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CLINICAL TRIAL REPORT

Effects of Fu's Subcutaneous Needling on Postoperative Pain in Patients Receiving Surgery for Degenerative Lumbar Spinal Disorders: A Single-Blind, Randomized Controlled Trial

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Background: Fu's subcutaneous needling (FSN) is a novel acupuncture technique for pain treatment. This study investigated the effects of postsurgical FSN on postoperative pain in patients receiving surgery for degenerative spinal disorders.

Methods: This single-center, single-blind, randomized-controlled study involved patients undergoing surgery for degenerative spinal disorders. Participants were randomized into either an FSN group or a control group that received sham FSN. The primary outcomes were scores on the Brief Pain Inventory Taiwan version (BPI-T) and Oswestry Disability Index before and at 1, 24, and 48 hours after surgery. Secondary outcomes were muscle hardness, pethidine use, and inflammatory biomarker presence.

Results: Initially, 51 patients met the inclusion criteria and were allocated (26 in the FSN group and 25 in the control group). Two patients were lost to follow-up, and finally, 49 patients (25 in the FSN group and 24 in the control group) who completed the study were analyzed. The FSN group had significantly lower pain intensity measured on the BPI-T compared with the control group at 1, 24, 48, and 72 hours after surgical treatment (all $p < 0.001$). Additionally, pain interference as measured on the BPI-T was lower in the FSN group than in the control group 1 hour ($p = 0.001$), 24 hours ($p = 0.018$), 48 hours ($p = 0.001$), and 72 hours ($p = 0.017$) after surgical treatment. Finally, the FSN group exhibited less muscle hardness in the latissimus dorsi and gluteus maximus 24, 48, and 72 hours (all $p < 0.05$) after surgery compared with the control group; patients in the FSN group also exhibited less muscle hardness in the L3 paraspinal muscle 48 hours ($p = 0.001$) and 72 hours ($p < 0.001$) after surgery compared with the control group. There were no significant differences in serum CRP, IL-1β, IL-2, IL-6, and TNF-α levels between the FSN and control groups at 24 hours, 72 hours, and 1-month post-surgery (all $p > 0.05$).

Conclusion: FSN treatment can reduce postoperative pain in patients receiving surgery for degenerative spinal disorders. However, larger sample sizes and multicenter clinical trials are required to verify these findings.

Keywords: Fu's subcutaneous needling, degenerative spinal disorders, postoperative pain, surgical treatment, clinical trial

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Introduction

The most common reason for lumbar spine surgery is a degenerative disease of the spine,[1] including spinal stenosis, disc herniation, and degenerative spondylolisthesis.[2] Lumbar spinal surgery procedures include spinal fusion, laminectomy, and discectomy and generally provide increased mobility and pain relief.[2,3] However, existing spinal surgery techniques damage subcutaneous tissues, muscles, bones, ligaments, and intervertebral discs.

Postoperative pain after spinal surgery is frequently caused by inflammation and can be nociceptive and neuropathic. Although neurological symptoms are attenuated in most patients after spinal surgery, severe acute pain at the surgical wound and the surrounding area is common. This extensive local pain results both from residual preoperative referred pain and from symptoms of radiculopathy.[4] Additionally, peripheral and central sensitization may cause a vicious cycle of acute pain after surgery.[5] Severe postoperative pain usually lasts for 3 days and may result in the patient being bedridden and having additional complications due to a lack of movement, including episodes of venous thrombosis that may prolong hospital stays and require large amounts of analgesics to manage.[6]

Moreover, treatment of postoperative pain after spinal surgery generally includes oral or intravenous analgesics such as nonsteroidal anti-inflammatory drugs, opioids, steroids, or other noninvasive treatments. NSAIDs reduce inflammation but risk gastrointestinal bleeding. Opioids are effective but can cause addiction and respiratory suppression. Steroids reduce inflammation but may lead to immunosuppression. Acetaminophen is generally safe but can harm the liver in high doses. In rare cases, epidural or intrathecal injections might be used, but they carry risks such as epidural hemorrhage and infection.[4] Therefore, novel, safe, and effective methods for relieving postoperative pain must be identified.

A systemic review and meta-analysis reported that acupuncture treatment reduces pain intensity 24 hours after back surgery.[7] A placebo-controlled clinical trial reports that acupuncture is an effective and safe method for reducing post-cesarean delivery pain and enhancing mobilization.[8] Fu's subcutaneous needling (FSN) is a novel acupuncture technique reported to achieve rapid pain relief, relax injured soft tissue, and relieve fascia and muscle tension.[9–12] FSN therapy involves inserting a needle into the subcutaneous layer between the skin and the muscles, then moving the needle in a swaying movement and applying the reperfusion approach (RA) movement, similar to the muscle energy technique developed in 1948 by Fred Mitchell, Sr, D.O. FSN is safe; it has almost no side effects or complications except for subcutaneous bruising lasting several days after treatment. Therefore, the present study investigates the effects of FSN on postoperative acute pain in patients receiving surgery for degenerative lumbar spine disorders.

Methods

Participants

The study was conducted from March 2021 to July 2022. Patients with degenerative spinal disorders who required surgical treatment were recruited from the outpatient clinic of China Medical University Hsinchu Hospital in Hsinchu, Taiwan. The study followed the ethical principles of clinical trials in the Declaration of Helsinki. The study protocol was reviewed and approved by the Research Ethics Committee of China Medical University Hospital, Taichung, Taiwan (CMUH109-REC2-116) and registered with the ClinicalTrials.gov Protocol Registration and Results System (registration number NCT05572931). Before treatment, the process and purpose of the clinical trial were explained to the Participants in detail, and their written informed consent was obtained.

We included individuals who 1) were between 20 and 85 years old, 2) had spinal degeneration between the L1 and S1 spinal columns, or 3) had a visual analog scale pain score ≥5 at 1 hour after lumbar spine surgery (once patients returned to the ward from the recovery room). Participants were excluded from the study if 1) they had pain not caused by spinal degenerative disorders; 2) they had comorbidities such as cardiopulmonary failure, severe malignancies, or cerebrovascular disease; 3) they had rheumatic diseases, autoimmune diseases, or fibromyalgia; 4) they had a history of substance abuse; or 5) they had a history of spinal surgery.

Sample Size Calculation

To attain an effect size between 0.25 and 0.4,[13] with a type I error (α) of 0.05 and 80% statistical power, a total of 32 to 80 participants were required. To account for a 10% dropout rate, we aimed to enroll 36 to 90 participants (18 to 45 individuals per group).

Allocation

Patients were assigned randomly into an FSN group and a control group by employing a computer-generated random sequence and a concealed Allocation with opaque closed envelopes. The FSN group received FSN therapy 1, 24, and 48 hours after surgery, whereas the control group received a sham FSN (simple acupuncture needle superficial skin insertion) at the same time points. All patients received acetaminophen 500 mg thrice daily after surgery.

