The clinical effectiveness of static resting splints in early rheumatoid arthritis: a randomized controlled trial

J. Adams¹, J. Burridge¹, M. Mullee², A. Hammond³ and C. Cooper⁴

Objective. To evaluate the effectiveness of static resting splints in early RA.

Methods. A multicentre, randomized, trial was conducted. Patients (n = 120) received either static resting splints [positioned with the wrist in neutral, MCP joint (MCPJ) and IP joint (IPJ) in a maximum of 60° and 30° of flexion, respectively] plus standardized occupational therapy or standardized occupational therapy alone. Change in grip strength (Ns), structural impairment (MCPJ ulnar deviation), applied dexterity (Button Board), self-report hand ability [Michigan Hand Outcomes Questionnaire (MHQ)], hand pain and morning hand stiffness were assessed at 0 and 12 months.

Results. Data for 56 (97%) splinted and 60 (97%) control group patients were analysed. Splint wear adherence was moderate; 24.5% ‘never wore’ the splints. The adjusted mean difference between groups for handgrip was –14.2 Ns (P = 0.342; 95% CI –31.4, 2.9); MCPJ ulnar deviation –1.1° (P = 0.657; 95% CI –2.0, 0.9); dexterity 0.1 s (P = 0.975; 95% CI –0.6, 2.5) and self-report ability –3.0 on the MHQ score (P = 0.426; 95% CI –10.5, 4.5). Pain scores were unchanged in either group (P = 0.15). The occurrence of morning hand stiffness was reduced in a small group of splinted patients (P = 0.021), but the duration shortened in control patients (P = 0.010).

Conclusions. There was no significant difference between the two interventions on grip strength, deformity, hand function and pain. The data favoured the control group and this study suggests that resting splints should not be used as a routine treatment of patients with early RA.

Key words: Static splint, Rheumatoid arthritis, Hand, Occupational therapy.

Introduction

RA is a chronic, systemic, autoimmune disorder of unknown aetiology. RA has a wide clinical spectrum, principally targeting synovium, and may vary from mild, non-erosive disease to severe inflammation and joint damage [1]. Referred to as ‘the commonest potentially treatable cause of functional disability’ [2], RA can lead to structural impairment [3], functional disability and restriction in social participation [4–6]. Synovitis affecting the wrist and hand may occur early [7, 8] leading to localized pain [9]; potential hand joint erosions [10], structural impairment and deformity [11, 12] and reduction in upper limb functional performance [13, 14] to potentially devastating levels [15]. Impaired hand function leading to an inability to carry out daily living activities has been cited as the main reason why institutional care is needed for individuals with RA [13].

One of the most widely used localized conservative interventions for addressing these potential localized wrist and hand difficulties by UK occupational therapists are static splints [16] (Fig. 1).

The static splinting position used in the UK is based upon the recommendations of Fess and Philips [17] placing the metacarpal joints in slight to moderate flexion. These splints have been used for the last 40 yrs in the UK with little change in design. Treatment goals include: decreasing hand and wrist pain, [16, 18]; improving hand function [19]; reducing swollen and inflamed hand joints [20]; reduction or prevention of deformity and soft tissue contractures [21]. Adherence to splint wear improves when soft rather than hard thermoplastic splints are used [22]. The literature currently available investigating the effectiveness of static resting splints is limited. The majority of studies have originated from a time when drug control of disease activity used different less aggressive protocols and have not considered splint usage in early disease [19, 20, 23]. The most recent systematic reviews [24–26] conclude that there is insufficient evidence to support their use. As such a randomized controlled trial in patients who receive optimal drug therapy during the early stages of RA was warranted.

The aim of this study was to evaluate the clinical effectiveness of static resting splints in an early RA population. The study hypothesis was that there would be a difference in the change of hand function after 12 months in patients with early RA who received standardized occupational therapy plus static resting splints compared with standardized occupational therapy alone.

Methods

Study design

The study was a prospective, multicentre single-blind randomized controlled trial conducted in the UK. The trial follow-up period was 12 months and measurements were taken at baseline (prior to randomization), and at 12 months by one independent therapy researcher (J.A.) masked to treatment allocation.

Patients

Outpatients aged 18 yrs and over with a confirmed (or suspected) diagnosis of RA from a consultant rheumatologist using ACR revised criteria [27], with a disease duration of <5 yrs, were asked to participate. Patients with a hemiparesis, from a vulnerable group or with severe cognitive difficulties were excluded.

Procedures

A study steering committee of collaborating expert clinical occupational therapists and clinical academics across the eight regional hospital departments was set up prior to the study commencing. This committee agreed on quality issues regarding splintage positioning, standardization of treatment and follow-up across centres.

