

Treatment effect and mechanism of Fu's subcutaneous needling among patients with shoulder pain: A retrospective pilot study

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Abstract

Fu's subcutaneous needling (FSN) is a new acupuncture therapy developed from acupuncture and Traditional Chinese Medicine models. The aim of this study was to investigate the effect of FSN on shoulder pain. In this retrospective comparative study, patient case files with shoulder pain (Group A) treated with FSN were analyzed and compared with the same number of patients with shoulder pain (Group B) treated with conventional acupuncture and physical therapy. Motion-related pain (MRP), pain under pressure (PUP), and Range of motion (ROM) were collected before and after intervention. In the 68 patients, there were 39 males and 29 females, aged 21–53 years old (mean $\pm$ SD = 36.4 $\pm$ 8.15) with onset time ranging from 1 day to 7 days (mean $\pm$ SD = 3.15 $\pm$ 1.73). MRP, PUP, and ROM scores were improved after FSN intervention ($p < .05$). There were significant differences between group A and group B in MRP, PUP, and ROM scores after FSN intervention and 1 week follow-up ($p < .05$). No adverse events, such as fainting and sharp pain, occurred during the treatment process. FSN can be an effective rehabilitation intervention for improving shoulder pain and shoulder range of motion.

KEYWORDS

acupuncture, complementary medicine, Fu's subcutaneous needling, shoulder pain

摘要

浮针是在针灸和中国传统医学基础上发展起来的一种新的针刺疗法。本研究的目的是探讨浮针(FSN)治疗肩痛的效果。本研究A组患者(34例)采用浮针治疗,与相同数量的常规针灸结合物理治疗的肩痛患者(B组)进行匹配比较。我们对所有肩痛患者在干预前后进行相关疼痛(MRP)、压力下疼痛(PUP)和运动范围(ROM)指标评估。在68例患者中,男性有39例,女性有29例,年龄在21-53岁(平均值 $\pm$ 标准差=36.4 $\pm$ 8.15)。肩痛发病时间为1-7天(平均值 $\pm$ 标准差=3.15 $\pm$ 1.73)。本研究结果发现,MRP、PUP、ROM评分干预后均有改善($P<0.05$)。A组和B组干预及随访后MRP、PUP、ROM评分差异均有统计学意义($P<0.05$)。患者在整个治疗过程中未发生晕厥、剧痛等不良事件。本研究提示,在缓解肩关节疼痛和改善肩关节活动范围方面,浮针可能是一种比传统康复干预更有效的方法。

关键词

浮针, 肩痛, 针灸, 补充医学

1 | INTRODUCTION

Shoulder pain is a common musculoskeletal disorder affecting the adult population. It is often considered a primary manifestation or accompanying symptom of other body regions. Shoulder pain is a subjective symptom that is characterized by an individual's perceived sense of shoulder discomfort, joint movement dysfunction and/or pain (Anwer, Alghadir, Al-Eisa, & Iqbal, 2018). Although episodes of shoulder pain can be self-limiting, patients may still experience substantial chronic pain that can result in significant disability in shoulder joint function (Pease & Ross, 2019).

There are many conditions that may induce shoulder pain, such as cerebrovascular accidents (Holmes, McManus, Koulouglioti, & Hale, 2020), rotator cuff injury (Sir & Eksert, 2019), subacromial bursitis (Chen, Jiang, & Huang, 2019), and heart disease (Mizokami et al., 2016). The pathogenesis of shoulder pain can be difficult to identify based on consensus or diagnostic criteria and can be a confounding problem for many practitioners. A common reason for shoulder pain that cannot be identified by physical or radiological examination may be due to local muscular pain (Matsel, Davies, & Uhl, 2020), and/or ischemia (Hagberg, 1984). Medications, such as non-steroidal anti-inflammatory drugs, for treating shoulder pain are act to inhibit the release of inflammatory cytokines and interact with the pain signaling pathway. However, in many patients, nonsteroidal anti-inflammatory drugs are unable to completely or temporarily relieve pain. Physical modalities, such as extracorporeal shockwave therapy (Muthukrishnan, Rashid, & Al-Alkharji, 2019) or electrical stimulation (Lin et al., 2019), may have temporary symptom-relief effects (Chen et al., 2019). Therefore, since pain without a clear etiology remains a challenge for physicians and rehabilitation professionals, exploring new approaches for treating shoulder pain is needed.

