

Clinical use of thread embedding acupuncture for facial nerve palsy

A web-based survey

Dahae Kang, KMD^a, Bonhyuk Goo, PhD^b , Jung-Hyun Kim, PhD^b, Joo-Hee Kim, PhD^c, Sang-Soo Nam, PhD^{d,*}

Abstract

Although thread embedding acupuncture (TEA) is widely used for facial nerve palsy (FNP) in Korea, it lacks clinical evidence. Therefore, a large-scale and long-term clinical trial is needed. It is necessary to standardize and optimize TEA treatment for clinical study. Hence, we collected information about how TEA in the facial region is performed in clinical practice using a web-based survey. A questionnaire was developed consisting of 22 essential items and 30 optional items including demographic characteristics, purpose of TEA, adverse events (AE), direct medical cost, required time, and current state of TEA treatment on FNP. The questionnaire was sent via e-mail to 23,910 traditional Korean medicine doctors (TKMD). A total of 427 respondents answered the questionnaire. The most common response for the purpose for TEA was cosmetic, followed by musculoskeletal disease and nervous system disease. The most common AE that resolved without medical treatment was bruising (90.4%). The most common AE that required medical treatment was dimple (30.5). Many respondents commonly used TEA for the sequelae of FNP (71.8%). The most frequent sequelae of FNP for which TEA was used as contracture around the mouth (75.3%). The most preferred treatment method was insertion of 6–10 monofilament threads using a 29-gauge needle at intervals of 2.2 ± 1.59 weeks in the sequelae period. The results of this survey can be used to standardize and optimize the procedure of TEA for FNP for further clinical research.

Abbreviations: AE = adverse events, FNP = facial nerve palsy, TEA = thread embedding acupuncture, TKMD = traditional Korean medicine doctor.

Keywords: facial nerve palsy, safety, survey, thread embedding acupuncture

1. Introduction

Thread embedding acupuncture (TEA) is a method of treating diseases by inserting medical thread, such as catgut or polydioxanone thread, into acupoints. Since inserted thread made of polydioxanone remains for over approximately 3 months, TEA is advantageous for diseases that require long-term needle retention by continuing physical and chemical stimulation.^[1]

Initially, TEA was predominantly used for cosmetic purposes such as wrinkles and improvement of elasticity.^[2] Currently, TEA is widely used for various purposes in Korea, including facial nerve palsy (FNP), obesity, and musculoskeletal diseases.^[3]

A systematic review of 45 randomized controlled trials and 16 case reports confirmed the safety of TEA for general purposes.^[4] However, regarding the safety of TEA for the facial region, there is a lack of evidence from large-scale studies. Furthermore, the efficacy of TEA for the treatment of FNP also lacks meaningful evidence.

Our previous randomized controlled trial comparing TEA group to sham TEA group demonstrated that TEA may improve physical function of the facial region in patients with FNP. Due to a lack of similar previous studies to act as references, there were many limitations with regard to development of a suitable study protocol.^[5] Therefore, to establish robust evidence for the

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

The data that support the findings of this study are available from the corresponding author upon reasonable request.

This study was approved by the institutional review board of Kyung Hee University Korean Medicine Hospital at Gangdong (approval number: KHNMCOH 2021-11-015).

^a Industry-Academic Cooperation Foundation, Kyung Hee University, Seoul, Republic of Korea, ^b Department of Acupuncture & Moxibustion, Kyung Hee University Hospital at Gangdong, Seoul, Republic of Korea, ^c Department of Acupuncture and Moxibustion Medicine, College of Korean Medicine, Sangji University, Wonju-si, Republic of Korea, ^d Department of Acupuncture &

Moxibustion, College of Korean Medicine, Kyung Hee University, Seoul, Republic of Korea.

*Correspondence: Sang-Soo Nam, Department of Acupuncture & Moxibustion, College of Korean Medicine, Kyung Hee University, 26, Kyungheedaero, Dongdaemun-gu, Seoul 02447, Republic of Korea (e-mail: dangun1966@khu.ac.kr).

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efficacy of TEA to treat FNP, it is necessary to conduct a large-scale, high-quality clinical trial.

