Knee Osteoarthritis: Does Transcutaneous Electrical Nerve Stimulation Work?

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Abstract: Transcutaneous electrical nerve stimulation has been proposed as a nonoperative treatment for osteoarthritis. The purpose of this study was to evaluate the outcomes of a novel transcutaneous electrical nerve stimulation device compared with those of other standard nonoperative modalities for the treatment of osteoarthritis of the knee. [Orthopedics. 2016; 39(1):e180-e186.]

Currently, it is estimated that 27 million Americans have clinical osteoarthritis (OA), with a prevalence rate of 33.6% for adults 65 years and older. As life expectancy continues to increase, the lifetime risk of total knee arthroplasty continues to rise. In 2010, more than 600,000 total knee arthroplasties were performed in the United States, and it is estimated that this will exceed 3 million procedures by 2030. It was estimated that the economic impact of treatment for pain associated with OA was $5700 per individual per year in 2000, and that total hospitalization charges exceeded $14 billion for total knee arthroplasty in 2004. Although prosthesis survivorship is greater than 10 years for total knee arthroplasty, given the increasing life expectancy, it is essential that the time period before patients require primary joint arthroplasty be extended. During this period, patients' pain must be managed so that they can maintain normal function and experience minimal disruption in lifestyle.

Transcutaneous electrical nerve stimulation involves placing electrodes around the knee that allow electrical currents to decrease pain through the stimulation of cutaneous afferent fibers, which activate the inhibitory interneurons. This has been proposed to decrease the transmission of pain signals from small-diameter nociceptive fibers. In addition, the use of TENS has been shown to result in endogenous release of opioids in the central nervous system. However, few studies have evaluated the use of a portable TENS device in a specialized wrap for the knee.

The purpose of this study was to evaluate the efficacy of a TENS device compared with the efficacies of standard treat-
ments for Kellgren-Lawrence grade 3 to 4 OA of the knee. Specifically, the authors assessed (1) pain, (2) objective functional outcomes, (3) subjective functional outcomes, (4) quality of life, and (5) the need for total knee arthroplasty.

**MATERIALS AND METHODS**

This prospective, randomized, single-blinded trial involved 40 patients (40 knees) who had radiographic evidence of Kellgren-Lawrence grades 3 and 4 OA and who were treated at one institution. Prior to initiation of the trial, institutional review board approval was obtained for this study. All patients provided written consent prior to being enrolled in the study. Patients were excluded from the study if they were younger than 18 or older than 85 years, had electrical implants (eg, pacemaker, deep brain stimulator, defibrillator), had a major traumatic event related to their knee pain (eg, a fracture), had a flexion contracture greater than 5°, had a radiographic deformity greater than 7° of varus or valgus on standing anteroposterior radiograph, had received corticosteroid injections in the affected knee within 3 months of the study, had a history of epilepsy or diabetic neuropathy, and were pregnant or planned to become pregnant during the trial period. Patients were enrolled in the study at one institution’s self-directed exercise therapy. Patients were blinded randomized to receive either a TENS device or standard treatment only (physical therapy or intra-articular corticosteroid injection, and self-directed exercise). Of the 40 patients, 4 were lost to follow-up, leaving 36 patients for the final analysis (18 in the treatment group and 18 in the control group). Of the 4 patients lost to follow-up, 2 chose to no longer participate in the trial and 2 did not keep their scheduled appointments despite numerous attempts to contact them.

The TENS cohort consisted of 18 patients (7 men and 11 women) with a mean age of 63 years (range, 43-83 years). The matched cohort consisted of 18 patients (9 men and 9 women) with a mean age of 61 years (range, 34-85 years). No significant differences were found between the 2 groups regarding sex, age, or body mass index (Table 1).

Of the patients who were randomized to the control cohort, 9 underwent nonoperative treatment involving corticosteroid injections and 9 received 6 weeks of physical therapy. Patients who opted for a corticosteroid injection received a mixture of 1 mL of 40-mg Kenalog (Bristol-Myers Squibb Co, Princeton, New Jersey) and 4 mL of 1% lidocaine intra-articularly after testing was performed at the initial appointment. Patients who opted for physical therapy were prescribed knee range of motion, strengthening modalities, and gait training for 3 times per week during 6 weeks.

