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Clinical application of shock wave therapy (SWT) in musculoskeletal disorders

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Currently the application of shock wave therapy (SWT) in musculoskeletal disorders has been primarily used in the treatment of tendinopathies (proximal plantar fasciopathy, lateral elbow tendinopathy, calcific tendinopathy of the shoulder, and patellar tendinopathy, etc.) and bone defects (delayed- and non-union of bone fractures, avascular necrosis of femoral head, etc.). Although the mechanism of their therapeutic effects are still unknown, the majority of published papers have shown positive and beneficial effects of using SWT as a treatment for musculoskeletal disorders, with a success rate ranging from 65% to 91%, while the complications are low or negligible. The purpose of this paper is to inform the reader about the published data on the clinical application of SWT in the treatment of musculoskeletal disorders. In this paper, with the help of a literature review, indications and success rates for SWT in the treatment of musculoskeletal disorders are outlined, while adequate SWT parameters (*e.g.*, rate of impulses, energy flux density, etc.) are defined according to the present state of knowledge.

KEY WORDS: Musculoskeletal diseases - Therapeutics - Bone and bones - Tendons.

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A shock wave is defined as an acoustic wave, at the front of which pressure rises from the ambient value to its maximum within a few nanoseconds.[1, 2] Shock waves are characterized by high peak-pressure amplitudes (500 bar) with rise times of less than 10 nanoseconds, a short lifecycle (<10 ms), and a frequency spectrum ranging from 16 Hz to 20 MHz.[3] After reaching the positive peak, the pressure rapidly drops to negative values within microseconds.

Both the positive and the negative phase of a shockwave have an effect on interfaces between tissues with different density (acoustic impedance). During the positive phase, shock waves with high pressure may hit an interface, leading to reflections, or they may pass and gradually become absorbed. The negative (tensile) phase of the shock wave causes cavitation at the tissue interfaces. During cavitation air bubbles are formed as a result of the negative pressure. These bubbles subsequently implode with high speed, generating a second wave of shock waves or microjets of fluid. These events cause the direct (physical) and indirect (biological) effects of the shock waves on the treating tissue.[4-6]

Since their introduction in clinical setting, several commercially available shock wave generators have been developed. Depending on the commercially generator, electromagnetically, electrohydraulically, piezoelectrically, or electropneumatically derived energy is transformed into a shock wave. Usually, electromagnetically, electrohydraulically, and piezo-

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electrically generated shock waves are defined as focused shock waves; while the electropneumatically generated shock waves are defined as unfocused or radial shock waves.

Electromagnetic systems utilize an electromagnetic coil and an opposing metal membrane. A high current impulse is released through the coil to generate a strong magnetic field, which induces a high current in the opposing membrane, accelerating the metal membrane away from the coil to the 100,000-fold of gravity, thus producing an acoustic impulse in surrounding water. The impulse is focused by an acoustic lens to direct the shock wave energy to the target tissue. The lens controls

the focus size and the amount of energy produced within the target.

Piezoelectric systems are characterized by mounting piezoelectric crystals to a spherical surface. When a high voltage is applied to the crystals they immediately contract and expand, thus generating a pressure pulse in surrounding water. The pulse is focused by means of the geometrical shape of the sphere.

Electrohydraulic systems incorporate an electrode, submerged in a water-filled housing comprised of an ellipsoid and a patient interface. The electrohydraulic generator initiates the shock wave by an electrical spark produced between the tips of the electrode. Vaporization of the water molecules between the tips of the electrode produce an explosion, thus creating a spherical shock wave. The wave is then reflected from the inside wall of a metal ellipsoid to create a focal point of shock wave energy in the target tissue. The size and shape of the ellipsoid control the focal size and the amount of energy within the target.

Unfocused shock wave is electropneumatically generated through the acceleration of a projectile inside the handpiece of the treatment device and then transmitted radially from the tip of the applicator to the target zone. The pressure and the energy density decrease by the third power of the penetration depth in the tissue. Radial shock waves show a lower peak pressure and a considerably longer rise time than focused shock waves. In radial shock wave therapy (SWT), the focal point is not centered on the target zone, as occurs in focused SWT, but on the tip of the applicator.

Each generator aim to couple the generated pressure impulse to the tissue while minimizing energy loss, concentrating the shock waves so that they can be applied in sufficient quantity to stimulate a desired tissue response.[3, 4, 6]

For their clinical use, the head of the focused and unfocused shock-wave generators are positioned over the area to be treated, which can be determined on the basis of previous diagnostic images or, if available on the device, by radiographic or ultrasound positioning systems. Once the position of the targeting site has been located, the treatment area is prepared with a coupling gel to minimize the loss of shock wave energy at the interface between the head of the device and the skin. Shock waves are dispersed from the application site and then may be absorbed, reflected, or dissipated depending on the properties of the tissue through which they pass.

The energy at the focal point of the shock wave per impulse is called the "energy flux density" (EFD) and is recorded as joules per area. The effective total energy of a treatment is defined by the number and EFD of the single impulses and by the geometrical measurement of the focal point.

