SYSTEMATIC REVIEW

Comparison of Custom-made Versus Prefabricated Thumb Splinting for Carpometacarpal Arthrosis: A Systematic Review and Meta-analysis

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Abstract

Background: The goal of this study was to compare the two types of orthoses, prefabricated soft splints versus short thermoplastic custom-made splints, that are the most commonly used for the management of first carpometacarpal (CMC) osteoarthritis (OA).

Methods: We conducted a meta-analysis and systematic review in the literature based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. We extracted the outcomes of disability scores, pain scores, grip and pinch strength and gathered the unified data accordingly.

Results: We included five randomized clinical trials with 230 patients with the mean age of 61 years and the mean follow-up of 8.1 weeks. The results of the pooled data demonstrated only a statistically significant difference in disability scores among splints in favor of the prefabricated splints. The rest of the outcome measures consisting of pain, grip strength, and pinch strength were not statistically different.

Conclusion: According to our systematic review and meta-analysis, both thumb-based splints improved pain and function in the first CMC OA in a short-term follow-up, nevertheless the efficacy of prefabricated splints in abatement of disability scores was significantly higher than custom-made splints. In contrast, the other outcome measures including pain, grip and pinch strength were improved identically after wearing either of the splints.

Level of evidence: II

Keywords: Carpometacarpal joint, Meta-analysis, Splint, Systematic review

Introduction

The thumb carpometacarpal (CMC) joint allows for wide range of motion critical for normal hand function. Osteoarthritis (OA) of the first CMC joint can be a debilitating condition and is the second most common affected joint of the hand affecting 15% of adults over age 30 with a 3:1 predilection for women (1-3).

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Non-operative treatments including nonsteroidal anti-inflammatory medications, bracing, and corticosteroid injections have demonstrated clinical efficacy and are considered the first line of treatment for the first CMC OA. Literature demonstrated that the use of hand exercises, orthotics and heat application significantly improved both grip strength and functional outcomes (4). A thumb spica splint is one of the most common palliative treatments for the first CMC OA to increase comfort and function (5, 6). The two commonly used splints are the prefabricated soft splints and the short thermoplastic custom-made splints. There is currently no clear consensus among providers whether a custom-made splint has any advantage over a prefabricated one. We conducted a systematic review and a meta-analysis to the pooled data from all randomized clinical trials comparing the efficacy of the 2 types of splints used in the management of the first CMC OA. We hypothesize that there is no significant difference in patient reported or functional outcomes between thermoplastic custom-made and prefabricated splints.

Materials and Methods

Eligibility criteria

We searched for the randomized clinical trials that compared the results of prefabricated versus custom-made splints as a non-operative modality for the treatment of the first CMC OA.

Search strategy

We searched in PubMed, EMBASE, Web of Science, Scopus, ScienceDirect, Springer and Wiley Blackwell. The search was done in June 2017, using the following search strings: "((cmc OR tmc OR carpometacarpal OR carpometacarp* OR trapeziometacarpal OR basilar OR basal OR trapeziometacarp*) AND (arthrosis OR degenerative OR osteoarthritis OR arthritis) AND (immobilization OR splint OR orthosis))".

Study identification and selection

This systematic review and meta-analysis was based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (7). In stage 1, we searched for all relevant articles electronically. In addition, all bibliographies referenced in the identified studies were hand searched by two reviewers (ARK and AB). A total of 148 clinical studies on splinting of the CMC joint osteoarthritis were identified. In stage 2, abstracts of all studies were checked manually in a primary screening by two independent reviewers. Eligible studies were discussed in the presence of an expert in systematic reviews and meta-analysis, and disagreements were resolved in a meeting. Eight articles met the preliminary inclusion criteria. In stage 3, two reviewers evaluated the full texts to extract the data and manually find other relevant articles in the reference list of the included papers. When there were shared data in articles, only the latest article was included. We excluded three articles because of shared data or inadequate reporting. Further, we found two more studies through hand search of the relevant references. After further exclusion via reviewing the full texts, five articles fulfilled all inclusion and exclusion criteria. In stage 4, two reviewers checked the data independently in a standardized fashion. Any conflicts were mediated by expert author review. Furthermore, the eligible articles were reviewed for quality assessment and included in the systematic review and the meta-analysis [Figure 1].

