



ELBOW

# Counterforce bracing of lateral epicondylitis: a prospective, randomized, double-blinded, placebo-controlled clinical trial



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**Background:** Counterforce bracing is one of the common treatment modalities for tennis elbow. The objective of this study was to determine whether counterforce bracing offers any additional benefit over placebo bracing in the treatment of tennis elbow.

**Methods:** This prospective, randomized, double-blinded, placebo-controlled clinical trial investigated the use of counterforce bracing (n = 17) compared with placebo bracing (n = 14) in the management of acute tennis elbow. Outcome measures included patient-rated pain and functional outcomes, epicondyle tenderness, and strength at 6 months and long term. Follow-up occurred at 2, 6, 12, and 26 weeks, as well as long term (mean follow-up, 3 years). The study duration was 5 years.

**Results:** The 2 groups, counterforce and placebo, were similar in age, sex, hand dominance, and duration of symptoms. Both braces improved patient-rated pain frequency and severity ( $P < .01$ ), difficulty with picking up objects and twisting motions, and overall elbow function ( $P < .001$ ) at 6 months and 3 years. Both braces also improved lateral epicondyle tenderness, grip strength ( $P < .01$ ), and modified ORI-TETS (Orthopaedic Research Institute–Tennis Elbow Testing System) force ( $P < .05$ ) at 6 months. Significant intergroup differences were detected for frequency of pain at rest at 6 and 12 weeks ( $P < .05$ ), level of pain at rest at 2 weeks ( $P < .001$ ), and patient-rated overall elbow function at 26 weeks ( $P = .041$ ).

**Conclusion:** The counterforce brace provides significant reduction in the frequency and severity of pain in the short term (2–12 weeks), as well as overall elbow function at 26 weeks, compared with the placebo brace.

**Level of evidence:** Level II; Randomized Controlled Trial; Treatment Study

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Tennis elbow, also known as “lateral epicondylitis” or “epicondylosis,” has been described as an entity for well over a century.<sup>5</sup> A number of theories have been proposed on what causes it, the most popular being that the mechanism of injury involves repetitive loads at the wrist and elbow, including

supination and extension of the wrist.<sup>8</sup> Patients affected by tennis elbow frequently complain of pain over the lateral humeral epicondyle, made worse by extending a pronated wrist against resistance, although in severe cases, patients often have pain at rest.<sup>26</sup>

Most authors agree that the structure responsible for the symptoms of lateral epicondylitis is the origin of the extensor carpi radialis brevis (ECRB).<sup>16,17</sup> The ECRB crosses both the elbow and wrist joints, acting as an elbow flexor, and stabilizes the wrist eccentrically during wrist flexion. Biomechanically, the ECRB is under the most strain during forceful gripping, with the forearm pronated and the wrist flexed and ulnar deviated.<sup>6</sup>

Although tennis elbow is generally self-limiting, a significant portion of patients find the symptoms debilitating and seek medical treatment.<sup>14</sup> Many treatments have been described, ranging from exercise programs to injections, acupuncture, and surgery.<sup>19</sup> One of the more popular treatments has been the use of a proximal forearm brace, also known as a “counterforce brace.”

Despite the popularity of counterforce bracing over the past 40 years, its mechanism of action is still debated. The principle behind many tennis elbow treatments is to unload the origin of the ECRB, allowing it to recover and heal. Bracing may achieve this by compressing the extensor bundle and thus dampening and dispersing some of the force away from the ECRB origin. Alternatively, by limiting the full muscular expansion of the extensors during contraction, the brace may limit the potential force developed at the extensor origin.<sup>16</sup> A small group of authors also suggested that the brace acts to enhance the proprioception around the elbow, thus improving the biomechanics of the joint and reducing overuse.<sup>2</sup>

Biomechanical studies in cadavers and healthy volunteers have suggested that bracing over the proximal forearm does reduce the stresses at the ECRB origin,<sup>12,13</sup> especially if the brace has some form of padding to specifically compress the ECRB.<sup>27</sup> Other studies have compared the use of a brace against other modalities, including stretching,<sup>23</sup> physical therapy,<sup>25</sup> and laser therapy,<sup>4,18</sup> with some positive results. A few studies have compared different types of braces with each other,<sup>7</sup> with no bracing,<sup>3</sup> and even with short-term placebo bracing.<sup>28</sup> The results were mixed, with some studies showing a positive effect on pain and strength and others showing no effect or even a detrimental outcome. Indeed, 2 systematic reviews found that although the currently available studies are trending toward some positive effect, at this stage, it is impossible to reach a definitive conclusion on the effectiveness of bracing for tennis elbow.<sup>1,24</sup>

Although the definitions of acute versus chronic tennis elbow vary enormously among studies,<sup>10</sup> the aim of this study was to determine whether the use of a counterforce brace improved the outcomes of pain, strength, and function in patients with acute symptoms (4 weeks to 6 months in duration) of lateral epicondylitis undergoing an exercise program, over and above the use of a placebo brace.

