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Current knowledge on evidence-based shockwave treatments for shoulder pathology

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ABSTRACT

Shoulder pain is one of the most common musculoskeletal pathologies. Treatment by ESWT (extracorporeal shockwave therapy) has emerged as an alternative when conservative treatment fails in rotator cuff calcific tendinopathy, prior to invasive procedures. The clinical efficacy of ESWT in non-calcific tendinopathy remains controversial. The good results in the treatment of rotator cuff calcifications, have led to indications of ESWT being expanded to other shoulder pathologies. We review the current state of indications and evidence based practice.

INTRODUCTION

Shoulder pain is one of the most common musculoskeletal pathologies. Its prevalence in the general population ranges between 4 and 26%, according to age and the existence of associated risk factor [1]. In approximately 75% of cases, symptoms originate in the subacromial space [1] but can also be a referred pain from various conditions such as cervical spine, abdominal viscera, lung apex and even accompanying myocardial ischemia. Therefore, it is essential to not just treat the symptoms of "shoulder pain" but establish a precise diagnosis to indicate the appropriate treatment.
We will analyze the main indications for ESWT in the field of shoulder pathology and present the evidence in the literature.

A. SHOULDER TENDINOPATHY

1.1. ROTATOR CUFF (RC) CALCIFIC TENDINOPATHY

Rotator Cuff (RC) calcifications are a relatively common disease of unknown cause, characterized by the presence of calcium hydroxyapatite crystal deposition in tendons that can be multifocal. Over a varied period of time, it can evolve into spontaneous resolution and eventual repair of the compromised tissue.
The most common site of this calcium deposit is at the supraspinatus tendon [2] (80%), followed by infraspinatus (15%), teres minor and subscapularis tendon in approximately 5%. Diagnosis is reached through clinical, radiology, with ultrasound being the most effective, sensitive and inexpensive; and magnetic resonance imaging (MRI) to complete the study and rule out associated pathologies.
Although the natural history can evolve to spontaneous resolution, the cycle can stagnate at any stage. Therapeutic approach depends on the intensity of symptoms, developmental stage and response to previous treatments.

The initial treatment of choice is conservative, typically including rest, analgesics, nonsteroidal anti-inflammatory drugs, rehabilitation and corticosteroid injections, with favorable results in 90-99% of cases, considering surgery as an exceptional indication [2,3,4]. De Palma [5], however, clarifies that in many cases this initial improvement deteriorates and the patient becomes a chronic carrier similar to patients showing subacromial impingement symptoms.
Gschwend [6], states that invasive procedures would be indicated when three conditions are met: symptomatic progression; constant and intractable pain and / or failure of conservative treatment. In this situation one can opt for surgical treatment, either open or arthroscopic and more recently injection under ultrasound guidance is being also performed, and still under investigation.

Extracorporeal Shockwave Therapy (ESWT) in Rotator Cuff Calcific Tendinopathy

Treatment by ESWT has emerged as an alternative when conservative treatment fails and prior to invasive procedures (Figures 1, 2 and 3). Its use in shoulder tendinopathy is mentioned in the literature from about 20 years ago [7] and its efficacy and low morbidity is well-demonstrated [2,7,8,9,10,11,12].
The application of ESWT is usually considered when conservative treatment has failed for 6 months [3,11], especially in deposits in stages I and II Gärtner (stage III calcifications have high chances of disappearing spontaneously).
The mechanism of calcium absorption post ESWT has not been fully elucidated. Brañes, Guiloff et al [13] were able to demonstrate the presence of neo- lymphangiogenesis phenomena from biopsies taken from RC repair surgery, previously treated with ESWT (one session) with 2 different types, electrohydraulic and electromagnetic, a similar dose (0.33 and 0.35 mJ/mm2 of energy, respectively). Their hypothesis was that new lymphangiogenesis is related to improved calcium reabsorption observed after ESWT treatments.
Clinical-radiological dissociation is not uncommon, and although the persistence of calcification may be associated with a good clinical outcome, complete resorption, statistically has better results than the partial disappearance or persistence of calcification.
According to ESWT efficacy, in a study over 30 months, Wang [12] prospectively compared two groups: the ESWT group had 90.9% excellent or good results, 3% regular and 6.1% bad; and complete disappearance of calcification in 57.6% of patients. The ESWT-placebo group showed 16.7% regular results, 83.3% poor results, and disappearance of calcification in 16.7% of these.
Rompe [11] compared the results of surgery with ESWT, finding no difference in outcomes at one year, with improvement in patients treated with ESWT at two years.
Gerdesmeyer [2] in a randomized clinical trial of 144 patients reported better results in patients treated with ESWT, both low energy and high energy, compared to placebo. Hearnden [7] in a prospective, single blinded, randomised control trial of 20 patients found a statistically significant result with shockwaves over the placebo group but reported that half of the patients failed to achieve a satisfactory outcome and required surgical excision. Hsu [8] in a prospective study with a control group achieved 87.9% good and excellent results with high energy.
Rebuzzi [3] compared the results of arthroscopic surgery treatment with low-energy ESWT in homogeneous calcification of the supraspinatus. Even as the rate of complete disappearance of most

