

There is inconclusive data to either support or refute the efficacy of splints in decreasing joint pain due to the progression of rheumatoid arthritis

Prepared by: Katrina Foo (kfoo6388@uni.sydney.edu.au) and Andrew Hollis (ahol7606@uni.sydney.edu.au)

Date: May 10, 2011 **Review Date:** --

CLINICAL SCENARIO:

Rheumatoid arthritis (RA) is an autoimmune disease that results in pain and loss of function (Lahita, 2001). It afflicts approximately 1% of the world population and is more common in women (Radomski & Trombly, 2008). Of these individuals, approximately, 75% have wrist arthritis (Flatt, 1968). These numbers are estimated to increase exponentially over the next years as a result of the aging population (Centers for Disease Control and Prevention, 2010).

One of the most common treatments prescribed by Occupational therapists (OT) as an adjunct to other medical treatments is the use of splints (Spoorenberg, Boers, & Van der Linden, 1994; Melvin, 1989). Splints are often used to decrease the deformation of joints and pain experienced (Ouellette, 1991; Deshaies, 2002). Whilst this evidence supports the use of splints to reduce deformity there is little evidence to support the use of splints to reduce pain (Egan et al., 2003). For these reasons, we propose that researching the efficacy of splinting in the hand and wrist to reduce pain in cases of RA is of clinical importance.

FOCUSSED CLINICAL QUESTION:

Among people with rheumatoid arthritis, does the use of hand and wrist splints reduce the intensity of pain in hands and wrists compared to not using splints?

SUMMARY of Search, 'Best' Evidence' appraised, and Key Findings:

- Comprehensive electronic search resulted in eight studies directly relevant to our clinical question—two were systematic reviews (SR), five were Randomized controlled trials (RCTs) and one was a controlled clinical trial (CCT).
- Two studies are included in this topic appraisal. One article is an SR of available literature on the use of splints in rheumatoid arthritis (Egan et al., 2003). The other article is an RCT on the efficacy of wrist splinting used to reduce pain and increase function in clients with rheumatoid arthritis (Veehof, Taal, Heijnsdijk-Rouwenhorst, & van de Laar, 2008).
- The overall results of the two appraised papers were inconclusive. The systematic review, which was completed 9 years ago, found no significant effect on pain experienced by RA patients when using hand and wrist splints. In the more recent RCT, it was found that wrist working splints decreased pain.

CLINICAL BOTTOM LINE: There is inconclusive evidence to support the clinical effectiveness of splint use to reduce pain in the hand and wrist joints of individuals diagnosed with rheumatoid arthritis.

Limitation of this CAT: This critically appraised topic has been peer-reviewed by one other independent person and by a university lecturer as part of an assignment.

SEARCH STRATEGY:

- Preliminary searching revealed a multitude of articles related to splints/orthoses and their relation to rheumatoid arthritis. Although many studies mentioned the relationship between splints and pain, eight studies directly measured pain as a primary outcome.
- The following databases were searched—Medline, CINAHL, Web of Science, OTseeker, PEDro, Cochrane library.

Terms used to guide Search Strategy:

- **P**atient/Client Group: People with rheumatoid arthritis.
- **I**ntervention (or Assessment): Use of splints.
- **C**omparison: Not using splints.
- **O**utcome(s): Level of pain experienced.

Databases and sites searched	Search Terms	Limits used
MEDLINE	<p>Title: rheumatoid arthritis OR RA AND</p> <p>MeSH terms: Pain AND splints</p> <p>Keywords: pain* OR pain symptom* OR pain manag* OR pain control* AND splint</p>	<p>Language: English Humans Publication Type: Case reports, clinical conference, clinical trials, and controlled clinical trials, comparative study, meta analysis, randomized controlled trial or "review" Published Date: 2002-2012</p>
CINAHL	<p>Title: rheumatoid arthritis OR RA</p> <p>Keyword as exact subject heading: splint* AND pain*</p> <p>Keyword in subject heading: orthos?s AND pain* OR pain control* OR pain manag* OR pain symptom*</p> <p>Keyword: splint* AND pain* OR pain control* OR pain manag* OR pain symptom*</p>	<p>Published Date from: 2000-2001 English Language; Human; Publication Type: Clinical Trial, Journal Article, Systematic Review</p>

Web of Science	Title = rheumatoid arthritis OR RA Keyword =rheumatoid arthritis OR RA AND pain* OR pain manag* OR pain control* OR pain percept* OR pain symptom* AND splint* OR orthos?s OR orthop?aedic brace* or brace*	Language: English Publication Year= 2000-2011 Databases= SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, CCR-EXPANDED, IC.
OTseeker	Keyword: Rheumatoid arthritis OR RA AND splint* OR orthos*s AND pain* Intervention: physical modalities/orthotics/splinting Diagnosis/Subdiscipline: Rheumatology	
PEDro	Abstract & Title: rheumatoid arthritis OR RA AND pain* AND splint* Therapy: orthoses, taping, splinting Problem: Pain Body Part: Wrist and hand	Published: From 2000 to current
Cochrane Library	Title, Abstract OR Keyword: rheumatoid arthritis OR RA AND pain* OR pain manag* OR pain control* OR pain percept* AND splint*	

