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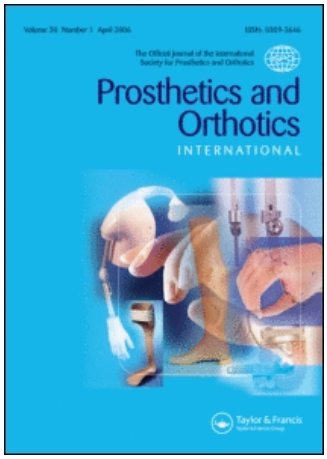

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The effect of a forearm/hand splint compared with an elbow band as a treatment for lateral epicondylitis

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Abstract

The aim of the present study was to compare the effect of a new prefabricated Thämert forearm/hand splint with the effect of a simple elbow band as a treatment for lateral epicondylitis. Forty-three (43) patients that met the inclusion criteria were randomly assigned to the elbow band group and the splint group. They wore the orthotic devices for 6 weeks. Outcome measures were obtained at baseline and directly after the intervention. These outcome measures were maximal grip strength on the involved side with a pain scale from 1 to 10 to determine the extent of pain during gripping, and the Patient-Rated Forearm Evaluation Questionnaire (PRFEQ). Analysis of variances with repeated measures, a Mann Whitney test and multiple linear regression analysis were used to compare the two groups. Main effect for time was significant for maximal grip strength and sum scores on the PRFEQ, but no differences between groups were found, even when a distinction between acute and chronic symptoms was made. Change in pain score during gripping did not differ significantly between the groups. A multiple linear regression analysis showed that the use of the splint did not significantly contribute to the prediction of change in maximal grip strength and in overall PRFEQ. The conclusion is that the forearm/hand splint is not more effective than the elbow band as a treatment for lateral epicondylitis.

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Introduction

Lateral epicondylitis or tennis elbow is a condition characterized by pain on the lateral epicondyle of the humerus (Assendelft *et al.*, 2002; Verhaar, 1994). Although the symptoms of patients with a tennis elbow are rather similar, the etiology is not uniformly explained (Verhaar, 1994; Haker and Lundeberg, 1993). The suggested causes can be classified into four groups: tendinopathy, intra-articular lesions, compression of the radial nerve and cervical radiculopathy (Verhaar, 1994). Tendinopathy is most often mentioned, and is characterized by a lesion of the common extensor tendon with or without inflammation. The lesion, which may cause the pain, results from overload of the extensors in the wrist. The muscle fibres do not get enough time to restore (Haker and Lundeberg, 1993; Wuori *et al.*, 1998).

There are many treatment modalities for tennis elbow; one of the more popular being orthotic devices such as an elbow trap or band. Some advise relief might be effective after a time period, others to wear only during the activities that provoke pain. Orthotic devices are commonly used as a treatment strategy for lateral epicondylitis. Twenty-one percent (21%) of the patients with a tennis elbow in Dutch primary care are prescribed an elbow support (Smidt, 2003). The aim of orthotic devices is primarily to attack the cause of lateral

epicondylitis by reducing the overload forces. In a recent review of the Cochrane Library, the effectiveness of orthotic devices is evaluated (Struijs *et al.*, 2001). The 5 studies, which met the eligibility criteria, are randomised control trials in which the use of a specific orthosis is evaluated. The conclusion of the review is that definite conclusions cannot be drawn about the effectiveness of orthotic devices due to the heterogeneity among the trials concerning type of orthotic device and the small study number of patients included per study.

One of the orthotic devices frequently used is the elbow band, which is worn on the forearm under the lateral epicondyle. The hypothesis is that binding the muscles limits expansion and decreases the contribution to force production made by muscle fibres proximal to the band. This way, the elbow band diminishes the overload forces (Haker and Lundeberg 1993; Snyder-Mackler and Epler, 1989). The elbow band is simple in design and comfortable to wear (Heimann, 1991). A rather new orthotic device is the splint. The theoretical assumption is that the splint forces the extensor muscles of the lateral epicondyle to relax. Expansion is completely limited and no force can be developed by muscle fibres. The overload forces are maximally reduced and the extensor tendons have the opportunity to recover. This way, the symptoms are thought to decrease (Haker and Lundeberg, 1993; Straijs *et al.*, 2001; Jansen et *al.*, 1997). The assumption is that the splint reduces the overload forces more than the elbow band, and will therefore be more effective as a treatment for lateral epicondylitis. In a study of Haker and Lundeberg (1993) one of the studies included in the review of the Cochrane Library, a cock-up splint and an elbow band were compared in patients with lateral epicondylitis. No differences in effect were found between the cock-up splint and the elbow band. There is still no scientific evidence to support the idea that a splint is more effective than an elbow band as a treatment for lateral epicondylitis.

