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The Effects of a Novel Type of Shock Wave (Diamagnetic Shock Wave) in the Treatment of the Osteoarthrosis of the Thumb: A Case Series Study and a Look upon a Painless Mechanotherapy

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Abstract

In therapeutic practice, Extracorporeal Shock Waves (ESWs) are known for their anti- inflammatory, antalgic and regenerative effects. For this reason, they are successfully applied in the majority of musculoskeletal disorders, including Osteoarthrosis (OA). We report a case series of 66 consecutive patients suffering from Thumb Osteoarthrosis (T-OA) classified in the II-III Eaton and Litter radiological stage and treated with a novel type of extracorporeal shock waves device (CTU-S-Wave). The machine generates mechanical shock waves by exploiting the repulsive phenomenon of diamagnetism which is based on the effects that High Intensity Low Frequency Pulsed Electromagnetic Fields (HI-LF-PEMF) exert on diamagnetic materials such as graphite, bismuth and others. From this repulsive effect the so-called diamagnetic shock wave originates. The primary outcome of our study was to evaluate the effectiveness of the ESWs on pain pre- and post-treatment. Then we evaluated the eventual discomfort for the patients in terms of perceived pain as consequence of the stimulation of the subchondral bone of the first carpo-metacarpal joint, attributable to the mechanical shock wave. All the patients reported a good compliance with the treatment, ameliorating the original pain due to the arthrosis ($p < 0,001$), while any discomfort has been reported. Diamagnetic shock wave demonstrated to be an effective and completely pain-free treatment.

Keywords: Diamagnetic; Extracorporeal shock waves; Mechanotherapy; Thumb osteoarthrosis

Introduction

T-OA is a multifactorial debilitating condition of the hand and represents the second most common site of OA, prevailing in women in post-menopausal age [1]. The clinical course is characterized by a progressive loss of grip function and it gradually impairs the performance of the hand in usual life activities [2]. In addition to genetic, metabolic, hormonal and biomechanical factors, this multifunctional joint can be subjected to the consequences of the overuse and functional constrains, consequently to the degenerative changes that usually occurs in osteochondral and periarticular capsule and ligaments. The term "T-OA" is referred to the first carpometacarpal joint (CMC-1), with or without the scapho-trapezial joint, more rarely to the scapho-trapezial one [3]. In addition to pain and variability of functional impairment, the severity of the disease is settled by the radiographic Eaton and Litter stages. With regard to the therapy, non-surgical procedures aim to slow down the anatomopathological damage and to delay the surgical options. Medications, orthoses, steroid or other substances injections and physical therapies have been proposed on this purpose, but none of these have been demonstrated to be superior to others [4]. Surgery, on its own, gives different results and retains controversial pros and cons both in terms of duration of the effect on pain and the functional recovery [5].

The rationale for the use of ESWs in bone starts from the first, successful, systematic application in delayed union and non-union of fractures [6] and naturally continues with the treatment of vascular, metabolic and degenerative diseases. Fundamental animal studies from Wang et coll. demonstrated how the treatment of Subchondral Bone (SB) was able to improve the structure of the Osteochondral Unit (OU) together, with positive changes in biomarkers of OA and of bone metabolism [7,8]. Furthermore, meaningful positive effects on pain have been observed in the OA of the knee [9] as well as in subchondral Bone Marrow Edema (BME) [10], a metabolic dysregulation occurring in SB and frequently associated to symptomatic OA. BME is currently considered a possible cause of the structural and functional weakening of the OU, reflecting in alterations of the physiological bone-cartilaginous cross talk and, for this reason, predictive factor of OA [11]. Clinical data reveal the effectiveness of ESWs also in the arthrosis of the thumb [12] and, on this basis, we designed a collective case series study. With this, we aimed to evaluate the effects on pain, in the short term, of a novel technology. This technology supplies the acoustic pulse by exploiting the impact of the HI- LF-PEMF with diamagnetic materials, obtaining a repulsive effect able to generate the so named "Diamagnetic Shock Wave". Furthermore, we aim to assess if the high-speed mechanical impact induced by the High Intensity Magnetic Field on the acoustic lens could be a cause of discomfort for the treated patients.

