

Pulsed Shortwave Treatment in Women With Knee Osteoarthritis: A Multicenter, Randomized, Placebo-Controlled Clinical Trial

Thiago Yukio Fukuda, Ronaldo Alves da Cunha, Vanessa Ovanessian Fukuda, Fabio Albanex Rienzo, Claudio Cazarini Jr, Nilza de Almeida Aparecida Carvalho, Aline Almeida Centini

Background. Several forms of conservative treatment have been the focus of many recent studies in knee osteoarthritis (OA). Among these techniques, the application of pulsed shortwave (PSW) treatment has been widely used, but the optimal dose and application time have not been well established.

Objective. The purposes of this study were: (1) evaluate the effect of PSW treatment in different doses and (2) to compare low-dose and high-dose PSW groups with control and placebo groups.

Design. This was a randomized clinical trial.

Setting. The study was conducted in the physical therapy department of 2 large urban hospitals.

Patients. One hundred twenty-one women (mean age=60 years, SD=9) with a diagnosis of knee OA participated in the study.

Intervention and Measurements. Participants were distributed randomly into 4 groups: 35 participants did not receive any treatment (control group), 23 received a placebo treatment, 32 received low-dose PSW treatment (power of 14.5 W, treatment duration of 19 minutes, and total energy of 17 kJ), and 31 received high-dose PSW treatment (power of 14.5 W, treatment duration of 38 minutes, and total energy of 33 kJ). An 11-point numerical pain rating scale and the Knee Osteoarthritis Outcome Score were used to assess pain and function in 3 stages: at initial evaluation (pretreatment), immediately after treatment, and at 12-month follow-up.

Results. The 4 groups were homogeneous prior to treatment with respect to demographics, pain, and functional scale data. The results demonstrated the short-term effectiveness of the PSW at low and high doses in patients with knee OA. Both treatment groups showed a significant reduction in pain and improvement in function compared with the control and placebo groups (effect size: range=20.0–23.4 for the low-dose PSW group and range=15.7–16.5 for the high-dose PSW group). There were no differences in results between PSW doses, although a low dose of PSW appeared to be more effective in the long term.

Limitations. These results were achieved without physical exercise, which could have positively influenced the results.

Conclusions. Pulsed shortwave treatment is an effective method for pain relief and improvement of function and quality of life in the short term in women with knee OA. On the basis of the results, application of PSW treatment is recommended in the female population with knee OA. However, conclusions regarding the 12-month follow-up should be analyzed carefully due to the high dropout rate.

T.Y. Fukuda, PT, PhD, Physical Therapy Department, Irmandade da Santa Casa de Misericórdia (ISCMSp), São Paulo, Brazil. Mailing address: Rua Dr. Cesário Motta Jr, 112, 01221-020, São Paulo, Brazil. Address all correspondence to Dr Fukuda at: tfukuda10@yahoo.com.br.

R. Alves da Cunha, PT, Physical Therapy Department, Irmandade da Santa Casa de Misericórdia.

V.O. Fukuda, PT, MSc, Physical Therapy Department, Irmandade da Santa Casa de Misericórdia.

F.A. Rienzo, PT, Institute of Orthopaedic and Traumatology, Clinics Hospital, University of São Paulo Medical School, São Paulo, Brazil.

C. Cazarini Jr, PT, MSc, Physical Therapy Department, Irmandade da Santa Casa de Misericórdia.

N.A.A. Carvalho, PT, MSc, Physical Therapy Department, Irmandade da Santa Casa de Misericórdia.

A.A. Centini, PT, Institute of Orthopaedic and Traumatology, Clinics Hospital, University of São Paulo Medical School.

[Fukuda TY, Alves da Cunha RA, Fukuda VO, et al. Pulsed shortwave treatment in women with knee osteoarthritis: a multicenter, randomized, placebo-controlled clinical trial. *Phys Ther.* 2011;91:1009–1017.]

© 2011 American Physical Therapy Association

Post a Rapid Response to this article at: ptjournal.apta.org

Osteoarthritis (OA) is a multifactorial disease characterized by inflammation and joint degeneration that results in the progressive loss of cartilage and usually is accompanied by subchondral bone sclerosis and, in many cases, formation of bone cysts and marginal osteophytes.¹ Besides these intrinsic disorders of the joints, other signs such as decreased range of motion, pain and joint effusion, crepitation, deformities, and functional loss often are present.²

Osteoarthritis is one of the most prevalent diseases in the world and is commonly present in the knee joint. It is the major cause of physical limitation and reduction in quality of life.^{1,2} Osteoarthritis affects more than 60% of the population over 40 years of age, and the commitment level varies according to age, especially in women.³ The exact etiology of OA remains unclear, but the disease is frequently associated with metabolic or endocrinological factors, heredity, obesity and joint overload, and repetitive microtraumas.^{4,5}

Because the major complaints of patients with OA are joint pain, stiffness, and functional deficits,⁵ the main treatment recommendations have focused on symptom relief and improvement of functional status.^{4,6} Many interventions have been used for lifestyle modification, including weight reduction, drugs, surgery, and specific physical therapy interventions such as exercises and phys-

ical agents.⁷⁻¹⁰ Among these agents, we are concerned with the electromagnetic radiation applied by a shortwave device in either continuous or pulsed form.¹¹⁻¹³

