# Short and Long-Term Results of Connective Tissue Manipulation and Combined Ultrasound Therapy in Patients With Fibromyalgia

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## Abstract

**Objective:** The aim of the study was to evaluate the short-term and 1-year follow-up results of connective tissue manipulation and combined ultrasound (US) therapy (US and high-voltage pulsed galvanic stimulation) in terms of pain, complaint of nonrestorative sleep, and impact on the functional activities in patients with fibromyalgia (FM).

**Methods:** This is an observational prospective cohort study of 20 female patients with FM. Intensity of pain, complaint of nonrestorative sleep, and impact of FM on functional activities were evaluated by visual analogue scales. All evaluations were performed before and after 20 sessions of treatment, which included connective tissue manipulation of the back daily, for a total of 20 sessions, and combined US therapy of the upper back region every other session. One-year follow-up evaluations were performed on 14 subjects. Friedman test was used to analyze time-dependent changes.

**Results:** Statistical analyses revealed that pain intensity, impact of FM on functional activities, and complaints of nonrestorative sleep improved after the treatment program ($P < .05$).

**Conclusion:** Methods used in this study seemed to be helpful in improving pain intensity, complaints of nonrestorative sleep, and impact on functional activities in patients with FM. (J Manipulative Physiol Ther 2006;29:524-528)

**Key Indexing Terms:** *Fibromyalgia; Musculoskeletal Manipulations; Electric Stimulation Therapy; Ultrasonic Therapy*

Fibromyalgia (FM) is characterized by chronic widespread pain, increased tenderness to palpation, and additional symptoms such as disturbed sleep, stiffness, fatigue, and psychological distress.[1] Although it is a syndrome of unknown etiology, there has been a renewed perception that autonomic nervous dysfunction could play a major role in the pathogenesis of this syndrome.[2] The basal autonomic state of patients with FM is characterized by increased sympathetic and decreased parasympathetic tones. Autonomic dysregulation may have implications regarding the symptoms and physical and psychological aspects of health status.[3] There are several earlier etiologic hypotheses regarding FM, including that FM is a rheumatoid-like disease or a disorder of muscular abnormality or repair; that it results from aberrant mechanisms of peripheral pain; that it is a psychoneuroendocrine-immune disorder; that it is a psychomatic disorder or; and that it is a psychiatric disorder related to major depression.[4] Recent research on genetics, biogenic amines, neurotransmitters, hypothalamic-pituitary-adrenal axis hormones, oxidative stress, mechanisms of pain modulation, and central sensitization in FM revealed various abnormalities.[5] All these etiologic explanations indicate that multiple factors and mechanisms are involved in the pathogenesis of FM.

Because there is no known cause, or cure, and therefore treatment focuses on the control or relief of symptoms.[6]

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Although medication mainly focuses on pain reduction, physical therapy is aimed at disease consequences such as pain, fatigue, deconditioning, muscle weakness, and sleep disturbances.[1]

Literature about nonpharmacologic management of FM includes the effects of physical exercise, massage techniques, cryotherapy, acupuncture, transcutaneous electrical nerve stimulation, ultrasound (US), relaxation, balneo and spa therapy, cognitive-behavioral therapy, body awareness therapy, chiropractic/osteopathic care, magnet therapy, and herbal and nutritional supplements.[1,7-14]

Connective tissue manipulation (CTM) is one style of massage technique and is thought to be an effective therapy, producing general body relaxation, reducing muscle spasm and connective tissue tenderness, and increasing plasma $\beta$-endorphins.[15] In the CTM technique, the strokes are applied to the defined zones of the body by using fingertips in a specific sequence and are believed to cause beneficial reflex effects in the organs and tissues innervated by the zones.[15-18] Connective tissue manipulation–related literature is mainly about its effects on autonomic responses, FM, migraine, tension type headache, and Raynaud's disease.[18-23]

