

Ultrasound Therapy of Subacromial Bursitis

A Double Blind Trial

DEBORAH SWAN DOWNING
and ARTHUR WEINSTEIN

Ultrasound (US) is used widely to treat patients with supraspinatus tendinitis, subacromial bursitis, or adhesive capsulitis (SSA). No double blind studies of US in the treatment of SSA, however, have been conducted. This study was designed to determine whether the addition of US can further decrease pain and increase range of motion in those receiving the usual courses of ROM exercises and nonsteroidal anti-inflammatory drugs (NSAIDs) or ROM exercises in patients with SSA. Twenty patients with SSA were randomized to receive true or sham US three times a week for four weeks. All other aspects of treatment remained constant (ROM exercises and NSAIDs or ROM exercises). The physician, the physical therapist, and the patients were blinded throughout the study regarding the delivery of the true or sham US. Of the multiple variables analyzed (pain, ROM, and function), no significant difference was found between the sham or true US groups. Although the study group was small, the results suggest that US is of little or no benefit when combined with ROM exercises and NSAIDs or ROM exercises in the treatment of SSA.

Key Words: *Bursitis, Pain, Ultrasonic therapy.*

Ultrasound (US) has been used for the treatment of shoulder periartthritis for 30 years.^{1,2} Its use is based on its many physiological effects, including augmentation of blood flow, increased capillary permeability and tissue metabolism, enhancement of fibrous tissue extensibility, elevation of pain threshold, and alteration of neuromuscular activity leading to muscle relaxation.³⁻⁶ The result of these effects on the inflamed, sore, stiff shoulder with bursitis or tendinitis might be a promotion of healing, reduction of muscle spasm, reduction of pain, and increased range of motion. Despite these theoretical benefits of US and its widespread use, our clinical experience shows that some patients do not improve with this therapy. Furthermore, the natural history of shoulder tendinitis or bursitis is variable; some

patients show dramatic improvement within weeks, but others do not respond to medical or physical therapy and have chronic problems for many months. Any therapy that might be helpful but is not curative should be subject to scientific, clinical studies using randomization of patients and a placebo control group.

The studies on US to date largely have lacked controlled procedures.^{1,2,7-9} One controlled, single blind study was performed on hemiplegic patients with painful shoulders.¹⁰ Ultrasound was not found to be effective in this study. Two studies that used sham US found no significant difference in improvement between the experimental (true) and placebo (sham) groups.^{11,12} One of these studies, however, involved patients with shoulder periartthritis that had resulted from a variety of contributing factors (trauma, wrist fracture, diabetes, multiple sclerosis, coronary heart disease, and degenerative joint disease of the cervical spine).¹¹ The other study admitted patients with myalgia (any muscular complaint), shoulder bursitis, or low back pain syndrome.¹² True and sham groups were formed for each of the three conditions, but established clinical criteria for diagnosis and guidelines for entry to the study were greatly lacking.

Our first aim was to determine whether US could be given in a double blind fashion. Next, the main purpose of our study was to determine whether

the addition of US, in a controlled, randomized double blind trial, can further decrease pain and increase ROM more than the usual program of ROM exercises and nonsteroidal anti-inflammatory drugs (NSAIDs) or ROM exercises in a group of patients with supraspinatus tendinitis, subacromial bursitis, or adhesive capsulitis (SSA).

Prestudy

Before beginning the US study, we conducted a prestudy on 10 volunteers to determine if US could be given in a double blind fashion. None of the volunteers had any shoulder complaints. The method of US administration was that as described below except only six "treatments" were given to each "patient." Neither the volunteer patients nor the therapist knew whether the US machine was connected to the electrical outlet during these treatments. After the six treatments, the volunteers and the therapist were asked whether they believed the US was true or sham.

At the conclusion of the prestudy, four volunteers had received the sham US and two had guessed their treatment correctly. Of the six true US volunteers, three guessed correctly and two did not. One individual who received the true US believed that the first three treatments were true US and the last three treatments were sham. These results were not significant ($\chi^2 = 0.07$, $df = 1$).

Ms. Downing is Instructor, Division of Rheumatic Diseases, Department of Medicine, University of Connecticut School of Medicine, Farmington, CT 06032 (USA).

Dr. Weinstein is Professor and Head, Division of Rheumatic Diseases and Immunology, New York Medical College, Valhalla, NY 10595.

