

Efficacy of pulsed electromagnetic field therapy in the treatment of knee osteoarthritis: A double-blind, randomized-controlled trial

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ABSTRACT

Objectives: This study aims to evaluate the efficacy of combined pulsed electromagnetic field (PEMF) treatment and physical therapy on pain, stiffness, and functional limitation in patients with knee osteoarthritis (OA).

Patients and methods: In this double-blind, randomized-controlled study, a total of 70 female patients with primary knee OA (mean age: 59.74±9.82 years; range, 40 to 80 years) were randomly allocated into PEMF and sham groups between March 2014 and July 2015. Both groups received 15 sessions of physical therapy over three weeks. Additionally, the PEMF group received PEMF treatment for 30 min/day, while the control group received sham PEMF. The patients were assessed by the Visual Analog Scale (VAS), Western Ontario and McMaster Universities Arthritis Index (WOMAC), and the Physician Global Assessment (PAG) scale before and three and seven weeks after treatment.

Results: Regardless of the group, all patients' pain levels were significantly improved in both scales at three and seven weeks after treatment ($p<0.001$). The PEMF group had significantly less pain than the sham group based on the VAS score ($p=0.003$). The PEMF group had significantly lower functional limitation and stiffness at seven weeks ($p=0.008$). Recovery ratios based on the PGA score were significantly higher in the PEMF group both at three and seven weeks ($p<0.05$).

Conclusion: Patients with knee OA who receive PEMF therapy in addition to physical therapy have more pain reduction and physical improvement. Based on these findings, PEMF is a safe and well-tolerated treatment of choice in this patient population.

Keywords: Knee, osteoarthritis, pain, pulsed electromagnetic field therapy.

Knee osteoarthritis (OA) is the most common type of OA, and pain is the most common symptom.^[1] The main goal of treatment is to reduce pain, improve mobility and function, and increase patients' quality of life. Management of OA requires a combination of non-pharmacological, pharmacological, and surgical interventions.^[2] The non-pharmacological methods including physical therapy (hot/cold packs), and electrotherapy modalities (ultrasound, transcutaneous electrical nerve stimulation, etc.) have an optimal safety profile. Therefore, they are frequently utilized to reduce knee OA-related pain in clinical practice.^[3]

Pulsed electromagnetic field therapy (PEMF) is a relatively novel electrotherapy modality that uses magnetic fields produced by strong electric currents

passing through a coil.^[4] It appears to be a promising therapeutic option for knee OA as it enhances fibroblast, chondrocyte, and osteoblast metabolism,^[5] prevents subchondral bone loss, and increases bone and cartilage synthesis.^[6] The benefits of PEMF in controlling pain and functionality have been reported for various musculoskeletal disorders.^[7-11] However, researchers have not yet reached a clear consensus on the effectiveness of PEMF therapy on pain and physical function in patients with knee OA.^[12-16] Meta-analysis and systematic reviews including current studies have shown that despite trends demonstrating improvement in pain and function following PEMF therapy, there is still a lack of high-quality evidence currently available to inform clinical practice.^[12-16]

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Received: December 22, 2023 **Accepted:** May 28, 2024 **Published online:** July 26, 2024

Cite this article as: Hashemi SE, Gök H, Güneş S, Ateş C, Kutlay Ş. Efficacy of pulsed electromagnetic field therapy in the treatment of knee osteoarthritis: A double-blind, randomized-controlled trial. Turk J Phys Med Rehab 2025;71(x):i-viii. doi: 10.5606/tftrd.2024.14486.



In the present study, we aimed to evaluate the efficacy of combined PEMF and physical therapy on pain, stiffness, and functional limitation in patients with knee OA.

PATIENTS AND METHODS

Study design and study population

This double-blind, randomized, placebo-controlled study was conducted at the Department of Physical Medicine and Rehabilitation of Ankara University Faculty of Medicine between March 2014 and July 2015. Patients with complaints of knee pain who were diagnosed with primary knee OA according to the American College of Rheumatology (ACR) criteria^[17] were included. Inclusion criteria were as follows: age between 40 and 80 years, having Grade 2-3 OA

according to the Kellgren-Lawrence (K&L) grading scale, and inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs). Exclusion criteria were as follows: having a disease contraindicated for PEMF therapy (tuberculosis, pregnancy, malignancy, pacemaker, bleeding diathesis, ischemia, edema, atrophic skin and scar tissue in the knee); receiving physical therapy, previous knee joint surgery or knee arthroplasty, and intra-articular injections in the past six months; patients with a body mass index (BMI) of >35 kg/m²; patients who had diabetes mellitus or a disease causing neuropathic pain; patients with active inflammation signs on knee joints; patients who could not cooperate and answer questions. Finally, a total of 100 patients were screened for eligibility. Thirty patients were excluded, as they did not meet the inclusion criteria. Seventy female patients