## Methods

The study was a prospective, randomized, double-blinded, placebo-controlled clinical trial comparing the use of a counterforce brace for tennis elbow with placebo bracing. Patients were recruited through advertising in the local newspaper and through direct referrals from local medical practitioners over a period of 3 years. The inclusion criteria for the clinical trial required that the patients be 18 years or older, have a clinical diagnosis of lateral epicondylitis (point tenderness over the lateral epicondyle and exacerbation of pain with the chair pick-up test and maximal hand grip), and have a duration of symptoms between 4 weeks and 6 months at presentation. The chair pick-up test, in which the patient attempts to lift a chair by gripping the back rest with the elbow flexed to 90°, hand in palmar flexion, and forearm pronated, was chosen as it loads the extensor tendons of the wrist.<sup>20</sup> Patients were excluded if they underwent previous surgery or suffered a dislocation of the affected elbow, if they received a corticosteroid injection in the affected elbow within the past 3 months, or if there was any scarring over the elbow or sensory and/or motor changes distal to the elbow. Patients were also excluded if they were unwilling or unable to attend the required follow-ups or to enter either treatment branch.

## Randomization

Patient randomization was performed via a computer-generated code that was printed and sealed in unmarked envelopes. Once the patients were assessed and recruited, they were seen separately by a research assistant who opened a randomly selected envelope and allocated a brace according to the randomization slip. The patient's name was then written on the envelope, and the randomization slip was sealed in the envelope; the envelope was sealed securely until the end of the trial. The patients were instructed on the use of their brace and reminded to remove their brace before each follow-up.

Blinding occurred at 2 levels: One author performed the assessments and follow-ups of patients and was blinded to the brace worn. The research assistant applied the braces and instructed the patients on their use but was blinded to the outcomes.

## Bracing protocol

The 2 braces chosen were the DonJoy Procure Universal Surround Elbow brace (DJO, Vista, CA, USA) as the study brace and the DonJoy Procure Clinic Tennis Elbow brace (DJO) as the placebo brace. The Universal Surround Elbow brace was selected as the study brace because it contained a foam-filled bladder that specifically compressed the extensor bundle, was made of neoprene for a comfortable fit, and had a one-size-fits-all closure mechanism. The Clinic Tennis Elbow brace was chosen as the placebo brace because of its simplicity, non-elasticity, and universal sizing.

Patients randomized to the study brace were asked to find the sorest spot on their elbow and follow along the muscle belly toward the wrist until they reached 5 cm below the elbow crease. They applied the brace with the foam bladder centered over this position and tightened the fastening strap until the brace was as tight as was comfortably tolerable, under the supervision of the research assistant. The patients then flexed and extended the elbow to make sure the brace was not obstructing their range of motion and clenched their fist to make sure the forceful grip did not make the brace too tight.

In patients randomized to the placebo brace, the research assistant applied the brace at a similar position (5 cm distal to the elbow crease) but at just enough tension to prevent the brace from sliding off. The patients then flexed and extended their elbow to make sure the brace did not impede their range of motion or slide off. Once the position was confirmed, the research assistant made a small mark on the brace, and the patient was instructed to apply the brace to the marked tension every time.

All patients were instructed to put on their braces on waking and to leave them on until bedtime, with the exception of showering or swimming. The patients were reviewed at each follow-up by the research assistant to make sure they were applying their braces according to the instructions, by having them demonstrate their application technique. If a patient in the placebo brace group needed the tension to be adjusted, a new mark was made on his or her brace. All braces were then removed before patients proceeded to their clinical assessment with 1 of the authors.

On the basis of previous studies, all patients were also instructed on a rehabilitation protocol.<sup>21</sup> This consisted of an unsupervised home strengthening program that commenced immediately and continued for 3 months. The exercises prescribed were wrist curls, reverse wrist curls, forearm pronation-supination, and biceps curls. Patients were instructed to perform these 3 times a day, with 10 repetitions in each set, initially with no weight and gradually increasing in 0.5-kg increments to a maximum weight of 2.5 kg. The technique and protocol adherence were reviewed at each follow-up visit.

