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Control of Postoperative Pain with a Wearable Continuously Operating Pulsed Radiofrequency Energy Device: A Preliminary Study

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Abstract
Background Pulsed radiofrequency energy (PRFE) has long been reported to have a therapeutic effect on postoperative pain. In this study, a portable, wearable, low-energy-emitting PRFE therapy device was used to determine the control of postoperative pain after breast augmentation surgery.
Methods The study enrolled 18 healthy women who underwent breast augmentation purely for aesthetic considerations. Postoperative pain after surgery was assessed with a 0- to 10-point visual analog scale (VAS). Baseline pain scores were taken at completion of the operation, and the patients were randomly assigned coded PRFE devices that were either active or placebo devices. For 7 days, VAS scores were recorded twice daily (a.m. and p.m.). Medication use also was logged for 7 days. The PRFE devices were left in place and in continuous operation for the 7 days of the study.
Results All the patients tolerated the PRFE therapy well, and no side effects were reported. The VAS scores for the active group were significantly lower on postoperative day 1. By day 7, the baseline VAS remaining in the active group was 7.9% versus 38% in the placebo group. Together with lower VAS scores, narcotic pain medication use was lower in the patient group that received PRFE therapy.
Conclusion Postoperative pain is significantly lower with PRFE therapy. According to the findings, PRFE therapy in this form is an excellent, safe, drug-free method of postoperative pain control.

Keywords Pain · Postoperative · Pulsed radiofrequency

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Postoperative pain after surgery is a major priority for both patients and doctors. Pain affects blood pressure, heart rate, appetite, and general mood. Despite advances in our understanding concerning the neurobiology of nociception, the development of new analgesics, and the refining of minimally invasive surgical techniques, postoperative pain continues to be undertreated [1]. A 2003 survey of pain management in the United States shows that there still is a need to enhance postoperative pain management [2].

Improvement of effective analgesia in the early postoperative period may lead to clinically important benefits in terms of long-term recovery, including a decreased incidence of chronic postsurgical pain [3]. Chronic pain after breast cancer surgical treatment, for example, is a major clinical problem, affecting 25–60% of patients [4]. An added benefit of improved analgesia is enhanced recovery, with shortened hospital stays and convalescence [5, 6].

An underused postoperative pain management method is pulsed radiofrequency energy (PRFE) therapy, also known as pulsed electromagnetic field therapy (PEMF), pulsed short-wave therapy (PSWT), and RF nonthermal diathermy. In 1947, the Federal Communications Commission (FCC) assigned three frequencies at the short end of the RF band (40.68, 13.56, and 27.12 MHz) [7] for medical use. The frequency of 27.12 MHz is the most widely used in clinical practice.

The first PRFE device, the Diapulse (Diapulse Corporation, Great Neck, NY, USA), was commercially available in the 1950s. It was followed by other commercially available machines. As a treatment for nonhealing bone fractures in humans, the use of PEMF is well established [8] and has been in use since the 1970s. Clinical studies have demonstrated its safety and efficacy as a treatment for pain, edema, and soft tissue injury.

Some of the first studies investigating postoperative edema and edema caused by soft tissue injury showed promising results [9, 10]. Studies on postoperative pain also showed good results [11–13]. Reduction of capsular contraction in 41 patients after breast augmentation surgery was achieved with PRFE therapy together with massage and closed capsulotomy treatment [14]. Pain and edema also have been treated with PRFE therapy in a number of orthopedic conditions [7, 15–18].

Findings also have demonstrated PRFE therapy to be effective for chronic wounds, including diabetic and venous stasis ulcers. A number of early studies showed good results [19], with improved healing of pressure ulcers with PRFE treatment [20].

A prospective, randomized, double-blind, placebo-controlled multicenter study assessed the clinical efficacy and safety of pulsed electromagnetic therapy delivered by a portable device. The device was used at home for the healing of recalcitrant, predominantly venous leg ulcers. Significant decreases in wound depth and pain intensity favoring the active group were observed [21].

Important recent studies on the use of PRFE for the treatment of chronic wounds may bring a new focus to its application in this field [22–25], including a retrospective study on the Regenesis Biomedical Wound-Healing Registry [24] (Regenesis Biomedical, Scottsdale, AZ, USA).

