

# Orthotic devices for tennis elbow: a systematic review

P A A Struijs, N Smidt, H Arola, C N van Dijk, R Buchbinder and W J J Assendelft

## SUMMARY

*Lateral epicondylitis (tennis elbow) is a frequently reported condition. A wide variety of treatment strategies has been described. As yet, no optimal strategy has been identified. The aim of this review was to assess the effectiveness of orthotic devices for treatment of tennis elbow.*

*An electronic database search was conducted using MEDLINE, EMBASE, CINAHL, the Cochrane Controlled Trial Register, Current Contents, and reference lists from all retrieved articles. Experts on the subjects were approached for additional trials. All randomised controlled trials (RCTs) describing individuals with diagnosed lateral epicondylitis and assessing the use of an orthotic device as a treatment strategy were evaluated for inclusion. Two reviewers independently assessed the validity of the included trials and extracted data on relevant outcome measures. Dichotomous outcomes were expressed as relative risks and continuous outcomes as standardised mean differences, both with corresponding 95% confidence intervals. Statistical pooling and subgroup analyses were intended. Five small-size RCTs (n = 7–49 per group) were included. The validity score ranged from three to nine positive items out of 11. Subgroup analyses were not performed owing 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 owing to the high level of heterogeneity of the 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.*

**Keywords:** orthotic devices; lateral epicondylitis; tennis elbow; randomised controlled trial.

## Background

Tennis elbow, or lateral epicondylitis, is a frequently reported condition characterised by pain over the lateral epicondyle of the humerus and aggravation of the pain on resisted dorsiflexion of the wrist.<sup>1–3</sup> The incidence in general practice is approximately between four and seven per 1000 patients per year,<sup>2–7</sup> with an annual incidence of 1–3% in the general population.<sup>4,8,9</sup> In The Netherlands, in approximately 10% of cases the complaint will result in sick leave for a mean period of 11 weeks.<sup>1</sup> Untreated, the complaint is estimated to last from six months to two years.<sup>10–13</sup>

Over 40 treatment options are described.<sup>14</sup> Examples include an expectant waiting policy, corticosteroid injections, orthotic devices, surgery, and physiotherapeutic modalities, such as exercises, ultrasound, laser, massage, electrotherapy, and manipulations. In Dutch primary care, 21% of the patients with lateral epicondylitis are prescribed an orthotic device as a treatment strategy.<sup>1</sup> Many different types of braces and other orthotic devices are available for treating tennis elbow. The main type is a band or strap around the muscle-belly of the wrist dorsiflexors. Theoretically, binding the muscle with a clasp, band or brace should limit expansion and decrease the contribution to force production made by muscle fibres proximal to the band. Immobilisation with a splint or a cast should completely limit expansion so that no force can be transmitted by the muscle fibres.

Labelle *et al* performed a systematic review of conservative treatment measures for lateral epicondylitis<sup>15</sup> but only one trial concerning an orthotic device was mentioned.<sup>16</sup> To date, there is no updated systematic review of trials which has studied the effectiveness of orthotic devices for treating tennis elbow.

A systematic review of randomised clinical trials was therefore performed to evaluate the evidence for effectiveness of orthotic devices for tennis elbow over the short, intermediate, and long term.

## Method

### Selection criteria

Only randomised clinical trials (RCTs) describing the use of an orthotic device as a treatment strategy were considered for inclusion. Results had to be published as a full report before April 1999.

No restrictions were made concerning the language of publication. Inclusion criteria required that the study had included patients with lateral epicondylitis of the humerus, involving at least identification of lateral elbow pain, increased by pressure on the lateral epicondyle, and with pain on resisted dorsiflexion of the wrist. At least one of the treatment groups should have received an orthotic device in

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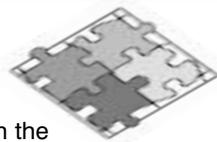
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**HOW THIS FITS IN***What do we know?*

Orthotic devices may be helpful in the treatment of tennis elbow.

