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ORIGINAL PAPER

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Effectiveness and Safety of Shockwave Therapy in Tendinopathies

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ABSTRACT

Introduction: People suffering from tendinopathies exhibit reduced mobility due to the pain caused by the movement of the tendons involved. Recently, shockwave therapy has been used as a treatment option, which is non-invasive, simpler, faster and safer. **Aims:** To record the intensity of the pain, the functionality of the upper and lower limbs and quality of life before treatment with shock waves, immediately after the treatment and the 4-week follow-up. **Methodology:** The sample consisted of 384 patients, suffering from a tendinopathy. 326 patients constituted the shockwave intervention groups and 58 patients made up the control groups. The researchers created a self-administered questionnaire (University of Peloponnese Pain, Functionality and Quality of Life Questionnaire) in which the intensity of pain, functionality and quality of life were evaluated on a five-point Likert scale, before, immediately after the treatment and at a 4-week follow-up. **Results:** The pain reduction and the improvement of functionality and quality of life after shockwave treatment increased by at least two points on the five-point Likert scale both post-treatment ($p < 0,001$) and at a 4-week follow-up ($p < 0,001$) compared to post-treatment in elbow tendinopathy, Achilles tendinopathy, plantar fasciitis and rotator cuff tendinopathy. **Conclusions:** Shockwave therapy significantly reduced the pain that accompanies tendinopathies and improves functionality and quality of life. It might be first choice because of its effectiveness and safety.

Keywords: shockwave therapy, musculoskeletal injuries, rehabilitation, tendinopathy, tendon injuries.

1. INTRODUCTION

Extracorporeal Shockwave Therapy (ESWT) was first introduced into clinical practice back in 1980 as a treatment for non-invasive lithotripsy

(1). However, in the last two decades, it has been used as a method for musculoskeletal disorders and the stimulation of bone growth (2). Thus, the shock waves are used for the treatment of various orthopedic conditions including plantar fasciitis, shoulder tendinopathy, elbow tendinopathy, patellar tendinopathy and Achilles tendinopathy (3-5). Recently, shockwave treatment has been extended to treat other conditions, including femoral head necrosis, patellar knee jaw, osteochondritis and calcified shoulder tendonitis.

Shock waves are high energy sound waves produced under water with a high voltage explosion and evaporation. In the case of lithotripsy, shock waves are used to dissolve nephrolithiasis while in orthopedic cases they are used to induce neovascularisation at the junction of the tendon-bone and the release of growth factors such as eNOS (endothelial nitric oxide synthase), VEGF (vascular endothelial growth factor) and PCNA (proliferating cell antinuclear antigen). Subsequently, these lead to the improvement of the blood supply and to an increase in cell proliferation and ultimately to the tissue regeneration of tendons and bones for tissue repair (6).

Shockwave treatment is a relatively new non-invasive therapeutic intervention, without the dangers of a surgical procedure and postoperative pain.

2. AIM

The purpose of this study was to record the pain, functionality and quality of life in individuals suffering from various tendinopathies and subsequently to investigate the pain reduction, the improvement in the patient's functionality and quality of life both immediately and 4 weeks after therapeutic intervention with shock waves. Furthermore, comparisons were also performed between the shockwave intervention groups and control groups.

3. MATERIALS AND METHODS

Research Population: The sample consisted of 384 patients (326 constituted the shockwave intervention groups and 58 the control groups) suffering from tendinopathies who presented themselves at an orthopedic clinic from February 2015 to December 2016 and the physician considered their need for the particular treatment. Patients in the control groups were treated with conservative therapy, which included local application of NSAIDs in the form of gels and creams, the use of supporting straps, an exercise program depending on the tendinopathy diagnosed by the doctor, modification of activity levels, friction massage, and placing hot or cold packs on the injured part of the body. The tendinopathies examined were elbow tendinopathy, plantar fasciitis, Achilles tendinopathy and rotator cuff tendinopathy.

