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A prospective randomized comparison of neoprene vs thermoplast hand-based thumb spica splinting for trapeziometacarpal arthrosis

S.J.E. Becker*, A.G.J. Bot, S.E. Curley, J.B. Jupiter, D. Ring

Orthopaedic Hand and Upper Extremity Service, Harvard Medical School, Massachusetts General Hospital, Boston, MA, USA

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SUMMARY

Objective: In patients with trapeziometacarpal arthrosis, we tested the hypothesis that there is no difference in arm-specific disability 5–15 weeks after prescription of a pre-fabricated neoprene or a custom-made thermoplast hand-based thumb spica splint with the metacarpophalangeal joint included and the first interphalangeal joint free.

Method: One hundred nineteen patients with a diagnosis of trapeziometacarpal arthrosis were prospectively randomized to wear either a neoprene or a thermoplast hand-based thumb spica splint. At enrollment, patients completed a set of validated questionnaires. An average of 9 weeks later, patients returned for a second visit. Bivariable analyses assessed factors associated with disability, pain and satisfaction. Analysis was by intention-to-treat.

Results: Sixty-two patients (32 with a neoprene and 30 with a thermoplast splint) completed the study, 51 patients (43%) did not return for the second visit, and six did not complete the protocol for other reasons. Non-completers were significantly younger than completers ($P < 0.00044$). On average completers rated the neoprene splint as more comfortable ($P = 0.048$), but there were no detectable differences in Disabilities of the Arm, Shoulder and Hand (DASH), change in DASH, pain, satisfaction, pinch or grip strength between the two splint types in our sample.

Conclusion: When compared to custom-made thermoplast splints, pre-fabricated neoprene hand-based thumb spica splints are, on average, more comfortable, less expensive, and as effective in treating trapeziometacarpal arthrosis.

This trial was registered at Clinicaltrials.gov (NCT00438763).

Introduction

A hand-based thumb spica splint with the interphalangeal (IP) joint free is a specific nonoperative palliative treatment for trapeziometacarpal (TMC) arthrosis. The goals of splint wear are improved comfort and function[1–4]. The data regarding specific splint materials are limited, but suggest that shorter more flexible splints are preferred by patients and equally effective[4,5].

This randomized prospective clinical trial of patients with a diagnosis of TMC arthrosis tested the null hypothesis that there is no difference in arm-specific disability 5–15 weeks after prescription of a pre-fabricated neoprene hand-based thumb spica splint with the metacarpophalangeal (MP) included and the IP joint free or a similar custom-made thumb spica splint from thermoplast. Secondary study questions addressed the null hypotheses that there are no statistically significant differences between a neoprene and thermoplast splint regarding improvement of disability, pain at follow-up and satisfaction with the splint; that arm-specific disability does not correlate with higher scores on instruments assessing psychological factors; and that no factors associate with higher arm-specific disability, pain and satisfaction. We also examined the percentage of patients that had surgery within the study period.

Method

The Human Research Committee at our institution in the United States approved this prospective, single center, unblinded, equally randomized [1:1] controlled parallel-group clinical trial comparing hand-based thumb spica splints of pre-fabricated neoprene with custom-made thermoplast for patients with TMC arthrosis.

* Address correspondence and reprint requests to: S.J.E. Becker, Orthopaedic Hand and Upper Extremity Service, Massachusetts General Hospital, Yawkey Center, Suite 2100, 55 Fruit Street, Boston, MA 02114, USA. Tel: 1-617-726-1569; Fax: 1-617-643-1305.

E-mail addresses: sbecker1@partners.org, sjebecker@gmail.com (S.J.E. Becker), abot@partners.org (A.G.J. Bot), securley@partners.org (S.E. Curley), jjupiter1@partners.org (J.B. Jupiter), dring@partners.org (D. Ring).

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From January 2006 through December 2011, English-speaking adult patients that requested a splint for TMC arthrosis were enrolled from the outpatient office of two hand surgeons at one tertiary care hospital. Patients were considered eligible for this trial if they were 18 years or older and clinically diagnosed with TMC arthrosis by the hand surgeon. Additional radiological assessment was not considered necessary for the diagnosis. Patients were not eligible if they had a history of surgically treated TMC arthrosis.

Randomization

The allocation was concealed from the independent research assistant until informed consent was obtained. After informed consent was obtained, patients were randomly assigned to either a neoprene or a thermoplast splint, according to a computer generated sequence of random numbers (Windows Excel; Microsoft, Redmond, WA). Splint assignment was not blinded to any of the involved parties.