A high-quality clinical study requires a consensus on standardized and optimized treatment methods, and it is necessary to gather detailed clinical information about adverse events (AE) and cost.

Therefore, in this study, we investigated how TEA in the facial region is used in actual clinical practice by traditional Korean medicine doctors (TKMDs) in Korea, including information on treatment method, safety, efficacy, and cost. Due to the large volume of responses, we were able to collect large amounts of clinical data, through which we aim to optimize the treatment method of TEA in the facial region to create the foundation for an upcoming clinical trial.

2. Methods

2.1. Questionnaire development

The internal development committee consisted of clinical experts in acupuncture and moxibustion who developed a draft questionnaire through research meetings.

The external multidisciplinary committee consisted of experts in clinical and safety research and economic research. Having no competing interests, they reviewed the draft and presented their revised opinions. After conducting a consensus of the modified questionnaire based on their opinions, we developed the final questionnaire.

The questionnaire consisted of 22 essential questions and 30 optional questions. Optional questions that can be selectively answered depending on each respondent's answer were presented after the essential questions. They included the general use of TEA (one essential item), cost of TEA in the facial region (three essential and eight optional items), AE of TEA in the facial region (four essential and 16 optional items), use in FNP (six essential and three optional items), use in sequelae of FNP (four essential and three optional items), and demographic characteristics (four essential items).

This study was approved by the institutional review board of Kyung Hee University Korean Medicine Hospital at Gangdong (approval number: KHNMC0H 2021-11-015)

2.2. Questionnaire distribution and collection

The questionnaire was converted to a web-based survey with a system that prevented duplicate or missing responses. The e-mail containing the link to the survey was sent twice on December 14 and 21, 2021 to 23,910 TKMDs in Korea registered with the Association of Korean Medicine. The web survey was accessible from December 14 to 24, 2021. In order to prevent bias and conflicts of interest, the development and implementation process of the survey, including web-based questionnaire development, e-mail distribution, and response collection, were performed by an external professional survey agency (Mediresearch, Seoul, Korea) using their own survey program.

2.3. Analysis of data

All categorical values are presented as n (%) and continuous variables are presented as mean \pm standard deviation.

All analyses were performed using Microsoft Excel. The results of the survey were summarized in a table and presented in a bar graph.

3. Results

3.1. Participants and demographic characteristics

We sent an e-mail containing links to our survey to 23,910 TKMDs, 1096 of whom accessed the survey. Among them, 427 who had experience in TEA responded to the questionnaire. The response rate was 1.79%. Of the 427 respondents, 356 people with experience in TEA in the facial region continued the survey, 209 of whom had experience using TEA to treat FNP. These respondents answered questions related to the treatment method of FNP (Fig. 1).

Demographic characteristics of respondents are shown in Table 1.

3.2. Purpose of TEA

The purposes of TEA are shown in Table 2. The most common use of TEA was for cosmetic purposes (67.2%), followed by the

