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RESEARCH ARTICLE

Wearable, noninvasive, pulsed shortwave (radiofrequency) therapy for postoperative analgesia: A randomized, double-masked, sham-controlled pilot study

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Abstract

Background: Nonthermal, pulsed shortwave (radiofrequency) therapy (PSWT) is a nonpharmacologic, noninvasive modality that limited evidence suggests provides analgesia. Its potential favorable risk–benefit ratio stems from its lack of side effects and significant medical risks, applicability to any anatomic location, long treatment duration, and ease of application by simply affixing it with tape. Even with a relatively small treatment effect, PSWT might contribute to a multimodal analgesic regimen, similar to acetaminophen. However, widespread clinical use is hindered by a lack of systematic evidence. The current randomized, controlled pilot study was undertaken to determine the feasibility and optimize the protocol for a subsequent definitive investigation and estimate the treatment effect of PSWT on postoperative pain and opioid consumption.

Methods: Within the recovery room following primary knee and hip arthroplasty, cholecystectomy, hernia repair, and non-mastectomy breast surgery, we applied 1–3 PSWT devices (Model 088, BioElectronics Corporation, Frederick, Maryland) over the surgical bandages. Participants were randomized to 28 days of either active or sham treatment in a double-masked fashion. The outcomes of primary interest were the cumulative opioid consumption and the mean of the "average" and "worst" daily pain measured with the Numeric Rating Scale over the first 7 postoperative days.

Results: During the first 7 postoperative days, oxycodone consumption in participants given active treatment ($n=55$) was a mean (SD) of 21 mg (24) versus 17 mg (26) in patients given sham ($n=57$): difference 4 (95% CI, −5 to 13), $p=0.376$. During this same period, the "average" daily pain intensity in patients given active treatment was 2.4 (1.6) versus 2.6 (1.7) in sham: difference −0.2 (95% CI −0.8 to 0.5), $p=0.597$. Concurrently, the worst/maximum pain for the active group was 4.6 (2.0) versus 4.7 (2.1) in sham: difference −0.1 (95% CI −0.8 to 0.7), $p=0.888$. No device-related systemic side effects or serious adverse events were identified.

Conclusions: Pulsed shortwave (radiofrequency) therapy did not reduce pain scores and opioid requirements to a statistically significant or clinically relevant degree during the initial postoperative week in this pilot study. These results must be replicated with a subsequent study before being considered definitive. Data from this preliminary study may be used to help plan future trials.

KEYWORDS
analgesia, postoperative pain, post-surgical pain, pulsed electromagnetic fields, surgical analgesia

INTRODUCTION

Postoperative pain continues to be inadequately treated, often due to a lack of adequate analgesic options.[1,2] Opioids have undesirable side effects as well as a risk of dependence, overdose, misuse, and diversion. Peripheral nerve blocks provide potent analgesia but have inadequate duration for many surgical procedures for which the pain can be measured in weeks and not days. And while ultrasound-guided percutaneous peripheral nerve stimulation shows potential, at the time of this writing the high cost impedes widespread adoption. Since there is currently no single option with adequate effectiveness and duration, "multimodal analgesia" has gained favor using multiple modalities/medications simultaneously, each with suboptimal potency but whose effects are additive.[3] Acetaminophen is an example: although its analgesic potency is modest compared with alternatives, it is included in most enhanced recovery after surgery (ERAS) protocols.[4,5]

One possible nonpharmacologic and noninvasive option is nonthermal, pulsed shortwave (radiofrequency) therapy (PSWT). The technology has no side effects—the energy cannot be detected by humans—no medication interactions, few contraindications or medical risks, is applicable to most anatomic locations, and has no misuse/dependence/diversion potential. Considering the relatively low cost (approximately US$15–300), benign risk profile, and absence of side effects and misuse/diversion potential,[6] PSWT has a significant potential to contribute to multimodal analgesia for hundreds of millions of surgical procedures performed annually.[7] Therefore, if found to be even modestly effective, PSWT might be a benign addition to multimodal analgesia for most surgical procedures, much like acetaminophen is presently used.

