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Research Article

The application of polydioxanone thread Implantation in rehabilitating sequelae of idiopathic peripheral facial paralysis: A pilot study

Hoa Khiet-Tieu Lieu[1,*], Khoa Tan Do[1], Nguyen Quang Doan[2], Quyen Thi-Le Nguyen[1], Senh Va Ly[1]

ABSTRACT

Background: Idiopathic peripheral facial paralysis often leads to chronic facial motor deficits in 30% of patients, significantly impacting their quality of life. Current treatment options for the chronic phase are limited. Polydioxanone (PDO) thread embedding has shown promise in improving facial disability in these patients, but evidence is scarce.

Objective: This pilot study aimed to explore the feasibility, preliminary safety, and potential effects of PDO thread embedding on improving facial motor function and disability in patients with chronic idiopathic peripheral facial paralysis.

Methods: In this prospective, single-arm, open-label clinical trial, 33 patients with chronic idiopathic peripheral facial paralysis (≥3 months) and Facial Disability Index (FDI) scores indicating significant impairment completed the study. Patients received weekly PDO thread embedding sessions for 6 weeks, with 10 threads per session. The primary outcome was the change in total FDI scores after 6 weeks. Secondary outcomes included changes in House-Brackmann grading (HB Grade), the proportion of patients achieving clinical improvement, and adverse events. **Results**: The intervention was associated with a significant improvement in the mean total FDI score, which increased from 88.30 ± 22.05 at baseline to 155.45 ± 18.39 at endpoint ($p < 0.001$). Both physical and social-well-being sub-scores improved significantly. Additionally, the proportion of patients classified as House-Brackmann Grade III (moderate) or better increased from 30.3% at baseline to 81.8% at endpoint ($p < 0.001$). Adverse events were mild and transient. **Conclusion**: This pilot study suggests that PDO thread implantation is a feasible and generally safe intervention, demonstrating promising preliminary evidence for improving facial motor function and overall quality of life in patients with chronic peripheral facial paralysis. The results warrant confirmation through larger-scale, randomized controlled trials.

Key words: Facial paralysis, PDO thread-embedding, Facial Disability Index, FDI, House-Brackmann grade

[1]*Traditional Medicine Hospital at Ho Chi Minh City, Vietnam*

[2]*Faculty of Traditional Medicine, University of Health Sciences, Vietnam National University Ho Chi Minh City, Vietnam*

Correspondence

Hoa Khiet-Tieu Lieu, Traditional Medicine Hospital at Ho Chi Minh City, Vietnam

Email: lieukhiethoa@gmail.com

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INTRODUCTION

Bell's palsy, or idiopathic peripheral facial paralysis, represents the most common acute mononeuropathy and primary cause of facial nerve dysfunction. Clinically, it manifests as unilateral loss of voluntary facial muscle control[1,2]. Although most patients recover, ~30% exhibit deficits beyond three months, with mild, moderate, and severe sequelae rates of 12%, 13%, and 4%, respectively[1-3]. In 2022, 732 patients presented at Ho Chi Minh City Traditional Medicine Hospital; 110 remained with unresolved deficits at three months. These chronic sequelae impair essential functions - eating, speaking, expression - and compromise social confidence and quality of life[1–3]. Management during the acute phase includes corticosteroids, antivirals, and physical therapy. However, chronic sequelae have few proven therapies: mime therapy is seldom used in Vietnam; botulinum toxin risks ptosis and headache; and surgical approaches carry anesthesia and infection risks and high cost[1–3]. These limitations create a clear unmet need for accessible, low-risk interventions that can restore function and quality of life in the chronic phase.

Approved by Decision No. 5480/QD-BYT of the Vietnamese Ministry of Health[4], thread embedding, also known as thread-embedding acupuncture (TEA), offers a practical alternative to frequent acupuncture sessions[5]. This technique inserts polydioxanone (PDO) threads into acupuncture points, providing sustained mechanical and biochemical stimulation over 90-210 days to promote collagen synthesis and muscle tone with minimal inflammation[5–10]. PDO threads induce localized fibrosis and collagen production, enhancing facial symmetry and motor function in chronic paralysis[11]. PDO thread implanta-

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tion likely exerts benefit through immediate mechanical support (lifting/repositioning), a localized fibroblastic/collagenogenic response around the absorbable PDO material, and prolonged low-grade mechanostimulation that may improve tissue tone, microvascularity and facilitate motor re-education. These mechanisms are supported by preclinical and clinical studies documenting PDO material properties and time-dependent tissue changes after insertion [7,8,11], as well as clinical reports of functional improvement after thread embedding [3,10].

While these mechanisms are supported by preclinical and descriptive clinical data, definitive high-quality evidence for its effectiveness in chronic facial palsy is still lacking [3]. Clinical trials designed to measure functional endpoints and to standardize implantation protocols are required to determine whether these tissue-level changes translate into meaningful improvements in facial motor function. To address this evidence gap, we performed a pilot, single-arm pre-post clinical study to examine the feasibility, safety and preliminary effectiveness of weekly PDO thread embedding in adults with chronic idiopathic peripheral facial paralysis. Our primary outcome was change in the Facial Disability Index (FDI) over six weeks, with secondary outcomes including changes in global facial grading and adverse events. The study was designed to generate effect-size estimates and safety data to inform future controlled trials.

MATERIALS-METHODS

Study Design

This study was a pre-post intervention clinical trial conducted at the Outpatient Department of Ho Chi Minh City Traditional Medicine Hospital, Vietnam, from July 2023 to July 2024.

Study Population

Sample Size

This study was designed and conducted as a pilot, single-arm, pre-post intervention study intended to (i) assess feasibility and safety of PDO thread embedding in chronic idiopathic peripheral facial paralysis and (ii) produce preliminary estimates of effect size and outcome variance to inform sample size calculations for a future definitive trial. A formal hypothesis-testing sample size calculation was not performed. We targeted an initial enrolment of 30 participants on pragmatic and pilot-study conventions (to provide stable preliminary estimates and to permit basic feasibility assessment), resulting in recruitment of 39 participants. Target enrollment of 39 was based on pilot conventions of Hertzog 2008 [12] and Julious 2005 [13], and an expected 20-30% attrition rate from similar facial palsy studies (e.g., Park et al. 2020 [3]).