Focused shock waves have an high (>0.2 mJ/mm^2) EFD; while the unfocused shock waves have a low (<0.2 mJ/mm^2) EFD. The EFD is one of the most important physical parameters of shock wave therapy for the treatment of musculoskeletal disorders.[7] In fact, high- and low-energy SWT sessions can yield equivalent EFD: a high-energy session using an energy level of 0.3 mJ/mm^2 and 1000 shocks and a low-energy session using 0.1 mJ/mm^2 and 3000 shocks yield an equivalent EFD of 300 mJ/mm^2 each.[6] The number of shocks, interval between shocks, number of treatments, and interval between treatments are additional parameters that can determine the therapeutic response.[4, 8]

The mechanisms by which an acoustic signal is converted into a biological reaction is not fully understood. However, it is possible to hypothesize that mechanotransduction is the basis of the biological response to shock wave impulse. Mechanotransduction is the mechanism by which reactive cells recognize and respond to mechanical stimulation, converting physical forces into biochemical signals. Mechanotransduction stimulate extracellular matrix binding proteins and the nucleus via the cytoskeleton resulting in response leading to tissue regeneration. Recent histologic, biochemical, and immunologic basic science studies have greatly advanced the understanding of how shock waves affect tis-

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sue regeneration.[9-13] These effects include enhanced neovascularity, accelerated growth factor release, selective neural inhibition, osteogenic stem cell recruitment, and inhibition of molecules that have a role in inflammation.[9-13]

SWT for bone disorders

Several studies investigated the effects of SWT on acute fracture healing, delayed unions, non-unions, and avascular necrosis. Experimental models demonstrate that SWT promotes bone healing through a typical biological response characterized by the up-regulation of bone growth factors and bone morphogenetic proteins. It has been shown that the growth of bone marrow mesenchymal cells, and their differentiation into the osteoblasts is mediated by the TGF-β 1 and vascular endothelial growth factor (VEGF), induced by SWT.[12, 14] The signal transduction in bone cells induced by SWT could be mediated by cyclin E2/CDK2 complex,[15] and ERK and p38 kinase activity;[16] early local production of angiogenic factors, including endothelial nitric oxide synthase, VEGF, was observed after SWT.[17, 18]

The importance of the biological stimulus induced by SWT was confirmed by a clinical study reporting that patients with nonunion who failed to heal after SWT, are those showing lower concentrations of bone turnover markers such as osteocalcin and bone-specific alkaline phosphatase.[19]

Non-unions and delayed unions

Several studies exploring the effects of SWT on non-unions and delayed unions of long bone fractures, reported promising results with a success rate ranging from 50% to 85%.[20-28]

Valchanou *et al.*[25] reported bony healing in 70 of 82 patients with delayed or chronic nonunion of fractures at various locations. Schaden *et al.*[24] reported, with a follow-up ranging from 3 months to 4 years, a healing of 87 of 115 patients (75.7%) with non-unions or delayed unions of various fractures who were treated with high-energy SWT and immobilization. Rompe *et al.*[27] reported their experience using high-energy SWT to treat 43 patients with either a tibial or femoral diaphyseal non-union. They noted bony healing in 31 of 43 patients (72%) after an average of 4 months post-treatment. Wang *et al.*[22] used high-energy SWT as a treatment of 72 non-unions of long-bone fractures. A 12-month follow-up was available for 55 patients, of these 44 (80%) healed.

Cacchio *et al.*[20] in a randomized clinical trial, compared 3 groups of patients. Groups 1 and 2 received SWT (4 treatments of 4000 shocks) with an EFD of 0.4 mJ/mm^2 and 0.7 mJ/mm^2, respectively. Patients in group 3 were treated with surgery. At 6 months post-intervention, 70% of non-unions in group 1, 71% in group 2, and 73% of in group 3 had healed. It was concluded that SWT was as effective as surgery in stimulating union of long-bone non-unions.

The analysis of the literature data indicate that SWT is more successful for hypertrophic non-unions than for atrophic ones. Haupt [23] reported a 100% healing rate among 27 patients with hypertrophic non-unions compared with only 23% (3 of 13 patients) with atrophic non-unions. Wang *et al.*,[22] found a success rate of 40% at three months, 61% at six months, and 80% at twelve months for hypertrophic non-unions but only 27% for atrophic non-unions. Beutler *et al.*[29] reported a success rate of 53% for hypertrophic non-unions but only 25% for atrophic non-unions. Xu *et al.*[30] reported an overall healing rate of 75.4% in their series of 69 non-unions, but none of the atrophic non-unions healed.

In a randomized controlled trials, Cacchio *et al.*,[20] reported that drop-out rate was greater for the patients with atrophic non-union (11 of 34; 32%) than it was for those with hypertrophic ones (4 of 92; 4%). Moreover, of the 23 atrophic non-unions that remained, 13 were treated with SWT; of these 6 healed while 7 did not. Non-unions are usually treated with 2000 to 6000 shocks using an EFD between 0.3 mJ/mm^2 and 0.6 mJ/mm^2. The total number of impulses is usually divided along the proximal and distal margins of the nonunion. The total number of treatments (typically ranging from 1-4) and the interval between treatments (typically ranging from 1-4 weeks) vary from center to center. Although treatment for the non-unions is performed with an high EFD, a retrospective clinical study about the efficacy of low-EFD (0.09 mJ/mm^2) SWT compared with that of a standard surgical procedure to treat pseudoarthrosis of the carpal scaphoid, reported that the radiographic consolidations and clinical results of SWT (75.9% and 86.3%, respectively) are comparable with those of surgical stabilization (76.7% and 83.4%, respectively).[31] Thus, currently, in the clinical setting, the procedure for SWT in bone disorders is

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similar to that used in soft tissues disorders: deeper structures should treated with high EFD, whereas more superficial structures with either a high- or low-EFD protocols.

