Short-term Effectiveness of Hyperthermia for Supraspinatus Tendinopathy in Athletes

A Short-term Randomized Controlled Study

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Background: Hyperthermia has been introduced as a physical therapy modality for soft tissue injuries.

Hypothesis: The authors tested the null hypothesis that there are no short-term differences after the use of hyperthermia, ultrasound, and exercises for tendinopathy of the supraspinatus tendon.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: The authors studied 37 athletes (29 men, 8 women; mean age, 26.7 ± 5.8 years; range, 19-43 years) with supraspinatus tendinopathy who had had symptoms between 3 and 6 months. Subjects were randomly assigned to 3 groups. Group A (n = 14) received hyperthermia at 434 MHz. Group B (n = 12) received continuous ultrasound at 1 MHz at an intensity of 2.0 w/cm^2 3 times a week. Group C (n = 11) undertook exercises, consisting of pendular swinging and stretching exercises 5 minutes twice a day every day. All interventions were undertaken for 4 weeks. Subjects were evaluated at baseline, immediately on completion of treatment, and at 6 weeks after the end of the intervention using mean pain score for pain at night, during movement, and at rest on a visual analog scale; pain on resisted movement and painful arc on active abduction between 40° and 120° on a 4-point scale; and Constant score.

Results: Patients who received hyperthermia experienced significantly better pain relief than did patients receiving ultrasound or exercises: group A, 5.96 to 1.2 (P = .03); group B, 6.3 to 5.15 (P = .10); group C, 6.1 to 4.9 (P = .09).

Conclusion: Hyperthermia at 434 MHz appears safe and effective in the short term for the management of supraspinatus tendinopathy.

Keywords: hyperthermia; ultrasound; microwave diathermy; rotator cuff; tendinopathy

About 20% of the general population suffers from 1 or more episodes of shoulder pain in the course of their lives.[33] Rotator cuff tendinopathy affects persons who impose repeated stress on their shoulders, including athletes engaged in overhead activities. More than 50% of patients with rotator cuff tendinopathy diagnosed by a general practitioner are referred for physical therapy.[31] Currently, no consensus exists as to the management of choice for supraspinatus tendinopathy. Various regimens are used,[40] and only a few well-designed studies have evaluated the effectiveness of physical therapy modalities for this ailment.[31]

Recently, hyperthermia has been introduced in physical medicine and rehabilitation.[11,14] Hyperthermia machines combine a superficial cooling system and a deep-heating source with a microwave power generator at 434 MHz. This frequency has been allowed in European Union countries since 1998 and raises tissue to therapeutic temperatures

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TABLE 1
Number of Subjects for Specific Sport Activities

Sport Activity	n
Gymnastics	5
Swimming	9
Water polo	8
Tennis	4
Volleyball	11

to a depth of several centimeters from the skin with no risk of overheating the superficial tissues.[12,13,24,25,28,29] In the system used in the present study, the target tissue temperatures rise from 41°C to 45°C in target volumes of approximately 100 to 200 cm^3, 1 to 4 cm deep in the skin, keeping the skin temperature under 36°C.[24]

We used hyperthermia in the management of muscle and tendon ailments in athletes, and we had the clinical impression that this management modality is effective in tendinopathies of the rotator cuff as well. We therefore performed a pilot study using a prospective randomized controlled design to evaluate the effectiveness of hyperthermia in the management of supraspinatus tendinopathy in athletes. We tested the null hypothesis that there are no short-term differences after the use of hyperthermia, ultrasound, and exercises.

PATIENTS AND METHODS

All procedures described in this study were performed after local ethical committee approval. Written informed consent was given by all patients entering the study.

Patient Selection

We studied 37 athletes (29 men, 8 women) (Table 1) with a mean age of 26.7 ± 5.8 years (range, 19-43 years) who attended the Physiotherapy Department of the Sport Science Institute in the period between July 1999 and January 2004 with a clinical and ultrasonographic diagnosis of supraspinatus tendinopathy of the dominant shoulder (right, 31 patients; left, 6 patients). All patients had suffered from a gradual onset of shoulder pain that impaired their sports activities for 3 to 6 months (mean, 4.8 ± 2.3 months) before entering the study. All patients were engaged in their sports at county (n = 11), regional (n = 6), national (n = 11), or international (n = 9) level, and all were training in their chosen sports at least 3 times a week (range, 3-11 times). They were asked to abstain from the movements that were causing pain during the treatment period, but they were allowed to perform modified training.