Fu's subcutaneous needling (FSN) is a new acupuncture therapy based on acupuncture and Traditional Chinese Medicine models. In the last 15 years, FSN has gained popularity in China, as well as worldwide for treating patients with pain pathology (Huang, Liu, Fu, Lin, & Chou, 2020). FSN acts mainly in the subcutaneous layer (Yu et al., 2019) and does not penetrate the muscular layer. Research has indicated that FSN can relieve pain and improve soft tissue pathology related to injury

in clinical practice (Liu et al., 2019). To our knowledge, there is no published evidence-based literature on FSN effects related to shoulder pain. Thus, the objective of this retrospective study is to investigate the effect of FSN on shoulder pain.

2 | MATERIALS AND METHODS

2.1 | Study design

This is a retrospective case-matched comparison study approved by the institutional ethics committee of the hospital where the principle investigators work (ID 2018sn022). Thirty-four patients (Group A) with shoulder pain treated with FSN were identified in the hospital's E-file system along with the same number of patients (Group B) matched by age (± 3 years) and shoulder pain intensity (± 1 in a 1–10 scale) treated with conventional acupuncture and therapeutic exercise. The sample size was calculated according to statistical formulas and tables (Day & Graham, 1991). Signed consent forms were obtained from all patients. All assessments were conducted by physical therapists who received identical training in the hospital.

2.1.1 | Subjects

Selection of patients with shoulder pain who received treatments from January 2018 to December 2020 in the rehabilitation department of a university-affiliated hospital were matched and retrieved from the hospital's E-file system based on the previously described criteria. Patient age ranged from 18 to 60 years. The inclusion criteria was: (a) intact cognition and ability to follow commands; (b) unilateral shoulder pain without radiation to or from elsewhere; (c) pain visual analogue scale score ≥ 5 ; (d) shoulder pain onset in the last 3 months and a most recent pain episode in the last 3 days; (e) no intracranial lesions per MRI; and (f) not allergic to ultrasound gel. Patients were excluded if they had: (a) shoulder pain secondary to cerebrovascular accident per MRI or physical examination, obvious rotator cuff injury or subacromial bursitis by diagnostic ultrasound exam; (b) a history of cardiac, liver, gallbladder, kidney, or gastric diagnoses; and (c) a deformity identified in both shoulders.