Avascular necrosis

Avascular necrosis (AVN) is a progressive condition characterized by bone death due to vascular insufficiency. Although its etiology remains unclear, several risk factors such as trauma, surgery, steroid use, alcoholism, coagulopathy, systemic lupus erythematosus (SLE), and hyperlipidemia have been found.[32] Conservative treatments include administration of bisphosphonates, anticoagulation, and activity modification, but are generally uneffective.[33] Core decompression with or without bone grafting is considered the gold standard of surgical procedures.[33] Several studies reported the positive effects of SWT for AVN, usually of the femoral head.[34-38] Wang *et al*.[34] compared at three time intervals (1, 2 and 9 years) 29 hips treated with SWT and 28 hips treated by core decompression with non-vascularized fibular bone grafting. Significant improvements in pain and function were noted at each time intervals in favor of SWT. Moreover, total hip arthroplasty was performed in 3% and 21% (P=0.039) of patients at 1 year, 10% and 32% (P=0.044) at 2 years, and 24% and 64% (P=0.002) at 9 years of follow-up for the SWT group and the surgical group, respectively. The same authors [37] compared 26 hips in patients with SLE with 29 hips of non-SLE patients. Total hip arthroplasty was performed in 12% and 14% of patients respectively, and there were no differences in pain and function between the two groups. The authors concluded that the rate of success of SWT on AVN in patients with SLE is comparable to that obtained I in non-SLE patients. Also Lin *et al*.[36] reported successful treatment of a 19-year-old patient with SLE who developed bilateral avascular necrosis of the femoral head. At 3-year follow-up, the authors noted that both hips had improved pain, Harris hip scores, and range of motion; moreover, MRI showed substantial reduction in bone marrow edema and no collapse of the subchondral bone. Vulpiani *et al*.[39] reported the results of SWT in 36 patients with unilateral AVN of the femoral head. Ten patients with stage I, eleven with stage II, and fifteen with stage III of AVN were treated with 4 sessions of high-energy (0.50 mJ/mm^2) SWT with 2,400 impulses. Follow-up examinations were scheduled at 3, 6, 12 and then 24 months. At all scheduled follow-ups, stage I and II patients showed significantly better results than stage III patients as regards pain score, the Harris hip score, and the Roles and Maudsley score. During the study period, 10 of the 15 stage III patients, but none of stage I and II patients, received a total hip arthroplasty.

Stress fractures

Stress fractures are overuse injuries of bone and are among the most common sports injuries. These fractures, which may be nascent or complete, result from repetitive sub threshold loading that, over time, exceeds the bone's intrinsic ability to repair itself.

Currently, there are no published prospective, randomized, blinded studies that have evaluated SWT as a treatment of chronic stress fractures. However, SWT has been used in the treatment of chronic stress fractures and has shown encouraging results.[40, 41]

Taki *et al*.[40] reported on their experience using focused SWT to treat 5 athletes with chronic stress fractures who had failed 6 to 12 months of traditional therapy. The fractures included the middle third of the tibia (N.=2), the base of the fifth metatarsal (N.=1), the inferior pubic ramus (N.=1), and the medial malleolus of the ankle (N.=1). A single high-energy treatment (0.29 mJ/mm^2-0.4 mJ/mm^2) was used in each case. All fractures healed after SWT with time to radiographic union ranging from 2 to 3.5 months post-treatment. All athletes were able to return to their sporting activities in a time ranging from 3.5 to 6 months post-treatment. No complications or recurrent stress fractures in any of the 5 cases was reported. Moretti *et al*.[41] reported on 10 male soccer players ranging in age from 19 to 29 years and suffering from either tibial or fifth metatarsal stress fractures who received 3 (for the metatarsus) to 4 (for the tibia) sessions of SWT with low-middle EFD (0.09-0.17 mJ/mm^2) and high number of impulses (N.=4000). At a mean of 8 weeks post-treatment, a 100% healing rate was noted. All athletes were able to return to their pre-injury level of sporting activity.

SWT for tendinopathies

Although the SWT mechanism of action in tendinopathies has not yet been fully understood, many

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authors [42-56] have achieved good results in the use of SWT in clinical setting, achieving both a proper stimulation of tendon tissue healing and a good modulation of pain.

Studies based on animal experiments have reported that SWT significantly increases the diffusion of cytokines across vessel walls into the pain-generating region, thereby stimulating the tendon healing response,[57] and significantly reduces the non-myelinated sensory fibers,[58] calcitonin gene-related peptide,[59] and substance P release.[10]

Taken together, these data indicate, as expressed above for the bone tissue, that tendon tissue can convert SWT stimulation into biochemical signals by means of TGF-β1 and IGF-I.[57, 60] Other authors have demonstrated that SWT acts on the pain system by means of hyper stimulation analgesia, which involves stimulation of a brainstem feedback loop through serotonergic activation via the dorsal horn that exerts descending inhibitory control over pain.[4]

Upper limb tendinopathies

Calcific tendinopathy of the shoulder

The first reports about the effectiveness of SWT on calcific tendinopathy of the shoulder date back to the first half of 90s, when preliminary data coming from non-controlled trials showed the efficacy and safety of this approach.[61-64] From then on, several research groups focused their attention on this topic, and the efficacy of SWT, its dose-dependent effect and its safety have been the object of a number of randomized controlled trials.

