



# A novel pulsed electromagnetic field device as an adjunct therapy to surgical treatment of distal radius fractures: a prospective, double-blind, sham-controlled, randomized pilot study

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## Abstract

**Introduction** The purpose of this study is to evaluate whether using a Fracture Healing Patch (FHP) device that generates pulsed electromagnetic fields (PEMF), applied at the fracture site immediately after open reduction and internal fixation surgery, can accelerate healing of acute distal radius fractures.

**Methods** In a prospective, double-blind, randomized, and sham-controlled study, thirty-two patients with DRFs treated with ORIF were included. Patients were allocated to a PEMF (active) group ( $n=15$ ) or a control (sham) group ( $n=17$ ). All patients were assessed with regard to functional Patient-Rated Wrist Evaluation (PRWE), SF12, and radiological union outcomes (X-rays and computed tomography (CT) scans) at 2, 4, 6, and 12 weeks postoperatively.

**Results** Patients treated with the FHP demonstrated significantly bone bridging at 4 weeks as assessed by CT (70% vs 54%,  $p=0.05$ ). Mean grip strength in the active group was significantly higher as compared to control ( $16 \pm 9$  kg vs  $7 \pm 3.5$  kg, respectively,  $p=0.02$ ). The function subscale of the PRWE was significantly better in PEMF-treated group at 6 weeks after surgery (27.2 VS 35.5,  $p=0.04$ ). No statistically significant differences were found in SF12.

**Conclusion** PEMF application after ORIF of DRFs is safe, may accelerate bone healing which could lead to an earlier return to daily life activities and work.

**Level of evidence** I

**Keywords** Distal radius · Fracture · ORIF · Union · Pulsed electromagnetic field · Bone growth stimulation · Electrical stimulation therapy

## Introduction

Distal radius fractures (DRFs) are among the most frequent fractures of the upper extremity, affecting both younger and older patients [1]. Although most distal radius fractures can be treated conservatively, unstable fractures may require surgical intervention, despite the inconclusive findings of

Cochrane reviews [2, 3]. In recent years, open reduction and internal fixation (ORIF) using volar locking plates (VLPs) have emerged as the preferred method for treating the majority of unstable DRFs, demonstrating good clinical and radiological outcome with low complication rate [4]. VLPs provide stable fixation, allowing earlier mobilization and improved outcomes compared to non-surgical management [5, 6].

Pulsed electromagnetic field (PEMF) is a non-invasive therapy that uses electromagnetic fields to stimulate cellular repair and the bony healing processes [7]. The results of multiple studies indicate that PEMF has the potential to shorten the healing time of long-bone fractures and allow patients to return to normal activities earlier, which can be cost-effective for both the patient and the health-care system. There are several different PEMF devices available on the market. Some devices are designed to be worn over the

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skin, while others are designed to be implanted directly on the bone [7].

The Fracture Healing Patch (FHP) (Pulsar Medtech Ltd., Israel) is an external, flexible silicone patch that integrates a power source and micro-electronic modules, which generates a PEMFs. The FHP produces a continuous, focused PEMF that affects only the target fracture site. In a recently published study, it was demonstrated that DRF treated conservatively with the FHP placed under a cast provided significantly higher union rates at 4 weeks as assessed by computed tomography (CT) in comparison to control group [8].

The primary aim of the present study was to determine whether adjunct PEMF application immediately after ORIF of acute DRF will stimulate bone growth and accelerate fracture healing. It was hypothesized that PEMF would accelerate fracture union rates as assessed by CT scans. The secondary aim was to evaluate the effect of PEMFs on functional outcomes.

## Materials and methods

### Study design

This prospective, double-blind, randomized, and sham-controlled study, was conducted at a Level I trauma center from July 2021 to March 2022. Approval from the institutional review board was obtained for all aspects of the study in accordance with institutional policies, and written informed consent was obtained from every patient. The study was registered at ClinicalTrials.gov, the registration number is NCT04287257.