Some authors have used pulsed shortwave (PSW) therapy with the goal of minimizing thermal effects generated by conventional, continuous applications, while emphasizing the effects of incremental cellular trophism and metabolism.^{11,14,15} Other authors have hypothesized that the effects of PSW treatment probably are related to increased local cellular activity and that PSW treatment reduces edema and the inflammatory process, increases the rate of fibrin and collagen deposits, and aids in tissue regeneration without interfering with the nervous system or the hypothalamus.¹⁶⁻¹⁸

However, the effectiveness of the PSW treatment in people with knee OA remains controversial. Results of some clinical trials have shown pos-

itive effects,^{10,11,19} whereas the results of other clinical trials have not shown positive effects.²⁰⁻²² These conflicting results seem to be related to the great variation of applied energy and treatment duration, which ranged between 2 and 180 kJ and 15 to 40 minutes, respectively. For this reason, controlled trials with different doses are needed to evaluate the effectiveness of the PSW application in the management of knee OA.

Therefore, this study aimed to evaluate the short-term and long-term effects of PSW treatment and to compare this treatment with control and placebo interventions, as well as to evaluate probable differences in low or high doses of PSW.

Method Participants

This prospective, randomized, placebo-controlled, multicenter study was performed in the physical therapy sectors of the Irmandade da Santa Casa de Misericórdia de São Paulo (ISC MSP)

The Bottom Line

What do we already know about this topic?

Electrothermotherapy devices have been used to treat patients with knee osteoarthritis in order to reduce pain and improve function. However, the effectiveness of these devices, especially pulsed shortwave, is still controversial.

What new information does this study offer?

According to this study, the application of pulsed shortwave is an effective method for reducing pain and improving function in women with knee osteoarthritis. High or low doses of pulsed shortwave treatment are more effective than placebo treatment or no treatment.

If you're a patient, what might these findings mean for you?

If you have knee osteoarthritis, adding pulsed shortwave treatment to your therapeutic exercise program may increase the benefits of therapy. More research is needed, however, to determine the duration of this improvement.

Available With
This Article at
ptjournal.apta.org

- [The Bottom Line Podcast](#)
- [Audio Abstracts Podcast](#)

This article was published ahead of print on June 3, 2011, at ptjournal.apta.org.

and the Institute of Orthopaedic and Traumatology–Clinics Hospital at the University of São Paulo Medical School (IOT/HCFMUSP) between August 2006 and December 2008 in patients with knee OA diagnosis. All patients were directly screened by medical referral to the responsible sectors.

One hundred twenty-one women (mean age=60 years, SD=9) were randomly assigned to 4 groups: 35 patients did not receive any treatment (control group), 23 received a placebo treatment, 32 received low-dose PSW treatment, and 31 received high-dose PSW treatment. The sample size calculations were based on detecting an 8-point difference in Knee Injury and Osteoarthritis Score (KOOS) pain subscale score and a 20% between-group difference according to minimal clinically important difference (MCID),^{23,24} assuming a standard deviation of 13 points, a sample with 2-tailed distribution, an alpha level equal to .05, and 80% power, while providing adequate protection against type II error.²⁵

The patients were included in the study if they were over 40 years of age, had primary grade II or III knee OA based on Gupta and colleagues' radiographic criteria,² and had had joint or anterior knee pain for at least 3 months. We excluded patients with a history of surgery or any invasive procedure of the affected knee, physical therapy for knee injuries or any medication that had changed in the last 3 months, or other diseases affecting function and patients who presented any contraindication for application of PSW treatment, especially metallic implants, pacemakers, lack of sensitivity, or tumor.²⁰ All volunteers were informed about the procedures for the study and signed informed consent agreements written in accordance with the National Health Council, resolution 196/96.

Inclusion criteria were established previously, and the patient's selection was performed by a physical therapist (T.Y.F.) with 8 years of experience in knee rehabilitation. This examiner was responsible for the pretreatment and posttreatment evaluations, as well as the 12-month follow-up (Figure). The examiner was blinded to the group assignments and did not participate in the intervention.

The assignment of participants to 4 groups was performed randomly using opaque and sealed envelopes containing the names of the groups: control, placebo, low-dose PSW, and high-dose PSW. The envelopes were picked by an individual not involved in this study. Group assignment was performed following the initial evaluation and just minutes prior to the initial treatment session. Two therapists in each center were trained in the application protocol for the study and provided all treatment.

Interventions

The treatment was performed with 2 previously calibrated Diatermed II devices* with a carrying frequency of 27.12 MHz, a peak power of 250 W, and a pulse duration of 400 microseconds. These parameters are predetermined in the device according to the manufacturer. We used the maximum power provided by the machine in a pulsed form with a pulse frequency of 145 Hz, resulting in a mean power of 14.5 W. These settings were based on the fact that applications with a mean power below 20 W minimize the thermal effects.^{11,18} To calculate the mean power, the following formula was used:

$$\begin{aligned} \text{Mean power (W)} = & \\ & \text{peak power (W)} \\ & \times \text{pulse duration (s)} \\ & \times \text{pulse frequency (Hz)} \end{aligned}$$

In the low-dose PSW group, the treatment had a duration of 19 minutes per session, with approximately 17 kJ of total energy. The high-dose PSW group received 38 minutes of treatment, with 33 kJ of total energy.^{11,18} To calculate these energy values, the following equation was used:

$$\begin{aligned} \text{Total energy (J)} = & \\ & \text{mean power (W)} \\ & \times \text{application time (s)} \end{aligned}$$

Both groups were given 3 applications of PSW treatment per week, totaling 9 sessions. The PSW treatment was administered using a standard size malleable electrode applied on the anterior area of the thigh, 5 cm above the superior border of the patella, and a second electrode applied on the posterior area of the leg, with the participant positioned supine. The knee was kept in semi-flexion at 20 degrees.