INCLUSION and EXCLUSION CRITERIA

- **Inclusion:**
 - Randomised controlled trials, systematic reviews, controlled-clinical trials
 - Having an experimental focus.
 - Evaluating the effect of the use of splints to reduce the pain associated with rheumatoid arthritis.
 - Studies must be in English.
- **Exclusion:**
 - Descriptive journal articles.
 - Studies that did not address pain directly nor had pain as a secondary/tertiary outcome.
 - Studies about juvenile rheumatoid arthritis.

- Studies published before year 2000.

RESULTS OF SEARCH

Eight relevant studies were located and categorised as shown in Table 1 (based on Centre for Evidence Based Medicine, 2009).

Table 1: Summary of Study Designs of Relevant Articles retrieved

Study Design/ Methodology of Articles Retrieved	Level	Number Located	Author (Year)
Systematic Review	1a	1	<ul style="list-style-type: none"> • Steultjens, Dekker, Bouter, Van Schaardenburg, Van Kuyk, & Van Den Ende, 2002
Systematic Review	-1a (lack of homogeneity)	1	<ul style="list-style-type: none"> • Egan, Brosseau, Farmer, Ouimet, Rees, Tugwell, & Wells, 2003
Randomized Control Trial	1b	4	<ul style="list-style-type: none"> • Silva, Jones, Silva, & Natour, 2008 • O'Brien, Jones, Mullis, Mulheri & Dziedzicm 2006 • Veehof, Taal, Heijnsdijk-Rouwenhorst & van de Laar, 2008 • Adams, Burrige, Mullee, Hammond & Cooper, 2008 • Tjhuis, Vliet Vlieland, Zwinderman, & Hazes, 1998
Controlled Clinical Trial	2b	1	<ul style="list-style-type: none"> • Rennie, 1996

BEST EVIDENCE

The following papers were identified as the 'best' evidence and selected for critical appraisal:

- "Splints and Orthoses for treating rheumatoid arthritis" by Egan, Brosseau, Farmer, Ouimet, Rees, Tugwell, & Wells (2003).
- "Efficacy of Wrist Working Splints in Patients with Rheumatoid Arthritis: A Randomized Controlled Study" by Veehof, Taal, Hijnsdijk-Rouwenhorst & van de Laar (2008).

Reasons for selecting this study were:

- Another SR (Steultjens et al., 2002) at a higher level of evidence as compared to the RCT chosen for critical appraisal was found. However, this SR was not chosen as it did not directly address the focused clinical question, as compared to the chosen RCT, which was directly correlated.
- The chosen SR is a Cochrane Review (regarded as high level of evidence) that relates directly to our focussed clinical question, and specifically addresses the efficacy of hand and wrist splints to reduce pain.

SUMMARY OF BEST EVIDENCE

Table 2: Description and appraisal of Cochrane systematic review “Splints and Orthoses for treating rheumatoid arthritis” by Egan, Brosseau, Farmer, Ouimet, Rees, Tugwell, & Wells (2003).

Objective of systematic review:

To assess the effectiveness of splint/orthosis use in adults with rheumatoid arthritis to relieve pain, decrease swelling, and/or prevent deformity, and to determine the impact of splint/orthotic use in improving function, mobility and strength of associated joints.

Study Design: This systematic review is a Cochrane review (n=449).

Search Strategy:

MESH terms used: *Orthotic devices, *Splints; Arthritis, Rheumatoid [rehabilitation; *therapy]; Hand Strength, shoes, Wrist Joint

Selection Criteria: Studies were selected based on a previously outlined protocol. All randomized controlled trials (RCT) and controlled clinical trials (CCT) were included. Case-control and cohort studies which compared the use of specific orthoses and a placebo, another intervention (including an alternate type of orthoses), or regular treatment were also included in this review. Only studies in English or French were considered.

Inclusion criteria: OMERACT criteria and other related inclusion criteria (Please see “Outcome measures” below for full list of inclusion criteria).

Databases searched:

Cochrane Registers: Cochrane Field of Physical and Related Therapies Register, Cochrane Musculoskeletal Group Register, Cochrane Controlled Trials Register to issue 4, 2001.

Major bibliographic databases: MEDLINE, EMBASE and PEDro.

Methods: Two reviewers independently completed a comprehensive electronic and hand search of all relevant studies based on a pre-existing search strategy developed by the Cochrane Collaboration. An electronic search was done on Cochrane registers and major bibliographic databases. This search included a hand search of bibliographic references of identified studies, abstracts which were published in special issues of specialized journals or conference proceedings, and current contents to locate any studies that have not been indexed in MEDLINE. Reference lists of published papers were also hand-searched and experts in the field were contacted to retrieve additional studies and/or unpublished data.

