



Clinical effect and safety of thread embedding acupuncture on facial nerve palsy sequelae A retrospective observational study

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Abstract

The purpose of this study was to investigate the clinical effect and safety of thread embedding acupuncture (TEA) in patients with facial nerve palsy sequelae. This was a retrospective observational study on 82 patients treated with TEA from January 2021 to May 2022. The Facial Disability Index (FDI) reported by patients and Sunnybrook Facial Grading System scores assessed by clinical practitioners were used to evaluate the intensity of facial movements, functional problems, and psychosocial status. One-way repeated measure analysis of variance showed that the Sunnybrook Facial Grading System scores improved significantly following the 2nd to 6th TEA treatments (Txs). FDI scores also showed significant increases except for the 4th Tx. Additionally, the physical scores improved significantly among the subscales of FDI, but the social/well-being scores did not. There were no reported serious adverse events or adverse events requiring medical Tx. TEA is a safe Tx that has a clinically cumulative effect, in terms of patient-oriented self-assessment of functional problems and objective facial movements, for treating facial nerve palsy sequelae.

Abbreviations: FDI = Facial Disability Index, RCT = randomized controlled trial, SFGS = Sunnybrook Facial Grading System, TEA = thread embedding acupuncture, Tx = treatment.

Keywords: facial nerve palsy sequelae, Facial Disability Index (FDI), Sunnybrook Facial Grading System (SFGS), thread embedding acupuncture (TEA)

1. Introduction

Facial nerve palsy is a mainly unilateral disorder of the cranial nerve VII (the facial nerve), which innervates the muscles of facial expression^[1]; it has been reported that 15 to 30% of facial nerve palsy patients experience various sequelae.^[2,3] Intractable sequelae of facial nerve palsy include synkinesis, contracture, facial spasm, crocodile tear syndrome, hearing impairment, and persisting weakness.^[3] These symptoms make social communication difficult for patients and decrease their quality of life, frequently leading to significant psychological disorders such as anxiety and depression.^[4] Therefore, it is important to focus not only on treating the functional problem of facial palsy, but also improving the patient's psychological condition.

Thread embedding acupuncture (TEA) is a special type of acupuncture that inserts a medical thread at acupoints. The thread used in TEA dissolves gradually and prolongs the effect of acupuncture by continuous stimulation, [5] making it suitable

for cases of chronic disease. As shown in a previous review, [6] TEA has been used for treating the sequelae of facial nerve palsy but the quality of studies in this systematic review was low. Also, our previously conducted randomized controlled trial (RCT) showed an improvement in the Facial Disability Index (FDI) physical score, but the sample size was small and the follow up duration was short.^[7]

This study aimed to evaluate the clinical effect and safety of TEA in patients with facial nerve palsy sequelae so that it can be implemented clinically, and to provide basic data for future large-scale clinical research.

2. Methods

2.1. Study design

This was a retrospective observational study that used patient medical records. We screened patients who underwent TEA treatment (Tx) based on the eligibility criteria and performed

 $M ext{-}JK$ and BG contributed equally to this work.

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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the analysis by extracting the evaluation index before and after Tx. Additionally, a database was created that included patient age, sex, duration from onset, interval between assessment and Tx, and interval between Txs. This study was approved by the institutional review board (approval number: KHNMCOH 2022-01-002) which waived the requirement for informed consent.

2.2. Participants

Participants were treated at the Facial Palsy Center of Kyung Hee University Hospital at Gangdong.

The inclusion criteria were as follows: patients who were diagnosed with facial nerve palsy (G510 Bell palsy, B002.004 Ramsay–Hunt syndrome, S045 injury of facial nerve), patients who scored >1 point for synkinesis of the Sunnybrook Facial Grading System (SFGS), and patients who underwent TEA Tx more than once between January 2021 and May 2022.

The exclusion criteria were as follows: patients who underwent initial TEA Tx within 6 months of onset, patients who had no evaluation record before TEA Tx, and patients who had no evaluation record after TEA Tx.

