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CASE REPORT

Wearable, noninvasive, pulsed shortwave (radiofrequency) therapy for analgesia and opioid sparing following outpatient surgery: A proof-of-concept case series

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Abstract

Background: It is often difficult to concurrently provide adequate analgesia while minimizing opioid requirements following ambulatory surgery. Nonthermal, pulsed shortwave (radiofrequency) fields are a noninvasive treatment used as an adjunct analgesic and wound healing therapy. The devices may be placed by nursing staff in less than a minute, are relatively inexpensive and readily available, theoretically provide analgesia for nearly any anatomic location, and have no systemic side effects—patients cannot detect any sensations from the devices—or significant risks. Here we present a case series to demonstrate the use of pulsed, electromagnetic field devices for outpatient herniorrhaphy and breast surgery.

Case Report: Following moderately painful ambulatory umbilical (n = 3) and inguinal (n = 2) hernia repair as well as bilateral breast surgery (n = 2), patients had taped over their surgical incision(s) 1 or 2 noninvasive, wearable, disposable, pulsed shortwave therapy devices (RecoveryRx, BioElectronics Corporation, Frederick, Maryland) which functioned continuously for 30 days. Average resting pain scores measured on the 0–10 numeric rating scale were a median of 0 during the entire treatment period. Six patients avoided opioid use entirely, while the remaining individual required only 5 mg of oxycodone during the first postoperative day.

Conclusions: These cases demonstrate that the ambulatory use of pulsed shortwave devices is feasible and may be an effective analgesic, possibly obviating opioid requirements following outpatient herniorrhaphy and breast surgery. Considering the lack of any side effects, adverse events, and misuse/dependence/diversion potential, further study with a randomized, controlled trial appears warranted.

KEYWORDS
ambulatory surgery, analgesia, outpatient surgery, postoperative analgesia

INTRODUCTION

Pain following outpatient surgery is often difficult to control without opioids, which are frequently associated with undesired side effects and a risk of misuse, dependence, and diversion. Peripheral nerve blocks deliver site-specific analgesia with few side effects, but surgical pain often outlasts their duration of action. A possible alternative is the use of nonthermal, pulsed shortwave (radiofrequency) fields which have been used to treat acute and chronic pain, decrease inflammation and edema, and hasten wound healing and bone regeneration.[1,2] The mechanism of action is complex, multifactorial, and only partially understood.[3] The most generally

accepted biochemical-based theory involves the promotion of calcium binding to calmodulin which activates endothelial and neuronal nitric oxide synthase isoforms, producing nitric oxide which has anti-inflammatory and analgesic effects, among other consequences such as decreasing edema while increasing blood and lymph flow.[4]

Pulsed radiofrequency has been used to treat postoperative pain with various degrees of success, primarily for breast and orthopedic surgery.[5] One randomized, controlled trial published in 1987 evaluated pulsed shortwave therapy to treat inguinal herniorrhaphy but found no analgesic benefit.[6] However, treatment was applied to inpatients only 15 min twice daily for 2 days since the pulsed electromagnetic field machines available in the mid-1980s were large, heavy, and required an external power supply.[7] In the last few decades, small, light, battery-powered, disposable, wearable devices have been developed and are now cleared by the United States Food and Drug Administration, with indications including the treatment of musculoskeletal and postoperative pain as well as edema. These wearable devices now allow for far more frequent and longer-duration treatment,[5] in contrast to the four 15-min treatments of the negative herniorrhaphy study.[6]

Optimism is warranted for the use of *perioperative* pulsed radiofrequency to treat pain following hernia surgery in the immediate postoperative period given there are 4 published case reports describing the successful treatment of *persistent/chronic* pain many *months* following inguinal herniotomy.[8–11] Consequently, we now report our experience with multiple cases to (1) explore the possibility of treating *ambulatory* patients *continuously* for 30 days with this modality and (2) estimate the treatment effect to help power and design a subsequent randomized, controlled pilot study.

CASE REPORT

Patients undergoing ambulatory umbilical hernia ($n = 3$), inguinal hernia ($n = 2$), and breast ($n = 2$) surgery provided written, informed consent for treatment with wearable pulsed shortwave electromagnetic field devices. They subsequently provided written, informed consent for unidentifiable inclusion in this publication. The University of California San Diego Institutional Review Board (San Diego, California) waives review requirements for case reports and short series.

