HOW CHANGES IN PAIN AND STRENGTH ASSOCIATE WITH MEANINGFUL CHANGE IN ACTIVITY AND PARTICIPATION FOLLOWING A 6 WEEK CLIENT-CENTERED PROGRAM FOR PATIENTS WITH THUMB CARPOMETACARPAL JOINT OSTEOARTHRTITIS

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ABSTRACT

Background: Osteoarthritis (OA) is a degenerative joint disease affecting an estimated 1 in 10 Canadians (1). The disease commonly presents at the carpometacarpal (CMC) joint of the thumb. Occupational therapists caring for patients with thumb CMC joint OA frequently use treatment strategies directed at impairment level outcomes. Patients, however, have been found to view themselves with respect to their activities and participation (2). Knowing the extent to which changes in impairment outcomes will impact activity and participation is important for therapists yet it has not been studied with respect to thumb CMC joint OA.

Objective: This study answered the following question: "In patients with stage I to IV osteoarthritis of the thumb carpometacarpal joint, to what extent do changes in pain and strength that occur following a client-centered, 6 week program of orthosis use, joint protection education and exercises associate with meaningful change in activity and participation?"

Design and Procedure: A pre-post design was utilized with assessment points at study entry and 6 weeks later. The study was conducted at the Centre Professionnel d'Ergothérapie in Montreal. At study entry, participants were provided with a client-centered, 6 week treatment program consisting of a thumb orthosis, home isometric strengthening exercises and joint protection education.

Population: Patients with thumb CMC joint OA who were referred to the Centre Professionnel d'Ergothérapie and occupational therapy at Maisonneuve Rosemont Hospital were recruited for the study. All subjects provided informed consent.

Measurement: Demographic information was collected for each participant. Exposure variables were measured with the visual analogue scale for pain and pinch strength. The primary outcome measure was the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH). Secondary outcome measures included joint goniometry for active range of motion, the Australian/Canadian Osteoarthritis Hand Index and the Canadian Occupational Performance Measure.

Analysis: Two continuous explanatory variables and one continuous outcome variable were analyzed using a multiple regression model. All other data was analyzed using descriptive statistics and Pearson correlation coefficients.

Sample Size: A total of 38 participants were recruited for the study.

Ethics: Approval was obtained from the McGill Institutional Review Board and the Maisonneuve Rosemont Hospital Research Ethics Board. Recruitment was carried out by a research assistant. Informed consent was obtained.

Results: The results demonstrated that pain and lateral pinch strength at 6 weeks had a statistically significant effect on change in activity and participation.

1. The Canadian Arthritis Society. Types of Arthritis. Retrieved from www.arthritis.ca

2. American Occupational Therapy Association Fact Sheet. *Occupational-based hand therapy. The unique role of occupational therapy in rehabilitation of the hand*. AOTA. Bethesda, Maryland.

ABRÉGÉ

Contexte : L'arthrose est une maladie dégénérative des articulations et l'on estime à un sur dix le nombre de Canadiens qui en seraient atteints¹. Elle touche généralement l'articulation carpo-métacarpienne (CMC) du pouce. Les ergothérapeutes qui traitent des patients souffrant d'arthrose de l'articulation CMC du pouce ont souvent recours à des stratégies visant à agir sur la déficience motrice. On a par contre observé que la perception des patients est plutôt fondée sur les activités et la participation². Il est donc important pour les thérapeutes de savoir dans quelle mesure les résultats sur le plan de la déficience motrice auront une incidence sur l'activité et la participation; or, cette question n'a pas encore été étudiée pour l'arthrose de l'articulation CMC du pouce.

Objectif : L'étude a répondu à la question suivante : « Chez les adultes souffrant d'arthrose de l'articulation carpo-métacarpienne du pouce de stade I à IV, dans quelle mesure les modifications de la douleur et de la force découlant d'un programme axé sur le patient d'une durée de six semaines alliant orthèse, enseignement sur la protection des articulations et exercice se traduisent-elles par un changement valable de l'activité et de la participation? »

Déroulement de l'étude : On a appliqué une méthodologie avant-après, consistant à évaluer des points donnés au début de l'étude et après six semaines. L'étude a été menée au Centre Professionnel d'Ergothérapie à Montréal. Au début de l'étude, les participants ont entamé un programme de traitement de six semaines axé sur le patient, combinant le port d'une orthèse, des exercices isométriques de renforcement à effectuer à la maison et de l'enseignement sur la protection des articulations.

Population : Des patients souffrant d'arthrose de l'articulation CMC du pouce, référés au Centre professionnel d'ergothérapie et en ergothérapie à l'Hôpital Maisonneuve-Rosemont, ont été recrutés pour l'étude. Tous ont signé un consentement éclairé.

Mesures : Des données démographiques ont été recueillies pour chaque participant. Les variables relatives à l'exposition ont été mesurées au moyen d'une échelle analogique virtuelle pour la douleur et la force de prise. La principale mesure des résultats a été réalisée au moyen du questionnaire DASH (« Disabilities of the Arm, Shoulder and Hand »). On a utilisé comme mesures secondaires des résultats la goniométrie articulaire pour l'amplitude articulaire active, l'indice AUSCAN (« Australian/Canadian Osteoarthritis Hand Index ») et la Mesure canadienne du rendement occupationnel.

Analyse : Deux variables explicatives continues et une variable continue pour les résultats ont été analysés au moyen d'un modèle de régression multiple. Toutes les autres données ont été analysées au moyen de statistiques descriptives et de coefficients de corrélation de Pearson.

 Taille de l'échantillon : En tout, 38 participants ont été recrutés pour l'étude.

Éthique : Le Comité d'éthique de la recherche de McGill et le Comité d'éthique de la recherche de l'Hôpital Maisonneuve-Rosemont ont approuvé l'étude. Un adjoint à la recherche a effectué le recrutement. Chaque participant a donné son consentement éclairé.

Résultats : Les résultats ont démontré que la douleur et la force de prise latérale après six semaines avaient un effet significatif sur l'activité et la participation.

1. La Société de l'arthrite du Canada. Formes d'arthrite. Consulté sur www.arthritis.ca

2. Fiche technique de l'American Occupational Therapy Association. *Occupational-based hand therapy*. *The unique role of occupational therapy in rehabilitation of the hand*. AOTA. Bethesda, Maryland.

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LIST OF ABBREVIATIONS

ACR	American College of Rheumatology	
ADL	Activities of Daily Living	
AUSCAN	Australian Canadian [Osteoarthritis Hand Index]	
СМС	Carpometacarpal	
cm	Centimeters	
СМОР-Е	Canadian Model of Occupational Performance and Engagement	
СОРМ	Canadian Occupational Performance Measure	
DASH	Disabilities of the Arm, Shoulder and Hand [Questionnaire]	
EULAR	European League Against Rheumatism	
ICF	International Classification of Functioning, Disability and Health	
kg	Kilogram	
lbs	Pounds	
OA	Osteoarthritis	
SD	Standard Deviation	
STT	Scapohotrapeziotrapezoidal	
VAS	Visual Analog Scale	

1. GENERAL INTRODUCTION

Osteoarthritis (OA) is a degenerative joint disease affecting an estimated 1 in 10 Canadians (1). It commonly presents at the carpometacarpal (CMC) joint of the thumb (2,3). Using the terminology of the International Classification of Functioning, Disability, and Health (ICF), the possible impairments secondary to thumb CMC joint OA may include pain, decreased range of motion, deformity and weakness of pinch and grip (4,5). Changes due to hand impairment may in turn contribute to changes in the ability to perform hand activities (4).

Occupational therapists providing hand therapy for thumb CMC joint OA frequently use treatment strategies such as exercises and orthoses which are primarily directed at impairment level outcomes. Patients, however, have been found to view their limitations with respect to occupational performance or activities and participation (6) rather than their impairment. Evidence suggests that there are benefits in using a client-centered therapeutic approach in which the therapist and patient work together to identify difficulties related to the occupational performance in work, leisure and self-care (7,8). Patient participation and self-efficacy are facilitated by a client-centered approach (9). When therapists use a client centered approach, it would be helpful to know what change in impairment is required to impact activity and participation.

This study proposes to estimate the extent to which changes in the impairment outcomes of pain and strength are associated with meaningful change in activity and participation in patients with thumb CMC joint OA following a six week, client-centered, evidence based treatment program. Unlike a treatment protocol driven approach for thumb CMC OA, the client-centered orientation of this study will facilitate the therapist and patient working together to identify

occupational performance difficulties and identifying strategies that are specific to the patient's roles and needs (9). Strategies included in the study intervention are the use of a thumb orthosis designed to optimize occupational performance, a joint protection education program with specific attention to activities that have been identified as being difficult by each participant as well as a home exercise program. The information that will be gained from this study is important for appropriate client-centered treatment planning and for guiding patients in self-management of their conditions. Previous studies have examined a group-based behavioural approach to patient education, exercises as well as the use of long and short thumb orthoses with different wearing schedules. None of the quantitative studies reviewed used a client-centered approach in which treatment strategies such as orthosis use and joint protection education were driven by occupational performance issues that were determined collaboratively by the patient and therapist.

2. LITERATURE REVIEW

2.1 Thumb Carpometacarpal Joint Osteoarthritis

Anatomically, the thumb CMC joint is a bi-concave saddle joint (2,3). CMC joint movement occurs due to contributions from both the intrinsic and extrinsic muscles of the hand (10). There are 16 ligaments that contribute to the stabilization of the thumb CMC joint. Of these, one of the most important is the palmar oblique ligament which is also known as the beak ligament (11-13). Haggert and colleagues (14) have recently found that the dorsal ligaments of the thumb CMC joint contain mechanoreceptors which may be responsible for proprioceptive input that can also impact joint stability.

Osteoarthritis of the CMC joint of the thumb has been linked to causal factors such as aging, genetic predisposition, other inflammatory diseases, congenital deformity, previous trauma, septic arthritis, and ligamentous laxity or injury (2,3). There is a higher incidence in females compared to males who develop CMC joint OA of the thumb. Studies have estimated an incidence of 7% in males, 15% in pre-menopausal women and 33% in post-menopausal women (3). Changes in joint laxity due to post-menopausal hormone shifts are thought to be a contributory factor to the increased incidence (2,3). The female thumb has also been found to have a smaller joint surface with lower congruity and a flat trapezial facet, thus making it more vulnerable to degenerative changes (2,3). Biomechanical analysis has shown that the CMC joint of the thumb is subjected to significant compressive and shearing force, particularly in a dorso-radial direction. Shearing forces can contribute to the erosion of soft tissue structures including

the palmar oblique ligament. Erosion of the palmar oblique ligament in turn permits dorso-radial migration of the metacarpal on the trapezium and eventual deformity (11-13). Studies of joint forces have shown that a pinch force of 1 kilogram (kg) at the thumb tip increases to a potentially compressive force of 13.42 kg at the CMC joint (11,15,16).

Clinically, patients with OA of the thumb CMC joint present with radiological joint changes, pain, weakness, oedema, joint instability, joint deformity, decreased range of motion, decreased strength and/or decreased dexterity (16-19). Eaton and Glickel have developed a 4 stage classification system to describe the severity of thumb CMC joint OA (2,17). In stage I articular surfaces are radiologically normal, however, synovitis may be present. Stage II includes a narrowing of the joint space, minimal subchondral sclerosis and the presence of osteophytes of less than 2 mm. In stage III the joint space is extremely narrow or absent, there is possible subluxation and the presence of osteophytes of greater than 2 mm. At stage IV there is severe articular degeneration at both the carpometacarpal joint and the scaphotrapeziotrapezoidal (STT) joint.

2.2 Overview of Conservative Treatment

The American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) have developed conservative treatment guidelines that support evidence based pharmacological and non-pharmacological strategies for the care of patients with OA of the thumb CMC joint (20,21). Their suggested pharmacological strategies included nonsteroidal anti-inflammatory medication, topical capsaisin and analgesics (20,21). Day and colleagues (22) demonstrated that an intra-articular corticosteroid injection combined with the use of a semi-rigid orthosis provided sustained pain relief for patients with early stage thumb CMC joint OA. The non-pharmacological conservative strategies recommended by the ACR and the EULAR included instruction in joint protection techniques, orthoses, heat before exercise and assessment of the ability to perform activities of daily living (ADL) with assistive devices (20,21). Davenport (23), conducted a survey of 115 therapists who treat thumb CMC joint OA. They reported using the following treatment strategies: exercises, neoprene orthoses, thermoplastic orthoses, joint protection education, acupuncture, heat, electrotherapy, friction massage, manual therapy and ice. In a systematic review of 21 studies of conservative interventions for hand OA Valdes and colleagues (24) found that there was moderate evidence to support the use of exercises, joint protection education, low level continuous heat wrap and orthoses. A systematic review of rehabilitation interventions for people with hand osteoarthritis carried out by Ye and colleagues (26) found that long term use of a thumb night orthosis had positive effects on pain, strength and hand function. Exercises were found to possibly improve hand strength. In two systematic reviews of conservative therapies for hand osteoarthritis, Towheed and colleagues (26, 27) found that there was some evidence from randomized controlled trials that supported the use of an orthosis for thumb CMC joint OA as well as occupational therapy, yoga, strength training exercises and spa therapy. Moe and colleagues (28) performed an overview of four high quality systematic reviews published between 2000 and 2008. These systematic reviews examined the randomized controlled trials that studied the effectiveness of conservative, non-pharmacological treatment methods for hand OA. The authors described a paucity of evidence in this area as supported by systematic reviews, but nonetheless concluded that there is limited evidence supporting the use of orthoses for pain relief due to thumb CMC joint OA and good outcomes when patients were provided with exercises and education programs.