The inclusion criteria were:

- Patients with a closed unilateral distal radial fracture that met the criteria for operative treatment through ORIF.
- 18 years or older
- Capacity to adhere to the visit schedule, protocol requirements, and completing the study.

Exclusion criteria included:

- Presence of hardware in the forearm or hand
- Previous fractures, or bone surgery on the fractured side
- Multiple trauma
- Joint diseases affecting the function of the wrist and/or hand of the injured limb.
- Pregnancy
- Breastfeeding
- The presence of a life-supporting electronic device.

Eligible patients were randomly assigned to one of two groups: the PEMF group, who received volar locking plate

(VLP) and active FHP, and the Sham group, who received VLP and sham FHP. Half of the PEMF devices were randomly deactivated before being applied to the Sham group. Two activators were used: active and sham. The sham-activated devices displayed normal function but did not generate a signal. Block randomization with a block size of four was used for treatment allocation, and the randomization was performed after the patients were admitted to the orthopedic department. The serial number of the FHP indicated whether it was an active device or not, but this information was not revealed until the end of the data processing. The study duration was 12 weeks following ORIF.

### FHP device

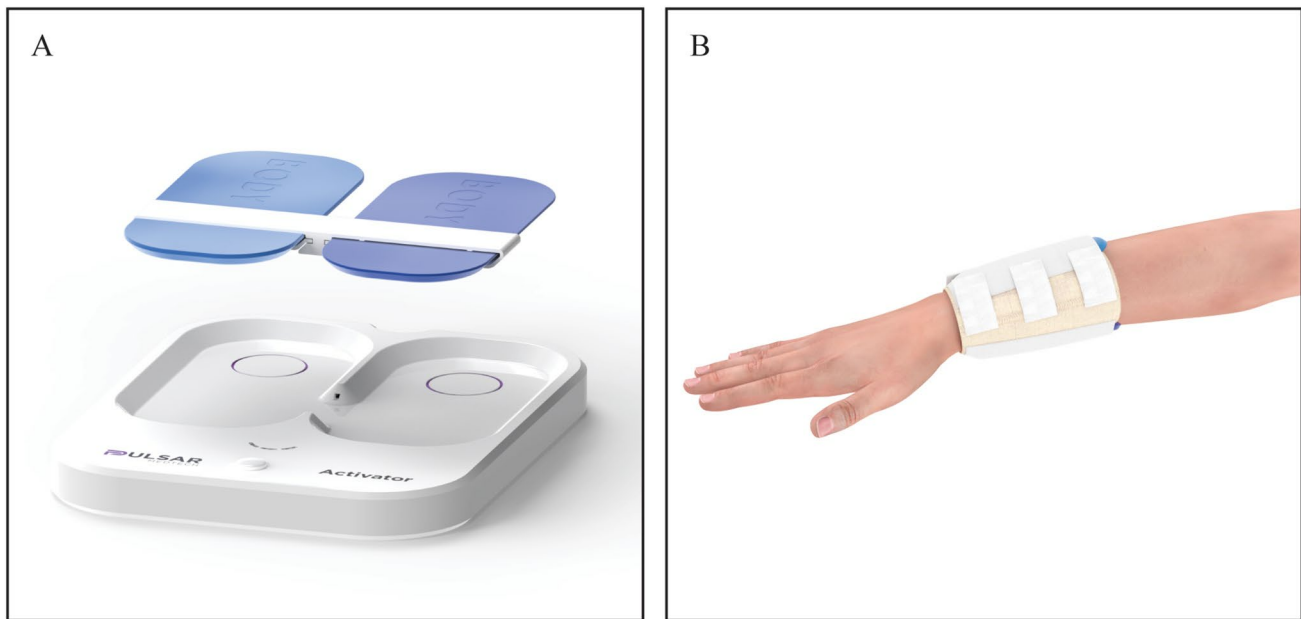
The FHP model used in this trial comprised 2 units, which are placed on the contralateral sides of the arm (volar and dorsal) (Fig. 1). The units communicate with each other and are able to adjust the intensity of the PEMF to conform to different arm dimensions, thus creating a uniform PEMF through the arm. The PEMF generated by the FHP is characterized by a pulse frequency of 20 kHz, cycle frequency of 10 Hz, and pulse intensity at fracture site between 0.05 and 0.5 mT.

