

Van de Streek M, van der Schans C, et al. The effect of a forearm/hand splint compared with an elbow band as a treatment for lateral epicondylitis. *Prosthetics and Orthotics International* 2004;28:183-189.

Design: randomized clinical trial

Population/sample size/setting:

- 43 patients (13 men, 30 women, mean age 43) with lateral epicondylitis treated in a university setting in the Netherlands
- Eligible if they had at least 3 weeks of symptoms and no other medical conditions that would influence the results
- Exclusion criteria were history of elbow surgery, an elbow injection in previous month, or any other treatment that would interfere with the study intervention

Main outcome measures:

- Randomized to one of two orthotic devices: an elbow band (n=20) or a forearm splint which fixed the wrist in 30° of dorsiflexion (n=23)
- Each group was told to wear the orthotic device as much as possible for 6 weeks during all daily activities; no activity restrictions were given
- Outcomes were measured at baseline and at the end of the 6 week intervention
- 6 patients wore the device for less than 4 weeks, 1 in the elbow brace and 5 in the forearm splint group; the reason for discontinuation was that the device interfered with work
- Four outcome measures were evaluated using multivariate analysis of variance (MANOVA): maximal grip strength, the total score on the Patient-Rated Forearm Evaluation Questionnaire (PRFEQ), the pain subscale of the PRFEQ, and the functional subscale of the PRFEQ
- At the end of 6 weeks, the grip strength and PRFEQ scores had significantly changed for both treatment groups, but the outcomes were equal for both treatment groups, with no influence of age, chronicity of symptoms, or type of job
- At the end of 6 weeks, the maximal grip strength increased and the PRFEQ scores decreased, but the treatment group made no difference in outcomes
- The power to detect a group difference (expressed as a time by treatment group interaction) was between 12% and 18% for the outcomes studied

Authors conclusions:

- The forearm splint is not more effective than the elbow band for treating lateral epicondylitis
- Adjustments need to be made for the forearm splint in order to make it better than the elbow band, and more research is needed to find an optimal orthotic design

Comments:

- The results are reported in the text in terms of test statistics and p values rather than in meaningful effect sizes in terms of kilograms of grip strength or functional and pain scores, which are given in Table 2
- Table 2, which reports mean values for the four outcomes, does not appear to be consistent with the discussion in the text of the article
- For example, maximal grip strength for the elbow band (Group I) in the first line of Table 2, appears to have worsened between the start and the end of the intervention (from 37.4 to 27.9)
- The “effect size” in the last column of Table 2, seems to have been calculated as the change score divided by the pooled standard deviation of the scores at the beginning and end of the study, and the effect size for the first line of Table 2 equals $-.73$ rather than plus $.73$ as given in the table
- This would mean that the group with acute symptoms in the elbow band group had a moderate to large worsening of their grip strength
- For Group I, Table 2 reports that the mean grip strength at the start of the intervention was 29.2, which is less than the mean grip strength for either the acute or chronic group (the actual mean grip strength should be 35 for the start of the intervention)
- In Table 3, a MANOVA test statistic (Pillai’s trace) is reported as if it were a meaningful effect size
- As the authors point out in the discussion, the power of the study to detect whether the treatment group made any difference in change scores is less than 20%, which is too low to conclude that no difference exists

Assessment: Inadequate (presentation of results is incorrect in several places, and the study is underpowered for the main conclusion that there is no difference between the elbow band and the forearm splint)

It may be appropriate to state in the guideline that the forearm splint may present some practical difficulties for the wearer in performing work tasks