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### **Review Article**

# Short-Term Evaluation of the Effectiveness of Shock Wave Therapy (Diamagnetic Shock Waves) Versus Physio Kinesiotherapy in Non-Calcific Tendinopathy of the Shoulder: A Preliminary Comparative Study

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### Introduction

Tendinopathies are a common painful condition that affects both active and inactive people [1]. The pathobiology is still not fully understood, but for the great part, the cause has been attributed to the repetitive mechanical overload, generally workrelated or sport-related, that leads to micro-trauma whose effects prevail on the poor regenerative potential of the tendons. Anyway, genetic, and behavioral factors have a significant role too. In the natural proceeding of tendinopathies, degenerative changes in tendon structure give rise to a chronic condition characterized by pain, restriction of the Range of Motion (ROM), and a decrease in physical activities, reflecting the quality of life in affected people. [2] The rotator cuff disease, well known as rotator cuff impingement or subacromial syndrome, is the most common tendinopathy of the upper limb. Its management must consider the anatomic deep location of the rotator tendons and the fact that multiple shoulder joint structures can contribute to the origin of pain [3]. The first-choice line of treatment for calcific and non-calcific shoulder tendinopathy includes conservative approaches, and they consist of different modalities: strengthening and stretching exercises, corticosteroids, platelet-rich plasma or blood injections, acupuncture, laser therapy, and many more [4]. However, there is still uncertainty as to which is the best non-surgical intervention, and a variable percentage of patients, between 4% and 11%, do not benefit from any conservative therapy and must-undergo surgery [5]. ESWT is a well-established conservative treatment for most tendinopathies [6] The therapeutic rationale for their use lies in

the mechanotransduction of the acoustic signal in biological responses firstly triggered in the extracellular matrix (ECM), then involving the membrane mechano- receptors, and finally selected endo-cellular pathways that promote the healing process [7] Nevertheless, several studies report controversial effectiveness on pain and functional recovery for different kinds of tendinopathies [8,9] and, despite current clinical evidence, doubts about the superiority of ESWT compared to other interventions remains, as resulting from Cochrane systematic reviews in epicondylitis [10] and shoulder tendinopathy [11]. These concerns could be due to our incomplete knowledge of tendinopathies in general and, for the shoulder, to the different therapeutic approaches required for calcific and non-calcific tendinopathy of the rotator cuff [12]. This observational study aims to evaluate the effects, in the short term, of a new kind of shock wave, called "diamagnetic shock wave" [13] in non-calcific tendinopathy of the shoulder versus physiotherapy and rehabilitation.

**Keywords**: Diamagnetic Shock Wave; Extracorporeal Shock Waves; Shoulder Tendinopathy

### **Material and Methods**

The present study is a preliminary observational trial conducted on 40 patients, divided into two groups. Group I was treated with ESWT, while group II underwent physio kinesitherapy. Inclusion criteria were diagnosis of non-calcific tendinopathy of the shoulder derived from ultrasound investigation, age >18

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years old. Exclusion criteria were shoulder stiffness or pathology contraindicating shockwave therapy, tendon lesions, previous locally corticosteroid injection or other substances, previous physiotherapy in the last six months, pregnancy, current neoplasia, and major coagulation disorders. All patients were evaluated before and after treatment using the CMS - Outcome Score, which was found to be a reliable rating scale for subacromial pathologies, including tendinitis of the shoulder [14] In addition to the total score, the following subitems results were analyzed and compared between groups: pain, activity level, strength, and range of motion (forward flexion, lateral elevation, internal and external rotation). Between May and July 2022, 40 outpatients suffering from shoulder tendinopathy were retrospectively analyzed into two groups, 20 in Group I (12 females and 8 males) and 20 in Group II (11 females and 9 males). The mean age was respectively 54,9 and 64,75 years.

