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Splints and Orthosis for treating rheumatoid arthritis (Review)

Egan M, Brosseau L, Farmer M, Ouimet MA, Rees S, Tugwell P, Wells GA

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[Intervention Review]

Splints and Orthosis for treating rheumatoid arthritis

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ABSTRACT

Background

Splints/orthoses are often recommended to patients with rheumatoid arthritis (RA) to decrease pain, reduce swelling, and/or prevent deformity. These orthoses include resting hand splints, wrist supports, finger splints, and special shoes and shoe inserts.

Objectives

To assess the effectiveness of splints/orthoses in relieving pain, decreasing swelling, and/or preventing deformity, and to determine the impact of splints/orthoses on strength, mobility, and function in people with RA.

Search methods

We searched the Cochrane Field of Physical and Related Therapies Register, Cochrane Musculoskeletal Group Register, Cochrane Controlled Trials Register to issue 4, 2001, MEDLINE, EMBASE, the PEDro data base, and Current Contents up to January 2002, using the search strategy developed by the Cochrane Collaboration. Unpublished studies were sought by handsearching conference proceedings and contacting key experts.

Selection criteria

All randomized control trials (RCTs) and controlled clinical trials (CCTs), case-control and cohort studies comparing the use of specific orthoses against placebo, another active intervention (including another type of orthoses), or regular treatment were selected according to an a priori protocol.

Data collection and analysis

Two reviewers independently selected the studies and extracted data. The methodological quality of the RCTs and CCTs was assessed using a validated scale.

Main results

Twelve papers reporting on 10 studies met the inclusion criteria. These studies dealt with the following: working wrist splints (5), resting hand and wrist splints (2), special shoes and insoles (3). There is evidence that wearing wrist splints during work statistically significantly decreases grip strength and does not affect pain, morning stiffness, pinch grip, or quality of life after up to six months of regular wear. We found no evidence that resting wrist and hand splints change pain, grip strength, Ritchie Index, or number of swollen joints. However, participants who wore these splints for two months reported that they preferred use to non-use, and padded resting splints to unpadded ones. The one study of special shoes provided evidence of significant benefits of wearing extra-depth shoes for two months, including less



pain on walking and stair climbing, and more minutes of pain free walking time. Extra-depth shoes with semi-rigid insoles provided better pain relief than extra-depth shoes alone when worn over 12 weeks. Supporting insoles prevented progression of hallux valgus angle but did not affect pain or function.

Authors' conclusions

There is insufficient evidence to make firm conclusions about the effectiveness of working wrist splints in decreasing pain or increasing function for people with RA. Potential adverse effects, such as decreased range of motion, do not seem to be an issue although some of these splints decrease grip strength and dexterity. Similarly, preliminary evidence suggests that resting hand and wrist splints do not seem to affect range of motion (ROM) or pain, although participants preferred wearing a resting splint to not wearing one. There is evidence that extra-depth shoes and molded insoles decrease pain during weight-bearing activities such as standing, walking, and stair-climbing. Supported insoles may be effective in preventing progression of hallux abductus angle but do not appear to have any impact on pain.

PLAIN LANGUAGE SUMMARY

Working wrist splints and extra-depth shoes appear to be helpful for people with rheumatoid arthritis

Ten studies examined the effects of working wrist splints, resting hand and wrist splints, and wearing special shoes/ insoles in people with rheumatoid arthritis. Although there is no evidence that wearing resting wrist and hand splints changed pain, grip strength, or number of swollen joints, participants who wore these splints for two months preferred to wear them, and also preferred padded splints. One study provided evidence that wearing extra-depth shoes for two months resulted in significant benefits of less pain on walking and stair climbing. Extra-depth shoes with semi-rigid insoles provided better pain relief than extra-depth shoes alone.

BACKGROUND

Currently, rheumatoid arthritis (RA) affects approximately 0.5 to 1% of the population in industrialized countries (Suarez-Almazor 2001). This figure is expected to rise as members of the post Second World War generation enter their senior years. Splints/orthoses are often prescribed as an adjunct to medical treatment (Ouellette 1991).

Splints and orthoses are "any medical device added to a person's body to support, align, position, immobilize, prevent or correct deformity, assist weak muscles, or improve function" (Deshaies 2002). We use both terms in this review, even though they are interchangeable, as there is a tendency among clinicians to use one or the other term when referring to specific devices. Splints/ orthoses for the treatment of rheumatoid arthritis include rigid or flexible wrist orthoses, static or dynamic finger orthoses, and specialized shoes and insoles. Goals of splint/orthotic use include reduction of pain and/or swelling, prevention of contractures, and/or provision of joint stability (Melvin 1989). While such interventions usually carry a relatively low cost, they do require skilled fabrication, and follow-up. They also require a commitment on the part of the participant to wear what is often a rather cumbersome device.

OBJECTIVES

To assess the effectiveness of orthoses in relieving pain, decreasing swelling, and preventing deformity.

To determine the impact of orthoses on strength, mobility, and function.

METHODS

Criteria for considering studies for this review

Types of studies

All randomized controlled trials (RCTs) and controlled clinical trials (CCTs), case-control and cohort studies comparing the use of specific orthoses against placebo, another active intervention (including another type of orthoses), or regular treatment were selected according to an a priori protocol, which included a requirement for at least five participants in each group. Only studies written in English or French were considered.

Types of participants

People 18 years of age and older who had been diagnosed with rheumatoid arthritis. Studies including diverse populations were accepted if 50% or more of the participants were diagnosed with rheumatoid arthritis.

Types of interventions

Rigid, semi-rigid, or soft orthotics designed to provide support and/ or pain relief at any joint, with the exception of joints of the neck or back.

Types of outcome measures

Studies were considered for inclusion if OMERACT outcomes were measured, that is, number of tender joints per participant, number of swollen joints per participant, pain, physician's global assessment, participant's global assessment, functional status, acute phase reactants, and radiological evidence of damage (OMERACT 1993). Studies were also considered for inclusion if any of the following additional outcomes were measured: 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. Compliance was not considered as an outcome measure.

Search methods for identification of studies

We searched the Cochrane Field of Physical and Related Therapies Register, Cochrane Musculoskeletal Group Register, Cochrane Controlled Trials Register (CCTR) to issue 4, 2001, MEDLINE, EMBASE, and the PEDro databases up to January 2002 (see Appendix for search details) (Dickersin 1994). The electronic search was complemented by handsearches of the following: 1) bibliographic references of identified studies; 2) Current Contents up to November 1998 (to identify articles not yet indexed in MEDLINE); 3) abstracts published in special issues of specialized journals or in conference proceedings. Reference lists were handsearched for additional studies reported in published papers, presentations at scientific meetings, and personal communications. Content experts were contacted for additional studies and unpublished data.

Data collection and analysis

Two of three reviewers (MAO, MF, and SR) determined the studies to be retrieved. These reviewers independently extracted data from the retrieved studies using a pre-developed form. They also independently assessed the methodological quality of the RCTs and CCTs. This data was checked by a third and fourth reviewer (LB, ME).

RESULTS

Description of studies

Twelve papers were identified that reported on 10 eligible studies with a total of 449 participants. Unfortunately none of the studies were similar enough to allow pooling of results. Five studies examined the effects of the use of working wrist splints. Three of these papers considered the effects of splint wear versus no splint (Anderson 1987, Pagnotta 1998, Kjeken 1995), while the two others were head to head studies of different splints (Tijhuis 1998, Stern 1996a, Stern 1996b). Two studies examined the effects of resting splints for the wrist and hand, one examining the effect of wear versus non-wear (Janssen 1990) while the other was essentially a head to head trial (Callinan 1996). Effects of foot orthoses and special shoes were reported in three studies. One examined the effects of extra-depth shoes versus regular footwear (Fransen 1997). Another was a trial of soft insoles in extra-depth shoes versus extra-depth shoes alone, and semi-rigid insoles in extra-depth shoes versus extra-depth shoes alone (Chalmers 2000). The third examined the effects of Rohadur supporting insoles versus placebo insoles (Budiman-Mak 1995, Conrad 1996).

Risk of bias in included studies

Methodological quality of the studies was assessed using a validated scale (Jadad 1996) focusing on the presence and quality of randomization, double-blinding, and description of withdrawals

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and drop-outs. Out of a possible total of 5 points, quality rating ranged from 1 to 5, with five of the ten studies receiving a score of 2 and three receiving a score of 3. Points were lost primarily for failure to describe randomization procedures, and failure to blind evaluators and/or participants. Withdrawals were well-described and exceeded 20% in only one study, where 21% of participants were lost to follow-up (Budiman-Mak 1995).

Effects of interventions

Working wrist splints

Three studies examined the effects of wearing working wrist splints versus no splint (Anderson 1987, Kjeken 1995, Pagnotta 1998). Grip strength was measured immediately after the splint was donned when four different types of splints (dorsal custom molded low temperature thermoplastic, palmar custom molded low temperature thermoplastic, palmar plastazote and polythene custom molded gauntlet, and ready-made elastic) were applied to the dominant or non-dominant hand. Results were expressed as mean difference (MD) with 95% confidence intervals (CI). The only significant differences were in lower grip strength of the nondominant hand, with both the palmar custom molded (MD -29.10 mm Hg [95% CI: -54.04 to -4.16]) and the elastic ready-made splints (MD -33.01mmHg [95% CI: -62.01 to -4.01]) (Anderson 1987). In a separate evaluation of a ready-made elastic splint after one week of use there were no differences in work performance or pain while using shears or a screwdriver, and no difference in dexterity with or without the splint (Pagnotta 1998). Finally, participants who wore a ready-made elastic splint for six months demonstrated smaller losses in passive dorsal-volar range of motion (ROM) compared with those who did not wear the splint. They showed, however, no differences in pain (at rest of in motion), grip strength, morning stiffness, pinch grip, forearm joint circumference, or quality of life (Kjeken 1995).

In head to head studies of two working wrist splints (a readymade elastic gauntlet or a custom-molded medium temperature thermoplastic splint), there was no difference, after two weeks of wear, on pain, joint tenderness, passive ROM, or grip strength with or without the orthoses (Tijhuis 1998). Similarly, there were no differences found with three different types of ready-made elastic splints (Alimed, Futuro, Rolyan) after one week of wear, on dexterity measured with or without the splint (Stern 1996a), or grip strength measured with the splint removed (Stern 1996b).

Resting wrist and hand splints

In studies of resting splints, after one month of wear participants preferred using a splint (low temperature thermoplastic splint) or a padded medium temperature thermoplastic splint) to no splint (relative ratio 5.5 [95% CI: 2.1 to 14.5]) (Callinan 1996). There were, however, no differences found in pain, grip strength, Ritchie Index, or number of swollen joints among participants who wore splints for six months versus those who did not (Janssen 1990).

Special shoes and insoles

With regard to studies of special shoes and insoles, participants who wore extra-depth shoes for two months were found to have less pain (100 mm visual analogue pain score [VAS]) when either walking (MD -18.70 [95% CI: -28.46 to -8.94]) or stair climbing (MD -27.00 [95% CI: -37.83 to -16.17]), and more minutes pain free walking time (MD 18.20 [95% CI: 8.22 to 28.18]), compared with those who wore regular footwear. No changes were seen on non-weight bearing pain, fatigue, or subjective wellness (Fransen 1997).

Participants who wore semi-rigid insoles in extra-depth shoes over 12 weeks reported better pain scores as measured on 100 mm VAS scale than when they wore extra-depth shoes alone (MD 1.90 [95% CI: -3.27 to -0.51]). However, no difference was found in functional evaluations or joint counts. When participants wore soft insoles in extra-depth shoes there was no difference on any measure compared to when they wore extra-depth shoes alone. Surprisingly therefore, after having experienced all three combinations, nearly half voiced a preference for the soft insoles, and nearly half preferred the semi-rigid insoles. Those who chose soft insoles had similar pain with both types of insoles, while participants who preferred semi-rigid insoles experienced significantly more pain with soft insoles (Chalmers 2000).

