

The Effects of Electro-Acupuncture and Transcutaneous Electrical Nerve Stimulation on Patients with Painful Osteoarthritic Knees: A Randomized Controlled Trial with Follow-Up Evaluation

M.M.L. NG, M.Sc., MASON C. P. LEUNG, Ph.D., and D.M.Y. POON, M.Phil.

ABSTRACT

Objectives: To examine the relative effectiveness of electro-acupuncture (EA) and transcutaneous electrical nerve stimulation (TENS) in alleviating osteoarthritic (OA)-induced knee pain.

Design: Single-blinded, randomized controlled study

Subjects: Twenty-four (24) subjects (23 women and 1 man), mean age 85, were recruited from eight subsidized Care & Attention Homes for the elderly.

Interventions: Subjects were randomly assigned to the EA, TENS, or control groups. Subjects in the EA group ($n = 8$) received low-frequency EA (2 Hz) on two acupuncture points (ST-35, Dubi and EX-LE-4, Neixiyan) of the painful knee for 20 minutes. Subjects in the TENS group ($n = 8$) received low-frequency TENS of 2 Hz and pulse width of 200 μ s on the same acupuncture points for 20 minutes. In both treatment groups, electrical treatment was carried out for a total of eight sessions in 2 weeks. Eight subjects received osteoarthritic knee care and education only in a control group. All subjects were evaluated before the first treatment, after the last treatment, and at 2-week follow-up periods.

Results: After eight sessions of treatment, there was significant reduction of knee pain in both EA group and TENS group, as measured by the Numeric Rating Scale (NRS) of pain ($p < 0.01$). Prolonged analgesic effect was maintained in the EA and the TENS groups at a 2-week follow-up evaluation. The Timed Up-and-Go Test (TUGT) score of the EA group was significantly lower than that of the control group ($p < 0.05$), but such change was not observed in the TENS group.

Conclusions: Both EA and TENS treatments were effective in reducing OA-induced knee pain. EA had the additional advantage of enhancing the TUGT results as opposed to TENS treatment or no treatment, which did not produce such corollary effect.

INTRODUCTION

The Framingham Study in the United States estimated the prevalence of symptomatic osteoarthritic (OA) knee in persons older than 65 years of age to be 9.5% (Felson et al., 1987).

Because the prevalence of knee OA increases with age (Felson et al., 1987; Felson 1998; Lawrence et al., 1989), the problem of suffering from OA knee-induced pain and disability is a common phenomenon in the older population. As treatment for OA knee, physiotherapy plays

an important role in relieving pain and preserving and maximizing function (Perrot and Menkes, 1996) before surgical intervention is considered.

Since the 1970s, transcutaneous electrical nerve stimulation (TENS) has been used to treat various acute and chronic pain conditions (Johnson, 2000; Thompson, 1998). It is more effective than any placebo treatment in reducing pain in OA knees, irrespective of the TENS parameters used (Aubin and Marks, 1995; Roche and Wright, 1990). Alternatively, acupuncture has been used to reduce pain without producing undesirable side-effects (Tsui and Leung, 2002). Most previous studies, however, suffer from a lack of randomized controlled trials (RCT) that render equivocal conclusions on the effectiveness of acupuncture treatment. Few RCT studies examined the effect of manual acupuncture for the reduction of OA knee pain (Berman et al., 1999; Christensen et al., 1992; Takeda and Wessel, 1994). Yurtkuran and Kocagil (1999) investigated the effect of electroacupuncture (EA) for OA knees; however, there was no follow-up evaluation and it was unclear if the analgesic effect of EA could be prolonged. Instead of using two acupuncture points (i.e., the minimum number of points for EA), four acupuncture points were utilized in Yurtkuran and Kocagil's study. We question whether all these acupuncture points were necessary for the efficacy of treatment because we would advocate a quicker and easier therapy with less acupuncture points. Because of the prevalence of OA knee in the older population, the aim of the present study was to evaluate the effect of EA and TENS in the treatment of OA knee in a group of older adults.

