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Original Research Article

Efficacy of Vibrating Gloves for Chronic Hand Pain due to Osteoarthritis

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Abstract

Objective. This study investigated the efficacy of vibration technology for women with hand pain due to osteoarthritis (OA) to see if mild compression and small vibrating motors were beneficial with periodic use.

Methods. Sixty-nine (N = 69) women with OA hand pain were randomized into two groups, one that used vibrating gloves once a day for 20 minutes (Experimental, N = 34) and one that was monitored for three months without gloves (Control, N = 35). All subjects completed baseline questionnaires, were administered mechanical quantitative sensory testing (QST), and uploaded a smartphone pain app for daily assessment. Patients were included if they had chronic pain for more than three months, reported a 4 or higher on a 0–10 pain intensity scale, and could speak and understand English.

Results. In general, compared with the control subjects, those in the experimental condition demonstrated reduced pain intensity ($P < 0.05$) after using the vibrating gloves. No differences were found between groups on activity interference, mood, or sleep. No differences were also noted based on age, pain duration, hand dominance, weight, body mass index, or hours sleeping. Those with greater sensitivity on QST demonstrated more disability, emotional distress, and pain catastrophizing ($P < 0.05$) but no differences in pain relief from or satisfaction with the vibrating gloves.

Discussion. Overall, the results demonstrated that the vibrating gloves were moderately helpful in reducing hand pain in women with OA (53.5%), and most expressed willingness to use the gloves (71.4%) and use the pain app (55.8%) in the future. Additional studies to determine the mechanism of action of the gloves in managing pain would be recommended.

Key Words. Osteoarthritis; Hand Pain; Vibration; Quantitative Sensory Testing; QST; Pain App; Gloves

Introduction

It is well known that vibration can decrease pain based on experimental studies among both healthy subjects and persons with neurogenic and musculoskeletal pain [1,2]. Cutaneous vibration designed to reduce both clinical and experimental pain has been called vibratory analgesia [3]. Although the primary mechanism for vibratory analgesia has not been definitively established, proposed theories to explain this effect in pain (both experimental and clinical) have included selective attention and distraction [4], diffuse noxious inhibitory controls (DNICs) [5], lateral inhibition within the spinal cord [6], and stimulation of coinciding cortical coding areas involved with pain and touch in the brain [7–9].

There has been a gradual increase in the number of older people as a percentage of the global population, and with age comes many chronic health conditions that have chronic pain as a component of their disorder [10,11]. Primary among these conditions are rheumatoid and osteoarthritis. They are inflammatory conditions often associated with chronic pain. The incidence of

osteoarthritis (OA) is 10 times greater than rheumatoid arthritis (RA) [12]. The pathophysiology of osteoarthritis (OA) pain is complex and multifactorial, with contributions of peripheral factors such as synovial inflammation and mechanical stresses on joint structures, as well as central and peripheral nervous system pathoplasticity. There are also fewer accepted treatments for OA pain compared with RA pain, and often, in extreme cases, the solution is surgery [13]. Similar to other chronic pain conditions, there is broad interpatient variability in OA pain. A review article by Wang and others [14] examined the effects of whole-body vibration on pain, stiffness, and physical function in older adults with knee OA. They concluded that whole-body vibration is beneficial in improving physical function in these patients but that whole-body vibration did not have a significant effect in reducing pain or stiffness. Rabini and colleagues [15] examined the effect of focal muscle vibration (FMV) in patients age 60 years and older with knee osteoarthritis. Results showed that FMV improved the mobility of those subjects who were assigned to receive this treatment compared with a placebo control group. To date, no controlled trials have examined the benefit of vibration on OA hand pain.

There are several commercially available medical devices that are designed to reduce painful symptoms and to enhance movement. Recently, vibrating gloves that were developed specifically to reduce hand pain and joint discomfort due to arthritis have been made available (www.brownmed.com) (Figure 1). These gloves, made of cotton material, were created to offer mild compression and to utilize small rechargeable battery-operated vibrating motors that serve to massage the hands when worn to help individuals with persistent hand pain. The gloves anecdotally reduce pain after periodic use, although no controlled study has been undertaken to demonstrate this effect (https://www.brownmed.com/product/intellinetix/vibrating-gloves/). This study was designed to examine the benefit of vibrating gloves among individuals with OA hand pain.

In psychophysical studies, individuals reporting persistent OA-related pain are characterized by enhanced pain sensitivity on quantitative sensory testing (QST), which refers to a set of psychophysical methods used to quantify somatosensory function [16] and frequently used to assess arthritis-related pain [17]. QST has been used for decades in a variety of research settings, often for the purpose of diagnosing and monitoring sensory neuropathies and pain disorders, as well as for the investigation of pain mechanisms, the characterization of somatosensory profiles in various pain disorders, and the elucidation of individual differences in pain sensitivity and pain modulation [16].

This proposed study was designed for patients with primary OA hand pain. The overall aim of the study was to determine the effect of vibrating gloves (using Intellinetix technology; https://www.brownmed.com/product/intellinetix/vibrating-gloves/) to manage hand pain due to OA compared with no gloves. We decided to limit this preliminary study to only women as they report a higher incidence of OA hand pain

Figure 1 The vibrating gloves.

compared with men [13]. We employed objective mechanical QST measures to assess pain intensity and tracked each of the subjects using a smartphone pain app. A secondary goal was to help understand individual differences in response to using the gloves and to identify specific demographic factors (e.g., age, pain duration, physical function) that could contribute the most to the benefit of these interventions for painful symptoms among individuals diagnosed with hand OA. We hypothesized that those assigned to using the gloves would report reduced pain compared with those in the control condition, with those using the vibrating glove more often showing greatest benefit. We also hypothesized that the gloves would be safe to use without any adverse effects. Finally, we planned to investigate whether certain individuals reported greater benefit from using the gloves than others and to gain some understanding of the mechanism of action of vibration analgesia. In particular, we predicted that older women with more intense and longer duration of pain would demonstrate the most benefit and that vibrating gloves would have little effect on other pain sites.

