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Orthotic devices for the treatment of tennis elbow (Review)

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[Intervention Review]

Orthotic devices for the treatment of tennis elbow

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ABSTRACT

Background

Lateral epicondylitis (tennis elbow) is a frequently reported condition. A wide variety of treatment strategies has been described. As of yet, no optimal strategy has been identified.

Objectives

To assess the effectiveness of orthotic devices for the treatment of tennis elbow.

Search methods

We searched Medline, Embase, CINAHL, the Cochrane Controlled Trial Register, Current Contents up to May 1999 and reference lists from all retrieved articles. Experts on the subjects were approached for additional trials.

Selection criteria

All randomised clinical trials (RCT) describing individuals with diagnosed lateral epicondylitis and comparing the use of an orthotic device as a treatment strategy were evaluated for inclusion.

Data collection and analysis

Two reviewers independently assessed the validity of the included trials and extracted data on relevant outcome measures. Dichotomous outcomes were expressed as Relative Risks (RRs) and continuous outcomes as Standardised Mean Differences (SMD), both with corresponding 95% confidence intervals (95% CI). Statistical pooling and subgroup analyses were intended

Main results

Five RCTs (N per group 7-49) were included. Validity score ranged from 3-9 positive items out of 11. Subgroup analyses were not performed due to the small number of trials. The limited number of included trials present few outcome measures and limited long-term results. Pooling was not possible due to large heterogeneity amongst trials.

Authors' conclusions

No definitive conclusions can be drawn concerning effectiveness of orthotic devices for lateral epicondylitis. More well-designed and well-conducted RCTs of sufficient power are warranted.

PLAIN LANGUAGE SUMMARY

Orthotic devices for the treatment of tennis elbow

Lateral epicondylitis (tennis elbow) is a frequently reported condition. A wide variety of treatment strategies has been described. As of yet, no optimal strategy has been identified.

Five RCTs (N per group 7-49) were included. Validity score ranged from 3-9 positive items out of 11. Subgroup analyses were not performed due to the small number of trials. The limited number of included trials present few outcome measures and limited long-term results. Pooling was not possible due to large heterogeneity amongst trials.

No definitive conclusions can be drawn concerning effectiveness of orthotic devices for lateral epicondylitis. More well-designed and well-conducted RCTs of sufficient power are warranted.

BACKGROUND

Epicondylitis lateralis humeri, or tennis elbow, is characterised by pain at the lateral epicondyle of the humerus and pain on resisted dorsiflexion of the wrist (Verhaar 1992, Lamberts 1975, Assendelft 1997). Tennis elbow is a frequently reported condition. The incidence in general practice is approximately 4 -7 per 1000 patients per year (Verhaar 1994, Lamberts 1975, Assendelft 1997, Blanken 1981, Hamilton 1986, Kivi 1983). The annual incidence of the condition is 1-3% in the general population (Allander 1974, Verhaar 1994, Chard 1989). The complaint is estimated to last 8 months to 2 years (Cyriax 1936, Bailey 1957, Binder 1983). In approximately 10% of the patients the complaint will result in sick leave for a mean period of 11 weeks (Verhaar 1992).

Over 40 treatment options are described (Ernst 1992). Examples are an expectant policy, ultrasound, laser, massage, electrotherapy, topical treatment, manipulations, corticosteroid-injections and surgery. In Dutch primary care 21% of the patients with epicondylitis lateralis humeri are prescribed an orthotic device as a treatment measure (Verhaar 1992). Many different types of braces and other orthotic devices are available for treating a tennis elbow. (Theoretically, Binding the muscle may limit expansion of muscle fibers and decrease the contribution to force production made by muscle fibres proximal to the band.) Immobilisation should completely limit expansion and no force can be made by the muscle fibres.

No evidence on efficacy of orthotic devices for treating lateral epicondylitis is present in the current literature. Labelle 1997 et al. performed a systematic review on conservative treatment measures for lateral epicondylitis (Labelle 1992). In this review only one trial concerning an orthotic device was mentioned (Burton 1988). The trial showed no significant difference in improvement within treatment groups comprising manipulation; manipulation with forearm strap; manipulation with nonsteriodal antiinflammatory drugs (NSAID).

To determine the efficacy of treatment of lateral epicondylitis by an orthotic device, a systematic review was performed of randomised controlled trials investigating this treatment modality.

OBJECTIVES

To assess the effectiveness of orthotic devices on short, intermediate and long term outcome measures in the treatment of patients with epicondylitis lateralis humeri (tennis elbow).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or controlled trials with or without blinded outcome measurement;
Treatment regimens were allocated by a random procedure (Schulz 1994);
Follow-up was at least 1 day;
Results were published as a full report before April 1999;
Trials in which all intervention groups receive an orthotic device as a co-intervention will be excluded;
No restrictions will be made concerning the language of publication.

Types of participants

Patients with lateral epicondylitis of the humerus (tennis elbow). This should at least involve identification of lateral elbow pain, increased by pressure on the lateral epicondyle, and with pain on resisted dorsiflexion of the wrist.

Types of interventions

An orthotic device in the form of a brace, splint, cast, band or strap. (Control interventions can be all types of conservative treatment like placebo bandage, expectant policy, ultrasound, laser, massage, electrotherapy, topical treatment, manipulations, corticosteroid-injections. Comparisons with operations were not included.) All non-surgical comparators were included.

Types of outcome measures

1. Pain
2. Global measure of improvement
3. Elbow-specific functional status
4. Maximum grip strength
5. Pain free grip strength
6. Generic functional status
7. Pressure pain on the lateral epicondyle

Search methods for identification of studies

A comprehensive, unbiased search was be performed. No restriction was made regarding language. Adaptations of the highly sensitive Cochrane Collaboration search strategy were used to identify all randomised and controlled clinical trials. The following computerised bibliographical databases have been searched:
· MEDLINE (01/1966 - 05/1999)
· EMBASE (01/1988 - 05/1999)
· CINAHL (01/1982 - 05/1999)
The following keywords were used:
-To identify RCT's: the highly sensitive Cochrane Collaboration search strategy using the words: randomised controlled trial.pt.;randomised controlled trials/;controlled clinical trial.pt.;random allocation/;double blind method/;exp single-blind method/;clinical trial.pt.;clinical trials/;(clin$ adj25 trial $).tw.;((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind $ or mask$)).tw.;placebos/;placebo$.tw.;random$.tw.;research design/;comparative study/;evaluation studies/;follow up studies/;prospective studies/;control$ or prospectiv$ or volunteer $).tw.;animal/ not (human/ and animal/)
-To identify epicondylitis humeri lateralis:
MEDLINE:tennis elbow;elbow;elbow joint;humerus;tendinitis;"sprains and strains";arm injuries;soft tissue injuries;athletic injuries;tendon injuries and related free textwords.
EMBASE:tennis elbow/;elbow joint/;humerus/;tendinitis/;arm injuries/;tendon injuries/;joint injury/;sport injury/;epicondylitis/;elbow disease/;epicondylitis.tw.;elbow.tw.;tennis elbow.tw.;joint injuries.tw.;tendon inj$.tw.;joint inj$.tw.;epicondyl$.tw.;sport injur $.tw.;humerus.tw.
CINAHL:elbow/in; tennis elbow/; tendinitis/;elbow joint/;humerus/;arm injuries/;tennis/;tendons/;epicondyl $.tw.;tennis elbow.tw.;joint injur.tw.;elbow.tw.
-To identify the intervention:
MEDLINE: braces;splints;immobilization;casts,surgical;orthotic devices; external fixators and related free textwords.

