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Treatment Protocol for Rotator Cuff Calcific Tendinitis Using a Single-Crystal Piezoelectric Focused Shock Wave Source

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Abstract

Focused shock waves have emerged as a highly effective noninvasive therapeutic option for the treatment of calcific tendinitis of the shoulder. There are three types of focused shock wave generators: electrohydraulic, electromagnetic, and piezoelectric. According to our literature search, there are no reports of results with the use of single-crystal piezoelectric generators in calcific tendinitis of the shoulder. In a consecutive retrospective series of 23 patients with Gärtner type I and II calcifications of the rotator cuff, we performed three applications of high-energy piezoelectric focused waves (4,000 pulses per session with a frequency of 6 Hz). At the final follow-up (average of 14 months), 82.6% of the cases showed complete resorption of the calcification in radiographic controls. In 8.7% of the cases, partial disappearance of the calcification was achieved, and in the remaining 8.7% there were no significant changes. Single-crystal piezoelectric generators have a success rate comparable to those already reported with electrohydraulic and electromagnetic devices.

Introduction

Calcium crystal deposits can appear in different regions of the musculoskeletal system, but their most frequent location is in the shoulder region. Gondos[1] reported that 69% of calcification cases occur in the shoulder location. Calcific shoulder tendinopathies are characterized by the presence of hydroxyapatite deposits in the rotator cuff tendons. It is estimated that the prevalence in the general population ranges from 2.7% to 20%[2].

Calcific tendinitis of the shoulder typically affects patients between 30 to 60 years old[2]. It is also more frequent in women (57%-76.7%) with respect to men[3]. The location of the calcium deposit is much more frequent in the distal

tendon of the supraspinatus muscle[4], while localizations in the infraspinatus, teres minor, subscapularis, and long head of the biceps have also been reported[4].

Women between 30 and 60 years old, with a calcification over 1.5 cm in length, have the highest chance of being symptomatic[5]. Although it tends to spontaneously resolve itself, the cycle can often be halted. In these cases, symptoms of pain and disability appear, and it is necessary to take active therapeutic action.

Gärtner's radiological classification[6] differentiates three types of images. In type I, the image is dense, with well-defined borders corresponding to the formative phase. In the type II image, the appearance is mixed, with a deposit that can be dense but with diffuse borders, or transparent with well-defined borders. Finally, type III, characteristic of the resorptive phase, presents a transparent deposit with diffuse borders. Active therapeutic action, including shock wave applications, ultrasound-guided interventions, or surgery, must be taken in Gärtner type I and II, since in type III cases, the chance of short-term spontaneous resorption is very high[6].

Conservative treatment is initially preferred. This classically includes rest, analgesics, non-steroidal and steroidal anti-inflammatory drugs, rehabilitation, and local injections. Good results of conservative treatment have been shown, especially in the resorptive stage, but a failure of conservative treatment has been reported in 27% to 39% of cases[7,8,9]. Several prognostic factors have been recognized as having a significant influence on the results of conservative treatment[7,8]. The location on both shoulders, the presence of a large-volume deposit, the location of the calcification in the anterior region of the acromion, and the spread of the deposit medially beyond the level of the acromioclavicular joint, are factors of poor prognosis[7,8]. A Gärtner stage III calcification and lack of sonographic extinction of the calcific deposit are considered predictors of good prognosis for conservative treatment[7].

When conservative treatment fails, many patients end up becoming chronic carriers of shoulder pain with similar clinical characteristics to chronic rotator cuff non-calcific tendinopathies. The usual alternative to conservative treatment failure was surgery. Gschwend[10] formulated three precise surgical indications for rotator cuff calcifications: symptom progression, constant and unmanageable pain, and failure of conservative treatment. Surgical treatment can be performed open or arthroscopically. Although open treatment was historically performed with good results[11], arthroscopic techniques have gained popularity[12,13]. Musculoskeletal ultrasound and ultrasound-guided interventions (UGI) have significantly developed and been used in clinical practice in recent years[14,15,16].

Extracorporeal shock wave treatment (ESWT) has emerged as an effective option prior to invasive procedures when conservative treatment has failed. Its therapeutic effect is not just mechanical, but based on mechanotransduction, a phenomenon by which cells can recognize a mechanical stimulus and react biologically[17]. However, shock wave treatment has limitations. Unlike lithotripsy, in which we only depend on the mechanical effect of the waves, there must also be a biological response by the patient. This response does not always occur.

