The Effects of Oscillatory Biofield Therapy on Pain and Functional Limitations Associated with Carpal Tunnel Syndrome: Randomized, Placebo-Controlled, Double-Blind Study

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Abstract

Objectives: Biofield treatments have been used for pain control in patients with cancer and chronic pain. However, research on the effect of biofield treatment on specific somatic disorders is lacking. This study intends to investigate the effect of oscillating biofield therapy (OBFT) on symptoms of carpal tunnel syndrome.

Design: Randomized, placebo-controlled, double-blind study.

Participants: Thirty patients with chronic carpal tunnel syndrome participated in the study.

Intervention: Patients were randomly assigned to active or placebo treatment groups. Those in the treatment group received six sessions of OBFT with intention to treat during a period of 2 weeks. Patients in the placebo group had the same number of treatment sessions with mock OBFT treatment.

Outcome measure: The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire; Symptom Severity Scale (SSS); and Functional Status Scale (FSS) were used for outcome assessment.

Results: Both clinically and statistically significant changes in intensity of pain with activity (95% confidence interval [CI], 2.5–4.2; $p=0.000$), night pain ($p=0.000$, 95% CI, 3.2–5.7), DASH questionnaire (95% CI, 12.0–21.9; $p=0.000$), SSS (95% CI, 0.64–1.15; $p=0.003$), and FSS (95% CI, 0.41–0.97; $p=0.029$) were found between the treatment and placebo groups. Statistically significant reduction in number of patients with positive results on the Phalen test (87%; $p=0.000$), Tinel sign (73%; $p=0.000$), and hand paresthesia (80%; $p=0.000$) was noted in the treatment group. During 6-month follow-up, 86% of patients in the treatment group remained pain free and had no functional limitations.

Conclusion: OBFT can be a viable and effective treatment for improving symptoms and functional limitations associated with chronic carpal tunnel syndrome.

Keywords: carpal tunnel syndrome, biofield, alternative treatment, hand pain, wrist pain, oscillation

Introduction

COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) is increasingly being sought by individuals with somatic pain and dysfunction.^{1,2} Biofield therapy was officially recognized as an alternative treatment by the National Institutes of Health in 1994.³ Biofield therapy is often implemented through delivery of a constant flow of energy via the practitioner's hands to the patient.

Upledger⁴ described practitioner's hand placement as two electrodes placed across the treatment area, passing a bio-magnetic energy between them. The source of biomagnetic energy in the body is not clearly understood. Moga⁵ recorded magnetic field activity from practitioners of healing touch during real and mock healing therapy sessions. The recorded magnetic field was extremely low during mock therapy sessions but increased to more than 1.0 milligauss during real treatment sessions. Moga attributed the variations in recorded

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magnetic fields to changes in the practitioner's inner feelings and emotions during therapy sessions. Seto et al.⁶ also recorded extremely large biomagnetic fields of 2–4 milligauss amplitude with 4- to 10-Hz oscillations from the palms of 3 of 37 *qigong* healers. Because Seto et al. could not detect any electrical current corresponding with such extraordinary large biomagnetic fields, they concluded that biomagnetic field is not a physical quantity like other magnetic fields but rather originates from *qi* energy, which is a “deep force” behind human's observable dimensions.⁶

Biofield energy can be delivered through direct or indirect methods. In the direct model, the practitioner lays hands on the patient over the treatment area.⁷ In the indirect model, the biofield energy is delivered without direct contact between the practitioner's hands and the clients' body.⁷ Biofield energy emitted from the practitioner's hands has a frequency between 0.3 and 30 Hz, with primary activity in the range of 7–8 Hz.³ This range of biofield frequencies is most effective for facilitating bone and soft tissue healing.^{8,9} Trained practitioners can initiate, modify, or stop the flow of biofield energy at will.^{5,6} The practitioner can deliver a constant flow of energy to the body without modifications or can oscillate the delivered energy in a back-and-forth fashion between the two hands.⁴ With oscillating energy, the healer intends to induce an oscillatory motion within the tissue and enhance tissue relaxation and extensibility.⁴

