



# Rotator Cuff Repair using Focused Ultrasound Energy in Three Individuals

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## Abstract

Rotator cuff injuries are common, especially in older individuals. These injuries can be partial or complete thickness tears and can require either therapy or surgical intervention and therapy. Three patients were treated with extracorporeal shock wave or FOCUS wave therapy to see if this would cause healing of supraspinatus tears. The FOCUS was directed at the belly of the supraspinatus tendon. Three subjects were examined in this present pilot study to see if focused ultrasound could increase the rate of healing in prior injuries. The subjects were treated with 35-50 joules of sound energy for 8 minutes 2 times a week. Their injury averaged 5.67 months before treatment with no history of recovery. They were evaluated with ultrasound imaging. They could not move through normal range of motion of the shoulder and they were evaluated between grades 2 and 3. After 10 treatments over a month in 2 subjects and 20 treatments in the third subject, the use of a focused sound pressure wave caused rapid healing in the supraspinatus tendon as assessed by reduction in pain and increase in range of motion and imaging. Range of motion was 100% normal and pain free. Dash scores showed a significant improvement comparing before to after therapy. The imaging and physical measurements clearly show that Focus is a promising adjunct to therapy for rotator cuff tears.

## Introduction

The glenohumeral joint is a complex structure commonly affected by injury such as rotator cuff tears [1]. The rotator cuff plays a key role in stabilizing the shoulder by putting pressure on the humeral head against the glenoid cavity. The rotator cuff dynamics allows for the large range of motion of the shoulder [2]. Because of this range of motion, the compressional and linear forces on the tendons of the rotator cuff are very large. This causes frequent injuries to these tendons. In particular, rotator cuff tears are very common at the attachment of the supraspinatus tendon. They are seen in 30-50% of the general population older than 50 years of age [3]. The impact of this condition

on earnings, missed workdays and disability payments is high [3]. Multiple factors can contribute to rotator cuff tears including familiar genetics, overuse, mechanical impingement, age-related degeneration and microtrauma and smoking [3-7]. The most common rotator cuff tear is the supraspinatus tear [8]. Another major issue is calcific tendonitis of the rotator cuff. It occurs in 20% of painful shoulders and 7.5% of asymptomatic shoulders [9,10]. It occurs in 70% of women especially over age 50 [10]. Calcific tendonitis refers to deposits of calcium on a tendon, most often in those of the rotator cuff. It occurs in 80% of the supraspinatus tendon, followed by the infraspinatus (15% of cases) and subscapularis (5% of cases) [10,11].



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The long term follow-up of rotator cuff injuries shows that physical therapy is just as effective as surgical repair in shoulder injuries when looking at the results one year later [12]. With physical therapy approximately 1/3 of people had an enlargement in tear size 1 year later [12]. Smaller symptomatic full-thickness tears have been shown to have a slower rate of progression, similar to partial-thickness tears [7].

There are a number of ways of treating rotator cuff injuries. Surgery can be performed but the results are often not good [13]. Progressive exercise with increasing loads is suggested after rotator cuff surgery. This involves a rehabilitation framework that includes a 2-week period of strict immobilization and a staged introduction of protected, passive range of motion during weeks 2-6 postoperatively, followed by restoration of active range of motion and then progressive strengthening beginning at postoperative week 12 [13]. In contrast, physical therapy and exercise can be used without surgery. But a recent review indicates that the evidence is poor for the effective use of exercise due to poor methodologies in the research articles that make them not reliable [14]. However, in multiple studies there was no clear advantage to physical therapy compared to surgical intervention in healing rotator cuff tears. Pressure wave, as an extracorporeal shock wave [15], has been used clinically for over 20 years but only recently in the United States [16]. It can use ultrasound pulses or electromechanical pressure waves. It is in two forms, both using ultrasound. One is radial with the sound dispersed over a large area [17]. This mode has lower power compared to the more focused ultrasound shock wave therapy and the power which is usually electrohydraulic and generate a radial pressure wave [17]. Radial shock waves may be better for reducing spasticity [18]. High-pressure shock waves (Focused Extracorporeal Shock Waves) (F-SW) have enough power to disrupt tissue and cause a healing in response [19]. High energy F-SW (>0.5 J/mm<sup>2</sup>) can be used to destroy tissue, such as kidney stones in lithotripsy, F-SW devices used in physical therapy offer low and medium energy F-SW (0.01-0.55 mJ/mm<sup>2</sup>) [20,21]. F-SW damages tissue to cause an inflammatory response [20,21]. They are much more effective than the radial machines. For reducing inflammation in the plantar fascia and other areas it has been shown to be beneficial [19,22]. It has been shown to be effective for tennis elbow [23,24]. It can be used to reduce inflammation [25]. They aid in tendon repair and bone growth [26]. They have also been shown to benefit Achilles tendonitis [15]. F-SW has not been used to stimulate supraspinatus repair. The hypothesis to be tested here is that shock wave therapy can repair supraspinatus tears and remove calcium deposits. There were 3 subjects in this pilot study as described below.