The four female and three male patients had a mean (SD) age of 51 (13), height of 165 (12) cm, weight of 76 (23) kg, and body mass index of 27.6 (6.4). The two patients having breast surgery (bilateral breast augmentation revision procedures) received preoperative bilateral single-injection paravertebral blocks with ropivacaine 0.5% and epinephrine (20 ml/side). All patients received a general anesthetic intraoperatively, and those undergoing hernia repair also received bupivacaine 0.25%–0.5% (10–20 ml) infiltrated into the surgical area prior to closure.

Within the recovery room, patients had affixed over their surgical incision(s) 1 (umbilical hernias) or 2 noninvasive, wearable, pulsed shortwave (radiofrequency) electromagnetic field devices (Model 088, BioElectronics Corporation, Frederick, Maryland) with included kinesiology and/or paper tape (Figure 1).

Patients were discharged home from the recovery room with a prescription for the synthetic oral opioid oxycodone (5 mg tablets). Patients 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 30 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. The electromagnetic pulses pass through bandages and clothing, so adherence to the skin is not required. Showering with the device(s) in place was acceptable, but not submerging the rings in water. Patients were to check daily that the light-emitting diode was green indicating a functioning unit, but no other device care or adjustment was required. Patients were contacted by telephone at intervals standard for our acute pain service on postoperative days 1, 2, 3, 4, 7, 14, 28, and 35.

Average daily pain at rest was a median of 0 as measured using a 0–10 numeric rating scale for the entire period of follow-up (Figure 1). Average pain with movement was a median of 3 and 1.5 on postoperative days 1 and 2, respectively, but subsequently fell to zero for the remaining time points (Figure 1). Similarly, maximum pain each day was a median of 4.0 and 4.5 for the first 2 days, respectively, 1.0 the following 2 days, and 0 thereafter (Figure 1). Six patients avoided opioid use entirely, while the remaining individual required 5 mg of oxycodone during the first postoperative day (Figure 1). After 30 days, the devices were removed at home and discarded.

No patient contacted a healthcare provider with a question or concern during the follow-up period, and no device-related localized irritation, side effects, or complications were identified during the telephone follow-up.

DISCUSSION

These cases demonstrate that nonthermal, pulsed shortwave therapy using devices applied in an outpatient surgical facility is feasible and may be an effective analgesic, decreasing—perhaps obviating—opioid consumption following ambulatory hernia and breast surgery. This modality could have a significant beneficial influence *vis-à-vis* the opioid epidemic if our present findings are validated in a future controlled trial: for opioid-naïve patients, the risk of chronic opioid use 1 year following