In this study, the effect of a new fabricated Thämert forearm/hand splint is compared with the effect of a simple elbow band. The splint is developed by an orthopaedist in the Netherlands and is an addition to the existing elbow band. The hypothesis is that the forearm/hand splint will be more effective than the elbow band.

Methods

Subjects

Patients were included on the basis of referral by a physician with a diagnosis of a tennis elbow to an orthopaedist for treatment with an orthotic device. Fifty-two (52) patients with a tennis elbow were asked to participate in this study. Forty-three (43) patients were eligible for the analyses. These patients had symptoms for at least three weeks and had no other medical conditions that would influence the results. Patients with a history of elbow surgery, an elbow injection within the previous month or any other treatment that would interfere with the intervention were excluded from the study. All the patients gave informed consent. They were randomly assigned by using sealed envelopes. The study was approved by the local medical ethics committee.

Study design

The study is a randomized clinical trial with 2 groups, the elbow band Group (I) and the splint Group (II). The intervention duration was six weeks. No other interventions were given nor was any advice given concerning activities. Outcome measures were obtained at baseline (t1) and directly after the intervention (t2).

Method of treatment

The patients were assigned to Group I or II. Group I got the elbow band or Thämert Epi-med, which is worn on the forearm under the lateral epicondyle. Group II got the splint, which is a composition of the Thämert Epi-med elbow band, a Thämert orthoflex brace and an aluminum bar from the elbow to the palm of the hand (Figs. 1 and 2). The aluminum bar bends about 30° at the joint of the wrist to keep the hand lightly in dorsiflexion. The joint of the wrist is fixed by the splint. The patients were told to wear the orthotic device as much as possible for six weeks during all daily activities. No restrictions in provoking activities were given.

Outcome measures

Maximal grip strength with pain score: In this study, maximal grip strength on the involved side was used as outcome measure, with a pain scale from 1 to 10 to determine the extent of pain during gripping. To measure maximal grip strength, a Jamar dynamometer was used.

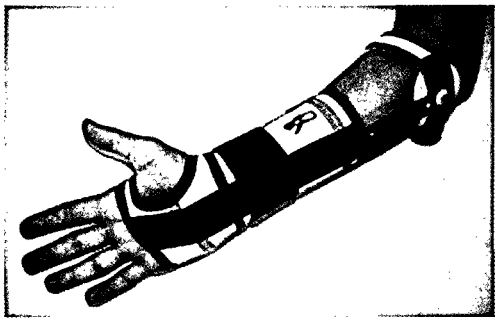

Fig. 1. Forearm/hand splint anterior view.

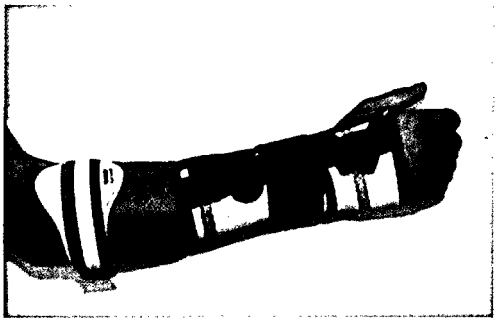

Fig. 2. Forearm/hand splint posterior view.

Maximal grip strength appears to be a reliable outcome measure in patients with lateral epicondylitis (Stratford *et al,* 1989; Shechtman *et al,* 2003). The grip strength was measured three times on the involved side. The highest score of the three measurements was used for the data analysis. At the assessment directly following the intervention, the patients determined the pain score during gripping compared with the pain score during gripping at baseline.