The mechanism of action is multifaceted, complex, and only partially understood.[8] The most widely recognized biochemical theory suggests it works by promoting calcium-calmodulin bonding, which activates neuronal and endothelial nitric oxide synthase isoforms, producing nitric oxide.[9] Nitric oxide impacts both immune[10] and nervous system cells,[11] serving as a crucial signaling molecule for maintaining organism homeostasis.[9] In addition, nitric oxide directly induces vasodilation, increasing lymph flow and reducing inflammation,[12,13] the latter producing analgesia.[13] Clinical evidence suggests possible reductions in acute and chronic pain, along with opioid sparing.[14–16]

Pulsed shortwave (radiofrequency) therapy technology has been in use for over a century,[17,18] although the devices for the majority of that time were relatively expensive, large, and heavy, rendering them nonportable and restricting treatment to a few hours in a hospital or clinic setting.[19] More recently, comparatively inexpensive, small, light, wearable, single-use devices have received United States Food and Drug Administration clearance to treat both acute and chronic pain.[20] Consequently, continuous treatment may now be provided to both in- and out-patients for a far longer duration: 4 weeks in the case of the devices used in the current study. This product evolution warrants a reassessment of the modality. In addition, studies involving cholecystectomy and knee/hip arthroplasty are unavailable, and the single controlled trial involving inguinal herniorrhaphy from 1987 included solely hospitalized patients treated for only 30 min each of 2 days.[21]

Consequently, we conducted a randomized, double-masked, sham-controlled pilot study to help plan a future definitive trial and estimate the potential analgesic benefits of nonthermal PSWT for various surgical procedures. Specifically, we sought to evaluate 28 days of wearable PSWT in both hospitalized and ambulatory patients following orthopedic (knee/hip arthroplasty) and soft tissue (hernia repair, cholecystectomy, and non-mastectomy breast surgery) surgery to (1) determine the feasibility of and optimize a study protocol and (2) estimate analgesia and opioid sparing with 28 days of treatment.

METHODS

This study followed Good Clinical Practice and was conducted within the ethical guidelines outlined in the Declaration of Helsinki. The study was prospectively registered. The protocol was approved by the local Institutional Review Board (University of California San Diego). Written, informed consent was obtained from all participants.

Participants

Enrollment was offered to adult patients at least 18 years of age scheduled for primary, unilateral, total knee or hip arthroplasty; cholecystectomy; laparoscopic cholecystectomy or laparoscopic/open unilateral/bilateral/midline hernia repair; or unilateral/bilateral non-mastectomy breast surgery. Patients were excluded for (1) chronic opioid use inclusive of tramadol (daily use within the 2 weeks prior to surgery and duration of use >4 weeks); (2) neuromuscular deficit of the surgical area; (3) concurrent use of an implanted pulse generator (e.g., cardiac pacemaker); (4) incarceration; (5) pregnancy; or (6) a planned postoperative perineural local anesthetic

infusion (single-injection peripheral nerve block was acceptable).

Randomization

An investigational pharmacist created the computer-generated randomization list in a ratio of 1:1 and blocks of 2. One, two, or three devices (all active or all sham) were placed in a bag labeled with a randomization number by the investigational pharmacist (Model 088, BioElectronics Corporation). The active and sham devices are indistinguishable in appearance, and therefore participants, clinical staff, and all investigators were all masked to treatment group assignment until the Day 28 data collection of the final participant for each surgical procedure cohort.

Ropivacaine or bupivacaine 0.5% with epinephrine was used for any preoperative single-injection peripheral nerve block: adductor canal for knee arthroplasty, paravertebral for breast surgery, and erector spinae plane, rectus sheath, or transversus abdominis plane blocks for cholecystectomy or hernia repair (Table 1). Within the recovery room, patients had affixed over their surgical incision(s) 1–3 PSWT devices (all active or all sham) with included kinesiology and/or paper tape. For knee arthroplasty, a unit was applied over the distal quadriceps femoris muscle, the patella, and in the popliteal fossa (Figure 1). For hip arthroplasty, two devices were applied the length of the incision and one posterior to the initial two devices. A single device was used for each involved breast. And for hernia and cholecystectomy, 2 devices were used if there were multiple incisions (Figure 1).

TABLE 1 Population and procedural information.

