On the treatment of tennis elbow. Effectiveness and prognostics of braces and physical therapy
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Chapter

Orthotic devices for tennis elbow
A Systematic Review

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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. The objective of this review was to assess the effectiveness of orthotic devices for treatment of tennis elbow.

Methods  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 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. 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.

Results  Five small-size 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.

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.
**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.\(^1\)\(^-\)\(^3\) The incidence in general practice is approximately 4-7 per 1000 patients per year \(^2\)\(^-\)\(^7\), with an annual incidence of 1-3% in the general population.\(^4\)\(^,\)\(^8\)\(^,\)\(^9\) In the Netherlands, in approximately 10% the complaint will result in sick leave, for a mean period of 11 weeks.\(^1\) Untreated, the complaint is estimated to last from 6 months to 2 years.\(^10\)\(^-\)\(^13\) Over 40 treatment options are described.\(^14\) 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.\(^1\) 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 and no force can be transmitted by the muscle fibres.

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

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

**Methods**

**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 (tennis elbow), 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 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: (1) improvement in pain; (2) global measure of improvement; (3) pain free grip strength; (4) maximum grip strength; (5) elbow-specific functional status; (6) pressure pain on the lateral epicondyle; or (7) 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. A computerised search of MEDLINE (01/1966-05/1999); EMBASE (01/1988-05/1999); CINAHL (01/1982-01/1999) was performed. 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 (CCTR) was searched for RCTs on elbow and on epicondylitis. 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; external fixators. The titles, abstracts and keywords of the articles identified, were checked independently by one reviewer (PS) and an independent colleague (GK, see acknowledgements). During a consensus meeting, final selection of trials was performed.

Quality Assessment
Differences in quality amongst trials indicate a possible difference in bias between these trials. Therefore, it is important to evaluate the quality of trials when evaluating the effectiveness of an intervention. Two independent reviewers (NS and HA) obtained the full text of all potentially eligible articles for independent methodological assessment, blinded for author, affiliation and source. Internal validity of each trial was assessed using the criteria from the Amsterdam-Maastricht Consensus List for Quality Assessment of Randomised Controlled trials (Table 1). The reviewers were provided with detailed guidelines. If sufficient information was available and bias was considered to be unlikely, a criterion was rated positive ('yes (+)'). If bias was considered to be likely, 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 negative, suggesting potential bias. Maximum possible score for methodological quality in this review is therefore limited to 9 points.

**Analysis**

Analysis was performed for the short-term (<6 weeks), intermediate-term (6 - 26 weeks) and long-term (≥26 weeks) effect of orthotic devices for lateral epicondylitis separately. In order to assess effectiveness, raw data (means and standard deviations of change scores; proportions) were extracted for reported outcomes where data was available in the published reports, or could be calculated. If necessary, standard errors of the mean (SEM) were converted to standard deviations (SD). For trials where the required data was 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 (WMD) for continuous outcomes and Standardised mean differences (SMD) if outcomes were reported on different scales. In case of heterogeneity, reasons for this were explored. Dichotomous outcomes are expressed as relative risks (RRs). For each result, the 95% confidence interval (95% CI) was calculated. The protocol included procedures for various analyses that were not carried out due to too limited data. For full details see the Cochrane Version of this review.
Results

Study selection (Figure 1)

![Flowchart: selection of trials](#)

**Table 2 - Characteristics Of Included Studies**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Sample size (n)</th>
<th>Smallest group (n)</th>
<th>Male/Female (%)</th>
<th>AGE, (y.) (mean)</th>
<th>Follow-up</th>
<th>Treatment</th>
</tr>
</thead>
</table>
| Burton 16   | 33 [33]         | 8                  | 52/48           | 45.1            | ST        | 1) Strap + manipulation  
2) Strap + anti-inflammatory cream + manipulation |
| Dwars 23    | 84 [120]        | 35                 | Unkn.           | Unkn.           | ST        | Elbow-support |
| Erturk 24   | 35 [35]         | 7                  | Unkn.           | 47.7            | ST        | Bandage |
| Haker 25    | 56 [70]         | 18                 | 66/34           | 47.9            | ST, IT, LT| 1) Elbow-band |
| Holdsworth 26| 34 [42]        | 7                  | 50/50           | 46.1            | ST        | 2) Splint  
1) Clasp + ultrasound (Aq.)  
2) Clasp + ultrasound (HC) |
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. 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 7 included patients with tennis elbow and no response was retrieved from a letter to the author requesting this data. The complete list of excluded trials is available from the first author, on request.