Rompe *et al.*[65] randomized 100 patients with calcific tendinopathy of the rotator cuff, experiencing pain for more than 12 months and with a history of previous unsuccessful conservative treatments, to either a low-dose SWT group (1 session of 1500 impulses at 0.06 mJ/mm² - no anesthesia before treatment) or a high-dose SWT group (1 session of 1500 impulses at 0.28 mJ/mm² – regional anesthesia needed). Constant and Murley score (CS), radiographic evidence of resorption of the calcifications and result of treatment were assessed at 6 and 24 months. The authors found improvement in both groups, with significantly better results achieved with high energies in all the outcome measures.[65]

Using 4 sessions of 1200 impulses at 0.28 mJ/mm², without anesthesia, Cosentino *et al.*[66] demonstrated an improvement of 69% in CS at 6 month follow-up, significantly higher compared to a sham therapy. In the same patients, the SWT therapy results in a partial or complete resorption of calcific deposit in 71% of patients.[66]

The dose-dependent effect of SWT on calcific tendinopathy of the shoulder has been evidenced by other researches.[46, 67] Particularly, Loew *et al.*[67] found that both low- and high-dose SWT are more effective compared to no treatment in terms of function and disappearance of calcifications, but higher doses show more efficacy than lower ones. Three months after therapy, patients receiving 2 sessions of 2000 impulses at 0.3 mJ/mm² achieved a CS of 71% of normal values, compared to 53% of those receiving 1 session of 2000 impulses at 0.1 mJ/mm². Similar results come from the only multicenter randomized controlled trial published on this topic,[46] in which the difference of mean improvement in CS between high- and low-dose SWT at three months follow-up was of 37%, increasing to 48% and 49% at 6 and 12 months.

We recently published a randomized controlled trial specifically designed to compare 2 different ranges of EFD in the treatment of calcific tendinopathy of the shoulder.[47] Forty-six patients were randomized to received high-dose (4x2400 impulses at 0.20 mJ/mm²) or low-dose SWT (4x2400 impulses at 0.10 mJ/mm²). Significant clinical improvement based on mean Constant scores was observed after 6 months in those receiving high-dose SWT (mean improvement=79.43±10.33) compared with low-dose SWT (57.91±6.53). Likewise, after 6 months, a significant decrease in VAS scores was found in high-dose SWT compared with low-dose SWT. Calcific deposits disappeared in the same percentage of patients in both groups.

Hsu *et al.*[68] prospectively studied SWT for calcific tendinopathy of the shoulder in 46 consecutive patients. The 33 patients in the treatment group received 2 courses of SWT at high-energy density (1000 impulses at 0.55 mJ/mm²). The control group underwent sham treatment with a dummy electrode (13 patients). The SWT results were good to excellent in 87.9% of shoulders (29/33) and fair in 12.1% (4/33), and the control results were fair in 69.2% (9/13) and poor in 30.1% (4/13). Among SWT patients, calcium deposits were completely eliminated in 7 cases (21.2%), partially eliminated in 11 (36.3%),

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and unchanged in 15 (45.4%). In contrast, elimination was partial in 2 control patients (15.3%) and unchanged in 11 (84.7%). Albert *et al.*[69] randomized 80 patients who had more than a three-months history of calcifying tendinopathy of the rotator cuff to high-dose SWT (2x2500 impulses at 0.45 mJ/mm^2) or to low-dose SWT (2x2500 impulses at 0.06 mJ/mm^2). Despite high-energy SWT significantly improves symptoms in refractory calcific tendinopathy of the shoulder after three months of follow-up, they found that the calcific deposit remains unchanged in size in the majority of patients. A recent systematic review and meta-analysis [70] designed to evaluate the effectiveness of SWT for functional improvement and the reduction of pain in patients with calcific tendinopathy of the shoulder, and to determine the rate of disappearance of calcifications after therapy at 6 month follow-up, found a pooled total resorption ratio of 27.19 and a pooled partial resorption ratio of 16.22.

Radial SWT have also been tested [42] and showed an improvement of shoulder function, pain and size of calcium deposit compared to a less active same therapy at 6 months follow-up.

In summary, evidences exist to consider SWT an efficacious therapy for calcific tendinopathy of the shoulder. The effect seems to be dose-dependent both on functionality, pan and resorption of calcium deposit. Because pain reduction generally occurs before radiographic demonstration of calcium deposit, however, the effect of SWT on calcific tendinopathy would not be completely related to a mechanical action, but rather to a neovascularization induced at the tendon junction with early release of angiogenesis-mediating growth and proliferating factors, including endothelial nitric oxide synthase, vascular endothelial growth factor, and proliferating cell antinuclear antigen, all of which lead to improved blood supply and tissue regeneration.[68]

Lateral elbow tendinopathy

The therapeutic use of SWT on lateral epicondylitis has been matter of research since the mid 90s. Despite several studies investigated the efficacy of various kind of SWT on lateral elbow pain, however, its usefulness still remain controversial.

Rompe *et al.*[71] evaluated the efficacy of low-EFD SWT (3 sessions, at weekly intervals, of 1000 impulses of 0.08 mJ/mm^2) delivered over the lateral epicondyle, compared to a sham therapy in 50 subjects experiencing pain for >12 months and who had previous unsuccessful conservative treatments. At 12 week follow-up, the reduction in pain was significantly greater in the treatment group, with good to excellent outcome in 56% of patients. Similar results were obtained by the same researchers in 100 patients with chronic and recalcitrant lateral elbow pain, who were randomized to a low-dose SWT protocol or to a sham protocol, with the same characteristics seen above.[72] Patients in the SWT group showed, at 24 weeks follow-up, a decrease in pain score with respect to baseline ranging from 64.5% for pressure pain to 78.9% for night pain. At the same time-point, patients in the sham group had no improvement, and even worsening, of pain scores.[72]

In a selected population of recreational tennis players suffering from chronic (>12 months) elbow pain of at least moderate intensity (pain ≥4 on a 10 cm VAS), un-responsive to conservative treatments, the efficacy of 3 weekly sessions of 2000 impulses at 0.09 mJ/mm^2 was compared to that of a sham treatment (3 weekly sessions of 20 impulses at 0.09 mJ/mm^2).[48] Seventy-eight patients were randomized to either the treatment or the sham group, and evaluated 3 months after therapy for pain during resisted wrist extension and functionality by means of the Upper Extremity Function Scale. A significantly higher improvement in pain during resisted wrist extension was observed in treatment group than in sham group (mean improvement 3.5±2.0 and 2.0±1.9, respectively) and in the Upper Extremity Function Scale (mean improvement 23.4±14.8 and 10.9±14.9, respectively).