Ultrasound therapy has achieved recognition as a suitable method in physical medicine treatment of acute and chronic musculoskeletal disorders. Ultrasound consists of sound waves with a frequency of more than 20 000 Hz/s. The sound waves are absorbed differently in tissue with low and high protein content. Experimental studies have shown that it is possible to heat deeper structures, such as joints, muscle, and bone, with US.[8] The efficiency of US treatment in myofascial pain is related to the effect of increasing blood flow, membrane permeability, and capillary density in skeletal muscles.[24]

Literature about high-voltage pulsed galvanic stimulation (HVPGS) is usually about its effects on force of induced muscle contraction, augmentation of muscle strength, muscle blood flow, reduction of pain and discomfort in patients with levator ani syndrome, and healing of thermal burns and dermal ulcers.[25-30] We did not find any study in the literature regarding its usage in patients with FM.

In the literature, there are few studies of physical methods claimed to be effective in treating FM. Given that CTM may regulate autonomic responses and decrease connective tissue tenderness, US may reduce muscle tension and increase microcirculatory flow at tender points, and that HVPGS plays a role in augmentation of muscle strength, increasing muscle blood flow and reducing pain, it is hypothesized that usage of CTM and combined therapy with HVPGS and US might be of clinical benefit in patients with FM. Therefore, this study was performed to evaluate the results of CTM and combined US therapy (US and HVPGS) in terms of pain, complaint of nonrestorative sleep, and impact on the functional activities of patients with FM, and to assess if these results were maintained 1 year after the study.

## Methods

This study was approved by the Ethics Committee of Hacettepe University, Faculty of Medicine, Ankara, Turkey. Twenty outpatients, who were diagnosed as FM by a physiatrist, according to the physical examination findings and FM diagnostic criteria of the American College of Rheumatology,[31] participated in this study. The sample was derived from a population of 83 FM outpatients of the Hacettepe University School of Physical Therapy and Rehabilitation, during the period of August 2003 to December 2004. Patients were eligible for the study if they met the following inclusion criteria: female; had FM pain with an intensity that interfered with activities of daily living for a duration of at least 6 months; able to participate in 20 physiotherapy sessions within a 4-week period; and volunteered for participating in the study without taking any drugs that act on the nervous system (eg, antidepressants, myorelaxants, analgesics, hypnotics) in the study period. Patients were excluded from the study if they showed evidence of neurologic, infectious, endocrine, and other inflammatory rheumatic diseases. Patients with an experience with any kind of manual and/or electrotherapy, within 6 months before the study, were also excluded. Informed consent was obtained from the subjects.

Age, weight, and height of the subjects were recorded as the physical characteristics. Subjects were asked if they were using medications (analgesics, myorelaxants, and antidepressants) before applying to the study. Duration of the complaints due to FM and working status (working full time/not working) were noted. Because the most common goals in the management of FM are to break the pain cycle, to restore sleep patterns, and to increase functional activity levels,[32] the parameters investigated in this study included intensity of pain, complaint of nonrestorative sleep, and impact of FM on functional activities which were evaluated by 0- to 10-cm-length visual analogue scales (VASs). On the VAS, "0" indicated "no pain" and the "10" indicated "the worst imaginable pain" for pain evaluation. Impact of FM on functional activities was assessed by VAS, on which the "0" referred to "no difficulty in functional activities" and "10" represented "great difficulty in functional activities." Complaint of nonrestorative sleep was also assessed by VAS, in which "0" meant "refreshing sleep" and "10" meant "nonrefreshing sleep." Subjects were asked to mark the point on the VAS that best matched their intensity of complaints.

All evaluations were performed before and after 20 sessions of treatment. The treatment program included CTM of the back daily, for a total of 20 sessions and HVPGS + US to the upper back region every other day during 4 weeks. An experienced physiotherapist (ICK) carried out the CTM technique, but did not have a role in the evaluations.