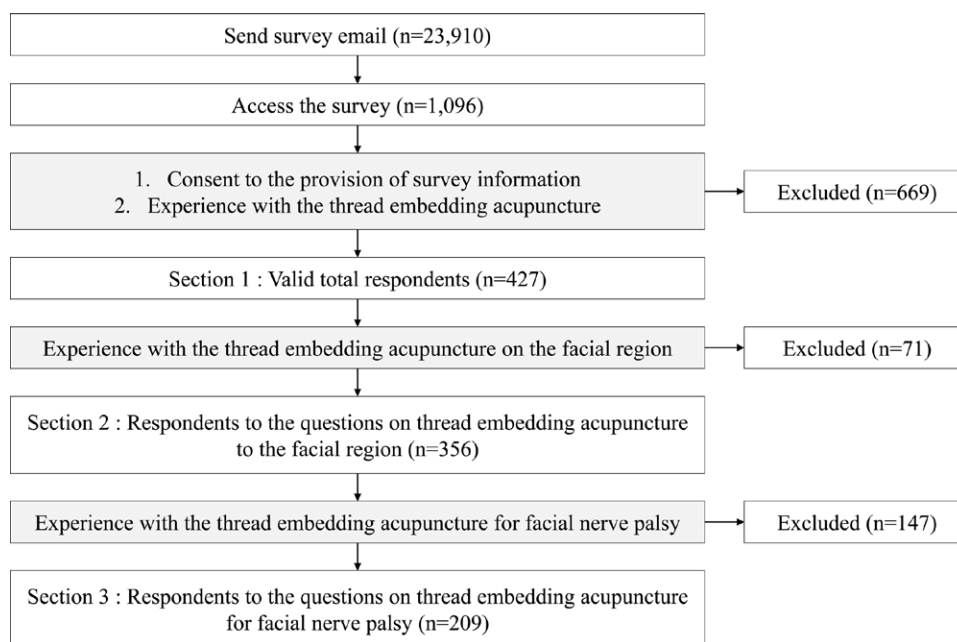


Figure 1. Flow chart.

Table 1
Demographic characteristics.

Characteristics (total = 427)	n (%)
Sex	
Male	273 (63.9)
Female	154 (36.1)
Age (years)	
20–29	32 (7.5)
30–39	189 (44.3)
40–49	139 (32.6)
50+	67 (15.7)
Clinical experience (years)	
0–4	86 (20.1)
5–9	120 (28.1)
10–19	146 (34.2)
20+	75 (17.6)
Type of workplace	
Traditional Korean medicine clinic	298 (69.8)
Traditional Korean medicine hospital	80 (18.7)
Public health center or military health center	18 (4.2)
Nursing hospital	14 (3.3)
Hospital	10 (2.3)
Other	6 (1.6)

Table 2
Purpose of thread embedding acupuncture.

Purpose (Total = 427)	n (%)
General purpose of thread embedding acupuncture (multiple choice)	
Cosmetic purpose	287 (67.2)
Diseases of the musculoskeletal system	253 (59.3)
Diseases of the nervous system	85 (19.9)
Diseases of the skin	81 (19.0)
Diseases of eye and adnexa	31 (7.3)
Diseases of the circulatory and respiratory systems	22 (5.1)
Diseases of genitourinary system	19 (4.4)
Diseases of the ear and mastoid process	17 (4.0)
Diseases of digestive system	17 (4.0)
Diseases of endocrine, nutritional and metabolic diseases	15 (3.5)
Diseases of mental and behavioral disorders	9 (2.1)
Purpose of thread embedding acupuncture on facial region (multiple choice)	
Cosmetic purpose	296 (83.1)
Disease treatment	168 (47.2)

treatment of musculoskeletal diseases (59.3%), nervous system diseases (19.9%) and skin diseases (19.0%). When asked about the purposes of facial TEA, most respondents answered that they use it for cosmetic purposes (83.1%) and 47.2% answered that they use it for disease treatment.

3.3. AE of TEA in the facial region

Treatment-related AE during TEA in the facial region were reported by 69.9% (249/356 respondents) who had experience using TEA in the facial region. Among those who encountered AE, 76.3% (190) encountered AE that required medical treatment or left sequelae. This amounts to 53.4% of respondents with experience in TEA in the facial region who encountered AE in their patients.

AE that resolved without medical treatment are shown in Table 3. The most common AE that resolved without medical treatment were bruising (90.4%), followed by pain in the treatment area (69.1%), foreign body sensation (52.6%) and edema (45.0%). Symptoms that took the longest time to resolve were visible thread through the skin (4.1 weeks), followed by inflammation (2.0 weeks).

Table 3
Adverse events resolved without medical treatment.

Symptoms (total = 249)	Number of experienced respondents (n, %)	Time to resolution (weeks)
(multiple choice)		
Bruising	225 (90.4)	1.9 ± 0.75
Pain on treatment area	172 (69.1)	1.4 ± 0.63
Foreign body sensation	131 (52.6)	1.7 ± 0.99
Edema	112 (45.0)	1.4 ± 0.73
Erythema	69 (27.7)	1.6 ± 0.81
Visible thread through skin	24 (9.6)	4.1 ± 4.99
Inflammation	1 (0.4)	2.0

AE that needed medical treatment or left sequelae are shown in Table 4. Among these AE, dimple (30.5%) was the most common, followed by fever/inflammation (28.9%), exposure of thread (28.1%), pain in the treatment area (24.9%), and hematoma (24.5%). The adverse event of longest duration was nerve damage (7.6 weeks), and the shortest was pain in the treatment area (1.7 weeks). A few AE such as salivary gland damage (37.5%), nerve damage (22.6%), and hyperplasia (12.5%) were long-term sequelae.