calcification associated with surgery (86.35%) compared with ESWT (58.33%) at two years, there were no significant differences in clinical and functional assessment according to the UCLA scale. The authors conclude that they prefer using ESWT as the first therapeutic option because it is a non-invasive method.

The absence of a dense calcification rim around the RC is a good predictor of treatment outcome with ESWT [11,14]. It has also been postulated that the results of ESWT are higher in non-homogenous deposits while some authors expect better results from surgery in homogeneous deposits [11].

The usual methods to target the shockwaves on the calcification are: topographic anatomy landmarks, feedback from the patient maximum tenderness using palpation, ultrasound and radiology. ESWT application on calcification by fluoroscopy is more effective than if performed on the distal area of the supraspinatus tendón [15]. While the use of ultrasound has been advised [16,17], localization with computed tomography (CT) has proven to be more effective [18]. Sabeti-Aschraf [18] compared the results of low-energy ESWT applied in one group according to feed-back from maximum tenderness by palpation and in the other group by three dimensional CT, with clinical improvement in both, however the CT group was more effective at 12 weeks. Tornese [19] compared two ultrasound-guided extracorporeal shock wave therapy techniques for the treatment of calcifying tendinitis of the shoulder. Clinically, there were no significant differences between them, but the rate of resorption was higher in patients treated with the arm positioned in hyperextension and internal rotation (66.6%) compared with those treated in neutral position (35.3%).

Regarding energy levels, the tendency has been to consider that higher energy is more effective in treating calcifications [2,20,21,22,23,24,25,26]. Although some studies described that low energy could have satisfactory results, there are numerous publications that have shown a high level of energy to be more effective [2,20,21,22,23,24,25,26]. Sabeti [16] reports comparable results with high and low energy, but more sessions are required when low energy is used. Verstraelen [27] reaffirms this concept and concludes that the use of high energy determines a higher rate of calcification resorption and better functional response, with evidence level I.

There is no general attitude towards the use of anesthesia. In general, upon applying high-energy ESWT, the application of anesthesia or sedation can be justified according to pain tolerance.

The rapid growth of radial ESWT in recent years has positioned it as an alternative to focal ESWT for the treatment for RC calcifications [28,29]. Cacchio [28] reported a high rate of reabsorption of calcifications using radial ESWT in a randomized study with control group. Time will tell if radial shockwaves has the same efficiency standards than focal shockwaves.

Although evidence on the effectiveness of ESWT for this condition is solid, there is no consensus on the most efficacious ESWT generator, number of sessions, number of impulses, frequency, energy level, use of anesthesia or method of localization, which shows heterogeneous therapeutic parameters and hinders comparison across studies [9].

The absolute contraindications for ESWT in shoulder pathology are malign tumor or infection within the shock wave field.

According to complications, the most commonly reported adverse events related to ESWT is local pain, particularly when applying high-energy ESWT, and in extreme cases intolerance, petechiae, local erythema and hematomas. Another possible side effect during treatment of calcifications is pain exacerbation, probably from increased pressure within the subacromial space by action of the inflammatory process generated. Thiele [30] studied a series of 1.800 patients with RC

calcifications without finding major complications after five years of follow-up. The worst outcome would be the lack of an adequate response, with no improvement or clinical or radiographic changes, which would not prevent the indication of surgery.
ESWT does not show damage of anatomical structures according to MRI exams [22]. We also know that previous application of ESWT does not alter the outcome of an eventual surgery for RC calcification [31].
There are two studies that indicate serious complications and should not be ignored. Both report on respective cases of humeral head necrosis after applying ESWT therapy. In one of them, a 59-year patient developed cephalic necrosis three years after treatment [32]. In the second case, necrosis appeared three months after initiating treatment [33]. It has been discussed whether in fact the initial painful symptoms in this patient corresponded to an early stage necrosis, and calcification could have been in a subclinical phase. Vascular lesions have been reported in patients undergoing renal lithotripsy, which may explain the mechanism of necrosis in patients with atypical vascularization of the proximal end of the humerus. ESWT candidate patients with shoulder tendinopathy should be informed of this rare but serious complication.
When analyzing RC calcifications efficiency, ESWT treatment avoids potential complications and costs of surgery, and reduces the time for rehabilitation. Dubs [34] compared the efficacy and costs of ESWT with usual treatments (control group). In addition to demonstrating that it was more efficacious, it also allowed for savings of an average of US $ 2,000 per patient, in comparison with alternative therapies. Eid [35] compares the cost of arthroscopy for RC calcification and showed it to be 6.4 times higher than of ESWT. Haake[36] showed a cost of between € 2,700-4,300 per patient treated with ESWT against € 13,400-23,450 for those treated surgically, concluding that surgery cost is 5-7 times higher than ESWT.
To sum up, for its efficacy in pain, function, resorption of calcification – which is dose-dependent -, safety, noninvasiveness, reduced recovery time after application and cost-effectiveness, ESWT are an efficacious and efficient alternative to surgery for RC calcification, and therefore the treatment of choice in this pathology.