Exclusion criteria: Patients under the age of 18 were excluded from the study. **Research Tools:** A self-administered anonymous questionnaire was created bearing the name ‘University of Peloponnese Pain, Functionality and Quality of life Questionnaire–UoP-PFQ’. The questionnaire consisted of four parts. The first and second parts were completed by the patients of both groups before the initiation of the therapy (pre-treatment). The first part was related to the demographic characteristics of the patients,

whereas the second part was further subdivided into three sections, one for the evaluation of the perception of pain upon precise movements on a five-point Likert scale where 0=no pain, 1=low pain intensity, 2=medium pain intensity, 3=high pain intensity and 4=severe pain intensity. The second section considered the functionality of certain movements of both the upper or lower limbs and the third section assessed the quality of life and examined the difficulties in performing certain daily tasks both on a five-point Likert scale where 0=no difficulty, 1=little difficulty, 2=occasional difficulty, 3=frequent difficulty and 4=extreme difficulty. The third part of the questionnaire was completed by the doctor and contained certain information derived from the medical evaluation such as the diagnosis, the reported pain, the type of treatment, the number of sessions to be used, the frequency and duration of each session, the medication etc. Finally, the fourth part of the questionnaire was exactly the same as part two and it was completed by the patients of both groups immediately after the completion of the therapeutic intervention (post-treatment) and the 4-week follow-up.

The internal consistency of the questionnaire (Cronbach’s alpha coefficient) was equal to 0.88.

Shockwave Therapy parameters: Shock waves were applied to the patients by using a STORZ MEDICAL Master Pulse MP200 device and using the parameters shown below.

Elbow Tendinopathy: For the initial session, the frequency was set to 21 Hz, the pressure at 1.8 bar and 2000 shocks to achieve analgesia. For all remaining sessions, the frequency was set to 15 Hz frequency, the pressure at 1.6 bar and 1500 shocks to achieve therapy.

Achilles tendinopathy: For the initial session, the frequency was set to 21 Hz, the pressure at 1.8 bar and 2000 shocks to achieve analgesia. For all remaining sessions, the frequency was set to 15 Hz, the pressure at 2.0 bar and 3000 shocks to achieve therapy. **Plantar fasciitis:** For the initial session, the frequency was set to 21 Hz, the pressure at 1.6 bar and 1500 shocks to achieve analgesia. For all remaining sessions, the frequency was set to 15 Hz, the pressure at 1.8 bar and 2500 shocks to achieve therapy.

Tendinopathy of the rotator cuff: For the initial session, the frequency was set to 21Hz, the pressure at 1.8 bar and 2000 shocks to achieve analgesia. For all remaining sessions, the frequency was set to 15 Hz, 1.8 bar pressure and 1500 shocks

TENDINOPATHY / PAIN	Shockwave group (n=117)	Control group (n=18)	Independent t-test differences	P-value*
ELBOW				
Pre-Treatment Mean±SD	1,99±0,5	2,01±0,15	-0,02	0,721
Post-Treatment Mean±SD	0,10±0,21	1,84±0,16	-1,75	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,01±0,09	1,98±0,10	-1,97	<0,001
P-value***	<0,001	<0,001		
ROTATOR’S CUFF				
Pre-Treatment Mean±SD	2,80 ±0,47	2,53±0,2	0,27	0,053
Post-Treatment Mean±SD	0,18±0,4	2,36 ±0,21	-2,18	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,01±0,05	2,46±0,21	-2,45	<0,001
P-value***	0,010	0,011		
ACHILLE’S TENDON				
Pre-Treatment Mean±SD	2,35±0,54	2,15±0,14	0,19	0,202
Post-Treatment Mean±SD	0,11±0,14	1,95±0,13	-1,84	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,00±0,02	1,84±0,11	-1,84	<0,001
P-value***	<0,001	<0,001		
PLANTAR FASCIITIS				
Pre-Treatment Mean±SD	2,52±0,42	2,52±0,19	-0,003	0,978
Post-Treatment Mean±SD	0,06±0,1	2,29±0,2	-2,23	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,00±0,00	2,27±0,19	-2,27	<0,001
P-value***	<0,001	0,165		

Table 1. Pain results of various tendinopathies in both shockwave and control groups pre-treatment, post-treatment and at the 4-week follow-up. *Comparison between shockwave and control groups pre-treatment, post-treatment and at the 4-week follow-up. **Comparison between pre-treatment and post-treatment within each group. ***Comparison between post-treatment and 4-week follow-up within each group.

to achieve therapy. **Ethical considerations:** This study met the fundamental ethical principles that govern the conduct of research. To be more specific, full confidentiality was ensured with regard to the information about the participants, the safety of the material was retained, the anonymity of the participants was protected and the results obtained were used only for the purposes of this study. Finally, the study protocol was in compliance with Helsinki Declaration and was approved by the University's Ethical Committee.