Inclusion Criteria

All patients were secondary referrals to fellowship-trained sports physicians or orthopaedic surgeons with a special interest in sports traumatology or shoulder surgery from family practitioners or physical therapists, as well as tertiary referrals from other orthopaedic surgeons or sports physicians. All patients had undergone nonoperative management, including complete or modified rest from their sports, and several (3-8) 1-week cycles of nonsteroidal anti-inflammatory drugs. The diagnosis of supraspinatus tendinopathy[6,32] was formulated if the following 3 criteria were met: (1) impingement with a positive Hawkins sign in internal rotation or impingement in 90° of forward flexion with forced external rotation,[9,17,30] (2) pain with supraspinatus muscle testing in the "empty can" position, and (3) ultrasonographic evidence of nonhomogeneous signal intensity without a frank tear in the supraspinatus tendon. Ultrasound scanning was performed bilaterally by a fully trained radiologist with a special interest in musculoskeletal imaging using a state-of-the-art, real-time ultrasound machine (Toshiba Sonolayer-V SAL 38B, Toshiba, Milan, Italy) equipped with a 13-MHz longitudinal transducer (Toshiba SM-708 A, Toshiba).

Exclusion Criteria

We excluded from the present study athletes without full passive range of motion of the affected shoulder. We also excluded athletes with supraspinatus tendinopathy after a single traumatic episode; athletes with severe neck pain, frozen shoulder, calcific tendinopathy, or degenerative joint disease of the acromioclavicular or glenohumeral joint; athletes who had received an intra-articular or subacromial injection of corticosteroids; and patients with a clinical or ultrasonographic diagnosis of a rotator cuff tear. Also, we excluded patients with previous surgery in the affected or contralateral shoulder.

Outcome Measures

All patients were assessed at baseline, immediately after the end of the treatment period, and 6 weeks after the end of treatment. The subjects were assessed by fully trained sports physicians who had never seen the patients and were unaware as to which intervention the patients had been allocated. We recorded the following clinical measures:

1. The mean pain score was recorded on a 10-cm horizontal visual analog scale (VAS; 0, no pain; 10, incredibly severe pain) at night, with movement, and at rest.
2. Pain with resisted movement was assessed on a 4-point scale (0, no pain; 1, slight pain but full strength; 2, moderate pain and reduced strength; and 3, severe pain and inability to exert any strength against minimal manual resistance). We recorded the mean pain score with active resisted abduction in the neutral position, active resisted abduction in external rotation, and active resisted abduction in internal rotation.
3. Painful arc on active abduction between 40° and 120° was assessed. The test was performed with the patient seated on a bench with his or her back against a wall to eliminate any other muscular influence. Pain was scored on a 4-point scale (0, no

