

Effect of pulsed short-wave diathermy on pain and function of subjects with osteoarthritis of the knee: a placebo-controlled double-blind clinical trial

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Objective: To examine the effects of pulsed short-wave diathermy (PSWD), delivered at an intensity sufficient to induce a thermal sensation and at an athermal intensity, in comparison with a placebo short-wave diathermy treatment, on reported pain, stiffness and functional ability and on mobility performance of patients with osteoarthritis of the knee.

Design: A placebo-controlled double-blind trial with sequential allocation of patients to different treatment groups.

Setting: Outpatient physiotherapy department.

Subjects: One hundred and three consecutive patients, mean age 73.7 (± 6.6) years with osteoarthritis of one or both knees for at least three months.

Interventions: All participants received three 20-min-long treatments per week for three weeks. One group received PSWD with mean power of 18 W (thermal effect), one group received PSWD with mean power of 1.8 W (athermal effect), and one group received sham short-wave diathermy treatment. Patients were assessed before the initial treatment, immediately following the last treatment, and at a three-month follow-up.

Main measures: Outcome measures included the WOMAC Osteoarthritis Index, which assessed reported pain, stiffness, and functional ability, and four measures of mobility performance: Timed Get Up and Go test (TGUG), stair-climbing, stair-descending and a 3-min walk.

Results: A difference across time was observed for the pain and stiffness categories of the WOMAC Osteoarthritis Index ($p = 0.033$ and $p = 0.008$, respectively), with no differences between groups. No other significant differences across time or between groups were observed in any of the other measures.

Conclusion: The findings do not demonstrate pulsed short-wave diathermy, as it is utilized in clinical settings, to be effective in the treatment of osteoarthritis of the knee.

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Introduction

Osteoarthritis (OA) of the knee joint occurs in over 6% of adults aged 30 and above, often resulting in extreme pain, stiffness, joint swelling, and loss of lower limb muscle strength.¹ These impairments result in marked functional limitations that account for the highest percentage of disability in walking, stair-climbing and housekeeping among the noninstitutionalized elderly population.²

Patients with OA of the knee are offered a variety of electrotherapy modalities including short-wave diathermy (SWD), which utilizes electromagnetic radiation at 27.12 MHz, delivered in either a continuous (CSWD) or a pulsed (PSWD) mode.^{3,4} It is generally accepted that the major physiological effects of CSWD are related to an induced increase in tissue temperature. These effects include vasodilatation, elevation of pain threshold, reduction in muscle spasm, acceleration of cellular activity and increased soft tissue extensibility.⁴⁻⁶

The existence of physiological effects unrelated to an increase in tissue temperature, that is, athermal effects, which might be achieved with PSWD is based primarily on research suggesting that cells are capable of absorbing energy from oscillating electrical fields of defined frequencies and/or amplitudes, which provokes or enhances cellular activity.^{7,8} Although PSWD has been reported to have positive effects on tissue healing, resorption of a haematoma, reduction of inflammation and swelling, and increase of collagen deposition and nerve growth, these effects are still under debate due to the small number of conflicting studies on which they are based.^{6,8,9} Furthermore, studies demonstrate that PSWD may also induce an elevation of tissue temperature that is dependent on the total average power delivered.^{10,11}

Despite the uncertainty concerning the general effectiveness of PSWD, surveys indicate that it is an extremely popular treatment modality.^{4,12,13} PSWD, as opposed to CSWD, is particularly popular in the treatment of OA, as early animal studies indicate that increasing joint temperature may increase proliferation of intracapsular connective tissue and formation of adhesions, which would be detrimental in arthritic conditions, especially in the acute stage.¹⁴

Despite the popularity of this modality, the effectiveness of SWD and in particular PSWD for the treatment of OA have been only sporadically examined, and most studies are characterized by poor experimental design.^{4,15,16} A recent relatively well-controlled study in patients with OA indicated no differences in pain level between the active and placebo PSWD treatments, although both tended to improve during treatment and worsen after its withdrawal.¹⁷ The purpose of the present study is to examine whether there are any differences between PSWD, whether delivered at an intensity sufficient to induce a thermal sensation or at an athermal intensity, and a placebo treatment in terms of their effect on pain, stiffness, and functional ability of patients with OA of the knees.

