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ORIGINAL RESEARCH

Reducing Pain and Improving Mobility Using Haptic Patch Technology: Results of the RESTORE Study

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ABSTRACT

***Introduction*:** Acute and chronic pain affects patients' overall health status and well-being, and the assessment and treatment of these patients can be challenging. Unfortunately, many patients fail to respond to the available multimodal treatment options, with some even failing advanced interventions including surgery. Therefore, alternative approaches to pain treatment represent an unmet medical need. Haptic vibrotactile trigger technology (VTT) is designed to target nociceptive pathways and is theorized to disrupt the neuromatrix of pain. The aim of this study was to evaluate the analgesic effects of a wearable VTT haptic patch in adults diagnosed with mild-to-moderate acute or chronic pain.

***Methods*:** This was a prospective, randomized, controlled, double-blind study. A total of 118 research participants (58 male, 60 female) met the inclusion criteria and were enrolled in the study. Participants were randomly assigned to either a treatment group receiving the active patch ($N=64$) or a control group which used a similar-appearing vehicle/placebo patch ($N=54$). Assessments were performed at baseline (day 0), day 7, and day 14. Reduction in pain severity and interference was assessed using the validated Brief Pain Inventory (BPI), and range of motion/flexibility assessment was performed using the Schober (only for low back pain), goniometer, and bubble inclinometer tests. Data for the active patch user group and the control group were aggregated and compared over the 14-day time frame of the study.

***Results*:** The active patch user group had significantly greater improvement in pain severity and reduction in pain interference; in addition, the active patch group showed greater objective improvement in range of motion (ROM)/flexibility than the control group at day 7 and day 14.

***Conclusion*:** These findings suggest that this non-pharmacological, noninvasive, topical VTT haptic patch (FREEDOM Super Patch with VTT) can reduce pain severity and increase ROM/flexibility. Considering the multitude of serious adverse effects associated with standard pharmacological pain treatments, clinicians should consider this readily available, over-the-counter VTT patch as a potential first-line or adjunct therapy to treat pain.

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Keywords: Haptic technology; Pain management; Vibrotactile trigger technology; FREEDOM Patch; Musculoskeletal pain

Key Summary Points

Pain can degrade patients' overall health status and well-being, including quality of life (QoL), impairments in activities of daily living (ADLs), and range of motion/flexibility.

There is a potential for serious adverse effects and toxicities with existing pharmacological pain treatments.

Alternative approaches are still needed that are less invasive, safe, and effective options and exhibit a reduced side effect profile.

Evidence shows that topical analgesic therapies including haptic technologies are safe and effective for pain conditions and should be considered as part of a multimodal treatment strategy.

INTRODUCTION

Alleviating pain is an age-old clinical challenge. Despite medication options and other current treatment modalities, alternative approaches are still needed, since not all patients respond to or are appropriate for the available therapeutics. Pain is well recognized to limit patients' interest in engaging in a daily exercise routine or physical therapy regimens; it can also interfere with nightly sleep, and can increase symptoms of depression [1, 2]. Patients living with neuropathy, recovering from injury or opioid addiction, and/or who are stroke or traumatic brain injury survivors are at especially high risk of chronic pain symptoms that can be harmful to long-term health. In addition, usual prescription and over-the-counter (OTC) drug treatments for pain can interact with other medications, have toxic effects over the long term, and/or have adverse side-effects. In addition, some patients are not candidates or fail surgical intervention (e.g., spinal fusion, joint replacement) to relieve their pain.

First developed in the 1970s, haptic technology has long been focused on the transmission of tactile information using generated sensations, touch, and force-feedback (e.g., cell phone vibration and joystick online game control) [3]. It was first used in the medical realm in the simulated training of different surgical procedures [4]. Medical haptic technology that is aimed at pain includes touchable, graspable, and wearable forms, including wearable patches that contain haptic vibrotactile trigger technology (VTT). The advantage of a drug-free VTT patch is that it is an over-the-counter therapy that patients can apply themselves as needed.