2.3 Orthoses and Thumb CMC Joint OA

Several studies have been conducted to investigate the clinical use and effectiveness of orthoses and thumb CMC joint OA (28-36). The dosage for orthosis use described in the literature varied between night time use (36), full time use (30) and orthosis use during heavy or painful activity (31,32). The materials used to fabricate the orthoses included textiles, leather, neoprene and thermoplastics (29, 32, 36). Orthosis designs included those that were hand based (short opponens) or forearm based (long opponens) (29-33). Colditz (10) has used a biomechanical analysis to support an orthosis design for thumb CMC OA that is hand based and leaves the metacarpophalangeal joint free. Moulton and colleagues performed cadaveric studies on normal specimens and specimens with thumb CMC joint OA (37). They found that flexion of the metacarpophalangeal joint of the thumb to 30° produced a more dorsal CMC joint center of pressure. Orthoses that position patients in this position can therefore reduce pain by redirecting forces away from the damaged volar surface to the healthier dorsal surface of the joint.

Controlled trials supported reduced pain with the use of orthoses. Weiss and colleagues (32) performed a cross-over trial with 25 participants with thumb CMC OA. They compared a handbased thermoplastic orthosis with a hand-based neoprene orthosis. Their results showed that pain was significantly less following use of the neoprene orthosis. Although participants preferred the neoprene orthosis, the results also indicated that the thermoplastic orthosis provided significantly better joint stabilization. Sillem and colleagues (38) used a cross-over design to compare a hand-based hybrid neoprene-thermoplastic orthosis and a neoprene orthosis. The results of their study with 54 participants showed that use of the hybrid neoprene-thermoplastic orthosis group was associated with an improvement in pain that was significantly greater than the results from the neoprene design. There was no statistically significant difference between the two designs in self-reported hand function. In a prospective, randomized trial, Becker and colleagues (39) compared upper extremity function, pain and strength after using either a thermoplastic or a neoprene orthosis for 3 to 15 weeks. The results for 62 participants showed significant improvement in upper extremity pain and strength with use of an orthosis but no difference between the two types of orthoses studied. A similar study performed by Bani and colleagues (40) compared two groups of 12 patients who were randomly assigned to use a hand based thermoplastic orthosis or a neoprene orthosis. They found statistically significant better pain control with the thermoplastic design. In a retrospective review of 141 cases, Swigart and colleagues (30) found that there was "symptom" improvement in 54% of patients with Stage I and II thumb CMC OA and 61% of patients with Stage III and IV CMC OA following use of a long opponens orthosis for 6 to 8 weeks. Weiss and colleagues (31) performed a prospective analysis of 23 participants to compare the use of a long opponens vs. a short opponens orthosis for thumb CMC joint OA. Their results suggested that both designs provide significant improvement in pain, however, patients preferred a short, hand based orthosis.

In a systematic review of 7 studies concerning the effectiveness of orthoses for thumb CMC joint OA, Egan and Brousseau (35) found that there is fair evidence that orthosis use can help to reduce pain and increase hand function. They also concluded that orthosis use may help to reduce joint subluxation in early stage CMC joint OA and that no specific design has been found to be optimal (35). Kjeken and colleagues performed a systematic review of 9 studies to assess the design and efficacy of orthoses and exercise programs for hand osteoarthritis. Seven of the included studies specifically addressed orthoses. Four of these seven studies were also reviewed by Egan and Brousseau (35). Kjeken and colleagues concluded that orthoses can significantly

reduce hand pain, however, there is no definitive consensus regarding optimal design (41). Rannou and colleagues (36) performed a randomized trial with 112 participants in which one group received a thumb based, rigid night orthosis and the other group received "standard treatment" which was not described. The results showed that the orthosis intervention group had a statistically significant improvement in pain and hand function at 12 months. Gomes Carreira and colleagues (34) conducted a randomized controlled trial to examine the effectiveness of a functional orthosis used to treat Stage II and III thumb CMC joint OA of the dominant hand. The intervention group received a hand-based, thermoplastic orthosis which was worn from baseline to 180 days. The control group received the same orthosis for daily use at 90 days. Both groups performed the outcome measure evaluations wearing their orthoses. Pain, functional capacity, grip strength, pinch strength and dexterity were assessed after 45 days, 90 days and 180 days. No significant differences were found between groups with the exception of pain. There was a statistically significant improvement in pain with the use of an orthosis. The effect size for the outcomes in the aforementioned studies is described in Appendix 1.

2.4 Joint Protection Education and Thumb CMC Joint OA

Two controlled trials have been carried out to study the benefits of joint protection education for patients with thumb CMC joint OA. In a randomized controlled trial with 40 participants with hand OA (42), the control group received an instruction sheet about joint changes and the pathomechanics of OA as well as a piece of dycem to facilitate opening jars. The intervention group received oral and written instructions for joint protection techniques and home exercises. The seven hand exercises were demonstrated to the participants and then carried out once a day. Moderate to large effect sizes were obtained in pain and strength outcomes when participants received joint protection education and daily exercises. Boustedt and colleagues (43) performed a controlled, randomized trial with 42 women with hand OA. They compared use of an orthosis and an exercise program to the use of an orthosis and exercise program with the addition of joint protection education. Participants used a custom-made, long, thumb spica orthosis at night and a prefabricated, elastic thumb orthosis during the day. Nine exercises were carried out with hot paraffin dough for 15 minutes a day. Specific details regarding the exercises were not provided. The joint protection education program consisted of written materials and 10 educational-behavioural group sessions over a 5 week period. The intervention group with joint protection education demonstrated significantly improved results that were significantly better when compared to the control group. Moderate to large effect sizes were seen in the outcomes of pain, grip strength and the score of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. A description of these effect sizes may be found in Appendix 1. Of note, the intervention treatment strategies were not client-centered.

2.5 Exercises and Thumb CMC Joint OA

Exercise programs that are provided for patients with thumb CMC joint OA may have several objectives including optimizing range of motion and strength as well as dynamic joint stabilization. Stretching of the first web space may help to overcome the tendency towards an adducted thumb posture since the adductor pollicis tethers the first and second metacarpal bones (15,16). The adductor pollicis and extensor pollicis longus are frequently not strengthened since they may contribute to the forces that potentially deform the thumb (44). Valdes and colleagues (45) performed a review of the literature to evaluate the biomechanics of thumb deformity and CMC joint OA. They then applied the conclusions of the studies they examined to thumb CMC joint OA exercises. With respect to strengthening, they suggested that there is potential benefit from exercises for the intrinsic thenar muscles, the thumb extensors, the extrinsic abductors and

the wrist extensors. According to their recommendations, pinch strengthening should be carried out with caution due to the possible presence of instability and subluxation and exercises that optimize CMC joint range of motion could be beneficial. In a response to this article, Colditz (46) suggested that exercise programs should be individualized and based on careful examination of the patient's thumb. She added that a treatment goal of full range of motion may not be ideal in an unstable, arthritic joint. In her opinion, therapists should work towards an exercise program that helps to re-establish a normal muscle balance in the thumb and suggested benefit to isometric pinching exercises that avoid deforming postures. She stated that exercises for the extensor pollicis longus should be avoided only if the tendon is observed as a contributor to adduction. During lateral pinch, Brand and Hollister (47) have described the role of the first dorsal interosseous muscle in contributing to thumb CMC joint stability.

Kjeken and colleagues (41) performed a systematic review of the literature that included an evaluation of the effects of exercise programs in hand OA. They concluded that there was very limited evidence to support the benefits of exercise programs in reducing pain and increasing range of motion and strength. They found no apparent consensus regarding exercise program design. Kjeken (48) performed a Delphi procedure with Norwegian occupational therapists working in rheumatology. One of the goals of the study was to develop recommendations for exercise programs developed for hand OA patients. The study concluded that therapists should design exercise programs that are client-centered and encourage patients to remain active in their daily activities. Furthermore, it was suggested that the exercise session should start with heat application and that thumb exercises should include palmar abduction, CMC joint stabilization, thumb extension and pinching movement.

Rogers and Wilder conducted two studies evaluating exercise programs for patients with hand OA (49,50). They used a pre-post design with 55 subjects to quantify the benefits of a three times per week strengthening program. Significant improvement was found in grip strength and pain (49). In their second study (50), they carried out a controlled cross over trial with 46 subjects to compare a 16 week program of daily hand strengthening and range of motion exercises vs. use of a sham cream applied to the hand. Significant improvement was seen in grip and pinch strength with the exercise group. Hennig and colleagues (51) carried out a randomized controlled trial to evaluate the effect of providing patient education and home based exercises vs. patient education with no exercises in a population of hand OA patients. All participants received an information sheet detailing joint protection principles. The home based exercise program was carried out three times per week. Exercises were designed to optimize hand movement, strength and joint stability in a pain free manner. Thumb exercises included resisted thumb abduction and extension using a rubber band. At 3 months, the results for 80 female participants demonstrated that there was a significant difference between the two groups and better outcomes in the education-exercise group with respect to patient-specific function, pain, grip strength, range of motion, and fatigue. The author concluded that hand exercises were beneficial for function, strength, endurance and pain in women with hand OA. O'Brien and colleagues (52) performed a retrospective chart review of 35 patients who were provided with a thumb CMC joint dynamic stabilization exercises. They defined dynamic stabilization as "pain-free function during stressful activities in the face of lax or injured ligaments" (reference 52, p. 45). Patients were also provided with joint protection education. Their provision of an orthosis was inconsistent and based on the patient's pain. The results indicated a statistically significant improvement in the pain and disability scores of the QuickDASH following an average of 2.37 treatments carried

out over an average of 44.5 days. They reported that the pain score improvement was 17.9% and the disability score improvement was 19.3%. Davenport and colleagues (53) performed a pilot, randomized controlled trial with 22 participants to compare thumb CMC joint stabilization exercises and general hand exercises. At the 6 month follow-up, the improvement in DASH scores was not significantly different between the two groups. Wajon and colleagues (54) performed a randomized controlled trial over a 6 week period using 40 participants with thumb CMC OA. They compared a group who received a thumb strap orthosis and thumb abduction exercises to a group that received a short opponens orthosis and pinching exercises. Participants used their orthoses full time for two weeks and then began an exercise program that was carried out three times per day for one month. At six weeks there was significant improvement in both groups in pain, tip pinch and hand function, however, there was no significant difference between the two groups. Villafane and colleagues (55) conducted a randomized controlled trial to evaluate the effectiveness of manual therapy techniques and exercises using 60 participants with thumb CMC joint OA. The experimental intervention consisted of grade 3 posterior-anterior glides with distraction, nerve gliding techniques, range of motion and hand strengthening exercises. Treatment frequency was 3 times per week for one month in physiotherapy. The control group received sham ultrasound with the same treatment frequency and duration. The results demonstrated a significant improvement in pain intensity for the intervention group receiving exercises vs. the sham ultrasound. No between group difference was noted in pinch and grip strength measurements. The effect sizes of the aforementioned studies are described in Appendix 1.

In summary the studies examining treatment strategies used for thumb CMC OA demonstrated good effect sizes associated with the effect of orthoses, particularly for pain control

(29-36). However, differences were not significant between orthosis designs (29-36). Moderate to large effect sizes supported the benefits of joint protection education and exercises (42,43), however, the approaches that were used were inconsistent and not client-centered.

2.6 The International Classification of Functioning, Disability and Health

The "International Classification of Functioning, Disability and Health" (ICF) model can be applied to OA of the thumb CMC joint. The model was developed in 1980 by the World Health Organization (56) in an effort to provide "a unified and standard language and framework for the description of health and health related states" (reference 56, p. 3). The ICF consists of 2 parts. The first includes the domains of body function, body structure, activities and participation. The second part includes the domains of environmental and personal factors (56). A diagram of the ICF model may be found in Figure 1. In CMC joint OA of the thumb, the constructs found in the domain of "Body Function and Structure" are pain and motor (eg. range of motion, strength and joint stability). The domain of "Participation" includes the constructs of employment, care of family and community activity and the domain of "Activity" includes the activities of daily living (57). In the Canadian Model of Occupational Performance and Engagement (CMOP-E), activities are further subdivided into three groups which are self-care, productivity and leisure (58,59). A diagram of the CMOP-E may be found in Figure 2. Townsend and Polatajko (59) have found good congruency between the Canadian Model of Occupational Performance and Engagement and the ICF. Both consider the client, their environment and the capacity to perform meaningful tasks. Stamm and colleagues (60) performed a literature search and linked the ICF with the CMOP-E. They found that the CMOP-E concepts of person, occupation and environment could be linked with similar ICF categories and components. Use of these models is facilitated by client-centered practice. A survey of members of the American Society of Hand

Therapists regarding practice patterns for thumb CMC joint OA showed that most therapists use assessment and intervention techniques that focus on the ICF domains of body functions and structures as opposed to those directed towards activity and participation (61). In order to adequately evaluate hand rehabilitation strategies, MacDermid (62) suggested that outcome measures must address impairment as well as disabilities and function.