At their initial appointment, all patients who were randomized to the control cohort also received thorough counseling regarding the authors’ institution’s self-directed exercise program. Self-directed exercise therapy consists of 3 simple exercises performed during a 20-minute period. For the first exercise, patients lie on their back, lift their leg 6 inches off the floor while slightly bending their knee, hold this position for 5 seconds, and then relax their leg back to the floor. This is repeated 10 times and then performed on the contralateral lower extremity. For the second exercise, patients lie on their side, hold their leg 6 inches laterally from their body for 5 seconds, and then relax their leg. This is repeated 10 times. In the third exercise, patients lie on their abdomen, raise their thigh off of the floor, and then complete the sequence described in the previous 2 exercises. Each exercise is performed for both lower extremities. Patients repeat this cycle 2 times. All patients performed each exercise for 3 sets with 10 repetitions. Patients were instructed to skip a day between performing exercises, and to add ankle weights until they reached 7.5 and 10 lb on both legs for women and men, respectively. This needed to be incrementally increased, starting with 2.5 lb.

Although both groups were not prohibited from receiving their previously prescribed pain medications (NSAIDs), the authors instructed patients to continue taking the same dosage of medication throughout the study. If increased dosages were needed, they were to be instituted only after patients’ 3-month follow-up appointment. In addition, no study patients were prescribed new pain medications at enrollment or during the trial.

The TENS device used in this study (Empi Active TENS, Knee; DJO, LLC, Vista, California) is housed in a specialized knee support and could be used for all activities but those involving water. The device provides an asymmetrical sim-

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**Table 1**

**Demographic Data**

<table>
<thead>
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<th>Demographic</th>
<th>Control</th>
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<td>Sex, No.</td>
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<tr>
<td>Female</td>
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<tr>
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<tr>
<td>Age, mean±SD, y</td>
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<td>63±11</td>
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<tr>
<td>Body mass index, mean (range), kg/m²</td>
<td>34.3 (25.1-47.5)</td>
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ple modulated pulse waveform that delivers repeating grouped pulses in 12-second intervals. Each cycle’s rate and pulse duration changes were based on the intensity set by the patient, ranging from 48 to 400 microseconds at 50% peak amplitude. This TENS device is integrated in a specialized knee wrap with 4 predetermined pads placed around the knee, which minimizes disruption of daily activities. This theoretically leads to better compliance, due to portability and increased ease of use.

The visual analog scale (VAS) was used to evaluate patients’ pain levels at both the initial visit and the 3-month follow-up. The difference in the scores of the 2 visits was calculated.

The following physical metrics were evaluated at the initial appointment and at the 3-month follow-up: timed up-and-go (TUG) test, 5-repetition chair rise test, timed stair climb test, 6-inch step test, 2-minute walk test, isokinetic strength, and active and passive range of motion.

The TUG test measures the time required for patients to rise from a seated position, walk 10 feet and back, and then revert to a seated position. For normal individuals, this should take no longer than 10 seconds.

The 5-repetition chair rise test measures the time required for patients to stand from a seated position and then return to a seated position for 5 times as rapidly as possible. Patients’ performance is considered below average when their time exceeds the following: 11.4 seconds for those 60 to 69 years old, 12.6 seconds for those 70 to 70 years old, and 14.8 seconds for those 80 to 89 years old.

The timed stair climb test measures the amount of time patients require to ascend and descend 15 steps. This test assesses patients’ activities of daily living and is a predictor of functionality. When performing the timed stair climb test, patients were instructed that they could use only 1 leg per step and alternated going up and down.

The 6-inch step test involved having patients place their affected leg on the step while keeping their unaffected side straight. Patients performed 20 single-leg steps, and their time doing so was monitored.