Suspected causes of AE of TEA are shown in Figure 2. Respondents were asked about suspected causes of AE of TEA. “Insertion depth” was the most frequent answer, followed by patient-specific wound healing capacity and location of treatment. Patient-specific wound healing capacity refers to individual differences in healing and response to treatment, such as in patients who are more prone to keloid scarring or inflammation than others.

3.4. Direct medical costs and required time

Direct medical costs and time required for facial TEA per session are shown in Table 5. For cosmetic purposes, the average cost was KRW 134,000. In disease treatment, it was KRW 68,000. The mean time required for a TKMD to perform TEA for cosmetic purposes was 15.1 min and 10.4 minutes for disease treatment.

The standard criteria to determine the direct medical cost of treatment per session is shown in Figure 3. The most commonly used criteria are “number of threads embedded,” followed by “difficulty by treatment location,” “type of thread” and “purpose of treatment.”

Table 6 summarizes how TEA is used for FNP in clinical practice. Over two-thirds of respondents (69.9%) answered “under 20%” when asked about the percentage of FNP patients who undergo TEA. Most respondents (71.8%) used TEA to treat FNP when patients were in the “sequelae period.” When asked about needles and thread used in TEA for FNP, 29-gauge needles (49.8%) and monofilament (90%) thread were most preferred. Monofilament thread is a single strand of thread used in TEA. Treatments were performed at mean intervals of 1.4 weeks in the acute period, 1.6 weeks in the recovery period, and 2.2 weeks in the sequelae period.

Respondents were asked about symptoms of FNP sequelae during TEA use (Table 7). The most frequent symptom was “contracture around mouth” (75.3%). “Contractures of other facial parts” and “incomplete recovery of FNP” followed at 40% to 50%. TEA was rarely used for tearing (4.7%) or hearing disorders (4.0%).

When asked about the criteria for determining treatment area, most (90%) respondents answered “anatomical structure”, followed by “local facial acupoints” (30.7%). Only 3.3% of respondents answered “distal acupoints.”

Table 4
Adverse events that needed medical treatment or resulted in long-term sequelae.

Symptoms (Total = 190)	Number of experienced respondents (n (%))	Time to resolution (weeks)	Outcome (%)			
			Cured			Unresolved
			Outpatient	Hospitalized	Transferred	
(multiple choice)						
Dimple	76 (30.5)	4.8 ± 4.46	75.0	0.0	19.7	5.3
Fever/inflammation	72 (28.9)	1.9 ± 0.98	51.4	1.4	45.8	1.4
Exposure of thread	70 (28.1)	2.0 ± 1.24	95.7	1.4	1.4	1.4
Pain in treatment area	62 (24.9)	1.6 ± 1.10	91.9	1.6	6.5	0.0
Hematoma	61 (24.5)	2.6 ± 1.19	77.0	1.6	21.3	0.0
Hyperplasia, nodules and sclerotic skin	40 (16.1)	7.3 ± 7.48	32.5	5.0	50.0	12.5
Nerve damage	31 (12.4)	7.6 ± 5.03	32.3	9.7	35.5	22.6
Salivary gland damage	8 (3.2)	3.8 ± 3.35	12.5	0.0	50.0	37.5
Hypersensitivity	1 (0.4)	2.0 ± 4.99	0.0	0.0	100.0	0.0