At the present time, the following would be our suggested protocol for Rotator Cuff Calcific Tendinopathy:

1. Focused ESWT:
   a. Electrohydraulic: 2.000 shocks; between 0,19 to 0.32 mJ/mm2, 1 to 3 sessions according to the device.
   b. Electromagnetic: 2.000 shocks; 0.35 mJ/mm2, 2 to 3 sessions according to the device.
2. Radial ESWT: 4.000 shocks; 4-5 bar, 3-5 treatments according to the device.

- Application interval: 1 to 2 weeks.
- Follow-up: 6, 12, 18, 24 weeks after treatment.
- No local anesthesia.

1.2. NON-CALCIFIC ROTATOR CUFF (RC) TENDINOPATHY

Non-calcified tendinopathy of RC present extrinsic and intrinsic pathogenic mechanisms. The term "non-calcified tendinopathy" generally includes degenerative processes determining tendinosis and partial tendon ruptures not eligible for surgery. The foremost include functional and structural disorders and mechanically affect the rotator cuff. The intrinsic includes the degenerative processes suffered by the muscles and tendons over the course of several years. ESWT cannot modify extrinsic factors but could improve vascularization of RC and stimulate the release of growth factors [28]. ESWT could be a valuable tool in cases of rotator cuff tears with surgical indication. On this scenario, we could wait better vascularization of the injured tissue and improved healing, according to histological results reported in treated tendons [13].
Guiloff and Brañes have obtained very promising results in interstitial partial-thickness tears of the rotator cuff (Figure 4).
The clinical efficacy of ESWT in non-calcific tendinopathy is controversial [21,25,29,37,38]. Some authors show that ESWT is not effective in these cases, but do not clarify the exact etiology and pathogenesis in these patients [38]. On the other hand, good results have been presented in papers that analyzed the effect of ESWT in patients affected by subacromial impingement syndromes stages I and II according to Neer. The results were statistically significant in long-term follow up. Galasso [39] studied patients with non-calcifying tendinopathy with strict criteria of inclusion and obtained satisfactory results with low doses of energy compared to placebo.
Engebretsen [40] however, evaluated patients with the generic diagnosis of "subacromial pain" including patients with rotator cuff ruptures, aged 18-70 years, which probably resulted in a variety of disease entities. He concluded that long-term radial ESWT offered similar results to those of a supervised exercise program, and that in the latter group there was higher return to employment. It is a misconception to believe that an isolated method that improves the quality of the tissue can improve joint mechanics. ESWT and supervised exercise programs are complementary and not mutually exclusive, thus they need to be implemented together.
In short, we believe that ESWT could have a complementary role in the treatment of chronic RC tendinopathy. Patient training with adequate muscle and capsular lengthening techniques, strengthening of the different muscle groups of the shoulder and scapula function control techniques are essential to obtain the best clinical and functional outcome possible. In these cases rehabilitation can be complemented but not replaced by any other method.

Evidence on shoulder tendinopathies (calcified and non-calcified) is shown in tables 1 and 2.

B. OTHER INDICATIONS

The good results in the treatment of rotator cuff calcifications, have led to indications of ESWT being expanded to other shoulder pathologies. There is still no solid evidence to support these remarks, but in some cases promising results have been reported.