Following full ethical committee approval, eligible patients referred to occupational therapy departments at eight
Effectiveness of static resting splints in RA

Measuring adherence in rehabilitation is predominantly reliant on self-report. Self-report is likely to overestimate real adherence levels [29]. As diarized options for measuring adherence were poorly received in this pilot study, an ordinal questionnaire was used.

Outcome measures

The primary outcome measure was grip strength 12 months after intervention, measured in newtons using an MIE digital grip analyser (MIE Medical Research, Leeds, UK) and standardized measurement protocols [30]. Handgrip strength has been validated as a sound indicator of broader subjective hand function, strongly correlated with hand pain [31], hand deformities, hand inflammation [32] and hand stiffness [33].

Secondary outcome measures evaluated structural impairment and hand functional ability. These included a summary score of dominant hand MCPJ ulnar deviation of the dominant index, middle ring and little fingers, using a 360° goniometer placed over the dorsum of the joint axis [34]. Hand function was measured using the applied dexterity task (the Button Board) from the Arthritis Hand Function Test [35]. The MHQ [36] measured self-report hand function. Self-report pain and stiffness levels were recorded using a 5-point scale for pain (1 = no pain to 5 = very severe pain) and a 6-point scale for duration of early morning wrist and hand joint stiffness (1 ≤ 30 min; 2 = 30 min to 1 h; 3 = 1–2 h; 4 = 2–4 h; 5 = 4 h; 6 = all day) [37].

Baseline disease characteristics recorded included: time since symptomatic onset and diagnosis; 28-joint articular index [38]; current medications; general functional ability using the HAQ [39]; and socio-demographic data.

Splint group patients also completed a 7-point ordinal scale of estimated hours per week of splint wear (1 = none; 2 ≤ 5; 3 = 5; 4 = 10; 5 = 20; 6 = 30; 7 = 48+) and perceived effectiveness of their splints using a 5-point ordinal scale (1 = not at all; 2 = a little; 3 = somewhat; 4 = moderately; 5 = very).

Sample size

Sample size was informed by published 12-month grip strength longitudinal data from two studies of early RA recruiting a similar UK RA population [6, 40]. A study sample of 57 patients per group provided 80% power to detect a 50% difference in treatment effect between the two groups, assuming two-sided significance levels of 5%. In the absence of similar longitudinal rehabilitation intervention trials, a clinically useful difference between treatments was informed by the steering committee for this trial.

Statistical analysis

Clinical effectiveness of the splints was analysed by comparing the two groups at 12 months for differences in grip strength, structural impairment, functional dexterity and self-report function and impairment. All outcomes were analysed on an intention to treat basis. Only fully completed self-report MHQ data were entered for analysis (n = 80, 69%).

Analysis of covariance (ANCOVA) was carried out for grip strength, MCPJ deviation, applied dexterity and the MHQ. The ANCOVA adjusted for baseline outcome measures and any potential confounders that differed between the groups by chance. These included baseline 28-joint articular index and number of wrist and hand IA steroidal injections. Mann–Whitney U-tests were used to compare ordinal, scaled self-report responses and Spearman’s r_{s} to explore correlations between self-report splint wear adherence and splint effectiveness. McNemar’s test compared changes from baseline to follow-up for binary outcomes.

Results

One hundred and forty-eight patients were assessed for eligibility; 120 were accepted and randomized. One hundred and eleven patients (95.7%) had active wrist or hand joint inflammation
at baseline as determined by the Ritchie tender joint count. Baseline demographic data and disease characteristics are shown in Table 1. There were no substantial clinical differences between groups at study entry in demographic and disease prognostic factors. The majority of patients were women, not currently employed and had left full-time education before 16 yrs of age. There were no substantial differences between groups for changes in medication and intramuscular steroid injections over the study duration. There were no losses to follow-up and progress through the trial is shown in Fig. 2.

Eighty patients (68.97%) had sufficient baseline and follow-up data to permit change scores to be computed for the MHQ. Data were not imputed and a responder’s analysis was carried out for self-report MHQ data.

Masking of the assessor to group allocation remained successful in 103 (89%) cases. Allocation concealment was lost when patients were wearing splints, had left their view during assessment home visits or had requested assistance in completing the splint adherence section of the questionnaire. None of the control group had worn static resting splints over the study duration.

Self-report adherence and splint effectiveness

Self-reported adherence to resting splint wear was moderate. Of the 49 (87.5%) patients who reported adherence, 12 (24.5%) reported that they had ‘never worn’ the splints during the 12 months; 10 (20.4%) wore the splints for <5 h per week; 11 (22.4%) wore their splints between 5 and 29 h; 4 (8.2%) wore the splints for >30 h a week; and 12 (24.5%) wore the splints for >48 h a week. Forty-seven (84%) splinted patients reported perceived resting splint effectiveness; six (12.8%) reported the splints to be very effective; 13 (27.7%) moderately effective; 4 (8.5%) somewhat effective; 12 (25.5%) a little effective; and 12 (25.5%) not at all effective. The relationship between splint adherence and perceived effectiveness was negative and weak ($r_s = -0.26$). Table 2 presents the main results.

