FOCUSED QUESTION
For adults with type I and type II boutonniere deformity as a result of rheumatoid arthritis in their dominant hand, what is the effectiveness of using a functional thumb orthosis, compared with the use of no orthosis, in improving hand function (i.e., reducing pain, improving grip and pinch strength, dexterity, range of motion, daily functioning, satisfaction)?


CLINICAL BOTTOM LINE:

The authors concluded that there was a significant improvement in pain reduction at the metacarpophalangeal joint of the thumb for participants who used the functional thumb orthosis daily compared with those who only used the orthosis at the evaluations. Though this was a significant improvement, dexterity, functional ability, grip, and pinch strength did not display significant improvements for those who used the orthosis daily compared to those who used it only at evaluations. In addition, participants who used the orthosis daily reported high levels of satisfaction.

However, it also should be noted that this study had many research design flaws, including failure to report results for range of motion, inappropriate statistical analysis used to determine if significant improvements occurred for functional ability, possible co-interventions, lack of information on how long the orthosis was worn, and contradictory information regarding number of research subjects. The authors did not discuss the clinical importance of the results. Further research on this orthotic design needs to be completed to substantiate and validate the effectiveness of this orthosis.

RESEARCH OBJECTIVE(S)
List study objectives.

The purpose of the study was to determine the effectiveness of a new functional thumb orthosis in reducing pain and improving strength, range of motion, dexterity, functional ability, and satisfaction in patients who have a type I or type II boutonniere deformity in their dominant hand with rheumatoid arthritis.
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 There is little research regarding the efficacy of orthoses for the conservative treatment of thumb arthritis. The orthosis used in this study was developed specifically for the study, so no previous evidence exists regarding its efficacy. A more exploratory lower level research design may have been more appropriate prior to completing a randomized controlled trial.

SAMPLE SELECTION
How were subjects selected to participate? Please describe.

Participants were sequentially recruited from Rheumatology Division outpatient clinics affiliated with the Universidade Federal de São Paulo, Brazil.

Inclusion Criteria
Participants were included in the study if they had rheumatoid arthritis and if their dominant hand had a type I or type II boutonniere thumb deformity as defined by the characteristics set by the American Rheumatism Association.

Exclusion Criteria
Participants were excluded from the study if they were less than 18 years old, their dominant hand deformity prevented them from opposing their thumb pad to their middle and index fingers, the boutonniere deformity was classified as non-reducible, the pain in their thumb metacarpophalangeal joint of their dominant hand was deemed too low (less than 3) or too high (higher than 7) on the visual analogue scale, they were currently using a thumb orthosis, they had a planned surgery for their hand within the next 6 months, they were allergic to Ezeform thermoplastic (the orthotic material used), they had a cognitive disability, or their geographical location prevented them from being able to participate in the study.

SAMPLE CHARACTERISTICS
N = 40 (There was an error in the number of subjects reported. The narrative states that 40 subjects were included; however, Table 1 states that there were a total of 41 subjects; 37 females and 4 males.)

% Dropouts 5%

#/ (%) Male 4/10% #/ (%) Female 37/90%

Ethnicity NR

Disease/disability diagnosis Participants all had rheumatoid arthritis
with either a type I or type II boutonniere deformity in the thumb of their dominant hand.

Check appropriate group:

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<th>&lt;20/study group</th>
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**INTERVENTION(S) AND CONTROL GROUPS**

*Add groups if necessary*

**Group 1: Intervention Group**

**Brief Description**

The intervention group (*N* = 20) used a new functional thumb orthosis, which was custom-made for each participant from 3.2 mm thickness Ezeform thermoplastic material. It was designed so that the metacarpophalangeal joint of the thumb was stabilized dorsally while having support on the volar surface. The interphalangeal joint was splinted to prevent hyperextension while the dorsal support on the distal phalanx still allowed the thumb pad to oppose the other fingers. The participants in the intervention group were instructed to use the thumb orthosis at home during daily activities.

**Setting**

The participants’ home and the outpatient clinic.

**Who Delivered?**

Member of the research team.

**Frequency?**

The participants were instructed to use the new functional thumb orthosis while engaged in their daily activities. They also were to use it at the outpatient clinic during the initial evaluation and 45 and 90 days after the initial evaluation. No specific time frames were provided for how long they were to wear it at home, or how long it was worn during the evaluations.

**Duration?**

The functional thumb orthosis was used for a total of 90 days.

**Group 2: Control Group**

**Brief Description**

Participants in the control group (*N* = 20) were fitted for a functional thumb orthosis that had the same orthotic design constructed for participants in the intervention group. The control group was not allowed to take the orthosis home and only used it during the evaluation sessions at the outpatient clinic. Participants were evaluated both using and not using the orthosis.

**Setting**

The outpatient clinic.

**Who Delivered?**

Member of the research team.