Radial ESWT has been proposed to treat bicipital tendinopathy [51] with good results, but in the field of shoulder surgery, primary tendinitis of the long head of the biceps is considered unusual. Its isolated presentation is uncommon and practically a diagnosis of exclusion. It would be a mistake to treat localized pain in the region of the biceps without a proper diagnosis.
Despite these promising outcome biceps tendinopathy as a standard indication is still discussed. Further studies have to confirm these initial data. No recommendation based on clinical trials can be given for focused shockwave therapy.
An initial good personal experience has been obtained in the treatment of distal clavicle osteolysis with ESWT by one of us (DM), both in terms of pain, and edema of the distal clavicle confirmed by MRI. (Figure 5) but further studies and statistical data must support these findings.
Finally, in recent studies the use of ESWT has been suggested for the treatment of adhesive capsulitis (frozen shoulder) [52,53,54]. Vahdatpour [52] conducted a randomized trial in 36 patients, which divided into intervention group (electromagnetic ESWT: 0.1-0.3 mJ/mm2, the maximum level tolerated by the patient, 1.200 pulses 4 sessions, once a week) and a placebo group (ESWT switched off, once a week for four weeks). As a strong bias, both groups got cortisone in a therapeutical dosage as a concomitant therapy and were encouraged to follow an exercise program. Improvement was noted in the ESWT group with respect to pain, disability according to SPADI (Shoulder Pain Disability Index), mobility, earlier return to normal activities compared with the control group, no significant differences in internal rotation in the two groups. Faster recovery was obtained at 2 months after treatment. Durante [53] performed a study in 20 patients with frozen shoulder with MR images that ruled out tendon rupture, evaluating the therapeutic effect of ESWT (4 sessions of 2.500 impulses, energy 0.07-0.11 mJ/mm2) associated with physiotherapy (3 days/week for 2 weeks) compared with physical therapy alone, and found improvement in joint mobility in the ESWT group.
Although the available evidence does not allow conclusions on the effectiveness of ESWT in frozen shoulder, research should continue with larger series of patients, randomized clinical trials and therapeutic parameters of homogeneous ESWT, and associated with a specific exercise program in all cases.

SUMMARY

Extracorporeal shockwave therapy has emerged as strong therapeutic tool for shoulder pathology. While many high quality papers support its efficacy and efficiency in the treatment of rotator cuff calcifications, clinical efficacy of ESWT in non-calcific tendinopathies remains controversial and needs further research. Promising results on other shoulder diseases have been reported but there is still no solid evidence to support these remarks.

CONCLUSION

There is evidence to support the use of shockwaves in certain shoulder pathologies. Its efficiency, safety and noninvasiveness justify its choice over surgical procedures in rotator cuff calcifications.

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Table 1.
ESWT Evidence on shoulder tendinopathies

Authors	Article	Sample	Groups	Generator	Device	Impulses	nº treatment	Energy	FU	Conclusion
CALCIFIC ROTATOR CUFF TENDINOPATHY										
Focused										
Rompe	J Shoulder Elbow Surg 1998	100	high vs low	EM	Siemens	1,500	1	0.06 vs 0.28	6 w, 24 w	Both improved, better high energies
Loew	J Bone Joint Surg Br 1999	195	high: 1 vs 2 treatment vs placebo	EH, EM	MFL Philips; Dornier	dif	1 or 2	0.3 vs 0.1	3, 6, 24, 30 mo	ESWT: 58% pain, function. Both but better 2 sessions and high energy at 6 mo
Cosentino	Ann Rheum Dis 2003	70	high vs placebo	EH	Orthima, Direx	1,200	3	0.28	6 mo	High-ESWT: 68% Improvement in Constant, resorption in 71%
Wang	Am J Sport Med 2003	39	medium vs placebo	EH	Ossatron	1,000	1 or 2	0.18	3, 6, 12 mo	ESWT: improved pain and dissolution of calcium deposits
Gerdesmeyer	JAMA 2003	96	high vs low-ESWT vs placebo (+ PT)	EM	Dornier	1500 vs 6000	2	0.32 vs 0.08	3, 6, 12 mo	Both high and low ESWT are beneficial; High: superior in pain, Constant, calcium deposit
Perlick	J Orthop Sci 2003	80	high-ESWT vs medium	EM	Siemens lithostar	2,000	2	either: 0.23, .42,.54	12 mo	NSS on Constant (Pain and ROM was not compared)
Peters	Skeletal Radiol 2004	61	high-ESWT vs medium vs placebo	EM	Storz (Modulith)	1,500	5	0.44 vs 0.15	6 mo	High-ESWT: lower recurrence of pain at 6 mo
Albert	J Bone Joint Surg Br 2007	80	high vs low-ESWT	EM	Storz (Modulith)	2,500	2	0.45 vs 0.06	3 mo	High-ESWT: better for Constant at 3 mo; no changes in calcification.
Hsu	J Shoulder Elbow Surg 2008	46	high-ESWT vs placebo	EH	Orthowave MTS	1,000	2	0.55	3, 6, 12 mo	ESWT: pain, Constant, calcium deposit
Ioppolo	Phys Ther 2012	46	high vs medium	EM	Storz (Modulith)	2,400	4	0.2 vs 0.1	3 m, 6 mo	Effectiveness: 0.2 mJ/mm2 better than 0.1 in pain and function. 50% complete resorption
Radial										
Cacchio	Phys Ther 2006	90	Radial vs placebo	Radial	Elettronica	(500) + 2000	4	(1.5 bar) 2.5 bar	1, 6 mo	RESWT: Improved function at 6 mo
NON-CALCIFIC ROTATOR CUFF TENDINOPATHY										
Focused										
Schmitt	J Bone Joint Surg Br 2001	40	Low vs placebo	EM	Storz (minilith)	2,000	3	0.11	12 mo	NSS in pain, function
Schmitt	Orthopade 2002	40	High vs placebo	EM	Storz (minilith)	2,000	3	0.33	12 mo	NSS in pain, function
Speed	J Bone Joint Surg Br 2002	74	Medium vs placebo	EM	Sonocur (Siemens)	1,500	3	0.12	3, 6 mo	NSS on night pain or function
Schofer	Acta Orthop Belg 2009	40	High vs low	EM	Storz (minilith)	2,000	3	0.78 vs 0.33	12 w, 12 mo	NSS in pain, function
Galasso	BMC Musculoskeletal Dis 2012	20	Low vs placebo	EM	Modulith Storz	3,000	2	0.068	6 w, 12 w	Low - ESWT is effective in short-term
Radial										
Kolk	J Bone Joint Surg Br 2013	82	Low- energy vs placebo	Radial	Swiss Dolorclast EMS	2,000	3	0.11	6 mo	NSS in pain or function