The 2-minute walk test involved having patients walk for a designated length (50 feet) repeatedly for 2 minutes while distance was recorded. Walking tests are used to evaluate functional capacity and are representative of activities of daily living.

An isokinetic quadriceps and hamstring muscle strength test was conducted using a dynamometer (Biodex Medical Systems, Shirley, New York) and was performed on both the involved and the uninvolved side. Dynamometer orientation, tilt kept at 0°, and seat orientation were kept at neutral with inclination of the seat back at 80°. The dynamometer was adjusted for each patient so that its axis was aligned with the center of the knee joint. The protocol for isokinetic knee flexion and extension was performed with the dynamometer set at 60° per second for 5 repetitions. Peak torque was recorded with each repetition; highest and lowest measurements were discarded. The 3 remaining measurements were averaged for both hamstring and quadriceps as mean torque. Care was taken to accurately measure the length of the dynamometer arm from the knee axis and this was reproduced for all of the subsequent measurements to ensure consistency of torque measurements. Peak torque measurements, in foot pounds, were normalized to body weight and expressed as ft/lb/BW*100. Normalization of the data allowed the authors to compare strength data within and across each study group.

Patients had both active and passive range of motion testing at each visit, with all measurements taken using a goniometer. All tests were conducted by 1 of 2 authors (J.C., M.J.M.).

In addition, at each appointment, patients were subjectively evaluated via functional and objective Knee Society Scores (KSSs), the Lower Extremity Functional Scale (LEFS), the Short-Form 36 Health Survey (SF-36), and the VAS for pain. The KSS is an objective and subjective tool for rating patients’ knee and functional abilities. The KSSs were reported as objective and functional scores. The LEFS is a self-reported assessment of physical function for patients with OA, and subjectively allows patients to score their ability to perform certain activities. The SF-36 has been shown to be reliable and valid for assessing patients’ functional health and well-being from patients’ point of view. Two patients in the control cohort were unable to complete the objective KSS.

Additionally, an individual evaluator (M.A.M.) monitored both cohorts for failure of pain relief and subsequent need for total knee arthroplasty during the study period. All patients were also monitored for adverse events that could be attributed to the device. Adverse events seen during the trial included skin irritation, increased pain, and local skin breakdown.

Mean differences from the initial visit to the 3-month follow-up were calculated for all metrics and were compared for the 2 groups. In addition, in the treatment cohort, all metrics were calculated as means and compared between the initial visit and the follow-up visit. Statistical analysis was performed using a 2-tailed t-test and SigmaStat version 3.0 software (Systat Inc, San Jose, California). All study data were recorded on an Excel spreadsheet (Microsoft Cor-
RESULTS

On evaluation of pain, patients who received TENS had a significant improvement in mean VAS score from the initial appointment to the 3-month follow-up compared with those who received standard treatment (-0.882 vs 0.388; *P*=.0416).

Compared with the control group, patients in the TENS cohort were noted to have substantial improvements regarding the mean differences on the following: TUG test, timed stair climb test, 2-minute walk test, 5-repetition chair rise test, 6-inch step test, and passive flexion motion. However, these were not significant (*P*>.1798) (Table 2). Despite the positive results on these tests, patients who received standard treatment had improved active range of motion and passive extension range of motion compared with those who received TENS. These negative results were not significant (*P*>.2992) (Table 2). On isokinetic quadriceps and hamstring strength testing, both cohorts had lost quadriceps and hamstring strength from the initial visit to the 3-month follow-up visit. However, patients who were treated with TENS had an overall lower decline in quadriceps and hamstring strength (*P*>.0716) (Table 3).

On evaluation of subjective functional outcomes and quality of life, patients who received TENS had a significantly greater improvement in mean objective KSS from the initial visit to the 3-month follow-up compared with patients in the control group (17.1 vs 2.7 points; *P*=.0068). On analysis of subjective KSS, SF-36 mental and physical components, and LEFS, patients who received TENS showed improvement compared with those in the control group, but this difference was not significant (Table 2).