EMBASE: brace/;dynamic splint/;milwaukee brace/;plaster cast/;splint/;immobilization/;rthotics/;brace.tw.;splint.tw.;cast.tw.;immobilization.tw.;orthotic.tw.
CINAHL: orthoses/; immobilization/;Immobilization.tw.

Furthermore the Current Contents database was searched and the references from all retrieved articles were checked for additional studies (citation tracking). The Cochrane Controlled Trial Register of the Cochrane Library (CCTR) was searched for RCT's on elbow and on epicondylitis (Cochrane 1999). Experts on the subject were approached for other possible studies on treatment of epicondylitis lateralis humeri by orthotic devices. Trials not present in the previously mentioned databases were thus retrieved.

Data collection and analysis

Selection of studies:
In collecting the evidence a comprehensive, non-biased search was performed, according to the current state-of-the-art (Dickersin 1992). No limitations regarding language were made. Explicit methods for quality assessment of the studies were used, assessing the possibility of pooling subsets of comparable studies. Titles, abstracts and keywords of the articles identified from the databases, reference lists and RCTs retrieved from experts was checked by one reviewer (PS). Two other reviewers (NS and HA) obtained the full text of all possible articles for independent assessment.

Analysis:
Analysis was performed for the short-term, intermediate-term and long-term effect of orthotic devices for lateral epicondylitis separately.
Means and standard deviations of change scores were extracted for reported outcomes where data was available in the published reports, or could be calculated. All standard errors of the mean were converted to standard deviations.
Wherever reported data was converted or imputed, this was recorded in the note section of the included studies table. For trials where the required data was not reported or able to be calculated, further details were requested from the authors. If this was unsuccessful, the study was included and fully described.

RevMan, using the following choices of statistic, was used to analyse the results:

Continuous Outcomes:
Standardised mean difference using a random effects model was selected as many of the outcomes are reported on non-standard scales, using differing units and methods of assessment. A random effects model is required to account for the anticipated large amount of heterogeneity among the primary trials. Reasons for heterogeneity were evaluated.

Dichotomous Outcomes:
The results of each RCT were expressed as relative risks with corresponding 95% confidence interval for dichotomous data, and as mean and standard deviation for continuous data. (Rosenthal 1994, Lau 1997, Mulrow 1997). A random effects model is required to account for the large amount of anticipated heterogeneity among the primary trials. Reasons for heterogeneity were evaluated.

Pre-planned stratified analyses were:
I) Character of control groups: Index group orthotic device treatment(s) versus control group: a) other orthotic device group (s), b) other conservative treatment(s) (e.g., oral medication or injection) c) placebo treatment(s) and d) no treatment(s) / waiting list;
II) Validity score: low validity trials versus high validity trials; (Moher 1998)
III) Type of orthotic device: Brace, splint, and cast separately.
IV) Prognostic factors: a) Lateral epicondylitis with additional neck and shoulder complaints versus lateral epicondylitis without neck or shoulder complaints and b) duration of elbow complaints: acute (< 6 weeks), subacute (6 weeks to 13 weeks), chronic (> 13 weeks);

RESULTS

Description of studies

Methodological quality assessment of randomised clinical trials on the effectiveness of orthotic devices for tennis elbow.
+ = item is described and potentially not leading to bias
- = item is described and potentially leading to bias
? = item is not properly described: unclear if leading to bias

For description of methodological quality of included studies: see Table 1
For description of study characteristics of included studies: see Table Characteristics of included studies and Table 1
For description of study characteristics of excluded studies: see Table Characteristics of excluded studies

Risk of bias in included studies

Table 2 shows the criteria used for methodological quality assessment, consisting of internal validity criteria, descriptive criteria and statistical criteria. The descriptive and statistical criteria refer to the external validity of the study and are used to identify homogeneous subgroups and conduct sensitivity analyses. This criteria list includes all criteria of the list of Jadad 1996 Schulz 1994 and Verhagen 1998 For this review, the operationalization of the methodological criteria items was adjusted for application to lateral epicondylitis and orthotic devices in specific.

For description of the validity assessment tool: see Table 2

† Operationalization of the criteria and original assessment forms are available on request from the first author

All articles eligible for the review were blinded for authors, journal and year of the trial. Included articles were independently assessed on methodological quality by two blinded reviewers (NS and HA). The success of blinding was determined by asking both reviewers to attempt to identify the author(s), journal and year of the trial. Initial disagreement between the reviewers about the assessment of the methodological quality of the articles was calculated per criteria item and expressed as percentage agreement and kappa. (Brennan 1992, Rosenthal 1994) Disagreements about the assessment of the methodological quality of the articles were discussed in a consensus meeting per e-mail. If consensus could not be reached, a third reviewer (WJA) made the final decision. As assessment by different reviewers might affect the accuracy of quality assessment and data extraction, all studies were assessed by 2 reviewers independently (NS and HA). To determine the internal validity of the study the presence of sufficient information and therefore the likelihood of potential bias will be evaluated for each validity criterion separately. If sufficient information is available and bias is considered to be unlikely, the criterion is rated positive ('yes / (+)'). If bias is considered to be likely, the criterion is rated negative ('no /

(-)'). When insufficient information is given, the criterion is rated as inconclusive ('don't know / (?)'). A total score for internal validity of the study ('study validity score') was calculated by summing up the number of positive criteria. Equal weights were applied, resulting in a validity score with a range of 0 to 10, higher scores indicating lower likelihood of bias. In addition, per outcome measure additional points were applied for adequate blinding of measurement, and for validity and relevance of the outcome measure.

Two blinded reviewers (NS and HA) independently extracted the data regarding the interventions, type of outcome measures, timing of outcome assessment, loss to follow-up and outcomes. The various outcome measures are presented separately. The results of each RCT are expressed as odds ratio's with corresponding 95% confidence interval for dichotomous data, and as mean and standard deviation for continuous data. (Rosenthal 1994, Mulrow 1997, Lau 1997)

Effects of interventions

Study selection
The MEDLINE search (1966-May 1999) resulted in identification of 10 potentially eligible studies, the EMBASE-search (1988-1999) in 7. Of these, 2 studies were found in both databases. The CINAHL search resulted in 3 possible studies, all found in previous mentioned databases. The Cochrane Controlled Trials Register resulted in 9 potentially eligible studies, of which 8 were already found in other databases. The total of studies identified in before mentioned databases was 16. Approaching experts on the subject resulted in 1 additional trial, for a total of 17. Reviewing the full articles resulted in 5 studies meeting the eligibility criteria (Burton 1988, Dwars 1990, Erturk 1997, Haker 1993, Holdsworth 1993) Of the excluded articles, one study was an RCT on orthotic devices for elbow complaints (Valle-Jones 1990). However, in the results no specification was made for the patients with tennis elbow. No response was received from a letter to the author for specification of the results. In summary, a total of 5 studies was identified which met the inclusion criteria for this review.