2.3. TEA Tx

Participants received TEA Tx with polydioxanone sutures with a 29 gauge × 38 mm needle (Thread USP 6-0, 50 mm in length, Hyundae Meditech Co., Wonju, South Korea) on facial acupoints. The acupoints were chosen based on the RCT^[7] model, and a specialist in acupuncture and moxibustion gave a slight deformation depending on the patients' facial condition. Ten threads were used for each Tx.

2.4. Outcome measures

Patients were evaluated based on the FDI and SFGS scores before and 1 to 2 weeks after TEA Tx.

The FDI is a questionnaire of 10 items with 2 subscale scores and a maximum scale of 100 points, and higher scores indicate less impairment in individuals. Five items are related to physical function, and include functional problems with eating, drinking, speaking, lacrimation, and oral hygiene. The other 5 items are related to social/well-being function, and include the subjective perception of anxiety, irritation, isolation, sleep-related problems, and limitations in social participation.^[8]

The SFGS is widely used in clinical practice for a static and dynamic assessment of facial muscles based on the degree of synkinesis. It consists of 3 sections: 3 facial regions at rest (eye, cheek, and mouth) and 5 facial regions during voluntary motion, with or without synkinesis (brow lift, gentle eye closure, snarl, open mouth smile, and lip pucker). The composite score of 100 implies normal facial function.^[9]

Serious adverse events or adverse events related to TEA, including infection, thread extrusion, dimpling, foreign body reactions and other medical conditions requiring medical Tx,^[10] were recorded.

2.5. Statistical methods

Categorical variables were described as number and proportion, and continuous variables were shown as mean \pm standard deviation. The paired t test was used to compare changes between baseline and after Tx measures. From the second Tx onwards, one-way repeated measure analysis of variance was used to analyze changes in continual Tx. PASW Statistics 18 (SPSS Inc., Chicago, IL) was used for statistical analysis and statistical significance was set at P < .05.

3. Results

3.1. Participants & demographic characteristics

Eighty-two patients were enrolled in this study, and 14 patients (17.1%) were excluded because they either had initial TEA Tx within 6 months of the onset of facial palsy (n = 7) or had no evaluation record before (n = 4) or after (n = 3) TEA Tx. Patients who did not receive further Tx were not included in the study. Sixty-eight patients received the 1st Tx, 43 patients received the 2nd Tx, 37 patients received the 3rd Tx, 28 patients received the 4th Tx, 21 patients received the 5th Tx, and 18 patients received the 6th Tx. Demographic characteristics are shown in Table 1. The procedure and number of participants are presented in a flow chart (Fig. 1), and the results after each TEA Tx are indicated in Table 2.

3.2. Changes after the 1st Tx

FDI scores showed a significant improvement from 144.4 ± 31.85 at baseline to 151.9 ± 27.54 after the 1st Tx (P < .05). However, there was no significant improvement in the SFGS scores (P = .183) (Table 2) (Fig. 2A).

3.3. Changes after the 2nd Tx

After the 2nd Tx, both FDI and SFGS scores indicated a significant increase from baseline (P < .05) (Table 2). The scores also had a significant cumulative improvement according to one-way repeated measure analysis of variance (Fig. 2B).

3.4. Changes after the 3rd Tx

After the 3rd Tx, both FDI and SFGS scores showed significant improvement (P < .05) (Table 2), and changes in the scores also indicated the significance of cumulative Tx (Fig. 2C).

3.5. Changes after the 4th Tx

After the 4th Tx, the scores of FDI showed no significant improvement (P = .129), but the scores of SFGS were significantly improved from 59.0 ± 17.26 at baseline to 69.4 ± 16.34 (P < .05) (Table 2). In addition, changes in SFGS scores were significant in terms of cumulative Tx, but changes in FDI scores were not (Fig. 2D).

