Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 51, No. 5, October 15, 2004, pp 792–799
DOI 10.1002/art.20699
© 2004, American College of Rheumatology

ORIGINAL ARTICLE

A Crossover Trial of Custom-Made and Commercially Available Wrist Splints in Adults With Inflammatory Arthritis

SANDRA HASKETT,[1] CATHERINE BACKMAN,[2] BARBARA PORTER,[1] JILL GOYERT,[1] AND GILLIAN PALEJKO[1]

Objective. **To compare the effect of 3 wrist splints (2 prefabricated commercial splints and 1 custom made) on perceived wrist pain, hand function, and perceived upper extremity function in adults with inflammatory arthritis.**

Methods. **Subjects (n = 45, mean age 49 years, mean disease duration 8.6 years) were randomly assigned to treatment order in a 3-phase crossover trial. Splints were worn for 4 weeks, separated by 1-week washouts. Outcomes were assessed at baseline, after each splint phase and washout period, and at 6 months' followup using a pain visual analog scale (VAS), the Arthritis Hand Function Test, and McMaster-Toronto Arthritis Patient Function Preference questionnaire. Data were analyzed with multivariate analyses of variance (MANOVAs), *t*-tests, and chi-square tests.**

Results. **There did not appear to be order or carryover effects. MANOVA indicated that wrist splints significantly reduced pain ($P = 0.007$). The custom leather splint was most effective in reducing pain, from 4.1 cm to 2.8 cm on the VAS ($P = 0.001$). All splints improved hand strength, and the commercial Rolyan splint provided significantly stronger grip than the Anatech commercial splint ($P = 0.04$). In contrast to previous studies, splints did not compromise dexterity. There were several significant differences among splints, depending on the outcome measure. Improvements were maintained at 6 months.**

Conclusion. **After 4 weeks' use, wrist splints reduce pain, improve strength, and do not compromise dexterity. Similar improvements were achieved with the custom leather splint and Rolyan commercial splint, which were superior to the Anatech commercial splint.**

KEY WORDS. Wrist orthoses; Wrist pain; Hand function; Dexterity; Rheumatoid arthritis; Occupational therapy.

INTRODUCTION

As part of the comprehensive management of rheumatoid arthritis (RA) and related conditions, splints or orthoses may be recommended to treat symptoms of the disease and improve performance of everyday activities. Wrist splints are prescribed to reduce joint pain and inflammation and to enhance function. They provide external support to the wrist joint while allowing movement of the thumb and fingers to grasp and manipulate objects in the course of everyday activities. Indications include wrist pain, synovitis, tenosynovitis, and nerve entrapment (1). Splints may be custom made to fit the individual or commercially available (prefabricated) in a variety of styles and sizes. The purchase price of custom-made splints is 2–3 times that of prefabricated commercial splints, depending on materials used and retail prices. In the past, it was generally accepted that commercial splints, available in a limited number of sizes, did not fit as well as custom-made splints. However, the proliferation of splint styles, sizes, features, and lower costs, together with pressure in clinics to minimize the time and expense of treatments, suggest that the effectiveness of commercially available splints be compared with custom-made splints.

Several studies have evaluated the effect of commercial splints in adults with rheumatoid arthritis or inflammatory arthritis affecting the wrist. Although the styles of splints differed across studies, as did the rigor of the research designs, collectively the results suggest that at least some

Supported by a research grant from the British Columbia Health Research Foundation.

[1]Sandra Haskett, BSc(OT), Barbara Porter, BSR, Jill Goyert, BSR, Gillian Palejko, BSR(OT): Mary Pack Arthritis Program, Vancouver Coastal Health Authority, Vancouver, British Columbia, Canada; [2]Catherine Backman, PhD: The University of British Columbia, Vancouver, British Columbia, Canada.

Address correspondence to Barbara Porter, BSR, Mary Pack Arthritis Program, 895 West 10th Avenue, Vancouver, British Columbia, Canada, V5Z 1L7. E-mail: bporter@vanhosp.bc.ca.

Submitted for publication June 5, 2003; accepted in revised form January 2, 2004.

splints reduce pain (2–4) and improve grip strength (2,5,8), but they may reduce dexterity and performance of some functional tasks (3,6,7). Two studies assessed custom-made wrist splints. One, a single-subject study replicated over 3 subjects, reported similar findings of improved hand strength and hindrance of dexterity (8), whereas the other study, a cross-over trial, found the custom-made splint had no impact on grip strength (9). A summary of the study designs, splint types, and outcomes, is presented in Table 1. A recent systematic review of occupational therapy interventions for rheumatoid arthritis, including splints, concluded there was "indicative findings" that the use of wrist splints reduces pain and improves grip strength but also decreases dexterity (10). Another systematic review (11) found it difficult to draw firm conclusions about the efficacy of wrist splints and recommended immediate and rigorous study of the most commonly prescribed orthoses.