Methods

Subjects

All patients living in the community and referred to a large outpatient physiotherapy department with a diagnosis of OA of the knee between November 2002 and May 2003 were screened for eligibility. Inclusion criteria were: (1) age 65 and above; (2) primary OA of one or both knee joints; (3) grade 2-3 knee OA, based on the Kellgren-Lawrence classification,¹⁸ as evidenced by a radiograph and interpreted by a trained rheumatologist blind to treatment allocation; (4) knee pain for at least three months; (5) independent ambulation with or without an assistive device; (6) no physiotherapy treatment for knee problems in the last month; (7) no previous knee surgery or knee joint injection in the last three months; (8) no change in medication in the last month; (9) normal sensation for warmth in the knee region; (10) no other orthopaedic or neurological disease that could affect pain and/or disability; and (11) no contra-indication to SWD, particularly no presence of metal implants, pacemakers, joint effusion or malignancy.

Procedure

The study was approved by the Institutional Ethical Review Board, and all of the subjects who met the inclusion criteria and who agreed to participate in the study gave their written informed

consent. Figure 1 presents the overall plan of the study. Initial screening for eligibility in accordance with the inclusion criteria was carried out by the secretary of the physiotherapy department, who reviewed the referrals, conducted a phone interview, and obtained a recent (up to three months old) knee radiograph to be assessed by the rheumatologist on the team (MN). The patient was then referred to a physical therapist (RZ), who explained to the patients the purpose and placebo-controlled design of the study, obtained their informed consent, and performed the initial assessment. This therapist was also responsible for conducting the subsequent assessments, while remaining blind to the patients' group allocation. Following the initial assessment, patients were referred to a physical therapist (RP), who was responsible for sequential allocation of the patients by order of acceptance in to the study to one of three groups, (two PSWD treatment groups and one SWD placebo group). This therapist was also responsible for carrying out all treatments, but was not involved in any of the assessments or data analysis.

Intervention

All SWD treatments were conducted without revealing to the subjects the type of treatment undertaken. Treatments were administered with one of two Curapuls 670 machines (manufactured by Enraf-Nonius, Delft, The Netherlands), which operate at a frequency of 27.12 MHz. The power output of the machines was examined prior to beginning the study. During the treatment, the subjects sat comfortably with a single Circuplode inductive electrode applied at a 3-cm distance from the anterior aspect of the knee. The machine's panel was directed out of the patients' view. Patients complaining of pain in both knees were given identical treatment for both knees.

All participants received three 20-min-long treatments per week for three weeks, for a total of nine treatments. No other treatment was offered to the patients during this period. The difference between the groups was in dosage only. For the high-intensity PSWD (H-PSWD) treatment, the machine's programme was set at 'chronic osteoarthritis' and delivered electromagnetic waves with a pulse duration of 300 µs; a pulse frequency of

