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Research Article

Effect of Vibration on Epicondylalgia: A Pilot Study

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Abstract

Introduction: Lateral epicondylalgia is a common overuse injury of the elbow. Many interventions have been attempted. The purpose of this study was to compare the effectiveness of 200 Hz vibration with the VibraCool® device to that of a counterforce strap on pain relief in individuals with epicondylalgia. This is a Level 3, Cohort study.

Methods: Treatment options were VibraCool® or counterforce strap utilized 30-mintes/day for three weeks. Outcomes data were Patient Rated Tennis Elbow Evaluation (PRTEE), Quick Disabilities of the Arm, Shoulder, and Hand (DASH), and Visual Analog Scale (VAS) collected at pre-treatment, post-treatment (3 wks), and follow-up (2 wks) time frames.

Results: VibraCool® demonstrated significant pain reduction (VAS), compared to the counterforce strap. DASH and PRTEE scores significantly improved over time but were not significantly different between groups.

Discussion/Conclusions: The VibraCool® device was effective, and interesting data were found in this pilot to impact future research. Some changes in the methodology to compare three 30-minute treatments with active exercise to active exercise only may be more clinically relevant.

Keywords: Elbow pain; epicondylalgia; tennis elbow; vibration therapy

Introduction

Lateral epicondylitis (LE) is a common overuse injury of the elbow. It has been reported to influence up to 3% of the population with a greater preponderance in the prime range of 30 to 55 years of age [1-6]. Nearly 40% to 50% of recreational tennis players will experience this condition in their lifetime [5]. However, one does not have to play a racquet sport to develop this overuse syndrome. Playing an instrument, manual labor, and repetitive keyboard activities are contributing factors. LE is often the result of microtrauma associated with tasks that involve gripping and wrist extension with forearm supination. The proximal attachment of the extensor carpi radialis brevis (ECRB) to the lateral aspect of the capitellum places the tendon at risk for undersurface abrasions with elbow flexion and extension [7]. Originally the repetitive microtrauma was believed to produce an inflammatory reaction. However, histological studies have shown inflammatory cells are absent in chronic LE [8,9]. Repetitive stretching and strain upon the tendon can cause denaturing of the protein matrix and proliferation of fibrous tissue [10]. Cyclic trauma and immature repairs result in failure of the musculotendinous biomechanics [11]. Pain symptoms will then result in under-usage which can lead to structural weakening of the tendon to make it more susceptible to injury [12].

Clinical presentation includes pain at the musculotendinous junction of the ECRB when gripping and twisting of the wrist/hand. Reduced wrist range of motion and a decrease in wrist

extension strength may also be present [1,13-15]. Clinical tests such as the Cozen sign and Maudsley sign are often positive [16]. These symptoms are attributed to histological changes in the tendon (angiofibroblastic hyperplasia), changes in the pain system (sensitization), and motor system impairments [14,15,16]. LE is generally a clinical diagnosis so radiographs are not typically needed but they may help identify bone disease, osteochondral defects, loose bodies, and calcification of the ECRB [18,1,14,5]. Ultrasound can be valuable in identifying degenerative changes in the tendon and neovascularization [19,20]. MRI can provide information about ECRB partial or full-thickness tears.

Although no universal treatment regime has been adopted for LE, non-operative treatment is a priority. In fact, it has been estimated that 90% of LE cases resolve without surgery [21,22]. Non-operative interventions include bracing/splinting, non-steroidal anti-inflammatories (NSAIDs), thermal modalities, electrotherapeutics, acupuncture, biological injections (autologous blood injections/platelet-rich plasma injections), and therapeutic exercises (emphasis on eccentric muscle activation). All have been reported to provide varying degrees of symptom relief. While LE is often considered to be self-limiting it can last 12 to 18 months [23].

In previous studies, corticosteroid injections initially relieved pain but with recurrence in 18-54% of patients [1]. Platelet-rich-plasma [15] and hyaluronic acid injection [6] studies reported relief for 8-12 weeks, with hyaluronic acid showing ongoing improvements up to 12 months. Mulligan mobilization with movement techniques with exercise and ice had positive effects on pain and functional tasks [24]. Kinesiotaping has revealed varying results. One study reported no change in strength [25] while another [26] reported a decrease in pain and an increase in grip strength. Dry needling effectively decreased pain pressure threshold and increased grip strength across a systematic review [27,28].