When assessing evidence from splint effectiveness trials, it is important to note the duration of treatment as well as the magnitude of the changes in hand function and not just the statistical significance. For example, in Stern and colleagues' trial, splints were used for 1 week and the decline in hand function was a fraction of a second for some Jebsen hand function test items (7). Such a small difference may not be of practical significance to individuals wearing wrist splints, and may, in fact, disappear over time once individuals become accustomed to wearing the splints. The trends in a repeated measures design (8) suggest that dexterity while wearing wrist splints improves over time, even though it did not attain the same level of function as the nonsplinted condition within the period of time studied (10–15 days).

Our objective for the present study was to incorporate a longer period of splint use into the research plan, comparing both custom and commercially available splints in the same trial. At the time the study began, the cost of purchasing a custom-made leather wrist splint (LWS) was $100 (Canadian dollars [CAD]), the Rolyan wrist extensor orthosis (RWS) was $46 (CAD) and the Anatomical Technologies (also known as Anatech) elastic wrist support (AWS) was $21 (CAD). The specific hypothesis tested was for an equivalency trial: there will be no differences in the effects of the 3 splints on perceived wrist pain, hand function, and perceived upper extremity function in adults with inflammatory arthritis who wear the splint for at least 10 hours per week for 4 weeks.

METHODS

Design. A 3-period crossover design was employed with consecutively referred patients randomly assigned to different orders of treatment.

Subject recruitment. Participants were identified from among patients referred by a physician to an outpatient occupational therapy department located in a specialized arthritis treatment center. Inclusion criteria were 1) inflammatory arthritis affecting the wrist (diagnosis confirmed by a rheumatologist), with any 2 of these symptoms: palpable swelling, pain on direct pressure, pain on motion, and wrist range of motion restricted by ≥20%; 2) adults aged ≥20 years; and 3) ability to speak, read, and write English. Potential participants were excluded if they 1) were obtaining a replacement wrist splint and were not willing to participate in a 2-week washout period with no splint use prior to commencing the trial; 2) required a combination wrist splint with thumb post or other custom design feature; 3) were referred for a postoperative splint following wrist joint fusion; 4) exhibited excessive subluxation of the wrist joint requiring a specially adapted splint or treatment protocol; 5) were in the process of or planning to adjust their medications. The study protocol was approved by the Behavioral Research Ethics Board at the University of British Columbia. Participants signed informed consent.

Interventions. Treatment consisted of a 4-week period using each of the 3 wrist splints in turn (Figure 1). All splints were fitted to the participant's wrist by an occupational therapist. The LWS was custom fabricated on a plaster mold of the patient's hand and forearm positioned in 15–20° wrist extension and 5° ulnar deviation. The most appropriately sized RWS and AWS were selected for each subject. The RWS is a circumferential fabric gauntlet with removable forearm stay, fastened with 3 D-ring straps. The AWS is an elasticized fabric splint that opens dorsally and fastens with 4 flat straps. The volar metal stays in the RWS and AWS were adjusted to the same degrees of wrist extension as the plaster cast, and contoured to fit the forearm. No further custom modifications were done to the commercial splints. Participants returned to the clinic after 1 week if adjustments were required. They were provided with a handout on the use and care of the splint, advised to use the splint during activities that caused pain or discomfort during the day, asked to wear the splint for a minimum of 10 hours/week, and asked to record splint use in a daily diary. Splints were provided free of charge. Patients were given all 3 at the end of the study and they were not otherwise reimbursed for participation. The total duration of the trial was 14 weeks, plus 1 followup visit at 6 months.

Randomization. There were 6 possible treatment orders, and a table of random numbers was used to develop treatment order assignments. Assignments were recorded inside the covers of a set of folders holding data collection forms and used consecutively. Participants were assigned to a splint sequence immediately after they were deemed eligible for the study and signed consent.