(RCT: Randomized Clinical Trial; DB: Double Blind; ESWT: Extracorporeal Shockwave Treatment; EH: electrohydraulic; EM: electromagnetic; PT: Physiotherapy; ROM: range of motion; FU: Follow-up; w: weeks; mo: months; NSS: not statistically significant)

Table 2.
ESWT evidence on shoulder tendinopathies (calcified and non-calcified)

Authors	Article	Statements
Systematic Review		
Huisstede	Manual Therapy 2011	Only high-EWST is effective for calcific RC tendinosis. No evidence for non-calcific tendinosis.
Bannuru	Ann Intern Med 2014	High-ESWT is effective for improving pain and function in calcific tendinitis, and can result in complete resolution of calcification (compared to low-ESWT and placebo)
Meta-Analysis		
Verstraelen	Clin Orthop Relat Res 2014	High ESWT is more likely to improve function and resorption of the deposits compared with low-ESWT
Systematic Review and Meta-Analysis		
Ioppolo	Arch Phys Med Rehabil 2013	ESWT improves shoulder function, reduce pain and is effective disolving calcific; maintained at 6 months.
Louwerens	J Shoulder Elbow Surg 2014	From minimally invasive therapies, high-ESWT is safe and effective in chronic calcific tendinopathy of RC.

(ESWT: Extracorporeal Shockwave Treatment)