Methods

From June to December 2020, we enrolled a series of 66 patients (21males, 45 females), average age of 63,28 years (44- 86 for ± 10,32 SD) with arthrosis of the thumb at the II - III stage of Eaton and Litter classification. They underwent 3 sessions of ESWs treatment, one per week. The level of energy varied from 0,09 - 0,11 mJ/mm^2 Energy Flux Density (EFD) with a number of 120 pulses per session at 2 cm of depth of the focus. The patients were evaluated for pain pre-treatment and immediately after the third session of shock wave therapy. The treatments were carried out at the Villa Gemma Clinic (Gardone Riviera- Italy) and at the Cell Regeneration Medical Organization (Bogotá, Colombia). Inclusion criteria to the study were: age > 40 years, pain at the first carpometacarpal (CMC) joint dated from at least 6 months. The cut off for pain was established in 4 points at the VAS score, while the radiological stage of the enrolled patients had to be in accord with the II - III stage of Eaton and Litter classification. No patients with previous traumas, injection of corticosteroids or ialuronic acid administrated in the last three months were admitted to the treatment. Were also excluded the participants that were going to receive physical therapies in the same time interval of the study. Usual contraindication for ESWs treatment were taken in account: pregnancy, malignant tumors in the target area (skin-bone in this case) and severe coagulopathy.

The shock wave device (CTU-S Wave® - Periso SA -Switzerland) is provided with a source of energy given by an electromagnetic coil which produces a high intensity pulsed electromagnetic field (2 Tesla). The electromagnetic pulse hits a discoid element consisting of an alloy of diamagnetic materials which, consequently, is moved up and down (Figure 1). According to the property of diamagnetic substances, once exposed to high values of a magnetic field, these undergo a strong and speed repulsive effect able to generate high energy pressure waves (Diamagnetic Shock Wave). Due to the necessity to ensure the adequate charging time of the electromagnetic coil placed in the handpiece, in this device the pulse rate is low (16 Hz per minute), but this offers, at the same time, constant and stable levels of energy. The diamagnetic disc (diamagnetic lens) is shaped with a series of concentring rings according to the Fresnel's optic principle. This states the possibility to modify a spherical lens in a plan lens without changing its optical properties (Figure 2). A series of acoustic lenses, different in the number of the rings, gives different depth of focusing of the pressure wave, from 2 to 6 cm. The protocol of the treatment included the stimulation of both volar and dorsal aspect of the CMC-1 joint, focusing the acoustic energy to the trapezius and the base of the first metacarpal bone. For each point, 30 shots were administered with a total of 120 pulses at a low frequency (16 Hz /min) of stimulation. As already explained, this high latency between two consecutive shots is necessary to ensure the optimal charge of the electromagnetic coil and the constant levels of the acoustic energy for the overall lifespan of the handpiece of the machine. In order to distribute the energy perpendicularly, proximally and distally to the joint, the hand was positioned in neutral position. An ultrasound gel was employed as conductive medium (Complex Gel ®Periso SA -Switzerland).

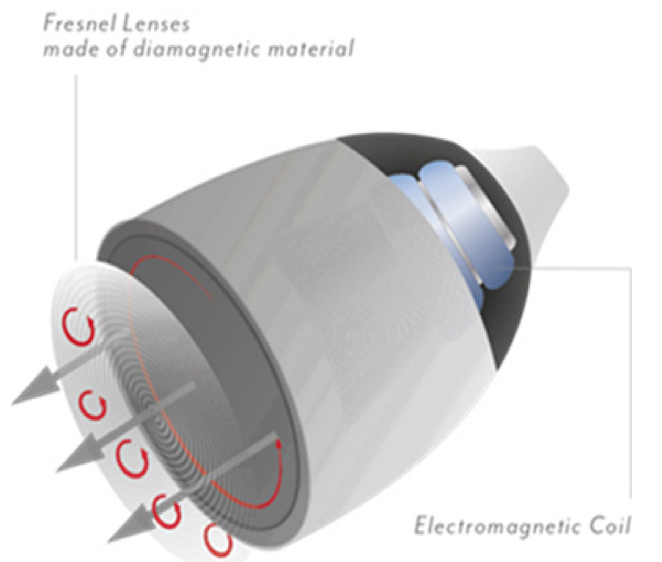

Figure 1: Handpiece of the CTU-S-Wave machine including the electromagnetic coil inside the probe and the acoustic lens. The Shock Wave originates from the high-speed movement of the Diamagnetic lens.