Methods

The Human Subjects Committee of Brigham and Women's Hospital (BWH) approved the study procedures, and written informed consent was obtained from

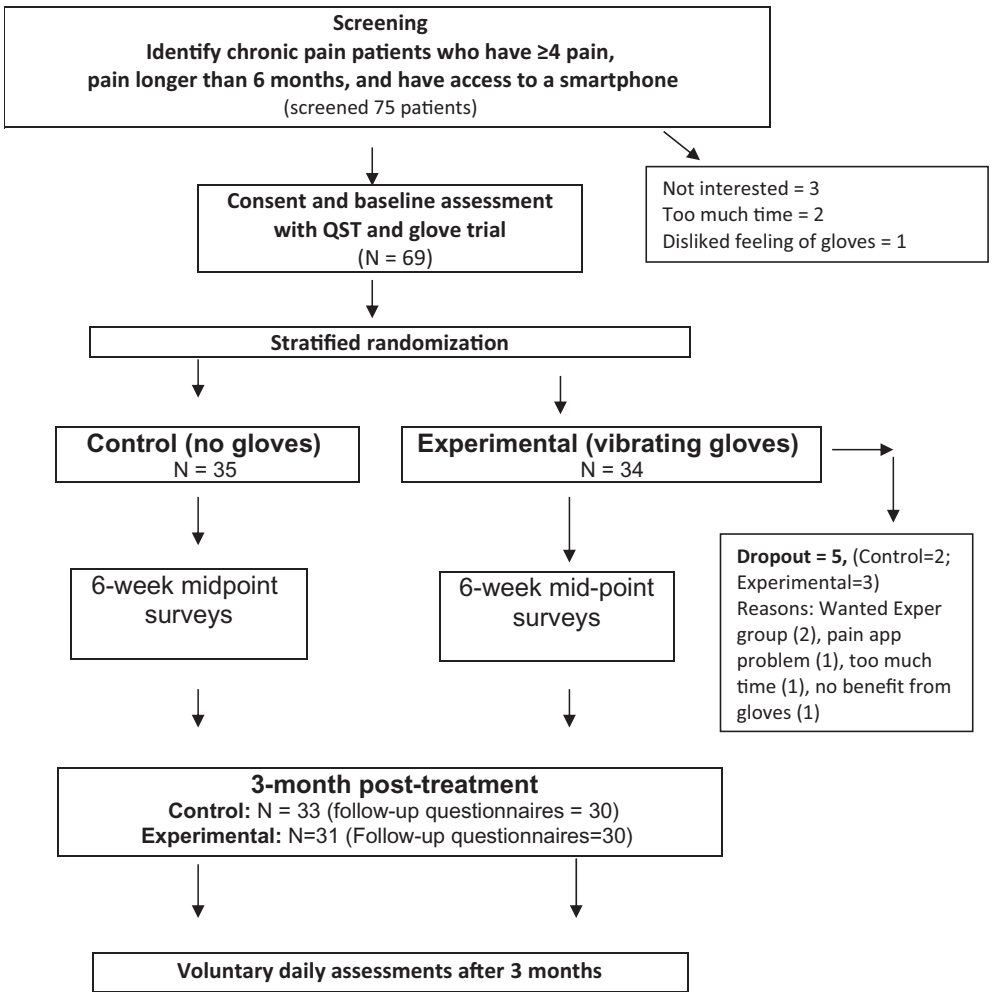

Figure 2 Study schema and CONSORT diagram.

every participant. Female volunteers with hand pain related to osteoarthritis were recruited and randomized to one of two treatment conditions: 1) Experimental group of vibrating gloves or 2) the Control group with treatment as usual (Figure 2). All participants were adults, age 21 years or older, and diagnosed with OA hand pain. Potential subjects were initially identified through the hospital electronic medical system, and verification of OA hand pain was obtained based on each subject's medical record notes. Interested subjects contacted the research assistant assigned to this study in response to a mailed brochure describing a study for persons diagnosed with OA hand pain. Patients were invited to participate if they owned a smartphone phone (iPhone or Android device) and were able to download the pain app program onto their device. Patients were also included if they 1) had chronic pain of more than three months' duration, 2) averaged 4 or greater on a pain intensity scale of 0 to 10, and 3) could speak and understand English.

All subjects completed assessment measures at baseline and were followed for three months. Recruitment was not restricted based on race or ethnicity. After signing an informed consent form, all participants were administered mechanical QST testing at baseline [18,19]. We used an enriched design by having the potential subjects try on the vibrating gloves. If they found that they would like to use the gloves, they were included in the study. If they disliked using the gloves on the initial trial, their age, ethnicity, and pain duration were noted and the participants were thanked for their interest in the study and dismissed.

A smartphone pain app developed and implemented by our center for iPhone and Android devices was included in this study to capture self-reported demographic, medical, and daily assessment data (Figure 3) [20,21]. The subjects were given assistance in downloading the pain app by a research assistant (RA) who answered questions and helped to manage any problems that the individuals encountered. The app included push notification reminders to complete daily assessments. It also had two-way messaging to connect with the RA if any issues arose related to the study. The smartphone pain

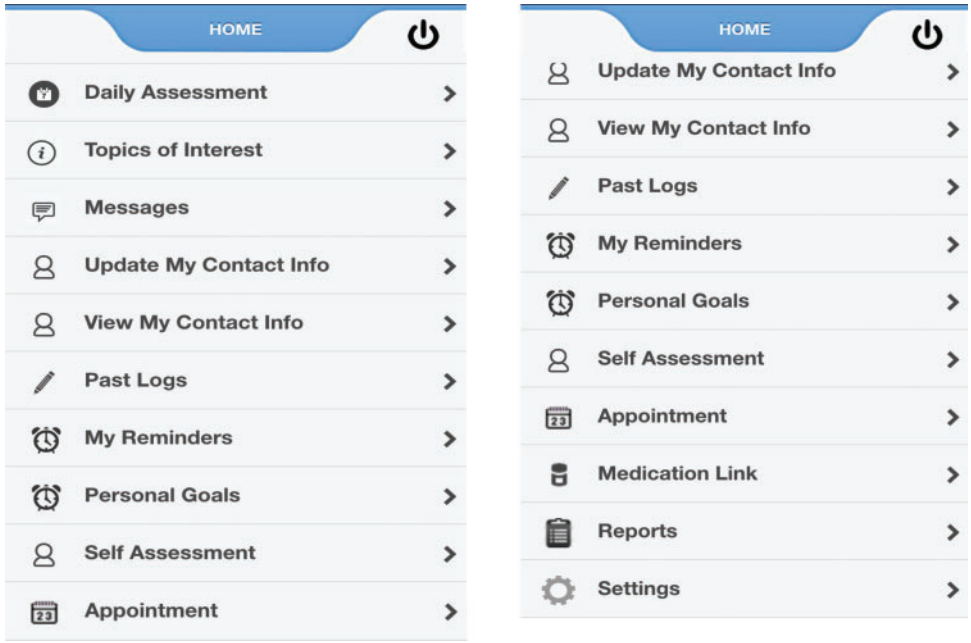

Figure 3 Pain app home page with links when scrolled down.

