Pulsed electromagnetic fields for postoperative pain: a randomized controlled clinical trial in patients undergoing mandibular third molar extraction

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Objectives. The clinical efficacy of a wearable pulsed electromagnetic field (PEMF) therapy device was assessed in terms of pain and quality of healing after tooth extraction.

Study Design. This randomized, parallel design, placebo-controlled study involved 120 patients undergoing unilateral mandibular third molar extraction and assigned to three groups after surgery. Test and placebo patients wore enabled or disabled PEMF devices, respectively, and controls wore no device. Patients recorded pain (on the visual analog scale) and analgesic use for a week, after which healing complications were assessed.

Results. Test patients had only slightly lower visual analog scale scores and analgesic use, but significantly fewer cases of dehiscence than placebo patients.

Conclusions. PEMF therapy delivered by a wearable device improved soft tissue healing and may be a useful adjunct for pain management after oral surgery. (Oral Surg Oral Med Oral Pathol Oral Radiol 2015;119:293-300)

Pulsed electromagnetic field (PEMF) therapy is a noninvasive method for delivering pulsed radiofrequency energy to tissues for the treatment of postoperative pain and edema. It is also used to treat chronic wounds and facilitate bone repair processes. PEMF therapy relies on short-lived emissions of electrical current, which generate an electromagnetic field in the tissues to be treated and have beneficial effects without affecting any of the main biologic functions. No side effects have been reported.

Several studies have tried to analyze the mechanisms of action behind PEMF therapy. The treatment alters the electrochemical balance in the cell membrane and interacts with biologic transduction mechanisms. Cell and animal studies have shown that PEMF therapy upregulates the mechanism that prompts nitric oxide production, increasing the levels of the calcium ion (Ca$^{2+}$)—binding protein calmodulin. The treatment has anti-inflammatory effects, both immediately—thanks to a greater blood supply and lymph flow—and in the longer term. PEMF therapy increases the production of fibroblast growth factor β-2, leading to angiogenesis and the development of granulation tissue. It may consequently improve all stages of the healing process, reducing pain and swelling in the initial lesion and favoring subsequent tissue regeneration and remodeling.

Several clinical studies have confirmed that using PEMF devices can positively influence postoperative morbidity. According to a recent meta-analysis of the literature, PEMF therapy is effective in treating postoperative pain and edema. Healing bone treated with PEMF has reportedly shown an increased calcification and greater mechanical strength, and these findings were confirmed by another meta-analysis. PEMF therapy has been used in the field of dentistry as well, with good outcomes in various in vitro, animal, and clinical studies.

Previously published studies mainly tested large appliances that were not portable; however, smaller, wearable devices are now being manufactured. Little has been written so far about the latter, and the literature only provides a preliminary clinical study that demonstrated that the use of a portable PEMF device coincided with significantly less postoperative pain.

The hypothesis is that applying a continuous low-energy PEMF close to a surgically traumatized target area, for example, by placing a PEMF device against a patient’s cheek after oral surgery, can be beneficial, providing both an analgesic effect (reducing use of painkilling medication) and a generally better soft and hard tissue healing process.

The aim of this randomized clinical trial was to assess the clinical efficacy of PEMF therapy delivered through a wearable device in terms of postoperative pain and quality of healing after mandibular third molar extraction.

Statement of Clinical Relevance

The results of this randomized clinical trial suggest that pulsed electromagnetic fields therapy can improve tissue healing and it is a viable option for pain management after oral surgery.
MATERIALS AND METHODS
A randomized, parallel-design, placebo-controlled study with an extra nontreatment group was designed and conducted at the Department of Oral Surgery, University of Padua, Italy. The study protocol (Prot. No. 2976 P, 23/09/2013) was approved by the University’s Ethical Committee on investigations involving humans and conformed to the Helsinki Declaration guidelines. The study was registered in a public trials registry (clinicaltrials.gov) in compliance with the recommendations of the International Committee of Medical Journal Editors. The Clinical trial registration number is NCT02273999.

