Efficacy of Wrist Working Splints in Patients With Rheumatoid Arthritis: A Randomized Controlled Study

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Objective. To investigate the efficacy of wrist working splints after a period of splinting in patients with rheumatoid arthritis (RA).

Methods. We performed a 4-week randomized controlled trial among 33 RA patients with wrist arthritis. Patients were randomly allocated to the splinting group (n = 17) or the control group (n = 16). Patients in the splinting group received a prefabricated wrist working splint and were instructed to use this splint as much as possible during the day. The primary outcome measure was average wrist pain during the past week, measured using a visual analog scale (VAS). Secondary outcome measures were grip strength and functional ability. The latter was measured using the Disabilities of the Arm, Shoulder, and Hand questionnaire and the short version of the Sequential Occupational Dexterity Assessment. Measurements were performed at baseline and after 4 weeks. Performance tests were performed without splint. Differences in change scores between the splinting and the control group were analyzed using analysis of covariance. To indicate the magnitude of the treatment effects, effect sizes were calculated.

Results. A large and highly significant treatment effect on wrist pain was found. VAS pain scores decreased by 32% in the splinting group and increased by 17% in the control group. Small and nonsignificant treatment effects were found with regard to nonsplinted grip strength and functional ability.

Conclusion. Prefabricated wrist working splints are highly effective in reducing wrist pain after 4 weeks of splint wearing in RA patients with wrist arthritis.

INTRODUCTION

Wrist arthritis is a prevalent health care problem. Seventy-five percent of rheumatoid arthritis (RA) patients have wrist arthritis (1). Arthritis is characterized by inflammation and proliferation of the synovial tissues. Clinical features are pain and swelling of the joint, and resulting features in the wrist are reduced grip strength and functional ability. Wrist working splints are prescribed, as an adjunct to drug treatment (2), to attempt to reduce pain and inflammation and improve functional ability by providing rest, support, and stabilization of the wrist (1–3).

Wrist working splints allow movement of the finger and thumb joints, enabling the performance of daily activities.

To our knowledge, 2 systematic reviews have been performed on the effects of wrist working splints in patients with RA (4,5). In the first review, the investigators concluded that there are indications that splints are effective in reducing pain, improving grip strength, and reducing dexterity (4). In addition to wrist working splints, different types of splints (resting splints, air-pressure splints, and antideformity splints) were included in the review. In the second review, the investigators indicated there is insufficient evidence to make conclusions about the effects of wrist working splints (5).

Most studies that have investigated the effects of wrist working splints have focused on effects measured immediately after the provision of the splint (6–12). In these studies, which were mostly noncontrolled, measurements with and without splint were successively taken and compared. The results of these studies show that the use of wrist working splints has positive effects on wrist pain (6–8,11), positive effects on perceived task difficulty and endurance (8), and negative effects on the time needed to accomplish tasks (7,10). Results with regard to grip strength were conflicting. Although the majority of these
studies found an improvement of splinted grip strength (6,11), some found a reduction of splinted grip strength (9) or no effect (12).

There have been few studies on the effects of wrist working splints measured after a period of splinting (9,11,13,14). In these studies, baseline measurements without splint were compared with measurements after a period of splinting (with and without splint). Statistically significant positive effects on pain and grip strength measured with splint were reported in only 1 noncontrolled study (14). No significant effects were found in the other studies. Controlled studies are necessary for drawing definite conclusions on the effects of wrist working splints after a period of splinting (4,5,14).

Adherence to the given treatment is a serious point of concern in efficacy studies because limited adherence affects outcome. Generally, adherence rates with splints are shown to be low (2,15), and data on adherence with wrist working splints are scarce. To our knowledge, only Haskett et al have reported detailed information on adherence (14). They found that 45 (96%) patients wore the splint according to the prescribed minimum of 10 hours per week. Because instructions for splint wear vary across studies, this result should be interpreted with caution.

The aim of this study was to investigate the efficacy of wrist working splints after 4 weeks of splinting in patients with RA. We used a randomized controlled study design. Because wrist working splints are primarily prescribed for pain relief (2), our primary outcome was wrist pain. For optimal adherence to splinting instructions, adherence-enhancing strategies based on our preceding study on the determinants of splint use (16) were applied.