Primary outcome: grip strength change

Baseline values for grip strength were comparable in both groups: the splint group had a lower mean baseline grip (120.27 ± 76.7 N) compared with the control group (137.72 ± 87.4 N). There was no evidence of significant adjusted differences in grip strength at 12 months between groups ($-14.2; 95\% \text{CI} = -43.7, 15.4; P = 0.342$) nor in the percentage of grip strength change over 12 months ($-46.55; 95\% \text{CI} = -110.7, 17.6; P = 0.152$).

Secondary outcomes

No significant differences between groups were detected for: dominant hand MCPJ ulnar deviation, difference $= -1.1^\circ$ ($-6.2, 3.9; P = 0.657$); carrying out the applied dexterity task (Button Board), difference $= 0.1$ s ($-6.6, 6.8; P = 0.975$); and self-report hand functional ability MHQ difference $= -3.0$ MHQ points ($-10.5, 4.5; P = 0.426$).

One hundred and five patients (91%) reported baseline and follow-up pain levels. Changes in wrist and hand pain scores were computed for 51 splint group (91%) and 54 control group (90%) patients. There was no evidence of significant differences in ordinal pain levels reported over the 12-month follow-up. The splint group and control group reported identical final pain levels $2.0 (2.0, -3.0; P = 0.150)$.

However, there was a significant decrease in the proportion of patients reporting early morning stiffness within the splint group [$73\% (37/51)$ at baseline vs $57\% (29/51)$ at follow-up, McNemar’s chi-square $P = 0.021$] but not within the control group [$81\% (43/53)$ at baseline vs $75\% (40/53)$ at follow-up, McNemar’s chi-square $P = 0.549$]. For the subgroup of patients reporting the occurrence of early morning stiffness, those within the control group reported a decrease in the median duration of early morning stiffness ($-40\%$) compared with the splint group ($-21\%$), but the difference was not significant ($P = 0.26$).
wrist and hand stiffness over 12 months 2.0 (1.0, −3.0); the splint group reported no change in early morning wrist and hand stiffness 3.0 (2.0, −6.0). The difference in change between the groups was statistically significant ($P = 0.01$).

**Discussion**

No statistically significant differences in the structural impairment and functional hand ability outcomes were found between patients receiving occupational therapy and static resting splints and occupational therapy alone over 12 months. Where clinical significant ranges have already been defined [41] there was no clinically significant difference in functional change between groups. The data showed that the control group improved when compared with the splint group in almost all outcomes. For a small subgroup of individuals the splints appeared to contribute a reduction in the occurrence of early morning stiffness. But for those people who continued to report early morning stiffness after 12 months the duration was significantly lowered in the control group.

This study indicates that static splinting provides no incremental beneficial effects in improving hand function in early RA. These results add further confirmation to the most recent systematic reviews [24–26, 42] that the current evidence to support static resting splints in early RA is lacking. However, clinicians have continued to provide these splints for many years and there must be confidence that they contribute to patient care in some way.

The trial recruited patients during early-stage RA disease. This has been seen to be a difficult time to establish the effectiveness of conservative rehabilitation therapies when disease activity is likely to be poorly controlled [43]. Uncontrolled disease activity will likely have a large effect on the measurement of functional performance and has the potential to contaminate results. Yet the aims of static splinting are pathophysiologically based, including the reduction of localized pain and inflammation control; these are early symptoms of the disease and ones that are likely to be present when the disease is less well controlled. The trial reflected the clinical practice and timing of static splint provision and controlled for baseline disease activity and localized IA injections in the ANCOVA analysis. Additionally, this trial was a relatively large longitudinal study when compared alongside other conservative rehabilitation studies, and was sufficiently powered to detect a clinically important difference if one existed. The direction of the change in outcomes favoured the control group and a larger, longer study may produce no difference in outcome. The two-tailed hypothesis for this study suggested that the starting point for this research was that the splint intervention could be considered to cause benefit or harm and negative results such as these need to be acknowledged [43].

The impact of medication may have overridden any beneficial impact between groups. Although not presented here, further analyses have been carried out examining subgroups of patients taking into account the differences by group for changes in medication and wrist and hand IA steroids. The results remained non-significant [44].