The study sample included 120 patients referred for unilateral mandibular third molar extraction between September 2013 and January 2014. Exclusion criteria were as follows: age under 14 years, poor oral hygiene, contraindications for surgery (or anesthesia), infectious and systemic diseases, immunosuppressant therapy, pregnancy or breastfeeding, and mental disorders.

At a preliminary visit (T0), panoramic radiographs were obtained for each patient, and the difficulty of the proposed surgery was assessed by using the Pell and Gregory and the Winter classifications. Patients meeting all of our inclusion criteria were invited to take part in the trial and given accurate written and verbal information. Participants (or their legal guardians) signed informed consent forms.

A standardized surgical procedure was used in all patients (T1). After local anesthesia (mepivacaine 2% plus epinephrine 1:100,000), a buccal mucoperiosteal flap was raised via an envelope incision. Bone removal and tooth section were performed, as necessary, with the use of burs cooled with sterile saline solution. The flap was put back in place and sutured with multifilament resorbable sutures (Novosyn 3-0, B. Braun, Melsungen, Germany). Any need for osteotomy, with or without tooth section, was recorded for each patient. One intravenous injection of 2 mL of triamcinolone acetonide (40 mg/mL Kenacort; Bristol-Myers Squibb, Sermoneta, Italy) was administered immediately after surgery in certain conditions (e.g., if the procedure had proved particularly invasive or if there was a risk of neurologic damage).

On completion of the surgical procedure, patients were randomly assigned to one of three groups. Patients in the test (T) and placebo (P) groups had PEMF devices attached to their cheeks (Recovery RX, Bio-Electronics Corporation, Frederick, MD), which were only enabled in the T group, and patients in the control (C) group were not equipped with a device. Patient randomization was done with the use of a computer-based random number generator, and patients were allocated to one of the three groups by means of sequentially numbered sealed envelopes, keeping the investigators blinded to the random assignment data. Investigators were aware of the location of the random assignments data.

The PEMF devices used in this study consisted of an elliptical coil that was 8 cm in size and a radio-frequency energy generator powered by battery (Recovery Rx) that had an emission frequency of 27.12 MHz, a pulse rate of 1000 pulses per second, and a 100-nanosecond burst width. The circuitry consisted of low-voltage (3 V) digital or analog electronics controlling all of the timing functions to produce the therapeutic radiofrequency field with the antenna’s field directly over the site to be treated. The devices applied to patients in the placebo group were switched on in the same way as were the active devices, but without producing an electromagnetic field. These devices cannot be switched off and continue to function until the battery fails. The operator and the patients in the T and P groups were unaware of which type of device they were using, making this phase of the study double-blinded.

The PEMF devices were attached to the skin over the extraction site (Figure 1). Patients were instructed to wear the device continuously for 7 days postoperatively. All patients were given antibiotic therapy (1 g of amoxicillin every 12 hours for 6 days; for allergic patients, 500 mg of clarithromycin every 24 hours for 6 days). For ethical reasons, analgesics were recommended for all patients (paracetamol 1000 mg or ibuprofen 600 mg, 2-3 times a day for 3 days) on an as-needed basis; patients could choose to discontinue this medication or take none if they had no symptoms, but they were advised to take an analgesic pill as soon as they began to experience any pain.

Patients were given detailed instructions on how to complete a daily diary for 7 days after surgery, recording the following: pain (self-assessed on a 10-cm visual analogue scale [VAS]), hours of usage of the PEMF device (in the test and placebo groups), use of analgesics (type, dosage, and timing). Patients were advised to avoid vigorous mouthwashes, to ensure a good oral hygiene, to rest, and to apply an ice pack in the early hours after surgery.

After 7 days (T2), patients came to have their stitches removed and handed in the diary they had kept during the previous week, and an operator recorded any evidence or reports of dehiscence, tumefaction, pus, local lymphadenopathy, pain on palpation, postoperative bleeding, or alveolitis (Figure 2). The operator recording these healing parameters was blinded to the patients’ grouping (T, P, or C).
Sample size
The sample size was calculated, taking into consideration the VAS score on the 7th postoperative day. A sample size of 40 individuals per group was required to identify a mean difference of 1 between the T group and either of the other groups (P or C; type I error set at 0.016), with a standard deviation of 1 and a power of 0.9.

