Clinical Investigation into the Effectiveness of Needleless Acupuncture in the Management of the Symptoms of Osteoarthritis of the Knee: A Preliminary, Single-blind and Sham-controlled Study

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ABSTRACT

This single-blind, sham-controlled study investigated the effectiveness of 'needleless acupuncture' in the management of osteoarthritis of the knee. The study employed a Silver Spike Point (SSP) Needle Free Acupuncture Device for administering treatments. Participants were randomly assigned to a treatment or control group (total $n = 36$). Needleless acupuncture (NA) was applied to a standardised group of acupuncture points selected in accordance with traditional Chinese medicine theory and from a range of points used in other similar studies, namely ST 36 *Zusanli*, GB 34 *Yanglingquan*, ST 35 *Dubi* and SP 10 *Xuehai*. Needleless sham acupuncture (NSA) was applied to the same group of acupuncture points by attaching the needle free device, but not providing any electrical stimulation. Interventions for both the active and control groups were applied for a period of 25 minutes in each session. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used to measure changes in knee pain, stiffness and physical activity. Participant blinding was shown to be effective, with no significant trend in either group 'guessing correctly' as to whether they had received real or sham treatment. The comparison of the treatment effects and control condition on WOMAC score was conducted using analysis of variance (ANOVA). The WOMAC scores decreased statistically significantly among participants in the NA group in comparison to the NSA control for all measures: pain of the knee ($p = 0.016$), stiffness of the knee ($p = 0.006$) and difficulty performing daily activities ($p = 0.032$). The results indicate that needleless acupuncture provides an effective, non-invasive alternative for osteoarthritis in the knee.

KEYWORDS needleless acupuncture, knee, osteoarthritis, sham acupuncture.

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Introduction

This study investigated the clinical effectiveness of needleless acupuncture in comparison to 'sham' acupuncture in managing the symptoms of osteoarthritis of the knee using the Silver Spike Point (SSP) Needle Free Acupuncture Device. The study focused upon one of the seven Australian Government National Health Priority Areas (NHPAs) – 'arthritis and musculoskeletal conditions'.

With an ageing Australian population, limited health resources and lengthened waiting lists for elective surgery, patients with severe osteoarthritis (OA) awaiting knee or hip replacement operations are often prescribed non-steroidal anti-inflammatory drugs (NSAIDs) for extended periods. The gastrointestinal side effects that normally accompany the extended use of NSAIDs, especially for the elderly and frail,[1] raise questions about the appropriateness of such pharmaceuticals. COX-2 inhibitors (such as Vioxx) previously used in the management of osteoarthritic pain have been withdrawn from the market due to unintended negative cardiovascular effects.[2] The identified side effects of NSAIDs and COX-2 inhibitors in the management of pain highlight the need to identify and evaluate viable adjunctive therapies in the management of OA of the knee.[3-5]

A large scale US clinical trial of the effect of acupuncture in treating osteoarthritis of the knee[6] and previous small scale studies suggest that standard acupuncture in which needles are inserted in defined points for approximately 25 minutes is effective in providing pain relief without undesirable side-effects.[7-13] These findings are supported by an extensive longitudinal audit of patients who received acupuncture as an adjunct therapy in the treatment of osteoarthritis of the knee.[14] The current study builds upon the existing research by examining the effectiveness of the SSP Needle Free Acupuncture Device in treating the symptoms of osteoarthritis of the knee.

In addition, randomised clinical trials (RCTs) by Haslam and Ng[15] indicate that acupuncture may be more effective than advice and patient education in the symptomatic relief of OA pain. Research into the neurological and physiological effects of acupuncture has shown that by producing rhythmic discharges in nerve fibres and releasing β-endorphins, acupuncture reduces pain and decreases stress level markers.[16,17] By altering dopaminergic and serotonergic systems in a way that correlates with anti-stress markers,[17] it is arguable that, in addition to pain relief, acupuncture has a broader effect on general wellbeing. These findings, when considered in the context of the deleterious psychological effects of pain,[18] add to the significance of this study.

The aim of this preliminary study was to explore the benefits of needleless acupuncture (NA) in comparison to needleless sham acupuncture (NSA) in the management of the symptoms of OA of the knee. In particular this controlled, single-blind study measured the effectiveness of NA in decreasing OA knee pain and improving knee joint movement and function. The effectiveness of the SSP has been previously demonstrated in clinical studies of paediatric enuresis[19] and this study was based on the premise that the device would also be beneficial in the treatment of adult osteoarthritis of the knee. In the treatment of OA of the knee, the researchers undertaking this study believed that the needle-free approach could provide a useful alternative to standard acupuncture for those patients who were needle-phobic or had a low pain threshold.

