



# Efficacy and safety of thread embedding acupuncture for knee osteoarthritis

## A randomized controlled pilot trial

Sang Ha Woo, KMD, MS<sup>a</sup> , Hyun-Jong Lee, KMD, PhD<sup>a</sup>, Yu-kyeong Park, KMD, BS<sup>a</sup>, Jihoon Han, KMD, BS<sup>a</sup>, Jae Soo Kim, KMD, PhD<sup>a</sup>, Jung Hee Lee, KMD, PhD<sup>a</sup>, Chung A. Park, MD, PhD<sup>b</sup>, Seong-Hun Choi, MD, PhD<sup>c</sup>, Woo Dong Lee, PhD<sup>d</sup>, Chang Sop Yang, KMD, PhD<sup>e</sup>, Min Ji Kim, MS<sup>f</sup>, Chang-Hyun Han, KMD, PhD<sup>e,g,\*</sup> 

### Abstract

**Background:** Thread embedding acupuncture (TEA) is a widely used clinical procedure for the treatment of musculoskeletal pain. However, few clinical studies have been conducted on the efficacy and safety of TEA for knee osteoarthritis (KOA), and data from randomized controlled trials are lacking. This randomized controlled pilot study aimed to assess the feasibility of conducting large-scale studies on the efficacy and safety of TEA for KOA.

**Methods:** Forty participants were included in the study and randomly divided into 2 groups (TEA and acupuncture) of 20 each. The intervention period was 6 weeks. The experimental group received TEA once a week (total of 6 sessions) on 14 defined knee areas, and the control group received acupuncture twice a week (total of 12 sessions) on 9 defined acupuncture points. The primary outcome measure was the visual analogue scale score, and the secondary outcome measures were the short-form McGill pain questionnaire, and Western Ontario and McMaster Universities Osteoarthritis Index scores. Participants were assessed prior to the intervention (baseline) and at 3, 6, and 10 weeks (4 weeks after the end of intervention). The adverse effects of TEA and acupuncture were documented. Hematological examination and biochemical tests were performed at the screening and at 6 weeks.

**Results:** Of the 40 participants, 37 completed the study and 3 participants dropped out. Both the TEA and acupuncture groups showed a significant improvement in the visual analogue scale, short-form McGill Pain Questionnaire, and Western Ontario and McMaster Universities Osteoarthritis Index scores in a time-dependent manner. However, there was no significant interaction between group and time. No serious adverse events were reported in the groups, and no clinically significant changes were observed in the hematological and biochemical parameters.

**Conclusion:** This pilot study suggests that TEA is a safe and effective procedure for relieving pain in patients with KOA. The results of this study provide basic data and indicate the feasibility of large-scale clinical studies to evaluate the efficacy and safety of TEA for KOA.

**Abbreviations:** KOA = knee osteoarthritis, RCT = randomized controlled trial, SF-MPQ = short-form McGill Pain Questionnaire, TEA = thread embedding acupuncture, VAS = visual analogue scale, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

**Keywords:** acupuncture, knee osteoarthritis, thread-embedding acupuncture

SHW and H-JL contributed equally to this study.

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The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

<sup>a</sup>Department of Acupuncture & Moxibustion, College of Korean Medicine, Daegu Haany University, Daegu, Republic of Korea, <sup>b</sup>Department of Diagnostics, College of Korean Medicine, Daegu Haany University, Daegu, Republic of Korea, <sup>c</sup>Department of Anatomy and Histology, College of Korean Medicine, Daegu Haany University, Daegu, Republic of Korea, <sup>d</sup>Pre-major of Cosmetics and Pharmaceuticals, College of Herbal Bio-Industry, Daegu Haany University, Daegu, Republic of Korea, <sup>e</sup>KM Science Research Division, Korea Institute of Oriental Medicine, Daejeon, Republic of Korea, <sup>f</sup>R&D Strategy Division, Korea Institute of Oriental Medicine, Daejeon, Republic of Korea, <sup>g</sup>Korean Convergence Medicine, University of Science &

Technology (UST), Campus of Korea Institute of Oriental Medicine, Daejeon, Republic of Korea.

\*Correspondence: Chang-Hyun Han, KM Science Research Division, Korea Institute of Oriental Medicine, Daejeon 34054, Republic of Korea (e-mail: chhan@kiom.re.kr).