Past research has shown that haptic VTT generates a feedback response to tactile sensations through bidirectional communication [4–6]. This bidirectional communication is a central aspect of haptic-controlled systems and devices. Meanwhile, the body's neural network via the peripheral nervous system (PNS) enables tactile sensations on the skin to be interpreted in the central nervous system (CNS; human brain). At the cellular level, specialized ion channels, particularly Piezo1 and 2 [7], in the brain open in response to tactile sensations. This work was noted by scientists who received the Nobel Prize in Medicine in 2021, showing that these channels play a central role in sensitivity to external mechanical stimuli [8].

According to the gate controlled theory of pain, rubbing an area of pain can provide relief due to the activation of large-diameter A-beta nerve fibers, which can inhibit the transmission of pain signals from smaller A-delta and C-fibers. It is postulated that VTT haptic devices can stimulate the opening of Piezo channels, modulating pain and influencing messages sent from the periphery to the CNS. A prospective VTT haptic patch study conducted in 2023 showed evidence of pain reduction resulting from its use [9]. By providing mechano-tactile feedback to amputees, positive outcomes in patient dexterity have been demonstrated using haptic wearables

in patients with prosthetic limbs [10, 11]. Furthermore, positive outcomes have been shown for haptic wearables in reducing both pain and anxiety, improving sleep, and improving athletic performance in elite athletes [12–15].

The purpose of this RESTORE clinical trial was to investigate whether using the VTT haptic patch (FREEDOM Super Patch with VTT; Srysty Holding Co.) (see Fig. 1) reduced self-perceived pain and improved function in patients with moderate-to-severe acute or chronic pain, as compared to a control group wearing a similar-appearing vehicle/placebo patch.

METHODS

Study Design

This was a prospective, randomized, double-blind controlled study to assess (1) changes in pain severity, (2) changes in pain interference, and (3) changes in range of motion (ROM) and flexibility in patients with self-reported myofascial/musculoskeletal pain, arthritis, and neuropathy/radiculopathy. Validated scales and functional measurement tools were utilized. These scaled tools included the Brief Pain Inventory (BPI) survey instrument (permission obtained), which uses a simple 0–10 scale (with 0 representing the lowest level, and 10 the highest level). The BPI is frequently used in analgesic research and assesses five variables: (1) severity of pain, (2) impact of pain on daily function, (3) location of pain, (4) pain medications utilized, and (5) amount of pain relief in the past 24 h or the past week. It also includes the BPI Interference section, which measures the extent to which pain interferes with various aspects of daily life (e.g., daily activities, mood, and social interactions), and is similarly scaled from 0 to 10.

Besides assessing pain relief and improvement in function, quantifiable measurements of ROM and flexibility were obtained using Schober's test for low back pain subjects, as well as goniometer and bubble inclinometer measurements.

Fig. 1 FREEDOM Patch; Srysty Holding Company, The SuperPatch Company, Toronto, Canada

Ethical Approval

All research subject data collection for this study was completed as of March 2025. This study involving human participants was reviewed and approved by Advarra, the institutional review board (IRB) of record. The study protocol was conducted in accordance with the ethical standards of the institutional and national research committees and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All patients provided written informed consent to participate in the study and for the use of outcome measures.

Study Participant Sample

A total of 118 research subjects (58 male, 60 female) were enrolled in this study. Following enrollment and randomization to either the active patch user group or the control group, 64 patients (28 male, 36 female) received the active haptic patch, and 54 patients (30 male, 24 female) were assigned to the control group that received the placebo patch.

Individuals eligible for inclusion in this study were adults aged 18–85 years diagnosed with mild to moderate acute or chronic pain. The exclusion criteria were as follows: (1) use of drugs of abuse (illicit) or prescription opioids, (2) pregnancy, or (3) existing or planned

implantation of pacemaker or other electrical devices. Subjects were allowed to continue their non-opioid pain medications and were asked at study visits about any change in their analgesic consumption.

The mean and median age in the active patch user group at baseline was 55.6 and 58.9 years, respectively. The mean and median age in the control group at baseline was 61.5 and 64.3 years, respectively. Minimum and maximum age at baseline for the active patch user group was 30.2 and 80.5 years, and for the control group was 28.4 and 83.2 years, respectively. All enrollees completed the study, and both age and gender demographics were similar between the active patch user group and control group.

Among the active patch user group, 39% had myofascial/musculoskeletal pain, 31% had arthritis, and 30% had neuropathy/radiculopathy, as compared to 43%, 33%, and 24% of the control group, respectively. For subjects self-reporting arthritis, the primary locations identified were the knee, hip, and foot. Due to the small sample sizes, no subgroup analyses were performed.