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The therapist was unable to guess what treatment each person was receiving. All volunteers experienced a sensation of superficial warmth because the gel was warmed. Thus, the prestudy demonstrated that US could be given in a double blind fashion.

METHOD

Patient Guidelines

Patients were considered for the study if they had a diagnosis of SSA confirmed by a rheumatologist (A.W.). The guidelines for entry of the patients into the study included

1. The presence of symptoms (shoulder pain and limitation of movement) for longer than one month (to eliminate the patients with acute bursitis or tendinitis who may have a tendency to recover after the first few treatments).
2. The presence of symptoms for less than one year (to eliminate the patients with recalcitrant chronic bursitis and chronic painful shoulder syndromes).
3. The presence of pain during at least one activity (Fig. 2) and at the end range of at least one ROM test (Tab. 2).
4. A loss of 10 degrees or more in one or more of the ROM tests.
5. Baseline glenohumeral abduction greater than 45 degrees (to eliminate those patients with established "frozen shoulders").
6. Absence of any complicating rheumatic disorder or direct shoulder trauma.
7. No previous US treatments for any condition.
8. No new medical therapy (including intra-articular or intrabursal corticosteroid) for at least one week before entry.
9. Signed, informed consent.

Ten of the study patients were referred by physicians who had prescribed NSAIDs. These patients remained at a constant dosage throughout the study. To ensure clinical stability, however, each patient took the NSAIDs for at least 10 days before the initial evaluation. An erythrocyte sedimentation rate (ESR) test, a rheumatoid factor test (latex fixation), and a roentgenogram of the involved shoulder were completed on all of the study patients to rule out any other arthritic conditions.

TABLE 1
Descriptive Pain Scale^a

Level of Pain	Definition	Scale
Severe	interference and great difficulty performing most activities	3
Moderate	some interference with daily activities and difficulty sleeping	2
Minimal	no interference with usual activities	1
Asymptomatic	...	0

^a Halfway increments (0.5, 1.5, 2.5) were given on the final assessment only in those patients who did not change enough to move into another whole category but who did improve or worsen in one specific activity.

Patient Population

Twenty patients (9, sham US; 11, true US) who conformed to the above guidelines were randomized to receive true or sham US by the procedures outlined below. The patients were 12 women (7 sham, 5 true) and 8 men (2 sham, 6 true), all white, who had a mean age of 53 years (52 years, sham; 54 years, true). The age range was 28 to 75 years. The mean time lapse from onset of the shoulder problem to entry into the study was 6.2 months (sham) and 6.5 months (true). Ten patients had right (5 sham, 5 true) and 10 had left (4 sham, 6 true) shoulder involvement. Three patients had calcium deposits (sham group). Five patients in each group received the NSAIDs. Two patients had positive rheumatoid factors of titers 1:40 (sham group) and 1:80 (true group). The results of their ESR tests were normal, however, and no other symptoms existed to consider an underlying rheumatic disease. One elderly patient had an ESR of 49 (true group) but no other signs indicative of an arthritic condition.

Patient Assessment

The therapist and the physician evaluated the patients independently of one another, recording present and past medical history. Using a goniometer, the physician and the therapist recorded active and passive movement of scapulothoracic flexion (SF), scapulothoracic abduction (SA), glenohumeral flexion (GF), glenohumeral abduction (GA), internal rotation (IR), and external rotation (ER). These ROMs were measured at the beginning and at the end of the study.

To evaluate the level of pain, we used a descriptive scale (Tab. 1). The physician, the physical therapist, and patients recorded the overall level of pain that

best described the patient's condition at entry into the study and at completion of the study.

In addition, the patients stated before the beginning and at the end of the study if their condition interfered with five common activities of daily living: sleeping, dressing, work, grooming, and sports activities. Their responses were recorded, and at the final assessment, the therapist asked them whether they had improved, worsened, or remained the same in performing each of the five activities.

Last, the overall status (much better, better, no change, worse) of the patients was determined by the physician, the physical therapist, and the patients. The patients were then asked if they thought they received the true or sham US.

Equipment and Materials

The US machine* we used had a frequency of 1 MHz. The machine was checked every six months for the duration of the study (3 years) to ensure accuracy. The applicator (sound head) had a radiating surface 10 cm² and a continuous output was used. Aquasonic gel† was the coupling medium applied to the shoulder.^{13,14} We warmed the gel in a beaker of water on a hot plate before each application so that the gel was hot to touch but tolerable. We heated the gel to blind the sham patients, because the coupling medium becomes warm during the administration of true US.