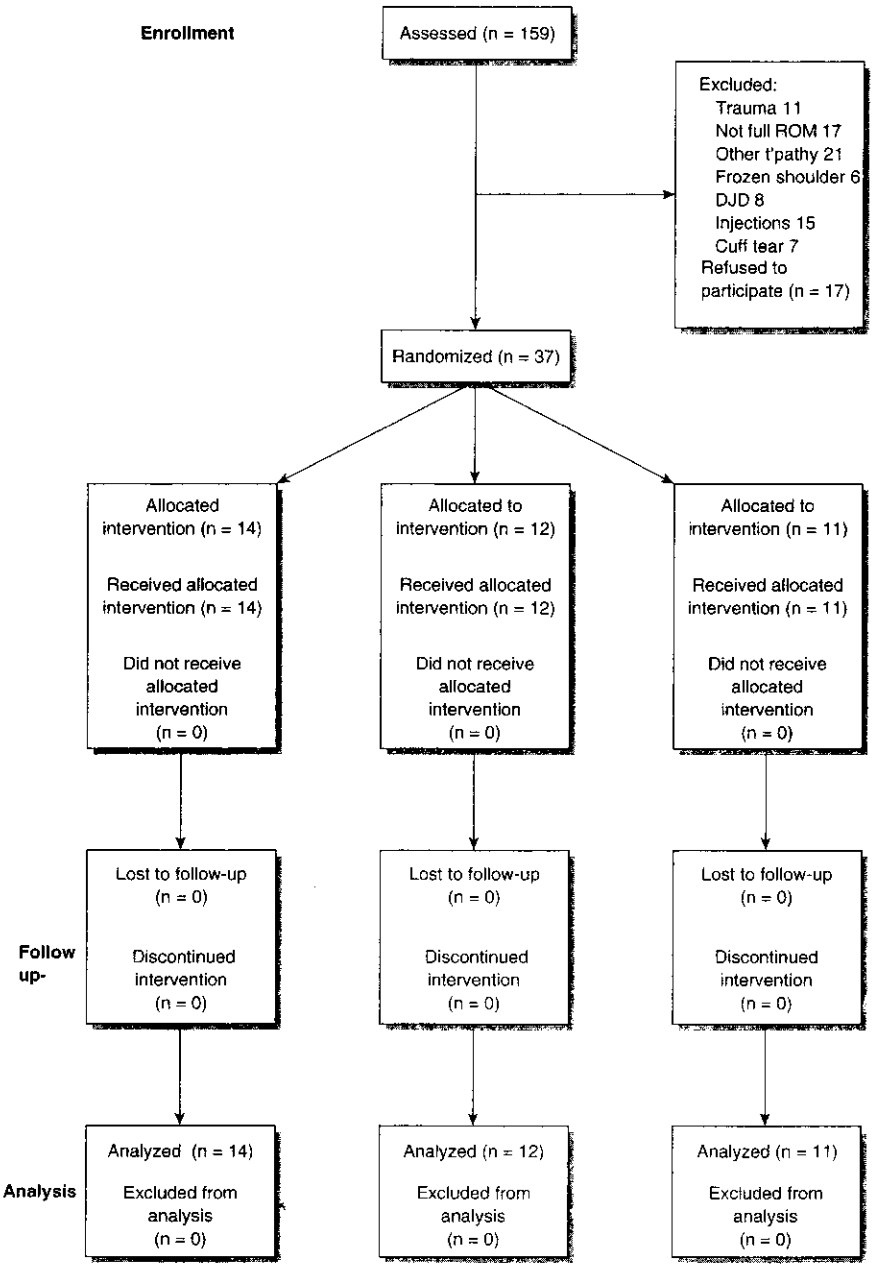

Figure 1. CONSORT statement. ROM, range of motion; t'pathy, tendinopathy; DJD, degenerative joint disease.

pain; 1, catching only at 1 point; 2, painful arc; 3, unable to actively overcome the painful arc).

4. The 100-point Constant and Murley score was used to provide an overall clinical assessment of the shoulder with respect to the subject's ability to perform normal tasks of daily living and power of the shoulder.[8]

We also recorded the number of subjects who felt ready to return to sport at the end of the experimental period. At the latest follow-up, we recorded the number of subjects who had returned to sport and the number of patients who had undergone further treatment.

Randomization Process

After eligibility to take part in the study had been determined and a diagnosis of supraspinatus tendinopathy had been made, eligible subjects consented to enter the study. They were then randomized into 3 groups using a computer-generated list (see Figure 1).

Intervention

Patients in group A (n = 14; 12 men; mean age, 25.3 ± 4.8 years; range, 19-37 years) underwent hyperthermia at 434

Figure 2. Positioning of hyperthermia apparatus in a patient with supraspinatus tendinopathy.

MHz. Patients in group B (n = 12; 8 men; mean age, 28.6 ± 6.6 years; range, 19-43 years) underwent ultrasound therapy at a frequency of 1 MHz. Patients in group C (n = 11; 9 men; mean age, 26.3 ± 6.2 years; range, 20-38 years) received no instrumented physical therapy. They were taught exercises consisting of pendular swinging in the prone position in flexion and extension of the shoulder and passive glenohumeral joint stretching exercises to tolerance by a fully trained rehabilitation specialist. These patients attended the department weekly to undertake a session under direct supervision of a fully trained rehabilitation specialist. We included this exercise regimen to ascertain any spontaneous recovery of shoulder tendinopathy because passive exercises alone do not seem to affect the natural history of the condition.[5]