Baseline and outcome measures. Baseline evaluation included demographic information (age, sex, diagnosis, year of diagnosis), current medications, comorbid conditions if any, hand dominance, and occupation. Disease activity measures included an upper limb active joint count (12), assessment of wrist range of motion, hours to fatigue, and duration of morning stiffness. The outcome measures for wrist pain, hand function, and patient perception of upper extremity function, described below,

Table 1. Summary of literature after using wrist splints for inflammatory arthritis*

Author, year (ref. no.)	Study design	Participants, n/sex	Type of splint(s)	Duration of splint use	Outcomes			
					Pain, VAS	Strength tests	Dexterity tests	Functional tasks
Backman and Deitz, 1988 (8)	Single subject (repeated measures), alternating treatments (splint versus no splint)	3/F	Custom-made polyethylene	10–15 days	N/R	Improved: grip, tip pinch, tripod pinch (vigorimeter)	N/R	Improved: ability to pour water Hindered: ability to write No significant effect on lifting groceries, manipulating coins
Kjeken et al, 1995 (5)	Clinical trial, random assignment (splint versus no splint)	69/52 F, 17 M	Experimental group: Rehband elastic Control group: no orthosis	6 months	No difference between groups; experimental group improved pain with splint use compared with baseline	No difference between groups; experimental group improved: grip, and pinch, with splint use (sphygmomanometer, pinch meter)	N/R	No difference between groups; experimental group improved: pain when pouring water, pain when slicing cheese (with splint use compared to baseline)
Nordenskiold, 1990 (2)	Single group, before and after	22/F	Camp elastic or Rehband elastic	N/R	Improved	Improved: grip (Grippit)	N/R	Improved pain associated with: setting table, filling a glass with milk, vacuuming for 3 min
Pagnotta, et al, 1998 (3)	Crossover trial, splint versus no splint (crossover occurred within outcome evaluation session)	40/33 F, 7 M	Futuro #33	1 week	Improved	N/R	Increased time to complete Jebsen hand function test	No significant effect on: simulated use of shears Hindered: simulated use of screwdriver (BTE work simulator)
Stern et al, 1996 (6)	Crossover trial, 3 phases of 1 week with each of 3 splints, separated by 1-week washout periods	36/18 F, 18 M	Futuro #33 Rolyan D-ring AliMed freedom long	1 week	N/R	No significant effect on grip with Rolyan; decreased grip with Futuro and AliMed (Jamar dynamometer)		Subjects reported splints helpful when doing farm chores, meal preparation, yard work, and some housework. Subject reported splints hindered some self-care tasks, writing, and typing.

(continued)

Table 1. Summary of literature after using wrist splints for inflammatory arthritis* *(Continued)*

Author, year (ref. no.)	Study design	Participants, n/sex	Type of splint(s)	Duration of splint use	Outcomes			
					Pain, VAS	Strength tests	Dexterity tests	Functional tasks
Stern et al, 1996 (7)	Crossover trial, 3 phases of 1 week with each of 3 splints, separated by 1-week washout periods	42/22 F, 20 M	Futuro #33, Rolyan D-ring AliMed freedom long	1 week	N/R	N/R	All splints: increased time to complete 6 of 7 Jebsen hand function test items, and Purdue pegboard	N/R
Tijhuis et al, 1998 (9)	Crossover trial, 2 phases of 2 weeks with each of 2 splints, separated by 1-week washout periods	10/8 F, 2 M	Futuro, Custom-made ThermoLyn	2 weeks	Improved (Futuro) No significant effect (ThermoLyn)	No significant effect on grip strength for either splint (vigorimeter)	N/R	N/R

* ref. = reference; VAS = visual analog scale; N/R = not reported; min = minutes.

Figure 1. Wrist splints used in the study, from left: Rolyan wrist extensor orthosis; custom-made leather wrist splint; Anatomical Technologies elastic wrist support.

were taken at baseline, at the end of each 4-week splint phase, and at the end of the 1-week washout period between splints.

Perceived wrist pain, the primary outcome, was measured using a 10-cm horizontal visual analog scale (VAS) (13). It was administered immediately following performance of the hand function test items using the question "On the following line, mark with an "x" the amount of pain you had in your splinted wrist while you were doing the test activities." The VAS was anchored with the phrases "no pain" and "pain as bad as it can be."

Hand function was measured using the Arthritis Hand Function Test (AHFT) (14,15). The AHFT is an objective assessment of both hand strength and dexterity and measures performance on 11 items: grip strength (mm Hg), tip pinch strength (thumb to index finger, kg), tripod pinch strength (thumb to index and middle finger, kg), 9-hole pegboard dexterity (seconds), tying a shoelace, fastening buttons, using safety pins, cutting with a knife and fork, manipulating coins, pouring water, and lifting a tray weighed with soup cans. The AHFT was administered without a wrist splint at baseline and following washout periods and with the assigned wrist splint at each 4-week intervention assessment.

