

Fu's Subcutaneous Needling: Possible Clinical Evidence of the Subcutaneous Connective Tissue in Acupuncture

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ABSTRACT

Objectives: Recently it was reported that the loose connective tissue in the subcutaneous layer rapidly responded to mechanical forces evoked by acupuncture, massage, and normal physical movements. However, there were no clinical studies to substantiate these findings so far. Fu's Subcutaneous Needling (FSN) is the innovative needling strategy acting specifically in the subcutaneous layer. A single-blinded and randomized trial was designed to compare the immediate effects of FSN with different needling directions on myofascial trigger points (MTrP) in the neck.

Design: For simplicity, we chose two mutually perpendicular needle directions in this study. In one group, the needle was along the local muscle fibers and pointed to the MTrP (Along Group). In the other group, the needle was across the local muscle fibers and also pointed to the MTrP (Across Group).

Subjects: Forty-seven (47) patients were randomly divided into two groups: the Along Group ($n = 22$) and the Across Group ($n = 25$). There were no significant differences with respect to age, duration of pain, and gender between the two groups.

Interventions: FSN needles were inserted and swayed in the subcutaneous layer 200 times in 2 minutes.

Results: Before and after FSN treatment, patients were subjected to the assessment of the following three parameters: motion-related pain, pain under pressure, and the range of cervical movement. Three parameters were all reduced after the FSN intervention. There were no significant differences in variation of the three parameters between the two groups.

Conclusion: Immediate effects of FSN on alleviating MTrP in the neck were not relevant to the needling directions.

INTRODUCTION

Although considerable efforts have been made to understand the underlying mechanisms of acupuncture, the way acupuncture works remains elusive.¹ Recent studies suggested that the loose connective tissue may be involved in the action of acupuncture.^{2,3} However, there were no such clinical studies addressing this issue.

Fu's Subcutaneous Needling (FSN) is a needling therapy like acupuncture. FSN mainly acts in the subcutaneous

layer,^{4,5} whereas acupuncture involves several layers: the skin, the subcutaneous layer, and the muscular layer. Therefore, to study the relationship between the needling therapy and the subcutaneous layer, it is better to use FSN than acupuncture.

FSN was able to relieve chronic low-back pain in our previous randomized study.⁶ In this study, we compared effects of FSN with different needling directions on alleviating the myofascial trigger-points (MTrP) in the neck by a single-blinded and randomized trial. In one group, the needle was

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inserted along the local muscle fibers. In the other group, the needle was inserted across the local muscle fibers. To exclude the influence by the natural course of disease,^{7,8} we observed the immediate effect of FSN instead of the long-term effects in this study.

MATERIALS AND METHODS

FSN needles

FSN needles⁴ (FSN Medical Appliances Company, Nanjing, China) consists of two parts: the soft tube, and the stainless steel needle (with a 10-mm diameter) and its handle (Fig.1). The steel needle is 3 mm longer than the soft tube in order to easily penetrate the skin.

Participants

Patients who referred to the Acupuncture Department outpatient clinic of TCM Hospital of Jiangsu Province and were diagnosed having MTrPs in the neck were given verbal as well as written information about this study.⁹ Those who gave autonomous informed consent were allowed to participate in this trial. From September 1 to December 31, 2005, 47 patients were enrolled in this study.

All of the procedures were approved by the Human Ethics Review Boards of TCM Hospital of Jiangsu province. All subjects met the following criteria.

Inclusion criteria

1. Presence of a tender spot characterized by spontaneous pain associated with movement of local muscle.
2. Reproduction or enhancement of the clinical symptoms by compression of the MTrP.

3. Presence of a palpable taut band peripheral to the MTrP.
4. Restricted range of motion of the related joint.
5. Age between 18 and 80 years.
6. Trigger points in neck and upper back having duration more than 10 days and less than 1 year with an intensive disturbed daily activity.

Exclusion criteria

1. Pregnancy.
2. Having a history of fractures.
3. Having a history of surgery of the cervical spine.
4. Having taken any analgesic drug and accepting other treatments within 1 week.

Interventions

Enrolled patients were first subjected to pre-intervention assessment (described below in the section on Outcome Measures) by a qualified physician (Dr. Wang) and then randomly divided into two groups using sealed envelopes: the Along Group and the Across Group.

For each patient, the most severe MTrP was identified and marked after the determination of the insertion points. In the Along Group, the insertion points were along the direction of the muscle fibers. In the Across Group, the insertion points were across the direction of the muscle fibers. In both groups, the chosen insertion points were 7–8 cm away from the MTrP (Fig. 2).