Both patients and evaluators were blinded to whether the FHP device was active or not.

The FHP device was placed immediately at the end of the operation using a dedicated bandage. The FHP was active (active group) for 24 h a day continuously throughout the study period. The patients were allowed to take the FHP off for washing. At study completion, device serial numbers were used to determine which patients received an active device.

### Operative technique

All operations were performed under general anesthesia, with the patient lying supine and the hand placed on a hand table under fluoroscopy guidance. After exsanguination with an Esmarch bandage, a padded pneumatic tourniquet was placed on the upper arm and inflated to 250 mmHg. The modified Henry approach was utilized for the procedure. Fixation of the fracture was done using a volar locking plate (Acumed® Acu-Loc® 2 Wrist Plating System). Prior to closing, the tourniquet was deflated and hemostasis achieved. Suture closure was achieved using Vicryl, while skin closure was performed using either nylon 3.0 or monocryl 3.0 sutures. All surgeries were performed by a board-certified hand surgeon.



**Fig. 1** **A** FHP model is comprised of an activator and 2 units which are placed on the contralateral sides of the arm (volar and dorsal). **B** FHP is placed on the wrist

## Outcome measures

The primary outcome was fracture union at 4 weeks based on CT scans. Evaluation of subjective and objective parameters, such as pain, function, range of motion (ROM), and radiological outcomes (both CT and X-rays), was performed at 2, 4, 6, and 12 weeks postoperatively. The presence of complications was also noted.

## Radiologic assessment

All radiographs and CT scans were reviewed independently by a musculoskeletal fellowship-trained radiologist and two senior orthopedic surgeons who were blinded to study groups. Fractures were classified based on the AOOTA classification [9, 10]. Radiographic healing was defined as bridging in three of four cortices as seen on X-ray images. A determination was made at each follow-up evaluation using Radius Union Scoring System (RUSS) score [11].

At 4 weeks, all patients underwent CT scan. All scans were performed on Brilliance 64-slice MDCT scanner (Philips, USA) using  $64.0 \times 0.625$  mm collimation, and a slice thickness of 1 mm. All scans were non-contrast. Direct multiplanar reformation function was used to generate coronal and sagittal reformations with a slice thickness of 3 mm. All CT scans were interpreted at Picture Archiving and Communications System workstations (Centricity; GE Healthcare, USA). The evaluation of the extent of fracture union was performed in each of the axial cuts, then calculating the average [12]. The extent of union was quantified as

described by Singh et al. [13]. Fractures were categorized as follows: no union (0–24% of the continuity of the trabecular bridging across the whole width of the distal radius), partial union (25–74% trabecular bridging), or union (75–100% trabecular bridging).

## Functional outcomes and Quality of life assessment

Pain and function were assessed by the SF-12 [14] survey and patient-rated wrist evaluation (PRWE) [15], before applying the FHP device, at 4, 6, and 12 weeks. The SF12 questionnaire is a valid and reliable instrument to measure pain and psychosocial well-being. The PRWE is a 15-item questionnaire designed to measure wrist pain and disability in activities of daily living. The PRWE allows patients to rate their levels of wrist pain and disability. While there is no specific MCID for just the upper limb on the SF-12, an improvement of 4–6 points on the PCS and 3–5 points on the MCS indicates a clinically important change in patients with upper extremity conditions. The MCID for the PRWE questionnaire is approximately 11 points for the total score, with 6 points and 9–10 points for the pain and function subscales, respectively [16].

## Functional assessments

Pain-free grip: assessment of grip strength via a JAMAR dynamometer [17]. The dynamometer measures in increments of 0.1 kg. The mean of three measurements, 2 min apart, was considered as the grip strength for a patient at

each visit. Flexion, extension, radial and ulnar deviation, pronation, and supination active range of motion (ROM) were also measured using digital goniometer—EasyAngle® (Meloq AB, Sweden). All tests were compared with the opposite unaffected side.