Inclusion and exclusion criteria

There were no limitations for time period and language. The level of evidence was classified according to the definition given by the Oxford Centre for Evidence-based Medicine. Prospective, randomized, controlled studies (Levels I and II) were accepted to be included in our study. All participants had to be >18 years of age with a follow-up of one month or more. We excluded all other study types.

Outcome measures

The primary outcome was the disabilities of the arm shoulder and hand (DASH) score which is a well-recognized self-report questionnaire. Secondary outcome measures were pain, grip strength and pinch strength. Extracted data included patient's demographics, study design, sample size and type of splinting for the affected thumb.

Assessment of methodological quality

Two reviewers independently assessed the methodological quality of the studies using the modified version of the Newcastle-Ottawa Scale for observational studies (8). Disagreements were resolved by means of discussion. We included studies with ≥ 5 points on the Newcastle-Ottawa Scale, with appropriate statistical analysis (9) [Table 1].

Analysis of raw data

Raw data were gathered in one database (Comprehensive Meta-analysis software, version 2.0) and analyzed using the technique of subgroup within study, as if they were results from one study. The amount of grip and pinch strength were unified and expressed as percentage of the uninjured side or least involved (in case of bilateral involvement). The follow-up scores for the pain visual analogue scale, DASH, grip strength and pinch strength were compared between the two groups.

Meta-analysis of outcomes

In the selected studies, different questionnaires were used to measure patient-reported outcome including DASH, Australian/Canadian Hand Osteoarthritis Index (AUSCAN) and Functional Index for Hand Osteoarthritis (FIHOA) function (10). These data were pooled in order to obtain one summary estimate. The results of different questionnaires were adjusted to reflect a scale ranging from 0 (no disability) to 100 (maximal disability). The standardized mean difference with 95% confidence interval was calculated for each study using the inverse variance method with fixed effects.