Following the selection of studies to be included, data were independently extracted using a pre-developed form and the methodological quality of the RCTs and CCTs was independently assessed. The data collected were then checked by a third and fourth reviewer (two of the authors).

The quality of the methodology of each included study of this review was assessed using a validated scale created by Jadad et al. (1996). This scale is an instrument used to assess the quality of reports of RCTs in pain research and is used to determine the effect of rater blinding on the assessments of quality. The assessors

focused on the presence and quality of randomization, double-blinding, and description of withdrawals and drop-outs.

Intervention Investigated: The interventions included rigid, semi-rigid or soft orthotics designed to provide support and/or pain relief in any joint. These included working wrist splints, resting hand and wrist splints, special shoes and insoles which were used during work and daily activities.

Participants: Adults (≥ 18 years old) diagnosed with RA (Total of 449 participants). Studies including diverse populations were accepted if more than 50% of the population of the participants were diagnosed with RA.

Outcome Measures: The SR considered a range of outcome measures in addressing the efficacy of splinting. None of these outcomes measures were prioritized in the sense of being the “primary” outcome measure. Studies were included if OMERACT (Egan et al., 2003, p. 3) outcomes (which are specific to rheumatoid arthritis) were measured.

OMERACT outcomes: number of tender joints, number of swollen joints, pain, physician’s & participant’s global assessment, functional status, acute phase reactants, and radiological evidence of damage (Egan et al., 2003, p. 3).

Other measured outcomes for inclusion include: duration of morning stiffness, muscle strength, endurance, range of motion (ROM), postural status, gait status, walking speed, walking distance, cadence, stride length, systemic components, concomitant medication use, adverse side effects, quality of life, length of stay, discharge disposition, cardiopulmonary capacity, return to work etc.

Pain – the outcome specified in our clinical question – was measured by subjective self-reporting by the participants. Two scales were used to report pain: a Visual Analog Scale (VAS) that plotted severity of pain experienced on a Lickert scale from 0 (no pain) to 10 (agonizing pain). In the case of pain in the feet, the Functional Foot Index (FFI) on a range from 0-100 was used.

Main Findings: The findings of this review are summarised with regard to our focussed clinical question. Only outcomes related to pain in the hands and wrists will be discussed.

There was no pooling of results from the twelve papers (ten studies) and therefore, no overall multiple analysis was possible. Mean differences between specific comparisons (e.g. pain measured when compared between splint-wearing and non-splint wearing groups) were extracted from the studies and shown in individual forest plots, which record confidence intervals by which to assess the significance of any differences (Table 2A). The small mean difference between the groups as well as the relatively narrow confidence intervals of each outcome shows that there was a very small difference between the two treatment groups in all the pain outcome comparisons shown in Table 2A. The forest plots were annotated to illustrate how divergence on a horizontal scale from a central (no effect) position relates to the favoured group. In most cases, the forest plot of each treatment and outcome of the studies included in this SR, showed a trivial deviation from the central position, favouring the treatment group slightly. However this outcome was shown to be statistically insignificant (seen in total effect scores P-value > 0.05 in Table 2A)).

Of these twelve studies, there was no statistically significant evidence proving that splinting changes pain experienced. Wearing wrist splints during work did not affect pain. There was no statistical evidence that resting wrist and hand splints changed the level of pain.

Table 2A: Results of treatments

Outcome (PAIN)	Treatment group 1 Mean(SD)	Treatment group 2 Mean (SD)	Mean Difference (95% confidence interval)	Favour treatment/ control	Test for overall effect	Statistical significance
On Motion (VAS 1-100mm)	Elastic Gauntlet (EG) 2(27.27)	No Splint 9.5(23.5)	-7.50 [-20.93, 5.93]	Treatment	Z=1.09 (P=0.27)	NO
At rest (VAS 1-100mm)	EG 0.2(3.37)	No splint 0.45(2.2)	-0.25 [-1.73, 1.23]	Treatment	Z=0.33 (P=0.74)	NO
Using screwdriver (VAS 1-10cm)	EG 1.99(2.08)	No splint 2.44(2.33)	-0.45 [-1.40, 0.50]	Treatment	Z =0.93 (P=0.35)	NO
Using shears (VAS 1-10cm)	EG 1.78(2.03)	No splint 2.3(2.32)	-0.52 [-1.48, 0.44]	Treatment	Z=1.07 (P=0.29)	NO
Pouring water (VAS 1-100mm)	EG 0(2.25)	No splint 0(1.75)	0.0 [-1.06, 1.06]	No difference in pain levels	Z=0.0 (P=1.0)	NO
Wrist pain on motion (VAS 1-100mm)	EG -2(33.5)	No splint 5(19.75)	-7.00 [-21.2, 7.2]	Treatment	Z=0.97 (P=0.33)	NO
Wrist pain (VAS 1-10cm)	Thermolyn 4.7(2.2)	Futuro 3.7(2.3)	1.00 [-0.97, 2.97]	Futuro	Z=0.99 (P=0.32)	NO
Tender joint in hand and wrist	Thermolyn 4.2(3.9)	Futuro 4.8(3.3)	-0.60 [-3.77, 2.57]	Thermolyn	Z=0.37 (P=0.71)	NO
Pain score (out of 48)	Splint 7.9(1.6)	No splint 6.3(0)	0[0,0]	No Effect	Z=0 (P<0.00001)	YES