Finally, after up to three years of wear, individuals who used posted insoles demonstrated less progression of hallux abductus angle (RR 3.6 [95% Cl: 2.19 to 5.93) (Budiman-Mak 1995) but no difference in pain or function (Conrad 1996).

DISCUSSION

Study of the effectiveness of wrist and hand splints in individuals with rheumatoid arthritis is a complex proposition. For example, working wrist splints are recommended in order to limit circumduction and reduce torque during heavy wrist activities (Cordery 1998). Generally patients are instructed to wear the splints during activities they feel are heavy. However, it is recognized that these splints may limit the dexterity required in certain activities, or the splints may become too soiled to be practical (Stern 1997). Therefore, both wearing time and amount and type of stress on the joints may vary widely among study participants, depending on the types of activities which they usually carry out. While efforts to standardize wearing time have been attempted in some studies (e.g. by requesting wearing the splints for at least four hours per day), it has been more difficult to standardize the amount of stress on the joints. It may not be realistic to assume that joint stress will average out in treated and control groups if, for example, the splinted group tends to feel more secure with heavy activities and is therefore exposed to greater joint stress.

Additionally, some of the outcomes measured in studies of working wrist splints were probably included, not because it was felt that treatment would lead to gains in these measures, but rather, to monitor potential adverse effects. Range of motion (ROM), dexterity, and possibly grip strength, fall into this category. No reference to these outcomes as potential adverse effects could be found in splinting textbooks yet clinicians must consider the potential for decreasing ROM and dexterity (potential adverse effects) when recommending the use of working wrist splints. Where these outcomes are actually potential adverse effects, a finding of no difference between treated and control participants could actually reflect a positive overall outcome if the patient was provided with pain relief during at least some of their daily activities.

The difficulty of studying the effectiveness of wrist and hand splints in rheumatoid arthritis is further illustrated with resting wrist and hand splints. These splints are designed to provide pain relief through immobilization of actively inflamed joints. Given the fluctuating course of the disease, it is difficult to know what the length of follow-up should be when pain relief is only likely to be evident during times of active joint inflammation.



Overall, the quality of the included studies was only fair. Most studies failed to receive higher ratings through failure to use a placebo and/or to document whether evaluators were unaware of the participant's study group. In only one of the studies was a placebo shoe insert, which was not built up to provide support, used (Budiman-Mak 1995, Conrad 1996). However, it should be noted that it may be difficult, if not impossible, to provide placebos and to blind participants to the treatment allocation in most studies with orthotics. Splints/orthoses provide support for a body part. How can this appear to be done without the patient knowing that no support is being provided? On the other hand, problems related to blinding of evaluators are not difficult to deal with since, in most cases, the splint/orthosis can be removed or otherwise hidden from the evaluator. However, in only five studies was it reported that evaluators were unaware of group allocation (Budiman-Mak 1995, Chalmers 2000, Conrad 1996, Janssen 1990, Tijhuis 1998). This could certainly be addressed in future studies to improve quality.

Other general problems in the studies reviewed included the analysis of cross-over trials as parallel trials (leading to potential over-estimation of results), and small trial size (number less than 100 in all trials, and less than 50 in four). However, given that the treatment results were, for the most part, in the expected direction, it is too early to conclude that the non-significant results demonstrate the lack of effectiveness of the orthotics examined.

To our knowledge, this is the first critical review of splints/orthoses in the treatment of rheumatoid arthritis. A previous literature review outlined the biomechanical and physiological conceptual basis for splinting the hand in rheumatoid arthritis (Ouellette 1991) but did not provide a critical synthesis of outcome studies.

AUTHORS' CONCLUSIONS

Implications for practice

Given the limitations in study designs, it is difficult to make conclusions from the identified studies of wrist and hand splints. It appears, though, that working wrist splints do not have short or long term detrimental effects for grip strength or range of motion (ROM), nor is there any clear indication that they provide pain relief. However, ready-made elastic wrist gauntlets are relatively inexpensive and, since they may provide pain relief for some patients in some activities, it seems reasonable to try patients with these orthoses until further data becomes available. The effectiveness of resting hand and wrist splints for night-time use in reducing pain and swelling was tested in only one study. In another study of patient preference following one month of use, participants were found to prefer wearing the splints to not wearing them. There is not currently enough evidence to make a recommendation for practice.

There is preliminary evidence to support the use of extra-depth shoes, with or without semi-rigid insoles, to relieve pain on walking and weight-bearing. Supported insoles appear to limit progression of hallux valgus angle but do not decrease pain or enhance function.

The potential of orthotics to provide pain relief for varying periods of time in certain patients, and at a relatively low cost, tends to support the current practice of recommending that patients try out various splints/orthoses in different activities in order to determine whether these splints are helpful to them.

Implications for research

Research in this area is in its infancy. To date, research questions have been poorly articulated and the rationale for the study designs needs to be more explicit. It was noted that a number of studies were excluded due to the fact that they examined compliance rather than effectiveness (Feinberg 1981, Feinberg 1992, Nicholas 1982). This is rather disconcerting given the fact that effectiveness has not been established, and there is, therefore, sound theoretical rationale for avoiding dogmatic application of splints (Melvin 1989).

We strongly recommend immediate study of the most commonly prescribed orthotics (especially resting hand and wrist splints, and splints prescribed to limit joint deformity such as the metacarpal ulnar deviation or MUD splint), with study questions which clearly address effects on pain, function, ROM and deformity. Furthermore, the hypotheses underlying follow-up time must be clearly articulated. Sample sizes must be large enough to ensure adequate power. Adverse effects must be considered. Placebos should be considered where possible. As well, in most cases it is possible to remove the orthosis prior to follow-up to ensure blind evaluation. This should be done when possible and reported clearly.

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* Indicates the major publication for the study



Anderson 1987

RA Female Mean Age Group 1: 51.3 SD: 16.7 Group 2: 51.1 SD: 15.8 Group 3: 56.9 SD: 12.5 Group 4: 55.7 SD: 13.0 Group 5: 57.3	
SD: 10.4	
Wrist Orthoses 1-Dorsal Working Splint 2-Palmar Working Splint 3-Gauntlet Working Splint 4-Elastic Ready-Made Splint 5-No splint (control group)	
1-Hand grip strength (mmHg) immediately after donning splint	
R=randomization B=blinding W=withdrawals R=2 B=0 W=1	
Authors' judgement	Support for judgement
Low risk	A - Adequate
	Wrist Orthoses 1-Dorsal Working Splin 2-Palmar Working Splir 3-Gauntlet Working Spl 4-Elastic Ready-Made S 5-No splint (control gro 1-Hand grip strength (r immediately after donr R=randomization B=blinding W=withdrawals R=2 B=0 W=1 Authors' judgement

Methods	Randomized, Parallel Group, Placebo controlled, Double-blind,Sample size at entry: 102		
Participants	Diagnosis of RA, functional class I and II, subjects were between 18 and 75 yrs of age, had foot pain, had radiologic changes of stage I and II in one or both feet, had active disease defined either as 6 or more joints that were painful on palpation and tender on motion or had 3 or more swollen joints with greater or equal to 45 min. of joint stiffness in the morning. Treatment Mean age: 60.2 yrs, Control Mean age: 58.8 yrs, Disease duration for treatment group: 9.8 yrs, and for control group: 6.1 yrs		
Interventions	Foot orthoses: 1-Functional posted foot by Rohadur 2-Placebo orthosis (thin flexible leather shell molded over a plaster impression of the patient's foot, covered with thin naugahyde of the same color and design as the thermoplastic functional posted foot orthosis)		

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Budiman-Mak 1995 (Continued)

Outcomes	1- Progression of hallux abductus angle by treatment status		
Notes	R=2 B=2 W=1		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Allocation concealment?	Low risk	A - Adequate	

Callinan 1996

Methods	Randomized, Crossove	er Study, Sample size at entry: 45 (one group over time)	
Participants	Mean age: 51 yrs	Diagnosis of RA, presence of hand pain, morning stiffness or both. Mean age: 51 yrs Mean Disease Duration: 14.5 yrs. 36 Females and 3 Males	
Interventions	Hand-Wrist Extension S 1- Hard Splint: circumf 2-Conventional resting	erential	
Outcomes	1- Compliance 2- Preference		
Notes	R=1 B=0 W=1		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Allocation concealment?	Unclear risk	B - Unclear	

Chalmers 2000

Methods	Crossover Study, Sample size at entry : 28 (they received in random order 3 interventions for 12 wks tri- als, separated by 2 wks washout).
Participants	Diagnosis of RA, minimum 2 subluxed MTP joints bilaterally and MTP joint pain as most significant foot problem. Mean age for men : 63 yrs, for women : 60 yrs. Mean disease duration: 15 yrs
Interventions	Foot/Ankle orthoses: 1- Subortholen 2- Plastazote 3- Extra-Depth shoes
Outcomes	1- RB*walking 2- RB stairs 3- RB stand

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Chalmers 2000 (Continued)	
	4- TADL** walking
	5- TADL stairs
	6- TADL sub walk
	7- 50' walking
	8- Lower extremity joint count
	9- MTP joint count
	10-Pain (VAS)
	*RB= Robinson Bashall Functional Assessment
	** TADL= Toronto Activities of Daily Living Measure
Notes	R=1
	B=0
	W=1
	W=1

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Conrad 1996

Methods	Randomized, Parallel group, Sample size at entry for experimental group:52, Control group:50. NB: This is the same study as Budiman-Mak		
Participants	Patients aged between 18 and 75yrs old, foot pain, definite RA, functional class I or II, radiological changes of stage I or II in one or both feet, 6 or more painful joints or 3 or more swollen joints, or sedi- mentation of 28mm or more per hour, flexible functional discrepancies in their feet, measured as cal- caneal valgus stance positions that could be controlled by a functional foot orthosis, minimum ROM in feet and ankle making ambulation position. Disease duration: longer than 2 yrs.		
Interventions	Foot/Ankle orthosis: 1-Functional posted foot orthosis 2-Placebo orthosis (thin naugahyde shoe insert)		
Outcomes	1-Painful foot joint count 2-Total painful joint count 3-Foot pain 4-FFI pain scale 5-Disability scale 6-Activity limitation scale 7-Total score(FFI) 8-Total disability (AIMS)		
Notes	R=1 B=2 W=1		
Risk of bias			
Bias	Authors' judgement Support for judgement		
Allocation concealment?	Low risk A - Adequate		



Feinberg 1981

Bias	Authors' judgement Support for judgement	
Risk of bias		
Notes	R=0 B=0 W=1	
Outcomes	1-Pain severity and changes (wrist/hand) 2-ROM and changes 3-Duration of morning stiffness and changes	
Interventions	Wrist/Hand splint: Group 1: compliant group that wore the splint more than 50% of the prescribed time Group 2: Non-compliant group that wore the splint less than 50% of the prescribed time.	
Participants	Patients with RA that have never been splinted with resting splints prior to study.	
Methods	Single intervention study. Sample size at entry: 50	

Allocation concealment?	High risk	C - Inadequate

Feinberg 1992

Methods	Randomized, Sample s	ize at entry for experimental group: 22, Control group: 24
Participants		tional class I or II, Control group mean age: 48.84yrs, Experimental group mean group mean disease duration: 4.44yrs, Experimental group mean disease dura-
Interventions		atient education (learning principles and assessment of the patient's expecta- l encounter) plus hand resting splint wear. sting splint
Outcomes	1-Wrist and hand pain s 2-Duration of morning 3-Days of splint use 4-Days of splinting use	stiffness
Notes	R=1 B=0 W=1	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Fransen 1997

Methods

Randomized, Sample size at entry for the experimental group: 15, Control group: 15

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Fransen 1997 (Continued)

Participants	Diagnosis of RA, foot p	ain of at least 1 year duration and stabilization of arthritis medications
Interventions	Experimental group: Extra-Depth shoes Control group: normal shoes	
Outcomes	1- Walk pain (VAS) 2- Stair pain (VAS) 3- NWB pain (VAS) 4- Fatigue 5- Well-being 6- Walk-time 7- HAQ* score * Health Assessment Q	uestionnaire
Notes	R=1 B=0 W=1	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Janssen 1990

Bias	Authors' judgement	Support for judgement
Risk of bias		
	W=0	
	B=0	
Notes	R=1	
	4- Grip strength (kPa)	
	3- Pain score	
0.000.000	2- Ritchie Index	
Outcomes	1- No. of swollen joints	
Interventions	Treatment group: Rest	ing splints a=on alternate hands every night for 1 yr.
raiticipalits	RA (AL IEASL 4 SWOLLEN W	hist of hinger joints and not more fitan 3 redressable deformities)
Participants	RA (at least 4 swollen wrist or finger joints and not more htan 3 redressable deformities)	
Methods	Randomized, parrallel group study. Sample size at entry: 29	

Kjeken 1995

Methods

Randomized, Parallel group, Sample size at entry for Treatment group: 36, Control group: 33.