The control group did not receive any form of treatment, and all participants in this group were instructed to maintain their daily activities. A placebo group also was established, for which the PSW device was turned on but kept in standby mode during 19 minutes without any electrical current being applied. The participants in the placebo group also received 9 sessions of treatment. The control and placebo groups were used for comparison of the results of the low-dose and high-dose PSW groups. It is important to highlight that the therapists did not remain beside the participants during treatment to avoid

* Carci, R. Dr. Siqueira Campos, 246 Liberdade, São Paulo, Brazil.

Pulsed Shortwave Treatment in Women With Knee Osteoarthritis

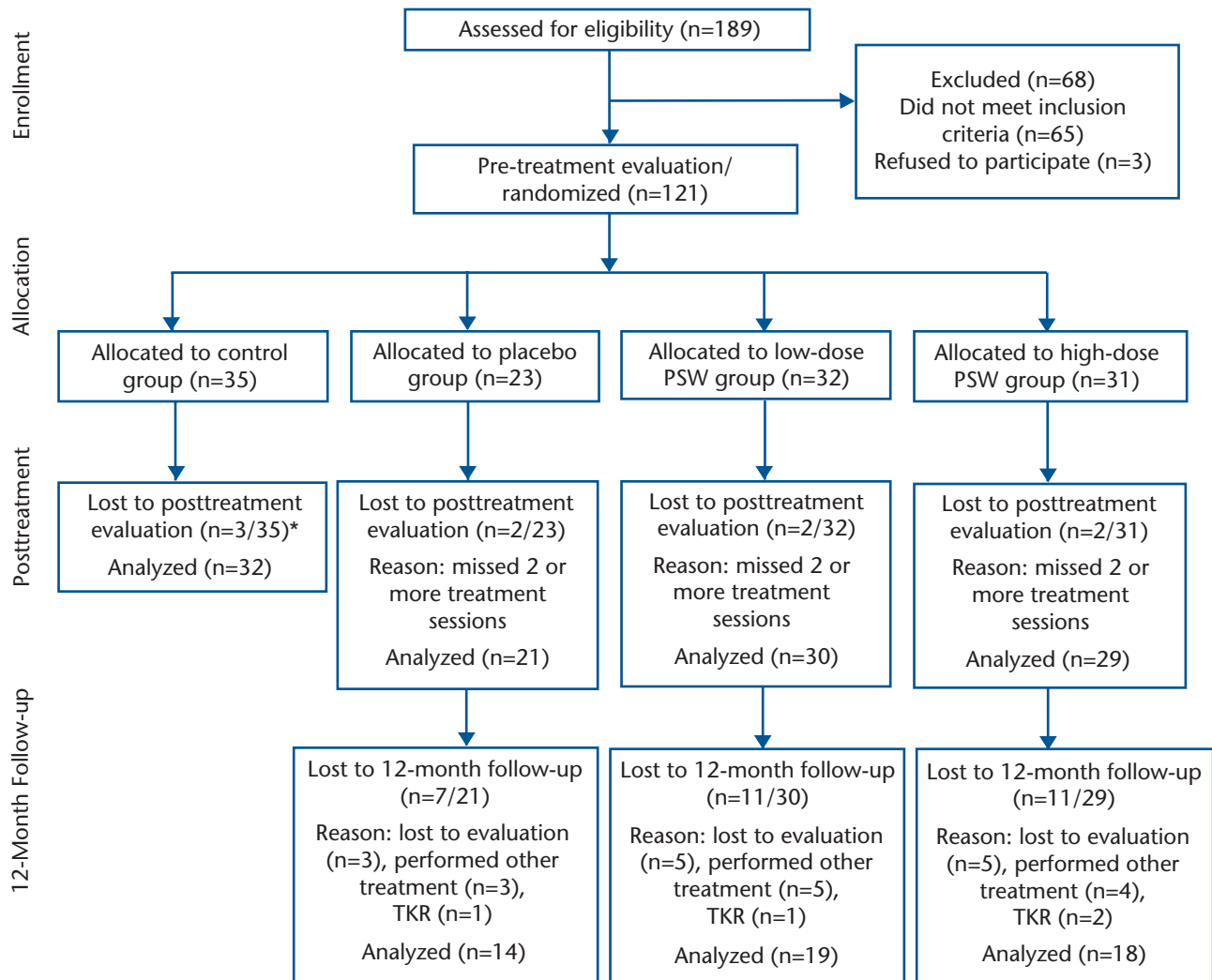


Figure. Participant flow diagram. PSW=pulsed shortwave, TKR=total knee replacement. *12-month follow-up not performed.

influencing the results. No advice was given to participants in both centers in relation to physical activities, except to maintain their daily activities and to avoid using anti-inflammatory drugs. Participants in the placebo and treatment groups remained blinded during the 12-month follow-up.