All patients began rehabilitation immediately after surgery, which included occupational therapy exercises, and self-active and active-assisted range of motion (ROM) for the wrist and fingers. It was recommended to avoid exertion and heavy weightlifting with the injured hand for 6 weeks. At 12 weeks, patients were permitted to start passive ROM.

## Statistical analysis

In the current study, a per protocol (PP) analysis was used. Power analysis was conducted with an expected outcome difference of 30% in the extent of the fracture union assessed by CT at 4 weeks as compared to the control group. The alpha error level was set at 5% (two-sided significance level); power was set at 80%. Including an anticipated dropout rate of 10%, this resulted in a sample size of 20 patients per group. Data were analyzed with IBM SPSS statistics software version 28.0. (SPSS Inc. Headquarters, 233 S. Wacker Drive, 11th floor Chicago, Illinois 60,606, USA). The significance levels were set at 0.05. Baseline characteristics are presented as means and standard errors for continuous variables and as frequencies and percentages for categorical variables. Chi-square tests and independent *t*-tests were performed to compare the two groups for categorical and continuous variables, respectively.

Agreements between raters were tested by the Friedman test. To reduce the within-variability in RUSS scale, we chose the mean and the median value from the 3 raters.

Differences in RUSS scale between the two groups were tested by independent *t*-test.

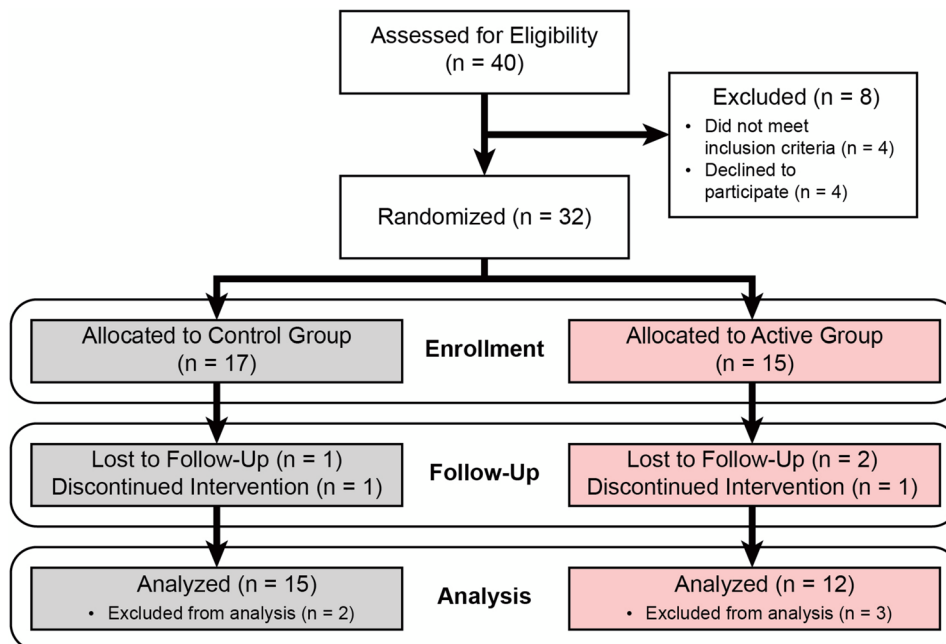
Differences in the CT results between the two groups were tested by the independent *t*-test.

## Results

A total of 40 patients were screened. 32 patients met the inclusion criteria and were randomized. One patient had to discontinue his participation in the study due to other medical conditions. The remaining 31 patients (31 fractures) (11 males, 20 females; mean age 55 years (range 24–77) made up the core group that adhered to the study protocol and were the basis for inferences regarding the efficacy of the FHP PEMFs device and were randomly treated with either active FHP or sham FHP device. Two patients refused to undergo a CT scan at 4 weeks; however, they completed all other tests as required by the protocol. Three patients and 2 patients were lost to follow-up in the active and the control group, respectively (Fig. 2).