Methodological quality
The methodological quality of the included trials is presented in the 'description of studies' -section. There was disagreement between the reviewers on 37 of the 104 items (36%). The Kappa values for inter-observer agreement were calculated for each validity item separately and a mean Kappa of 0.44 (+/- 0.58) was found. After an e-mail round disagreements remained on 8 items, on which a third reviewer (WJA) made the final decision. the results of our methodological quality assessment were sent to the (first) authors of the included trials with the asking them if they agreed with our assessment and, if not, to provide arguments for disagreements. We also requested for additional information on which our final decision was unclear ('don't know' / (?)) All authors responded to our request. We changed 13 scores: 10 from unclear (?) to positive (+); 1 from unclear (?) to negative (-); 2 from negative (-) to positive (+). The final results based on the additional comments of the authors are presented.

Analysis
Quality of included trials was partially acceptable, with validity scores between three and nine out of 11 items. We did not perform the pre-planned stratified analyses for validity-score, type of orthotic device or prognostic factors as the limited data on these items was too heterogeneous. Due to the heterogeneity, no pooling of data was possible, and results were described for each trial separately.

For the following comparisons data was available:

Ia) Orthotic devices versus other conservative treatment
Four studies (Burton 1988, Dwars 1990, Erturk 1997, Haker 1993) compared an orthotic device with a conventional treatment: 2 studies with a corticosteroid injection (Erturk 1997, Haker 1993), 1 study compared an elbow-support with a physiotherapy treatment (Dwars 1990) and 1 study compared an elbow-strap with anti-inflammatory cream (AI-cream) (Burton 1988). The results of the 2 studies comparing orthotic devices with corticosteroid-injection could not be pooled, because different outcome measures were used. One study (Erturk 1997) failed to demonstrate any difference between treatments in terms of short-term reduction in pain (weighted mean difference (WMD) = 13.49 95% CI -4.6;31.6) or increase in maximum grip strength (WMD = -3.24 95% CI-6.6;0.1), while the second study showed significantly better short-term results with respect to global measure of improvement favouring corticosteroid-injection (RR=2.91 95% CI 1.5;5.7) (Haker 1993). The study comparing an elbow-support with physiotherapy (Dwars 1990) failed to demonstrate a difference between groups with respect to short-term patient satisfaction (RR= 1.03 95% CI 0.6;1.6) or decrease in pain, although the latter could not be verified as standard deviations could not be estimated and were unable to be retrieved from the author. This latter study reported a drop-out rate of 30% at follow-up visit. The results of the study comparing AI-cream with an elbow-strap found no differences for wither pain reduction in the short-term (WMD= 0.38 95% CI 0.02;0.7) or increase in pain free grip strength (WMD= -7.06 95% CI -16.7;2.6) (Burton 1988).

Ib) Orthotic device as an additional treatment
Three studies (Burton 1988, Erturk 1997, Holdsworth 1993) studied the additive use of an orthotic device. Two studies reported only short-term results, one study (Holdsworth 1993) only long-term results. Burton (Burton) compared (a) an elbow-strap and AI cream with AI cream only, and (b) strap and manipulation with manipulation only. For either comparison, no differences were identified for either decrease in pain (WMD=-0.13 95% CI -1.4;1.1; WMD= 1.68 95%CI -29.1;32.4 respectively), or increase in pain free grip strength (WMD=0.13 95% CI -1.4;1.7; WMD= 0.00 95%CI -21.6;21.6 respectively). Erturk et al. compared bandage + injection with injection (Erturk 1997) and showed no differences for either decrease in pain (WMD=13.79 95% CI -4.2;31.8) or increase in maximum grip strength (WMD=1.74 95% CI -0.9;4.4). Holdsworth et al. (Holdsworth 1993) compared (a) the use of an epicondylitis-clasp combined with ultrasound with a conventional aquasonic coupling medium with the same ultrasound treatment and (b) the use of an epicondylitis clasp combined with ultrasound with a hydrocortisone coupling medium with the same ultrasound treatment. Subjective outcome on global measure of improvement was reported using a 100 mm VAS score, showing no differences for either comparison (WMD=-0.40 95% CI -11.6;10.8; WMD= 6.30 95%CI -7.3;19.9 respectively). Standard deviations for differences in mean decrease in pain or mean increase in maximum grip strength could not be calculated, or be retrieved from the authors.

Ic) Orthotic device versus another orthotic device
Only one study (Haker 1993) compared 2 types of orthotic devices. In this study an elbow-band was compared with a splint. Over the short-term, intermediate term and long-term no significant

difference on global measure of improvement was found (RR= 0.94 95% CI 0.8;1.1, RR= 1.17 95% CI 0.6;2.2 and RR=1.06 95% CI 0.6;1.8 respectively). The authors stated that the results also did not differ with respect to pain-free grip strength. Standard deviations could not be calculated because median scores were used, and further information could not be retrieved from the authors.

DISCUSSION

Orthotic devices are commonly used as treatment strategy for tennis elbow. Despite this common use, there is no clear evidence-base for application.

Heterogeneity was present for type of control-intervention and study population. The heterogeneity amongst the trials, concerning type of orthotic device and study population, in addition to the limited number of RCTs available makes it difficult to draw clear conclusions on effectiveness of orthotic devices. Based upon our review of included trials only one difference between interventions was identified: in one study results with respect to global measure of improvement favoured corticosteroid injections compared to an elbow-band (Haker 1993). In a systematic review on effectiveness of corticosteroid injections it was concluded that injection seemed effective in the short-term (Assendelft 1996). This finding could also indicate that corticosteroid injection simply was a more effective comparison. Comparisons with physiotherapy (Dwars 1990), with Al-cream (Burton 1988) or with cast immobilisation showed no differences.

When the orthotic device was used as an additive treatment, none of three studies showed a an additive but not statistically significant effect of an orthotic device elbow-bandage on short-term pain-relief (Erturk 1997). These three trials all present very small groups of patients per intervention (n<10). Because of the very low power of these studies, it is impossible to draw any conclusions concerning effectiveness of an orthotic device as a treatment or as an additive treatment for tennis elbow.

Despite the extensive search, possible relevant trials may have been missed. We identified one eligible trial (Valle-Jones 1990) in which the effectiveness of an orthotic device in patients with acute elbow-complaints was studied but as no separate analysis of the seven patients with tennis elbow was presented in the publication. We plan to update this review if additional eligible trials are found.

After initial assessment of the validity of the included trials, the reviewers found scores varying from 1 to 4. After contacting the authors for further information on the validity criteria the scores increased from 3 to 9 (Burton 1988); from 1 to 3 (Dwars 1990); from 2 to 7 (Erturk 1997); from 3 to 6 (Haker 1993) from 4 to 5 (Holdsworth 1993). The increase of scores after contact with the authors suggest that poor reporting and not lack of methodological quality was the main reason for the initial low scores for assessment of methodological quality.

Because of the heterogeneity of the included studies, we refrained from pooling. There was heterogeneity in character of control groups, type of outcome measures, type of orthotic device used, duration of the complaints and presence of prognostic factors.
In addition to the small number of trials included in this review, these studies have their limitations in study design. Only one out of five presented intermediate-term and long-term results and the highest number of relevant outcome measures was three. No functional outcome measures, like the Pain Free Function Questionnaire, were reported (Stratford 1987).