Study Procedures and Assessments

Written informed consent was obtained from all participants who met inclusion criteria before enrollment in the study. The self-reported level of pain was determined at baseline (day 0), day 7, and day 14 (study endpoint), as well as patients' perception of hours of pain per day over the past 3 days. In addition, the self-reported level of physical activity over the past week and perceived interference from the pain as measured by the BPI were recorded. The BPI also included scaled statements pertaining to overall quality of life (QoL). Flexibility and ROM were evaluated, and we also queried participants regarding their level of satisfaction with the patch, any changes in oral analgesic consumption, and any adverse events between the active and placebo patch groups.

The Schober test assesses lumbar spine flexibility, and the goniometer and bubble inclinometer tests measure joint ROM; these tests were utilized as a general assessment of mobility. Schober's test measurement is denoted in centimeters, while the goniometer score and bubble inclinometer measurement are denoted in degrees of rotation/360.

Patches were identified by a number on the external package and were recorded and tracked by the clinical research organization (CRO)'s compliance team. Block randomization was utilized, and blinding integrity was maintained with no risk of bias, as all packaging and patches (active and placebo) appeared and felt similar. The tactile vibrohaptic effects are imperceptible and thought to occur at a microscopic level; therefore, no bias or unblinding was possible due to the "feel" of the patch. The patch was applied and replaced daily, and placed near the source of the subject's pain.

Data Analysis and Statistical Tools

On day 0, day 7, and day 14, the BPI scores for both the active patch and control groups were analyzed and compared. Between-subject and between-group differences were evaluated. Parametric and non-parametric statistical tools (i.e., Shapiro–Wilk test, Wilcoxon signed-rank test, and Mann–Whitney *U* test) were utilized.

Utilizing the Shapiro–Wilk test for normality, it was found that the majority of data were non-normally distributed. Therefore, non-parametric tests for continuous data were employed; these were the Wilcoxon signed-rank test (for within-group comparisons) and the Mann–Whitney *U* test (for between-group comparisons).

For the active patch user group at baseline (day 0), 12% reported their pain as moderate and 88% as severe, with no one reporting their pain as mild. For the control group on day 0, 15% reported their pain as moderate and 85% as severe, with no one reporting their pain as mild.

For Schober's ROM testing, within-group changes from baseline to F1 and baseline to F2 were analyzed using paired-samples *t* tests. The normality of distributions at each time point was confirmed using the Shapiro–Wilk test (all $p > 0.05$), permitting the use of parametric statistical tests. Between-group differences in change scores (Δ baseline to day 7 and δ baseline to day 14) were analyzed using independent-samples *t*

tests with Welch's correction for unequal variances. Effect sizes were reported as Cohen's *d*, and 95% confidence intervals (CI) for mean changes were obtained by bootstrap resampling (10,000 iterations).

The SPSS statistical package (version 30.0) was used for all data analyses and was performed by an independent organization unrelated to any of the authors or sponsor in order to maintain data transparency and integrity.

RESULTS

The mean number of reported hours per day that pain was experienced by the active patch user group decreased from day 0 to day 7, and further decreased from day 7 to day 14, suggesting a positive analgesic effect of the haptic patch. While the control group also reported a decrease in pain, it was not as pronounced as that experienced by the active patch user group (see Table 1).

For the self-reported times per day in which physical activity occurred (categorized as light, moderate, or heavy activity), a significant increase in physical activity was reported by the active patch users, but not by the control group. This was especially the case for moderate and heavy activity, and suggestive of a positive mitigation of pain in the active patch users as opposed to placebo (see Table 2).

At day 14, statistically significant differences were shown in the active patch user group, with decreases in both pain severity and interference scores. Marked improvements in ROM and flexibility scores were found compared to baseline. At day 14, the active patch user group reported that they were very/extremely satisfied with the patch. Results also showed statistically significant and positive outcomes in quality of life (QoL) components among the active patch user group, with improvements in particular shown in general activity, normal work, and walking ability. There were no reported adverse events during the clinical trial among either active patch users or the control group.