Intervention

According to the randomization, a trained occupational therapist provided either a pre-fabricated neoprene Comfort Cool® Thumb CMC Restriction Splint (North Coast Medical, Gilroy, CA) or a customized 3.2 mm thick thermoplast hand-based thumb spica splint with the MP included, and the IP joint and wrist free. Patients were told to wear the splint as needed for pain relief with daily activities and even at night if it helped them sleep. This was a pragmatic clinical trial, and consistent with usual practice, patients were not prohibited from using other treatments including other splints. Patients were allowed to have their splint adjusted.

Evaluation

An independent research assistant not involved in patient care evaluated patients at both time points.

At time of enrollment, each patient completed the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire[6], the Pain Anxiety Symptoms Scale (PASS)[7], the Pain Catastrophizing Scale (PCS)[8], the Center for Epidemiological Studies – Depression scale (CES-D)[9,10] and the Whiteley Index[11]. In addition, pinch and grip strength were recorded, and pain was measured on an ordinal scale from 0 (no pain) to 10 (worst pain you ever had). Pain improvement was calculated by deducting the follow-up pain score from the initial pain score.

Patients were asked to return 5–15 weeks later to complete the DASH questionnaire, ordinal scales for pain and satisfaction with the splint, and grip and pinch strength. The six 11-point ordinal satisfaction scales asked for (1) satisfaction with the splint, (2) how the splint helped in terms of pain relief, (3) how the splint helped in keeping active, doing daily living activities, (4) if the splint improved quality of life, (5) how comfortable wearing the splint was, and (6) how easy it was to follow the hand therapist instructions regarding splint use. A higher score indicates greater satisfaction or help. If patients did not return within the approved window between 5 and 15 weeks after enrollment, an independent research assistant tried to contact them by phone, a maximum of three times, to schedule a research appointment.

Both grip and pinch strength were measured as the average of three attempts. Grip strength was measured using the Jamar dynamometer (Asimov Engineering, Los Angeles, California) with the hand grip placed at the second or third station depending on the hand size. During the grip strength testing, the arm was at the side, the elbow at 90° flexion, and the forearm and wrist in neutral position. Key pinch strength was recorded using the B&L pinch gauge (B&L Engineering, Santa Ana, California) with the thumb pad on the pinch gauge and the lateral aspect of the middle phalanx of the index finger underneath. Both grip and pinch strength of the affected hand were compared with the opposite or least involved (in case of bilateral involvement) side. Whenever grip and pinch strength are mentioned, these refer to the percentage of strength calculation (involved/noninvolved hand).

Outcome measures

This study was designed with a single primary study question with a single primary endpoint. All other analyses should be considered secondary and hypothesis-generating. The primary endpoint was the DASH score at 5–15 weeks follow-up. Secondary endpoints were DASH score at enrollment, improvement in DASH score, pain intensity at both time points, improvement in pain intensity, grip and pinch strength at both time points, and satisfaction at follow-up. The remaining variables were all considered to be explanatory variables. Study participation was considered complete if the DASH questionnaire was completed at both time points.

Sample size analysis

An a-priori sample size analysis using a two-tailed Student's *t* test estimated the need to evaluate 60 participants to detect a clinically relevant difference of 10 points in follow-up DASH scores between the two prospective cohorts at 90% power, and a significance level of 0.05. When we were close to our target enrollment number of 60 subjects, approximately half of the study population had not returned for the 5–15 weeks evaluation. Therefore, the target was raised to 120 patients.

Statistical analysis

Analysis was by intention-to-treat, meaning that patients were analyzed based on the type of splint assignment irrespective of what splint they actually received from the occupational therapist. In other words, this was a pragmatic trial[12,13] comparing the effectiveness (the effect of prescribing a certain type of splint in actual practice where patients do not follow prescriptions precisely) rather than the efficacy (how the splints work under ideal conditions) of each splint.

Continuous variables are reported with means, standard deviations, and ranges. The data was not normally distributed according to the Kolmogorov–Smirnov test and therefore nonparametric tests were done to determine the relationship between two variables. The Mann–Whitney *U* test was conducted to evaluate the difference in mean between two groups. The Kruskal–Wallis test was used to assess the difference in mean between more than two groups. The relationship between categorical variables was evaluated with use of the Pearson Chi-Square test. Spearman correlations were used to assess the relationship between continuous variables. The difference between items measured at both time points (e.g., DASH questionnaire) were evaluated with the Wilcoxon Signed-Rank test.

Any DASH questionnaires with 4 and 5 missing items (5 at enrollment and 1 at follow-up) were analyzed. In case of missing items on a questionnaire, the score was scaled based on the number of items completed by the patient, taking into account any reverse scored items. The adjusted total scores were rounded to the nearest integer. This method was used for the following questionnaires (not more than 21% of items were missing per patient): PASS, PCS, CES-D and Whiteley Index. Only for data of the patients that completed study participation, a few missing data points were imputed with the mean cohort score for the specific questionnaire or scale. One or