Two studies on postoperative pain using a wearable form of PRFE from Ivivi Technologies (SofPulseTM; Ivivi Technologies, Northvale, NJ, USA) have been reported. In the first study, a double-blind, placebo-controlled, randomized clinical trial on breast augmentation showed a significant decrease in postoperative pain [26]. The second study, using the same form of wearable PRFE device after breast reduction surgery, also showed significant control of postoperative pain [27]. In this study, a decrease in interleukin 1-β was reported, suggesting a modulation of the wound-healing process.

A potential mechanism of action for PRFE therapy has been put forward and is reviewed by Strauch et al. [28]. Moreover, recent reports have further contributed to understanding concerning the mechanisms of PRFE therapy for wound healing [29, 30].

Continued technological advancement has allowed PRFE devices to be produced that are smaller and less obtrusive, as shown in Fig. 1 (BioElectronics Corp, Frederick, MD, USA). The small size allows them to be potentially applied to most areas of the body. They are inexpensive to produce and easy for both the physician and the patient to use.

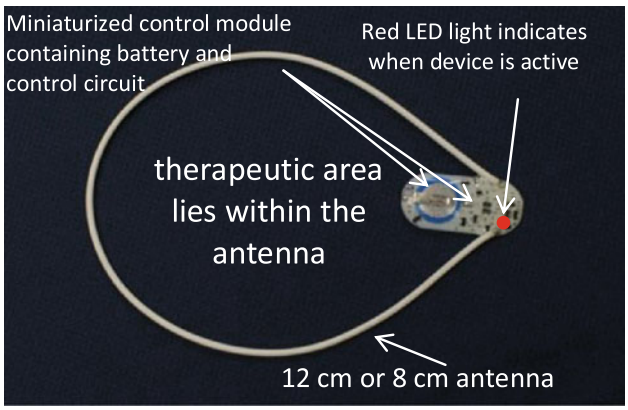

Fig. 1 Latest version of a pulsed radiofrequency energy (PRFE) device. The therapeutic field lies within the 12-cm antenna. The control module containing the battery is small (4.2 × 2.0 cm, with a depth of 0.3 cm) and streamlined, allowing for comfortable application

Materials and Methods

Patients

The ethics review board of North Texas Independent Review Board at Medical City, Dallas, Texas approved this study. All the patients enrolled in the study signed a consent form.

PRFE Device

The device used in this study was a PRFE device (RecoveryRx, BioElectronics Corp) that emits a safe form of nonionizing electromagnetic radiation. The carrier frequency of this device is 27.12 MHz, the assigned FCC medical frequency. It has a pulse rate of 1,000 pulses per second and a 100-μs burst width. The peak burst output power of the 12-cm antenna is approximately 0.0098 W covering a surface area of approximate 100 cm^2. The circuitry consists of low-voltage (3 V) digital/analog electronics that control all timing functions to produce the therapeutic RF field with the antenna field placed directly above the therapeutic site.

Study Design

The study was a double-blind, placebo-controlled randomized study to determine postoperative pain after breast augmentation. The 18 patients recruited into the study had elected the surgery for purely aesthetic reasons. Silicone breast implants (Allergan, Irvine, CA, USA) were used for

all the patients, and each operation was performed in less than 1 h.

Breast augmentation was performed in submuscular fashion via either an inframammary or periareolar approach. Randomization resulted in 10 patients receiving active devices on each breast and 8 patients receiving placebo devices on each breast. There were no patient dropouts. The demographics of the active and placebo patient groups very closely matched in terms of average age (32 vs. 31.3 years), weight (134.4 vs. 134.1 lb), and height (5.61 vs. 5.44 ft).

Once the surgery was completed, the PRFE devices were activated and secured in place with a surgical bra. The placebo devices were activated in the same way. A red indicator light showed activation of both the placebo and active devices. The active devices were not felt by the patient, ensuring that the patients were unable to determine the treatment group.

At completion of the operation, a baseline score was assessed for each patient. The pain scores were assessed using a visual analog scale (VAS) ranging from 0 (no pain) to 10 (extreme pain). The pain scores were logged in the a.m. and p.m. for the 7 days of the study. The use of VAS scores to document pain is well established [31]. The medication use by each patient also was logged. The medications used by patients were opiate-based drugs, oxycodone, hydrocodone, and propoxyphene.