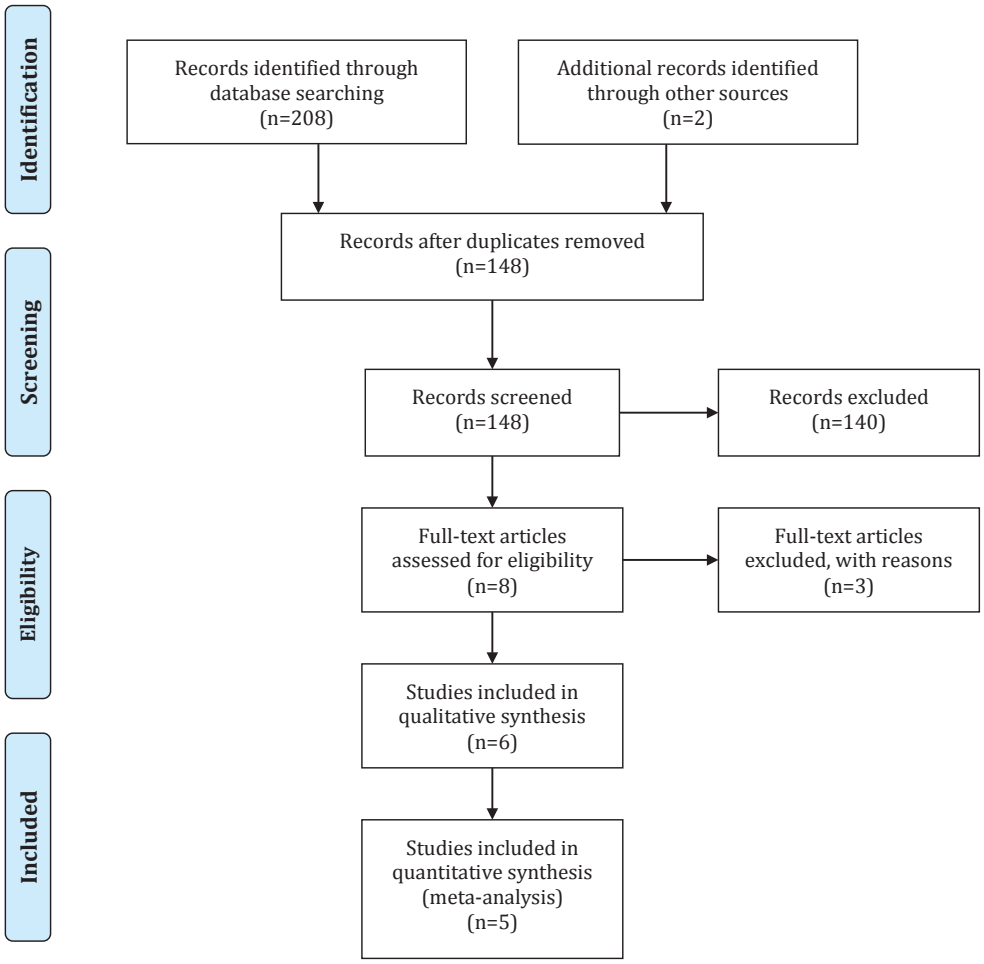

Figure 1. PRISMA flow diagram.

Table 1A. Quality Assessment of the Studies Using Newcastle-Ottawa Scale for Case-Control Studies

Study Number	First Author	Case definition adequate	Representativeness of cases	Selection of controls	Definition of controls	Comparability	Ascertainment of exposure	Same ascertainment method	Nonresponse rate	Total
1	Bani	*	*	*	*	*	*	*	*	8
2	Sillem	*	*	*	*	*	*	*	*	8
3	Weiss	*	*	*	*	*	*	*	*	8

Table 1B. Quality Assessment of the Studies Using Newcastle-Ottawa Scale for Cohort Studies

Study Number	First Author	Represen-tativeness of the exposed cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Outcome not present at start of study	Comparability	Assessment of outcome	Follow-up length	Follow-up adequacy	Total
4	Becker	*	*	*	*	**	**	**		10
5	Vegt	*	*	*	*	**	**	**		10

These standardized mean differences were meta-analyzed using the method of differences in means with random effects.

Results

Study characteristics

A total of five randomized clinical trials were included for data extraction. The overall study cohort included 230 patients divided to 181 female and 49 male patients. 200 hands were allocated in the prefabricated splint group while 198 hands were in the custom-made splint group. The reason for inconsistency between the total number of the patients and the sum of the allocated hands is that four studies used a crossover design with different periods of washout after having the splints on for 1 to 4 weeks after which patients were relocated to use the other type of splint. As a result, all hands in these studies were added up into both splint groups.

The overall mean follow-up was 8.1 weeks, and the mean age of the patients was 61 years in four studies, while one study did not report the mean age of the patients (6, 11-13) [Table 2].

DASH score

Four out of 5 studies had reported disability scores as an outcome measure including 2 studies using DASH, one study using AUSCAN score, and another using FIHOA, which were standardized to accommodate the scoring range of the DASH score (0 to 100). The pooled DASH and AUSCAN and FIHOA means were significantly in favor of the prefabricated splints (175 CMC joints) versus custom-made splints (173 CMC joints), *P=0.008* (SD difference=3) (Cochrane Q value=1.96, I^2=0, and *P=0.58*) [Figure 2].

Grip strength

No significant difference in grip strength was found between the two groups (*P=0.42*) (SD difference=3) (Cochrane Q value=0.74, I^2=0, and *P=0.42*) [Figure 3].

VAS score

No significant difference in VAS score was observed between the two groups (*P=0.07*) (SD difference=4) (Cochrane Q value=46.19, I^2=91.34, and *P<0.001*) [Figure 4].

Pinch strength

Among five studies that reported pinch strength, one was excluded by leave-one-out cross-validation technique. Testing all possible ways by dividing the original sample into a training and a validation set, and computing the statistics separately (6). No significant difference in pinch power was observed between the two groups (*P=0.15*) (SD difference=3) (Cochrane Q value=12.81, I^2=76.58, and *P=0.005*) [Figure 5].