app was developed as an assessment and communication program to provide improved care for patients who suffer from chronic pain. The users were asked to answer five questions each day: 1) Over the past 24 hours, what has been your average pain (1 = least;10 = worst)?; 2) How much has your pain interfered with your daily activities?; 3) How much has your pain interfered with your sleep?; 4) How depressed and anxious have you been?; and 5) How much have things changed (1 = better; 5 = same; 10 = worst) (Figure 4)? The smartphone pain app was used to monitor the subjects' progress each day over the three-month trial.

Patients assigned to the Experimental group (vibrating gloves) were encouraged to use the gloves at least 20 minutes every day and to enter daily reports of how long they used the gloves through the two-way messaging of the pain app. All data were stored on a secure server (Veracode tested), and messages were sent via the two-way messaging pain app program to help track use of the gloves. Patients who wished to discontinue the study could do so at their request. If the participant was willing, she was asked for the reasons for discontinuing the study and whether she would be willing to complete poststudy questionnaires. All subjects were asked to complete midpoint assessments approximately six weeks after the start of the study. All subjects were also asked to complete postintervention assessments after three months. Each subject was compensated $25 at baseline and $50 at study completion. Subjects in the Experimental group could keep their gloves at the end of the study, and those women in the Control group were sent vibrating gloves after they completed the three-month monitoring period. It was expected that 15% of the subjects would drop out before completing the study.

Mechanical Quantitative Sensory Testing

Mechanical pain thresholds were assessed using a Wagner manual pressure algometer (Wagner Force Ten Digital Force Gage; www. wagnerinstruments.com). Pressure pain thresholds (PPThs) were determined twice, bilaterally at the trapezius muscle and both wrists. At each site, mechanical force was applied using a 0.5-cm^2 probe covered with pressure-transducing material; pressure was increased gradually until the subject indicated that the pressure was "first perceived as painful." Participants then underwent an assessment of mechanical temporal summation at the metacarpophalangeal joint of the middle finger using weighted pinprick stimulators (Touch-Test Sensory Evaluator; www.ncmedical.com) developed by the German Research Network [22]. The lowest-force stimulator that produced a sensation of discomfort (128 or 256 mN for most subjects) was used to apply a train of 10 stimuli to the skin on the dorsum of the hand at the rate of one per second. Participants rated the painfulness of the first, fifth, and tenth stimuli; mechanical temporal summation was defined as the increase in pain from the first stimulus to the final stimulus. These procedures are similar to those we have utilized in prior studies of patients with OA and other chronic pain conditions [23,24].

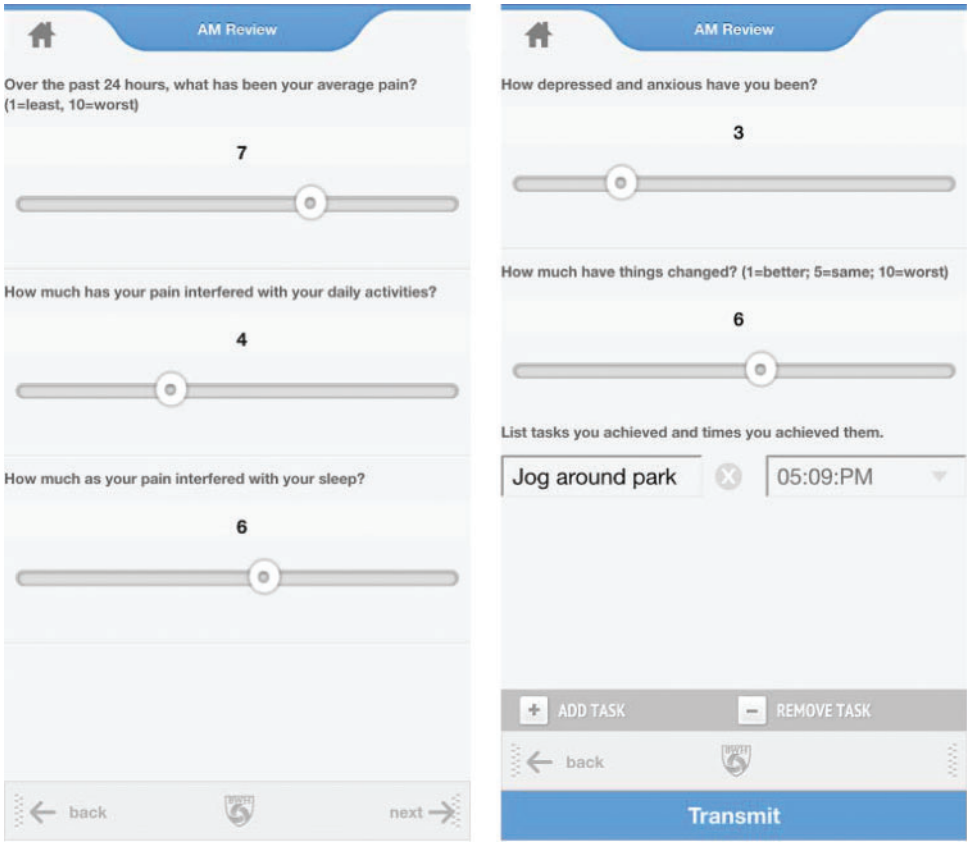

Figure 4 Pain app daily ratings screens.

Patient Measures

A packet of study measures was completed at the time of recruitment, and follow-up questionnaires were mailed to the subjects with a self-addressed stamped envelope so that they could be completed and returned. We documented any reported safety issues and determined outcome efficacy through standardized pre-post measures. The following measures were administered to all study participants at baseline, six-week midpoint, and three-month follow-up time points.