Intervention

FSN therapy was administered using Fu's subcutaneous needles (FSN Trocar Acupuncture Needles, Nanjing FSN Medical, Jiangsu, China; Figure 1A and B). The puncture sites included the bilateral lower border of the scapula and the posterior–superior iliac spine. As described in a previous study, the procedure is as follows.[14] The tip of an FSN needle is pointed toward a tightened muscle (TM) and inserted into the subcutaneous fibers without penetrating the muscle layer.[12] TMs indicate pathological tightness and stiffness of a muscle or a group of muscles that results in pain.[12]

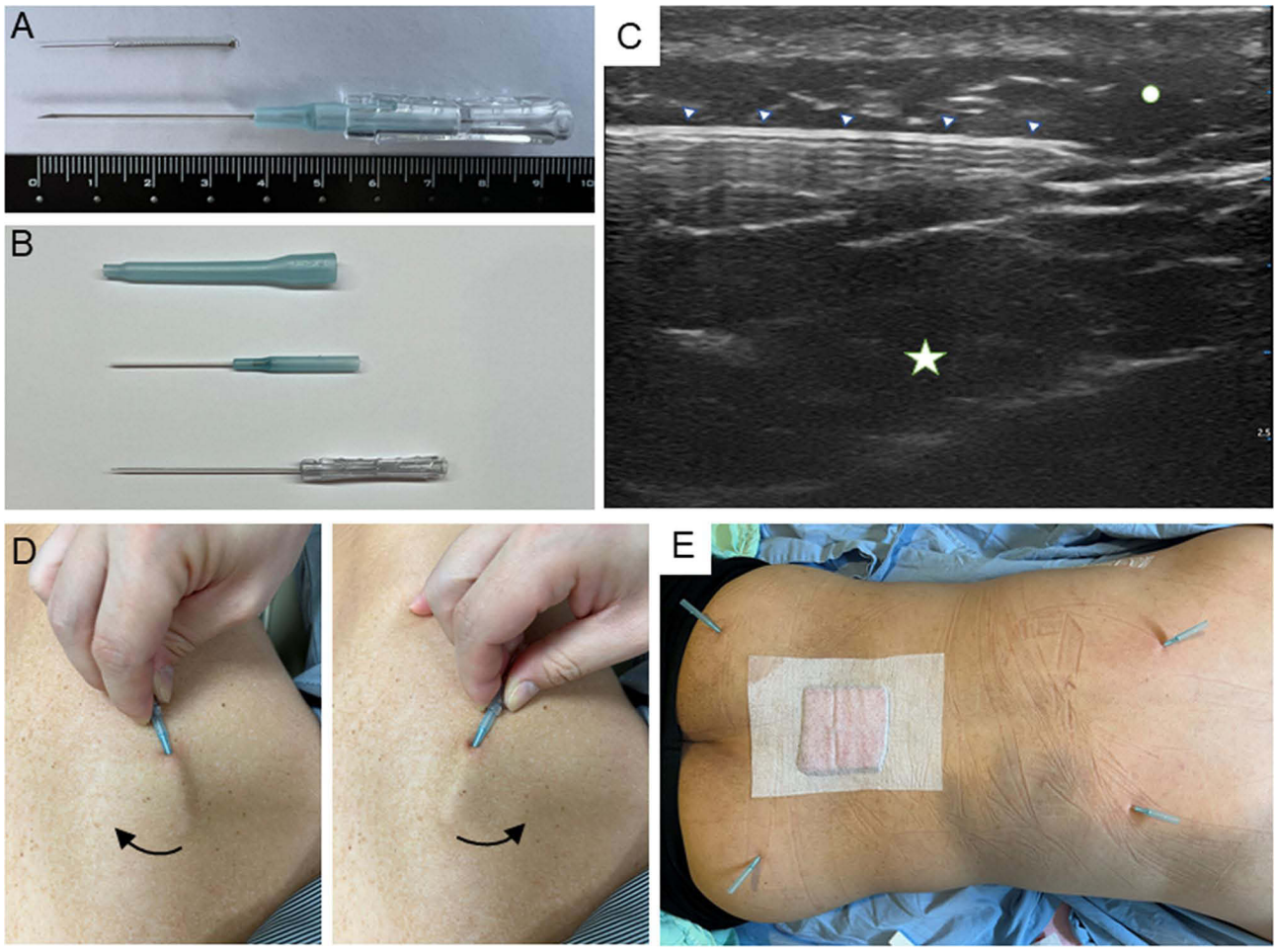

Figure 1 Fu's subcutaneous needling (FSN) therapy. (**A**) The fine acupuncture needle used in the control group (top), and the FSN needle used in the FSN group (bottom); (**B**) the FSN needle contains a protective sheath (top), a cannula tube (middle), and a solid needle (bottom); (**C**) The tip of the FSN needle (white triangle) is guided to the subcutaneous layer (white circle) above the target muscle (star) using ultrasound; (**D**) The swaying movement. (**E**) When the therapy is finished, the solid needle is removed, and the cannula tube is left under the subcutaneous layer of the acupuncture site for 8 hours.

During FSN needle insertion, the retracted needle tip is guided to the subcutaneous layer using ultrasound (Figure 1C). After complete insertion, the needle tip is retracted back to the hose, and a swaying motion, repeated 200 times in 2 minutes, is applied to the needle (Figure 1D). The needle tip is maintained at the same horizontal level during the swaying process, and the base of the needle is employed as a fulcrum to enable a seesaw-like swaying. When the needle is swayed, an RA movement (hip extensions against the doctor's hand) is executed for 10 seconds by the patient as they lie in a prone position, after which the patient rests for 10 seconds; these hip extensions and rests are repeated for three cycles on each side. When the RA movement and swaying movement are finished, the solid needle is removed, leaving the soft cannula tube under the subcutaneous layer of the needling site for 8 hours (Figure 1E).

The control group received a superficial skin puncture using a standard acupuncture needle (Ø0.22 × 13mm, Wujiang City Cloud & Dragon Medical Device, Wujiang, China), with neither penetration of the subcutaneous layer nor RA movement. The subcutaneous needle embedding was left in place for 8 hours to facilitate comparison of the control treatment with the FSN treatment.

Outcome Measures

The primary outcomes were pain and functional disability. Pain was assessed in terms of pain intensity and pain interference, both evaluated using the Taiwanese version of the Brief Pain Inventory (BPI-T) Short Form before surgery and 1, 24, 48, and 72 hours after surgery.[14] The BPI-T scores for pain intensity were rated on a numerical scale from 0 (*no pain*) to 10 (*worst possible pain*) and pertained to the extent to which the participants experienced *worst pain, least pain, average pain*, and *pain right now* in the preceding 24 hours. The BPI-T scores for pain interference were obtained by asking participants questions rated on a numerical scale from 0 to 10 about the interference of pain in their daily activities, emotions, abilities to walk and work, social interactions, sleep, and ability to enjoy life. A score of 0 indicates "no interference", whereas a score of 10 indicates "complete interference".[14] Functional disability was assessed utilizing the Oswestry Disability Index (ODI) before surgery, 72 hours post-operation, and again 1, 2, and 3 months after surgery.[15]

Secondary outcome measures comprised the use of pethidine, the presence of inflammatory markers, and the hardness of muscles. The total dose of intravenously administered pethidine within 72 hours after surgery was recorded as a measure of pethidine use. Pethidine was prescribed to reduce acute systemic inflammation from the body's natural immune defense against bacterial infection caused by surgical trauma, accelerating the wound and tissue healing process.[16] However, pethidine use is not the only indicator of surgical recovery and remission of back pain. Several studies have shown a strong association between postoperative pain and proinflammatory cytokines. Preemptive analgesia such as pethidine may be used to prevent the release of these cytokines, potentially resulting in decreased postoperative pain and a less pronounced illness response.[17,18] Therefore, the present study examined concentrations of inflammatory biomarkers consisting of serum concentrations of C-reactive protein (CRP), interleukin (IL)-1β, IL-2, IL-6, and tumor necrosis factor (TNF)-α as an additional measure of recovery. Venous blood samples (3 mL) were collected before surgery and again 24 and 72 hours after surgery; a final sample was collected 1 month after surgery. Serum concentrations of cytokines were assessed using enzyme-linked immunosorbent assay kits following manufacturer instructions.