Pettrone *et al.*,[73] enrolled 108 patients with chronic lateral epicondylitis patients un-responsive to previous conservative treatments and randomized them in a treatment group receiving three consecutive weekly sessions of low-dose SWT (2000 impulses at 0.06 mJ/mm^2) and in a placebo group. Three months after therapy, 60% of patients receiving SWT experienced a reduction of at least 50% of baseline pain, compared to 30% of those receiving placebo.

Radial SWT has been also successfully used to treat lateral epicondylitis.[54] In a prospective randomized controlled trial, 62 patients with lateral elbow pain of at least 10 months duration, refractory to previous conservative treatments, were randomized to either radial SWT (1 treatment a week for 4 weeks; 2000 impulses of radial SWT, accounting for a low-

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to-medium dose SWT) or less active same therapy (1 treatment a week for 4 weeks; 20 impulses of radial SWT) group. Pain, pain-free grip strength test and functional impairment were evaluated before treatment, at the end of treatment and at 6 month follow-up. The authors observed in the treatment group but not in the sham group a significant improvement in all the analyzed outcome variables, with results maintained 6 months after therapy.

A number of trials, however, lack to find similar positive results. Speed *et al*.[74] randomly assigned 75 patients experiencing lateral elbow pain for more than 3 months to a treatment group, receiving 3 monthly sessions of medium dose SWT (1500 impulses at 0.18 mJ/mm^2) or to a sham group (1500 impulses at 0.04 mJ/mm^2). At three month follow-up, 35% of those assigned to treatment group and 34% of patients in the sham groups showed more than 50% improvement from baseline pain. It should be noted that, contrarily to all the other studies in literature and to general manufacturers indications, monthly sessions were used. The distance between two consecutive treatments might have contributed to failure in the SWT group.

Unsuccessful treatment was also described by Melikyan *et al*.[75] In a randomized controlled trial, the Authors assigned 74 patients with chronic lateral epicondylitis awaiting surgery, to high energy SWT (total energy delivered 1000 mJ/mm^2 over three sessions) and 37 to placebo. Outcomes were assessed using the Disabilities of Arm, Shoulder and Hand questionnaire, measurement of grip strength, level of pain, analgesic usage and the rate of progression to surgery. According to their results, none of the outcome measures significantly differ between groups at 1, 3 and 12 month follow-up visits, thereby concluding for un-efficacy of SWT compared to placebo in lateral epicondylitis.

The only multicenter study performed in this field was conducted on 272 patients randomly assigned to SWT group (3 sessions, 2000 impulses at 0.06 mJ/mm^2) or to placebo.[76] All treatments were conducted following administration of local anesthesia. The primary end point was based on the rate of success, as determined with the Roles and Maudsley score and whether additional treatment was required, twelve weeks after the intervention. The success rate was similar in the two groups, being 25.8% in the group treated with SWT and 25.4% in the placebo group.

The doubtfulness of the present results is also attested by a systematic review of nine placebo-controlled trials involving 1006 participants, in which the authors found a "Platinum" level evidence that SWT provides little or no benefit in terms of pain and function in lateral elbow pain.[77] Too many discrepancies, however, exist in to the current literature in terms duration of the disorder, type, frequency and total dose of SWT, period of time between SWT, type of management and control group, timing of follow-up and outcomes assessed, to consider appropriate a pooled meta-analysis of SWT for lateral elbow tendinopathy.[78]

It seems, in fact, that low-energy SWT delivered without local anesthesia in patients with chronic lateral epicondylitis recalcitrant to conservative treatments is more effective than placebo in improving symptoms.[48, 54, 71-73, 78] Proper selection of patients, as well as of treatment protocols, is, thereby crucial in order to obtain positive results in these patients.

Interestingly, the success rate of SWT is similar than that of percutaneous tenotomy,[79] while, compared to corticosteroid injections, results are still controversial, with an apparent superiority of the latter in terms of pain reduction.[80]

Carpal tunnel syndrome

Carpal tunnel syndrome (CTS) is the most frequent entrapment neuropathy in the general population.[81] This syndrome may result in substantial disability owing to a sensory and/or motor deficit in the hand and a consequent loss of hand function. Despite surgery represents the gold-standard in CTS therapy,[82] several conservative approaches exists, including physical agents.[83, 84] SWT has been recently reported to be of value in the treatment of CTS. In a group of 36 patients with CTS, a single session of 1000 impulses of SWT delivered over the carpal tunnel with the probe oriented perpendicular to the patient's palm, was found to be as effective as a single corticosteroid injection in relieving symptoms and improving nerve conduction.[85] The energy level was set at the maximum level tolerated by the patient (0.09 to 0.29 mJ/mm^2).