AUTHORS' CONCLUSIONS

Implications for practice

No definitive conclusions can be drawn concerning effectiveness of orthotic devices for lateral epicondylitis. More well-designed and well-conducted RCTs of sufficient power are warranted.

Implications for research

Further, high-quality, sufficiently powered randomised trials are warranted to investigate the effectiveness of orthotic devices in treatment of lateral epicondylitis, both as a single strategy and in combination with other measures. A standard set of valid and reliable outcome measures should be incorporated in the RCTs. This will be necessary to provide convincing evidence for the effectiveness of relatively cheap orthotic device as a treatment strategy or as an additive to any other conventional treatment. Finally, cost-effectiveness of orthotic devices should be incorporated since the use of orthotic devices might reduce costs on sick-leave, by reduction of the experienced pain during activities.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Burton 1988

Methods	V1: + V6: - V2: + V7: - V3: + V8: + V4: + V9: + V5: + V10: +

Burton 1988 *(Continued)*

	Validity score: 8
Participants	Tennis elbow <3 months duration presenting in primary care
Interventions	(I1) Elasted forearm strap (and manipulation) (R1) (manipulation only) (I2) Elasticated forearm strap, anti-inflammatory cream and manipulation (R2) Anti-inflammatory cream and manipulation
Outcomes	Shortterm (3wk) 1) Pain VAS (0-5) 5) Pain Free Grip Strength
Notes	Raw data from author were used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Dwars 1990

Methods	V1: + V6: - V2: + V7: - V3: + V8: + V4: + V9: + V5: + V10: + Validity score: 8
Participants	Patients presenting with > 6 weeks of tennis elbow complaints in an outpatient clinic.
Interventions	(I) Orthotic device (epitrain) for 6 weeks; (R) Physical therapy treatment (unspecified) for 6 weeks.
Outcomes	Short-term (6 wk) 1) Pain 2) Subjective ouctome on global measure of improvement
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Erturk 1997

Methods	V1: + V6: - V2: + V7: - V3: + V8: + V4: + V9: + V5: + V10: +

Erturk 1997 *(Continued)*

	Validity score: 8
Participants	Patients presenting with tennis elbow in an outpatient clinic
Interventions	(I) epicondylitis bandage (R) local injection of 20mg triamcinolone acetate with 0,5ml 2% lidicaine
Outcomes	Shortterm (3wk) 1) Pain during wrist extension (VAS 100mm) 4) Maximum Grip Strength
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Haker 1993

Methods	V1: + V6: - V2: + V7: - V3: + V8: + V4: + V9: + V5: + V10: + Validity score: 8
Participants	Patients with tennis elbow >1 month complaints referred by primary physician or physiotherapist
Interventions	(I) Elbow-band, daily during activity for 3 mth (R1) Splintage, daily during activity for 3 mth (R2) 1 steroid injection of 0.3ml marcaine and 0.2 ml triamcinolone acetonide, if necessary repeated at 1 week
Outcomes	Short-term (2wk), intermediate term (6m) and longterm (12m): 2) Subjective outcome on global measure of improvement 5) Pain Free Grip Strength
Notes	Median values were entered. Mean values could not be retrieved from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Holdsworth 1993

Methods	V1: + V6: - V2: + V7: - V3: + V8: + V4: + V9: + V5: + V10: +

Holdsworth 1993 *(Continued)*

	Validity score: 8
Participants	Patients with tennis elbow, no additional complaints, referred to a physiotherapy outpatients clinic
Interventions	(I1) Clasp during activity with ultrasound (12 times in 6 weeks) using conventional coupling medium (R1) Ultrasound (12 times in 6 weeks) using conventional coupling medium (I2) Clasp during activity with ultrasound (12 times in 6 weeks) with a hydrocortisone coupling medium (R2) Ultrasound (12 times in 6 weeks) using a hydrocortisone coupling medium
Outcomes	Longterm (12m) 1) Pain (at resisted dorsiflexion of the wrist) using a 100mm VAS-scale 5) Pain Free Grip Strength Long-term: Subjective outcome on global measure of improvement
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

*V1-V10 see Table 1 for description

Characteristics of excluded studies *[ordered by study ID]*

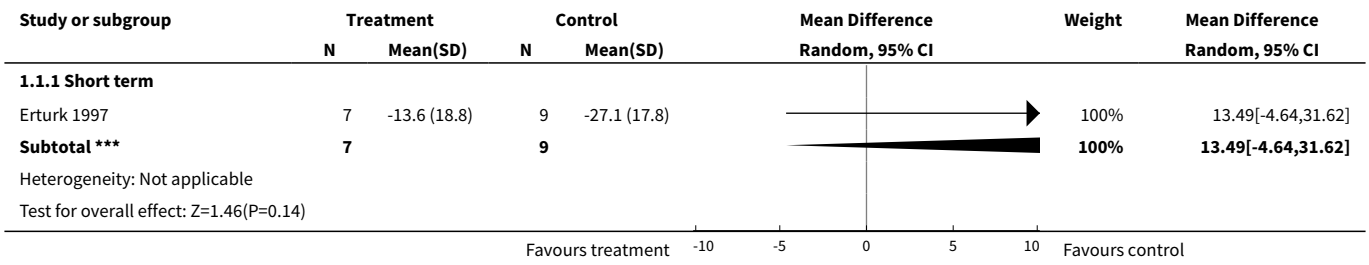
Study	Reason for exclusion
Clements 1993	Lack of randomisation
Fillion 1991	Lack of randomisation
Forster	Lack of randomisation
Froimson 1971	Lack of randomisation
Gruchow 1979	Lack of randomisation
Ilfeld 1966	Lack of randomisation
Kivi 1983	Lack of randomisation
Labelle 1997	Device applied in all groups
Solveborn 1997	Lack of randomisation
Thurston 1998	Lack of randomisation
Valle-Jones 1990	No specified results
Wadsworth 1987	Lack of randomisation

DATA AND ANALYSES

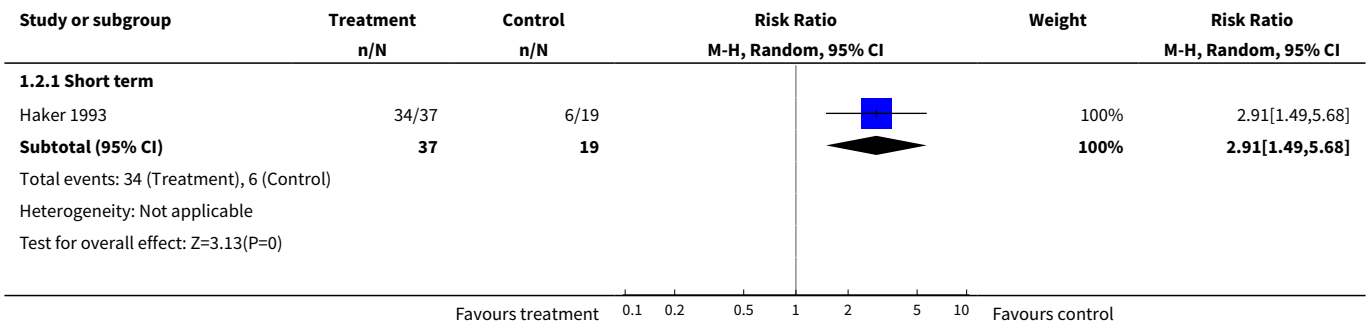
Comparison 1. Orthotic device versus corticosteroid injection