Statistical Analysis

Means with standard deviations are reported. The differences between the active and placebo groups were determined by *t*-tests and repeated measures analyses of variance (ANOVA). The *F*-test for the equality of variances was performed. A *P* value of 0.05 was considered significant.

Results

The PRFE therapy devices were well tolerated by all the patients, and no adverse effects were noted. Data were obtained from all the patients and available for statistical analysis. The baseline score, obtained at completion of the operation before treatment, did not differ significantly between the active and placebo groups. Therefore, the baseline VAS score was determined from all the patients. The VAS scores, collected twice daily (a.m. and p.m.), were averaged to a daily mean. The mean daily VAS scores and standard deviations are presented in Table 1.

The mean baseline VAS score was 6.46 on the 0- to 10-point scale. As shown in Fig. 2, the postoperative day 1 VAS score for the active group was 2.06 points lower than the baseline score ($P = 0.02$, significant difference). The placebo group VAS score was 6.80, which was not significantly lower than the baseline score ($P = 0.65$). The VAS score for the active group was 2.40 points lower than that for the placebo group ($P = 0.017$, significant difference).

The VAS scores in the active group were significantly lower than the placebo group on all days except day 2 ($P = 0.23$), but were 1.35 VAS points (35%) lower. Figure 3 shows the comparison of the active and placebo VAS scores with the baseline score at postoperative day 3. On postoperative day 3, the placebo group VAS was 5.40 points. The active mean VAS score (2.57) was significantly lower than the placebo mean VAS score (5.40) on day 3 ($P = 0.003$), showing a difference of 2.83 points. The

Table 1 Mean daily visual analog scale (VAS) scores and standard deviations for the active group (A-VAS) and the placebo group (P-VAS) during the 7 days of the study

Day	P-VAS	A-VAS
Baseline	6.46 ± 1.98	6.46 ± 1.98
1	6.80 ± 1.74	4.40 ± 2.09
2	5.20 ± 2.08	3.85 ± 2.36
3	5.40 ± 2.21	2.57 ± 1.32
4	4.25 ± 2.37	2.00 ± 1.27
5	3.40 ± 1.99	1.55 ± 1.23
6	3.80 ± 2.01	0.75 ± 0.65
7	2.40 ± 1.02	0.50 ± 0.40

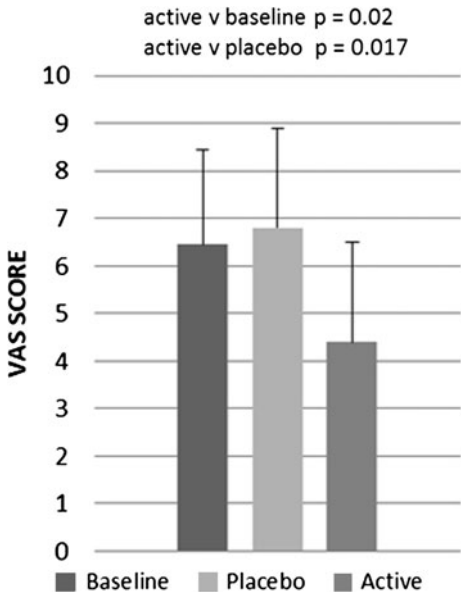

Fig. 2 On postoperative day 1, the active group mean visual analog scale (VAS) score at 4.40 is significantly lower than the mean baseline score of 6.46 ($P = 0.02$) and the placebo mean VAS score of 6.80 ($P = 0.017$)

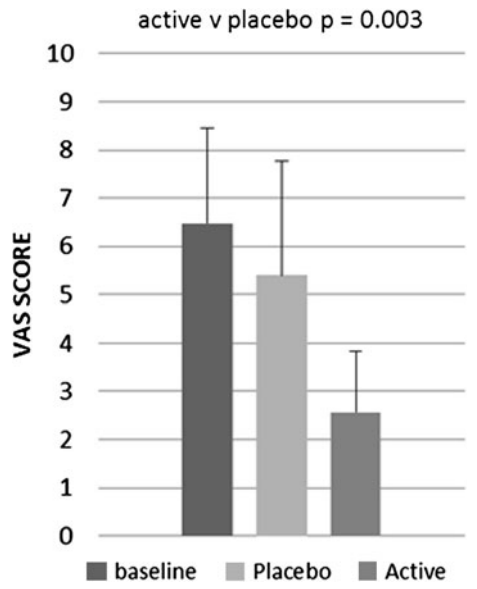

Fig. 3 On postoperative day 3, the mean visual analog scale (VAS) score is 2.83 points lower in the active group than in the placebo group and has recovered 60% from the baseline score compared with a 17% recovery in the placebo group ($P = 0.003$)