The position of the patients during treatment sessions was sitting with the hips and knees at 90° flexion and feet supported, arms relaxed on the thighs, back naked and

**Table 1.** *Pretreatment, posttreatment, and 1-year follow-up values of VAS (0-10 cm)*

| | Pretreatment (n = 20) | | Posttreatment (n = 20) | | Follow-up (n = 14) | |
|---|---|---|---|---|---|---|
| | | 95% CI | | 95% CI | | 95% CI |
| | Mean | Lower-upper bound | Mean | Lower-upper bound | Mean | Lower-upper bound |
| Pain intensity | 6.87 | 5.95-7.79 | 3.24 | 2.27-4.21 | 4.00 | 2.52-5.49 |
| Impact on functional activities | 6.64 | 5.51-7.76 | 2.72 | 1.57-3.87 | 4.29 | 2.90-5.67 |
| Complaint of nonrestorative sleep | 7.37 | 6.24-8.50 | 3.15 | 2.11-4.18 | 5.36 | 3.76-6.95 |

*CI*, Confidence interval.

straight, allowing optimal tension of the connective tissue. The CTM procedure consisted of treating 5 sections in the back. These sections were basic (sacral and lumbar regions), lower thoracic (L1 through T7), scapular, interscapular (T7 through C7), and cervico-occipital (C7 through occiput). The physiotherapist applied strokes by her middle finger of the right or left hand to the defined zones of the mentioned sections in the back. The treatment started from the basic section, and progress to other regions was decided according to the vascular reaction of the connective tissue. Each session lasted for 5 to 20 minutes, depending on the extent of the treated area.

High-voltage pulsed galvanic stimulation and US were applied to all of the subjects in the prone lying position, by the same physiotherapist (FD), for a duration of 10 minutes. The frequency of HVPGS was 50 Hz, and the duty cycle was set at 5 seconds on and 5 seconds off during the stimulation. Intensity of the current was increased up to the patient's maximum tolerance. Pulsed US frequency was 1 MHz, 1.5 W/cm$^2$ (Intellect 340 Combo, Chattanooga Group, Inc, Chattanooga, Tenn).

Before the subjects were discharged, they were informed about ergonomic principles and correct posture related to working, resting, and daily activities to prevent the overload of the body segments and to maintain the gains from the treatment.

One year after the treatment, subjects were asked to participate in follow-up evaluations. In the follow-up evaluations, current pain intensity, complaint of nonrestorative sleep, and impact of FM on functional activities were reevaluated by the same method as the pre- and posttreatment ones. In addition, subjects were asked how long the effects of the treatment lasted (months) and if they had needed to attend to any other medication and/or physical therapy programs (yes/no) after discharge. Patient satisfaction with the treatment program was evaluated on the 0- to 10-cm-length VAS (0 = no satisfaction at all, 10 = completely satisfied).

### Statistical Analyses

SPSS 11.5 for Windows (SPSS, Inc, Chicago, Ill) was used for statistical analyses. Mean values and 95% confidence intervals of the investigated data were presented for each measurement time. The Friedman test was used to analyze time-dependent changes of the values. Level of significance was set at $P < .05$.

**Table 2.** *Changes of VAS values from pretreatment to follow-up visit ($\chi^2$: Friedman test)*

| | $\chi^2$ | $P$ |
|---|---|---|
| Pain intensity | 13.857 | .001 |
| Impact of FM on functional activities | 9.927 | .007 |
| Complaint of nonrestorative sleep | 14.815 | .001 |

## Results

The mean age of the subjects was 40.1 ± 15.0 years and the duration of FM symptoms was 4.75 ± 3.97 years. Mean body mass index value of the subjects was 23.58 ± 4.06 kg/m$^2$. Fifty-five percent of the subjects were working full time. All of them were using medications for their FM symptoms before the treatment program.