MATERIALS AND METHODS

Patients

Twenty-four (24) residents of the Care & Attention Homes, who complained of knee pain and who had been diagnosed with OA knee, were referred by the geriatricians of the Hong Kong West Community Geriatric Assessment Team of the Fung Yiu King Hospital in Hong Kong. The inclusion criteria were: (1) knee pain for most days of the preceding month; (2) crepi-

tus on active joint motion; (3) morning stiffness less than 30 minutes in duration; (4) bony enlargement of the knee on examination; and (5) stabilized condition on a present regime of arthritis medication (Flores and Hochberg, 1998). The exclusion criteria were: (1) other connective tissue diseases affecting the knee; (2) serious neurologic diseases or psychiatric disorders; (3) knee joint steroid injections within the preceding 3 months; (4) having a hearing aid or pacemaker *in situ*; (5) having acupuncture or TENS treatment within the preceding 3 months; and (6) inability to understand instructions or give consent (Christensen et al., 1992; Grimmer, 1992).

Instrumentation

Single use, sterilized stainless steel needles (0.25×40 mm) with guide tubes were used in all acupuncture procedures. A dual-channel Magnetic Electro Therapy Unit (model F-2, ITO Co. Ltd, Tokyo, Japan) was used in the EA group and a dual-channel TENS (model 120Z, ITO Co. Ltd.) was used in the TENS group. The machines were calibrated before the commencement of the study. The battery was replaced after every 10 hours of operation (Grimmer, 1992).

Experimental procedure

Study design and protocol. This was a single-blinded, randomized controlled study. Subjects were randomly assigned by drawing a piece of paper that designated each person to the EA, TENS, and control groups, respectively, with eight subjects in each group. If there was bilateral knee complaint, the more severe knee was tested and treated during the study. The study had been duly approved by the Departmental Research Committee of the Department of Rehabilitation Sciences of the Hong Kong Polytechnic University, and the Hospital Research Committee of the Fung Yiu King Hospital. Informed consent was duly obtained by the principal investigator before the commencement of the study. An educational pamphlet designed specifically for general education and self-management of OA knee was given to all subjects.

EA treatment. The acupuncture points chosen were ST-35 (Dubi) and EX-LE-4 (Neixiyan) be-

cause they are common local points for treating knee problems (Christensen et al., 1992; Takeda and Wessel, 1994). Skin was cleansed with an alcoholic swab. Sterile needles were inserted 0.5–1.0 cun (10–15mm) into the two acupuncture points. A *de qi* (a needle sensation of heaviness, numbness, soreness, or paresthesia) sensation was preferably sought before a constant electrical current of 2 Hz (Anderson and Holmgren, 1975) was connected to the needles via the EA machine. The intensity was increased slowly up to a tolerable, nonpainful “pounding” sensation level (White, 1998). The treatment lasted for 20 minutes and the intensity of the EA was readjusted, if necessary, after 5 minutes to maintain the desired sensation (Grimmer, 1992). Treatment was carried out on alternate days for 8 sessions within 2 weeks.

TENS treatment. Treatment for the TENS group was similar to that of the EA group except surface electrodes (area: $50 \times 35 \text{ mm}^2$) were used instead of needle insertion to the same sites. A low-frequency constant mode TENS of 2 Hz and pulse width of 200- μs was used. This treatment protocol is thought to be comparable to that of the EA group. The intensity was increased until a strong, tolerable, stroking sensation, preferably producing visible phasic muscle contraction, was achieved (Johnson, 1998).

Control group. Subjects received general education on osteoarthritic knee care only.

Evaluations/outcome measures

There were three sessions of evaluation for each subject: prior to the first treatment (T1); after eight sessions of treatment (T2); and 2 weeks after the last treatment session (T3). All evaluations were performed by the same assessor who was not informed about the group assignment of the subjects. Evaluations were taken at approximately the same time of the day, and subjects were asked to maintain their activity level during the period of study (Takeda and Wessel, 1994). In each evaluation session, three outcome measures were collected: numerical rating scale of pain; passive range of movement of the OA knee; and the Timed Up-and-Go test (TUGT).

The Numerical Rating Scale (NRS) of pain is a scale containing numbers of 1 to 10 on a straight line to measure the magnitude or intensity of pain. It has been shown to have good predictive validity (Jensen et al., 1986) premised on a high concurrent correlation of NRS with the Visual Analogue Scale ($r = 0.8$, $p < 0.01$) (Wilkie et al., 1990). The NRS could be administered in written or verbal form (Cole et al., 1994). The mode of administration of NRS (i.e., written or verbal form) was chosen by each subject. All subjects participating in the study were asked to select a number, from 1 to 10 to the nearest 0.5 interval, to represent their maximal OA-induced knee pain in the recent 2 to 3 days.