Health Condition (disorder or disease) Body Functions Activity Participation & Structure Environmental Factors
Personal Factors

Figure 1: International Classification of Functioning, Disability and Health

Adapted from: 56

Figure 2: The Canadian Model of Occupational Performance and Engagement



Adapted from: 59

2.7 Client-Centered Practice in Occupational Therapy

Law and colleagues (9) have defined client-centered practice as "an approach to providing occupational therapy, which embraces a philosophy of respect for, and partnership with, people receiving services. Client-centered practice recognizes the autonomy of individuals, the need for client choice in making decisions about occupational needs, the strengths clients bring to a therapy encounter, the benefits of client-therapist partnership and the need to ensure that services are accessible and fit the context in which the client lives" (reference 9, p. 25). In the traditional medical model, the patient is a more passive recipient of treatment based on goals set by the therapist and the medical team (64). The practice of hand therapy is often based on a medical model in combination with a biomechanical framework (65). When using a client-centered

approach, the therapist and patient work together to identify difficulties regarding the patient's occupational performance. The person, their occupations and their environment are all taken into consideration to determine relevant treatment goals (64). Whalley Hammell (66) found that a fundamental principle in client-centered practice is respect. Consequently, therapists and patients work together in an atmosphere of active listening, awareness of power, and an awareness of culture. Respect is applied to the patient's abilities, their right to make decisions, their resources and their barriers. Colaianni and colleagues (65) performed a mixed methods study to examine opinions regarding a more occupational performance/client-centered approach to hand therapy. Respondents were 105 occupational therapists specialized in hand therapy. They reported the following benefits from occupation-based treatments: meaningful therapeutic exercise, facilitating functional activity and facilitating holism.

Clinicians who treat upper extremity problems, including thumb CMC OA, are becoming increasingly aware of the importance of considering occupational performance and the impact on activity limitations and participation restrictions (6). Wressle and colleagues (58) have suggested that "individuals should have a fundamental part in the therapeutic process in order to enhance their performance of activities of daily living, production and leisure" (reference 58, p34). The benefits of using this type of client-centered approach have been demonstrated in several studies (7,8). McKee and Rivard utilized a client-centered approach to orthoses fabrication for OA of the thumb CMC joint (67). They concluded that the client's occupational performance goals and their individual needs must be considered to optimize the benefit from an orthosis. With this approach, the orthosis enabled occupation using a design that the client found convenient, cosmetically acceptable and comfortable (67).

2.8 Self Efficacy

Kjeken and colleagues (4) studied the functional impact of hand OA and the associations between personal factors, hand impairment, activity limitations and participation restrictions in women. They measured function, occupational performance, range of motion and strength in 87 women who were diagnosed with hand OA. The results of the regression analysis in the study showed that activity and participation were associated with hand impairment as well as personal factors (4) such as age, disease duration, self-efficacy and co-morbidity. In their regression model, self-efficacy was the most significant variable (p=.004) when analyzing associations with occupational performance. Gage and colleagues (68) identified that a discrepancy occasionally exists between occupational performance in a clinical setting versus the client's normal environment. Perceived self-efficacy was thought to be a possible reason.

Self-efficacy is a concept developed by Bandura (69) that is based on the notion of a person's self-perception regarding their capacity to carry out treatment or a required action. It can impact a person's behaviour when performing activities and the emotions related to the experience. Bandura found that lower self-efficacy can cause people to limit the range of their activities, and demonstrate less perseverance or effort (70).

Clinically, self-efficacy has been shown to impact outcomes related to health, disability and function. In a longitudinal study of 4,030 men and women over 70 years of age with no more than one reported mild disability, the results showed that lower self-efficacy outcomes were associated with a higher risk of diminished self-reported functional ability (71). Brekke and colleagues (72) found that high baseline self-efficacy scores correlated with positive changes in health status measures in patients with rheumatoid arthritis over a two year period. Rejeski and

colleagues (73) examined the effects of exercise on self-efficacy beliefs in knee osteoarthritis patients. A total of 357 patients received either a videotaped presentation on arthritis management and occasional phone contact from a health professional or a supervised exercise program for strengthening or aerobics. The results showed a significant improvement in self-efficacy as related to stair climbing in the groups that received the exercise programs. Benyon and colleagues (74) performed a systematic review to examine coping strategies and self-efficacy as outcome predictors in OA. They concluded that self-efficacy is predictive of reduced disability. In patients with painful OA, Marks and colleagues (75) suggest that self-efficacy is improved by treatment programs that include skills mastery, exposure to vicarious experience, verbal persuasion by someone with knowledge about the activity and interpreting physical symptoms before and after activity. A patient-therapist relationship that permits information sharing, problem solving and goal-setting was also found to be beneficial.

Patient beliefs and their adherence to treatment and disease self-management may also account for the change in impairment level outcomes and the impact on activity and participation (76). The Health Belief Model was developed by Becker in 1974 (76) in an effort to understand the internal and external factors related to compliant behaviour in health care recipients. This model was applied to hand rehabilitation by Grothe and colleagues in 1995 (77). The internal factors that they identified were perceived susceptibility to loss of hand function, perceived severity of injury, perceived efficacy of rehabilitation, perceived cost/benefit of rehabilitation, self-efficacy and the patient-therapist relationship. External factors were the socioeconomic environment and the medical environment (77). For optimal outcomes, a client-centered rehabilitation program considering both internal and external factors was suggested.

2.9 Conclusions

Thumb CMC joint OA is a common disease that can impact the ICF domains of "Body Function and Structure" as well as "Activity" and "Participation". Evidence suggests that changes in hand impairment contribute to changes in hand activity (4). Occupational therapists providing hand therapy for CMC OA frequently use strategies directed at an impairment level despite the identified importance of occupational performance, activities and participation with this population (41, 64). Research has also shown a strong association between occupational performance and self-efficacy in hand OA patients (41).

Evidence supports the benefits of orthosis use for pain control and hand function with thumb CMC joint OA, however there is no consensus regarding optimal design, materials or wearing schedule (29-36). A case study (67) presented the importance of linking occupational performance goals to the design of a thumb CMC OA orthosis, however, no empirical evidence was presented. There is limited evidence (45-55) regarding the benefits of exercise programs for CMC joint OA and no apparent consensus regarding the type of exercise and dosage. Two studies (42-43) suggest that there is benefit from joint protection education, however, neither study used a client-centered approach in which the education program was tailored to the occupational performance issues that the patient had identified.

This review of the literature underlines the importance of client-centered practice (63-66) as well as hand therapy programs for thumb CMC OA that consider both impairment and occupational performance based activity and participation (41). Knowing the amount of change in impairment outcomes that is required to impact occupational performance is important for therapists using a client-centered approach for thumb CMC OA yet, to date, this question has not

been specifically addressed in the literature. Unlike a protocol driven approach to the treatment of thumb CMC OA, a client-centered approach uses identified occupational performance difficulties as the basis for guiding treatment strategies. Specifically, orthosis design and wearing schedules are determined collaboratively with the client and are based on the client's daily activity requirements (67). Additionally, joint protection education would focus on activities that are most relevant to the client.

3. RESEARCH QUESTION AND OBJECTIVES

3.1 Question

This study estimated a parameter by answering the following question: "In patients with stage I to IV osteoarthritis of the thumb carpometacarpal joint, to what extent do changes in pain and strength that occur following a client-centered 6 week program of orthosis use, joint protection education and exercises associate with meaningful change in activity and participation at 6 weeks?"

3.2 Statement of the Null Hypothesis

In patients with stage I to IV osteoarthritis of the thumb carpometacarpal joint, changes in pain and strength following a client-centered 6 week program of orthosis use, joint protection education and exercises do not associate with meaningful change in activity and participation.

3.3 Objectives

3.3.1 Primary Objective

The primary objective of this study was to examine the changes in pain and lateral pinch strength following a 6 week program of orthosis use, thumb exercises and joint protection education. Unlike previous studies, the treatment program was client-centered. The associations between the changes in pain and lateral pinch strength and activity and participation were explored.

3.3.3 Secondary Objectives

• Examine the association between self-efficacy and activity and participation.

•Examine the associations of the three outcome measures examining activity and participation (DASH, AUSCAN and COPM).

•Examine the associations of the two outcome measures examining pain (Visual Analog Scale and AUSCAN) and their association with activity and participation.

• Examine the association between range of motion and activity and participation.

4. METHODOLOGY

4.1 Research Design

A pre-post study design was utilized with assessment points at study entry and 6 weeks. Evaluation at study entry and 6 weeks has been supported in the literature (22,54). Day and colleagues performed a prospective trial of orthosis use and steroid injection for the treatment of thumb CMC OA. Their participants were evaluated at baseline and 6 weeks as well as a long term follow-up at 18 months or greater (22). Wajon and Ada compared two orthoses and exercise programs for thumb CMC OA and performed measurements at baseline, 2 weeks and 6 weeks (54). For this study, the evaluations that were carried out at the stated time points are described in Chapter 4 of this thesis.

4.2 Subjects

4.2.1 Subject Recruitment

The proposed recruitment objective for this study was 60 consecutive patients during an 18 month period. Referrals sent to the Centre Professionnel d'Ergothérapie from rheumatologists, hand surgeons and occupational therapists, particularly from Maisonneuve Rosemont Hospital were initially targeted. Upon receiving approval from the McGill Institutional Review Board for the study to proceed in December 2011, 24 publicity letters were sent to rheumatologists and hand surgeons in the Montreal area. In addition, the occupational therapist at Maisonneuve Rosemont Hospital was advised regarding the project. Three months later an additional 28 publicity letters were sent to rheumatologists as well as occupational therapists in a wider geographic area in Greater Montreal. In May of 2012, the project was discussed with Montreal based hand therapists at the annual conference of the Canadian Society of Hand Therapists. In

January, 2013, permission was granted by Maisonneuve Rosemont Hospital to collaborate with their occupational therapy department directly in the hospital in an effort to identify potential study participants. In May of 2013, 54 publicity letters were sent to rheumatologists in the Greater Montreal area and a scientific poster reviewing the literature findings of the study was presented at the annual meeting of the Canadian Society of Hand Therapists. Montreal based therapists attending the meeting were advised that recruitment was continuing. In June of 2013, 29 publicity letters were sent to plastic surgeons in the Greater Montreal area. In October of 2013, the project was listed on the Canadian Arthritis Society website in English and French. An attempt to find a patient-advocate for the study was made with the Canadian Arthritis Society, however, no appropriate person was available. In December of 2013 and January of 2014, 44 publicity letters were sent to rheumatologists and hand surgeons in the Greater Montreal area.

Despite the ongoing publicity efforts, recruitment of participants was slower than expected. A possible explanation for this may stem from the fact that not all physicians utilize rehabilitation services for their patients and patients seen by hand surgeons may not be optimal candidates for conservative treatment strategies since referrals to surgeons are usually made when surgical options are considered to be the best approach due to advanced disease progression.

By April of 2014, 38 participants had been recruited, signed the consent form and completed the baseline evaluation. Three participants were unable to return for the evaluation at 6 weeks due to illness. Thus, 35 full sets of data were collected at baseline and at 6 weeks. For the three participants who could not return to the clinic at 6 weeks, the questionnaires were completed by telephone interview and mail, however it was not possible to measure lateral pinch and range of motion.

Permission was granted from the thesis supervisory committee and the Director of Graduate Studies in the School of Physical and Occupational Therapy to submit the collected data for analysis and proceed with a pilot-study using a smaller sample size. A summary of the monthly recruitment of participants may be found in Table 1. Copies of the publicity letters may be found in Appendices 2 and 3.

Date	Number of Participants Recruited (Inclusion Criteria Met, Consent Signed, Baseline Evaluation Completed)	Number of Participants Who Did Not Return for Evaluation at 6 Weeks
February 2012	2	
March 2012	4	
May 2012	2	
June 2012	1	
July 2012	1	1
September 2012	2	
October 2012	1	
November 2012	2	
December 2012	1	
January 2013	3	2
April 2013	1	
July 2013	4	
August 2013	3	
September 2013	1	
November 2013	4	
December 2013	3	
March 2014	3	

Table 1: Chronology of Participant Recruitment

4.2.2 Inclusion Criteria

The inclusion criteria were the following:

- Adults with grade I to IV osteoarthritis of the CMC joint of the thumb. The diagnosis had to be made by a physician and confirmed radiologically. Participants were included if they had CMC joint OA in one or both thumbs.
- 2) Participants had to be able to communicate in French or English.

4.2.3 Exclusion Criteria

The exclusion criteria were the following:

- History of surgery of the thumb CMC joint, other inflammatory diseases (eg. rheumatoid arthritis), DeQuervain's tendonitis, carpal tunnel syndrome or trigger thumb.
- Participants concurrently receiving other therapeutic interventions in occupational therapy or physiotherapy to treat their thumb CMC joint OA.

4.3 Procedure

Approval of this study protocol was obtained from the McGill Institutional Review Board as well as the Comité d'éthique de la recherche at Maisonneuve Rosemont Hospital. The study was conducted at the Centre Professionnel d'Ergothérapie, a private occupational therapy clinic in Montreal with a specialization in hand and upper extremity rehabilitation. Participants who met the inclusion criteria were approached by an assistant who explained the study objectives and determined if they wished to participate. If they accepted, a consent form was signed. A copy of the English version of the consent form may be found in Appendix 4. Three visits were required for each participant. The visits occurred at study entry, 3 weeks and 6 weeks. No fees were charged for any of the services provided. All clinical assessments and treatment were carried out by the author, Barbara Shankland, who is a member of the Ordre des ergothérapeutes du Québec. The orthosis was made by a qualified orthotist under the supervision of the occupational therapist since this is the current practice at the Centre Professionel d'Ergothérapie due to financial reimbursement regulations.