Determination of Dosage

Before the beginning of the US treatments for each patient, the US dosage

* Rich-Mar IV, Rich-Mar Corp, PO Box 879, Inola, OK 74036-0879.

† Aquasonic 100, Parker Laboratories, Inc, 307 Washington St, Orange, NJ 07050.

to be used throughout the study was determined by the patient's tolerance.¹⁵ The maximal dosage was defined as the intensity at which the patient experienced a dull ache in the joint. An intensity 10% lower than the maximal (submaximal dosage) was used for each treatment so that the patient was comfortable during the treatment.⁴

Randomization and Blinding Procedure

We randomly assigned the patients according to a table of random numbers

to receive the true or sham US. After the therapist turned the intensity of the US to the submaximal dosage, she covered the controls of the machine so that neither she nor the patient were aware of whether true US was being administered. A third party kept the envelopes containing numbers that assigned the patients to the true or sham group. This person was responsible for leaving the machine connected to the electrical outlet if the patient was to receive the true US or disconnecting the machine from the electrical plug if the patient was to receive the sham US. The mean dose

setting for the sham group was 1.3 W/cm², and the mean dose setting for the true US group was 1.2 W/cm².

Each US treatment lasted six minutes and covered a field size of about 150 cm².¹⁵⁻¹⁷ If the patient appeared to suffer from localized tendinitis, the US was concentrated in that particular area in addition to the anterior, medial, and posterior aspects of the glenohumeral joint. If a patient suffered from adhesive capsulitis, the US was concentrated near the capsule line covering the anterior, medial, and posterior areas surrounding the joint. If spasm existed in the trapezius muscle or supraspinatus muscle area, US was applied to that area for an additional five minutes.

Hot gel was applied at the beginning and periodically throughout the true or sham US treatment. As an extra precaution, the therapist avoided touching the gel during and after each US application to prevent knowing, by the coolness or warmth, which treatment the patients received. Towels were used to clean the gel from the transducer head. Active, active assisted, and passive ROM exercises followed each US or sham treatment. Home exercises were given to each patient, and the use of a heating pad was suggested. Each patient received a total of 12 treatments in the double blind phase at the rate of three treatments each week.

Upon completion of the four-week, double blind phase, patients who were still symptomatic had the option of entering an open phase to receive true US and exercise treatments. If the patients had no improvement after the six treatments in the open phase, the program was discontinued. If they had improvement, then the treatments were continued until the patient was asymptomatic.

Data Analysis

The mean changes in ROMs from the initial and final visit in both groups were analyzed using Student's *t* test. The differences in the mean change of ROMs between the true and sham US groups also were analyzed using the *t* test. Improvement in overall pain for both groups was assessed by the sign test. The improvement in pain and in the ability to perform five functional tasks was compared in the sham and true US groups using chi-square analysis. The level of significance was considered to be $p < .05$.

TABLE 2
Degrees for Each Range of Motion (Mean \pm Standard Error of the Mean)

Motion	Normal	Initial		Final		Change	
		Sham	True	Sham	True	Sham	True
Scapulothoracic flexion	180	137 \pm 10	146 \pm 10	157 \pm 6	161 \pm 7	20 \pm 7	15 \pm 6
Scapulothoracic abduction	180	112 \pm 16	135 \pm 14	140 \pm 11	149 \pm 13	28 \pm 13	14 \pm 7
Glenohumeral flexion	90	87 \pm 2	85 \pm 3	89 \pm 1	87 \pm 2	2 \pm 1	2 \pm 1
Glenohumeral abduction	90	71 \pm 5	77 \pm 6	80 \pm 3	85 \pm 4	9 \pm 4	8 \pm 3
Internal rotation	90	57 \pm 7	66 \pm 6	58 \pm 9	76 \pm 7	1 \pm 2	10 \pm 4
External rotation	80	66 \pm 8	67 \pm 9	72 \pm 8	75 \pm 12	6 \pm 7	8 \pm 3