The total passive range of movement (ROM) of the OA knee was measured with a standard goniometer by the same assessor throughout the study. Because the smallest marking on the goniometer was in a 5° interval, the passive ROM was recorded to the nearest 2.5° . With the patient in a supine position, passive knee extension and flexion range were recorded twice to calculate an average score. The total passive ROM of the knee was then deduced (= mean flexion range – mean extension range).

The TUGT was developed based on the repeated measurements on 60 elderly subjects (mean age, 79.5 years) referred by a geriatric day hospital (Podsiadlo and Richardson, 1991). High interrater and intrarater reliability were reported (ICC = 0.99) and the test demonstrated a good correlation to the Berg Balance Scale, gait speed, and Barthel Index. The test could be administered quickly (1 to 2 minutes), required minimal equipment (Whitney et al., 1998), and was easily carried out in the Care and Attention Homes. In this study, TUGT was chosen to reflect on the basic functional mobility of subjects. Standardized instructions were used to administer the test. On the word “go” the subject was requested to get up from a chair and walk at a comfortable and safe pace to a destination 3 m away, turn around, return to the chair, and sit down again (Podsiadlo and Richardson, 1991). Two trials were conducted: the first was the practice trial and the result of the second trial was recorded with a stopwatch, to the nearest second, as the final score.

Statistical analysis

The characteristics of each subject including age, gender, and the duration of knee pain were recorded. Repeated measures of analysis of variance (ANOVA) were used to examine group and time effects on pain, total passive knee range of movement and functional mobility, respectively (i.e., TUGT). The *post hoc* multiple comparison procedure of Tukey's honestly significant difference (HSD) was used to identify any differences among groups.

If there was a significant interaction between time periods and the results of the three groups from repeated measures of ANOVA, we would further analyze these differences across sessions in each group as well as any difference among the three groups in each time period. To investigate the time effects, separate repeated measures of ANOVA were used to test the change in outcome parameters in each group across sessions followed by the within-subjects contrasts test as the *post hoc* test. For comparing between groups, one-way ANOVA for each time point was used.

The percentage change in the outcome measures of each subject was calculated at post-treatment (T2) and at 2-week follow-up evaluation (T3) using the following formula.

$$\text{Percentage change at post-treatment} \\ = ([T2 - T1]/T1) \times 100\%, \text{ and}$$

$$\text{Percentage change at 2-week follow-up} \\ = ([T3 - T1]/T1) \times 100\%$$

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS Ver-

sion 10.0 for Windows, Chicago, IL) on a personal computer. The level of significance was set at $p < 0.05$.

RESULTS

Baseline data of subjects

Twenty-four (24) subjects (23 women and 1 man) participated in the study. Twelve (12) subjects had bilateral knee signs and symptoms but only the knee with more pain was tested and treated. We found that most subjects had difficulty in tolerating a high intensity of stimulation that produced muscle twitching in both the EA and TENS groups. The characteristics of subjects were shown in Table 1. The mean age of all subjects was 85 (range, 75–96) years. There was no significant difference in the average age, mean level and duration of knee pain, total passive knee ROM, and TUGT scores among the three groups at baseline evaluation ($p > 0.05$). Any change in outcome measures would therefore be accounted for by the effect of intervention, or confounders, or error from measurement.

Comparing the three groups, the average level of knee pain (range, 4.19–4.69) showed that subjects were suffering from moderate levels of OA knee pain before any intervention. The total passive knee ROM was within functional range (range, 104°–118°). TUGT scores (range, 22.25 seconds–32.19 seconds) and large standard deviation (SD; range, 9.72–15.63) revealed that subjects' performance of balance, gait speed and function was variable (i.e., within the gray zone of performance [Podsiadlo and Richardson 1991]).

TABLE 1. THE AVERAGE AGE, HISTORY OF KNEE PAIN, AND BASELINE DATA OF THE THREE GROUPS

	EA n = 8	TENS n = 8	Control n = 8	ANOVA (p)
Age	84.38 ± 6.48	85.88 ± 5.96	85.00 ± 6.85	0.897
Duration of knee pain (range) (year)	4.69 ± 6.34 (5–20)	4.94 ± 4.35 (5–15)	5.38 ± 5.15 (1–17)	0.967
NRS	4.69 ± 1.71	4.19 ± 1.49	4.19 ± 0.96	0.722
ROM (°)	118.75 ± 24.60	115.63 ± 25.28	104.63 ± 22.03	0.418
TUGT (sec)	22.25 ± 9.72	26.25 ± 15.63	32.19 ± 8.90	0.260

Values were shown as mean ± SD. One-way ANOVA of each baseline data of the three groups revealed no significant differences.