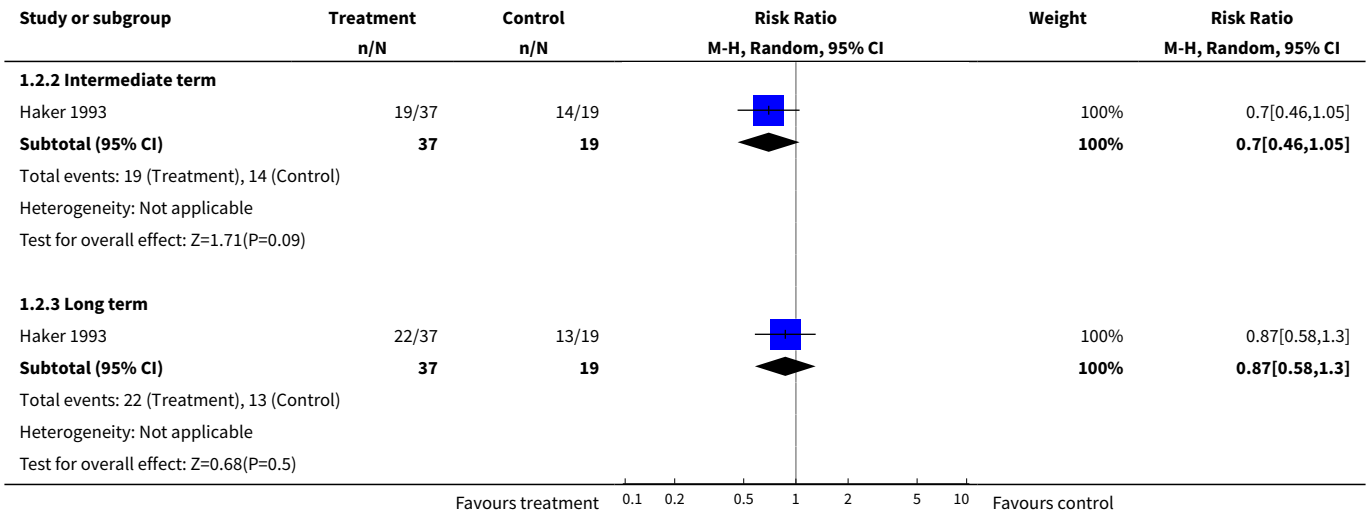
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Short term	1	16	Mean Difference (IV, Random, 95% CI)	13.49 [-4.64, 31.62]
2 Subjective outcome on global measure of improvement	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Short term	1	56	Risk Ratio (M-H, Random, 95% CI)	2.91 [1.49, 5.68]
2.2 Intermediate term	1	56	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.46, 1.05]
2.3 Long term	1	56	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.58, 1.30]
3 Increase in Maximum Grip Strength	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 Short term	1	16	Mean Difference (IV, Random, 95% CI)	-3.24 [-6.57, 0.09]

Analysis 1.1. Comparison 1 Orthotic device versus corticosteroid injection, Outcome 1 Pain.

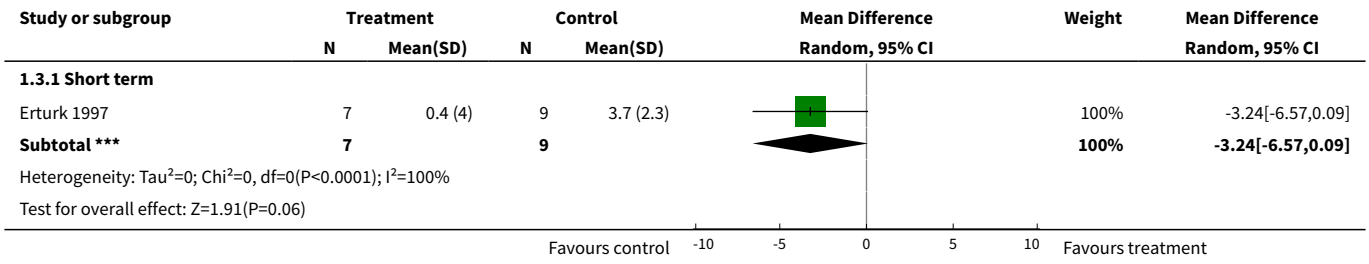


Analysis 1.2. Comparison 1 Orthotic device versus corticosteroid injection, Outcome 2 Subjective outcome on global measure of improvement.





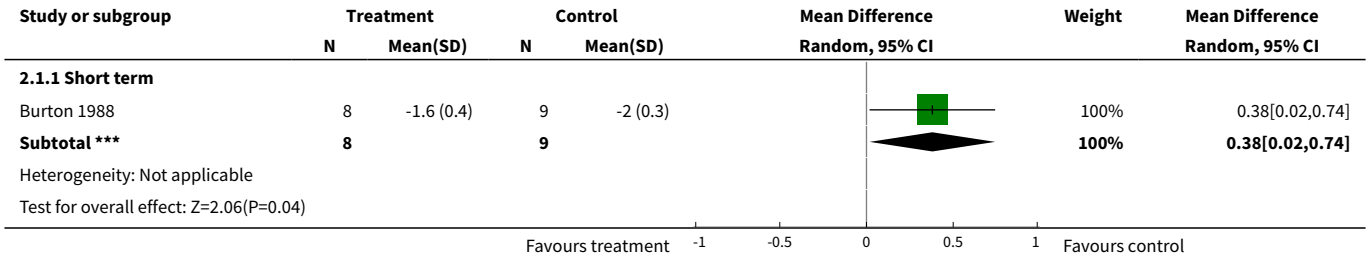
Analysis 1.3. Comparison 1 Orthotic device versus corticosteroid injection, Outcome 3 Increase in Maximum Grip Strength.



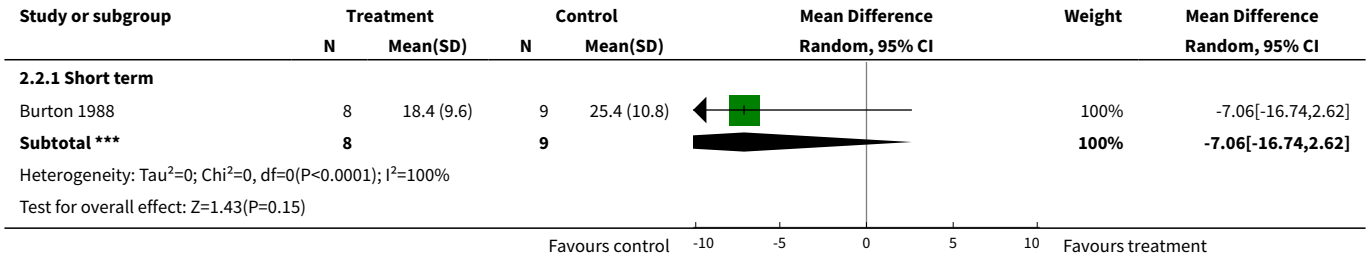
Comparison 2. Orthotic device versus anti-inflammatory cream

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Short term	1	17	Mean Difference (IV, Random, 95% CI)	0.38 [0.02, 0.74]
2 Increase in Pain Free Grip Strength	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Short term	1	17	Mean Difference (IV, Random, 95% CI)	-7.06 [-16.74, 2.62]

Analysis 2.1. Comparison 2 Orthotic device versus anti-inflammatory cream, Outcome 1 Pain.