	Active ($n=59$)	Sham (placebo) ($n=60$)
Age (years)	57 (15)	59 (16)
Female (%)	58% (34)	73% (44)
Height (cm)	170 (10)	169 (10)
Weight (kg)	78 (19)	79 (17)
Body mass index (kg/m^2)	27 (5)	27 (5)
Surgery duration (min)	86 (29)	93 (39)
Surgical procedures		
Breast surgery	24% (14)	25% (15)
Cholecystectomy	12% (7)	10% (6)
Hernia	14% (8)	15% (9)
Hip arthroplasty	25% (15)	25% (15)
Knee arthroplasty	25% (15)	25% (15)
Peripheral nerve block[a]		
Adductor canal block	25% (15)	25% (15)
Paravertebral block	24% (14)	25% (15)
Erector spinae plane block	0% (0)	2% (1)
Rectus sheath block	2% (1)	2% (1)
Transversus abdominis plane block	0% (0)	2% (1)
No peripheral nerve block	49% (29)	45% (27)

Note: Values are reported as mean (SD) or percentage (number of subjects).
[a]Totals not equal to 100% due to rounding error.

Postoperative analgesic regimen

While hospitalized, patients received acetaminophen 975 mg 3 times daily, celecoxib 200 mg twice daily (knees and hips), and, if needed, the synthetic oral opioid oxycodone (5 mg tablets). Patients were instructed to remove the devices when bathing and then reaffix them in the same location(s). Participants were provided with the contact phone numbers of the administering physician and acute pain service and instructed to wear their device(s) continuously through postoperative day 28 when they could discard the disposable, single-use devices (30-day battery life). If a device fell off, it could be reaffixed with either the included kinesiology tape, another type of tape, or any bandage/clothing that would hold the device in place (e.g., Ace bandage following knee arthroplasty). The electromagnetic pulses pass through bandages and clothing, so adherence to the skin is not required. Participants were to check daily that the light-emitting diode was green, indicating a functioning unit, but no other device care or adjustment was required. Participants were discharged home with a prescription for immediate-release oral opioid tablets (oxycodone 5 mg), with the exception of a limited number of hernia cases. Following study completion, the results were provided to all participants using non-technical language.

Outcome measurements (end points)

Participants were contacted by telephone for endpoint collection on postoperative days 1, 2, 3, 7, 14, 21, 28, and 180. We selected outcome measures that have established reliability and validity, with minimal inter-rater discordance, and are recommended for pain-related clinical trials by the World Health Organization and the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus statement.[22]

Primary outcome measures

The outcome measures of greatest interest were the (1) cumulative oral opioid consumption (in oxycodone equivalents) and (2) mean value of the "average" and worst/maximum daily pain scores measured on the 0–10 Numeric Rating Scale (NRS) within the initial 7 postoperative

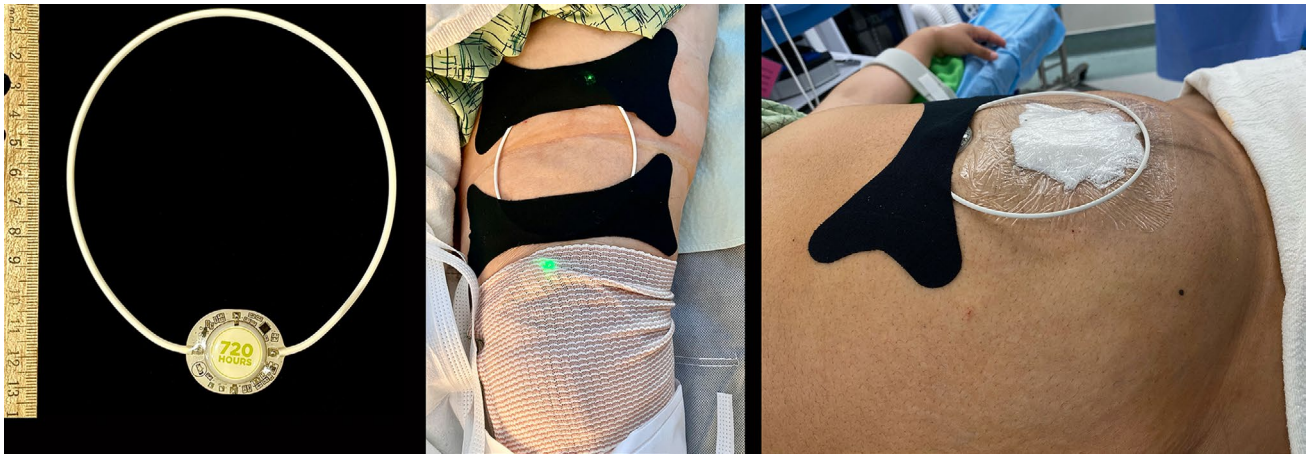

FIGURE 1 A wearable pulsed shortwave therapy device with a pulse generator and flexible 12 cm-diameter antenna. The unit is secured with an included cotton-based kinesiology or paper tape. The single control is an on/off button on the back of the pulse generator, and the green light emitting diode indicates the unit is activated. Imaged are knee arthroplasty and umbilical hernia repair. Used with permission from the first author.