Publication bias

A funnel plot is generated to assess publication bias. We expect the studies to be symmetrically about the combined effect size as long as there is no publication bias [Figure 6].

Table 2. Extraction of variables from included studies

Author, year	Study Design	Patients (n)	Hands (n)	Female (n)	Male (n)	Prefabricated (n)	costume-made (n)	Age (years)	Follow-up (week)	Disability score	VAS score	Grip strength	Pinch strength	Prefabricated splint type	Costume-made splint type
Weiss et al., 2004	cross-over	25	25	21	4						Yes		Yes	Neoprene, Cool Comfort	Thermoplast, Omega Max
Sillem et al., 2011	cross-over	56	56	51	5			64.04	9	AUSCAN	Yes	Yes	Yes	Neoprene, Cool Comfort	Hybrid splints
Becker et al., 2013	prospective, non-blinded	62	62	48	14	32	30	63	8.68	DASH	Yes	Yes	Yes	Neoprene, Cool Comfort	Thermoplast
Bani et al.,2013	cross-over	24	24	17	7			54.165	10	DASH	Yes	Yes	Yes	Neoprene, Cool Comfort	Orfit
Vegt et al., 2017	cross-over	63	63	44	19			60.1	6	FIHOA	Yes	Yes	Yes	Push Ortho Thumb Brace	Orfit

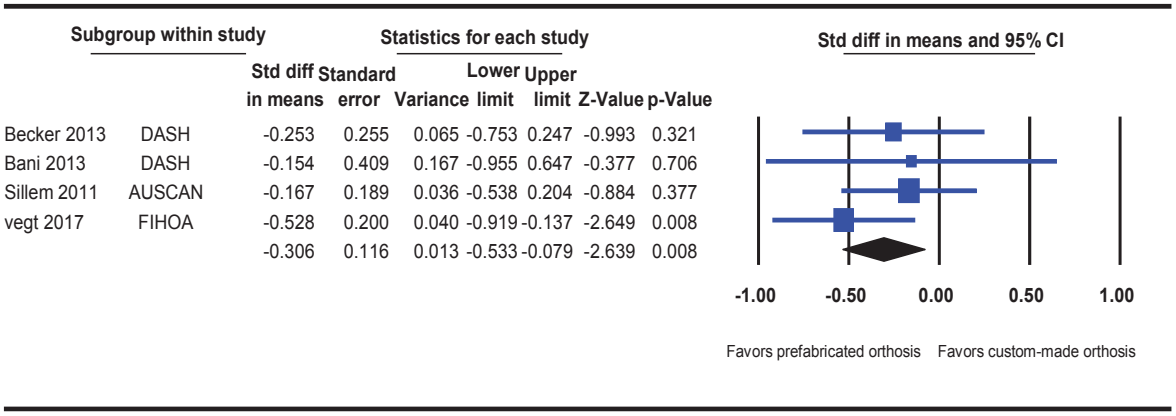

Figure 2. Forest plot of disability scores after standardizing 3 scores of DASH, AUSCAN and FIHOA using random effect model shows significant difference between the 2 types of splints favoring prefabricated splint.

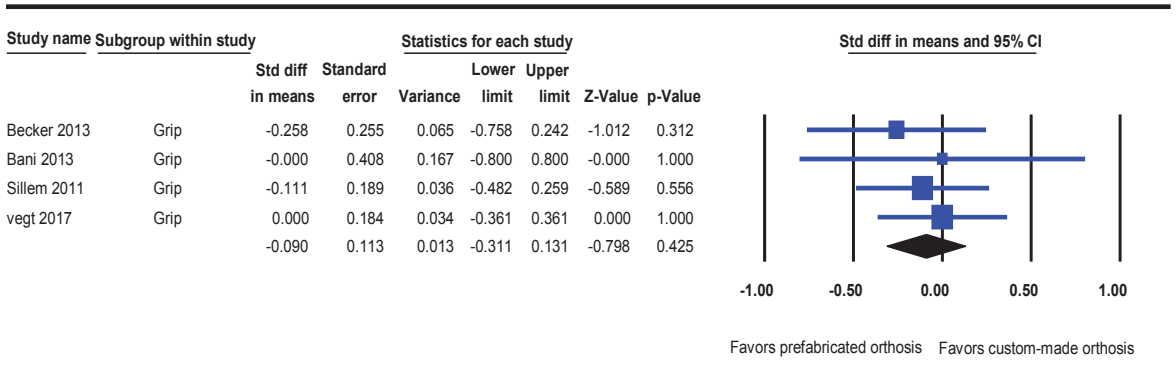

Figure 3. Forrest plot of grip strength using random effect model shows no significant difference between the 2 types of splints.