### PATIENTS AND METHODS

**Study design and patients.** A randomized controlled trial was conducted. Participants were patients attending the rheumatology outpatient clinic of Medisch Spectrum Twente Hospital in Enschede, The Netherlands. They were selected by their attending rheumatologist. Inclusion criteria were diagnosis of RA according to the 1987 American College of Rheumatology (ACR; formerly the American Rheumatism Association) revised criteria (17), clinical signs of active arthritis of the wrist due to RA (clinical judgment of the attending rheumatologist), painful wrist (visual analog scale [VAS] score ≥30), stable disease-modifying antirheumatic drug therapy within the preceding 3 months and no expected changes for the next 4 weeks, stable symptomatic therapy (nonsteroidal antiinflammatory drugs and corticosteroids) within the preceding 2 weeks and no expected changes for the next 4 weeks, and age ≥18 years. Potential participants were excluded if they had received an injection of corticosteroid in the wrist or hand within the preceding month; exhibited severe deformities of the wrist and/or fingers affecting hand function or requiring a different splint than a prefabricated, commercially available wrist splint; had a history of wrist surgery; had a diagnosis of carpal tunnel syndrome or another neurologic disorder affecting hand function; or had used a wrist splint within the 2 weeks prior to participation in the study.

**Procedure.** After obtaining informed consent, patients were randomly allocated to the splinting group or the control group. Block randomization with a block size of 4 was used to ensure balance in the numbers of patients allocated to the groups. Group allocation was accomplished by the patients’ selection and opening of sealed envelopes.

Directly preceding the baseline assessments, patients in the splinting group were seen by an occupational therapist (OT). The OT fitted the patient’s most affected wrist with a commercially available, prefabricated wrist working splint at 10–20° of wrist extension. Because no particular splint suits all patients (13,18,19), patients had the choice of the following splints: the Rolyan D-Ring (Sprofit, Genk, Belgium), the GM005H, the GM008, and the GM009 (GM Medical Bracing, Best, The Netherlands). These splints all consist of a fabric gauntlet and have a removable volar metal stay. They differ in material, strapping method, and/or color. Patients were instructed to wear the splint during the day as much as possible, especially during activities, for a period of 4 weeks. To stimulate splint use, several educational and behavioral strategies were applied by the OT (Table 1). These strategies were established in a former study on the determinants of splint wearing (16). Patients were asked to record the number of hours that they wore the splint in a daily diary.

Patients in the control group received usual care for 4 weeks. After the study they were offered a wrist working

### Table 1. Strategies to increase patients’ adherence to wearing the wrist working splint*

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Description</th>
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<tbody>
<tr>
<td>Splint prescription by an expert (OT) to optimize splint fitting and perceived comfort.</td>
<td>Prescription of 2 splints (for the same wrist). Plastic gloves. Adjustment of the straps (cutting them at the correct size and folding and sewing them at the end). Distribution of written instructions on the purpose and function of the splint, wearing instructions, potential barriers, and washing instructions. Explanation of the importance of adherence. Keeping a daily diary of splint use by the patient. Telephone evaluation of splint use after 1 week of prescription by the OT. If necessary, advice is given and/or measures are taken.</td>
</tr>
</tbody>
</table>

* Strategies were derived from a former study on the determinants of splint use in patients with RA (16). OT = occupational therapist.
sclent. The study protocol was approved by the Ethics Committee of Medisch Spectrum Twente Hospital, Enschede, The Netherlands.

Outcome measures. At baseline, information was collected on age, sex, and disease activity (Disease Activity Score in 28 joints [DAS28]) (20). The primary outcome measure was wrist pain, and the secondary outcome measures were grip strength and functional ability. Measurements were performed at baseline and after 4 weeks, and the patient’s perceived change was noted afterwards. Neither the patients nor the assessor were blinded for the treatment allocation.

Pain. Wrist pain was measured using a 100-mm pain VAS with verbal anchors of no pain (0) and pain as bad as it can be (100) at each end. Patients were asked to mark with a vertical line the average amount of wrist pain they had perceived during the past week. The VAS pain belongs to the ACR core set of outcome measures for RA trials (21).

Grip strength. Grip strength was measured in kPa using a Martin Vigorimeter (Gebrüder Martin, Tuttlingen, Germany), which is a dynamometer with an air-filled rubber balloon. Patients were instructed to squeeze the balloon as hard as possible, and the mean of 3 measurements was used. Measurements were taken without splint. The Vigorimeter has been shown to be a reliable instrument for assessing grip strength in patients with RA (22).

Functional ability. Functional ability was measured with the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, and the short version of the Sequential Occupational Dexterity Assessment (SODA-S). The DASH is a self-administered, 30-item questionnaire designed to measure physical function and symptoms associated with any condition in the upper limb (23,24). The questionnaire includes 21 physical function items (e.g., prepare a meal, turn a key), 5 symptom items (e.g., pain, weakness), and 4 social/role function items (e.g., extent to which arm, shoulder, or hand problems interfere with normal social activities with family and friends). The questionnaire has been validated in rheumatic conditions (25–27) and many languages, including Dutch (27). The DASH score ranges from 0 to 100, where 0 = minimum disability and 100 = maximum disability.