*What does this paper add?*

There is no definitive evidence of an optimal strategy at present in the literature. This review was conducted to give direction to the discussion of the treatment of tennis elbow.



the form of a brace, splint, cast, band or strap. Control interventions could be all types of conservative treatment, including placebo bandage, expectant policy, ultrasound, laser, massage, electrotherapy, topical treatment, manipulations, strengthening exercises, or corticosteroid injections. Surgical treatments were excluded. As outcome measures, at least one of the following had to be described: (a) improvement in pain; (b) global measure of improvement; (c) pain-free grip strength; (d) maximum grip strength; (e) elbow-specific functional status; (f) pressure pain on the lateral epicondyle; or (g) generic functional status.

**Search strategy**

A comprehensive, unbiased search was performed. Adaptations of the highly sensitive Cochrane Collaboration search strategy were used to identify all randomised clinical trials.<sup>17</sup> A computerised search of MEDLINE (January 1966–May 1999), EMBASE (January 1988–May 1999), and CINAHL (January 1982–January 1999) was performed. In addition, 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 (CCTR) was searched for RCTs using 'elbow' and 'epicondylitis'.<sup>17</sup> Experts on the subject were approached for additional studies that may not have been retrieved from the above strategy. The keywords and related free text words used were: 'tennis elbow', 'elbow', 'elbow joint', 'humerus', 'tendinitis', 'injury', 'sprains and strains', 'arm injuries', 'soft tissue injuries', 'athletic injuries', 'tendon injuries', 'braces', 'splints', 'immobilisation', 'casts', 'orthotic devices', and 'external fixators'. The titles, abstracts, and keywords of the articles identified were checked independently by one reviewer and an independent colleague. During a consensus meeting, the final selection of trials was performed.

**Quality Assessment (Table 1)**

The differences in quality among the trials indicate a possible difference in bias between these trials. It is therefore important to evaluate the quality of trials when evaluating the effectiveness of an intervention. Two independent reviewers obtained the full text of all potentially eligible articles for independent methodological assessment, blinded for author, affiliation, and source. The internal validity of each trial was assessed using the criteria from the Amsterdam–Maastricht Consensus List for Quality Assessment of Randomised

Controlled Trials<sup>18</sup> (Table 1). The reviewers were provided with detailed guidelines. If sufficient information was available and bias was considered to be unlikely then a criterion was rated positive ('yes/(+)'). If bias was considered to be likely then the criterion was rated negative ('no/(-)'). When insufficient information was given, the criterion was 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 on all validity items. Equal weights were applied, resulting in a validity score ranging from 0–11, with higher scores indicating lower likelihood of bias. However, in treatment with an orthotic device it is impossible to blind the care providers and patients, and these items will always score negatively, suggesting potential bias. The maximum possible score for methodological quality in this review is therefore limited to nine points.

**Analysis**

Analysis was performed separately for the short-term (fewer than six weeks), intermediate-term (six to 26 weeks) and long-term (26 weeks or more) effect of orthotic devices for lateral epicondylitis. To assess effectiveness, raw data (means and standard deviations of change scores; proportions) were extracted for reported outcomes where data were available in the published reports, or could be calculated. If necessary, standard errors of the mean were converted to standard deviations. For trials where the required data were not reported or could not be calculated, further details were requested from the authors. If this was unsuccessful, the study was described as extensively as possible. Review Manager 4.0.3 was used to analyse the results. Statistical pooling was intended, using weighted mean differences for continuous outcomes and standardised mean differences if outcomes were reported on different scales.<sup>19</sup> Reasons for heterogeneity were explored where this occurred. Dichotomous outcomes are expressed as relative risks (RRs). For each result, the 95% confidence interval (95% CI) was calculated.<sup>19,20</sup> The protocol included procedures for various analyses that were not carried out owing to limited data. For full details see the Cochrane Version of this review.<sup>21</sup>