After disinfection with 75% ethanol, a 3.5-cm FSN needle was quickly inserted through the skin and into the subcutaneous layer. It was vital to make sure the needle tip is not too deeply and to stop when the needle tip just touched the muscular layer. It was necessary to draw a little back into the subcutaneous layer and then push the needle forward parallel to the skin surface and toward the MTrP un-



FIG. 1. Schematic illustration of FSN needles. **A.** The whole parts of Fu's Subcutaneous Needling (FSN) needles; **B.** The separated parts of FSN needles are the steel needle (upper) and the soft tube (lower).

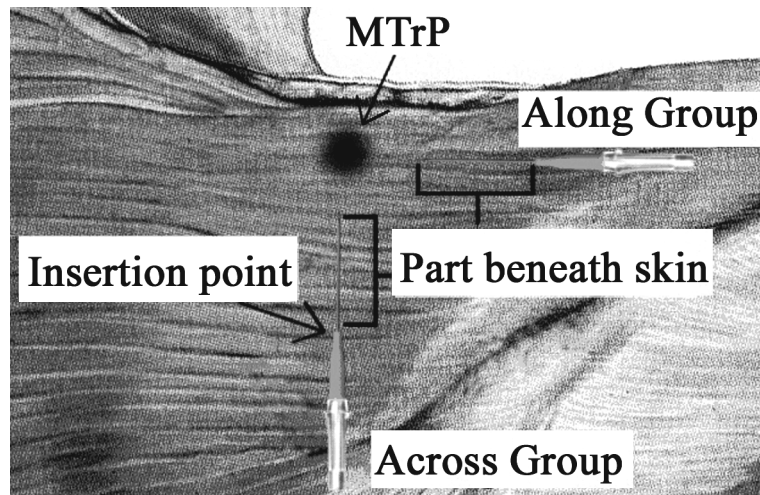


FIG. 2. Schematic illustrations of different needling directions in the two groups. In the along group, needles were inserted along the local fibers, whereas in the across group, needles were inserted across the local fiber. The insertion points in both groups were equidistant from the MTrP (7–8 cm).

til the whole soft tube was beneath the skin. Then it was necessary to draw the steel needle back 3 mm to wrap the steel tip in the soft tube in order not to injure blood vessels or other tissues during the following procedure. The needles were moved smoothly and rhythmically from one side to another horizontally 200 times in 2 minutes in both groups. Normally whole needles are pulled out at the end of the swaying. However, in the clinic only the steel needle was pulled out instead of the whole needle at the end of the treatment. The soft tube of the needle remained under the skin for 8–24 hours.⁵ In this study, the whole needle was pulled out only so we could observe the immediate effects of FSN therapy.

Outcome measures

After the treatment procedure, patients were subjected to the same assessments with the pre-intervention. The following parameters were quantified and compared between the two groups and between pre- and postintervention.

Motion-related pain (MRP). Patients rated the most painful intensity for a certain movement using an 11-point visual analogue scale. The certain movement was one of the following six movements: flexion and extension, lateral flexion right/left, and rotation right/left.¹⁰ The one that was the most difficult for the patient to move was chosen and the patient did the same movement after intervention. Patients

were clearly instructed to rate the MRP intensity on a continuum from “absence of pain” at one end of the line to “intolerable pain” at the other.¹¹

Pain under pressure (PUP). It is important to assess PUP because MTrP is a site of exquisite tenderness to palpation and local tenderness is the top diagnostic feature of MTrP.^{12,13} We used an algometer (Nanjing FSN Medical Appliances Company) with a maximal pressure of 20 N.⁶ During measuring, the algometer was placed on the MTrP and 20-N pressure was applied for 2 seconds. Then the patients were asked to rate the PUP intensity in the same 11-point linear scale as in MRP.

Range of motion (ROM). ROM was assessed for the six movement directions mentioned above: flexion and extension, lateral flexion right/left, and rotation right/left. In order to avoid biases by the different bodily dimensions of the subjects, these assessments were expressed as scores from 0 to 3: 0—no abnormality; 1—the patient felt a bit of discomfort during one of the six movements while there was no obvious hindrance; 2—there was obvious difficulty during one of the six movement or the patient could not easily complete one of the movements; 3—the patient was incapable of completing each of the six movements.¹⁴ The score definition was a little different from what was normally defined with small numbers to represent good situations.

The above three parameters (MRP, PUP, and ROM) were

TABLE 1. INFORMATION ON ENROLLED PATIENTS

	Along group (n = 22)			Across group (n = 25)		
	50	25	75	50	25	75
Age (years)	54.50	38.25	64.00	48.00	35.00	64.00
Duration (months)	1.50	0.32	6.00	1.00	0.30	3.50

Median = 50, percentiles 25 and 75.