The SODA-S is designed to measure bimanual hand function in RA (28), and it consists of 6 standardized, hand-related daily activities (3 unilateral, 3 bilateral) performed under controlled conditions without splint. A research nurse rated the patient’s performance on each activity (4 = able to perform in the requested way, 3 = able to perform in a different way, 2 = unable to perform). The bilateral tasks were scored separately for each hand. The patient rated the level of difficulty with an activity (2 = not difficult, 1 = some difficulty, 0 = very difficult). The total score, which is a combination of these 2 scores, was computed, ranging from 0 to 48, where 0 = low dexterity and 48 = high dexterity. The SODA-S pain score was computed by counting the number of activities that caused pain (range 0–6). The psychometric properties of the SODA-S have shown to be acceptable (28,29).

Patients’ perceived changes. After 4 weeks, patients completed several transition items to describe the magnitude and direction of perceived changes in wrist pain, grip strength, and functional ability over the 4-week period. Patients were asked to compare their current situation with their situation 4 weeks previous. Perceived changes were scored on a 5-point scale (where −2 = much deteriorated, −1 = a little deteriorated, 0 = unchanged, 1 = a little improved, and 2 = much improved) (30,31).

Statistical analyses. Power calculation yielded a target sample size of 54 patients (27 in each group) to detect a difference of 15 mm on the VAS for wrist pain with 80% power and a 1-sided significance level of 0.05. For this calculation we used data from a previous study on wrist working splints, in which the mean ± SD VAS pain score at baseline was 54 ± 22 (13). A difference of 15 mm corresponds to an improvement of ~30%, which is considered clinically relevant (32–35). Comparison of the splinting group and the control group at baseline was evaluated using the independent samples t-test and the Mann-Whitney U test for continuous variables, and the chi-square test for categorical variables.

Change scores were computed by subtracting the baseline scores from the scores at 4 weeks. Differences in change scores between the splinting group and the control group were analyzed using analyses of covariance (ANCOVAs) with the baseline scores of the outcome variable as the covariate. Assumptions for performing parametric ANCOVA were normal distributed data, homogeneity of variance, and homogeneity of regression. If the change scores of a variable did not fulfill the assumption of homogeneity of regression, nonparametric ANCOVA was performed (36–38). First, residuals were calculated by linear regression analysis with the change scores of this variable as the dependent variable and the baseline scores as the independent variable. The residuals were then used as data points, and differences between the splinting group and the control group were analyzed with the Mann-Whitney test. The Mann-Whitney test was also used to compare patients’ perceived changes with regard to changes in wrist pain, grip strength, and functional ability.

To give an indication of the magnitude of the treatment effects, effect sizes or standardized mean differences (Hedges’ g) were calculated as the difference between the mean change of the intervention group and the control group divided by the pooled SD. A correction factor was applied to adjust for small and unequal sample sizes (39). An effect size of 0.2 was considered a small effect, 0.5 a moderate effect, and 0.8 a large effect (40).

Data analysis was performed using the Statistical Package for the Social Sciences, version 12.0.1 (SPSS, Chicago, IL). Data were analyzed on an intent-to-treat basis.

RESULTS

A total of 33 patients were enrolled in this study. Seventeen patients were allocated to the splinting group and 16 to the control group. All patients completed the study. Mean ± SD age was 60.3 ± 10.8 years in the splinting
Table 2. Baseline scores on outcome measures, changes at 4 weeks, and indices for the treatment effect.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Splinting Group (n = 17)</th>
<th>Control Group (n = 16)</th>
<th>Treatment Effect</th>
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<tbody>
<tr>
<td></td>
<td>Changes at 4 weeks</td>
<td>Baseline</td>
<td>P</td>
</tr>
<tr>
<td>VAS wrist pain score (range 0–100)</td>
<td>52.9 ± 16.8</td>
<td>55.1 ± 10.0</td>
<td>0.002</td>
</tr>
<tr>
<td>SODA-S painful activities, n (range 0–6)</td>
<td>1.8 ± 1.5</td>
<td>1.3 ± 1.3</td>
<td>0.045</td>
</tr>
<tr>
<td>GRIP strength, kPa</td>
<td>25.0 ± 15.5</td>
<td>20.5 ± 13.9</td>
<td>0.047</td>
</tr>
<tr>
<td>DASH score (range 0–30)</td>
<td>39.0 ± 13.5</td>
<td>40.5 ± 12.1</td>
<td>0.349</td>
</tr>
<tr>
<td>SODA-S score (range 0–48)</td>
<td>44.0 ± 5.1</td>
<td>43.5 ± 3.9</td>
<td>0.600</td>
</tr>
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</table>

**Effect size**

- **Power**: 0.90

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**Pain outcomes.** Mean VAS pain scores at baseline and after 4 weeks are shown in Figure 1. In the splinting group, mean VAS pain scores decreased by 32% after 4 weeks of splinting. In the control group, mean VAS pain scores increased by 17%. Change scores were significantly different between both groups (F[1,30] = 11.1, P = 0.002). The effect size was −1.24, indicating a large treatment effect of wrist working splints on VAS-measured pain.