days. The NRS is a highly sensitive measure of pain intensity with numbers ranging from 0 to 10, zero equivalent to no pain and 10 equivalent to the worst imaginable pain; it is a valid and reliable measure for evaluating analgesic interventions.[23] Additionally, NRS scores correlate well with other measures of pain intensity[24] and demonstrate high test–retest reliability.[25] These NRS characteristics led to World Health Organization and the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials consensus recommendations for use of the 10-point NRS of pain intensity for pain trials.[22]

Secondary outcome measures

The primary instrument was the Brief Pain Inventory (short form), which assesses pain and its interference with physical and emotional functioning.[26] The instrument includes three domains: (1) *pain*, with four questions using an NRS to evaluate 4 pain levels: "current," "least," "worst," and "average" [collected postoperative days 7–28]; (2) percentage of *relief* provided by pain treatments with one question [not utilized for this study]; and (3) *interference* with physical and emotional functioning using a 0–10 scale (0 = no interference; 10 = complete interference) [collected postoperative days 7–28]. The seven interference questions involve general activity, mood, walking ability, normal work activities (both inside and outside of the home), relationships, sleep, and enjoyment of life.[26] These seven functioning questions can be combined to produce an interference subscale (0–70). The use of both single items (e.g., mood) and the composite scores is supported by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials consensus recommendations for assessing pain in clinical trials.[22,27] Opioid consumption and awakenings due to pain were also recorded during each phone contact. Additional outcomes included the time until discharge, device location changes during the treatment period, the postoperative day device(s) were permanently removed, and for joint arthroplasty, the degrees of passive flexion at the 6-week surgical visit. A question regarding the desirability of device use in a hypothetical future surgery was inadvertently excluded from the case report forms.

Statistical analysis

This investigation was designated a priori as a pilot study to assist in planning a subsequent definitive trial, and we therefore used a convenience sample of 30 participants undergoing each of the surgical procedure cohorts (knee arthroplasty, hip arthroplasty, cholecystectomy and hernia repair, non-mastectomy breast surgery, nasal surgery; and general orthopedic surgery). We also requested 20 additional participants to account for drop-outs and protocol deviations for a total of 200 potential participants. We decided against including nasal and general orthopedic surgical procedures due to a lack of adequate volume and homogeneity among procedures, respectively.

While the outcomes of greatest interest were specified prior to enrollment and designated "primary outcomes," there was no specific data analysis plan defined prospectively. All analyses were intention-to-treat. Continuous, normally distributed data are reported as mean ± standard deviation. Normality of distribution was tested using the Komogorov-Smirnov test, and continuous data normally distributed are reported as mean (SD), while data not normally distributed are reported as median [interquartile range]. Comparisons of independent samples were performed using a two-tailed t-test or Mann–Whitney *U* test, as appropriate. The Chi-Square test was used for differences in proportions. $p < 0.05$ was considered statistically significant, and adjustments were not made for multiple comparisons. Prism 10.1.1 (GraphPad) was used for all analyses.