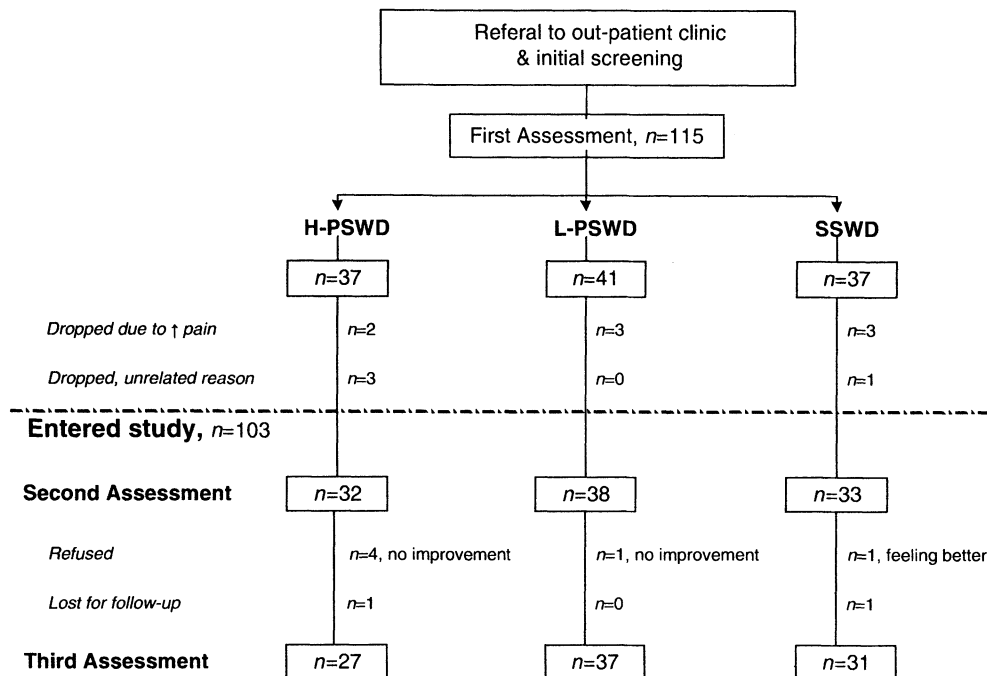


Figure 1 Overall plan of the study.

300 Hz; peak power of 200 W; and mean power of 18 W. All subjects treated with this dose reported a comfortable feeling of warmth. For the low-intensity PSWD (L-PSWD) treatment, the machine's programme was set at 'acute osteoarthritis' and delivered electromagnetic waves with a pulse duration of 82 μ s; a pulse frequency of 110 Hz; peak power of 200 W; and mean power of 1.8 W. All subjects treated with this dose reported no feeling of warmth. The placebo treatment with the sham SWD (SSWD) consisted of turning on the SWD apparatus and setting the timer for 20 min without raising the power. All the patients were told that a feeling of warmth was not necessary for the treatment to be effective.

Assessment

Patients were assessed three times: (1) before the initial treatment (pre-test); (2) at the end of the last treatment (post-test); and (3) 12 weeks following the last treatment (follow-up). General biographical data were obtained in the initial evaluation. Patients reported analgesic and anti-inflammatory medications taken in the last week prior to each assessment. Each assessment included a disease-related health status questionnaire and four tests examining functional mobility. For all functional mobility tests the subjects wore shoes, and those who habitually used a cane while walking were permitted to use it during the tests. Test order was maintained in all assessments, and patients were allowed 3–5 min rests between the mobility tests. The following outcome measures were included in each evaluation:

- *WOMAC Osteoarthritis Index (version VA 3.0)* This is a disease-specific, patient-centred health status questionnaire, used to evaluate pain, stiffness and functional ability of the subjects.^{19,20} Each of the 17 items of the questionnaire was scored by the patient on a 10-cm rule, with responses rounded to the nearest whole number. Overall scores and scores of the items composing each category were used for analysis.
- *The Timed Get Up and Go (TGUG) test* For the TGUG test, subjects were seated on the same straight chair with their feet flat on the floor. A stopwatch was used to measure the time it took the subjects to stand up, walk

3 m, turn around, and return safely to a sitting position on the chair. The test has been shown to be a reliable measure of functional mobility for subjects with knee OA.²¹

- *Timed stair-climbing* Number of seconds (measured with a stopwatch) taken to climb a flight of 15 stairs, with each step 15 cm high. Subjects were allowed to use the rail as necessary.
- *Timed stair-descending* Number of seconds taken to descend the same flight of stairs, as measured with a stopwatch.
- *Three-minute walk* Number of meters subjects walked during a 3-min walk. The test was performed in a 14-m-long corridor, with patients walking back and forth. Time was measured with a stopwatch, and distance was measured to the nearest metre.