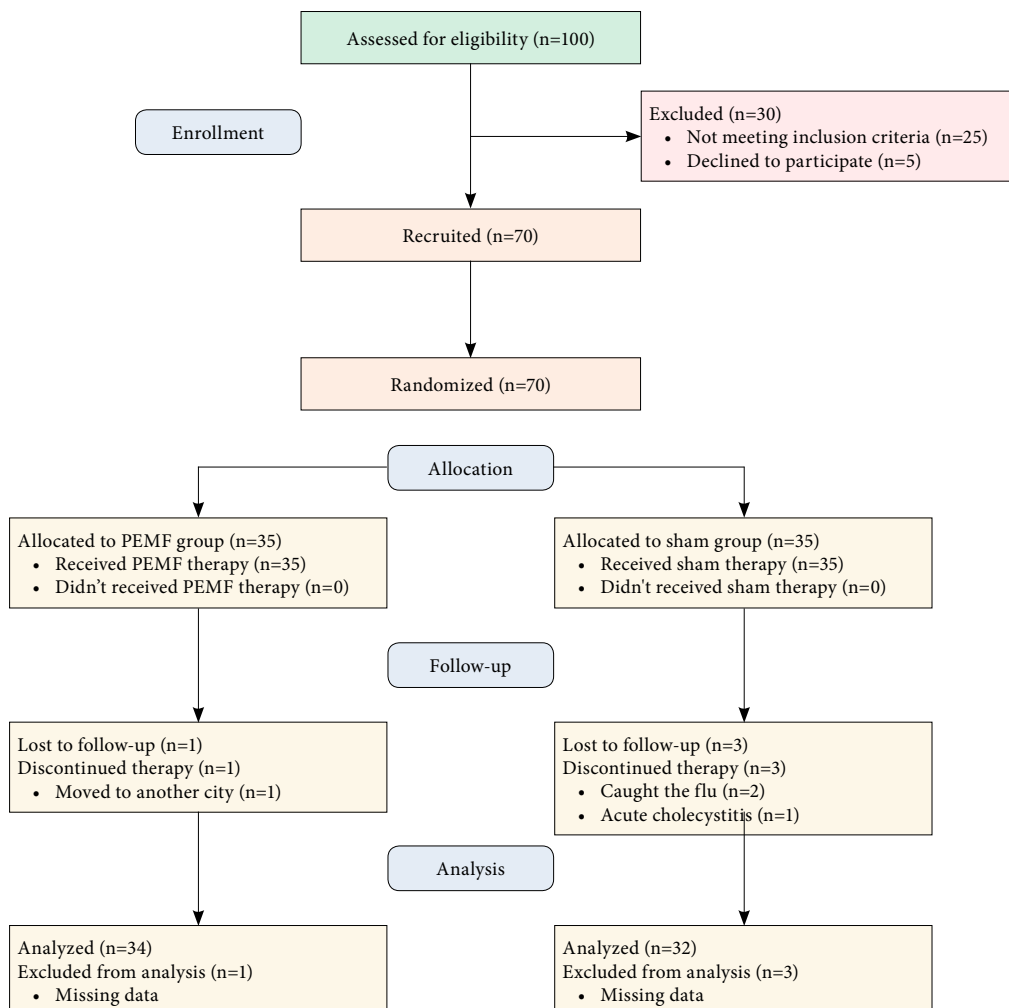


Figure 1. Study flowchart.

PEMF: Pulsed electromagnetic field.

(mean age: 59.74±9.82 years; range, 40 to 80 years) were randomized into two groups as the PEMF group (n=35) and the sham group (n=35). The study flowchart is shown in Figure 1.

Procedures

Block randomization was done to reduce bias and achieve balance in the allocation of participants to treatment arms. The Random Allocation Software (RAS) was used for this purpose and a block size of four was preferred.^[18] The sealed envelope method was preferred to ensure concealment. The physician and patients were blind to the allocation group. All patients were evaluated by the same physician, and treatments were administered by the same physiotherapist.