On evaluation of patients who eventually progressed to total knee arthroplasty, fewer patients in the TENS group than in the control group underwent the procedure (11% vs 6%; *P*=1.000). On comparison of mean values for all metrics at the initial visit and the 3-month follow-up, it was found that all metrics had improved with the use of TENS. However, all of the test results, except the objective KSS, were found not to be significant. In the TENS cohort, the objective KSS had significantly improved at the 3-month follow-up (57.61 vs 73.71 points; *P*=.0006; 95% confidence interval, -26.243 to -7.993).

DISCUSSION

The prevalence of knee OA is increasing along with life expectancy. Symptomatic knee OA can result in severe and debilitating pain, which ultimately inhibits functionality and mobility. Currently, standard nonoperative treatment for osteoarthritic knee
pain consists of physical therapy, NSAIDs, corticosteroid injections, hyaluronic acid injection, and bracing. Given the increasing life expectancy, it is essential to evaluate methods of reducing pain and improving functionality to prolong the duration of nonoperative treatment in order to delay or perhaps prevent the need for total knee arthroplasty. This study evaluated the efficacy of TENS for patients with Kellgren-Lawrence grade 3 and 4 arthritis of the knee in relation to the assessment of pain, objective and subjective functional outcomes, quality of life, and the need for total knee arthroplasty.

This study had several limitations. The small patient population was most likely the result of a combination of factors. Some patients declined participation because of the possibility of not receiving a brace and the potential added cost of physical therapy if they were allocated to the standard treatment cohort. Given the improvements seen for this small number of patients, the authors believe that if the power of the study had been higher, statistical significance would have been reached for many of the metrics evaluated. In addition, brace compliance was difficult to assess objectively because frequency of brace use was patient reported. The use of pain medications in both cohorts also might have been a confounding variable, although the authors attempted to mitigate this effect by not changing medications or initiating new medications during the study. Additionally, due to physical limitations, some patients were unable to complete all physical metrics. The short follow-up of 3 months was a limitation, but significant improvements for the patients receiving TENS were shown in this time frame. The authors believe that longer follow-up would further validate the results and more accurately assess the long-term use of TENS.

Conflicting evidence regarding the benefits of TENS for the treatment of knee pain in patients with OA has been reported. However, studies have reported positive results with the use of TENS for the treatment of knee pain associated with OA compared with a control cohort. A meta-analysis of 7 randomized controlled trials (184 patients) performed by Osiri et al evaluated the use of TENS compared with a control cohort. Osiri et al found 3 randomized controlled trials (87 patients) that evaluated OA as the sole diagnosis. In these 3 studies, the TENS cohort had a significant difference in the number of patients with pain improvement after 1 month of treatment of up to 46% when compared with the control cohort (P value not reported). In addition, 5 of the 7 trials had marked improvements in VAS with therapy lasting more than 3 weeks. When these results were pooled, it equivocated to a 41% improvement in pain above baseline when compared with the control group. Similarly, Lone et al studied 35 patients with knee OA, comparing the analgesic effects of TENS with diclofenac sodium. Patients underwent 3 phases of treatment lasting up to 2 weeks each followed by a 1-week washout period between each arm of the study. During phase 1, patients received both placebo medication and TENS. During phase 2, patients received placebo TENS and 50 mg of diclofenac sodium 3 times a day. During phase 3, patients received TENS and placebo medication. Lone et al found a significant difference in pain scores at the end of phase 3 compared with at the end of phase 1, at the end of phase 2, and at baseline (P < 0.001 for each). The results of the current study correlate with the results of these studies in that patients who received TENS showed a significant improvement in VAS when compared with patients who received standard treatment.