Biofield therapy has previously been used for reducing pain and discomfort in patients with cancer,^{7,10} chronic pain,¹¹ and fatigue and anxiety,¹² as well as for improving general health.³ Other investigators have also shown its positive effects on biological factors, such as hemoglobin and hematocrit level,¹³ immunologic factors,¹⁴ vital signs,¹⁵ healing rate of wounds,¹⁶ and arterial blood flow in the lower extremities.¹⁷ Additionally, biofield therapy has been used as a viable and effective treatment for osteoarthritis¹⁸ and other musculoskeletal conditions. A randomized, double-blinded, placebo-controlled study using oscillatory biofield therapy (OBFT) showed a significant lessening of pain and improvement in functional activities in patients with chronic lateral epicondylitis.¹⁹

However, Blankfield and colleagues' randomized clinical trial² showed that constant flow of biofield energy (therapeutic touch) was not any better than placebo treatment for symptoms of carpal tunnel syndrome (CTS). Considering frequency-specific effects of biofield energy on tissue healing,^{8,9} OBFT might be more effective for improving somatic dysfunction than treatments that use a constant flow of energy. OBFT is defined as a delivery of biomagnetic field that is intentionally oscillated between the practitioner's hands, in an alternate and back-and-forth fashion, through the treated structure.⁴

Although there is no validated scientific explanation for the mechanism of OBFT, it is speculated that oscillating biofield energy may induce a similar physiological effect as mechanical oscillation applied to a tissue. A series of *in vitro* and *in vivo* studies demonstrated positive effects of mechanical oscillatory motions on improving tissue extensibility,^{20,21} decreasing inflammatory response,²² and enhancing tissue vascularity.²³ The symptoms of CTS could be due to impaired blood flow to the median nerve²⁴ or to compression of the nerve under the transverse carpal ligament.²⁵ Therefore, it is speculated that OBFT could improve symptoms of CTS by enhancing blood flow to the hand and increasing extensibility of the transverse carpal ligament.

The purpose of the present study was to determine the effect of OBFT on improving symptoms of chronic CTS. It is hypothesized that oscillatory biofield therapy could improve pain, paresthesia, and functional impairments of the hand in patients with chronic CTS.

Materials and Methods

Participants

Sixty individuals with wrist and hand pain who responded to the advertisement placed in a local newspaper were screened for symptoms of CTS. From these respondents, 30 persons who had a positive history of numbness and tingling in the thumb, index, and middle fingers of the hand²⁶ and positivity for the Phalen test and Tinel sign^{26,27} were selected. Most participants had previously been diagnosed with CTS; had had symptoms of CTS for at least 1 year before this study; and reported having previous unsuccessful treatments, such as wearing wrist braces or receiving steroid injections. No participants had received treatments for their symptoms at least 3 months before or during the 2-week study period. On the basis of the patient's history and performance of objective physical therapy assessments, individuals with cervical pain, shoulder or elbow pain, thoracic outlet syndrome, diabetes, arthritis, systemic peripheral neuropathies, thyroid disease, or wrist trauma; history of wrist surgery; or current pregnancy were excluded.

Sample size calculation

The following formula was used for power analysis²⁸ to determine the required sample size for this study:

$$n = \frac{(r + 1)(Z_{\alpha/2} + Z_{1-\beta})^2 \sigma^2}{rd^2}$$

Z_{α} is the level of significance (Z_{α} is 1.96 for 5% level of significance); $Z_{1-\beta}$ is the power (0.84 at 80% power). $r = n_1/n_2$ is the ratio of sample size required for 2 groups ($r = 1$ for equal sample size between the two groups); σ is the pooled standard deviation; and d is the effect size (difference of means between the 2 groups). Previously reported data were used for the effect of oscillatory biofield therapy on pain with activity in patients with lateral epicondylitis¹⁹ for power analysis. From that study, the obtained standard deviation ($\sigma = 2.8$) and the effect size, calculated by subtracting post-test value for mean improvement in pain with activity (8.5 points) from the pretest value (5.2 points), were used for sample size calculation:

$$n = \frac{(1 + 1)(1.96 + 0.84)^2 2.8^2}{1(8.5 - 5.2)^2} = 11.3$$

To have a power of 0.80, a minimum of 11 participants were needed in each group.