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## 1. Introduction

Osteoarthritis is a degenerative disease characterized by loss of articular cartilage, synovitis, and subchondral bone remodeling.<sup>[1,2]</sup> The prevalence of osteoarthritis increases with age, and it affects an estimated 10% of the adults above the age of 60 years.<sup>[3]</sup> Osteoarthritis is one of the major causes of disability in elderly years.<sup>[4]</sup> The main symptoms of this disease include joint pain, restricted movement, and loss of joint function.<sup>[5]</sup> Osteoarthritis most commonly affects the knee joint, and can be treated conservatively or surgically. Conservative treatment comprises of non-pharmacological (muscle strengthening exercises, weight loss, physical therapy, and education) and pharmacological therapies (nonsteroidal anti-inflammatory drugs, glucocorticoids and hyaluronic acid injections, opioid analgesics).<sup>[6,7]</sup> There is no consensus regarding the efficacy of conservative treatment for knee osteoarthritis (KOA), and a definitive conservative approach for treating KOA is yet to be established.<sup>[8]</sup> Therefore, many patients with KOA seek complementary and alternative therapies. Acupuncture is one of the most accepted forms of complementary and alternative medicine. It has been reported to have a significant effect on the reduction in pain and functional improvement in KOA.<sup>[9]</sup> Thread embedding acupuncture (TEA) is a special form of acupuncture that involves the insertion of absorbable threads into specific acupoints to produce long-lasting therapeutic effects. Derived from catgut-embedding therapy, TEA is one of the latest forms of acupuncture, and is widely used in clinical practice.<sup>[10]</sup> Randomized controlled trials (RCTs) have investigated the efficacy of TEA in treating chronic neck pain and chronic lower back pain.<sup>[11,12]</sup> However, few studies have reported the efficacy and safety of TEA for KOA, and data from RCTs are lacking.<sup>[13]</sup> Therefore, this pilot study was conducted to provide basic data and build a strong foundation for future large-scale studies on the efficacy and safety of TEA for KOA.

## 2. Methods

### 2.1. Study design

This study was a 2-arm, assessor-blinded, randomized controlled pilot trial to compare the efficacy and safety of TEA for KOA. The protocol of our study has been previously registered and published.<sup>[14]</sup> Forty patients diagnosed with KOA participated in the study between May 2020 and January 2021 at Daegu Oriental Hospital. This study was performed in accordance with the Korean Good Clinical Practice guidelines and the Declaration of Helsinki. Ethical approval was obtained from the Institutional Review Board of Daegu Oriental Hospital, Daegu Haany University (DHUMC-D-20001-AMD-01), and the study was registered at the Clinical Research Information Service (KCT0004844).

### 2.2. Participants

During the screening visit, all participants were explained the clinical procedure in detail and a written consent was obtained. The eligibility of the participants was determined on the basis of physical examination and X-rays. The inclusion criteria were as follows: age  $\geq 50$  years; morning stiffness persisting for 30 minutes; visual analogue scale (VAS)<sup>[15]</sup> score of 4 to 7; grade II or III osteoarthritis (Kellgren–Lawrence classification); knee pain persisting  $>3$  months; and voluntary consenting participants. The exclusion criteria were as follows: previous knee surgery for KOA or other diseases; intra-articular (steroid, hyaluronic acid) or prolotherapy injections within the last 3 months; severe psychiatric or psychological disorders; use of glucocorticoids or nonsteroidal anti-inflammatory drugs for other diseases; skin diseases (allergies, ulcers, or infections); diabetics on insulin injections; use of anticoagulants; aspartate aminotransferase (8–40 IU/L) and alanine aminotransferase (5–43 IU/L) levels 3 times higher than normal; blood urea nitrogen (BUN, 5–23 mg/dL) and creatinine (0.6–1.3 mg/dL) levels 3 times higher than normal; and ineligibility judged by the researcher.

### 2.3. Randomization and blinding

Random numbers were generated through block randomization and sealed, opaque, assignment envelopes were used for allocation concealment by an independent statistician. The participants were randomly assigned into experimental (TEA) and control (acupuncture) groups. There was an equal probability of being allocated to either group. The outcome assessor did not participate in the randomization and intervention procedure.