Lower back pain is frequently associated with fascia tension.[19,20] Several user-friendly and relatively inexpensive tools have been developed to measure fascia tension.[21] Measurements of fascia tension are crucial in cases of lumbar spine surgery because such surgery substantially disrupts the connection between the back fascia and muscles. We measured the hardness of the back muscles and fascia tension to determine whether acute postoperative lumbar surgery pain was related to tissue and muscle hardness. Accordingly, before surgery and again 1, 24, 48, and 72 hours after surgery, hardness was measured in three back muscles: 1) the muscle at the lower border of the scapula and the latissimus dorsi, 2) the L3 paraspinal muscle 2 cm from the midline, and 3) the muscle at the midpoint between the sacroiliac joint to the greater trochanter of the femur and the gluteus maximus (referred to hereafter as the gluteus maximus for convenience). A tissue hardness meter (OE-220, ITO, Tokyo, Japan) was used to obtain measurements.

Despite the relative safety of the FSN procedure, some patients developed severe complications consisting of neurological deficits, wound or pinhole infection, subcutaneous hematoma, and needle fainting.

The checklist of the Consolidated Standards of Reporting Trials (http://www.consort-statement.org,2010) was scrupulously followed.

Statistical Analysis

Continuous data with normal distribution are presented as means ± standard deviations (SDs) and were analyzed for between-group differences using Student's *t*-test, otherwise, data without normal distribution are presented as median (25th - 75th percentile) and were analyzed for between-group differences using Wilcoxon rank sum test. Categorical data are presented as counts and percentages, with the difference between study groups determined using the chi-square test or Fisher's exact test, whichever was most suitable for the evaluated outcome. For repeated data, generalized estimating equations (GEE) with a first-order autoregressive matrix were performed to evaluate the effects of group, time, and interaction (group x time) for outcomes, including BPI score, ODI score, and tissue hardness. Based on the GEE models, least-squares means (LS-means) corresponding to the specified effects for the linear predictor part of the model were conducted to investigate differences between groups at the follow-up time. All statistical analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA). A 2-sided p-value of <0.05 was considered statistically significant. Because inflammatory biomarkers were skewed, we used Wilcoxon rank sum test to compare the difference between groups in each follow-up time and when $p < 0.0125$ (0.05/4) reached significance based on Bonferroni correction.

Results

Baseline Characteristics

A total of 153 patients received lumbar spine surgery during the study period from March 2021 to July 2022 at China Medical University Hsinchu Hospital. Of these, 51 patients met the inclusion criteria and consented to participate in the present study. They were segmented into the following groups: an FSN group of 26 patients and a control group of 25 patients. Two patients were lost to follow-up (one in the FSN group and one in the control group); Accordingly, a final sample of 49 (25 in the FSN group and 24 in the control group) patients who completed the trial was analyzed (Figure 2).

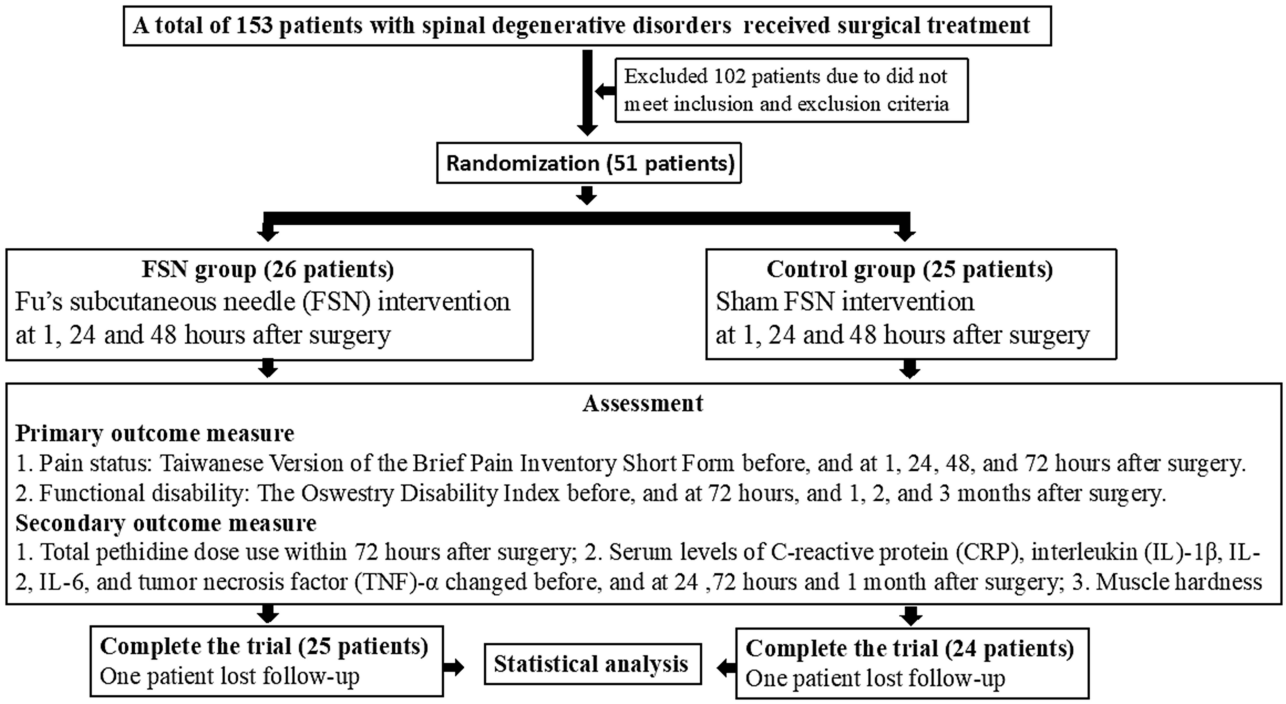

Figure 2 Screening and enrollment flowchart of the clinical trial.