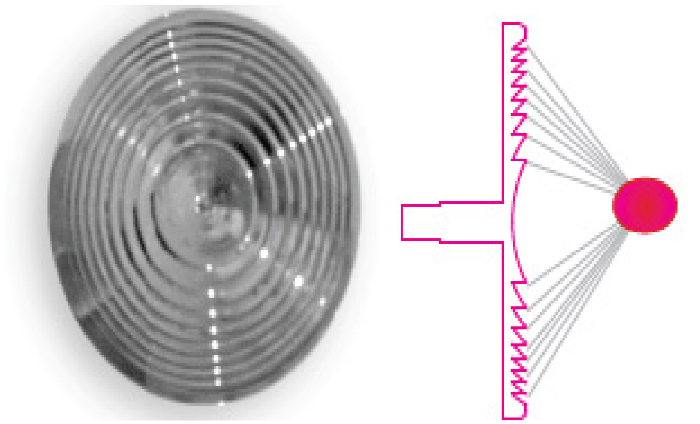

Figure 2: Diamagnetic Lens. The acoustic Fresnel lens is a concave lens obtained by the decomposition of a convex one. This allows to bring high resolution acoustic signals focusing the energy at a specific depth. Fresnel's lenses are formed by a set of concentric rings with decreasing width: each ring is called "Fresnel region" and between two consecutive regions there is a π phase difference. The main energy contribution to the focus is given by the central regions of the lens.

Statistical Analysis of the result of the treatment included the sum of the scores attributed to all the patients to the assessment of pain on the Visual Analogic Scale (VAS) measured pre- treatment (T0) and at the end of the third treatment (T1). The collected data were analysed as mean difference values ± standard deviations (SD) for discrete numeric variables. The «*t*» test for normal distribution of the data was chosen to determine the statistical significance between the pre- and post-treatment and stratified for sex and age, in this case under and over 60 years. The significance level has been chosen for p< 0,05.

Results

All the treated patients showed significant decline of pain throughout the observational period, compared to the baseline. Pain assessment showed a meaningful statistically improvement in pain pre- and post-treatment, without substantial differences for sex and age. VAS varied from 6,3 pre- treatment to 3,27 points at the end of treatments as mean value (SD ± 1,90- P < 0,001) (Figures 3,4). The analysis stratified by age showed the following mean values of VAS variation: 6,51 points pre- treatment to 2, 93 points for 29 samples aged under 60 (SD ±1,91 - P<0,001) respect the variation from 6,62 to 3,5 points for 37 samples aged over 60 (SD ±1,91 -P< 0,001). The mean variation of pain values stratified by sex showed, respectively, 6,33 to 3,33 points pre- treatment and post-treatment for men (SD ±2,42 - P<0,001) and 6,8 to 3,2 points for women (SD ± 1,63 - P<0,001). All the treated patients have been able to complete the treatment and no pain, discomfort or adverse events have been reported despite the mechanical impact of the acoustic lens.