The generic term "extracorporeal shock waves" includes two different technologies: focused shock waves and radial pressure waves[17,18,19]. The two technologies have therapeutic efficacy but differ in their physical characteristics and indications. Focused shock waves have a wide frequency

range (from approximately 150 kHz up to 100 MHz), large pressure amplitude (up to 150 MPa) with a short rise time and small pulse width, followed by a low-stress wave (up to -25 MPa)[18,19]. Focused shock waves are generated by electrohydraulic, electromagnetic, and piezoelectric sources[17,18,19].

Radial pressure waves are sound waves with pressure peaks of up to 30 MPa and much higher rise times than focused shock waves (about 3 µs)[18,19]. Radial pressure waves are generated by accelerating a projectile inside a cylindrical guiding tube by compressed air. The projectile hits an applicator at the end of the tube and produces a radial pressure wave that expands into the target tissue[17,18,19].

Focused shock waves have a grade "A" recommendation for the treatment of rotator cuff calcifications[17]. This means that there is high-quality scientific evidence supported by level I studies with consistent findings. In the case of radial waves, the level of recommendation for rotator cuff calcifications is "I". This means that the evidence is insufficient to make a recommendation[17].

Therapeutical efficacy of focused shock waves in calcific tendinopathies of the shoulder has been compared with open[20] and arthroscopic[21] surgery, with comparable results. However, shock waves have less frequent and less severe complications[20,21], and the method is also cost-effective. Haake[22] reported a significant difference between surgical costs (€13,400-23,450) and those of focused shock waves (€2,700-4,300). His results match with other studies that have shown a five- to sevenfold decrease in the cost of shock wave treatment compared to arthroscopic surgery[23,24]. There are also studies in which shock waves have been compared with ultrasound-guided interventions with controversial results[15,25]. Several publications[4,17,26,27,28,29,30,31,32,33] have reported that a high level of energy is more effective when treating calcific tendinitis of the shoulder. Verstraelen[27] reported that the use of high energy determines a higher rate of calcific resorption in a level I evidence study. This is a clear advantage for focused devices over radial ones because they can generate higher levels of energy. Numerous studies have reported good results with electrohydraulic[4,17,34,35] and electromagnetic[4,17,36,37,38] focused devices. A report has also been published using a multi-crystal piezoelectric device to treat rotator cuff calcifications[39]. We are not aware of any reports publishing the technique and results of single-crystal piezoelectric devices as of yet.

This report aims to describe the treatment protocol using a single-crystal piezoelectric device and to report the preliminary results.

Protocol

The protocol follows the guidelines of the Buenos Aires British Hospital's human research ethics committee.

1. Patient evaluation

1. Clinical evaluation
    1. Evaluate patients clinically to rule out symptoms propagating from other anatomical regions or other associated pathology in the shoulder that may be the source of symptoms.
    2. Include shoulder inspection and palpation, evaluate the active and passive range of motion, and perform pain provocative maneuvers and integrity tests. In addition, evaluate the cervical spine and the elbow joint.

2. Radiological evaluation

    1. Use radiographic anteroposterior (AP) projections, a lateral scapular view, and an axillary view of the shoulder.

    2. Classify the calcifications by their evolutionary stage according to Gärtner[6]. Request an MRI to rule out any associated pathology in the shoulder.

3. Inclusion criteria

    1. Include patients classified as having Gärtner type I and II calcifications who have undergone at least 3 months of previous conservative treatment without result.

    2. Never inject corticosteroids into the subacromial space when treating rotator cuff tendinopathy, as they have a deleterious effect on the elastic fibers of the tendons[40,41].

4. Exclusion criteria: Do not include patients with Gärtner type III calcifications or other associated pathology in the affected shoulder.

2. Application technique

1. Patient positioning: Position the patient comfortably and in a way that allows exposure to the area to be treated.

    1. Supraspinatus or infraspinatus tendon location: Treat by placing the patient in the supine or sitting position.

    2. Subscapularis: Treat by placing the patient in the supine position.

    3. Teres minor: Treat by placing the patient in the sitting, lateral decubitus, or oblique decubitus position for better access to the posterior aspect of the shoulder.

2. Coupling pads

    NOTE: Three pad sizes are available, each determining a specific depth of treatment focus (**Figure 1**).