The Brief Pain Inventory

The Brief Pain Inventory (BPI) [25], a self-report questionnaire formerly known as the Wisconsin Brief Pain Questionnaire [26], is a well-known measure of clinical pain and has shown sufficient reliability and validity. This questionnaire provides information about pain history, intensity, and location as well as the degree to which the pain interferes with daily activities, mood, and enjoyment of life. Scales (rated from 0 to 10) indicate the intensity of pain in general, at its worst, at its least, average pain, and pain "right now" over the past 24 hours. A figure representing the body is provided for the patient to shade the area corresponding to his or her pain. Test-retest reliability for the BPI reveals correlations of 0.93 for worst pain, 0.78 for usual pain, and 0.59 for pain now.

Pain Catastrophizing Scale

The Pain Catastrophizing Scale (PCS) [27,28] is a 13-item instrument that examines three components of catastrophizing: Rumination, Magnification, and Helplessness. Each item is rated from "not at all" to "all the time" on a 0–4 scale. The PCS is found to predict levels of pain and distress among clinical patients, and scores have been related to thought intrusions. It has good psychometric properties with adequate reliability and validity and is associated with levels of pain, depression, and anxiety.

Pain Disability Inventory

The Pain Disability Inventory (PDI) [29] is a seven-item questionnaire rated from 0 to 10 on level of disability of seven areas of activity interference, including family/home responsibilities, recreation, social activity, occupation, sexual behavior, self-care, and life-supporting behaviors. Each item is rated based on how much the

pain prevents the user from doing what would normally be done. It has shown to have excellent test-retest reliability and validity and is sensitive to high levels of disability.

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) [30,31] is a 14-item scale designed to assess the presence and severity of anxious and depressive symptoms over the past week. Seven items assess anxiety, and seven items measure depression, each coded from 0 to 3 (e.g., not at all to most of the time). The HADS has been used extensively in clinics and has adequate reliability (Cronbach's alpha = 0.83) and validity, with optimal balance between sensitivity and specificity.

Weekly telephone interviews were also conducted. Once a week, all the participants were called and asked to rate the following items on a 0–10 scale: 1) pain now; 2) average level of pain; 3) how much the pain interfered with a) routine daily activities, b) social activities, c) outdoor and recreational activities, d) sleep, e) appetite, and f) ability to work; and 4) how much their pain affected their mood. These interview questions were developed as part of a prior investigation [32]. The participants were also asked if they were taking pain medication (yes/no) and if there was a change in their medication (yes/no). If they stated that changes in their medication were made, these changes were noted. Those in the Experimental group were asked to recall how many days in the past week they wore their gloves and approximately how long they wore their gloves each day. Finally, they were asked if there was anything else they wanted to tell the RA.

At the end of the study, the subjects were mailed the same questionnaires they completed at the start of the trial, and they were asked to complete 14 questions developed for this study to assess the benefit of the vibrating gloves and the smartphone pain app. Similar satisfaction questions had been developed and used in a previous study [32]. On a 0–10 scale, the participants rated 1) how helpful the vibrating gloves were for their hand pain, 2) how helpful the gloves were for other pain sites, 3) how bothersome the gloves were, 4) how easy it was to recharge the gloves, 5) how willing the user was to use the gloves in the future, 6) how many days per week the subject used the gloves, 7) how many minutes, in general, the subjects wore the gloves each time they used them, and 8) whether there were any things about the vibrating gloves that they felt were particularly helpful or harmful. The subjects were also asked questions about their use of the smartphone pain app on a 0–10 scale: 1) how easy was the pain app to use, 2) how useful the daily reminders were, 3) how easy the app was to navigate, 4) how helpful the pain app was in coping with their pain, and 5) how willing they would be to use the pain app in the future. They were also asked if there was anything about the pain app that they would change.

Statistical Analysis

This study was designed to gather data on the feasibility, tolerability, safety, and efficacy of vibrating gloves among persons with chronic hand pain due to osteoarthritis. Analyses were conducted using an intent-to-treat analysis. Differences between groups at baseline were assessed, and univariate and multivariate descriptive analyses were performed on all the dependent variables. Chi-square, *t* tests, and logistic regression analyses were conducted as appropriate. We examined the qualitative responses of the participants in response to their use of the vibrating gloves and the pain app. We also used survival statistics to examine differences in vibrating glove and pain app use over time comparing differences between those assigned to the experimental condition and the control condition. Although there were a limited number of subjects in this trial, repeated measures analysis of variance and preliminary mixed linear models procedures were also conducted as appropriate. The data from this preliminary study were analyzed to gather information about the use and utility of vibrating gloves for persons with chronic OA hand pain.

Results

Seventy-five (N = 75) individuals responded to the research study flyer, and 69 women with osteoarthritis and chronic hand pain were successfully recruited. Of those who were approached but were not consented, three (4.0%) decided not to participate after learning more about the study without giving a cause, two (2.7%) felt that they did not have the time it would take to participate, and one (1.3%) did not like the sensation of using the vibrating gloves after an initial trial. Of the 69 participants who were consented, the average age was 63 years (SD = 7.8 years), and 91% were Caucasian (Table 1). All the subjects reported having multiple pain sites, primarily in the joints of their hands. Their pain duration averaged less than 11 years. Thirty-nine percent (38.8%) fell within the healthy normal weight category, 61.2% were considered overweight (≥25.0 body mass index [BMI]), and of these 34.3% were classified as obese (≥30.0 BMI) [33]. At baseline, 21 (30.4%) participants were taking ibuprofen as well as other medication, and seven subjects (10.1%) were reportedly taking acetaminophen alone for their pain (Table 2). Four (7.8%) subjects were prescribed gabapentin, three (4.3%) were taking oxycodone, three (4.3%) were taking tramadol, one (1.4%) was taking methadone, and one (1.4%) was using medical marijuana. Two of the subjects were unable to download the pain app due to a noncompatible device. Fifty-one (73.9%) of the 69 subjects had Apple iPhones, and 18 (26.1%) of the subjects had Android smartphones. No demographic differences were found between subjects with an iPhone and those with an Android device.

