CRITICALLY APPRAISED PAPER (CAP)

Focused Question
For individuals with Grade II and III osteoarthritis (OA) of the trapeziometacarpal (CMC) joint in the dominant hand, is using a short opponens orthosis effective in decreasing pain and increasing strength and hand function for ADL performance?


CLINICAL BOTTOM LINE:
The clinical implications of this study show that, although there is not a statistically significant change in hand function, the use of a CMC thumb stabilization orthosis does decrease pain in the dominant hand of individuals with CMC joint osteoarthritis (OA). Not only did pain significantly decrease in the study group, pain was also found to improve in the control group, once the orthosis was applied for ADL performance.

These outcomes indicate that orthotic use continues to be beneficial in the conservative treatment of CMC joint pain, especially during ADL performance. The use of a thumb stabilization orthosis may also provide pain relief that could delay the need for surgery. Furthermore, the outcomes of this study reinforce the belief that patients should be educated regarding their diagnosis of thumb CMC OA, actively participating in the in the decision to use an orthosis for thumb CMC OA.

RESEARCH OBJECTIVE(S)
The purpose of this study was to determine if the use of a short opponens orthosis, in the treatment of Grade II and III OA of the CMC joint, for the dominant hand, is effective at decreasing pain and at increasing strength and hand function.
DESIGN TYPE AND LEVEL OF EVIDENCE:

Level I
Randomized controlled trial

Limitations (appropriateness of study design):
Was the study design type appropriate for the knowledge level about this topic? *Circle yes or no, and if no, explain.*

YES/NO
This is a well-designed study, as a control group is present for the first 90 days for comparison with the study group receiving the intervention. The design is also appropriate for answering the proposed question of the effectiveness of orthosis use in the treatment of CMC OA in the dominant hand.

SAMPLE SELECTION
How were subjects selected to participate?

This article does not discuss how the subjects were recruited for this study. The subjects were randomized from a group of 40 to compensate for a possible 20% loss of subjects by the end of the study.

Inclusion Criteria
Inclusion criteria were clinical and radiographic diagnosis of Grade II or III CMC joint OA in the dominant hand; individuals ages 40 years or older; and pain reported between 3–7 on the visual analog scale (VAS) for pain.

Exclusion Criteria
Exclusion criteria were severe deformities in the dominant hand that did not allow gripping; deformities of the distal interphalangeal joint; use of a thumb orthosis in the past 6 months; surgery on the hand in the past 6 months or scheduled for 6 months in the future; allergy to the orthotic material; inability to complete the questionnaire and perform the tests; geographical limitations; injections in the hand in the past 6 months; other concurrent conditions such as carpal tunnel or wrist fractures; or alterations in the use of anti-inflammatory medication in the previous 3 months.

SAMPLE CHARACTERISTICS

\[ N = 40 \]

<table>
<thead>
<tr>
<th>% Dropouts</th>
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<tbody>
<tr>
<td>#/ (%) Male</td>
<td>2/ 5%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>NR</td>
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</tbody>
</table>
Disease/disability diagnosis: CMC joint osteoarthritis to the dominant hand. The sample of this study was well-chosen, as the subjects all met the stringent inclusion and exclusion criteria. The groups were representative of the population, as CMC OA is more predominant in females versus males.

Check appropriate group:

<table>
<thead>
<tr>
<th>&lt;20/study group</th>
<th>20–50/study group</th>
<th>51–100/study group</th>
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**INTERVENTION(S) AND CONTROL GROUPS**

**Group 1/Control Group**

**Brief Description**
The control group had 18 women and 2 men, mean age 65.1 years, with duration of the disease of 7.7 years. Mean report of pain on the VAS was 5.1 without the orthosis at baseline. For the first 90 days of the study, the control group used a custom-fabricated short opponens orthosis for the evaluations only. After 90 days, the group was instructed to use the orthosis for the performance of ADLs, with orthosis removal for bathing and sleeping.

**Setting**
Outpatient clinic in Brazil.

**Who Delivered?**
All of the short opponens orthoses for the study group and control group were fabricated by 1 occupational therapist.

**Frequency?**
For the first 90 days of the study, the control group used a custom-fabricated short opponens orthosis for the evaluations only. After 90 days, the group was instructed to use the orthosis for the performance of ADLs, with orthosis removal for bathing and sleeping.

**Duration?**
90 days without the splint, then 90 days with the orthosis. Study was for 180 days.

**Group 2/Intervention Group**

**Brief Description**
The study or intervention group had 20 women mean age 62.8 years, with duration of the disease of 6.3 years. Mean report of pain on the VAS was 5.1 without the orthosis at baseline. The group was instructed to use the short opponens orthosis for all ADLs for the entire 180-day period, with orthosis removal for sleeping and bathing.

**Setting**
Outpatient clinic in Brazil.

**Who Delivered?**
All of the short opponens orthoses for the study group and control group were fabricated by 1 occupational therapist.
Frequency?  The study group was instructed to use the short opponens orthosis for all ADLs for the entire 180-day period, with orthosis removal for sleeping and bathing.

Duration?  Orthosis was worn for 180 days.

**Intervention Biases:**  *Circle yes or no and explain, if needed.*

**Contamination**

Indicate and explain:

- **YES**  Contamination was avoided as the same occupational therapist fabricated all of the orthoses. Also the subjects in both groups were seen by an occupational therapist, and the orthoses were applied by the same occupational therapist prior to having measurements taken by a physiotherapist, who was blinded to group allocation. All of the subjects wore their orthosis when entering the room to have measurements taken by the physiotherapist. The same physiotherapist took all of the measurements throughout the study.