Kjeken 1995 (Continued)	
Participants	Adults with either RA or persistent seronegative arthritides, a diagnosis of inflammatory arthritis dis- ease with at least 2 of the following signs: sweeling, pain on motion, and limited motion, Involvement of the dominant wrist joint. Orthoses group mean age: 62 yrs, Control group mean age: 66yrs.
Interventions	Wrist orthoses: 1- Treatment group:Rehband elastic wrist orthosis (10-15 degrees of dorsiflexion) 2-Control group: no splint wear.
Outcomes	 1-Morning stiffness 2-Pain at rest (wrist) 3-Pain on motion 4-Wrist pain on motion 5-Active dorsal and volar joint motion 6-Passive dorsal and volar joint motion 7-Active ulnar and radial joint motion 8-Active pronation and supination 9-Pinch grip 10-Grip strength 11-Activity pain (cutting cheese) 12-Activity pain (pouring water) 13-Joint circumference 14-Forearm circumference 15-HAQ score
Notes	R=1 B=0 W=1
Risk of bias	

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Nordenskiöld 1990

Methods	Randomized, Parallel Group, Sample size at entry: 104	
Participants	Treatment Group: Diagnosis of RA, Functional classes 2 and 3, Treatment group mean age: 53 yrs, Con- trol group mean age: 40 yrs.	
Interventions	Soft Volar Wrist Orthoses (neutral position) 1-Camp Splint with larger thumb opening 2-Rehband Splint with more material on the dorsal side	
Outcomes	1-Mean Grip Strength of R and L hands 2-Average pain experienced durind ADL with and without wrist orthosis	
Notes	R=1 B=0 W=0	
Risk of bias		
Bias	Authors' judgement Support for judgement	

Splints and Orthosis for treating rheumatoid arthritis (Review)



Unclear risk

Nordenskiöld 1990 (Continued)

Allocation concealment?

B - Unclear

Pagnotta 1998

Methods	Crossover study, sample at entry: 110
Participants	Diagnosis of RA, splinting of the dominant hand indicated by pain either at rest or on exertion. Chronic pain. Total mean age: 52.4, SD: 13.9yrs, range: 25-81yrs. Disease duration: 9.2yrs, SD: 12.3yrs.
Interventions	Commercial working wrist splint (Futuro Kendall #33)
Outcomes	Work performance out put in 10 sec.:
	1-Shears
	2-Screwdriver
	3-Dexterity
	Pain:
	1-Shears
	2-Srewdriver
Notes	R=0
	B=0
	W=0

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Rennie 1996

Methods	One group over time, S	ample size at entry: 26 subjects (27 hands)
Participants	Diagnosis of RA, Mean a	age: 64 yrs
Interventions	Ulnar Deviation Finger	orthosis (MCP)
Outcomes	Ulnar Drift Angle (degre	ees)
Notes	R=0 B=0 W=1	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate



Stern 1996a

Methods	One over time, Crossover study, sample size at entry : 36	
Participants	Definite RA, functional class 2 or 3, dominant wrist active extension of equal or greater than 20 degrees, Group mean age: 56.5, SD:13.6.	
Interventions	Wrist orthoses: 1-Kendall-Futuro #33 2-Alimed Freedom Long 3-Rolyan D-Ring	
Outcomes	1-Grip strength (kg)	
Notes	R=1 B=0 W=1	
Risk of bias		
Bias	Authors' judgement Support for judgement	

Allocation concealment? Unclear risk

B - Unclear

Stern 1996b

Methods	Block- randomized, Crossover Study, Sample size at entry: 42 (one group over time)
Participants	Subjects falling within functional class 2 or 3 and demonstrated active wrist extension greater or equal to 20 degrees and reported wrist involvement (pain at rest, pain during function or wrist instability) of the dominant hand, Mean Age: 56,50 yrs, Mean of Disease Duration: 11.05 yrs, 20 males and 22 females.
Interventions	Wrist orthoses : 1- Futuro 33 2- Rolyan D-Ring 3- Alimed Freedom Long Frequency of splint wearing: used intermittently during functional tasks for a minimum of 4 hrs/day ac- cross 5 of the 7 days of wear (1 wk wash-out between orthoses).
Outcomes	 Placing (# of pins placed) Assembly (# of pieces assembled) Writing (sec.) Writing (log) Card turning (sec.) Pick up small objects (sec.) Feeding (sec.) Checkers (sec.) Empty cans (sec.) One pound cans (sec.) (For Purdue Pegboard and Jebson-Taylor Tests)
Notes	R=1 B=0 W=1 (all subjects completed the study)

Risk of bias

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Stern 1996b (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Stern 1997 Methods Randomized study. Sample size at entry:42 (one group over time) RA (functional class 1 or 2, active wrist extension greater than 20 degrees, wrist involvement of the Participants dominant hand -pain at rest, pain during function or wrist instability) Total sample mean: 11.05 yrs, SD: 11.03 Total sample mean: 56.50 yrs SD: 13.60 yrs Interventions Wrist Orthoses: 1-Futuro (gauntlet: dorsal opening) 2-Alimed (gauntlet: dorsal-radial opening) 3-Rolyan (gauntlet: dorsal opening) 1-Increase in hand or wrist strength Outcomes Notes R=1 B=0 W=1 **Risk of bias** Bias **Authors' judgement** Support for judgement Allocation concealment? Unclear risk B - Unclear

Swigart 1999

Methods	Single Interventions, S	Single Interventions, Sample size at entry: 114							
Participants	Diagnosis of RA, Total s	Diagnosis of RA, Total sample mean age: 53.8 yrs							
Interventions		humb splint: Long Opponens Splint Holding the thumb in abd. Comparison is made between differant tages of the disease as well as subjects that underwent surgery or not.							
Outcomes	1-Symptom Improvem	ent							
Notes	R=0 B=0 W=1								
Risk of bias									
Bias	Authors' judgement	Support for judgement							
Allocation concealment?	Unclear risk	B - Unclear							

Splints and Orthosis for treating rheumatoid arthritis (Review)



Tijhuis 1998

Methods		Randomized crossover study, Sample size at entry: Futuro group: 5 Thermolyn group: 5 (they both tried the two types of splints)								
Participants		swollen and a painful wrist of the dominant hand Gender: 2 men, 8 women, nge: 28-71. Disease Duration: 6.4 yrs, range: 1-15								
Interventions	Futuro and Thermolyn splints.	uturo and Thermolyn Splints worn for two weeks each with a one week wash-out period between plints.								
Outcomes	1-Pain in Wrist (VAS) 2-Tender joint count ir 3-Swelling of wrist 4-Wrist ROM (degrees) 5-Grip Strength with o 6-Grip strength withou (kPa)	rthosis (kPa)								
Notes	R=1 B=0 W=1									
Risk of bias										
Bias	Authors' judgement	Support for judgement								
Allocation concealment?	Unclear risk	B - Unclear								

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Backman 1988	Only 3 subjects were used for the study
Bennett 1965	Not a clinical trial
Convery 1967	No numerical data
Craxford 1982	This article makes a comparison between Conservative and Surgical Methods, and we decided to exclude surgery data from this research.
Gruen H	Not a clinical trial
Gumpel 1981	No results data available. Study was not completed.
Kim 1995	The proportion of OA patients is greater than the RA patients.
Kock 1980	Not a clinical trial
McKnight 1982	No SD available. Only changes between hands reported with no raw data values for baseline peri- od. Therefore, we are unable to calculate absolute value at end of treatment.

Study	Reason for exclusion
McKnight 1992	Patients were wearing two types of gloves at the same time on both hands. There was no control period.
Moncur 1990	No control group and only subjective data
Nicholas 1982	There are no times intervals available and no mention of the type of splint patients were wearing.
Ouellette 1991	Literature review
Palchik 1990	No data is available concerning the significance (p value), and there is no mention of what statisti- cal tests they have done.
Souter 1971	Not a clinical trial
Stern 1994	The subjects used in this study were healthy women with a mean age of 26.26 yrs. Rheumatoid arthritis was never mentioned in this article.

DATA AND ANALYSES

Comparison 1. Working wrist gauntlet versus no splint (immediate)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Grip strength of dominant hand (mmHg)- dorsal working splint vs no splint	1	37	Mean Difference (IV, Fixed, 95% CI)	0.20 [-30.65, 31.05]
2 Grip strength of dominant hand (mmHg) - Palmar splint vs no splint	1	38	Mean Difference (IV, Fixed, 95% CI)	6.0 [-28.27, 40.27]
3 Grip strength of dominant hand (mmHg) - Plastazote and polythene sheeting custom made gauntlet vs no splint	1	36	Mean Difference (IV, Fixed, 95% CI)	-20.70 [-44.81, 3.41]
4 Grip strength of dominant hand (mmHg) - Elastic with metal stay ready made gauntlet vs no splint	1	38	Mean Difference (IV, Fixed, 95% CI)	-22.20 [-49.62, 5.22]
5 Grip strength of non-dominant hand (mmHg) - Dorsal working splint versus no splint	1	37	Mean Difference (IV, Fixed, 95% CI)	4.20 [-33.07, 41.47]
6 Grip strength of non-dominant hand (mmHg) - Palmar splint versus no splint	1	38	Mean Difference (IV, Fixed, 95% CI)	-29.10 [-54.04, -4.16]
7 Grip strength of non-dominant hand (mmHg)- Plastazote and polythene sheeting custom made gauntlet vs no split	1	36	Mean Difference (IV, Fixed, 95% CI)	-23.51 [-50.01, 2.99]
8 Grip strength of non-dominant hand (mmHg) - Elastic with metal stay ready made gauntlet vs no splint	1	38	Mean Difference (IV, Fixed, 95% CI)	-33.01 [-62.01, -4.01]

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Analysis 1.1. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 1 Grip strength of dominant hand (mmHg)- dorsal working splint vs no splint.

Study or subgroup	Dorsal working		ne	no splint		Mean Difference				Weight	Mean Difference
	N Mean(SD)		N Mean(SD)		Fixed, 95% CI						Fixed, 95% CI
Anderson 1987	18	97.7 (54.4)	19	97.5 (39.8)		-		-		100%	0.2[-30.65,31.05]
Total ***	18		19					-		100%	0.2[-30.65,31.05]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.01(P=0.99)											
			Fa	vours control	-100	-50	0	50	100	Favours treatr	nent

Analysis 1.2. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 2 Grip strength of dominant hand (mmHg) - Palmar splint vs no splint.

Study or subgroup	Paln	nar splint	No splint			Mean Difference			Weight I	lean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% CI			Fixed, 95% CI
Anderson 1987	19	103.5 (65)	19	97.5 (39.8)					100%	6[-28.27,40.27]
Total ***	19		19						100%	6[-28.27,40.27]
Heterogeneity: Not applicable										
Test for overall effect: Z=0.34(P=0.73)										
			Fa	vours control	-100	-50	0 5	0 100	Favours treatme	nt

Analysis 1.3. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 3 Grip strength of dominant hand (mmHg) - Plastazote and polythene sheeting custom made gauntlet vs no splint.