## Outcome measures

Patients' symptoms were ranked using a questionnaire containing a series of Likert verbal descriptor pain scales based on a modified L'Insalata shoulder rating questionnaire.<sup>11</sup> The symptoms rated included the frequency of pain with activity and rest, severity of pain with activity and rest, frequency of extreme pain, and severity of pain during sleep, as well as difficulty with picking up objects and twisting motions. In addition, patients were asked to give an overall impression of their elbow stiffness and function, also using Likert scales. The frequency of elbow pain during activity at 6 months was selected as the primary outcome measure, and all the remaining parameters were considered secondary outcome measures. These measures were selected as they have been used in other studies and have been shown to be responsive.<sup>9,11,15,21</sup>

Point tenderness on firm palpation over the lateral epicondyle (applied by the assessor) was selected as a clinical test, also using a Likert verbal descriptor pain scale. A clinical test that has been accepted as a suitable measure for ECRB function is the chair pick-up test.<sup>6</sup> By keeping the wrist in pronation and neutral extension and the elbow at 90° of flexion, this test dynamically stresses the muscle as it crosses both the wrist and elbow joints. To measure the function of the ECRB, the Orthopaedic Research Institute–Tennis Elbow Testing System (ORI-TETS) handle<sup>20</sup> was used with a Mecmesin force gauge (Compact Force Gauge CFG+ 200N; Mecmesin, West Sussex, UK) in place of the load cell. The maximal force of wrist extension was used as an outcome measure.<sup>20</sup>

The last clinical outcome measure was performed with a hand-grip dynamometer (Saehan Hydraulic Hand Dynamometer SH5001; Saehan, Changwon, Republic of Korea) assessing maximal grip strength, given that forceful gripping is one of the activities that cause

patients the most discomfort and is frequently reduced in lateral epicondylitis.<sup>22</sup>

All measures were taken at the initial randomization and then at 2, 6, 12, and 26 weeks. One year after the last patient had completed the 6-month follow-up, all contactable patients were asked to complete a long-term follow-up questionnaire over the telephone.

## Statistical analysis

The outcome measures were analyzed using an intention-to-treat analysis. Parametric data (grip strength and ORI-TETS maximal force) were analyzed using Student paired *t* tests for differences over time within each group, and nonparametric data (the remaining measures) were analyzed using Wilcoxon signed rank tests to compare differences over time within each group. The differences between groups were compared using unpaired Student *t* tests for parametric data and Mann Whitney rank sum tests for nonparametric data. The level of significance was defined as  $P < .05$ .

A pre-study power analysis, with  $r = 0.8$  and  $P < .05$ , determined that to have a 90% chance of finding a 40% difference between the standard and sham groups in the frequency of elbow pain with activity at 6 months (the primary outcome measure), the trial would require 40 symptomatic patients to be recruited and treated in each group.

## Results

The study was initially powered for 40 subjects in each group, with 45 patients recruited in total over the study period of 5 years. Because of recruitment difficulties, the study was stopped before the projected numbers were achieved and statistical analysis was performed.

Of the 45 patients recruited into the trial, 23 were randomized to the sham brace and 22 to the padded brace. In the sham brace group, 5 patients dropped out within the first 2 weeks, citing a rash ( $n = 2$ ), catching on clothes ( $n = 1$ ), unrelated shoulder injury ( $n = 1$ ), and inability to attend the clinic ( $n = 1$ ) as the cause for their withdrawal. Four more patients withdrew subsequently with no reason given.

In the padded-brace group, 2 patients dropped out in the first 2 weeks, with discomfort ( $n = 1$ ) and inability to attend the clinic ( $n = 1$ ) being the reasons given. Three more patients withdrew subsequently without giving a reason.

In total, 14 patients in the sham-brace group and 17 patients in the padded-brace group completed their 26-week follow-up. One year after the last patient was seen in the clinic, all patients were contacted via telephone and the study questionnaire was administered over the telephone. In total, 14 patients in the sham-brace group and 17 patients in the padded-brace group were contactable for the long-term follow-up. The mean long-term follow-up period was 3 years in both groups (range, 77–238 weeks).

The demographic data of both groups are presented in [Table I](#), with no significant differences shown between the 2 groups. No significant complications were reported with the bracing or rehabilitation protocol. The investigators remained blinded until the long-term data were collected.

**Table I** Demographic data

	Sham brace (n = 23)	Padded brace (n = 22)
Sex, n	15 male and 8 female	14 male and 8 female
Age at presentation, mean (range), yr	51 (40-73)	51 (38-66)
Symptom duration, mean (range), mo	4 (1-8)	4 (1-9)
Dominant side affected, n	16 (70%)	13 (59%)
6-mo follow-up, n	14 (61%)	17 (77%)
Long-term follow-up, n	14 (61%)	17 (77%)

## Frequency of pain

Patients presenting to our clinic reported the frequency of pain with activity as “always” or “daily” before their bracing (Fig. 1). After brace application, both groups reported significant improvement in the frequency of pain with activity, starting from 6 weeks. At 26 weeks, the sham-brace group had pain weekly ( $P = .004$ ) whereas the padded-brace group had pain weekly or monthly ( $P < .001$ ), and at long-term follow-up, both groups had less than monthly pain with activity ( $P < .001$ ).