Study Entry:

An initial interview to obtain demographic data, a history of the condition and information regarding the home and work environment was conducted at study entry. At that time, participants were asked to identify difficulties due to their thumb CMC joint OA in the occupational domains of self-care, leisure and productivity using the Canadian Occupational Performance Measure (COPM). The COPM was specifically selected since it is a measure based on client-centered practice that is "designed for use by occupational therapists to assess client outcomes in the areas of self-care, productivity and leisure" (reference 64, p83). The French and English third edition of the COPM was utilized since this was the version available at the Centre Professionnel d'Ergothérapie. A description of the procedure that was carried out with each participant is listed as follows: 1) Using a semi-structured interview, the daily occupations that the participant wanted to do, needed to do or expected to do were identified in the categories of self-care, leisure and productivity. The listed items were then reviewed to identify the activities that were difficult for the participant. 2) Each of the identified items was then weighed by the participant on a 1 to 10 scale based on the level of importance. With the aid of this information, the participant then selected the five items that were the most urgent or important to them. 3) The five most important items were then rated on a 1 to 10 scale based on self-perceived satisfaction when performing the activity and the ability to carry out the activity. For the purposes of this study, participants were also asked to rate their confidence when performing the identified activity. A 1 to 10 rating scale was used. Means were then calculated for the categories of self-perceived satisfaction, confidence when performing the activity and the ability to carry out the activity. A systematic review of the literature by Parker and Sykes (7) concluded that the COPM facilitates the development of client-centered goals and establishes a partnership
framework between the therapist and the client. The COPM is a generic measure, however, validity has been established with a hand OA population (64). In addition to the COPM, the DASH and the Australian/Canadian Osteoarthritis Hand Index (AUSCAN) questionnaires were completed and baseline measurements were taken for pain, range of motion and lateral pinch strength. A full description of the evaluations may be found in the measurement section of this thesis. The 6 week treatment program was initiated at study entry. It consisted of patient education, fabrication of an orthosis and instruction in performing daily strengthening exercises to facilitate pinch and thumb stability. A summary of the treatment program may be found in Appendix 5.

Using a client-centered approach, the participant and therapist worked together to determine which thumb CMC OA orthosis design, wearing schedule and material were best suited for the participant's occupational needs. Joint protection education was based on the principles of client centered practice and customized to address the problematic activities in self-care, leisure and productivity identified by the participant in the COPM. Participants were asked to complete a daily log sheet in order to monitor treatment adherence to exercises and use of the orthosis. An example of the daily log sheet may be found in Appendix 6.

3 Week Follow-Up Visit

A follow-up visit was carried out with the participant at 3 weeks in order to reinforce the joint protection techniques that were provided and to insure that they were being incorporated into the participant's daily activities. This visit also provide an opportunity to problem-solve through activities where barriers have been encountered by the participants when trying to incorporate

the joint protection principles. Daily strengthening exercises were reviewed and verification of the orthosis was carried out to insure that it was comfortable.

6 Week Visit

At the 6 week visit participants returned their daily log sheet and the following outcome measures were repeated: COPM, DASH, AUSCAN, thumb range of motion, lateral pinch strength, and pain Visual Analog Scale. Participants were encouraged to continue with management of their thumb CMC joint OA using the treatment strategies that had been provided.

4.4 Measurement

4.4.1 Demographic Data:

An initial interview was conducted to determine the subject's age, home and work environments, family/social support, hand dominance, hand affected by thumb CMC joint OA, occupation, leisure activities, medication, previous medical history and current treatments or therapy.

4.4.2 Exposure

Pain Visual Analogue Scale (VAS): Pain is one of the most common symptoms occurring in CMC joint OA (2). According to the ICF definition, upper limb pain is a "sensation or unpleasant feeling indicating potential or actual damage to some body structure felt in either one or both upper limbs including hands" (reference 56, p. 69). The Visual Analogue Scale was selected to measure pain. It uses a 10 cm horizontal line where 0 represents no pain and 10 represents the worst pain imaginable. The patient's self-perceived pain during the past week is indicated with an x on the horizontal line anchored by the statements "no pain" and "worst pain

imaginable". Test-retest reliability of the pain VAS has been found to be good with values of .41 to .99 (78). Testing of construct validity indicates that patients are able to distinguish between different levels of pain intensity (78). Criterion related validity is good with values of .42 to .91 (54). The clinically meaningful change for the pain VAS has been found to be .9 cm (79).

Pinch Meter for Lateral Pinch Strength: Pinch strength is commonly diminished with thumb CMC joint OA. Lateral pinch is the maximum isometric effort using the thumb and flexed index finger. Using the ICF model, strength falls within the motor construct in the domain of "Body Structure and Function". Pinch strength measurements were carried out using a calibrated B and L pinch gauge (B & L Engineering, Santa Ana, California) (80-82). Reliability and norm values have been established using three trials of lateral pinch (80-82). The clinically meaningful change for lateral pinch in patients with OA of the hand has been found to be 2.2 lbs (81).

4.4.3 Primary Outcome Measure

The Disabilities of Arm, Shoulder and Hand Questionnaire: The DASH was developed by the Institute for Work and Health, the American Academy of Orthopedic Surgeons and the Council of Musculoskeletal Specialty Society to measure activity limitations in patients with upper extremity pathology (83, 84). Dr. Dorcas Beaton, a scientist with the Institute for Work and Health, confirmed in a personal communication that the DASH would be an appropriate primary outcome measure for this study (84). The DASH is a questionnaire that is completed by patients. The disability/symptom component consists of 30 items. Each item is answered using a scale from 1 to 5 (1=no difficulty, 2=mild difficulty, 3=moderate difficulty, 4=severe difficulty, 5=unable). A score of 0 to 100 is obtained by adding all item scores, dividing by the number of

items answered (minimum 27), subtracting one from the average obtained and then multiplying that value by 25 (85). A lower score represents fewer problems (86). Two studies that link the DASH items to the ICF model have been carried out (87,88). The results of a study by Dixon and colleagues (87) indicate that the DASH contains 19 activity limitation items, 3 participation restriction items and 7 items that measure both activity limitation and participation restrictions. According to the ICF definitions, "activity limitations are difficulties an individual may have in executing activities" (reference 56, p.10) and "participation restrictions are problems an individual may experience in involvement in life situations" (reference 56, p.10). In addition, 5 items were found to correspond with impairment (87) which the ICF defines as "problems in body function or structure" (reference 56, p. 10).

The secondary objectives of this study were to examine the associations of activity and participation with all DASH items except for those that corresponded with impairment. In an evaluation of 15 measurement tools used to assess activity and participation in the upper extremity, Schoneveld and colleagues (89) found that the DASH had superior clinimetric properties when applied to hand injuries. Content validity and responsiveness were found to be excellent and test retest reliability, construct validity and internal consistency were found to be good (83). The French-Canadian version has demonstrated good internal consistency and item to item correlations (83). Beaton and colleagues (90) reported that a score change of 15 or more is clinically meaningful.

4.4.4 Secondary Outcome Measures (Exploratory Variables)

Joint Goniometry for Active Range of Motion: Decreased active range of motion occurs commonly with thumb CMC joint OA due to joint stiffness and muscle-tendon tightness. The

ICF defines the mobility of joint functions as "the range and ease of movement of more than one joint" (reference 56, p.94). Thumb active range of motion is typically measured with a digital goniometer. Device reliability has been found to be $\pm 5^{\circ}$ (80). The normal active joint movement at the CMC joint of the thumb has been found to be 40° of abduction, 50° of flexion and 80° of rotation relative to the third metacarpal (12). A higher number of degrees of movement indicates a greater amount of movement at the joint. Hyperextension is represented by notation with a (+) sign and lack of extension is represented by notation with a (-) sign. The total active range of motion value for the thumb phalangeal joints was determined by adding the amount of flexion at the metacarpophalangeal and interphalangeal joint and subtracting from this value the lack of extension at each joint.

The Australian/Canadian Osteoarthritis Hand Index (AUSCAN): The AUSCAN is a 15 item patient questionnaire evaluating hand pain, stiffness and function. It was developed specifically for populations with hand OA. Each item uses a 5 point descriptive scale. The total is a sum score of the three subscales (91). Test-retest reliability was found to be high (.70 to .90) and internal consistency was high with a Cronbach's alpha of .90 to .98. Construct validity has been established. In a population with hand OA, the minimal percentage change that is potentially detectable has been found to be 5% for the pain subscale, 25% for the stiffness subscale and 2.8% for the physical function subscale (93). In a verbal communication, Dr. Dorcas Beaton (84) suggested that comparing the responses of the activity/participation items in the DASH and the hand function (activity based) items of the AUSCAN would allow for the examination of the consistency of the two instruments.

<u>*The Canadian Occupational Performance Measure:*</u> The COPM is a client centered measure used by occupational therapists to assess self-care, productivity and leisure (63). Specific details

regarding how the COPM is conducted may be found in the Procedure section of this thesis. Kjeken and colleagues (64) studied the Norwegian version of the COPM with a hand OA population. They stated that the COPM is "constructed as an individual measure, rating activities that are important and difficult for the patient to do" (reference 64, p. 711). Their results showed that 79 patients identified 864 occupational performance problems (64). They also demonstrated criterion validity and good responsiveness of the COPM. In addition positive comments were provided by clinicians and patients regarding the feasibility of using the COPM with a hand OA population.

4.4.5 Confounding Variables

<u>*Gender:*</u> Females are more likely to develop thumb CMC joint OA (2,3). Hormonal changes causing increased joint laxity and anatomical variation may contribute to more severe symptoms. Gender was noted in the demographic information and analyzed using descriptive statistics.

<u>Age:</u> Older participants may have more joint degeneration than younger patients (2,3). Thus, more severe symptoms may be present which in turn could influence activity and participation. Age was noted in the demographic information and a descriptive analysis carried out.

<u>Medication</u>: Participants may have received an intra-articular steroid injection or they may be using medication such as anti-inflammatories, analgesics or glucosamine (20-22,26,27). These medications can influence pain and how easily activities are carried out. All medications used by participants were noted in the initial interview. A descriptive analysis of the type of medication used was conducted (eg. cortisone injection, anti-inflammatory medication or acetominophen).

Hand Dominance: Participants who have thumb CMC joint OA of their dominant hand or of both hands may be more limited in their activities and participation (18). Hand dominance was noted in the initial interview and a descriptive analysis was carried out.

4.5 Data Analysis

4.5.1 Parameter Estimation

The analysis estimated in patients with stage I to IV OA of the thumb CMC joint, to what extent do changes in pain and pinch strength that occur following a client-centered 6 week program of splinting, joint protection education and exercise associate with meaningful change in activity and participation? A summary of the variables may be found in Table 2.

Variable	Definition	Type of variable	Scale
Pain	Pain intensity as	Explanatory	Continuous
	measured in cm on a		
	visual analogue		
	scale		
Lateral pinch	Isometric lateral	Explanatory	Continuous
strength	pinch strength as		
	measured by a B&L		
	pinch gauge in lbs.		
Activity and	DASH (score 0-	Outcome	Continuous
participation	100)		

 Table 2: Summary of Variables

The analysis for this study was carried out using a multiple regression model with SAS and JMP statistical software. Assistance in designing and conducting the analysis was received from Dr. José Correa, Department of Mathematics and Statistics, McGill University. This study used a pre-post design with measurements taken at baseline and 6 weeks. The primary outcome variable for the study was continuous and represented the change in the DASH score between baseline and 6 weeks (y=DASH score 6 weeks-DASH score 0 weeks). The two explanatory

variables, pain (VAS) and lateral pinch strength were continuous. Dr. Correa suggested that a multiple regression method of analysis most appropriately addressed the research question, the design and the type of variables (92). All statistical tests performed were two sided and at a significance level of α =.05.

4.5.2 Mathematical Summary of the Multiple Regression Used:

 $Y = \beta o + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 + \beta_5 x_5 + age + sex + medication$

Where: Y = DASH Score at 6 weeks –DASH Score at 0 weeks $x_1 = DASH$ at 0 weeks $x_{2=}VAS$ at 0 weeks $x_3=VAS$ at 6 weeks $x_4=Lateral$ Pinch at 0 weeks $x_5=Lateral$ Pinch at 6 weeks

4.5.3 Descriptive Analysis and Outcome Measure Change

Descriptive statistical analysis was used for all raw scores and demographic information. The changes between the baseline and 6 week mean outcome values were analyzed using a t-test for paired data (57).

4.5.4 Correlations

Pearson correlation coefficients were calculated to examine the associations of the following: a) COPM Satisfaction sub-scale vs. Self-efficacy subscale and DASH activity and participation items score, b) VAS score vs AUSCAN pain sub-scale and DASH activity and participation items score, c) range of motion, AUSCAN stiffness sub-scale and DASH activity and participation items score and d) the COPM Performance sub-scale vs. the AUSCAN Activities of Daily Living sub-scale vs the DASH activity and participation items. Linking studies (87,88) have compared the DASH to the ICF model and identified the items related to activity limitations and participation restrictions. At the recommendation of Dr. Correa (92) the correlations were performed using the raw scores of the outcome measures.

4.6 Sample Size Calculation

The initial sample size calculations for an 80% power level were carried out by Dr. José Correa using the following software: http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main /PowerSampleSize. The initial recommendation was as follows: "Sample size calculation was made for investigating a change in DASH scores from baseline to post in a similar population. This prior data indicates that the difference in the response of the baseline-post DASH scores has an estimated standard deviation of 18.9. If the true difference in the mean baseline-post DASH scores is 7, we need to study 60 subjects to be able to reject the null hypothesis of no change in DASH from baseline. This sample size was determined with a probability (power) of 0.8, using a two-tailed T-test for paired data. The Type I error probability associated with this test of this null hypothesis is .05. The calculation is based on the assumption that differences in the baseline-post DASH measures are normally distributed" (93, 94).

Due to difficulties with participant recruitment, the project was modified to a pilot-study with a sample size of 38.

5. RESULTS

5.1 Description of the Participants

A total of 38 participants were recruited for this study, signed the consent form and completed the baseline evaluations. Three of the participants were unable to return for the final appointment due to illness. The questionnaires for these participants were completed by telephone interview and by mail, however, it was not possible to obtain lateral pinch strength and range of motion measurements. At the recommendation of Dr. Correa, only the 35 full sets of data were used in the quantitative statistical analysis (92).