The mechanisms of action of SWT in CTS may only be speculated. It has been recently demonstrated that chronic compression of a nerve, as occurs in CTS, leads to an increased release of neuropeptides [86] which triggers vasodilation mediated by cyclic-GMP and by endothelial nitric oxide (NO).[87]

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From this point of view, low energy flux density levels (0.03 to 0.08 mJ/mm²) of SWT significantly reduce the number of cutaneous nerve fibers and the immune-reactivity to the CGRP.[58, 59] SWT is also known to induce a short-term anti-inflammatory effect and a long-term tissue regeneration effect, both of which are mediated by NO induction.[88]

Lower limb tendinopathies

Patellar tendinopathy

Some studies found significant improvement of clinical outcomes in patients with patellar tendinopathy treated with SWT with a success rate ranging from 73.5% to 87.5%,[55, 89-92] whereas in other study there was no improvement.[93] However, the athletes in this study were all still active in their sport (basketball, volleyball or handball).

Peers *et al.*[92] compared surgical treatment (13 patients) and low-EFD SWT in 14 patients (15 tendons) with patellar tendinopathy. SWT was administered in 3 sessions of 0.08 mJ/mm². At 2 year follow-up, no significant differences in VAS and VISA scores was found between groups, but the surgical treatment group had a longer absence from work period postsurgically. Although the retrospective nature of the study, the authors concluded that SWT is an effective alternative to surgical treatment when conservative treatments fail in chronic patellar tendinopathy. The same lead author, confirmed the efficacy of SWT *vs.* placebo in the treatment of patellar tendinopathy in a randomized controlled study of its thesis.[94] Low-EFD SWT, consisting of three sessions of 0.2 mJ/mm² was administered to 21 patients, while the placebo treatment (three sessions with an EFD of 0.03 mJ/mm²) was administered to 20 patients. After 12 weeks VISA score, R&M classification and degree of functional impairment was evaluated, and there was a significant improvement in pain and function after SWT treatment, but not after placebo treatment.

Taunton *et al.*, in a randomized clinical study evaluated the effects of SWT in patients with patellar tendinopathy. Ten patients in the study group received from 3 to 5 sessions of SWT with an EFD of 0.17 mJ/mm². In the placebo group, 10 patients received the same treatment but with an absorbing pad between skin and probe. Twelve weeks after the last treatment the VISA score and a vertical jump test, used as outcome measures, improved significantly only in the study group.

Wang *et al.*[55] in a randomized controlled study evaluated the efficay and safety of a single SWT treatment compared to standard conservative treatment in patients with patellar tendinopathy. A single session of SWT with an EFD of 0.18 mJ/mm² was administered to 27 patients (30 tendons), while 23 patients (24 tendons) received standard conservative treatment. Follow-ups were scheduled at 1, 3, 6, 12, 24 and 36 months and VISA and VAS scores, function on ADL and sport activity, as well as ultrasonographic examination of the patellar tendon were evaluated as outcome measures. The results showed a significant improvement in function, VISA, and VAS scores in patients who underwent SWT. Moreover, ultrasonographic examination revealed a significant increase in vascularity of the tendon and a reduction on tendon thickness in patients who underwent SWT compared with those who underwent conservative treatment.

Vulpiani *et al.*[89] in an observational study on 73 patients (83 tendons) with patellar tendinopathy for at least 3 months, refractory to conservative treatments, performed 3 to 5 sessions of SWT with an EFD ranging from 0.08-0.44 mJ/mm². Their results showed an improvement in the average score of VAS already in the first month after treatment, with a constant increase at the short-term (6-12 months), medium-term (13-24 months) and long-term (>24 months) follow-ups.

Lohrer *et al.*,[95] in a prospective non-randomized pilot study evaluated in 45 athletes of various sport activities with patellar tendinopathy the effectiveness of radial SWT administered with 3 to 5 sessions with an EFD from 0.06 to 0.18 mJ/mm². VAS score at rest, during exercise, and at local pressure exerted by an algometer, as well as pain-free running time (in minutes) were evaluated after 1, 4, 12, 26 and 52 weeks. During 1 year all scores improved significantly. One year after the last treatment 40 of 45 athletes (88.9%) were re-assessed. Of these 40% were pain-free, 24.4% improved, and 36.5% showed no improvement.

Achilles tendinopathy

Many studies investigated the effect of SWT in Achilles tendinopathy, and most reported favorable

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results with similar success rate as patellar tendinopathy.[43, 49, 96, 97]

Furia investigated with two separate case controlled studies [43, 97] the efficacy of SWT for both chronic insertional and noninsertional Achilles tendinopathy. In the first of these two case controlled studies, 35 patients were treated with a single session of SWT (3000 impulses and EFD of 0.21 mJ/mm^2), and 33 patients with conventional treatments. SWT was administered either with a local anesthesia field block (12 patients) or with a regional block (23 patients). Visual Analog Scale and Roles and Maudsley score were used for evaluation. Patients were followed up at 1, 3, and 12 months after treatment. Twelve months after treatment 83% of patients in SWT group and 39% of those in conventional treatment group showed an improvement of their symptoms according to the Roles and Maudsley score. The VAS scores at 1, 3, and 12 months for SWT conventional treatment were 4.2 and 8.2, 2.9 and 7.2, and 2.8 and 7.0, respectively.