From a theoretical perspective, it is suggested that by using a small electrical current delivered in precise fashion on an acupuncture point, Qi circulation is stimulated and blockages in the channel are diminished. The SSP therapy is a recognised form of needle-free electroacupuncture (EA) and has been shown to have similar analgesic effects to needle EA, being reportedly superior to TENS according to practitioners and researchers' experience.[22] SSP is an advanced form of low-frequency electrical therapy that was developed in 1976 in Japan as a joint academic industrial study between Osaka Medical College (Department of Anaesthesiology) and Nihon Medix Company Limited, one of Japan's leading medical equipment manufacturers. SSP therapy stimulates the analgesic effect of needle electroacupuncture, without using needles. Low-frequency treatment, using SSP therapy has been found to provide effective pain relief. The therapy also has the added benefits of being simple to apply, non-invasive, free from side effects, and with no limit to the number or duration of treatments. There are two features unique to SSP that set it apart from needle electrotherapy and TENS. These are: the distinctive SSP electrode and the 1/f yuragi frequency fluctuation system.

SSP electrodes were designed to allow practitioners to achieve comparable results to needle electroacupuncture while eliminating the disadvantages of using needles.[22,23] The electrodes are manufactured from silver-plated brass to ensure reliable transference of the electrical stimulation. The electrode's conical shape enables both deep and peripheral stimulation to a wide range of treatment points on the body. The electrodes are housed within a rubber cup where an adjustable vacuum mechanism maintains contact with the skin. The vacuum facilitates compression of the electrode against the skin surface for constant electrical stimulation.

To ensure comfortable treatment with unrestricted placement of paired electrodes, SSP treatment utilises spike waves and bi-directional waveforms. Nihon Medix introduced 1/f yuragi

fluctuated, irregular pulse stimulation into low-frequency electrical therapy, based on research from a number of studies.[24,25] It reported marked benefits of 1/f yuragi compared to regular electrical stimulation, especially for 'difficult to treat' pain. The most comfortable waveforms, such as the relaxed alpha rhythm of an electroencephalogram and classical music, conform to the 1/f yuragi fluctuation pattern.

According to the Nihon Medix SSP Operational Manual (Felicia Trimix, Instruction Manual, 1977), SSP needle-free electroacupuncture can offer many superior benefits to needle acupuncture, such as:

- No hazardous waste (environmentally friendly);
- No risk of the contraindications or complications associated with needle use;
- No skin penetration, thus ensuring pain-free, needle-free treatment and reduced danger of infection or contagion;
- SSP EA is also suitable for hypersensitive patients, young children and the elderly.

Research concerning the SSP needle-free acupuncture device has not previously been undertaken in Australia and certainly no studies have been undertaken on the benefits of the device in treating OA of the knee. Potential treatment benefits associated with the device in the Australian context for specific population groups and conditions is warranted.

Methods

This single-blind study drew upon the methodology of a large-scale American RCT that compared the relative effects of acupuncture (active group) and sham acupuncture (control group)[6] using standardised groupings of needle insertion sites. A group of persons living in the western suburbs of Melbourne, Australia, who had been diagnosed by a medical practitioner as having a moderate level of OA of the knee (i.e. prescribed some form of pain-relieving medication for the condition), were recruited with the assistance of health professionals. Consenting participants were paired according to the level of OA pain (indicated by the WOMAC score), age and gender. Participants were then randomly allocated to the NA or NSA group according to the order of recruitment, and were not informed of whether they were receiving NA or NSA until after the completion of the study. Treatments were administered twice weekly by a qualified and registered acupuncturist for a period of three weeks. Participants were asked to keep the acupuncturist informed if there was any change of their medical treatment related to OA. Based on a review of small-scale studies[20] that used standard acupuncture to treat OA of the knee, this preliminary study aimed for a total sample of 40 participants, with 20 in each group. Those in the control group were offered the opportunity of a free course of treatment after the completion of the study. Figure 1 shows the flow of participants through each stage of the trial.

INCLUSION CRITERIA

Participants were included if they were diagnosed by a medical practitioner as having a moderate level of OA of the knee and prescribed some form of pain relieving medication.