### 2.4. Interventions

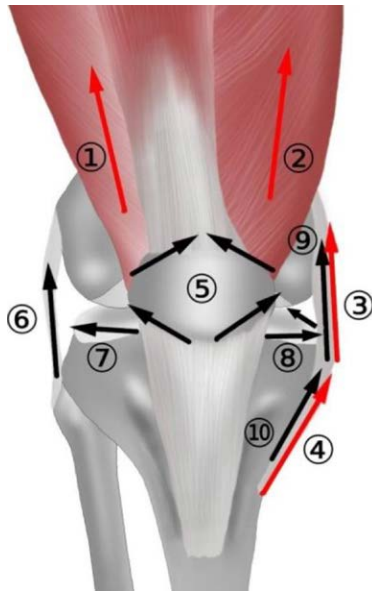
The intervention period was 6 weeks. The experimental group received TEA once a week (total of 6 sessions), and the control group received acupuncture twice a week (total of 12 sessions). The participants received treatment for only one side of the participant's left or right knee, which is more painful. The use of drugs and injections related to knee pain during intervention period (from baseline to 6 weeks) were prohibited and allowed during the observation period (from 6 to 10 weeks).

**2.4.1. Experimental group.** The sites, directions, and lengths of the TEA are described in Table 1 and Fig. 1. TEA was performed using 27 gauge  $\times$  60 mm and 29 gauge  $\times$  40 mm needles (Miracu, feeltech Inc. Gunsan, Republic of Korea) by a Korean medical doctor. There are 2 components in TEA, a guide needle, and the medical thread (Fig. 2). Medical thread is attached to a

**Table 1**

The sites, directions, and needle lengths of thread embedding acupuncture.

Localization	Direction of insertion	Needle length	Number of pieces inserted
Vastus lateralis	Horizontal needling upwards from ST34	60 mm	1 piece
Vastus medialis	Horizontal needling upwards from SP10	60 mm	1 piece
Medial collateral ligament	Horizontal needling towards the direction of medial epicondyle of the femur	60 mm	1 piece
Pes anserinus	Horizontal needling from SP9 along the pes anserinus	60 mm	1 piece
Side of patella	Horizontal needlings along the upper outer, upper inner, lower outer, and lower inner of the patella	40 mm	4 pieces
Lateral collateral ligament	Horizontal needling in the direction of lateral epicondyle of the femur	40 mm	1 piece
Lateral joint line	Horizontal needling toward the lateral back along the lateral joint line	40 mm	1 piece
Medial joint line	Horizontal needlings toward the medial back along the medial joint line	40 mm	2 pieces
Medial collateral ligament	Horizontal needling toward the direction of medial epicondyle of the femur	40 mm	1 piece
Pes anserinus	Horizontal needling from SP9	40 mm	1 piece
Total			14 pieces



**Figure 1.** Sites and directions of thread embedding acupuncture. The short black arrows mean 40 mm long thread, and the long red arrows mean 60 mm long thread.

guide needle, and guide needle inserts into the skin. The guide needle is removed after insertion and the medical thread remains embedded overlying specific point.

**2.4.2. Control group.** Acupuncture was performed using 0.30×40 mm disposable acupuncture needles (Dong Bang Acupuncture Inc., Boryeong, Republic of Korea) by a Korean medical doctor. In this study, 9 acupoints were selected: unilateral GB33, LR08, SP09, SP10, ST34, ST36, Ex-LE02, Ex-LE04, and Ex-LE05 (Fig. 3). The needle was inserted to a depth of 5 to 20 mm and was retained for 20 ± 5 minutes.