Statistical analysis
The Shapiro-Wilk test revealed a violation of the normality assumption, so nonparametric tests were used. Continuous data were expressed as medians and interquartile ranges (IQR). Categorical data from the three groups were compared by using the Fisher test, and continuous data were compared by using the Kruskal-Wallis test. Pairwise comparisons (using the Fisher or Mann-Whitney test) were performed for multiple comparisons, with the Bonferroni adjustment, as appropriate. Correlations between continuous data were assessed by using the Spearman correlation coefficient. The daily VAS scores were analyzed by using the Friedman nonparametric analysis of variance, including the treatment, the time, and the treatment \times time interaction in the model. A logistic regression was estimated to identify any independent predictors of on the 7th day. A \( P \) value of > .05 was considered significant. The statistical analyses were run blindly using the R 2.12 language.

RESULTS
The PEMF devices were well tolerated, and no adverse events were reported. Six from the initially enrolled 120 patients (2 in each group) abandoned the study, leaving a final sample of 114, evenly distributed among the three groups (C, P, and T). The three groups were comparable in terms of their demographic details and surgical aspects (Tables I and II) except with regard to tooth section and the Winter classification. No differences among the three groups were evident in terms of the cortisone therapy administered immediately after surgery (see Table II). The use of analgesics was compared in terms of the number of pills taken during the week after the procedure and revealed no statistically significant differences among the three groups (Table III), although the T group had taken slightly less medication.

The day-by-day and cumulative VAS scores during the week after surgery were statistically similar in the three groups, although the cumulative VAS score was much lower for group T (144) compared with groups C or P, and the latter two had much the same scores (198 and 196, respectively) (Table IV). Median cumulative treatment periods for the P and T groups were 79 and 94 hours, respectively.

The results of the estimates obtained with the model reveal a significant reduction in the VAS scores with time (\( P < .0001 \)) but no significant differences between the treatments (\( P = .99 \)); nor was the effect of the treatment \( \times \) time interaction statistically significant (\( P = .96 \)).

In group P, there was a significant positive correlation between the VAS scores and the hours of wearing the nonfunctioning PEMF device each day (correlation coefficient = 0.22; \( P = .0003 \)), whereas in group T, no association was observed between the VAS scores and the hours of wearing the functioning device (correlation coefficient = 0.06; \( P = .35 \)).

The correlation between the cumulative VAS scores and the cumulative hours of wearing the device was not significant in group P (correlation coefficient = 0.16; \( P = .34 \)) or in group T (correlation coefficient = −0.10; \( P = .58 \)).

There was evidence of a significant positive correlation between the VAS scores and the use of nonsteroidal anti-inflammatory drugs (NSAIDs).
The greater the pain, the greater was the use of medication. The total quantity of NSAIDs used over 7 days was, therefore, included as a confounder in the subsequent multivariate analysis on the quality of healing at the 7th-day follow-up. The results relating to the healing parameters at 7 days are shown in Table V. There was a significant difference among the three groups in terms of dehiscence \((P = .008)\). In particular, with pairwise comparisons, dehiscence was seen to be similar for C and P \((P = .06)\), similar for C and T \((P = .99)\), and different for P and T \((P = .02)\). The three groups were similar in terms of the other variables considered.