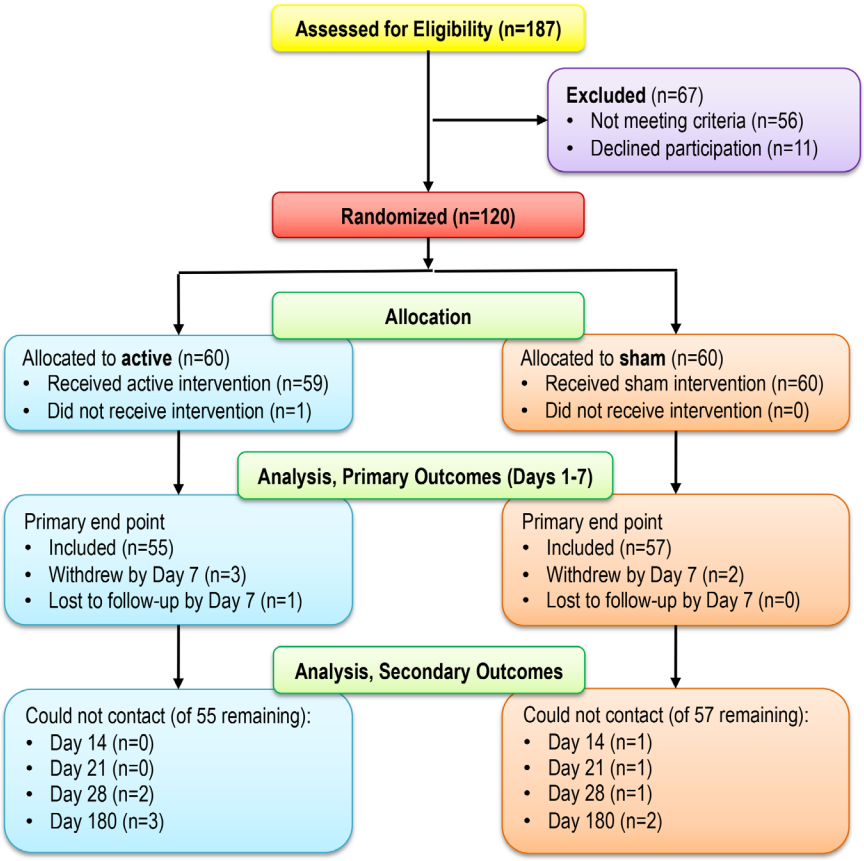

FIGURE 2 Consolidated Standards of Reporting Trials (CONSORT) diagram.

RESULTS

Between July 18, 2022, and October 3, 2023, a total of 120 participants were enrolled (Table 1), randomized to either active treatment ($n=60$) or sham ($n=60$). One patient randomized to active treatment was discovered to have an exclusion criterion prior to device application, and she withdrew participation. The remaining participants ($n=119$) had PSWT device(s) applied successfully, although 5 withdrew, and one was lost to follow-up by Day 7 and was therefore excluded from being included in the primary outcome measures (Figure 2).

Analysis of each of the four grouped surgical procedures failed to identify any statistically significant or clinically relevant differences between the groups for any of the outcome measures other than sleep disturbances, and therefore all are here presented combined.

Primary outcomes

During the first 7 postoperative days, oxycodone consumption in participants given active treatment ($n=55$) was a mean (SD) of 21 mg (24) versus 17 mg (26) in patients given sham ($n=57$): difference 4 (95% CI, −5 to 13), $p=0.376$. During this same period, the "average" daily pain intensity in patients given active treatment was 2.4 (1.6) versus 2.6 (1.7) in sham: difference −0.2 (95% CI −0.8 to 0.5), $p=0.597$. Concurrently, the worst/maximum pain for the active group was 4.6 (2.0) versus 4.7 (2.1) in sham: difference −0.1 (95% CI −0.8 to 0.7), $p=0.888$.

Secondary outcomes

Minimal differences were found between the treatment groups for all daily pain severity scores, opioid consumption, and interference with physical and emotional functioning as measured using the Brief Pain Inventory (Figures 3 and 4). Total oxycodone consumed over the entire 28 days following discharge from the recovery room for active treatment was a mean (SD) of 24 mg (27) versus 22 (32) for sham ($p=0.190$). Nineteen participants (34%) who received active stimulation avoided opioids for the entire study period following discharge from the recovery room, versus 23 (40%) in those given sham ($p=0.680$). Cumulative awakenings due to pain for the entire treatment period were 3.9 (7.0) for active versus 2.2 (3.4) for sham ($p<0.001$). Six months postoperatively, no participant was requiring opioids, with 12% of the active treatment group experiencing persistent post-surgical pain versus 15% in the sham group ($p=0.938$). Subgroup analysis for individual surgical procedures (e.g., knee arthroplasty