Inclusion Criteria

Patients were included if they met the following criteria: (1) aged 18 years or older; (2) diagnosed with primary peripheral facial paralysis for at least 3 months; (3) FDI physical score <70 and FDI social score <80; and (4) provided informed consent to participate in the study.

Exclusion Criteria

Patients were excluded if they presented with any of the following: (1) pregnancy, recent childbirth ($\leq$6 months), or breastfeeding; (2) history of allergy to PDO threads or severe keloid scarring; (3) skin infection at the implantation site, bleeding disorders, or use of anticoagulant medications; (4) acute illnesses, psychiatric disorders, or other systemic diseases requiring immediate intervention at the time of the study; (5) bilateral or recurrent peripheral facial paralysis (more than two episodes).

Methods

Baseline Assessment

Prior to intervention, the following baseline characteristics were recorded for each patient: (1) age; (2) gender; (3) duration of illness; (4) history of diabetes or hypertension; (5) previous treatments (e.g., corticosteroids, acupuncture, massage, physical therapy, thread embedding); (6) FDI total score, FDI physical score, and FDI social score; and (7) House-Brackmann grading (HB Grade).

Intervention

Patients underwent PDO thread embedding once weekly for six consecutive weeks, treatments were scheduled exactly 7 days apart (day 0, day 7, day 14, day 21, day 28 and day 35). Each session utilized 10 PDO threads, with needle sizes (31G-30 mm, 29G-40 mm, or 29G-50 mm) selected based on the muscle thickness at the implantation site. The procedure was performed by certified traditional medicine specialists trained in thread embedding. The technique involved thread insertion through specific acupuncture points, the selected points were: Taiyang (EX-HN5) - Tongziliao (GB1), Yangbai (GB14) - Yuyao (EX-HN4), Cuanzhu (BL2) - Jingming (BL1), Daying (ST5) - Jiache (ST6), Dicang (ST4) - XiaGuan (ST7), Dicang (ST4) - Yingxiang (LI20), Yingxiang

(LI20) - Jingming (BL1), Yingxiang (LI20) - Shangguan (GB3), Yingxiang (LI20) - Xia Guan (ST7), Yingxiang (LI20) - Quanliao (SI18). The additional facial acupoints included in our implantation protocol were selected to ensure comprehensive targeting of the principal motor zones of facial expression (periorbital, midface/zygomatic and perioral/nasolabial regions) and to align with current national procedural guidance and contemporary thread-embedding practice. This approach is supported by the Vietnamese Ministry of Health procedural guidance[4] and by prior TEA/thread-embedding reports indicating that denser, muscle-centric placements over the superficial musculoaponeurotic system increase local mechanical support and promote sustained collagenogenic responses[3,10,11] in targeted functional units.

Assessment

The FDI is a 10-item questionnaire that evaluates physical and social disabilities resulting from facial paralysis. The questionnaire was translated into Vietnamese following a standard forward-backward translation procedure. Facial paralysis severity was assessed using the HB Grade system (HB Grade I-VI), which evaluates facial appearance at rest and voluntary movement (Grade I = normal; Grade VI = total paralysis; mean assessment time 1.06 $\pm$ 0.24 min)[2,14,15], and functional impact by the FDI (physical α = 0.88; social α = 0.83; validated against the Short Form-36 Health Survey (SF-36)). Assessments were performed using standardized clinical maneuvers (forehead wrinkling, gentle eye closure, broad smile, lip puckering) to evaluate resting symmetry and voluntary movement. The HB system and its clinical definitions are described in the original publication and validated comparisons[14,15]. At the same time, the study monitored adverse events (e.g., fainting, bleeding, swelling, infection, bruising) throughout the study period. Facial paralysis severity was assessed using the HB grading system (grades I-VI); in our sample the observed HB grades ranged from I to V.

Outcome Measures

Primary Outcome

The primary outcome was the change in FDI scores at baseline, 3 weeks, and 6 weeks of treatment.

Secondary Outcomes

Secondary outcomes included:

1. Change in HB Grade after 6 weeks of treatment (ranging from Grade I [normal] to Grade VI [total paralysis]).
2. Proportion of patients achieving effective improvement in facial motor function, defined as HB Grade $\leq$ II and a reduction of at least one grade from baseline after 6 weeks. Patients who achieved complete recovery (HB Grade=I) before 6 weeks were discontinued from intervention and classified as having achieved effective improvement.
3. Incidence of adverse events, including fainting, bleeding, swelling, infection, and bruising following thread embedding.

Statistical Analysis

Descriptive statistics (means $\pm$ Standard Deviation [SD], counts and percentages) were computed using Stata 14.0. HB grade was analyzed as an ordinal outcome. To evaluate change in HB grade over time we fitted a mixed-effects ordinal logistic regression (proportional-odds) model with a cumulative logit link. Time (week 0, week 3, week 6) was entered as a categorical predictor and a random intercept for patient ID was included to account for within-subject correlation. The proportional-odds assumption was tested using the Brant test; if violated, an alternative model (e.g., generalized estimating equations) would be used. Results are reported as odds ratios (ORs) and 95% confidence intervals (CIs); an OR < 1 indicates reduced odds of being in a more severe HB category (i.e., clinical improvement) compared with the reference time (week 0). For FDI scores (continuous), changes were analyzed using a linear mixed-effects model with time as a categorical fixed effect and a random intercept for patient ID. Efficacy analyses were performed based on a Per-Protocol set, defined as participants who completed the full 6-week intervention and underwent all scheduled assessments (n=33). Participants who withdrew prior to the first follow-up assessment (week 3) or failed to complete the intervention protocol were excluded from the primary efficacy analysis due to the absence of post-baseline data. For the included participants, the Linear Mixed-Effects Model (LMM) was employed to evaluate changes over time, as LMM is robust in handling longitudinal data. Effect sizes (Cohen's d for FDI changes) and variance estimates were calculated to inform future trial sample sizes. Model fitting was performed in R (version 4.4.3) using the *clmm()* function from the ordinal package for HB and *lmer()* from lme4 for FDI. R code used to reproduce the analysis is provided in the Supplementary File. If

the proportional-odds model showed signs of instability (e.g., due to data separation), sensitivity analyses were conducted using non-parametric Wilcoxon signed-rank tests for paired ordinal changes between time points.