The frequency of extreme pain was reduced in both groups, starting at weekly and reducing to monthly or never at 26 weeks and at long-term follow-up for the sham-brace group ( $P = .002$  and  $P = .006$ , respectively) and to almost never at 26 weeks and at long-term follow-up for the padded-brace group ( $P < .001$ ).

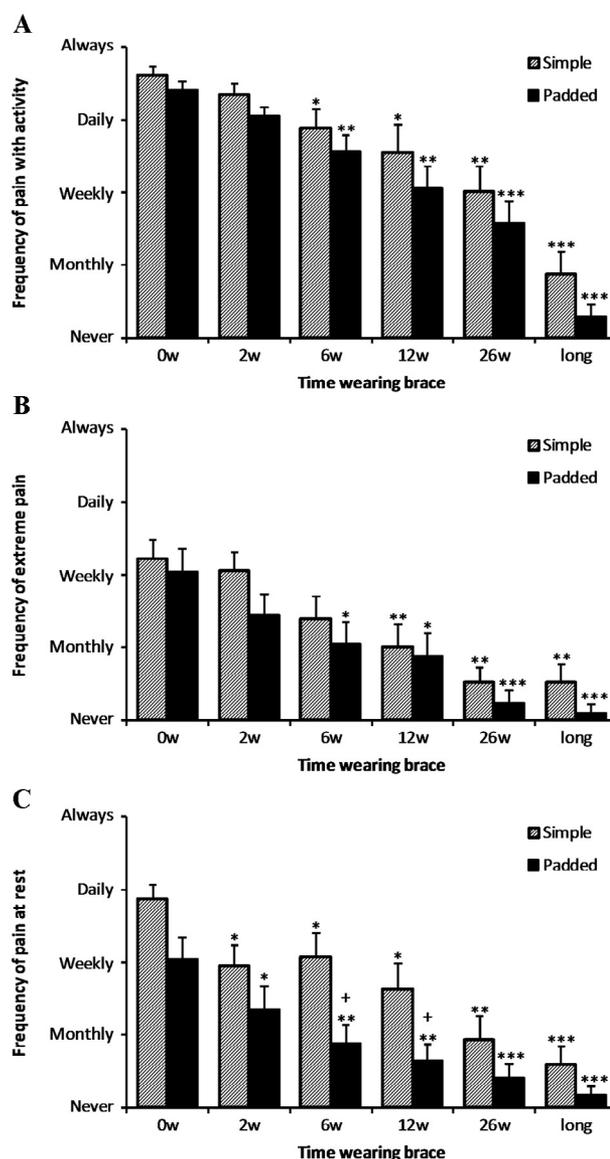
The frequency of pain at rest also significantly improved in both groups, with the sham-brace group initially reporting daily pain at rest, reducing to monthly at 26 weeks ( $P = .002$ ) and monthly or never at long-term follow-up ( $P < .001$ ). The padded-brace group started with weekly pain at rest, reducing to monthly or never at 26 weeks ( $P < .001$ ) and almost never at long-term follow-up ( $P < .001$ ).

The only significant difference between groups was in the frequency of pain at rest at 6 weeks and 12 weeks: The padded-brace group reported significantly less frequent pain ( $P = .015$  and  $P = .042$ , respectively).

## Severity of pain

Both groups experienced a significant improvement in the severity of pain with activity from their moderate or severe starting point (Fig. 2). The sham-brace group reported moderate pain at 26 weeks ( $P = .008$ ) and mild pain at long-term follow-up ( $P = .002$ ), whereas the padded-brace group reported mild pain at 26 weeks ( $P < .001$ ) and mild to none at long-term follow-up ( $P < .001$ ).