**Results****Study selection (Figure 1)**

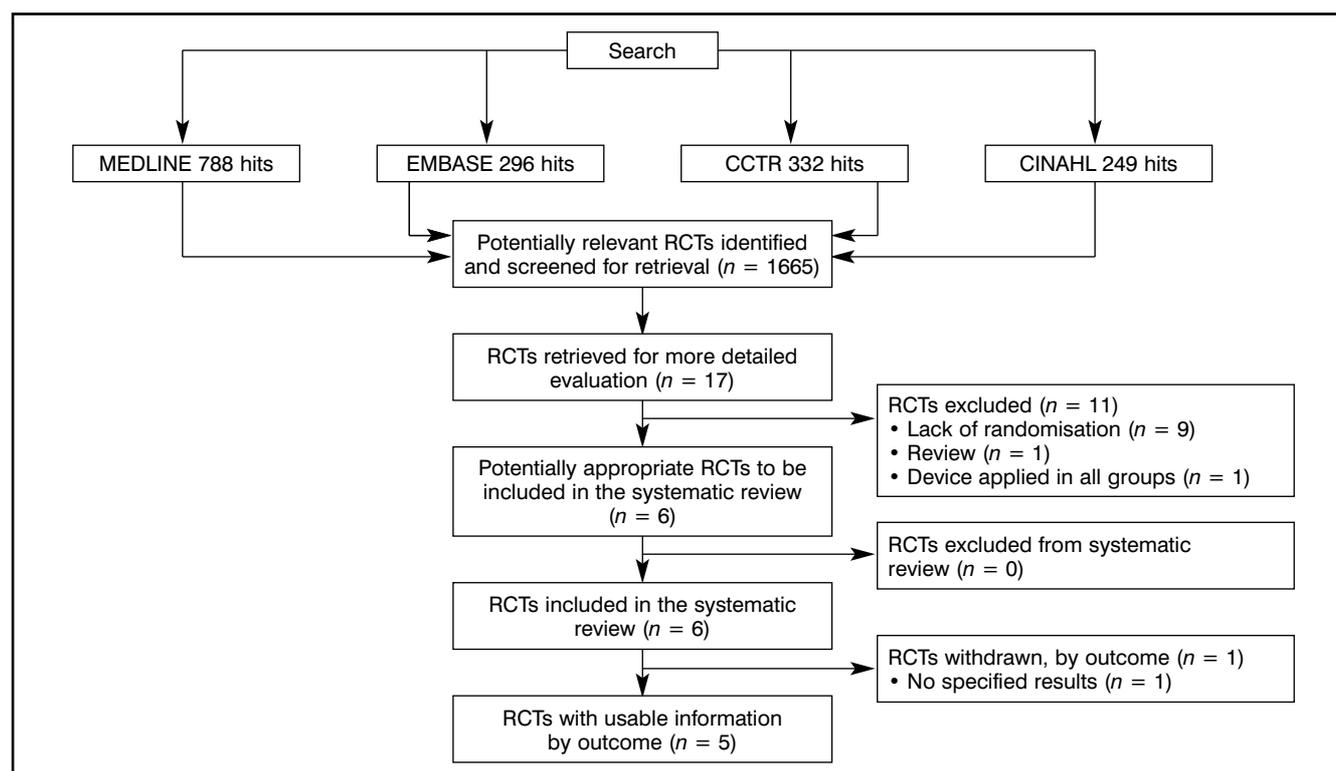
After the first extensive search, a total of 1665 titles was found. After evaluation of titles and abstracts, a total of 17 potentially eligible trials was identified. Of these, five studies met the eligibility criteria.<sup>16,23–26</sup> These are summarised in Table 2. All included studies were published in English. One potentially eligible study was excluded because there was no separate presentation of results for seven included patients with tennis elbow and no response was retrieved from a letter to the author requesting this data.<sup>27</sup> The complete list of excluded trials is available from the first author, on request.