EA, electro-acupuncture; TENS, transcutaneous electrical nerve stimulation; ANOVA, analysis of variance; NRS, numerical rating scale; ROM, range of motion; TUGT, Timed-Up-and-Go Test; SD, standard deviation.

Change in mean NRS of knee pain

The change in mean NRS of knee pain across the study period for each group is presented in Figure 1. For the EA group, there was a significant reduction of mean NRS of knee pain (-29%) after eight sessions of treatment ($p < 0.01$), and the treatment effect was well maintained (-31%) at the 2-week follow-up evaluation ($p < 0.01$).

Similarly, a reduction of mean NRS of knee pain (-28%) was significant in the TENS group after eight sessions of treatment ($p < 0.01$). However, at the 2-week follow-up evaluation, the treatment effect became less pronounced (-15%) albeit there was still a significant improvement in knee pain ($p < 0.01$) compared with pretreatment level.

Not surprisingly, there was no significant difference in mean NRS of knee pain in the control group across the period of study.

Change of total passive knee ROM

Figure 2 showed that the total passive knee ROM was not significantly different among the three groups across the period of study.

Change in TUGT scores

In Figure 3, the statistics demonstrate that there was a significant improvement (11%) in

the TUGT scores in the EA group after eight sessions of treatment ($p < 0.01$). Nevertheless, the treatment effect diminished (down to 9% improvement) at the 2-week follow-up evaluation and became indistinguishable from pretreatment level ($p > 0.05$).

A similar trend was observed in the TENS group, although there were no significant differences in TUGT scores ($p > 0.05$) across the study period: there was a 7% improvement in the TUGT scores after eight sessions of treatment, but the scores regressed to pretreatment level at the 2-week follow-up evaluation.

The control group showed no significant differences in TUGT scores across all evaluation sessions.

DISCUSSION

This study has recruited the oldest subject group (i.e., 85 years old) among all the clinical studies on acupuncture and TENS in clients with OA knees. They were suffering from moderate levels of OA knee pain as implied by their pretreatment TUGT scores. Some would need help in matters of personal hygiene, such as with their toilet routines, or assistance in getting in and out of a bathtub or shower (Podsadlo and Richardson, 1991). The purpose of this

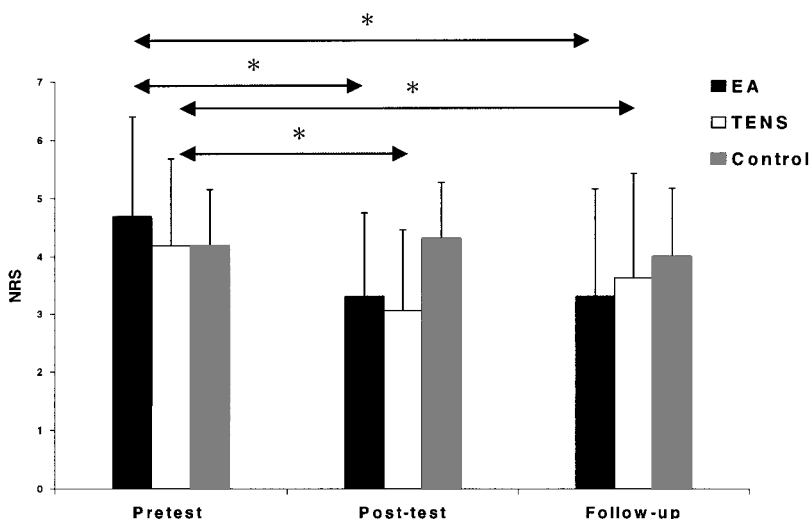


FIG. 1. The mean numerical rating scale (NRS) scores of the 3 groups at different time points. Values were shown as mean \pm SD (standard deviation). Both the electro-acupuncture (EA) and transcutaneous electrical nerve stimulation (TENS) groups had improvement in post-test ($p < 0.01$) and follow-up compared to pretest ($p < 0.01$) but the control group did not. It was noted that the extent of improvement was more obvious in the EA group. *denotes the observation of significant differences.