Information in table retrieved from Appendix of original publication, "Splints and Orthoses for treating rheumatoid arthritis" by Egan, Brosseau, Farmer, Quimet, Rees, Tugwell, & Wells (2003)

Original Author's conclusion: Authors of this review found that there is insufficient evidence to conclude that working splints or resting wrist/hand splints were effective in decreasing pain in patients with rheumatoid arthritis.

Critical Appraisal:

Validity:

This systematic review will be critically appraised based on the PRISMA (2009) Checklist for Appraisal.

NOTE: The criteria of the PRISMA checklist will be denoted by the corresponding item number in square brackets [Number of Criteria].

Methodology:

Strengths:

- The main clinical question and all the PICO elements are outlined clearly in the objective of this SR. This serves as a clear foundation for searching for valid studies to be included. [6]

- A robust search methodology protocol was developed prior to review by Cochrane Collaboration. This produced a comprehensive and reliable search strategy. [5-11]
- The search covered most major bibliographic databases, hand searched reference lists, bibliographies and found unpublished studies. This in depth approach of searching covered all the bases of information collection to obtain a representative pool of studies to be reviewed. [7]

*This comprehensive search criteria (electronic and hand search) yields a well-rounded pool of possible studies to be included and controls for the possibility of source biases and publication bias.

- The review provided detailed information on the studies characteristics including the PICO elements, methodology and risk of bias within each individual included or excluded study. [18, 19]
- Results were not pooled but a statistical comparison of specific interventions (specific types of orthoses or hand and wrist splints) and the outcomes related to these interventions was given. Statistical information on the mean difference, confidence intervals, and overall effect was given on a forest plot for each intervention comparison and outcome. (See Table 2A) [20]

Limitations:

- Did not present full electronic search strategy. MESH terms were listed but text words and direct search terms were not provided. Since terms and the direct search strategy were not provided, this search is not reproducible and we cannot irrefutably say that it is unlikely for the review to have missed out on important/relevant studies.

Possible source biases [8]

- Did not clearly outline whether studies were published or unpublished. If unpublished, they did not outline whether they statistically examined the outcomes of published and unpublished studies. Possible publication bias since published studies tend to show more positive or larger effect. [6]
- The SR only considered studies in the English language. This limits the studies found (scope bias).

Screening:

Strengths:

- Inclusion criteria comprised of outcomes specific to rheumatoid arthritis (OMERACT outcomes), other related outcomes, types of splint/orthoses, and population characteristics. [11] Studies chosen to be included in the review were of high levels of evidence (RCT, CCT, case control and cohort studies) which directly addressed the focussed clinical question of this review. [6, 7, 9]

Limitations:

- The specific number of studies screened for this review was not given, this information can be extracted from the reference list of all studies reviewed (included and excluded from review). [17]

Selection:

Strengths:

- Data were collected by two reviewers, individually, from selected studies using a form developed prior to the review and data were checked by another set of reviewers working independently although part of the same authorship [10].

- In addition, by using a standardized form to collect data, a consistent manner of data collection was used for all relevant studies. This limited the possibility of rater bias.
- Rigorous methodology regarding selection of studies reduced the possibility of selection bias [9].

Limitations:

- The studies chosen for review were not similar enough to allow for pooling of results. Therefore, a summary of measures and synthesis of results of the studies was not provided by this review. [13, 14]
- The detail behind deciding whether a study was eligible and the reasons studies were excluded were not given. [9, 17]
- Inter-rater reliability regarding outcome measures was not provided. [17] Possible selection bias and rater bias
- How data was extracted from the included studies was not stated. [10]

Biases:

Strengths:

- Quality of methodology and risk of bias in the studies included was assessed using a validated scale that was specific for pain research that focused on randomization, double-blinding and description of withdrawals and drop-outs in each of the studies. [12]

Limitations:

- Since results were not pooled due to a lack of similarity across studies, the risk of bias across all studies was also not reported. Although the reviewers had reported the risk of bias within each study, they did not report the statistical differences between studies using a chi-square test. In addition, they did not report any possible reasons for the heterogeneity of the results of the studies included. [15, 22]
- Scores on quality of methodology of each individual study was not provided. Quality scores were not examined for co-variation with study outcomes. [12, 19]
- Statistics were not given to show that data from the individual studies was sound. [12, 19]

Table 2B: PRISMA SCALE CRITERIA ANALYSIS OF SYSTEMATIC REVIEW by Egan et al., 2003