4. RESULTS

Elbow tendinopathy was diagnosed in 135 patients. Out of these, 117 patients were treated with shock waves (67 men and 50 women) and 18 patients constituted the control group (7 men and 11 women). 48% of the total sample was in the age group of 40-49 and 27% in the age group of 50-59. 83% of the shockwave group was submitted to 3 shockwave treatments and 9% to 4 shockwave treatments. The mean of reported pain, functional impairment and quality of life impairment decreased from 1.99, 1.79 and 2.17 points pre-treatment to 0.10, 0.10 and 0.83 post-treatment with shock waves, respectively. Thus, the results revealed significant improvements in pain, functionality and quality of life ($p < 0.001$). These results were even more pronounced after the four-week follow-up ($p < 0.001$). Accordingly, patients in the control group showed significant reductions, and thus improvements, in all parameters tested post-treatment but in the 4-week follow-up, the results in the shockwave group were significantly better compared to control group both post-treatment and the 4-week follow-up (Tables 1-3).

Plantar fasciitis was diagnosed in 103 patients, of which 88 patients constituted the shockwave group (36 men and 52 women) and 15 the control group (7 men and 8 women). 27% was in the age group of 40-49 and 25% and 23% were in the age groups of 60-69 and 50-59 respectively. 80% of the patients was submitted to 3 shockwave treatments and 17% to 4 shockwave treatments. Similar results were observed as those in elbow tendinopathy shown above in both shockwave and control groups (Tables 1-3) and these results were all statistically significant ($p < 0.001$).

Achilles tendinopathy was diagnosed in 78 patients, 65 patients in the shockwave group (27 men and 38 women) and 13 patients in the control group (6 men and 7 women). The most common age groups treated with shock waves were 50-59 (28%) and 40-49 (22%). 66% of the patients were subjected to 3 shock-

wave treatments, whereas 26% to 4 shockwave treatments. Accordingly, the results also showed similar reductions in pain, functional impairment and quality of life impairment (Tables 1-3) as those observed in elbow tendinopathy and these results were all statistically significant ($p < 0.001$).

Rotator cuff tendinopathy was diagnosed in 68 patients, 56 in the shockwave group (26 men and 30 women) and 12 in the control group (6 men and 6 women). The most common age groups were 40-49 (34%) and 50-59 (29%). 71% of the patients was submitted to 3 shockwave treatments and the 29% to 4 shockwave treatments. Once again, similar results were noticed (Tables 1-3) as those in elbow tendinopathy on both the shockwave and control groups. These results also were statistically significant ($p < 0.001$).

5. DISCUSSION

Shockwave therapy represents an innovative method for the treatment of various musculoskeletal diseases especially when other conservative methods of therapy have failed. This type of therapy is considered safe, non-invasive, low cost and without the dangers of the surgical procedure and postoperative pain.

Although the exact ESWT mechanism of action has not been fully elucidated, it has been postulated that shock waves

TENDINOPATHY / FUNCTIONAL IMPAIRMENT	Shockwave group (n=117)	Control group (n=18)	Independent t-test differences	P-value*
ELBOW				
Pre-Treatment Mean±SD	1,79±0,54	1,97±0,11	-0,18	0,158
Post-Treatment Mean±SD	0,10 ±0,2	1,81 ±0,14	-1,71	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,00±0,03	1,94±0,08	-1,94	<0,001
P-value***	<0,001	<0,001		
ROTATOR'S CUFF				
Pre-Treatment Mean±SD	2,73±0,48	2,51±0,17	0,22	0,128
Post-Treatment Mean±SD	0,29±0,45	2,32±0,15	-2,03	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,01±0,05	2,38±0,16	-2,36	<0,001
P-value***	<0,001	0,100		
ACHILLE'S TENDON				
Pre-Treatment Mean±SD	2,36±0,5	2,14±0,14	0,22	0,118
Post-Treatment Mean±SD	0,17±0,24	2,00±0,12	-1,83	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,01±0,04	1,99±0,11	-1,98	<0,001
P-value***	<0,001	0,670		
PLANTAR FASCIITIS				
Pre-Treatment Mean±SD	2,46±0,4	2,40±0,25	0,06	0,431
Post-Treatment Mean±SD	0,15±0,21	2,27±0,2	-2,11	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,01±0,04	2,23±0,17	-2,23	<0,001
P-value***	<0,001	0,082		