Interventions

The patients were randomly allocated into two groups: PEMF and sham. Both groups received 15 sessions of physical therapy (hot pack 15 min/day, interferential current therapy [80 to 100 Hz 20 min/day], range of motion, and progressive resistance exercise) over a period of three weeks. The PEMF group received PEMF therapy additionally for 30 min to the knee joints by a magnetotherapy device called ASV with a solenoid diameter of 80 cm, for 30 min every weekday with 40% intensity, and 10 to 100 Hz frequency range. In the sham group, the device was switched off immediately, after it was switched on and sham PEMF was applied for 30 min. The patients were allowed to use paracetamol up to 4 g/day, when needed to reduce pain.

Outcome measures

The primary outcome measure was pain assessed by the Visual Analog Scale (VAS). The scores ranged from 0 (no pain) to 100 (most severe pain). The secondary outcome measures were functioning and treatment response assessed by the physician. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC 3.0) was used to assess the function.^[19] This index evaluates pain (5 items), physical function (17 items), and stiffness (2 items). The scoring ranges from 0 to 4: none (0), mild (1), moderate (2), severe (3), and extreme (4). The scores for each subscale were summed up ranging between 0 and 20 for pain, 0-8 for stiffness, and 0-68 for physical function. The total WOMAC score was also calculated (0-100). Higher scores indicate more pain, stiffness, and deterioration in physical function. The Physician Global Assessment (PGA) was used to evaluate the overall response to treatment by the same physician. The outcome measures of the patients were evaluated before therapy,

three weeks after the treatment, and seven weeks after the treatment. Treatment-related side effects were also documented.

Statistical analysis

A *priori* power analysis was conducted using G*Power version 3.0 software^[20] (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) to test the difference between two independent group means using a two-factor mixed-way analysis of variance (ANOVA), a Cohen's d coefficient of 0.10, and an alpha value of 0.05. The results showed that a total sample of 60 participants with two equal-sized groups of n=30 was required to achieve a power of 0.80. Considering a dropout rate of 15%, the adjusted sample size was 70.

Statistical analysis was performed using the R Statistical Program version 3.6.2 (R statistical software, Institute for Statistics and Mathematics, Vienna, Austria). Data were expressed in mean ± standard deviation (SD) or median (min-max) for continuous variables, and in number and frequency for categorical variables. The Kolmogorov-Smirnov test was used to evaluate the normal distribution of data. The chi-square test was used for proportions and the Fisher exact test was used when the data were sparse. The difference between the two groups, three-time points, and the interaction of these two main effects were tested with two-factor mixed-design ANOVA. The sphericity assumption was tested by using Mauchly's test of sphericity. When there was a violation of this assumption, the Wilk's Lambda statistics were used as the multivariate test. When the *p* value from the ANOVA test statistics was statistically significant, pairwise comparisons were used to know which time point differs from which others. A *p* value of <0.05 was considered statistically significant.

RESULTS

One patient in the PEMF group and three in the sham group discontinued the therapy. Finally, there were 34 patients in the PEMF group and 32 patients in the sham group. The two groups were similar in terms of disease duration and K&L grading. The baseline sociodemographic and clinical characteristics of the patients are shown in Table 1.

Figure 2 shows the estimated marginal means of the VAS and WOMAC pain scores at baseline, three and seven weeks after the intervention. The decreasing trend in pain level over time as measured by the VAS and WOMAC pain scores were found to be parallel to each other between the two groups (Figure 2).

TABLE 1 Sociodemographic and clinical characteristics of the PEMF and sham groups							
	PEMF group (n=35)			Sham group (n=35)			p
	n	%	Mean±SD	n	%	Mean±SD	
Age (year)			59.9±9.6			59.6±10.2	0.923
Sex							
Female	35			35			
Disease duration (month)			14.19±5.91			13.29±5.84	0.590
Level of education							0.446
Illiterate	10	28.6		12	34.3		
Literate	2	5.7		2	5.7		
Primary education	13	37.1		17	48.6		
Middle/High School	9	25.7		3	8.6		
University	1	2.9		1	2.9		
K&L grading scale (%)							0.112
Grade 2	28	80		22	62.9		
Grade 3	7	20		13	37.1		

SD: Standard deviation; PEMF: Pulsed electromagnetic field; K&L: Kellgren Lawrence.