**Methodological quality**

The methodological quality of the included trials is present-

Table 1. Validity assessment: description of criteria.<sup>18</sup>

Item (validity criteria)	Description
V1	Was a method of randomisation performed?
V2	Was the treatment allocation concealed?
V3	Were the intervention groups similar at baseline regarding prognostic factors?
V4	Was the care provider blinded for the allocated intervention?
V5	Were co-interventions avoided or standardised?
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 analysis include an intention-to-treat analysis?

Figure 1. Flowchart: selection of trials.<sup>22</sup>

ed in Table 3. There was initial disagreement between the reviewers on 29 out of the 55 validity items (47%). The  $\kappa$ -values for inter-observer agreement were calculated for each validity item separately and ranged from -0.43 to 1.00, with a median value of 0.29. Items with lowest disagreement were V1, V5, and V9. After a consensus round, disagreements remained on eight items on which a third reviewer made the final decision. The results of the methodological quality assessment were sent to the (first) authors of the included trials, asking them if they agreed with our assessment and, if not, to provide arguments for change of score. In addition, additional information was requested to aid in the validity assessment. All five authors responded to our request. We changed 21 scores: 16 from unclear (?) to positive (+); three from unclear (?) to negative (-); and two from negative (-) to positive (+). Table 3 presents the final results after the additional comments from the authors.

### Analysis

The pre-planned stratified analyses for validity score, type of orthotic device, and prognostic factors were not performed, as the data on these items were too limited and too heterogeneous. Owing to this heterogeneity, no pooling of data was possible and results were described for each trial separately.

Data were available for the following comparisons (Table 4):

(a) *Orthotic devices versus other conservative treatment.* Four studies<sup>16,23-25</sup> compared an orthotic device with a conventional treatment. Of these, two of the studies were with a corticosteroid injection.<sup>24,25</sup> One study compared an elbow support with a physiotherapy treatment<sup>23</sup> and one study compared an elbow strap with anti-inflammatory cream. The results of the two studies comparing orthotic devices with corticosteroid injection could not be pooled because differ-

Table 2. Characteristics of included studies.

Trial	Sample size (n) <sup>a</sup>	Smallest group (n)	Male/female (%)	Age in years (mean)	Follow-up	Treatment	Control	Outcomes <sup>b</sup>
Burton <sup>16</sup>	33 (33)	8	52/48	45.1	ST	1. Strap plus manipulation 2. Strap plus anti-inflammatory cream plus manipulation	(a) Anti-inflammatory cream plus manipulation (b) Manipulation (a) Anti-inflammatory cream plus manipulation	1,4
Dwars <sup>23</sup>	84 (120)	35	Unknown	Unknown	ST	Elbow support	Physiotherapy	1,2
Erturk <sup>24</sup>	35 (35)	7	Unknown	47.7	ST	Bandage	Corticosteroid injection	1,3
Haker <sup>25</sup>	56 (70)	18	66/34	47.9	ST, IT, LT	1. Elbow-band 2. Splint	(a) Splintage (b) Corticosteroid injection (a) Corticosteroid injection	2,4
Holdsworth <sup>26</sup>	34 (42)	7	50/50	46.1	ST	1. Clasp plus ultrasound (Aq) 2. Clasp plus ultrasound (HC)	(a) Ultrasound (Aq) (a) Ultrasound (HC)	1,4

<sup>a</sup>n = total number of randomised patients. <sup>b</sup>Outcome measures: 1 = pain; 2 = global measure of improvement; 3 = pain-free grip strength; 4 = maximum grip strength. ST = short term; IT = intermediate term; LT = long term; Aq = aquasonic coupling medium; HC = hydrocortisone coupling medium.