Early-stage RA could be ‘too early’ for splinting intervention. Hammond et al. [40] report that the success of occupational therapy requires patients to participate in positive changes to their health behaviours. During the early stages of disease people may not be ready to change behaviour (i.e. wear their splints) and may not perceive the potential threats of the disease as

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**Table 2. Primary and secondary outcomes at 12-month follow-up**

<table>
<thead>
<tr>
<th>Treatments</th>
<th>Splints plus occupational therapy (n = 58)</th>
<th>Occupational therapy (n = 60)</th>
<th>Difference between groups</th>
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</thead>
<tbody>
<tr>
<td><strong>Primary outcome: handgrip (n = 58)</strong></td>
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<tr>
<td>Grip strength (Ns)</td>
<td></td>
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<tr>
<td>LS mean*</td>
<td>147.2</td>
<td>161.3</td>
<td>−14.2</td>
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<td>10.6</td>
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<tr>
<td>95% CI</td>
<td>−43.6, 15.4</td>
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<tr>
<td>$P$-value</td>
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<tr>
<td>Grip strength (% change)</td>
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<td>LS mean*</td>
<td>32.7</td>
<td>79.3</td>
<td>−46.6</td>
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<tr>
<td>S.E.M.</td>
<td>23.1</td>
<td>21.6</td>
<td>32.2</td>
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<tr>
<td>95% CI</td>
<td>−110.7, 17.6</td>
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<td><strong>Secondary outcomes</strong></td>
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<td>MCPJ ulnar deviation</td>
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<tr>
<td>LS mean</td>
<td>36.3</td>
<td>37.4</td>
<td>−1.1</td>
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<td>S.E.M.</td>
<td>1.8</td>
<td>1.7</td>
<td>2.5</td>
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<tr>
<td>95% CI</td>
<td>−6.2, 3.9</td>
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<td>0.657</td>
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<td>$P$-value</td>
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<tr>
<td>Applied dexterity (s)</td>
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<tr>
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<td>30.3</td>
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<td>2.2</td>
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<tr>
<td>95% CI</td>
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<td>$P$-value</td>
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<td>Self-report ability (MHQ)</td>
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<tr>
<td>LS mean</td>
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<td>64.3</td>
<td>−3.0</td>
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<tr>
<td>95% CI</td>
<td>−10.5, 4.5</td>
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<td>0.426</td>
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*Mean (least squares) at 12-month follow-up adjusted for baseline using ANCOVA.
personal or serious. The relatively high percentage of self-reported non-adherence to splint wear in this study may have been affected by this. In patients who are well motivated and achieve high adherence levels to this type of splint the results may be different; yet this study reflected current clinical practice and recruited those patients likely to be referred for splinting intervention.

In spite of comprehensive preparation for the study led by the steering committee, there was potential for the splinting and treatment to differ between centres. On conducting a separate within-centre sub-analysis, results were similar to the overall study [43]. So whilst treatment deviation between centres could have occurred, this did not seem to play a substantial part in the results.

The study duration may have been too short. Twelve-month follow-up may be insufficient to measure and detect change in impairment and functional measures. The splints may not have been worn for long enough to have a measurable impact on hand impairment and function. The role of secondary prevention in occupational therapy intervention in early RA is important [45] and it may be that the positive impact of resting splints is not evident until longer term use. Conversely, any immediate or short-term benefits from the splints could not have been identified within this study. However, whether a clinically important difference among 120 patients could be found in a shorter or longer time span seems unlikely.

This study is not the first randomized controlled trial in RA that produces negative results for rehabilitation therapies. Expert commentators have warned against carrying out clinical effective-ness RCTs of rehabilitation therapies. Wade [46] argues that to isolate just one aspect of a complex rehabilitation package fails to consider and measure the interaction effect of the whole intervention and this argument could be true of this trial.

It may be that the design of the static resting splint requires review. The design and application of resting splints used in the UK follows a moderate ‘intrinsic plus’ position [47] (Fig. 1). Collateral MCPJ and IP ligaments are positioned in mid-range during immobilization, and possibly at a time when joint capsules and ligaments are vulnerable from effusions and inflammation a more contracted resting state or ‘intrinsic minus’ position is adopted. This may serve to reduce the stretch on ligaments and protect joints and soft tissues from inflammatory and deforming forces.

Conclusion

Immobilizing wrist and hand joints using resting splints throughout the early disease process has been seen not to confer additional benefits over early standardized occupational therapy in improving grip, pain, function or deformity. Significantly fewer individuals reported the occurrence (but not the duration) of early morning hand stiffness, over 12 months in the splint group. All other outcomes favoured the control group rather than the splinting intervention group. Both the Cochrane analysis and this study do not support that static resting splints should be used in the routine treatment of patients with early RA and the continued use of static resting splints in early RA needs to be considered carefully by clinicians.

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The authors have declared no conflicts of interest.

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