Table 1 Patient demographic characteristics and baseline questions (N = 69)

Variable	Total Sample (N = 69)
Age ± SD (range), y	63.0 ± 7.8 (40–72)
Ethnicity, % Caucasian	91.3
% Hispanic	2.9
% African American	2.9
% Asian	2.9
Pain duration ± SD (range), y	10.8 ± 9.0 (0.5–50)
Hand most painful: % right	47.1
% left	20.6
% both	32.4
Dominant hand, % right	88.2
Average weight ± SD (range), lbs	149.6 ± 36.0 (86–275)
Average BMI ± SD (range), kg/m^2	28.0 ± 7.0 (12.2–52.2)
Average sleep time ± SD (range), h	6.7 ± 1.1 (4–9)
Avg. times wake up during night ± SD	2.2 ± 2.1
% with 6+ hours of sleep	86.5
% take naps during the day	14.9
QST average shoulders ± SD*	8.07 ± 2.18
QST average arms ± SD*	6.76 ± 2.50
QST temporal summation aver ± SD†	0.95 ± 1.41

BMI = body mass index; QST =quantitative sensory testing.
*Average mean scores of eight measures from the pressure algometer: four left and four right.
†Average left and right change scores of 60 seconds minus one second ratings.

Table 2 Patient descriptive characteristics from the pain app assessment at baseline

Variable	Baseline (N = 67)
Pain description (% yes)*	
Aching	95.5
Throbbing	62.7
Stabbing	56.7
Shooting	53.7
Numbing	41.8
Burning	23.9
Pricking	20.9
Pulling	13.4
Activity interference ± SD†	
Outdoor recreat. activity	4.5 ± 2.9
Daily routine activity	4.3 ± 2.5
Ability to work	4.0 ± 3.0
Social activity	2.9 ± 2.6
Sexual activity	1.9 ± 1.7
Appetite	1.7 ± 1.5
Mood‡	
Tense/anxious	2.3 ± 2.0
Depressed	2.4 ± 2.4
Angry/irritable	1.9 ± 1.8
Side effects (% yes)	
Dry mouth	4.5
Constipation	3.0
Dizziness	3.0
Memory lapse	3.0
Confusion	3.0
Itching	3.0
Headache	1.5
Sweating	1.5
Weakness	1.5
Nightmares	0
Sneezing	0
Visual problems	0
Medications	# pts taking
Over the counter	34
Opioids§	6
Antiseizure meds	4
NSAIDS	3
Tranquilizers	2
Muscle relaxants	0

NSAID = nonsteroidal anti-inflammatory drug.
*% checked this word to describe their pain.
†1 = no interference; 10 = extreme interference.
‡1 = none; 10 = extreme.
§Including two patients taking tramadol.

All the subjects were given a link to the pain app ("BWH painapp" on the App Store or Google Play) and were assisted in downloading the program with the RA present or, if time or circumstances did not allow, were instructed in downloading the program remotely by the RA (Figures 3 and 4). They were also encouraged to contact the RA if they encountered difficulties. Sixty-seven (97.1%) of the 69 subjects successfully downloaded the pain app program, and 65 (94.2%) of the subjects submitted daily reports. Over the course of the study, five (7.2%) subjects withdrew from the trial (Figure 2). Two withdrew shortly after being randomized to the Control group. They were both hoping to be in the Experimental group but were assigned to the Control group. One dropped out after being unable to download the pain app onto her smartphone. She had forgotten her Apple password and did not want to contact Apple to get a new password. One subject withdrew because she did not feel any benefit from the gloves, and another withdrew from the study because she felt that the daily phone assessments were too tedious. Six subjects experienced some difficulties in downloading the pain app and needed assistance, two subjects had problems resetting their password, and one had trouble transmitting the daily assessments. Two of the subjects did not submit any daily assessments. The total number of daily assessments from the pain app over three months averaged 60.6 (SD = 29.6;

Table 3 Six-week comparison questionnaire scores between those using the vibrating gloves (N = 28) and controls (no gloves; N = 29)

Variable	Total ± SD (N = 57)	Gloves ± SD (N = 28)	No Gloves ± SD (N = 29)	*P*
Pain intensity: worse	4.9 ± 2.3	4.6 ± 2.3	5.1 ± 2.4	NS
Least	2.3 ± 2.1	2.1 ± 1.7	2.5 ± 2.5	NS
Average	3.8 ± 2.0	3.6 ± 1.7	4.0 ± 2.2	NS
Now	3.7 ± 2.4	3.4 ± 2.0	4.0 ± 2.7	NS
Pain relief %	48.5 ± 28.8	52.0 ± 27.2	39.6 ± 32.7	NS
Interference[†]				
General activity	2.7 ± 2.6	2.8 ± 2.4	2.7 ± 2.8	NS
Mood	2.0 ± 2.5	2.1 ± 2.4	1.9 ± 2.6	NS
Walking ability	1.7 ± 2.7	2.4 ± 2.4	1.0 ± 2.2	t = 2.0*
Normal work	3.0 ± 2.6	3.0 ± 2.4	3.1 ± 2.9	NS
Relations w/ others	1.3 ± 2.1	1.3 ± 1.8	1.4 ± 2.5	NS
Sleep	2.0 ± 2.4	2.1 ± 2.4	1.8 ± 2.3	NS
Enjoyment of life	2.4 ± 2.7	2.4 ± 2.5	2.4 ± 3.0	NS
Pain Disability Index	17.0 ± 15.4	18.2 ± 13.6	15.8 ± 17.2	NS
Pain Catastroph. Scale	8.3 ± 9.2	9.1 ± 8.2	7.5 ± 10.3	NS
HADS Total Score	9.8 ± 7.4	11.5 ± 8.1	8.2 ± 6.4	NS
HADS Anxiety	5.9 ± 4.3	6.6 ± 4.3	5.2 ± 4.3	NS
HADS Depression	4.0 ± 3.8	5.0 ± 4.5	3.0 ± 2.7	t = 2.1*

HADS = Hospital Anxiety and Depression Scale; NS = not significant.
*$P < 0.05$.
[†]0–10 scale; 0 = no interference; 10 = extreme interference.

range = 0–106). The total number of weekly telephone interviews averaged 9.6 (SD = 3.3; range = 0–13). One subject did not complete any of the weekly phone interviews; she did not respond to any phone calls despite multiple attempts. Forty-eight subjects missed at least one of the weekly phone calls. No differences were found between those who dropped out of the study and those who completed the trial, and no differences were found in the number of daily pain app assessments and the number of weekly phone calls between those in the Experimental and Control groups.