3.6. Changes after the 5th Tx

After the 5th treatment, the FDI and SFGS scores improved significantly (P < .05) (Table 2). Moreover, there was a significant cumulative improvement in both FDI and SFGS scores (Fig. 2E).

Table 1

Demographic characteristics.

Results (n = 68)	n (%) or mean \pm SD	
Sex		
Male	23 (32.8)	
Female	45 (66.2)	
Age	52.2 ± 14.69	
Duration from onset (mo) 50.04 ± 8		
Assessment interval from treatment (d)	8.6 ± 2.86	
Interval between treatments (d)	40.0 ± 30.59	

SD = standard deviation. After 1st TEA treatment (n=68)

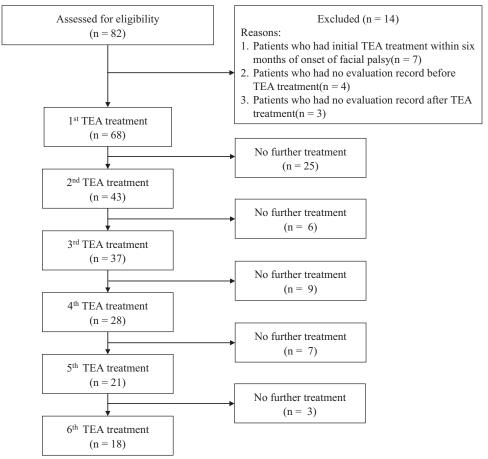


Figure 1. Flowchart of the study. TEA = thread embedding acupuncture.

3.7. Changes after the 6th Tx

After the 6th Tx, both FDI and SFGS scores improved significantly (P < .05) (Table 2), and there was a significant cumulative improvement in both FDI and SFGS scores (Fig. 2F).

3.8. Additional analysis of subscales of FDI

The subscales of the FDI score, including physical and social/well-being scores, were analyzed individually. Changes in the physical scores were significantly improved after each Tx, but changes in social/well-being scores did not show any significance (Fig. 3).

3.9. Safety of TEA

At each visit after TEA Tx, patients were required to report adverse events, and a doctor evaluated the patients' facial condition. No serious adverse events or adverse events requiring medical Tx were reported during the study.

4. Discussion

SFGS scores improved significantly after each TEA Tx. FDI scores showed significant improvement after the 1st, 2nd, and 3rd Txs, but not after the 4th Tx. However, further analysis of FDI subscales demonstrated that there was a statistically significant increase in the physical scores, but not in the social/well-being scores.

We excluded patients who received TEA Tx within 6 months of onset, since facial nerve palsy sequelae usually occur after 3 to 6 months.^[11] The mean duration from onset was over 50

months, indicating that the patients' sequelae were chronic and persistent. Synkinesis and contracture are known as the most common sequelae symptoms, [12] and the patients in our study also commonly suffered from synkinesis and contracture. Synkinesis is an involuntary associated facial movement, such as eye closure during smiling or mouth movement during blinking, and is considered to be the result of aberrant regeneration of the facial nerve. [13] Contracture is the condition of stiff and tense facial muscles, which is most common around the mouth. Long-term unresolved synkinesis may result in permanent contracture, which appears as a deep nasolabial fold and deviation of the philtrum. [14]

These sequelae may last either for several months or permanently, so patients need Tx that has long-lasting effects. Since TEA sustains the effect of acupuncture, patients do not need to undergo frequent Tx. Also, according to a previous experiment of polydioxane injected into animal tissue, there are tissue changes including newly developed fibrous connective tissue and increased capillary vessel size, [15] resulting in increased elasticity and blood circulation in the local area. Therefore, considering these findings from mechanical and chemical stimulation, we chose TEA as a Tx tool. We advised our patients to undergo TEA Tx every 1 to 2 months, and the patients in our study were treated approximately every 40 days, and with the minimum interval between Txs approximately 13 days.