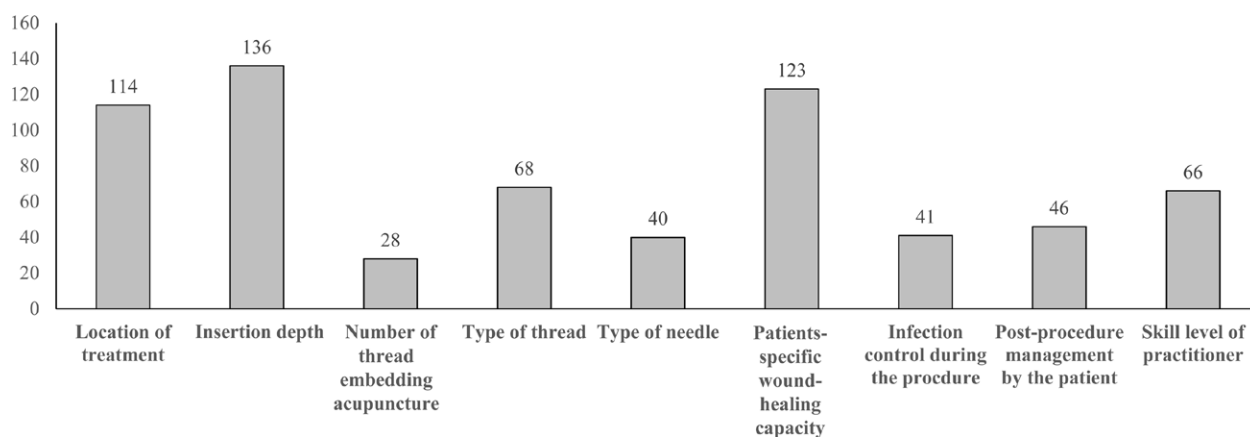


Figure 2. Suspected causes of adverse events of thread embedding acupuncture.

Table 5
Direct medical cost and required time of thread embedding acupuncture in the facial region per session.

Purpose	Cost/Session (KRW 10,000)	Required time/Session (min)	
		Traditional Korean medicine doctor	Nurse or assistant
Cosmetic purpose	13.4 ± 17.54	15.1 ± 12.11	13.9 ± 15.18
Disease treatment	6.8 ± 8.23	10.4 ± 9.00	8.7 ± 9.81

KRW = Korean Won.

For the minimum number of TEA treatments for FNP sequelae to achieve a significant improvement, respondents reported a mean of 5.9 (±2.64) treatment sessions. Most respondents (40.7%) answered that they required 6–10 threads when asked about the number of threads used for TEA for FNP sequelae.

The area where TEA is targeted for sequelae of FNP was divided into seven zones according to the anatomical location (Fig. 4). Respondents were asked about the most preferred zones in order of frequency. To help visual comprehension, we suggested a facial anatomical picture divided into seven zones in the survey. The most frequently used area was zone 3, followed by zone 6, zone 5 and zone 4.

Respondents were asked about the acupoints they prefer when using TEA for FNP sequelae (Table 8). They answered that local acupoints were distributed where symptoms appear, such as around the eyes and mouth. Among local acupoints, ST6 and ST4 were most preferred. For distal acupoints, LI4 and ST36 were the most preferred.

4. Discussion

We conducted a survey of TKMDs who use TEA in clinical practice to determine the purpose, safety, and cost of TEA in their practices. Particular attention was paid to the use of TEA for FNP, namely to determine what specific methods, materials, periods, and areas are used.

The results of this study showed that TEA is most commonly used for cosmetic purposes. This concurs with the findings of Kwon, who reported that cosmetic purpose was the most common indication for the use of TEA in eight of 37 studies published in Korean traditional medicine journals.^[3] A systematic review of safety of TEA in China found that the most common use of TEA was to treat obesity.^[4] Secondly, TEA is commonly used for musculoskeletal diseases. Clinical studies on chronic neck pain, knee osteoarthritis, and low back pain are ongoing.^[6] The third most common use of TEA was for diseases of the nervous system, of which FNP was selected by 19.9% (n = 85) of respondents.

Most respondents (83.1%) answered that they perform TEA for cosmetic purposes in the facial region. Therefore, when investigating AE of TEA in the facial region, we included not only FNP but also cosmetic purposes.

Of the AE that resolved without medical treatment, bruising, pain in the treatment area and foreign sensation were the most common. Most of them resolved within 2 weeks; however, visible thread through the skin remained until week 4.