- **NO**  Co-intervention was not discussed; however, the exclusion criteria appear to have minimized factors that may contribute to co-intervention.

**Timing**

- **YES/NO**  NR

**Site**

- **YES/NO**  Site bias is minimal, as the site was the same for both the study group and control group in this study.

**Use of different therapists to provide intervention**

- **YES/NO**  All of the short opponens orthoses for the study group and control group were fabricated by 1 occupational therapist. The same physiotherapist took all of the measurements throughout the study.

**MEASURES AND OUTCOMES**

Complete for each relevant measure when answering the evidence-based question:

**Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article--yes/no/NR [not reported]), and how frequently the measure was used.**

**Primary Outcome:**  Visual analog scale (VAS) for pain at the base of the thumb with orthosis use and without orthosis use. The VAS was rated from 0 to 10, with 0 = *no pain* and 10 = *unbearable pain*. Measurement validity and reliability was not reported. A physiotherapist blinded to group allocation collected VAS data at baseline and at 45, 90, and 180 days from baseline.
Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article--yes/no/NR [not reported]), and how frequently the measure was used.

### Secondary Outcomes:

**Hand function:** Measured by the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire. Reliability and validity have been established for this test.

**Grip strength with and without the orthosis:** The Jamar Dynamometer was used with standardized testing. This is considered to be a reliable and valid tool.

**Pinch strength with and without the orthosis:** A pinch gauge was used according to standardized testing procedures. This is considered to be a reliable and valid tool.

**Upper-limb dexterity with and without the orthosis:** The O’Connor Test was used according to standardized testing procedure. Normative data is available; however, they were not used, as performance times were compared between groups and with and without orthosis use.

Data were collected at baseline and at 45, 90, and 180 days from baseline by a physiotherapist blinded to group allocation.

### Measurement Biases

Were the evaluators blind to treatment status? *Circle yes or no, and if no, explain.*

- **YES**

**Recall or memory bias.** *Circle yes or no, and if yes, explain.*

- **YES**

  The duration between measurement periods was sufficient to lessen memory or recall bias.

**Others (list and explain):**

- The type of material used for orthosis fabrication was not described. This may be a bias as the type of material used may increase compliance with orthosis wear/use during ADL performance, thus influencing study outcomes.

### RESULTS

List results of outcomes relevant to answering the focused question.

- Include statistical significance where appropriate \((p < 0.05)\).
- Include effect size if reported.

The results were analyzed by comparing the groups over a period of time. Period A was analyzed from Day 1 to Day 90. Period B was analyzed from Day 1 to Day 180. Analysis of variance (ANOVA) was used to determine the differences in the behaviors of the control and study groups over time. When a statistical difference was found, the Mann–Whitney U or \(t\) tests were used to analyze the differences at each time. An independent sample \(t\) test was used...
to analyze the VAS pain scores with orthosis use at Day 45, Day 90, and Day 180.

For Period A, pain reduction with orthosis use was observed in the study group, while pain did not change in the control group. The difference was statistically significant at \( p = 0.003 \), indicating pain reduction in the first 45 days and continuing into the 90-day period. No significant intragroup differences were noted for pinch strength, grip strength, or dexterity over time. However, there was a reduction in Quick DASH (Q3) scores for both groups. No significant differences between groups were noted for the DASH Q1 or DASH Q2 scores. (DASH Q1 is an optional module for athletes and musicians, and DASH Q2 is an optional module for workers.)

For Period B, there was a statistically significant difference between groups regarding pain with orthosis use as follows: Day 45, \( p < 0.001 \); Day 90, \( p = 0.001 \); and Day 180, \( p = 0.026 \). The control group did improve with pain after orthosis use; however, the control group never matched the progress made by the study group for pain relief with orthosis wear. No statistical significance was noted in differences between the groups in this period for the DASH, strength or dexterity.

Was this study adequately powered (large enough to show a difference)? *Circle yes or no, and if no, explain.*

**YES/NO**

The predetermined number of subjects was 17 in order to show a 2-point improvement on the VAS for pain.

Were appropriate analytic methods used? *Circle yes or no, and if no, explain.*

**YES/NO**

See the “Results” section above.

Were statistics appropriately reported (in written or table format)? *Circle yes or no, and if no, explain.*

**YES/NO**

The statistical results as described above were reported in written and table format.

**CONCLUSIONS**

State the authors’ conclusions that are applicable to answering the evidence-based question.

This study concluded that the use of a thumb orthosis to the dominant hand during the performance of ADLs reduces pain experienced with Grade II–III thumb CMC OA. The clinical implications of this study are that, despite no change in functional measures, pain is decreased in the dominant hand of individuals wearing a CMC thumb stabilization orthosis. Not only did pain decrease in the study group, pain was also found to improve in the control group once the orthosis was applied for ADL performance.
DASH scores decreased for both groups during orthosis wear; however, they did not decrease enough to be statistically significant. These scores may not be an adequate predictor of function, as the DASH does not have thumb-specific questioning and may not be responsive for this population.

This work was completed in November 2012 by Karol Spraggs-Young, MS, OTR/L, CHT, and Debra T. Zizik, MS, OTR.

AOTA has determined that this CAP has met AOTA-established criteria and guidelines for research design, format, and structure. The CAP has been peer reviewed by CAP reviewers who are selected and trained by AOTA. However, the vigorous peer review process is conducted independently of the AOTA review and editorial processes.

For more information about the Evidence Exchange, e-mail evidenceexchange@aota.org