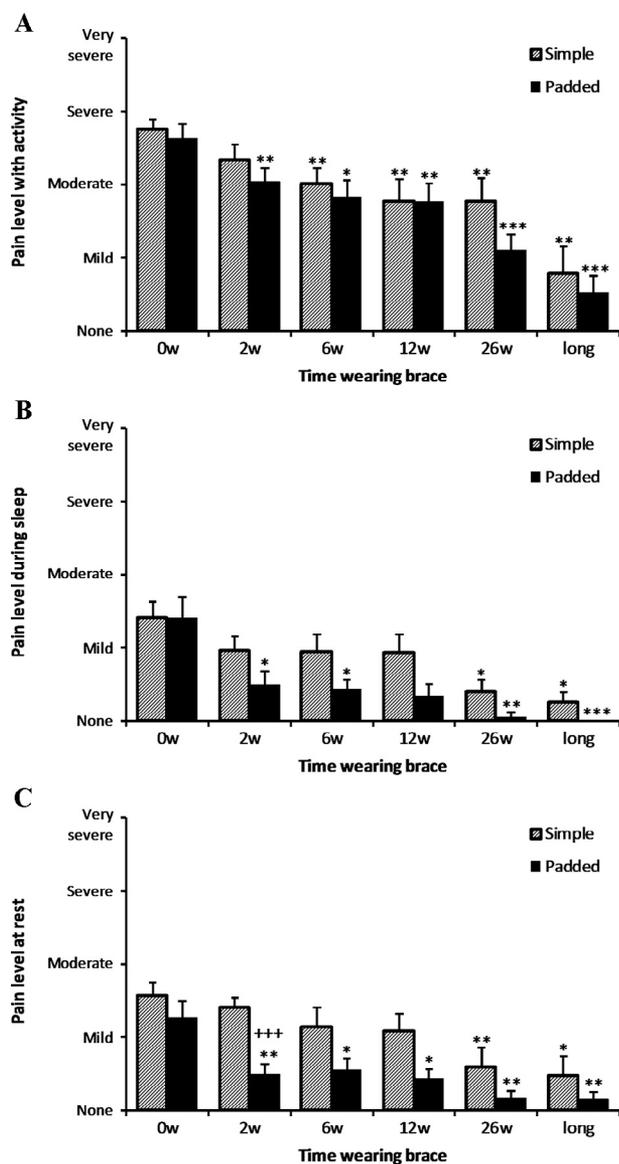
The level of pain during sleep also improved in both groups, with the sham-brace group improving from mild or moderate pain to mild or none at 26 weeks and at long-term follow-



**Figure 1** (A) Patient-rated frequency of pain with activity. (B) Patient-rated frequency of extreme pain. (C) Patient-rated frequency of pain at rest. Data are presented as mean (standard error of mean). \* $P < .05$ , \*\* $P < .01$ , and \*\*\* $P < .001$  compared with time 0 using Wilcoxon signed rank tests. + $P < .05$  for comparison between groups using Mann-Whitney rank sum test. w, weeks.

up ( $P = .012$ ). The padded-brace group showed even more improvement, with a reduction in the level of pain during sleep from mild or moderate at the beginning of the study to almost none at 26 weeks ( $P = .002$ ) and none by long-term follow-up ( $P < .001$ ).

The pain level during rest showed significant improvement in the padded-brace group from week 2, with a reduction to almost none at week 26 and at long-term follow-up ( $P = .003$  and  $P = .002$ , respectively) from the mild or moderate initial levels. The sham-brace group also showed an improvement, with a reduction from mild or moderate to mild or none at 26 weeks ( $P = .007$ ) and long-term follow-up ( $P = .02$ ).



**Figure 2** (A) Patient-rated level of pain with activity. (B) Patient-rated level of pain during sleep. (C) Patient-rated level of pain at rest. Data are presented as mean (standard error of mean). \* $P < .05$ , \*\* $P < .01$ , and \*\*\* $P < .001$  compared with time 0 using Wilcoxon signed rank tests. +++ $P < .001$  for comparison between groups using Mann-Whitney rank sum test. w, weeks.

The only significant difference between the groups in the severity of pain occurred in the level of pain at rest: At 2 weeks, the padded-brace group reported significantly less pain than the sham-brace group ( $P < .001$ ).

## Function

The patient-reported level of stiffness improved in both groups from the little or mildly stiff starting levels, reducing to little or none at 26 weeks and at long-term follow-up ( $P = .049$  and  $P = .027$ , respectively, for sham brace and  $P = .014$  and  $P = .002$ , respectively, for padded brace) (Fig. 3).

The degree of difficulty with picking up objects was improved in both groups from week 6 onward. From the moderate or severe initial levels, the sham-brace group improved to mild or none at 26 weeks and at long-term follow-up ( $P < .001$ ) whereas the padded-brace group improved to mild or none at 26 weeks and almost none at long-term follow-up ( $P < .001$ ).

Twisting difficulty showed significant improvement in both groups from moderate or severe, reaching mild in the sham-brace group at 26 weeks and at long-term follow-up ( $P < .001$ ). The padded-brace group reached mild at 26 weeks and improved further to almost none at long-term follow-up ( $P < .001$ ).

In terms of patient-reported overall elbow function, both groups started with fair or poor function. The sham-brace group improved to good or fair at 26 weeks and at long-term follow-up ( $P < .001$ ), whereas the padded-brace group improved to good at 26 weeks and good or excellent at long-term follow-up ( $P < .001$ ).