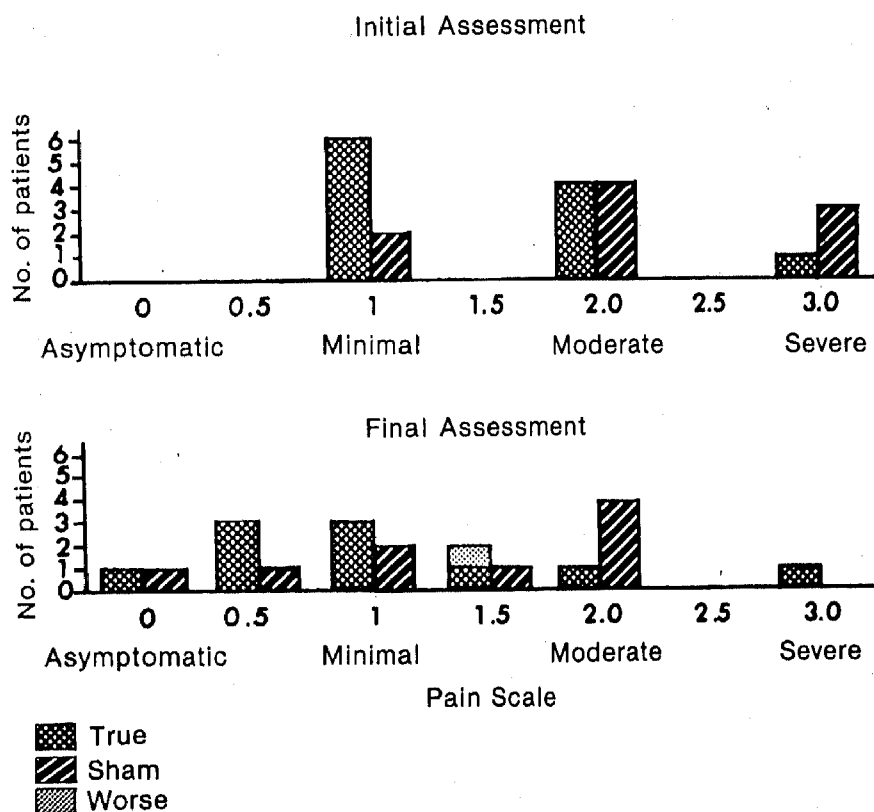


Fig. 1. The numerical values given in the scale represent the level of pain appropriate for the 20 study patients at initial and final assessment. For description of each level corresponding to the numerical value, refer to Table 1.

RESULTS

No significant difference existed between the sham and true US groups in any of the variables described under the patient population section. Of the three sham patients with calcium deposits, two improved and one did not. Of the five true US patients on NSAIDs, four did not improve and one patient was considered much better than at the beginning of the study. Three sham patients on NSAIDs did not improve, and two sham patients on NSAIDs were determined better than at the beginning of the study.

The mean initial, final, and change in ROM measurements for both groups of patients are shown in Table 2. We found no significant difference between the sham and true US groups in any of these ROMs at the initial assessment. At the final assessment for the sham US group ($df = 8$), significant improvement existed only in mean SF ($t = 3.03, p < .05$); for the true US group ($df = 10$) significant improvement existed in mean SF ($t = 2.54, p < .05$), mean ER ($t = 2.28, p < .05$), and mean IR ($t = 2.49, p < .05$). Thus, statistical and clinical improvement existed in some ROMs in both groups. Comparison of the mean change between the sham and true US groups for the various ROMs, however, showed no statistical significance except for mean IR ($t = 2.2, df = 18, p < .05$).

Results of change in overall pain are illustrated in Figure 1. On the initial assessment, most of the patients had moderate to severe pain and, on the final assessment, most patients had mild to moderate pain. Two patients became asymptomatic. One patient (true US group) experienced an increase in pain. This change in the group as a whole was statistically significant ($p < .01$). No significant difference between the sham and true US groups, however, existed in the proportion of patients who improved ($\chi^2 = 0.74, df = 1$).

Assessment of the difficulty of performing certain functional tasks is illustrated in Figure 2. Approximately one half of the patients in both groups improved in each category but, again, no significant difference existed between the mean scores of the sham and true US groups by χ^2 analysis. Only one patient (true group) had worsened at the final assessment, complaining of addi-

