**Forogh B, Khalighi M, Javanshir MA, and et al. The effects of a new designed forearm orthosis in treatment of lateral epicondylitis. *Disability and Rehabilitation: Assistive Technology* 2012; 7(4): 336–339.**

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**Reviewer:** Linda Metzger 3-10-16

**Design:** Randomized controlled trial

**Objective:** To compare the effectiveness of a newly designed forearm orthosis with the standard counterforce strap brace orthosis in patients with lateral epicondylitis.

**Summary of Results:**

* A total of 24 participants were divided into 2 treatment groups: 1) newly designed forearm orthosis, and 2) a standard forearm counterforce strap brace.
* The new-designed forearm orthosis is composed of wrist and below elbow counterforce straps that are connected by a non-flexible middle part.
* The findings of this study clearly demonstrated that both orthoses, counterforce and new-designed, significantly relieved pain, and improved function, pain threshold, and grip strength of all patients after 4 weeks application.
* There was no significant difference in improvements between groups at 4 weeks post-treatment in the total patient rated tennis elbow evaluation (PRTEE) score which is a valid and reliable instrument for evaluation of pain and function or in grip strength. Both the pain subscore of the PRTEE and the pain threshold score showed a significant difference in improvements between groups favoring the newly designed forearm orthosis.
* It appears that there was not any significant difference in the effectiveness of the two types of orthoses regarding function, but the new-designed orthosis significantly increased the pain threshold.

**Reasons not to cite as evidence:**

* Clinical outcomes measures were the total patient rated tennis elbow evaluation (PRTEE) score, pain threshold, and grip strength. It is unclear which outcome is the primary outcome, since none was designated as such. The total PRTEE score also has subscores for both pain and function.
* In evaluating the individual subscores of the total PRTEE score which were clearly not primary outcome measures, it was found that pain relief was significantly better with the new-designed orthosis. Thus, the authors concluded that the new-designed orthosis allows a greater degree of pain relief than does the standard forearm strap brace for patients with lateral epicondylitis. This represents selective outcome reporting by the authors, since the main results of the study as were measured using the total scores from the PRTEE showed no difference in clinical outcomes between the 2 groups. In addition, the PRTEE subscore for function and grip strength also showed no difference in functional gains between the 2 groups.
* The sample size for this study was extremely small (24). No information was provided to indicate that a power analysis was performed to determine if sufficient sample size was obtained to achieve 80% power to detect a difference in means. It is unknown if an adequate sample size was achieved. The study may have been underpowered to find an effect. This represents poor study planning.
* The randomization process was not described at all. How were the participants assigned to groups? Omitting this information is a major error that fails the test of evidence.
* This study only evaluated the short-term effects of the 2 orthotics, with no longer-term follow-up. Since lateral epicondylitis is usually a long term condition, it would seem clinically relevant to evaluate effectiveness of the orthotics in the long term.
* The study lacked a control group which received no treatment. Since the effectiveness of the conventional forearm brace is in question, it does not serve as an adequate control.
* The outcomes assessor was blinded to treatment groups. It is not clear how blinding occurred and if the participants were wearing their orthoses during assessment. If blinding was not successful, this could certainly introduce both performance and detection bias.
* The newly designed forearm orthosis developed by the authors in Iran may not be available or readily used in this area.

**Assessment:**

* There is an absence of evidence that any particular orthotic design or counterforce forearm brace differ in their effectiveness in treating people with lateral epicondylitis.