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# Comparison of Two Carpometacarpal Stabilizing Splints for Individuals with Thumb Osteoarthritis

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Osteoarthritis (OA) of the thumb carpometacarpal (CMC) joint is a common disorder, affecting up to 20% of men and women older than 40 years.<sup>1</sup> Prevalence rates of radiographic CMC OA have been cited as high as 42% in males and 57% in females older than 75 years.<sup>2</sup> Symptomatic CMC OA, although slightly less prevalent than radiographic hand OA,<sup>3</sup> manifests itself through pain, joint stiffness, and weakness of the thumb. When individuals with symptomatic hand OA were compared with asymptomatic individuals, they reported two to three times as many functional limitations with dressing, eating, and carrying a 10-pound load.<sup>3</sup> Symptomatic hand OA has also been associated with difficulties in performing work tasks<sup>4</sup> and with weak grip and pinch strength.<sup>5</sup> In the Framingham study,<sup>6</sup> participants with

**ABSTRACT:** Splinting the thumb in carpometacarpal osteoarthritis (CMC OA) is a common practice; however, research evidence is lacking to support the use of one specific splint design. The purpose of the study was to compare the effect of two different splints on hand function, pain, and hand strength in adults with CMC OA. Fifty-six participants were assigned randomly to splint order in a two-phase, four-week crossover trial. Hand function, the primary outcome, was assessed using the Australian Canadian Hand Osteoarthritis Hand Index. Differences between the two splints were not statistically significant for effect on hand function, and grip and pinch strength. However, the custom-made splint showed a greater average reduction in pain scores. Both splints demonstrated modest improvements in hand function. The prefabricated splint was the preferred splint although the custom-made splint decreased pain slightly more. This reinforces the client-centered approach to splinting.

**Level of Evidence:** 2b.

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symptomatic hand OA had 2–3 kg (10%) less grip strength (measured with a hand-held dynamometer) compared with those without symptomatic hand OA. Kjekken et al.<sup>7</sup> reported that women with OA had only 60% of the expected grip strength norms for their age.

Given the prevalence of CMC OA, it is a frequent clinical diagnosis seen by occupational therapists, physiotherapists, and hand therapists. The first line of conservative treatment is splinting. The intention of splinting is to provide support to the CMC joint while permitting functional movement of the hand. A variety of thumb splints are available, both prefabricated and custom-made, and in different types of material. Unfortunately, there are no guidelines specifying the type of splint suitable for CMC OA and only a few studies are available on the effectiveness of splinting the CMC joint.

Recently, a systematic review of the evidence for splinting in CMC OA concluded that there was fair evidence to support using thumb splints for pain reduction.<sup>8</sup> Statistically significant improvement in pain with the use of thumb splints was found in three of the seven included studies.<sup>9–11</sup> Of the four comparative trials, only one showed a significant difference between the two thumb splints' effects on pain.<sup>11</sup> However, most of the included studies were limited

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by small sample sizes, short treatment times, and other methodological flaws; hence, the evidence to support splinting for pain relief is considered limited. Of the three studies that considered the effects of splinting on muscle strength, no improvement was observed in objective measures such as pinch and grip strength. Activities of daily living (ADL) performance showed a statistically significant improvement in only two of the four studies that measured it.<sup>9,12</sup>

The purpose of the present study was to compare the effectiveness of two different splints. Because the trend in splinting the thumb in CMC OA has moved toward a minimalist approach, one design is the short custom-made CMC stabilizing splint used in Weiss et al.'s studies,<sup>10,11</sup> as modified by McKee, using a thinner thermoplastic and incorporating neoprene to make the splint more flexible for grip and pinch, and improve comfort (personal communication, P. McKee, Sept 15, 2007). We labeled this modified design the Hybrid splint. The Hybrid allows full wrist range of movement and thumb metacarpal joint movement. The second splint is the prefabricated, neoprene, Comfort Cool (North Coast Medical, Morgan Hill, CA), the preferred splint for comfort, function, and strength in Weiss et al.'s 2004 study.<sup>11</sup> The decision to compare McKee's Hybrid splint with the Comfort Cool™ was based on findings from the cited studies, and expert opinion and usual practice at the clinics involved in this trial. The objectives of this study were to determine if the splints had an equivalent effect on self-reported hand function, pain, and hand strength after four weeks of use.

## METHODS

### Participant Recruitment

Participants were recruited from three outpatient hand therapy departments on Vancouver Island, British Columbia. Participants with a clinical diagnosis of CMC OA were referred by their family physicians, hand surgeons, or rheumatologists for splinting intervention. This was standard practice for these three clinics, where participants were referred for thumb splinting intervention based on a physician's referral rather than the X-ray confirmation. Adults who were aged 45 years or older (the target population for thumb OA), and able to communicate in English were eligible. Participants were excluded from the study if they had previous thumb surgery, or concomitant neurological diagnoses, and if they had a diagnosis of OA that extended into the wrist.