Table 2. Functional impairment results of various tendinopathies in both shockwave and control groups pre-treatment, post-treatment and at the 4-week follow-up. *Comparison between shockwave and control groups pre-treatment, post-treatment and at the 4-week follow-up. **Comparison between pre-treatment and post-treatment within each group. ***Comparison between post-treatment and 4-week follow-up within each group.

cause stimulations that activate small diameter fibers, which in turn activate a serotonergic system that regulates the transmission of pain stimuli and therefore increase the patient's pain tolerance above their existing original pain. Additionally, ESWT causes a localized metabolic reaction, due to increased vascularity and less formation of adhesions, which occur in promoting the natural healing process (7).

The results of the present study clearly indicate that shockwave therapy achieved a significant reduction in pain as well as a significant improvement in both the functionality and quality of life after the completion of the therapeutic intervention and the 4-week follow-up in patients suffering from plantar fasciitis, elbow tendinopathy, Achilles tendinopathy and rotator cuff tendinopathy. Significant pain reduction and improvement in functionality and quality of life were also observed in the control groups of each tendinopathy, but these findings were less pronounced than those in the group treated with shock waves.

Although the direct comparison of the results from other studies is difficult due to the use of different devices and different mechanisms of output of shock waves or the different dosage of energy flux employed in these studies. However, in the present study, shockwave treatment showed similar results of previous studies in patients suffering from plantar fasciitis, elbow tendinopathy, Achilles tendinopathy and rotator cuff tendinopathy.

Many studies have investigated the effect of shockwave therapy in the treatment of plantar fasciitis. The results showed significant alleviation of pain and improvement in functional ability immediately after the treatment and these findings continued during the entire follow up of 3, 6 and 12 months (4, 8). Othman and Ragab (9) applied shock waves of energy intensity from 17 to 21 kV, 2 Hz and 1,500-3,000 pulses and showed a marked improvement in pain and 50% of the patients had no limitation of activities after the 6 to 11 month follow-up. Other researchers (10) applied high energy of shock waves (1,500 shocks with total energy of 324.25J) and showed improvements in pain and functionality which was maintained between week three and twelve post-intervention, and continued to a lesser extent for up to one year. Another study (11) also showed significant alleviation of pain immediately after the treatment and three-month and twelve-month follow-up.

Supporting evidence for our results has also been noticed in the case of elbow tendinopathy. Spacca, Necozone and Cacchio (12) assessed pain using the VAS scale and functional impairment using the DASH questionnaire. They applied radial shockwave therapy consisting of 4 weekly sessions

TENDINOPATHY / QUALITY OF LIFE IMPAIRMENT	Shockwave group (n=117)	Control group (n=18)	Independent t-test differences	P-value*
ELBOW				
Pre-Treatment Mean±SD	2,17±0,48	2,14±0,19	0,03	0,801
Post-Treatment Mean±SD	0,83±0,28	2,03±0,13	-1,20	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,01±0,04	2,00±0,14	-1,99	<0,001
P-value***	<0,001	0,083		
ROTATOR'S CUFF				
Pre-Treatment Mean±SD	2,73±0,47	2,72±0,16	0,01	0,957
Post-Treatment Mean±SD	0,28±0,37	2,43±0,17	-2,15	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,01±0,03	2,36±0,22	-2,36	<0,001
P-value***	<0,001	0,053		
ACHILLE'S TENDON				
Pre-Treatment Mean±SD	2,01±0,5	2,28±0,14	-0,27	0,131
Post-Treatment Mean±SD	0,16±0,23	2,07±0,09	-1,90	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,00±0,02	2,04±0,09	-2,04	<0,001
P-value***	<0,001	0,337		
PLANTAR FASCIITIS				
Pre-Treatment Mean±SD	2,23±0,38	2,40±0,15	-0,17	0,900
Post-Treatment Mean±SD	0,14±0,18	2,27±0,16	-2,13	<0,001
P-value**	<0,001	<0,001		
4-Week Follow-up Mean±SD	0,00±0,02	2,24±0,14	-2,24	<0,001
P-value***	<0,001	0,334		

Table 3. Quality of life results of various tendinopathies in both shockwave and control groups pre-treatment, post-treatment and at the 4-week follow-up. *Comparison between shockwave and control groups pre-treatment, post-treatment and at the 4-week follow-up. **Comparison between pre-treatment and post-treatment within each group. ***Comparison between post-treatment and 4-week follow-up within each group.