Counterforce braces have been used for many decades. The intent of the brace is to reduce pain via ECRB inhibition and the dispersion of stress on the musculotendinous junction across a wider surface area to facilitate the repair process [29]. Bisset et al reported an immediate positive effect but no lasting relief [30]. Whereas, Kachanathu et al stated a forearm band increased grip strength and function when compared to elbow taping [31]. In a recent randomized controlled study comparing counterforce bracing to placebo, pain frequency and severity was reduced for 2-12 weeks and elbow function was improved at 26 weeks for the bracing group [32]. The only vibration study published specifically on tennis elbow used a convex unit (low surface area contact) and failed to reveal the frequency of the vibration. The authors did not report statistically significant improvement [33], although two outliers with resolved pain in the vibration group were not included in analysis. Likewise, frequency, amplitude and surface area contact are important components of the intervention not reported in the study.

All substances vibrate at a unique resonance frequency, including tissues of the human body. Focal (local) vibration [34,35] can be generated with off-center motors or air forced by diaphragms, acting on frequency-sensitive mechanoreceptors or force-gated ion channels to achieve a variety of clinical effects. Focal vibration has been used to produce analgesic action in a variety of clinical conditions via central, neurotransmitter, and inhibitory mechanisms [36]. The best described analgesic effect of vibration has been attributed to spinal gating, previously called "gate control theory" [35]. Stimulation of the Pacinian mechanoreceptors carried along Aβ afferent fibers release adenosine in the substantia gelatinosa (dorsal horn of the spinal cord), blocking glutamate from nociceptive fibers from activating the ascending spinothalamic tract [10,37,38]. Electrical devices activate Meissner corpuscles sensitive to 20 – 50 Hz, while vibration is optimally activating Pacinian corpuscles at 150-240 Hz [39,40]. The mechanical activity of vibration has been theorized to decrease muscle guarding via reduced actin-myosin bond coupling and increased range of motion [41,34,35], potentially via recalibrating the neuromotor reflex [42]. Finally, increased blood flow from vibratory nitric oxide-mediated vasodilation may also facilitate the removal of pain-inducing cytokines [41,34]. The VibraCool® device provides focal stimulation at a frequency of 200 Hz, pressed in a concave casing devised to maximize Pacinian exposure directly to affected muscles. The purpose of this study was to compare the effectiveness of vibration with the VibraCool® device to that of a known intervention (counterforce strap) on pain relief in individuals with epicondylalgia.

Methods

All procedures in this study were performed in compliance with relevant laws and institutional guidelines and were approved by the University Office of Institutional Review Board (#154-23) on November 10, 2023. Participants were recruited via social media and flyers. All participants provided written informed consent prior to the collection of any data. A total of 27 participants meet the inclusion criteria: over 18 years of age, lateral elbow pain, free of sensory deficits in the arms, no history of elbow, wrist, or hand surgery, no history of fibromyalgia or diabetes, and no cold sensitivity (if in VibraCool® group).

Baseline data included: wrist flexion and extension range of motion, grip strength at five positions on a Jamar hand dynamometer (Performance Health, Indianapolis, IN), pain pressure threshold, Cozen test, and Maudsley test. These measures were made to confirm the diagnosis of lateral epicondylitis. In addition, three questionnaires were administered: Patient Rated Tennis Elbow Evaluation (PRTEE), Quick Disabilities of the Arm, Shoulder, and Hand (DASH), and Visual Analog Scale (VAS). These questionnaires have been used extensively in prior studies: PRTEE Interclass correlation (ICC) is 0.89-0.99 (Pain ICC = 0.89-0.99, Function ICC = 0.83-0.99); Dash reliability is 0.91 with a minimal detectable change at the 90% confidence level being 12.85; VAS reliability is 0.94 [43].

This study was an intention to treat design. Thus, we asked about prior treatments. If a person had a negative experience with a counterforce strap, we offered them the VibraCool® option. If they never used a counterforce strap, we offered them both options. The

counterforce strap (Figure 1) was a polyester, nylon, spandex blend adjustable to fit each forearm (Sleeve Stars, Santa Barbara, CA). The VibraCool® device (Figure 2) was a small device that fits in a pouch to strap onto the elbow (PainCareLabs, Atlanta, GA). VibraCool® is pre-set to vibrate at 200 Hz. While packaging of the VibraCool® includes an ice pack which can be used concurrently, this study only evaluated vibration. All participants were provided a color-coded treatment diary to log the daily treatment and write any notes about their activity levels. Each treatment was performed for 30-minutes each day. After the first treatment the VAS was completed (post-treatment 1). After 21 consecutive days of treatment, the PRTEE, DASH, and VAS were completed (post-test data). Each participant was then to refrain from using any treatments for two weeks and the 3 questionnaires were repeated (follow-up data).