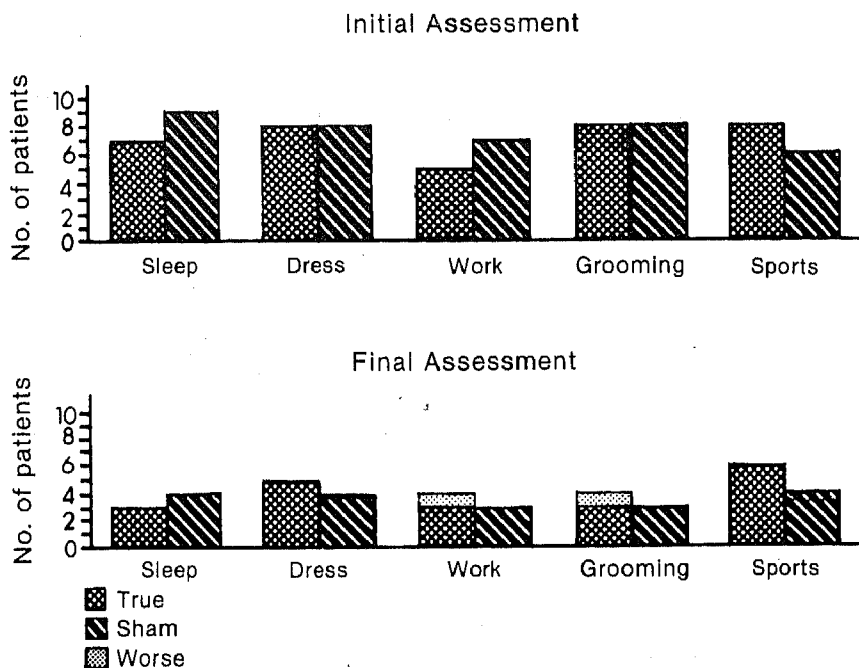


Fig. 2. Patients experiencing difficulties with certain common activities are represented in five categories at initial and final assessment. Each patient may have had difficulties with one or more activities.

tional pain during two functional activities (work, grooming).

Both the patients and the physician recorded that 50% of the patients improved their overall status. Forty-five percent of the patients were considered unchanged and one patient was worse. The physical therapist considered that 60% of the patients were better or much better than at the beginning of the study, 35% were unchanged, and one patient was worse.

Both the patients and the therapist were inaccurate in guessing whether the sham or true US was used. Six patients (2 sham, 4 true) guessed correctly, and 3 (1 sham, 2 true) guessed incorrectly. Eleven (6 sham, 5 true) were uncertain whether they had received the US ($\chi^2 = 1.71, df = 2$). The therapist guessed 11 patients (3 sham, 8 true) correctly and 6 (4 sham, 2 true) incorrectly. She was uncertain about 3 patients (2 sham, 1 true) ($\chi^2 = 1.68, df = 2$).

Ten patients (five sham, five true) entered the open phase, and only two patients (20%) improved. One of the patients who improved in the open phase was receiving the true US in the study and was already showing improvement. The other patient was not receiving the US in the study but was improving during the study and continued to improve in the open phase.

DISCUSSION

Very few double blind studies have been conducted of therapeutic US in musculoskeletal or other conditions. One double blind study of US used in patients with plantar warts found US not to be of benefit.¹⁸

One other study that incorporated double blind techniques used US with 10% hydrocortisone and US with placebo hydrocortisone.¹⁷ The use of hydrocortisone and US was found to be more effective than US alone; approximately 86% of the patients improved. Similar to our study, 45% were reported to improve with US alone. In the other study, a variety of musculoskeletal problems, including bursitis, tendinitis, and arthritis, were treated, but at various anatomical sites. Interpretation of these results, therefore, is difficult to formulate. In contrast, all patients in our study conformed to uniform diagnostic entry criteria.

Despite the lack of scientific clinical trials to determine the efficacy of US, therapeutic US is a modality that is used widely in physical therapy clinics. It can be commonly prescribed with other modalities (eg, hot packs, electrical stimulation) and with other therapeutic treatments such as exercise, massage, or mobilization. Furthermore, US can be

recommended for many musculoskeletal ailments (arthritis, bursitis, tendinitis, sprains, or strains). Much time, money, and energy are being invested in this mode of therapy. Hence, we thought a double blind study with careful controls was warranted and, therefore, undertook this study.

Subacromial bursitis and rotator cuff tendinitis are inflammatory disturbances of the periarticular tissues of the shoulder.¹⁹ The two often coexist and can lead to overlapping symptoms and signs.¹⁹ Thus, we made no attempt to distinguish between them in our study. We excluded patients with acute bursitis or acute tendinitis because these patients often are successfully treated with local corticosteroid injections and also may improve spontaneously.¹⁹⁻²¹

Patients with frozen shoulders of long duration were not admitted to the study because, very often, they have a history of unsuccessful treatment approaches. Recovery in these patients can be a slow process, even with the most vigorous of treatments. In addition, the pathogenetic mechanism of frozen shoulders may be different because of the formation of capsular adhesions and capsular shrinkage.^{19,21} We studied patients who had more localized inflammation with or without mild to moderate adhesive capsulitis.