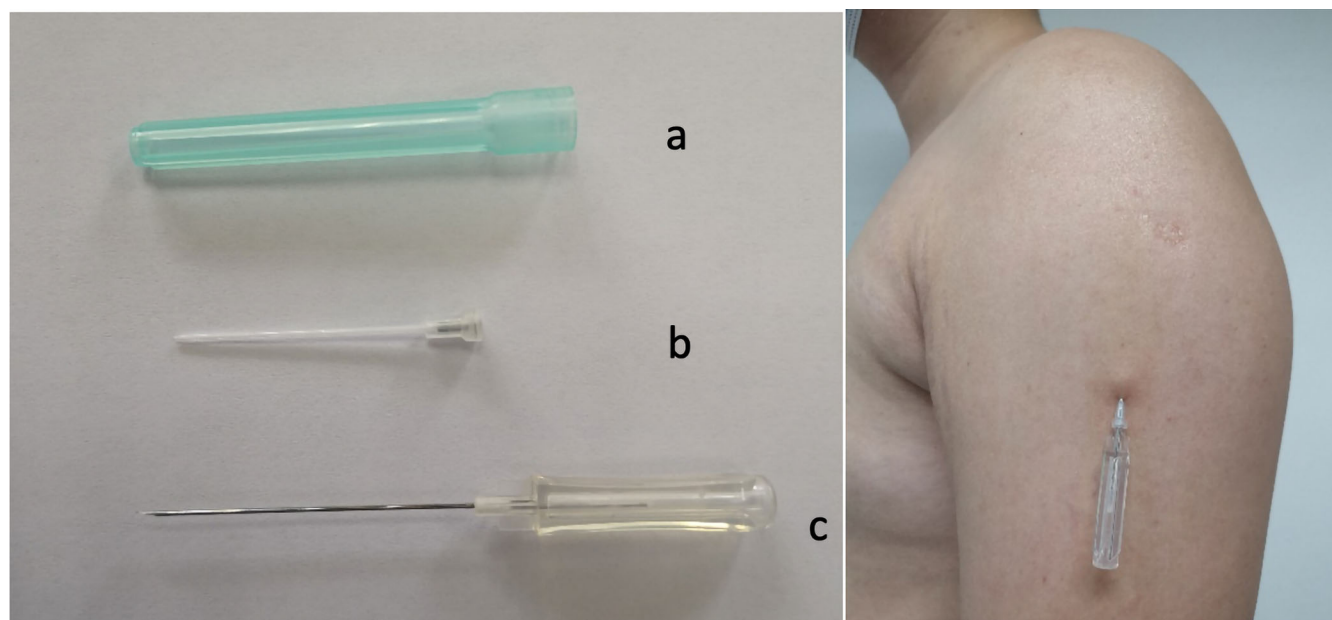


FIGURE 1 Left picture: Fu's subcutaneous needling (a: cap, b: the soft casing tube, c: the stainless steel needle and its handle). Right picture: The operation was shown

2.1.2 | FSN intervention

Fu's subcutaneous needles Yu et al., 2019 (FSN Medical Appliances Company, Nanjing, China) consist of three parts: cap, the soft casing tube, and the stainless-steel needle and its handle (Figure 1). The steel needle is 3 mm longer than the soft casing tube in order for the needle to easily penetrate the skin.

For each patient, the area with the most severe pain reaction by palpation was considered as the most tender point. The needle insertion spot was located four fingers (based off patients' hand) below the severe pain reaction point. Each point was locally disinfected with 75% ethanol. Then, the skin was pinched the insertion point, followed insertion of the FSN needle insertion into the subcutaneous layer (needle depth into the skin is ~4 mm). The angle of insertion is parallel to the pinched skin. It is important to make sure the needle tip stays in subcutaneous layer and does not penetrate the muscular layer and was monitored by ultrasound. After insertion into the subcutaneous layer for approximately 2–3 s, the needle was retracted (~5 mm) in the subcutaneous layer and aligned to be parallel to the skin surface as possible and position the needle into the painful area until the FSN was in the subcutaneous layer of the painful area. If two or more reaction points were identified, the needle was directed toward the most painful point. In the subcutaneous layer the needle was swiped gently, smoothly, rhythmically, and horizontally back and forth from one side to another about 50–100 times within a 2-min time period. After the needle-swiping and with

the needle left subcutaneously, the patient was asked to move his/her treated shoulder joint with minimum resistance in 3-D planes (flexion and extension, adduction, abduction, internal rotation, and external rotation), 5–10 times in each plane according to FSN reperfusion theory (Fu, Chen, Lu, Lin, & Xu, 2006). Immediate pain suppression effects of FSN were evaluated by taking their pain scores and then after 5 min, performed an additional 1–2 sets movement of shoulder joint in 3-D planes, 10 times each set while seated. Each patient received just one FSN treatment and total time of FSN was within 20 min. FSN was performed to all Group A patients using the same treatment protocol by all FSN practitioners.

Subjects in Group B received acupuncture combined with physical therapy modalities and exercise. Routine acupuncture stimulation acupoint included Jianyu (LI15), Jianqian (EX-UE12), Jianhou (Extra), Jianliao (TE14), Waiguan (TE5), and Hegu (LI4) (Wang et al., 2019) on the affected side. Physical therapy modalities included transcutaneous electrical nerve stimulation was applied to the shoulder immediately following the routine acupuncture. Patients performed 1–2 sets of movement of the shoulder joint in 3-D planes, 10 times each set Immediate pain suppression effects of acupuncture treatment combined with physical therapy were assessed by taking their pain scores and then after 5 min an additional 1–2 sets movement of shoulder joint in 3-D planes, 10 times each set was performed while seated. Acupuncture therapy time was approximately 15 min and modality intervention time were 20 min.