**Frequency?**

The participants used the orthosis 3 times, once at the initial evaluation, and again 45 and 90 days after the initial evaluation. The amount of time in which the orthosis was worn during these sessions was not specified.

**Duration?**

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

**Contamination**

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No contamination occurred in the research that could bias the results.

**Co-intervention**

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Co-intervention was likely a bias for both groups in this study as participants were on different pain medications; thus participants in both groups could report decreased pain on the visual analogue scale.

**Timing**

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The intervention occurred over 90 days, which is a reasonable amount of time to observe any changes in the desired outcome measures. The length of the study would not have biased the results.

**Site**

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The intervention group received the intervention at home and at the outpatient clinic, while the control group received the intervention only at the clinic. The purpose of the study was to determine the effectiveness of the functional thumb orthosis when used at home; therefore, the varying interventions sites would not be considered a bias.

**Use of different therapists to provide intervention**

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The study was unclear as to if there was a different therapist who provided and created the orthosis for the different groups. However, a different therapist providing this intervention would not likely bias the results.

**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.

**Pain:** A visual analogue scale was used to assess pain in the metacarpophalangeal joint of the thumb in the dominant hand. The pain level was indicated on a scale from 0 to 10. Type of pain measured (i.e., whether it was maximum pain, overall pain, pain that day) was not specified.

Validity and reliability NR.

The test was performed 3 times at the outpatient clinic, once at the initial evaluation, then again 45 and 90 days after the initial evaluation.

**Dexterity:** The O’Connor Dexterity Test was used to assess the dexterity of the participant’s dominant hand both with and without the use of the orthosis.
Validity and reliability NR.
The test was performed three times at the outpatient clinic, once at the initial evaluation, then again 45 and 90 days after the initial evaluation.

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.

**Grip Strength:** The Jamar dynamometer was used to assess grip strength in the dominant hand both with and without the use of the orthosis.
Validity and reliability NR.
The test was performed 3 times at the outpatient clinic, once at the initial evaluation, then 45 and 90 days after the initial evaluation.

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.

**Pinch Strength:** A pinch gauge was used to assess key, two point, and three point pinch strength in the dominant hand both with and without the use of the orthosis.
Validity and reliability NR.
The test was performed three times at the outpatient clinic, for each type of pinch, once at the initial evaluation, then 45 and 90 days after the initial evaluation.

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.

**Range of Motion:** A manual goniometer was used to assess range of motion. The joint and type of range of motion were not specified.
Validity and reliability NR.
The test was performed three times at the outpatient clinic, once at the initial evaluation, then 45 and 90 days after the initial evaluation.

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.

**Functional Ability:** The Health Assessment Questionnaire was used to assess functional ability in performing daily tasks. This questionnaire is not limited to tasks involving just the use of the upper extremity.
Validity and reliability NR.
The questionnaire was completed three times at the outpatient clinic, once at the initial evaluation, then 45 and 90 days after the initial evaluation.

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.

**Satisfaction:** A Likert scale was used to assess the intervention group’s satisfaction with the functional thumb orthosis in improving the functioning of their hand. The Likert scale used a
scale of 1–4, corresponding with, respectively, worse, the same, better, or much better.

Validity and Reliability NR.
The scale was used with the intervention group twice during the study and 45 and 90 days after the initial evaluation.

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

YES/NO The single evaluator who conducted the evaluations at baseline, 45, and 90 days was blinded to group assignment, thereby reducing bias during the evaluation process.

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

YES/NO The visual analogue scale, the Health Assessment Questionnaire, and the Likert scale are all self-report outcome measures. Being self-report measures, the participants may have been more likely to remember and report positive results. Also, the terms used on the Likert scale (worse, the same, better, or much better) could have had the potential to bias the results in favor of the intervention from positive memory recall.

Others (list and explain):

The Health Assessment Questionnaire used to assess functional ability was not solely specific to measuring upper limb functioning. It may have been too broad in terms of functioning, and therefore biased the results for both groups by indicating greater functional ability than if the questionnaire was specific to just the upper extremity. The researchers would have benefited from an assessment that focused specifically on measuring functional ability of the hand.

RESULTS
List results of outcomes relevant to answering the focused question
Include statistical significance where appropriate (p<0.05)
Include effect size if reported

Pain: Pain was measured by the visual analogue scale. There was a statistically significant difference between the groups for pain reduction. The intervention group displayed statistically significant improvements in pain reduction at the metacarpophalangeal joint of the thumb \( (p = .030 \) or \( p = .003 \)) compared to the control group. (The \( p \) values stated for this between-group analysis were reported as two different numbers in the research narrative and data tables of the study.) In addition, there was an overall statistically significant reduction in pain between the three evaluations within the intervention group \( (p=.001) \). Within this group, significant improvements were observed from the initial evaluation to the 45-day follow-up \( (p = .001) \), and from the initial evaluation to the follow-up at 90 days \( (p < .001) \). However, there were no statistically significant improvements in pain reduction from the 45-day evaluation to the 90-day evaluation \( (p = .088) \). Within the control group, there were no statistically significant improvements in pain reduction between any of the three
evaluations \((p = .412)\).