Study design and randomization process

This study used a randomized, double-blinded, placebo-controlled experimental design. All real and placebo OBFT treatments were performed by an orthopedic clinical specialist trained in biofield and craniosacral therapy (treating

FIG. 1. Randomization chart.

therapist); all the pre- and postexaminations and measurements were performed by other therapists (assessing therapist). After the initial assessment, persons who met the inclusion criteria were asked to draw a coded card to be randomly assigned into the treatment or placebo group. The code was documented on the participant's record for data analysis. Only the treating therapist was aware of code for participants' group assignment. Participants and the assessing therapists were blinded to the group assignment until the conclusion of post-treatment data collection. The randomization flow chart is presented in Figure 1.

Examination procedure

Each participant signed an informed consent form, approved by the Institutional Review Board of University of North Georgia, before participating in this study.

The following instruments were used for sensory and functional assessments:

1. An 11-point numerical rating scale was used to quantify intensity of pain with activity as well as level of night pain.
2. A Jamar Hand Dynamometer was used to measure grip strength in the affected arm.²⁹
3. The B&L Pinch Gauge was used to assess lateral pinch strength.³⁰

4. The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire was used to measure changes in participants' upper-extremity functional abilities.^{31,32}
5. The Levine outcome assessment questionnaire³³ was used for measuring changes in functional abilities of the patients. This questionnaire, which is specifically designed for functional assessment of individuals with CTS, has two separate sections: Symptom Severity Scale (SSS) and Functional Status Scale (FSS).³³
6. Semmes-Weinstein monofilaments, with a reported sensitivity of 83% and specificity of 76%, were used for assessing cutaneous sensation.^{26,34} During this test, while the patient was seated, the patient's eyes were closed. Starting with the lowest scale filament for normal sensation (4.86), the filament was pressed perpendicularly to the tip of the thumb, index, and middle fingers until the filament was slightly bent. Progressively larger-scale filaments were used until the patient felt the pressure applied to each fingertip. The average gram-force of pressure recorded for the three fingers was used for data analysis.
7. A Baseline Two-point Aesthesiometer was used to test sensitivity of two-point discrimination sense in the area of median nerve distribution.³⁵ Two-point discrimination assessment has a low sensitivity of 24% but a high specificity of 95% for diagnostic evaluation of cutaneous intervention.³⁶

Treatment Procedure: OBFT

OBFT was administered to the transverse carpal ligament and along the length of the radial artery at the wrist. Participants in both treatment and control groups were told that because of the subtle nature of the treatment, they may not feel the energy delivered to their hand.

To administer OBFT to the transverse carpal ligament, participants were comfortably seated on a chair with their involved arm rested on a treatment table. The treating therapist bracketed the attachments of the transverse carpal ligament by placing one hand over the scaphoid and the other hand over the hamate bone at the wrist (Fig. 2A). After proper hand placement, the therapist applied biofield energy along an imaginary line through the length of the transverse carpal ligament with intention to treat.^{2,13,19,37} Upon starting the OBFT, the therapist sensed the flow of energy by feeling warmth, heaviness, and tingling in his hands and felt the rhythmic, back-and-forth oscillation of energy between his hands. The same treatment was then applied to the cross-section of transverse carpal ligament by placing his hands over the upper and lower edges of the transverse carpal ligament (Fig. 2B).

After treatment for the transverse carpal ligament, OBFT was applied along the radial artery at the wrist joint. The therapist palpated the radial pulse, then placed one hand inferiorly over the thenar prominence and the other hand superiorly over the distal part of the radius bone. Then OBFT was administered longitudinally along the bracketed segment of the radial artery at the wrist joint (Fig. 2C). Each treatment session lasted between 20 and 30 minutes. All participants received six treatment sessions in a 2-week period. The post-test data were collected the day after the final session of OBFT.

FIG. 2. Hand placement and direction of oscillating biofield therapy (OBFT) application across the carpal tunnel area. (A) Hand placement and direction of OBFT application along the length of the transverse ligament. (B) Hand placement and direction of OBFT application across the width of the transverse ligament. (C) Hand placement and direction of OBFT application along the radial artery. Note: Arrows show direction of biofield treatment applied to the underneath structure.