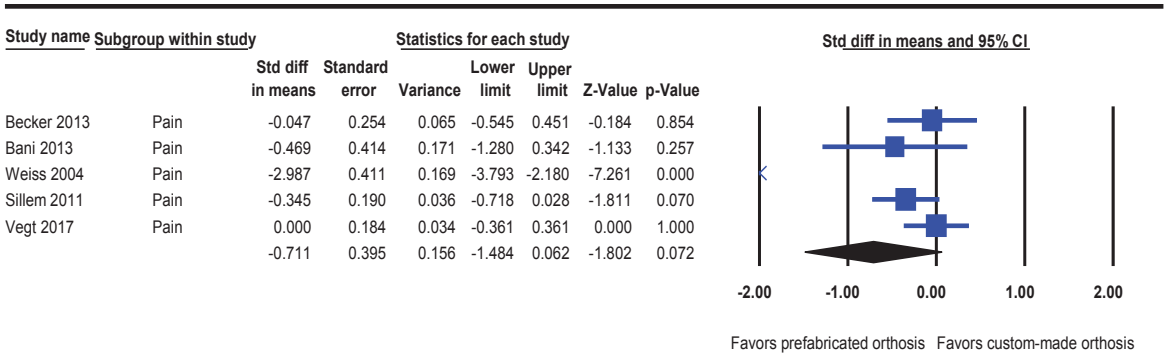

Figure 4. Forrest plot of VAS scores using random effect model shows no significant difference between the 2 types of splints.

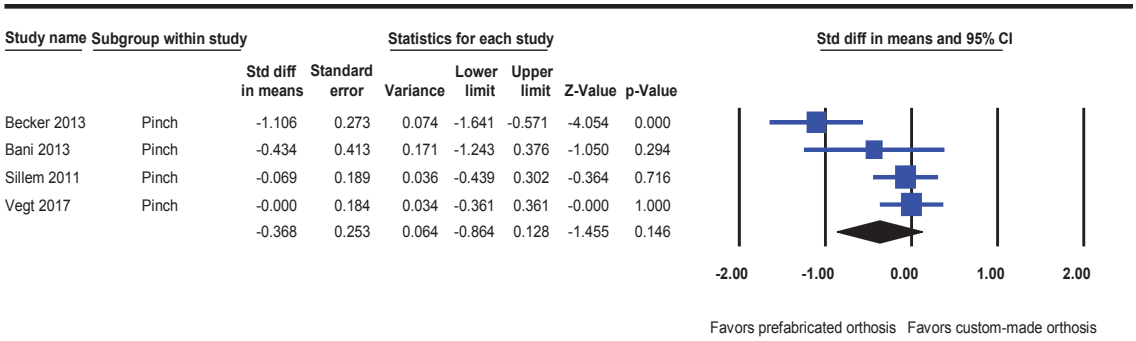

Figure 5. Forrest plot of pinch strength using random effect model shows no significant difference between the 2 types of splints.