Participants with bilateral CMC OA were included in the study if they had been referred for the fabrication of only one thumb splint or if they were willing to wait nine weeks before having the second thumb splinted. In these cases, the most

symptomatic thumb based on the subjective report of pain was studied. The risks and benefits were explained verbally when reviewing the study procedures and written consent form. Signed informed consent was obtained from all the participants. The study protocol was approved by the Clinical Research Ethics Board at the University of British Columbia and the Clinical Research Ethics Board at Vancouver Island Health Authority. The study was registered at [ClinicalTrials.gov](http://ClinicalTrials.gov) (NCT00705146).

### Research Design

An equivalence trial using a two-period crossover design was conducted with consecutively referred patients randomly assigned to different treatment order. A table of random numbers was used to determine treatment order assignments, allocated to the clinics in sealed envelopes. The two four-week treatment periods were separated by a one-week washout period. The washout period is required in a crossover design to reduce the chance of carryover effect<sup>13</sup> from either splint and from psychological expectations. A washout period of one week was deemed adequate for return to baseline, similar to other splinting crossover trials<sup>14</sup> where no carryover effect was observed after splint withdrawal. The total duration of the study was nine weeks plus one follow-up phone call at three months.

This was designed as an equivalence trial<sup>15</sup> anticipating both splints to have a similar effect on hand function, thumb pain, and strength. The hypothesis states that a small difference exists between the Comfort Cool™ and Hybrid splints, using an a priori equivalence margin of eight points on the Australian Canadian Osteoarthritis Hand Index version 3.1 (AUSCAN; Queensland, Australia)<sup>16</sup> function subscale. That is, a difference of less than eight points on the AUSCAN function subscale (possible total 90 points), after wearing each splint requires that we reject the null hypothesis and consider the thumb splints equivalent.<sup>17</sup>

### Interventions

The prefabricated neoprene Comfort Cool™ splint (Figure 1) was fit according to size (S, M, M+, L). The custom-made Hybrid splint (Figure 2) was fabricated from neoprene and 1.6 mm Rolyan Aquaplast Watercolors (Bollingbrook, IL). Two therapists at each site provided the splints (a primary therapist and an alternate in case of vacation or other absence). Participants were instructed to contact the therapists as necessary for adjustments if the splints were uncomfortable. Participants were instructed to wear the splints when symptomatic, during heavier manual tasks, and at nighttime if they desired. Therapists did not provide exercises or education



**FIGURE 1.** *Comfort Cool™ splint.*

regarding joint protection until the final outcome measurement session at nine weeks. During the one-week washout period, participants were required to leave their first splint at their respective hand clinics. This prevented contamination into the second intervention period.

All participants were asked to keep a daily log reporting how many hours per day they wore their splint. Splints were provided free of charge and at the end of the study, participants were given both splints. Participants were given a \$10 gift card at each appointment as a token recognition of time given to the study.

To ensure standardized treatment protocols, therapists at each of the three sites attended a two-hour orientation session detailing instructions on splint fabrication and study protocol, including standardized outcome measures. Therapists had an opportunity to practice splint fabrication at these orientation sessions. In addition, they received a DVD with video instructions for splint fabrication.

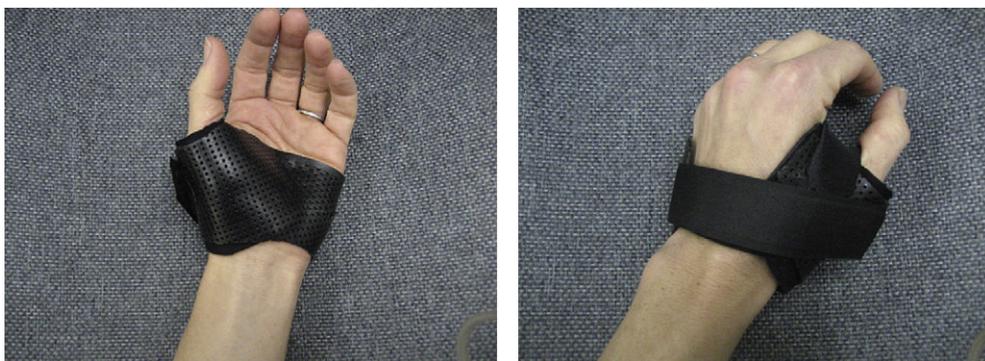
### **Baseline and Outcome Measures**

Data collection occurred at the initial visit (baseline, week 0), after the use of the first splint (week 4), after the washout period (week 5), and after the use of the second splint (week 9). [Figure 3](#) outlines the schedule of study visits and measures. The treating