Placebo OBFT

Participants in the placebo group underwent the same hand placement procedure as the treatment group. However, the therapist deliberately stopped and prevented flow of energy to the patient's hand by having no intention to provide therapy² and by diverting his attention from treatment by performing

mental calculations. It has been demonstrated that trained biofield therapists have the ability to divert, start, and stop the flow of energy from their hands at will.^{5,6} During the placebo treatment sessions the therapist did not feel the warmth, heaviness, tingling, and rhythmic flow of energy between his hands as he did during the real treatment sessions. Similar procedure was followed for performing placebo treatment over the radial artery at the wrist joint. We acknowledge that some unintended biofield energy still could have transferred from the practitioner's hands to the patient's wrist during the placebo treatments. Lack of intention to treat plays a critical role in the effect of biofield therapy,³⁸ which can severely diminish the therapeutic effect of such inadvertently transmitted energy to the patient. Participants in the placebo group had the same number of treatment sessions as those in the treatment group.

Statistical analysis

Two-way multivariate analysis of variance was used for assessing equality of baseline measures (pretest values) and for comparing treatment effect between the two groups. Treatment effect, defined as improvement, was determined for each variable by subtracting posttest from pretest measurements. A paired *t*-test was used to assess within-group improvement for all variables. Chi-square analysis was used to compare the number of participants with paresthesia, positivity for the Tinel sign, and positivity for the Phalen test between the two groups after treatment. IBM SPSS Statistics software (Version 22.0. Armonk, NY: IBM Corp.) was used for data analysis.

Results

Sample size, participant selection, and equality of baseline assessment

Thirty participants age 21–71 years participated in this study. Descriptive statistics for the treatment and placebo groups are presented in Table 1. Figure 3 presents the baseline measures for all variables between the two groups. There was no statistically significant difference in the baseline measures between the treatment and placebo groups ($p \geq 0.05$).

TABLE 1. CHARACTERISTICS OF PARTICIPANTS

Variable	Treatment group	Placebo group
Mean age (yr)	49.6 ± 15.77	48.0 ± 9.87
Sex (n)		
Male	6	2
Female	9	13
Affected side (n)		
Right	10	9
Left	5	6
Mean duration of symptoms (mo)	26.1 ± 12.6	23.1 ± 11.6
Patients with previous unsuccessful treatments (n)	11	12
Patients with medical diagnosis of CTS before study (n)	13	12

Values with a plus/minus sign are the mean ± standard deviation. CTS, carpal tunnel syndrome.

FIG. 3. Comparison of baseline measurements of all variables between treatment and placebo groups. No statistically significant difference was found in baseline measurements for all variables between the treatment and placebo groups. DASH, Disabilities of the Arm, Shoulder and Hand; SE, standard error.

*Effect of OBFT on measured variables:
within-group and between-group comparisons*

Table 2 presents changes in each variable within the treatment and placebo groups. In the treatment group, there were statistically significant changes between the pretest and post-test measurements in intensity of pain with activity ($p=0.0001$), night pain ($p=0.0001$), DASH questionnaire ($p=0.0001$), SSS ($p=0.0001$), and FSS ($p=0.0001$). A positive trend of non-statistically significant ($p>0.05$) improvement was found in grip strength, pinch strength, monofilament sensory assessment, and two-point discrimination in the treatment group only. In the placebo group, changes between the pre- and post-treatment measurements

were not statistically significant for any of the variables (Table 2).

For between-group assessments, the amount of improvement in each variable between the two groups was compared (Fig. 4). Statistically significant improvements were found in intensity of pain with activity (95% confidence interval [CI], 2.5–4.2; $p=0.000$), night pain (95% CI, 3.2–5.7; $p=0.000$), DASH questionnaire outcome (95% CI, 12.0–21.9; $p=0.000$), SSS (95% CI, 0.64–1.15; $p=0.003$), and FSS (95% CI, 0.41–0.97; $p=0.029$) compared with the placebo groups. A fairly strong power (0.6–1.0) was observed for the variables that showed a statistically significant difference between the groups (Table 2). Figure 5 presents two sample scatter plots for