Study outcomes (day 0 to day 14) were determined utilizing the following: (1) BPI severity, (2) BPI interference, (3) Schober test (only for patients with low back pain), (4) inclinometer measurements, and (5) goniometer measurements, plus (6) QoL scores (scaled BPI). The active patch user group outcomes were as follows:

1. ***BPI severity*** (including QoL measurements)***:*** A significant reduction was observed at day 14 ($W = 1.0$, $p < 0.001$, $r = 0.87$). The median decrease was −2.75 points (95% CI [−3.00, −2.50]), reflecting strong and sustained benefit from the intervention.
2. ***BPI interference:*** A continued and more substantial reduction was observed at day 14 ($W = 4.5$, $p < 0.001$, $r = 0.85$). The median decrease was −0.79 points (95% CI [−1.00, −0.71]), showing sustained improvements in pain interference with daily life.
3. ***Schober testing:*** Active patch group baseline to day 14: paired *t* test showed $t = -8.07$, $p < 0.001$, Cohen's $d = 1.80$. The mean increase was 3.18 cm (95% CI [2.39, 3.92]). Improvement in Schober scores remained

Table 1 Hours of pain per day over the past 3 days experienced by active patch user group versus control group (mean, standard deviation, minimum, maximum)

	Baseline		Day 7		Day 14	
	A ($n = 64$)	P ($n = 54$)	A ($n = 64$)	P ($n = 54$)	A ($n = 64$)	P ($n = 54$)
Time (h)	*M* 5.36	5.52	2.98	3.74	2.00	2.96
	SD 1.07	1.08	0.98	1.23	1.14	1.80
	Min 2	4	2	1	1	1
	Max 8	8	6	6	7	6

A active patch group, *P* placebo patch group, *M* mean, *SD* standard deviation, *min* minimum, *max* maximum

Table 2 Physical activity (number of times) per day over the past week (mean, standard deviation, minimum, maximum)

Activity	Baseline		Day 7		Day 14	
	A ($n=64$)	P ($n=54$)	A ($n=64$)	P ($n=54$)	A ($n=64$)	P ($n=54$)
Light physical activity for 30 min or more	*M* 1.58	1.24	2.94	1.93	4.00	2.59
	SD 1.21	1.23	1.34	1.78	1.59	2.34
	Min 0	0	0	0	0	0
	Max 6	5	6	5	8	7
Moderate physical activity for 30 min or more	*M* 0.67	0.54	1.30	0.98	1.47	1.41
	SD 0.71	0.77	0.75	1.10	0.87	1.45
	Min 0	0	0	0	0	0
	Max 4	3	3	4	4	4
Heavy physical activity for 30 min or more	*M* 0.56	0.41	1.00	0.74	1.23	0.93
	SD 0.69	0.63	0.54	0.81	0.68	1.01
	Min 0	0	0	0	0	0
	Max 4	3	2	2	4	4

A active patch group, *P* placebo patch group, *M* mean, *SD* standard deviation, *min* minimum, *max* maximum

statistically significant at day 14, suggesting sustained functional improvement over the 2-week period.

4. ***Inclinometer measurement:*** A statistically significant improvement was observed by day 14 ($W=43.5$, $p<0.001$, $r=0.83$). The median increase was 1.0° (95% CI [1.0, 2.0]), indicating sustained functional benefit.
5. ***Goniometer measurement:*** Continued improvement was observed by day 14 ($W=130.5$, $p<0.001$, $r=0.76$). The median increase was 2.0° (95% CI [1.0, 2.0]), supporting sustained functional gains in flexibility.

As displayed in Fig. 2, comparative results for these outcomes between active patch users and the control group using a similar-appearing placebo patch were as follows:

BPI severity (including QoL measurements)***:*** The active patch group demonstrated a statistically significant greater reduction in scores compared to the placebo patch group ($U=1107.0$, $p=0.001$, $r=0.31$).

BPI interference: The active patch group showed a statistically significant greater reduction in scores compared to the placebo patch group ($U=1262.5$, $p=0.012$, $r=0.23$).

Schober test: For low-back-pain subjects, the active patch group demonstrated a statistically significant greater improvement compared to the placebo patch group. Baseline to day 14 with the active patch improved +2.17 cm greater than placebo ($t=3.60$, $p=0.0015$, $d=1.29$, 95% CI 0.95–3.21). Between-group comparisons confirmed a substantial advantage for the active patch of approximately 2 cm at both follow-up time points.