The only difference between the groups was in overall elbow function: At 26 weeks, the padded-brace group reported a significantly better outcome than the sham-brace group ( $P = .041$ ).

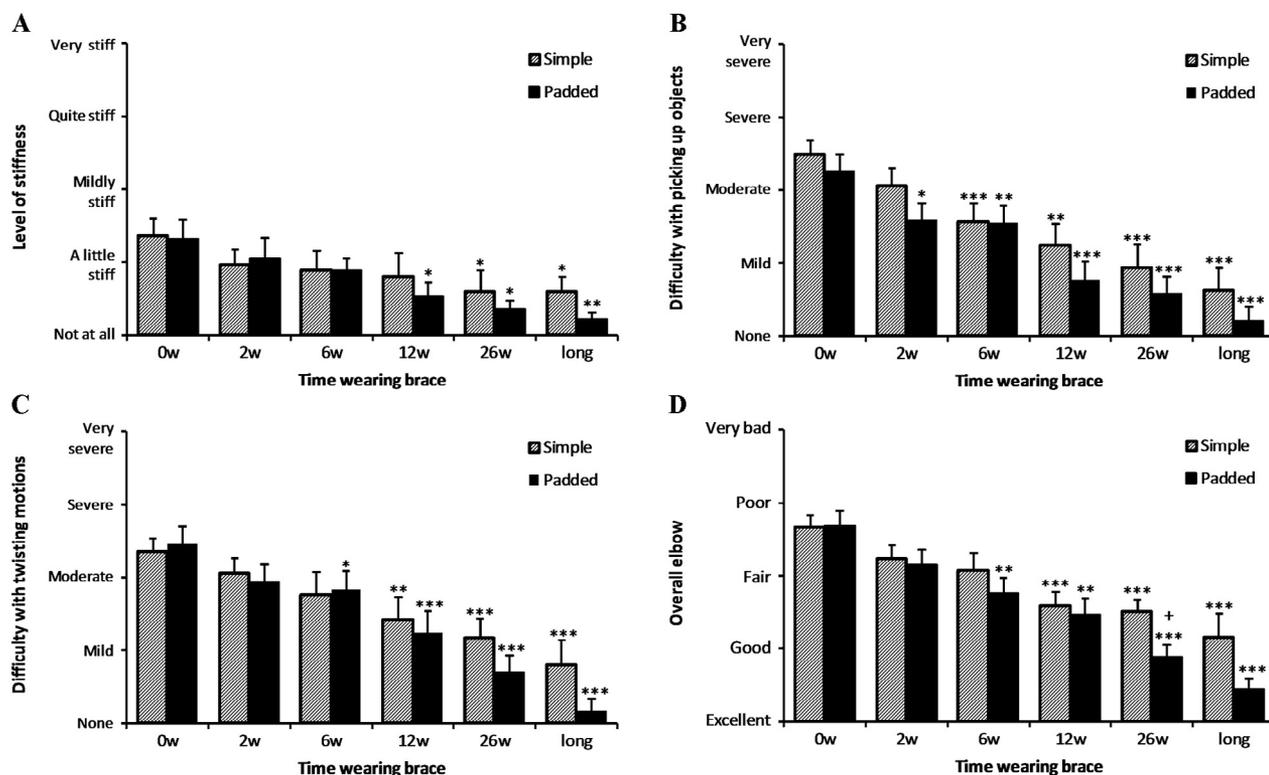
## Clinical tests

Patient-reported epicondyle tenderness on firm palpation improved in both groups from week 2, decreasing from the moderate or severe initial levels to mild (sham brace,  $P = .005$ ) or to mild or none (padded brace,  $P < .001$ ) by 26 weeks (Fig. 4). The grip strength improved in both groups by 26 weeks (by 19% in the sham-brace group and 44% in the padded-brace group), reaching significance levels of  $P < .001$  in the sham-brace group and  $P = .001$  in the padded-brace group.

In the ORI-TETS force measurements, both groups showed an improvement from week 12, with a final improvement by week 26 of 8% in the sham-brace group ( $P = .034$ ) and 69% in the padded-brace group ( $P = .045$ ). Intergroup analysis showed no significant differences between the groups in any of the clinical measures at any point in time.