The McMaster-Toronto Arthritis Patient Function Preference (MACTAR) questionnaire (16) was used to ascertain patients' perceptions of function. This tool uses an individualized approach: patients identify the activities they would most like to be able to do, but currently have problems doing because of their arthritis. They then rate their ability to do the tasks at baseline and each subsequent outcome evaluation. For the purpose of the present study, only activities related to upper limb function were used to generate MACTAR scores, since wrist splints would not logically affect such activities as walking.

All assessments were conducted by 1 of 2 independent evaluators (occupational therapists not involved in the study or provision of the splints to study participants) at a consistent time of day. To assess return-to-baseline or potential carryover effects, disease activity measures (active joint count, perceived fatigue, morning stiffness), pain VAS, AHFT, and MACTAR were administered at the end of each washout period.

At the end of each splint phase, participants rated vari-

ous splint characteristics, including ease of donning/doffing, and satisfaction with the fit, comfort, and appearance. At the end of the 3 splint phases, participants rated the splints on an ordinal scale to determine splint preference. They used their preferred splint for an additional 6 months to assess the long-term effects of splint use and to assess the durability of the splint. Four categorical (yes/no) questions were used for durability: Did the body of the splint show signs of wear and tear? Were splint edges or stitching worn out? Were straps worn out? and Was the splint condition adequate for continued use?

The total cost of treatment was estimated by summing the initial cost of the splint and the cost of therapist time spent on splint fitting, adjustments, and instructing on splint use and care.

Sample size. The primary outcome of perceived wrist pain was used to estimate sample size, and the minimum sample size required was 40, based on the following parameters: $\alpha = 0.05$, $\beta = 0.10$ (for 90% power given an equivalency trial), standard deviation of the differences in pain scores of 0.975 (derived from a convenience sample of previous clinic patients), and minimal meaningful change score of 0.5 cm on the VAS.

Data analysis. Disease activity, pain VAS, and AHFT data were evaluated for potential carryover or sequence effects prior to proceeding to the main analysis. Differences were assessed using multivariate analyses of variance (MANOVAs), paired *t*-tests, and chi-square tests, using the conventional level of $P = 0.05$ to indicate statistically significant differences.

RESULTS

Forty-seven participants were recruited for the trial, but 2 withdrew due to changes in their arthritis medications after the baseline measures were taken. Characteristics of the sample (n = 45) are listed in Table 2. The dominant wrist was splinted in 30 (67%) participants. The randomization process assigned participants to 1 of 6 groups based on the order in which the 3 splints were received (5–9 participants per group). A comparison of demographic characteristics across the 6 groups showed no statistically significant differences (F statistic for continuous data, chi-square for categorical), indicating that the groups were balanced. Four participants did not complete 1 of the splint phases because of a change in medications or a complicating medical problem, leaving 43 subjects for assessing return to baseline after the AWS, and 44 subjects each for the LWS and the RWS. There were between 40 and 42 participants for pair-wise comparisons.

Disease activity measures (joint count, perceived fatigue, morning stiffness) and outcome measures (perceived pain, AHFT, MACTAR) were assessed after each 1-week washout period for return to baseline. Although scores varied across sessions, there were only 3 significant differences from baseline, indicating relatively stable disease activity throughout the trial and no apparent order or carryover effect. Two of the differences were for the applied dexterity scores on the AHFT, which did not return to baseline following the washout periods after the AWS and RWS. In each case, the score was ~10 seconds better than the baseline score. The third failure to return to baseline was for pegboard dexterity at the washout following the LWS, and this difference was only 1.7 seconds.

Table 2. Baseline characteristics of participants*

Characteristic	Data
Age, years	49.1 ± 13.0 (25–75)
Disease duration, years	8.6 ± 9.2 (0.5–45)
Active joint count	13.1 ± 8.0 (1–30)
Fatigue, hours to fatigue	6.2 ± 3.6 (0–17)
Morning stiffness, hours	1.2 ± 2.0 (0–12)
Wrist ROM, degrees flexion	53.4 ± 18.9 (15–90)
Wrist ROM, degrees extension	43.4 ± 21.7 (5–85)
Sex, no. (%)	
Female	39 (87)
Male	6 (13)
Diagnosis, no. (%)	
Rheumatoid arthritis	35 (78)
Psoriatic arthritis	4 (9)
Juvenile arthritis	3 (6.5)
Other inflammatory	3 (6.5)

* Data reported as mean ± SD (range) unless otherwise noted.
ROM = range of motion

Participants wore the splints for an average of 29 hours per week. On average, subjects wore the AWS for 31 hours per week, the RWS for 29 hours, and the LWS for 26 hours. All but 2 participants met the minimum expectation of 10 hours per week. One participant wore the LWS splint only 8 hours per week but exceeded 10 hours per week for the RWS and AWS, and another subject wore all 3 splints for an average of 8 hours per week. These 2 participants were retained in the analyses.