EXCLUSION CRITERIA

Participants were excluded if they had another disease affecting the knee (e.g. connective tissue, neurological, etc.); wore any biomedical-electrical devices (e.g. pacemaker, hearing aid); had acupuncture, moxibustion or TENS for OA of the knee during the previous three months; or were unable to understand instructions or give consent.

Prior to commencing the study the protocol was approved by the Human Research Ethics Committee at Victoria University and participants signed an informed consent.

OUTCOME MEASURES AND ANALYSIS

In accordance with accepted outcome measures in other studies,[6,10,15] this clinical trial utilised the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), which is validated for use in Australia by this research group under licence. The WOMAC measures pain, stiffness of the knee and difficulty performing daily activities and was administered before the commencement of the study, mid-study (1.5 weeks after commencement) and at the conclusion of the three-week treatment period. It is a 0–10 scale, with 0 being no pain or no knee stiffness or no difficulty performing daily activities, and 10 being most severe pain, stiffness or difficulty performing daily activities. Participants in the treatment and control groups were asked to report any adverse events that could have been related to treatment.

The data collected from the WOMAC scale were analysed statistically and reported in 'participant de-identified' numerical form. Scores from pre-testing, 1.5-weeks and 3-weeks were compared for the treatment and control conditions using analysis of variance (ANOVA, General Linear Model). Post-hoc analyses were conducted with Bonferroni corrected t-tests. All data collected during the course of the study were coded and kept in a locked filing cabinet to ensure participant confidentiality and privacy of information.

INSTRUMENTATION

A needleless acupuncture point stimulator (SSP Needle Free Acupuncture Device, Felicia Trimix TM21, manufactured by Nihon Medix Co. Ltd, Japan) was used. The SSP Needle Free Acupuncture Treatment machine is approved by the TGA for sale and use as a therapeutic device in Australia

(TGA approval number L68571), being tagged and approved according to Australian Standards. In the NA group, needleless acupuncture was applied to a standardised group of acupuncture points selected in accordance with traditional Chinese medicine (TCM) theory and from points used in other studies of osteoarthritis of the knee.[6,8] Selected treatment points were: ST 36 *Zusanli*, GB 34 *Yanglingquan*, ST 35 *Dubi* and SP 10 *Xuehai*. These points were selected on the basis of TCM practice as points commonly used in the treatment of OA of the knee. The researchers recognised that according to TCM theory, it would be more beneficial if points were selection in each treatment in accordance with the specific pattern of disharmony. However, a set formula was chosen in this study to minimise the degree of variables in this small-cohort, preliminary investigation. Mixed mode low-frequency treatments (3 Hz/4 s, 10 Hz/4 s and 20 Hz/4 s) were used in this study as experience suggests that this setting is optimal in producing an analgesic effect.[22,24,25] The intensity of the stimulation was set at the level where individual participants considered it comfortable.

In the NSA group, the same group of acupuncture points were applied with SSP but without electrical stimulation. The interventions for each group lasted 25 minutes in each treatment session, as this has been suggested as the optimal period for treatment.[6,7,21]

Results

Forty applicants were assessed for eligibility. One applicant refused to commence the study as he wanted to know to which group he was assigned and refused to be in the control group if he was assigned to it. Three participants were excluded before commencing the study as their level of pain was beyond the moderate level as inclusive criteria required. Four participants withdrew from the study between the first and the fourth treatment as they did not feel the therapeutic effect (see Figure 1). Thirty-two (mean age = 59.91 ± 12.70 years) completed the trial, 16 in the NA group and 16 in the NSA group; 22 were female and 10 were male. None of the participants who completed this study changed their medical treatment during