Ethical Considerations

The study was approved by the Ethics Committee of Ho Chi Minh City Traditional Medicine Hospital (Decision No. 01/YHCT-HDDD, dated June 28, 2023). All participants provided written informed consent prior to enrollment.

RESULTS

Of the 39 participants enrolled, 33 completed the study; six withdrew due to geographical constraints.

Baseline Characteristics

A total of 39 participants were enrolled and received the first treatment. However, 6 participants were lost to follow-up for unknown reasons prior to the week 3 assessment. Consequently, 33 participants completed the full 6-week protocol and were included in the final analysis. The flow of participants is detailed in Figure 1 (CONSORT Diagram).

Participants had a mean age of 47.70 $\pm$ 15.09 years, with 75.80% female. The mean illness duration was 32.88 $\pm$ 41.48 weeks. Electroacupuncture was the most common prior intervention, utilized by 27 participants (81.80%). Within this group, the indication for moxibustion was consistently performed concurrently with electroacupuncture, and 22 participants (66.70%) underwent moxibustion. Other interventions included: massage and acupressure (69.70%), and physical therapy (54.50%). No prior thread embedding was reported. See Table 1 and Table 2 for details.

Effectiveness of the Intervention

PDO thread implantation suggested preliminary improvements in facial motor function. The mean total FDI score rose from 88.30 $\pm$ 22.05 (95% CI: 81.0-95.6) at baseline to 155.45 $\pm$ 18.39 (95% CI: 149.4-161.5) at week 6 ($p < 0.001$ from linear mixed model), with a mean change of 67.15 (95% CI: 58.2-76.1) and Cohen's d = 3.05 indicating a large effect size. Significant gains were observed in physical and social subscores ($p < 0.001$). Detailed numerical data for FDI subscales and total scores are provided in **Supplementary Table S2**. The trajectory of improvement over the 6-week period is illustrated in Figure 2.

The distribution of HB grades changed markedly over time, as shown in Figure 3 and Figure 4**.** In a mixed-effects ordinal logistic regression with a random intercept for patient, the odds of being in a more severe HB category were substantially lower at week 3 and week 6 compared with baseline. Specifically, compared with week 0, the OR for week 3 was 7.06×10^{-5} (95% CI: 7.05×10^{-5} - 7.07×10^{-5}, $p < 0.001$ via Wald test) and for week 6 was $1.68 \times 10^{-}$ (95% CI: $1.67 \times 10^{-}$ - $1.68 \times 10^{-}$, $p < 0.001$). These extremely small ORs and narrow CIs reflect near-complete separation in the data (e.g., no severe grades at later timepoints), indicating model instability despite no violation of proportional-odds (Brant test $p = 0.12$); interpret with caution due to the small sample size. Sensitivity analyses using Wilcoxon signed-rank tests confirmed significant improvements (week 3 vs. baseline: $p < 0.001$; week 6 vs. baseline: $p < 0.001$). The raw distribution of House-Brackmann grades for the 33 completers is detailed in **Supplementary Table S1**. In the mixed-effects ordinal logistic regression, the odds of being in a more severe HB category were significantly lower at week 3 and week 6 compared with baseline (Table 3). The model yielded extremely small odds ratios with narrow confidence intervals, reflecting the complete separation of data points (e.g., no severe grades remained at week 6). Given this model behavior, we confirmed the statistical significance of improvement using the Wilcoxon signed-rank test as a non-parametric sensitivity analysis, which consistently showed significant gains ($p < 0.001$ for both timepoints). Effective improvement (HB Grade $\leq$ II with at least a one-grade reduction) occurred in 60.60% of participants (95% CI: 42.1-77.1%), as reported in Table 4.

Adverse Events

Mild, self-limiting adverse events included cumulative per-patient incidence of bleeding (66.70%), swelling (45.50%), and bruising (24.20%), as shown in Table 5.

DISCUSSION

General Characteristics of the Study Sample

The mean age of study participants was 47.7 $\pm$ 15.1 years, which is comparable to the mean ages reported in similar thread-embedding or TEA trials (e.g., Park et al. reported group means of 50.07 $\pm$ 13.6 and 49.39 $\pm$ 9.99 years for TEA and sham groups, respectively[3]). Our sample therefore reflects an adult population in the middle-age range rather than a predominantly young cohort; this pattern is likely attributable

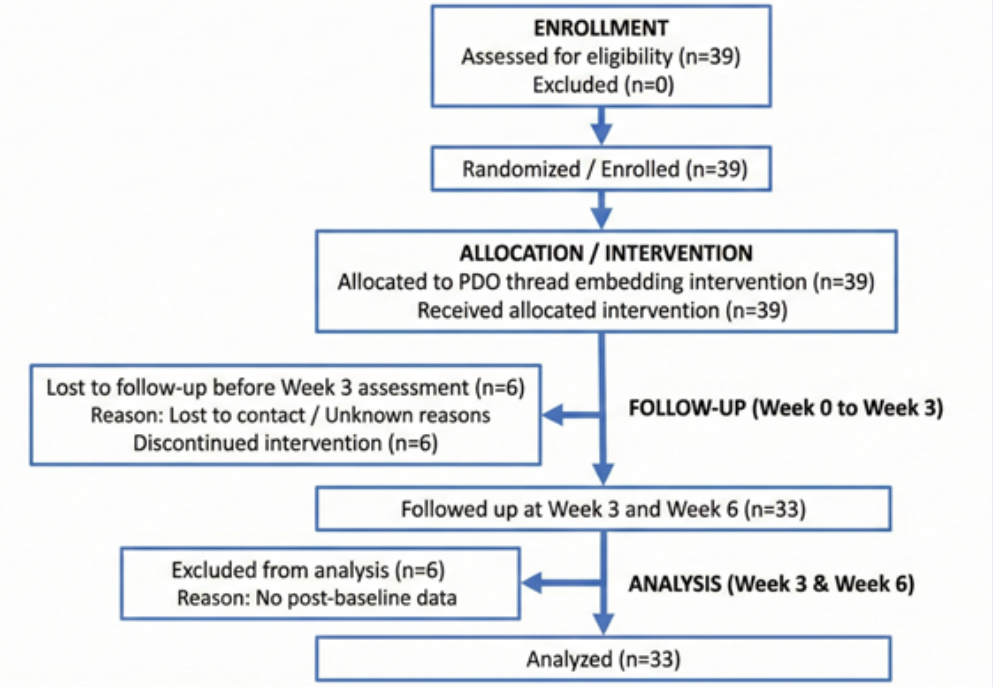

Figure 1: CONSORT Flow Diagram. Source: Authors

Table 1: Baseline Characteristics of Age, Gender, and Duration of Illness

Characteristic		Mean ± SD or N (%)
Age (years)		47.70 ± 15.09
Gender	Male	8 (24.20%)
	Female	25 (75.80%)
Duration of illness (weeks)		32.88 ± 41.48