Patients in Group I, ESWT group, have been treated by an orthopedic expert with the use of the technology. The protocol of treatment consisted of 1 session /week of SW for three weeks, employing Energy Flux Density (EFD) values of 0,10-0,15 mg/ mm2, at the frequency of 1-2 Hz /sec, for a total of 300 shots focussing at 2 cm of depth. The device (CTU-S-Wave device - Periso SA- Pazzallo -Switzerland) is provided with a source of energy given by an electromagnetic coil that produces a High-Intensity Pulsed Electromagnetic Field (2 Tesla). The electromagnetic pulse hits a discoid element (acoustic lens) consisting of an alloy of diamagnetic materials which, for their repulsive property, once exposed to the high pulsed magnetic field, undergoes a strong and speed pulsed repulsive effect able to generate a high energy series of acoustic waves. Hence the term "Diamagnetic Shock Waves". The diamagnetic lens is shaped with a series of concentring rings according to Fresnel's optic principle applied to the acoustic. The principle states the possibility to modify a spherical lens into a plane mono-focal lens, without changing the focusing properties, mainly in the central part, while a series of surrounding concentric rings of decreasing width, known as Fresnel Zone Plates (FZPs) occupy the remaining area (Figure 1). Such characteristics allow the focusing of the acoustic pulse energy in a specific area in the same way that optical lenses focus light because the underlying theory applies to both mechanical and electromagnetic waves [15]. An ultrasound gel was employed as a conductive medium for each treatment (Complex Gel ®Periso SA -Switzerland).

Patients in group II have been treated with 3 daily consecutive sessions of Physiotherapy five days per week, for two weeks, consisting of laser therapy, and ultrasounds for a total of 10 sessions for each of them. Supervised assisted kinesiotherapy, for a total of 10 sessions was brought forward by an expert physiotherapist in shoulder rehabilitation. In detail, rehabilitation included a totally of 10 sessions twice a week of Codman Exercises, stretching of the pectoral muscles, and isometric strengthening of the rotatory muscles with exercises for flexion, extension, and internal and external rotation as resistance training with low intensity/ resistance, high frequency and approximately 3-4 sets per muscle group [16] and postural education. Informed consent has been

obtained from each of the subjects regarding the processing and dissemination of personal data, according to the specific laws. All the patients were evaluated for the CMS pre-treatment and 1-week post-treatment



Figure 1: Diamagnetic Lens. The acoustic Fresnel lens is obtained by smoothing an acoustic lens of a convex one. This allows bringing high-resolution acoustic signals and focusing the energy at a specific depth. Fresnel's lenses are formed by a set of concentric rings with decreasing width and each ring is called the "Fresnel region". Between two consecutive regions, there is a  $\pi$ -phase difference. The main energy contribution to the focus is given by the central regions of the lens.

### **Results**

All the treated patients completed the study, no side effects, or adverse effects due to the therapy were observed in the two groups and no patients reported discomfort during the treatments. Means pre- and post-therapy regarding total CSM Outcome Score and the subdomains are reported in Table 1. The mean total pretreatment at the CMS Outcome Score was 58.65 points in group I versus 42.65 points for group II. At the end of the treatments, the mean score in the two groups was 68.25 points in Group I and 50.90 points in Group II. Regarding autonomy in daily and work activities (AQL), the average pre-treatment was 6.3 points for group I and 5.7 points for group II. At the end of the treatments, the average in the two groups was respectively 9.1 and 7.00. The pain score showed a pre-treatment average of 10.9 points for group I and 6.9 points for group II. In the end was 16.1 points and 9.00 points. The mean functional assessment score pre-treatment was 32.00 points for group I versus 21.3 points for group II. At the end of treatment, it was 34.8 points for group I and 24.9 points for group II. For muscle strength, the respective reports show a pre-treatment average of 5.1 points for group I and 1.9 points for group II. In the end was 5.5 and 2.6 respectively. The total Constant score, not weighted by age group given the number of subjects studied, shows satisfactory results regarding pain in the ESWT group waves, where the pre-and post-treatment means are to be considered statistically significant (p< 0.05, Student's t-test). The means of the parameters concerning functional recovery in daily and work activities are not significantly different in the two groups. The averages of the total Constant score, of the joint range, were statistically different (p< 0.05, Kruskal-Wallis's test.