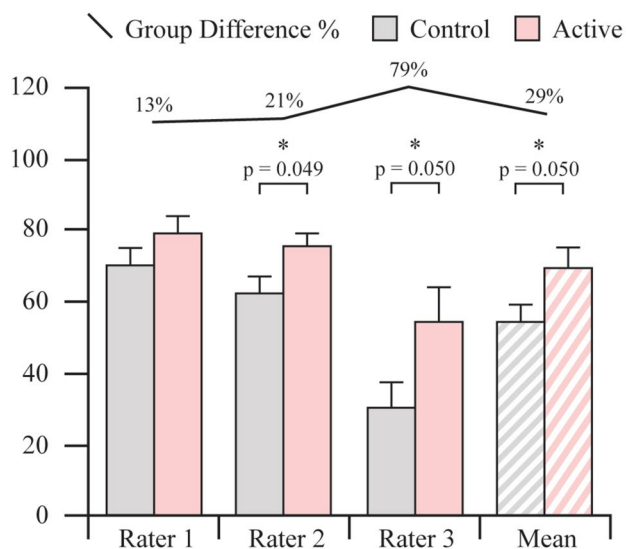
There was no significant difference between the two treatment groups with regard to any of the patient or fracture-related parameters; therefore, the randomization process produced similar treatment groups for the efficacy comparisons (Table 1).

**Fig. 2** Study consort flow diagram demonstrating the method of patient recruitment



**Table 1** Patient's demographics

Variable	Control Group, N=15	Active Group, N=12	P
Age (years)	59	49	0.124
Male (n, %)	4, 26%	5, 42%	0.437
Fracture in dominant hand (n, %)	10, 66%	6, 50%	0.554
Fracture type, AO classification (n, %)			0.841
2R3A2	7, 46%	6, 50%	
2R3B1	1, 6%	0, 0%	
2R3B3	2, 13%	1, 9%	
2R3C1	5, 33%	4, 33%	
Smoking (n, %)	1, 6%	1, 9%	0.819
Osteoporosis (n, %)	0, 0%	0, 0%	1
Corticosteroids (n, %)	0, 0%	0, 0%	1

**Fig. 3** Radiological assessment of percentage of the extent of fracture union at 4 weeks as assessed by CT. Graphs are reported as mean  $\pm$  SE. Student's *t*-test

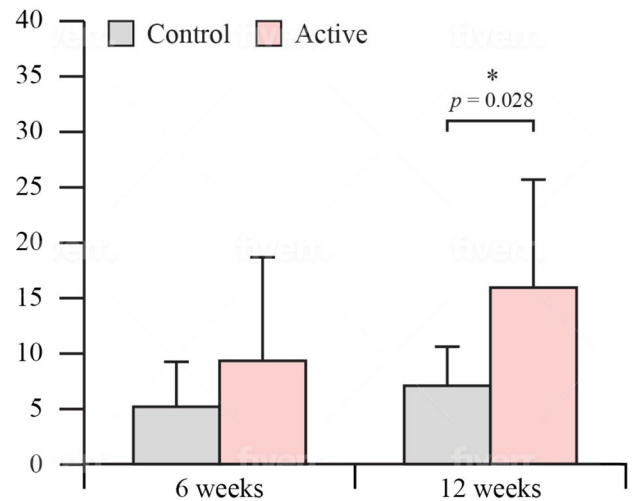
### Radiological assessment

Fractures treated with active FHP device demonstrated significantly higher extent of union at 4 weeks as assessed by CT (70% Vs 54%,  $p=0.05$ ) (Fig. 3). Two out of three raters gave a significantly higher healing percentage to the PEMF-treated group. Four patients in the active FHP group achieved complete union (above 75% of bridging) compared to none in the control group. All patients in the control group and the remaining patients in the active group revealed partial fracture union (25–74%) (see Table 2).