Table 2: History of Previous Interventions

Intervention	N (%)	Start Day (Mean ± SD)	Duration (Mean ± SD)	Dose/Frequency
Corticosteroid	14 (42.40%)	1.93 ± 0.73 days	7.21 ± 0.80 days	22.85 ± 8.22 mg/day
Electroacupuncture	27 (81.80%)	3.78 ± 2.06 days	12.96 ± 4.63 weeks	5.81 ± 1.00 sessions/week
Moxibustion	22 (66.70%)	3.78 ± 2.06 days	12.96 ± 4.63 weeks	5.81 ± 1.00 sessions/week
Massage and acupressure	23 (69.70%)	3.78 ± 2.09 days	12.91 ± 4.26 weeks	5.61 ± 1.40 sessions/week
Physical therapy	18 (54.50%)	13.22 ± 20.91 days	6.61 ± 3.70 weeks	4.89 ± 1.08 sessions/week
Thread embedding	0 (0.00%)	-	-	-

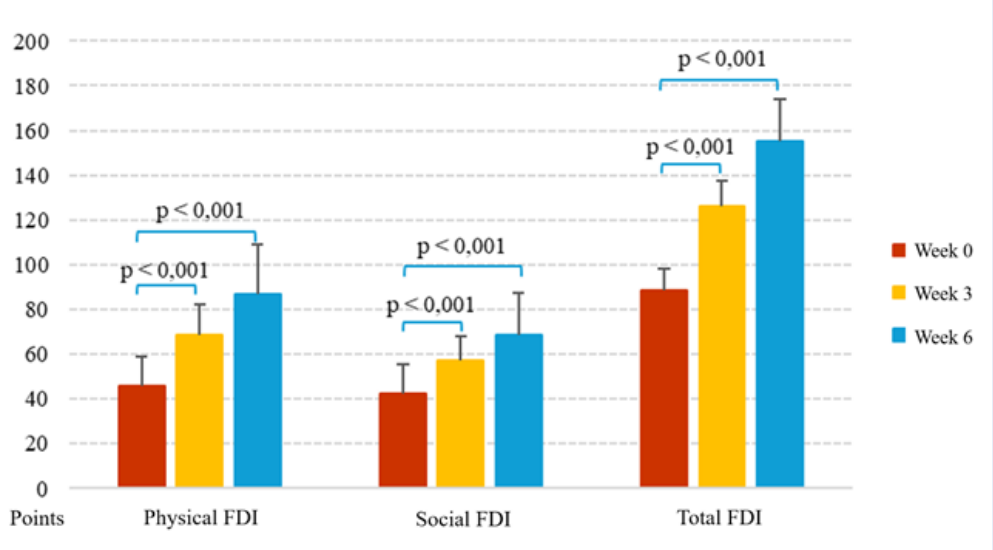

Figure 2: MeanFDI scores at baseline, week 3, and week 6 following PDO thread implantation. Caption: Mean FDI scores atbaseline, week 3, and week 6 following PDO thread implantation, with 95% Clerror bars. Changes tested via linear mixed-effects model ($p < 0.001$).
Source:Authors

Table 3: Odds Ratios for improvement in House-Brackmann grade derived from mixed-effects ordinal logistic regression

Comparison	Odds ratio (OR)	95% CI
Week 3 vs Week 0	7.06×10^{-5}	7.05×10^{-5} - 7.07×10^{-5}
Week 6 vs Week 0	$1.68 \times 10^{-}$	$1.67 \times 10^{-}$ - $1.68 \times 10^{-}$

*Statisticaltest: mixed-effects ordinal logistic regression (cumulative logit,proportional-odds) with random intercept for patient. ORs (95% CI) compare week3 and week 6 with week 0. HB grade treated as ordered categories (HB grades I-VI;observed range I-V) *Interpretation:* Compared with week 0, the odds of belongingto a more severe HB category were substantially lower at week 3 and week 6, indicating marked clinical improvement over time. (OR < 1 denotes decreased odds of worse HB grades.)