where 2,000 impulses were administered in each session. They found a statistically significant reduction (improvement) in pain and functional impairment after the completion of the therapy and the 6-month follow-up compared to pain before treatment. Ilieva, Minchev and Petrova (13) also used radial shockwave therapy of 2,500 impulses and performed a total number of 5 treatments one per week. They showed a significant difference between the mean pain scores before treatment and immediately after the treatment, and this decrease was sustained at 3, 6 and 12 months. The pain, function and the total score as assessed on the patient-rated scale (PRTEE) also showed statistically significant improvement after completion of therapy and at the 3, 6 and 12 month follow-up. Melikyan et al (14) also showed a significant decrease in the DASH function/symptom score, which reflects to an increase in functional level, after the 1, 3 and 12 month follow-up. Other studies, also found significant improvement with respect to the reduction of pain, functional scale and patient activity score not only post-treatment but also after a 12 week follow-up and in comparison to placebo (15, 16).

ESWT is also effective in the treatment of Achilles tendinopathy as it has been confirmed by some randomized controlled trials. Rasmussen et al (17) showed improvements in

function and activity of the ESWT group after the completion of the therapy with better results seen at the 8 and 12 week follow-up as measured by the AOFAS score, which assesses subjective pain and function provided by the patients and objective scores based on the physical examination of the patient. Lakshmanan and O'Doherty (18) treated Achilles tendinopathy by giving 3 radial shockwave sessions with one week between each session (2,000 impulses of radial shock waves, 2.5 bar pressure and a frequency of 6-10 Hz). The results showed a significant decrease ($p < 0.001$) in the mean pain score by the VAS and thus an improvement after the treatment. The VISA-A score, which analyses the function of the Achilles tendon, also significantly improved after the treatment ($p < 0.001$). Rompe et al (19) also showed an improvement in the VISA-A scale, which assesses pain, function and activity both after the completion of the therapy and the 4-month follow-up.

Many studies have evaluated the impact of ESWT on the tendinopathies of the rotator cuff. Wang et al (20) found significant improvement in pain intensity, activity and motion after the treatment in one, two or three sessions with 1,000 impulses of shock waves and this improvement was also evident at the 3- and 6-month follow-up. Rompe et al (21) also found similar results in shoulder functionality at 6 and 24 weeks after treatment by using a single session of 1,500 impulses. Accordingly, Cosentino et al (22) found a significant improvement in pain, daily activities and range of motion by applying 4 shockwave sessions of 1,200 shocks after the treatment and the follow-up evaluations at one and six months using a VAS and Constant-Murley score. Hsu et al (23) showed significantly better results in both pain reduction and improvement of function measured by the Constant-Murley score after administration of a high-energy shockwave. Cacchio et al (24) reported a study with high-energy shock waves versus sham treatment, where a significant reduction of pain and increases in function were evident from 4 weeks to 6 months of follow-up. Other studies assessed high energy ESWT versus low energy ESWT and comparisons between them and a placebo were estimated. Significant relief in pain and a greater increase in the functional outcome were seen in both high energy and low energy ESWT compared to control treatment at 3 and 6 months post-treatment, but significantly better results were seen in high energy treatment (3, 25-27).

6. CONCLUSIONS

From the results of the present study, extracorporeal shockwave therapy is an effective modality in relieving pain intensity and increase the functionality and quality of life in various tendinopathies such as plantar fasciitis, elbow tendinopathy, Achilles tendinopathy and rotator cuff tendinopathy. It can be done on an out-patient basis with no patient restrictions and there are no significant side effects. Extracorporeal shockwave therapy as utilized in the current study seems to be a safe and effective treatment in all tendinopathies examined. Thus, patients who failed to respond to conventional treatment for any of the above tendinopathies can use shockwave therapy as an alternative method, which can significantly improve pain, functionality and quality of life.

The differences between various studies in the effectiveness of ESWT when used in different tendinopathies may be

directly related to a number of factors including study designs, differences in study populations, differences in treatment parameters such as shockwave intensity, focal energy and different design of the devices used. Further research and clinical trials may be necessary to elucidate the ideal parameters on the efficacy of shockwave therapy.

• **Conflict of interest:** none declared.

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