**Table 2** Fractures categorization by extent of the union at 4 weeks

Group	No union (0–24%)	Partial union (25–74%)	Union (75–100%)
Control	0	14	0
Active	0	7	4

Two patients refused to undergo a CT scan at 4 weeks postoperatively

**Fig. 4** Hand Grip. At 12 weeks, mean grip strength in the active group was significantly higher as compared to control 16  $\pm$  9 kg vs 7  $\pm$  3.5 kg, respectively,  $p=0.02$ ) Graphs are reported as mean  $\pm$  SE. Student's *t*-test

X-rays were evaluated using RUSS by the same blinded reviewers. No statistically significant differences between the groups were found for all time points.

### Functional assessment

Hand grip strength was measured at 6 and 12 weeks postoperatively. At 6 weeks, the mean grip strength in the active group was higher as compared to control, however not statistically significant (9  $\pm$  8 kg vs 5  $\pm$  4 kg, respectively,  $p=0.23$ ) At 12 weeks, mean grip strength in the active group was significantly higher as compared to control 16  $\pm$  9 kg vs 7  $\pm$  3.5 kg, respectively,  $p=0.02$ ) (Fig. 4).

### Range of motion

No statistically significant differences were found between the groups in all parameters of ROM for all time points.

## PRWE

No statistically significant differences between the groups were found in total PRWE score and in pain subscale. The function subscale of the PRWE was significantly better in PEMF-treated group at 6 weeks after surgery (27.2 VS 35.5,  $p=0.04$ ) (Fig. 5). The difference between group in the function subscale of the PRWE was near but did not exceed the MCID.

## SF 12

No differences between the groups were noticed in either physical or mental scores.

## Adverse events

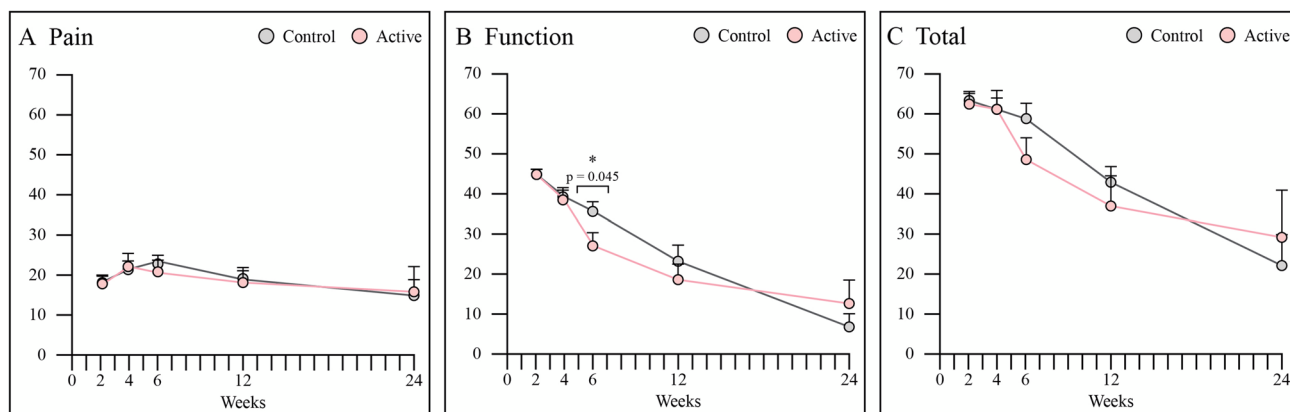
No adverse events or complications attributable to the device and no contraindications to use of the device were reported during the study. No mechanical or technical difficulties with use of the device were reported by the patients.

## Discussion

The principal results of this study demonstrated that patients treated with active PEMF demonstrated a significantly higher extent of union at 4 weeks as assessed by CT. Four patients in the active FHP group achieved complete union (above 75% of bridging) compared to none in the control group. The mean early grip strength in the active group was significantly higher as compared to control. The function subscale of the PRWE was significantly better in PEMF-treated group at 6 weeks after surgery. No adverse effects related directly to the device were reported.

