Immediate Effects of 2 Types of Braces on Pain and Grip Strength in People With Lateral Epicondylalgia: A Randomized Controlled Trial

**STUDY DESIGN:** Repeated-measures, crossover, double-blinded randomized controlled trial.

**OBJECTIVES:** To compare the immediate effectiveness of 2 types of counterforce braces in improving pain-free grip strength, pressure pain threshold, and wrist angle during a gripping task in individuals with lateral epicondylalgia.

**BACKGROUND:** Sports medicine management of lateral epicondylalgia often includes application of a counterforce brace, but the comparative effectiveness of different braces is unclear. The most common brace design consists of a single strap wrapped around the proximal forearm. A variation of this brace is the use of an additional strap that wraps above the elbow, which aims to provide further unloading to the injured tissue.

**METHODS:** Pain-free grip strength, pressure pain threshold, and wrist angle during a gripping task were measured on 34 participants with a clinical diagnosis of lateral epicondylalgia (mean ± SD age, 47.8 ± 8.5 years). Measurements were made without a brace, as well as immediately before and after the application of 2 types of counterforce braces. Each condition was tested during a separate session, with a minimum of 48 hours between sessions. Analysis-of-variance models were used to test the differences within and between conditions.

**RESULTS:** Pain-free grip strength (172 N; 95% confidence interval: 7.5, 26.8) and pressure pain threshold (42.2 kPa; 95% confidence interval: 16.5, 68.0) significantly improved on the affected side immediately following the intervention conditions as well as the control condition. There was no significant difference between braces or the control condition for any outcome.

**CONCLUSION:** Both types of counterforce braces had an immediate positive effect in participants with lateral epicondylalgia, without differences between interventions and similar to a no-brace control condition. Therefore, while the use of a brace may be helpful in managing immediate symptoms related to lateral epicondylalgia, the choice of which brace to use may be more a function of patient preference, comfort, and cost. Further research is required to investigate the comparative longer-term and clinical effects of the 2 braces. Trial registration: ACTRN12609000354280 (www.anzctr.org.au).


**KEY WORDS:** braces, lateral epicondylitis, tendinopathy, tennis elbow

Lateral epicondylalgia, colloquially known as “tennis elbow,” is prevalent in 0.8% to 3% of the general population,15,33,39,43 15% of those in occupations requiring repetitive hand tasks,8,34,20 and 50% of tennis players.1 Pain experienced over the lateral elbow during gripping can negatively affect daily and work tasks.2,20,44 Lateral epicondylalgia commonly involves the extensor carpi radialis brevis and common wrist extensor tendons at their proximal insertion, and more often affects the dominant side in those 35 to 55 years of age.1,3,16,20 Clinical features of lateral epicondylalgia include decreased pain-free grip strength (PFG),20 hyperalgesia on palpation over the lateral epicondyle,35,47 as well as neuromuscular deficits, such as slower upper-limb reaction time6 and altered wrist posture with gripping.7

Sports medicine management of lateral epicondylalgia often involves a combination of taping, bracing, manual
therapy, and exercises. Clinically, bracing has been used to reduce pain severity and to assist early introduction of pain-free exercise into the plan of care. Most commonly prescribed is a counterforce brace, which consists of a single strap that wraps around the proximal forearm just distal to the elbow. It is thought that the counterforce brace applies compression over the common extensor muscle mass to disperse stresses generated by muscle contraction, thereby reducing painful inhibition and allowing the patient to contract more forcefully. Furthermore, the contact of the brace with the skin and underlying tissue may facilitate muscle contraction through sensory stimulation and/or pressure to the muscle itself.

Also commercially available is a counterforce brace consisting of a forearm strap similar to that of the more standard counterforce brace but with an additional strap that wraps above the elbow. The purpose of this extra strap is to provide additional de-loading to the lateral epicondyle by compressing and lifting the proximal aspect of the wrist extensors near their attachment on the lateral epicondyle. However, although the efficacy of counterforce braces consisting of a strap wrapped around the forearm has been evaluated in previous studies, with evidence of variable effectiveness, a brace consisting of an additional strap wrapping above the elbow has yet to be assessed for its ability to relieve symptoms or improve function. The primary aim of this study was to compare the immediate effectiveness of 2 types of counterforce brace, 1 with and 1 without an elbow strap, in relieving pain and improving function in people with lateral epicondylalgia.