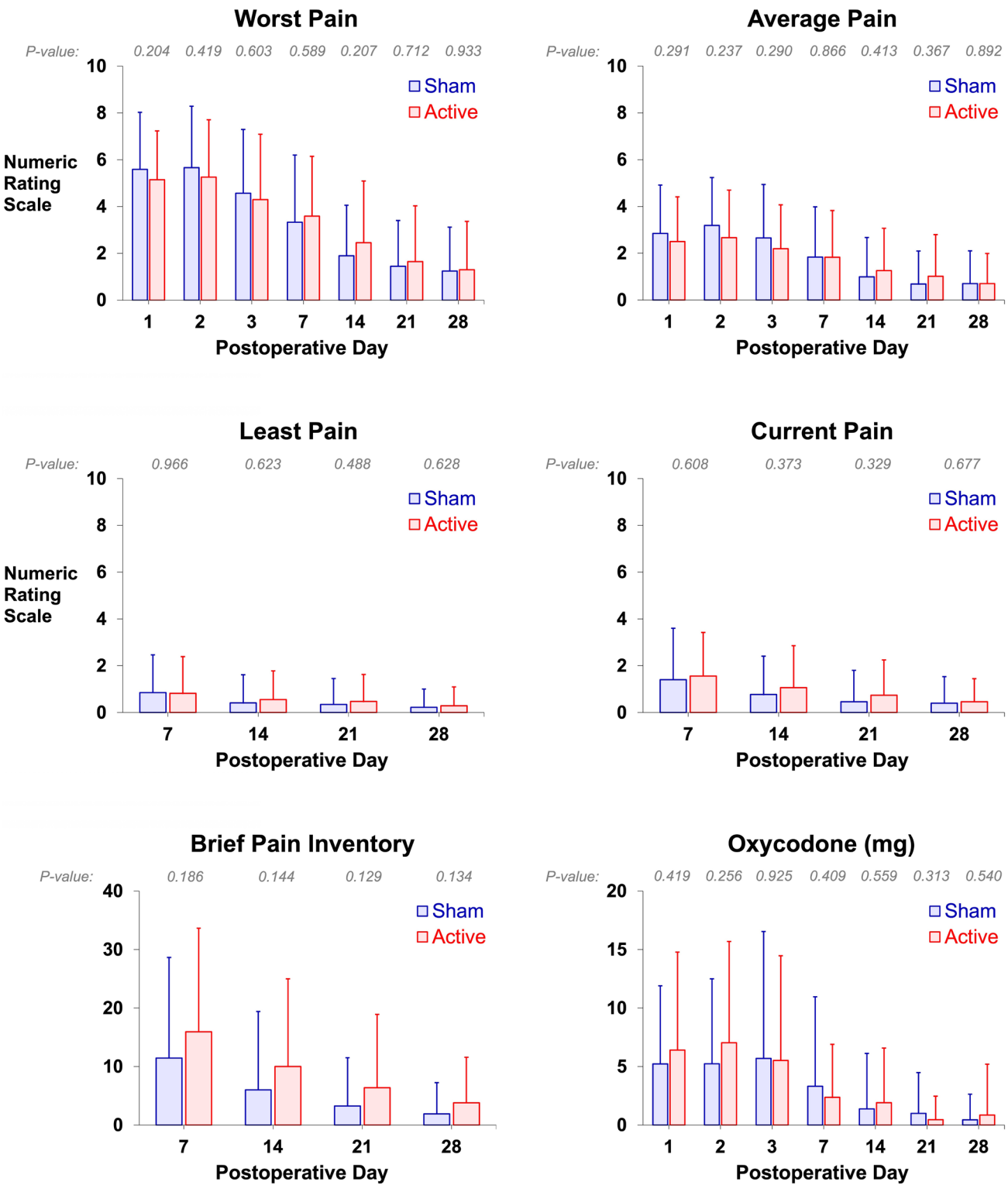

FIGURE 3 Effects of 28 days of pulsed shortwave therapy on daily *pain*, *opioid* consumption, and pain's *interference in functioning*. Pain severity was measured using a numeric rating scale with 0 equal to no pain and 10 being the worst imaginable pain. Oxycodone is a synthetic opioid and presented in milligrams. Regarding the Brief Pain Inventory, pain interference indicated using a numeric rating scale of 0–70, with 0 and 70 equal to no and maximal interference, respectively. Data expressed as mean (top of box) with standard deviation (whisker). There were no statistically significant differences between the treatment groups at any time point.