No significant interaction was found between time and group factors affecting the level of the pain for the VAS, and WOMAC ($p=0.811$ and $p=0.851$, respectively). Therefore, the main effects of time and group were evaluated separately. Regardless of the group, a significant improvement in pain levels of all patients was found in both scales at three and seven weeks ($p<0.001$ and $p<0.001$, respectively). Regardless of the time, the PEMF group had significantly less pain than the sham group based on the VAS score but

not the WOMAC pain score ($p=0.003$ and $p=0.092$, respectively) (Figure 2, Table 2).

The improvements observed in the WOMAC stiffness, function, and total scores over time were not found to be parallel to each other between the two groups (Figure 3). A significant interaction was found between time and group factors affecting the WOMAC stiffness, function, and total scores ($p<0.001$, $p=0.004$, and $p<0.001$ respectively). In other words, the two groups behaved differently from each

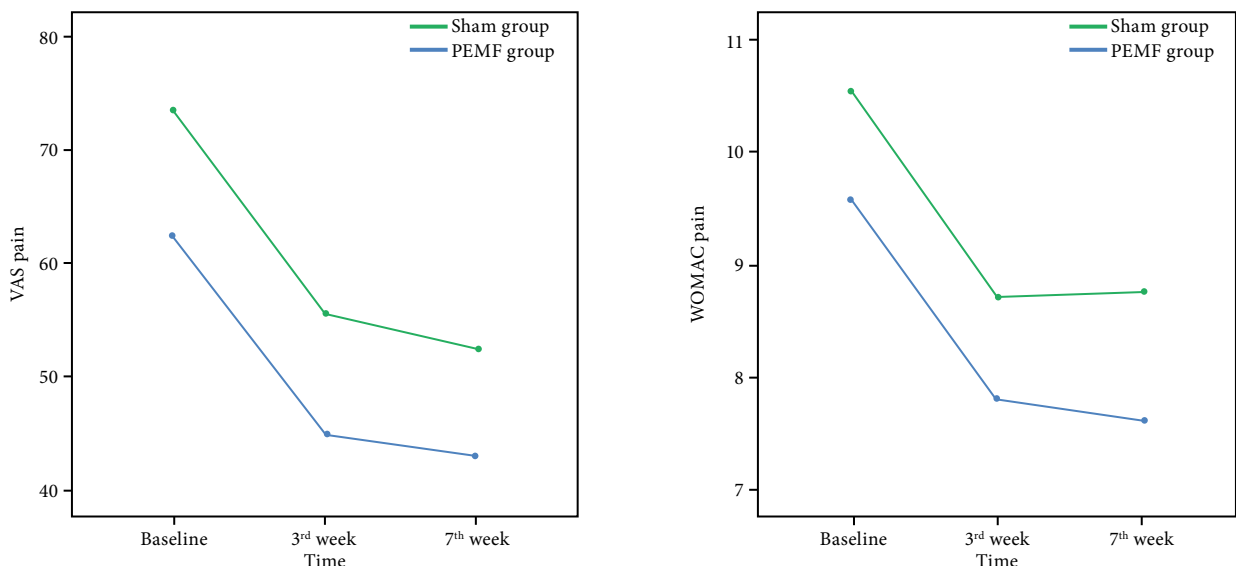


Figure 2. Estimated marginal means of VAS and WOMAC pain.

VAS: Visual Analog Scale; WOMAC: The Western Ontario and McMaster Universities Arthritis Index; PEMF: Pulsed electromagnetic field.

TABLE 2
Effect of PEMF therapy on pain

	PEMF group	Sham group	p^a	p^b	p^c
	Mean±SD	Mean±SD			
Pain (VAS)					
Baseline	62.32±19.60	73.50±14.05	<0.001*		0.003*
3 rd week	44.88±15.07	55.66±13.72		<0.001*	
7 th week	43.03±14.21	52.56±12.91		<0.001*	
Pain (WOMAC)					
Baseline	9.56±3.17	10.53±2.37			
3 rd week	7.79±2.71	8.72±2.02	<0.001*	<0.001*	0.092
7 th week	7.62±2.59	8.75±2.29		<0.001*	

PEMF: Pulsed electromagnetic field; SD: Standard deviation; VAS: Visual Analog Scale; WOMAC: The Western Ontario and McMaster Universities Arthritis Index; p^a : comparison between time points (regardless of the group); p^b : Post hoc comparison (compared to pre-treatment); p^c : comparison between groups (regardless of the time); * $p<0.05$.

other with respect to the change over time. There was a significant improvement in the WOMAC stiffness score compared to the baseline both at three and seven weeks after the treatment in the PEMF group ($p<0.001$). The sham group showed a significant improvement only after seven weeks ($p<0.001$). When the two groups were compared in all time periods, the PEMF group at seven weeks had a significantly lower stiffness level than the sham group ($p=0.008$) (Figure 3, Table 3).