We analyzed the group effect on parameters indicative of the quality of healing, after adjusting for the effect of certain confounding variables of clinical

### Table V. Patients’ details

<table>
<thead>
<tr>
<th>Variables</th>
<th>Category</th>
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<th>Controls</th>
<th>Placebo</th>
<th>Test</th>
<th>P value</th>
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<tbody>
<tr>
<td>N</td>
<td>114</td>
<td>38</td>
<td>38</td>
<td>38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender M:F (n = 114)</td>
<td>44:70</td>
<td>12:26</td>
<td>19:19</td>
<td>13:25</td>
<td>.23</td>
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<td>Age(^1)</td>
<td>23 (20-28)</td>
<td>22 (21-29)</td>
<td>25 (21-29)</td>
<td>22 (19-24)</td>
<td>.07</td>
<td></td>
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<td>10 (26.3)</td>
<td>8 (21.1)</td>
<td>8 (21.1)</td>
<td>.89</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>88 (77.2)</td>
<td>27 (73.7)</td>
<td>30 (78.9)</td>
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</table>

\(^1\)Medians (IQR).

### Table II. Preoperative and operative details

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<th>Controls</th>
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<th>Test</th>
<th>P value</th>
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<td>8 (21.0)</td>
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<td>30 (79.0)</td>
<td>30 (79.0)</td>
<td>28 (73.7)</td>
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<td>Side (n = 111)</td>
<td>Right</td>
<td>57 (51.4)</td>
<td>18 (47.4)</td>
<td>17 (47.2)</td>
<td>22 (59.5)</td>
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<td>Left</td>
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<td>20 (52.6)</td>
<td>19 (52.8)</td>
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<td>Eruption (n = 112)</td>
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<td>9 (24.3)</td>
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<td>.81</td>
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<td>22 (59.5)</td>
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</tr>
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<td>Not impacted</td>
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<td>8 (21.1)</td>
<td>6 (16.2)</td>
<td>4 (10.8)</td>
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<tr>
<td>Pell class (n = 109)</td>
<td>A</td>
<td>44 (40.4)</td>
<td>12 (34.3)</td>
<td>15 (40.5)</td>
<td>17 (46.0)</td>
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<td>B</td>
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<td>C</td>
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<td>7 (19.0)</td>
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<td>2</td>
<td>55 (50.5)</td>
<td>20 (57.1)</td>
<td>15 (40.5)</td>
<td>20 (54.1)</td>
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<tr>
<td></td>
<td>3</td>
<td>7 (6.4)</td>
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<td>Winter classification</td>
<td>Distoangular</td>
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<td>8 (21.1)</td>
<td>6 (15.8)</td>
<td>.01</td>
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<tr>
<td></td>
<td>Mesioangular</td>
<td>45 (39.5)</td>
<td>20 (52.6)</td>
<td>16 (42.1)</td>
<td>9 (23.7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Horizontal</td>
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<td>5 (13.2)</td>
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<td>3 (7.9)</td>
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<tr>
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<td>Vertical</td>
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<td>7 (18.4)</td>
<td>14 (36.8)</td>
<td>20 (52.6)</td>
<td></td>
</tr>
<tr>
<td>Flap (n = 114)</td>
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<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
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<td></td>
<td>Envelope flap</td>
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<td>36</td>
<td>37</td>
<td>36</td>
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<td></td>
<td>Mesial incision release</td>
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<td>2</td>
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<td>0</td>
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<tr>
<td>Ostectomy (n = 114)</td>
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<td>106 (93.0)</td>
<td>38 (100.0)</td>
<td>34 (89.5)</td>
<td>34 (89.5)</td>
<td>.12</td>
</tr>
<tr>
<td></td>
<td>No</td>
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<td>0 (0.0)</td>
<td>4 (10.5)</td>
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</tr>
<tr>
<td>Tooth section (n = 113)</td>
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<td>87 (77.0)</td>
<td>34 (89.5)</td>
<td>30 (81.1)</td>
<td>23 (60.5)</td>
<td>.02</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>26 (23.0)</td>
<td>4 (10.5)</td>
<td>7 (18.9)</td>
<td>15 (39.5)</td>
<td></td>
</tr>
<tr>
<td>Postoperative cortisone (n = 114)</td>
<td>Yes</td>
<td>31 (27.2)</td>
<td>8 (21.0)</td>
<td>14 (36.8)</td>
<td>9 (23.6)</td>
<td>.28</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>83 (72.8)</td>
<td>30 (79.0)</td>
<td>24 (63.2)</td>
<td>29 (76.4)</td>
<td></td>
</tr>
</tbody>
</table>

