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Patient satisfaction with the CMC controller: A cohort study

Kristin Valdes OTD, OT, CHT [a,*], Nancy Naughton OTD, OTR, CHT [b], Malgorzata A. Szelwach OTS [a]

[a] Occupational Therapy Department, Gannon University, Ruskin, FL, USA
[b] Department of Occupational Therapy, Hand Surgery Associates, Olyphant, PA, USA

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ABSTRACT

Study Design: Cohort study.
Introduction: The evidence specific to understanding patient satisfaction, preference and the effects on occupational performance using a CMC orthosis is sparse.
Purpose of the Study: The main purpose of this study was to determine patient satisfaction, aspects of the orthotic preference, and the effect on pain and function of the CMC Controller Plus neoprene orthotic device.
Methods: This research was conducted at two outpatient clinics located in Pennsylvania and Florida during 2019. The subjects of this study included any individuals referred to one of two participating hand therapy facilities with either a primary or secondary diagnosis of thumb CMC joint arthritis or present with this diagnosis as a comorbidity. The CMC Controller Plus orthosis (Hely & Weber) was provided to each patient by the treating therapist at no cost to the patient after the patient agreed to take part in the study. None of the patients received hand therapy treatment for the CMC pain; the only intervention provided was the CMC Controller Plus.
Results: The CMC Controller Plus orthosis improved the patients' functional status and reduced their pain. The effect size for the change in function was large (1.29) compared to the effect size for the reduction in pain which approached moderate at 0.49.
Discussion: The CMC Controller Plus orthosis improved the patient's functional status by 52% and reduced their pain by 29%.
Conclusion: The results were both statistically and clinically significant.

Introduction

The saddle-shaped thumb carpometacarpal (CMC) joint has an articular geometry that makes this joint susceptible to instability and osteoarthritis (OA).[1] CMC OA has an estimated incidence of 7% in men, 15% in premenopausal women, and 33% in postmenopausal women.[2,3] The pain and inflammation that accompany thumb CMC OA directly affect an individual's activities of daily living and cause impairment in the upper extremity.[1-3] Etiology is thoroughly investigated and described and comprises theories of anterior oblique ligament degeneration, ligamentous laxity, hormonal changes with menopause, genetic predisposition, repetitive use, and abnormal load transmission.[4-9]

The functional implications of this diagnosis are vast and earnestly investigated. Some of the identified effects include pain during activity,[2] loss of pinch strength,[10,11] decreased fine motor ability,[3] and reduced cylindrical grasp.[12] It has been reported that some of these deficits may be recognizable before being identified in diagnostic studies.[11-13] Ultimately, the symptoms associated with CMC joint arthritis in combination with the progression of anatomic changes lead to activity limitations and participation restrictions in one's daily life.[14-16]

The hallmark sign of pain and its association to CMC joint arthritis is likely the most identified and measured variable in studies ranging from surgical techniques[17] to orthotic interventions.[18] Similarly, there are systematic reviews that investigated conservative interventions and their effectiveness in the treatment of CMC joint arthritis[19,20] with the ultimate outcomes of interest being pain control and optimizing hand function. Survey results have demonstrated that the use of orthotics is a strong preference for therapists treating thumb CMC joint arthritis.[21,22] High-level evidence[19,23,24] investigating conservative treatments for CMC joint arthritis supports the provision of an orthosis and findings suggest both pain relief and improved hand function.[19,20,23,24] Although support exists in the literature for the use of orthotics,[19,20,23,24] there remains a wide variation in orthotic design, material, and wearing schedule and the most ideal orthosis. There are numerous options available for orthotic design: rigid,

* Corresponding author. Occupational Therapy Department, Gannon University, Ruskin, FL 33573, USA.
E-mail address: hotglassgal@comcast.net (K. Valdes).

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semi-rigid, or neoprene support orthoses, custom or prefabricated designs, and patterns that include or exclude the wrist and thumb metacarpophalangeal joint. A cross-sectional descriptive study[25] surveyed occupational therapists, physiotherapists, and rheumatologists across Brazil with questions regarding orthosis design, materials, and barriers to the use of orthotic interventions and found significant variation in the number of joints included in the device and stabilization strategies adopted. There was a preference by professionals for orthoses made from rigid materials that included the wrist, carpometacarpal, and metacarpophalangeal joints.[25] However, the overall results indicated widespread clinical variation in practices and preferences.[25]

A recent randomized controlled trial[26] compared immobilization of the CMC joint only versus immobilization of both the MCP and CMC joints immobilized. They found no difference between the groups for either pain or function as measured by the visual analogue score (VAS) and the Quick Disabilities Arm, Shoulder and Hand (Quick DASH) and both groups had decreased pain and improved functional ability.[26] Similarly, in a quasi-experimental trial,[27] the comparison of two different orthoses reported a clinically significant reduction in pain intensity and improvement in functional abilities with both orthoses.

The evidence specific to understanding patient satisfaction, preference, and the effects on occupational performance is sparse and yields inconclusive findings due to the lack of valid instruments to accurately assess these areas.[16,26-29] The purpose of this study was to determine the patient satisfaction, aspects of the orthotic preference, and the effect on pain and function of the CMC Controller Plus neoprene orthosis.