Of the 38 participants, 35 were female and 3 were male. All participants were right-hand dominant. The mean age of the study participants was 64.1 years (standard deviation=9.4). The age range was from 49 years to 88 years. A total of 15 participants were treated for the right hand, 12 participants were treated for the left hand and 11 participants were treated for both hands. A summary of the participant demographics may be found in Table 3.

Mean (SD)	n=35 •Participants Completed Evaluation at Baseline and 6 Weeks •Participants Included In Quantitative Analysis	n=3 • Participants Did Not Complete Evaluation at 6 Weeks •Participants Not Included In Quantitative Analysis
Age	Mean (Standard Deviation)	Mean (Standard Deviation)
	63.4 (8.8) years	60.0 (1.7) years
	n	(%)
Gender	Female: 32 (91.4)	Female: 3 (100)
	Male: 3 (8.6)	
Handedness	Right Handed: 35 (100)	Right Handed: 3 (100)
Right Hand Treated in Study	15 (42.9)	0
Left Hand Treated in Study	9 (25.7)	3 (100)
Both Hands Treated in Study	11 (31.4)	0
Type of Medication:	n (%)	
Analgesic (Tylenol)	12 (34.3)	0
Anti-inflammatory	10 (28.6)	0
(Voltaren, Celebrex)		
Steroid Injection	7 (20.0)	3 (100)
None	6 (17.1)	0

 Table 3: Participant Demographics

A total of 36 out of 38 participants returned their daily log sheet for orthosis use and exercises. All participants reported that they completed the prescribed exercises. The results showed that 33 participants completed their exercises once a day, two participants completed the exercises three times a day and one participant completed the exercises twice a day. During the visit at 3 weeks, an interview was conducted in which participants were asked how they were modifying their methods of carrying out activities based on the instructions provided at baseline. Each participant was provided with the opportunity to problem solve through activities where barriers had been encountered (ex. how assistive devices were utilized or obtained). Each participant provided examples of how they were incorporating joint protection techniques when

performing daily activities (ex. using a pillow to support a book when reading in bed, using an assistive device to open jars, taking breaks more often while knitting, carrying a bag on their shoulder rather than using their hand).

The mean number of hours per day of orthosis use was 6.8 hours (standard deviation 5.2). The mean minimum duration for orthosis use was $\frac{1}{2}$ hour per day and the mean maximum duration for orthosis use was 15 $\frac{1}{2}$ hours per day. The reasons provided for not using the orthosis more often included the following: did not want to handle food while wearing an orthosis, found that the orthosis made the hand feel hot and/or found the orthosis too rigid. Some participants also reduced their orthosis use because they felt that their pain had improved. The orthosis designs that were utilized included a) a thermoplastic short thumb spica that immobilized the thumb MP joint in 30° of flexion and the CMC joint in opposition in order to permit the distal phalanx to touch the index finger (n=24), b) a hand based orthosis with the MP joint of the thumb left free, as described by Colditz (10), using a hybrid thermoplastic-neoprene material (n=12), c) a leather, hand based orthosis with the MP joint at 30° of flexion (n=1) and d) a thermoplastic orthosis that included the wrist in a neutral position and the thumb MP joint at 30° of flexion (n=1). Participants who demonstrated thumb MP joint hyperextension during pinching activities generally preferred to have the joint immobilized by the orthosis in order to enhance stability. The hybrid neoprene-thermoplastic design that left the MP joint free was preferred by participants who used a computer mouse on a regular basis. The leather orthosis was selected on the basis of durability during heavy daily activities. The orthosis that immobilized the wrist and thumb was utilized by a participant who demonstrated significant deformity of the thumb CMC joint from subluxation as well as severe, constant pain. A summary of the exercise and orthosis interventions may be found in Table 4.

Interventions			
Orthosis Use	Mean (SD)		
Average wearing time	6.8 (5.2) hours per day		
	n (%)		
Use of short thumb spica design with MP joint	24 (63.2)		
at 30° of flexion			
Use of hybrid orthosis (thermoplastic and	12 (31.6)		
neoprene) with MP joint free			
Use of short, leather thumb spica with MP joint	1 (2.6)		
at 30° of flexion			
Use of long thumb spica with wrist and thumb	1 (2.6)		
MP immobilized			
Exercises	n (%)		
Exercises carried out 1 time per day	33 (91.6)		
Exercises carried out 2 times per day	1 (2.8)		
Exercises carried out 3 times per day	2 (5.6)		

 Table 4: Exercise and Orthosis Interventions

5.2 Description of Outcome Measure Results

A t-test for paired data was used to examine the changes in the outcome measures between baseline and 6 weeks. All outcome measurements demonstrated improvement from baseline to 6 weeks. Statistically significant differences were found for pain (VAS), lateral pinch, the AUSCAN pain subscale, the COPM Performance Subscale, the COPM Satisfaction Subscale, Self-Efficacy and range of motion. Clinically significant change was noted with the Visual Analog Scale, COPM Performance, COPM Satisfaction and range of motion. A summary of the mean raw scores, the standard deviation values, the change between baseline and 6 weeks, the standard error, the p-values and clinically significant change values may be found in Table 5.

Outcome Measure	Raw Score:Baseline (mean and standard deviation)	Raw Score: 6 weeks (mean and standard deviation)	Change in raw score	Standard Error	P Value	Clinically Significant Change (reference)
DASH**	38.8 (8.5)	32.1(18.0)	-6.74	3.70	0.07	15 (90)
VAS (cm)	4.7 (2.4)	3.6 (2.0)	-1.13	.4	0.0095*	.9 (79)
Lateral Pinch (lbs)	9.0 (3.7)	10.1 (4.7)	1.09	.5	0.03*	2.2 lbs (81)
AUSCAN Pain Scale	11.5 (4.2)	9.6 (3.8)	-1.9	.67	0.0075*	
AUSCAN Stiffness Scale	1.6 (1.02)	1.42 (1.0)	-0.21	0.14	0.15	
AUSCAN Function (ADL) Scale	18.2 (7.4)	16.1 (6.3)	-2.1	1.1	0.06	
COPM Performance Scale	4.1 (1.8)	6.4 (1.9)	2.2	.3	<0.0001*	2 points (96)
COPM Satisfaction Scale	4.0 (2.0)	6.4 (2.0)	2.5	.3	<0.0001*	2 points (96)
Self- Efficacy	4.6 (2.1)	7.0 (1.9)	2.4	2.4	<0.0001*	
TAROM (°)	112.7 °(16.9)	120.8° (17.9)	8.1	2.2	0.0007*	5° (81)

 Table 5: Summary of Outcome Measure Results n=35

* Denotes statistically significant p value

**A lower DASH score indicates a higher level of activity and participation

5.3 Parameter Estimations

A multiple regression model was used to investigate the effects of pain (VAS) and lateral pinch (lbs) at baseline and 6 weeks with respect to changes in activity and participation as defined by [DASH score at 6 weeks –DASH score at baseline]. All analyses were performed using SAS version 9.2 (SAS Institute). Adjustments were made for the variables sex, age and

medication use. In addition, adjustments were also made for possible differences in [DASH score at 6 weeks – DASH score at baseline] by using it as a covariate in the model. According to Dr. Correa (94), assumptions of the regression model including the randomness of errors, homogeneity of variance, normality and the presence of outliers, were investigated using graphical analyses of residuals. All hypothesis tests were 2-sided and significance was set at the 0.05 level. A summary of the results may be found in Table 6.

The results demonstrated that, after adjusting for age, sex and medication use, pain (VAS) at 6 weeks had a statistically significant effect on changes in activity and participation (DASH). In particular, a one unit (1 cm) increase in pain (VAS) at 6 weeks resulted in a 3.8 point change in the mean DASH score. With respect to lateral pinch, its value at 6 weeks also had a statistically significant effect on changes in activity and participation (DASH). A 1.43 point decrease in the DASH score occurred for every one unit (1 lb) increase in the lateral pinch score. The effects of the variables age, sex and medication use were not significant. The statistically significant negative estimate value for the DASH score at 0 weeks indicated that participants with a higher baseline DASH score demonstrated less change in the DASH score between 0 and 6 weeks.

Table 6: Multiple Regression Analysis Results, n=35

 $Y=Bo + B_{1}x_{1} + B_{2}x_{2} + B_{3}x_{3} + B_{4}x_{4} + B_{5}x_{5} + age + sex + medication$ Where: Y= DASH Score at 6 weeks - DASH Score at 0 weeks $x_{1} = DASH at 0 weeks$ $x_{2}=VAS at 0 weeks$ $x_{3}=VAS at 6 weeks$ $x_{4}=Lateral Pinch at 0 weeks$ $x_{5}=Lateral Pinch at 6 weeks$

Effect	Estimate (B)	Standard Error	T Value	P Value
DASH 0	-0.57	0.14	-3.92	0.0007*
weeks				
VAS 0 weeks	0.43	1.07	0.40	0.69
VAS 6 weeks	3.8	1.14	3.32	0.0031*
Lateral Pinch	0.22	0.9	0.23	0.82
0 Weeks				
Lateral Pinch	-1.43	0.69	-2.09	0.05*
6 Weeks				
Age	0.34	0.28	1.21	0.24
Sex	2.38	6.97	0.34	0.74
Medication	-4.78	5.94	-0.80	0.43
(analgesic)				
Medication	-6.05	5.61	-1.08	0.29
(anti-				
inflammatory)				
Medication	0.03	6.19	0.01	0.99
(steroid				
injection)				

*Denotes statistically significant p value

5.4 Correlations

5.4.1 Self-Efficacy Sub-scale, COPM Satisfaction Sub-scale and DASH Activity and Participation Items

Pearson correlation coefficients were calculated to examine the association between the selfefficacy sub-scale, the COPM Satisfaction sub-scale and the raw score total of the activity and participation items from the DASH. The results demonstrated statistically significant strong correlations between the self-efficacy sub-scale and the COPM satisfaction sub-scale at baseline and 6 weeks. At baseline, the DASH activity and participation items had a statistically significant, weak correlation with the self-efficacy sub-scale and a statistically significant, moderate correlation with the COPM satisfaction sub-scale. At 6 weeks, the DASH activity and participation items score had a statistically significant, strong correlation with the self-efficacy sub-scale and a statistically significant, strong correlation with the self-efficacy sub-scale and a statistically significant, strong correlation with the coPM satisfaction sub-scale. A summary of the results may be found in Table 7.

	Baseline (r value)	6 Weeks (r value)
Self-efficacy and COPM	0.74	0.88
Satisfaction sub-scale	p<0.0001	p<0.0001
DASH Activity+Participation	-0.33	-0.65
Items Score and Self-efficacy	p=0.05	p<0.0001
sub-scale		
DASH Activity+Participation	-0.46	-0.67
Items Score total and COPM	p=0.005	p<0.0001
Satisfaction sub-scale		

 Table 7: Correlations for Self-Efficacy Sub-scale, COPM Satisfaction Sub-scale and DASH

 Activity and Participation Items

5.4.2 Pain (VAS), AUSCAN Pain Sub-scale and DASH Activity and Participation Items

Pearson correlation coefficients were calculated to examine the association between pain (VAS), the AUSCAN pain sub-scale and the raw score total of the activity and participation items from the DASH. The results demonstrated statistically significant strong correlations between the pain (VAS) scores and the AUSCAN pain sub-scale scores at baseline and 6 weeks. At baseline, the DASH activity and participation items score had a statistically significant, moderate correlation with pain (VAS) and a statistically significant, moderate correlation with the AUSCAN pain sub-scale. At 6 weeks, the DASH activity and participation items score had a statistically significant, store had a statistically significant, moderate correlation with pain (VAS) and a statistically significant, moderate correlation with pain sub-scale. At 6 weeks, the DASH activity and participation items score had a statistically significant, store had a statistically significant, moderate correlation with AUSCAN pain sub-scale. A summary of the results may be found in Table 8.

Baseline (r value)	6 Weeks (r value)
0.70	0.75
p<0.0001	p<0.0001
0.64	0.72
p<0.0001	p<0.0001
0.50	0.56
p=0.0017	p=0.0004
	_
	Baseline (r value) 0.70 p<0.0001

 Table 8: Correlations for Pain (VAS), AUSCAN Pain Sub-scale and DASH Activity and
 Participation Items

5.4.3 Active Range of Motion, AUSCAN Stiffness Sub-scale and DASH Activity and

Participation Items

Pearson correlation coefficients were calculated to examine the association between active range of motion, the AUSCAN stiffness sub-scale and the raw score total of the activity and participation items from the DASH. The results demonstrated weak correlations that are not

statistically significant between the active range of motion results and the AUSCAN stiffness sub-scale scores at baseline and 6 weeks. At baseline and 6 weeks, the DASH activity and participation items score had a weak correlation with active range of motion that was not statistically significant. At baseline and 6 weeks, the DASH activity and participation items score had a statistically significant, moderate correlation with the AUSCAN stiffness subscale. A summary of the results may be found in Table 9.

 Table 9: Correlations for Total Active Range of Motion, AUSCAN Stiffness Sub-scale and

 DASH Activity and Participation Items

	Baseline (r value)	6 Weeks (r value)
Active Range of Motion and	-0.12	-0.06
AUSCAN stiffness sub-scale	p=0.49	p=0.75
DASH Activity+Participation	0.54	0.49
Items Raw Score total and	p=0.0006	p=0.002
AUSCAN stiffness sub-scale		
DASH Activity+Participation	-0.27	-0.09
Items Raw Score total and	p=0.12	p=0.57
TAROM		

5.4.4 COPM Performance Sub-scale, AUSCAN Function (ADL) Sub-scale and DASH Activity and Participation Items

Pearson correlation coefficients were calculated to examine the association between the COPM Performance sub-scale, the AUSCAN Function sub-scale and the activity and participation items from the DASH. At baseline and 6 weeks, the results demonstrated a moderate, statistically significant correlation between the AUSCAN Function sub-scale and the COPM Performance sub-scale. At baseline, the DASH activity and participation items score had a statistically significant, moderate correlation with the COPM Performance sub-scale and a statistically significant, strong correlation with the AUSCAN Function sub-scale. At 6 weeks,

the DASH activity and participation items score had a statistically significant, moderate correlation with the COPM performance sub-scale and a statistically significant, moderate correlation with the AUSCAN Function sub-scale. A summary of the results may be found in Table 10.