Study or subgroup		Plasta- zote-polythene		No splint		Mean Difference				Weight	Mean Difference
	N	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% CI				Fixed, 95% CI
Anderson 1987	17	76.8 (34)	19	97.5 (39.8)						100%	-20.7[-44.81,3.41]
Total ***	17		19							100%	-20.7[-44.81,3.41]
Heterogeneity: Tau ² =0; Chi ² =	0, df=0(P<0.0001	.); I ² =100%									
Test for overall effect: Z=1.68	(P=0.09)				ı						
			Fav	vours control	-100	-50	0	50	100	Favours trea	atment

Analysis 1.4. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 4 Grip strength of dominant hand (mmHg) - Elastic with metal stay ready made gauntlet vs no splint.

Study or subgroup	Elasti	ic gauntlet	No splint			Mean Difference				Weight	Mean Difference
	N	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% (CI			Fixed, 95% CI
Anderson 1987	19	75.3 (46.2)	19	97.5 (39.8)						100%	-22.2[-49.62,5.22]
Total ***	19		19							100%	-22.2[-49.62,5.22]
			Fa	vours control	-100	-50	0	50	100	Favours trea	tment

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Study or subgroup	Elast	ic gauntlet	N	lo splint		Mean Difference			Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)	Fixed, 95% CI				Fixed, 95%		
Heterogeneity: Not applicable											
Test for overall effect: Z=1.59(P=0.11)											
			F	avours control	-100	-50	0	50	100	Favours treat	ment

Analysis 1.5. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 5 Grip strength of non-dominant hand (mmHg) - Dorsal working splint versus no splint.

Study or subgroup	Dor	sal splint	No splint			Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% Cl					Fixed, 95% CI
Anderson 1987	18	106 (67.7)	19	101.8 (45.1)		-				100%	4.2[-33.07,41.47]
Total ***	18		19			-	-			100%	4.2[-33.07,41.47]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.22(P=0.83)											
			Fa	vours control	-100	-50	0	50	100	Favours treat	nent

Analysis 1.6. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 6 Grip strength of non-dominant hand (mmHg) - Palmar splint versus no splint.

Study or subgroup	Paln	nar splint	N	o splint	Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fix	ed, 95% CI			Fixed, 95% CI
Anderson 1987	19	72.7 (32.3)	19	101.8 (45.1)					100%	-29.1[-54.04,-4.16]
Total ***	19		19						100%	-29.1[-54.04,-4.16]
Heterogeneity: Not applicable										
Test for overall effect: Z=2.29(P=0.02)										
			Fav	ours controls	-100	-50	0	50 100	Favours tre	atment

Analysis 1.7. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 7 Grip strength of non-dominant hand (mmHg)- Plastazote and polythene sheeting custom made gauntlet vs no split.

Study or subgroup	-	Plasta- zote-polythene		No splint		Mean Difference				Weight	Mean Difference	
	N	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% C	I			Fixed, 95% CI	
Anderson 1987	17	78.3 (35.9)	19	101.8 (45.1)						100%	-23.51[-50.01,2.99]	
Total ***	17		19							100%	-23.51[-50.01,2.99]	
Heterogeneity: Tau ² =0; Chi ² =0	0, df=0(P<0.0001	.); I ² =100%										
Test for overall effect: Z=1.74	(P=0.08)											
			Fa	vours control	-100	-50	0	50	100	Favours trea	atment	

Analysis 1.8. Comparison 1 Working wrist gauntlet versus no splint (immediate), Outcome 8 Grip strength of non-dominant hand (mmHg) - Elastic with metal stay ready made gauntlet vs no splint.

Study or subgroup	Elasti	ic gauntlet	N	o splint		Mear	n Differei	nce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixe	ed, 95% (CI			Fixed, 95% CI
Anderson 1987	19	68.8 (46.1)	19	101.8 (45.1)			-			100%	-33.01[-62.01,-4.01]
Total ***	19		19							100%	-33.01[-62.01,-4.01]
Heterogeneity: Not applicable											
Test for overall effect: Z=2.23(P=0.03)								1			
			Fa	vours control	-100	-50	0	50	100	Favours trea	atment

Comparison 2. Working wrist gauntlet (elastic with metal insert) versus no splint (immediate after 1 week of wear)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Work performance output in 10 sec. using screwdriver (engals)	1	80	Mean Difference (IV, Fixed, 95% CI)	-213.0 [-445.31, 19.31]
2 Work performance output in 10 sec. using shears (engals)	1	80	Mean Difference (IV, Fixed, 95% CI)	49.0 [-214.18, 312.18]
3 Dexterity (VAS 0 to 10)	1	80	Mean Difference (IV, Fixed, 95% CI)	4.40 [-3.97, 12.77]
4 Pain on using screwdriver (VAS)	1	80	Mean Difference (IV, Fixed, 95% CI)	-0.45 [-1.40, 0.50]
5 Pain on using shears (VAS)	1	80	Mean Difference (IV, Fixed, 95% CI)	-0.52 [-1.48, 0.44]

Analysis 2.1. Comparison 2 Working wrist gauntlet (elastic with metal insert) versus no splint (immediate after 1 week of wear), Outcome 1 Work performance output in 10 sec. using screwdriver (engals).

Study or subgroup	Elast	ic gauntlet	No	o splint		Mean Difference			Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		Fiz	xed, 95% C	:1			Fixed, 95% CI
Pagnotta 1998	40	431 (444)	40	644 (604)						100%	-213[-445.31,19.31]
Total ***	40		40							100%	-213[-445.31,19.31]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.8(P=0.07)					1	1					
			Fa	vours control	-1000	-500	0	500	1000	Favours trea	atment

Analysis 2.2. Comparison 2 Working wrist gauntlet (elastic with metal insert) versus no splint (immediate after 1 week of wear), Outcome 2 Work performance output in 10 sec. using shears (engals).

Study or subgroup	Elast	ic gauntlet	N	o splint		M	ean Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		I	ixed, 95% C	:1			Fixed, 95% CI
Pagnotta 1998	40	1085 (596)	40	1036 (605)				-		100%	49[-214.18,312.18]
Total ***	40		40				-	-		100%	49[-214.18,312.18]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.36(P=0.72)					1						
			Fa	vours control	-1000	-500	0	500	1000	Favours trea	tment

Analysis 2.3. Comparison 2 Working wrist gauntlet (elastic with metal insert) versus no splint (immediate after 1 week of wear), Outcome 3 Dexterity (VAS 0 to 10).

Study or subgroup	Elast	ic gauntlet	No	No splint		Ме	an Differer	ice		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	ixed, 95% (3			Fixed, 95% CI
Pagnotta 1998	40	62 (20.9)	40	57.6 (17.1)						100%	4.4[-3.97,12.77]
Total ***	40		40				•			100%	4.4[-3.97,12.77]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.03(P=0.3)								1			
			Fa	vours control	-100	-50	0	50	100	Favours treatme	ent

Analysis 2.4. Comparison 2 Working wrist gauntlet (elastic with metal insert) versus no splint (immediate after 1 week of wear), Outcome 4 Pain on using screwdriver (VAS).

Study or subgroup	Elastic gauntlet		N	o splint		Me	ean Differer	nce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (CI			Fixed, 95% CI
Pagnotta 1998	40	2 (2.1)	40	2.4 (2.2)						100%	-0.45[-1.4,0.5]
Total ***	40		40				•			100%	-0.45[-1.4,0.5]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.93(P=0.35)											
			Favo	urs treatment	-10	-5	0	5	10	Favours contro	l

Analysis 2.5. Comparison 2 Working wrist gauntlet (elastic with metal insert) versus no splint (immediate after 1 week of wear), Outcome 5 Pain on using shears (VAS).

Study or subgroup	or subgroup Elastic gauntlet N Mean(SD)		N	o splint		М	ean Differen	ce		Weight	Mean Difference
			Ν	Mean(SD)		F	ixed, 95% C	1			Fixed, 95% CI
Pagnotta 1998	40	1.8 (2)	40	2.3 (2.3)						100%	-0.52[-1.48,0.44]
Total ***	40		40				•			100%	-0.52[-1.48,0.44]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.07(P=0.29)										
			Favo	urs treatment	-10	-5	0	5	10	Favours control	

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Comparison 3. Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Pain on motion (VAS:1-100mm)	1	55	Mean Difference (IV, Fixed, 95% CI)	-7.5 [-20.93, 5.93]
2 Pain at rest (VAS:1-100mm)	1	55	Mean Difference (IV, Fixed, 95% CI)	-0.25 [-1.73, 1.23]
3 Activity pain (pouring wa- ter)(VAS:1-100mm)	1	55	Mean Difference (IV, Fixed, 95% CI)	0.0 [-1.06, 1.06]
4 Wrist pain on motion (VAS:1-100mm)	1	55	Mean Difference (IV, Fixed, 95% CI)	-7.00 [-21.20, 7.20]
5 Grip strength (mmHg)	1	55	Mean Difference (IV, Fixed, 95% CI)	-4.0 [-24.04, 16.04]
6 Morning stiffness (min.)	1	55	Mean Difference (IV, Fixed, 95% CI)	0.0 [-41.88, 41.88]
7 Active dorsal and volar joint motion (degrees)	1	55	Mean Difference (IV, Fixed, 95% CI)	7.5 [-4.80, 19.80]
8 Passive dorsal and volar joint motion (degrees)	1	55	Mean Difference (IV, Fixed, 95% CI)	12.5 [0.55, 24.45]
9 Active ulnar and radial joint motion (degrees)	1	55	Mean Difference (IV, Fixed, 95% CI)	0.0 [-7.23, 7.23]
10 Active pronation and supina- tion (degrees)	1	55	Mean Difference (IV, Fixed, 95% CI)	-5.0 [-30.35, 20.35]
11 Pinch grip (mmHg)	1	55	Mean Difference (IV, Fixed, 95% CI)	-1.0 [-25.12, 23.12]
12 Joint circumference (cm)	1	55	Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.42, 0.52]
13 Forearm circumference (cm)	1	55	Mean Difference (IV, Fixed, 95% CI)	0.2 [-0.23, 0.63]
14 HAQ (score 0-3)	1	55	Mean Difference (IV, Fixed, 95% CI)	-0.25 [-0.52, 0.02]

Analysis 3.1. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 1 Pain on motion (VAS:1-100mm).

Study or subgroup	Elast	ic gauntlet	No splint		Mean Difference				Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (CI			Fixed, 95% CI
Kjeken 1995	31	2 (27.3)	24	9.5 (23.5)						100%	-7.5[-20.93,5.93]
Total ***	31		24				•			100%	-7.5[-20.93,5.93]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.09(P=0.27)											
			Favo	urs treatment	-100	-50	0	50	100	Favours contro	

Analysis 3.2. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 2 Pain at rest (VAS:1-100mm).

Study or subgroup	Elast	ic gauntlet	No	No splint		Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (CI			Fixed, 95% CI
Kjeken 1995	31	0.2 (3.4)	24	0.5 (2.2)						100%	-0.25[-1.73,1.23]
Total ***	31		24				•			100%	-0.25[-1.73,1.23]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.33(P=0.74)										
			Favo	urs treatment	-10	-5	0	5	10	Favours control	

Analysis 3.3. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 3 Activity pain (pouring water)(VAS:1-100mm).

Study or subgroup	Elast	tic gauntlet No s		No splint Mo		Ме	an Differer	nce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (21			Fixed, 95% CI
Kjeken 1995	31	0 (2.3)	24	0 (1.8)						100%	0[-1.06,1.06]
Total ***	31		24				•			100%	0[-1.06,1.06]
Heterogeneity: Not applicable											
Test for overall effect: Not applicable						1			i.		
			Favo	urs treatment	-10	-5	0	5	10	Favours contro	l

Analysis 3.4. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 4 Wrist pain on motion (VAS:1-100mm).