Analysis

Statistical analysis of the test variables employed preplanned contrasts within repeated measures analysis of variance (ANOVA), where treatment group, time and their interaction served as independent variables. Excel (Microsoft Corporation, Redmond, WA, USA) and JMP (SAS Institute, Cary, NC, USA) were employed for data management and data analysis.

Results

Figure 1 presents the overall plan of the study, the number of subjects in each group, attrition numbers, and the causes for attrition during the course of the study. No adverse reactions to the treatment were reported by the subjects. Subjects' characteristics by treatment group are presented in Table 1. All means and standard deviation scores of the outcome measures by treatment group are presented in Table 2. Mean and standard deviation of change scores between the pre- and post-tests and between the pre-test and follow-up are presented in Table 3.

ANOVAs of the WOMAC overall and functional ability scores indicate no interactions between groups and time and no significant differences between groups or test time. ANOVAs of the WOMAC pain and stiffness scores indicate

Table 1 Subjects' characteristics by treatment group

| | H-PSWD (n = 32) | L-PSWD (n = 38) | S-SWD (n = 33) |
|---|------------------|------------------|------------------|
| Age (mean \pm SD) | 72.66 \pm 6.36 | 74.79 \pm 6.58 | 73.33 \pm 6.91 |
| Gender (F/M) | 29/3 | 31/7 | 22/11 |
| Painful knee (R/L) | 16/11 | 15/20 | 14/13 |
| Knees treated (1/2) | 6/26 | 10/28 | 10/23 |
| Used a cane | 1 | 6 | 1 |
| Subjects' daily drug intake at second assessment | | | |
| Analgesic | 5 | 3 | 2 |
| NSAID | 9 | 6 | 6 |
| Changes in drug intake at the three-month follow-up | | | |
| Started NSAID | 1 | 1 | - |
| Stopped NSAID | 2 | 3 | 3 |

NSAID, nonsteroidal anti-inflammatory drug; H-PSWD, high-intensity pulsed short-wave diathermy; L-PSWD, low-intensity pulsed short-wave diathermy; S-SWD, sham short-wave diathermy.

no significant interaction between group and time, and no significant differences between groups. The effect of test time, however, was significant, with $p = 0.033$ and $p = 0.008$ for pain and stiffness, respectively. Preplanned contrasts within each group indicate a change over time for stiffness only in the group receiving placebo treatment (comparison between pre- and post-test, and between pre-test and follow-up: $p = 0.0008$ and $p = 0.0265$, respectively). Preplanned contrasts within each group indicate a trend for a change between pre-test and follow-up ($p = 0.0855$) for pain only in the group receiving L-PSWD.

ANOVAs of all functional mobility outcome measures (TGUG, 3-min walk, stair-climbing and stair-descending) indicate no interactions between groups and time and no significant differences between groups or test time.

Discussion

The results of the present study demonstrate no differences between the effects of PSWD and an SWD placebo treatment on the self-reported measures of pain, stiffness and functional activity (WOMAC) or on objective measures of functional performance. This was true whether the PSWD was delivered at intensity sufficient to induce a thermal sensation (H-PSWD) or at an athermal level (L-PSWD). The results also indicate a decrease in reported joint stiffness and pain over time, which did not differ between groups. No

changes in functional performance over time were observed in any of the groups.