	Pre treatment mean		Post treatment mean		Difference	
	Group I	Group II	Group I	Group II	Group I	Group II
Total Constant-Murley Shoulder Outcome Score	58.65	42.65	68.25	50.90	9.60	8.25
Pain	10.90	6.90	16.10	9.00	5.20	2.10
Activity level	6.30	5.70	9.10	7.00	2.80	1.30
Range of motion	32.00	21.30	34.80	24.90	2.80	3.60
Strength	5.10	1.90	5.50	2.60	0.40	0.70

**Table 1:** Mean score pre- and post-treatments with related differences of total Constant-Murley Shoulder Outcome Score and pain, activity level, range of motion, and strength subdomains, for Group I and Group II.

### Discussion

Shoulder tendinopathy occurs in conditions of relative overload (low or excessive load) on the components of the rotator cuff. The differences within and between individuals have been related to the activity levels, the combination of intrinsic, extrinsic, and environmental factors in the context of specific morphology of the rotator cuff tendons, and the effects of stress shielding [17] Leong et al, report twenty-two potential risk factors for shoulder tendinopathy, and among them, strong evidence has been shown for age over 50 and working with the shoulder above 90°. In our study, the main risk factor (age) was representative and given by mean of, respectively, 54,9 and 64,75 years in both groups. Besides, genetic factors, metabolic diseases, smoking, endocrine disorders, and obesity must be considered as risk factors. [18] Anatomic pathology of tendinopathy reveals acute or chronic inflammation, and structural damage to the tendon matrix. This last has been attributed to chronic compression, while the intrinsic mechanisms are associated with degeneration of the rotator cuff tendons. This means that rotator cuff tendinopathy is not a homogenous entity, and thus may require different treatment interventions. [19]

The therapeutic approach consists of various possibilities. Specific rehabilitation has an important role, mainly when based on the principle of adapted guide-line exercise like controlled reloading and gradual progression from simple to complex shoulder movements, while postural and rehabilitative activities aim to correct the effect of extrinsic factors and prevent tendon damage. These programs also contain relative rest, modification of painful activities, progressive painless exercise strategy, postural rehabilitation according to specific education measures, and attention to lifestyle factors such as smoking, diet, stress, and sleep management [17]. These concepts have been applied in our study, regarding the subjects of Group II. Conventional treatment of tendinopathy also includes corticosteroid injection in the sub-

acromial space in case of unsuccessful NSAID therapy and during the acute phase. Nevertheless, the tendon tear risks and collagen synthesis inhibition must be considered a side-effect [20]. Platelet Rich Plasma injections contain growth factors and pro-active substances like TGF- $\beta$ 1(Transforming Growth Factor  $\beta$ ,) PDGF (Platelet-derived growth factors), b FGF (b Fibroblastic Growth Factor), VEGF (Vascular Endothelial Growth Factor. These procedures are safe and may be an alternative for corticosteroid injections in rotator cuff tendinopathy [21] while subacromial peritendinous HA (Hyaluronic Acid) injections have shown high efficacy in the treatment of supraspinatus tendinopathy mainly if combined with rehabilitation sessions. [22] Furthermore, Corrado et al. report satisfactory results in patients with chronic tendinopathy of the supraspinatus tendon treated with an ultrasound-guided injection of porcine collagen [23].