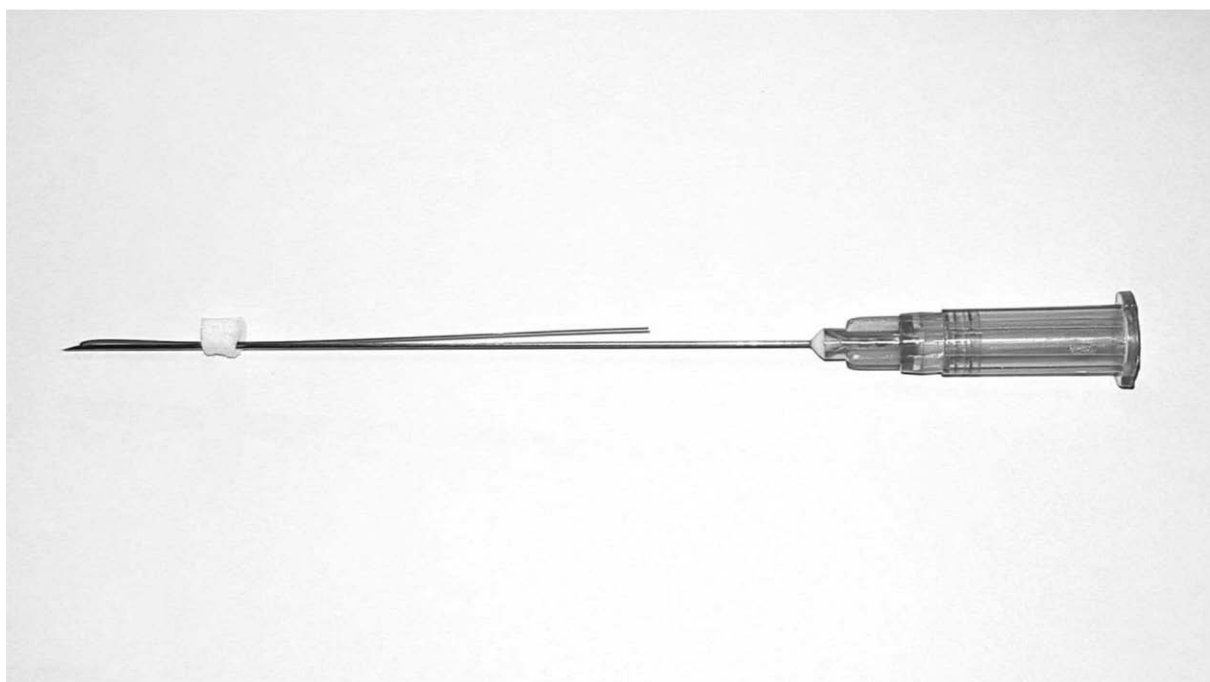
## 2.5. Outcome measurement

The primary outcome measure was the VAS score, and the secondary outcome measures were the short-form McGill pain questionnaire (SF-MPQ),<sup>[16]</sup> and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)<sup>[17]</sup> scores. High scores were associated with more severe KOA. To determine the VAS score, all participants were asked to mark a point on a 10-cm vertical line (0—no pain, 10—severe pain) to indicate the pain intensity in the past week. The length was measured by the investigator to evaluate the degree of pain. The SF-MPQ consisted of 15 descriptors (11 sensory and 4 affective) and a present pain intensity (PPI) scale. Each descriptor was scored from 0 (no symptoms) to 3 (severe), and the final score was obtained by summing the individual scores of all the descriptors. The PPI scale evaluated the current pain severity of the participants from 0 (no pain) to 5 (excruciating). The WOMAC consisted of 24 questions categorized into 3 subscales: pain (5 questions), stiffness (2 questions), and physical function (17 questions). All items were scored on a scale from 0 (none) to 4 (extreme).

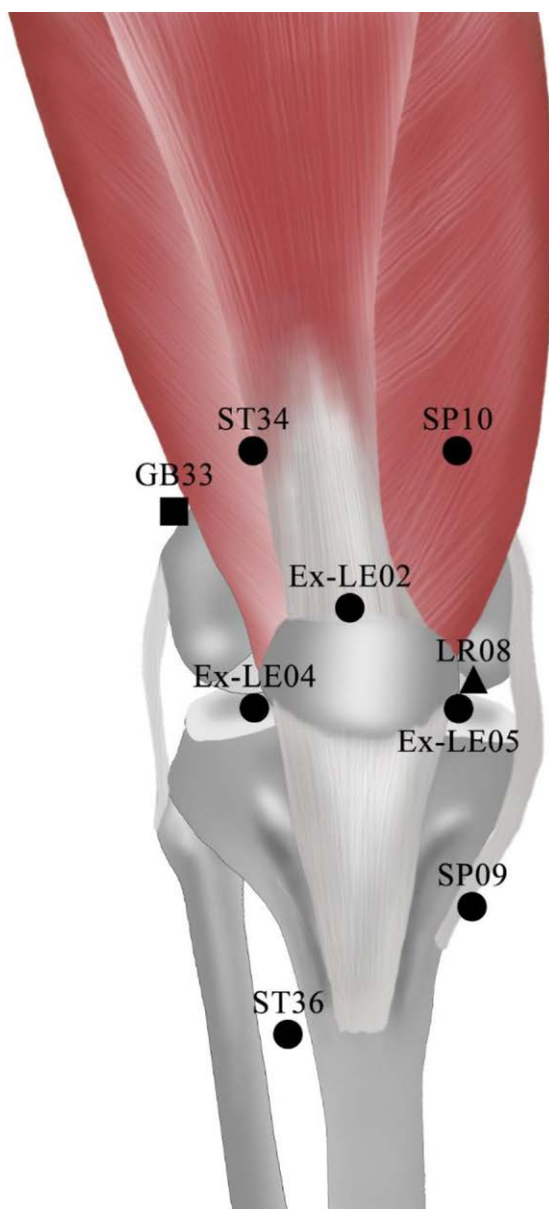
The participants were assessed on the following occasions: at baseline; 3 and 6 weeks after the start of the intervention; and 4 weeks after the end of the intervention.