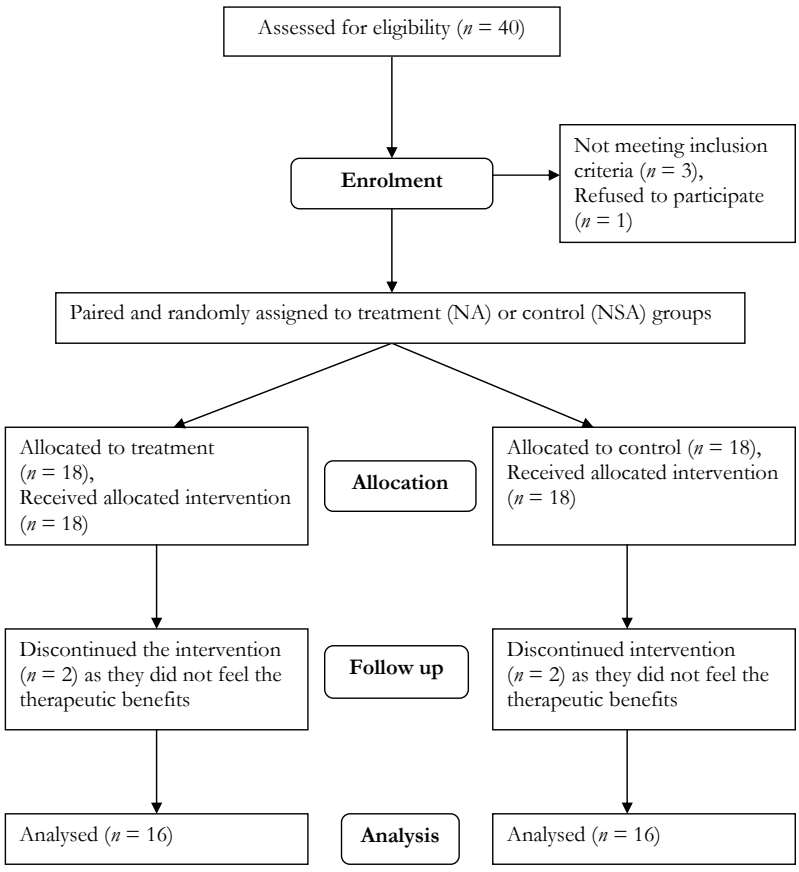

FIGURE 1 Flow chart of participants through each stage of the trial

TABLE 1 WOMAC scores of pain, stiffness and difficulty performing daily activities, from baseline to three weeks (mean ± SD)

Groups		Needless acupuncture (NA) (n = 16)	Needless sham acupuncture (NSA) (n = 16)
WOMAC pain scores	Baseline	3.02 ± 1.60	3.78 ± 2.17
	1.5 weeks	3.22 ± 2.28	3.94 ± 1.83
	3 weeks	1.83 ± 1.60*	3.89 ± 2.46
WOMAC stiffness	Baseline	4.77 ± 2.49	4.44 ± 3.25
	1.5 weeks	4.63 ± 2.28	4.13 ± 2.82
	3 weeks	2.55 ± 1.79*	4.34 ± 3.01
WOMAC difficulty performing daily activities	Baseline	4.28 ± 2.11	4.48 ± 2.40
	1.5 weeks	3.66 ± 2.15	4.43 ± 2.28
	3 weeks	2.41 ± 1.74*	4.11 ± 2.17

* Statistically significant difference between NA and NSA (Bonferroni corrected t-tests, $p < 0.008$).

the course of the study. The two treatment groups were comparable in their age and WOMAC scores.

The mean WOMAC scores are presented in Table 1. The NA group had statistically significant reduction in pain of the knee ($F(2,60) = 4.56$, $p = 0.014$), stiffness of the knee ($F(2,60) = 5.54$, $p = 0.006$) and difficulty performing daily activities ($F(2,60) = 3.66$, $p = 0.032$) in comparison to the NSA. Post-hoc t-tests showed that the two groups were statistically significantly different at week three. Compared with baseline, in the NA group at the end of the three-week treatment the average pain score had decreased by 61%, knee stiffness score by 53% and difficulty performing daily activities score by 56%. There were no significant changes in WOMAC scores for participants in the control group. There were no adverse events reported.

Participants in the study were asked whether they believed that they had received real or sham treatment. In the NA group five participants guessed correctly, while the other 11 were unclear about which group they belonged to. In the NSA group, five participants thought they were actually in the treatment group and the other 11 were unclear about which group they belonged to (Table 2). The results indicated that blinding in the study was reasonably effective and therefore participants' beliefs about group status did not appear to have a significant bearing upon the results.

Discussion

This preliminary study showed that the SSP Needle Free Device was effective in treating the symptoms of osteoarthritis of the knee. Pain and knee stiffness and participants' daily physical ability improved significantly in the NA (active acupuncture) group by the end of the study, but not at the 1.5-week period. There was no significant change in these scores for the NSA (control) group.

As described in the results, some applicants did not understand the nature of this clinical trial and withdrew from the study at an early stage of the study. This indicates that public awareness of clinical research and acupuncture is still limited.