Pathogenesis of tendinopathies includes genetics [24] altered neuro-angiogenesis, [25,26] structural changes of the Extracellular Matrix (ECM) induced by Matrix Metalloproteases activity (MMPs) [27] the synthesis of type III collagen and altered production of GAG and PGs. In other words, the failure of the regulatory cell-ECM and cell-cell mechanotransduction that normally guides tendon differentiation [28]. The possibility to correct this bio-mechanical impairment using appropriate biophysical stimuli is given by ESWT by which incrementing proof of evidence demonstrates the positive effects of the transformation of the acoustic signal in biological responses [29] Fibroblasts, are a basic model of mechanosensitive cells which easily react to shock waves in vitro and in vivo by the activation of gene expression for transforming growth factor β1 (TGF- β1), Collagen Types I and III, in addition to the nitric oxide (NO) release and the subsequent activation of Vascular Endothelial Growth Factor (VEGF) related to TGF- β1 rise [30]. Although the experiments in vitro cannot be directly generalized to the in vivo conditions, the effects of

shock waves in tendon models are shedding light on the possible mechanisms of action of such treatment, once it is established that the optimal dosage determines a stimulatory effect on the tendon healing process, also thanks to the activation of a complex network of modulatory molecules, including a large panel of cytokines and metalloproteinases [31] A dosage-related effect of shock waves on cells and extracellular matrix metabolism has been shown in terms of up-regulation of Proliferating Cell Nuclear Antigen (PCNA) collagen type I and type III, TGF-β1 and NO expression. [32] Furthermore, in vitro setting of human tendinopathy-affected tenocytes, SW decreased the expression of MMPs and ILs.[33]. De Girolamo et al observed that after a single treatment, Tendon cells (TC) proliferate and express specific tenocyte markers like Scleraxis (SCX), and produce collagen I, and III (COL1/COL3) while the production of TNFα is not affected by SW. Furthermore, a significantly larger amount of IL-1b, not correlated with the increase of MMPs 3 and MMPs 13, showed that SW treatment is not correlated with the degradation of ECM. Rather, related to a physiological increase in IL-6 which, in turn, promotes the increase in IL-10. This pathway agrees perfectly with the healing inflammatory mechanism characterized by the initial acute response followed, about 48 h after the stimulus, by the production of IL-10, an anti-inflammatory cytokine responsible for the selfresolving phase of inflammation [34].

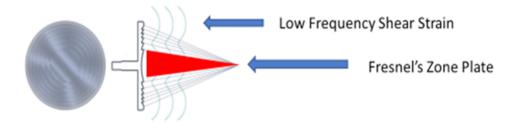
The effectiveness of ESWT, including shoulder tendinopathy, is consolidated in time but the greater part of the literature refers to calcific tendinopathy rather than non-calcific ones. Nonetheless, the efficacy and safety of low energy ESWT in chronic noncalcified tendinopathy of the shoulder have been demonstrated compared to placebo [35] After two treatment sessions, each consisting of 3000 shockwaves every 7 days, at an energy flux density of 0.068 mJ/ mm<sup>2</sup>, at the final follow-up (3 months), a significant improvement in the total CMS and all the subscales (except power) in the ESWT group when compared to the baseline values. Anyway, some studies are controversial. In a double-blind placebo-controlled trial low shock wave energy (1500 pulses monthly for three months at 0.12 mJ/mm<sup>2</sup>) in chronic non-calcific tendonitis of the rotator cuff gave no significant differences with placebo [36] as well as in a long-term (10-year) follow up with a protocol of 6000 impulses at EFD of 0.11 mJ/mm<sup>2</sup>) in three sessions of treatment [37]. The degenerative traits of shoulder tendinopathy can lead to partial tendon ruptures and there is still a common, erroneous, tendency to consider the possibility that SW may cause adjunctive damage to the tendon. Despite this, Branes et al demonstrated the positive effects in a series of patients with a complete tear in rotator cuff tendinopathy to be treated with surgery. The pre-surgery single treatment (4000 pulses) of High Energy (0,30 mJ/mm<sup>2</sup>) focused ESWT induced increased neovascularization and neolymphangiogenesis as well neo-angio /vasculogenic foci in treated patients, also demonstrating increased cellularity and higher expression of CD34, PCNA, and Tenascin-C, as signs of active re-vascularization and a tissue repair. [38] The results of our study show a fast positive effect of ESWT in non-calcific tendinopathies of the shoulder, compared to a control group of subjects treated