Questionnaire: The Patient-Rated Forearm Evaluation Questionnaire (PRFEQ) was used to evaluate functional limitations and symptom relapse. This questionnaire appears to be a reliable tool for assessing pain and function in patients with lateral epicondylitis. The concurrent validity has been determined by correlating performance on the pain-free grip strength test with scores on the PRFEQ. Although the correlations were significant, they were relatively weak (r=-0.35) (Overend *et al,* 1999). The original English version of the PRFEQ was linguistically validated by forward and backward translation. The PRFEQ consists of visual analog pain and function scales to provide a simple and quick estimate of arm pain and function in patients with lateral epicondylitis. The sum score of the overall PRFEQ, the sum score of the pain subscale and the sum score of the function subscale were taken for data analysis. A missing score on an item was replaced by the mean score of the other items. More than 20% missing scores on a sum score was not accepted. At the assessment after six weeks, the baseline scores were given to the patients and they were asked to score their present situation. Information about age, gender, job, health insurance act, duration of symptoms, earlier treatments, other disorders and sport was also recorded at the start of the intervention.

Statistical analyses

Data were analysed with an intention to treat basis using SPSS version 8.0. Baseline characteristics of the 2 groups were compared using the chi-square test or the t-test as appropriate.

Changes in maximal grip strength, sum score of the overall PRFEQ, sum score of the pain subscale and sum score of the function subscale were analyzed with a MANOVA repeated design in which these 4 variables served as dependent variables. The repeated measure (within-subject factor) in this design was the time factor with 2 levels: start and end of the intervention. Between-subject factors were 'group' (elbow band group, splint group) and 'type of symptom' (acute: less then 12 weeks, chronic: more then twelve weeks). The 4 dependent variables were analyzed separately. A Mann-Whitney test was used to analyze whether there was a difference between the groups in change of pain score during gripping (t1-t2).

To explore how much the 'group' variable, controlled for other variables, contributes to the prediction of the dependent variables 'change in maximal grip strength' and 'change in sum score of the overall PRFEQ', a multiple linear regression analysis (method: enter) was done. The following variables were included as predictors: group, type of symptom, symptom recidivism, age and job. The critical value for statistical significance for all tests was set at $p<.05$.

Results

Of the 43 patients who were included in this study, 20 were assigned to Group I and 23 to

Table I. Baseline characteristics of participants.

Characteristics		Group I elbow band (n=20)	Group II splint (n=23)	P[b]
Mean age in years		43.50 (9.39)[a]	42.30 (9.88)[a]	.69
Sex	male	6(30%)	7(30%)	.98
Type of symptoms	acute	12(60%)	13(57%)	.82
Recidivism of symptoms	yes	2(10%)	5(22%)	.30
Prior treatment for tennis elbow	yes	1(5%)	9(39%)	.13
Job*	yes	14(70%)	22(96%)	.02**
Sports before tennis elbow	yes	10(50%)	13(57%)	.67
Dominant hand	right	19(95%)	18(78%)	.11
Involved	right	15(75%)	20(87%)	.32

[a] Standard deviations in parentheses

[b] Determined by t-test or chi-square test

* Of the 14 participants in the experimental group, 10 perform mental work (office jobs, positions in education and research, management tasks). The remaining 4 perform mainly manual work (factory work, nursing). Of the 22 participants in the control group, 16 perform mental work and 6 perform manual work

** Significant

Table 2. Mean values and standard deviations at the start and end of the intervention.