The patients' baseline characteristics were sex (male and female), age, and body mass index; the FSN and control groups did not differ significantly in these characteristics (all $p > 0.05$, Table 1). The other characteristics that were examined were histories of smoking, diabetes, hypertension, type of surgery, scores for pain intensity and pain

Table 1 Patient Baseline Characteristics of the FSN and Control Groups

	FSN (n = 25)	Control (n = 24)	*p*-value
Demography			
Gender			0.196
Male	18 (72.00)	13 (54.17)	
Female	7 (28.00)	11 (45.83)	
Age (years)	58.80 ± 14.22	60.88 ± 11.47	0.578
BMI (kg/m^2)	24.53 ± 1.45	24.20 ± 1.93	0.501
Smoking	4 (16.00)	4 (16.67)	1.000
Diabetes	5 (20.00)	5 (20.83)	1.000
Hypertension	7 (28.00)	6 (25.00)	0.812
Type of surgery			0.858
Discectomy	15 (60.00)	15 (62.50)	
Fusion	10 (40.00)	9 (37.50)	
Pain measurement			
Pain intensity (0–10)	6.80 ± 1.43	7.13 ± 1.69	0.470
Pain interference (0–10)	5.50 (4.00–7.00)	7.00 (5.00–7.00)	0.147
ODI (%)	52.51 ± 16.05	52.96 ± 18.30	0.926
Muscle Hardness (%)			
Latissimus dorsi muscle	67.51 ± 9.24	61.82 ± 8.18	**0.027**
L3 paraspinal muscle	62.15 ± 9.27	58.47 ± 11.03	0.212
Gluteus maximus muscle	54.64 ± 10.94	53.17 ± 11.25	0.645
Inflammatory biomarker			
C-reactive protein (mg/dl)	1045.27 (645.68–2703.66)	1864.03 (893.43–3850.18)	0.177
IL-1β (pg/mL)	1.53 (0.00–3.26)	2.03 (0.95–3.81)	0.157
IL-2 (pg/mL)	2.69 (0.00–7.82)	5.16 (2.93–9.08)	0.328
IL-6 (pg/mL)	0.00 (0.00–4.59)	1.24 (0.00–5.95)	0.269
TNF-α (pg/mL)	0.00 (0.00–0.97)	0.76 (0.00–3.33)	0.361
Pethidine use			
OP day			0.095
No	12 (48)	6 (25)	
Yes	13 (52)	18 (75)	
POD1			0.321
No	15 (60)	11 (45.83)	
Yes	10 (40)	13 (54.17)	
POD2			1.000
No	21 (84)	20 (83.33)	
Yes	4 (16)	4 (16.67)	
POD3			1.000
No	24 (96)	23 (95.83)	
Yes	1 (4)	1 (4.17)	
Cumulative			0.279
No	10 (40)	4 (16.67)	
Yes	15 (60)	20 (83.33)	
Dose (mg)	80.00 (50.00–100.00)	82.50 (50.00–100.00)	0.833

Notes: Continuous data with normal distribution are presented as means ± standard deviations (SDs), otherwise, data without normal distribution are presented as median (25th - 75th percentile); Categorical data are presented as n (%). Significant results are shown in bold.

Abbreviations: FSN, Fu's subcutaneous needling; BMI, body mass index; IL, interleukin; ODI, Oswestry Disability Index; TNF, tumor necrosis factor; POD, post-operation day; POD1, 1 day post-operation; POD2, 2 days post-operation; POD3, 3 days post-operation; Dose, pethidine dose; Yes, pethidine was used; No, no pethidine used.

interference on the BPI-T, and scores on the ODI; in these measures, no significant difference between the FSN and control groups was observed (all $p > 0.05$, Table 1). The hardness of the latissimus dorsi was greater in the FSN group than in the control group ($p = 0.027$, Table 1).

Effects of FSN on Pethidine Use in Patients Receiving Surgical Treatment for Spinal Degenerative Disorders

Total cumulative pethidine use was similar in the FSN and control groups ($p = 0.279$, Table 1). Specifically, the cumulative dose of pethidine used was 88.67 ± 47.04 mg in the FSN group, which did not differ significantly from the 85.75 ± 50.48 mg used in the control group ($p = 0.863$, Table 1).

Effects of FSN Treatment on Pain Status and Functional Disability in Patients Receiving Surgery for Spinal Degenerative Disorders

The Results of the GEE analysis on pain intensity and interference are depicted in Figure 3. Pain intensity and pain interference measured by the BPI-T and ODI all had significant decreasing trends over time, with no group-time interaction observed (Figure 3).