with conventional physical and rehabilitative procedures. This aspect mainly concerns pain and functional recovery according to the CMS score, respectively from a pre-treatment score of 58,65 points in the shock wave group versus 42,65 points in the group physio kinesiotherapy and respectively 68,25 points in the group shock waves and 50,90 points in the second group at the end of the treatments (p<0,05). Statistic power was also found for CMS subcategories about pain in the ESWT concerning the physio kinesiotherapy group (p<0,05).

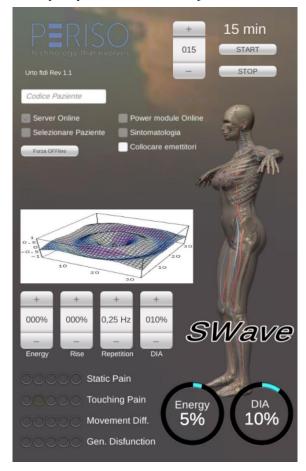
These results were obtained with a lower number of shots (300) with respect to other studies previously reported and concerning the assorted shock wave devices employed in muscle-skeletal disorders. This is due to the peculiarity of the acoustic pulse originating from this innovative device, in detail (Figure 2).

- The machine provides a double form of energy given by longitudinal (typical of the Shock Waves) and transversal components (typical of mechanical waves). So, the maximum energy is given in the central part of the acoustic lens (Central Fresnel's Zone Plate) while an adjunctive volume of mechanical energy is given by a low-frequency shear strain that attenuates with the distance [39,40].
- The longitudinal component of the Shock Wave can be modulated as a percentage concerning the maximum pressure (Pmax) as well as the percentage of the rise time from 10% to 100%. This allows reaching the maximum of the energy delivered in time without creating discomfort for the patient. The transversal component (shear strain volume of mechanical energy) is modulated by the Intensity of the Magnetic Field at the origin of the Diamagnetic effect on the Fresnel's Lens (DIA) always in percentage terms from 10% to 100% (Figure 3).
- Due to the characteristics of shear strain, this kind of stimulation does not produce nociceptive pain. This occurs when the mechanical impact of the energy of the lens could activate mechanosensitive ion channels in mechanosensitive afferent nerves. Nevertheless, since the increasing size of the stimulating source would reduce shear strains near the source for a given amplitude, in this machine the larger area of the acoustic lens (36 cm2) avoids disturbances to the patients during the shock wave treatment, according to the mechanoreactivity of the great part of human body cells for external mechanical stimuli [41].

Limitations of this preliminary study are lack of randomization and the fact that is not a blind study, furthermore it has a short follow-up (1 week after the end of the treatments). Nevertheless, the statistical difference in subjective and functional results between the two groups has been positive, although in the short term, and confirms the values of this novel technology whose main advantage is given by the absence of pain during treatment, effectiveness, and the low number of shots necessary. Further high-quality RCT studies are necessary to better define the potentiality of this technology.



**Figure 2:** The red-colored triangle identifies the maximum of the acoustic energy derived from the fast-pulsed movements of the acoustic lens (Fresnel's Lens) corresponding to the Central Fresnel's Zone Plate- the concave part of the lens. The grey lines correspond to the nearby rings of the lens converging towards the focal area (see also Figure 1). The wave-shaped parallel lines given by the large area of the rounded lens represent the Low-Frequency Shear Strain as an adjunctive form of mechanical energy.



**Figure 3:** The screen of the machine provides the modulation of EFD in percentage from the minimum values to the maximum  $(0.05/0.50 \text{ mJ/mm}^2)$ , as well as the mechanical impulse given by the intensity of the Magnetic Field that moves the lens (0.2-2T) at the origin of the shear strain.

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