Title	1	✓ Stated "Review"
Structured summary in abstract	2	✓ Met most criteria
Introduction		
Rationale	3	✓ Stated importance of splints
Objectives	4	✓
Methods		
Protocol and registration	5	✓ Review protocol available; no registration number
Eligibility Criteria	6	✓ PICO criteria & report characteristics given
Information sources	7	✓
Search	8	X Cannot be repeated
Study selection	9	✓
Data collection process	10	X Process not described; simply stated
Data items	11	✓
Risk of bias in individual studies	12	✓
Summary measures	13	X No summary because no pooling of results
Synthesis of results	14	X No combining; Measures of consistency not given

Risk of bias across studies	15	X No cumulative evidence
Additional analyses	16	X No additional analyses done
Results		
Study selection	17	X Reasons for exclusion not provided
Study characteristics	18	✓ Appendix of all included and excluded studies
Risk of bias within studies	19	✓ Outcome level assessment not done
Results of individual studies	20	✓
Synthesis of results	21	X No pooling of results due to heterogeneity
Risk of bias across studies	22	X No pooling
Additional analyses	23	X
Discussion		
Summary of evidence	24	✓
Limitations	25	✓
Conclusions	26	✓
Funding		
Funding	27	X

Interpretation of Results

The results considered were only related to pain as this is the outcome stated by our clinical question.

- Difficult to standardize wearing time and amount of stress put on joints in working splints making it a challenge to compare the experiences of the treatment and control groups and establish a firm correlation between treatment and outcomes.
- Some of the OMERACT outcome measures (e.g. pain, functional status etc.) (OMERACT, 1993) looked at in studies may not have been looked at to find a treatment effect but rather, to look for potential adverse effects. As no statistically significant difference was found between control and treatment groups, this would mean, given that there was pain relief in some daily activities, there was a positive outcome overall. Hence, depending on the reasons for outcome measures to be put in place in studies, this could positively change the meaning of results found in the included studies of this SR.
- The quality of included studies was only fair – receiving a quality rating of only an average of 2-3/5. These studies were of low quality because most failed to use blinding. Therefore, results of effect size of these studies may have been skewed due to the Hawthorne effect or rater bias.
- Authors were dealing with continuous outcomes of pain (Visual Analog scale). The effect size was presented as the standard weighted mean (mean difference with a 95% confidence interval) of the treatment outcome. It was not mentioned that the visual analog scale was adjusted for end-aversion bias where it is more common for individuals to veer closer to the centre or end of a continuous scale.
- Overall, the effect size of each outcome related to pain was not statistically significant ($P > 0.05$). Therefore, there is in-significant evidence to prove that the effect of wrist/hand splints decreases pain experience in patients with RA. However, because of the ‘fair’ quality of studies included and small trial sizes, we would not conclusively say there is ‘NO’ clinical significance of splinting of the hand/wrist to reduce pain in patients with RA.

Summary/Conclusion:

The evidence provided in this review on the effect of splinting/orthoses on pain is that:

- Overall, there is non-significant evidence supporting the use of wrist/hand splints to reduce pain in patients with RA.

- Effects were not found to be statistically significant based on p-values of the comparisons. However, this lack of statistical significance does not revoke the clinical significance of splinting. Splints are often prescribed as a secondary treatment in association with other forms of medical treatment.

Therefore, there is not enough evidence to support or refute the wearing of splints to reduce pain in joints of persons with RA.

Table 3: Description and appraisal of randomized control trial “Efficacy of Wrist Working Splints in Patients with Rheumatoid Arthritis: A Randomized Controlled Study” by Veehof, Taal, Hijnsdijk-Rouwenhorst & van de Laar (2008).

Aim/Objective of the Study/Systematic Review:

The randomized controlled trial investigated the efficacy of wrist working splints after splinting for a period of time in patients with RA.

Study Design: This study is a randomized controlled trial. Participants were randomly allocated using block randomization, with a block size of four, to the splinting or control group. Subjects and assessors were not blinded to treatment allocation. Group allocation was concealed via patient selection of sealed envelopes. Measurements were performed at baseline and four weeks after the start of treatment.

Setting: Rheumatology outpatient clinic of Medisch Spectrum Twente Hospital in Enschede in the Netherlands.

Participants:

- Patients attending a rheumatology outpatient clinic in the Netherlands. Participants of the study were chosen by the rheumatologist of the clinic.
- Seventeen participants in splinting group; sixteen in control group
- All patients completed the study
- Two patients did not fully complete the daily diary on splint use and one patient did not return diary.

Inclusion criteria: Diagnosis of RA; clinical signs of active arthritis of the wrist due to RA; painful wrist (as assessed by the visual analog scale (score greater than or equal to 30)); stable disease-modifying anti-rheumatic drug therapy (a non-steroidal anti-inflammatory drugs and corticosteroids) three weeks prior to baseline measurement with no expected changes for the next four weeks; and age 18 or above.

Exclusion criteria: Received injection of corticosteroid in wrist or hand within preceding month; exhibit adverse deformities of wrist an/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.