Despite the prevalent use of SWD for the treatment of arthritic conditions,⁴ literature reviews conducted in 1999 and in 2001 revealed only two studies utilizing an experimental model of arthritis in animals and 10 clinical trials investigating the effect of SWD on osteoarthritic conditions.^{15,16} To the best of our knowledge, no further studies on this issue have been published since. However, more surprising is that in spite of the popularity of PSWD, only one animal study and two clinical studies have focused on the effectiveness of this form of SWD delivery for the treatment of OA. Whereas the early animal study demonstrated that PSWD significantly inhibited inflammation during experimental joint damage,²² the clinical studies are less conclusive. In the earlier of these two studies, different electrotherapy modalities (ultrasound, direct current and PSWD) were compared when delivered with either an anti-inflammatory medication or with a placebo drug.²³ While pain was reportedly reduced in all groups, this was significant only when physiotherapy was combined with drug treatment. The results as to the effectiveness of PSWD were thus inconclusive, especially because the groups were not sufficiently controlled and the SWD treatment dosage was unconventional, involving an extremely high-pulse frequency (46 MHz) and short (2-min) treatment durations.

In a more recent well-controlled study, Moffett *et al.*¹⁷ compared the effectiveness of PSWD with

Table 2 Results of all subjects by group and test time (means \pm SD)

| | H-PSWD | | | L-PSWD | | | S-SWD | | |
|-------------------------|--------------------|-------------------|--------------------|--------------------|--------------------|-------------------|-------------------|--------------------|--------------------|
| | Pre-test | Post-test | Follow-up | Pre-test | Post-test | Follow-up | Pre-test | Post-test | Follow-up |
| WOMAC scores | | | | | | | | | |
| Pain score (0–10) | 4.43 \pm 3.35 | 4.03 \pm 3.30 | 4.09 \pm 3.49 | 4.89 \pm 3.30 | 4.73 \pm 3.48 | 4.48 \pm 3.58 | 4.97 \pm 3.52 | 4.44 \pm 3.51 | 4.33 \pm 3.69 |
| Stiffness score (0–10) | 4.25 \pm 3.47 | 3.69 \pm 3.79 | 3.81 \pm 3.28 | 4.87 \pm 3.50 | 4.39 \pm 3.66 | 4.43 \pm 3.85 | 4.92 \pm 3.58 | 2.98 \pm 3.26 | 3.60 \pm 3.78 |
| ADL score (0–10) | 4.69 \pm 3.41 | 4.61 \pm 3.43 | 4.8 \pm 3.25 | 5.16 \pm 3.52 | 5.06 \pm 3.54 | 4.98 \pm 3.61 | 5.05 \pm 3.45 | 4.89 \pm 3.44 | 4.82 \pm 3.42 |
| Overall | 4.60 \pm 3.40 | 4.40 \pm 3.44 | 4.56 \pm 3.31 | 5.13 \pm 3.49 | 4.93 \pm 3.63 | 4.82 \pm 3.71 | 5.02 \pm 3.40 | 4.63 \pm 3.54 | 4.60 \pm 3.58 |
| Functional tests | | | | | | | | | |
| Get up & go (s) | 15.84 \pm 5.77 | 15.31 \pm 5.77 | 15.27 \pm 4.49 | 17.82 \pm 8.82 | 16.86 \pm 7.58 | 17.73 \pm 10.80 | 17.93 \pm 6.90 | 16.85 \pm 8.11 | 18.87 \pm 10.31 |
| 3-min walk (m) | 145.41 \pm 36.98 | 146.41 \pm 36.3 | 144.53 \pm 30.06 | 137.32 \pm 39.07 | 138.08 \pm 37.54 | 135.42 \pm 34.4 | 137.57 \pm 43.8 | 137.21 \pm 43.44 | 133.62 \pm 49.32 |
| Upstairs (s) | 14.31 \pm 5.33 | 14.94 \pm 6.39 | 14.37 \pm 5.34 | 16.5 \pm 9.14 | 15.87 \pm 7.91 | 16.79 \pm 9.26 | 17.41 \pm 11.86 | 16.19 \pm 10.25 | 17.38 \pm 10.15 |
| Downstairs (s) | 15.79 \pm 7.36 | 15.28 \pm 7.66 | 15.37 \pm 7.17 | 17.11 \pm 8.87 | 16.81 \pm 9.49 | 16.48 \pm 8.07 | 16.11 \pm 8.98 | 16.79 \pm 11.4 | 16.99 \pm 9.25 |

H-PSWD, high-intensity pulsed short-wave diathermy; L-PSWD, low-intensity pulsed short-wave diathermy; S-SWD, sham short-wave diathermy.