active group recovered to 50% of baseline pain between postoperative days 2 and 3, whereas the placebo group recovered to 50% of baseline by postoperative day 6. These results show that the active group recovered faster than the placebo group.

Narcotic Pain Medication

The pain medication was logged by each patient on a daily basis. Patients used narcotic pain medication consisting of oxycodone 2.5/325 (O), hydrocodone 5/500 (H), hydrocodone 7.5/500 (H+), and propoxyphene (P). The total narcotic pain pill use was 145 pills in the placebo group (81 H, 9 H+, 55 O) and 110 pills in the active group (67 H, 2 H+, 26.5 O, 14. 5 P). The individual patient use of narcotic pain pills in the active group was as follows: 2.5, 4, 5, 6, 7, 10, 14, 14, 14.5, and 33. In the placebo group, the individual narcotic pill use was 6, 13, 18, 19, 20, 21, 23, and 23. Of the 10 patients in the active group, 6 patients used 10 or fewer narcotic pain pills. One patient in the placebo group used 10 or fewer narcotic pain pills. A single patient in the active group used 33 narcotic pain pills (H). This represents 30% of the total narcotic medication use in the active group and more than twice as much as the next highest total of 14.5.

The statistics for patient use of narcotic medication are shown in Table 2. The means were 11 pills per patient in the active group and 18.1 pills per patient in the placebo group, representing a 68% increase in narcotic medication use in the placebo group ($P = 0.07$, nonsignificant increase). However, with the outlier (patient 10) excluded, the mean narcotic pill use becomes 18.1 for the placebo group and 8.5 for the active group ($P = 0.002$, a significant difference). The median value, which better controls for any outliers in the data set provides a more representative value for pain pills per patient in the active group. The median number of prescription pills per patient was 8.5 in the active group and 20 in the placebo group.

Discussion

The patients who received PRFE therapy experienced significantly less postoperative pain than the patients assigned the placebo devices. Because VAS scores are a measure of the pain level, it is interesting to note that totaling the mean VAS points for each day resulted in an accumulated average total of 31.25 VAS points for the placebo patient group and 15.62 VAS points for the active group during the 7-day study period. This indicates that the active group patients experienced an average of 50% less pain than those who received the placebo device. This is a considerable decrease in postoperative pain. It also must be considered that the placebo patients still were experiencing 37% of the baseline VAS score, whereas the active group had 7.7% of the baseline VAS score remaining. Thus, the placebo group continued to experience significant pain beyond day 7. This was highlighted by the fact that the day 7 placebo VAS point mean of 2.40 was equivalent to the day 3 VAS point mean of 2.57 in the active group.

The data presented also show that the patients who received PRFE therapy required less narcotic pain medication, which is not surprising, because with lower pain scores, less pharmacologic pain medication use would be expected. Taken together, decreased postoperative pain and lower narcotic medication use suggests that postsurgical complications would be reduced and that opiate-related

Table 2 Total narcotic pills used by patient group

	Total	Mean	SD	Median	*P* value	Total	Mean	SD	Median	P value
Placebo	145	18.1	5.9	20	–	*145*	*18.1*	*5.9*	*20*	–
Active	110	11.0	8.9	8.5	0.07	*77*	*8.5*	*4.6*	*7*	*0.002*

Mean, median, SD, and *P* value as well as the total, mean, median, SD, and *P* value with the outlier removed (italics)

SD standard deviation

side effects also would be less frequent. These data therefore indicate that PFRE is a safe and effective method for combating postoperative pain.