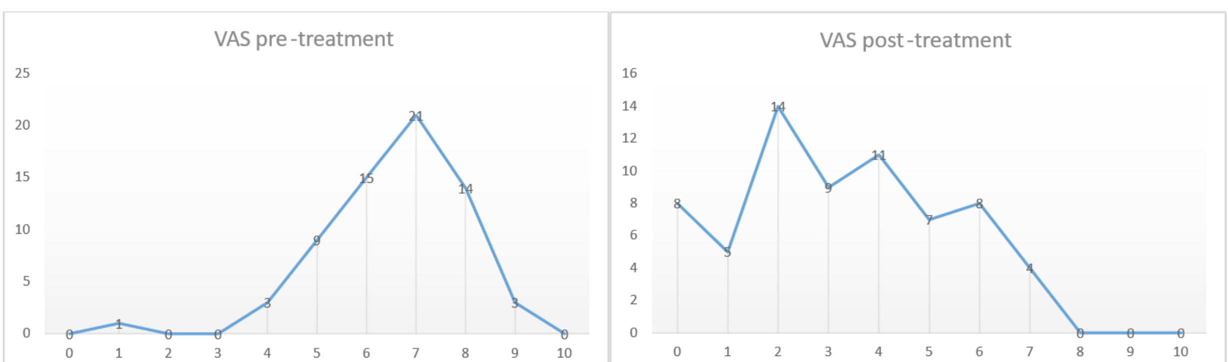

Figure 3: Graphics show the representation of absolute frequencies (AF) per VAS score pre-treatment and post-treatment with Diamagnetic Shock Wave (Abscissa: VAS score. Ordinate: number of patients per VAS score). Pre-treatment AF show a line skewed to the right: high scores of the VAS are more reported, with 7 as mode and median and 7,75-6 as interquartile range (upper). In the graphic of the post-treatment AF (below), the line is more skewed to the left; lower values are reported with 2 as mode, 3 as median and 5-2 as interquartile range.

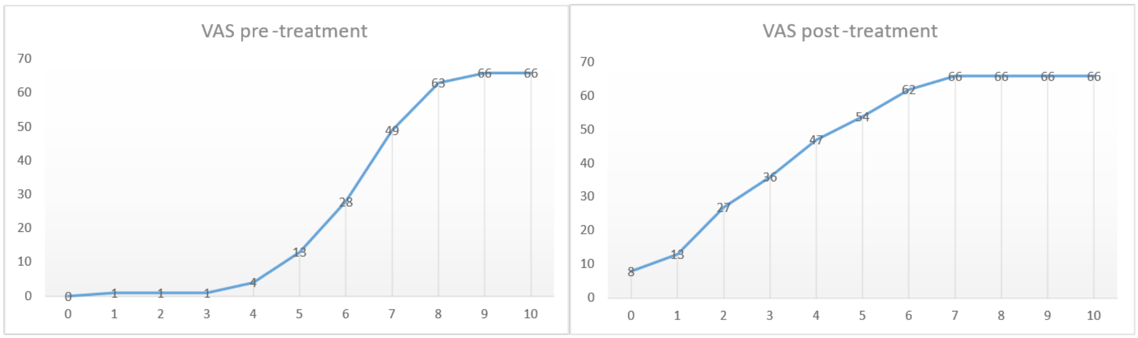

Figure 4: Graphic representation of the absolute VAS score cumulative frequencies (CF) pre-treatment and post treatments per VAS scores (Abscissa: VAS score. Ordinate: absolute cumulative frequencies). Pre-treatment score: the highest scores of the VAS are more reported, with 7 as mode and median and 7,75-6 as interquartile range (upper). The graphic of the post-treatment CF shows that lower values are more reported with 2 as mode, 3 as median and 5-2 as interquartile range.

Discussion

Current concepts in the comprehension of pathogenesis of OA emphasize the complexity and the multifactorial nature of the disease, including structural changes of the whole joint that are at the origin of a progressive loss of function [13]. The involvement of the thumb has a remarkable proportion in woman (2 times respect to men) mainly in post-menopause, where the radiographic evidence of T-OA has been observed in 36% of women [14].

The first-line approach for T-OA is conservative treatment. Nevertheless, symptomatic or modifying disease drugs, orthoses, joint injections and physical therapies, aimed at slowdown the progression of the disease, have not yet been demonstrated to be superior to each other's. In a recent meta-analysis, Aherna et al. conclude that there is high quality evidence that unimodal or multimodal physical therapy treatment can result in clinically worthwhile improvements in pain and function in patients with T-OA (e.g., neurodynamic treatments, use of orthosis, ultrasounds, passive exercises and occupational therapy) [4]. Nevertheless, previous non-pharmacological treatments and the strong motivation of the patients have been considered predictors for surgery, which, on its own, still would not offer standardized techniques superior to others in terms of duration of the effects on pain and functional recovery, benefit or harms. Moreover, comparison to non-operative treatments is controversial [5,15].