## Methods

Imaging-Ultrasound imaging was provided with a Sonosite Micro Max imager set at 10 mHz and using an I35 linear probe. (Sonosite Micro Max, Seattle Washington) All images were made with the subjects arm behind their back and the probe held over the rotator cuff to show the head of the humerus.

**Shock Wave:** The patient was treated using extracorporeal shock wave or FOCUS wave therapy (Chattanooga electronics, Chattanooga Tennessee). The FOCUS was directed at the belly of the supraspinatus tendon. The supraspinatus tendon is difficult to reach. Based on anatomical landmarks the FOCUS was placed on the area of the shoulder between the clavicle and the spine of the scapula. The proximal portion of the acromion was palpated, the FOCUS was held on the soft tissue during each treatment session. For this treatment, the depth of the electro-

magnetic beam was set on 13 cm with 40-50 jewels of energy.

**Measurement of function:** The subjects were tested to full pain-free PROM, AROM, strength & stability throughout the right shoulder before and at the end of the study. In addition, DASH scores were used to assess function. Scores range from 0 (no disability) to 100 (most severe disability). This score was designed be useful in patients with any musculoskeletal disorder of the upper limb.

**Exercises:** Exercises used for strengthening the Rotator Cuff Muscles supraspinatus, Infraspinatus and teres minor. Emphasizing eccentric loading to strength the tendon and stimulate collagen production. The exercises were performed using weights that were between 60-80% of the maximum effort. Therefore, the reps were started with a weight they could do 12 reps x 3 sets after 2-3 sessions the weight was increased so the patient could only do 6-8 reps and 3 sets. As the patient became stronger the reps increased until 3 sets of 12 was reached and then there was another increase in weight that allowed 6-8 reps.

## Case number 1

### Description: Subjective history and system review one

A 40 y.o. male mechanic was referred to physical therapy for left shoulder pain. The first occurrence was 4 months ago while working as an automobile mechanic. After several weeks the patient made an appointment with his general practice physician. The physician referred him to physical therapy. Diagnostic ultrasound was used to determine the location and size of the rotator cuff tear. The ultrasound findings indicated a 1.4 cm partial thickness tear of the supraspinatus. The patient reported the pain was limiting his job activities as a car mechanic. The job involved reaching and lifting heavy objects keeping his arm elevated at 90 degrees of abduction while working on cars.

**Examination:** Manual muscle testing indicated weakness and pain with testing of the supraspinatus, no pain but weakness of infraspinatus and teres minor. Manual muscle testing indicated the painful and weak supraspinatus which was graded 3. Manual muscle testing of the infraspinatus and teres minor indicated the manual muscle grade was 3. Active range of motion was limited to 100 degrees of elevation in the plane of the scapula with pain at the end of the ROM. Active Abduction was limited to 100 degrees, secondary to pain and weakness. Passive pain free elevation was limited to 130 degrees, in the plane of the scapula, with pain at the end of the range. Passive pain free abduction was limited to 90 degrees. Passive external rotation in the adducted position was limited to 30 degrees. The subject demonstrated two positive Impingement tests, Neer's and Hawkins/ Kennedy [27,28].

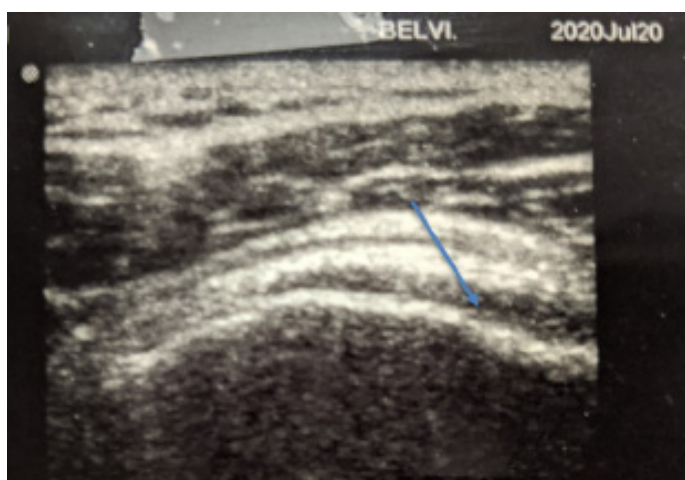
**Treatment:** The patient started physical therapy on 07/17/2020 and ended on 08/25/2020 and was in for a total of 10 sessions, 2 times per week.