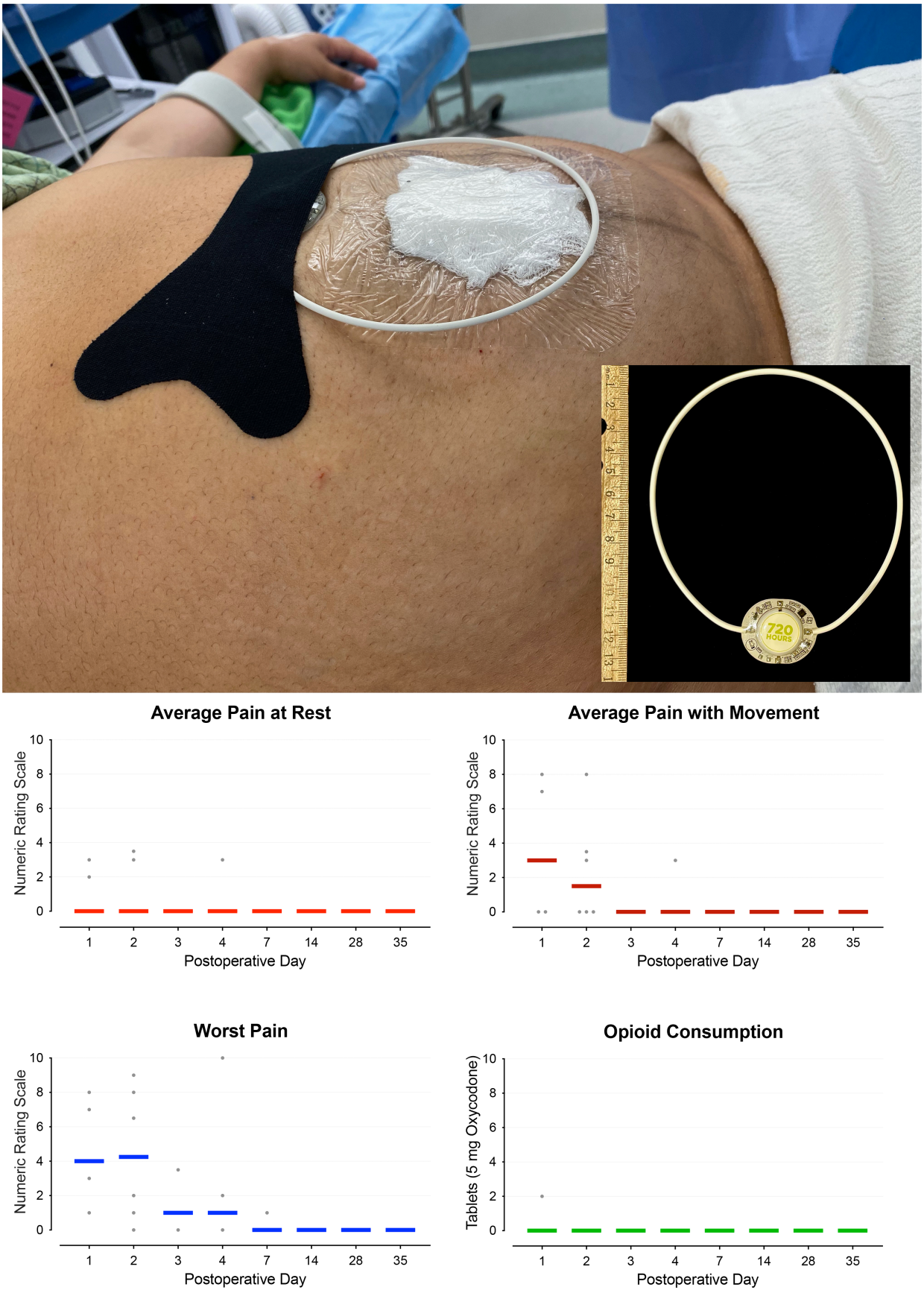

FIGURE 1 Top panel: A wearable, pulsed shortwave (radiofrequency) electromagnetic field device with a pulse generator and flexible 12cm-diameter antenna. The unit is secured with included cotton-based kinesiology tape (black bandage in image). The single control is an on/off button on the back of the pulse generator. Bottom panel: Pain and opioid consumption during ambulatory pulsed shortwave (radiofrequency) electromagnetic field therapy following outpatient hernia and breast surgical procedures. Each circle represents one patient, and the median for each time point is denoted with a horizontal line

surgery is 6%.[12] Disturbingly, 65–80% of current heroin users initiated their dependence by misusing prescription opioids.[13,14] Moreover, the number of prescribed opioid tablets is directly correlated with the probability of continuing their use,[15] and therefore, a modality allowing the prescription of just a few opioid tablets could prove greatly beneficial. Finally, pulsed electromagnetic fields may bring benefits beyond analgesia by decreasing inflammation and edema, and hastening wound healing.[1,2]

While a randomized, masked, placebo-controlled study is necessary to validate this modality and quantify benefits, the attributes of pulsed electromagnetic field therapy suggest an extraordinary potential to treat postoperative pain: the devices are noninvasive and weigh <10 g, may be applied to nearly any part of the body, function through surgical bandages and clothing, produce no perceptible sensations, have no side effects, once initiated require no intervention by patient or provider, have a duration of up to 30 days (unlimited duration using serial devices), and have no potential for misuse, dependence, or diversion. They are inexpensive compared with the cost of most medical devices, and an equivalent version may be purchased without a prescription, demonstrating that application can be performed without any medical training.

A number of independent societies and government agencies have investigated and confirmed the safety of nonthermal, pulsed, electromagnetic fields.[16–18] For example, the Institute for Electrical and Electronics Engineers Standards for Radio Frequency Electromagnetic Field Exposure concluded that "there are no adverse health effects that are not thermally related."[16] Within the past 25 years, over 3 million treatments with pulsed electromagnetic field devices have been delivered without reports of significant adverse events or side effects.[19] However, there are contraindications, including use in an area of preexisting malignancy, pregnancy, placement within 6″ of an existing implanted pulse generator (eg, cardiac pacer), and use in children <17 years of age.[18]

With its low cost and extraordinary record of safety spanning 7 decades, the benefits from this modality need not be great to still have a favorable risk/cost-to-benefit ratio. Acetaminophen may be an appropriate comparator: although its analgesic benefits are modest compared with alternative analgesics, it is used in every enhanced recovery after surgery (ERAS) protocol for abdominal wall reconstruction due to its ease of administration, lack of side effects, and relatively benign risk profile.[20] Compared with acetaminophen, the device used in the present report requires less cumulative time for administration (one-minute application for 30 days of analgesia vs. taking oral medication every 6 h); has an equivalent lack of side effects; and possesses a superior safety profile (no known significant complications vs. the most common cause of acute liver failure in the United States).[21] Nonetheless, clinical adoption is limited by a lack of systematic evidence, historically a limited understanding of the mechanism of action, and "a wide variety of unsubstantiated claims that are used for marketing purposes."[19]