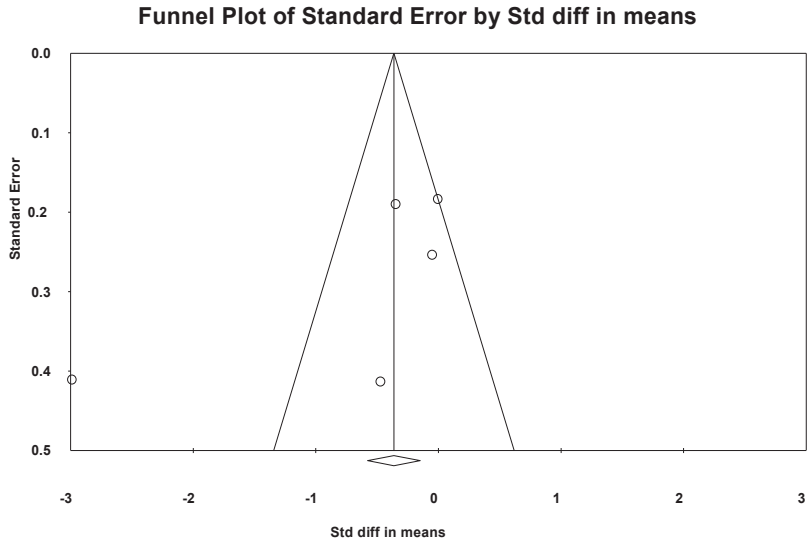

Figure 6. Funnel plot of standard error by standard difference in means.

Discussion

Most hand surgeons are in agreement with treating CMC OA with a thumb-based splint, but the type of splint is still a point of challenge to whether use a neoprene prefabricated soft splint or a thermoplastic custom-made one (6, 13). We conducted a review of trials comparing the effectiveness of the two most commonly used splints in the treatment of the first CMC OA in regard to improving function and pain, which showed comparable efficacy of both types of splints.

Splints are designed to rest the CMC joint in palmar abduction with slight flexion and medial rotation. The use of thumb-based splints has shown to provide pain relief (14). The custom-made splints are constructed based on a pattern, which matched the dimensions of the patient's hand using low temperature-molding materials (thermoplast) (11). Prefabricated splints are off-the-shelf orthosis immobilizing the first CMC joint and placing the thumb in a functional position (15). Patients are typically instructed to wear the splints when symptomatic, during heavier manual tasks, and at nighttime if they desired (12, 13).

As consistent with the original studies, the pooled data also showed that both types of splints help improve pain, pinch power, grip strength and function in a short to medium-term follow-up. Bani et al. attributed the effect of pain reduction to immobilization of the covered joint, decreased inflammation, increased proprioception and creation of local warmth with splinting. With pain reduction, increased function was expected. Sillem et al. demonstrated improved grip and lateral pinch strength as well as increased satisfaction rated by the patients.

The pooled data demonstrated that neither orthosis

was superior over the other in improving hand function, but pain scores are significantly lower in patients using the prefabricated splints. Weiss et al. found that the prefabricated splint providing a greater pain relief than the thermoplast splint, while Sillem et al. reported the opposite (13). Sillem et al. showed no difference in improving subjective and objective hand functions except slight but significant improvement in subjective domains with the use of the thermoplastic splint. Vegt et al. concluded that there was no significant difference in pain reduction between orthoses or in any other outcome measures (except for the nine-hole peg test and key grip while wearing the splints) compared to not wearing them, which were worsened with both splints at any time but less aggravated while wearing prefabricated splints.

The major limitation of our study was the number of clinical trials available in the literature. Another challenge comes from the inconsistency when pooling different outcome measures to make a direct statistical comparison (16). For the primary aim of this study, we had to pool FIHOA, AUSCAN and DASH scores together in order to make a meaningful subgroup analysis with corresponding direction. In addition, none of the included studies in our analysis used tools that address patient satisfaction, including personal, environmental and health-related factors. Because there was no difference between the two types of splints, patient satisfaction and provider's preference might remain as the main indicator when choosing a splint. Lastly, we could not separate our data by gender as studies have pointed out that females may be more likely to report worse symptoms, while they could also have recalled their prior symptoms differently (17).

Our systematic review and meta-analysis demonstrated that both thumb-based splints improve pain and function in patients with the first CMC OA in a short-term follow-up. However, no difference was noted between the custom-made versus prefabricated thumb spica splints in improving pain and functional outcomes, but disability outcomes were significantly in favor of prefabricated splints. Although there has been no cost analysis study, we find it important enough to point out that prefabricated splints are less costly and potentially are cost saving. Further studies assessing patient satisfactions are warranted to compare these two splints.

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