Evaluation

The participants were evaluated in 3 phases: at the initial evaluation (pre-treatment), immediately after treatment, and at a 12-month follow-up. An 11-point numerical pain rating

scale (NPRS) was used to measure pain during the last 2 days of treatment, where 0 corresponded to “no pain” and 10 corresponded to “worst imaginable pain.” The NPRS has been shown to yield reliable and valid scores, with an MCID of 2 points.^{25,26}

We administered a validated KOOS questionnaire as a functional measure.^{27,28} The KOOS questionnaire is designed specifically for patients with knee injuries and OA. It consists of 5 subscales: symptoms, daily activities, pain, recreational function, and

quality of life. The answers are based on reports from the previous week, where a score of 0 corresponds to “functional impairment” with exacerbated symptoms and a score of 100 corresponds to “normal function” without symptoms. Each subscale was normalized and analyzed individually. The MCID of the KOOS is not yet well defined, but may vary between 10% and 40% depending on the initial result.^{23,24} We did not perform a 12-month follow-up of the control group because after the first arm of the study, the participants in

that group were referred for traditional physical therapy.

Data Analysis

Data were analyzed with SPSS, version 13.0.[†] Descriptive statistics for demographic data and all outcome measures were expressed as means and standard deviations. Comparisons among groups were performed, using one-way analyses of variance (ANOVAs), for age, body mass, height, and body mass index to show homogeneity of the sample at baseline. The data for the KOOS and the NPRS were analyzed using a mixed model (group \times time) ANOVA. The factor "group" had 4 levels (control, placebo, low-dose PSW, and high-dose PSW), and the repeated factor "time" had 3 levels (preintervention, postintervention, and 12-month follow-up, except for the control group). We also compared the proportion of participants who met or exceeded the MCID in the posttreatment evaluation compared with baseline for the pain and functional scales in the studied groups.

Results

Baseline and Demographic Data

There were no statistically significant differences ($P>.05$) for age, height, body mass, and body mass index among the 4 groups (Tab. 1). There also were no statistically significant differences ($P>.05$) among groups for any of the outcome variables at baseline (preintervention) (Tab. 2). Knee pain for at least 3 months was used as an inclusion criterion; however, all participants had had pain for more than 6 months.

Pain and Function

The group \times time interaction for the mixed-model ANOVA (pretreatment \times posttreatment) was statistically significant ($P<.05$) for the

Table 1.

Demographic Characteristics of the Control, Placebo, Low-Dose Pulsed Shortwave (PSW), and High-Dose PSW Groups^a

Variable	Control Group (n=32)	Placebo Group (n=21)	Low-Dose PSW Group (n=30)	High-Dose PSW Group (n=29)
Age (y) ^b	61.0 \pm 10.0	57.0 \pm 9.0	62.0 \pm 8.0	63.0 \pm 9.0
Body mass (kg) ^b	67.4 \pm 11.9	71.7 \pm 9.4	74.2 \pm 10.4	69.8 \pm 11.8
Height (m) ^b	1.6 \pm 0.1	1.6 \pm 0.1	1.6 \pm 0.1	1.6 \pm 0.1
Body mass index (kg/m ²) ^b	26.7 \pm 3.0	27.6 \pm 3.7	29.4 \pm 4.5	27.1 \pm 4.2
Injured limb, n (%)				
Left	16 (50%)	5 (24%)	10 (33%)	6 (21%)
Right	16 (50%)	16 (76%)	20 (67%)	23 (79%)

^a Only data for those participants remaining at the end of the intervention are included. All values are mean \pm SD, unless otherwise indicated.

^b There were no differences between groups ($P>.05$).

NPRS and for the KOOS subscales, except for the KOOS recreational activities subscale ($P>.05$). Planned pair-wise comparisons indicated that both low-dose PSW and high-dose PSW groups showed significant differences for the KOOS symptoms subscale ($P<.01$; effect size [95% confidence interval (CI)] of 20.0 [10.2] and 15.7 [9.5], respectively), the KOOS daily activities subscale ($P<.01$ and $P<.05$; effect size [95% CI] of 15.7 [10.2] and 11.5 [9.3], respectively), the KOOS pain subscale (both, $P<.001$; effect size [95% CI] of 23.4 [9.1] and 16.5 [8.0], respectively), and the NPRS ($P<.001$ and $P<.01$; effect size [95% CI] of -3.3 [1.3] and -2.1 [1.3], respectively). In relation to the KOOS quality of life subscale, only the low-dose PSW group showed a significant difference ($P<.01$; effect size [95% CI] of 10.9 [7.2]). There was no difference for the control and placebo groups (both, $P>.05$) in the post-treatment evaluation compared with the baseline evaluation.

The posttreatment analysis showed that both low-dose PSW and high-dose PSW groups were statistically different compared with the control and placebo groups for the

KOOS symptoms and daily activities subscales (range= $P<.05$ - $P<.001$). There was no difference between the treatment groups ($P>.05$). For the KOOS pain and quality of life subscale analyses, the low-dose PSW and high-dose PSW groups were statistically different only when compared with the control group (range= $P<.05$ - $P<.001$). We did not find any difference for the KOOS recreational activities subscale ($P>.05$). In the NPRS analysis, only the low-dose PSW group showed decreases in pain compared with the control and placebo groups ($P<.05$ and $P<.01$), respectively. There was no difference between the placebo and control groups for any of the scales ($P>.05$).