Fifty-seven of the 64 subjects (89.1%) completed and mailed back the midstudy questionnaires after six weeks, and 60 of 64 subjects (93.8%; 30 Experimental and 30 Control) completed and mailed back the post-study questionnaires after three months. No safety issues or significant adverse effects were reported related to the use of the gloves during the trial. Also, no other medical or safety issues were reported among the participants during the trial. The subjects in the Experimental group reported being very compliant in using the gloves and following the study protocol, as suggested. They reportedly used the gloves an average of 6.5 days a week for 36 minutes each time. Most of the subjects described their pain as aching in nature, and most used over-the-counter medication to manage their pain. Few reported experiencing any unwanted symptoms or side effects. The most frequently reported side effect was dry mouth (4.5%). Three percent reported experiencing constipation, itching, dizziness, confusion, and memory lapse, none of which were considered related to use of the gloves (Table 2). There were no differences between groups at baseline on pain, activity interference, disability, catastrophizing, mood, or QST results.

Although improvements were noted from baseline, no mean significant differences were found among all the study subjects in pain intensity, activity interference, anxiety, depression, or catastrophizing over the course of the three-month monitoring period. In general, compared with other populations of chronic pain patients (e.g., low back pain) [34], the subjects in this study demonstrated lower levels of pain, activity interference, emotional distress, or catastrophizing. This suggests that they were less disabled due to their pain compared with persons with chronic pain treated in a specialty pain center.

The number of days and minutes using the gloves were found to be unrelated to age, pain intensity, or pain duration. At six weeks, those in the Control group reported less interference with walking and less depression based on the six-week questionnaires ($P < 0.05$) (Table 3). No other differences were noted between groups. After three months, those assigned to the Experimental group (vibrating gloves) reported significantly less average pain than those in the Control condition ($P < 0.05$) (Table 4). Although not significant, those in the

Table 4 Three-month comparison questionnaire scores between those using the vibrating gloves (N = 30) and controls (no gloves; N = 30)

Variable	Total ± SD (N = 60)	Gloves ± SD (N = 30)	No Gloves ± SD (N = 30)	*P*
Pain intensity: worse	4.6 ± 2.3	4.3 ± 2.0	4.8 ± 2.5	NS
Least	2.4 ± 2.3	1.8 ± 1.7	2.8 ± 2.6	NS
Average	3.6 ± 2.0	3.1 ± 1.5	4.1 ± 2.3	t = 2.1*
Now	4.2 ± 3.1	3.0 ± 2.1	3.9 ± 2.7	NS
Pain relief %	42.3 ± 30.7	51.0 ± 30.0	34.4 ± 30.0	NS
Interference†				
General activity	2.6 ± 2.4	2.4 ± 1.7	2.8 ± 2.8	NS
Mood	1.9 ± 2.3	1.9 ± 2.1	1.8 ± 2.5	NS
Walking ability	1.9 ± 2.8	1.8 ± 2.3	2.0 ± 3.1	NS
Normal work	2.8 ± 2.5	2.6 ± 2.3	3.0 ± 2.6	NS
Relations w/ others	1.3 ± 2.3	1.5 ± 2.3	1.2 ± 2.4	NS
Sleep	2.0 ± 2.3	2.0 ± 2.2	2.0 ± 2.5	NS
Enjoyment of life	2.4 ± 2.5	2.2 ± 2.2	2.5 ± 2.7	NS
Average interference	2.1 ± 2.2	2.1 ± 1.9	2.1 ± 2.4	NS
Pain Disability Index	16.2 ± 14.8	17.1 ± 13.3	15.2 ± 16.3	NS
Pain Catastroph. Scale	8.6 ± 8.7	9.0 ± 7.8	8.3 ± 9.5	NS
HADS Total Score	9.8 ± 7.6	11.2 ± 7.6	8.5 ± 7.4	NS
HADS Anxiety	5.7 ± 4.3	6.2 ± 4.0	5.2 ± 4.5	NS
HADS Depression	4.0 ± 3.9	4.9 ± 4.3	3.3 ± 3.3	NS

HADS = Hospital Anxiety and Depression Scale; NS = not significant.
*$P < 0.05$.
†0–10 scale; 0 = no interference; 10 = extreme interference.

Experimental group reported greater pain relief (51.0%) compared with the Control group (34.4%). No differences were noted between groups on the pre- and post-testing self-report questionnaires that measured activity interference, sleep, pain disability, pain catastrophizing, depression, or anxiety. Those with greater sensitivity on the QST demonstrated more disability, emotional distress, and pain catastrophizing ($P < 0.05$), but no differences in pain relief from or satisfaction with the vibrating gloves. Figure 5 presents the average weekly "now" pain intensity ratings between groups over the 13-week trial. Overall, those randomized to the vibrating gloves group (Experimental) reported less weekly hand pain compared with those without the gloves (Control), with significant differences found in pain intensity for weeks 1, 2, 4, and 12 ($P < 0.05$).

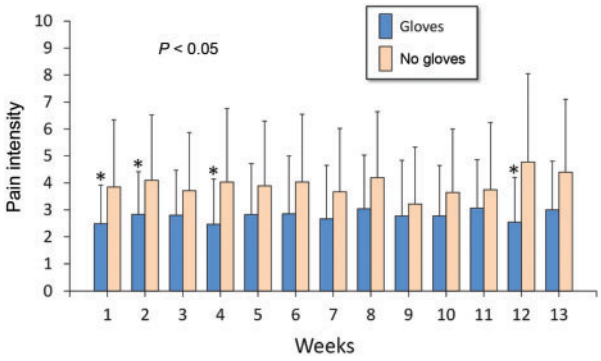

Figure 5 Average weekly "now" pain intensity between those with vibrating gloves (N = 31) and those without the gloves (N = 33).

Patient satisfaction survey results among those in the Experimental group showed that 53.5% felt that the vibrating gloves were helpful in reducing their pain (≥6/10; 0 = not at all helpful; 10 = very helpful) (Table 5), while only 12.5% felt that the gloves were helpful in relieving pain in other areas of the body. Few felt that the gloves were bothersome to use (12.5%), and most found the gloves easy to recharge (89.3%). Overall, 71.4% in the Experimental group reported that they would continue to use the gloves after the study was concluded. Satisfaction with use of the gloves was unrelated to anxiety or depression scores, pain disability, pain interference, activity level, or mechanical QST results.