METHODS

Study Design

A double-blinded randomized controlled trial was used, which conformed to CONSORT guidelines. Ethical approval was granted by the Griffith University Human Research Ethics Committee. All participants provided written informed consent prior to entry into the study.

Participants

Participants aged 18 to 67 years, with a clinical diagnosis of lateral epicondylalgia, were recruited from the community of the Gold Coast region of Queensland, Australia between June 2009 and May 2010. Volunteers responded to advertisements in print media, as well as notices in university staff and student newsletters. An experienced physiotherapist performed all screening assessments to determine eligibility, using clinical presentation criteria consistent with previous studies. Clinical diagnostic criteria for lateral epicondylalgia are considered the gold standard, as the correlation of imaging with symptoms is variable in lateral epicondylalgia.

Volunteers were eligible for inclusion if they had pain over the lateral elbow for a minimum of 6 weeks that increased with palpation of the lateral epicondyle, gripping, or resisted extension of the wrist or the second or third finger. Exclusion criteria included bilateral elbow symptoms; cervical radiculopathy; any other elbow joint pathology or peripheral nerve involvement; past history of elbow surgery, dislocation, fracture, or tendon rupture; shoulder, wrist, or hand pathology; systemic or neurological disorders; treatment for elbow pain by a health care practitioner within the preceding 3 months; and corticosteroid injection for elbow pain within the previous 6 months. In light of the lack of firm diagnostic accuracy in excluding cervical spine or neural factors as the primary source of elbow pain, we took a clinical-reasoning approach based on the participant history (negative likelihood ratio [−LR] range, 0.5-1.1), neurological exam (−LR range, 0.12-1.16), upper-limb neural provocation test (−LR = 0.85), and cervical rotation range of movement (−LR range, 0.23-0.27).

Sample Size

Based on estimates of between-group differences from a previous study of similar design, to detect significant mean ± SD differences of 33 ± 60 kPa in pressure pain threshold (PPT) and 27 ± 44 N in PFG, at 90% power (α = 0.05), a sample size of 35 was required. This sample size would also provide 90% power (α = 0.05) with an effect size of 0.2 and 0.8 correlation among repeated measures (G*Power Version 3.1.3; Heinrich-Heine University, Düsseldorf, Germany). The sample size was not adjusted to account for dropouts, based on there being no loss to follow-up in previous studies of similar design.

Outcome Measures

Outcome measures were taken by a blinded assessor skilled in their application and were performed on both the affected and unaffected sides preintervention and postintervention. The primary outcome was PFG, measured using a digital analyzer grip dynamometer (MIE Medical Research Ltd, Leeds, UK). Participants were positioned in sitting, with their test arm at 90° of shoulder flexion, elbow fully extended, and wrist pronated. A gutter splint was positioned under the elbow to allow the wrist and hand to adopt a spontaneous posture during the gripping task. Participants were instructed to squeeze the dynamometer, slowly increasing the force until the first onset of pain. The assessor manually recorded the maximum force output displayed on the screen. This was repeated 3 times, with an intervening 30-second rest interval, and the average of 3 measures was calculated. PFG measurements have previously been shown to be reliable (intratester intraclass correlation coefficient [ICC] = 0.96; 95% confidence interval [CI]: 0.92, 0.98) in individuals with lateral epicondylalgia.

In light of preliminary evidence suggesting that wrist posture during a gripping task may be altered in people with lateral epicondylalgia, we chose to include sagittal plane wrist angle dur-
ing PFG as a secondary outcome. A 3-D motion-tracking sensor (MTi; Xsens Technologies BV, Enschede, the Netherlands) was placed on the dorsal aspect of the hand and secured with Velcro (Velcro USA Inc, Manchester, NH). Neutral wrist flexion/extension was identified as 0° by the software, with the palmar aspect of the hand and pronated forearm placed flat on a table and the software calibrated prior to data collection. Wrist-angle data during each PFG test were recorded using LabVIEW software (Version 8.5; National Instruments Corporation, Austin, TX) and exported into Microsoft Excel (Microsoft Corporation, Redmond, WA) for processing. The mean angle for wrist flexion/extension across the 3 gripping efforts was calculated, with positive scores indicating wrist extension.