*Data expressed as numbers (%) or medians (IQR).
interest. The possible explanatory variables initially included as confounders in the first stage of the model were: smoking habit, roots, Pell classification, tooth section, postoperative cortisone, and total NSAID use. Among all the variables considered, multivariate analysis identified only group as an independent predictor of dehiscence. In particular, a protective effect emerged for the functioning device (group T) as opposed to the nonfunctioning device (group P), whereas there was no difference between the placebo group and the controls (Table VI).

**DISCUSSION**

This randomized clinical trial suggests that adjunctive PEMF therapy can reduce patients’ postoperative pain and morbidity after mandibular third molar extractions. Patients in the test group (who used the enabled device) experienced less pain during the week after surgery: The cumulative VAS scores were similar in the control and placebo groups but lower in the test group (see Table IV), although the difference did not reach statistical significance; and the daily VAS scores were always lower for the T group, except for postop day 2 (see Table IV).

A highly significant positive correlation was found between the patients’ VAS scores and the number of analgesic pills they took. During postoperative follow-up, patients in group T were found to have taken a median 3 analgesic pills, as opposed to 4 and 5 in groups C and P, respectively. These trends point to a likely pain-reducing effect of the PEMF therapy in the T (see Table III).

It is currently not known what effect the use of a wearable PEMF device might have on pain after oral surgical procedures. Third molar extraction is often considered a model for studying the efficacy of analgesics in the treatment of acute pain because severe pain and a heavy burden on oral function (chewing, opening the mouth, and speaking) are commonly reported, especially on the first day after surgery. Pain perception and oral function gradually improve over the course of a week, but social and recreational activities, as well as daily routines, are affected, especially during the first 3 postoperative days. Corticosteroids and NSAIDs are commonly prescribed to control pain and inflammation after third molar surgery (narcotic analgesics and NSAIDs for pain, and glucocorticoids for swelling and trismus). When this concept is extended to wearable devices, PEMF therapy may be seen as an adjunct to pain medication with a view to improving pain relief, reducing the need for painkillers in order to contain side effects, or both. The adverse effects of opiate-based drugs, acetaminophen, and NSAIDs have been well documented. Opiates are associated with postoperative nausea and vomiting, urinary retention, ileus, constipation, and sedation, and acetaminophen and NSAIDs can cause hepatic and renal toxicity, coagulation, confusion, sedation, and dizziness. The present study supports the use of PEMF therapy in an adjunctive role for pain control after oral surgery, since patients using the device made less use of analgesic medication.

The effect of PEMF therapy on the healing process was also examined. Our results showed a significant difference in the number of patients experiencing wound dehiscence, which was apparent after 7 days in fewer patients in the T group than in the P group (P = .02). On multivariate analysis, the only parameter influencing this difference was the group (T, P, or C), which suggested that a better wound closure might be expected in patients wearing the enabled PEMF therapy device. Other parameters, such as smoking habit, the technical difficulty of the extraction, or the use of...
TABLE VI. Multivariate analysis on dehiscence

<table>
<thead>
<tr>
<th>Group</th>
<th>Odds ratio (95% confidence interval)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test versus Placebo</td>
<td>0.18 (0.06-0.52)</td>
<td>.01</td>
</tr>
<tr>
<td>Control versus Placebo</td>
<td>1.00</td>
<td>.46</td>
</tr>
<tr>
<td>Smoker</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Roots</td>
<td>1.00</td>
<td>.15</td>
</tr>
<tr>
<td>Pell</td>
<td>1.00</td>
<td>.89</td>
</tr>
<tr>
<td>Tooth section</td>
<td>1.00</td>
<td>.26</td>
</tr>
<tr>
<td>Postoperative cortisone</td>
<td>1.00</td>
<td>.22</td>
</tr>
<tr>
<td>Total nonsteroidal anti-inflammatory drugs</td>
<td>1.00</td>
<td>.93</td>
</tr>
</tbody>
</table>

application and the distance between the device and the target tissue seem to be crucial. In a meta-analysis performed by Guo et al., several different treatment regimens were considered because different treatment times and different types of device have been used over the years. The duration of the treatment would seem to be the most plausible predictor of the PEMF therapy’s efficacy, but how the different technologies adopted might influence its beneficial effects is still not clear.