TABLE 2. COMPARISON OF WITHIN-GROUP EFFECTS BETWEEN TREATMENT AND PLACEBO GROUPS

Variable	Treatment group			Placebo group		
	Pretest	Post-test	p-Value	Pretest	Post-test	p-Value
DASH questionnaire	30.7 ± 3.8	13.7 ± 2.84	0.0001	31.5 ± 3.9	29.0 ± 3.45	0.06
Night pain	5.1 ± 0.67	0.86 ± 0.40	0.0001	4.5 ± 0.68	3.7 ± 0.73	0.17
Pain intensity	4.1 ± 0.43	0.8 ± 0.32	0.0001	4.2 ± 0.14	4.8 ± 0.39	0.10
Symptom Severity Scale	2.6 ± 0.15	1.66 ± 0.13	0.0001	2.6 ± 0.17	2.36 ± 0.1	0.09
Functional Status Scale	2.1 ± 0.17	1.46 ± 0.11	0.0001	2.0 ± 0.16	1.7 ± 0.13	0.07
Grip strength	64.3 ± 6.1	67.5 ± 6.0	0.13	53.3 ± 6.7	54.9 ± 6.17	0.33
2-point discrimination	7.7 ± 1.5	5.0 ± 0.51	0.07	6.72 ± 0.6	6.65 ± 0.57	0.91
Monofilament test	0.96 ± 0.3	0.54 ± 0.12	0.14	0.82 ± 0.2	0.86 ± 0.20	0.72
Pinch strength	14.1 ± 1.4	15.0 ± 1.35	0.25	11.5 ± 1.0	11.8 ± 1.0	0.37

Unless otherwise noted, values are expressed as mean ± standard error.
DASH, Disabilities of the Arm, Shoulder and Hand.

FIG. 4. Comparison of post-treatment improvement in all variables between treatment and placebo groups. This figure presents the mean improvement (difference between pretest and post-test measures) between the treatment and placebo groups. *Statistically significant ($p < 0.05$).

level of individual improvement in DASH questionnaire and pain intensity with activity.

To determine the relative effects of OBFT on skin sensation, participants in the treatment group were categorized as “improved” or “not improved.” Participants who had more than 50% increase in gram-force sensation, measured through Semmes-Weinstein monofilament assessment, were classified as “improved.” Those with less than 50% change in gram-force skin sensation were categorized as “not improved.” The number needed to treat (NNT) was calculated according to the method described by Portney and Watkins.³⁹ Results showed an NNT of 2.33 for the effect of OBFT on skin sensation.

Chi-square analysis was used to compare the proportion of individuals who had negativity for the Tinel sign, Phalen test, and paresthesia after treatment between the two groups. In the treatment group, 87% of the participants had a negative result for the Phalen test ($p=0.000$), 80% had no paresthesia ($p=0.000$), and 73% had negativity for the Tinel sign ($p=0.000$). In the placebo group, except for one patient who had a negative result for the Tinel sign, there were no changes in the number of participants with positive Phalen test result or with paresthesia (Table 3).

Follow-up data analysis

Six-month follow-up data were collected from the patients in the treatment group. Not all participants were available for in-person assessment. Therefore, follow-up phone interviews were conducted with all participants in the treatment group, except for one who could not be located. Patients were asked if they had any experienced any of the

following two symptoms: (1) night pain, tingling (paresthesia), or pain with activity and (2) difficulty performing daily functional activities. They were also asked if they were satisfied with the outcome of their treatment and if they had any other form of treatments during the past 6 months. Subjective self-reported data for pain level, functional activity, paresthesia, and overall satisfaction with the treatment were collected. Objective examinations of cutaneous sensation and grip and pinch strength and outcome measures questionnaires were not performed during the follow-up assessments. Twelve of the 14 contacted participants (86%) remained pain free and had no night pain or paresthesia after OBFT treatment. One patient (7%), although reporting no pain, reported having minimal numbness and paresthesia after manual work. These 13 participants (93% of treated participants) were satisfied with their treatment and did not pursue any further medical care. One patient (7%) still had same level of pain and paresthesia in his hand and was considering surgical interventions at the time of follow-up assessment.