**Methodological quality**

The methodological quality of the included trials is presented in Table 3. There was initial disagreement between the reviewers on 29 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, with a median value of 0.29. Items with lowest disagreement were V1, V5 and V9. After a consensus round, disagreements remained on 8 items, on which a third reviewer (WJJA) made the final decision. The results of our 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, we requested additional information to aid in the validity assessment. All 5 authors responded to our request. We changed 21 scores: 16 from unclear (?) to positive (+); 3 from unclear (?) to negative (-); 2 from negative (-) to positive (+). Table 3 presents the final results after the additional comments from the authors.

<table>
<thead>
<tr>
<th>Control</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Anti-inflammatory cream + manipulation</td>
<td>1,4</td>
</tr>
<tr>
<td>b) Manipulation</td>
<td></td>
</tr>
<tr>
<td>a) Anti-inflammatory cream + manipulation</td>
<td></td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>1,2</td>
</tr>
<tr>
<td>Corticosteroid injection</td>
<td>1,3</td>
</tr>
<tr>
<td>a) splintage</td>
<td>2,4</td>
</tr>
<tr>
<td>b) corticosteroid-injection</td>
<td></td>
</tr>
<tr>
<td>a) corticosteroid-injection</td>
<td></td>
</tr>
<tr>
<td>a) Ultrasound (Aq.)</td>
<td>1,4</td>
</tr>
<tr>
<td>a) Ultrasound (HC )</td>
<td></td>
</tr>
</tbody>
</table>

* Between square brackets [ ] is the total of randomised patients
† Unkn. = unknown
‡ ST=short-term; IT=Intermediate-term; LT=Long-term
§ Aq. = aquasonic coupling medium; HC=Hydrocortisone coupling medium;
¶ 1= pain; 2= global measure of improvement; 3=Pain-free grip strength; 4= Maximum grip strength
Table 3 - Validity assessment of included studies*

<table>
<thead>
<tr>
<th>Study</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
<th>V6</th>
<th>V7</th>
<th>V8</th>
<th>V9</th>
<th>V10</th>
<th>V11</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burton</td>
<td>++</td>
<td>+</td>
<td>(?)</td>
<td>(++</td>
<td>-</td>
<td>+</td>
<td>(?)+</td>
<td>+</td>
<td>(?)</td>
<td>+</td>
<td>+</td>
<td>9</td>
</tr>
<tr>
<td>Dwarss</td>
<td>+</td>
<td>(?)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>(?)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Erturk</td>
<td>+</td>
<td>(?)</td>
<td>+</td>
<td>(?)</td>
<td>-</td>
<td>+</td>
<td>(?)</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>7</td>
</tr>
<tr>
<td>Haker</td>
<td>+</td>
<td>(?)</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>(?)</td>
<td>?</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>Holdsworth</td>
<td>+</td>
<td>(?)</td>
<td>+</td>
<td>(?)</td>
<td>-</td>
<td>-</td>
<td>?</td>
<td>(?)</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>5</td>
</tr>
</tbody>
</table>

* For explanation of items: see table 1
† An item was rated positive ‘+’ when bias was considered unlikely; negative ‘-’ when bias was considered likely; inconclusive ‘?’ when insufficient data was present.
‡ Ratings between brackets ( ) represent the initial assessment by the blinded reviewers (NS, HA)

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 was too limited and 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 (table 4)

Ia) Orthotic devices versus other conservative treatment

Four studies \(^{16,23-25}\) compared an orthotic device with a conventional treatment: 2 studies with a corticosteroid injection \(^{24,25}\), 1 study compared an elbow-support with a physiotherapy treatment \(^{23}\) and 1 study compared an elbow-strap with anti-inflammatory cream (AI-cream).\(^{16}\) The results