Study or subgroup	Elasti	ic gauntlet	No splint			Mean Difference		nce		Weight	Mean Difference
	N	Mean(SD)	Ν	Mean(SD)		F	ixed, 95%	CI			Fixed, 95% CI
Kjeken 1995	31	-2 (33.5)	24	5 (19.8)						100%	-7[-21.2,7.2]
Total ***	31		24				•			100%	-7[-21.2,7.2]
Heterogeneity: Tau ² =0; Chi ² =0,	df=0(P<0.0001	.); I ² =100%									
Test for overall effect: Z=0.97(P	9=0.33)										
			Favou	urs treatment	-100	-50	0	50	100	Favours contro	l

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Analysis 3.5. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 5 Grip strength (mmHg).

Study or subgroup	Elast	Elastic gauntlet		o splint		Me	ean Differen	ce		Weight M	lean Difference
N		Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	1			Fixed, 95% CI
Kjeken 1995	31	-14 (49)	24	-10 (25.5)						100%	-4[-24.04,16.04]
Total ***	31		24				•			100%	-4[-24.04,16.04]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.39(P=0.7)											
			Fa	vours control	-100	-50	0	50	100	Favours treatme	nt

Analysis 3.6. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 6 Morning stiffness (min.).

Study or subgroup	Elast	ic gauntlet	No splint			Mean Difference			Weight		Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI					Fixed, 95% CI
Kjeken 1995	31	0 (97.5)	24	0 (60)						100%	0[-41.88,41.88]
Total ***	31		24							100%	0[-41.88,41.88]
Heterogeneity: Not applicable											
Test for overall effect: Not applicable											
			Favo	urs treatment	-100	-50	0	50	100	Favours contro	l

Analysis 3.7. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 7 Active dorsal and volar joint motion (degrees).

Study or subgroup	Elast	ic gauntlet	No splint		Mean Difference			Weight I	Mean Difference		
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	ixed, 95% CI				Fixed, 95% CI
Kjeken 1995	31	0 (27)	24	-7.5 (19.5)						100%	7.5[-4.8,19.8]
Total ***	31		24				•			100%	7.5[-4.8,19.8]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.2(P=0.23)											
			Fa	vours control	-100	-50	0	50	100	Favours treatme	nt

Analysis 3.8. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 8 Passive dorsal and volar joint motion (degrees).

Study or subgroup	Elast	ic gauntlet	No splint			Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% CI				Fixed, 95% CI
Kjeken 1995	31	-5 (27.5)	24	-17.5 (17.5)						100%	12.5[0.55,24.45]
Total ***	31		24				•			100%	12.5[0.55,24.45]
Heterogeneity: Not applicable											
			Fa	vours control	-100	-50	0	50	100	Favours trea	itment

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Study or subgroup	Elas	tic gauntlet	N	No splint		Ме	an Differer	nce		Weight Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD) Fixed, 95% CI			Fixed, 95% CI			
Test for overall effect: Z=2.05(P=0.04)					_			1		
			F	avours control	-100	-50	0	50	100	Favours treatment

Analysis 3.9. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 9 Active ulnar and radial joint motion (degrees).

Study or subgroup	Elast	ic gauntlet	N	o splint		Mean Difference				Weight I	lean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fiz	ked, 95% (3			Fixed, 95% CI
Kjeken 1995	31	0 (18.8)	24	0 (7.4)						100%	0[-7.23,7.23]
Total ***	31		24							100%	0[-7.23,7.23]
Heterogeneity: Not applicable											
Test for overall effect: Not applicable					1	1					
			Fa	vours control	-10	-5	0	5	10	Favours treatme	nt

Analysis 3.10. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 10 Active pronation and supination (degrees).

Study or subgroup	Elast	Elastic gauntlet		No splint		Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI				Fixed, 95% CI	
Kjeken 1995	31	-12.5 (44.3)	24	-7.5 (50)		-				100%	-5[-30.35,20.35]
Total ***	31		24			-				100%	-5[-30.35,20.35]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.39(P=0.7)											
			Fa	vours control	-100	-50	0	50	100	Favours treatme	ent

Analysis 3.11. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 11 Pinch grip (mmHg).

Study or subgroup	Elast	ic gauntlet	No	splint	Mean Difference			Weight	Mean Difference		
	Ν	Mean(SD)	Ν	Mean(SD)		Fiz	xed, 95% (CI			Fixed, 95% CI
Kjeken 1995	31	-28 (54.8)	24	-27 (36.3)	•					100%	-1[-25.12,23.12]
Total ***	31		24							100%	-1[-25.12,23.12]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.08(P=0.94)								1			
			Fa	vours control	-10	-5	0	5	10	Favours treatm	ent

Analysis 3.12. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 12 Joint circumference (cm).

Study or subgroup	Elastic gauntlet		No splint			Ме	an Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI				Fixed, 95% CI	
Kjeken 1995	31	0 (1)	24	-0 (0.8)			+			100%	0.05[-0.42,0.52]
Total ***	31		24				•			100%	0.05[-0.42,0.52]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.21(P=0.84)				1			1			
			Favo	urs treatment	-10	-5	0	5	10	Favours contro	

Analysis 3.13. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 13 Forearm circumference (cm).

Study or subgroup	Elast	ic gauntlet	No splint		Mean Difference				Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (21			Fixed, 95% CI
Kjeken 1995	31	0 (0.6)	24	-0.2 (1)			+			100%	0.2[-0.23,0.63]
Total ***	31		24				•			100%	0.2[-0.23,0.63]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.92(P=0.36)					1					
			Favo	urs treatment	-10	-5	0	5	10	Favours contro	l

Analysis 3.14. Comparison 3 Working wrist gauntlet (elastic with metal insert) versus no splint (6 mos), Outcome 14 HAQ (score 0-3).

Study or subgroup	Elast	Elastic gauntlet No splint			Me	an Differen	ce	Weight	Mean Difference		
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	I			Fixed, 95% CI
Kjeken 1995	31	0 (0.5)	24	0.3 (0.5)			+			100%	-0.25[-0.52,0.02]
Total ***	31		24				•			100%	-0.25[-0.52,0.02]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.79(P=0.07)											
			Favo	urs treatment	-10	-5	0	5	10	Favours control	

Comparison 4. Futuro wrist gauntlet vs Thermolyn custom made wrist gauntlet (2 weeks)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Pain in wrist (VAS:1-10cm)	1	20	Mean Difference (IV, Fixed, 95% CI)	1.0 [-0.97, 2.97]
2 Tender joint count wrist and hand (Ritchie scale)	1	20	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-3.77, 2.57]

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Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
3 Number of swollen joints	1	20	Mean Difference (IV, Fixed, 95% CI)	1.50 [-1.30, 4.30]
4 Total passive wrist ROM (de- grees)	1	20	Mean Difference (IV, Fixed, 95% CI)	-18.0 [-91.77, 55.77]
5 Grip strength (kPa) with ortho- sis	1	20	Mean Difference (IV, Fixed, 95% CI)	4.0 [-10.93, 18.93]
6 Grip strength (kPa) without or- thosis	1	20	Mean Difference (IV, Fixed, 95% CI)	-3.0 [-18.35, 12.35]

Analysis 4.1. Comparison 4 Futuro wrist gauntlet vs Thermolyn custom made wrist gauntlet (2 weeks), Outcome 1 Pain in wrist (VAS:1-10cm).

Study or subgroup	Th	ermolyn	F	uturo		Mean Difference			Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% C	I			Fixed, 95% CI
Tijhuis 1998	10	4.7 (2.2)	10	3.7 (2.3)				-		100%	1[-0.97,2.97]
Total ***	10		10				-			100%	1[-0.97,2.97]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.99(P=0.32)										
			Favou	rs Thermolyn	-10	-5	0	5	10	Favours Futuro	

Analysis 4.2. Comparison 4 Futuro wrist gauntlet vs Thermolyn custom made wrist gauntlet (2 weeks), Outcome 2 Tender joint count wrist and hand (Ritchie scale).

Study or subgroup	Th	ermolyn	F	uturo		Mean Difference		Weight		Mean Difference	
	Ν	Mean(SD)	N	Mean(SD)		Fi	xed, 95% C	1			Fixed, 95% CI
Tijhuis 1998	10	4.2 (3.9)	10	4.8 (3.3)						100%	-0.6[-3.77,2.57]
Total ***	10		10							100%	-0.6[-3.77,2.57]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.37(P=0.71)											
			Favou	rs Thermolyn	-10	-5	0	5	10	Favours Futuro	

Analysis 4.3. Comparison 4 Futuro wrist gauntlet vs Thermolyn custom made wrist gauntlet (2 weeks), Outcome 3 Number of swollen joints.

Study or subgroup	Thermolyn		F	Futuro		Ме	an Differen	ce	Weight	Mean Difference	
	N	Mean(SD)	N	Mean(SD)		F	ixed, 95% C	I			Fixed, 95% CI
Tijhuis 1998	10	4.1 (4)	10	2.6 (2.1)						100%	1.5[-1.3,4.3]
Total ***	10		10							100%	1.5[-1.3,4.3]
			Favou	rs Thermolyn	-10	-5	0	5	10	Favours Futuro	

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Study or subgroup	Thermolyn			Futuro		Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI			Fixed, 95% CI		
Heterogeneity: Not applicable											
Test for overall effect: Z=1.05(P=0.29)											
			Favo	urs Thermolyn	-10	-5	0	5	10	Favours Futuro	

Analysis 4.4. Comparison 4 Futuro wrist gauntlet vs Thermolyn custom made wrist gauntlet (2 weeks), Outcome 4 Total passive wrist ROM (degrees).

Study or subgroup	Th	ermolyn	F	uturo	Mean Difference			Weight	Mean Difference		
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95%	CI			Fixed, 95% CI
Tijhuis 1998	10	255 (73)	10	273 (94)						100%	-18[-91.77,55.77]
Total ***	10		10							100%	-18[-91.77,55.77]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.48(P=0.63)											
			Fa	avours Futuro	-100	-50	0	50	100	Favours The	rmolyn

Analysis 4.5. Comparison 4 Futuro wrist gauntlet vs Thermolyn custom made wrist gauntlet (2 weeks), Outcome 5 Grip strength (kPa) with orthosis.

Study or subgroup	Th	ermolyn	Futuro			Me	ean Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	I			Fixed, 95% CI
Tijhuis 1998	10	32 (18)	10	28 (16)						100%	4[-10.93,18.93]
Total ***	10		10				•			100%	4[-10.93,18.93]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.53(P=0.6)											
			Fa	avours Futuro	-100	-50	0	50	100	Favours Thermo	lyn

Analysis 4.6. Comparison 4 Futuro wrist gauntlet vs Thermolyn custom made wrist gauntlet (2 weeks), Outcome 6 Grip strength (kPa) without orthosis.

Study or subgroup	The	ermolyn	F	uturo	uro Mean Difference		nce		Weight	Mean Difference	
	N	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI				Fixed, 95% CI	
Tijhuis 1998	10	30 (17)	10	33 (18)						100%	-3[-18.35,12.35]
Total ***	10		10				-			100%	-3[-18.35,12.35]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.38(P=0.7)											
			Fa	vours Futuro	-100	-50	0	50	100	Favours The	ermolyn

Comparison 5. Futuro wrist gauntlet vs Alimed wrist gauntlet (immediately after 1 week of wear)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Unilateral dexterity (splint on) (Purdue Pegboard placing)	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.06 [-1.21, 1.09]
2 Bilateral dexterity (splint on) (Purdue Pegboad assembly)	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.04 [-4.22, 4.14]
3 Grip strength (splint off) (kg)	1	72	Mean Difference (IV, Fixed, 95% CI)	0.42 [-4.10, 4.94]

Analysis 5.1. Comparison 5 Futuro wrist gauntlet vs Alimed wrist gauntlet (immediately after 1 week of wear), Outcome 1 Unilateral dexterity (splint on) (Purdue Pegboard placing).

Study or subgroup	F	Futuro	A	limed		Mean Difference			Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI				Fixed, 95% CI	
Stern 1996b	42	13.1 (2.8)	42	13.1 (2.6)		_		-		100%	-0.06[-1.21,1.09]
Total ***	42		42			-	$ \bullet $			100%	-0.06[-1.21,1.09]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.1(P=0.92)											
			Fa	vours Alimed	-4	-2	0	2	4	Favours Futuro	

Analysis 5.2. Comparison 5 Futuro wrist gauntlet vs Alimed wrist gauntlet (immediately after 1 week of wear), Outcome 2 Bilateral dexterity (splint on) (Purdue Pegboad assembly).