Table 4: Proportion Achieving Treatment Effectiveness

Outcome		%
Achieved	20	60.60%
Did not achieve	13	39.40%

Table 5: Adverse Events of the Intervention

Adverse Event	N	%
Bleeding	22	66.70%
Swelling	15	45.50%
Bruising	8	24.20%

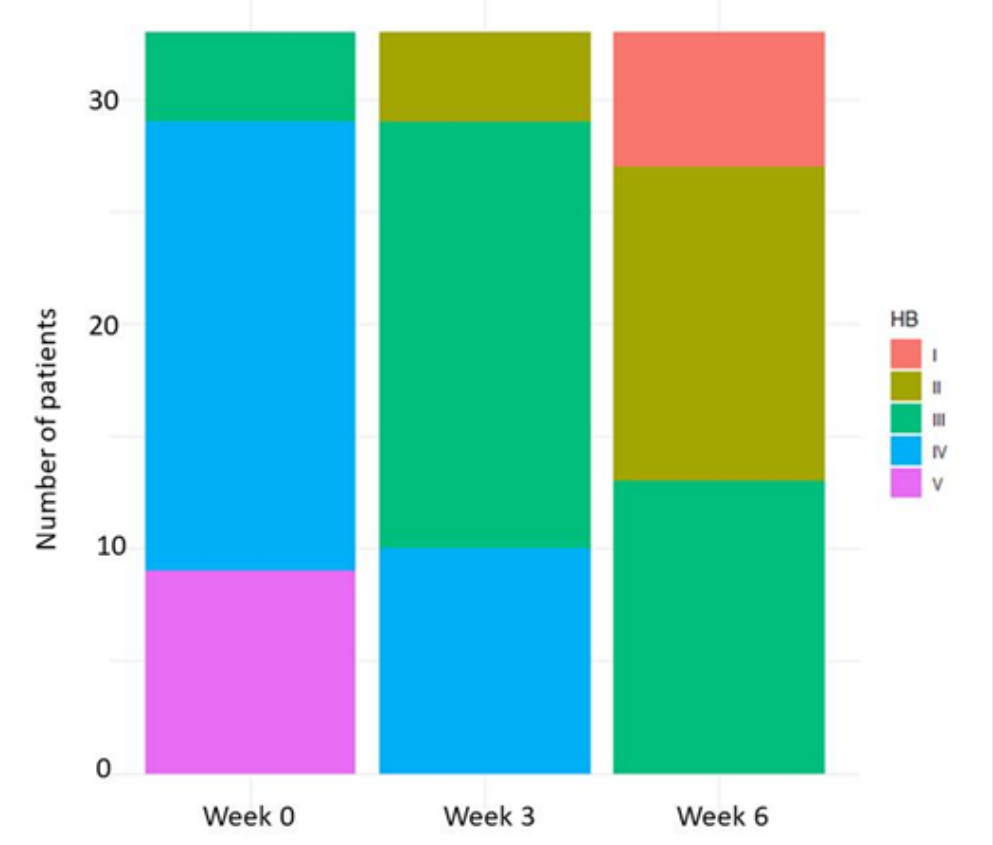

Figure 3: Stackedbar showing distribution of HB grades at week 0, week 3 and week 6. HB = House-Brackmann grade. Ordinal logistic regression with randomintercepts was used to test change over time (see Methods).
Caption: Stacked bar chart illustratingthe distribution of HB grades across study timepoints (Baseline, Week 3, andWeek 6). The height of each color segment represents the count of patients withthat specific HB grade. Note: Analysis at Week 6 includes n=33 participants, as6 patients were lost to follow-up.
Source: R (version 4.4.3)

to the study's inclusion of chronic cases (≥3 months), referral pathways to a traditional medicine outpatient service, and the tendency for older patients to seek sustained conservative management for persistent functional or aesthetic concerns. These recruitment and healthcare-seeking factors plausibly explain any departure from the younger age distribution reported in some acute-phase cohorts.

The majority of participants in our study were female (75.80%). This may be attributed to female patients being more likely to seek traditional medicine or having a greater concern for facial aesthetics, thus exhibiting a stronger desire for complete recovery. However, a survey by Fujiwara et al.[16] involving 679 patients with primary peripheral facial paralysis found that gender does not influence recovery prognosis. Therefore, the predominance of female participants is not a result of our selection criteria, which included only patients with significant facial disability after three months.

The mean duration of illness in our sample was 32.88 weeks, ranging from 13 to 156 weeks. Previous reports indicate that approximately 85% of patients with primary peripheral facial paralysis show partial recovery within the first three weeks, with the remaining 15% recovering after three to five months. About 70% achieve complete recovery, while among those with incomplete recovery, 12% have very mild paralysis, 13% mild paralysis, and 4% severe paralysis[17]. Our study included patients with primary peripheral facial paralysis persisting beyond three months and with significant facial disability (physical FDI <70 and social FDI <80), indicating a poor prognosis for spontaneous recovery. Furthermore, Holland et al.[18] suggest that patients who do not recover within three weeks may have severe facial nerve degenera-

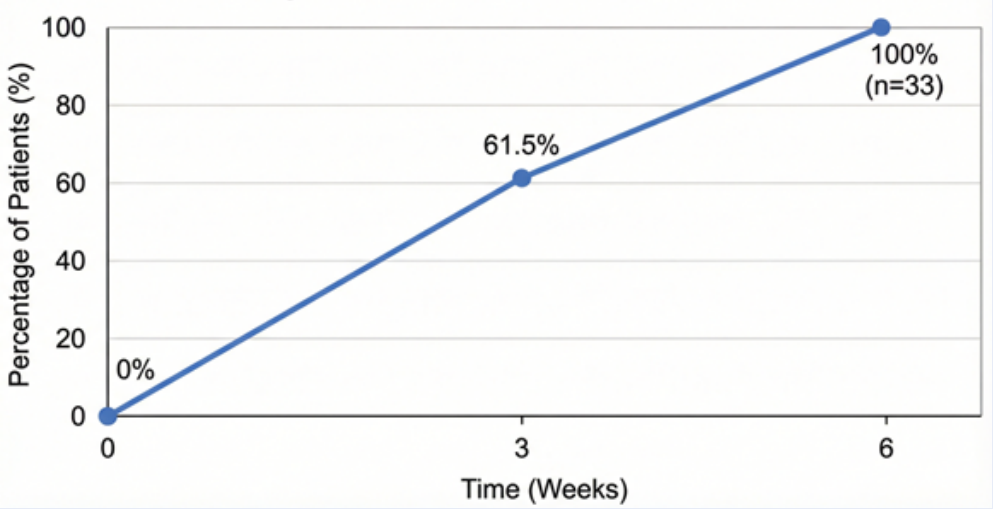

Figure 4: Percentage of Patients with HB Grade II overtime. HB = House-Brackmann grade. Ordinal logisticregression with random intercepts was used to test change over time (seeMethods).
Caption: Line graph showing thecumulative percentage of patients achieving clinically significant recovery (HB-grade II) overtime. Data points represent the proportion of analyzed patients achieving HBgrade I or II at Baseline (0%), Week 3 (~61.5%), and Week 6 (100% ofcompleters).
Source: Authors.

tion. Xiao et al.[19] found that the rate of incomplete recovery increases by 7.99 times when acupuncture is initiated during the chronic phase compared to the acute phase (95% CI: 4.57-13.99). This explains why most patients in our study, despite prior acupuncture, still exhibited significant facial disability. Thus, the patients in our sample had severe impairment and a lower likelihood of spontaneous recovery, suggesting that the observed improvements in facial disability are likely associated with the thread embedding intervention.