Table 4 - Results

<table>
<thead>
<tr>
<th>Author</th>
<th>Comparison*</th>
<th>Outcome measure$^{5}$</th>
<th>Short-term $^{1}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burton</td>
<td>O.D. versus AI-cream†</td>
<td>Pain (0-5 scale)</td>
<td>D 0.96 [-0.1;2.0]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improvement in PFGS (mmHg)</td>
<td>D 0.65 [-0.3;1.6]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pain (0-5 scale)</td>
<td>D -0.24 [-0.8;0.3]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improvement in PFGS (mmHg)</td>
<td>D -0.01 [-0.7;0.7]</td>
</tr>
<tr>
<td>Dwarss</td>
<td>O.D. versus Physiotherapy</td>
<td>Global measure of improvement (3 point scale)</td>
<td>RR 1.03 [0.61.6]</td>
</tr>
<tr>
<td>Erturk</td>
<td>O.D. versus injection</td>
<td>Pain (VAS 100mm)</td>
<td>D 0.70 [-0.3;1.7]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improvement in MGS (kg)</td>
<td>D 0.97 [-0.1;2.0]</td>
</tr>
<tr>
<td>Haker</td>
<td>Band versus cast (1-5 scale)</td>
<td>Global measure of improvement</td>
<td>RR 0.94 [0.8;1.1]</td>
</tr>
<tr>
<td></td>
<td>O.D. versus injection (1-5 scale)</td>
<td>Global measure of improvement</td>
<td>RR 2.91 [1.8;4.7]</td>
</tr>
<tr>
<td>Holdsworth</td>
<td>O.D. as additive treatment</td>
<td>Global measure of improvement (VAS 100mm)</td>
<td>D 0.18 [-0.5;0.9]</td>
</tr>
</tbody>
</table>
of the 2 studies comparing orthotic devices with corticosteroid-injection could not be pooled, because different outcome measures were used. One study failed to demonstrate any difference between treatments in terms of short-term reduction in pain (difference (D) = 0.70 95% CI -0.3;1.7) or increase in maximum grip strength (D = -0.97 95% CI-2.0;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;4.7 and RR=1.76 95% CI 1.1;2.8 respectively). The study comparing an elbow-support with physiotherapy 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 favoured AI-cream for pain reduction in the short-term (D= 0.96 95% CI -0.1;2.0) but found no differences in terms of pain free grip strength (D= -0.65 95% CI -1.6;0.3) (16).

**Orthotic device as an additional treatment**

Three studies studied the additive use of an orthotic device. All 3 studies reported only short-term results. Burton compared (a) an elbow-strap and AI cream with AI cream only, and (b) strap and manipulation with manipulation only. Erturk et al. compared bandage + injection with injection and Holdsworth et al. compared (a) the use of an epicondylitis-clasp combined with ultrasound with a conventional coupling medium with the same ultrasound treatment and (b) the use of an epicondylitis clasp combined with ultrasound with a

<table>
<thead>
<tr>
<th>Intermediate-term</th>
<th>Long-term</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR 0.75 [0.5;1.2]</td>
<td>RR 1.06 [0.6;1.8]</td>
</tr>
<tr>
<td>RR 1.76 [1.1;2.8]</td>
<td>RR 0.87 [0.6;1.2]</td>
</tr>
</tbody>
</table>

* O.D. = Orthotic Device † AI cream = Anti-inflammatory cream ‡ PFGS = Pain-Free Grip Strength § MGS = Maximum Grip Strength RR = Relative Risk with accompanying 95% Confidence Intervals between square [ ] brackets ¶ D = Difference with accompanying 95% confidence intervals between square [ ] brackets: differences presented are differences in mean increase/decrease ** = Mean values and/ or standard deviations could neither be calculated nor be retrieved from the authors †† = Results in favour of corticosteroid-injection.
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Hydrocortisone coupling medium with the same ultrasound treatment. There was no significant difference in decrease in pain (D = -0.24 95% CI -0.8;0.3). From one study, however, it was not possible to retrieve standard deviations. In this study the authors conclude that no additional effect was derived from the use of the clasp. Subjective outcome on global measure of improvement was reported in 1 study, using a 100mm VAS score. There were no significant differences in outcome between orthotic device and no treatment (D=0.18 95% CI -0.5;0.9). Increase in maximum grip strength and pain-free grip strength showed no significant differences: D for maximum grip strength was 0.56 (95% CI -0.4;1.5) and D for increase in pain-free grip strength 0.01 (95% CI -0.7;0.7).

Ic) Orthotic device versus another orthotic device

Only one study 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= 0.75 95% CI 0.5;1.2 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.

Five RCTs were included in our systematic review. 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 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. In a systematic review on effectiveness of corticosteroid injections it was concluded that injection seemed effective in the short-term. This finding could also indicate that corticosteroid injection simply was a more effective comparison. Comparisons with physiotherapy, with AI-cream or with cast immobilisation showed no differences.
When the orthotic device was used as an additive treatment, none of three studies showed a statistically significant effect of an orthotic device. 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 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; from 1 to 3; from 2 to 7; from 3 to 6 from 4 to 5. 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.

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.
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.

Note: This review will be published in a more extensive version and updated regularly in the Cochrane Library.17

Acknowledgements

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Potential conflict 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.

Reference List