Study or subgroup	F	uturo	A	Alimed		Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI					Fixed, 95% CI
Stern 1996b	42	33.6 (9.5)	42	33.6 (10)						100%	-0.04[-4.22,4.14]
Total ***	42		42							100%	-0.04[-4.22,4.14]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.02(P=0.99)											
			Fa	vours Alimed	-10	-5	0	5	10	Favours Futuro	

Analysis 5.3. Comparison 5 Futuro wrist gauntlet vs Alimed wrist gauntlet (immediately after 1 week of wear), Outcome 3 Grip strength (splint off) (kg).

Study or subgroup	F	Futuro	Alimed			Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (21			Fixed, 95% CI
Stern 1996a	36	21.9 (9.4)	36	21.5 (10.2)						100%	0.42[-4.1,4.94]
Total ***	36		36							100%	0.42[-4.1,4.94]
Heterogeneity: Not applicable											
			Fa	vours Alimed	-10	-5	0	5	10	Favours Futuro	•

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Study or subgroup		Futuro		Alimed			Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI					Fixed, 95% CI	
Test for overall effect: Z=0.18(P=0.86)									1		·	
				Favours Alimed	-10	-5)	5	10	Favours Futuro	

Comparison 6. Alimed wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Unilateral dexterity (splint on) (Pur- due Pegboard placing)	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.31 [-1.45, 0.83]
2 Bilateral dexterity (splint on) (Purdue Pegboard placing)	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.07 [-4.35, 4.21]
3 Grip strength (splint off) (kg)	1	72	Mean Difference (IV, Fixed, 95% CI)	-0.56 [-5.18, 4.06]

Analysis 6.1. Comparison 6 Alimed wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear), Outcome 1 Unilateral dexterity (splint on) (Purdue Pegboard placing).

Study or subgroup	P	limed	R	olyan		Mean Difference			Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		Fiz	xed, 95% C	:1			Fixed, 95% CI
Stern 1996b	42	13.1 (2.6)	42	13.4 (2.8)						100%	-0.31[-1.45,0.83]
Total ***	42		42							100%	-0.31[-1.45,0.83]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.53(P=0.59))										
			Fa	vours Rolyan	-4	-2	0	2	4	Favours Alimed	

Analysis 6.2. Comparison 6 Alimed wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear), Outcome 2 Bilateral dexterity (splint on) (Purdue Pegboard placing).

Study or subgroup	ŀ	limed	Rolyan			Ме	an Differe	nce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI					Fixed, 95% CI
Stern 1996b	42	33.6 (10)	42	33.7 (10)						100%	-0.07[-4.35,4.21]
Total ***	42		42							100%	-0.07[-4.35,4.21]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.03(P=0.97)										
			Fa	vours Rolyan	-10	-5	0	5	10	Favours Alimed	

Analysis 6.3. Comparison 6 Alimed wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear), Outcome 3 Grip strength (splint off) (kg).

Study or subgroup	Alimed		Rolyan			Mean Difference				Weight	Mean Difference
	N Mean(SD)		N Mean(SD)		Fixed, 95% CI					Fixed, 95% CI	
Stern 1996a	36	21.5 (10.2)	36	22 (9.8)						100%	-0.56[-5.18,4.06]
Total ***	36		36							100%	-0.56[-5.18,4.06]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.24(P=0.81)											
			Fa	vours Rolyan	-10	-5	0	5	10	Favours Alimed	

Comparison 7. Futuro wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Unilateral dexterity (splint on) (Pur- due Pegboard placing)	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.37 [-1.56, 0.82]
2 Bilateral dexterity (splint on) (Purdue Pegboard assembly)	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.11 [-4.28, 4.06]
3 Grip strength (splint off) (kg)	1	72	Mean Difference (IV, Fixed, 95% CI)	-0.14 [-4.57, 4.29]

Analysis 7.1. Comparison 7 Futuro wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear), Outcome 1 Unilateral dexterity (splint on) (Purdue Pegboard placing).

Study or subgroup	F	uturo	F	Rolyan		Mean Difference		Mean Difference Weight		Weight	Mean Difference
	Ν	Mean(SD)	N	Mean(SD)			Fixed, 95% C	I			Fixed, 95% Cl
Stern 1996b	42	13.1 (2.8)	42	13.4 (2.8)						100%	-0.37[-1.56,0.82]
Total ***	42		42							100%	-0.37[-1.56,0.82]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.61(P=0.54)											
			Fa	avours Rolyan	-4	-2	0	2	4	Favours Futuro	

Analysis 7.2. Comparison 7 Futuro wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear), Outcome 2 Bilateral dexterity (splint on) (Purdue Pegboard assembly).

Study or subgroup	F	uturo	R	lolyan		Mean Difference		nce Weight		Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95%	CI			Fixed, 95% CI
Stern 1996b	42	33.6 (9.5)	42	33.7 (10)						100%	-0.11[-4.28,4.06]
Total ***	42		42							100%	-0.11[-4.28,4.06]
Heterogeneity: Not applicable											
			Fa	vours Rolyan	-10	-5	0	5	10	Favours Futuro	

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Study or subgroup		Futuro		Rolyan		Ме	an Differen	ice		Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% C	3			Fixed, 95% CI	
Test for overall effect: Z=0.05(P=0.96)					_							
				Favours Rolyan	-10	-5	0	5	10	Favours Futuro		

Analysis 7.3. Comparison 7 Futuro wrist gauntlet vs Rolyan wrist gauntlet (immediately after 1 week of wear), Outcome 3 Grip strength (splint off) (kg).

Study or subgroup	F	uturo	Rolyan			Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% Cl				Fixed, 95% CI	
Stern 1996a	36	21.9 (9.4)	36	22 (9.8)						100%	-0.14[-4.57,4.29]
Total ***	36		36							100%	-0.14[-4.57,4.29]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.06(P=0.95)											
			Fa	avours Rolyan	-10	-5	0	5	10	Favours Futuro	

Comparison 8. Resting hand and wrist splint vs no splint (1-6 months)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Preference (1 month) (# of pa- tients prefering soft or hard splint vs no splint)	1	78	Risk Ratio (M-H, Fixed, 95% CI)	5.5 [2.09, 14.49]
2 Grip strength (6 months)	1	58	Mean Difference (IV, Fixed, 95% CI)	1.74 [-6.36, 9.83]
2.1 Grip strength - right (mmHg) (6 months)	1	29	Mean Difference (IV, Fixed, 95% CI)	3.0 [-7.64, 13.64]
2.2 Grip strength left (mmHg) (6 months)	1	29	Mean Difference (IV, Fixed, 95% CI)	0.0 [-12.47, 12.47]
3 Number of swollen joints (6 months)	1	29	Mean Difference (IV, Fixed, 95% CI)	-3.2 [-7.50, 1.10]
4 Ritchie Index (6 months)	1	29	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-3.26, 2.86]
5 Pain score (out of 48)	1	29	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 8.1. Comparison 8 Resting hand and wrist splint vs no splint (1-6 months), Outcome 1 Preference (1 month) (# of patients prefering soft or hard splint vs no splint).

Study or subgroup	Hard or soft splint	No splint		Risk Ratio M-H, Fixed, 95% Cl			Weight	Risk Ratio	
	n/N	n/N		M-H	I, Fixed,	95% CI			M-H, Fixed, 95% CI
Callinan 1996	22/39	4/39						100%	5.5[2.09,14.49]
Total (95% CI)	39	39				•		100%	5.5[2.09,14.49]
Total events: 22 (Hard or soft splin	t), 4 (No splint)								
Heterogeneity: Not applicable									
Test for overall effect: Z=3.45(P=0)						I			
		Favours no splint	0.01	0.1	1	10	100	Favours hard or soft	

Analysis 8.2. Comparison 8 Resting hand and wrist splint vs no splint (1-6 months), Outcome 2 Grip strength (6 months).

Study or subgroup	Rest	ing splint	N	o splint		Меа	an Difference		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% CI			Fixed, 95% CI
8.2.1 Grip strength - right (mmHg)	(6 mont	hs)								
Janssen 1990	14	34 (16)	15	31 (12.9)	-				57.86%	3[-7.64,13.64]
Subtotal ***	14		15		_				57.86%	3[-7.64,13.64]
Heterogeneity: Not applicable										
Test for overall effect: Z=0.55(P=0.58)									
8.2.2 Grip strength left (mmHg) (6	months)									
Janssen 1990	14	32 (12.8)	15	32 (20.8)	◀—		•	\rightarrow	42.14%	0[-12.47,12.47]
Subtotal ***	14		15						42.14%	0[-12.47,12.47]
Heterogeneity: Not applicable										
Test for overall effect: Not applicable	9									
Total ***	28		30						100%	1.74[-6.36,9.83]
Heterogeneity: Tau ² =0; Chi ² =0.13, df	=1(P=0.7	2); I ² =0%								
Test for overall effect: Z=0.42(P=0.67)									
Test for subgroup differences: Chi ² =0).13, df=1	L (P=0.72), I ² =0%								
			Fav	ours no splint	-10	-5	0 5	10	Favours splint	

Analysis 8.3. Comparison 8 Resting hand and wrist splint vs no splint (1-6 months), Outcome 3 Number of swollen joints (6 months).

Study or subgroup	Rest	ing splint	N	o splint		Mean Differe		ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI		:1			Fixed, 95% CI
Janssen 1990	14	7.8 (7.1)	15	11 (4.2)						100%	-3.2[-7.5,1.1]
Total ***	14		15							100%	-3.2[-7.5,1.1]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.46(P=0.14)											
			F	avours splint	-10	-5	0	5	10	Favours no splir	nt

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Analysis 8.4. Comparison 8 Resting hand and wrist splint vs no splint (1-6 months), Outcome 4 Ritchie Index (6 months).

Study or subgroup	Rest	Resting splint		o splint		Mean Differe	nce		Weight I	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI				Fixed, 95% CI
Janssen 1990	14	5.1 (5.1)	15	5.3 (3)					100%	-0.2[-3.26,2.86]
Total ***	14		15						100%	-0.2[-3.26,2.86]
Heterogeneity: Not applicable										
Test for overall effect: Z=0.13(P=0.9)					1					
				Favours splint	-4	-2 0	2	4	Favours no splin	t

Analysis 8.5. Comparison 8 Resting hand and wrist splint vs no splint (1-6 months), Outcome 5 Pain score (out of 48).

Study or subgroup	1	Splint	No splint			Me	an Difference	Weight		Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 9		Fixed, 95% Cl		Fixed, 95% CI
Janssen 1990	14	7.9 (1.6)	15	6.3 (0)						Not estimable
Total ***	14		15							Not estimable
Heterogeneity: Not applicable										
Test for overall effect: Not applicable										
			I	Favours splint	-10	-5	0 5	10	Favours no spli	nt

Comparison 9. Circumferential cotton-padded splint wrap versus pan-type hard thermoplastic splint (1 month)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Preference (# of patients prefering the soft splint vs the hard splint)	1	78	Risk Ratio (M-H, Fixed, 95% CI)	1.69 [1.00, 2.85]

Analysis 9.1. Comparison 9 Circumferential cotton-padded splint wrap versus pan-type hard thermoplastic splint (1 month), Outcome 1 Preference (# of patients prefering the soft splint vs the hard splint).