    1. Select a coupling pad size depending on the required penetration depth of the focused point (**Table 1**). The selection of the coupling pad varies in shoulder calcification cases according to patient's build and location. The most frequently used sizes are large and medium.

3. Location of the area to be treated: Locate the area to be treated, considering anatomical landmarks and, if necessary, with the help of ultrasound images (**Figure 2**).

    NOTE: It is very important to locate the exact area of the calcification and to focus the treatment on it[4,42]. The use of anatomical references and the help of ultrasound localization allows identifying the correct location. The need for a diagnostic ultrasound to locate the area is disputed, as there are studies that have not found significant differences with its use[43]. The application of focused waves is risky if done on large vessels and nerves or in areas close to the pleura[44]. Anatomical approaches that avoid these structures should be used.

4. Operator positioning: The use of this type of device implies the support of an applicator by the operator. Work in an ergonomic position.

    NOTE: The operator must always be aware of the condition of the patient, as exceptional cases of fainting during treatment have been reported[44].

5. Anesthesia: Do not use anesthesia. The use of local anesthesia is contraindicated because the presence of fluids alters the acoustic impedance of the tissue. In

general, tolerance to treatment with this type of device is good, even when working with high energy levels.

6. Contact gel: Apply adequate contact gel to the skin in the area to be treated.

7. Navigation controls: Turn on the computer and access the touch screen. Select the **Manual** option at the top of the screen. The controls of the various treatment parameters are displayed. Use the rotary selection knob to set the parameters, including the intensity, frequency, and number of shocks.

8. Intensity: Set the initial intensity of the treatment. The energy flux density (EFD) is graduated in the device used in millijoules per square millimeter of tissue (mJ/mm^2).
    1. Increase the intensity progressively as tolerated by the patient. Start with low intensity. Reach at least an energy level above 0.40 mJ/mm^2 to obtain reproducible results[19,20,21,22,23,24,25,26]. The mean maximum intensity used is 0.50 mJ/mm^2.

9. Frequency: Select the frequency to be used. The equipment has a frequency between 1-25 Hz. Use 4-6 Hz.

10. Number of shocks: Select the number of shocks to be applied using the rotary selection knob. Apply at least 4,000 shocks per session.

11. Modification of parameters during treatment: Modify the frequency and especially the intensity during the application. Use the display located on the applicator head to easily modify the application parameters during the treatment without having to interrupt it.

12. The interval between sessions: Carry out three sessions at weekly intervals.

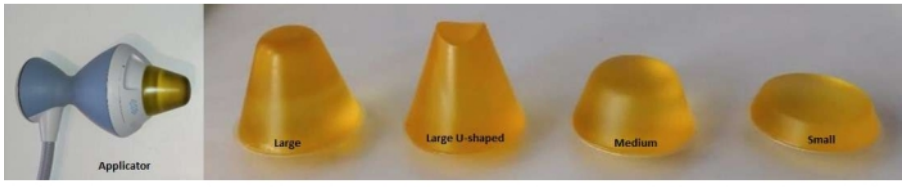

Figure 1: Applicator and coupling pad variations. Three different sizes of coupling pads are available. Each one allows the focus to be taken to a different depth in the tissues. Please click here to view a larger version of this figure.

Figure 2: Applicator positioning. Focused wave application in the supraspinatus tendon. Please click here to view a larger version of this figure.

3. Post-treatment protocol

1. After the first session, alert the patients that in approximately 5% of cases, they may suffer an acute resorption process with intense pain. If discomfort occurs, recommend the patient to apply ice to the areas of pain in short sessions of no more than 10 min.
   NOTE: Paracetamol is preferred over non-steroidal anti-inflammatory drugs. Shock waves modulate the inflammatory process, and it is better not to alter it by other means while the treatment lasts.
2. Immobilization: It is not necessary to immobilize the treated limb. Advise the patient to avoid extreme efforts and range of motions that may cause pain.
3. Rehabilitation program
   1. As the sessions progress, if tolerance is good, increase the range of movement and incorporate exercises to strengthen the depressors of the humeral head.
   2. If symptomatic relapses do not occur, include recovery exercises for the extreme ranges of movement. The strengthening of the three portions of the deltoid and the scapular stabilizers are also indicated.
4. Radiological follow-up:
   1. Perform the first radiographic examination at 6 weeks after the sessions and the second one at 12 weeks. In the case of observing a partial resorption process that has not been completed after 12 weeks, continue the radiological follow-up.
   2. If there have been no changes, opt for a new treatment module or move on to invasive procedures.
      NOTE: In many patients, very important changes can be seen in the first control x-ray. In other cases, variable changes can be seen from baseline studies, and there may be no change even on long-term radiographs in other cases.