Although the studies considered in the above-mentioned meta-analysis assessed a short-lived treatment administered by an operator (for a total of 2 to 5 hours), we focused on a therapy that was delivered continuously over the course of 1 week. The treatment time was consequently much longer in our sample (amounting to a median cumulative treatment period of 94 hours). However, no correlation between the cumulative VAS score and the cumulative treatment time could be seen in our sample. The device used in our study, however, is battery powered, so a gradual decline in the magnetic field it generates is to be expected, and this may have reduced its overall efficacy.

The vicinity of the device to the target tissue also seems to be important for the electromagnetic field to have an effect. By definition, electromagnetic fields are largely dependent on their distance from the source—and this aspect could become relevant when using a PEMF device after oral surgery. Unlike the case of previous studies, the tissues to treat after oral surgery are not on the same plane as the antenna; they lie underneath several layers of skin, muscle, and bone. For our study, the anatomic area to treat was assumed to lie approximately 3 cm below the skin, and at this distance, the field may well be more limited (a circumstance that could have influenced our results). Future studies should assess the impact of the distance between the PEMF source and the targeted tissues on the outcome. Abdelrahim et al. were dealing with a similar situation when they applied a PEMF device for 2 hours a day for 12 days (using the EM- probe Solo device, with a pulse duration of 200 nanoseconds, a rise time of 8 nanoseconds, an electromagnetic segment at 50 MHz and down to kilohertz range, with the pulse carrier modulated at 72 Hz) immediately after completing a closed reduction and stabilization of mandibular fractures. They compared a test versus a control group of 6 patients each: They found a higher bone density in the test group and concluded that the PEMF therapy was effective even when not in direct contact with the target tissue. Conversely, Markov stated that the magnetic field should not be expected to be as beneficial in the treatment of superficial wounds as in healing fractures, due to differences in the exposure system, in such a way that the target tissue should receive the required magnetic field density.
The device tested in the present study proved to be safe, cost-effective and user-friendly. A potential problem is that the device has to be positioned over the patient's face, and this may limit its use for esthetic reasons. The patients in our T and P groups seemed to accept the PEMF device willingly, however, and some were even enthusiastic about it subsequently. This, however, may have to do with the patients' perception of the device as concrete proof of the surgeons' concern about their postoperative well-being, as already mentioned elsewhere. Furthermore, this kind of wearable therapeutic technology is also seen as a portable access to drug-free pain relief, as seen with other similar health care appliances.

This study had some limitations in that the study population was clinically inhomogeneous with regard to certain features. In fact, the three groups were similar in terms of the technical difficulty of the surgical procedure (the tooth's degree of impaction and root morphology) but differed with regard to the Winter classification and the need for tooth sectioning. The influence of these aspects on the outcome may have been minimal, but it should, nonetheless, be borne in mind.

CONCLUSIONS
This randomized clinical trial suggests that adjunctive continuous PEMF therapy delivered with a portable device can reduce postoperative pain and the need for analgesics after oral surgery, although not to any statistically significant degree. It can also improve the quality of the healing process, significantly reducing postoperative dehiscence. In spite of the limitations of the present study, we found the wearable therapeutic technology tested here to be a simple, drug-free option for use in multimodal pain management that was well accepted by patients. When considering the application of this technology in oral surgery, the distance of the targeted tissues from the device needs to be borne in mind because it may reduce the beneficial effects of PEMF therapy. Future studies are needed to ascertain the influence of distance and treatment duration and also to assess the efficacy of PEMF for pre-emptive analgesia immediately before surgery.

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REFERENCES


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