## 2.6. Adverse events and safety

The participants who underwent more than one session of TEA or acupuncture were monitored for adverse events. The researcher identified the expected and unexpected adverse events associated with the intervention. The safety of TEA was evaluated by comparing the hematological and biochemical parameters at screening and at 6 weeks. The hematological evaluation included red blood cell count, total white blood cell count, differential count, hemoglobin, hematocrit, platelet count, and erythrocyte sedimentation rate. The biochemical parameters assessed were aspartate aminotransferase, alanine aminotransferase, BUN, creatinine level, C-reactive protein, prothrombin time, partial thromboplastin time, and serum sodium, and potassium and chloride levels.



**Figure 2.** The thread embedding acupuncture used in our study.



**Figure 3.** Sites and directions of acupoint. ●: The acupoints on the front, ■: the acupoint on the lateral side, ▲: the acupoint on the back.

## 2.7. Statistical analysis

Since this was a pilot study, the participants (20 in each group) were randomly allocated to the groups based on practical consideration, without calculating the sample size. All statistical analyses were conducted using IBM SPSS version 19.0 for windows (IBM Corp., Armonk, NY) in accordance with the “Statistical Guidelines for Clinical Testing (KFDA, 2000).” The last observation carried forward method was used for missing data from the dropouts. Data were analyzed using the intention-to-treat (ITT) analysis and the level of statistical significance was set at 5%. Student *t* test (parametric analysis) and Mann–Whitney *U* test (nonparametric analysis) were used to analyze the baseline characteristics of the groups. The qualitative data were analyzed using the chi-square ( $\chi^2$ ) test. To compare the VAS, SF-MPQ, and WOMAC scores at baseline and at 3, 6, and 10 weeks (4 weeks after the intervention), the paired *t* test was used for parametric analysis, and the Wilcoxon signed-rank test was performed for nonparametric analysis. Repeated-measures analysis of variance was conducted to analyze the

difference between the groups, and the interaction between group and time in the VAS, SF-MPQ, and WOMAC scores.

## 3. Results

### 3.1. Participant enrollment

Of the 43 participants screened, 40 were enrolled in the trial (acceptance rate of 93.02%). Two participants withdrew the consent, while 1 could not meet the Kellgren–Lawrence grading criteria. Of the 40 participants, 37 completed the trial and 3 dropped out (drop-out rate of 7.5%) of the study. In the TEA group, 1 participant withdrew because of surgery for wrist fracture and the other pulled out due to a residual movement problem. In the acupuncture group, 1 participant withdrew for the treatment of lower back pain. The compliance rate for the remaining 37 participants was 98.22% (Fig. 4).

### 3.2. Baseline characteristics

The baseline characteristics and outcome measurements of the 40 enrolled participants are presented in Table 2. Despite a significant difference in age, the outcome measures (VAS, SF-MPQ, and WOMAC scores) were similar between the 2 groups.

### 3.3. Outcome measurement

A significant improvement in the VAS score was observed in the TEA and acupuncture groups at 6 and 10 weeks from the baseline, and at 3, 6, and 10 weeks from the baseline, respectively. Both groups showed a significant improvement in the SF-MPQ and WOMAC scores at 6 and 10 weeks from the baseline. According to repeated-measures analysis of variance, both groups showed a significant improvement in the VAS, SF-MPQ, and WOMAC scores in a time-dependent manner. However, no significant interaction between group and time was observed (Table 3).