Intervention Investigated

Control: Participants allocated to the control group received normal care by the occupational therapist for four weeks.

Experimental: Participants received normal treatment and splinting. They were fitted for their preferred splint directly after baseline assessments were conducted by an OT. The patients had a choice between four splints. They wore the splint for four weeks. Participants were encouraged to wear their splints as often as possible and asked to record the number of hours they wore the splint in a daily diary. Participants in the splinting group were taught the functional importance of wearing the splint in order to encourage/stimulate splint use.

Outcome Measures:**Primary outcome:** Pain

Pain was measured with a 100-mm pain visual analog scale (VAS). The markers were no pain (0) and pain as bad as it can be (100) located at each end. Patients were asked to mark a vertical line on the average amount of wrist pain their perceived during the past week.

Secondary outcome: Grip strength and functional ability

Grip strength was measure in kPa using the Martin Vigorimeter, which is a dynamometer with an air-filled rubber balloon. Patients were asked to squeeze the balloon to get pressure reading. Three trials were done and the mean of these three trials was taken. These measures were taken without a splint.

Functional ability was measured using the Disabilities of arm, shoulder, and hand (DASH) questionnaire and the short version of the sequential Occupational dexterity assessment (SODA-S).

Main Findings:

Findings of this study are summarised in relation to the primary outcome of pain.

- The mean VAS pain scores decreased by 32% after the 4 week period of splinting. In the control group, mean VAS scores increased by 17%. Change scores were found to be statistically significant between both groups ($F[1, 30] = 11.1, P=0.002$). The effect size of the treatment was $-1.24 (-1.98, -0.49)$, indicating a large treatment effect of wrist working splints on VAS-measured pain.
- The number of SODA-S painful activities decreased by 50% in the treatment group and 6% in the control group. However, this difference was not statistically significant ($P=0.191$). The effect size calculated (Hedges' $g = -0.45$, with a confidence interval of $(-1.14, 0.24)$) indicated a small treatment effect.
- As seen in Table 3B, patient's in the splinting group perceived their pain to have decreased while the control group perceived an increase pain. These differences were statistically significant ($P \leq 0.01$).
- Results show that perceived wrist pain scores decrease significantly with the use of splints for 4 weeks.

Table 3A: Table of findings- Baseline scores on outcome measures, changes at 4 weeks, and indices for the treatment effect*

	Splinting group (n=17)			Control group (n=16)			Treatment effect			
	Baseline	Changes at 4 weeks	P	Baseline	Change at 4 Weeks	P	F [1,30]	P	Power	Effect Size (95% CI)
VAS wrist pain score (0-10)	52.9±16.8	-16.8±21.5	0.005	42.4 ± 28.5	7.4 ± 16.1	0.087	11.07	0.002	0.9	-1.24 (-1.98, -0.49)
SODA-S Painful activities, n (0-6)	1.8 ±1.5	-0.9 ± 1.9	0.074	1.7 ± 1.9	-0.1 ± 1.3	0.708	N/A	-	-	-0.45 (-1.14, 0.24)

Table adapted from original publication, "Efficacy of Wrist Working Splints in Patients with Rheumatoid Arthritis: A Randomized Controlled Study" by Veehof, Taal, Hijnsdijk-Rouwenhorst & van de Laar(2008) on pg. 1701

Table 3B: Participant perceived changes in pain in splinting and control group over 4 weeks

Splinting (n=17)	Control (n=16)	P
0.59 ± 0.87	-0.50 ± 0.63	0.001

Table retrieved from original publication, "Efficacy of Wrist Working Splints in Patients with Rheumatoid Arthritis: A Randomized Controlled Study" by Veehof, Taal, Hijnsdijk-Rouwenhorst & van de Laar (2008) on pg. 1702

Original Authors' Conclusions The authors found that prefabricated wrist working splints are extremely effective in reducing wrist pain after 4 weeks of splinting in adults with RA with wrist arthritis.

Critical Appraisal:

Validity

The validity of the methodology of this RCT was critically appraised based on the PEDro criteria. (PEDro, 2011) The RCT has met 5/8 internal validity criterion of the scale and received a 2/2 on the statistical reporting score. Eligibility criteria were considered. Therefore, this RCT is considered to be a robust and sound RCT.

Table 3C: Internal Validity Score based on PEDro Rating Scale (/8)

Criteria	Rating:
Random allocation	YES
Concealed Allocation	YES
Baseline Similarity	YES
Blinding of all subjects	NO
Blinding of therapists	NO
Blinding of all assessors	NO
Measures of minimum one outcome obtained from more than 85% of participants of initial groups	YES
Intention to treat	YES

Ratings based on information from study by Veehof, Taal, Hijnsdijk-Rouwenhorst & van de Laar (2008)