Inclinometer measurement: The active patch group demonstrated a statistically significant greater improvement compared to the placebo patch group ($U=2672.0$, $p<0.001$, $r=0.47$).

Goniometer measurement: The active patch group showed a statistically significant greater improvement compared to the placebo patch group ($U=2205.0$, $p=0.009$, $r=0.24$).

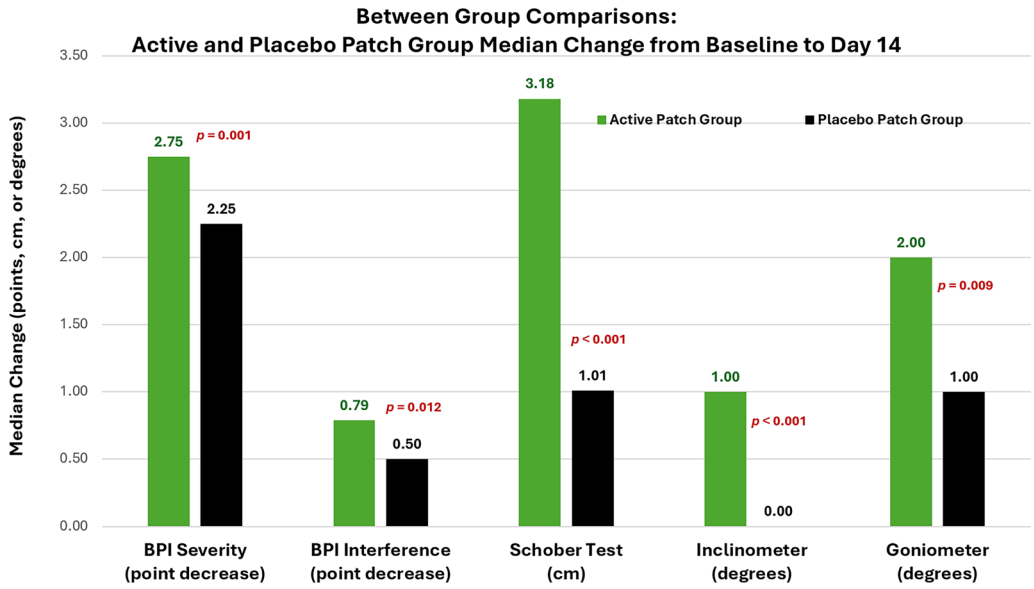

Fig. 2 Comparative change from day 0 to day 14 for BPI, BPI interference, Schober, inclinometer, and goniometer scores of active patch users versus placebo users (control group). Active patch group ($n = 64$) for BPI, inclinometer measurement, goniometer measurement; ($n = 20$) for Schober measurement (low-back-pain patients); placebo patch group ($n = 54$) for BPI, inclinometer measurement, goniometer measurement; ($n = 11$) for Schober measurement (low-back-pain patients)

Schober Test Results

The Schober test assesses lumbar range of motion, and differences were calculated only for subjects with low back pain as their primary complaint. Schober test measurements were collected at baseline, day 7, and day 14 in patients with low back pain who were randomized to the active patch or placebo patch groups (see Table 3).

Inclinometer Test Results

Within the active patch user group from day 0 to day 7, the Wilcoxon signed-rank test showed a statistically significant improvement in inclinometer scores ($W = 104.5$, $p < 0.001$, $r = 0.78$). The median increase was 1.0° (95% CI [0.5, 1.0]), reflecting gains in joint ROM. Moreover, from day 0 to day 14, a statistically significant improvement was shown ($W = 43.5$, $p < 0.001$, $r = 0.83$). The median increase was 1.0° (95% CI [1.0, 2.0]), suggesting joint ROM benefit.