The first aim of our study was to determine whether it was possible to administer US in a double blind fashion. Our results show that the volunteers in the prestudy, the patients, and the therapist were unable to guess accurately whether the patients were receiving the true or sham US. The patients and the therapist claimed that their guesses were based on whether the patients improved and whether they felt any sensations (internal warmth or tingling) during the various treatments. No patients were admitted to the study who previously had received US treatments for any condition. The absence of this prior experience probably aided in the blinding of the volunteers and patients. Another way the therapist, the patients, and volunteers were kept blinded was by warming the ultrasonic gel before each treatment because it becomes warm during true US application. In addition, we chose ultrasonic gel as the coupling agent because its consistency does not change when heated.

Furthermore, when US is given therapeutically, patients may experience

various sensations either during or after the US treatment. Some patients claim to feel a warm sensation in the shoulder after a treatment is given. One of the sham patients claimed to feel this sensation each time after three of her treatments. Sometimes patients claim to experience a burning or tingling sensation during an US treatment when either the dosage is too high or the transducer head passes over a bony prominence.⁶ One of our patients (sham US) felt a tingling sensation, so the dosage was reduced (the control panel remained covered). Two patients (true US) stated they felt an unusual sensation during one of their treatments, so the dosage was lowered slightly. Both of these patients, however, had localized tenderness where the US was applied. Therefore, the sensation could have resulted from the rubbing or pressure from the US transducer head. One patient (true US) stated she experienced a tingling sensation during a treatment, and the dosage was lowered slightly. Thus, all these untoward effects in both groups of patients were side effects as seen in both the placebo and experimental groups in drug studies.^{22,23}

The major conclusion from this study is that US adds no further benefit over treatment with ROM exercise and NSAIDs or ROM exercise for patients who have SSA. Fifty percent of our patients in the sham US group improved with exercise and NSAIDs or ROM exercise alone. Multiple variables were tested, and virtually no statistically significant difference was seen between the sham or true US groups. If US had a profound effect, many of the variables analyzed should have demonstrated statistical improvement despite the small sample size. The passage of time, the initiation of the exercise program, and the admission of patients into a clinical study where they received attention and monitoring all likely contributed to the 50% recovery rate in both the sham and true US groups.

Certain considerations, however, should be discussed regarding the study design. Both US and exercise can be considered to contain certain properties that might lead to an eventual reduction of pain and increase in range of motion. Exercise, however, possibly has such a profound beneficial effect that it masked any minor benefit from US. But US and exercise usually are prescribed together for the treatment of adhesive capsulitis, tendinitis, or bursitis of the shoulder

and, thus, the above concern is more theoretical than practical.

Another consideration for such a study involves the methodology in applying US. The literature reveals many different methods to obtain treatment dosage. Controversy persists over the size of the treatment field and the duration of an individual treatment application. In addition, studies conflict over which coupling medium is the best.

Another important issue to discuss is the sample size of our study. The probability of detecting a clinically important difference between true and sham US is the power of the study and is dependent on sample size. If we assume that a clinically important difference would be 60% improvement in the treated group compared with 30% in the placebo group, then analysis of this study with 10 patients in each group reveals a power of only 30%. Thus, our study certainly is subject to a Type II error.²⁴ We can state with certainty that very large treatment differences do not exist. To detect, however, the deemed clinically important difference with a power of 80% (a common standard), the necessary sample size would be about 60 patients in each group. Thus, our study is only suggestive that US is of no important therapeutic benefit in the treatment of SSA. A more definitive statement awaits the results of a study on a larger patient population.

CONCLUSION

Double blind techniques were used successfully in our pilot study to determine the therapeutic value of ultrasound in the treatment of SSA. Of the multiple variables tested (ROM, pain, function), no apparent benefit appeared from receiving US. A large-scale, randomly controlled, and blinded study of US is warranted. Such a study would determine whether the use of US for SSA is justified clinically. Perhaps our pilot study will serve to initiate other clinical studies to validate US and other modalities used in physical therapy.

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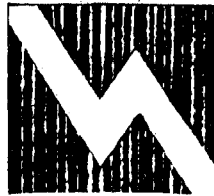
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