- This randomized controlled trial randomly allocated participants to the experimental/control groups. This ensured there was no selection bias and that the two groups were as comparable as possible at baseline.
- Participants were informed of their allocation by sealed envelope. This met the criterion of the PEDro scale of concealed allocation.
- Participants were assessed at baseline prior to randomization to eliminate persons with exceptional circumstances so that the comparison is meaningful. Paired t-tests and analysis of covariance were done to determine there were no significant differences at baseline between the splinting and control groups.
- Since all participants remained in the study until the end of the treatment period, there was no risk of results being skewed as a result of attrition.
- The absence of blinding raises the possibility of bias affecting the self report of pain scores. These scores may have been influenced by participants' expectations of splinting or they may have altered their behaviour during the trial due to the awareness of being observed (the Hawthorne effect) and as a result skew the results of the treatment effect.
- In this trial, the assessor was the therapist who ran the trial. Therefore, the assessor could not have been blinded as they were the ones to implement the splinting on the participant. If the assessors were different from the therapist running the trial, than blinding could have occurred had the splints been removed prior to the assessment at four weeks.

Interpretation of Results

- In this CAT, we are looking at the primary outcome of pain (wrist pain score and painful activities). The data reported are continuous data.

- The results of this study demonstrate statistically significant reduction in pain following the use of splints. The authors conclude that their study supports the use of wrist working splints in reducing wrist pain in RA patients.

- Data from a previous study on wrist working splints were used to develop power calculations and determine the number needed to treat (NNT). The minimum sample size to give a definitive answer about clinical significance (detect a difference of 15mm on VAS for wrist pain with 80% power and a one-sided significance level of 0.05) was calculated to be 54 patients (27 in each group). From a previous study, they found that a difference of VAS pain score of 155mm corresponds to an improvement of approximately 30% which is the level of improvement considered to be clinically relevant. It would have been preferable had this study met that group size.

- Although the effect of wrist working splints on VAS-pain scores was found to be statistically significant (exceeded minimal improvement factor of 30% to be clinically significant), this RCT was 'underpowered' – the minimum sample size (n=54) was not recruited. Therefore, although the effect of splinting significantly reduced VAS pain scores, we cannot say, conclusively, that the results of this study were clinically significant.

- The small but statistically insignificant effect as reported by the SODA-S scores could have been affected by the small sample sizes. - Furthermore, participants not wearing splints when asked to do activities may have contributed to the insignificant SODA-S scores.

- Although the results were statistically significant, it is not clear whether the effect found could be transferable to the general population due to the study's disputed clinical significance.

- As the investigators attempted to take into account a feature common to many splinting studies - the amount of time the splint is actually used - self-reporting was used. Therefore, due to the lack of random allocation of the assessors and the participants, possible bias due to self-report may also influence the results.

Summary/Conclusion:

This randomized controlled trial produced statistically significant evidence that the use of wrist working splints reduces the hand and wrist pain experienced in patients with RA. The treatment effect on VAS pain scores met the criteria, which was set out prior to the start of this RCT, that the minimum clinically significant improvement factor was 30% from baseline measures. This RCT revealed a statistically but not *clinically* significant outcome as a result of the study being slightly underpowered. However, the data from this RCT does not irrefutably indicate the clinical significance of the use of wrist working splints to decrease pain in patients with RA.

IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH

This CAT has sought to determine the efficacy of splinting in reducing hand and wrist pain in people with rheumatoid arthritis (RA) through an appraisal of best evidence. The outcomes of the studies critiqued were inconclusive. It is, however, worth noting that the RCT examined found that such treatment was beneficial and there is no evidence of the treatment leading to detrimental consequences. Therefore, our

recommendation for clinical practice is that splinting for four weeks as per the studies may be worth trying on RA patients with a view to reducing pain experienced. Our rationale is that therapists need to use consistent and sensitive outcome measures and be prepared to modify their intervention even if the target of a 30% change is not met. Although the effects found in the SR were not statistically significant it was reported that splinting treatments usually favoured the treatment group slightly. Whilst the RCT described focusses specifically on working splints, the SR covered both working and resting splints. Therefore, our CAT has most application to the question of the efficacy of working splints regarding pain in RA patients. Working splints are particularly appropriate orthoses to consider as function and joint movement has the potential to exacerbate the issue of joint pain raised in this CAT.

IMPLICATIONS FOR EDUCATION AND RESEARCH

The search and appraisal of best evidence in this CAT has found the body of research regarding efficacy of hand and wrist splints to reduce pain in people with RA to be inconclusive. Thus, further research is necessary to establish whether splinting is or is not effective in treating pain experienced by RA patients. Although research has been published on this clinical question it would be helpful for researchers to publish more updated SRs on this topic so that more decisiveness will be possible in clinical settings; more recent RCTs would be able to inform new SRs. Newer RCTs should follow strict methodology guidelines on blinding as this has been a recurrent problem with many studies done on splint use and its outcomes. Furthermore, newer RCTs should consider such matters as duration/timing of splint usage, the size of group participating and the specific outcome measures in order to uncover unambiguous and transferrable results.