Pressure algometry was also used as a secondary outcome to measure PPT. PPT measurements have good intratest reliability in individuals with lateral epicondylalgia, with an ICC of 0.76 (95% CI: 0.56, 0.89) on the affected side.
in randomized order: forearm, forearm-elbow, no brace. The computer-generated randomization sequence, created by an investigator who was not involved with either treatment or outcome assessment, was delivered via sealed, opaque envelopes, which were held by the treating therapist and opened in consecutive order.

Participant blinding was facilitated by visually obstructing the participant's view while each intervention was applied, and by not disclosing the purpose of each brace. Following application of each condition, opaque fabric was draped over the arm and forearm, covering the brace straps and leaving only the lateral epicondyle visible for measure of PPT. This ensured maintenance of assessor and participant blinding. The blinded assessor then repeated the PFG, wrist angle, and PPT measures with the test condition in situ. Due to the location of the braces, PPT was applied above the forearm brace and between the top and bottom straps of the forearm-elbow brace. The arm was also covered and measures taken immediately following the control condition. At the conclusion of each test session, assessor blinding was examined via a questionnaire. Participants were also questioned at the conclusion of the study regarding their condition preference.

Statistical Analysis
Statistical analyses were performed on an intention-to-treat basis using SPSS software (Version 19.0; SPSS Inc, Chicago, IL), with an alpha set at \( P < .05 \). ICC, and the standard error of measurement (standard deviation \( \times \sqrt{1 - ICC} \)) were calculated from the 3 trials to determine intratester within-session reliability and magnitude of measurement error, respectively, for each dependent variable (PFG, wrist angle, PPT). In addition, we calculated the minimal detectable change \((1.96 \times \sqrt{2} \times \text{standard error of measurement})\) to ensure with 95% confidence that the true value of the measure was contained within this range.

To assess the similarity between pre-condition measures collected at the beginning of each of the 3 testing sessions, a 2-way, repeated-measures analysis of variance was used, with side (affected, unaffected) and condition (forearm brace, forearm-elbow brace, control) included as independent variables for each outcome (PFG, wrist angle, PPT) at baseline. In addition, we calculated the minimal detectable change \((1.96 \times \sqrt{2} \times \text{standard error of measurement})\) to ensure with 95% confidence that the true value of the measure was contained within this range.

To assess the similarity between pre-condition measures collected at the beginning of each of the 3 testing sessions, a 2-way, repeated-measures analysis of variance was used, with side (affected, unaffected) and condition (forearm brace, forearm-elbow brace, control) included as independent variables for each outcome (PFG, wrist angle, PPT). Given that the condition was only applied to the affected elbow, each side was analyzed separately to determine the effect of the condition over time, using repeated-measures general linear models, with time (preintervention, postintervention) and...
condition as independent variables. Post hoc testing using paired t tests \((P<.05)\) was conducted if the omnibus analyses reported significant interaction or main effects. In the presence of significant interaction or main effects, the between-and/or within-condition effect size was expressed as Cohen’s \(d\), with less than 0.5 considered a small effect, between 0.5 and 0.8 a moderate effect, and greater than 0.8 a large effect.\(^9\)

## RESULTS

**SIXTY-ONE VOLUNTEERS WERE PHYSICALLY SCREENED FOR INCLUSION, WITH 34 PARTICIPANTS ENROLLED IN THE STUDY (FIGURE 3).** All participants received the conditions as per the randomization schedule, and there were no losses to follow-up. Participant demographics, baseline outcome measures, and measurement error (MDC) are reported in **TABLE 1**. To be confident that any change in PFG and PPT on the affected side was real and not related to measurement error, we calculated that a change greater than 40 N for PFG, 135 kPa for PPT, and 6.3° for wrist angle would be required.