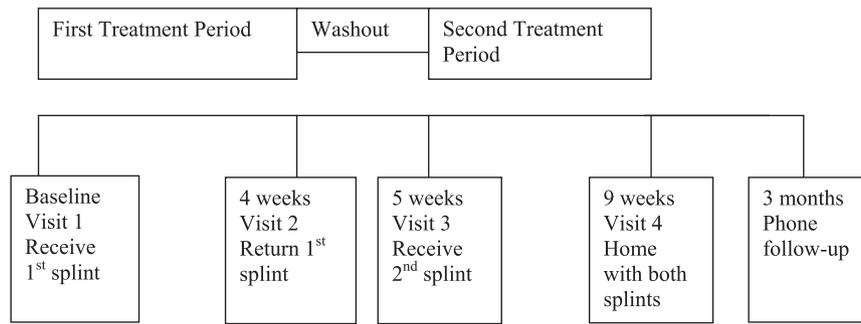
therapists provided the participants with their splints and collected data at baseline and outcome sessions. Evaluation at baseline included demographic information, current medication use, hand dominance, and occupation.

The primary outcome was hand function measured by the functional subscale of the AUSCAN. The AUSCAN is a self-report tool designed for people with hand OA. It consists of 15 questions with three subscales to rate pain, function, and joint stiffness, measured using an 11-point (0–10) numerical rating scale (NRS). The AUSCAN function subscale consists of nine questions regarding the level of difficulty to perform daily tasks such as opening a jar, holding a full pot with one hand, turning a doorknob, wringing out a washcloth, and fastening jewelry or watches. Possible scores range from 0 to 90, with higher scores indicating worse function.

Secondary outcomes were pain, measured with the AUSCAN hand pain subscale (possible score range 0–50), and hand strength as measured by grip and lateral pinch. Grip and pinch strength were assessed using the Jamar dynamometer and Preston pinch gauge, respectively, in kg. We followed the protocol for measuring grip and pinch strength of the American Society of Hand Therapists,<sup>18</sup> which has well-established reliability and is widely used in therapy clinics in North America. The mean of three trials was recorded for both grip and pinch measurements



**FIGURE 2.** *Hybrid splint.*



**FIGURE 3.** Schedule of outcome measurements.

of the splinted hand. Grip and pinch strength measurements at baseline and at week 5 (return to baseline) were taken without splints, and at weeks 4 and 9 with the splints on (to measure splint effects). Patient preference with respect to the splints was assessed by asking participants to rate their satisfaction with comfort (fit), appearance, convenience, and durability, using a five-point Likert scale.

### Sample Size and Data Analysis

The primary outcome of hand function was used to estimate sample size. An a priori power calculation indicated that 48 participants were required to test the null hypothesis of a small difference in hand function between the Hybrid and Comfort Cool™ splints. Up to this date, there had been no published studies to determine the minimum clinically important difference for the AUSCAN NRS version. On the basis of a review of the literature using the AUSCAN Likert and VAS versions, an estimate was calculated using a standard deviation of the differences in AUSCAN VAS function scores of 15.91<sup>19</sup> and minimal meaningful change scores of 5.8–8.97. To allow for possible attrition of 15%, a total of 56 participants were recruited.

Descriptive statistics (range, means, and standard deviations) for the study sample were tabulated. The AUSCAN function subscale score, pain subscale score, grip strength, and lateral pinch strength were evaluated for potential carryover and order effects using paired t-tests. Paired t-tests were used to compare the effects of the two splints with regard to changes from baseline to four weeks for AUSCAN function and pain scores, grip strength, and lateral pinch strength (between-group comparisons). Paired t-tests were also used to assess the effect of each splint on AUSCAN function, pain, grip strength, and pinch strength (within-group comparisons). Paired t-tests are the mathematical equivalent of a repeated-measures ANOVA for a two-period crossover trial.<sup>20</sup> Chi-square tests were used for the assessment of splint satisfaction questions and splint preference. Using an intent-to-treat analysis, the last observation

was carried forward for two participants who dropped out before study completion. A post hoc analysis examined outcomes based on hand dominance (compared participants whose dominant vs. nondominant hand was splinted). Statistical analysis was performed using SPSS Statistics Grad Pack version 17.0 (SPSS Inc., Chicago, IL). Significance was accepted at a probability value of  $p \leq 0.05$ .

## RESULTS

### Participants

Fifty-nine patients with CMC OA were invited to the trial between April 1, 2008 and March 31, 2009 (Figure 4). Three declined to participate due to travel and time commitment. Fifty-six participants were randomized to splint order. Participants were 45–84 years of age, with a mean age of 64 years (standard deviation [SD] = 8.61), demographics are presented in Table 1. There was one dropout in each splint group; both were retained in the analysis.