The group \times time interaction between the pretreatment evaluation and the 12-month follow-up was significant only for the KOOS symptoms, pain, and daily activities subscales ($P<.05$). Planned pair-wise comparisons indicated that both low-dose PSW and high-dose PSW groups maintained improvement on the KOOS pain subscale (both, $P<.05$; effect size [95% CI] of 20.1 [10.9] and 15.1 [9.6], respectively). The low-dose PSW also showed a significant difference for the KOOS

[†] SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.

Table 2.

Outcome Measures at Initial Evaluation (Pretreatment), Immediately After Treatment (Posttreatment), and at 12-Month Follow-up for the Control, Placebo, Low-Dose Pulsed Shortwave (PSW), and High-Dose PSW Groups^a

Measure	Pretreatment	Posttreatment	12-Month Follow-up
KOOS			
Symptoms subscale			
Control	46.3±19.8 (6.9)	46.3±19.8 (6.8)	
Placebo	42.0±17.9 (7.8)	44.8±16.3 (7.1)	40.7±11.2 (4.9)
Low-dose PSW	46.5±19.8 (7.4)	66.5±20.3 (7.2)	61.6±19.7 (7.0)
High-dose PSW	47.0±18.0 (6.5)	62.7±18.6 (6.8)	54.9±21.6 (7.8)
Daily activities subscale			
Control	49.0±16.9 (5.9)	48.1±17.7 (6.2)	
Placebo	45.7±16.3 (7.1)	51.5±17.5 (7.6)	41.6±16.9 (7.3)
Low-dose PSW	45.8±19.8 (7.1)	61.5±20.3 (7.2)	68.9±20.2 (7.2)
High-dose PSW	51.7±19.1 (6.9)	63.2±16.5 (6.0)	51.9±15.0 (5.5)
Pain subscale			
Control	40.9±17.2 (6.0)	42.3±17.3 (6.1)	
Placebo	38.0±13.5 (5.9)	43.8±16.1 (7.0)	33.0±9.9 (4.3)
Low-dose PSW	37.4±17.4 (6.2)	60.8±18.6 (6.6)	57.5±21.0 (7.5)
High-dose PSW	42.5±16.0 (5.8)	59.0±15.5 (5.6)	57.6±16.1 (5.8)
Recreational activities subscale			
Control	22.7±16.2 (5.7)	21.4±22.0 (7.8)	
Placebo	18.2±15.0 (6.5)	18.4±11.1 (4.8)	11.0±7.1 (3.1)
Low-dose PSW	16.6±10.3 (3.7)	25.0±17.6 (6.3)	24.6±25.4 (9.0)
High-dose PSW	15.3±17.6 (6.4)	21.3±23.4 (8.5)	15.9±17.6 (6.4)
Quality of life subscale			
Control	27.9±19.0 (6.7)	26.4±21.8 (7.6)	
Placebo	27.8±29.7 (5.5)	29.7±13.7 (5.9)	33.0±12.8 (5.6)
Low-dose PSW	26.1±12.0 (4.3)	37.0±16.2 (5.8)	31.8±10.7 (3.8)
High-dose PSW	32.4±15.0 (5.4)	39.4±18.7 (6.8)	41.2±20.6 (7.5)
NPRS			
Control	6.1±2.1 (0.7)	5.6±2.1 (0.7)	
Placebo	7.7±1.4 (0.6)	6.9±2.0 (0.9)	7.5±1.6 (0.7)
Low-dose PSW	7.1±2.8 (1.0)	3.8±2.2 (0.8)	5.7±3.0 (1.1)
High-dose PSW	6.7±2.5 (0.9)	4.6±2.5 (0.9)	5.2±2.1 (0.8)

^a All values are presented as mean±SD (95% confidence interval). KOOS=Knee Injury and Osteoarthritis Outcome Score; a higher score on the KOOS represents better function. NPRS=11-point numerical pain rating scale (0–10 cm), where 0 means “no pain” and 10 means “worst imaginable pain.”

symptoms subscale ($P<.05$; effect size [95% CI] of 15.1 [11.5]) and the KOOS daily activities subscale ($P<.01$; effect size [95% CI] of 23.1 [11.6]). As in the previous analysis, there was no difference in the control and placebo groups for the

12-month follow-up when compared with the baseline evaluation (both, $P>.05$).

In this long-term evaluation, the differences among groups showed that only the low-dose PSW group was

statistically different compared with the placebo group for the KOOS symptoms subscale ($P<.05$), the KOOS daily activities subscale ($P<.01$), and the KOOS pain subscale ($P<.01$). There was no difference between the treatment groups ($P>.05$) (Tab. 3). It is important to highlight that we did not perform a 12-month follow-up with the participants who remained in the control group.