			Start of intervention			End of intervention			ES
Dependent variable	Group	Type of symptom	Mean	SD	N	Mean	SD	N	
Maximal grip strength (kg_f)	Group I	acute	37.4	13.7	11	27.9	12.3	11	.73
		chronic	31.6	10.3	8	34.4	8.6	8	.29
		total	29.2	12.2	19	30.6	11.1	19	.12
	Group II	acute	26.3	11.8	11	31.3	16.0	11	.35
		chronic	26.7	5.2	10	29.4	6.4	10	.46
		total	26.5	9.0	21	30.4	12.2	21	.36
Sum score overall PRFEQ (0-150)	Group I	acute	81.8	28.0	10	59.3	25.4	10	.84
		chronic	83.4	12.9	8	53.3	23.4	8	1.15
		total	82.5	22.0	18	56.6	24.0	18	1.13
	Group II	acute	72.7	24.0	11	50.6	28.0	11	.84
		chronic	82.7	28.9	10	66.7	41.3	10	.45
		total	77.5	26.3	21	58.3	35.1	21	.62
Sum score pain subscale (0-50)	Group I	acute	25.5	7.5	10	19.0	7.7	10	.85
		chronic	28.2	5.5	8	18.6	6.7	8	1.56
		total	26.7	6.7	18	18.8	7.0	18	1.15
	Group II	acute	25.2	8.0	11	18.7	11.4	11	.66
		chronic	28.0	8.1	10	23.3	13.4	10	.42
		total	26.6	8.0	21	20.9	12.3	21	.55
Sum score function subscale (0-100)	Group I	acute	56.3	21.6	10	40.4	18.3	10	.79
		chronic	55.1	12.6	8	34.6	17.6	8	1.33
		total	55.8	17.7	18	37.8	17.7	18	1.01
	Group II	acute	47.5	18.5	11	31.9	18.1	11	.85
		chronic	54.7	21.4	10	43.4	28.5	10	.45
		total	50.9	19.7	21	37.4	23.5	21	.62

ES = effect size ES <.20 = small ES .50 = moderate ES >80 large

The effect size calculations are based on the following formula: $\frac{(\bar{X}\,1 - \bar{X}\,2)\ \text{treated subjects} - (\bar{X}\,1 - \bar{X}\,2)\ \text{controls}}{\text{SD pooled baseline}}$

Table 3. Results of the multivariate tests.

Dependent variable	Effect*	F	p
Condition 1**			
Maximal grip strength	.17	7.15	.00
Sum score overall PRFEQ	.46	29.80	.00
Sum score pain items	.44	27.73	.00
Sum score function items	.44	27.55	.00
Condition 2**			
Maximal grip strength	.03	1.15	.29
Sum score overall PRFEQ	.02	.80	.39
Sum score pain items	.03	.89	.35
Sum score function items	.02	.63	.43
Condition 3**			
Maximal grip strength	.03	1.20	.28
Sum score overall PRFEQ	.02	.68	.45
Sum score pain items	.03	.88	.35
Sum score function items	.02	.54	.47

* Pillay's Trace

** condition 1: time (pretest-posttest); condition 2: time (pretest-posttest) related to group (experimental vs control); condition 3: time (pretest-posttest) related to group (experimental vs control) related to symptoms (acute vs chronic)

Group II. There were 3 dropouts, 1 in Group I and 2 in group II. Six (6) persons wore the orthotic device less than 4 weeks altogether, 1 in Group I and 5 in Group II. Some of these patients reported they could not execute their work well while wearing the splint. Another reason was that the splint caused too much skin irritation. One (1) person in Group I refused to fill in the questionnaire, only maximal grip strength was measured.

Results of comparing the baseline characteristics of the two groups are presented in Table 1. The only significant difference between the groups at baseline is the characteristic job.

The 4 dependent variables used in the MANOVA repeated analyses are all normally distributed. In Table 2, means and standard deviations of the dependent variables for the different groups at the start and the end of the intervention are shown. In all analyses the assumption of sphericity was violated and therefore the multivariate analysis was used. The results of the multivariate tests are shown in Table 3. The main effect for time was significant for all dependent variables, using Pillay's trace. The time*group and time*group*type of symptom interactions did not achieve significance for all dependent variables. The main effect of the between-subject 'group' factor and the effect of the interaction group*type of symptom were not significant; for maximal grip strength: F=.30 (df=1), p=.59 and F=.78 (df=1), p=.39; sum score overall PRFEQ: F=.03 (df=1), p=.88 and F=.92 (df=1), p=.35; sum score pain subscale: F=.14 (df=1), p=.71 and F=.23 (df=1), p=.63; and for sum score function subscale: F=.15 (df=1), p=.70 and F=1.22 (df=1), p=.28.

Mean rank and sum of ranks for change in pain score during gripping (t1-t2) were 20.89 and 397.00, respectively, for Group I (n=19), and 20.14 and 423.00, respectively, for Group II (n=21). No significant difference was found between the groups (Mann-Whitney U=192.00; p=.84).