Study or subgroup	Soft splint	Hard splint		Risk Ratio					Weight	Ris	k Ratio	
	n/N	n/N			M-H, F	ixed,	95% CI				M-H, Fi	xed, 95% CI
Callinan 1996	22/39	13/39					-			100%		1.69[1,2.85]
Total (95% CI)	39	39								100%		1.69[1,2.85]
Total events: 22 (Soft splint), 13 (H	ard splint)											
Heterogeneity: Not applicable												
Test for overall effect: Z=1.97(P=0.0	05)		1					1	1			
		Hard splint	0.1	0.2	0.5	1	2	5	10	Soft splint		

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Comparison 10. Extra-depth shoes versus regular footwear (2 months)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 change on Stanford Health Assess- ment Questionnaire (HAQ)	1	30	Mean Difference (IV, Fixed, 95% CI)	-0.2 [-0.35, -0.05]
2 change on Pain on walking (VAS)	1	30	Mean Difference (IV, Fixed, 95% CI)	-18.7 [-28.46, -8.94]
3 change on Pain on stair climibing (VAS)	1	30	Mean Difference (IV, Fixed, 95% CI)	-27.0 [-37.83, -16.17]
4 change on Pain on non-weight bearing (VAS)	1	30	Mean Difference (IV, Fixed, 95% CI)	-5.0 [-15.04, 5.04]
5 change in Fatigue (VAS)	1	30	Mean Difference (IV, Fixed, 95% CI)	-14.8 [-31.40, 1.80]
6 change in Subjective well-being (VAS)	1	30	Mean Difference (IV, Fixed, 95% CI)	-12.5 [-27.25, 2.25]
7 change in Pain free walking time (minutes)	1	30	Mean Difference (IV, Fixed, 95% CI)	18.2 [8.22, 28.18]

Analysis 10.1. Comparison 10 Extra-depth shoes versus regular footwear (2 months), Outcome 1 change on Stanford Health Assessment Questionnaire (HAQ).

Study or subgroup	Extra-	depth shoes	Reg	Regular shoes		Mean Difference			Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% CI			Fixed, 95% CI
Fransen 1997	15	-0.2 (0.2)	15	0 (0.2)			+		100%	-0.2[-0.35,-0.05]
Total ***	15		15				•		100%	-0.2[-0.35,-0.05]
Heterogeneity: Not applicable										
Test for overall effect: Z=2.54(P=0.01)									
			Favo	urs treatment	-4	-2	0	2 4	Favours contro	l

Analysis 10.2. Comparison 10 Extra-depth shoes versus regular footwear (2 months), Outcome 2 change on Pain on walking (VAS).

Study or subgroup	Extra-	depth shoes	Regular shoes		Mean Difference		ce		Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)			Fixed, 95% C	I			Fixed, 95% CI
Fransen 1997	15	-17.2 (16.5)	15	1.5 (10.1)						100%	-18.7[-28.46,-8.94]
Total ***	15		15				•			100%	-18.7[-28.46,-8.94]
Heterogeneity: Not applicable											
Test for overall effect: Z=3.75(P=0)											
			Favo	urs treatment	-100	-50	0	50	100	Favours contro	

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Analysis 10.3. Comparison 10 Extra-depth shoes versus regular footwear (2 months), Outcome 3 change on Pain on stair climibing (VAS).

Study or subgroup	r subgroup Extra-depth shoes		Regu	ılar shoes		Me	ean Differer	nce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (21			Fixed, 95% CI
Fransen 1997	15	-18.4 (17.3)	15	8.6 (12.6)		-				100%	-27[-37.83,-16.17]
Total ***	15		15							100%	-27[-37.83,-16.17]
Heterogeneity: Not applicable											
Test for overall effect: Z=4.88(P<0.	0001)				1	1			1		
			Favo	urs treatment	-100	-50	0	50	100	Favours control	

Analysis 10.4. Comparison 10 Extra-depth shoes versus regular footwear (2 months), Outcome 4 change on Pain on non-weight bearing (VAS).

Study or subgroup	Extra-	depth shoes	Regular shoes			Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95%	сі			Fixed, 95% CI
Fransen 1997	15	-7.5 (14.3)	15	-2.5 (13.7)						100%	-5[-15.04,5.04]
Total ***	15		15				•			100%	-5[-15.04,5.04]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.98(P=0.33	3)					1					
			Favo	urs treatment	-100	-50	0	50	100	Favours contro	l

Analysis 10.5. Comparison 10 Extra-depth shoes versus regular footwear (2 months), Outcome 5 change in Fatigue (VAS).

Study or subgroup	Extra-	depth shoes	oes Regular shoes		Mean Difference			ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)			Fixed, 95% C	I			Fixed, 95% CI
Fransen 1997	15	-10.4 (28.4)	15	4.4 (16.4)						100%	-14.8[-31.4,1.8]
Total ***	15		15				•			100%	-14.8[-31.4,1.8]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.75(P=0.08)											
			Favo	urs treatment	-100	-50	0	50	100	Favours contro	

Analysis 10.6. Comparison 10 Extra-depth shoes versus regular footwear (2 months), Outcome 6 change in Subjective well-being (VAS).

Study or subgroup	Extra-	depth shoes	Regular shoes			М	ean Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		I	Fixed, 95% C	:1			Fixed, 95% CI
Fransen 1997	15	-8.2 (18.9)	15	4.3 (22.2)						100%	-12.5[-27.25,2.25]
Total ***	15		15				•			100%	-12.5[-27.25,2.25]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.66(P=0.1)											
			Fa	vours control	-100	-50	0	50	100	Favours trea	atment

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Analysis 10.7. Comparison 10 Extra-depth shoes versus regular footwear (2 months), Outcome 7 change in Pain free walking time (minutes).

Study or subgroup	Extra-	depth shoes	Regular shoes			Me	an Differenc	:e		Weight	Mean Difference
	N Mean(SD) N Mean(SD)		F	ixed, 95% CI				Fixed, 95% CI			
Fransen 1997	15	19.7 (18.9)	15	1.5 (5.7)						100%	18.2[8.22,28.18]
Total ***	15		15				•			100%	18.2[8.22,28.18]
Heterogeneity: Not applicable											
Test for overall effect: Z=3.57(P=0)											
			Fa	vours control	-100	-50	0	50	100	Favours treatm	ent

Comparison 11. Semi-rigid insoles vs extra-depth shoes (12 weeks)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Pain (VAS: 1-10cm)	1	48	Mean Difference (IV, Fixed, 95% CI)	-1.9 [-3.29, -0.51]
2 RB Walking (sec.)	1	48	Mean Difference (IV, Fixed, 95% CI)	-2.0 [-13.61, 9.61]
3 RB Stairs (sec.)	1	48	Mean Difference (IV, Fixed, 95% CI)	0.80 [-5.51, 7.11]
4 RB Stand (sec.)	1	48	Mean Difference (IV, Fixed, 95% CI)	-9.30 [-62.35, 43.75]
5 Toronto Activities of Daily Living measure (TADL) walk- ing	1	48	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.62, 0.62]
6 TADL stairs	1	48	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.12, 0.12]
7 50' walking (sec.)	1	48	Mean Difference (IV, Fixed, 95% CI)	0.20 [-2.15, 2.55]
8 Lower extremity joint count (# of painful joints)	1	48	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-4.89, 4.49]
9 MTP joint count (# of painful joints)	1	48	Mean Difference (IV, Fixed, 95% CI)	0.0 [-1.67, 1.67]

Analysis 11.1. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 1 Pain (VAS: 1-10cm).

Study or subgroup		mi-rigid D shoes	ED sł	oes alone	Mean Difference	Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
Chalmers 2000	24	3 (2)	24	4.9 (2.8)		100%	-1.9[-3.29,-0.51]
Total ***	24		24			100%	-1.9[-3.29,-0.51]
Heterogeneity: Not applicable							
Test for overall effect: Z=2.69(P=0.01)						
			Favours	Subortholen	-4 -2 0 2	⁴ Favours sho	oes alone

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Study or subgroup	Semi-rigid +ED shoes		ED shoes alone			Me	ean Differenc	e		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% CI				Fixed, 95% CI
Chalmers 2000	24	86.9 (21.4)	24	88.9 (19.6)						100%	-2[-13.61,9.61]
Total ***	24		24				•			100%	-2[-13.61,9.61]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.34(P=0.74)											
			Favour	s shoes alone	-100	-50	0	50	100	Favours sub	ortholen

Analysis 11.2. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 2 RB Walking (sec.).

Analysis 11.3. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 3 RB Stairs (sec.).

Study or subgroup	Semi-rigid +ED shoes N Mean(SD)		ED sho	oes alone		Me	an Differer	ice		Weight	Mean Difference		
			Ν	Mean(SD)		F	ixed, 95% (21			Fixed, 95% CI		
Chalmers 2000	24	• •		92.4 (11.3)	24	91.6 (11)						100%	0.8[-5.51,7.11]
Total ***	24									100%	0.8[-5.51,7.11]		
Heterogeneity: Tau ² =0; Chi ² =0,	, df=0(P<0.0001	.); I²=100%											
Test for overall effect: Z=0.25(F	P=0.8)	0.8)											
				shoes alone	-10	-5	0	5	10	Favours Sub	oortholen		

Analysis 11.4. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 4 RB Stand (sec.).

Study or subgroup	Semi-rigid +ED shoes		ED sl	noes alone		Ме	an Difference		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	ixed, 95% CI			Fixed, 95% CI
Chalmers 2000	24	561.1 (100.5)	24	570.4 (86.5)					100%	-9.3[-62.35,43.75]
Total ***	24		24						100%	-9.3[-62.35,43.75]
Heterogeneity: Not applicable										
Test for overall effect: Z=0.34(P=0.73)										
			Favour	rs shoes alone	-100	-50	0 50	100	Favours sub	ortholen

Analysis 11.5. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 5 Toronto Activities of Daily Living measure (TADL) walking.

Study or subgroup		ni-rigid D shoes	ED sh	ioes alone	Me	an Differe	nce		Weight I	Mean Difference
	N	Mean(SD)	Ν	Mean(SD)	F	ixed, 95%	CI			Fixed, 95% CI
Chalmers 2000	24	7 (1.1)	24	7 (1.1)					100%	0[-0.62,0.62]
Total ***	24		24						100%	0[-0.62,0.62]
		Favours		Subortholen ⁻¹	-0.5	0	0.5	1	Supportive shoe	S

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Study or subgroup		emi-rigid ED shoes	ED sho	es alone		Mea	an Differe	nce		Weight Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95%	CI		Fixed, 95% CI
Heterogeneity: Not applicable					_					
Test for overall effect: Not applicable										
			Favours S	Subortholen	-1	-0.5	0	0.5	1	Supportive shoes

Analysis 11.6. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 6 TADL stairs.

Study or subgroup		ni-rigid D shoes	ED sh	oes alone		Ме	an Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	1			Fixed, 95% CI
Chalmers 2000	24	5 (0.2)	24	5 (0.2)			-			100%	0[-0.12,0.12]
Total ***	24		24				•			100%	0[-0.12,0.12]
Heterogeneity: Not applicable											
Test for overall effect: Not applicable											
			Favours	Subortholen	-1	-0.5	0	0.5	1	Supportive shoe	s

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Analysis 11.7. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 7 50' walking (sec.).

Study or subgroup		mi-rigid D shoes	ED sh	oes alone		Mea	an Differen	ce		Weight	Mean Difference
	N	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% C	I			Fixed, 95% CI
Chalmers 2000	24	14.1 (4.3)	24	13.9 (4)						100%	0.2[-2.15,2.55]
Total ***	24		24							100%	0.2[-2.15,2.55]
Heterogeneity: Tau ² =0; Chi ² =0, df	=0(P<0.0001	L); I ² =100%									
Test for overall effect: Z=0.17(P=0	.87)										
			Favours	Subortholen	-4	-2	0	2	4	Favours sho	es alone

Analysis 11.8. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 8 Lower extremity joint count (# of painful joints).

Study or subgroup		mi-rigid D shoes	ED sh	ioes alone		Me	an Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	:1			Fixed, 95% CI
Chalmers 2000	24	14.9 (7.9)	24	15.1 (8.7)						100%	-0.2[-4.89,4.49]
Total ***	24		24							100%	-0.2[-4.89,4.49]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.08(P=0.93)											
			Favours	Subortholen	-10	-5	0	5	10	Favours sho	es alone

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Analysis 11.9. Comparison 11 Semi-rigid insoles vs extra-depth shoes (12 weeks), Outcome 9 MTP joint count (# of painful joints).