Table 3 Schober test measurements from day 0 to day 14 for patients with low back pain in erect position (5–10 cm distance)

Group/time point	Mean	SD	Min	Max	N
Active patch Schober at baseline	6.57	1.81	3.3	9.3	20
Active patch Schober at day 7	9.31	2.70	5.6	14.3	20
Active patch Schober at day 14	9.75	2.74	6.1	14.8	20
Placebo patch Schober at baseline	5.62	1.55	3.6	8.6	11
Placebo patch Schober at day 7	6.38	2.00	3.9	9.3	11
Placebo patch Schober at day 14	6.63	2.10	4.0	10.0	11

Low-back-pain active patch group ($n = 20$); low-back-pain control group ($n = 11$)

In contrast, for the control group from day 0 to day 7, the Wilcoxon signed-rank test showed no statistically significant change in inclinometer scores ($W = 55.0$, $p = 0.276$, $r = 0.81$). The median change was 0.0° (95% CI [0.0, 0.0]). However, no significant change was observed at day 14 ($W = 107.5$, $p = 0.211$, $r = 0.74$); the median change remained 0.0° (95% CI [0.0, 0.0]).

In comparing the two groups, the active patch user group showed a statistically significant improvement from day 0 to day 14 as compared to the control group ($U = 2522.5$, $p < 0.001$, $r = 0.40$). The median difference between groups was 0.10 cm (95% CI [0.10, 0.15]), suggesting a haptic patch effect favoring the active patch user group (see Table 4).

Goniometer Test Results

Within the active patch user group from day 0 to day 7, the Wilcoxon signed-rank test showed a statistically significant improvement in goniometer scores ($W = 108.0$, $p < 0.001$, $r = 0.78$). The median increase was 1.0° (95% CI [1.0, 1.0]), reflecting gains in joint ROM. From day 0 to day 14, progressive improvement in goniometer results were demonstrated by day 14 ($W = 130.5$, $p < 0.001$, $r = 0.76$). The median increase was 2.0° (95% CI [1.0, 2.0]), suggesting joint ROM benefit.

For the control group from day 0 to day 7, the Wilcoxon signed-rank test also detected a minimal and slight increase in goniometer scores ($W = 98.0$, $p = 0.001$, $r = 0.76$). The median increase was 0.0° (95% CI [0.0, 1.0]), indicating that the small positive effect was concentrated solely among a subset of control group participants. An aggregated improvement was found at day 14 ($W = 62.0$, $p < 0.001$, $r = 0.80$). The median increase was 1.0° (95% CI [0.0, 1.0]). The reason for this improvement in joint ROM was not determined.

In comparing the two groups, the active patch user group showed a statistically significant improvement in goniometer scores from day 0 to day 14 as compared to the control group ($U = 2205.0$, $p = 0.009$, $r = 0.24$). The median difference between groups was 1.0° (95% CI [0.0, 2.0]), suggesting a haptic patch effect favoring the active patch user group (see Table 5).

Combined Self-Reported Pain/Daily Life Interference and ROM/Flexibility Test Results

The greatest comparative level of difference at day 14 between the active patch users and the control group using the placebo patch was in their overall improved flexibility and ROM. This suggests that using a VTT haptic patch to lessen pain can foster improved spine and joint ROM.

Table 4 Inclinometer test measurements from day 0 to day 14 (inclinometer baseline measurement: 0–360°, calibrated to 0)

Flex measurement (0–360°) Outer ring measurement	Baseline		Day 7		Day 14	
	A ($n = 64$)	P ($n = 54$)	A ($n = 64$)	P ($n = 54$)	A ($n = 64$)	P ($n = 54$)
Mean	92.6	83.5	94.0	83.5	95.0	83.7
Median	62.0	58.0	63.5	57.5	65.0	57.5
SD	73.7	57.3	74.6	57.4	74.7	57.3
Min	34	31	34	31	34	31
Max	301	213	302	213	301	213

A = Active patch group, P = placebo patch group

Table 5 Goniometer test measurements from day 0 to day 14 (goniometer baseline measurement: 0–360°)

Joint/angle measurement (0–360°) Angle measurement	Baseline		Day 7		Day 14	
	A ($n=64$)	P ($n=54$)	A ($n=64$)	P ($n=54$)	A ($n=64$)	P ($n=54$)
Mean	69.9	69.2	71.4	69.7	72.1	71.1
Median	25.5	23.5	27.5	24.0	29.0	26.5
SD	81.8	74.8	83.7	74.8	83.4	75.1
Min	17	18	17	18	17	16
Max	284	224	288	224	285	224