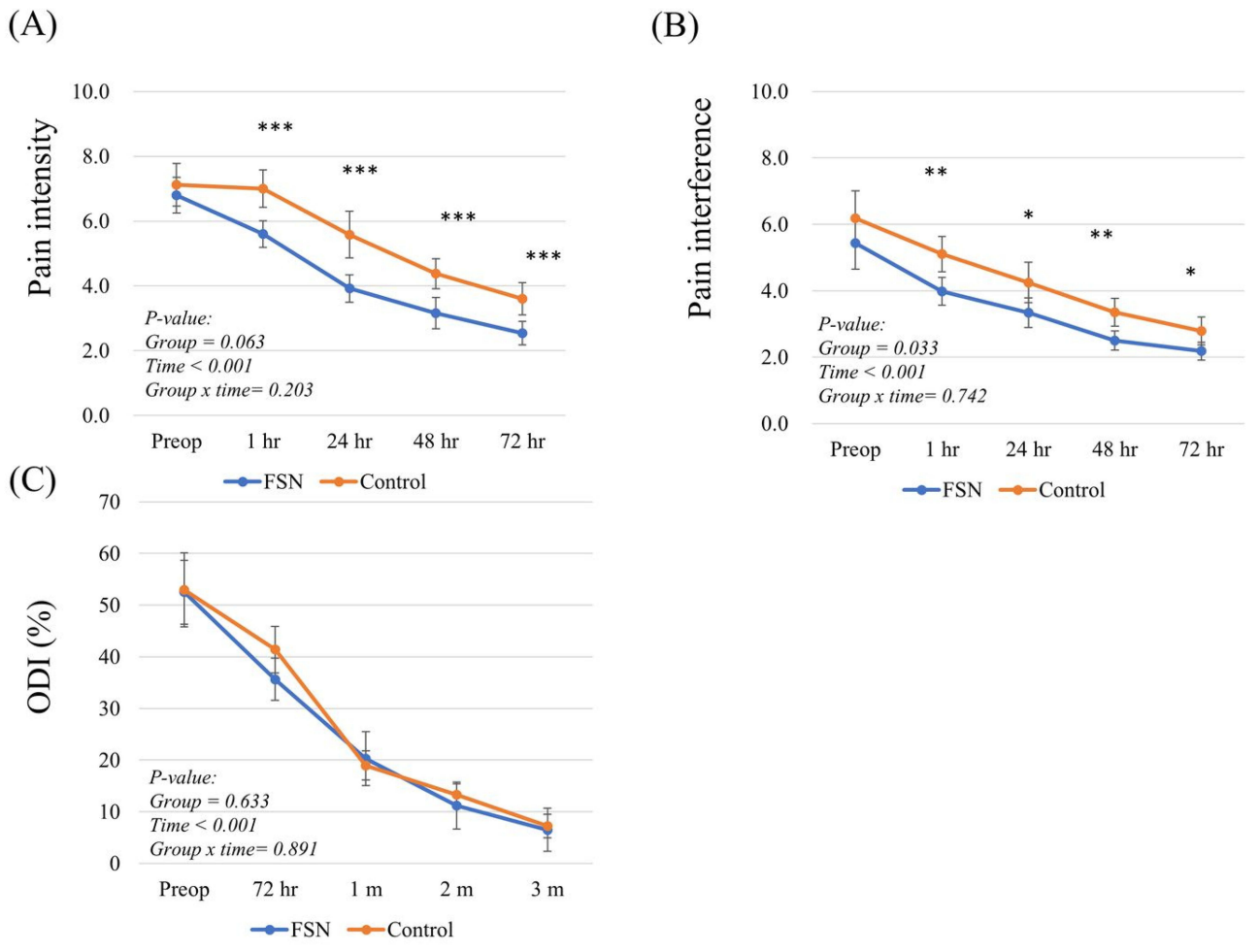

Figure 3 Estimated pain score or index between FSN and control group over time using GEE analysis. (**A**) Pain intensity. (**B**) Pain interference. (**C**) ODI. Line charts presented as mean and 95% confidence interval. FSN, Fu's subcutaneous needling; BPI, the Taiwanese version of the Brief Pain Inventory Short Form; ODI, Oswestry Low Back Pain Disability Index. *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

For between-group differences at each time point, pain intensity as measured on the BPI-T was similar in the FSN and control groups before surgical treatment ($p = 0.459$); pain intensity was lower in the FSN group than in the control group 1 hour, 24 hours, 48 hours, and 72 hours after surgical treatment (all $p < 0.001$; Table 2 and Figure 3A).

The pain interference scores as measured on the BPI-T were similar in the FSN and control groups before surgical treatment ($p = 0.197$); the pain interference scores were lower in the FSN group than in the control group 1 hour, 24 hours, 48 hours, and 72 hours after surgical treatment ($p = 0.001$, $p = 0.018$. $p = 0.001$, and $p = 0.017$, respectively; Table 2 and Figure 3B).

ODI values were similar in the FSN and control groups before surgical treatment and again at 72 hours, 1 month, 2 months, and 3 months after surgery (all $p > 0.05$, Table 2 and Figure 3C).

Effects of FSN on Muscle Hardness in Patients Receiving Surgical Treatment for Spinal Degenerative Disorders

The results of the GEE analysis on muscle hardness are demonstrated in Figure 4. Interactions between group and time were observed (all $p < 0.001$; Figure 4).

For between-group differences at each measurement time, the hardness of the latissimus dorsi was greater in the FSN group than in the control group before surgical treatment ($p = 0.020$). Moreover, the hardness of the latissimus dorsi was similar in the FSN and control groups 1 hour after surgical treatment ($p = 0.299$); however, the hardness of the latissimus dorsi was greater in the control group than in the FSN group 24, 48, and 72 hours after surgical treatment ($p = 0.002$, $p < 0.001$, and $p < 0.001$, respectively; Table 3 and Figure 4A).

The hardness of the L3 paraspinal muscle was similar in the FSN and control groups before surgery; the L3 paraspinal muscle also exhibited similar hardness at 1 hour and 24 hours after surgical treatment ($p = 0.198$, $p = 0.574$, and $p =$

Table 2 Effects of FSN Treatment on Acute Pain in Patients Receiving Surgery for Degenerative Lumbar Spinal Disorders

Variable	Group		*p*-value
	FSN (n = 25)	Control (n = 24)	
Pain intensity (0–10)			
Before	6.80 ± 1.43	7.13 ± 1.69	0.459
1 hour	5.60 ± 1.06	7.00 ± 1.49	**<0.001**
24 hours	3.92 ± 1.10	5.58 ± 1.85	**<0.001**
48 hours	3.16 ± 1.25	4.38 ± 1.17	**<0.001**
72 hours	2.54 ± 0.93	3.60 ± 1.28	**<0.001**
Pain interference (0–10)			
Before	5.44 ± 2.05	6.19 ± 2.09	0.197
1 hour	3.98 ± 1.08	5.10 ± 1.35	**0.001**
24 hours	3.34 ± 1.16	4.25 ± 1.55	**0.018**
48 hours	2.50 ± 0.75	3.35 ± 1.08	**0.001**
72 hours	2.18 ± 0.71	2.79 ± 1.07	**0.017**
ODI (%)			
Before	52.51 ± 16.05	52.96 ± 18.30	0.925
72 hours	35.64 ± 10.61	41.39 ± 11.53	0.064
1 month	20.30 ± 13.52	18.98 ± 7.24	0.662
2 months	11.22 ± 11.82	13.33 ± 5.36	0.407
3 months	6.52 ± 10.92	7.24 ± 5.78	0.768

Notes: Before: before operation. 1 hour: 1 hour after operation. 24 hours: 24 hours after operation. 48 hours: 48 hours after operation. 72 hours: 72 hours after operation. 1 month: 1 month after operation. 2 months: 2 months after operation. 3 months: 3 months after operation. Continuous data are expressed as means ± standard deviations (SDs) and were analyzed for between-group differences using GEE. Significant results are shown in bold.

Abbreviations: FSN, Fu's subcutaneous needling group; Control, control group; ODI, Oswestry Disability Index.