The currently reported cases will be used to help power and design a subsequent randomized, controlled pilot study. Any systematic investigation of perioperative pulsed shortwave therapy should collect data from remote time points in addition to the immediate postoperative period because it has been hypothesized that this modality applied in the acute postoperative period may decrease the risk of central sensitization and development of *persistent* post-surgical pain.[22] Chronic pain has been identified as a syndrome of central sensitization, whereby an increase in synaptic efficacy and decrease in inhibitory pain pathways results in central amplification of previously subthreshold synaptic inputs.[23,24] Although a full discussion is outside the scope of this report, a biophysical-based theory for the mechanism of action involves stochastic resonance: the radiofrequency stimulation modulation of Aα and Aβ nerve fibers results in a barrage of nonpainful stimuli that essentially raise the perioperative pain threshold.[3] If accurate, this approach to modulate the activity of the sensory nervous system to modulation effect of the central nervous system by increasing "afferent noise" may mitigate the onset of central sensitization and development of *persistent* post-surgical pain.[22]

Today, all nonthermal shortwave devices cleared by the United States Food and Drug Administration for use in treating superficial soft tissue use a 27.12 MHz carrier wave frequency.[10] However, pulse width and frequency in addition to other parameters such as antenna diameter vary greatly among devices. These factors determine the shape, size, and intensity of the generated magnetic and electric fields. Therefore, different devices can have substantially different physiologic effects.[9,13] This is an inconvenient reality which dramatically decreases generalizability of the results from any one clinical study to other devices. The device used in the current reports has a pulsed width of 100 microseconds, pulse repetition rate of 1000 pulses per second, peak spatial power density of 73 microwatts/cm^2, 12 cm diameter antenna resulting in a 110 cm^2 treatment area, and 720 h duration battery.

Although the majority of cases described in this report involve hernia repair, we included two patients undergoing breast surgery since the specific device used in the present series has not been reportedly used for breast surgery previously. And although most data from randomized, controlled studies treating acute pain involve breast surgery,[25–28] further investigation is required for each specific device with its unique attributes.

These cases demonstrate that the ambulatory use of pulsed shortwave (radiofrequency) therapy devices is feasible and may be an effective analgesic, possibly obviating opioid requirements following outpatient herniorrhaphy and breast surgery. Considering their ease of placement,

few contraindications, applicability to nearly any surgical site, low patient/provider burden, lack of systemic side effects and serious adverse events as well as any misuse/dependence/diversion potential, further study with a randomized, controlled trial appears warranted to document and quantify potential analgesic and opioid-sparing benefits of these noninvasive and wearable devices.

AUTHOR CONTRIBUTIONS

Brian M. Ilfeld: This author identified the intervention as a possible treatment for post-amputation pain, identified and contacted potential patients, collected data, wrote the initial manuscript draft, and approved the final draft. Engy T. Said: This author treated and educated patients, helped revise the manuscript, and approved the final draft. Rodney A. Gabriel, MD: This author treated and educated patients, helped revise the manuscript, and approved the final draft. Matthew W. Swisher: This author treated and educated patients, helped revise the manuscript, and approved the final draft. Brian P. Curran: This author treated and educated patients, helped revise the manuscript, and approved the final draft. Garth R. Jacobsen: This author helped identify possible patients, follow patients, revise the manuscript, and approve the final draft. Anne M. Wallace: This author helped identify possible patients, follow patients, revise the manuscript, and approve the final draft. Jay Doucet: This author helped identify possible patients, follow patients, revise the manuscript, and approve the final draft. Laurie Adams: This author helped identify possible patients, follow patients, revise the manuscript, and approve the final draft. George Ventro: This author helped identify possible patients, follow patients, revise the manuscript, and approve the final draft. Baharin Abdullah: This author helped collect information, revise the manuscript, and approved the final draft. John J. Finneran IV: This author treated and educated patients, helped revise the manuscript, and approved the final draft.

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CONFLICT OF INTEREST

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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

This was not a prospective investigation and did not require clinical trial registration.

PATIENT CONSENT

Patients provided written, informed consent for treatment with wearable pulsed shortwave electromagnetic field devices. They subsequently provided written, informed consent for unidentifiable inclusion in this publication. The University of California San Diego Institutional Review Board (San Diego, CA) waives review requirements for case reports and short series.

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