Effect of wrist splints on pain. Table 3 lists the means for all outcome variables at baseline and following 4 weeks' use of each splint. The primary outcome measure was perceived pain; at baseline, wrist pain was moderate (mean 4.1 cm on VAS). Repeated measures analysis of variance indicated that splints significantly reduced pain ($P = 0.007$) compared with baseline (Table 4). A second MANOVA excluding baseline data showed there was a difference due to splint type at $P = 0.07$ (Table 5). Because this was close to the a priori level of significance (0.05), pair-wise comparisons were conducted using *t*-tests. These indicated that the LWS was more effective in reducing pain than the AWS. The differences between LWS and RWS, and RWS and AWS were not statistically significant (Table 6). Using paired *t*-tests to compare the effect of each splint with baseline, all 3 improved perceived wrist pain but only the change with the LWS was statistically significant, although the RWS was very close to achieving significance (LWS $P = 0.001$; RWS $P = 0.06$; AWS $P = 0.38$).

Effect of wrist splints on hand function. The AHFT has 11 items, but the 5 applied dexterity items are summed to

Table 3. Pain and hand function at baseline, after using wrist splint for 4 weeks, and at 6-month followup with preferred splint*

Outcome measure	Baseline	Custom LWS	*P*	RWS	*P*	AWS	*P*	Six-month followup
Pain, 10-cm VAS	4.1 ± 2.4	2.8 ± 2.4	0.001	3.3 ± 2.6	0.06	3.8 ± 2.6	0.38	3.1 ± 2.5
Grip, mm Hg	121 ± 41	144 ± 56	< 0.001	148 ± 58	< 0.001	140 ± 52	< 0.001	154 ± 61
Two-point pinch, kg	2.4 ± 0.93	2.9 ± 1.2	< 0.001	2.8 ± 1.1	0.001	2.8 ± 1.3	0.001	2.8 ± 1.3
Three-point pinch, kg	3.3 ± 1.3	3.61 ± 1.5	0.02	3.58 ± 1.5	0.001	3.61 ± 1.5	0.01	3.6 ± 1.6
Pegboard dexterity, sec	24.6 ± 6.4	24.7 ± 6.0	0.56	24.2 ± 6.0	0.63	23.8 ± 7.1	0.26	24.9 ± 6.9
Dexterity, sec (lacing shoes, buttons, pins, coins, knife/fork)	119.1 ± 40.6	111.7 ± 37.2	0.02	113.3 ± 42.6	0.04	112.0 ± 36.3	0.009	116.0 ± 55.7
Pouring water, ml	1,737 ± 235	1,822 ± 284	0.01	1,798 ± 245	0.02	1,813 ± 255	0.04	1,859 ± 216
Lifting cans, no.	11.3 ± 1.6	11.5 ± 1.3	0.26	11.5 ± 1.1	0.24	11.5 ± 1.0	0.14	11.5 ± 1.3

* Data reported as mean ± SD. *P* values reflect significance of the difference between splint and baseline using paired *t*-tests. LWS = leather wrist splint (custom); RWS = Rolyan wrist extensor orthosis; AWS = Anatomical Technologies elastic wrist support; VAS = visual analog scale

create 1 score, resulting in 7 hand function outcome scores (Table 3). Using MANOVA to assess the main effect of wrist splints (regardless of splint type), grip strength, 2-point pinch strength, 3-point pinch strength, aggregate applied dexterity, and pouring water were significantly improved over baseline ($P < 0.02$, data not shown). Paired *t*-tests showed that each of the 3 splints significantly improved these variables compared with baseline. Pegboard dexterity and lifting were not improved with splint use. Pair-wise comparisons between splints yielded only 2 significant differences: the RWS resulted in significantly stronger grip than the AWS ($P = 0.04$) and the LWS compromised pegboard dexterity marginally more than the AWS ($P = 0.03$). There were no differences between the LWS and RWS on any of the AHFT items.

A MACTAR unweighted score of 10 indicates no change has occurred in the functional task rated. The MACTAR scores demonstrated very little change over the duration of the trial, with scores ranging from 10 to 10.9. Thus, there were no significant differences in the functional items rated using this tool, compared with baseline or across the 3 splints evaluated.