Corticosteroid therapy in the acute phase of Bell's palsy is recommended by major guidelines and systematic reviews and has been shown to reduce the risk of incomplete recovery[2,20]. In our study, 14 participants (42.4%) reported prior corticosteroid treatment yet continued to exhibit persistent functional deficits at $\geq$3 months, indicating that a subset of patients progress to chronic sequelae despite receiving acute-phase therapy. This observation supports the rationale for investigating alternative rehabilitative approaches, such as PDO thread embedding, in patients with chronic facial paralysis. Detailed analysis of corticosteroid regimens, dosing, and timing is beyond the scope of this pilot study and would be better addressed in larger, prospectively designed investigations.

Most patients had previously undergone electroacupuncture (81.80%), and some also receiving moxibustion (66.70%). Electroacupuncture is widely used clinically for primary peripheral facial paralysis and has become increasingly popular in recent years[21,22]. Therefore, the fact that most patients in our study had already received electroacupuncture reflects current clinical practice and indicates that these patients responded poorly to electroacupuncture, necessitating alternative interventions to address their facial disability.

Effectiveness of the Intervention

The study results demonstrated statistically significant improvements in the mean physical FDI scores at weeks 3 and 6 compared to baseline ($p < 0.001$ from linear mixed model), with large effect sizes (Cohen's $d > 3.0$). This pattern was consistent across the mean social FDI and total FDI scores. These findings corroborate reports by Lin et al.[22]. Notably, our study observed a substantial effect size (Cohen's $d = 3.05$), numerically higher than that implied in the study by Park et al. ($d \approx 1.5$)[3]. However, this comparison should be interpreted with caution, as open-label designs may overestimate treatment effects compared to blinded, controlled trials due to non-specific effects. Lou et al.[23] emphasized that the choice of acupuncture points is the most critical determinant of electroacupuncture efficacy in treating primary peripheral facial paralysis, suggesting that our enhanced FDI

outcomes may partly stem from the specific acupuncture points selected for thread embedding. The implantation points used in this trial (listed in Methods and Table 6) were selected to provide focal mechanical support to weakened facial soft tissues, to induce sustained fibroblastic/collagenogenic remodeling that restores soft-tissue bulk and symmetry, and to deliver prolonged low-grade local stimulation that may facilitate peripheral re-innervation and motor re-education. These mechanistic effects are the rationale for concentrating PDO-thread placement across the functional facial zones relevant to eye closure, midface elevation and oral commissure movement. Park et al. (2020) performed a rigorous randomized, patient-assessor-blinded trial using ten predefined TEA trajectories together with concurrent acupuncture in both groups[3]. While there is overlap in many core points (for example ST4, ST5, ST6, ST7, SI18, LI20 and BL1 appear in both studies), our regimen differs in two operationally important ways: (1) point density and repeat targeting of perioral/zygomatic motor zones - we systematically included additional perioral/zygomatic per-session placements (e.g., repeated ST4/ST6/ST7 region threads across the superficial musculoaponeurotic system layer) to concentrate mechanical and biochemical stimulus over the oral commissure and zygomatic muscles; and (2) broader periorbital coverage - we included supplementary lateral and medial periorbital points (e.g., GB1, BL2, EX-HN4/5, GB14) in each treatment to address eye closure and brow asymmetry more directly. These operational differences may partially contribute to the relatively larger gains in oral-motor components of composite scoring (FDI physical and HB Grade oral aspects) observed in our cohort: re-establishing symmetry and tone of the zygomaticus/levator labii complexes produces disproportionate improvement in oral commissure elevation and overall visible facial symmetry, which are heavily weighted in the outcome measures used. Because Park et al. and our trial both combined TEA with concurrent acupuncture and used similar outcome instruments, a head-to-head point-by-point comparison is an appropriate explanatory strategy - but causal attribution to any single point is limited by the multifocal nature of TEA and by differences in point density, thread trajectories and implantation technique. For transparency we provide a supplementary mapping of each acupoint to its putative anatomical target and functional role (Table 6), and we recommend that future trials either harmonize point-maps or prospectively randomize point-sets to test this mechanistic hypothesis.

A once-weekly regimen was chosen for this pilot because it is commonly used in clinical TEA trials and allows reproducible, repeated mechanical stimulation across an early treatment window (see Park et al. for a comparable trial design)[3]. From a biological perspective, PDO threads produce an immediate mechanical lift and trigger time-dependent fibroblastic and collagenogenic responses that evolve over days to weeks; delivering sessions at 7-day intervals provides repeated local stimuli that may accumulate structural and neuro-functional changes within the short-term follow-up used here[8,11]. Finally, weekly scheduling improves participant adherence and aligns with the week-3 and week-6 outcome assessments used in this prospective pilot. Although cosmetic PDO practice sometimes spaces procedures at longer intervals for maintenance (commonly 2-3 weeks), the weekly TEA cadence is defensible for a short-term mechanistic/clinical pilot; definitive trials should evaluate alternative spacing (e.g., 14-21 days) to compare early functional gains versus longer-term remodeling[3].

On the other hand, at baseline, most patients were classified as HB Grade IV (60.60%). Post-intervention, this shifted to Grade III (57.60%) at week 3 and Grade II (42.40%) at week 6, with statistically significant differences ($p < 0.001$ from ordinal model and Wilcoxon sensitivity). However, the extreme OR estimates suggest data separation, limiting the reliability of the proportional-odds model; future studies should use larger samples to avoid this issue. Effective improvement in facial motor function, defined as HB Grade $\leq$ II with at least a one-grade reduction after 6 weeks, was observed in 60.60% of patients. In comparison, Zhu et al.[24] reported an 85.7% effectiveness rate (>26% HB Grade improvement). Redefining effectiveness as HB Grade $\leq$ III, all patients in our study met this threshold after 6 weeks. A meta-analysis by Lin et al.[22] of 10 randomized controlled trials (n = 845) further supports thread embedding's efficacy, showing a 1.13-fold increase in treatment success compared to acupuncture alone (95% CI: 1.02-1.26, $p = 0.03$) and a 1.18-fold increase versus electroacupuncture (95% CI: 1.11-1.25, $p < 0.001$).