 Table 10: COPM Performance Sub-scale, AUSCAN ADL Sub-scale and DASH Activity and
 Participation Items

	Baseline (r value)	6 Weeks (r value)
COPM Performance and	-0.46	-0.56
AUSCAN Function sub-scale	p=0.0041	p=0.0003
DASH Activity+Participation	0.74	0.63
Items and AUSCAN Function	p<0.0001	p<0.0001
sub-scale.		
DASH Activity+Participation	-0.53	-0.56
Items and COPM Participation	p=0.0008	p=0.0003
Items		

6. **DISCUSSION**

6.1 Study Demographics

The participants enrolled in this study were primarily female (92%) with a mean age of 64.1 years. This concurs with reports of the incidence of thumb CMC joint OA which suggest that it occurs most commonly in post-menopausal women (2). All subjects were right handed. Gilbert and colleagues studied 1,177 American men and women between the ages of 10 and 86. They found that there was a decrease in prevalence of left hand dominance after age 50 due to societal tendencies to favour right handedness and modify or eliminate left handedness (95). The medications used by the participants were representative of those that are typically prescribed (3).

The majority of participants (36/38) returned their daily log sheets confirming the number of hours per day that the orthosis was worn and if the exercises were completed. The mean number of hours per day of orthosis use was 6.8 hours per day (SD 5.2) with results ranging from 1 ½ hours per day to 15 ½ hours per day. These results are consistent with a client-centered approach and they concur with the literature which demonstrated a wide range for orthosis dosage for thumb CMC joint OA (30-32, 36). Reported dosage examples included night time use, use when the thumb was painful, use during heavy activity, use "each day" and use from 5-6 hours per day (30-37). In this study, the therapist and participant worked together to determine the best orthosis design in order to optimize occupational performance, stabilize the thumb joints and rest inflammation. Participants preferred hand based designs and materials that were thin and /or less rigid. O'Brien has suggested that adherence to orthosis use is enhanced by the following: an immediate perceived benefit such as pain relief, orthosis comfort, orthosis appearance and by

minimizing the interference with the completion of daily occupational tasks (96). O'Brien's suggestions for enhancing adherence to orthosis use were incorporated in this study by using a client-centered approach to select an orthosis design and a material that could optimize occupational performance. In addition there was a statistically significant improvement in pain from baseline to six weeks which could potentially be a perceived benefit.

Exercises were generally carried out one time per day with the exception of three of the participants who reported that they performed their program two to three times per day. They reported that they felt benefit from the exercises and thus, wanted to perform them more often. Perceived efficacy of rehabilitation has been identified by Groth and colleagues (77) as a factor that potentially influences adherence to treatment. Strategies that they have identified to enhance adherence include customizing treatment plans, repeating instructions and incorporating family support (77).

6.2 Key Findings

6.2.1 Change in Pain, Strength and Activity and Participation

This study examined to what extent changes in pain and strength associate with meaningful change in activity and participation in patients with stage I to IV thumb CMC joint OA following a client-centered 6 week treatment program. The results demonstrated that from 0 to 6 weeks, if there is a one unit (one cm) increase in pain (VAS), there will be a 3.8 point change in the DASH score. This result was statistically significant. In this study, the mean VAS score decreased by 1.13 points between baseline and 6 weeks. This change in the VAS score was clinically significant and statistically significant. The decrease in the DASH score was neither clinically nor statistically significant. In this study, the mean baseline DASH score was 38.3 and the final

mean DASH score was 32.1. When the change in DASH scores were analyzed individually, it was noted that only 10 participants in the sample of 35 had a DASH baseline to final score difference of 15 points or greater.

Orthoses for thumb CMC joint OA have been shown to reduce pain (34-36). In studies examining the efficacy of a thumb orthosis for CMC joint OA, Rannou and colleagues (36) had results demonstrating a mean VAS change of 2.22 cm from baseline to 1 year while Gomes and colleagues (34) had a mean VAS change of 1.4 cm from baseline to 180 days. Boustedt and colleagues (43) reported a mean VAS change of 1.7 cm and a 10 point change in the DASH score at one year following a joint protection education program, home exercises and use of an orthosis. Of note, none of the reported changes in VAS scores were above 3 cm and the DASH score change that was reported by Boustedt and colleagues (43) was not clinically significant. Thus, the results follow the same pattern as those of this study. Responsiveness of the DASH has been established in the literature, however, not with a thumb CMC joint OA population (90, 97).

The AUSCAN pain sub-scale results for this study demonstrated a significant decrease in pain between baseline and 6 weeks. The Pearson correlation showed a strong association between the VAS and AUSCAN pain sub-scale results. Moderately strong association was found between the DASH activity and participation items raw score and the AUSCAN pain sub-scale as well as the VAS. These study results support the fact that two outcome measures indicated improvement in pain symptoms however only with moderate association with activity and participation when measured by the DASH. Thus indicating that participants with higher pain levels are more likely to have difficulty with their activities and participation.

The lateral pinch results of this study demonstrated that a one unit (1 lb) increase in lateral pinch strength at 6 weeks resulted in a statistically significant 1.43 point decrease in the DASH score. To achieve a 15 point clinically significant change in the DASH, a 10.5 unit change would be necessary in lateral pinch strength. It is noteworthy that a clinically significant change in pinch strength is 2.2 lbs (81). A 10.5 unit change in strength is very large for a person with arthritic joints. A time period of 6 weeks may also be considered too brief when trying to effect significant change in strength with a chronic condition.

In their studies of orthosis efficacy and thumb CMC joint OA, Rannou and colleagues demonstrated a 5.1 Newton increase in lateral pinch strength at one month (36). Gomes and colleagues had a pinch strength change of 1.76 lbs at 6 months (34). Following a 4 month hand strengthening program for participants with hand osteoarthritis, Rogers and colleagues had a .04 lbs difference in lateral pinch strength (50). Boustedt and colleagues (43) in their one year follow-up results showed a 10 point change in the DASH and a 3 Newton decrease in the lateral pinch strength. Their reported pinch strength changes and DASH score changes are higher than those found in this study. This may be explained by the difference in time lines (one year vs. 6 weeks). As in this study, their changes in the DASH score were not clinically significant.

6.2.2 Comparison of the DASH, COPM Performance Sub-scale and AUSCAN ADL Sub-Scale

Moderate, statistically significant correlations were found between the AUSCAN ADL subscale, the COPM performance sub-scale and the DASH activity and participation items. Each of the above demonstrated improvement from baseline to 6 weeks, however, only the COPM performance sub-scale change was significantly different.

Taking into account the differences between the three outcome measures may help to explain why the correlation is only moderate. The DASH is a self-report questionnaire that "is not specific to a particular pathology or condition or functional complication" (reference 88, p. 337). The AUSCAN is also a self-report questionnaire that is specific to hand osteoarthritis, however, the sub-scale evaluating ADL has only 9 items (93). The COPM is a patient specific measure with items generated in a client-centered, semi-structured interview. Kjeken and colleagues assessed the validity, responsiveness and feasibility of the COPM with 79 adults with hand OA between the ages of 50 and 70 (64). Their sample generated a list of 161 different activities that were problematic for the participants. Their baseline COPM performance score was 4.34 (SD 1.59) which was very similar to the results found in this study. The authors found that the COPM was highly responsive with a hand osteoarthritis population. They found low correlation (-.23) between the COPM Performance sub-scale and the AUSCAN Function sub-scale. The authors attributed this difference to the client-centered perspective brought forth by the COPM. They hypothesized that improvement was more apparent when occupational performance problems were specifically identified by the client. This identification process is possible due to the semistructured interview method used in the COPM. The DASH and AUSCAN are self-report measures that use structured lists of items that are scored by the participant. In the case of the DASH, these lists may not include those activities that are problematic or significant to a participant with thumb CMC OA. In the case of the AUSCAN, the list of ADL items may not be extensive enough to address their identified occupational performance issues. In this study, individual occupational performance issues were identified and joint protection education was customized to address these problems. This fact may help to account for the significant change in the COPM performance sub-scale between baseline and 6 weeks.

6.2.3 Comparison of the DASH, COPM Satisfaction Sub-scale and Self-efficacy Sub-scale

At 6 weeks, strong correlation was found between the self-efficacy sub-scale and the COPM Satisfaction sub-scale. Strong correlations were also found between the DASH activity and participation item scores, the self-efficacy sub-scale and the COPM Satisfaction sub-scale. Each of the above demonstrated improvement from baseline to 6 weeks, however, only the COPM satisfaction sub-scale change and self-efficacy sub-scale change were significantly different.

In this study the self-efficacy sub-scale asked participants to rate their self-confidence in carrying out the important activities identified in the COPM. The difference between the baseline and 6 week mean was 2.4 points which was very similar to the COPM satisfaction difference of 2.5 points. Kjeken and colleagues found a difference of 2.22 points in the COPM satisfaction scale following four months of treatment for hand osteoarthritis (64). The application of the self-efficacy sub-scale to the specific activities identified in the COPM may account for the high level of correlation between the two. The strong correlation between the DASH activity and participation item scores and the COPM satisfaction sub-scale and self-efficacy sub-scale may be explained by the fact that if participants have improvement in their ability to carry out their activities, it is likely that they will be more satisfied and feel more self-confident.

The intervention in this study was client-centered and provided participants with tools for self-management of their thumb CMC OA. Bijsterbosch and colleagues found that the perceived level of control over their OA was a predictive factor for disability in patients (98). A greater understanding of their condition helped to decrease negative emotions. Landa-Gonzalez and colleagues studied the effects of an occupational therapy intervention on self-care, satisfaction

and self-efficacy in 29 female participants who were 62 years of age or older and had OA (99). Comparison was made between one group that received heat, exercises as well as minimal advice regarding activity modification and a second group that received basic instruction in use of heat and exercises as well as detailed, occupational performance specific information on activity modification. The occupational performance specific intervention showed greater benefit with respect to ADL function and self-efficacy. Gignac and colleagues performed 16 focus groups to explore health experiences in middle-older age adults with moderate OA (100). Their results found that participants "focused on remaining independent and employed, engaging in leisure activities and social activities and maintaining supportive close relationships" (ref. 99, page 910). Thus, greater satisfaction and self-confidence would likely occur with greater ability to perform and participate in daily activities.

6.2.4 Comparison of the DASH, AUSCAN Stiffness Sub-scale and Active Range of Motion

At baseline and 6 weeks, weak correlations that were not statistically significant were found between the DASH activity and participation items raw scores and AROM as well as the DASH activity and participation items raw scores and the AUSCAN stiffness subscale. Moderate, statistically significant correlation was found between the AUSCAN stiffness subscale and the DASH activity and participation items raw scores. These results may have been influenced by the fact that the AUSCAN stiffness subscale is only one question item, thus little detail is provided. In addition, since the DASH addresses the entire upper extremity, it is possible that a change in the AROM of the thumb is not sufficient for a high correlation with the change in activity and participation at 6 weeks. Furthermore, the client-centered, modified approach to activities discussed in this study intervention may have helped participants to perform their ADLs despite their lack of thumb AROM. For example, when holding an object a palmar grasp

could be used rather than grasping the object by using a flexed interphalangeal joint of the thumb. Thus, decreased thumb AROM may not have a strong influence on the final DASH results.

A statistically significant improvement was seen with thumb AROM between baseline and 6 weeks in this study. Although participants carried out an intervention in which the exercises focused on strengthening, they performed a warm up thumb abduction exercise before strengthening. Participants may have also been able to move the joint more easily if it was less painful. Boustedt and colleagues (43) noted a statistically significant improvement in stiffness at one year as measured by a 10cm VAS with 42 women who had thumb CMC OA. The one year improvement in the DASH was 10 points. The participants in their study performed 9 range of motion exercises once a day in addition to orthosis use and joint protection education.

6.3 Study Limitations and Strengths

This study had several limitations which are described as follows:

- 1) Small Sample Size: The small sample size of this study resulted in a power level that is below 80%. "The power of a significance test measures its ability to detect an alternative hypothesis" (reference 101, p. 410). When the significance level is fixed, a larger sample size will increase the power level (101). A high level of variance was also noted in the outcome measure results. Larger sample sizes can help to reduce variability (101). In addition to greater statistical strength, a larger sample size may have permitted more rigorous evaluation of the influence of medication use on the participants.
- *2) Grade of OA Unknown:* Because it was not possible to have access to the radiology reports, the thumb CMC OA severity grade was unknown. It is possible that participants

with a more severe grade would have had greater pain and less strength. The impact of the treatment intervention on pain and strength may not have been the same for participants with different grades of thumb CMC OA.

- 3) No Objective Measurement of Adherence to Joint Protection Techniques: Although participants were debriefed regarding their utilization of joint protection techniques, there was no objective recording method to evaluate adherence to the intervention. Use of a daily journal focusing on occupational performance issues may be helpful in similar, future studies. A lower level of adherence could impact the change in pain, strength, activity and participation.
- 4) No Control Group: Although it is a reasonable assumption that participants would improve with an intervention, the lack of a control group in this study limits the ability to make a cause-effect conclusion. In addition, with no control group it is not possible to rule out contamination from other treatment influences such as medication.