Table 1 presents pretreatment, posttreatment, and 1-year follow-up mean values of the pain intensity, impact of FM on functional activities, and complaint of nonrestorative sleep. Statistical analyses revealed that pain intensity, impact of FM on functional activities, and complaint of nonrestorative sleep improved after the treatment program ($P <$ .05) (Table 2).

One year after the treatment, 14 of 20 subjects could be reached by phone calls and accepted to attend the follow-up evaluations. Approximately 30% of the subjects could not be reached or did not attend the follow-up visit, so their follow-up findings were not included in this study.

The duration of symptom improvement was evaluated 1 year after the treatment. According to the statements of the subjects, the minimum duration of the treatment effectiveness was 3 months. Of 14 subjects, 6 (43%) reported that FM-related problems began to rise up 3 months after the treatment. Three subjects (21%) were still free of FM symptoms 1 year after the treatment. The mean duration of treatment relief was 6.50 ± 3.76 months.

Subjects were asked if they had attended to any other medical and/or physical therapy programs during the

follow-up period. It was found that none of the subjects had attended to any physical therapy programs, but 5 (36%) of 14 subjects began to use medications since their FM-related symptoms reoccurred. The rest of them (64%) reported that they did not have the need of any medications. Patient satisfaction with the treatment program as evaluated by the 0- to 10-cm-length VAS was 7.14 ± 2.83 cm.

## Discussion

This observational prospective cohort study examined the results of a physiotherapy program including a manual technique and a combined electrotherapy approach in patients with FM. Although the present study did not include a control group, it can be said that CTM and combined HVPGS and US seemed to provide benefits in patients with FM in aspects of pain relief, restoration of sleep, and improving the impact of FM on functional activities, which was maintained for a mean duration of 6 months after the program.

Brattberg[33] investigated the effect of CTM on FM. In that study, it was presented that CTM was a treatment giving pain relief, decreasing depression, and increasing quality of life in patients with FM. It was reported that the analgesic effect appeared gradually with the first 15 treatments (1-2 per week) and positive effects decreased gradually after the last treatment session.

Almeida et al,[24] who performed the first study investigating the effects of a combined electrotherapy approach in FM, pointed out that combination of interferential current and pulsed US was more effective than each of them separately, and this combination provided an effective pain treatment with consequent sleep improvement in FM. They also suggested that sleep disorder in FM might be due to a presleep pain condition; thus, the improvement in sleep could lead to less pain in the morning.

Parallel to the findings of Almeida et al,[24] although not supported with comparison to each other or with sham techniques, our study also indicates that combination of CTM, HVPGS, and US leads to improvements in disease consequences such as pain, sleep disturbance, and impaired functional activities. As mentioned in the introduction section, current concepts about pathophysiology of FM are mainly about autonomic and central nervous system dysregulation. Therefore, improvements achieved in this study may be thought mainly due to the effects of CTM including the regulation of autonomic responses, producing general body relaxation, and increasing plasma $\beta$-endorphins.[15] In addition, the previously presented effects of the methods on reducing muscle tension, relieving connective tissue tenderness and pain, increasing microcirculatory muscle blood flow, and augmentation of muscle strength[15,24-30] might have played role in improving the disease symptoms such as muscle tenderness and tension rather than directly regulating the suspected underlying mechanisms of FM, although these parameters are not included as the findings.

When the design of this study is considered, it is difficult to say which modality led to improvement in investigated parameters, and if suggestions directed to maintain the gains from the treatment program in the follow-up period played role in the long-term results. Missing follow-up values of 30% of the cases are a limitation of this study, and it is difficult to comment if their values would change the results positively or negatively. However, it can be concluded that combination of the methods used in this trial seemed to be helpful in patients with FM, although placebo effect or natural history cannot be ruled out.

## Conclusion

CTM, HVPGS, and US seemed to be helpful in improving pain intensity, complaints of nonrestorative sleep, and impact on functional activities in patients with FM. Effectiveness of these methods is thought to be worthy of investigation in further studies, including comparisons with other methods or sham/controlled protocols.

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