Figure 1: Counterforce Strap.

Figure 2: VibraCool Device.

Data analysis included descriptive statistics run for demographic variables and for the dependent variables. Chi-square analysis was run to determine if there were between-group differences on those who had pain for greater than one year versus those who experienced pain for less than one year. A repeated-measures MANOVA was conducted to examine the effects of three levels of time (pre-test, post-test, and two-week follow-up) and two groups (VibraCool® or Counterforce Strap) on the dependent variables VAS, DASH, and PRTEE. A Mann-Whitney U was run to evaluate between-group differences for the VAS post one treatment. The Mann-Whitney U was run due to unequal group sizes.

Results

Demographic data - Of the 22 VibraCool® participants, 16 were right and 6 were left involved elbows. Of these, 16 had the dominant and 6 non-dominant elbows involved. The age was 53.7 ± 11.5 years with 11 experiencing pain for over one-year and 11 less than 1-year. The distribution of the groups is displayed in Table 1.

Table 1: Demographic Data by Group and Duration of Symptoms.

	N	Involved elbow		Dominant	Age ± SD
VibraCool® >1 year	11	7 right	4 left	8 dominant	57.0 ± 12.01 yrs
VibraCool® <1 year	11	9 right	2 left	7 dominant	50.45 ± 10.04 yrs
Counterforce strap	5	4 right	1 left	4 dominant	49.4 ± 9.71 yrs

Screening Data - Of the 22 VibraCool® participants, 14 had a positive Cozen test, 10 had a positive Maudsley test, 17 had decreased wrist flexion/extension, 14 had decreased grip strength, and 22 had a diminished pain pressure threshold. In summary, 19 participants had 3 or more of these deficits.

Of the 5 counterforce strap participants, 2 had a positive Cozen test, 3 had a positive Maudsley test, 4 had decreased wrist flexion/extension, 3 had decreased grip strength, and 5 had a diminished pain pressure threshold. In summary, 4 participants had 3 or more of these deficits. Outcome Data - A summary of the outcomes data is provided in Table 2. Deltas over time and Minimal Clinically Important Differences (MCID) are displayed in Table 3. Chi square was significant (p = .04) for between-group differences in pain duration. All five members of the counterforce strap group had pain of less than 1 year; the VibraCool® group had 11 participants who had pain of less than and 11 that had pain for greater than one year.

Table 2: Dependent Variable Means and Standard Deviations for Each Group and Time Point.

		Means and Standard Deviations			
Measure	**Variable**	**Pre-test**	**Post treatment 1**	**3 Week Post-test**	**2 Week Follow-up**
VAS	VibraCool®	3.2 ± 1.9	2.5 ± 1.9	2.2 ± 1.8	2.3 ± 1.9
	Counterforce Strap	3.8 ± 1.3	4.0 ± 1.2	2.9 ± 0.9	2.5 ± 1.4
DASH	VibraCool®	23.4 ± 5.6	Not tested	18.9 ± 7.0	18.7 ± 6.4
	Counterforce Strap	23.6 ± 8.4	Not tested	20.4 ± 6.9	18.0 ± 5.4
PRTEE	VibraCool®	51.2 ± 20.6	Not tested	27.4 ± 26.7	26.1 ± 26.0
	Counterforce Strap	54.8 ± 31.4	Not tested	40.2 ± 33.1	28.8 ± 37.4

Table 3: Delta Values Over Time & Minimal Clinically Important Differences (MCID).

		Delta Values over Time & Minimal Clinically Important Differences			
Measure	**Variable**	**Pre-test to Post-test**	**Pre-test to Follow-up**	**Post-test to Follow-up**	**MCID**
VAS	VibraCool®	-1.0	-0.9	+0.1	
	Counterforce Strap	-0.9	-1.3	-0.4	≥ 1.8
DASH	VibraCool®	-4.5	-4.7	-0.2	
	Counterforce Strap	-3.2	-5.6	-2.4	≥ 14
PRTEE	VibraCool®	-23.8	-25.1	-1.3	
	Counterforce Strap	-14.6	-26.0	-11.4	≥ 11

For the repeated-measures ANOVA, sphericity was violated for within-subjects' effects for time for the VAS (p < 0.01), DASH (p < 0.02), and PRTEE (p < 0.01). The violation of sphericity was likely due to unequal group sizes and thus the Pillai's trace correction was applied for overall between- and within-subjects' tests. There were no between group differences found (p = 0.76) or time by group interaction (p = 0.58). However, there was a significant overall within-subjects effect of time (p = 0.001). Univariate effects were examined for the impact of time using the Huynh-Feldt correction, as epsilon was > 0.75.