## Post hoc power analysis

Both groups improved significantly in all measured parameters at 26 weeks and, where measured, at long-term follow-up compared with their initial examination. Significant intergroup differences were detected in the level and frequency of pain at rest, as well as the overall elbow rating. Furthermore, in most of the remaining parameters, the results trended heavily toward the padded brace. To determine what patient numbers would be required to see a significant difference between groups at 26 weeks and at long-term follow-up (where applicable), a post hoc power analysis was



**Figure 3** (A) Patient-rated degree of elbow stiffness. (B) Patient-rated difficulty with picking up objects. (C) Patient-rated difficulty with twisting motion. (D) Patient-rated overall elbow function. Data are presented as mean (standard error of mean). \* $P < .05$ , \*\* $P < .01$ , and \*\*\* $P < .001$  compared with time 0 using Wilcoxon signed rank tests. + $P < .05$  for comparison between groups using Mann-Whitney rank sum test. w, weeks.

performed based on the data collected. The results are presented in Table II.

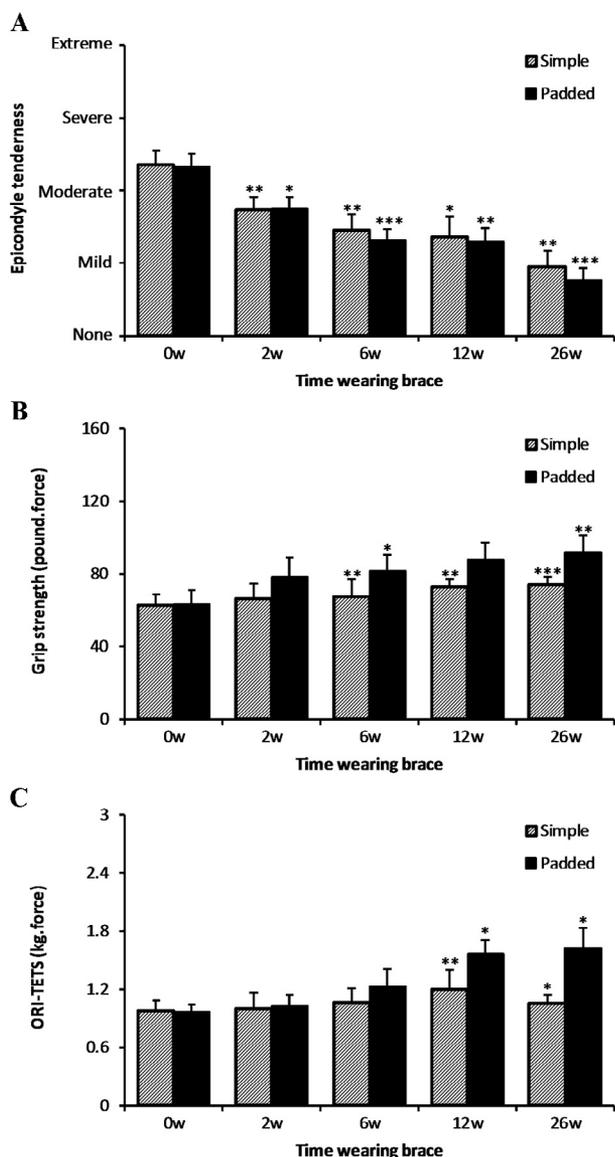
## Discussion

This trial was a prospective, randomized, double-blinded, placebo-controlled study that aimed to determine whether counterforce forearm bracing offered any benefits in acute tennis elbow over and above those of a placebo brace. The results showed that patients in both the padded- and placebo-brace groups had significant improvements in their pain measures, functional outcomes, and clinical tests, including the frequency of pain with activity at 26 weeks, the primary outcome measure of this study. These results were either maintained or further improved over the 1- to 4-year follow-up period after recruitment. The outcomes in most measures favored the padded brace, with significant intergroup differences detected for the frequency of pain at rest at 6 to 12 weeks, level of pain at rest at 2 weeks, and patient-rated overall elbow function at 26 weeks. No significant difference between groups was detected for the frequency of pain with activity at 26 weeks, the primary outcome measure.

The study was initially powered for 40 subjects per group, and over the study period of 5 years, 45 patients were recruited into the study. Because of recruitment difficulties, we

electd to unblind the study early and evaluate the results. As outlined earlier, a significant difference between the groups was detected in 3 separate parameters even with the reduced group numbers. We performed a post hoc power analysis based on the collected data and found that, had the full complement of 40 patients per group been recruited, we could have expected a significant intergroup difference in 5 parameters at 26 weeks and 2 parameters at long-term follow-up. Had we been able to recruit 60 patients per group, the power analysis suggested a significant difference between the 2 groups in 6 parameters at 26 weeks and 7 parameters long term, all in favor of the padded brace.