Intention-to-Treat Analysis

The dropout of 9 participants in the first part of the study did not affect the potential validity of the study (effect size of interest), because in terms of intention to treat (ITT), these dropouts did not exceed 10% of the total.^{29,30} However, there was a dropout of 29 participants (approximately 30%) in the second part of the study, which showed a clear necessity to conduct an ITT analysis. As shown in the Figure, 7 participants in the placebo group were lost to 12-month follow-up: 3 did not attend the invitation after 2 telephone calls (lost to evaluation), 3 performed other therapies such as acupuncture and traditional physical therapy in other services, and 1 had a total knee replacement (TKR). Eleven participants in the low-dose PSW group were lost to 12-month follow-up: 5 were lost to evaluation, 5 performed other therapies such as physical therapy and acupuncture, and 1 had a TKR. Finally, 11 participants in the high-dose PSW group were lost to 12-month follow-up: 5 were lost to evaluation, 4 performed other therapies such as physical therapy and infiltration, and 2 had a TKR. Thus, we performed an ITT analysis using the last observation carried forward, and the results were consistent with the per-protocol analysis, as previously presented.

MCID Analysis

Based on the MCID for the NPRS (2 points), the proportion of patients who met or exceeded the MCID in

the posttreatment evaluation compared with baseline was 15% in the control group, 15% in the placebo group, 75% in the low-dose PSW group, and 50% in the high-dose PSW group, and the difference between the treatment groups and the control and placebo groups was significant ($P < .05$). Unfortunately, we did not find an MCID standard value for the KOOS questionnaire, but there is speculation that improvement can be significant when the proportion of patients who meet or exceed the MCID is above 10% to 40%. Thus, when we examined the first part of the study, the proportion of patients who met or exceeded 40% of improvement was 15% in the control group, 15% to 25% in the placebo group, 55% to 65% in the low-dose PSW group, and 35% to 50% in the high-dose PSW group.

In the second part of the study, we conducted a 12-month follow-up to assess the long-term effects of PSW application in patients who received some intervention. We observed in the per-protocol analysis and confirmed in the ITT analysis that low-dose PSW treatment maintained the therapeutic effect for the KOOS symptoms, quality of life, and pain subscale (ie, the proportion of patients who met or exceeded the MCID ranged around 40%). The high-dose PSW group maintained the results only for KOOS pain subscale (MCID of 50%).

Discussion

The results of this study demonstrate the short-term effectiveness of PSW treatment at low or high doses in patients with knee OA. Both treatment groups showed significant reduction in pain and improvement in function compared with the control and placebo groups. However, recent studies have been concerned with analyzing these results regarding the clinical meaningfulness of the observed effect sizes.^{24,26,31}

Table 3.

Within-Group Difference in Change Score (Pretreatment, Posttreatment, and 12-Month Follow-up) for the Control, Placebo, Low-Dose Pulsed Shortwave (PSW), and High-Dose PSW Groups^a

Measure	Pretreatment to Posttreatment Mean Change Score (95% CI)	Pretreatment to 12-Month Follow-up Mean Change Score (95% CI)
KOOS		
Symptoms subscale		
Control	0.0 (9.7)	
Placebo	2.8 (10.4)	-1.3 (7.4)
Low-dose PSW	20.0 (10.2)	15.1 (11.5)
High-dose PSW	15.7 (9.5)	7.9 (11.5)
Daily activities subscale		
Control	-0.9 (8.4)	
Placebo	5.8 (8.2)	-4.1 (11.3)
Low-dose PSW	15.7 (10.2)	23.1 (11.6)
High-dose PSW	11.5 (9.3)	0.2 (10.6)
Pain subscale		
Control	1.4 (8.4)	
Placebo	5.8 (9.0)	-5.0 (8.5)
Low-dose PSW	23.4 (9.1)	20.1 (10.9)
High-dose PSW	16.5 (8.0)	15.1 (9.6)
Recreational activities subscale		
Control	-1.3 (9.4)	
Placebo	0.2 (8.1)	-7.2 (8.7)
Low-dose PSW	8.4 (7.3)	8.0 (10.1)
High-dose PSW	6.0 (10.6)	0.6 (10.5)
Quality of life subscale		
Control	-1.5 (10.0)	
Placebo	1.9 (14.3)	5.2 (17.1)
Low-dose PSW	10.9 (7.2)	5.7 (6.7)
High-dose PSW	7.0 (8.7)	8.8 (10.3)
NPRS		
Control	-0.5 (1.0)	
Placebo	-0.8 (1.0)	-0.2 (1.0)
Low-dose PSW	-3.3 (1.3)	-1.4 (1.7)
High-dose PSW	-2.1 (1.3)	-1.5 (1.4)

^a 95% CI=95% confidence interval. KOOS=Knee Injury and Osteoarthritis Outcome Score; a higher score on the KOOS represents better function. NPRS=11-point numerical pain rating scale (0-10 cm), where 0 means "no pain" and 10 means "worst imaginable pain."

By itself, a per-protocol analysis of the raw data has not been accepted as the only way to compare groups. An MCID analysis also is required to

obtain parameters and significance of scales,²⁹ and for this reason it was used in the present study (see the "MCID Analysis" section). Two impor-

tant points should be taken into account when analyzing these data. First, therapeutic exercises, which could have helped in the maintenance of long-term effects, were not performed in this study. Second, we did not perform a long-term analysis of the participants who did not receive any treatment (control group). However, it is important to emphasize that there were a large number of participants (approximately 30%) who did not attend the 12-month follow-up assessment.