**Precondition**

There was no significant interaction (condition by side) or main effect of condition for any precondition outcome, indicating no difference between measures taken at the beginning of each testing session for either the affected or unaffected side. This confirms that the time between appointments was sufficient to have a washout effect and restore baseline levels between conditions (**TABLE 2**). There was, however, a significant difference between affected and unaffected sides for all outcomes. Compared with the unaffected side, the affected side produced 170.9 N lower PFG (95% CI: 142.7, 199.0 N), 317 kPa lower PPT (95% CI: 247.8, 386.3 kPa), and 5.0° less wrist extension (95% CI: 2.0°, 8.0°).

**Conditions**

There were no adverse events reported by participants during the study. There was no significant condition-by-time interaction on the affected side for PFG \((P = .07)\), PPT \((P = .48)\), or wrist angle \((P = .2)\). There was a significant main effect for time \((P = .001)\) but not condition \((P = .1)\) for PFG on the affected side. At post hoc testing, the affected side demonstrated a small improvement of 17.2 N in PFG (effect size, 0.2; 95% CI: 7.5, 26.8 N), regardless of the intervention condition. There was no significant change in PFG on the unaffected side, either over time or between conditions (**TABLE 2**).

**Reliability**

Intratester reliability for PFG (ICC = 0.945; 95% CI: 0.902, 0.971), PPT (ICC = 0.935; 95% CI: 0.884, 0.966), and wrist angle (ICC = 0.933; 95% CI: 0.884, 0.966) on the affected side was excellent,\(^27\) as was reliability on the unaffected side (PFG, ICC = 0.975; PPT, ICC = 0.901; and wrist angle, ICC = 0.956).

### TABLE 1

**Baseline Participant Characteristics**

<table>
<thead>
<tr>
<th>Participant Characteristics</th>
<th>Values</th>
<th>MDC(_{\text{95}})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>18 (52.9)</td>
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<tr>
<td>Age, y</td>
<td>47.8 ± 8.5 (28-67)</td>
<td></td>
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<tr>
<td>Employment status, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual labor</td>
<td>7 (20.6)</td>
<td></td>
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<tr>
<td>Nonmanual labor</td>
<td>25 (73.5)</td>
<td></td>
</tr>
<tr>
<td>Not employed</td>
<td>2 (5.9)</td>
<td></td>
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<tr>
<td>Right side dominant, n (%)</td>
<td>31 (91.2)</td>
<td></td>
</tr>
<tr>
<td>Dominant side affected, n (%)</td>
<td>28 (82.4)</td>
<td></td>
</tr>
<tr>
<td>Duration of condition, wk</td>
<td>64.6 ± 137.4 (6-570)</td>
<td></td>
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<tr>
<td>Recurrent condition, n (%)</td>
<td>9 (26.5)</td>
<td></td>
</tr>
<tr>
<td>PRTEE(^1)</td>
<td>38.7 ± 15.0 (11-69)</td>
<td></td>
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<tr>
<td>Average function in the past wk(^2)</td>
<td>76.0 ± 22.5 (6-100)</td>
<td></td>
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<tr>
<td>Worst pain in past week(^3)</td>
<td>578 ± 211 (19-100)</td>
<td></td>
</tr>
<tr>
<td>Resting pain(^4)</td>
<td>16.0 ± 14.6 (0-60)</td>
<td></td>
</tr>
<tr>
<td>Affected side</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain-free grip, N</td>
<td>1177 ± 697 (23.3-250.3)</td>
<td>40.1</td>
</tr>
<tr>
<td>Pressure pain threshold, kPa</td>
<td>403.1 ± 146.3 (947-816.7)</td>
<td>134.3</td>
</tr>
<tr>
<td>Wrist angle during gripping, deg</td>
<td>29.6 ± 8.9 (9.3-49.4)</td>
<td>6.3</td>
</tr>
<tr>
<td>Unaffected side</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain-free grip, N</td>
<td>2886.6 ± 945 (125-5657)</td>
<td>40.8</td>
</tr>
<tr>
<td>Pressure pain threshold, kPa</td>
<td>7201 ± 1957 (263.8-1789.3)</td>
<td>214.9</td>
</tr>
<tr>
<td>Wrist angle during gripping, deg</td>
<td>34.5 ± 83 (12.3-54.4)</td>
<td>5.2</td>
</tr>
</tbody>
</table>

Abbreviations: MDC\(_{\text{95}}\), minimal detectable change at 95% confidence; PRTEE, Patient-Rated Tennis Elbow Evaluation.