A active patch group, *P* placebo patch group

DISCUSSION

Data are lacking on the analgesic and functional benefits of emerging vibrohaptic analgesic technologies. This study was designed as an exploratory trial to assess pain and function using both subjective responses and objective evidence in pain patients using a vibrohaptic patch. This was part of a larger study also evaluating potential benefits on sleep using the same technology. Overall outcomes were consistent with our stated hypothesis. Improvements for the active patch user group compared to placebo from day 0 to day 14 were demonstrated by the pain and functional assessments on the BPI, and also on all three ROM/flexibility test results. In terms of pain severity scores, a significant reduction was observed at day 14 ($W=1.0$, $p<0.001$, $r=0.87$). The median decrease was –2.75 points (95% CI [–3.00, –2.50]), demonstrating a strong and sustained benefit from the haptic patch as compared to placebo. In terms of daily activity interference scores, a continued and more substantial reduction over placebo was observed at day 14 ($W=4.5$, $p<0.001$, $r=0.85$). The median decrease was –0.79 points (95% CI [–1.00, –0.71]), demonstrating decreased pain interference with daily activities. Sustained benefits (e.g., beyond 2 weeks) or potential tolerance to patch effects over time warrant further investigation.

The results presented here align with those from previous vibrohaptic studies in the published literature [9, 16]. However, due to this evolving area and ongoing research into haptic technologies, there is much that is not yet known about the overall impact of this novel technology on the general population. A better understanding of the full impact of haptic technology in the healthcare field will be identified through additional research. The data in this and previous research indicate the potential for a positive impact on patient health due to the introduction of haptic technology into clinical practice. The exact mechanism of action (MOA) of haptic technology remains elusive; however, as our understanding of Piezo and other ion channels involved in neuroperception improves, so should our quest for targeted therapies.

We utilized an exploratory approach to investigate the overall benefits of an emerging technology. Some of the limitations of our study include small sample size, limited number of trial sites, subacute trial duration, and diffuse nature of allowed painful inclusion criteria. Strengths of our study include its prospective nature, controlled and randomized placebo-controlled design, and use of an identical vehicle/placebo patch to eliminate subject/investigator bias or unblinding. Still, it is important to consider the context of the research and the practical significance of the effect. The magnitude of the improvement in pain and range of motion was statistically significant, but whether the actual degrees of improvement represent a clinically meaningful difference can be inferred by the participants' global impression of change. On follow-up, 92% of active patch users described pain relief within 20 min by day

14, 95% reported reduced reliance on oral pain medications, and 94% (vs. 56% placebo) were extremely satisfied. As discussed, there were no reported adverse effects in the active patch group.

One must also consider other confounding effects that influence clinical trials. The placebo effect can mask or exaggerate the true effect of a treatment, leading to inaccurate conclusions about the treatment's effectiveness [17]. In addition, patents can improve simply because they are being observed in a clinical trial—known as the Hawthorne effect. Many analgesics have been plagued by these confounders, which have historically contributed to failed clinical trials of known analgesics [18].

CONCLUSION

Pain is the most frequent symptom reported to doctors across a wide range of injuries and conditions, and a common reason to seek medical attention. Older-aged adults are at an especially high risk of chronic pain, as well as adverse effects from pharmacotherapies. For this reason, there is an unmet need to identify novel and noninvasive analgesic therapies.

This study adds to the growing base of literature showing that sensory processing can be influenced by noninvasive therapies. Our results suggest that this non-pharmacological, topical VTT haptic patch reduces pain severity and increases ROM and/or flexibility with minimal side effects as compared to a placebo patch. Clinicians should consider alternative therapies including emerging vibrohaptic technologies as first-line therapies based on their potential to provide safe and effective pain relief and functional benefits.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Janet Fason, DO, was compensated for her role as Principal Investigator of this study. Jeffrey Gudin, MD, was compensated for his role as an investigator on this study. Peter Hurwitz is President of Clarity Science, LLC, the clinical research organization (CRO) that was compensated for the administration of the study.

Ethical Approval. All research subject data collection for this study was completed as of March 2025. This study involving human participants was reviewed and approved by Advarra, the Institutional Review Board (IRB) of record. The study protocol was conducted in accordance with the ethical standards of the institutional and national research committees and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All patients provided written informed consent to participate in this study and for the use of outcome measures.

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