Facial nerve palsy sequelae lead not only to awkward facial movement and functional problems, but also to psychological distress and reduced quality of life. Facial expressions of patients with facial nerve palsy sequelae are often perceived negatively by others, leading to avoidance of social interactions and frequently reported poor mood and depressive symptoms. [17]

Table 2

Results after the treatments.

After 1st TEA treatment	(n=68)			
	FDI total	FDI physical	FDI social/well-being	SFGS
Baseline	144.4 ± 31.85	74.9 ± 19.19	69.5 ± 19.75	56.0 ± 19.52
1 st	152.9 ± 27.54	79.0 ± 16.94	73.9 ± 17.77	58.3 ± 18.83
P value	<.05	<.05	<.05	.183
After 2nd TEA treatment	t (n = 43)			
	FDI total	FDI physical	FDI social/well-being	SFGS
Baseline	139.0 ± 32.47	71.3 ± 21.10	67.7 ± 19.27	54.1 ± 21.22
1st	148.2 ± 29.15	76.6 ± 18.38	71.5 ± 17.83	56.8 ± 19.52
2nd	152.6 ± 22.51	80.4 ± 13.78	72.3 ± 15.30	60.1 ± 18.82
P value	<.05	<.05	.220	<.05
After 3rd TEA treatment		1,00	.220	1,00
7 ittor ord 127 t doddinone	FDI total	FDI physical	FDI social/well-being	SFGS
Baseline	141.1 ± 33.45	74.3 ± 20.82	66.8 ± 19.48	57.4 ± 20.01
1st	149.7 ± 27.80	78.4 ± 18.03	71.4±17.73	59.1 ± 19.55
2nd	154.3 ± 21.92	81.6±13.13	72.7 ± 15.65	61.0±18.90
3rd	151.7 ± 25.61	81.2 ± 15.87	70.5 ± 13.87	64.5 ± 19.32
P value	<.05	<.05	<.05	<.05
After 4th TEA treatment		<.00	<.00	<.00
AILGI 4III ILA IIGAIIIGIII	FDI total	FDI physical	FDI social/well-being	SFGS
Baseline	143.1 ± 28.79	75.4 ± 19.34	67.7 ± 17.55	59.0±17.26
1st	147.4 ± 30.18	75.4 ± 19.54 76.3 ± 19.66	71.1 ± 18.80	59.9±19.02
2nd	152.8 ± 21.75	80.5 ± 13.70	71.1±16.60 72.3±15.77	62.9±16.48
3rd	152.0 ± 21.75 150.4 ± 27.29	79.8 ± 16.91	72.3 ± 13.77 70.6 ± 15.05	66.1 ± 17.47
4th	150.4 ± 27.29 150.6 ± 25.58	81.8 ± 16.06	68.9 ± 14.90	69.4±16.34
P value	.129	<.05	.565	09.4±10.34 <.05
		<.00	.505	<.00
After 5th TEA treatment		FDI physical	FDI accial/wall baing	SFGS
Baseline	FDI total	FDI physical	FDI social/well-being	57.8±16.27
	143.0 ± 29.08	76.0 ± 19.98	67.1 ± 15.90	
1st	152.6 ± 30.78	80.2 ± 19.52	72.4 ± 18.06	59.0 ± 18.03
2nd	154.0 ± 22.78	81.4 ± 14.42	72.6 ± 15.46	62.5 ± 14.78
3rd	150.0 ± 27.37	81.4 ± 16.59	68.6 ± 15.40	67.7 ± 17.34
4th	153.1 ± 25.84	84.5 ± 15.65	68.6 ± 16.26	69.1 ± 16.40
5th	160.1 ± 26.07	85.2 ± 16.39	74.9 ± 15.24	72.2±16.76
P value	<.05	<.05	.08	<.05
After 6th TEA treatment				
B "	FDI total	FDI physical	FDI social/well-being	SFGS
Baseline	149.7 ± 24.27	80.6 ± 17.31	69.1 ± 14.83	61.3 ± 12.25
1st	159.6 ± 24.96	84.7 ± 16.49	74.9 ± 17.18	62.4 ± 14.59
2nd	158.7 ± 17.04	84.4 ± 11.87	74.2 ± 14.66	64.9 ± 14.39
3rd	155.4 ± 22.59	85.0 ± 13.83	70.4 ± 14.53	71.7 ± 14.40
4th	158.6 ± 21.67	88.6 ± 11.22	70.0 ± 16.71	72.1 ± 14.43
5th	165.3 ± 20.81	88.9 ± 12.55	76.4 ± 15.09	75.0 ± 14.78
6th	163.1 ± 25.52	89.7 ± 13.66	73.3 ± 14.97	75.4 ± 13.46
P value	<.05	<.05	.253	<.05