For the VAS scores, the main effect of time was not statistically significant ($p = 0.13$), with a small effect size (partial $\eta^2 = 0.08$). DASH scores showed a significant main effect of time ($p < 0.01$) with a medium effect size (partial $\eta^2 = 0.20$). PRTEE scores demonstrated a significant main effect of time ($p < 0.01$), with a large effect size (partial $\eta^2 = 0.46$). Post-hoc testing for time with Bonferroni correction found that there was no significant difference in DASH from pre-test to post-test ($p = 0.07$) or from post-test to two-week follow-up ($p = 0.67$). DASH scores significantly improved from pre-test to two-week follow-up ($p = 0.02$). The results indicate that disability significantly decreased over time. PRTEE scores significantly improved from pre-test to post-test ($p < 0.01$) and pre-test to two-week follow-up ($p < 0.01$), but not between post-test and two-week follow-up ($p = 0.07$). This indicates that elbow-related disability significantly decreased over time and the treatment effect was retained over the 2-week follow-up. Mann-Whitney U testing demonstrated significant between-group differences for the VAS ($p = 0.02$), with the VibraCool® demonstrating significant pain reduction, compared to the counterforce strap. Cohen's d was 0.94, indicating a large effect size.

As a pilot study interested in learning about the impact of the VibraCool® device on pain and disability, a secondary data analysis was performed. A Friedman's ANOVA with Wilcoxon signed-ranks post-hoc tests were run on just the VibraCool® data. Friedman ANOVA results indicated significant differences between time points ($p < 0.01$). Wilcoxon signed ranks post-hoc testing affirmed that upper extremity disability measured by the DASH reduced from pre-test to post-test ($p = 0.01$) and from pre-test to follow-up ($p < 0.01$), but not from post-test to two-week follow-up ($p = 0.93$). Elbow-related disability as measured by the PRTEE also improved from pre-test to post-test ($p < 0.01$) and pre-test to two-week follow-up ($p < 0.01$), but not from two-week follow-up to post-test ($p = 0.41$). Pain as measured by the VAS was not significantly different from pre-test to post-test ($p = 0.09$), from pre-test to two-week follow-up ($p = 0.07$), or from post-test to follow-up ($p = 0.90$). These results indicate that disability improvements are sustained from a post-test to two-week follow-up (Table 2). Likewise, Table 3 also reveals the PRTEE was the only measure to reach the MCID value.

Discussion

Epicondylalgia is a musculoskeletal disorder that is characterized by pain at the lateral epicondyle. It frequently includes limited wrist range of motion, wrist/grip weakness, positive Cozen Sign (incriminating the ECRB muscle; sensitivity 84-91%), positive Maudsley Sign (incriminating the extensor digitorum longus muscle; sensitivity 66-88%), and/or increased tenderness to palpation (reduced pain pressure threshold) at the musculotendinous junction of the proximal elbow extensors [43]. These signs and symptoms were used as screening tools to confirm the presence of epicondylalgia for participation in the study [44]. The original intent of the study was to randomize the assignment of participants to the VibraCool® device or counterforce strap intervention. However, many participants had unsuccessfully used a counterforce strap in the past and did not want to use it again. They were interested in using the VibraCool® device so this led to a very unequal sample size.

One of the pre-screening questions asked about the duration of the participant's signs/symptoms. When viewing this data, there was an interest in seeing if symptom duration made a difference in the response to treatment. A period of one-year appeared to be a reasonable break point since Bisset et al identified "tennis elbow" as a self-limiting condition with up to 80% cases recovering within one year[45]. It would have been helpful to differentiate by tissue pathology instead of time, i.e. epicondylitis (inflammation of ECRB) versus epicondylosis (chronic degenerative process of the proximal common extensor tendon). However, this would have required imaging or an invasive process. Coincidentally, this one-year differentiation resulted in 11 participants in each group. A study by Kraushaar and Nirschl (1999) evaluated cadaveric specimens of nine people who failed conservative management for lateral epicondylitis. Histology and electron microscopy found a paucity of evidence to suggest an inflammatory response. Since their study did not evaluate the tissue in the early stages of epicondylalgia, it is unclear when the elbow dysfunction transitions from an inflammatory to a degenerative status [9]. In fact, this could happen at different times in different people. Nonetheless, out of curiosity, the current data was analyzed by three groups: VibraCool® with symptoms less than one year, VibraCool® with symptoms more than one year, and counterforce strap. The intent was to see if people with a longer period of symptoms responded differently, i.e. were the tissues histologically dissimilar. Although there were differences over time, there were no significant differences between groups. It is possible the one-year mark was not an appropriate breakpoint but without imaging, this is not known.