Discussion

In this study, different outcomes were obtained for the effect of OBFT on symptoms of CTS. The primary outcomes were related to changes in pain, paresthesia, and functional activities, which showed both statistically and clinically significant improvement in the 2-week OBFT period. Secondary outcomes were related to changes in cutaneous sensation and grip strength, which showed some improvement but perhaps needed more time to reach a level of statistical significance.

FIG. 5. Scatter diagram for DASH questionnaire and intensity of pain with activity. All patients in the treatment group showed improvement in DASH score and intensity of pain with activity as compared with individuals in the placebo group.

TABLE 3. COMPARISON OF TREATMENT EFFECT ON RATE OF POSITIVE SPECIAL TESTS FOR CTS BETWEEN TREATMENT AND PLACEBO GROUPS

Special tests for CTS	Treatment group		Placebo group		p-Value (chi-square analysis)
	Negative	Positive	Negative	Positive	
Phalen test	13	2	0	15	0.000
Paresthesia	12	3	0	15	0.000
Tinel sign	11	4	1	14	0.000

Primary outcomes

The results of this randomized study showed statistically and clinically significant improvement in intensity of pain with activity, night pain, paresthesia, functional outcome, and increased number of participants with negative results on special tests for CTS in patients who were treated with OBFT compared with those who received placebo treatment.

Effect of OBFT on night pain and pain with activity. There was an 83% (4.24 points; $p=0.0001$) decrease in night pain and an 80% (3.3 points; $p=0.0001$) reduction in intensity of pain with activity in the treatment group. A minimum of 1.3 points decrease in the numeric rating scale or 25% reduction in pain is considered a minimal clinically important difference (MCID) for pain intensity.^{40,41} Findings of this study, therefore, suggest that OBFT could produce clinically meaningful improvement in pain associated with chronic CTS. These findings agree with those of other clinical trials.^{7,10,11} A comprehensive systematic review⁴² also showed a strong evidence for the effect of biofield therapy on reducing pain associated with various chronic pathologies. The findings of this study, however, conflict with those of another randomized controlled trial on the effect of constant flow of biofield energy (therapeutic touch) on nerve conduction velocity (NCV), pain level, and relaxation index in patients with CTS.² Many methodologic and procedural differences can explain these contradictory findings.

In the aforementioned study, the authors did not control for presence of systemic disorders, which could affect wrist and hand pain. Participants with wrist arthritis, rheumatoid arthritis, diabetes, thyroid diseases, or a history of surgery for CTS were included. That study used a crossover design, which allowed participants who received placebo treatment for 6 weeks to cross over to the treatment group. Not excluding individuals with systemic disorders and sharing of participants between treatment and placebo groups are serious limitations that could have negatively affected the findings of that study. Additionally, those authors mainly relied on NCV assessment and did not perform any clinical evaluation or special tests for diagnosing CTS or use any outcome assessment tool for measuring patient progress. Many investigators, however, believe that use of clinical symptoms, outcome measure tools, and special tests are more reliable means, compared with NCV, for diagnosing and monitoring treatment effect in patients with CTS.^{26,43} In this study, in addition to pain assessment, three special tests for diagnosis of CTS were conducted and three reliable outcome assessment tools were used for evaluating patient's symptoms before and after OBFT.

Effect of OBFT on functional activity. In this study, participants in the treatment group demonstrated both statistically and clinically significant improvements in functional activities measured by the DASH questionnaire (17 points), SSS (0.94 points), and FSS (0.64 points) (Table 2). Similar ranges of improvement in SSS and FSS have been reported for the effect of steroid injection,⁴⁴ massage,⁴⁵ or oscillatory neuromobilization⁴⁶ on the symptoms of CTS. Previous studies have found an MCID of 10 points⁴⁷ to 15 points⁴⁸ decrease in the DASH score for surgical interventions, an

MCID of 1.04 point for the effect of steroid injection,⁴⁴ and a median decrease in SSS between 0.58 and 1.16 points and a median decrease in FSS between 0.46 and 0.74 points for the effect of various injection strategies on CTS.⁴⁹ Considering the current findings of 17-point improvement in DASH score, 0.94-point decrease in SSS, median decreases of 0.82 and 0.51 for SSS and FSS, respectively, one might speculate that OBFT could be as effective as other invasive treatments for improving hand and wrist function in patients with CTS.