ent outcome measures were used. One study<sup>24</sup> failed to demonstrate any difference between treatments in terms of short-term reduction in pain (difference = 0.70 [95% CI = -0.3 to 1.7]) or increase in maximum grip strength (difference = -0.97 [95% CI = -2.0 to 0.1]), while the second study showed significantly better short and intermediate-term results with respect to global measure of improvement favouring corticosteroid injection (RR = 2.91 [95% CI = 1.8 to 4.7] and RR = 1.76 [95% CI = 1.1 to 2.8] respectively.<sup>25</sup> The study comparing an elbow support with physiotherapy<sup>23</sup> failed to demonstrate a difference between groups with respect to short-term patient satisfaction (RR = 1.03 [95% CI = 0.6 to 1.6]) or decrease in pain, although the latter could not be verified, as standard deviations could not be estimated and could not be retrieved from the author. This latter study reported a drop-out rate of 30% at the follow-up visit. The results of the study comparing anti-inflammatory cream with an elbow strap favoured anti-inflammatory cream for pain reduction in the short term (difference = 0.96 [95% CI = -0.1 to 2.0]) but found no differences in terms of pain-free grip strength (difference = -0.65 [95% CI = -1.6 to 0.3]).<sup>16</sup>

(b) *Orthotic device as an additional treatment.* Three studies<sup>16,24,26</sup> studied the additional use of an orthotic device. All three studies reported only short-term results. Burton<sup>16</sup> compared (a) an elbow strap and anti-inflammatory cream with anti-inflammatory cream only, and (b) elbow strap and manipulation with manipulation only. Erturk *et al* compared use of a bandage plus an injection with injection only.<sup>24</sup> Holdsworth *et al*<sup>26</sup> compared (a) the use of an epicondylitis clasp plus ultrasound with a conventional coupling medium plus the same ultrasound treatment, and (b) the use of an epicondylitis clasp plus ultrasound with a hydrocortisone coupling medium plus the same ultrasound treatment. There was no significant difference in decrease in pain (difference = -0.24 [95% CI = -0.8 to 0.3]). However, it was not possible to retrieve standard deviations from one of the studies.<sup>26</sup> Holdsworth *et al* conclude that no additional effect was derived from the use of the clasp. Subjective outcome on global measure of improvement was reported in one study<sup>26</sup> using a 100 mm VAS score. There were no significant differences in outcome between using an orthotic device and having no treatment (difference = 0.18 [95% CI = -0.5 to 0.9]). Increase in maximum grip strength and pain-free grip strength showed no significant differences: the difference for maximum grip strength was 0.56 (95% CI = -0.4 to 1.5) and the difference for increase in pain-free grip strength was 0.01 (95% CI = -0.7 to 0.7).

(c) *Orthotic device versus another orthotic device.* Only one study<sup>25</sup> compared one type of orthotic device with another: an elbow band and 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 to 1.1]; RR = 0.75 [95% CI = 0.5 to 1.2]; and RR = 1.06 [95% CI = 0.6 to 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.

Table 3: Validity assessment of included studies.<sup>a</sup>

Study	V1 <sup>b,c</sup>	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	Total
Burton <sup>16</sup>	+ (?)	+ (?)	+ (?)	-	+ (-)	+ (?)	-	+	+ (?)	+	+	9 (3)
Dwars <sup>23</sup>	+ (?)	-	- (?)	-	-	+ (?)	-	-	-	+	- (?)	3 (1)
Erturk <sup>24</sup>	+ (?)	+ (?)	+ (?)	-	+ (?)	+ (?)	-	+	-	+	- (?)	7 (2)
Haker <sup>25</sup>	+ (?)	+ (-)	+ (?)	-	+	? (?)	-	-	+	+	-	6 (3)
Holdsworth <sup>26</sup>	+ (?)	+ (?)	-	-	? (?)	+	-	-	+	+	-	5 (4)

<sup>a</sup>See Table 1 for explanation of items. <sup>b</sup>An item was rated positive (+) when bias was considered unlikely, negative (-) when bias was considered likely, and inconclusive (?) when insufficient data were present. <sup>c</sup>Ratings between brackets represent the initial assessment by the blinded reviewers

Table 4. Results.