There is fast-growing evidence that noninvasive PEMF treatment is a safe, and convenient modality that may enhance fracture healing, thus attracting great attention in recent decades. PEMF have been used for several years to enhance bone healing in various clinical settings including orthopedic surgery, such as treatment of fracture non-union [18, 19]. Data from numerous in vitro and in vivo studies reveal that PEMF positively effects bone healing by altering voltage-gated ion channels, increasing cytosolic and early angiogenesis, and promoting osteoblast differentiation and maturation [20]. In addition, it has been demonstrated that PEMF exposure increased proliferation, adhesion, and the osteogenic commitment of mesenchymal stem cells (MSCs), even in inflammatory conditions [21].

To the best of our knowledge, this is the first study demonstrating that patients undergoing distal radius fracture repair with adjunctive PEMFs fare better and heal earlier than patients undergoing ORIF alone. A study by Del Buono et al. [22] compared clinical and functional outcomes of two groups of patients who underwent reduction and nailing fixation for diaphyseal fractures of the tibia with and without post-operative PEMF application. They concluded that PEMF application following intramedullary nailing of the tibia is safe and reduces post-operative pain, use of analgesics, and the time of healing fracture. At 1 year, there was no difference in outcome measures, regardless of PEMF application. The current study was conducted following the recently published study [8] that examined the effects of the FHP-generated PEMF as an adjunct to cast immobilization for acute DRF. The results revealed that fractures treated with active PEMF demonstrated significantly higher extent of union at 4 weeks in comparison to control group. Time to cast removal was significantly shorter in PEMF-treated patients. Additionally, functional outcomes in terms of SF12 physical score and PRWE score were better in PEMF-treated



**Fig. 5** PRWE score. (A) Pain subscale (B) function subscale and (C) total score. The function subscale of the PRWE was significantly better in PEMF-treated group at 6 weeks after surgery. Graphs are reported as mean  $\pm$  SE. Student's *t*-test

group. The current study results are in line with the previously reported study.

There are several FDA-approved bone growth stimulators available. The PhysioStim™ device (Orthofix, US) provides a non-invasive option for treating nonunion fractures. CMF OL1000 (DJO, US) is a portable, battery-powered device indicated for use in the noninvasive treatment of an established nonunion fracture, excluding all vertebrae and flat bones. The Bioventus Exogen system (Bioventus, US) is an ultrasound bone healing device. It uses low-intensity pulse ultrasound to stimulate the bone healing process. It is primarily indicated for the treatment of fresh fractures and the acceleration of healing in delayed unions and non-unions. All of these devices are cumbersome, need to be recharged, and cause some discomfort to the patients. The FHP device used in the current study is much smaller and lighter, does not require recharge. Bestowed to these features, a higher compliance with the treatment is expected.

## Limitations

The study has certain limitations regarding the loss of patients and the relatively low numbers reported. It is possible that with a larger sample size, the observed effect could have balanced out or yielded different functional outcomes. Moreover, there remains some uncertainty surrounding the optimal treatment parameters, necessitating further research to establish the most effective approach. In the current study, a per protocol analysis was used. The per protocol analysis can introduce bias as patients who do not adhere to the protocol may differ systematically from those who remain in the study, and the generalizability of the findings to the broader patient population may be reduced in a per protocol analysis compared to an intent-to-treat analysis. Lastly, it is crucial to emphasize that PEMF therapy should not be employed as a replacement for standard medical care, but rather as an adjunctive therapy.

## Conclusion

The DRP is a safe and effective adjunct treatment for improving the healing of surgically treated acute distal radius fractures. The available evidence suggests that it may be a promising therapeutic option for patients with DRFs treated surgically.

**Author contributions** GE and TP are equal contributors as last author. All authors that have contributed to this manuscript have agreed on the final revised version of this manuscript. Data are available at reasonable request from the corresponding author.

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**Availability of data and materials** The data that support the findings of this study are available from the corresponding author, upon reasonable request.

## Declarations

**Conflict of interest** The authors declare that there is no conflict of interest. No company had influence in the collection of data or contributed to or had influence on the conception, design, analysis and writing of the study.

**Ethical approval** Institutional review board approval was obtained for all aspects of this study in accordance with the institutional policies (0597-19-TLV).

**Informed consent** Written informed consent was obtained from every patient.

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