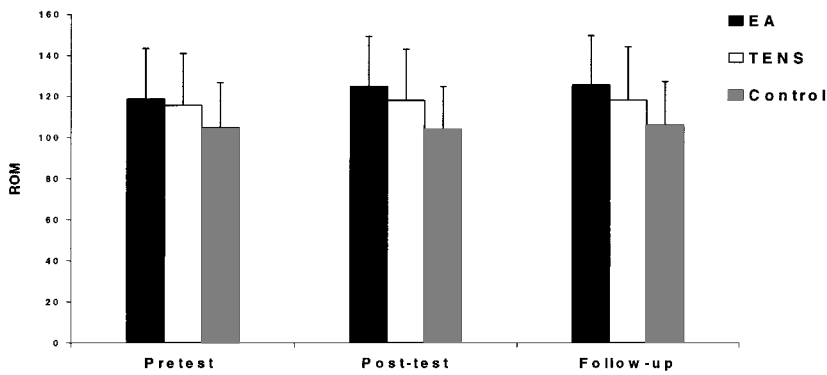


FIG. 2. The mean range of movement (ROM) of knee in degrees ($^{\circ}$) of the 3 groups at different time points. Values were shown as mean \pm standard deviation. There was no significant difference among the three groups at different time points. EA, electro-acupuncture; TENS, transcutaneous electrical nerve stimulation.

study was to identify an effective treatment modality to alleviate pain so as to enhance the functional status and improve the quality of life of the elders suffering from OA knee pain.

EA is an invasive technique that requires needles plus electrical stimulation whereas TENS entails electrical stimulation only. However, it is important to note that with a minimum duration of 20 minutes per session, TENS initially was as effective as EA. The main findings from this study showed that both EA and TENS treatments demonstrated a significant reduction of knee pain after eight sessions of treatment. It has been suggested that pain modulation by low-frequency EA or low-frequency TENS could be caused by the release of endor-

phins within the central nervous system (Johnson, 1998). The onset and offset of analgesia was believed to be gradual, with a peak occurring at about 20 minutes of stimulation (Anderson and Holmgren, 1975). The result of this study confirmed that 20 minutes of stimulation could produce the desirable analgesic effect of pain relief. We noted a similar result in other conditions such as tennis elbow (Tsui and Leung, 2002) and chronic low-back pain (Yeung et al., 2003).

Because EA and TENS are postulated to have a similar mechanism of pain modulation, this explains the parallel trend in change of pain in both study groups. At the 2-week follow-up evaluation, the prolonged analgesic effect was

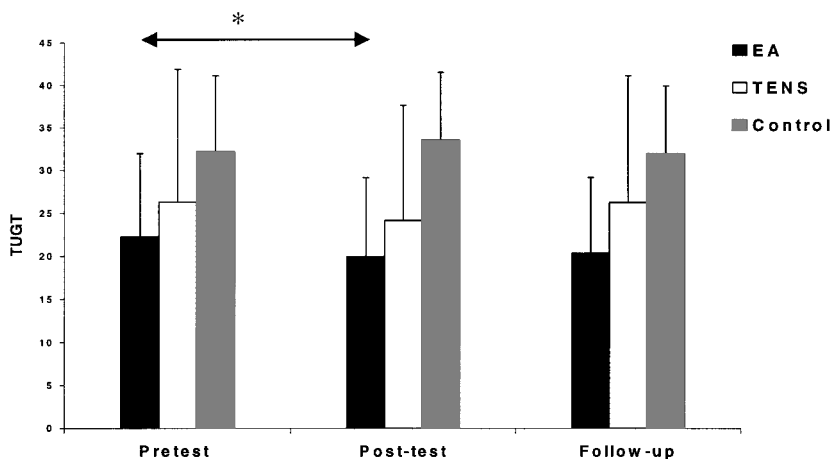


FIG. 3. The mean (Timed Up-and-Go Test) TUGT in seconds (sec.) of the 3 groups at different time points. Values were shown as mean \pm standard deviation. It was noted that only the electro-acupuncture (EA) group showed a significant difference between post- and pretest ($p < 0.01$). * denotes the observation of significant differences. TENS, transcutaneous electrical nerve stimulation.

maintained in the EA and TENS groups. Thompson (1998) stated that the main difference in analgesia produced by TENS and acupuncture was in the "duration" of pain relief. Acupuncture has been shown to produce a prolonged analgesic effect that lasts for weeks after a course of treatment.