TABLE 2 Participants' belief as to whether they had received real or sham acupuncture

Groups	Guessed correctly the group they were in	Guessed incorrectly the group they were in	Did not know whether they were in group A or B
Active acupuncture (A) (n = 16)	5	0	11
Sham acupuncture (B) (n = 16)	0	5	11

The participants were paired firstly according to the level of OA pain in the knee and then further stratified according to age and gender, and then randomised into the NA treatment and the NSA control group. This method was chosen to reduce the differences between the two groups at the commencement of the experiment. If future studies of this kind were conducted using a bigger sample size, a full randomised grouping without pairing participants would be possible. As it is essential to have qualified acupuncturists to conduct the intervention (treatment or control), a single-blind method was considered to be appropriate for this clinical trial.

The dose level of needleless acupuncture stimulation in the study was set at the level wherein individual participants indicated a comfortable stimulation level during each treatment session. We noticed that the level was continuously increasing for most of the participants toward the end of the study, as the pain was decreasing. The detailed data of the stimulation levels are suggested to be recorded in future studies.

Arguably, the needle-free approach provides a useful alternative to standard acupuncture for patients who are needle-phobic and/or have low pain thresholds. The effective treatment duration suggested by this study is three weeks. The device is easy to operate. However, to avoid incorrect diagnosis and inappropriate and/or detrimental treatment, it is imperative that a qualified acupuncturist operate the SSP Needle Free Device.

As the Australian population ages, a higher proportion of the population will suffer from degenerative diseases such as osteoarthritis in weight-bearing joints such as the knee. Persons with OA of the knee have substantial pain levels, which are normally treated with pharmacological agents, all of which have side effects of varying severity. Chronic pain, loss of mobility and the side-effects of pain-relieving pharmaceuticals impact negatively upon quality of life and arguably contribute to depression and anxiety. While the researchers undertaking this study were not able to locate information that quantified the cost of OA of the knee to the Industry, Employers or National Health Budget, it is clear that this study has demonstrated an inexpensive, drug-free, alternative treatment for this condition.

Acupuncture has the potential to relieve pain, increase mobility, improve the quality of life and possibly reduce patient dependence upon pharmacological agents. A recent large-scale randomised clinical trial of 570 subjects with OA of the knee concluded that standard acupuncture was more effective than sham acupuncture (the insertion of acupuncture needles on non-acupuncture points) in reducing pain and increasing knee joint mobility.[6] Similarly, this preliminary study employing an SSP Needle Free Acupuncture Device, demonstrated positive outcomes for participants in the active acupuncture treatment group. Arguably this needle-free approach has benefits for patients who have difficulties with traditional acupuncture needling and at the same time are interested in a non-pharmacological approach to treating osteoarthritis of the knee.

Conclusion

Based on the differences in WOMAC scores between participants in the active acupuncture treatment and control groups, pre- and post-intervention, this study showed that needleless acupuncture is effective in treating the symptoms of osteoarthritis of the knee. The study has also shown that in addition to traditional acupuncture, trained acupuncture practitioners have another valid non-pharmacological approach to treating OA, which is commonplace in Australia's ageing population.

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Clinical Commentary

The research showed that the SSP Needle Free Device was therapeutically beneficial and as such offered an alternative to standard acupuncture in clinical practice. Arguably, the device has particular clinical benefits in the treatment of patients who are needle-phobic, prone to 'needle shock' and/or have low pain thresholds. The device is easy to operate. However, as with all electrical stimulators, the device should not be used with patients who have electrical implants in order to prevent any possible interference. It is imperative that the SSP Needle Free Device is operated by a qualified acupuncturist in order to ensure appropriate application, avoid incorrect diagnosis or treatment, and provide optimal therapeutic benefit.