Splint preference. The LWS was ranked most preferred, followed by the RWS and then the AWS, all of which were preferred over no wrist splint. Participants also indicated whether or not each splint was difficult to put on and remove, and whether or not they were satisfied with its comfort, fit, support, and appearance. More people rated the RWS as easy to put on and remove (82%), followed by the LWS (64%) and AWS (51%). The splints were rated as comfortable by approximately the same proportion of participants: RWS 86%, LWS 84%, and AWS 81%. Splint fit favored the LWS (93% satisfied) over the RWS (82%) and AWS (81%), as did satisfaction with splint appearance (LWS 91%, RWS 75%, AWS 72%).

Splint cost. At our clinic, patients are not charged a fee for the time to fit and adjust commercial splints, however, this is included in the purchase price of the LWS. The average time to fit and instruct patients on splint use was as follows: AWS 18 minutes, LWS 53 minutes, and RWS 24 minutes. The total cost for each splint, including fitting time and patient instructions were as follows: AWS $30 (CAD), RWS $58 (CAD), and LWS unchanged at $100 (CAD).

Six-month followup. At the end of the crossover trial, participants used the splint of their choice; 16 each selected the LWS and RWS, whereas 10 chose the AWS. Thirty-seven returned for a 6-month followup evaluation, 15 using the LWS, 14 with the RWS, and 8 with the AWS. Treating this as a single "splinted" group compared with baseline, improvements in pain and hand function were maintained at followup (last column, Table 3), with 1 exception. The AHFT applied dexterity score was not significantly different from the original baseline performance. Differences in response to the splint durability questions were as follows. A lower proportion of the LWS showed wear on the body of the splint (33% compared with 36% for RWS and 63% for AWS), but this was not a significant difference in chi-square analysis ($\chi^2 = 2.06$, $P = 0.36$). A higher proportion of the AWS showed worn edges and stitching (88% compared with 27% for LWS and 14% for RWS; $\chi^2 = 12.8$, $P = 0.002$). None of the RWS showed worn straps, whereas 13% of the AWS and 33% of the LWS did ($\chi^2 = 6.0$, $P = 0.05$). None of the 15 LWS required

Table 4. Effect of wrist splints on pain: repeated measures analysis of variance for within-subject effect of splints use compared with baseline

Source	Sum of squares	Degrees of freedom	Mean square	F	Significance
Within cells	35,154.75	114	308.37		
Splint use	3,920.26	3	1,306.75	4.24	0.007

Table 5. Effect of type of wrist splint on pain: repeated measures analysis of variance for within-subject effect of 3 splints

Source	Sum of squares	Degrees of freedom	Mean square	F	Significance
Within cells	23,790.52	76	313.03		
Splint type	1,719.36	2	859.68	2.75	0.07

replacement; however, 2 (25%) of the AWS and 1 (7%) of the RWS needed replacement ($\chi^2 = 4.4$, $P = 0.11$). Participants reported wearing their chosen splint an average of 12 hours per week. This report was their best estimate, as daily diaries were not kept for the 6 months between study end and followup.

DISCUSSION

The primary outcome of interest in this trial was perceived wrist pain because this is the main reason patients are referred to our clinic for wrist splints. The study participants, on average, reported moderate pain at baseline. Although all 3 splints reduced pain, the LWS showed the greatest benefit reducing pain from 4.1 to 2.8 cm on the VAS, a difference of approximately half a standard deviation. The LWS may have provided better pain relief because of its custom fit. Whether or not the magnitude is of practical importance is something that is best determined by the individuals experiencing the pain. However, on the splint preference questionnaire administered at the end of the third intervention, all subjects indicated that they preferred using a splint over no splint at all. That 37 of the 45 who entered the trial returned for followup 6 months later, were still using their splints, and continued to report less pain, suggests that they were satisfied with this change.

After 1 month of use, all wrist splints improved grip and pinch strength, consistent with 3 previous studies (2,5,8) but not with all studies summarized in Table 1. The magnitude of the improvement is small and the practical significance of these changes is difficult to assess. However, even a small improvement may enable a person to complete a task, especially if the person is near the threshold for the strength required to do it. A report on pinch forces noted that nondisabled female workers use an estimated 4.2 lb (1.9 kg) to use a staple remover (17). If an individual's strength was just below that threshold and the splint improved their pinch by as little as 0.3–0.5 kg (as observed in the present study), this could make the difference between function and dysfunction in the everyday tasks of the worker with arthritis. The cumulative effect of improving strength for a repetitive activity may also have a greater impact over the course of the day.