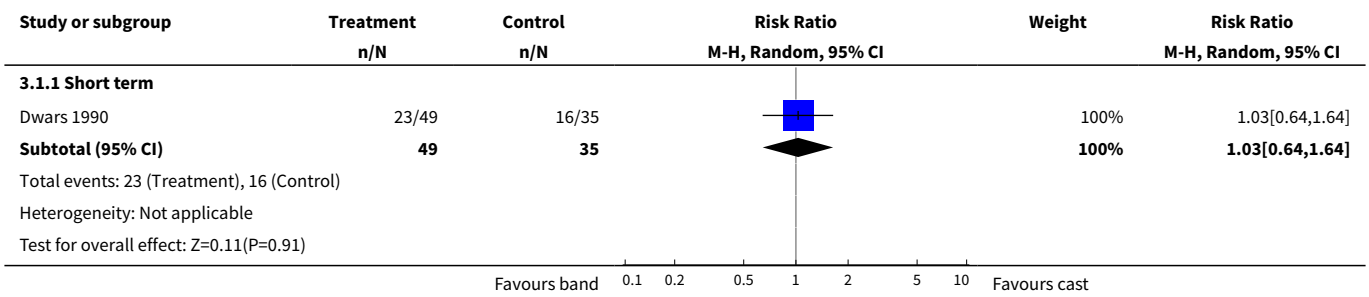
Analysis 2.2. Comparison 2 Orthotic device versus anti-inflammatory cream, Outcome 2 Increase in Pain Free Grip Strength.



Comparison 3. Orthotic device versus physiotherapy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective outcome on global measure of improvement	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Short term	1	84	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.64, 1.64]

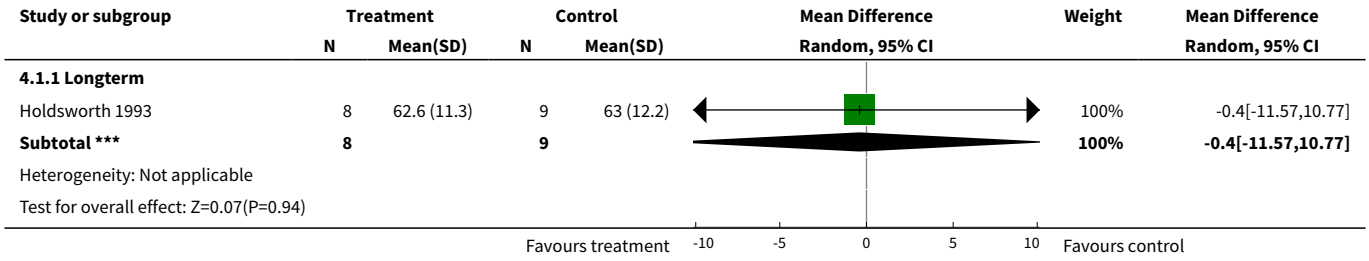
Analysis 3.1. Comparison 3 Orthotic device versus physiotherapy, Outcome 1 Subjective outcome on global measure of improvement.



Comparison 4. Orthotic device as additive to Ultrasound + Aquasonic coupling medium

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective outcome on global measure of improvement	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Longterm	1	17	Mean Difference (IV, Random, 95% CI)	-0.40 [-11.57, 10.77]

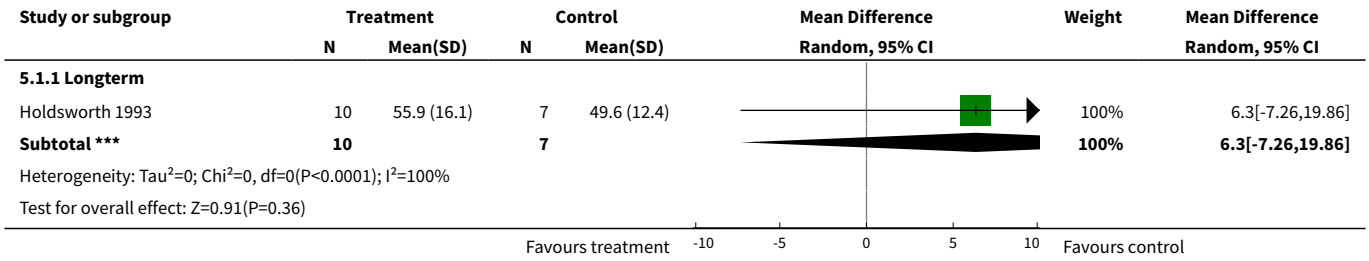
Analysis 4.1. Comparison 4 Orthotic device as additive to Ultrasound + Aquasonic coupling medium, Outcome 1 Subjective outcome on global measure of improvement.



Comparison 5. Orthotic device as additive to Ultrasound+ Hydrocortisone coupling medium

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective outcome on global measure of improvement	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Longterm	1	17	Mean Difference (IV, Random, 95% CI)	6.30 [-7.26, 19.86]

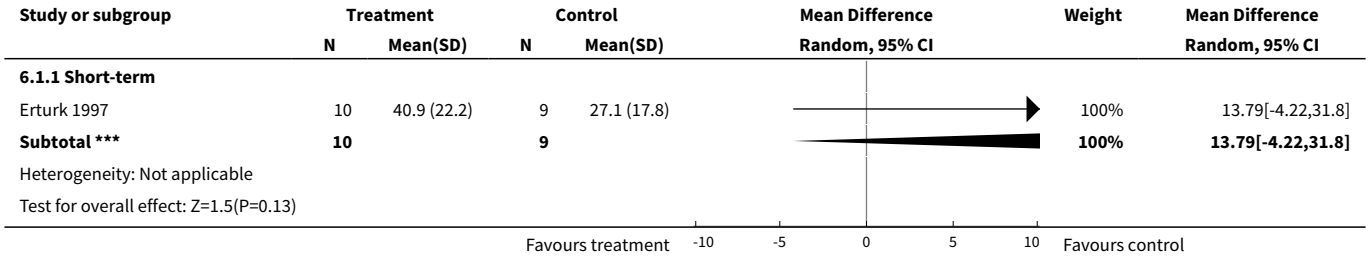
Analysis 5.1. Comparison 5 Orthotic device as additive to Ultrasound+ Hydrocortisone coupling medium, Outcome 1 Subjective outcome on global measure of improvement.