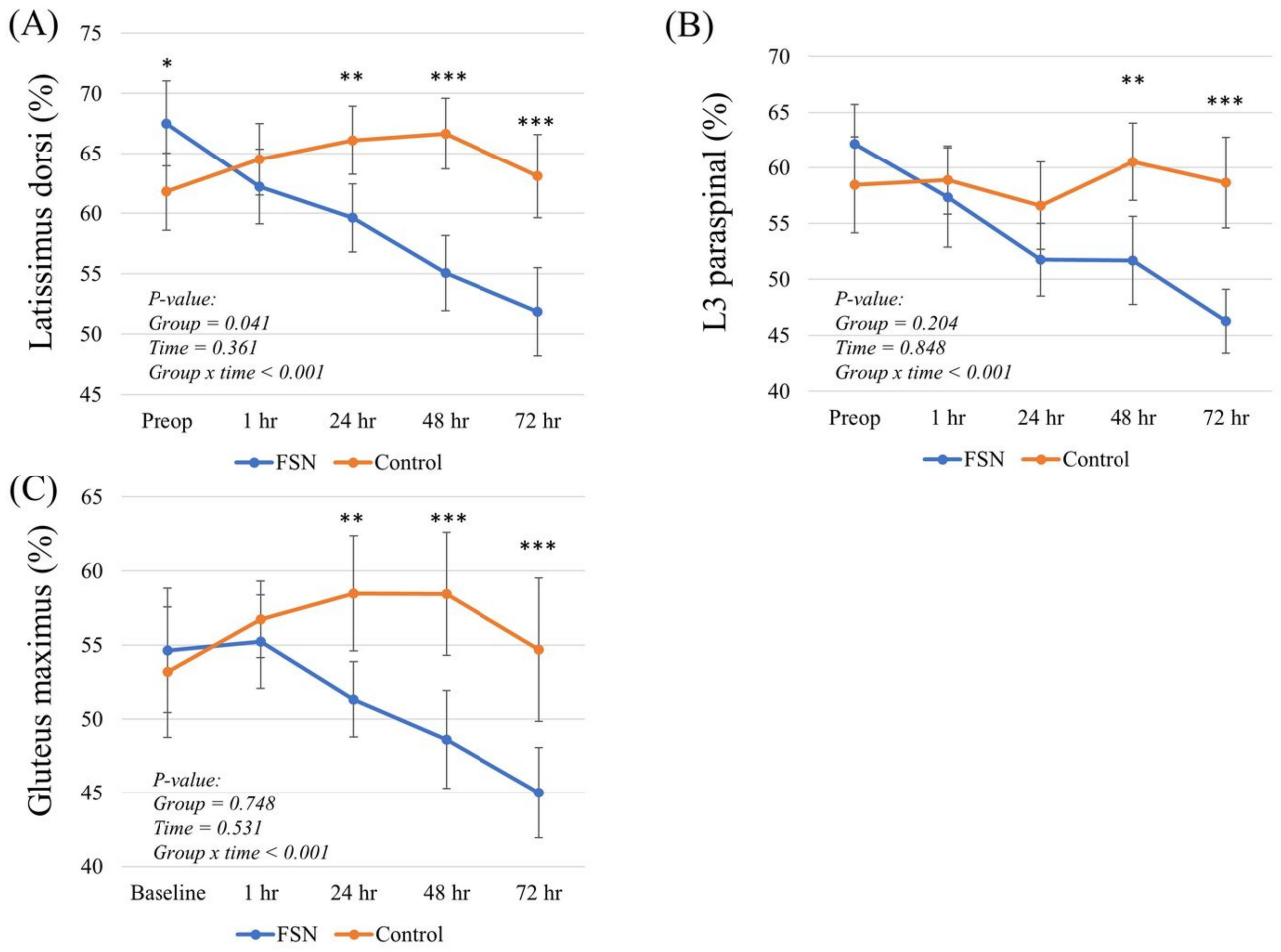

Figure 4 Estimated tissue hardness between FSN and Control group over time using GEE analysis. (**A**) Latissimus dorsi, (**B**) L3 paraspinal, and (**C**) Gluteus maximus muscle. Line charts presented as mean and 95% confidence interval. *$p < 0.05$; ** $p < 0.01$; ***$p < 0.001$.

0.063, respectively). However, the hardness of the L3 paraspinal muscle was greater in the control group than in the FSN group at 48 and 72 hours after surgical treatment ($p = 0.001$ and $p < 0.001$, respectively; Table 3 and Figure 4B).

The hardness of the gluteus maximus was similar in the FSN and control groups before surgery and again 1 hour after surgical treatment ($p = 0.636$ and $p = 0.469$, respectively; Table 4). However, the hardness of the gluteus maximus was greater in the control group than in the FSN group 24, 48, and 72 hours after surgical treatment ($p = 0.003$, $p < 0.001$, and $p < 0.001$, respectively; Table 3 and Figure 4C).

Effects of FSN on Inflammatory Biomarkers in Patients Receiving Surgical Treatment for Spinal Degenerative Disorders

For between-group differences at each time point, serum CRP, IL-1β, IL-2, IL-6, and TNF-α levels did not differ significantly between the FSN and control groups before surgery and at follow-up ($p > 0.05$, Table 4 and Figure 5).

Side Effects and Adverse Events

Five patients in the FSN group (20%) developed a subcutaneous hematoma. The subcutaneous hematoma was treated using external compression only and resolved completely within 2 weeks. No neurological deficits, infections, or incidences of needle fainting were observed in the FSN patients.

Table 3 Effects of FSN Treatment on Muscle Hardness in Patients Receiving Surgery for Degenerative Lumbar Spinal Disorders

Variables	Group		p-value
	FSN (n = 25)	Control (n = 24)	
Latissimus dorsi muscle			
Before	67.51 ± 9.24	61.82 ± 8.18	**0.020**
1 hour	62.24 ± 8.10	64.53 ± 7.65	0.299
24 hours	59.63 ± 7.35	66.11 ± 7.24	**0.002**
48 hours	55.06 ± 8.13	66.64 ± 7.52	**<0.001**
72 hours	51.85 ± 9.53	63.11 ± 8.87	**<0.001**
L3 paraspinal muscle			
Before	62.15 ± 9.27	58.47 ± 11.03	0.198
1 hour	57.35 ± 11.59	58.90 ± 7.87	0.574
24 hours	51.75 ± 8.50	56.59 ± 10.01	0.063
48 hours	51.69 ± 10.28	60.54 ± 8.90	**0.001**
72 hours	46.26 ± 7.41	58.66 ± 10.43	**<0.001**
Gluteus maximus muscle			
Before	54.64 ± 10.94	53.17 ± 11.25	0.636
1 hour	55.23 ± 8.24	56.74 ± 6.62	0.469
24 hours	51.34 ± 6.58	58.47 ± 9.90	**0.003**
48 hours	48.62 ± 8.63	58.45 ± 10.59	**<0.001**
72 hours	45.01 ± 7.99	54.68 ± 12.36	**<0.001**

Notes: Before: before operation. 24 hours: 24 hours after operation. 72 hours: 72 hours after operation. Continuous data are expressed as means ± standard deviations (SDs) and analyzed for between-group differences using GEE. Significant results are shown in bold.
Abbreviations: FSN, Fu's subcutaneous needling group; Control, control group.

Stratified Analysis by Surgery Type for the Effects of FSN on Pain, Inflammatory Biomarkers, and Muscle Hardness

Among patients underwent discectomy, the FSN group had significantly lower pain intensity at 1, 24, and 48 hours post-surgery ($p = 0.005$, $p = 0.008$, and $p = 0.031$), and lower pain interference 1-hour post-surgery ($p = 0.003$). The FSN group had greater latissimus dorsi hardness before surgery ($p = 0.007$) but lower hardness 24–72 hours post-surgery (all $p < 0.05$). For the L3 paraspinal and gluteus maximus muscles, the FSN group showed lower hardness 24–72 hours post-discectomy.