Satisfaction ratings were also obtained on the use of the smartphone pain app. Overall, the app was rated easy to use (88.7%, 1.8/10; 0 = not at all easy; 10 = very easy), 79.2% found the daily reminders helpful, 92.5% felt that the app was easy to navigate, and 55.8% of the subjects reported willingness to use the

Table 5 Patient poststudy satisfaction questionnaire responses after 3 months for those with vibrating gloves (Experimental) and those without the gloves (Control)

Variable (0–10)	Total Sample ± SD	Experimental ± SD (N = 30)	Control ± SD (N = 30)	*P*
How helpful were the vibrating gloves for your hand pain?*	–	5.6 ± 3.1	–	–
How helpful were the vibrating gloves for other pain sites?*	–	1.9 ± 3.0	–	–
How bothersome were the vibrating gloves to use?†	–	2.5 ± 2.4	–	–
How easy was it to recharge the gloves?‡	–	8.9 ± 2.3	–	–
How willing would you be to use the gloves in the future?§	–	7.6 ± 3.1	–	–
In general, how many days per week did you use the gloves?	–	6.5 ± 1.0	–	–
In general, how many minutes did you wear the gloves each time you used them?	–	35.7 ± 15.0	–	–
Questions Re: Pain App				
How easy was the smartphone pain app to use?‡	8.9 ± 2.3	8.5 ± 2.5	9.2 ± 2.1	NS
How useful were the daily reminders¶	7.8 ± 3.6	7.1 ± 4.1	8.5 ± 2.8	NS
How easy was the app to navigate?‡	8.9 ± 1.9	8.7 ± 2.1	9.1 ± 1.8	NS
How helpful was the pain app in coping with your pain?*	3.1 ± 3.5	2.7 ± 3.2	3.7 ± 3.8	NS
How willing would you be to use the pain app in the future?§	6.2 ± 3.9	5.6 ± 3.9	6.8 ± 3.0	NS

NS = not significant.
*0 = not at all helpful; 10 = very helpful.
†0 = not at all bothersome; 10 = very bothersome.
‡0 = not at all easy; 10 = very easy.
§0 = not at all willing; 10 = very willing.
¶0 = not at all useful; 10 = very useful.

software program to monitor daily progress after the study was over (Table 5). Daily assessments were completed at different times of the day, but most were completed in the late afternoon and early evening (42.4%; 28.1% in the AM, 10.6% at noon, 18.9% at night). Those subjects who entered more daily assessments on the pain app reported more satisfaction with the gloves ($r = 0.58$; $P < 0.01$), more often reported that the gloves were easy to charge and use ($r = 0.39$; $P < 0.05$), and were more willing to use the gloves in the future ($r = 0.82$; $P < 0.01$). They also believed that the pain app helped them cope better with their pain ($r = 0.50$; $P < 0.01$), and they were more willing to use the pain app in the future ($r = 0.50$; $P < 0.05$). Overall, frequency of use of the pain app did not significantly affect pain intensity, activity interference, or mood and level of catastrophizing. No differences were also noted based on hand dominance, weight, BMI, hours sleeping, or QST results.

Subjective comments about the vibrating gloves and about use of the smartphone pain app were collected during the weekly phone interviews and at the end of the trial. None of the glove users experienced any perceived harm, and many believed that the gloves reduced their pain while in use; many also reported a continued reduction in hand pain after the gloves had been removed. Some felt that the gloves distracted them from the pain, and a few of the users remarked that the gloves were especially beneficial when driving. Also, a number reported that the gloves helped to relax their hands; they perceived that their use increased hand flexibility, and the vibrating gloves made their hands feel lighter. Some also thought that the compression helped to improve their pain, and a few noticed a reduction in swelling in their hands.

Some experienced some negative effects of the gloves and offered suggestions of ways to improve the vibrating gloves. A few of the subjects felt that the gloves were not helpful in reducing their pain, and sometimes they reported that their hand pain got worse when wearing the gloves. Some users also perceived that the gloves restricted their activity. Thus, there were individual reactions, both positive and negative, in response to use of the gloves. Some in the Experimental group recommended making the batteries last longer, including heat sensors in the gloves, including more vibrating motors, especially in the thumb, and making the gloves washable. Many also thought that including intensity settings so that the user could adjust the levels of intensity of the vibrating motors would be valuable.

General comments about use of the pain app suggest that the app was relatively easy to use and no one felt that it caused any difficulties. Some problems were encountered with resetting the password, using the goal-setting feature, and getting the daily reminders. It was pointed out by a few users that not all the functions of the app were working (e.g., summary graphs).

Suggestions for improving the app included 1) make the app in sync (compatible) with the gloves in order to keep track of the minutes used and to be able to adjust the intensity, 2) correct some of the differences in the ways the pain app worked between the Android and iPhone devices (e.g., no push notification with the Android), 3) allow the user to go back and enter missed assessments (although memory for pain is not very accurate), and 5) offer more instruction on the app and allow for more practice in using the app during the initial session.

Discussion

This study was designed to gather information about the efficacy of vibrating gloves for persons with chronic OA hand pain. We hypothesized that those assigned to using the gloves would report reduced pain compared with those in the control condition, with those using the vibrating glove showing significantly lower pain scores. We further hypothesized that frequency of using the gloves (increased tolerability and adherence) would be correlated with greater reduction in pain. We also predicted that the gloves would be safe to use without any adverse effects. Finally, we planned to investigate whether certain factors would predict greater benefit from using the gloves than others; in particular, those women with greater baseline pain, longer pain duration, more emotional distress, and greater hypersensitivity based on mechanical QST results would demonstrate most benefit. Although we used an enriched study design, only one subject who was screened for the study decided not to participate because she did not like the sensation of the vibrating gloves. Thus, the results were not significantly influenced by self-selection due to the exclusion of individuals who disliked the gloves at the beginning of the trial.