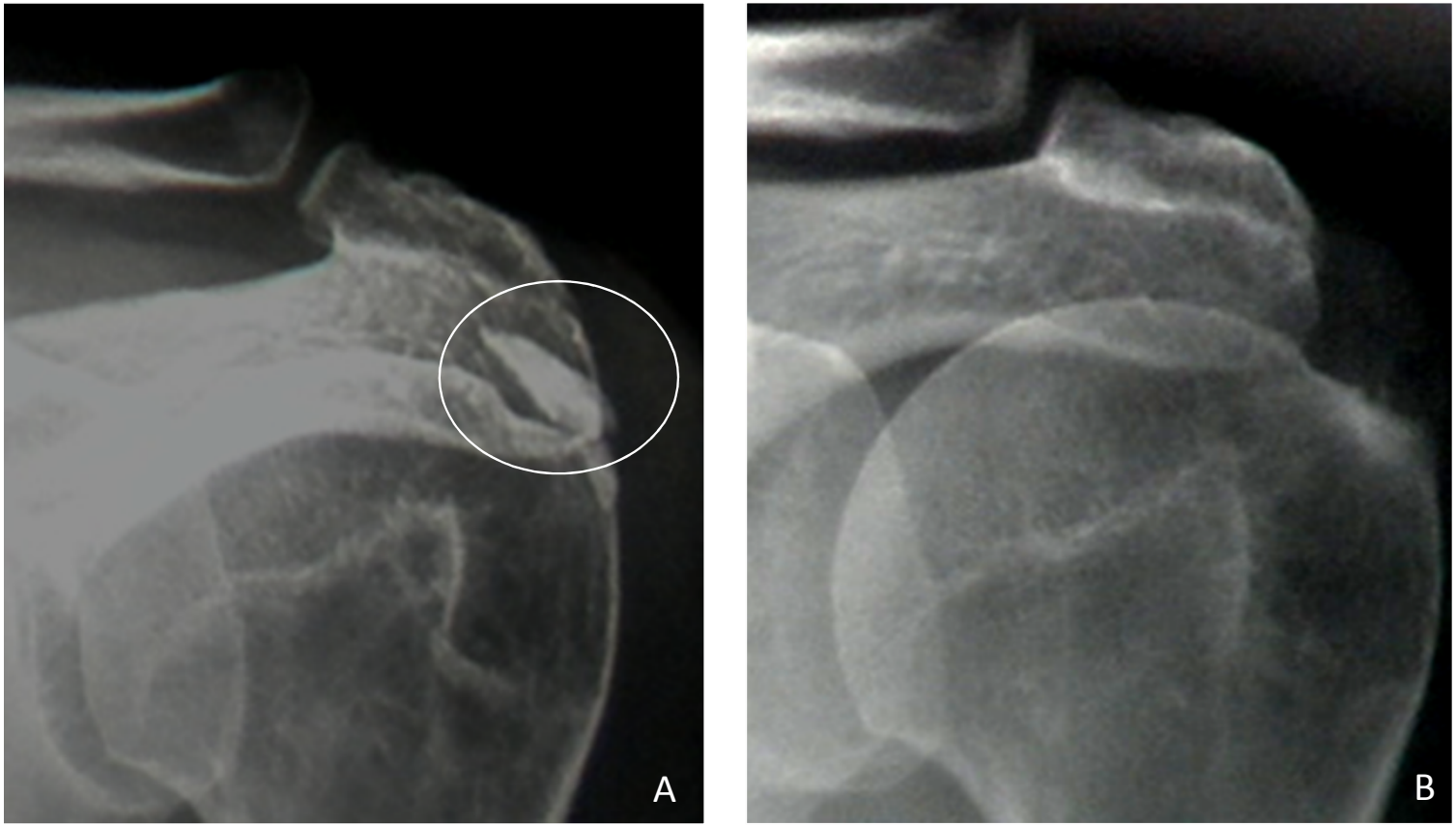

Figure 1. A. 42 years old female. Gärtner type 1 calcification. B. After just one session with an electrohydraulic focused device (2000 pulses, 0.32 mJ/mm^2) the patient underwent an acute and painful resorption. X-ray was taken 1 month after the session showing complete resorption.