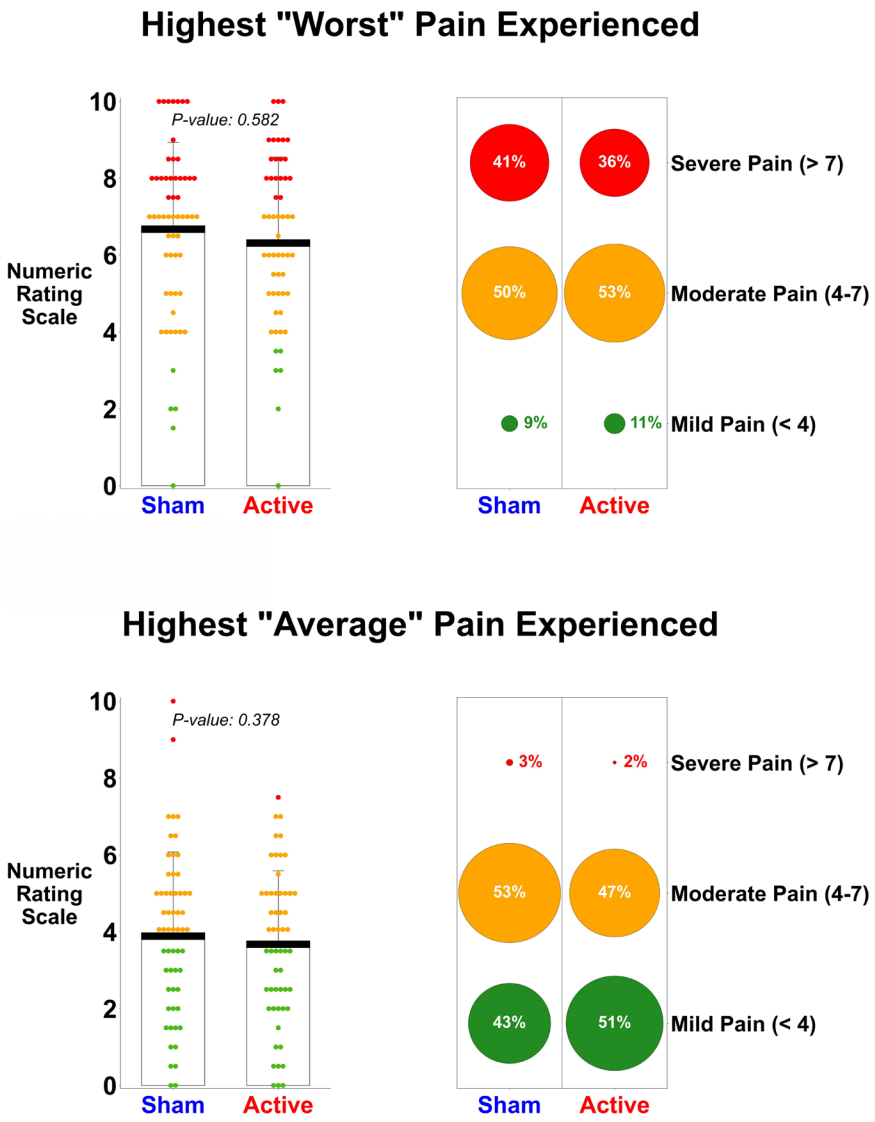

FIGURE 4 Effects of pulsed shortwave therapy on the *highest worst and average pain* level experienced *over the entire 28-day treatment period*. Pain severity was measured using a numeric rating scale with 0 equivalent to no pain and 10 being the worst imaginable pain. Data expressed as mean (top of box) with standard deviation (whisker). There were no statistically significant differences between the treatment groups.

or breast surgery) did not produce differing results for any outcome measure.

Feasibility

No systemic side effects or other adverse events directly related to the PSWT devices were identified, although three participants withdrew due to tape-related dermatitis. Two additional participants withdrew as they did not want to participate in data collection. One participant reported one of his three devices ceased to function on Day 17 based on the inactivation of the LED and an inability to restart the device. Participants did not have any complaints regarding the devices, and the anatomic locations chosen for device placement were acceptable to both surgeons and patients.

DISCUSSION

This randomized, double-masked, sham-controlled pilot study failed to find evidence that PSWT provides analgesia or opioid sparing in the week following knee and hip arthroplasty, cholecystectomy, hernia repair, or breast surgery. However, these results must be replicated with a subsequent clinical trial before being considered definitive. The only difference between treatment groups reaching statistical significance was the total number of awakenings due to pain, with participants who received active treatment reporting a mean of 3.9 versus only 2.2 for the sham group ($p < 0.001$). However, considering all other comparisons failed to reach statistical significance, this is most likely a false positive (Type I error) in a secondary outcome. We were successful in realizing the two major

aims of the current pilot study: (1) to determine the feasibility and optimize the protocol for a subsequent investigation and (2) estimate the treatment effect of PSWT on postoperative pain and opioid consumption.