### 3.4. Adverse events and safety

Some participants in both the groups reported expected adverse events which were associated with the intervention. These included mild pain, edema, bruising, and itching at the intervention sites. The unexpected adverse events, which included sore throat, toothache, itching (away from the intervention sites), and pain in the abdomen, lower back, shoulder, neck, and fingers, were unrelated to the intervention. No serious adverse events were reported in either group. No clinically significant change was observed in the hematological and biochemical parameters at baseline and at 6 weeks.

## 4. Discussion

In complementary and alternative medicine, acupuncture has been widely used in the conservative management of KOA. In a recent meta-analysis, acupuncture for KOA resulted in short-term pain relief and improved function, and long-term improvement in function.<sup>[18]</sup> TEA is a special form of acupuncture that involves the insertion of an absorbable thread at selected acupoints to provide continuous stimulation. During absorption, TEA produces a strong and long-term stimulation at the insertion site. Although TEA for KOA has been applied clinically, no RCT has investigated its efficacy. Therefore, this pilot study was thus conducted as a preliminary study to confirm the efficacy of TEA for KOA.

In this study, there was a significant improvement in the VAS, SF-MPQ, and WOMAC scores in a time-dependent manner in both the TEA and acupuncture groups. However, no significant interaction between the group and time was observed. A recent