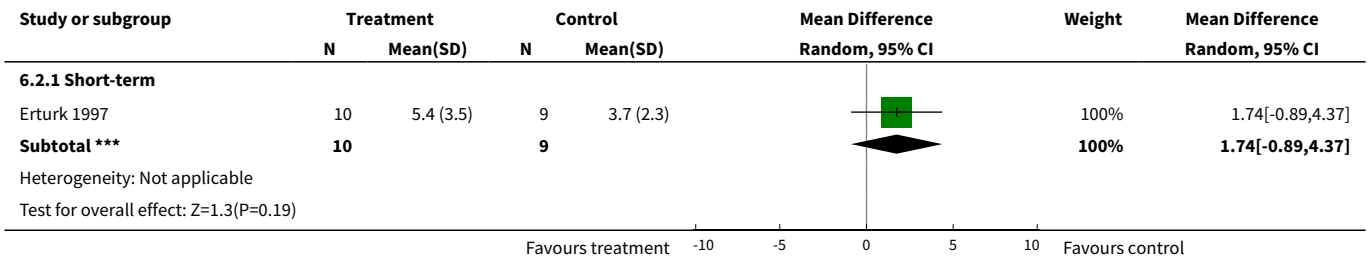
Comparison 6. Orthotic device as additive to corticosteroid injection

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Decrease in pain	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Short-term	1	19	Mean Difference (IV, Random, 95% CI)	13.79 [-4.22, 31.80]
2 Increase in maximum grip strength	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Short-term	1	19	Mean Difference (IV, Random, 95% CI)	1.74 [-0.89, 4.37]

Analysis 6.1. Comparison 6 Orthotic device as additive to corticosteroid injection, Outcome 1 Decrease in pain.



Analysis 6.2. Comparison 6 Orthotic device as additive to corticosteroid injection, Outcome 2 Increase in maximum grip strength.

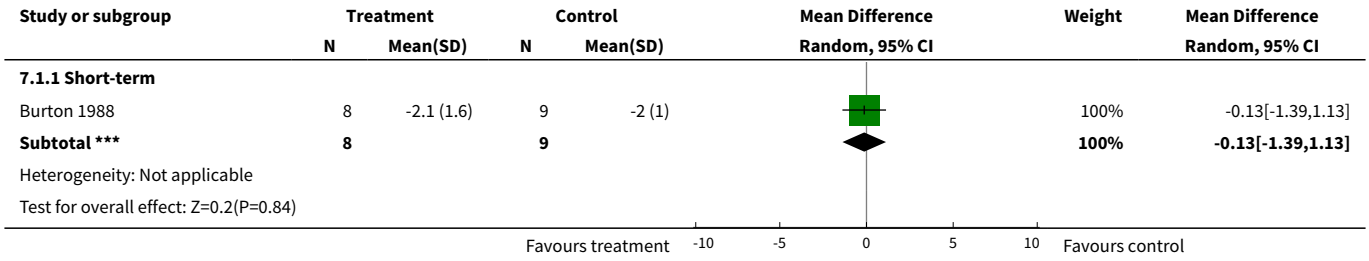


Comparison 7. Orthotic device as additive to anti-inflammatory cream

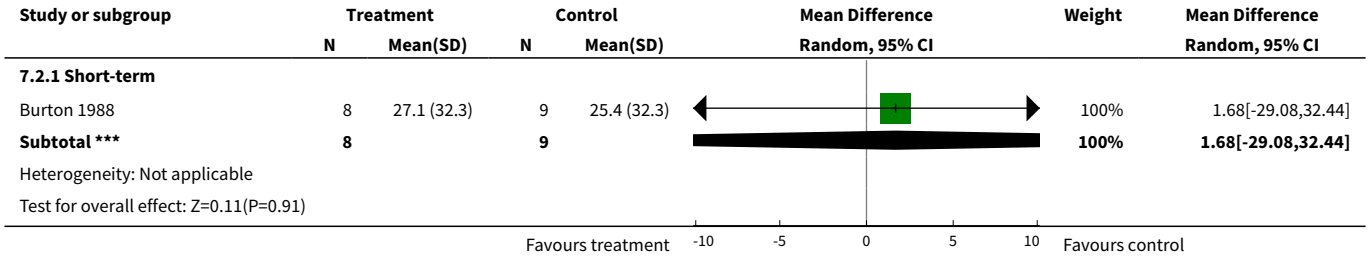
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Short-term	1	17	Mean Difference (IV, Random, 95% CI)	-0.13 [-1.39, 1.13]
2 Increase in pain free grip strength	1		Mean Difference (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Short-term	1	17	Mean Difference (IV, Random, 95% CI)	1.68 [-29.08, 32.44]

Analysis 7.1. Comparison 7 Orthotic device as additive to anti-inflammatory cream, Outcome 1 Pain.



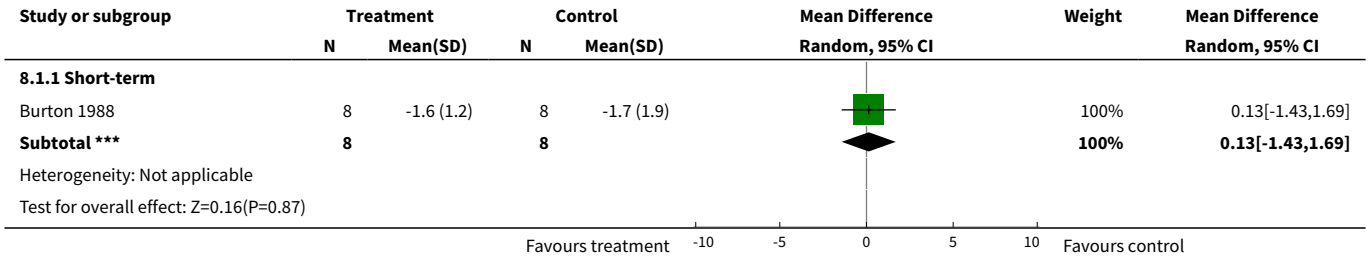
Analysis 7.2. Comparison 7 Orthotic device as additive to anti-inflammatory cream, Outcome 2 Increase in pain free grip strength.



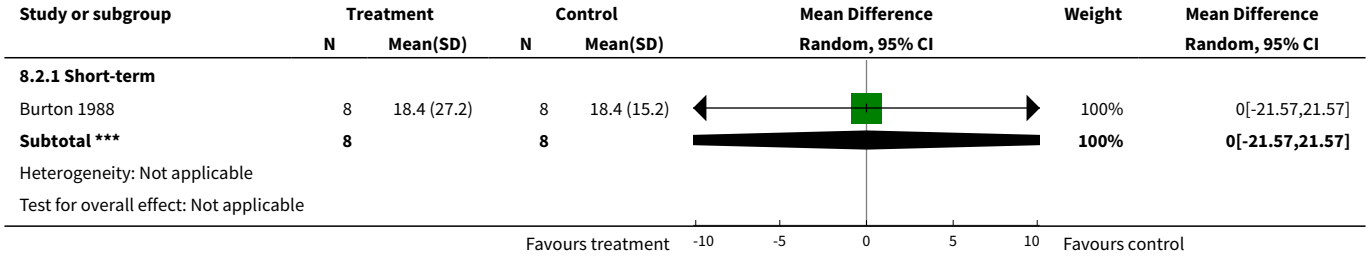
Comparison 8. Orthotic device as additive to manipulation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Short-term	1	16	Mean Difference (IV, Random, 95% CI)	0.13 [-1.43, 1.69]
2 Increase in pain free grip strength	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Short-term	1	16	Mean Difference (IV, Random, 95% CI)	0.0 [-21.57, 21.57]

Analysis 8.1. Comparison 8 Orthotic device as additive to manipulation, Outcome 1 Pain.