Patients in groups A and B received a total of 12 treatment sessions (1 session 3 times a week for 4 weeks). Each session lasted 30 minutes for group A (hyperthermia) and 15 minutes for group B (ultrasound). Group C performed the passive exercises 5 minutes twice a day, every day, for 4 weeks. Hyperthermia treatment was administered at a power between 50 and 70 W, a pilot temperature on the skin between 38°C and 40°C, and a water pad temperature between 35°C and 37°C, according to the depth of the target area and the thickness of the subcutaneous fat of each patient. The water pad thickness ranged from 0.5 to 1.5 cm. The thermocouple was placed on the shoulder with the patient lying supine and the arm at 60° of abduction and externally rotated. It was placed over the middle third of the joint line between the glenoid fossa and the humeral head (Figure 2). The thermocouple on the skin was perpendicular to the electromagnetic field. The positioning of thermocouple on the skin is of primary importance to minimize the coupling between the thermocouple and the applied electromagnetic field.

Continuous ultrasound treatment at an intensity of 2.0 W/cm^2 was administered with the patient in the same position as patients in group A by slowly moving the transducer in a circular fashion along the area distal to the anterior border of the acromion and the inferior third of a line between the glenoid fossa and the humeral head. A gel couplant was used between the ultrasound transducer and the skin of the area undergoing treatment. The output of the device was checked regularly, according to the manufacturer's instructions.

During the treatment period, no other physical therapy modalities, injections with corticosteroids, and oral analgesia or nonsteroidal anti-inflammatory drugs were allowed. All subjects were asked to keep a treatment diary, which was checked weekly by a fully trained rehabilitation specialist and by the independent assessor at the final treatment session. Subjects were reminded weekly by a receptionist to fill in the treatment diary.

Deep-Heating Instruments

Hyperthermia. An ALBA Hyperthermia System (Restek SRL, Rome, Italy) was used (Figure 2). The hyperthermia system was equipped with a 433.92-MHz microwaves generator with a maximum output power of 100 W; a microstrip antenna applicator, with a curve shape specific for semicylindrical joint volumes of 20 to 30 cm in diameter and with a total radiating area of 240 cm^2 and an effective field size (50% specific absorption rate on surface of 96 cm^2 and a 50% specific absorption rate maximum depth of 2.3 ± 0.3 cm); and a pad of silicone 0.5-cm thick, filled with thermostatic deionized water that allows the greatest energy transfer to be achieved while preventing overheating of superficial tissues near the radiant source. A hydraulic thermoregulation complex, whose function is to keep water temperature between 30°C and 42°C, and 1 or 2 skin temperature sensors, measuring the temperature of the skin in contact with the pad, were also used. The accuracy of the temperature control system in the treatment area was ±0.2°C.

All functions pertaining to treatment control, data storage, and security systems were performed using a dedicated PC and software.

Ultrasound. A Level 730 device (Mettler Electronics Corp, Anaheim, Calif) was used. It was equipped with an emission probe of 1-MHz frequency, a sound head with an effective radiating area of 10 cm^2, and a maximum output power of 22 W.

Statistical Analysis

A statistician who was unaware of treatment allocation analyzed the data. A Kruskal-Wallis test was used to determine if there were any differences between the 3 treatments. A paired Student t test was used to compare the changes before and at the follow-up for pain score and the other outcome measures between the 3 groups, and an

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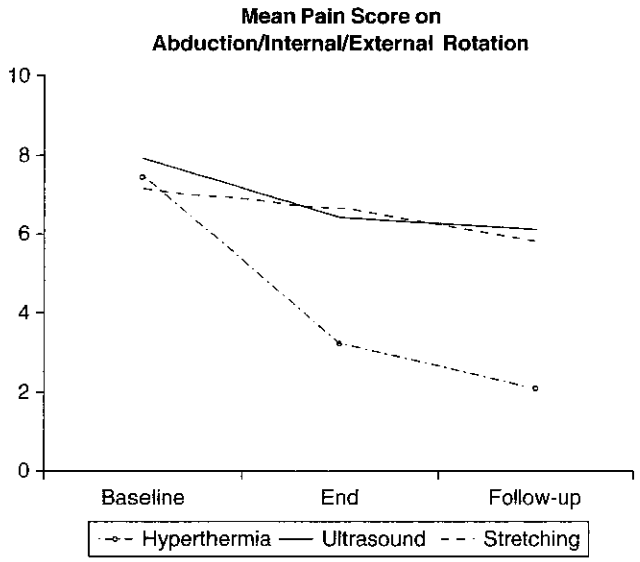

Figure 3. Improvement in pain on resisted movement over time.