The patient was requested to start physical therapy using FOCUS wave therapy (Chattanooga electronics, Chattanooga Tennessee). FOCUS was placed on the area of the shoulder between the clavicle and the spine of the scapula. The proximal portion of the acromion was palpated, the FOCUS was held on the soft tissue medial to the acromion during each treatment session. The patient reported a deep ache during the entire treatment session lasting 10 minutes. The FOCUS is an electromagnetic beam that can target the depth of the supraspinatus was at 13 cm at 55 jewels of energy. The FOCUS is an electromagnetic

beam that can target tissues at varying depths, of 13 cm, 9 cm or 6 cm. For this treatment, the depth of the electromagnetic beam was set on 13 cm with 35-40 jewels of energy. The patient was treated for 5 weeks, 2 times per week which included 10 treatments. At each treatment session, the patient experienced a deep dull ache with the FOCUS treatment. The patient was also instructed in three strengthening exercises emphasizing eccentric loading of the supraspinatus and infraspinatus.

**Outcomes:** The final evaluation demonstrated 180 degrees of active and passive elevation in abduction and in the plane of the scapula. Patient's initial DASH score was 100%, showing full disability. The final DASH score was 1.67%. The overall difference on DASH Scores was 98.33%. The difference between the two DASH scores shows a statistical and clinical significance.

At that time re-evaluation demonstrated 100% reduction in pain with full active elevation. The imaging picture before intervention is shown in (Figure 1) while (Figure 2) shows the post treatment image of the supraspinatus.



**Figure 1:** The supraspinatus before treatment. Shown is the head of the Humerus and the supraspinatus attachment to the greater tuberosity of the humerus. The overlying muscle is the deltoid. The arrow shows the partial tear at the point of attachment and the resulting edema.



**Figure 2:** Imaging of supraspinatus post treatment. Fibers are continuous and healed.

## Case number 2

### Description: Subjective history and system review

A 63 y.o. female Fitness Instructor. Patient reported the right shoulder was injured with lifting weights. Patient was unable to lift her right shoulder overhead secondary to pain and weakness. Patient reports having pain and stiffness within her right shoulder for 6 months. The patient had to give up her job as a fitness instructor because of her right shoulder pain and stiffness.

**Evaluation:** Manual muscle testing indicated weakness and pain with testing of the supraspinatus and infraspinatus. Manual muscle testing indicated the painful and weak supraspinatus which was graded 2. Manual muscle testing of the infraspinatus and teres minor indicated the manual muscle grade was 2. Active range of motion was limited to 60 degrees active elevation in the plane of the scapula with pain at the end of the. Active horizontal abduction was limited to 60 degrees, secondary to pain and weakness. Passive elevation in the plane of the scapula was limited to 90 degrees, in the plane of the scapula, with pain at the end of the range. Passive abduction was limited to 70 degrees with pain at the end of the range. Passive external rotation was limited to 30 degrees in the adducted position

**MRI diagnosis:** Right shoulder tear of the posterior 7mm of the supraspinatus tendon occurring 10 mm medial to the footprint, characterized by a full-thickness component involving the posterior fibers measuring 3mm in anterior-posterior width. Full thickness tear of the supraspinatus tendon of the right shoulder.