Overall, the results showed that the vibrating gloves were perceived to be useful by most of the subjects in the Experimental group, and there was a significant reduction in self-reported pain compared with those who did not have the gloves over the 13-week study period. Several of our proposed secondary hypotheses were not supported. In particular, those frequently using the vibrating gloves did not show a significant benefit in self-reported pain compared with those who used the gloves less frequently; this observation that patients may obtain lasting pain reduction with only occasional use might suggest that the vibratory stimulation is activating central pain-modulatory pathways whose inhibitory effects outlast the physical stimulation produced by the gloves [35]. We also found no relationship between age, pain intensity rating at baseline, and pain duration and self-reported benefit from the vibrating gloves. Future investigations would benefit from larger trials and following individuals for longer periods of time. Additional studies with larger numbers of subjects could explore outcome differences based on handedness, weight, activity level, and lifestyle.

This study demonstrated similar findings to other studies, that persons with chronic pain who demonstrated greater hypersensitivity to pressure and repeated pin prick based on the mechanical QST results also reported increased self-reported disability, emotional distress, and recurrent worried thoughts (catastrophizing) [36]. The QST results, however, did not predict benefit from long-term use of the vibrating gloves. Again, these results suggest that individuals could perceive benefit from the vibrating mechanisms in the gloves unrelated to their pain severity, pain duration, and general qualities of hypersensitivity, or demographic factors such as age or weight.

This study was not designed to determine the primary mechanism for vibratory analgesia. However, based on self-reported responses, the vibrating gloves did not help to reduce pain in other areas of the body, in agreement with past studies [2,37–39]. Further support by a study that showed no effect of noxious and vibratory stimuli that was removed from a painful experimental pain site [3] suggests that the DNIC effect alone did not account for the benefit from vibration [40]. Even though some of the glove users believed that the gloves distracted them from their pain, other studies have found little support for the widely held belief that distraction is the primary reason accounting for vibratory analgesia [3,4]. Inhibition of pain by stimulation of large, myelinated fibers may have played a role in producing the beneficial effects of the gloves. Inhibitory effects of large fiber-stimulating treatments such as transcutaneous electrical nerve stimulation (TENS) have been observed to occur in the periphery, in the spinal cord, and in the brainstem and cortex via engagement of descending inhibitory systems [35]. The report of residual pain relief after the gloves were removed might lend some support that cortical stimulation may have been helpful in reducing the pain mediated by lateral inhibition in the spinal cord [3]. Also, interactions between two cortical areas in the brain involved with pain and touch may help to account for the analgesia [1,6]. Overall, we discovered individual differences in response to the vibrating gloves that were unrelated to baseline hyperalgesia (QST results) or demographic factors such as age, weight, pain duration, or levels of emotional distress. Although wearing gloves alone could have had some beneficial effect (e.g., limiting movement and warming the hands), we collected frequent comments from the subjects throughout the trial that allowed us to conclude that the vibration served as a useful component to the gloves in reducing pain. Future investigators may benefit from asking whether aspects of wearing gloves other than those that vibrate helps in reducing hand pain.

Most of the participants in this study were older women, which is typically found when recruiting persons with OA. We were pleased to find that almost all of the subjects who expressed interest in the trial had a compatible smartphone and were able to download a pain app and use it to enter daily assessments. Even though some described themselves as “not app people,” they

were very compliant in using the pain app, and no significant problems were encountered based on their age (mean age = 63 years). Future development of the gloves may take advantage of the comments and feedback of the study participants by considering incorporation of heat sensors in the gloves, including different intensity levels of vibration (low, medium, high), adding additional vibrating motors, and making the gloves washable.

There are several limitations of this study that should be acknowledged. First, our sample size was small, and the study should be considered preliminary. It is possible that with larger numbers of subjects some significant differences between groups may have emerged, but replication is needed with larger samples. Second, our sample was mostly Caucasian (91%) and only included women in the trial, so we were not able to determine whether outcome differences would exist based on race or gender. Third, we followed the subjects for only three months, and it is possible that some long-term effects of the gloves may exist that we did not assess. Future studies would benefit from a longer period of follow-up to help determine any long-term benefit from the gloves. Fourth, it should be highlighted that the participants in this study did not report having significant pain intensity levels or disability, and they reported lower levels of negative affect compared with other pain patient populations (e.g., chronic lower back pain) [41]. It would be interesting to determine whether vibration technology would have a greater effect on persons with higher levels of pain (e.g., 8/10). Fifth, there may be some risk of selection bias that might have affected the results of this study as only those with a smartphone were included. This seems to be less of a concern, however, as very few who expressed interest in the study were excluded due to the lack of a compatible smartphone. We also excluded only one person who did not like the feeling of the vibrating gloves, so the enriched study design did not select out many who disliked the vibrating gloves. Sixth, this study relied exclusively on self-report measures. Future trials may consider using activity monitors to assess pain interference and objective devices or smartphone apps that could accurately assess the time that the individuals used the gloves. Seventh, there are several reported factors that could have affected hand pain among the participants (e.g., weather, overuse of hands, etc.), and we did not track all the external factors that might have relieved or heightened hand pain among the participants. Some subjects had minor surgery, received acupuncture or cortisone injections, used daily heat treatments, and had physical therapy during the trial. Although we made every effort to track other treatments or external factors, including use of medication, it is hard to know how other treatments or environmental factors (such as changes in the weather) might have affected the outcome of this study. Some of the participants also had comorbid medical conditions (e.g., temporomandibular joint pain, degenerative disc disease, etc.) that might have affected the pain reports and outcome of this trial. Although we did not find a significant effect of the use of pain medication on the overall report of pain, some of the participants were taking strong pain medication to treat their pain. Outside treatments were shown to be evenly divided between the Experimental and Control groups, so one group did not have an advantage with these external factors compared with the other. Finally, although all subjects received the same amount of attention, the effect of having a device can have a positive effect on outcome. A weakness of the study design is that we did not include a control condition of gloves that did not vibrate. A more rigorous design is needed in future investigations on the effects of vibration for OA hand pain. Also, even though overall compliance with this trial was very high, not all subjects were compliant in using the gloves and in entering assessments every day. As with any clinical trial, we encountered missing data and inconsistencies in using the gloves that might have influenced the outcome of this study.

Despite these limitations, these results suggest initial support that vibrating gloves using small vibrating motors can have a positive effect in reducing pain among women with primary hand pain due to osteoarthritis. The gloves were perceived to be safe and useful when performing certain activities (e.g., driving) and had a moderately prolonged effect in reducing pain after the gloves were removed. Future studies are needed with larger numbers of subjects over a longer period to further determine the effect of vibration on hand pain related to osteoarthritis.

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