There are a few animal studies about the absorption of thread. When 4-0 polydioxanone thread was inserted into a Yucatan pig, whose skin structure is similar to that of humans, there was no change after 12 weeks. At week 24, polydioxanone thread was observed to be fragmented.^[7] A study in rats using 5-0 polydioxanone thread demonstrated slow fragmentation of thread after 3 months.^[8] However, there are no clear data on the rate of polydioxanone absorption in humans.

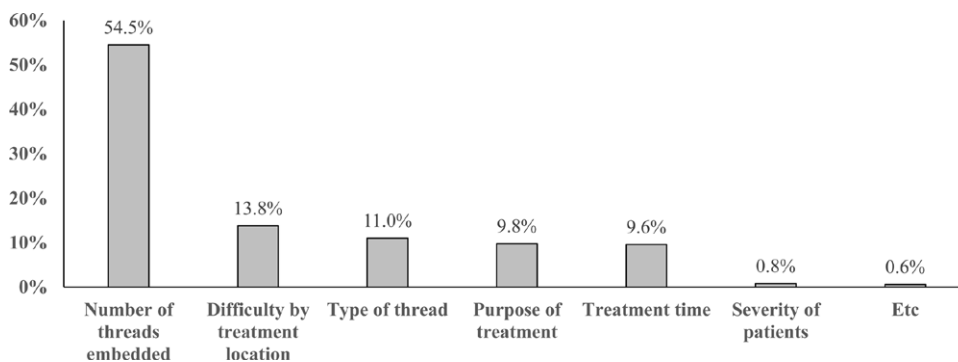


Figure 3. Standard criteria to determine the direct medical cost of treatment.

Table 6

Current state of thread embedding acupuncture use for facial nerve palsy.

Answers (total = 209)	n (%) or mean ± SD
Proportion of thread embedding acupuncture use in patients with facial nerve palsy	
0–19%	146 (69.9)
20–39%	32 (15.3)
40–59%	14 (6.7)
60–79%	8 (3.8)
80%	9 (4.3)
Stage of thread embedding acupuncture use (multiple choice)	
Acute inflammatory period and subacute period	53 (25.4)
Recovery period	100 (47.8)
Sequelae period	150 (71.8)
Concurrent treatment with thread embedding acupuncture (multiple choice)	
Acupuncture	193 (92.3)
Electroacupuncture	124 (59.3)
Herb medicine	123 (58.9)
Pharmacopuncture	110 (52.6)
Moxibustion	75 (35.9)
Cupping treatment	67 (32.1)
Physical therapy	61 (29.2)
Chuna manual treatment	32 (15.3)
Only thread embedding acupuncture	18 (8.6)
Needle size (multiple choice)	
18-gauge	1 (0.5)
21-gauge	29 (13.9)
23-gauge	14 (6.7)
25-gauge	24 (11.5)
27-gauge	49 (23.4)
29-gauge	104 (49.8)
31-gauge	60 (28.7)
Thread type (multiple choice)	
Monofilament	188 (90.0)
Cogfilament	27 (12.9)
Screwfilament	23 (11.0)
Multifilament	8 (3.8)
Interval of using thread embedding acupuncture on facial nerve palsy (weeks)	
Acute inflammatory period and subacute period	1.4 ± 0.69
Recovery period	1.6 ± 1.10
Sequelae period	2.2 ± 1.59

SD = standard deviation.

The safety of polydioxanone has been verified in a systematic review. Polydioxanone thread had lower rates of surgical site infection, inflammatory reactions, foreign body response and postoperative fever than non-polydioxanone thread.^[9] As a result, polydioxanone absorbs into tissue over time safely, and therefore, visible thread itself is not considered to be a severe adverse event.

Table 7

Current state of thread embedding acupuncture use for facial nerve palsy sequelae.