Although the exact mechanism is not clear at this stage, acupuncture is believed to produce autonomic effects that strengthen the body's homeostatic responses (White, 1998) and general well-being, which bring about the prolonged effect in analgesia.

Previous reports have shown that the immediate "successful" rates of acupuncture-induced analgesic effect on various musculoskeletal conditions ranged from 50% to 70% (Chen and Hwang, 1977; Lee et al., 1976; Ulett et al., 1998). Moreover, the percentages of improvement in pain were 96% and 53%, respectively, when using EA and TENS in the treatment of OA knee pain (Yurtkuran and Kocagil, 1999). Contrary to previous reports, the results of this study indicate a "less positive analgesic effect" for both EA and TENS treatment. One explanation for such an observation might be because of the difficulty of the elderly subjects in tolerating a high intensity of stimulation. Although the *de qi* sensation was usually sought in the EA group, most subjects could not tolerate a high intensity with strong electrical pulses to produce muscle twitching. Similar issues surfaced in the TENS group. Therefore, the authors postulate that the subjects in the two treatment groups have not received the optimal "intensity" of stimulation to produce the desired physiological effects in body tissues.

Johnson (2000) suggested that a reduction in mild or moderate pain was harder to detect than a reduction in severe pain. As such, any detectable reduction may lose sensitivity in the recording of outcome measures. The analgesic effect of EA or TENS might be more significant if the pain level of the subjects were more than moderate to begin with (as experienced by subjects recruited in the study).

There was a significant reduction in the total passive knee ROM of the subjects, which was more often than not accompanied by deformities. Great improvement of ROM was not expected, as Clarke et al. (1974) suggested: that

in patients with chronic conditions, objective measures were unlikely to undergo change over a short period of time and more attention should be paid to pain as the main symptom. At the late stage of osteoarthritic knee, the pain may vary but any consequent bony deformity and soft tissue thickening may become more permanent. Therefore, it is not easy to change the ROM compared to change in pain level.

On the contrary, a decreased walking speed could in turn be a precursor of functional limitations (Gibbs et al., 1993). The use of TUGT to reflect the physical functional status of the arthritic person would be appropriate as an outcome measure to determine the efficacy of treatment (Fransen et al., 1997). The reduction of TUGT scores was significant in the EA group but not in the TENS group after eight sessions of treatment. The improvement in TUGT was not significant in the EA group at the 2-week follow-up session. We proffer the following to explain the results. First, one accepts that symptomatic lower joint impairment caused by arthritis can affect walking speed (Gibbs et al., 1993) and that TUGT was a direct or indirect reflection of the degree of knee pain. Both EA and TENS have similar pain modulation mechanisms but the degree of pain reduction may not be the same. EA consistently demonstrated a greater pain relieving effect than TENS (Fox and Melzack, 1976; Lehmann et al., 1986). Therefore, the effect of EA in pain reduction might be reflected by the change in NRS as well as TUGT. The effect of TENS in pain reduction might only be reflected by NRS measures but paradoxically may not be evidenced by any change to the TUGT scores.

Second, one can understand that the result of TUGT might be affected by factors other than knee pain, such as the general well-being of the subjects, the mood of the subjects, or even trivial events affecting the subjects such as poor bowel movement. There was evidence that patients showed overall improvement in their general physiologic condition (Chen and Hwang, 1977). On the other hand, Lehmann and coworkers (Lehmann et al., 1986) have commented that electrical stimulation, similar to TENS, is a pain-relieving modality; its efficacy should be judged solely on its ability to relieve pain rather than its ability to affect disability.

It is ideal that a change in pain level may be reflected in a change of functional status (TUGT). However, one can also safely conclude that a change of pain level does not guarantee a change in functional status in a clinical situation. In the present study, some of the subjects suffered from bilateral OA knee pain, a condition that may be a potential confounder in the analysis and is a limitation of the study. The other limitations are the small sample size and the relatively short interval between immediate post-treatment and the follow-up evaluation.

In conclusion, both EA and TENS treatments demonstrated a significant pain reduction effect on patients with OA-induced knee pain. Therefore, both treatments are recommended for treating OA knee pain.

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Address reprint requests to:

Mason C.P. Leung, Ph.D.

Department of Rehabilitation Sciences

The Hong Kong Polytechnic University

Hung Hom, Hong Kong, China

E-mail: rsmcpleung@polyu.edu.hk