Of the 54 participants who completed the study, 43 (80%) returned their daily logs for both splints. Participants reported wearing the Comfort Cool™ splints for an average of 7.71 (SD = 5.18) hours per day and the Hybrid splints for 8.20 (SD = 5.42) hours per day. There was no significant difference between wearing times. One participant reported not wearing her second splint (Hybrid) at all because her symptoms had completely resolved.

When analyzing for treatment order effect, no significant differences were found in any of the outcomes (AUSCAN function and pain, grip strength, and pinch strength) between those who received the Comfort Cool™ first and those who received the Hybrid first. There were no significant differences in any of the four outcome measures after the one-week washout period compared with baseline, indicating no carryover effect was present.

Table 2 presents the mean baseline and four-week scores for all the four outcomes for each of the Comfort Cool™ and the Hybrid. The between-splints comparison is presented in Table 3.

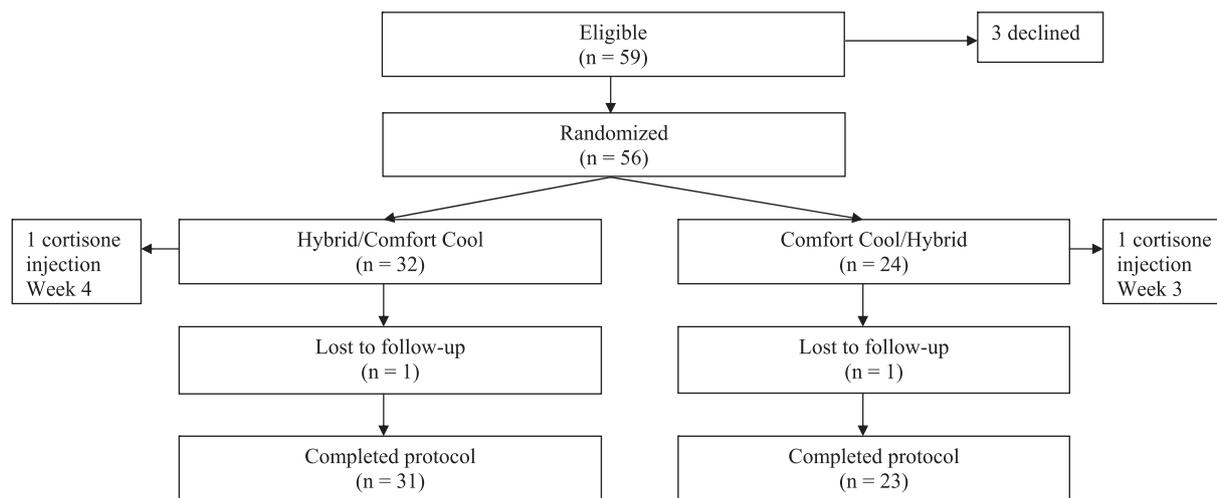


FIGURE 4. CONSORT flow chart.

### Hand Function (Primary Outcome)

The change scores for self-reported hand function using the AUSCAN did not differ significantly between the two splints (Table 3). The AUSCAN function subscores improved with both the Hybrid and the Comfort Cool™ splints, by 5.54 and 2.69 points, respectively; however, paired t-tests showed that this improvement over baseline was statistically significant only for the Hybrid (Table 3).

### Pain

Participants who wore the Hybrid had a significantly greater reduction in pain symptoms than those wearing the Comfort Cool™ (Table 3). Pain improved after wearing both the Hybrid and the Comfort Cool™ splints for four weeks, but only the Hybrid had a statistically significant effect, as measured by the AUSCAN pain subscale.

TABLE 1. Participant Characteristics, n = 56

Characteristic	Mean (SD)
Average age, yr (SD)	64.05 (8.61)
Duration of CMC OA, yr	2.99 (4.68)
	n (%)
Dominant hand splinted	23 (41)
Bilateral CMC OA	32 (57)
Sex	
Females	51 (91)
Males	5 (9)
Family history CMC OA	23 (41)
Employment status	
Employed	20 (36)
Retired	36 (64)
Taking medication for symptoms	25 (45)

SD = standard deviation; CMC OA = carpometacarpal osteoarthritis.

### Strength

Both grip and lateral pinch strength improved slightly, but not significantly, after wearing the splints for four weeks (Table 2).

### Splint Satisfaction Rating

The Comfort Cool™ was rated as the preferred splint by 63% of the participants and the Hybrid by the remaining 37%. In chi-square analyses, an association was found between those who preferred the Hybrid and high comfort ratings. For those who preferred the Comfort Cool™, there was an association with high ratings for durability. No other ratings of splint characteristics were significantly associated with splint preference.