There was a significant improvement in the WOMAC function score compared to the baseline both at three and seven weeks after the treatment in the PEMF group ($p<0.001$). However, the sham group had a significant improvement only at three weeks ($p=0.005$). When the two groups were compared in all time periods, the PEMF group at seven weeks had a

significantly lower functional limitation than the sham group ($p=0.008$) (Figure 3, Table 3).

Both groups had a significant improvement in the WOMAC total score compared to the baseline both at three and seven weeks after the treatment ($p<0.001$). However, the sham group had a significant improvement only at three weeks ($p<0.001$). When the two groups were compared in all time periods, the PEMF group at seven weeks had a significantly lower total score than the sham group ($p=0.017$) (Figure 3, Table 3).

Recovery ratios based on the PGA score were significantly higher in the PEMF group than the sham group both at three weeks (52.9% and 25%, respectively) and seven weeks (73.5% and 15.6%, respectively) ($p<0.05$). The percentage of improvement in the PEMF group continued to increase at seven

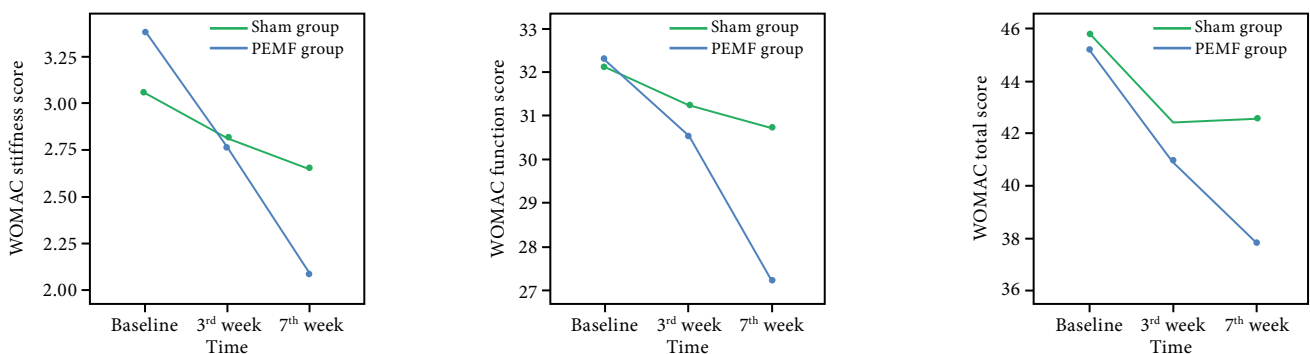


Figure 3. Estimated marginal means of WOMAC stiffness, function and total scores.

WOMAC: The Western Ontario and McMaster Universities Arthritis Index; PEMF: Pulsed electromagnetic field.

TABLE 3
Effect of PEMF therapy on the WOMAC function, stiffness, and total scores

	PEMF group (n=35)		Sham group (n=35)		<i>p</i> ^b
	Mean±SD	<i>p</i> ^a	Mean±SD	<i>p</i> ^a	
WOMAC function					
Baseline	32.26±7.37		32.16±5.83		0.948
3 rd week	30.53±6.83	<0.001*	31.25±5.57	0.005*	0.642
7 th week	27.24±6.47	<0.001*	30.72±5.18	0.095	0.019*
WOMAC stiffness					
Baseline	3.38±1.18		3.06±1.32		0.303
3 rd week	2.76±1.10	<0.001*	2.81±1.20	0.100	0.867
7 th week	2.09±0.67	<0.001*	2.66±1.00	0.017*	0.008*
WOMAC total					
Baseline	45.21±10.52		45.75±8.5		0.819
3 rd week	40.94±9.27	<0.001*	42.47±7.60	<0.001*	0.469
7 th week	37.82±7.99	<0.001*	42.53±7.66	<0.001*	0.017*

PEMF: Pulsed electromagnetic field; WOMAC: The Western Ontario and McMaster Universities Arthritis Index; SD: Standard deviation; *p*^a: Within-group change (compared to baseline); *p*^b: Between-group change (considering all time points); * *p*<0.05.

weeks of follow-up (*p*=0.038). No serious side effects associated with the PEMF treatment were observed. Two patients had temporary dizziness and one patient had hypotension in the PEMF group. No side effects were observed in the sham group.