The dependent variables 'change in maximal grip strength' and 'change in overall PRFEQ score' are both normally distributed. The predictor variables used in the multiple linear regression analyses are not related to each other. Including the five predictor variables, R^2 is .19 for 'difference in maximal grip strength' and .08 for 'difference in overall PRFEQ'.

Discussion

This study shows that the forearm/hand splint is not more effective than the simple elbow band as a treatment for lateral epicondylitis. The effect of time is significant ($p<.05$) for the outcome measures of maximal grip strength, sum score of the overall PRFEQ, sum score of the pain subscale and sum score of the function

subscale. The maximal grip strength increases and the sum scores on the PRFEQ decrease. The effect of the interactions time*group and time*group*type of symptom are not significant ($p>.05$) for maximal grip strength, sum score of the overall PRFEQ, sum score of the pain subscale and sum score of the function subscale. The change in pain score during gripping (t1-t2) does not differ significantly between the groups either. The multiple linear regression analysis also shows that use of the splint does not significantly change the maximal grip strength and PRFEQ score. Therefore, change in maximal grip strength and in overall PRFEQ cannot be explained by the type of orthotic device (elbow band or splint) that was used. One of the variables controlled for was the 'job' variable, which was significantly different between the groups at baseline.

The results of this study concur with the results of the study of Haker and Lundeberg (1993). In this study no differences were found between the cock-up splint and the elbow band. The new designed forearm/hand splint was thought to give more rest to the extensors of the wrist than the cock-up splint and therefore would be more effective. However, the forearm/hand splint did not have added value on the elbow band either. Although no differences were found between the elbow band and the new forearm/hand splint, the significant time effect in this study suggests there is a certain reduction in symptoms. From a study executed parallel to this study, it appears that the forearm/hand splint does not reduce muscle activity in the extensors of the wrist in normal subjects. The assumed working mechanism, that the splint primarily gives rest to the extensors of the wrist, does not hold for the forearm/hand splint. Therefore, this mechanism cannot explain the effect of the forearm/hand splint over time. A factor that must be considered as a possible explanation for this effect is the behavioural condition. A strong belief in the treatment might influence someone's pain experience. This mechanism is called the novelty effect. It can result in lower sum scores on the PRFEQ and higher maximal grip strength, because a person might be well-motivated to grip harder. In the questionnaire, social desirability might also play a role, because the patient does not want to report disappointing results. Another factor that can influence the effect of the orthotic devices is the fact that the involved arm is spared. The orthotic device might remind the patient to keep quiet or force the patient not to use the involved arm. Less might also be demanded from patients in a working situation, because the symptoms are taken more seriously by other people.

The statistical power analyses ranges from .74 to 1.00 for the main effect time, from .12 to .18 for the interaction effect time*group and from .11 to .19 for the interaction effect time*group*type of symptom. The difference in calculated statistical power can partially be attributed to the small sample size of the study. To say something more reliable about the difference between the elbow-band-group and the splint-group, more patients would be needed.

In this study the authors used maximal grip strength as an outcome measure. Another outcome measure mentioned in the literature for patients with lateral epicondylitis is pain-free grip strength. Both pain-free and maximal grip strength appear to be reliable (Stratford *et al.*, 1989). However, it applies to both methods that there is no insight into the perceived exertion during gripping. According to Hamilton *et al*, (1994), no differences in grip strength testing reliability exist between taking the mean score or the highest score of 3 trials. The authors in this study have chosen to take the highest score of 3 trials. Because patients with a tennis arm experience pain when gripping, they might not be motivated to grip maximally 3 times. The spread between the 3 scores obtained in this study confirms it. Benjamin *et al.* (1999) used normalised measurement, i.e. comparing the measurements from the involved arm with the uninvolved arm, as a method to detect changes in patient responses. This method could not be used in this study because many of the patients also had symptoms in the other arm.

This study underlines again the need for more research to find an optimally-designed splint that improves on the elbow band. The acquired practical experience proves that lateral epicondylitis is a very serious problem, especially in a time of increasing work pressure. A solution for this problem is highly necessary. Application of a treatment for lateral epicondylitis in practice, like the forearm/hand splint, is in fact based on personal experiences (Labelle *et al.*, 1992). This study shows, however, that adjustments have to be made on the forearm/hand splint to make it more effective

than the elbow band, and that more scientific research is needed before it can be further prescribed.

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