### Hand Dominance and Duration of Symptoms

To explore the characteristics of participants more likely to benefit from splints, post hoc analyses were conducted based on hand dominance and duration of CMC OA. When comparing results by hand dominance, a statistically significantly larger improvement in function (9.24 points, SD = 20.27, p = 0.05) and pain (9.62 points, SD = 12.42, p < 0.01) was reported for the Hybrid, compared with the Comfort Cool™ by those participants whose dominant hand was splinted. In contrast, no significant changes were found for any of the outcomes for participants whose nondominant was splinted. There were no significant differences in outcomes between those participants who had recent CMC OA (symptoms for less than a year) and those who reported their onset of thumb pain more than a year ago.

### Three-Month Follow-Up

At the end of the nine-week crossover trial, participants were given both splints. Three months after

**TABLE 2. Function, Pain, and Strength Scores at Baseline and at 4 Wk for Each Splint, *n* = 56**

Variable	Baseline	4 Wk	Mean Difference (Change)	SDD	<i>t</i>	<i>p</i>	95% CI
<b>Comfort Cool™</b>							
AUSCAN function*	53.09	50.40	2.69	16.33	1.221	0.23	-1.73, 7.11
AUSCAN pain†	27.84	25.78	2.05	9.54	1.596	0.12	-0.53, 4.63
Grip strength	18.17	18.54	-0.37	4.14	-0.660	0.51	-1.50, 0.76
Lateral pinch strength	4.40	4.72	-0.33	1.84	-1.299	0.20	-0.83, 0.18
<b>Hybrid</b>							
AUSCAN function*	52.67	47.13	5.54	17.37	2.34	0.02	0.80, 10.28
AUSCAN pain†	27.67	21.98	5.69	11.08	3.772	<0.001	2.66, 8.71
Grip strength	18.43	19.25	-0.83	3.80	-1.584	0.12	-1.88, 0.22
Lateral pinch strength	4.40	4.60	-0.21	1.14	-1.342	0.19	-0.52, 0.10

AUSCAN = Australian Canadian Hand Osteoarthritis Hand Index; SDD = standard deviation of the differences; CI = confidence interval.

\*Lower scores indicate better function.

†Lower scores indicate less pain.

initial baseline assessment, a follow-up phone call was made, and 44 participants (81%) were contacted. Four of those participants (9%) indicated that they were no longer wearing either splint: three because their symptoms had improved to the point that they no longer needed the splints and the fourth reported that both splints fell apart. Seven (13%) participants reported that they were still using both splints. Two of these reported wearing the Hybrid at nighttime and found the Comfort Cool's™ flexibility was better for gym workouts and golf.

The AUSCAN was administered over the phone. The results are presented in Table 4. Three-month scores for the AUSCAN function and pain subscales were not significantly different from the scores after the initial splinting period (four weeks) for either splint. When compared with baseline scores, both the function and pain subscores improved significantly.

## DISCUSSION

The main purpose of this study was to compare the effect of two CMC splints on hand function. In the current head-to-head comparison of the Comfort

Cool™ and the Hybrid, we failed to detect even a small difference between the two splints' effects on hand function; hence, both splints appear to have similar effects on function.

The primary outcome of function was selected to focus on the real-life impact of CMC OA on everyday activities rather than pain alone. Three measures of function were chosen, including the self-report AUSCAN questionnaire function subscale, grip strength, and pinch strength measurements. In hand OA, grip strength has been strongly correlated with hand function.<sup>7</sup> By combining the performance-based indicators of function with perceived functional ability, it was intended that actual functional improvement (or impairment) would be better captured.

In this study, the AUSCAN function subscores improved by a mean of 5.54 points after wearing the Hybrid for four weeks; however, this improvement was not significantly different from the 2.69 mean improvement with the Comfort Cool™, although it was better than participants' mean baseline function scores. The reported minimally clinically important improvement (MCII) for the AUSCAN NRS function subscale was determined to be 3.47 in a group undergoing four weeks of non-steroidal anti-inflammatory drugs (NSAID) treatment.<sup>21</sup> The Hybrid and the Comfort Cool™ did not differ more than the MCII on their effect on hand function, nor did they differ more than our predefined equivalence margin of eight points on the AUSCAN function subscale. On the basis of this finding, we reject our null hypothesis of nonequivalence.