Data was shown as mean \pm standard deviation.

FDI = Facial Disability Index, SFGS = Sunnybrook Facial Grading System, TEA = thread embedding acupuncture.

Several studies have shown an association between persistent sequelae and depressive symptoms related to these social aspects.^[18] Therefore, it is necessary to assess not only appearance and functional disability but also quality of life.

To evaluate objective facial symptoms as well as the functional and psychological status of patients, we selected the FDI and SFGS as evaluation tools. The FDI is a self-report questionnaire that assesses the physical disability and psychosocial status of facial nerve palsy patients. It is divided into 2 sections, which include physical and social/well-being functions, and provide an account of the patients' daily experience of living with a facial nerve disorder. [19] The SFGS is a reliable tool for assessing facial movement, especially for patients with facial nerve palsy sequelae. It indicates the status of the facial condition, including the symmetry at rest and during voluntary movements, and the presence and severity of synkinesis. [9] The assessment interval from Tx was about 8 days and did not exceed a maximum of 3 weeks.

Significant improvement in the SFGS score shows that 2 or more Txs with TEA, especially up to 6 Txs, have a clinically cumulative effect on treating facial nerve palsy sequelae. In particular, since the SFGS is scored based on facial appearance, our results show that TEA has a clinical effect on the improvement of facial movement. It is presumed that TEA has a clinical effect in lifting folds,^[20] especially the nasolabial fold that is made by contracture. It leads to a resolution of the facial muscle stiffness and correction of the deviation of the philtrum, thereby alleviating the contracture. Furthermore, when contracture is relieved, the degree of synkinesis can improve because muscles around the lips are pulled less during eye closure. Also, considering the long interval of Tx (approximately 40 days), we confirmed the long-term effect of TEA Tx.

Moreover, there was a statistically significant increase in physical scores, but not in the social/well-being scores of the FDI. This is consistent with the results of our previous rigorous RCT, which showed that TEA has a clinical effect in improving the physical score of the FDI.^[7] Since participants suffered from sequelae for a long time, it is difficult to improve psychosocial problems in a short period. This result shows that treating patients' psychosocial problems requires more time and further Tx.

^{*}P < .05 by paired t test.

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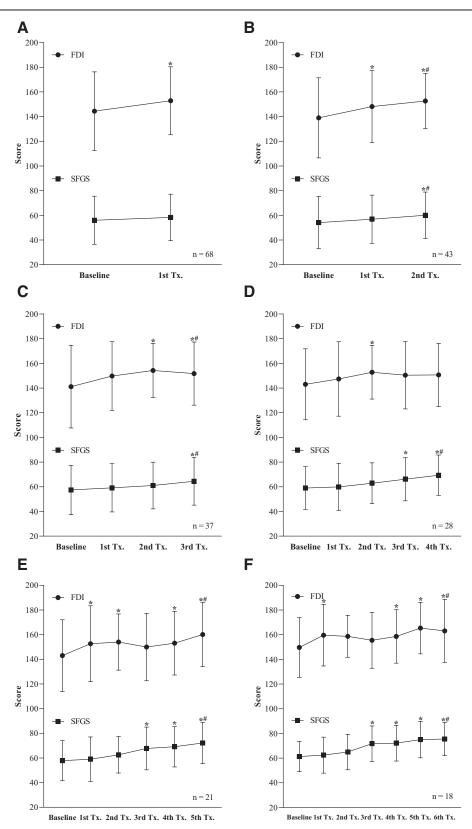