Answers (total = 150)	n (%) or mean ± SD
What symptoms do you treat using thread embedding acupuncture? (multiple choice)	
Contracture around mouth	113 (75.3)
Incomplete recovery of cheek movement	80 (53.3)
Contracture of nasolabial fold and cheek	75 (50.0)
Incomplete recovery of lips movement	75 (50.0)
Incomplete recovery of forehead movement	66 (44.0)
Contracture around eye	57 (38.0)
Synkinesis	43 (28.7)
Incomplete recovery of eye movement	42 (28.0)
Spasm of face	33 (22.2)
Tearing	7 (4.7)
Hearing disorders (hyperacusis, tinnitus, etc.)	6 (4.0)
What are the criteria to determine treatment area? (multiple choice)	
Anatomical structure	135 (90.0)
Local acupoints (on face region)	46 (30.7)
Distal acupoints based on meridian system	5 (3.3)
How many threads do you use?	
0–5	35 (23.3)
6–10	61 (40.7)
11–20	37 (24.7)
21–30	12 (8.0)
31+	5 (3.3)
How many treatments do patients need to get a significant improvement? (Sessions)	5.9 ± 2.64

SD = standard deviation.

When obtaining informed consent in a future study, we will notify participants of expected AE related to treatment. To examine the AE in further detail, causes of the AE, as cited by respondents, will need to be considered to design a careful treatment plan. Hence, particular attention will be paid to insertion depth, treatment area, type of thread, and skill level of the TKMD.

Regarding AE requiring medical treatment, dimple, fever, inflammation, and exposure of thread were the most common, but the proportion of sequelae was relatively low. However, damage to the salivary gland and hyperplasia, although rare, resulted in many patients requiring an extended recovery period or experiencing ongoing sequelae. There was a case report on granuloma in the treatment area after TEA on the face. The granuloma, which lasted months, resolved with the use of steroid injections.^[10]

Salivary gland damage and nerve damage were among those AE with a high tendency to lead to further sequelae. They are estimated to be closely related to insertion depth, treatment area, and skill level of the TKMD. Therefore, we need to consider

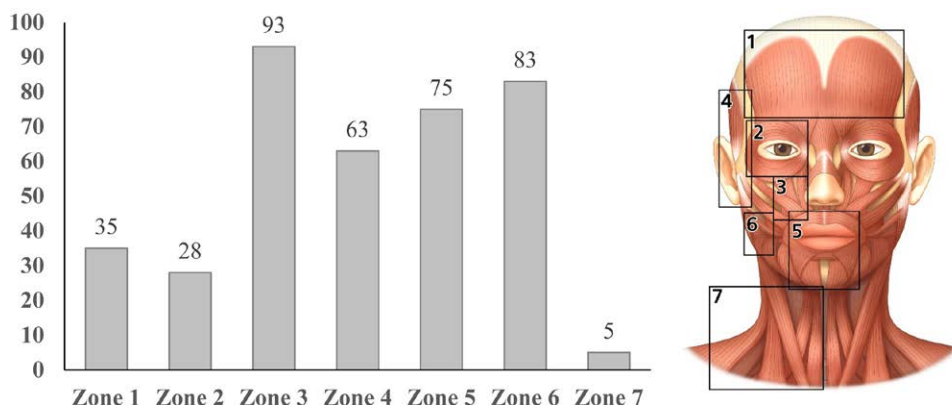


Figure 4. Anatomical structures used in thread embedding acupuncture for facial nerve palsy sequelae. Zone 1: around the frontalis muscle and galea aponeurotica. Zone 2: around the orbicularis oculi and corrugator supercilii muscles. Zone 3: around the levator anguli oris and levator labii superioris muscles. Zone 4: around the zygomaticus and temporal muscles. Zone 5: around the orbicularis oris and depressor anguli oris muscles. Zone 6: around the masseter and buccinator muscles. Zone 7: around the sternocleidomastoid and platysma muscles.

these factors closely to improve safety when determining treatment methods for clinical research.

In the case of hyperplasia, it is estimated that the wound-healing capacity of the individual patient or the type of thread are related. To identify the cause of hyperplasia, it is necessary to collect specific treatment information. In addition, a close consideration of the wound-healing capacity of patients is required when determining eligibility criteria for further studies.