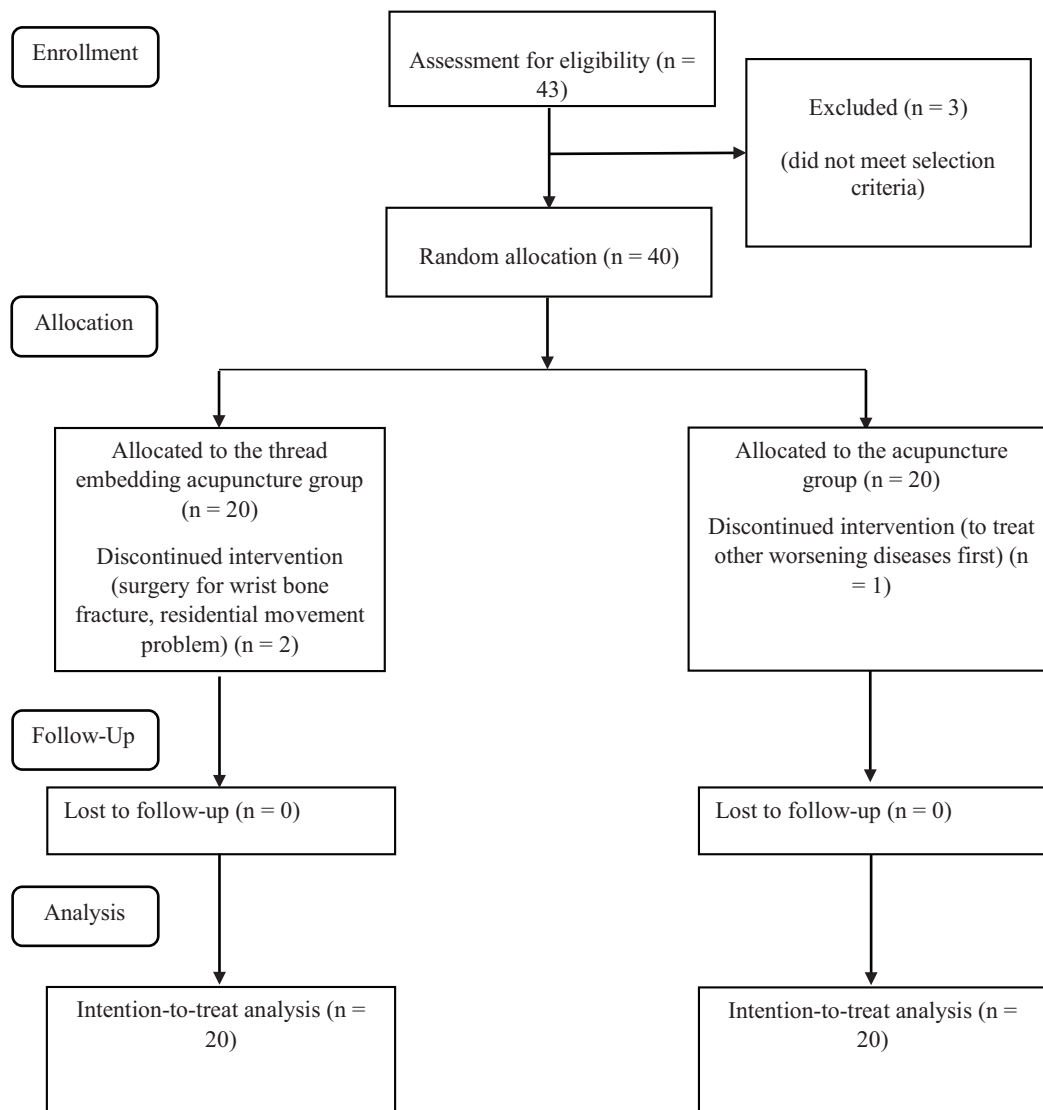


Figure 4. Flow chart for randomized controlled pilot trial on the efficacy and safety of thread-embedding acupuncture for knee osteoarthritis.

**Table 2**  
Baseline characteristics and outcome measurements for participants with knee osteoarthritis who received thread-embedding acupuncture or acupuncture.

Variable	Group		P value
	TEA group (n = 20)	Acupuncture group (n = 20)	
Sex, n (%)			
Male	4 (20.00)	3 (15.00)	.677*
Female	16 (80.00)	17 (85.00)	
Mean age, years	67.45 ± 7.39	62.70 ± 6.40	.036#
VAS	5.20 ± 1.30	5.18 ± 0.86	.932#
SF-MPQ			
Descriptive scale	11.95 ± 5.63	12.75 ± 8.00	.947†
PPI	2.10 ± 0.64	2.20 ± 0.41	.529†
WOMAC	36.50 ± 15.74	36.0 ± 15.69	.920#

Values are expressed as means ± standard deviations.  
 PPI = present pain intensity scale, SF-MPQ = short-form McGill Pain Questionnaire, TEA = thread-embedding acupuncture, VAS = visual analog scale, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.  
 \*Chi-square (χ<sup>2</sup>) test.  
 #Student t test.  
 †Mann-Whitney U test.

meta-analysis reported a short-term relief in pain and improvement in function, and a long-term improvement in function following acupuncture in KOA patients.<sup>[9]</sup> Acupuncture for 6 weeks in this study also improved physical function and pain. No significant difference was found in the physical function and pain relief between the TEA and acupuncture groups. These results suggest that both TEA and acupuncture have similar effects in KOA.

According to a study by Huang et al,<sup>[19]</sup> who reported the safety of TEA, the most common adverse events were induration, bleeding and ecchymosis, redness and swelling, fever, and pain, and serious adverse events such as necrosis, multiple skin ulcers, and suppuration. In this study, participants experienced mild pain, edema, bruising, and itching at the intervention sites. However, all recovered without any aftereffects. Although symptoms such as sore throat, toothache, itching (away from the intervention sites), and pain in the abdomen, lower back, shoulder, neck, and fingers were also reported, they were unrelated to the intervention. No severe adverse events were observed in the present study.

The most important point of caution when performing TEA is infection. Huang et al<sup>[19]</sup> recommended that TEA should be performed under sterile conditions, and patients must be screened before and after the procedure to minimize the risk

**Table 3**  
**Changes in outcome measures.**

Variable	Group	Time (mean ± SD)				P value	
		Baseline	3 weeks	6 weeks	10 weeks	Time	Time × group
VAS	TEA	5.21 ± 1.30	4.96 ± 1.29	4.58 ± 1.62*	3.77 ± 1.54*,*	<.001†	.265
	Acupuncture	5.18 ± 0.86	4.80 ± 0.89*,*	3.96 ± 1.05*,*	3.60 ± 1.14*,*		
SF-MPQ Descriptive scale	TEA	11.95 ± 5.63	10.40 ± 6.00	7.90 ± 5.35#,#	6.80 ± 5.16#,#	<.001†	.919
	Acupuncture	12.75 ± 8.00	10.70 ± 6.03	7.85 ± 5.49#,#	6.90 ± 4.18#,#		
PPI	TEA	2.10 ± 0.64	2.05 ± 0.69	1.60 ± 0.50#,#	1.45 ± 0.76#,#	<.001†	.940
	Acupuncture	2.20 ± 0.41	2.15 ± 0.59	1.65 ± 0.59#,#	1.60 ± 0.60#,#		
WOMAC	TEA	36.50 ± 15.74	33.90 ± 18.64	25.10 ± 14.35*,*	23.45 ± 15.59*,*	<.001†	.956
	Acupuncture	36.00 ± 15.69	32.85 ± 13.83	23.25 ± 13.84*,*	21.95 ± 11.59*,*		