TABLE 2. VALUES OF MRP, PUP, AND ROM IN THE TWO GROUPS (MEAN $\pm$ STANDARD DEVIATION)

Group	Preintervention			Postintervention		
	MRP	PUP	ROM	MRP	PUP	ROM
Along group (22)	6.05 $\pm$ 2.44	6.23 $\pm$ 1.69	2.32 $\pm$ 1.04	3.59 $\pm$ 1.89**	3.82 $\pm$ 1.33*	1.36 $\pm$ 0.90*
Across group (25)	5.32 $\pm$ 2.14	6.16 $\pm$ 1.25	1.80 $\pm$ 1.04	2.76 $\pm$ 1.88*	3.28 $\pm$ 1.06*	1.12 $\pm$ 0.88**
<i>p</i> -value	0.37	0.15	0.94	0.95	0.38	0.38

MRP, motion-related pain; PUP, pain under pressure; ROM, range of movement.

** and *, parameters were significantly reduced after intervention with *p*-values less than 0.01 and 0.05, respectively.

often used to quantify pain in the clinic, and their values were sufficient to demonstrate the difference between the FSN group and the minimal needling group in our previous study.^{6,10–14}

For pre- and postintervention assessment of MRP and ROM, the patients replicated the same movement direction.

RESULTS

Participants

Characteristics of the patients (male 15, female 32) are presented in Table 1. There was no significant difference between the two groups with respect to age and duration of pain through a *t*-test for Equality of Means.

A chi-square test showed no significant between-group difference for Gender (Along Group: male 9, female: 13; Across Group: male 6, female 19).

MRP, PUP, and ROM

MRP, PUP, and ROM all reduced significantly after FSN treatment in both groups ($p < 0.05$ or $p < 0.01$, Table 2). There were no significant differences with MRP, PUP, and ROM in both groups either before or after intervention ($p > 0.05$, Table 2). All these data showed that the two needling methods had similar pain relief effects, and this was directly supported by the nonsignificant difference in the variation of MRP, PUP, and ROM after intervention between the two groups (Table 3).

DISCUSSION

This study showed that the immediate effects of FSN on alleviating MTrPs in the neck were less relevant to the direction of the needle inserted.

Patients normally had more than one MTrP. As a pilot study, we didn't treat each MTrP. The most severe one was selected to simplify the experiment.

Pressure threshold and tolerance were often used to quantify the single-point pain in pain measurements. However, both parameters usually varied with time, the intensity implied, and the patients' response.^{15,16} Therefore, this trial used PUP instead of pressure threshold and tolerance to quantify the pain.

FSN is quite different from the traditional acupuncture in the selection of the insertion points, the tissue layer involved, and the rules obeyed during manipulation. FSN mainly acts in the subcutaneous layer, whereas in acupuncture the needles penetrate into the muscular layer. The needle manipulation strategy was also different in the two needling methods. Needles in acupuncture were rotated and moved up and down; while in FSN the needles were swayed in the subcutaneous layer. *De qi* was a characteristic feature either sensed by the participants as soreness, ache, and numbness or sensed by the acupuncturist as though the tissues were grasping the needles or both. Recently, the histologic basis for the "needle grasp" phenomenon was discovered as the winding of the connective tissue around the needles.¹⁷ In FSN, both the participants and the needle manipulator had no such feelings as in acupuncture.

TABLE 3. VARIATION OF MRP, PUP, AND ROM AFTER INTERVENTION IN BOTH GROUPS (MEAN $\pm$ STANDARD DEVIATION)

	Variation		
	MRP	PUP	ROM
Along group (22)	2.46 $\pm$ 1.68	2.41 $\pm$ 1.47	0.96 $\pm$ 0.90
Across group (25)	2.56 $\pm$ 1.83	2.88 $\pm$ 1.44	0.68 $\pm$ 0.85
<i>p</i> -value	0.84	0.65	0.29

MRP, motion-related pain; PUP, pain under pressure; ROM, range of movement.

CONCLUSIONS

Although we are confident about the location of the FSN needle tips during the manipulation, we need more objective methods, such as ultrasound imaging, to address this issue. However, FSN provides a very convenient way to alleviate pain.

FSN is superior to acupuncture in the following aspect. FSN is easy to learn and exercise in the clinic because of the optional insertion points. In acupuncture, the insertion points for a certain disease are fixed and the distribution of the meridian points in the whole body must be learned first before the acupuncture clinic.

According to our experience, there was little possibility that the nervous system is involved in the action of FSN. However, we cannot exclude the possibility completely. Recently, it was reported that the mechanical forces could induce signal transduction and gene expression in fibroblasts of the subcutaneous tissue.¹⁷⁻¹⁹ Diverse cell types such as fibroblasts, adipocytes, and immune cells were incorporated in the loose connective tissue and may mediate mechanics-induced downstream events.²⁰

The easy manipulation without knowing how to stimulate *de qi* and the immediate effects of FSN allowed it to become more easily acceptable in the clinic setting. Moreover, FSN provides a convenient way to study the needling mechanisms and may have some implications for uncovering the underlying mechanism of traditional acupuncture.

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