Effect of OBFT on paresthesia. Contrary to the results of the study by Blankfield et al.,² which showed no improvement in median nerve function with therapeutic touch, the results of this study indicate that 80% of the participants who received OBFT had no hand paresthesia or tingling after OBFT (Table 3). Blankfield and colleagues² mainly relied on assessing changes in NCV with therapeutic touch. However, many authors believe that electrodiagnostic measurement has a limited role in predicting the outcome of treatment for CTS^{50–52} and that it does not add any diagnostic value to clinical findings, such as positive history and special clinical tests for diagnosis of CTS.⁵³ In this study, instead of using NCV test, changes in cutaneous sensation were measured with Semmes-Weinstein monofilaments, which have validity similar to that of NCV assessment²⁶ and higher correlation with changes in symptoms of CTS.²⁶

Secondary outcomes

In this study, participants who received OBFT showed a 56%, not statistically significant, improvement in monofilament sensation (pretest, 0.96 g; post-test, 0.54 g) compared with almost no changes in cutaneous sensation in the placebo group (Table 2). For Semmes-Weinstein monofilament assessments, feeling a minimum of 0.16, 0.40, and 0.6–2.0 g of pressure is considered normal cutaneous sensation, diminished light touch, and diminished protective sensation, respectively.^{26,54} The level of change in cutaneous sensation, found in this study, indicate that participants in the treatment group had a meaningful improvement from being in the unsafe “diminished protective sensation” (feeling 0.96 g of pressure) category to a safer “diminished light touch” (feeling 0.54 g of pressure) category. Moreover, the finding of an NNT of 2.33 for OBFT indicates that almost 43%, or 1 of every 2.3 individuals with CTS treated with OBFT, will show at least 50% improvement in monofilament skin sensation compared with those in the control group.

These findings suggest that OBFT can be effective for improving skin sensation. However, the 2-week treatment period perhaps was not long enough to allow detection of larger statistically and clinically significant changes in cutaneous sensation. Blankfield and colleagues² also reported similar nonsignificant improvement in motor nerve distal latencies for the median nerve in both treatment and placebo groups. They attributed improved latencies in the placebo group to the effect of the practitioner's hand temperature or to the effect of inadvertently emitted biofield energy from the practitioner's hands on the nerve function. If this notion is true, then, in this study, the slight improvements noted in some of the variables in the placebo group (Table 2) also can be attributed to unintentional flow of constant biofield

energy from the practitioner's hands to the patient. Because patients in the treatment group, who received OBFT with intention to treat, showed larger statistically and clinically significant improvements compared with those in the placebo group, who might have had unintentional constant biofield energy, one can speculate that intentional OBFT is more effective than unintentional constant flow of energy from a practitioner's hands.

Speculated mechanism for the effects of OBFT. Biomedical researchers advocate use of oscillatory and frequency-specific biofield energy as a key element for regulating biologic function and enhancing rate of healing in a tissue.^{8,37} There is a lack of scientific explanation for the mechanism of effect of OBFT; however, there is scientific evidence for similar effects with application of mechanical oscillatory motion to the tissue. It has been shown that application of low-load cyclic motion to the strained tissue in humans can normalize cell alignment,²¹ enhance tissue extensibility,^{20,22} decrease arterial peripheral resistance,¹⁷ and enhance blood flow to the tissue.^{23,55} On the basis of these findings, one can speculate that oscillatory motion induced with OBFT across the transverse ligament and along the radial artery at the wrist could have induced similar effects as the mechanical oscillation on increasing the extensibility of the transverse ligament and increasing circulation to the hand, and that it led to improved symptoms in participants with chronic CTS.

Study limitations

Although the participants in this study had had chronic CTS for more than 1 year, variation in the onset time, severity of symptom, and number of participants with previous unsuccessful treatment in each group could have led to different results between groups.

Conclusions

The results of this study indicate that OBFT can be used as a viable, effective, and efficient treatment for reducing pain and paresthesia and improving functional abilities in patients with chronic CTS. Alternative treatments, readily available, can provide similar results to more invasive treatments.

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