References

1. AGS Panel on Persistent Pain in Older Persons. The management of persistent pain in older persons. J Am Geriatr Soc 2002;50(6):205–24.
2. Bannwarth B. Do selective cyclo-oxygenase-2 inhibitors have a future? Drug Safety 2005; 28(3):183–9.
3. Creamer P, Flores R, Hochberg MC. Management of osteoarthritis in older adults. Clin Geriatr Med 1998;14(3):435–54.
4. Hochberg MC. What a difference a year makes: reflections on the ACR recommendations for the medical management of osteoarthritis. Curr Rheumatol Rep 2001;3(6):473–8.
5. Shmerling R. Options for arthritis pain. Newsweek 12 Feb 2002; 140(23):53.
6. Berman BM, Lao L, Langenberg P, Lee WL, Gilpin AMK, Hochberg MC. Effectiveness of acupuncture as an adjunctive therapy in osteoarthritis of the knee: a random controlled trial. Ann Intern Med 2004;141(12):901–10.
7. Tsui P, Leung MCP. Comparison of the effectiveness between manual acupuncture and electro-acupuncture on patients with tennis elbow. Acupunct Electrother Res Int J 2002;27(1–2):107–17.
8. Ng MM, Leung MC, Poon DM. The effects of electro-acupuncture and transcutaneous electrical nerve stimulation on patients with painful osteoarthritic knees: a randomized controlled trial with follow-up evaluation. J Altern Complement Med 2003;9(5):641–9.
9. Soeken KL. Selected CAM therapies for arthritis-related pain: the evidence from systematic reviews. Clin J Pain 2004;20(1):13–8.
10. Tukmachi E, Jubb R, Dempsey E, Jones P. The effect of acupuncture on the symptoms of knee osteoarthritis: an open randomized controlled study. Acupunct Med 2004;22(1):14–22.
11. Ferrández Infante A, García Olmos L, González Gamarra A, Meis Meis MJ, Sánchez Rodríguez BM. Efectividad de la acupuntura en el tratamiento del dolor en la artrosis de rodilla [Effectiveness of acupuncture in the treatment of pain from osteoarthritis of the knee]. Atención Primaria 2002;30(10):602–9.
12. Ezzo J, Hadhazy V, Birch S, Lao L, Kaplan G, Hochberg M, Berman B. Acupuncture for osteoarthritis of the knee: a systematic review. Arthritis Rheum 2001;44(4):819–25.
13. Jiang A, Zhang L, Zhao C, Yang F. Clinical effect of acupuncture treatment in 109 cases of knee osteoarthritis. J Tradit Chin Med 2001;21(4):282–5.
14. Vas J, Perea-Milla E, Méndez C. Acupuncture and moxibustion as an adjunctive treatment for osteoarthritis of the knee – a large case series. Acupunct Med 2004;22(1):23–8.
15. Haslam R. A comparison of acupuncture with advice and exercises on the symptomatic treatment of osteoarthritis of the hip – a randomized controlled trial. Acupunct Med 2001;19(1):19–26.
16. Andersson S, Lundeberg T. Acupuncture – from empiricism to science: functional background to acupuncture effects. Med Hypotheses 1995;45(3):271–81.
17. Yano T, Kato B, Fukuda F, Shinbara H, Yoshimoto K, Ozaki A et al. Alterations in the function of cerebral dopaminergic and serotonergic systems following electro-acupuncture and moxibustion. Neurochem Res 2004;29(1):283–93.
18. Vallerand AH. Treating osteoarthritis pain. Nurse Pract 2003;28(4):7–15.
19. Fujimura N. Clinical studies on surface acupuncture point stimulation therapy for children with enuresis. Western Japan Urology 1991;53:297–99.
20. Berman BM, Lao L, Greene M, Anderson RW, Wong RH, Langenberg P et al. Efficacy of traditional Chinese acupuncture in the treatment of symptomatic knee osteoarthritis: a pilot study. Osteoarthritis Cartilage 1995;3(2):139–42.
21. Yeung CKN, Leung MCP, Chow DHK. The use of electro-acupuncture in conjunction with exercise for the treatment of chronic low-back pain. J Altern Complement Med 2003;9(4):479–90.
22. Hyodo M, Kitade T. A guide to silver spike point (SSP) therapy. 2nd ed. Tokyo: The Silver Spike Point Therapy Study Group; 1979.
23. Sugimoto K, Konda T, Shimahara M, Hyodo M, Kitade T. A clinical study on SSP (silver spike point) electro-therapy combined with splint therapy for temporo-mandibular joint dysfunction. Acupunct Electrother Res 1995;20(1):7–13.
24. Kishida H, Sakai E, Kanbara H, Ohno M, Hyodo M. [A study on post operative analgesic effect of TENS, evaluated particularly with lung vital capacity and leg ability]. Masui 1987;36:1160–5.
25. Ishimaru K, Shinohara S, Kitade T, Kouda H, Kudou D, Watanabe K et al. [Experimental study to increase analgesic effects for pain following abdominal surgeries by silver spike point therapy]. Bull Meiji Univ Orient Med 1989;5:1–6.