\(^{1}\)Values are mean ± SD (range) unless otherwise indicated.

\(^{2}\)0 to 100 points, where 100 is maximal disability.

\(^{3}\)100-mm visual analog scale, where 0 is no pain/disability and 100 is worst pain/disability.

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**TABLE 2**
on the unaffected side \( (P = .004) \); however, the difference was small \( (1.7\degree; 95\% \text{ CI: } 0.6\degree, 2.7\degree) \) and not meaningful, based on the MDC of 5.2\degree (TABLE 1).

**Blinding**

The assessor guessed the correct intervention condition on 39 of 102 (38\%) occasions. Specifically, the assessor correctly guessed the use of the forearm-elbow brace on 14 (41\%) occasions, the use of the forearm brace on 15 (44\%) occasions, and the control condition on 10 (30\%) occasions. At the end of the study, 21 (62\%), 11 (32\%), and 2 (6\%) participants reported a preference for the forearm-elbow-brace, forearm-brace, and control (no-brace) conditions, respectively.

**DISCUSSION**

**This study showed that there was a small but statistically significant immediate improvement in PFG strength and PPT preintervention to postintervention on the affected side, but this improvement did not discriminate between the brace and control conditions. Regardless of the bracing intervention, minimum improvements of 17.2 N in PFG and 42.2 kPa in PPT were achieved on the affected side. However, the improvements in PFG and PPT reported in this study are smaller than the MDCs, and may therefore be due to measurement error rather than a true clinical change. Furthermore, the change in PPT on the unaffected side approached statistical significance \( (P = .06) \), which may reflect a lack of statistical power (ie, insufficient sample size). We should note that this study only measured immediate effects, and it may be that a larger change in outcomes on the affected side occurs with increased time spent in the brace.**

Our findings are somewhat consistent with a number of other studies that have investigated the effect of bracing on grip...
and pain in lateral epicondylalgia. These studies, with various degrees of rigor, have assessed the effectiveness of a variety of elbow braces against other currently accepted treatments or placebo/control. Overall, despite variations in study designs, timing of outcomes, type of brace, and comparator groups, most studies have shown that elbow or forearm braces improve pain and function in people with lateral epicondylalgia. Although the results of our study found an improvement between prebracing and postbracing measures, overall, the brace conditions were no more effective than the control at improving immediate outcomes. As such, it appears that the additional strap on the forearm-brace does not improve the efficacy of the existing forearm brace to immediately relieve pain or improve function.

It is hypothesized that the mechanism by which the forearm brace exerts its clinical efficacy is by decreasing the muscle and tendon forces acting at the lateral epicondyle, thereby offloading the site of pain. There is some evidence to support this theory. Studies have shown a 46% decrease in acceleration amplitudes at the lateral epicondyle with the use of a forearm brace with a silicon pad, decreased electromyographic activity in the wrist extensors with both the standard and air-pillow forearm braces, and decreased strain at the origin of the extensor carpi radialis brevis muscle when a forearm brace was applied. If this mechanism of action is accepted, then by association with our outcomes, the additional strap located on the forearm-brace does not appear to enhance this muscle-tendon deloading.

In contrast, the effect of bracing on neuromuscular performance in lateral epicondylalgia is less convincing. The current study found that neither brace significantly influenced the angle of wrist extension spontaneously adopted during the pain-free gripping task. In fact, a previous study found that bracing may adversely affect wrist joint position error but may have no effect on stretch latency of the extensor carpi ulnaris. Interestingly, we did identify a significant difference in wrist angle between sides, with the affected side gripping with approximately 5° less wrist extension than the unaffected side. This has implications for the performance of everyday activities, as gripping with a flexed wrist posture has been shown to be inefficient in producing maximum grip force in normal populations. As our lateral epicondylalgia cohort did still grip with some degree of wrist extension, further research is required to investigate the contribution of wrist posture to muscle activity and the relationship between wrist angle and other symptoms in people with lateral epicondylalgia. However, these findings may help to explain some of the symptoms experienced by those with lateral epicondylalgia, such as weakness during gripping tasks.