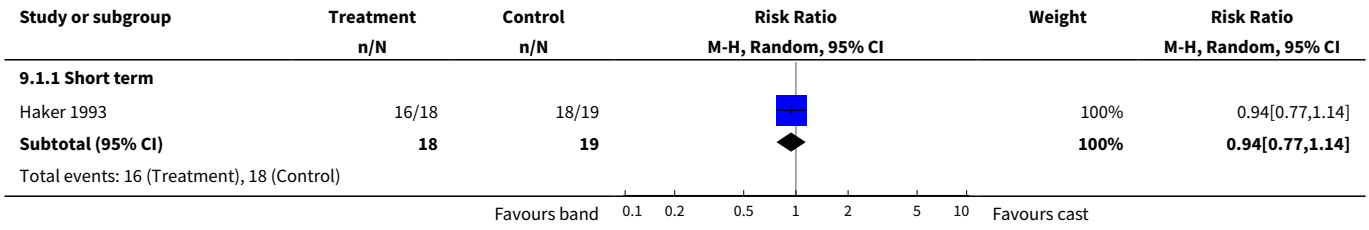
Analysis 8.2. Comparison 8 Orthotic device as additive to manipulation, Outcome 2 Increase in pain free grip strength.

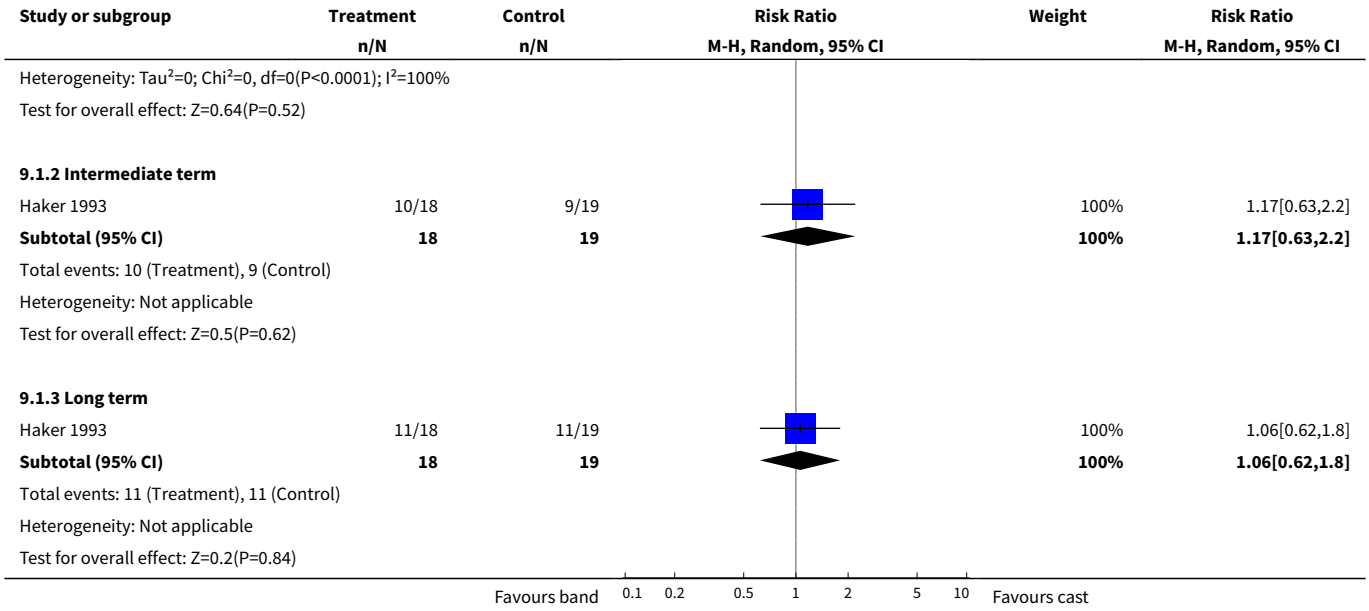


Comparison 9. Orthotic device versus other orthotic device: elbow-band versus splintage

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective outcome on global measure of improvement	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Short term	1	37	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.77, 1.14]
1.2 Intermediate term	1	37	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.63, 2.20]
1.3 Long term	1	37	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.62, 1.80]

Analysis 9.1. Comparison 9 Orthotic device versus other orthotic device: elbow-band versus splintage, Outcome 1 Subjective outcome on global measure of improvement.





ADDITIONAL TABLES

Table 1. Characteristics of included studies

TRIAL	SAMPLE SIZE n *	SMALLEST GROUP (n)	MALE/FEMALE (%)	MEAN AGE (Y.)	FOLLOW-UP	TREATMENT	CONTROL	OUTCOMES
Burton	33 [33]	8	52/48	45.1	Short-term	1) Strap + manipulation	a) Anti-inflammatory cream + manipulation	Pain, Pain-free grip strength
							b) Manipulation	
						2) Strap + anti-inflammatory cream + manipulation	a) Anti-inflammatory cream + manipulation	
Dwars	84 [120]	35	Unknown	Unknown	Short-term	Elbow-support	Physiotherapy	Pain, Global measure of improvement
Erturk	35 [35]	7	Unknown	47.7	Short-term	Bandage	Corticosteroid injections	Pain, Maximum grip strength
Haker	56 [70]	18	66/34	47.9	Short-term, Intermediate-term, Long-term	1) Elbow band	a) Splintage (cast)	Global measure of improvement, Pain-Free Grip Strength
							b) Corticosteroid-injections	
						2) Splintage (cast)	a) Corticosteroid injections	
Holdsworth	34 [42]	7	50/50	46.1	Short-term	1) Clasp + Ultrasound (aquatic coupling medium)	Ultrasound (aquatic coupling medium)	Pain, Pain-free grip strength
						2) Clasp + Ultrasound (hydrocortisone coupling medium)	Ultrasound (hydrocortisone coupling medium)	
* between	square brackets is the number	of randomised patients						

Table 1. Characteristics of included studies *(Continued)*

Table 2. Validity Assessment: description of criteria

ITEM	Description
V1	Was a method of randomisation performed ?
V2	Was the treatment allocation concealed ?
V3	Were the intervention groups similiar at baseline regarding prognostic factors ?
V4	Was the care provider blinded for the allocated intervention ?
V5	Were co-interventions avoided or standardized ?
V6	Was adherence to interventions acceptable in all groups ?
V7	Was the patient blinded to the allocated intervention ?
V8	Was the withdrawal/drop-out rate described and acceptable ?
V9	Was the outcome assessor blinded to the intervention ?
V10	Was timing of outcome assessment comparable in both groups ?
V11	Did the anlaysis include an intention-to-treat analysis ?

WHAT'S NEW

Date	Event	Description
7 November 2008	Amended	Converted to new review format. CMSG ID: C060-R

DECLARATIONS OF INTEREST

A randomised clinical trial by PAA Struijs, CN van Dijk and WJJ Assendelft has been funded by fa. Bauerfeind, manufacturer of orthotic devices.

SOURCES OF SUPPORT

Internal sources

- Academic Medical Center, Netherlands.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Orthotic Devices; Randomized Controlled Trials as Topic; Tennis Elbow [*therapy]

MeSH check words

Humans