Given the sample size of this pilot cohort, we did not perform formal subgroup or interaction analyses to test whether age modifies treatment response. Prior literature indicates age can influence spontaneous recovery after acute Bell's palsy; whether age also modifies response to later-stage interventions such as PDO thread embedding remains an open question and should be addressed in larger, prospectively powered studies.

Table 6: Point-by-point mapping comparison with the study of Park et al (2020)

Acupoint (standard name)	Clinical/anatomical rationale	Functional role for facial palsy recovery	Used in Park et al. (2020)?	Used in our study?
ST4 (Dicang)	Corner of mouth - orbicularis oris, levator anguli oris, risorius	Elevation of oral commissure, lip mobility, smile symmetry	Yes	Yes
ST6 (Jiache)	Over masseter region - zygomaticus/levator complex adjacent	Buccal cheek tone, oral commissure support (affects smile dynamics)	Yes	Yes
ST5 (Daying)	Lower cheek / masseter border	Midface bulk/support, cheek tone	Yes	Yes
ST7 (Xiaguan)	Pre-auricular / masseter/zygomatic region	Zygomaticus/buccinator complex - smile and lateral facial tone	Yes	Yes
SI18 (Quanliao)	Infra-orbital / zygomatic region	Elevation of oral commissure, infra-orbital soft-tissue support	Yes	Yes
LI20 (Yingxiang)	Nasolabial region / alar base	Nasolabial tone, nasal-lip symmetry, upper lip position	Yes (used as target in several trajectories)	Yes
BL1 (Jingming)	Medial periorbital / orbicularis oculi	Eye closure, corneal protection, resting symmetry	Yes	Yes
BL2 (Cuanzhu)	Medial eyebrow / corrugator region	Brow and medial eye lid symmetry, orbicularis oculi modulation	(Park used BL1/BL2 in acupuncture; TEA list emphasizes BL1; paper describes periorbital coverage)	Yes
GB1 (Tongziliao), GB14 (Yangbai), EX-HN4/5 (Yuyao/Taiyang)	Lateral periorbital and forehead	Lateral eye closure, brow elevation, frontalis modulation for asymmetry	Not emphasized in Park TEA trajectories (Park focused TEA trajectories toward LI20/BL1 and midface); these points were part of concurrent acupuncture in Park but not primary TEA trajectories.	Yes (our study included these for expanded periorbital coverage).

These results align with prior studies, affirming thread embedding's effectiveness in ameliorating facial disability in peripheral facial paralysis. Despite the absence of a control group, our inclusion criteria - patients with primary peripheral facial paralysis exceeding 3 months and significant disability despite prior electroacupuncture - provide promising preliminary evidence of thread embedding's efficacy in this cohort at Ho Chi Minh City Traditional Medicine Hospital.

Potential mechanisms of action of PDO thread embedding

The observed clinical improvements after PDO thread implantation can be plausibly explained by three complementary biological and biomechanical mechanisms: (1) sustained mechanical support (immediate lifting and repositioning) of lax or atrophic soft tissues, which produces an immediate improvement in symmetry; (2) a persistent local tissue response characterized by fibroblast activation and subsequent collagen and extracellular-matrix deposition around the thread, producing longer-term volume restoration and tissue tightening; and (3) low-grade, chronic local stimulation and mechanotransduction, which may enhance microvascularity, modulate local inflammation, and provide a permissive environment for motor re-learning and peripheral nerve terminal sprouting. Together these mechanisms explain how PDO threads may convert a transient mechanical effect into more durable changes in facial contour, tone and dynamic function - especially when threads are placed over key motor units targeted by our point selection. These mechanisms are supported by histologic and in-vitro evidence showing fibroblastic proliferation and collagen upregulation around PDO material, by clinical histopathologic descriptions of perithread fibrosis and neocollagenesis, and by broader cell-biological data demonstrating that sustained mechanical cues regulate fibroblast phenotype and matrix production [25–28]. While the current study cannot isolate the relative contribution of each mechanism (mechanical vs. histological vs. neuro-modulatory), the convergence of these processes - delivered to anatomically and functionally relevant facial zones - provides a biologically credible explanation for the durable functional gains we observed.

Adverse Events

Adverse events included bleeding (66.70%), swelling (45.50%), and bruising (24.20%), with no instances of fainting. Park et al.[3] noted only occasional bruising, with no significant changes in biochemical or vital parameters, while Zhu et al.[24] reported no adverse effects in their thread embedding group. Other studies omitted safety data. The elevated adverse event rate in our study may reflect the use of larger needles (31G-30 mm, 29G-40 mm, 29G-50 mm) compared to standard acupuncture needles, compounded by the dense facial vascular network, increasing bleeding and bruising risks. Nonetheless, all events resolved spontaneously without intervention or patient discomfort, supporting the conclusion that thread embedding is a safe treatment option for peripheral facial paralysis.

Limitations and future directions

We analyzed HB grade as an ordinal outcome and used a mixed-effects proportional-odds model to preserve ordering information and to account for repeated measures. This approach is preferred to dichotomization with Fisher's exact test because it retains the full information in the six-level scale and increases statistical efficiency. The proportional-odds assumption was assessed and found not to be violated (see Methods). Additionally, the ordinal model exhibited instability due to near-perfect separation in HB grade improvements (e.g., zero patients remaining in severe grades at endpoint), which results in extremely small odds ratios that should be interpreted as indicative of a trend rather than a precise magnitude estimate.

Our study was an open-label clinical trial, a design inherently prone to a high risk of bias due to the absence of blinding. Crucially, the study utilized a single-arm, pre-post design without a concurrent control group. This limits our ability to definitively dissociate the specific therapeutic effects of PDO thread embedding from potential confounders, such as the placebo effect, regression to the mean, or the natural course of the disease, although the inclusion of chronic cases minimizes the likelihood of spontaneous recovery. The lack of blinding may have influenced both participant and investigator expectations, potentially overestimating the intervention's effects and compromising the reliability of the findings. Furthermore, the small sample size (n=33) limited the statistical power of the study, reducing its ability to detect significant differences and generalize results to a broader population. We were underpowered to detect interaction effects by age. This limitation is compounded by the gender imbalance in our sample, with 75.80% being female, which may reflect selection bias and further restrict the applicability of the findings. Additionally, the study was conducted at a single center, which may

have constrained the diversity of the sample and the relevance of the results across different clinical settings.