Representative Results

A retrospective study of a series of patients with shoulder pain due to calcium deposits in the rotator cuff tendons was carried out in our institution. The inclusion criteria were Gärtner stage I and II calcifications and at least 3 months of previous conservative treatment without satisfactory results. Patients with Gärtner III calcifications, other associated pathology in the affected shoulder, previous local cortisone injection, and a history of surgery in the affected shoulder were excluded.

The study group consisted of 23 consecutive patients (**Table 2**), 13 female and 10 male, with an average age of 52.8 years. The supraspinatus muscle was affected in 82.6% of cases (19 shoulders), the infraspinatus in 13% (three shoulders), and the subscapularis in 4.4% (one shoulder). In all cases in this series, only one tendon was involved.

The previously described treatment protocol was applied to all the patients. The minimum follow-up was 6 months, with an average of 14 months (6-30 months). Complete disappearance was considered when at least 90% of the deposit disappeared compared to the initial studies; when the disappearance was between 40% to 90%, it was considered partial. When the deposit was like the initial one, it was included in the group with no changes. When resorption was less than 40%, it was considered not significant. In all cases, the size of the calcification was measured in the coronal image of the subacromial space (AP view). All the previous and subsequent radiological studies were evaluated by the first author, an orthopedic surgeon specialized in shoulder pathology with 30 years of experience. In 82.6% of the cases, complete resorption of the calcification was achieved (**Figure 3** and **Figure 4**) with the disappearance of the symptoms. In 8.7%, partial disappearance with symptomatic improvement was obtained but without complete disappearance of symptoms. In the remaining 8.7%, there were no significant changes, and an ultrasound-guided puncture was performed. With the exception of one case of fainting during application and two cases of transient pain during the resorption process, there were no complications. Tolerance to the application of focused waves was highly variable according to each patient, but in all cases, it was possible to reach a therapeutic dose.

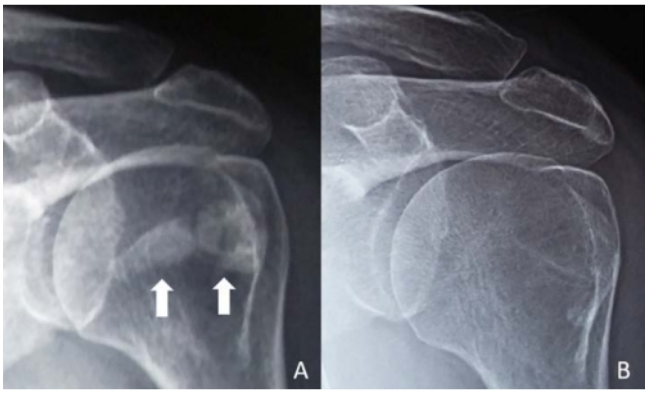

Figure 3: Calcification of the tendon of the subscapularis muscle. (**A**) Before treatment (white arrows). (**B**) Control at 6 weeks. Please click here to view a larger version of this figure.

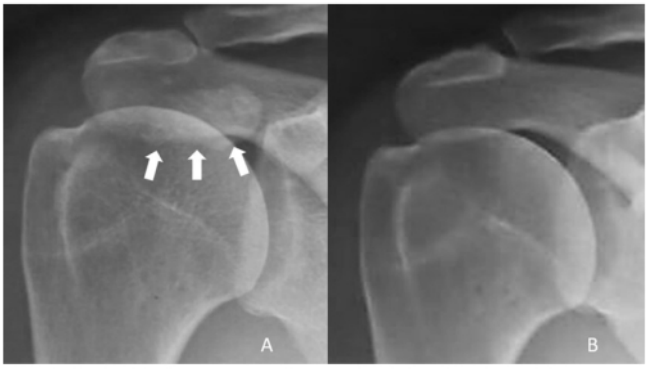

Figure 4: Calcification of the supraspinatus muscle tendon. (**A**) Before treatment (white arrows). (**B**) Control at 12 weeks. Please click here to view a larger version of this figure.