Over the last few decades, the biophysical stimulation of damaged musculoskeletal tissue provided by ESWs has spread worldwide thanks to a great variety of biological activities. They consist in neo-angiogenesis, production of growth factors, the stimulation of differentiated cells to produce Extracellular Matrix (ECM), as well as direct regenerative effects mediated by the activation, the homing and the differentiation of mesenchymal stem cells [16]. Furthermore, more sophisticated mechanisms open new horizons in the understanding of the mechanism of action of ESWs, for example the delivery of exosomes and the regulatory shift of macrophages in connecting inflammation and tissues regeneration [17-19]. The rationale for the treatment of OA with ESWs starts from a series of animal studies, that demonstrate the effectiveness of the stimulation of subchondral bone in the early stage of the disease. Better cartilaginous score and additional effects on the mechanical properties of the bone have been observed together with the higher expression of anabolic biomarkers (Osteocalcin, Bone Morphogenetic Proteins) and lower expression of catabolic ones (Cartilage Oligomeric Protein, Matrix Metalloproteases, Collagen Telopeptide II) as result of ESWs treatment [8].

Besides the typical mechanisms of inflammation, the cause of pain (chronic pain) in OA has been also attributed to the dysregulation of Neuropeptides (NP) as the Substance P and Calcitonin Gene-Related- Peptide (CGRP). Their expression has been observed both in the nerve endings of osteoarthritic joints and in the posterior roots of the corresponding medullary segment by orthodromic and antidromic ways of transmission of the painful stimuli [20]. In an experimental model of knee OA, the ESWs treatment showed to ameliorate the walking duration time that matched the reduction of CGRP positive neurons [21]. Since neuropeptides have shown to reduce the threshold of nociceptors in osteoarthritic joints [22], we may better consider the possible role of ESWs in the treatment of chronic joint pain, by modulating the NP production. ESWs are categorised as mechanotherapy acting by the mechanism of Mechanotransduction [23]. This phenomenon refers to the translation of a mechanical stimuli into biological signals, thanks to the activation of mechano-sensors and intracellular mechano-signalling pathways. This occurs, besides ESWs, also for other forms of mechanotherapy involving micro-deformation, tissue expansion and distraction osteogenesis [24]. A fundamental role in these well-orchestrated processes is played by the ECM and its capacity to interact with cells. For its nature and structure, bone can easily react under mechanical stimuli by deforming or causing local strains (micro-strains). In bone, pressure gradients flow across the osseous trabecular structure stretching osteocytes and moving the extracellular fluids. Taken together, strains and fluid flow induce, respectively, the piezoelectric effect and the creation of streaming electric potentials, that, as observed in cells cultures, play a key role in Mechanotransduction [25].

The release of acoustic energy from the shock wave machine employed in this study is rather peculiar. The high energy (2T) generated by the electromagnetic coil, discharges on the acoustic diamagnetic lens placed outside the handpiece. This causes a high speed and high energy alternating repulsive movement of the lens which generates, in turn, a high-pressure focused acoustic wave. The term "diamagnetic" refers to the peculiar magnetic property of the matter that, in opposite to ferromagnetism, undergoes to a repulsive effect in presence of a HI- LF- PEMF.

The acoustic signal produced from the machine at 2 cm of Focal Area (2,14 cm2) provides a maximum value (Peak Pressure) of 42 Mpa with a decay at - 6 dB measured in 21 Mpa. The negative Pressure varies from -6.87 MPa to -1.7 Mpa [data provided from the producer of the machine CTU-S-Wave® - Periso SA - Switzerland]. The pulse rate is low (16 Hz per minute) to ensure the adequate charging time of the electromagnetic coil during the treatment. This aim to supply constant and stable high intensity of the Magnetic Field and, consequently, the kinetic energy necessary to move the lens and to produce the Diamagnetic Shock Wave. Besides, in addition to the energy released in the focal area, a supplementary front of mechanical energy results from the impact of the shaped discoid lens (6 cm of diameter) with the body. It generates transverse shear waves (shear strains) formed in the elastic component of the tissues traversed by the acoustic wave, bringing potential bioeffects from the transduction of this kind of mechanical signal [26]. In details, the movement of the plane acoustic lens of the machine distributes, besides the long axis section of the focussed shock wave, transverse waves whose direction is normal to the long axis. Given the radius of the acoustic lens (3 cm) and the focal distance (2 cm) a theoretical cylindrical volume of energy (56,6 cm^3) surrounding the focal area is conceivable, although attenuated with the distance. This means the possibility of an additional energy available for the Mechanotransduction of the acoustic signal beyond that resulting from to the focal energy produced by the acoustic lens. Appropriate measurement should be better investigating the characteristics of the shear waves produced by the machine.