Some divergent aspects became very clear when we analyzed the literature regarding patients with OA. Therapeutic results have not been shown in PSW applications with power ranging between 1.8 and 23 W.^{20,21,32} However, even more surprising is the fact that despite the popularity of shortwave diathermy, few studies demonstrated the effectiveness of this form of treatment for knee OA.³³

In a recent double-blind, randomized, placebo-controlled clinical trial,²² the authors evaluated the efficacy of PSW treatment associated with exercises compared with a placebo intervention in the same population. In the active group, the PSW treatment was applied with a mean power of 3.2 W and a session time of 20 minutes. The results indicated that there was no difference in function and pain levels between the active group and the placebo group.

In another clinical trial²⁰ in patients with knee and hip OA, the outcome did not demonstrate therapeutic effects using shortwave treatment with a mean power of 23 W for 15 minutes in relation to the placebo group. The difference between groups, although not statistically significant ($P > .05$), was close to statistical significance ($P = .07$). On the other hand, the study conducted by

Tuzun et al¹⁰ associated ultrasound and shortwave therapy and obtained clinically significant results with a mean power of 8 and 25 W and a final energy level between 7 and 24 kJ. In addition, the study by Bezalet et al¹⁹ associated with a home-based exercise program utilizing a shortwave mean power of 21.6 W, demonstrated short-term benefits in patients with knee OA. Shortwave therapy associated with other techniques also showed therapeutic improvement when compared with the control group.⁸

In the present study, we showed the effectiveness of PSW treatment with either a low dose (power of 14.5 W, treatment duration of 19 minutes, and total energy of 17 kJ) or a high dose (power of 14.5 W, treatment duration of 38 minutes, and total energy of 33 kJ). These results were maintained over the long term, especially for the low doses, despite the obvious high dropout rate. Although it was not the aim of the study, we believe that the reduction in pain, increased joint lubrication and tissue relaxation, and improvement in function may have stimulated a better movement and gait pattern, as well as increased physical activity over time. However, no advice or orientation was given to patients in relation to physical or sports activities, except to maintain their daily activities and to avoid using anti-inflammatory drugs.

Finally, in addition to the beneficial effects of the PSW treatment for patients with knee OA, it was noted that a prolonged application time is not necessary because a total time of 20 minutes can reach the therapeutic window proposed in the literature. It is noteworthy that these results were achieved without physical exercise, which could have positively influenced the results. Thus, PSW therapy can be an important

tool associated with kinesiotherapy in the rehabilitation program.

Conclusion

Pulsed shortwave treatment is an effective method for providing pain relief and improvement in function and quality of life in the short term for women with knee OA. Treatments with low or high doses are more effective than placebo treatment or no treatment. There were no differences between PSW treatment doses, despite the fact that low-dose PSW treatment appears to be more effective in the long term. However, conclusions regarding the long-term effects need to be carefully considered due to the excessive dropout rate during the 12-month follow-up. On the basis of our results, we recommend PSW application in the female population with knee OA.

Dr Fukuda, Mr Alves da Cunha, Ms Fukuda, Mr Cazarini, Ms Carvalho, and Ms Centini provided concept/idea/research design. Dr Fukuda, Mr Alves da Cunha, Ms Fukuda, Mr Rienzo, and Ms Centini provided writing. All authors provided data collection and analysis and consultation (including review of manuscript before submission). Mr Alves da Cunha, Ms Fukuda, and Ms Carvalho provided participants. Mr Cazarini provided facilities/equipment. Ms Carvalho provided institutional liaisons. Ms Fukuda provided clerical support.

The protocol for this study was approved by the Ethics Committee on Research of Irmandade da Santa Casa de Misericórdia and the University of São Paulo Medical School, São Paulo, Brazil.

ClinicalTrials.gov registration: NCT01331174.

This article was submitted September 14, 2010, and was accepted March 22, 2011.

DOI: 10.2522/ptj.20100306

References

- 1 Buckwalter JA, Lane NE. Athletics and osteoarthritis. *Am J Sports Med.* 1997;25: 873-881.
- 2 Gupta KB, Duryea J, Weissman BN. Radiographic evaluation of osteoarthritis. *Radiol Clin North Am.* 2004;42:11-41.