The second of these case controlled study investigated the efficacy of SWT in patients with noninsertional chronic Achilles tendinopathy. In this second study, the procedures used to administer the SWT were the same used in the study already described above. Thirty-four patients were treated with SWT and 34 patients with conventional treatments. VAS and Roles and Maudsley score were again used to evaluate outcomes. Patients were followed up at 1, 3, and 12 months after treatment. Twelve months after treatment 85% of patients in SWT group and 27% of those in conventional treatment group showed an improvement of their symptoms according to the Roles and Maudsley score. VAS scores at 1, 3, and 12 months for SWT and conventional treatment were 4.4 and 8.4, 2.9 and 6.5, and 2.2 and 5.6, respectively.

Vulpiani *et al.*[56] in a non-randomized observational study, evaluated the efficacy of SWT on 105 patients (127 tendons) with Achilles tendinopathy. Patients were treated in 3 to 5 sessions, at a 2/7-day interval, with 1500-2500 impulses for each session, with an EFD ranging from 0.08 to 0.40 mJ/mm^2. Their results showed satisfactory results on VAS score in 47.2% of cases (60 of 127 tendons) at 2 months follow-up, in 73.2% of cases (93 of 127 tendons) at medium-term (13–24 months) follow-up, and in 76% of cases (92 of 121 tendons) at long-term (>24 months) follow-up.

Four randomized controlled trials have investigated the effects of SWT on Achilles tendinopathy.[49, 52, 96, 98] Three of these studies reported that SWT is effective in the management of patients with chronic Achilles tendinopathy.[49, 52, 96] On the contrary the study of Costa *et al.* reported that SWT has no efficacy in the management of patients with chronic Achilles tendinopathy.[98]

Rompe *et al.*[52] in a randomized triple-arm study compared 25 patients in a wait and-see policy with 25 patients treated by eccentric exercises and with 25 patients treated with SWT. SWT was administered in 3 sessions at weekly intervals with 2000 impulses for each session with an EFD of 0.1 mJ/mm^2. At 4 months from baseline, 15 of 25 (60%) patients in eccentric exercises group, 13 of 25 (52%) patients in SWT group, and 6 of 25 (24%) patients in wait-and-see group reported symptoms "completely recovered" or "much improved". For all outcome measures, no difference was found between the eccentric and SWT groups. However, both these groups showed better results than the wait-and-see group.

The same authors [49] compared 25 patients treated by eccentric exercises with 25 patients treated with SWT, and the results showed that SWT was better than eccentric exercises in the treatment of patients with chronic recalcitrant Achilles tendinopathy.

Rasmussen *et al.*[96] compared low-energy SWT *versus* sham therapy. Forty-eight patients were randomized to receive active (N.=24) or sham (N.=24) SWT. American Orthopaedic Foot and Ankle Society (AOFAS) score and pain were used as outcome measures. Patients were followed-up at 4, 8, and 12 weeks. AOFAS increased more over time in the active SWT group (70 to 88 points) than in the sham SWT group (74 to 81 points). Pain score was reduced in both groups without statistically significant differences.

Costa *et al.*[98] reported no treatment efficacy in 49 patients with Achilles tendinopathy treated with SWT. SWT was administer in 3 sessions at 1-month intervals with 1500 impulses and an EFD of 0.2 mJ/mm^2. Patients with insertional and noninsertional forms of Achilles tendinopathy were included in this study. Pain during walking measured in a 100mm VAS scale was used as outcome measure. Baseline VAS score was 55 for both SWT and control groups. The score after intervention was 34 points in the SWT group and 50 in the control group.

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WITHDRAWN ARTICLE

Although the authors affirm that their results do not support the use of SWT in the management of patients with chronic Achilles tendinopathy, their study could be vitiated by several bias: 1) a too small simple size to detect a significant treatment effect (the authors affirm in their conclusion that: "the confidence intervals include the potential for a clinically relevant treatment effect."); 2) the use of monthly intervals between sessions is not recommended. Although until now there is no consensus on the procedures for SWT use, in fact, it is widely accepted that weekly intervals between sessions lead to better results; and 3) the inclusion of both noninsertional and insertional Achilles tendinopathy as a single group, may have turned down the positive effects of SWT. In fact, several studies have shown a lower percentage of satisfactory results in insertional Achilles tendinopathy when compared to noninsetional Achilles tendinopathy.

Plantar fasciopathy

The safety and efficacy of SWT in the management of chronic plantar fasciopathy has been reported by several randomized clinical trials. These studies have shown that low-energy SWT, when applied directed to the most tender point at the medial calcaneal tubercle, and performed without local anesthesia, leads to significant and persistent improvement of recalcitrant plantar fasciopathy symptoms within a reasonable time frame.[99-109]

Rompe *et al.*[51] and more recently Dizon *et al.*[110] have already reviewed the results of using SWT to treat chronic plantar fasciopathy.

Rompe *et al.*[99] firstly investigated the efficacy of SWT in the plantar fasciopathy in 30 patients randomized in either SWT group (N.=15) or placebo group (N.=15). The SWT was administered with 3 sessions at weekly intervals with 1000 impulses in each session with an EFD of 0.06 mJ/mm^2, without local anesthesia. Twelve weeks after the last treatment, only patients in the SWT group experienced a significant alleviation of pain and improvement of function.

Cosentino *et al.*,[100] in a randomized controlled trial involving 60 patients randomized to receive SWT (N.=30) or placebo treatment (N.=30), reported a significant decrease in VAS score only in SWT group at 12 weeks. SWT was administered in 6 sessions at weekly intervals with 1200 low-energy impulses, without local anesthesia.