Some studies have not reported results as positive as those of the current study. In a Cochrane review performed by Rutjes et al, the efficacy of TENS was compared with that of control in 813 patients across 18 trials. With all data collected on a 10-cm VAS, Rutjes et al reported that TENS led to a standardized mean difference of 0.2 cm of pain relief, which was not significant. They could not show that the use of TENS provided pain relief. However, Rutjes et al reported that their study was limited by studies with poor methodological quality, small samples, and inadequate reporting. Similarly, Palmer et al evaluated the use of TENS as an adjunct to an exercise program for the treatment of pain in patients with OA of the knee. Their study consisted of 224 participants allocated to 3 groups: TENS and exercise, sham TENS and exercise, or exercise only. Palmer et al reported that there were significant improvements in total Western Ontario and McMaster Universities Arthritis Index (WOMAC) score and WOMAC functional score after 6 weeks (P < 0.05), but no

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<th>Muscle Strength</th>
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<td>Isokinetic quadriceps</td>
<td>-4.88 (-21.1 to 6.3) (n=15)</td>
<td>-0.1294 (-10.5 to 7.6) (n=17)</td>
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<td>Isokinetic hamstring</td>
<td>-2.64 (-15 to 8.9) (n=15)</td>
<td>-0.04118 (-6.5 to 8.9) (n=17)</td>
<td>.1694</td>
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Abbreviation: TENS, transcutaneous electrical nerve stimulation.
difference between groups in terms of overall pain improvement. Palmer et al excluded patients who had comorbidities preventing exercise—perhaps a large population of patients with knee OA who may have benefited from treatment with TENS.

Decreased function and mobility are known complications of painful knee OA. Theoretically, if a patient’s pain can be decreased, better movement and function can be achieved. This was validated in the current study in that patients receiving TENS had significant improvements in objective KSS. In addition, patients who received TENS had marked improvements on the TUG test, timed stair climb test, 2-minute walk test, 5-repetition chair rise test, 6-inch leg step test, and passive flexion motion when compared with the control group. These findings are supported by a study performed by Law et al11 comparing the effects of TENS units vs placebo devices on the physical performance of patients who had knee arthritis during a period of 10 days. Law et al found that the use of TENS units significantly improved range of motion by the 10th day (from 104.5° to 122.2°; P<.001). Similar to the current study, Law et al reported that patients receiving TENS had substantial improvements in the TUG test parameters compared with the control cohort (P>0.05). The current authors believe that the patients’ improvement in functional outcomes was due to the ability of the TENS device to be worn during most activities of daily living, thus providing pain relief throughout the day. However, patients receiving TENS had less improvement in range of motion in flexion and extension than patients receiving standard treatment. The authors believe that a significant difference might have resulted if the TENS device had been compared with a placebo device. In addition, although range of motion was significantly decreased in the TENS cohort, this was not found to be clinically relevant.

When compared with standard treatment, TENS was found to have minimal effect on function (KSS functional score and LEFS) and quality of life (SF-36 score). Paker et al32 compared subjective outcomes (WOMAC and SF-36) with the use of hyaluronic acid injection vs TENS for patients who had osteoarthritis knee pain. Paker et al showed that there was no significant difference in SF-36 scores after treatment between the 2 groups. However, Paker et al suggested that this was an evaluation of overall health rather than just knee function.32 Currently, there are few studies analyzing the use of TENS for OA of the knee evaluating functional outcomes using the KSS and LEFS. However, the current authors believe that patients’ ability to wear the brace during virtually all activities of daily living allowed them to return to their normal physical activities with minimal disruptions.

Many patients with Kellgren-Lawrence grade 3 and 4 arthritis will ultimately require total knee arthroplasty. In this study, patients in the treatment cohort had fewer total knee arthroplasties overall, but this did not reach statistical significance. This may be a result of the low power of this study due to the small sample; a study with larger power may show significance. Larger, prospective, randomized studies are needed to fully evaluate the effect of TENS in delaying the need for total knee arthroplasty.

**CONCLUSION**

In this study, patients had significant relief of pain when receiving TENS vs standard treatment. In addition, TENS significantly reduced the progression of loss of strength in the quadriceps muscle. The use of TENS may be a viable adjunct to current standard treatment for pain associated with OA of the knee. Moreover, TENS may improve patients’ function. Larger, randomized studies with longer follow-up are needed to better evaluate the safety and efficacy of TENS.

**REFERENCES**