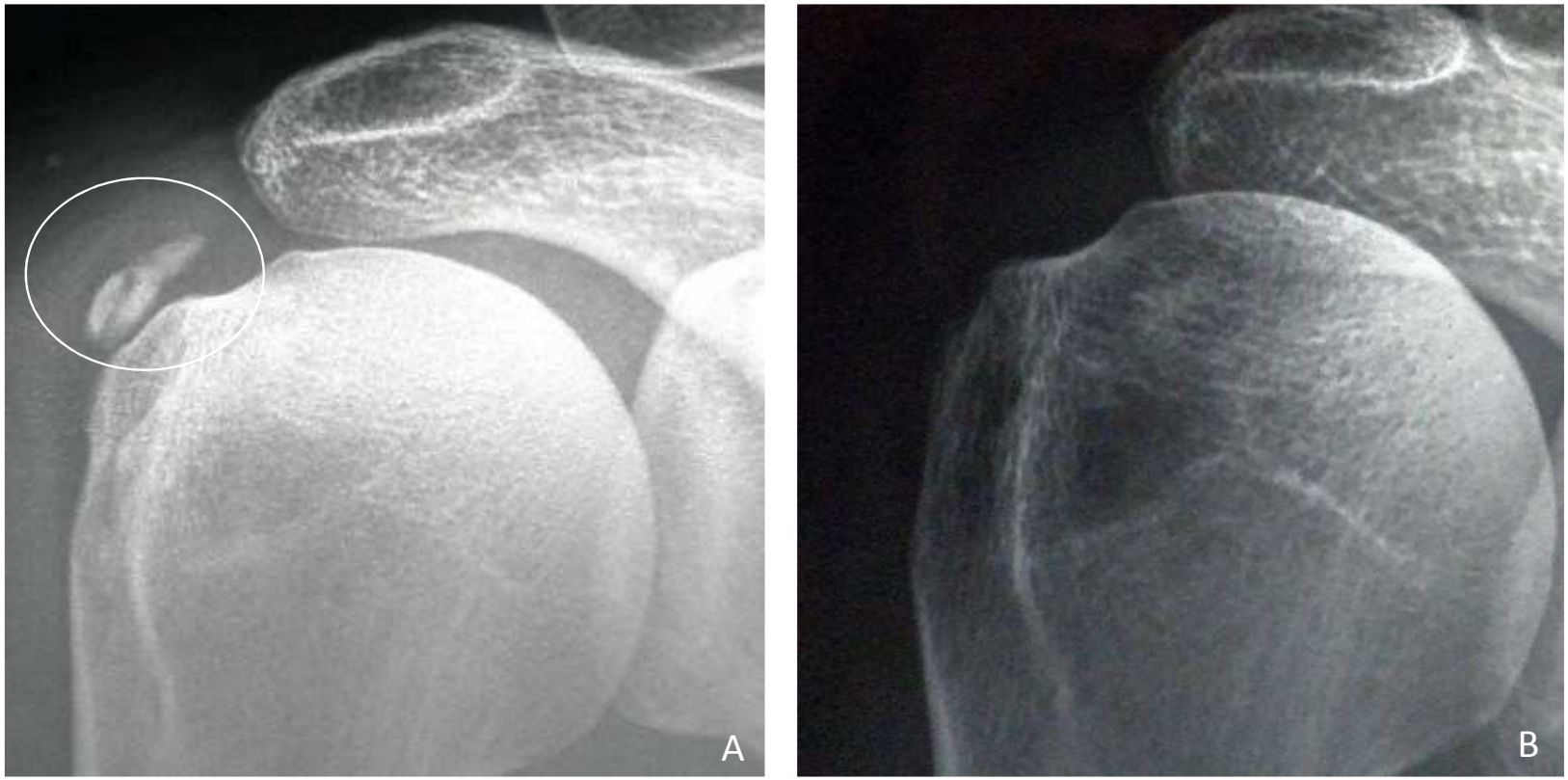

Figure 2. A. 55 years old female. Gärtner type 2 calcification. B. After 3 sessions with an electrohydraulic focused device (2000 pulses, 0.32 mJ/mm^2) X-ray was taken 3 months after the shockwave treatment.

Figure 3. A. 62 years old male. Gärtner type 1 calcification. B. After 3 sessions with an electrohydraulic focused device (2000 pulses, 0.32 mJ/mm^2) X-ray was taken 3 months after treatment.

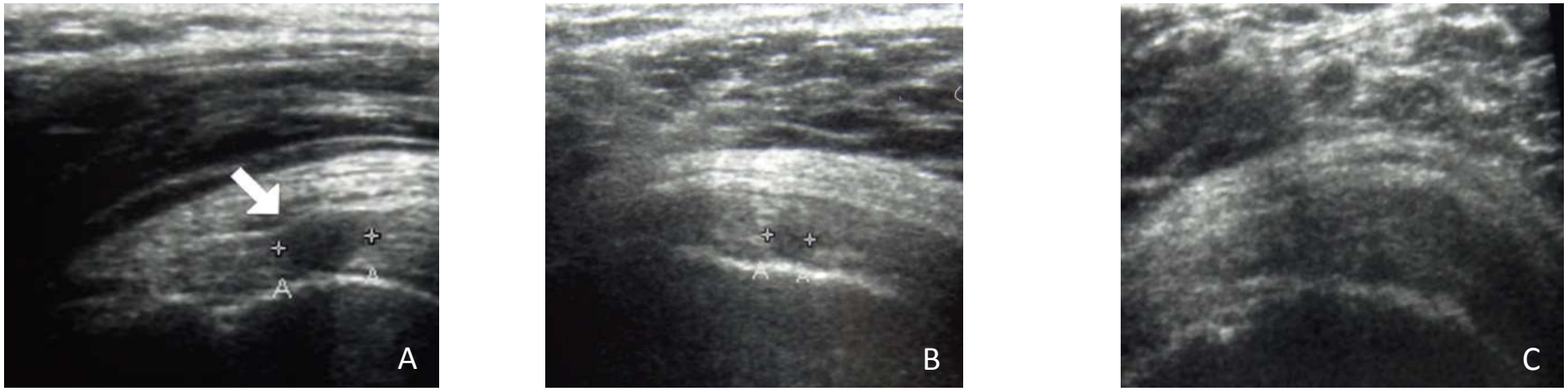

Figure 4. A. 47 years old male, 6mm intramural tear located on the supraspinatus. Treated with an electromagnetic focused device (4000 impulses, 0,25mJ/mm2) B The same ecographist described a reduction in size of the lesion to 3mms, 7 weeks later. C. By 16 weeks, the same ecographist described significant lessening of the tendinopathic aspect of the tendon with resolution of the lesion.