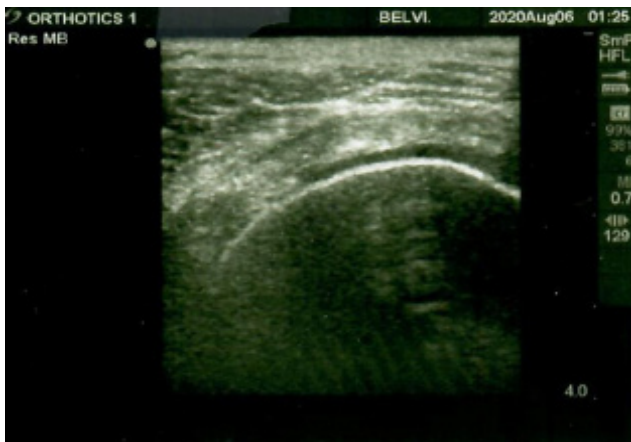
**Treatment:** Patient started Physical Therapy on 07/02/2020 and ended on 10/13/2020 and was in for a total of 22 sessions consisted of FOCUS to the right supraspinatus tendon using 50 jewels of energy. The depth of the electromagnetic beam was 13 cm. Patient experienced a deep ache during the treatment. The patient received 36 FOCUS treatments. Patient was also instructed in right shoulder strengthening exercises emphasizing eccentric loading of the supraspinatus, infraspinatus. Patient was treated 3 times per week for 12 weeks. At that time re-evaluation demonstrated 100% reduction in pain with full active elevation. The final assessment demonstrated 180 degrees of active and passive elevation in abduction and in the plane of the scapula.

**Outcomes:** The patient was able to return to all daily activities with no pain. Manual Muscle testing indicated a grade 5 for the supraspinatus, infraspinatus. All within normal limits.

Patient was instructed in continuing the strengthening exercises at home for 3 times per week for 4-6 weeks. Patient was instructed that the exercises we used to heal his tendon should be perform 1-2 time per week indefinitely to prevent future attritional tears and dysfunction. The final Ultrasound demonstrated healing of the supraspinatus tendon tear as shown in Figures 3 and 4. Figure 3 shows 2 tears with edema (black area) in the supraspinatus. Figure 4 shows the tendon is fully healed even after 6 weeks of treatment.



**Figure 3:** The supraspinatus before treatment- tear shown by the letter A as a 0.7cm tear. Shown is the head of the Humerus and the supraspinatus attachment to the greater tuberosity (arrow) of the humerus. The overlying muscle is the deltoid.



**Figure 4:** The supraspinatus after treatment showing healing and reduction in the tear.

### Case number 3

#### Description: Subjective history and system review

The patient was initially seen on 7/30/20 with c/o right shoulder pain and weakness with overhead activities. The initial injury was a fall on to his right shoulder. Ten days after the initially injury he made an appointment with an orthopedic surgeon, who ordered an MRI. The MRI demonstrated a full thickness tear of the supraspinatus and a mild tear of the infraspinatus. The orthopedic surgeon recommended surgery to repair the tendon tear. The patient elected not to have the surgery. The patient reported shoulder pain for 6 months that limited his daily activities of living. The patient started physical therapy on 07/30/20 was only able to attend physical therapy once per week because of the long distance between the physical therapy clinic and his home.

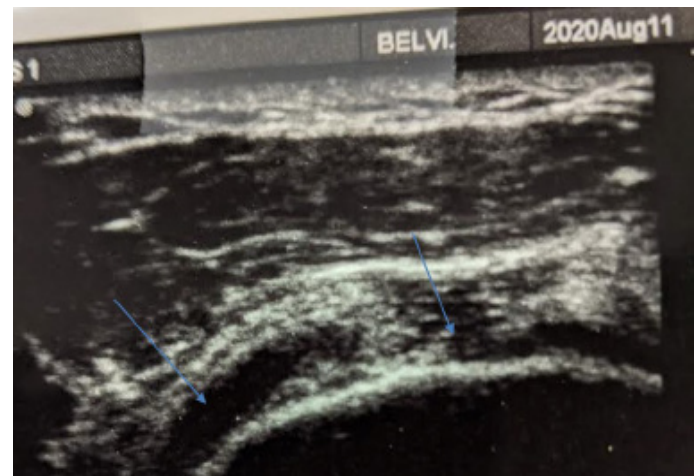
**Evaluation:** Manual muscle testing indicated weakness and pain with testing of the supraspinatus. In addition, there was weakness of the infraspinatus and teres minor. Manual muscle testing indicated the painful and weak supraspinatus, graded 2. Manual muscle testing of the infraspinatus & teres minor indicated the manual muscle grade was 2. Active range of motion was limited to 90 degrees of elevation in the plane of the scapula with pain at the end of the ROM. Active Abduction was limited to 80 degrees, secondary to pain and weakness. Passive elevation was limited to 95 degree, in the in the plane of the scapula, with pain at the end of the range. Passive abduction

was limited to 90 degrees. Passive external rotation was limited to 40 degrees in the adduction position.