Rompe *et al.*,[103] also evaluated 45 running athletes with chronic plantar fasciopathy. Athletes were either assigned to a treatment group that received 3 sessions of 2100 impulses of 0.09 mJ/mm^2 without local anesthesia or to a placebo treatment. At 24 weeks, 60% versus 27% of patients reported >50% reduction of pain on first walking in the morning.

Wang *et al.*[102] reported that SWT was efficacious in the treatment of 79 patients (85 plantar fascia) with chronic plantar fasciopathy. SWT was administered with a single session of 1000 impulses with an EFD of 0.18 mJ/mm^2. However, at the end of the study only 58 patients (73%, 60 plantar fascia) received one session of SWT, while 16 patients (19 plantar fascia) also received a second session of SWT, and, similarly 5 patients (6 plantar fascia) received a third treatment. At one-year follow-up, the overall results were 75.3% complaint free, 18.8% significantly better, 5.9% slightly better and none unchanged or worse. The recurrent rate was 5%.

Malay *et al.*[111] compared the outcomes of 172 participants treated with SWT with those treated with placebo. SWT with 3800 impulses or placebo was administered without local anesthesia. Although the amount of energy delivered was not specified in this study, at 12 weeks, 43% versus 20% of patients reported a 50% decrease of pain from baseline.

Gerdesmeyer *et al.*,[106] in a prospective, randomized, double-blinded, placebo-controlled international multicenter study, demonstrated safety and efficacy of radial SWT for chronic plantar fasciopathy. In this study 245 patients with chronic plantar fasciopathy were enrolled and randomly assigned either to radial SWT or placebo. Radial SWT was administered in 3 sessions, each at 2 weeks (±4 days) apart with 2000 impulses per session and an EFD=0.16 mJ/mm^2. The patients were assessed 12 weeks and 12 months after the first session of SWT. A statistically significant difference in the reduction of pain at VAS score between the patients treated with radial SWT (-56.0%) and the placebo-treated patients (-44.1%) was found at 12 weeks, and even more at 12 months (radial SWT=-61.9% *vs.* placebo=-46.5%).

Ibrahim *et al.*[109] in a prospective, randomized, double-blinded, placebo-controlled study randomly assigned a total of 50 patients with unilateral, chronic plantar fasciopathy to either radial SWT (N.=25) or placebo (N.=25). Radial SWT was administered in 2 sessions 1 week apart with 2000 impulses per

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session with an EFD of 0.16 mJ/mm². Placebo treatment was performed with a clasp on the heel. Endpoints were changes in the VAS score and the modified Roles and Maudsley score from baseline to 4-, 12-, and 24-week follow-up. The authors found the mean VAS scores reduced after SWT from 8.52 at baseline to 0.64 at 4 weeks, 1.08 at 12 weeks, and 0.52 at 24 weeks. Similar changes were found for mean of Roles and Maudsley scores after radial SWT but were not observed after placebo treatment.

Speed *et al.*[112] in a randomized controlled trial investigated 88 patients randomized to receive either 3 sessions at monthly intervals of 1500 impulses of 0.12 mJ/mm² without local anesthesia or sham SWT. Follow-up was 4 weeks only: 37% and 24% of the groups showed a 50% improvement from baseline with respect to pain, without statistically significant difference.

Haake *et al.*[113] in a randomized controlled trial investigated 272 patients that were allocated to SWT with 3 sessions at weekly intervals of 4000 impulses of 0.08 mJ/mm² under local anesthesia or placebo SWT under local anesthesia. At 12 weeks the success rate was 34% in the SWT group and 30% in the placebo group, without statistically significant difference.

Buchbinder *et al.*[114] in a randomized controlled trial investigated 166 patients with acute or chronic (symptoms ranging from 8 to 980 weeks) plantar fasciopathy. Patients were randomly assigned to receive active or placebo SWT. In the active group, 3 sessions at weekly intervals, with 2000 or 2500 impulses per session and an EFD varying from 0.02 mJ/mm² to 0.33 mJ/mm² were administered. Patients in the placebo group received 3 sessions at weekly intervals with only 100 impulses per session with an EFD of 0.02 mJ/mm². At 6 and 12 weeks, there were significant improvements in overall, morning, and activity pain, walking ability, and other outcomes in both groups, without statistically significant differences between groups.

This three last studies confirm that if SWT is administered with monthly intervals between sessions, under anesthesia, and in patients with acute symptoms, their efficacy in the management of tendinopathies is reduced.[104, 115] Related to the administration of SWT in patients with acute plantar fasciopathy, a randomized controlled trial of Rompe *et al.*[116] comparing the efficacy of plantar fascia-specific stretching and radial SWT on patients with acute (time of onset symptoms ≤6 weeks) plantar fasciopathy, showed that stretching exercises specific to the plantar fascia is superior to radial SWT for the treatment of acute symptoms of plantar fasciopathy.

Other tendinopathies

Several studies reported a positive effect of shockwave therapy in other tendinopathies such as greater trochanter pain syndrome (GTPS),[53, 117] chronic proximal hamstring tendinopathy (PHT),[118] and medial tibial stress syndrome (MTSS).[119]

Conclusions

Although there is conflicting evidence regarding its effectiveness in musculoskeletal disorders, the SWT is a relatively new non-invasive therapeutic modality with proved effectiveness, convenience, and safety. Moreover, in some musculoskeletal disorders, SWT has the potential of replacing surgery with at least the same results, but without its complications. Further studies with well defined objective diagnostic criteria, homogeneity of the enrolled patients, particularly regarding stages of pathology, and well defined SWT parameters such as focal depth, number and intensity of impulses (energy flux density), are required to draw final conclusions.

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