2.2 | Clinical assessments

The baseline information included age, gender, pain location and onset time. Motion-related pain (MRP), pain under pressure (PUP), and Range of motion (ROM) were collected before, after intervention and 1-week follow-up.

Motion-related pain (MRP) was measured by means of a visual analogue scale with 0 indicating no pain and 10 indicating unbearable pain. The movements assessed were: shoulder flexion and extension, internal rotation external rotation, and horizontal abduction/adduction (Wilke et al., 2014).

2.2.1 | Pain under pressure

It is vital to measure the PUP, because local tenderness is the top clinical characteristic. An algometer (Nanjing FSN Medical Appliances Company) with a maximal pressure of 20 N was used to test PUP (Melia et al., 2019). The algometer was placed on the tender spot (the contact surface area is $\sim 3 \text{ cm}^2$) for 3 s. Pain was measured by means of a visual analogue scale with 0 indicating no pain and 10 indicating unbearable pain.

2.2.2 | Range of motion

The ROM was assessed for the three planes of movement, including flexion and extension, adduction, abduction, internal rotation and external rotation. Assessments used the following criterion as scores from 0 to 3:0—normal; 1—the patient felt discomfort or pain during one or more of the six movements with no limitation of movement; 2—there was limited movement and pain during one or more of the six movement or the patient could not easily complete one of the movements; and 3—the patient was incapable of completing each of the six movements (Anwer et al., 2018).

2.3 | Statistical analysis

The data was analyzed using SPSS for Windows version 20. Continuous Data was expressed as a mean and standard deviation. The comparison of baseline with post-intervention within each group was performed by the paired *t* test. The comparison between groups before and after intervention was performed by the use of independent sample *T*-test. Significant level was set at $p < .05$.

3 | RESULTS

As shown in the flow chart (Figure 2), a total of 82 participants were admitted to the study in the beginning and 14 patients were excluded according to exclusion criteria (three patients withdrew, six patients had a rotator cuff injury, and five had subacromial bursitis). Sixty-eight patients met the inclusion criteria and consented to receive intervention and assessments and completed the study. There was no significant difference among groups in terms of sex, age, or onset time (Table 1).

3.1 | Primary outcomes

The comparisons within groups for MRP, PUP, and ROM were shown in Table 2. MRP, PUP, and ROM scores were improved after intervention ($p < .05$). There were significant differences between Groups A and B in MRP, PUP, and ROM scores after intervention ($p < .05$).

3.2 | Secondary outcomes

The follow-up at 1 week after intervention are shown in Table 3. MRP, PUP, and ROM scores were not improved at 1 week compared to postintervention ($p > .05$). However, there were significant difference between Groups A and B on MRP, PUP, and ROM scores at 1 week follow-up ($p < .05$).

No adverse events occurred during the treatment, assessment, and follow-up times such as fainting or sharp pain.

4 | DISCUSSION

This study aimed to investigate the effects of FSN treatment in patients with shoulder pain. The main finding of this study was that FSN reduced shoulder pain of patients immediately and improved subject symptoms.

4.1 | The physiological basis and assumptive mechanism of FSN

The physiological basis of shoulder pain is very complicated. It can be caused by various reasons, poststroke (Holmes et al., 2020), rotator cuff injury (Sir & Eksert, 2019), subacromial bursitis (Chen et al., 2019), and heart disease (Mizokami et al., 2016). However, it is often seen that many patients with shoulder pain may