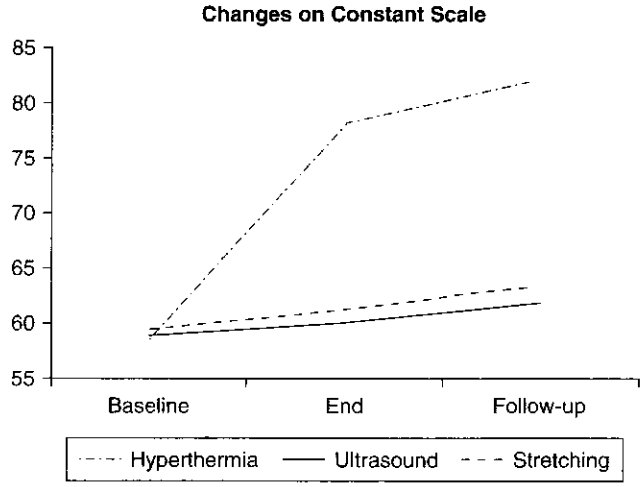

Figure 4. Improvement in Constant score over time.

unpaired Student t test was used to determine which of the 3 treatment modalities was more effective on the resolution of symptoms and recovery of functional status. $P < .05$ was considered statistically significant.

RESULTS

Random allocation produced groups well matched at baseline with respect to age, pain intensity, and functional disability. The Kruskal-Wallis test applied to the difference between pretreatment and posttreatment VAS scores showed a statistically significant difference between the effectiveness of the 3 treatment regimens ($\chi^2 = 25.5$, $P < .01$). A paired t test of the effectiveness of each treatment showed a statistically significant reduction of the VAS before treatment and at follow-up for only group A ($P = .03$; group B, $P = .10$; group C, $P = .09$) (Figure 3). By the end of the treatment period, 11 patients in group A, 6 in group B, and 4 in group C declared themselves ready to return to their chosen sports. By the end of the study, 12 patients in group A, 4 in group B, and 4 in group C had returned to their chosen sports. Three patients in group A, 8 in group B, and 9 in group C were receiving further treatment for supraspinatus tendinopathy.

The Constant scale measures showed a statistically significant improvement between the preintervention and follow-up time periods only in group A ($P = .031$; group B, $P = .13$; group C, $P = .07$). The unpaired t test showed significant difference between the 3 treatments. Group A patients reported greater reduction of VAS scores and better Constant score assessment when compared with ultrasound and the stretching only group (VAS score: group A vs group B, $P = .045$; group A vs group C, $P = .04$; group B vs group C, $P = .62$; Constant score: group A vs group B, $P = .04$; group A vs group C, $P = .03$; group B vs group C, $P = .7$) (Figure 4 and Table 2).

TABLE 2
Visual Analog Scale (VAS) and Constant Scores

	VAS		Constant	
Group and Time	Score	SD	Score	SD
Group A				
Entry in the study	5.96	0.83	58.57	3.92
End of treatment	2.4	0.46	78.1	4.23
6-week follow-up	1.2	0.63	82	5.73
Group B				
Entry in the study	6.3	0.86	58.91	2.84
End of treatment	5.8	0.96	60	3.21
6-week follow-up	5.15	0.87	61.75	4.18
Group C				
Entry in the study	6.1	0.89	59.45	2.67
End of treatment	5.3	0.65	61.2	4.28
6-week follow-up	4.9	0.88	63.27	5.56

There were no adverse effects. Four athletes in group A reported transient discomfort from the high temperature reached, but the treatment session was not interrupted for this reason.

DISCUSSION

Overuse tendinopathies commonly cause loss of time from sports and decrease of physical performance, affecting amateurs and elite athletes. A high incidence of shoulder tendinopathy has been demonstrated in several sports activities. In swimming, 42% to 70% of athletes complain of shoulder pain, and in throwing sports, about 50% of participants report shoulder pain.[5,8] The role of physical modalities in the management of tendinopathies remains unclear, and it is not possible to draw firm, evidence-based conclusions on their effectiveness.[3,31,40] This is also true for modalities based on increasing the temperature of the tissues to be treated.[3,31,40] Lack of consistent nomenclature

for histopathologic findings has limited progress in understanding the pathologic basis of tendinopathies, which are characterized by absence of inflammatory cells and a tendency for poor healing.[2,3,16] Ultrasound has been used for decades in calcific tendinopathy of the shoulder[19] and for nonspecific shoulder pain. Some studies found continuous ultrasound effective for these conditions,[10,23] but to our knowledge, there are no randomized controlled trials.