Table 6. Pair-wise comparisons, using *t*-tests; showing effect of splints on pain*

Splint pair (n)	Mean pain rating (10-cm VAS)	SD	*t* statistic	*P*
AWS versus	3.8	2.6	2.63	0.01
LWS (41)	2.9	2.4		
AWS versus	3.8	2.7	1.27	0.21
RWS (40)	3.2	2.6		
LWS versus	2.7	2.5	−1.36	0.18
RWS (42)	3.3	2.6		

* VAS = visual analog scale; AWS = Anatomical Technologies elastic wrist support; LWS = leather wrist splint (custom); RWS = Rolyan wrist extensor orthosis.

In contrast to previous studies, hand dexterity was not compromised by any of the splints. In fact, splint use improved the speed with which participants could complete 5 of the 6 dexterity tasks in the AHFT. Pegboard dexterity was not significantly different from baseline after 4 weeks of splint use. Previous studies reported declines in dexterity activities (3,7), although they used different measures of dexterity than the AHFT. These studies may have demonstrated a detrimental effect of wrist splints on hand dexterity because they measured the effect of the splints after a shorter period of time (1 week). Because repeated measures were used in the present study, it could be argued there was a practice effect on the dexterity measures, and the dexterity data show a return to baseline in the washout following the LWS but not after the AWS or RWS. Therefore, it would be inappropriate to attribute the small improvement in hand dexterity to the wrist splints. The important finding, however, is that the splints did not hamper dexterity. We measured hand function after 4 weeks of splint use, which provided participants with ample time to adapt to using the splint and slightly new patterns of movement. The clinical implication is that clients should be informed that it may take some time to become accustomed to using the splint, after which the splint is likely to reduce pain and increase strength, without compromising dexterity.

A strength of this study was the length of the intervention period for each splint, 4 weeks, which improves upon prior studies on splint effectiveness assessing immediate or short-term effects. It is limited, however, by one of the measures selected to capture the effect of the wrist splints. The MACTAR did not seem to show changes in functional activities—at least, the scores did not change. However, patients in our clinic reported functional improvements and this has also been noted by Nordenskiold (2). In that study, patients suggested that splints were helpful for activities requiring endurance, such as vacuuming a room. One-quarter of their subjects had to stop a 3-minute vacuuming task due to pain, but were able to complete it when wearing a wrist orthosis. There may be a mismatch between the MACTAR and the construct we had hoped it would measure—perceived functional ability, a construct of importance to people with RA. Perhaps a different functional measure, such as a VAS with specific functional

performance questions or the Canadian Occupational Performance Measure (18,19), would better capture changes in function reported by patients. Or, given the highly localized nature of the intervention, perhaps an upper limb functional questionnaire like the Disabilities of the Arm, Shoulder and Hand (20) or Cochin Hand Disability Scale (21) would be more appropriate. Further research should also seek to identify what magnitude of change in pain, hand function, or other measures are required to translate into meaningful improvements for participating in everyday activity.

The use of a wrist splint improved pain and enhanced hand function compared with no splint. The custom-made LWS and commercially available RWS had similar effects and both were superior to the AWS. Although the LWS demonstrated greater pain relief, and the RWS resulted in greater hand strength; in pair-wise comparisons they were not significantly different from each other. Stern and colleagues (4) reported that splints fastened with D-ring straps, like the LWS and RWS in the present study, were preferred by a higher proportion of patients. An equal number of participants preferred the LWS and RWS. The custom-made LWS, however, is more expensive than the RWS, and if cost is a consideration the difference between the 2 splints may not be adequate to justify the more expensive option. Furthermore, not all occupational therapy departments will be equipped to provide custom-fabrication services, in which case the RWS appears to be a satisfactory choice.

We wanted to evaluate the LWS, a popular choice for custom splints in our setting, but acknowledge that other settings use custom splints made with low-temperature thermoplastics. Our results may not generalize to other splint designs. Tijhuis and colleagues (9) compared a high-temperature thermoplastic splint with the Futuro commercial splint, and reported essentially equivalent effects for both. The present study adds to the body of knowledge regarding the effect of wrist splints on pain and function in adults with inflammatory arthritis. As noted in the systematic review by Egan and colleagues (11), additional clinical trials are required to gather sufficient evidence to conclude that wrist splints achieve their intended purpose of reducing pain and enhancing function.

ACKNOWLEDGMENTS

The authors thank Lori Cyr and Hazel Mackie for their service as the independent outcome evaluators, Jonathan Berkowitz for providing statistical analyses, and Andrea Mitchell for updating the literature review.