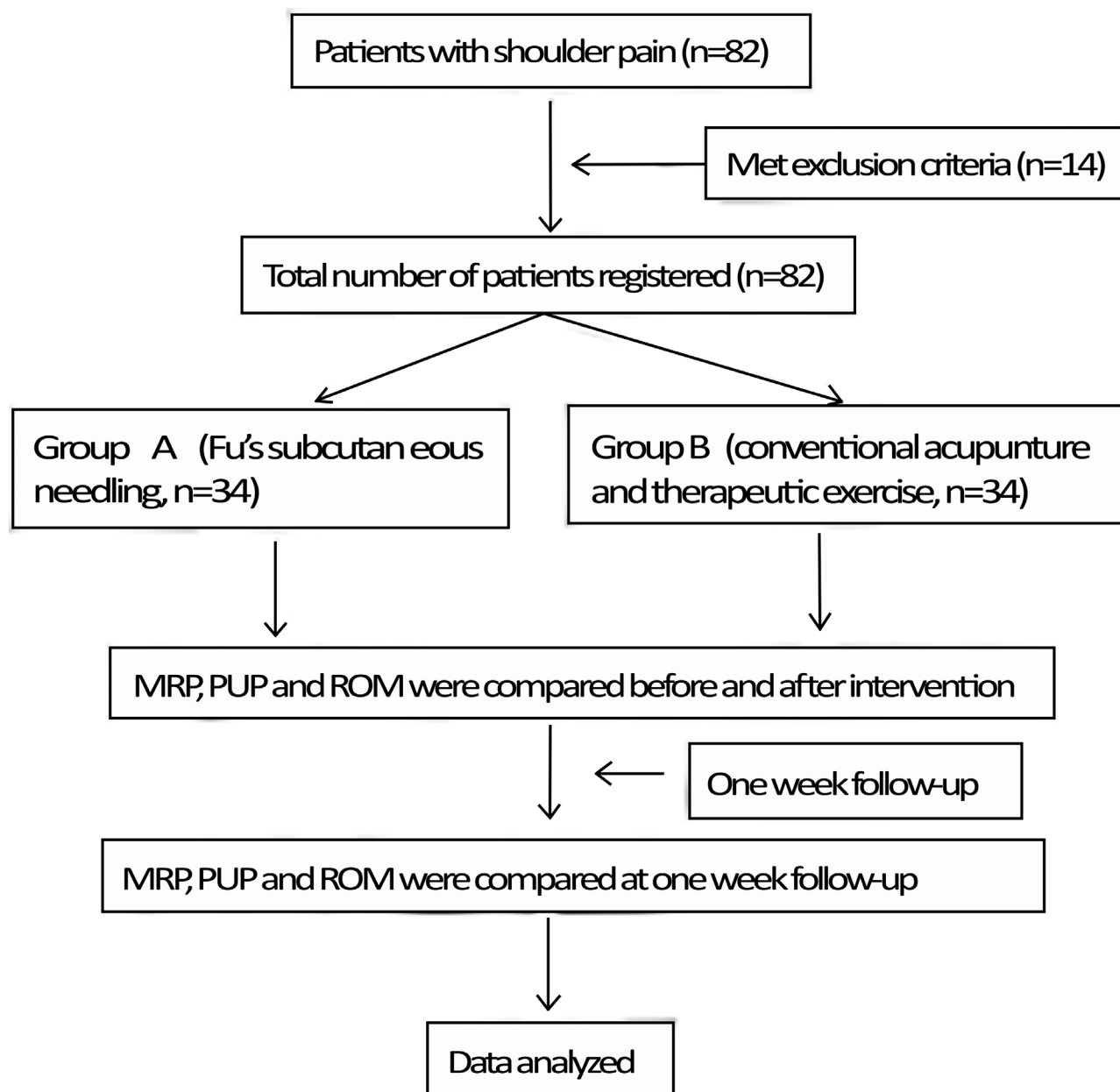


FIGURE 2 Flow chart of the study

Group	N	Sex (male/female)	Age (year)	Onset time (day)
A	34	21/13	35.5 ± 8.31	3.5 ± 1.91
B	34	18/16	37.3 ± 7.89	2.8 ± 1.46

TABLE 1 Demographic data

Note: Demographic data of all patients were presented.

not be categorized based on various clinical examinations including ultrasound, MRI or X ray examination. In this study, patients had no history of shoulder trauma. A suggestive explanation is that this type of shoulder pain could likely be contributed to local muscular tension or muscular ischemia (Gawke, Gorgievski, & van der Linden, 2012; Huysmans, Blatter, & van der Beek, 2012;

Robstad Andersen & Westgard, 2014), which were induced by overuse, repetitive movements or static position of the joint. Local muscular tension or ischemia may cause muscle damage and accumulation of metabolites with release of pain mediators, eventually leading to pain. With all of these factors in mind, we propose that FSN intervention may impact shoulder pain by