Hyperthermia has been used in cancer therapy, especially in combination with ionizing radiations or drugs.[18,27] The hyperthermia device used in this study was approved in 1999 by the relevant European Union body (Italian Institute of the Quality Mark) according to the European Economic Community 93/42 regulations. Its clinical use has become widespread in physical medicine and sports traumatology in central and southern Europe in the past few years. We have recently reported the short-term effectiveness and safety of hyperthermia in controlled clinical trials.[14,15]

Damage to tendon tissue results in alterations of cellular homeostasis. Recovery can occur through cell proliferation and protein synthesis[38] under aerobic conditions.[37] Local hyperthermia increases local blood flow and oxygen supply in a range between 2.7 mL/100 g/min and 40 mL/100 g/min,[39] favoring drainage of cellular debris.

To our knowledge, few studies on the use of this modality have been published. In a previous randomized trial of 44 athletes with patellar or Achilles tendinopathies, hyperthermia was more successful than was therapeutic ultrasound in reducing pain, producing better subjective overall satisfaction.[15] The present study confirms those findings, demonstrating the effectiveness of hyperthermia in the short-term management of supraspinatus tendinopathy compared with conventional therapeutic ultrasound. Athletes in group A showed significantly better results at follow-up as assessed by the visual pain scores, resisted movement, painful arc, and Constant Murley functional assessment (Figures 3 and 4).

A partial criticism is that we did not perform imaging studies on our patients at the end of our study. This was a conscious decision. We wished to put ourselves in the position of a clinician who had to make decisions based on clinical examination alone, as most physicians will not have easy access to ultrasonography or to MRI, and clinical and functional evaluations are the best indicators for the resolution of the pathologic lesion. Also, although imaging is readily able to identify supraspinatus tendinopathy, it is unlikely to show any significant changes in tendon structures over such a short study period. Finally, intratendinous changes identified on ultrasound or MRI may not correlate with the clinical picture.[15,20] The short-term nature of the follow-up is a limitation. We do not claim that this modality "cures" supraspinatus tendinopathy. However, the short-term improvement maintained for 6 weeks is still relevant for competitive athletes.

It is possible that our results may not be extrapolated to the general population. Athletes may have greater motivation and better direction in the rehabilitation process, and they may be more compliant to the recommendation of their treating physicians. Studies including a mixed population of patients would be warranted.

This study focused on patients with a single, well-defined clinical ailment to give definite answers to a precise clinical problem. These promising clinical results support the use of hyperthermia at 434 MHz in the management of supraspinatus tendinopathy and bring into question the effectiveness of ultrasound modalities for supraspinatus tendinopathy. The reasons for the pain-reducing effects and improvement in shoulder function of hyperthermia are open to discussion and may result from the temperature gradients reached during the sessions.[14,26] Above 41.5°C and up to 45°C, the increase in tissue temperature enhances local blood flow.[4,22,26,30] How this is effected is open to debate.[36]

In this study, the temperatures reached at different depths were calculated using the dedicated temperature software in the hyperthermia unit.[1] This temperature simulation software has been used to optimize the treatment variables to achieve therapeutic temperatures at the site of the lesion. Ultrasound is ineffective as a thermal modality over large areas, as it can heat target areas up to only twice the size of the area of the transducer.[4,7,21,40] Hyperthermia, on the other hand, is able to produce and maintain therapeutic temperature in target volumes of 300 to 400 cm,[3,29,34,35] avoiding overheating using a dedicated cooling system. This increases the energy transfer considerably, via its coupling effect, avoiding overheating of the superficial tissues. The results of this study also demonstrated little evidence of short-term recovery of established supraspinatus tendinopathy using exercise modalities alone.

CONCLUSION

Hyperthermia is effective in the management of established supraspinatus tendinopathy. This modality warrants further studies with a greater number of patients and a longer term follow-up to confirm its therapeutic effectiveness. Also, its use in tendinopathies of the other components of the rotator cuff complex should be studied.

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