In TEA treatment for FNP, the utilization rate of TEA increased as FNP progressed from the acute period to recovery to sequelae. To reduce nerve damage in the acute period, evidence-based treatments, namely steroids and antiviral drug treatments are provided. We estimated that low TEA use in the acute period is related to this standardized treatment protocol.^[11–13] However, there is no standardized treatment protocol for the sequelae of FNP. Therefore, a study on TEA can provide evidence to support its use as an adjunct to the current standardized treatment protocol in the post-acute phase of FNP within the field of alternative medicine.

In addition, participants responded that the most common purposes of TEA were incomplete movement and contracture around the mouth and cheeks, particularly since contractures are stubborn complications and an annoying discomfort to patients. Contracture itself is defined as a muscle that has shortened sufficiently to prevent complete range of motion of the joint.^[14] It is one of the common complications of FNP.^[15] During facial palsy, the affected muscles contract over time, which can cause a feeling of tightness. Shortening of the facial muscles can make the affected side of the face appear to be lifted, and the affected eye can appear smaller.^[16]

TEA is usually inserted between the subcutaneous and muscle layers, creating the same effect as subcision. Subcision cuts the adhered part of the subcutaneous layer with a needle, inducing bleeding in the area and resulting in the production of new connective tissue.^[17] Yoon also reported that connective tissue newly developed and capillary vessel size increased after thread insertion.^[7] These findings support the positive effect of TEA on contractures.

In order to evaluate the cost-effectiveness as well as the efficacy and safety of TEA, it is essential to collect information on the actual cost of the treatment.^[18] As TEA is not used in the national healthcare system in Korea, each medical institution charges different prices; therefore, it is difficult to create a standard cost system.^[19]

When TEA was used for disease treatment, an average of KRW 6.8 million was charged. The most important factor in calculating the cost was the number of threads used in treatment. Due to the nature of TEA, costs of material according to

Table 8

Acupoints used in thread embedding acupuncture for facial nerve palsy sequelae.

Answers	n (%)
Local acupoints used in thread embedding acupuncture for facial nerve palsy sequelae	
ST6	37 (84.1)
ST4	17 (38.6)
SI18	16 (36.4)
LI20	12 (27.3)
BL2, EX-HN5	11 (25.0)
EX-HN4	9 (20.5)
ST3, GV26, TE23	8 (18.2)
GB14, ST1, GB1	6 (13.6)
TE17, TE21	5 (11.4)
Distal acupoints used in thread embedding acupuncture for facial nerve palsy sequelae based on the meridian system	
LI4	3 (60.0)
ST36	2 (40.0)
LI5, LR3, SI5, LI2, KI20	1 (20.3)

the number of threads used in treatment and manpower administration time are important considerations. Therefore, it is necessary to develop a model that can be effective with minimal procedures to increase cost-effectiveness.

A standard treatment method should be derived for increased cost-effectiveness. We collected specific information on the general treatment method by survey. The most widely used method was insertion of 6 to 10 monofilament threads using a 29-gauge needle. In the treatment of sequelae, the treatment interval was about 2 weeks, and at least 5.9 sessions of treatment were required to observe meaningful improvement in symptoms.

From the specific detailed method of TEA for FNP presented in this study, we will be able to design a high-quality study in the future. Through specific investigation of the causes and symptoms of AE, we can create a safer treatment model. Moreover, we can evaluate cost-effectiveness through information obtained on real costs.

However, respondents represented 1.79% of all TKMDs who received the questionnaire. Because of the small proportion of TKMDs who responded, the results of this survey may not represent the opinion of all TKMDs using TEA. In addition, in order to determine a specific treatment method for the clinical study in the future, it is necessary to consult with a group of clinical experts.

Through this study, we identified expected AE and commonly used methods and details of TEA treatment. This study makes it possible to derive eligibility criteria and a standardized TEA treatment method that will reduce possible AE and increase efficacy in future studies.

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Author contributions

Conceptualization, Project administration, Formal analysis, Writing—Original Draft: Bonhyuk Goo.

Methodology, Writing—Review & Editing: Joo-Hee Kim.

Investigation, Writing—Original Draft: Dahae Kang.

Investigation, Writing—Review & Editing: Jung-Hyun Kim.

Writing—Review & Editing, Supervision, Funding acquisition: Sang-Soo Nam.

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