A problem we faced with the study was the large dropout rate of patients. Although the padded-brace group's 6-month and long-term follow-up rates stayed at 77%, in the placebo-brace group, only 61% of patients returned for follow-up. Patients in both groups cited an inability or unwillingness to attend the clinic, and patients in both groups had an issue with the comfort of the braces. Two patients in the placebo-brace group discontinued because of a rash, which is surprising as the material for both braces is similar and the placebo brace was worn very loosely. Seven patients across both groups gave no official reason for withdrawing from the study, but some reported feeling better and therefore did not see a benefit in coming to follow-up. More patients continued wearing the padded brace than the placebo brace, which in itself may be



**Figure 4** (A) Patient-rated lateral epicondyle tenderness on palpation. Data are presented as mean (standard error of mean). \* $P < .05$ , \*\* $P < .01$ , and \*\*\* $P < .001$  compared with time 0 using Wilcoxon signed rank tests. (B) Maximal grip strength. Data are presented as mean (standard error of mean). \* $P < .05$ , \*\* $P < .01$ , and \*\*\* $P < .001$  compared with time 0 using Student paired  $t$  tests. (C) Maximal Orthopaedic Research Institute–Tennis Elbow Testing System (ORI-TETS) force. Data are presented as mean (standard error of mean). \* $P < .05$  and \*\* $P < .01$  compared with time 0 using Student paired  $t$  tests.  $w$ , weeks.

an indication of the efficacy of the padded brace. At the end of the study, overall satisfaction with the padded brace was also much higher, with more than 80% of patients indicating they would be happy to wear it again and recommend it to others, whereas only 56% of patients in the placebo-brace group said they would wear the brace again. Overall, only half the patients in the placebo-brace group believed they benefitted from wearing their brace, as opposed to 82% in the padded-brace group. These numbers exclude the study

**Table II** Patient numbers required (per group) to observe difference between groups

	26 weeks	Long term (3-yr average)
Pain frequency		
Activity	150	46
Rest	61	60
Extreme	150	58
Pain level		
Activity	40	368
Sleep	31	28
Rest	55	80
Elbow stiffness	225	51
Difficulty with picking up objects	163	86
Difficulty with twisting motion	75	43
Overall elbow	20	29
Point tenderness	340	
Grip strength	23	
ORI-TETS force	12	

ORI-TETS, Orthopaedic Research Institute–Tennis Elbow Testing System.

dropouts, which would likely further widen the gap between the placebo- and padded-brace groups.

To our knowledge, this study is the only randomized clinical trial comparing counterforce bracing for tennis elbow with placebo bracing over the medium and long term. Wuori et al<sup>28</sup> compared a counterforce brace, a placebo brace, and no brace and found no difference in pain-free grip strength between the groups in the short term. However, their protocol involved all braces being tested on all patients on 1 occasion, with rest periods between different braces and no provision for follow-up. Struijs et al<sup>25</sup> conducted a study over a period of 52 weeks, comparing forearm bracing alone, physical therapy alone, and a combination of forearm bracing and physical therapy. Their results were mixed, with each group showing some benefits in the short term, but by 26 and 52 weeks, no difference between the groups was found in any outcome. Although their short-term benefits of forearm bracing (severity of complaints, disability, and satisfaction) are in keeping with our results, we have shown a significant difference between our groups at 26 weeks in overall elbow function as well.

The average duration of tennis elbow has been estimated to be between 6 and 24 months, with over 80% of patients being markedly better or having completely recovered by 12 months with a “wait-and-see” approach.<sup>14</sup> Both our groups showed significant improvement in all parameters by 26 weeks and maintained or improved on this at the long-term follow-up. The padded brace, however, appears to have accelerated the recovery process, with significant improvements in the level and frequency of pain in the short term over the placebo brace.

In a study performed by our group comparing Nirschl excision of the degenerative portion of the ECRB versus placebo surgery in chronic tennis elbow, we found no difference in

outcomes between the groups.<sup>9</sup> Using the same observer and outcome measures, this study has found a number of significant positive effects in the counterforce-brace group, reinforcing the relatively powerful clinical benefit of this simple and well-tolerated intervention.

The main limitation of this study was the small number of patients and the relatively high dropout rate. Indeed, the post hoc analysis suggests that with 60 patients in each group, a significant difference between the groups could be seen in 6 parameters at 26 weeks and 7 parameters at long-term follow-up. The strengths of the study were the study design, subjective and objective measures selected, and clear inclusion and exclusion criteria, as well as good follow-up. Data were analyzed on an intention-to-treat basis, and all patient assessments were performed by 1 investigator.

## Conclusion

The counterforce brace provided significant relief regarding the frequency and level of pain at rest in the short term (2-12 weeks), as well as a significant improvement in overall elbow function at 26 weeks, compared with the placebo brace. In summary, the data support the use of a counterforce forearm brace in the management of acute lateral epicondylitis.

## Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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