Among patients underwent fusion, L3 paraspinal hardness was higher in the FSN group before surgery ($p = 0.003$), with no significant post-surgery differences. No significant between-group differences were found in ODI and inflammatory biomarkers. (Supplementary Table 1)

Discussion

The results of the present study demonstrate that both the pain intensity and pain interference as measured on the BPI-T were similar in the FSN and control groups before surgical treatment (baseline), whereas pain intensity and pain interference were greater in the control group than in the FSN group 1, 24, 48, and 72 hours after surgical treatment. These results suggest that FSN treatment can reduce postoperative pain after surgical treatment in patients with spinal degenerative disorders who require surgery. The BPI-T has been demonstrated to be reliable when used among cancer patients in Taiwan.[14] Conventional acupuncture is thought to work through a mechanical coupling between the needle and connective tissue, in which needle insertion, twisting, and mechanotransduction induce signal transmission.[22] Similar to acupuncture, FSN relieves pain by stimulating loose connective tissue under the skin containing collagens with liquid crystalline structures and piezoelectric properties.[23,24] That is, as the FSN needle moves under the loose subcutaneous connective tissue, bioelectricity is released. When this bioelectricity reaches injured tissue, a reverse piezoelectric effect

Table 4 Effects of FSN Treatment on Inflammatory Biomarkers in Patients Receiving Surgery for Degenerative Lumbar Spinal Disorders

Variables	Group		*p*-value
	FSN (n = 25)	Control (n = 24)	
C-reactive protein (ng/mL)			
Before	1045.27 (645.68–2703.66)	1864.03 (893.43–3850.18)	0.177
24 hours	4800.55 (3836.94–5284.48)	5282.43 (4625.68–5475.60)	0.073
72 hours	5105.30 (4202.62–5404.54)	5109.02 (4308.01–5555.06)	0.384
1 month	2062.88 (579.99–3567.69)	2242.47 (845.17–3641.91)	0.667
IL-1β (pg/mL)			
Before	1.53 (0.00–3.26)	2.03 (0.95–3.81)	0.157
24 hours	2.68 (1.69–4.38)	3.10 (1.87–4.67)	0.803
72 hours	1.90 (1.17–3.14)	2.82 (1.09–3.83)	0.484
1 month	2.54 (1.22–3.43)	2.02 (1.03–3.99)	0.490
IL-2 (pg/mL)			
Before	2.69 (0.00–7.82)	5.16 (2.93–9.08)	0.328
24 hours	11.22 (7.16–17.53)	10.39 (6.46–15.11)	0.696
72 hours	6.51 (0.00–10.19)	3.02 (0.48–10.68)	0.606
1 month	12.26 (7.24–15.78)	10.76 (7.05–17.79)	0.726
IL-6 (pg/mL)			
Before	0.00 (0.00–4.59)	1.24 (0.00–5.95)	0.269
24 hours	8.47 (0.18–15.78)	12.31 (2.94–22.51)	0.218
72 hours	6.78 (1.83–12.31)	8.92 (1.99–13.54)	0.665
1 month	2.18 (0.00–5.12)	1.29 (0.25–3.60)	0.482
TNF-α (pg/mL)			
Before	0.00 (0.00–0.97)	0.76 (0.00–3.33)	0.361
24 hours	1.10 (0.00–6.71)	0.71 (0.00–2.15)	0.342
72 hours	0.00 (0.00–2.66)	0.00 (0.00–1.06)	0.160
1 month	1.21 (0.00–4.07)	0.26 (0.00–0.95)	0.085

Notes: Before: before operation. 24 hours: 24 hours after operation. 72 hours: 72 hours after operation. 1 month: 1 month after operation. Continuous data are expressed as median (25^{th} - 75^{th} percentile) and were analyzed for between-group differences using Wilcoxon rank sum test and the significant level was 0.0125.

Abbreviations: FSN, Fu's subcutaneous needling group; Control, control group; IL-1β, interleukin-1β; IL-2, interleukin-2; IL-6, interleukin-6; TNF-α, tumor necrosis factor-α.

occurs, altering ion channels and promoting disease resistance.[25,26] Pain is the most common complaint in patients with musculoskeletal disorders.[27] Therefore, relaxing the fascia and muscles can alleviate pain. FSN therapy is thought to work by targeting latent tightness in muscles that are present even when relaxed. These TMs have several myofascial trigger points (MTrSs), the stimulation of which can result in increased pain, decreased strength, and decreased function. Electrophysiological experiments in animals have shown that the endplate noise (EPN), a type of aberrant bioelectricity, of MTrSs is reduced by remote FSN; this reduction in endplate noise indicates that excitation of MTrSs has been inhibited.[28] Additionally, FSN's efficacy in improving mitochondrial structure and function in sciatica models supports its analgesic mechanisms.[29] Effective FSN needle insertion techniques in chronic constriction injury rat models minimize discomfort and enhance study efficiency, indicating better research outcomes.[30] However, the exact mechanisms underlying the findings of the current study still require further investigation.

The thoracolumbar fascia (TLF) is a girdle-like structure extending from the lumbar region to the base of the skull that is crucial to maintaining the stability and balance of the body's core muscles. In the lower back, the TLF forms a mesh support structure in the paraspinal muscles and sacral area,[31] which is often damaged during lumbar spine surgery. Damage to the TLF explains the acute pain after lumbar spine surgery experienced on both sides of the wound and the buttocks, in addition to the pain at the cutaneous incision site. Palpation of a patient's sacral and paraspinal muscles after surgery reveals stiffness and tightness; the sacral and paraspinal muscles are common TMs after lumbar

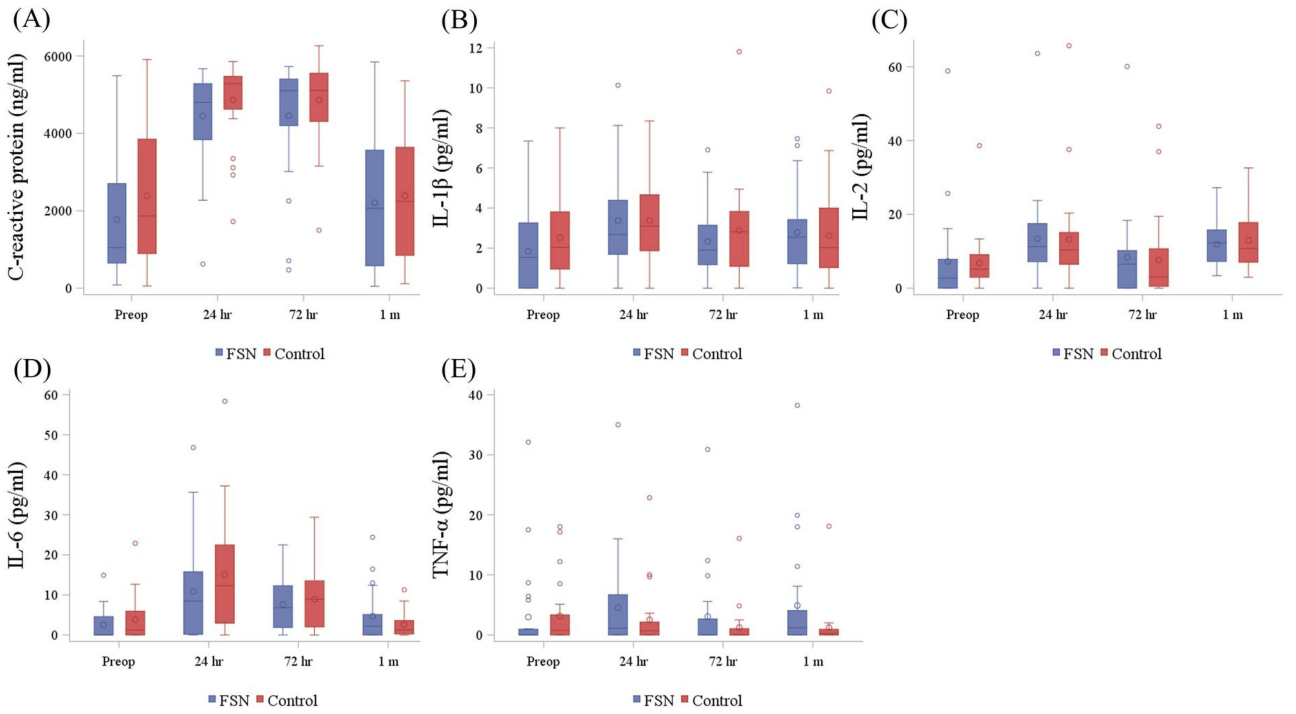

Figure 5 Boxplot of inflammatory biomarkers between FSN and Control group over time. (**A**) C-reactive protein. (**B**) IL-1β. (**C**) IL-2. (**D**) IL-6. (**E**) TNF-α.
Abbreviations: FSN, Fu's subcutaneous needling; IL, interleukin; TNF, tumor necrosis factor.