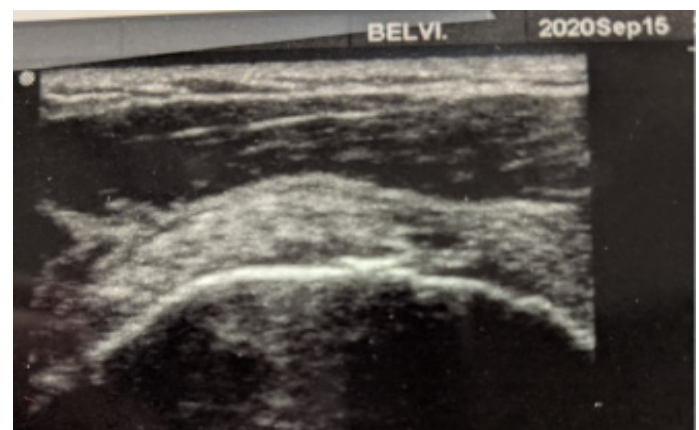
**Treatment:** Consisted of the FOCUS to right shoulder supraspinatus tendon. In addition, the patient was instructed in strengthening exercises emphasizing eccentric loading of the supraspinatus, infraspinatus. Patient was treated 1 time per week for 11 weeks. Patient was instructed in strengthening exercises for the supraspinatus and infraspinatus at the office once per week and then at home two more times per week. The patient was informed that the exercises used to help heal his tendon should be perform 1-2 time per week indefinitely to prevent future attritional tears and dysfunction.

#### Outcomes

On the final treatment session, the re-evaluation demonstrated 100% reduction in pain with 180 degrees of active and passive elevation in abduction and in the plane of the scapula. Manual Muscle testing indicated a grade 5 for the supraspinatus and infraspinatus. The Patient was able to return to all daily activities with no pain. The final ultrasound demonstrated healing of the tendon tear. DASH SCORE Before the treatment 33.3%. Final DASH Score 2.5% Overall Difference in DASH Scores 30.8% The difference between the two DASH Scores shows a statistical and clinical significance. The before (Figure 5) and after treatment (Figure 6) showed clear improvement. The tear is clearly shown with edema in (Figure 5) (arrows) while (Figure 6) shows that the area is free of edema and tendon normal. In (Figure 5) the disrupted tendon appears as fibrous tears.



**Figure 5:** The supraspinatus before treatment black area shows tear and edema.



**Figure 6:** The supraspinatus after treatment.

## Discussion

The rotator cuff is integrative to proper shoulder function. It stabilizes the shoulder and increases the range of motion of the joint as well as adding stability. It has been estimated that 20% of the population has a rotator cuff tear at one time or another [29]. A primary cause is age related tendon degeneration. Half of the full thickness tears occur in people over 70 years old [30]. There are numerous protocols involving surgery and rehabilitation but little consistency in how these are applied. This leaves inconsistent results on healing and reinjury rates as well. It is evident however that tendons require loading to heal and without that loading healing is either absent or delayed [31]. As cited above, high pressure shock waves have enough power to disrupt tissue and cause a healing in response [19]. Therefore, we conducted this pilot study to test this hypothesis on the supraspinatus tendon. In the present pilot investigation, on 3 patients, there was significant healing in torn supraspinatus tendons after use of shock wave therapy. This is evidenced in several ways. First, pain was reduced and range of motion increased. Since these injuries were chronic and no reduction in pain or range of motion was seen for months, the only logical answer is that the shock waves promoted healing. Second, as a measure of healing, the Dash scores were reduced significantly. Finally, ultrasound imaging showed significant reductions in edema and healing.

The mechanism is probably related to the disruption of tissue seen in animal and human models with shock wave therapy. Even in chronic diabetic ulcers, shock wave therapy has been shown to increase the rate of healing and wound closure [32-34]. Shock wave therapy increased wound healing and cellular metabolism [35]. In a similar manner, foot ulcers, venous leg ulcers, pressure ulcers and burns have shown increased healing with extracorporeal shock waves [36]. In the present investigation, this increased rate of healing caused rotator cuff tears to heal. Normally healing is poor and over months, here, at least in this pilot study, healing was rapid as was the reduction in pain and increased range of motion. While there was some exercise along with shock wave therapy, the literature clearly shows that therapy alone allows for slow healing if at all and therefore the shock wave treatment was responsible for healing. It would be good to examine shock wave alone and in a larger population to fully understand this technology, but this will await future studies and on larger populations.

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