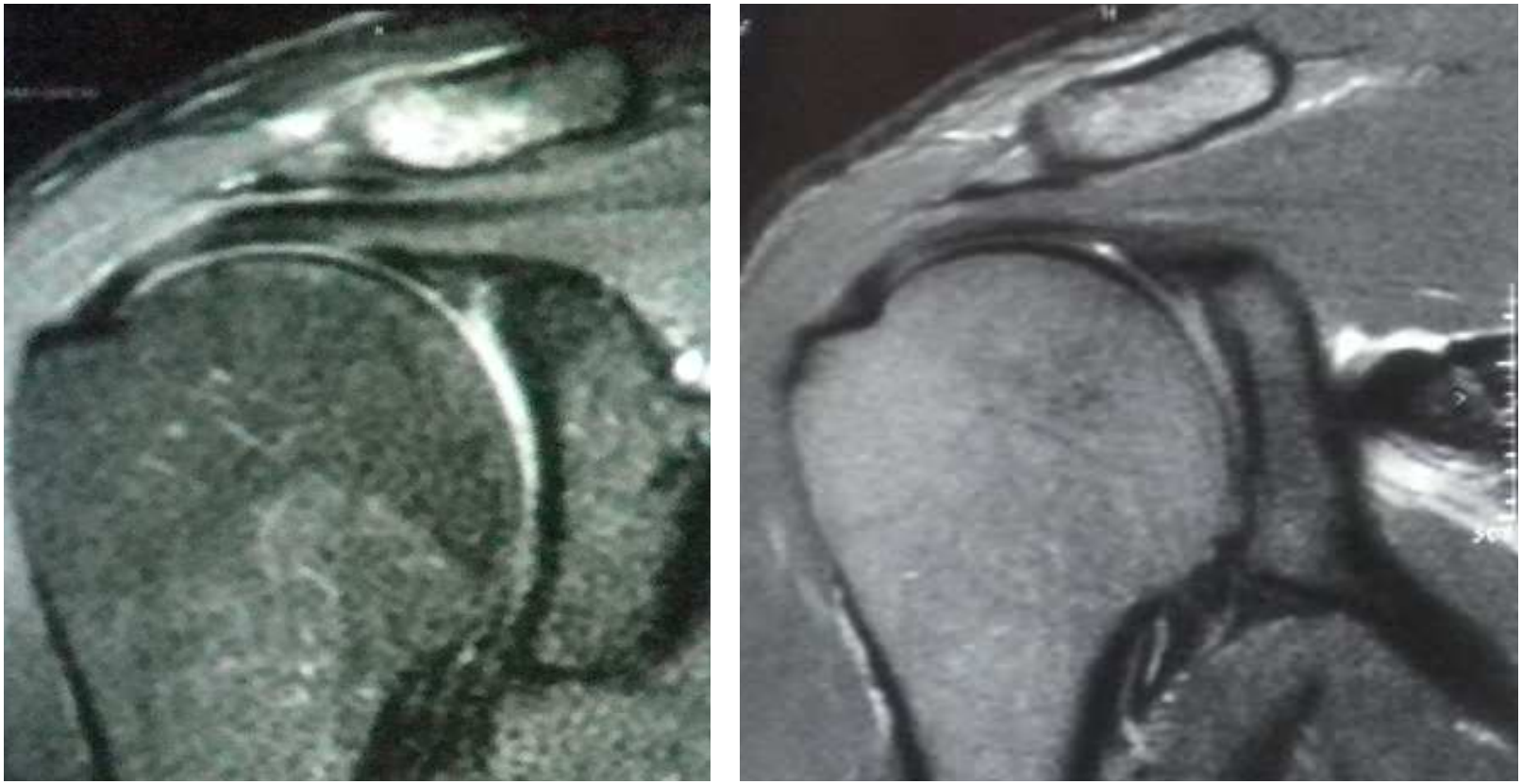

Figure 5. A. A 32 years old male undergoing distal clavicle osteolysis. Initial MRI shows diffuse bone marrow edema on the distal clavicle. B. The same case after 3 focused sessions with an electro-hidraulic device (2000 pulses, 0.50 mJ/mm^2). The edema has disappeared and the symptoms resolved after three months.

HIGHLIGTHS

- We present the current knowledge on shockwave treatments for shoulder pathology.
- ESWT is an efficient tool for the treatment of rotator cuff calcifications.
- The clinical efficacy of ESWT in non-calcific tendinopathies is controversial.
- Promising results have been reported on other shoulder pathologies.