From the initial evaluation to the 90-day follow-up, the intervention group reported a 2.65 point reduction in pain on the visual analogue scale. This was an approximately 3.3 times greater reduction in pain than the control group, who reduced their pain by .8 points during this time period.

List results of outcomes relevant to answering the focused question
Include statistical significance where appropriate \((p < 0.05)\)
Include effect size if reported

**Dexterity:** Dexterity was measured by the O’Connor Dexterity Test. The results indicated that there were no statistically significant differences in dexterity between the intervention group and the control group. This was true for both the evaluation with the use of the orthosis \((p = .198)\) and without the use of the orthosis \((p = .770)\).

List results of outcomes relevant to answering the focused question
Include statistical significance where appropriate \((p < 0.05)\)
Include effect size if reported

**Grip Strength:** This was measured by the Jamar dynamometer. The results indicated that there were no statistically significant differences in grip strength between the intervention group and the control group. This was also true for the evaluation of grip strength both with the use of the orthosis \((p = .668)\) and without the use of the orthosis \((p = .085)\).

List results of outcomes relevant to answering the focused question
Include statistical significance where appropriate \((p<0.05)\)
Include effect size if reported

**Pinch Strength:** Pinch strength was measured by a pinch gauge.

**2-Point Pinch:** There were no statistically significant differences in pinch strength between the intervention and control groups. This was true for both the evaluation with the orthosis \((p = .573)\) and without the use of the orthosis \((p = .718)\).

**Key Pinch:** There were no statistically significant differences in pinch strength between the intervention and control groups. This was true for both the evaluation with the orthosis \((p = .642)\) and without the use of the orthosis \((p = .848)\).

**3-Point Pinch:** There were no statistically significant differences in pinch strength between the intervention and control groups. This was true for both the evaluations with the orthosis \((p = .225)\) and without the use of the orthosis \((p = .678)\).

List results of outcomes relevant to answering the focused question
Include statistical significance where appropriate \((p < 0.05)\)
Include effect size if reported

**Range of Motion:** Range of motion was measured by a goniometer NR.

While the methods section stated that there would be an evaluation of range of motion, no data was provided or mentioned after the methods section of the article.
List results of outcomes relevant to answering the focused question
Include statistical significance where appropriate \((p < 0.05)\)
Include effect size if reported

**Functional Ability:** Functional ability of the hand was measured by the Health Assessment Questionnaire. There were no statistically significant differences found between the intervention group and the control group in improving functional ability \((p = .088)\).

List results of outcomes relevant to answering the focused question
Include statistical significance where appropriate \((p < 0.05)\)
Include effect size if reported

**Satisfaction:** Satisfaction with the use of the functional thumb orthosis in improving use of the hand was measured by a Likert scale. At 45 days after the initial evaluation, 85% of the intervention group rated their satisfaction as better (70%) or much better (15%), while only 15% had the same level of satisfaction as before intervention. At 90 days after the initial evaluation, 75% of the intervention group rated their satisfaction as better (60%) or much better (15%), while only 20% rated their satisfaction as unchanged. At both 45 and 90 days after initial evaluation, no participant felt that their degree of satisfaction in performance was worse after using the orthosis. The statistical significance of these results were not reported.

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

**YES** An apriori power analysis indicated that 36 participants were needed for an adequately powered sample. There were 40 participants included in the study.

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

**YES** The study did not use correct analytic methods, as the data in the Health Assessment Questionnaire to rate functional ability are ordinal data. A repeated measures ANOVA was used; however, since the data were ordinal, the nonparametric test should have been used.

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

**YES** No information was provided on the range of motion measurements in either the table or in the narrative. Also, the \(p\) value for the between group analysis for pain was reported as two different numbers in the table \((p = .030)\) and in the narrative \((p = .003)\).

**CONCLUSIONS**
State the authors’ conclusions that are applicable to answering the evidence-based question.
The authors concluded that this new functional thumb orthosis was effective at reducing pain in the metacarpophalangeal joint of the thumb in patients who have a type I or type II boutonniere deformity secondary to rheumatoid arthritis. Functional ability, dexterity, grip, and pinch (2-point, key, and 3-point) did not show statistically significant improvements between groups, indicating that the orthosis did not have a positive effect in improving these outcomes. However, the authors stated that the orthosis did not negatively impact these functions, and the majority of the patients who used it daily indicated that they were satisfied with the use of this new orthosis.

This work is based on the evidence-based literature review completed by: Andrew Kangas, MOTS, and Michael Borst, OTD, OTR, CHT, Faculty Advisor, Concordia University Wisconsin.


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