To address these limitations, future studies should adopt a blinded, controlled design, ideally a randomized controlled trial, to minimize bias and enhance the validity of the results. Incorporating a control group would allow for a more robust comparison and help isolate the true effects of the intervention. Moreover, increasing the sample size and conducting multicenter trials would improve statistical power and generalizability, ensuring a more representative and diverse participant pool. Additionally, long-term studies, such as those with a 6-month follow-up period, are recommended to assess the sustained efficacy of the intervention, providing critical insights into its role in managing primary peripheral facial palsy sequelae.

Definitive attribution of clinical benefit to any single mechanism (mechanical lift, collagenogenesis, or neuromodulation) is not possible in this observational pilot study; future mechanistic studies that combine histology, high-resolution imaging and functional electrophysiology will be required to parse the relative contributions of these processes.

CONCLUSIONS

The findings of this pilot study suggest that PDO thread implantation is a feasible intervention with a manageable safety profile, showing potential for improving facial deficits in individuals with chronic primary facial paralysis. Large-scale randomized controlled trials are warranted to confirm these results.

ABBREVIATION

CI: Confidence Interval
FDI: Facial Disability Index
HB: House-Brackmann
OR: Odds Ratio
PDO: Polydioxanone
SD: Standard Deviation
SF-36: Short Form-36 Health Survey
TEA: Thread-Embedding Acupuncture

COMPETING INTERESTS

This study received no funding and declares no conflicts of interest related to its findings.

AUTHORS' CONTRIBUTIONS

Hoa Khiet-Tieu Lieu: Conceptualization, Methodology, Investigation, Formal Analysis, Visualization, Writing – Original Draft. Khoa Tan Do: Resources, Supervision. Nguyen Quang Doan: Formal Analysis, Validation, Writing – Review & Editing. Quyen Thi-Le Nguyen: Formal Analysis, Investigation, Visualization, Data Curation. Senh Va Ly: Methodology, Supervision, Project Administration.

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Bài nghiên cứu

Ứng dụng cấy chỉ Polydioxanone trong phục hồi di chứng liệt mặt ngoại biên vô căn: Nghiên cứu thí điểm

Liêu Khiết Tiểu Hoa[1,*], Đỗ Tân Khoa[1], Đoàn Quang Nguyên[2], Nguyễn Thị Lệ Quyên[1], Lý Và Sểnh[1]

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TÓM TẮT

Đặt vấn đề: Liệt mặt ngoại biên vô căn thường để lại khiếm khuyết vận động cơ mặt mạn tính ở 30% số bệnh nhân, gây ảnh hưởng đáng kể đến chất lượng cuộc sống. Các phương pháp điều trị cho giai đoạn mạn tính hiện còn nhiều hạn chế; trong khi đó, phương pháp cấy chỉ Polydioxanone (PDO) đã cho thấy tiềm năng trong việc cải thiện tình trạng khuyết tật vùng mặt ở nhóm bệnh nhân này, dù các bằng chứng lâm sàng vẫn còn khá ít.

Mục tiêu: Nghiên cứu thí điểm này nhằm khảo sát tính khả thi, độ an toàn bước đầu và hiệu quả tiềm năng của phương pháp cấy chỉ PDO trong việc cải thiện chức năng vận động cũng như tình trạng khuyết tật cơ mặt ở bệnh nhân liệt mặt ngoại biên vô căn mạn tính.

Phương pháp: Trong thử nghiệm lâm sàng tiến cứu, một nhánh, nhãn mở này, 33 bệnh nhân liệt mặt ngoại biên vô căn mạn tính (từ 3 tháng trở lên) có điểm Chỉ số khuyết tật vùng mặt (FDI) ở mức suy giảm đáng kể đã hoàn thành nghiên cứu. Bệnh nhân được can thiệp cấy chỉ PDO định kỳ hàng tuần trong vòng 6 tuần, với 10 sợi chỉ mỗi phiên. Kết cục chính của nghiên cứu là sự thay đổi tổng điểm FDI sau 6 tuần. Các kết cục phụ bao gồm sự thay đổi theo phân độ House-Brackmann, tỷ lệ bệnh nhân đạt cải thiện lâm sàng và các biến cố bất lợi. **Kết quả**: Can thiệp cấy chỉ mang lại sự cải thiện có ý nghĩa thống kê về tổng điểm FDI trung bình, tăng từ 88,30 ± 22,05 ở thời điểm ban đầu lên 155,45 ± 18,39 ở thời điểm kết thúc ($p<0.001$). Cả hai điểm thành phần về chức năng thể chất và chức năng xã hội đều được cải thiện đáng kể. Hơn nữa, tỷ lệ bệnh nhân đạt phân độ House-Brackmann từ Độ III (mức độ trung bình) trở lên đã tăng từ 30,3% ở thời điểm ban đầu lên 81,8% ở thời điểm kết thúc ($p<0.001$). Các biến cố bất lợi được ghi nhận đều ở mức độ nhẹ và chỉ thoáng qua. **Kết luận**: Nghiên cứu thí điểm này cho thấy cấy chỉ PDO là một can thiệp khả thi, an toàn, cung cấp bằng chứng bước đầu đầy hứa hẹn về hiệu quả cải thiện chức năng vận động cơ mặt và chất lượng cuộc sống toàn diện ở bệnh nhân liệt mặt ngoại biên mạn tính. Những kết quả này cần được khẳng định thêm thông qua các thử nghiệm lâm sàng ngẫu nhiên có đối chứng với cỡ mẫu lớn hơn.

Từ khoá: Liệt mặt, cấy chỉ PDO, Facial Disability Index, FDI, phân độ House-Brackmann

[1]*Bệnh viện Y Học Cổ Truyền Thành phố Hồ Chí Minh, Việt Nam*

[2]*Trường Đại học Khoa học Sức khoẻ, Đại học Quốc gia Thành phố Hồ Chí Minh, Việt Nam*

Liên hệ

Liêu Khiết Tiểu Hoa, Bệnh viện Y Học Cổ Truyền Thành phố Hồ Chí Minh, Việt Nam

Email: lieukhiethoa@gmail.com

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