The limited previously published randomized, controlled trials mainly involve foot/ankle, dental, and breast surgery, the results of which vary greatly.[28] Treatment effects of PSWT are correlated not just with therapy duration but also with aggregate energy exposure, which is determined by multiple factors.[29] The parameters determining the electromagnetic waveform include the size and shape of the antenna as well as the pulse duration, width, frequency, and power of the devices.[20] Since the various available devices have different parameters, they may have substantially different physiologic effects, possibly explaining the variable outcomes of this and previous investigations.[28] Therefore, it is an inconvenient truth that the results of one study may not necessarily be extrapolated to other devices with different parameters. The device used in the current report has US Food and Drug Administration clearance to treat postoperative pain and edema. It uses a 27.12 MHz carrier wave frequency and has a pulsed width of 100 microseconds, a pulse repetition rate of 1000 pulses per second, a peak spatial power density of 73 microwatts/cm^2, a 12 cm diameter antenna resulting in a 110 cm^2 treatment area, and a 720 h (30 day) duration battery.

There is evidence from randomized, controlled studies that the device of the current study decreases chronic pain derived from limb amputation,[30] plantar fasciitis,[31] and knee osteoarthritis.[32] It remains unknown why the negative findings of the current study differ from these three preceding investigations but may involve differentiating factors such as acute versus chronic pain, anatomic location placement of the devices, or the differing indications themselves. And although there are theoretical reasons to anticipate a possible protective effect of PSWT in preventing persistent post-surgical pain, we detected no such benefit in the current study.

The principal limitations of this pilot study include the limited number of participants for each type of surgery (about 30 for each) and the absence of a pre-established plan for analysis. Despite these shortcomings, the universal lack of positive results across all primary and secondary outcomes—with the single exception of awakenings due to pain—provides strong evidence against a false negative (Type II error). An additional weakness was our failure to assess overall patient mobility, raising the possibility that enhanced pain management might have inadvertently increased mobility, which increased pain scores. Future research should aim to track patient movement, perhaps by incorporating wearable technology to measure activity.[33]

In conclusion, this randomized, controlled pilot study failed to produce evidence that PSWT reduces pain scores and opioid requirements to a statistically significant or clinically relevant degree during the initial postoperative week following knee and hip arthroplasty, cholecystectomy, hernia repair, and breast surgery. However, these results must be replicated with a subsequent study before being considered definitive.

AUTHOR CONTRIBUTIONS

Brian M. Ilfeld, MD, MS (Clinical Investigation). This author conceived of the project, acquired the necessary funding, developed the protocol, oversaw the regulatory process, device application, and data collection, performed the statistical analysis, and authored the initial manuscript. John J. Finneran IV, MD, and Engy T. Said, MD. These authors helped develop the protocol, applied the intervention clinically, and revised the manuscript. Scott T. Ball, MD, Anne M. Wallace, MD, Ryan C. Broderick, MD, Bryan J. Sandler, MD, FACS, and Jay J. Doucet, MD. These authors helped develop the protocol, manage participants clinically, and revise the manuscript. Sandy R. Hu, BS, Brannon J. Cha, BS, and Adhithi Narayana Murthy. These authors helped create the initial manuscript and revise subsequent versions. Baharin Abdullah, MD. This author helped develop the protocol, perform the regulatory work, apply the intervention clinically, and revise the manuscript.

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CONFLICT OF INTEREST STATEMENT

Drs. Ilfeld, Finneran, Said, and Abdullah: The University of California San Diego has received funding and/or products from the following companies for other research studies of these authors: Epimed International, SPR Therapeutics, Infutronix, Avanos Medical, Masimo, and Varian Medical Systems. Dr. Ball: Consulting with OrthAlign, Inc. Mr. Cha: The University of California San Diego has received product from Masimo for other research studies. Remaining authors: No conflicts to disclose.

DATA AVAILABILITY STATEMENT

Deidentified patient-level data will be shared for collaborative analyses on request to Brian M. Ilfeld (email: bilfeld@health.ucsd.edu) shortly after publication. The data dictionary and statistical tables and code will be provided as appropriate; a data-sharing contract will be required. The protocol is available by request.

CLINICAL TRIAL REGISTRATION

Clinicaltrials.gov; NCT05399355.

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