After four weeks of wearing the Hybrid, the AUSCAN pain subscore improved by a mean of 5.69 points (on a scale of 0–50) compared with the Comfort Cool™ mean improvement of 2.05 points. The improvement in pain scores was significantly greater, although small in magnitude, for the Hybrid splint compared with the Comfort Cool™. The MCII for the AUSCAN NRS pain subscale is reported to be

**TABLE 3. Comparing Function, Pain, and Strength Scores between Comfort Cool™ and Hybrid Splints (After 4 Wk of Use, *n* = 56)**

Variable	Mean Difference	SDD	95% CI		<i>t</i>	<i>p</i>
			(Lower)	(Upper)		
AUSCAN function*	3.13	15.56	-1.12, 7.38	1.48	0.15	
AUSCAN pain*	3.72	11.13	0.68, 6.76	2.46	0.02	
Grip strength†	-0.48	4.01	-1.58, 0.63	-0.87	0.39	
Lateral pinch strength†	0.12	1.68	-0.34, 0.58	0.51	0.61	

AUSCAN = Australian Canadian Hand Osteoarthritis Hand Index; SDD = standard deviation of the differences; CI = confidence interval.

\*Positive score in favor of Hybrid, negative score in favor of Comfort Cool™.

†Negative score in favor of the Hybrid.

TABLE 4. AUSCAN Function and Pain Scores at 3 Mo (n = 44)

Follow-up Period	AUSCAN Function				AUSCAN Pain			
	Mean Difference	SDD	t	p	Mean Difference	SDD	t	p
Comfort Cool™ (4 wk–3 mo)	3.25	15.53	1.39	0.17	1.50	9.67	1.03	0.31
Hybrid (4 wk–3 mo)	1.32	14.32	0.61	0.55	-1.52	9.08	-1.11	0.27
Baseline to 3-mo follow-up	6.30	17.16	2.43	0.02	4.25	9.40	3.00	<0.01

AUSCAN = Australian Canadian Hand Osteoarthritis Hand Index; SDD = standard deviation of the differences.

7.46 points.<sup>20</sup> The effect of the Hybrid on the AUSCAN pain subscale came close to a seven-point improvement. It is possible that a longer duration of splint use would improve pain even further, but this is not supported by our three-month follow-up: the mean improvement in the pain subscale from baseline to three months was 4.25 points, showing that some of the improvement in pain gained immediately after four weeks of splint use had been lost by three months. Because not all participants could be contacted at three months, several had stopped using their splints, and splint use was not obtained for the rest, our follow-up phone call is not evidence of long-term effects. Further research would be required to evaluate the longer-term effects of splinting.

Interestingly, when the results were considered in the context of hand dominance, those participants who had their dominant hand splinted had a significantly larger improvement with the Hybrid than the Comfort Cool™ for both function (12.43) and pain reduction (10.62). This difference is not only statistically significant, but exceeds the MCII and our a priori equivalence margin, indicating an important clinical improvement. This could be attributed to the larger role the dominant hand has in daily functional activities. CMC OA of the dominant hand has been found to have a significant association with hand disability.<sup>22</sup> Improvements in symptoms maybe more noticeable in the more frequently used dominant hand. Future studies should be stratified for hand dominance to better evaluate whether or not the beneficial effect of thumb splints differs according to hand dominance.

The AUSCAN asks about performance of both unilateral and bilateral daily tasks. Most daily tasks are bilateral; however, when CMC OA is present in one hand, there may be value in separate evaluation of each hand. Unilateral tasks may not be problematic if the nondominant hand is affected with CMC OA. The AUSCAN-HI User Guide<sup>16</sup> states that having OA in the dominant hand can have a higher impact on hand function and influence AUSCAN scores more. This could limit the ability of the AUSCAN function subscale to measure true change in function after the treatment of the nondominant hand.

Overall, participants reported that they found the splints beneficial for tasks such as driving, handwriting, gardening, golfing, reading, and housework. At

the three-month follow-up, participants made comments to the effect that the splints are supportive, provide immediate relief, assist with grip, and even allowed some to reduce their pain medication. The fact that 40 out of 44 participants reported still wearing one of their splints, three months later, suggests these splints were beneficial.

Performance of everyday activities has only been measured in six previous studies of splinting effects in CMC OA. The measures used included nonvalidated and nonstandardized questionnaires. Our findings of improved function with the Hybrid splint support similar findings for short thumb splints.<sup>9–11,23</sup> Our findings for the Comfort Cool™ differed from those of previous studies of long splints, some of which used shorter treatment periods.<sup>10–12,24</sup> In this study, the duration each splint was worn was set at four weeks, assuming that this would be ample time to become accustomed to the splints. Nevertheless, it may take even longer to achieve the full effect of splints on function, given the improvement noted at the three-month follow-up call.

Our results differ slightly from previous studies in regard to the effect of thumb splinting on pain. Pain was significantly reduced with both splints in both comparative trials by Weiss et al.,<sup>10,11</sup> and in McKee and Eason-Klatt's unpublished comparative study,<sup>25</sup> pain was also found to be significantly better after 21 participants wore one of the two different thumb splints for four weeks. One explanation for the difference may be the measures used, although our study had double the participants of Weiss et al.'s, and the findings may be more stable.