The number of SODA-S activities that were painful to perform decreased by 50% in both splinting and control groups. Differences in change scores between the groups were not significant (P = 0.191). The majority of patients in the splinting group were female (71%) and in the control group, male (69%). Disease duration was 8.2 ± 6.8 years in the splinting group and 5.0 ± 4.6 years in the control group. The majority of patients in both groups were female (71% and 69%, respectively). Mean ± SD DAS28 scores at baseline were 4.37 ± 1.01 and 4.34 ± 1.33, respectively, both indicating moderate disease activity. There were no significant differences in patient characteristics between the splinting and the control group at baseline (P ≥ 0.05).

The majority of the patients (n = 10) in the splinting group were fitted with the Rolyan D-Ring. Three patients chose the GM005H, 3 patients chose the GM009, and 1 patient chose the GM008. In most patients (n = 10), the dominant hand was splinted. Two patients did not fully complete the daily diary on splint use, and 1 patient did not return the diary. The other patients wore the splint during 60–100% of the days. During these days they wore the splint for at least 2 hours, with a mean ± SD duration of 11.4 ± 2.5 hours per day.

During the treatment period, 2 patients in the control group reported changes in their usual treatment. One patient stopped prednisone treatment without exacerbation and another patient unsuccessfully decreased prednisone dosage and had to return to the previous dosage. Replication of the analyses without these patients did not change the results substantially (data not shown).

The scores on the outcome measures at baseline and the change scores at 4 weeks are shown in Table 2. No baseline differences were found between the splinting and the control group. Table 2 also shows the results of the ANCOVAs and the effect sizes.
effect size indicated a small treatment effect (Hedges’ $g = -0.45$).

**Grip strength outcomes.** Mean grip strength scores were slightly increased (5%) in the splinting group and slightly decreased (8%) in the control group. No significant differences were found between the change scores in the groups. The effect size indicated a small treatment effect (Hedges’ $g = 0.45$).

**Functional ability outcomes.** In the splinting group and the control group, DASH and SODA-S scores were slightly improved after 4 weeks. Change scores were not significantly different between both groups. Treatment effects were small, as shown by the effect sizes (Hedges’ $g \leq 0.34$).

**Changes perceived by patients.** Patients’ retrospective judgments of changes in wrist pain, grip strength, and functional ability are summarized in Table 3. Patients in the splinting group generally judged their wrist pain and functional ability to have improved, but patients in the control group judged their wrist pain and functional ability to have deteriorated. These differences between the groups were significant ($P \leq 0.01$). No significant differences were found with regard to grip strength. Both the splinting group and the control group judged their grip strength as unchanged.

**DISCUSSION**

To our knowledge, this is the first randomized controlled study that clearly reveals evidence that wrist working splints are effective in reducing wrist pain in patients with RA who have wrist arthritis. We empirically studied the effects of wrist working splints after a period of splinting. Although it is tempting to question the underlying mechanism, we can only generate hypotheses about this. Wrist working splints are supposed to reduce wrist motion and to provide rest, support, and stabilization of the wrist. On the one hand, this might reduce pain and improve function only while worn, but, on the other, it might reduce pain and improve function by reducing local inflammation.

Because wrist working splints are mainly prescribed for pain reduction, wrist pain was our primary outcome measure (2). To measure wrist pain we used a VAS, which is a common measure in pain and splint studies and belongs to the ACR core set of outcome measures for RA trials. We asked patients to report their average amount of wrist pain during the past week. Patients in the splinting group showed an average pain reduction of 32%, but the controls showed an average pain increase of 17%. This difference in change scores between the groups was significant and indicated a large and clinically meaningful treatment effect (32–35). Because all patients in the splinting group used wrist working splints in the week preceding the final assessments, this treatment effect might be attributed to both the immediate effect of wrist working splints (i.e., wrist support, wrist stabilization, and reduced wrist motion) and to reduced inflammation.