One of the most interesting topics in acoustic physics lies in the possibility to concentrate, deriving from the Fresnel's optical principle, high resolution acoustic signals by means of converging mono-focal planar lenses formed by concentric rings of decreasing width, known as Fresnel Zone Plates (FZPs) [27]. These acoustic lenses focus the sound in the same way as the optical lenses focus the light; this because the underlying theory is applicable for both mechanical and electromagnetic waves. For example, one of the uses of these acoustic lenses in the medical field is tumors ablation through High Intensity Focused Ultrasound (HIFU) therapies [28]. The focussing acoustic lens supplied from the machine follows the design, the parameters, the geometry and the efficiency required for the FZP plate (Figure 2), changing only in the structural and original composition by a diamagnetic alloy. An incremental number of clinical studies demonstrate the effectiveness of ESWs in OA, mainly in the knee. The biological rationale is based on in vitro and in vivo studies. The results on cartilaginous cells are controversial. Moretti et al. observed the normalization, at intra-cellular levels, of TNF-alpha and IL-10 expression in human articular chondrocytes from osteoarthritic patients [29]. On the other side, detrimental effects have been observed with high energies (0,5 mJ/mm2), unusual in clinical practice, such ultrastructural damages of the rough-surfaced endoplasmatic reticulum, detachment of the cell membrane and necrosis of chondrocytes in animal samples [30]. More important seems to be the role of SB, not only in pathogenesis, but also in the treatment of OA. More satisfactory results have been reported by Wang and coll. in animal studies. The authors showed significative improvement of the cartilage score, increased concentration of chondrocytes and serum type II collagen, better sub-chondral bone structure, production of neo-angiogenic markers and specific bone growth factors, cell proliferation [7,8].

Clinical trials report the efficacy of ESWs, both for radial and focused shock waves, in reducing pain and improving the functionality of degenerate joints as resulting from specific scores [31]. Favourable results are also described in comparison with other therapies, such isokinetic exercises and ultrasound therapy [32], while there have been reported equivalent effects between radial SWs treatments and intra-articular injections of hyaluronic acid, as well as better subjective and functional results compared with the laser therapy [33,34]. The indication to shock waves treatment usually includes the radiologic Kallgren and Lawrence in II-III stage. Nevertheless, as for the great part of the clinical applications of ESWs, the extreme variability of protocols, intensity, frequency and all the individual parameters of the machines that the market offers do not allow to define homogeneous procedures of treatment. For radial pressure waves a moderate intensity of EFD is recommended in the clinical management of knee OA (0.12 to 0.25 mJ/ mm^2) and the shock number could be applied with 2,000 or 4,000 impulses with similar results [35]. Similarly, for focused ESWs, medium dosage (EFD 0,09 mJ/mm^2) would be more effective than lower (0,04 mJ/mm^2) at 12 weeks post-treatment, as reported for VAS, Roles and Maudsley score, WOMAC score and the Lequesne index with 1000 shots per treatment [36]. It is equally interesting the subjective and functional result in non-severe knee OA (K-L stage 1) in a series of post stroke patients, treated with 1.000 pulses weekly for 3 weeks with an energy dose of 0.05 mJ/ mm^2 on the proximal medial tibia of the affected knee [37].