Study or subgroup		ni-rigid D shoes	ED sh	ioes alone		I	Mean Diffe	rence		Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)			Fixed, 95	% CI			Fixed, 95% CI	
Chalmers 2000	24	7 (2.9)	24	7 (3)		-				100%	0[-1.67,1	67]
Total ***	24		24			-				100%	0[-1.67,1	.67]
Heterogeneity: Not applicable												
Test for overall effect: Not applicable												
			Favours	Sobortholen	-4	-2	0	2	4	Favours sho	es alone	-

Comparison 12. Soft insoles versus extra-depth shoes (plastazote) (12 weeks)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Pain (VAS: 1-10 cm)	1	48	Mean Difference (IV, Fixed, 95% CI)	-0.92 [-2.39, 0.55]
2 RB Walking (sec)	1	48	Mean Difference (IV, Fixed, 95% CI)	2.5 [-8.67, 13.67]
3 RB Stairs (sec)	1	48	Mean Difference (IV, Fixed, 95% CI)	0.70 [-5.78, 7.18]
4 RB Stand (sec.)	1	48	Mean Difference (IV, Fixed, 95% CI)	13.60 [-49.24, 76.44]
5 Toronto Activities of Daily Living measure (TADL) walk- ing	1	48	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.54, 0.74]
6 TADL stairs	1	48	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.12, 0.12]
7 50' walking (sec.)	1	48	Mean Difference (IV, Fixed, 95% CI)	0.0 [-2.29, 2.29]
8 Lower extremity joint count (# of painful joints)	1	48	Mean Difference (IV, Fixed, 95% CI)	-2.40 [-7.31, 2.51]
9 MTP joint count (# of painful joints)	1	48	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-1.90, 1.50]

Analysis 12.1. Comparison 12 Soft insoles versus extra-depth shoes (plastazote) (12 weeks), Outcome 1 Pain (VAS: 1-10 cm).

Study or subgroup	Soft	+ ED shoes	ED sh	ioes alone		Mea	n Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fix	(ed, 95% C	1			Fixed, 95% CI
Chalmers 2000	24	4 (2.4)	24	4.9 (2.8)						100%	-0.92[-2.39,0.55]
Total ***	24		24							100%	-0.92[-2.39,0.55]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.22(P=0.22)											
			Favou	rs soft insoles	-4	-2	0	2	4	Favours sho	es alone

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Analysis 12.2. Comparison 12 Soft insoles versus extra-depth shoes (plastazote) (12 weeks), Outcome 2 RB Walking (sec).

Study or subgroup	soft -	+ ED shoes	ED sł	ioes alone		Me	ean Differen	ice		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	3			Fixed, 95% CI
Chalmers 2000	24	88.9 (19.6)	24	86.4 (19.9)						100%	2.5[-8.67,13.67]
Total ***	24		24				•			100%	2.5[-8.67,13.67]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.44(P=0.66)											
			Favour	s shoes alone	-100	-50	0	50	100	Favours soft	insoles

Analysis 12.3. Comparison 12 Soft insoles versus extradepth shoes (plastazote) (12 weeks), Outcome 3 RB Stairs (sec).

Study or subgroup	soft -	+ ED shoes	ED shoes alone			Me	an Difference		Weight	Mean Difference
	N	Mean(SD)	Ν	Mean(SD)		Fi	xed, 95% CI			Fixed, 95% CI
Chalmers 2000	24	91.6 (11)	24	90.9 (11.9)					100%	0.7[-5.78,7.18]
Total ***	24		24						100%	0.7[-5.78,7.18]
Heterogeneity: Tau ² =0; Chi ² =0	0, df=0(P<0.0001	L); I ² =100%								
Test for overall effect: Z=0.21((P=0.83)									
			Faura	s shoos alana	-10	-5	0	5 1		inceles

Favours shoes alone -10 -5 ¹⁰ Favours soft insoles

Analysis 12.4. Comparison 12 Soft insoles versus extradepth shoes (plastazote) (12 weeks), Outcome 4 RB Stand (sec.).

Study or subgroup	Soft	+ ED shoes	ED sh	oes alone		Me	an Difference	2		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	ixed, 95% CI				Fixed, 95% CI
Chalmers 2000	24	570.4 (86.5)	24	556.8 (131.1)			+			100%	13.6[-49.24,76.44]
Total ***	24		24				•			100%	13.6[-49.24,76.44]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.42(P=0.67)											
			Favour	s shoes alone	-1000	-500	0	500	1000	Favours soft	insoles

Favours shoes alone Favours soft insoles

Analysis 12.5. Comparison 12 Soft insoles versus extra-depth shoes (plastazote) (12 weeks), Outcome 5 Toronto Activities of Daily Living measure (TADL) walking.

Study or subgroup	Soft +	ED shoes	ED sh	oes alone		Ме	an Differen	ce		Weight	Mean Difference
	N	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	1			Fixed, 95% CI
Chalmers 2000	24	7 (1.1)	24	6.9 (1.2)			-			100%	0.1[-0.54,0.74]
Total ***	24		24				•			100%	0.1[-0.54,0.74]
			Favou	rs soft insoles	-4	-2	0	2	4	Favours shoe	es alone

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Study or subgroup	Soft	+ ED shoes	ED s	hoes alone			Mean I	Differen	nce			Weight Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)			Fixed	l, 95% C	21			Fixed, 95% CI
Heterogeneity: Not applicable												
Test for overall effect: Z=0.31(P=0.76)					1							
			Favoi	urs soft insoles	-4	-2	2	0	2	2 4	1	Favours shoes alone

Analysis 12.6. Comparison 12 Soft insoles versus extra-depth shoes (plastazote) (12 weeks), Outcome 6 TADL stairs.

Study or subgroup	Soft	+ ED shoes	ED sh	ioes alone		Me	ean Differei	nce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95%	CI			Fixed, 95% CI
Chalmers 2000	24	5 (0.2)	24	5 (0.2)						100%	0[-0.12,0.12]
Total ***	24		24				•			100%	0[-0.12,0.12]
Heterogeneity: Not applicable											
Test for overall effect: Not applicable					ı	1					
			Favou	rs soft insoles	-1	-0.5	0	0.5	1	Favours shoes	alone

Analysis 12.7. Comparison 12 Soft insoles versus extra-depth shoes (plastazote) (12 weeks), Outcome 7 50' walking (sec.).

Study or subgroup	Soft	+ ED shoes	ED sh	ioes alone		Me	an Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	N	Mean(SD)		F	ixed, 95% C	I			Fixed, 95% CI
Chalmers 2000	24	13.9 (4)	24	13.9 (4.1)						100%	0[-2.29,2.29]
Total ***	24		24				-			100%	0[-2.29,2.29]
Heterogeneity: Not applicable											
Test for overall effect: Not applicable											
			Favour	s shoes alone	-10	-5	0	5	10	Favours insoles	5

Analysis 12.8. Comparison 12 Soft insoles versus extra-depth shoes (plastazote) (12 weeks), Outcome 8 Lower extremity joint count (# of painful joints).

Study or subgroup	Soft	+ ED shoes	ED sh	oes alone		Меа	n Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fix	ed, 95% C	I			Fixed, 95% CI
Chalmers 2000	24	15.1 (8.7)	24	17.5 (8.7)						100%	-2.4[-7.31,2.51]
Total ***	24		24							100%	-2.4[-7.31,2.51]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.96(P=0.34)											
			Fa	vours insoles	-10	-5	0	5	10	Favours sho	es alone



Analysis 12.9. Comparison 12 Soft insoles versus extra-depth shoes (plastazote) (12 weeks), Outcome 9 MTP joint count (# of painful joints).

Study or subgroup	Soft -	+ ED shoes	ED sh	ioes alone		Mean Difference		Weight		lean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)		Fi	ixed, 95% (CI			Fixed, 95% CI
Chalmers 2000	24	7 (3)	24	7.2 (3)						100%	-0.2[-1.9,1.5]
Total ***	24		24				•			100%	-0.2[-1.9,1.5]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.23(P=0.82)										
			Favou	rs soft insoles	-10	-5	0	5	10	Favours shoes alo	one

Comparison 13. Rohadur posted foot orthosis vs placebo insole (End of therapy - 3 yrs)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Hallux abductus angle re- mained < 21 degrees	1	98	Risk Ratio (M-H, Fixed, 95% CI)	3.60 [2.19, 5.93]
2 Painful foot joint count	1	88	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.55, 0.95]
3 Foot Function Index	1	88	Mean Difference (IV, Fixed, 95% CI)	-1.40 [-10.29, 7.49]
4 Foot pain (adapted from Melzack)	1	88	Mean Difference (IV, Fixed, 95% CI)	0.20 [-2.18, 2.58]

Analysis 13.1. Comparison 13 Rohadur posted foot orthosis vs placebo insole (End of therapy - 3 yrs), Outcome 1 Hallux abductus angle remained < 21 degrees.

Study or subgroup	Treatment	Control			Risk Ratio)		Weight	Risk Ratio
	n/N	n/N		M-H	I, Fixed, 95	5% CI			M-H, Fixed, 95% CI
Budiman-Mak 1995	45/50	12/48				+		100%	3.6[2.19,5.93]
Total (95% CI)	50	48				•		100%	3.6[2.19,5.93]
Total events: 45 (Treatment), 12 (Contr	ol)								
Heterogeneity: Not applicable									
Test for overall effect: Z=5.04(P<0.0001)									
		Favours control	0.01	0.1	1	10	100	Favours treatment	



Analysis 13.2. Comparison 13 Rohadur posted foot orthosis vs placebo insole (End of therapy - 3 yrs), Outcome 2 Painful foot joint count.

Study or subgroup	Tre	eatment	с	ontrol		Ме	an Differen	ce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% C	I			Fixed, 95% CI
Conrad 1996	44	1.5 (1.9)	44	1.3 (1.7)						100%	0.2[-0.55,0.95]
Total ***	44		44				-			100%	0.2[-0.55,0.95]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.52(P=0.6)											
			Favo	urs treatment	-4	-2	0	2	4	Favours contro	l

Analysis 13.3. Comparison 13 Rohadur posted foot orthosis vs placebo insole (End of therapy - 3 yrs), Outcome 3 Foot Function Index.

Study or subgroup	Tre	eatment	Control			Mean Difference				Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		F	ixed, 95% (:1			Fixed, 95% CI
Conrad 1996	44	26.5 (20.3)	44	27.9 (22.2)						100%	-1.4[-10.29,7.49]
Total ***	44		44				•			100%	-1.4[-10.29,7.49]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.31(P=0.76	5)										
			Favou	urs treatment	-100	-50	0	50	100	Favours control	

Analysis 13.4. Comparison 13 Rohadur posted foot orthosis vs placebo insole (End of therapy - 3 yrs), Outcome 4 Foot pain (adapted from Melzack).

Study or subgroup	Tre	eatment	Control			Mea	n Differe	nce		Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)		Fixed, 95% CI					Fixed, 95% CI
Conrad 1996	44	5.4 (5.5)	44	5.2 (5.9)						100%	0.2[-2.18,2.58]
Total ***	44		44							100%	0.2[-2.18,2.58]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.16(P=0.87)					ı			L			
			Favo	urs treatment	-4	-2	0	2	4	Favours contro	

WHAT'S NEW

Date	Event	Description
9 November 2008	Amended	Converted to new review format.
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CONTRIBUTIONS OF AUTHORS

ME and LXXB were responsible for writing the manuscript, extracting and analyzing the data, selecting trials, quality assessment of trials



JM devised the search strategies MF, MAO and SR helped with study selection, data extraction and quality assessment GW and PT contributed methological expertise

DECLARATIONS OF INTEREST

None known.

INDEX TERMS

Medical Subject Headings (MeSH)

*Orthotic Devices; *Splints; Arthritis, Rheumatoid [rehabilitation] [*therapy]; Controlled Clinical Trials as Topic; Hand Strength; Randomized Controlled Trials as Topic; Shoes; Wrist Joint

MeSH check words

Humans