Methods

This research was conducted at two outpatient clinics located in Pennsylvania and Florida during 2019. The subjects of this study included any individuals referred to one of two participating hand therapy facilities with either a primary or secondary diagnosis of thumb CMC joint arthritis or present with this diagnosis as a comorbidity. Inclusion criteria included patients of 18 years of age or greater. Exclusion criteria included individuals who did not understand English or patients who received skilled hand therapy interventions for CMC OA. All participants gave both oral and written informed consent. The treating certified hand therapist educated each potential participant on the purpose of the study, the use of the participant's health information, the study's commitment for the participant which includes the participant's right to withdraw from the study at any time. The university's Institutional Review Board approved the study. The study was registered at Clinical Trials.gov, NCT03736252.

Materials and procedures

The CMC Controller Plus orthosis (Hely & Weber) was provided to each patient by the treating therapist at no cost to the patient after the patient agreed to take part in the study. None of the patients received hand therapy treatment for the CMC pain; the only intervention provided was the CMC Controller Plus. All participants received a follow-up phone call after one month of orthosis use, to collect follow-up data.

Outcome measures

The Numeric Pain Scale was used to assess pain. The scale rates pain from 0 to 10 and has good-to-excellent correlation with the Visual Analog Scale ($r = 0.94$), a standard error of measurement of 0.48, a minimal detectable change of 1.33, and an ICC of 0.95 (0.93-0.96).[30] The patient's usual pain experienced during the week was gathered at the initial visit and follow-up phone call.

The Function Index for Hand OsteoArthritis[31] (FIHOA) score was assessed at the two time points. The FIHOA is a self-reported measure of hand function for individuals with hand OA and takes 3 min to complete. The 10 questions are focused on if an individual is able to use a key, cut different objects, lift, button, use tools, write, and shake hands. Items are rated from 0 (possible without difficulty) to 3 (impossible) with low scores indicating better hand function. The Cronbach's alpha for the FIHOA is 0.85, ICC 0.95, and validity 0.33 to 0.82.[31]

The QUEST 2.0 (Quebec User Evaluation of Satisfaction with assistive Technology) comprises 12 items, of which 8 items relate to user satisfaction with assistive devices and 4 items relate to service provision. Responses for the QUEST items are based on a 5-level response scale, with 1—not satisfied at all; 2—not very satisfied; 3—more or less satisfied; 4—quite satisfied; and 5—very Satisfied. The device subscale, services subscale, and total QUEST 2.0 scores achieved good test-retest stability (ICC 0.82, 0.82, 0.91).[32]

Data analysis

A priori power analysis was conducted to determine sample size. Group data were summarized using means and standard deviations. The paired student *t*-tests were used to determine the level of statistical significance of the differences between the pre-treatment and post-treatment scores. Statistical significance was set at less than 0.05. The normalcy of the data was checked using the Shapiro-Wilk test. Cohen's *d* was interpreted using Cohen's interpretation of effect size. Cohen suggested that $d = 0.2$ be considered a "small" effect size, 0.5 represents a "medium" effect size, and 0.8 a "large" effect size. This means that if two groups' means do not differ by 0.2 standard deviations or more, the difference is trivial, even if it is statistically significant.

Results

Between January 2019 and June 2019, a total of 78 patients participated in the study. Three patients were lost to follow-up. The percentage of patients who completed the study was 96%. See Table 1 for baseline measurements.

Outcomes

The mean current pain score at the time the orthosis was distributed was 3.3 (SD 2.42). The mean current pain score at the 1-month follow-up was 2.3 (SD 1.97). The mean change score was 0.95 and the effect size was calculated to be 0.49, which is moderate. The result was statistically significant, $p = .006$. See Table 2. The mean FIOHA score was 14.1 at baseline and decreased to 6.8 after one month. The effect size of the change was 1.21, which was considered large. The result was statistically significant, $p = .0005$.

QUEST 2.0

The mean total QUEST 2.0 score for the CMC Controller Plus orthosis was 4.4/5, the mean device score was 4.3/5 and the mean service score was 4.6/5. Regarding the top 3 satisfaction items, participants selected comfort, ease of use, and weight as being the

Table 1
Baseline measurements

Outcome	Mean	Standard deviation
Usual pain	3.3	2.4
FIHOA score	14.1	6.5

FIHOA = Function Index for Hand OsteoArthritis.

Table 2
Outcomes

Outcome	Baseline	4 Weeks	Change	t	*P* value	Effect size
Usual pain	3.3	2.3	0.95	−4.2	.007[a]	0.49
FIHOA score	14.1	6.8	7.3	−11.2	.0005[a]	1.29

FIHOA = Function Index for Hand OsteoArthritis.
[a] Indicates the result was statisically significant.

most important regarding the device. The top 3 items were in relation to the device rather than the service provision (Tables 3 and 4).