The increases in grip strength and pinch strength were very small for the Comfort Cool™ (0.37 and 0.33 kg, respectively) and the Hybrid (0.83 and 0.21 kg, respectively), not statistically significant, and it is difficult to assess their clinical relevance. Forces required to open various containers such as medicine bottles and trigger pumps have been shown to be as little as 0.91–4.5 kg.<sup>26</sup> There is a fair relationship between pinch strength and the ability to open different containers.<sup>26</sup> If the strength improvement resulting after wearing a thumb splint helps an individual over the necessary threshold of 0.9 kg to open a container, this would be a meaningful improvement.

In contrast to our findings, two studies have reported increases in pinch strength after splinting

the CMC joint, as much as 0.6–2 kg in tip pinch after two to four weeks of splinting.<sup>23,25</sup> McKee and Eason-Klatt<sup>25</sup> reported a significant improvement in pinch from baseline to follow-up with and without the splints on. Our results for pinch strength were similar to Weiss et al.,<sup>11</sup> where there were no significant differences in pinch strength generated in either splint compared with baseline without a splint. Additionally, they did find that participants were able to generate more pinch strength in the Comfort Cool™ compared with the custom-made CMC splint as did we.

The preferred splint in this study was the Comfort Cool™, which was the same as in Weiss et al.'s trial.<sup>11</sup> Similar reasons for the preference were given, including ease of use, appearance, comfort, and durability.

### Limitations of the Study

This was a multicenter study, where two therapists at each site were responsible for the treatment and carrying out the study protocol. The therapists were not blinded to the splinting intervention, as they were required to fabricate and fit each splint. They were not blinded to the outcome measures as they measured grip strength, and pinch strength. This raises the possibility of bias if therapists had a strong preference for one splint or were swayed by participant comments. Because both splints were currently being used at all three sites, it is unlikely that there was a strong preference, and the findings show no significant improvement in hand strength for either splint.

The primary outcome measure, the AUSCAN was a self-report outcome; therefore, the therapists could not influence the score. None of the previous thumb splint studies blinded their evaluators. Although the therapists were trained in the study protocol and given the opportunity to consult the study therapist at anytime, intra- and inter-rater reliability for the evaluation methods were not determined. On the basis of the prior studies of the AUSCAN, and grip and pinch dynamometers, these measures have been shown to have high test-retest reliability.<sup>19</sup>

The crossover design has an inherent weakness in the assumption that each treatment sequence group is identical because all participants receive both splints and serve as their own control. However, there is a possibility that participants were exposed to other interventions during one treatment period but not the other. This was the case with two participants who received cortisone injections near the end of the first splint period, before the second splint period. Exposure to other treatments and/or medication changes was not monitored, although the informed consent process asked that participants be on stable treatment regimes for the duration of the nine-week study. Thirty of fifty-six participants recorded using some sort of analgesic. Changes in medication may

have increased the effect of the splints on pain relief; however, this replicates the “real-life” experience of using both analgesics and splints for symptom relief, and no systematic pattern was observed to bias findings.

The population in this study was a homogenous group with regard to their baseline characteristics, being predominantly females in their 60s. Participants were admitted to this study based on a clinical diagnosis of CMC OA. This is the typical referral method at these clinics and is usual practice for hand therapists to only have a physician's diagnosis or referral before fabricating a splint. Given the skill level and expertise of hand therapists, we would screen for differential diagnoses and alter the splinting treatment accordingly. Severity of OA was not assessed in this study, although there is some evidence to support the benefits of conservative splinting in the earlier stages of CMC OA.<sup>27</sup> There may have been a larger splinting effect, if we had used radiological evidence of stages 1 and 2 CMC OA as inclusion criteria.

### Strengths of the Study

The crossover design of this study compared the effects of each splint on the same participant, reducing variability and strengthening internal validity. This design requires half as many participants as a parallel groups design,<sup>28</sup> thereby increasing the power of the study to detect even a small treatment effect between the splints; hence, it is an efficient design for equivalence trials. Crossover designs are also appropriate for stable conditions such as CMC OA.

The four-week splinting intervention improves on previous studies that used one and two weeks.<sup>10,11,23</sup> This is the only crossover study that incorporated a one-week washout period between splints. The one-week washout period was deemed to be sufficient time to allow the effects of the first splint to disappear as splinting is thought to have an immediate effect when applied, thus when the splint is removed that effect disappears.