spine surgery. Identifying TMs is crucial to FSN treatment because the needle must be aimed in the direction of specific TMs rather than generally pointed toward muscle fibers.[32] Therefore, we targeted the upper and lower edges of the TLF (the lower edge of the scapula [latissimus dorsi] and posterior–superior iliac spine;[31,33] for FSN insertion in developing a standardized FSN therapy protocol that was subsequently administered to all included patients.

The results of the present study also indicated that the hardness of the L3 paraspinal muscle and the gluteus maximus was similar in the FSN and control groups before surgical treatment, whereas the hardness of the latissimus dorsi, the L3 paraspinal muscle, and the gluteus maximus was greater in the control group than in the FSN group 48 and 72 hours after surgical treatment; this result demonstrates that FSN treatment can reduce muscle hardness. Muscle hardness is the resistance of muscle tissue to deformation by external forces and can be affected by passive and active muscle tension and intramuscular pressure.[34] Muscle hardness, as measured in local tenderness of the trapezius muscle, is positively associated with headache duration in patients with tension-type headaches.[35] The hardness of the trapezius muscle is greater in patients with tension-type headaches than in patients who do not have tension-type headaches, with reductions in clinical symptoms accompanied by reductions in muscle hardness.[36] These results suggest that therapies targeting TMs can effectively relieve acute pain. Consistent with these findings, FSN treatment in the present study reduced the hardness of the latissimus dorsi, the L3 paraspinal muscle, and the gluteus maximus, reducing postsurgical acute pain. Specifically, the reduction in baseline hardness of the latissimus dorsi, which was greater in the FSN group than in the control group, may explain the observed benefits of the FSN treatment compared with the control treatment.

Our results indicate that pain intensity and pain interference as measured by BPI-T scores were experienced as soon as 1 hour after surgical treatment, whereas the muscle hardness of the latissimus dorsi, the L3 paraspinal muscle, and the gluteus maximus were reduced between 24–48 hours after surgical treatment. This result suggests that FSN treatment may effectively reduce muscle hardness and relieve pain. However, further studies are required to verify this finding.

The results of the present study reveal that the ODI value was similar in the FSN and control groups before surgery and again at 72 hours, 1 month, 2 months, and 3 months after surgical treatment; the ODI value decreased considerably over time in both groups. These results indicate that FSN treatment was less effective at relieving pain than we hypothesized. The ODI measures the effect of lower back pain (including the perception of pain) on daily activities

and functions, personal care, and the ability to work. The ODI is extensively used in medical research and clinical assessments to help health-care professionals understand the severity of a patient's lower back pain and the level of a patient's functional impairment.[15]

Pethidine (meperidine) is a potent opioid analgesic classified as a synthetic opioid. Pethidine is crucial in postoperative pain management[37] because it works rapidly and has strong analgesic properties and sedative effects. However, because pethidine is a synthetic opioid, it must be used with caution to prevent addiction. Additionally, several side effects are associated with pethidine use, including respiratory depression, sedation, and constipation.[37] The results of the present study indicate that the frequency of using pethidine and the cumulative dose of pethidine used was similar in the FSN and control groups before surgery and 24, 48, and 72 hours after surgical treatment. Whether treatment with FSN can reduce pethidine use requires confirmation in a study with a larger sample size.

The results of the present study also indicate that serum CRP, IL-1β, IL-2, IL-6, and TNF-α levels did not differ significantly between the FSN and control groups before surgery, nor again 24 hours, 72 hours, or 1 month after surgical treatment. CRP is synthesized by hepatocytes and is thus a biomarker of acute inflammation that is produced in response to proinflammatory cytokines.[38] The proinflammatory cytokines IL-1β, IL-2, IL-6, and TNF-α can be released from macrophages when surrounding tissues are injured or infected and play a protective role and also can enter circulation active immune cell,[39] also can represent an inflammatory response play as a biomarker of inflammation.[40] In conclusion, further studies are required to uncover the potential relationship between FSN treatment and a reduction in pain intensity, pain interference, muscle hardness, and inflammation.

Five patients in the FSN group developed a subcutaneous hematoma, which resolved completely within 2 weeks when treated with external compression. The occurrence of such minor side effects suggests the safety of FSN as a treatment for degenerative spinal disorders.

We did not conduct comparisons between FSN and traditional acupuncture. Nevertheless, in recent years, several studies have explored the comparative effectiveness of FSN and other acupuncture techniques. A network meta-analysis comparing seven acupuncture techniques for knee osteoarthritis showed that FSN ranked highly, only behind the silver needle in overall effectiveness.[41] Another study on patients with shoulder pain demonstrated significant improvements in pain and range of motion with FSN, outperforming traditional acupuncture and physical therapy.[42] Additionally, FSN has been found to be more effective than electroacupuncture in improving joint function and alleviating pain in patients with knee osteoarthritis and those recovering from neck fracture surgery.[43,44] Nevertheless, more evidence and trials are needed to further validate these findings.

The present study has several limitations. First, the sample included only 51 patients, and the study was limited to a single institution. Second, the study was a single-blind, randomized, controlled clinical trial, as opposed to a double-blind, randomized, controlled clinical trial. Third, our sham FSN design involves fine acupuncture needle punctures on the superficial skin. However, it is unclear whether such a design can genuinely discern the effects of FSN. Therefore, standardizing sham FSN is a consideration for the future; Fourth, the present study lacked a control group utilizing the traditional acupuncture and moxibustion techniques in order to emphasize the comparative advantages of the study.

Conclusions

FSN treatment significantly reduced pain intensity and pain interference as measured by the BPI-T and also reduced muscle hardness. These results suggest that FSN can safely be used for postoperative pain treatment in patients with degenerative spinal disorders receiving spinal surgery. Future studies with larger sample sizes, multiple centers, and double-blind, randomized controlled designs are required to confirm these results.

Data Sharing Statement

The original data will preserve at Department of Neurosurgery, China Medical University Hsinchu Hospital for at least 5 years after publication of the study results. The datasets are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

The study protocol was approved by the Human Research Protection Center of China Medical University Hospital, Taichung, Taiwan. Informed consent was obtained from the patients.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

All authors declare that they have no potential conflicts of interest in the study.

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