Functional improvement with use of CMC Controller Plus

Twenty-nine (38%) of the 78 subjects also stated that the CMC Controller Plus orthosis provided improved functional status in a specified way. Eight of the subjects reported they were able to twist a key or bottle top with the device. Five subjects indicated they were able to hold a mug or plate better. Three subjects reported being able to perform cleaning tasks or yard work better with the orthosis. Others reported the following benefits: write better, sleep better, fasten bra, fasten jewelry, and that it helped with "everything."

Discussion

Our findings support that the CMC Controller Plus orthosis improved the patients' functional status by 52% and reduced their pain by 29%. The results were both statistically and clinically significant as demonstrated by the effect size calculations. Our findings agree with a recent systematic review and meta-analysis reported that a thumb-based orthosis improves function and pain for patients with CMC OA at the short-term follow-up.[33] They found no difference noted between custom-made verses prefabricated thumb spica orthoses; however, disability outcomes were in favor of prefabricated orthoses.[33] We found a greater effect on functional status than pain when looking at the effect size calculations in this study. The effect size for the change in function was large (1.29) compared to the effect size for the reduction in pain which approached moderate at 0.49. A consideration for this finding may be that the patients did not wear the orthosis long enough to fully appreciate the pain benefits of the device. Rannou et al reported no reduction in pain after wearing a CMC orthosis for 1 month; however, pain reduction was both clinically and statistically significant at 12 months.[34]

Joseph et al investigated client satisfaction with the QUEST 2.0 for custom-fabricated orthosis.[35] They reported the top 3 categories for a participant's orthotic device characteristics: comfort (81%), effectiveness (75%), and ease of use (74%).[35] Our study found comfort (77%), ease of use (70%), and weight (48%) to be the top 3 categories established by the participants. Perhaps, our subjects determined weight to be of greater value because they wore the device to perform activities of daily living, whereas the majority of the clients in the Joseph et al study wore the orthotic device for protection after hand surgery.[35] Their QUEST 2.0 total mean score was 4.61 and this compares with our total mean score of 4.43.[35] In another study that used the Dutch version QUEST 2.0 to determine patient satisfaction with a CMC orthosis, the authors reported a total score of 30.6 out of 40 possible points.[36] Our total score was 53.1 out of 60 possible points. When converted to percentages, their satisfaction score was 76.5% and our mean satisfaction score was 88.5%.[36]

Table 3
QUEST 2.0 outcomes

Outcome	Mean	Standard deviation
Total quest score	4.4/5	0.66
Device score	4.3/5	0.90
Service score	4.6/5	0.67

Table 4
Top 3 items rated as most important regarding the orthosis

Characteristic	Percentage of respondents who provided this answer
Comfort	77%
Easy to use	70%
Weight	48%
Durability	41%
Effectiveness	32%
Dimensions	12%
Safety	4%
Adjustments	1%
Professional service	1%
Service delivery	1%
Repairs/servicing	0%
Follow-up services	0%

In a systematic review of CMC orthoses that linked outcome measures to the International Classification of Functioning, it was reported that only 4 of the 9 included studies assessed orthotic satisfaction and only one study asked about the participant's experience using the device. Hermann et al interviewed the participants in their study to determine both the positive and negative experiences regarding the prefabricated device.[37] They found the orthosis to be useful for tasks, such as washing the floor, dressing, driving, and writing, among others and not useful for activities that involve water due to the orthotic device feeling uncomfortable when wet.[37] These findings are similar to our findings. Thirty-eight percent of our subjects reported improvements in functional activities such as cleaning, dressing, and other activities of daily living.

Clinically, it is important to address the client's specific functional deficits when providing a CMC orthotic device. A client-centered approach for determining the optimal orthosis needs to be reflective of the patient's daily-required tasks along with patient preference. Squitieri et al[38] reported that activity and participation variables contributed the most to patient satisfaction after distal radius fracture. In a randomized controlled trial, Rannou et al[34] found that an optimal orthosis needs to be reflective of the patient's daily life and activity level along with inclusion of patient preference. Similarly, Squitieri et al[38] found activity and participation variables contributed the most to variation in patient satisfaction.

This study had a number of strengths and limitations. An important strength of this study was that data were gathered in a consistent manner using measurement guidelines with supported validity and reliability. The CMC Controller Plus orthosis (Hely & Weber) was also provided to participants free of charge so the participant was able to judge the device without consideration of cost. The device cost in August 2019 is $28.26, which is not exorbitant and accessible for many individuals. In addition, this study did not focus on the combination of an orthosis and hand therapy intervention eliminating the confounding variable of the effect of hand therapy on the reduction of pain or improvement in functional status. Another limitation was that there was no comparison group and we are unsure if a better outcome could have been achieved with a different orthosis. Finally, the primary limitation is the relatively short follow-up time period.

For future research, it would be beneficial to study to the effect of an orthosis combined with hand therapy services with a regression analysis performed to determine the effect of each variable on the outcome. Future studies should also focus on the effect of wearing compliance. In addition, it would be useful to have a follow-up time period of 1 year.

Conclusion

The CMC Controller Plus orthosis improved the patient's functional status by 52% and reduced their pain by 29%. The results were both statistically and clinically significant.

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