaStayo, P., Mills, A., & Bramlet, D. (2000). Prospective analysis of splinting and the first carpometacarpal joint: An objective, subjective and radiographic assessment. *Journal of Hand Therapy, 13*, 218-226.

Weiss, S., LaStayo, P., Mills, A., & Bramlet, D. (2004). Splinting the degenerative basal joint: Custom-made or prefabricated neoprene? *Journal of Hand Therapy, 17*, 401-406.

Wilder, F.V., Hall, B.J., & Barrett, J.P. (2003). Osteoarthritis pain and weather. *Rheumatology, 42,* 1-4.

Zhang, W., Doherty, M., Leeb, B., Alekseeva, L., Arden, J., Bijlsma, J., Dincer, F., Dziedzic, K., Hauselmann, H., Herrero-Beaumont, G., Kaklamanis, P., Lohmander, S., Verbruggen, G. and Zimmermann-Gorska, I. (2007). EULAR evidence based recommendations for the management of hand osteoarthritis: Report of a task force of the EULAR standing committee for International Clinical Studies Including Therapeutics (ESCISIT). *Annals of Rheumatic Diseases, 66,* 377-388.

Appendices

Appendix A: Ethics Certificate

The University of British Columbia
Office of Research Services
Clinical Research Ethics Board – Room
210, 828 West 10th Avenue, Vancouver,
BC V5Z 1L8

ETHICS CERTIFICATE OF EXPEDITED APPROVAL

PRINCIPAL INVESTIGATOR:	INSTITUTION / DEPARTMENT:	UBC CREB NUMBER:
Catherine L. Backman	UBC/Medicine, Faculty of/Occupational Science and Occupational Therapy	H07-03133

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:	
Institution	**Site**
N/A	N/A
Other locations where the research will be conducted: Vancouver Island Health Authority Victoria's Island Hand Clinic	

CO-INVESTIGATOR(S):
William C. Miller
Linda Li
Helia Suzanne Sillem

SPONSORING AGENCIES:
British Columbia Medical Services Foundation

PROJECT TITLE:
Comparison of Two Carpometacarpal Stabilizing Splints For Individuals with Thumb Osteoarthritis

THE CURRENT UBC CREB APPROVAL FOR THIS STUDY EXPIRES: April 1, 2009

The UBC Clinical Research Ethics Board Chair or Associate Chair, has reviewed the above described research project, including associated documentation noted below, and finds the research project acceptable on ethical grounds for research involving human participants and hereby grants approval.

DOCUMENTS INCLUDED IN THIS APPROVAL:			APPROVAL DATE:
Document Name	Version	Date	
Protocol:			
Research (Thesis) Proposal	February 4, 2008	February 4, 2008	
Protocol Summary	February 4, 2008	February 4, 2008	
Consent Forms:			
Consent Form	N/A	March 21, 2008	**April 1, 2008**
Questionnaire, Questionnaire Cover Letter, Tests:			
Data Collection Form	February 4, 2008	February 4, 2008	
Instructions to Study Therapists	February 4, 2008	February 4, 2008	
Other Documents:			
Information Letter to local physicians	February 4, 2008	February 4, 2008	

CERTIFICATION:

In respect of clinical trials:

1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.

2. The Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.

3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

The documentation included for the above-named project has been reviewed by the UBC CREB, and the research study, as presented in the documentation, was found to be acceptable on ethical grounds for research involving human participants and was approved by the UBC CREB.

Approval of the Clinical Research Ethics Board by one of:

Dr. Bonita Sawatzky, Associate Chair

Appendix B: Glossary

ADL – activities of daily living
ASHT – American Society of Hand Therapists
AUSCAN – Australian Canadian Hand Osteoarthritis Hand Index
CM –Custommade
CMC – Carpometacarpal
CC – Comfort Cool, prefabricated thumb splint
CRH – Campbell River Hospital
DASH – Disabilities of the Arm, Shoulder and Hand
EULAR – European League Against Rheumatism
Equivalence trials – a trial designed to show that two treatments do not differ in effect by more than a predefined clinically significant amount
HY - Hybrid
Hybrid – neoprene and 1/16 inch thermoplastic short thumb splint
LK – Likert
MCIC – Minimally Clinically Important Change
MCID – Minimally Clinically Importance Difference
MCII – Minimally Clinically Important Improvement
MCP – metacarpalphalangeal
MDC – Minimal Detectable Change
NRGH – Nanaimo Regional General Hospital
NRS – Numerical rating scale
OA – Osteoarthritis
OARSI – Osteoarthritis Research Society International
OMERACT -
OT – Occupational Therapy
PF –Prefabricated
PRWHE –Patient rated Wrist/Hand Evaluation
Superiority trial – a trial designed to show that one treatment is better than another
VAS – visual analogue scale

Appendix C: AUSCAN Index Information Provided by the Author.

The AUSCAN is protected under licence and the author releases only the following description for inclusion in study reports and theses.

The AUSCAN index is a disease-specific, tri-dimensional self-administered questionnaire for assessing health status and health outcomes in osteoarthritis of the hand. The questionnaire contains 15 questions, targeting areas of pain, stiffness and physical function, and can be completed in less than 5 minutes. Usually patient self-administered, the Index is amenable to interview administration by telephone. Available in over 30 alternative language forms, there are several different forms of the AUSCAN Index suitable for different clinical practical and clinical research applications. The most recent version of the Index is AUSCAN 3.1.

Questionnaire Content:

Pain Subscale
1. At rest
2. Gripping
3. Lifting
4. Turning
5. Squeezing

Stiffness Subscale
6. After first wakening in the morning

Physical Function Subscale
7. Turning taps/faucets on
8. Turning a round doorknob or handle
9. Doing up buttons
10. Fastening jewelry
11. Opening a new jar
12. Carrying a full pot with one hand
13. Peeling vegetables/fruits
14. Picking up large heavy objects
15. Wringing out wash cloths

Appendix D: Sample Size Estimates

Sample size Estimates based on previous studies

Study & AUSCAN version	Standard Deviation (SD)	Minimal Clinically Important Difference (MCID)	Sample size Estimate
Bellamy, Campbell, Haraoui, Gerecz-Simon, Buchbinder, Hobby & MacDermid, (2002). NSAID washout Week - AUSCAN LK3.0 Function subscale	0.60	-0.32	39
Bellamy et al. (2002) AUSCAN VA3.0 Function subscale	15.91	-8.97	36
Bellamy et al. (2002) AUSCAN VA3.0 Function subscale Week 6 – pre washout	15.91	-5.8	82
Allen, Jordan, Renner & Kraus,(2006) AUSCAN LK3.0	10.4	1.3	675
Rogers & Wilder (2009) AUSCAN VAS Function subscale (mm)	170	100	33
Unpublished study by UBC MOT students (2007) AUSCAN LK	3.6	2	37

Proposed Sample Sizes for Future Studies

Study & AUSCAN version	Standard Deviation (SD)	Minimal Clinically Important Difference (MCID)	Sample size Estimate
Bellamy & Wilson (49th Annual Scientific Meeting, Sydney, May 2007) AUSCAN NRS Function subscale	17.36	3.47	265
"	17.36	4.5	159
"	17.36	6	90
"	17.36	7.5	59
"	17.36	8	52
"	17.36	9	42