Table 3 Change scores between pre- and post-tests and pre-test and follow-up by group (means \pm SD)

| | H-PSWD | | L-PSWD | | S-SWD | |
|-------------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|-----------------------|
| | Pre- to post-test | Pre-test to follow-up | Pre- to post-test | Pre-test to follow-up | Pre- to post-test | Pre-test to follow-up |
| Pain score (0–10) | -0.41 \pm 2.05 | -0.86 \pm 2.47 | -0.40 \pm 2.16 | -0.77 \pm 2.58 | -0.53 \pm 1.76 | -1.04 \pm 2.62 |
| Stiffness score (0–10) | -0.56 \pm 3.85 | -1.11 \pm 3.10 | -0.47 \pm 3.02 | -0.55 \pm 3.95 | -1.94 \pm 3.17 | -1.65 \pm 3.5 |
| ADL score (0–10) | -0.06 \pm 1.72 | -0.46 \pm 1.98 | -0.10 \pm 1.56 | -0.31 \pm 1.83 | -0.12 \pm 1.54 | 0.06 \pm 1.81 |
| Overall | -0.18 \pm 1.71 | -0.55 \pm 1.94 | -0.20 \pm 1.54 | -0.42 \pm 1.91 | -0.37 \pm 1.42 | -0.81 \pm 1.97 |
| Functional tests | | | | | | |
| Get up & go (s) | 0.06 \pm 5.41 | -0.64 \pm 5.00 | -1.00 \pm 3.78 | 0.94 \pm 7.57 | -1.76 \pm 4.42 | -0.63 \pm 3.62 |
| 3-min walk (m) | -1.34 \pm 27.58 | -8.24 \pm 40.33 | -2.00 \pm 18.63 | -3.27 \pm 23.48 | 5.94 \pm 20.28 | 3.00 \pm 19.32 |
| Upstairs (s) | -0.17 \pm 4.91 | -0.46 \pm 6.23 | -0.63 \pm 7.03 | 0.67 \pm 6.21 | -0.57 \pm 3.02 | -0.53 \pm 3.17 |
| Downstairs (s) | 0.90 \pm 6.23 | -0.53 \pm 6.01 | 0.26 \pm 3.53 | 0.46 \pm 4.21 | -1.37 \pm 4.82 | -0.24 \pm 3.24 |

H-PSWD, high-intensity pulsed short-wave diathermy; L-PSWD, low-intensity pulsed short-wave diathermy; S-SWD, sham short-wave diathermy.

placebo PSWD and no treatment for the relief of pain in patients with OA of the knee or hip. The active treatment protocol involved PSWD at a mean wattage of 23 W with pulse frequency set at 82 Hz (the relevant data concerning pulse duration and peak wattage were not reported). The treatment was administered three times per week for 15 min over a three-week period, for a total of nine treatments. Outcome measures included a general health questionnaire and a self-report on pain and general benefit, which were assessed pre and post treatment and at one- and three-month follow-ups. Results indicated no differences in pain level between the active and placebo treatments, although both tended to improve during treatment and worsen after its withdrawal. There were no significant differences between groups over time in the other outcome variables.