CURRENT CLINICAL GUIDELINES

According to Australian guidelines (Musculoskeletal Health Network, 2009), splinting swollen hands/wrists is good practice amongst RA patients despite the evidence for efficacy of splinting remaining uncertain as suggested by this CAT. Our findings do not necessarily falsify current best OT practice. In the face of inconclusive empirical evidence we recommend continuing to follow extant clinical guidelines as there is no evidence pointing to splinting causing harm.

Due to limited numbers of SRs available, focussing on the effects of splinting on pain, it is necessary for further research to establish if the clinical use of splinting can be measured to decrease pain in RA patients to a statistically significant degree.

REFERENCES

- Adams, J., Burridge, J., Mullee, M., Hammond, A. & Cooper, C. (2008.) The clinical effectiveness of static resting Splints in Early Rheumatoid Arthritis: A randomized controlled trial. *Rheumatology*, 47(10), 1548-1553.
- Centers for Disease Control and Prevention (CDC). (2010). *Arthritis related statistics*. Retrieved from http://www.cdc.gov/arthritis/data_statistics/arthritis_related_stats.htm
- Centre for Evidence Based Medicine (CEBM). (2009). *Levels of evidence*. Retrieved April 17, 2011, from <http://www.cebm.net/index.aspx?o=1025>
- Deshaies, L.D. (2002). Upper extremity orthoses. In C. A. Trombly, & M.V. Radomski (Eds.). *Occupational Therapy for Physical Dysfunction, 5th Edition* (pp.313-349). Baltimore MD: Lippincott, Williams & Wilkins.
- Egan, M., Brosseau, L., Farmer, M., Ouimet, M. A., Rees, S., Tugwell, P., & Wells, G. A. (2003). Splints and orthoses for treating rheumatoid arthritis. *Cochrane Database of Systematic Reviews*, 1
- Flatt, A. (1968). *The Care of the Rheumatoid Hand. 7th ed.* St. Louis: CV Mosby.
- Jadad, A.R., Moore, R.A., Carroll, D., Jenkinson, C., Reynolds, D.J., Gavaghan, D.J., & McQuay, H.J. (1996). Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Controlled Clinical Trials*, 17(1), pp.1–12.
- Lahita, R. (2001). *Rheumatoid Arthritis, Everything You Need to Know*. Knoxville, TN: Avery.
- Melvin, J.L. (1989) *Rheumatic disease in the adult and child: Occupational therapy and rehabilitation*. Philadelphia: F.A. Davis.
- Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med*, 6(6).
- Musculoskeletal Health Network. (2009). *Clinical guideline for the diagnosis and management of early rheumatoid arthritis*. Retrieved from http://www.healthnetworks.health.wa.gov.au/docs/Clinical_guidelines_Rheumatoid_Arthritis.pdf
- O'Brien, A.V., Jones P., Mullis R., Mulheri D. & Dziedzic K. (2006) Conservative hand therapy treatments in rheumatoid arthritis: A randomized controlled trial. *Rheumatology*, (45), pp. 577-583.
- Ouellette, E.A. (1991). The Rheumatoid Hand: Orthotics as Preventative. *Seminars in Arthritis and Rheumatism*. 21(2), pp. 65–72.
- PEDro Physiotherapy Evidence Database. (2011). *PEDro Scale*. Retrieved May 6, 2011, from <http://www.pedro.org.au/english/downloads/pedro-scale/>
- Radomski, M. V. & Trombly, C.A. (2008). *Occupational Therapy for Physical Dysfunction, 6th edition*. Philadelphia: Lippincott Williams & Wilkins.
- Rennie H. (1996) Evaluation of the effectiveness of a metacarpophalangeal ulnar deviation orthosis. *Journal of Hand Therapy*, 9(4), pp. 371-377.
- Silva, A.C., Jones A., Silva P.G., & Natour J. (2008). Effectiveness of a night-time hand positioning splint in rheumatoid arthritis: A randomized controlled trial. *Journal of Rehabilitation Medicine*, (40), pp. 749-754.
- Spoorenberg, A., Boers, M., & Van der Linden, S. (1994). Wrist splints in rheumatoid arthritis: A question of believe? *Clinical Rheumatology*, 13(4), pp. 559-63.
- Steultjens, E. M. J., Dekker, J., Bouter, L. M., Schaardenburg, D.V., Van Kuyk, M.H., & Van Den Ende, C. H. M. (2002). Occupational therapy for rheumatoid arthritis: A systematic review. *Arthritis & Rheumatism*, 47(6), pp.672-685.

- Tijhuis, G., Vliet Vlieland, T., Zwinderman, A., & Hazes, J. (1998). A comparison of the futuro wrist orthosis with a synthetic thermoLyn orthosis: Utility and clinical effectiveness. *Arthritis Care Res*, 11(3), pp.217-22.
- Veehof, M.M., Taal, E., Heijnsdijk-Rouwenhorst, L.M., & van de Laar, M.A. (2008). Efficacy of wrist working splints in patients with rheumatoid arthritis: a randomized controlled study. *Arthritis and Rheumatism*, (12), pp.1698-704.