Author	Comparison	Outcome measure	Short term (95% CI)	Intermediate term (95% CI)	Long term (95% CI)
Burton <sup>16</sup>	OD versus anti-inflammatory cream	Pain (0–5 scale)	D = 0.96 (-0.1 to 2.0)	-	-
		Improvement in pain-free grip strength (mmHg)	D = 0.65 (-0.3 to 1.6)	-	-
	OD as additional treatment	Pain (0–5 scale)	D = -0.24 (-0.8 to 0.3)	-	-
		Improvement in pain-free grip strength (mmHg)	D = -0.01 (-0.7 to 0.7)	-	-
Dwars <sup>a23</sup>	OD versus physiotherapy	Global measure of improvement (3-point scale)	RR = 1.03 (0.6 to 1.6)	-	-
Erturk <sup>24</sup>	OD versus injection	Pain (VAS 100 mm)	D = 0.70 (-0.3 to 1.7)	-	-
		Improvement in maximum grip strength (kg)	D = 0.97 (-0.1 to 2.0)	-	-
	OD as additional treatment	Improvement in maximum grip strength (kg)	D = -0.56 (-1.5 to 0.4)	-	-
Haker <sup>25</sup>	Band versus cast	Global measure of improvement (1–5 scale)	RR = 0.94 (0.8 to 1.1)	RR = 0.75 (0.5 to 1.2)	RR = 1.06 (0.6 to 1.8)
	OD versus injection	Global measure of improvement <sup>b</sup> (1–5 scale)	RR = 2.91 (1.8 to 4.7)	RR = 1.76 (1.1 to 2.8)	RR = 0.87 (0.6 to 1.2)
Holdsworth <sup>26</sup>	OD as additional treatment	Global measure of improvement (VAS 100 mm)	D = 0.18 (-0.5 to 0.9)	-	-

<sup>a</sup>Mean values and/or standard deviations could neither be calculated nor retrieved from the authors. <sup>b</sup>Results in favour of corticosteroid injection. OD = orthotic device; RR = relative risk; D = difference (differences in mean increase/decrease).

## Discussion

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

Five RCTs were included in our systematic review. The 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. Heterogeneity was also present for type of control intervention and study population. The heterogeneity among 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 the 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 when compared with an elbow band.<sup>25</sup> In a systematic review on effectiveness of corticosteroid injections it was concluded that injection seemed effective in the short term.<sup>28</sup> This finding could also indicate that corticosteroid injection was simply a more effective comparison. Comparisons of physiotherapy with anti-inflammatory cream<sup>16</sup> or with cast immobilisation

showed no differences.

When the orthotic device was used as an additional treatment, none of the three studies showed that an orthotic device had a statistically significant effect. 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 the effectiveness of an orthotic device as a treatment or as an additional treatment for tennis elbow.

Despite the extensive search, possible relevant trials may have been missed. We identified one eligible trial in which the effectiveness of an orthotic device in patients with acute elbow complaints was studied but 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,<sup>16</sup> from 1 to 3,<sup>23</sup> from 2 to 7,<sup>24</sup> from 3 to 6,<sup>25</sup> and from 4 to 5.<sup>26</sup> The rise in 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 within their 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, such as the Pain Free Function Questionnaire, were reported.<sup>29</sup>

Further high quality sufficiently powered randomised trials are warranted to investigate the effectiveness of orthotic devices in the 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 a relatively cheap orthotic device as a treatment strategy, or as an addition to any other conventional treatment. Finally, the cost-effectiveness of orthotic devices should be incorporated, since the use of orthotic devices might reduce costs of sick leave by reduction of the pain experienced during activities.

## Conclusion

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.

*This review will be published in a more extensive version and updated regularly in the Cochrane Library.*<sup>17</sup>

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## Conflict of interest

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