In evaluating the effectiveness of the counterforce strap, prior studies examined the impact on various parameters with a single application [18,45,31,32,23,46]. A study [45] comparing a forearm strap to a forearm-elbow strap (counterforce band with an additional elbow strap) and control demonstrated slight increases in pain-free grip strength and pressure pain threshold for both braces compared to control. However, the increases were less than the MCID. The rationale offered for this pain reduction was a decrease in the muscle/tendon forces (ECRB) on the lateral epicondyle to offload the pain. Likewise, the integrated EMG activity with an Aircast band was found to be less than a standard strap and a control but a rationale for this outcome was reported to be perplexing [46]. While the literature [31] has supported the use of a counterforce strap as a standard of care, there are no recommendations for the "wear-time." Thus, despite trying to establish research parity by rendering equal treatment times with the two interventions, it might have been better to use the counterforce strap longer each day. Clinicians often suggest people wear the strap during active periods of their day to achieve the above stated outcomes. This tends to be for periods greater than the 30-minutes per day in this study. Further studies are needed to provide clinically relevant "wear-time," precise placement, and magnitude of compression to allow for comparisons of best treatment options.

When outcome measures for all VibraCool® data were compared to the counterforce strap, improvement was identified in both groups over time. Pain (VAS) was reduced in both groups and neither achieved a minimal clinically important difference (MCID) as identified in Table 3 [47]. The disability questionnaires (DASH and PRTEE) indicated significant improvement over time for both groups. Although there were no differences between the groups, a MCID was achieved for the PRTEE questionnaire. So, what would be the physiological rationale for these outcomes? Given that the duration of the symptoms for numerous participants was many months to years, it would make sense that the stage of injury was degenerative/failed tendon healing and a mechanical device might help the symptoms as compared to an anti-inflammatory product. The physiology of the counterforce strap has been discussed. The VibraCool® device delivered a 200 Hz vibration blocking significant a-delta nociceptor pain [48,49]. Single-motor 200 Hz devices have been found to be effective for pain reduction in over 100 studies [50-52]. This study administered a 30-minute treatment daily over three weeks but a recent study by Fattorini et al recommended 30-minutes, three-times per day [42]. Unfortunately, the Fattorini study (2023) was published after the current study was initiated. Furthermore, active muscle contractions have been suggested to be used with vibration to reset dysfunctional reflexed and asynchronous proprioception [9]. Exercise also stimulates regional hyperemia and the delivery of cyclic loading can stimulate collagen remodeling [9]. The inclusion of therapeutic exercise is consistant with multi-modal interventions that typically happen in the clinical setting. However, the isolation of individual treatments was performed in the current study to identify a cause-and-effect relationship of the interventions. Given this expanded data, a decision to stop this study, report the results, and make modifications to the methodology seemed reasonable.

Conclusion

In summary, all outcome measures improved over time regardless of the data analysis performed. It appears that the longer the duration of the symptoms, the more likely the participant was to have tried a variety of other interventions, including a counterforce strap. Thus, the counterforce strap group reported epicondylagia for shorter periods of time. This disparity and the potential indication for increased duration of the VibraCool® treatment time resulted in the researchers deciding to stop data collection, review the results to date, and begin to design an alternative approach. However, the results to date are worth sharing. This is the best way to enhance research protocols to determine best treatment options. Future research with the VibraCool® device should follow Fattorini et al and compare three 30-minute treatments daily for three days with active exercise compared to active exercise only [42]. The outcome measures used in the current study were consistent with other studies and should be used again [27,28,24,47]. Overall, vibration has the potential to be a valuable, convenient, and inexpensive treatment technique for a common but challenging diagnosis like epicondylalgia.

Clinical Relevance

a) Identification of the stage of lateral epicondylgia can play a significant role in determining effective treatment(s).

b) Vibration has the potential to be a valuable, convenient, and inexpensive treatment technique for a common but challenging diagnosis like epicondylalgia.

c) Precise treatment parameters are in the process of being established.

d) The combination of vibration with active exercise needs to be explored.

Ethical Approval

All procedures in this study were performed in compliance with relevant laws and institutional guidelines and were approved by the University Office of Institutional Review Board.

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Conflict of Interest Disclosures

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