Despite the limitations, this study had several strengths which are described as follows:

- 1) Different Outcome Measures: In addition to estimating a parameter, this study also used a variety of outcome measures to examine change following a 6 week, client-centered intervention for participants with thumb CMC OA. The outcome measures utilized permitted an evaluation of baseline to 6 week change as well as the associations between the outcomes.
- **2)** *Longitudinal Data:* This study has provided longitudinal data that examines the change in pain, strength, self-efficacy, AROM, and activity and participation following a 6 week client-centered intervention for participants with thumb CMC OA.

7. CONCLUSIONS

This pilot study has examined patients with thumb CMC joint OA in an effort to determine to what extent changes in pain and strength associate with meaningful change in activity and participation following a client-centered, 6 week program of orthosis use, joint protection education and exercise. The statistically significant results demonstrated that from 0 to 6 weeks, if there was a one unit increase in pain (VAS as measured in cm) there would be a 3.8 point change in the DASH score and a one unit increase in pinch strength (as measured in lbs.) would result in a 1.43 point decrease in the DASH score.

The results of this study demonstrated that a change in pain had the greatest relationship with activity and participation as measured by change in the DASH. In addition, moderate to strong association was found between pain as measured by the VAS and the AUSCAN pain sub-scale and activity and participation as measured by the DASH. Therapists should continue to use client-centered treatment strategies that are targeted to control pain during meaningful activity. For example, using an assistive device while preparing a meal or wearing a thumb orthosis when gardening.

In the review of the literature, previous studies have demonstrated an improvement in pain with use of an orthosis, joint protection and exercise programs (34,36,43). It is noteworthy that neither this study nor previous studies (34,36,43) produced a change in the pain (VAS) score that was above 3cm nor a difference in the DASH that was clinically significant. Unlike the COPM, the responsiveness of the DASH with a thumb CMC OA population has not been established (64, 90, 97). The chronicity and severity of thumb CMC OA may be such that impairment can be improved and positively impact activity and participation, however, not to the point where there are no limitations present.

Clinically, this study used a client-centered approach that specifically targeted occupational performance issues that were identified at baseline by the patient and therapist. Use of the COPM facilitated this task and helped to focus the interventions on the occupational performance issues which were most important to the patient rather than a protocol driven approach. With a client-centered approach the COPM can be used as an initial evaluation and then rather than providing the same orthosis and list of joint protection techniques for every patient, individual needs may be more closely considered and interventions more specifically tailored. This in turn may facilitate the patient's self-management of their chronic condition. The benefits of this approach were supported by the results of this study which demonstrated a clinically significant and statistically significant change in satisfaction, performance and self–efficacy using the COPM. Furthermore, there was a strong association found between the COPM sub-scale, the self-efficacy sub-scale and the DASH activity and participation item scores.

Although the COPM proved to be a very useful outcome measure in this study, further work is suggested to better understand how researchers can be confident about grouping scores into averages or correlations when the COPM activity items are generated individually and may vary greatly. Beaton (102) has suggested that a method such as Rasch analysis could be applied in order to allow participants to choose different items from a pool. The pool could be scored to permit weighting according to the level of difficulty.

Since this master's thesis has presented the work of a pilot-study, it is suggested that future research should continue to address the same question with a larger sample size. Results could

be analyzed to help therapists know how much change in pain and strength they should aim for, in order to effect meaningful change in activity and participation in patients with thumb CMC OA.

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APPENDIX 1

THUMB CMC OA: EVIDENCE FOR TREATMENT STRATEGIES (ORTHOSES, JOINT PROTECTION AND EXERCISES)

Author/Year	Design	Treatment	Outcomes	Effect Size	Significant Results
Berggren, Joost- Davidson, Lindstrand, Nylander and Povisen, 2001 (29)	•7 year prospective study •n=33	Group 1=no orthosis Group 2=textile orthosis	Desire for surgery at 7 months	NA*	No difference between groups.
		Group 3=leather orthosis	Desire for surgery at 7 years	NA*	
Swigart, Eaton, Glickel and Johnson, 1999 (30)	•Retrospective review •n=114	Continuous wear of a long opponens orthosis for 3 to 4 weeks then gradual decrease for 4 weeks	Pain relief (25%, 50%, 75% or 100%)	NA*	
Weiss, LeStayo, Mills and Bramlet, 2000 (31)	Prospective analysisn=26	Two orthoses used: long and short	Pain (VAS)	Short vs long=0.8*	V
			Pinch strength	1.19*	V
Weiss, LeStayo, Mills and Bramlet, 2004 (32)	•Cross-over •n=25	Neoprene vs. thermoplastic short thumb opponens orthosis	Pain at 1 week (VAS) rest	-3.33*	V
			Pinch strength	1.71*	V
Burke, Grady, deVries and Baten, 1999 (33)	•Prospective with randomized cross over •n=10	3 orthoses worn consecutively: 1) semi-rigid with wrist free, 2) firm elastic with reinforcement of	Pain (VAS) 1 vs 2 1 vs 3 2 vs 3 Function 1 vs 2	0.21* 0.23* 0.03* 0.04*	
		thumb, 3) supple elastic wrist gauntlet	1 vs 3 2 vs 3	-0.93* -1.09*	
Gomes, Carreira, Jones, Natour, 2010 (34)	•Randomized controlled trial •n=40	Group 1: orthosis during ADL for 180 days Group 2: orthosis for	Pain (VAS) 45 days 90 days Pinch 45 days	1.25** 1.17** 0.40**	√ √
		90 days then for ADL for 90days	90 days	0.12***	

Author/Year	Design	Treatment	Outcomes	Effect Size	Significant Results
					(V)
Rannou and colleagues, 2009 (36)	•Randomized controlled trial	Intervention group: night	Pain (VAS) 1 year	.83**	V
	•11-112	orthosis, Control group: "usual	Pinch Strength 1 year	.26**	
		treatment"	Hand Function 1 year	.33**	
Sillem, Backman, Miller and Li, 2011 (38)	●Crossover trial ●n=56	Use of a neoprene splint and a hybrid neoprene and thermoplastic	Pain (AUSCAN)	.33	v
			Function (AUSCAN)	0.20	
		spint	Pinch Strength	0.07	
Becker, Bot, Curley, Jupiter, Ring, 2013 (39)	•Prospective randomized trial	Use of a neoprene splint or a custom	Pain (Pain Catastrophizing Scale)	Not calculable	V
	•II-02	thermoplastic splint	DASH	Not calculable	
		1	Pinch Strength	Not calculable	V
Bani, Arazpour, Kashani, Mousavi and	•Randomized controlled trial	Comparison of a prefabricated	Pain (VAS)	-2.05	V
Hutchins, 2013 (40)	•n=35	and custom made splint and	DASH	1.9	V
		control group with no splint	Pinch Strength	2.4	V
Boustedt, Nordenskiold, Lungren, 2009 (43)	•Controlled trial •n=44	Experimental group: thumb splint, exercises and joint protection education Control group: thumb orthosis	Pain at night 0-6 weeks 0-1year	0.75** 0.90**	√ √
			Pain on motion 0-6 weeks 0-1year	.75 ** .90**	√ √
		and exercises	DASH 0-6weeks 0-1year	.98** 1.09**	√ √
			Pinch Strength 0-6 weeks 0-1 year	.26** .62**	

Author/Year	Design	Treatment	Outcome	Effect Size	Significant Results (√)
Stamm,	•Randomized	Experimental	Pain (VAS)	.4	
Machold,	controlled trial	Group: joint	TT 1.1		
Smoken,	●n=40	protection	Health	0	
Fischer,		education and	Assessment		
Redlick,		daily exercises	Questionnaire		
Graninger, Ebnor		control Group:			
Euller, Erlacher 2002		written	Grin strength	Right: 15	N
(42)		instructions	at 3 months	Left: 3.0	v
(42)		about hand	at 5 months	Lett. 5.0	
		arthritis			
Rogers and	•Pre-post	3 times per	Arthritis	Not calculable	
Wilder, 2007	•n=55	week global	Impact		
(49)		strengthening	Measurement		
		(including grip	Scale		
		strength) for			
		two years	Grip strength	Not calculable	V
				NT / 1 111	
D 1		D	Pain (VAS)	Not calculable	V
Rogers and	•Controlled	Experimental	AUSCAN	Not calculable	
Wilder, 2009	cross-over trial	Group: 16	Crim Streen ath	Nat aslaulable	-1
(50)		hand	Grip Strength	Not calculable	v
		strengthening	Pinch Strength	Not calculable	
		and exercises	i men suengui	Not calculable	v
		Control.	Dexterity	Not calculable	
		application of a	Denterity		
		sham cream for			
		16 weeks			
Wajon and	 Randomized 	Group 1:	Pain (VAS)		
Ada, 2005 (54)	controlled trial	thumb strap	6 weeks	.21**	V
	●n=40	orthosis and			
		abduction			
		exercises,	Pinch Strength		
		Group 2: short	6 weeks	.34**	V
		opponens		0.16	
		orthosis and	Hand Function	-0.16	V
		pinching	(Solleman)		
Davannart	• Dilot	Croup 1:	o weeks	Not oplowlable	
Davenport,	• Filot	Group 1:	rain	inot calculable	
Veandle 2012	controlled trial	evercises	Pinch	Not calculable	
(53)	•n=22	Group 2. joint			
	-11 22	stabilization	DASH	Not calculable	V
		exercises			

Author/Year	Design	Treatment	Outcome	Effect Size	Results Significant (√)
Hennig, Haehre, Mornburg, Mowinckel, Norli and Kjeken, 2013 (51)	•Randomized controlled trial •n=80	Comparison of patient education regarding OA vs. hand exercises and patient education	Patient Specific Function Scale	1.0	V
Villafane, Cleland and De-Las-Penas, 2013 (55)	•Randomized controlled trial •n=60	Comparison of a multimodal manual therapy treatment program to sham ultrasound	Pain (VAS) Pressure Pain Threshold (CMC)	.7 .2	V
O'Brien and Giveans, 2013 (52)	•Retrospective cohort •n=35	Evaluation of patient evolution following thumb CMC joint dynamic stabilization exercises	QuickDASH Pain Score QuickDASH Disability Score	Not calculable	v v

* Denotes that all effect size calculations were taken from the following:

Egan, M., Brosseau, L., *Splinting for osteoarthritis of the carpometacarpal joint: a review of the evidence.* American Journal of Occupational Therapy, 2007. **61:** p.70

**Denotes that all effect size calculations were taken from the following:

Kjeken, I., Smedslund, G., Rikke, H., Slatkowsky-Christensen, B., Till, U., Birger Hagen, K., *Systematic review of design and effects of splinting and exercise programs in hand osteoarthritis*. Arthritis Care and Research, 2011. **63**: p. 834.

All other calculations of effect size were performed using the following formula: Effect size=Amean/SD

Effect size has been described by Mayo (57) as follows:

<.2=trivial

.2-.3=small

.5=moderate

.8=large

APPENDIX 2: PUBLICITY LETTER (ENGLISH VERSION)



DATE

Dear XXX:

This letter is to inform you that a research study is currently being conducted at the Centre Professionnel d'Ergothérapie in order to answer the following question:

"In adults with stage I to IV osteoarthritis of the thumb carpometacarpal joint, to what extent do changes in pain and strength that occur following a client- centered, 6 week program of splinting, joint protection education and exercise translate into meaningful change in activity and participation".

Patients will be required to complete DASH and AUSCAN questionnaires and undergo assessment of strength and pain at baseline and 6 weeks. All patients will receive a thumb splint, isometric strengthening exercises and joint protection education. The inclusion criteria are adults with stage I to IV osteoarthritis of the thumb CMC joint that has been confirmed radiologically. The exclusion criteria include patients with DeQuervain's tendonitis, carpal tunnel syndrome, trigger thumb, previous surgery of the thumb CMC joint or other inflammatory rheumatic diseases such as rheumatoid arthritis. Use of medication or intraarticular steroid injections are NOT exclusion criteria. The study has been approved by the McGill Faculty of Medicine Institutional Review Board and is being supervised by Dr. Bernadette Nedelec, PhD, Associate Professor, School of Physical and Occupational Therapy, McGill University.

Should you have any patients whom you wish to refer for the study, please do not hesitate to contact me.

Sincerely,

Barbara Shankland, erg. CHT

Occupational Therapist Centre Professionnel d'Ergothérapie 6960, rue Sherbrooke est, Montréal (514) 255 3777

APPENDIX 3: ARTHRITIS SOCIETY PUBLICITY (ENGLISH VERSION)



Dear XXX:

This letter is to inform you that a research study is currently being conducted at the Centre Professionnel d'Ergothérapie in order to answer the following question:

"In adults with stage I to IV osteoarthritis of the thumb carpometacarpal joint, to what extent do changes in pain and strength that occur following a client- centered, 6 week program of splinting, joint protection education and exercise translate into meaningful change in activity and participation".

Patients will be required to complete DASH and AUSCAN questionnaires and undergo assessment of strength and pain at baseline and 6 weeks. All patients will receive a thumb splint, isometric strengthening exercises and joint protection education. The inclusion criteria are adults with stage I to IV osteoarthritis of the thumb CMC joint that has been confirmed radiologically. The exclusion criteria include patients with DeQuervain's tendonitis, carpal tunnel syndrome, trigger thumb, previous surgery of the thumb CMC joint or other inflammatory rheumatic diseases such as rheumatoid arthritis. Use of medication or intraarticular steroid injections are NOT exclusion criteria. The study has been approved by the McGill Faculty of Medicine Institutional Review Board and is being supervised by Dr. Bernadette Nedelec, PhD, Associate Professor, School of Physical and Occupational Therapy, McGill University.

Should you have any patients whom you wish to refer for the study, please do not hesitate to contact me.