TABLE 2 Comparison of MRP, PUP, and ROM before and after intervention

Group	N	MRP			PUP			ROM		
		Baseline	PI	p1 value	Baseline	PI	p1 value	Baseline	PI	p1 value
A	34	7.0 ± 1.15	1.8 ± 0.91	<.01	7.1 ± 1.22	2.2 ± 0.74	<.01	2.2 ± 1.60	0.7 ± 0.64	<.01
B	34	6.5 ± 1.26	3.2 ± 0.78	<.01	7.3 ± 0.91	3.4 ± 1.23	<.01	2.3 ± 0.64	1.6 ± 0.49	<.01
p2 value		0.47	<.01		0.69	<.05		0.74	<.01	

Note: Values were presented as a number, mean ± SD. p1, comparison between baseline and postintervention; p2, comparison between A group and B group at baseline and postintervention.

Abbreviations: MRP, motion-related pain; PI, postintervention; PUP, pain under pressure; ROM, range of motion.

TABLE 3 Comparison of MRP, PUP, and ROM after 1 week follow-up

Group	N	MRP			PUP			ROM		
		PI	1 week	p1 value	PI	1 week	p1 value	PI	1 week	p1 value
A	34	1.8 ± 0.91	1.4 ± 0.48	0.24	2.2 ± 0.74	1.5 ± 0.81	0.07	0.7 ± 0.64	0.6 ± 0.48	0.71
B	34	3.2 ± 0.78	2.7 ± 0.78	0.12	3.4 ± 1.23	2.3 ± 0.64	<0.05	1.6 ± 0.49	1.5 ± 0.67	0.72
p2 value		<.01	<.01		<.05	<.05		<.01	<.05	

Note: There were clinical data for three groups. Values were presented as a number, mean ± SD. p1, comparison between baseline and postintervention; p2, comparison between groups A and B at baseline and postintervention.

Abbreviations: MRP, motion-related pain; PI, post-intervention; PUP, pain under pressure; ROM, range of motion.

improving the patient's local muscular tension or blood flow, which were consistent with a previous study (Fu et al., 2006). The physiological mechanism underlying pain reduction to FSN had not yet been elucidated, but studies have indicated that FSN is effective treatment (Feng, Lin, Zhang, Yang, & Li, 2020; Li, Tan, Du, & Shen, 2017).

4.2 | The difference of FSN and acupuncture

Acupuncture and FSN are both needling therapies for pain relief. However, FSN is quite different from acupuncture in the following three aspects: (a) FSN needle is confined in the subcutaneous layer, but acupuncture may affect the muscle layer, (b) movement of FSN needle is smooth and rhythmic, while acupuncture is characterized by “rotation and up-and-down” movement, and (c) FSN does not elicit Deqi (a Traditional Chinese Medicine [TCM] term to describe the feature when a patient experiences soreness, ache, or numbness during acupuncture time) while acupuncture goes deep into the muscular layer and elicit “Deqi”. In consideration of the more rapid and effective effects of FSN than the traditional acupuncture, we attributed the immediate effects of FSN to its larger influence on improving local muscular tension or ischemia because of FSN could influence neural regulation.

In this pilot study, we used FSN to treat shoulder pain. We found pain and range of motion were improved immediately after intervention. Although there was no significant difference between postintervention and 1-week follow-up, clinical signs were improved at 1 week. We speculate that FSN inhibits the release of pain transmitters or destroys the nerve terminal in the subcutaneous layer. However, local numbness was not found in our study. The exact mechanism remains unknown. We did not find any adverse event in our study, indicative of the safety of this intervention. Although results are encouraging, some study limitations should be noted. Statistically, the sample size is small, which might cause insufficient statistical power and type II statistic error. Outcomes were evaluated postintervention and 1 week after intervention, so we are not sure how long the effective time from post-intervention last.

5 | CONCLUSION

The use of FSN intervention has increased in the last decade. FSN, as a new medical technology, may improve shoulder pain after intervention and could be an effective and safe method for treating shoulder pain.

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AUTHOR CONTRIBUTIONS

Ming-hong Wang: Writing-review & editing. **Howe Liu:** Investigation; methodology. **Hong-Fei Shi:** Data curation. **Yasser Salem:** Validation. **Zhi-min Zhu:** Visualization. **Ju-ying Xie:** Project administration.

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