SD = standard deviation, PPI = present pain intensity scale, SF-MPQ = short-form McGill Pain Questionnaire, TEA = thread embedding acupuncture, VAS = visual analog scale, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

\* $P < .05$ , \*\* $P < .01$ : significant difference between baseline measurement and measurements at 3, 6, and 10 weeks according to the paired  $t$  test.

# $P < .05$ , ## $P < .01$ : significant difference between baseline measurements and measurements at 3, 6, and 10 weeks according to the Wilcoxon signed-rank test.

† $P < .05$ : significant difference according to the repeated-measures analysis of variance.

of infection. In this study, no cases of infection were reported. In addition, the erythrocyte sedimentation rate and C-reactive protein levels assessed for post-intervention infection were within the normal range. Therefore, in this study, TEA was considered to be safe.

Of the 40 participants, 3 dropped out (drop-out rate of 7.5%) of the study. The compliance rate of the remaining 37 participants was 98.22%. The mean VAS score at 6 weeks for the TEA and acupuncture groups was 4.575 and 3.955, respectively. The mean difference between the groups was 0.62 ( $\delta$ ), and the standard deviation ( $\sigma$ ) was 1.363. Based on the results of this study, we calculated the sample size for evaluating the efficacy of TEA in future clinical trials. As per our analysis, 85 participants per group would be necessary considering a statistical power ( $1 - \beta$ ) of 80% at 5% level of significance ( $\alpha$ ), and a dropout rate of 10%.

Our study has some limitations. First, there was no appropriate sham device for TEA; thus, the efficacy of TEA could not be evaluated directly. Second, the assessor was blinded, but it was difficult to blind the participants and practitioners. This means that the risk of bias cannot be fully avoided. If a sham device is developed, double-blind RCTs will reduce the risk of bias. Third, due to the nature of this pilot study, the sample size was small, thereby limiting the efficacy evaluation. In addition to the small sample size, only 7 out of 40 participants were men, resulting in an imbalance in the male to female ratio. And this could cause a deviation in the result. Finally, participants were followed-up for 10 weeks after the start of the procedure. Therefore, it was not possible to measure its impact on the KOA over a long period of >13 weeks. More than 13 weeks of studies are needed to confirm the long-term efficacy and safety of TEA.

## 5. Conclusion

This pilot study suggests that TEA is a safe and effective procedure for relieving pain for KOA. This study provides basic data and indicates the feasibility of large-scale clinical studies to confirm the efficacy and safety of TEA for KOA.

## Author contributions

Conceptualization: Chang-Hyun Han, Hyun-Jong Lee

Data curation: Hyun-Jong Lee, Sang Ha Woo

Formal analysis: Woo Dong Lee

Funding acquisition: Chang Sop Yang, Chang-Hyun Han, Min Ji Kim

Investigation: Jihoon Han, Sang Ha Woo, Yu-Kyeong Park  
Methodology: Hyun-Jong Lee, Jae Soo Kim, Jung Hee Lee  
Project administration: Hyun-Jong Lee, Jae Soo Kim, Jung Hee Lee, Sang Ha Woo

Resources: Chung A Park, Seong-Hun Choi

Software: Jung Hee Lee

Supervision: Chang-Hyun Han, Hyun-Jong Lee, Jae Soo Kim, Min Ji Kim

Validation: Woo Dong Lee

Visualization: Yu-Kyeong Park

Writing – original draft: Hyun-Jong Lee, Jung Hee Lee, Sang Ha Woo

Writing – review & editing: Hyun-Jong Lee, Jung Hee Lee, Sang Ha Woo

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