DISCUSSION

In the present study, we evaluated three-week low-frequency additional PEMF therapy which provided more improvement in pain, stiffness, and physical function in patients with knee OA. The pain relief started immediately after the treatment, while the improvement in functionality and stiffness started seven weeks after the treatment. On PGA, the PEMF group yielded more favorable treatment outcomes.

The efficacy of PEMF as a treatment modality in patients with knee OA has been investigated in various research including meta-analyses.^[21-25] There are conflicting results among the meta-analyses and systematic reviews.^[21-25] The first systematic review found that PEMF was ineffective for both pain relief and improving physical function.^[21] However, the inclusion of five non-English studies in the analysis (selection bias) and the presence of patients with both hip and knee OA may have affected the results. In another meta-analysis, Vayken et al.^[22] reported that PEMF had a moderate effect on clinical scores reflected in activities of daily living, and a weak effect

on stiffness, but had no significant effect on pain in patients with knee OA. In subsequent meta-analysis, PEMF was significantly more effective in alleviating pain at four and eight weeks than the placebo,^[23] but a significant improvement was observed eight weeks after the treatment initiation in terms of physical function. More recent meta-analyses emphasized that the effect of PEMF on physical functions occurs within four to six weeks of use, and this effect was not seen in applications shorter than four weeks.^[25] In this study, a significant reduction in the pain VAS scores was detected at three and seven weeks after the PEMF therapy, whereas an improvement in stiffness and physical function was observed with three weeks of treatment.

Currently, there is no standardized treatment protocol in terms of the duration, frequency, and intensity of PEMF therapy sessions. The pulse frequency and duration varied across the randomized clinical trials available, making it difficult to compare efficacy and safety. In the literature, particular emphasis is placed on the fact that a significant pain relief was observed in trials using low pulse frequencies.^[26] Our results support this finding.

Although we found a significant decrease in pain VAS scores of patients after PEMF treatment in our study, this improvement was not reflected in the

WOMAC pain scores. The WOMAC pain subscale evaluates pain related to different types of activities (e.g., walking, standing) with five-item, but the VAS is based on a single-item questionnaire measuring any type of pain specific to the index joint.^[27] Although the WOMAC index is currently regarded as one of the most sensitive outcome measure to evaluate the treatment outcome in knee OA, in a meta-epidemiological study, the VAS for global OA pain showed higher assay sensitivity than the WOMAC pain subscale in detecting treatment effects at the level of individual trials.^[27,28]

Nonetheless, there are some limitations to this study. Although patients were allowed to take up to 4 g/day of acetaminophen as needed for pain relief throughout the study, most patients did not accurately and regularly record the total dose taken. Therefore, it was not possible to compare the groups for total dose. The long-term course of the improvement in pain and function is unknown, as the follow-up assessment was made at a relatively early period (at seven weeks after treatment). Also, we were unable to evaluate the effectiveness of PEMF treatment on the quality of life of the patients. In addition, the results cannot be generalized to the entire knee OA population, as the patients included in the study were all female.

In conclusion, PEMF therapy is a safe and well-tolerated plausible option for patients with knee OA. It provides more pain relief and physical improvement when used in conjunction with physical therapy in the management of knee OA. However, there is still a need for the development of standardized treatment protocols that can ensure the effective use of PEMF in the current clinical practice.

Ethics Committee Approval: The study protocol was approved by the Ankara University Faculty of Medicine Clinical Research Ethics Committee (date: 14.03.2014, no: 04-175-14) and the Turkish Medicines and Medical Devices Agency (24/06/2014, 1333250). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, design: H.G., Ş.K., S.E.H.; Control/supervision: H.G., Ş.K.; Data collection and/or processing: S.E.H., H.G.; Analysis and/or interpretation: S.E.H., H.G., C.A.; Literature review, writing the article: S.G., H.G., Ş.K.; Critical review: H.G., Ş.K.; References and fundings: S.G., H.G., Ş.K.; Materials: S.E.H.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding: The authors received no financial support for the research and/or authorship of this article.

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