Coupling pad	Focal point size	Depth of focal zone
Small	45 mm	30–65 mm
Medium	30 mm	15–50 mm
Large	15 mm	0–35 mm

Table 1: Coupling pad variations. Each type of coupling pad has a focal point of specific size and depth.

Clinical findings		
Age	52.8 years (range: 41–70)	
Gender	Female	13 patients (56.5%)
	Male	10 patients (43.5%)
Location	Supraspinatus muscle	82.60%
	Infraspinatus muscle	13%
	Subscapularis muscle	4.40%
Follow-up	14 months (range: 6–30)	
Radiological results	Complete resorption	82.60%
	Partial resorption	8.70%
	No changes	8.70%
Complications	Faiting	1 patient
	Transient pain	2 patients

Table 2: Clinical findings. Demographic characteristics and follow-up data. Abbreviations: sup = supraspinatus, infra = infraspinatus, sub = subscapularis

Author	Device	Complete resorption	Partial resorption
Cosentino et al[34]	EH	31%	40%
Hsu et al[35]	EH	21.2%	36.3%
Wang et al[36]	EM	57.6%	15.1%
Gerdesmeyer et al[37]	EM	86%	
Peters et al[38]	EM	100%	None
Louwerens et al[39]	PMC	34%	25%

Table 3: Radiological results of the use of focused waves in calcified tendonitis of the shoulder. Abbreviations: EH = electrohydraulic, EM = electromagnetic, PMC = piezoelectric multi-crystal.

Discussion

This study shows encouraging results with the application of focused shock waves generated by a single-crystal piezoelectric device in a series of retrospectively evaluated patients with calcific tendinitis of the shoulder. According to the bibliographic search we carried out, this is the first study that reports results with a single-crystal piezoelectric device. Recently, Louwerens[39] published a study using a piezoelectric shock wave device for the treatment of rotator cuff calcifications. However, the author used a generator with multiple piezoelectric crystals in his study.

Significant publications[34,35,36,37,38,39] show great radiological variability in the treatment of calcific tendinitis of the shoulder with the use of focused shock waves (**Table 3**). The rate of complete disappearance of calcifications ranges from 21.2%[35] to 100%[38], compared to 82.6% in the present series. The greater maneuverability of the application head of the device used and the better tolerance to the application compared to our experience with electromagnetic generators contribute to the reproducible results of this study.

Focused shock waves have therapeutic results like those of invasive methods such as UGI and surgery, but the potential complications are less frequent and less severe[20,21]. The effectiveness of shock waves has been compared with minimally invasive techniques; Kim et al.[15] reported that ultrasound-guided needling was more effective than radial pressure waves for treating calcifications of the rotator cuff. However, the focused waves are in fact indicated for the treatment of calcifications, not radial waves[17]. Unfortunately, there is great confusion and erroneous overlap of concepts between focused and radial waves in the literature[19]. Furthermore, numerous methodological flaws have been pointed out in Kim's study[25]. Other studies have also suggested that UGI is effective in relieving pain and restoring shoulder function in the short term[20,45,46]. However, De Witte et al.[16] concluded that a large part of the patients who underwent barbotage had a recurrence of symptoms. In comparison, in a 10 year follow-up study in patients treated with shock waves for calcific tendonitis of the shoulder, Raedel[47] demonstrated that the resorption rate was 90% with a recurrence rate of only 5%.

Louwerens et al.[39] reported similar clinical results for high-energy focused waves and ultrasound-guided needling at 1 year of follow-up; however, they found that puncture was more effective in removing calcium deposits.

We believe that once the chance of rehabilitation has been exhausted, the ideal strategy is to consider shock waves as the first choice because it is a noninvasive procedure. The application of shock waves does not alter the good results of a future surgery[48] or puncture, which is why its indication is fully justified before moving on to invasive procedures.

This study does of course have limitations. It is a retrospective study without a control or sham group. The sample is small, and the follow-up is short. In any case, the short follow-up and the choice of Gärtner I and II calcifications rule out the possibility of spontaneous reabsorption.

Focused shock waves are a noninvasive, efficient, and cost-effective therapeutic option for treating calcific tendinopathies of the shoulder. Single-crystal piezoelectric generators have a success rate comparable to electrohydraulic and electromagnetic generators.

Disclosures

None

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None

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