Given the high incidence of knee OA and referral to physiotherapy for SWD treatment, the authors of the present study took it upon themselves to revisit this important study with some modifications. The first modification relates to the treatment dosage. Although the existence of the athermal effects of SWD are controversial, PSWD is generally considered to be an appropriate treatment modality due to its ability to deliver electromagnetic energy to the tissues with no concurrent increase in tissue temperature.⁶ However, studies have demonstrated that PSWD may in fact produce a heating effect, which is dependent on treatment dosage. Thus, Bricknell and Watson²⁴ have demonstrated that when pulse frequency and

duration were maintained at a constant setting of 400 Hz and 400 μ s, respectively, a definite thermal sensation was reported at an average power of 10.88 (\pm 3.22) W. In another study, where peak power and pulse duration were maintained at a constant setting of 190 W and 400 μ s, respectively, and only pulse frequency was varied, a 'possible' thermal sensation was obtained at an average power of 13.8 (\pm 7.1) W and a 'definite' thermal sensation at an average power of 21.2 (\pm 8.2) W.¹⁰ Thus, there is a high probability that the mean power of 23 W used by Moffett *et al.*¹⁷ did in fact induce a temperature increase in the tissues.

It has been demonstrated in an experimental model of OA using rabbit knees that increases in joint temperature induced by SWD may adversely affect knee mobility.¹⁴ Thus, in order to fully examine the possible positive outcomes of PSWD, it seems imperative that a truly athermal dosage be used. Therefore, in the present study a comparison was made between treatments with a mean dose of 18 W, which induced a definite thermal sensation, and an athermal mean dose of 1.8 W. It should be noted that these dosages were chosen in accordance with the recommendations of the manufacturer of the SWD machine used, as these were the preprogrammed dosages for acute OA (1.8 W) and chronic OA (18 W).

The second modification in this study relates to the outcome measures used. Rather than using a general health questionnaire, we chose to employ the WOMAC Osteoarthritis Index, which is a disease-specific health status measure used exten-

Clinical messages

- Nine, 20-min treatments with pulsed short-wave diathermy, whether delivered at a power intensity inducing a thermal sensation (mean dose 18 W), or at an athermal level (mean dose 1.8 W), was not shown to be effective in the treatment of chronic osteoarthritis of the knee.

sively to evaluate treatment efficacy in patients with OA of the knee.¹⁹ Furthermore, it is suggested that because self-report measures of function are limited to determining the perception of one's ability to perform a given task, whereas performance-based measures assess the person's actual ability to do so, a comprehensive examination should probably include the latter measures as well.²⁵ It has been demonstrated that such performance-based measures can identify limitations in the physical function of community-dwelling older women earlier and more frequently than can self-reported measures. Thus, the performance-based outcome measures that are most closely related to the disabilities associated with knee OA were also incorporated into the present study.

Despite the differences in research methodology, the present study supports the conclusion of the previous study, indicating no therapeutic benefit of PSWD in the treatment of OA of the knee. Only stiffness and pain were reported to change across time, but given that for both parameters there were no interactions between group and time, a placebo effect can be assumed. This assumption is further strengthened not only by the lack of change in reported disability, but also by the lack of concurrent improvement in functional performance.

However, several study limitations must be noted. While patients were allocated to treatment groups by sequential order of acceptance into the study by a therapist blind to the patients' condition and not involved in patient assessment, this is not a randomized study and some bias is nonetheless possible. A post-hoc power analysis never approached the desired value, indicating that the sample size was not sufficient to show significance. While this may be largely attributable to the subclinical magnitude of differences between treat-

ment effects (mostly less than 1.0 points in the 10-point VAS), further studies with larger populations are warranted. Additionally, although all the subjects were diagnosed as suffering from OA of the knees at a medium level of severity, the chronicity of their conditions was not delineated. It is possible that subcategorizing the subjects by chronicity and other relevant variables such as gender and muscular strength might have shown a different pattern of response.

Lastly, the present study utilized the parameter settings recommended by the manufacturer which is probably the reason for them being used in many physiotherapy clinics. The conclusions must, however, be limited to the methodology used. It may be, for instance, that in order for PSWD to be effective, it is necessary to significantly increase treatment time so as to compensate for the very short duration of total exposure to the electromagnetic field. In the final analysis, however, even when taking these limitations into consideration, the findings of the present study seriously question the efficacy of PSWD as it is currently applied in the clinical setting for the treatment of knee OA.

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