As an additional measure, we counted the number of SODA-S activities that caused pain. A small but not significant treatment effect was found. This might be explained by the small number of patients included in this study and/or the lack of responsiveness of the selected outcome measure. Because all SODA-S activities were performed without splint, the explanation also might be that wrist working splints only have an immediate effect on wrist pain and do not reduce inflammation.

Our findings are largely in line with the results of previous studies on the effects of wrist working splints after a period of splinting. We have to note, however, that differences exist between our study and these other studies with regard to the amount of splint use, outcome measures, and/or splinting period. Tijhuis et al (13) and Haskett et al (14) performed noncontrolled studies and found reduced VAS pain scores after 2 and 4 weeks of splinting, respectively. Only the results of Haskett et al (14) reached statistical significance. They focused on activity pain and compared measurements taken without splint at baseline with measurements taken with splint at followup. Whether Tijhuis et al assessed wrist pain with or without splint cannot be deduced from their report (13). Kjeken et al performed a randomized controlled study and found no significant difference in VAS activity pain scores between patients who used a wrist working splint for 6 months and patients who did not (11). Their followup measurements, however, were performed without splint. Therefore, Kjeken et al did not include the immediate effect of wrist working splints. Further investigation of the underlying mechanism of the effect of wrist working splints after a period of splinting is recommended. This knowledge will help clinicians give adequate wearing instructions.

In the current study, small and nonsignificant treatment effects were found with regard to nonsplinted grip strength and functional ability. These findings are in accordance with previous studies. Although wrist working splints may immediately increase splinted grip strength (6,11,14), they do not seem to affect nonsplinted grip strength after a period of splinting (9,11,13). We used the subjectively rated DASH and the more objectively rated SODA-S as measures of functional ability. Both measures are intended to assess a patient’s ability to perform hand-related daily activities. In literature, no gold standard measure of functional ability or dexterity exists. Several subjective and objective measures have been used to assess the effect of

| Table 3. Patients' perceived changes in the splinting group and the control group over 4 weeks* |
|---------------------------------|-----------------|-----------------|-----------------|
|                                | Splinting (n = 17) | Control (n = 16) | $P^+$           |
| Pain                           | 0.50 ± 0.87      | −0.50 ± 0.63    | 0.001           |
| Grip strength                  | 0.00 ± 0.87      | 0.00 ± 0.89     | 0.858           |
| Dexterity                      | 0.50 ± 0.87      | −0.50 ± 0.63    | 0.001           |

* Values are the mean ± SD. Splinting group used a wrist working splint as adjunct to usual treatment; control group received usual care. Scores range from −2 (much deteriorated) to 2 (much improved).

$^+$ Between-group differences investigated with Mann-Whitney tests.
wrist working splints on functional ability (7,8,10,11,14). No significant treatment effects on functional ability were found after a period of splinting (irrespective of splint use) (10,11,14). Although different outcome measures were used, this finding is in line with our study results.

We used transition items as additional measures to assess the effects of wrist working splints. Transition items provide a retrospective assessment of perceived change. Although transition items have been criticized for being prone to recall bias, they might be more responsive in detecting small but important changes than change scores that are derived from repeated measurements (31,41). The results with regard to pain and grip strength were highly in accordance with the results obtained with serial measurements. Functional ability results were conflicting, however. The transition item revealed significant differences between the splinting and the control group with regard to perceived changes from baseline, but the DASH and the SODA-S responses did not show these differences. As stated, this might be attributed to a lack of responsiveness of both measures for detecting small changes.

Patients in the splinting group were instructed to wear the splint during the day as much as possible, especially during the performance of daily activities, for the duration of 4 weeks. This wearing time is supposed to be sufficient to capture the effects of wrist working splints after a period of splinting. A strength of this study is that we took into account the adherence of the patients to these wearing instructions, first by applying adherence-enhancing strategies and second by evaluating the amount of splint use with a daily diary. Generally, adherence was considered good, as shown by the number of hours the splints were worn during the day. We should note, however, that we cannot conclude with certainty that our adherence-enhancing strategies improved splint use.

Our study has several limitations. The first possible limitation concerns the small sample size. We were not able to include the intended number of patients derived from the power analysis. The small sample size reduced the power of this study to find significant treatment effects (Table 2). Another limitation concerns the possibility of expectation bias. Neither the patients nor the assessor were blinded to the treatment allocation. The results might therefore have been influenced by the expectation of a treatment effect.

In conclusion, the results of this randomized controlled study show that 4 weeks of splinting with a prefabricated wrist working splint has a large and significant effect on perceived wrist pain in RA patients who have wrist arthritis. Small but nonsignificant treatment effects were found with regard to nonsplinted grip strength and functional ability.

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REFERENCES