To our knowledge, this is the first study to identify side-to-side differences in wrist extension angle during gripping in individuals with unilateral lateral epicondylalgia. A previous paper found that those with lateral epicondylalgia gripped with 11° less wrist extension than an age- and gender-matched healthy control cohort; however, the authors found no difference between sides within groups. This difference in results between studies might be due to the equipment used. The previous study used digital photographs and computer software to measure wrist extension angle, whereas the present study used a 3-D motion-tracking sensor. It is possible that the level of error in the photographic technique was higher than the error using the motion sensor. Limits of agreement using the digital-image technique compared to a universal goniometer have been reported at −1.9° to 1.8° for knee flexion, whereas the manufacturers of the MTi device (Xsens Technologies BV) report a static accuracy of less than 0.5°. Therefore, it is plausible that the lower measurement error associated with the motion sensor allowed identification of side differences within our lateral epicondylalgia population that previously went unseen.

While this is the first study, to our knowledge, to evaluate the immediate effects of the forearm-brace compared to the forearm brace in lateral epicondylalgia, there are limitations that must be acknowledged. The physiotherapist applied the braces in a manner reflective of clinical practice, ensuring that the brace felt supportive but comfortable. Although the physiotherapist attempted to apply the braces with consistent tension on the straps, it is possible that the level of tension varied between applications, as this was not quantified. However, considering that brace tension does not appear to influence wrist extension strength, it is unlikely to have influenced the PFG measures. Though the use of analgesic and anti-inflammatory medication was not controlled in this study, it is unlikely to have improved the results, as analgesia would minimize the change between baseline and postcondition measures, providing a more conservative estimate of effect. Furthermore, we attempted to blind participants (and the assessor) to the type of brace by not revealing the difference between the 2 braces, by applying a blindfold while the braces were applied, and by draping the limb that covered the arm, except for a small area through which the PPT measures could be taken. It appears that the assessor blinding was not completely successful, as the assessor correctly guessed the intervention on more occasions than would be expected by chance alone. Approximately 60% of participants preferred the forearm-brace, suggesting that, while these results do not support the use of one brace over another, participants’ choice of brace may be based on features other than random selection. Furthermore, while patients typically wear an elbow brace to improve pain-free function, the impact of the test braces on general upper-limb function was not assessed in this study. Finally, this study only evaluated the immediate effects of the forearm braces, with no longer-term follow-up. This should be addressed in future studies of brace
effectiveness. Nevertheless, considering that the application of a forearm brace is expected to have an immediate effect on symptoms and is rarely applied in isolation within the clinical setting, the evaluation of the braces’ immediate effects was believed to be most clinically relevant as an initial stage in comparing effectiveness.

CONCLUSION

Statistically significant immediate improvements in PFG and PPT were identified in individuals with lateral epicondylalgia, preapplication to postapplication of a forearm brace, a forearm–elbow brace, and no brace (control condition), with no difference found between conditions. The improvements in outcomes may be due to measurement error rather than true clinical change. As neither brace appeared to provide superior immediate benefits, decisions regarding their use in clinical practice should not be based on type, but rather on other factors such as patient preference, comfort, and cost. Further research is required to investigate longer-term effects and improve our understanding of the significance of neuromotor deficits, such as wrist angle with gripping, in lateral epicondylalgia.

KEY POINTS

FINDINGS: The application of a forearm brace or a forearm–elbow brace has an immediate positive effect on grip strength and pain in people with lateral epicondylalgia, although this improvement may be a function of measurement error, as reflected by a similar improvement in the control condition. There was no difference in outcomes between the braces tested.

IMPLICATIONS: The choice of brace should not be based on the brace type but, rather, on other factors, such as patient preference, comfort, and cost.

CAUTION: The improvements identified in this study may be due to measurement error. The long-term effectiveness of braces requires further investigation.

ACKNOWLEDGEMENTS: We thank Mr Neil Moyer, inventor of the forearm–elbow brace, for supplying and advising on use of the brace, which is now manufactured as the Go-Strap by Sportstek Physical Therapy Supplies Pty Ltd, Oakleigh, Australia, and United Pacific Industries Pty Ltd, Kilcoy, Australia, for supply of the forearm counterforce brace.

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