Therefore, the treatment of the SB appears to be the key in the treatment of OA, also considering its pathogenetic role as a site of metabolic disorder [10] and one of the outbreaks of pain activating the neurogenic inflammation in the joints [21,38]. This happens because sensory and sympathetic nerve fibres and their neurotransmitters are neuronal effectors able to regulate pathophysiology of cartilage and bone and the resident cells of the osteoarticular system, which have receptors for sympathetic and sensory neurotransmitters [39]. Taken together, these premises lead to exploit the treatment with ESWs to other locations of the disease, such as the CMC-1 joint. In a RCT about ESWs versus hyaluronic acid, has been reported, in two series of patients with CMC-1 joint OA, a meaningful reduction of pain, an improvement in the pinch test performance and the decrease of hand disability for at least 6 months post treatment (2400 pulses - 4 Hz of frequency- 0,09 mJ/mm^2 of EFD). Compared to the patients treated with intra-articular hyaluronic acid, the reduction of pain was likely to be superior in the ESWs group; the functional aspect was equal at 6 months after treatments [12]. Our experience is not comparable with the above mentioned one. It is not a controlled study and, despite the conspicuous number of patients, it has a single cohort of consecutive patients and the post-treatment pain is the only outcome. Nevertheless, this study has been aimed to explore the primary effect on pain of an original machine which deliveries focused mechanical shock waves (diamagnetic shock waves) and, in our knowledge, this is the first clinical study with this device. A particularity of this study is the use of the same EFD levels employed in other studies on OA but, in contrast, with a very limited number of shots (no more than 120 pulses per treatment) necessary to achieve beneficial result on pain, as demonstrated by the pre- and post-treatment comparison ($p< 0,001$). The behaviour of the VAS mean values were statistically independent from age and sex.

In this type of machine, besides the longitudinal component of the focused wave, a transversal component of the energy can be attributed to the mechanical movement of the lens, which delivers a supplementary volume of energy, according to the physics of low frequency shear strain. In these models, the bioeffects obtained by Mechanotransduction are more related to the resulting mechanical changes (strains) in the tissue than to the forces that cause those changes (amount of external energy) [26]. In this device, the above-described dissipating volume of energy would produce these little transversal forces (shear strain) to gain biological effects in addiction to those derived from the focused acoustic energy. In summary, the bi-modal tuning of the acoustic energy delivered by the CTU-S-Wave machine involves both changes of the EFD, as occurs for all the SWs machines, while the intensity of the magnetic field that impacts the diamagnetic lens originates a dissipating volume of energy surrounding the focal area, where a transverse component prevails. The acoustic lens is a Fresnel lens, a concave lens obtained by the decomposition of a convex one. It was originally conceived to focus electromagnetic waves, then it was extended to acoustic waves. It is effective in focusing acoustic energy in a specific area at a specific depth, fulfilling the various ongoing treatment needs of musculoskeletal disorders. Fresnel lenses are formed by a set of concentric rings with decreasing width: each ring is called "Fresnel region" and between two consecutive regions there is a π phase difference [27]. The main energy contribution to the focus is given by the central regions of the lens and the different number of rings gives focus at different depths. We can have a better focusing efficiency according to the material constituting the lens, that minimizes the reflection coefficient and has a large impedance mismatch with the host medium (diamagnetic alloy).

The diamagnetic effect originates from the magnetic force and the magnetic torque deriving, on their own, from well-defined magnetic energy at the ultrastructural level of the diamagnetic matter [40,41]. It means that high intensities of the magnetic field are necessary to make the up-ward opposite diamagnetic force able to move the diamagnetic lens, producing the shock wave in a mechanical way. The mechanical impact could activate mechanosensitive ion channels in mechanosensitive afferent nerves and it could cause discomfort or pain in patients. 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 cm^2) avoids disturbances to the patients during the shock wave treatment, according to the mechano-reactivity of the great part of human body cells for external mechanical stimuli [42].

Transferring these concepts to the characteristics of the machine, some conclusive considerations can be done:

- The shape of the acoustic lens permits to focus the acoustic energy at different levels of energy;
- Although subjected to a high mechanical stress, necessary to produce the shock wave, the larger area of the lens (36 cm^2) would reduce shear strains near the source and avoid the over stimulation of cutaneous nerve endings;
- Besides the focused shock wave, the movement of the lens produces a volume (56,6 cm^3) of supplementary attenuating energy with potential biologic effects, given by transverse slow waves which generates physiological shear strain.

These concepts should partially explain the absence of pain and discomfort reported by the patients during the treatments and, moreover, a certain number of them did not perceive the impact of the acoustic lens on the skin, despite the mechanical impulse. This hypothesis would require further and specific studies.

Conclusion

We collected a series of data relative to the treatment of T-OA with an original focused ESWs device (CTU-S-Wave). We observed a meaningful improvement in pain pre- and post-treatment, irrespective of the age and sex of the patients. Characteristically, despite of the high-energy movement of the lens, no side effects have been reported by the patients, included pain or discomfort, as well as the perception of the mechanical pulse.

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