Figure 2. The results of FDI and SFGS score after the: (A) first Tx, (B) second Tx, (C) third Tx, (D) fourth Tx, (E) fifth Tx, and (F) sixth Tx. Measurements are expressed as mean \pm standard deviation. *P < .05 by paired t test compared with baseline, #P < .05 by one-way repeated measured analysis of variance. Tx = treatment, FDI = Facial Disability Index, SFGS = Sunnybrook Facial Grading System.

Furthermore, TEA Tx was done about 215 times during our study, but no serious adverse events such as death and life-threatening or adverse events requiring medical Tx were reported. This shows that TEA Tx is safe Tx.

There are some limitations of our study. First, this is a retrospective observational study, so the TEA Tx was not conducted independently, but occurred with acupuncture and bee-venom pharmacopuncture. However, we assessed TEA Tx in patients

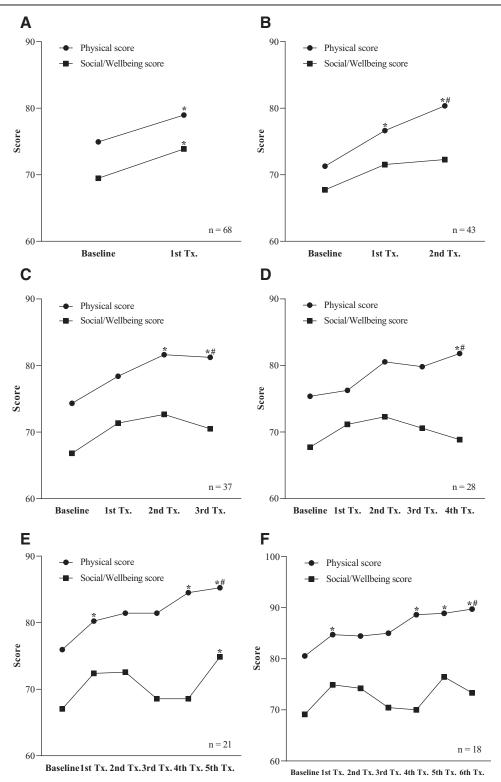


Figure 3. The results of FDI subscale score after the: (A) first Tx, (B) second Tx, (C) third Tx, (D) fourth Tx, (E) fifth Tx, and (F) sixth Tx. Measurements are expressed as mean \pm standard deviation. *P < .05 by paired t test compared with baseline, #P < .05 by one-way repeated measured analysis of variance. Tx = treatment, FDI = Facial Disability Index, SFGS = Sunnybrook Facial Grading System.

who did not have much improvement with conventional Tx s, including acupuncture and bee-venom pharmacopuncture, so we could conclude that the significant improvement was due to TEA Tx. Additionally, some patients were lost to follow-up due to the voluntary nature of the study. Therefore, participant sample size decreased after each Tx, raising the possibility of bias in the interpretation of the results.

Our study is meaningful because of its several strengths. First, the results were similar to that of our previous study, [7] which was a controlled trial. Second, it provides basic information for further clinical research such as the number of Txs, sample size, and outcome measurements. Third, because we proved the safety of TEA Tx, it serves as an opportunity to increase the application of TEA in the Tx of other diseases.

5. Conclusion

In conclusion, we confirmed the cumulative clinical effect of TEA Tx, especially in the SFGS score and the physical function of the FDI. It is considered safe as there were no serious adverse events. However, to assist with the psychosocial issues faced by patients, alternative Tx is needed. We hope that this study will be helpful in further research on TEA Tx for facial nerve palsy sequelae.

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Author contributions

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