Sincerely,

Barbara Shankland, erg. CHT Occupational Therapist Centre Professionnel d'Ergothérapie 6960, rue Sherbrooke est, Montréal (514) 255 3777

APPENDIX 4: CONSENT FORM (ENGLISH VERSION)



RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Title: How changes in pain and strength translate into meaningful change in activity and participation following a 6 week client-centered treatment program for patients with thumb carpometacarpal joint osteoarthritis.

Investigators: Bernadette Nedelec, BScOT(C), erg., PhD, McGill University, Barbara Shankland, BScOT(C), erg, CHT, Centre Professionnel d'Ergothérapie, MSc Candidate, McGill University

Preamble

We are seeking your participation in a research project. However, before accepting to participate in this project and signing the information and consent form, please take the time to read and carefully examine the following information.

This form may contain words and information that you do not understand. We encourage you to ask the researcher or any other team member, any questions that you may have about the research project.

Introduction

In this study we are interested in people who have osteoarthritis (joint degeneration) at the base of the thumb. We are requesting your participation because your doctor has indicated that you suffer from this condition. It is common for people with osteoarthritis at the base of the thumb to experience weaker pinch strength and pain. The treatments that are normally provided for this condition include splinting, exercises and joint protection education.

In this study we are aiming to provide treatment that is tailored to the activities you perform in your daily life that you define as meaningful for you. This is called "client-centered treatment". There are some differences between a standard treatment program and a clientcentered treatment program for thumb osteoarthritis. These differences are outlined on the table that follows:

Treatment Method	Standard Treatment	Study (Client-centered)	
		treatment	
Splinting	A short splint is made by an orthotist from a thin plastic material. The splint is worn at night and during painful activities.	The design and material of the splint will be based on what your daily activity needs are. The splint will be made by an orthotist. The wearing schedule is the same as the standard treatment.	
Exercises	Four thumb exercises will be provided by an occupational therapist.	Identical to standard treatment.	
Joint protection education	General instructions will be provided verbally and with a written instruction sheet on techniques to protect your joints.	You will be provided with information on how to perform your specific daily activities in a way that reduces joint stress and the potential harm these activities may be causing.	

The duration of both standard treatment and the study (client-centered) treatment is the same.

In this study, we want to measure the change in thumb pain and strength following a 6 week client-centered treatment program consisting of splinting, exercises and joint protection education and how these changes impact your ability to perform your daily activities.

Study Procedures

Before starting the study, you will receive this document. If all of your questions are answered and you want to be part of the study, we ask you to sign this consent form and you will keep one signed copy. The occupational therapist will insure that you meet all of the criteria to be included in the study. If all of the criteria are met, you will be enrolled in the study. In total, 60 people with base of thumb osteoarthritis will be invited to participate in this study.

You will be asked to meet with your occupational therapist for an initial evaluation and on two other occasions (at 3 weeks and at 6 weeks). This frequency is typical of what might occur in normal treatment.

If you agree to enroll, the client-centered study procedure will be followed. In addition you will be asked to perform the following steps that are not part of standard treatment:

-More questions may be asked about your daily activities in the interview.

-You will be asked to complete two questionnaires. The first questionnaire requires 5-10 minutes to complete and the second one requires 10 minutes to complete.

-You will be asked to complete a daily log sheet to document how many hours per day you wore your splint and if you did the exercises.

The study procedure is as follows:

Initial Visit:

-An initial assessment will be carried out including an interview for background information and to identify difficulties with daily activities.

-Thumb movement, pain and strength will be evaluated.

-Two questionnaires regarding thumb pain, stiffness and the ability to perform daily activities will be completed.

Treatment provided at the initial visit:

-4 exercises will be provided by an occupational therapist. These exercises should be done on a daily basis.

-A splint will be provided for your painful thumb. The material and style of the splint that is best suited for you will be decided between you and your therapist. The splint will be worn at night and during heavy or painful activities.

-You will be provided with information on how to perform your daily activities in a way that reduces the joint stress and potentially the harm that these activities may be causing. These principles are referred to as joint protection techniques.

Visit at 3 weeks:

-A follow up visit will be carried out to verify that there are no problems with your splint, the exercises or your use of the joint protection techniques.

Visit at 6 weeks:

-Thumb movement, pain and strength will be evaluated. The two questionnaires completed during the initial visit will be repeated.

Study Duration

Your participation in this study will be for 6 weeks.

Risks and Benefits

The risks are identical for a standard treatment program and the study "client-centered" program. Occasionally, people may experience a pressure point or skin irritation from using a splint. The risk of this happening is low. If this does happen, the occupational therapist will adjust the splint for you immediately. Occasionally, people may have a slight increase in pain when they start new exercises. The risk of this is also low. If this happens, the occupational therapist will adjust the exercises so that they are more tolerable for you.

Splinting, exercises and joint protection can help people with base of thumb osteoarthritis but this is not guaranteed. Your participation will help us to learn how much this treatment improves your pain and strength and how that impacts your ability to perform your daily activities.

Withdrawal from the Study

Your participation in this study is completely voluntary and you are completely free to participate or not in the present research project. You have the right to ask questions at any time. You will be free, at any time, to withdraw from the project without penalty, without affecting the quality of the care that you receive. The study's researcher could also withdraw you from the study, without your consent, if one or more of the following situations arises:

-Not being present for the required appointments (initial assessment, 3 weeks and 6 weeks).

-Not completing the required log sheets.

-If the researcher believes it is in the best interest of the patient to withdraw.

-Disease or medical complications not connected with the study.

Alternative Therapy

If you do not participate in the study you will receive all of the treatments that you need.

Cost

With a prescription for a thumb splint signed by a plastic surgeon, an orthopedic surgeon, a rheumatologist or a physiatrist, there is no direct cost to you for the splint provided if it is made by an orthotist. The orthotist will bill for the splint using your health card number. There is no cost for the occupational therapy treatment provided.

Compensation

No financial compensation will be provided for participation in this study.

Participant's Rights

If you should suffer an injury during your participation in the research project, you will receive the appropriate care and services for your medical condition without any charge to you. By accepting to participate in this project, you are not waiving any of your legal rights nor discharging the researchers, or the institution of their civil and professional responsibility.

Privacy and Confidentiality

During your participation in this project, the researcher will collect and record the information concerning you in a study file. Only the data required to meet the project scientific goals would be collected. This data could include information concerning your past and present health, your lifestyle and daily activities as well as your name, gender and date of birth.

All of the information collected during the research project will remain strictly confidential to the extent prescribed by law. In order to protect your identity and confidentiality of this information, only a code number will identify you.

The key to the code linking your name to your study file will be kept by the project researcher. This data will be stored for a period of 7 years by the project researcher. Following the 7 year storage period, all data will be destroyed by shredding. This will be carried out by the project researcher.

The data could be published in medical journals or shared with other individuals during scientific meetings, however, it would not be possible to identify you.

For surveillance and control purposes, your study file could be examined by a person mandated by the Institutional Review Board of McGill University by HMR or by a person mandated by the authorized public bodies. All of these individuals and organizations agree with the privacy policy. For security purposes, especially to be able to communicate with you rapidly, your family name, first name, coordinates and the start and end date of participation in the project would be stored for one year after the termination of the project in a separate registry maintained by the researcher in charge of the project.

You have the right to consult your study file in order to verify the information gathered and to correct them, if necessary, as long as the project researcher or the institution holds this information. However, in order to protect the scientific integrity of the research project, you would have access to certain information only once your participation has come to an end.

Contact Information

If you have any question concerning the research project or if you feel you have a problem related to your participation in the research project, you can communicate with the project researcher at the following number:

Barbara Shankland, occupational therapist

Centre Professionnel d'Ergothérapie

(514) 255 3777

If you have any questions concerning your rights as a research subject participating in this research study or you need to file a complaint or comment, you could call:

McGill University Institutional Review Board (514) 398 8302

Or "Le commissaire local aux plaints de l'HMR" at (514) 252 3400, extension 3510.

Ethical Aspects Review

The "Comité d'éthique de la recherché de l'HMR" has approved this research project and assures that it will be followed. In addition, any modifications made to the consent form, information form or research protocol will be subject to review and require approval.

Consent

I have reviewed the information/consent form. I acknowledge that the research project was explained to me, that my questions were answered to my satisfaction, and that I was given sufficient time to make a decision.

I agree to participate in this research project (**How changes in pain and strength translate into meaningful change in activity and participation following a 6 week client-centered treatment program for patients with thumb carpometacarpal joint osteoarthritis**) according to the conditions stated above. A dated and signed copy of the present information/consent form was given to me.

I do not wave any of my legal rights by signing this consent form.

Name of the research subject

Signature of the research subject

Date

I have explained to the research subject the terms of the present information/consent form and I answered all of his/her questions

Name of the person who obtains the consent

Signature of the person who obtains the consent

Date

Responsibility of the Researcher

I certify that I have explained to the above stated research participant the terms of this information and consent form, that I have answered all questions regarding the project and that I have clearly indicated that the research participant may stop their participation in the project at any time with no prejudice.

I certify that, with the research team, I will respect all of the terms of this information and consent form and will give a signed copy to the study participant.

Signature of the researcher and date of signature

APPENDIX 5: SUMMARY OF 6 WEEK TREATMENT PROGRAM Orthosis:

The participant and the therapist worked together to determine the best thumb orthosis design and material in order to optimize the participant's occupational performance. Participants who demonstrated MP joint hyperextension during pinching activities were provided with a thermoplastic, hand based, short thumb spica that included MP joint immobilization in order to facilitate thumb stability. Participants who did not display MP joint hyperextension and reported frequent writing and computer use during the day were provided with a hand based composite neoprene-thermoplastic orthosis with the MP joint left free in order to facilitate pen, mouse, and keyboard use. Participants who were concerned about the durability of the orthosis during daily activity were provided with a hand based thumb spica fabricated with leather. Participants who demonstrated significant dorsal subluxation of the first metacarpal bone at the thumb CMC joint and reported distal forearm pain during daily activities where provided with a thermoplastic long thumb spica orthosis. Pre-fabricated orthoses were not provided due to reimbursement issues. Participants were asked to wear the orthosis from 8 to 24 hours per day for a 6 week period in order to maximize pain reduction. The participants were asked to wear the orthosis for heavy and/or painful activities. Adherence to orthosis use was monitored using a daily log sheet (Appendix 9). Verbal instructions were provided advising participants to keep the orthosis away from direct heat sources and to contact the occupational therapist immediately if the orthosis was causing discomfort or skin irritation. Spot adjustments were made for pressure points, as needed, by either the orthotist or the occupational therapist. The orthosis was provided during the study entry visit.

Joint Protection Education

Joint protection education was provided by the occupational therapist. Each point of information was customized to the occupational performance issues identified by the participant with additional consideration given to their personal and environmental factors. Examples of assistive devices (eg. adapted jar opener) were shown and discussed with the participant as needed. Joint protection education was provided during the study entry visit. A summary sheet was provided which stated the following general principles of joint protection:

•Respect pain: recognize the indicators of joint inflammation such as swelling and persistent pain.

- Take mini-breaks as needed.
- •Establish a balance between heavy and light activity.
- •Organize work spaces to minimize the required physical effort.
- •Establish work priorities.
- •Use light weight, ergonomically designed equipment whenever possible.
- •Avoid working in positions that will stress your joints (ex. pinching objects)
- •Use larger joints whenever possible (ex. shoulder straps)
- •Avoid holding a pinching position for a prolonged period.
- •Use assistive devices as needed (ex. electric can opener).

These general principles were applied in the context of the participant's personal factors, environmental factors and occupational performance issues. Participants were seen for a followup visit at 3 weeks. At that time, the joint protection techniques that were provided were reinforced. Participants had the opportunity to problem-solve through activities where barriers had been encountered. Specific examples of how the joint protection techniques were applied to the participant's daily activities were requested as a means of verifying treatment adherence.

Exercises:

Participants received verbal and written instructions consisting of isometric strengthening exercises for the thumb. The exercises were performed one time per day, 5 repetitions each, as per pain tolerance. An exercise dosage of one time per day has been supported in the literature (50). Adherence was monitored with a daily log sheet (Appendix 9). The participants were provided the option of soaking their hand in warm water for 10 minutes prior to performing the exercises to increase comfort. As an additional warm-up, participants were encouraged to perform 10 pain-free repetitions of thumb abduction before performing the strengthening exercises. All exercises were explained to the participant by the occupational therapist. The exercise program was provided during the study entry visit. The isometric exercises were as follows: a) squeeze an imaginary ball (kinesthetic awareness of the abductor pollicis longus and abductor pollicis brevis), b) place and hold the thumb in opposition with the little finger for 5 seconds, c) isometric strengthening of the abductor pollicis longus and brevis as described below, and d) isometric strengthening of the first dorsal interosseous muscle as described below. Participants were provided with an instruction sheet with the following information:

Perform the following exercises one time per day, 5 repetitions each:

•Bend and straighten your fingers as if you are squeezing the imaginary ball.

•Use the opposite hand to push the thumb and little finger together. Squeeze the thumb and the little finger together for five seconds (without the help of the opposite hand).

•Open the thumb and the index finger as if forming the letter "C". The thumb should remain in front of the index finger and not directly beside the index finger (eg. the same position if you are

picking up a glass). Using the opposite hand, apply a gentle resistance to the thumb as you are opening it away from the index finger.

•With the hand palm side down on a table, try to move the index finger towards the thumb. Resist the movement by using the other hand and placing a gentle pressure on the proximal phalanx of the index finger.

APPENDIX 6: PARTICIPANT DAILY LOG SHEET (ENGLISH VERSION)

Daily Log Sheet

Please indicate the date and check each column to confirm that you used your splint and did your exercises on that day.

Date	Number of hours per day	Exercises one time during
	of splint use ($$)	the day ($$)
eg) May 11, 2011	eg) 20	eg) v