The effects of splinting for pain relief were already known; however, there had been a lack of evidence regarding the use of splinting to enhance hand function. The primary outcome of hand function was measured using the AUSCAN-HI version 3.1, a standardized questionnaire specific to hand OA. The Osteoarthritis Research Society International has recommended that condition-specific clinical outcome measures be used in their guidelines on hand OA Clinical Trials.<sup>29</sup>

The sample size in this study was greater than all but one of the previous CMC OA splinting studies.<sup>27</sup> Our final group size ( $n = 54$ ) exceeded the minimum sample size requirement of 48 to have enough power to detect a small difference between splints based on

the existing responsiveness data regarding the AUSCAN tool.

Compliance to the study protocol by the participants was recorded with the use of daily logs. Forty-six participants (85%) returned their logs. Previous studies have measured adherence to splinting protocol by setting a specific amount of time, such as ten hours per week as the minimum expectation.<sup>14</sup> A more recent study<sup>30</sup> rated adherence as high when participants wore their splints five to seven nights a week. Considering these parameters, our participants reported wearing the splints an average of eight hours per day.

## Clinical Implications

Splinting is the first choice of conservative treatment of CMC OA,<sup>8,31,32</sup> despite this there are no guidelines as to which splint design is most useful for which patients. This study considered subjective and objective outcomes in comparing two different splints for CMC OA. The results demonstrate that the Comfort Cool™ and Hybrid splint have an equivalent effect on hand function, grip strength, and pinch strength. However, the Hybrid splint was statistically significantly better than the Comfort Cool™ at reducing pain.

The difference in pain relief between the two splints may be explained by the more rigid property of the thermoplastic used in the Hybrid fabrication. This may limit certain movements, types, or amount of activities engaged in, thereby reducing pain. When participants were asked to choose their preferred splint, each participant had strong preferences for one or the other. None chose both splints or neither splint. Interestingly, the preferred splint for most of the participants (63%) was the Comfort Cool™, and the reason usually given was because it was judged more comfortable although the AUSCAN pain scores were significantly better after wearing the Hybrid. The post hoc analysis showed that the Hybrid improved both pain and function for participants whose dominant hand was splinted.

A larger percentage of participants (68%) in this study preferred the Comfort Cool™ splint, as was the case when previously studied,<sup>11</sup> yet, the Hybrid provided greater pain relief according to the AUSCAN pain subscale scores. Still, 20 of 54 participants had a definite preference for the Hybrid. Factors such as the kind of activities for which the splint is worn and when the splint is to be used may contribute to preference. The prefabricated Comfort Cool™ was reportedly more durable; however, some of the participants' comments concerning the Hybrid indicated that it offered better pain relief.

Given that there was a clinical improvement in three-month follow-up, AUSCAN pain and function scores for both splints indicate that CMC splinting

may have a longer-term improvement on pain and hand function. Perhaps, a study with an intervention period longer than one month would have led to greater reduction in pain and improvement in hand function. In a study<sup>30</sup> of nighttime splinting for individuals with CMC OA, pain reduction was found to be clinically significant at 12 months, whereas at one month there was no effect on pain. CMC OA is a chronic condition and could require splinting for an extended period of time.

These findings may guide therapists and patients selecting splints to meet individual needs, but more research specific to participant characteristics may be required to provide greater direction in identifying which splints are most effective for whom.

## CONCLUSION

In summary, the Hybrid and Comfort Cool™ splints had an equivalent therapeutic effect on hand function, grip strength, and lateral pinch strength. The Hybrid had a greater effect on decreasing pain than the Comfort Cool™. Because a difference for pain relief did exist between the two splints in this study, the choice of splint may be determined based on the patient's current symptoms and the patient's preference.

Given the variety of splint designs and splint materials for CMC OA, further research should compare different splints with a no splint control group and look at improved function over a longer term. The results of this study add to the knowledge base regarding the effect of thumb splints on function and pain in adults with CMC OA.

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- #1. Symptomatic CMC OA has been associated with
- increased grip strength
  - difficulties with ADL
  - increased pinch strength
  - slower performance at work
- #2. The strengths of this study are
- the crossover design increases the internal validity
  - the 4 weeks splinting intervention is longer than previous studies
  - the AUSCAN outcome measure is specific to hand OA
  - all of the above
- #3. Since both the Comfort Cool TM and the Hybrid thumb splints were expected to have similar effects on hand function and pain, this study was designed as
- a non-equivalence trial

- a non-inferiority trial
  - an equivalence trial
  - a superiority trial
- #4. Participants with bilateral CMC OA
- had both thumbs splinted
  - only had their more symptomatic thumb splinted
  - only had the thumb with the more severe radiographic OA splinted
  - could choose which thumb they wanted splinted
- #5. The Comfort Cool TM CMC stabilizing splint was found to
- have the smaller effect on pain reduction as compared to the Hybrid
  - have the greater effect on hand function as measured by the AUSCAN
  - be the least restrictive splint
  - have the greater effect on pinch strength

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