REFERENCES

1. Harrell PB. Splinting of the hand. In: Robbins L, Burckhardt CS, Hannan MT, DeHoratius RJ, editors. Clinical care in the rheumatic diseases. 2nd ed. Atlanta (GA): American College of Rheumatology; 2001. p. 191–6.
2. Nordenskiold U. Elastic wrist orthoses: reduction of pain and increase in grip force for women with rheumatoid arthritis. Arthritis Care Res 1990;3:158–62.
3. Pagnotta A, Baron M, Korner-Bitensky N. The effect of a static wrist orthosis on hand function in individuals with rheumatoid arthritis. J Rheumatol 1998;25:879–85.
4. Stern EB, Ytterberg SR, Larson LM, Portoghese CP, Kratz WN, Mahowald ML, et al. Commercial wrist extensor orthoses: a descriptive study of use and preference in patients with rheumatoid arthritis. Arthritis Care Res 1997;10:27–35.
5. Kjeken I, Moller G, Kvien TK. Use of commercially produced elastic wrist orthoses in chronic arthritis: a controlled study. Arthritis Care Res 1995;8:108–13.
6. Stern E, Ytterberg SR, Krug HE, Mullin GT, Mahowald ML. Immediate and short-term effects of three commercial wrist extensor orthoses on grip strength and function in patients with rheumatoid arthritis. Arthritis Care Res 1996;9:42–50.
7. Stern E, Ytterberg SR, Krug HE, Mahowald ML. Finger dexterity and hand function: effect of three commercial wrist extensor orthoses on patients with rheumatoid arthritis. Arthritis Care Res 1996;9:197–205.
8. Backman C, Deitz JC. Static wrist splint: its effect on hand function in three women with rheumatoid arthritis. Arthritis Care Res 1988;1:151–60.
9. Tijhuis G, Vliet Vlieland TPM, Zwinderman AH, Hazes JMW. A comparison of the futuro wrist orthosis with a synthetic thermolyn orthosis: utility and clinical effectiveness. Arthritis Care Res 1998;11:217–22.
10. Stueltjiens EMJ, Dekker J, Bouter LM, Van Schaardenburg D, Van Kuyk M-AH, Van Den Ende CHM. Occupational therapy for rheumatoid arthritis: a systematic review. Arthritis Rheum 2002;47:672–85.
11. Egan M, Brousseau L, Farmer M, Ouimet MA, Rees S, Wells G, et al. Splints/orthoses in the treatment of rheumatoid arthritis. Cochrane Database of Systematic Reviews; 2003. URL: www.cochrane.org.
12. Klinkhoff A, Bellamy N, Bombardier C, Carette S, Chalmers A, Esdaile JM, et al. An experiment in reducing interobserver variability of the examination of joint tenderness. J Rheumatol 1988;15:492–4.
13. Huskisson EC. Measurement of pain. J Rheumatol 1981;9: 768–9.
14. Backman C, Mackie H, Harris J. Arthritis hand function test: development of a standardized assessment tool. Occup Ther J Res 1991;11:245–56.
15. Backman C, Mackie H. Arthritis hand function test: inter-rater reliability among self-trained raters. Arthritis Care Res 1995; 8:10–5.
16. Tugwell P, Bombardier C, Buchanan WW, Goldsmith CH, Grace E, Hanna B. The MACTAR patient preference disability questionnaire: an individualized functional priority approach for assessing improvement in physical disability in clinical trials in rheumatoid arthritis. J Rheumatol 1987;14:446–55.
17. Bao S. Grip strength and hand force estimation. Safety and Health Assessment and Research for Prevention (SHARP) Program; technical report no. 65-1-2000. Olympia (WA): Department of Labor and Industries; May 2000.
18. Law MC, Baptiste S, Carswell A, McColl MA, Polatajko H, Pollack N. The Canadian occupational performance measure. 3rd ed. Ottawa (ON): CAOT Publications; 1998.
19. Ripat J, Etcheverry E, Cooper J, Tate R. A comparison of the Canadian Occupational Performance Measure and the Health Assessment Questionnaire. Can J Occup Ther 2001;68:247–53.
20. Beaton D, Katz JN, Fossel AH, Wright JG, Tarasuk V, Bombardier C. Measuring the whole or parts? Validity, reliability and responsiveness of the Disabilities of the Arm, Shoulder and Hand outcome measure in different regions of the upper extremity. J Hand Ther 2001;14:128–46.
21. Duruoz MT, Poiraudeau S, Fermanian J, Menkes CJ, Amor B, Dougados M, et al. Development and validation of a rheumatoid hand functional disability scale that assesses functional handicap. J Rheumatol 1996;23:1167–72.