- 3 Peat G, McCarney R, Croft P. Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care. *Ann Rheum Dis*. 2001;60:91-97.
- 4 Jordan KM, Arden NK, Doherty M, et al. EULAR recommendations 2003—an evidence based approach to the management of knee osteoarthritis: report of a task force of the standing committee for international clinical studies including therapeutic trials (ESCISIT). *Ann Rheum Dis*. 2003;62:1145-1155.
- 5 Oliveira SA, Felson DT, Reed JI, et al. Incidence of symptomatic hand, hip, and knee osteoarthritis among patients in a health maintenance organization. *Arthritis Rheum*. 1995;38:1134-1141.
- 6 Zhang W, Moskovitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage*. 2008;16:137-162.
- 7 Bjordal JM, Johnson MI, Lopes-Martins RA, et al. Short-term efficacy of physical interventions in osteoarthritic knee pain: a systematic review and meta-analysis of randomised placebo-controlled trials. *BMC Musculoskelet Disord*. 2007;8:51.
- 8 Cetin N, Aytar A, Atalay A, Akman MN. Comparing hot pack, short-wave diathermy, ultrasound, and TENS on isokinetic strength, pain, and functional status of women with osteoarthritic knees: a single-blind, randomized, controlled trial. *Am J Phys Med Rehabil*. 2008;87:443-451.
- 9 Van Nguyen JP, Marks R. Pulsed electromagnetic fields for treating osteoarthritis. *Physiotherapy*. 2002;88:458-470.
- 10 Tuzun EH, Otman S, Kirdi N. Comparison of different methods of pulsed shortwave diathermy in knee osteoarthritis. *The Pain Clinic*. 2003;15:421-427.
- 11 Fukuda TY, Ovanessian V, Alves da Cunha R, et al. Pulsed short wave effect in pain and function in patients with knee osteoarthritis. *J Appl Res*. 2008;8:189-198.
- 12 Seiger C, Draper DO. Use of pulsed short-wave diathermy and joint mobilization to increase ankle range of motion in the presence of surgical implanted metal: a case series [erratum in *J Orthop Sports Phys Ther*. 2010;40:122]. *J Orthop Sports Phys Ther*. 2006;36:669-677.
- 13 Shields N, O'Hare N, Boyle G, Gormley J. Development and application of a quality control procedure for short-wave diathermy units. *Med Biol Eng Comput*. 2003;41:62-68.
- 14 Garrett CL, Draper DO, Knight KL. Heat distribution in the lower leg from pulsed short-wave diathermy and ultrasound treatments. *J Atbl Train*. 2000;35:50-55.
- 15 Shah SG, Farrow A. Investigation of practices and procedures in the use of therapeutic diathermy: a study from the physiotherapists' health and safety perspective. *Physiother Res Int*. 2007;12:228-241.
- 16 Evans P. The healing process at cellular level: a review. *Physiotherapy*. 1980;66:256-269.
- 17 Hill J, Lewis M, Mills P, Kilty C. Pulsed short-wave diathermy effects on human fibroblast proliferation. *Arch Phys Med Rehabil*. 2002;83:832-835.
- 18 Kitchen S, Partridge C. Review of short-wave diathermy continuous and pulsed patterns. *Physiotherapy*. 1992;78:243-252.
- 19 Bezalel T, Carmeli E, Katz-Leurer M. The effect of a group education programme on pain and function through knowledge acquisition and home-based exercise among patients with knee osteoarthritis: a parallel randomised single-blind clinical trial. *Physiotherapy*. 2010;96:137-143.
- 20 Laufer Y, Zilberman R, Porat R, Nahir AM. Effect of pulsed short-wave diathermy on pain and function of subjects with osteoarthritis of the knee: a placebo-controlled double-blind clinical trial. *Clin Rehabil*. 2005;19:255-263.
- 21 Moffett JA, Richardson PH, Frost H, Osborn A. A placebo controlled double blind trial to evaluate the effectiveness of pulsed short wave therapy for osteoarthritic hip and knee pain. *Pain*. 1996;67:121-127.
- 22 Rattanachaiyanot M, Kuptniratsaikui V. No additional benefit of shortwave diathermy over exercise program for knee osteoarthritis in peri-/post-menopausal women: an equivalence trial. *Osteoarthritis Cartilage*. 2008;16:823-828.
- 23 Ehrlich EW, Davies GM, Watson DJ, et al. Minimal perceptible clinical improvement with the Western Ontario and McMaster Universities Osteoarthritis Index questionnaire and global assessments in patients with osteoarthritis. *J Rheumatol*. 2000;27:2635-2641.
- 24 Tubach F, Ravaud R, Baron G, et al. Evaluation of clinically relevant changes in patient reported outcomes in knee and hip osteoarthritis: the minimal clinically important improvement. *Ann Rheum Dis*. 2005;64:29-33.
- 25 Bellamy N, Carette S, Ford PM, et al. Osteoarthritis antirheumatic drug trials, III: setting the delta for clinical trials: results of a consensus development (Delphi) exercise. *J Rheumatol*. 1992;19:451-457.
- 26 Salaffi F, Stancati A, Silvestri CA, et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *Eur J Pain*. 2004;8:283-291.
- 27 Roos EM, Roos HP, Lohmander LS, et al. Knee Injury and Osteoarthritis Outcome Score (KOOS): development of a self-administered outcome measure. *J Orthop Sports Phys Ther*. 1998;28:88-96.
- 28 Roos EM, Toksvig-Larsen S. Knee Injury and Osteoarthritis Outcome Score (KOOS): validation and comparison to the WOMAC in total knee replacement. *Health Qual Life Outcomes*. 2003;1:17.
- 29 Jaeschke R, Singer J, Guyatt GH. Measurement of health status: ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989;10:407-415.
- 30 Moher D, Schulz KF, Altman DG; CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *Ann Intern Med*. 2001;134:657-662.
- 31 Farrar JT, Young JP Jr, LaMoreaux L, et al. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain*. 2001;94:149-158.
- 32 Callaghan MJ, Whittaker PE, Grimes S, Smith L. An evaluation of pulsed short-wave on knee osteoarthritis using radioleucoscintigraphy: a randomised, double blind, controlled trial. *Joint Bone Spine*. 2005;72:150-155.
- 33 Marks R, Ghassemi M, Duarte R, Van Nguyen JP. A review of the literature on shortwave diathermy as applied to osteoarthritis of the knee. *Physiotherapy*. 1999;85:304-316.