The pain medication side effects of opiate-based, acetaminophen, and nonsteroidal antiinflammatory (NSAID) drugs have been well documented. The side effects of opiate drugs are postoperative nausea and vomiting, urinary retention, ileus, constipation, and sedation. With acetaminophen and NSAIDs, side effects such as hepatic and renal toxicity, coagulation, confusion, sedation, and dizziness have been reported.

To improve analgesia and combat these side effects, the concept of multimodal, or balanced analgesia was introduced aimed at combining analgesics with additive or synergistic effects [32]. The theory behind this approach is that varying combinations of drugs for managing postoperative pain improve safety and efficacy due to their different mechanisms of action. There is some indication that this has led to a reduction in opioid-related side effects and improved analgesia [33, 34]. However, patient pain surveys indicate that postoperative pain management still is in need of significant improvement [2, 32]. Delivered in this form, PRFE energy would add another dimension to the multimodal analgesia approach. However, to be widely used and accepted, the PRFE device needs to be unobtrusive and seamlessly applied to wound dressing and recovery protocols. The RecoveryRx device used in this study is a one-time-use disposable device that operates for a minimum of 7 days, requires minimal patient involvement, and is very economical to produce.

Figure 1 shows the latest version of the PRFE device. The control module containing the battery measures 4.2 × 2.0 cm and has a depth of 0.3 cm. With a 12- or 8-cm antenna, the device weighs 8 g and could be simply applied for most surgical recovery protocols without having an impact on patient comfort while improving outcome. Whereas this study demonstrates the control of postoperative pain, this form of lightweight, wearable PRFE device also has been shown to promote the healing of chronic wounds [25].

The results of the study presented in this report show control of postoperative pain using a unique, continuously operating low-energy PRFE device. The control of postoperative pain is equivalent to that in the breast augmentation study by Heden and Pilla [26], with both studies showing significantly lower VAS scores by postoperative day 3 and both studies using portable wearable PRFE devices. However, the two studies had major differences. The PRFE device used in the Heden study was the Ivivi Technologies Torino, which has a higher peak output at 0.5 W than the RecoveryRx at 9.8 mW. The operation of the Ivivi device follows a protocol of being on initially 30 min every 4 h for the first 3 days, then 30 min every 8 h for the next 3 days. This contrasts with the continuous operation of the RecoveryRx device used in this study and shows that continuous low-energy application is as effective as a shorter treatment time with higher-energy devices in controlling postoperative pain. The most significant difference is the physical size of the two PRFE devices used in the studies. The Ivivi Technologies Tourino has a weight of 28 g, a 15- or 19-cm antenna, and a control module with an approximate size of 6.35 × 6.22 cm and a depth of 1.68 cm. The weight of the Ivivi device and the size of its control module are therefore about 3.5 times greater.

The concept of replacing short high-power PRFE energy treatments with extended-use, low-energy treatments was first developed by Dr. Bentall, who presented data comparing the effects of a 15-W PRFE device at 27.12 MHz (Diapulse) with those of a 2-mW pulsed device at 3 MHz on the tensile strength of rat abdominal wounds [35]. Despite the large difference in the physical size and power output of the two devices, they showed a very similar profile in enhancing the tensile strength of the wounds. The 15-W Diapulse treatment was given for 20 min three times per day, whereas the 2-mW treatment was an overnight exposure. The control condition was a 15-W light bulb. Applying this concept to postoperative recovery, Nicolle and Bentall [10] demonstrated the control of edema and bruising during postoperative recovery from blepharoplasty using a low-energy, extended-use PRFE device.

Larger-scale clinical trials still are needed for further validation of this postoperative therapy. However, the findings have shown the use of RecoveryRx PRFE therapy in a clinical setting to be as effective as the results presented in this report. For example, RecoveryRx is estimated to reduce postoperative pain by 60% after cesarean section (personal communication with Ian Rawe from Charge Nurse, Labor, and Delivery Ward).

Given the clear need to improve postoperative analgesia, extended-use, low-energy PRFE devices potentially offer a new dimension to multimodal analgesic techniques given that PRFE therapy has a long history of use and that side effects have not been reported. This mode of postoperative analgesia and improved wound healing could be used in almost all situations, allowing for greater flexibility in the use of pharmacologic interventions.

Conflict of interest David G. Genecov received honoraria from BioElectronics Corporation for the study. Ian M. Rawe is a paid consultant for BioElectronics Corporation.

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