Introduction

Achilles tendinopathy is a degenerative disorder of the tendon with changes in the collagen fiber structure, which lack inflammation. It is included among the most common foot diseases, with overuse being the leading pathological cause, which decreases physical capability in everyday living, occupation and sports \cite{1, 2}. The disease often involves recreational runners and elite athletes, although it can be seen in patients with a sedentary lifestyle \cite{3, 4}. When the tendon is overloaded repeatedly beyond its reasonable threshold, it counteracts with inflammation of its membrane, degeneration of its body or a combination of the two \cite{5}. Repeated tendon micro-injuries without adequate time for healing and restoration, even if within the normal range, can also lead to tendinopathy \cite{6}. The micro-injuries are associated with non-uniform strains between the gastrocnemius and the soleus muscles, due to their different contributions to the strength, and lead to abnormal intra-tendon load concentrations, frictional forces between the fibrils and localized damage to fibers \cite{7}. Tendon injury due to overuse is caused by the repeated strain of the affected tendon, so it can no longer withstand tensile stress. As a result, tendon fibers start to rupture microscopically, resulting in pain. Overloading of the legs and training errors are the external risk factors \cite{8}. The normal thickness of the Achilles tendon is 5-8 mm. Thickness greater than 8 mm indicates a pathological state in the healing process \cite{9}. Variations of treatment, including surgical and conservative, have been used in the treatment of Achilles tendinopathies \cite{10, 11}. Among conservative methods used are eccentric loading, orthotics, non-steroidal anti-inflammatory drugs (NSAIDs), photo biostimulation with laser, ESWT and therapeutic ultrasound, among others.

Abstract

Introduction: People suffering from Achilles tendinopathy exhibit pain and reduced mobility of the involved tendon. Pain and limited functionality negatively affect their life quality.

Aims: The aim of the present study was to compare the efficiency of radial shockwave therapy and therapeutic ultrasound in improving pain, functionality of lower limbs and quality of life in patients suffering from Achilles tendinopathy.

Methodology: From the total sample of 130 patients who suffered from Achilles tendinopathy, 65 constituted the shockwave intervention group, 52 the ultrasound group and 13 the control group. A questionnaire was used to evaluate pain intensity, functionality and quality of life at pre-treatment, post-treatment and 4-week follow-up.

Results: Pain reduction and improvement in functionality and quality of life after shockwave treatment significantly increased at post-treatment and 4-week follow-up compared to pre-treatment for both shockwave intervention group and therapeutic ultrasound group \((p< 0.001)\). However, the results obtained with the shockwave intervention group were more pronounced than those in the therapeutic ultrasound in all parameters tested both at post-treatment and at 4-week follow-up.

Conclusions: Ultrasound therapy was less effective than shockwave therapy in treating Achilles tendinopathy.

Keywords: Shockwave therapy, musculoskeletal injuries, rehabilitation, tendinopathy, tendon injuries

Achilles tendinopathy: Comparison between shockwave and ultrasound therapy

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ESWT induces stimulations that activate small diameter fibers, which in turn enable the serotonergic system that regulates the transmission of pain stimuli and thus increase the patient’s pain tolerance level above its original state. Additionally, ESWT causes a localized metabolic reaction due to increased vascularity and reduced formation of adhesions, which occur in promoting the natural healing process [17, 18]. On the other hand, therapeutic ultrasound exerts its effects which are usually attributed to both its thermal and non-thermal effects in tissues. The thermal effects induce a rise in tissue temperature locally, which increases blood flow that aids to a decrease in both swelling and muscle spasms and also increases the extensibility of collagen fibers. The non-thermal effect is cavitation, which enhances the acoustic micro streaming events. Micro streaming alters the structure, function and permeability of cell membranes by increasing the activity levels within the cell and thus stimulates the tissue repair [19, 20].

**AIM**

The purpose of this study was to evaluate pain, functionality and quality of life in individuals suffering from Achilles tendinopathy and subsequently to compare the pain reduction, the improvement in the patient’s functionality and quality of life both immediately and four weeks after therapeutic intervention with shockwaves and ultrasound therapy. Furthermore, comparisons were also performed between the shockwave intervention group and the control group, and the therapeutic ultrasound group and the control group.

**Materials and Methods**

**Research Population:** The researchers effectuated a power sample test to define the minimum number of the subjects in each group. With a minimum sample of 28 subjects in the shockwave and the ultrasound group and 13 subjects in the control group, there was a 95% likelihood that the study will yield a statistically significant effect. This fact allowed the researchers to conclude that the mean response differs for shockwave versus ultrasound and control group. For every 5 patients assigned in the shockwave group, 4 patients were assigned in the ultrasound group, and 1 patient to the control (randomization ratio 5:4:1). The sample of the present study consisted of 130 patients with Achilles tendinopathy who visited the orthopaedic clinic between February 2017 and September 2018, and the physician considered their need for the particular treatment. From the total sample, 65 patients were treated with radial shockwaves and constituted the shockwave intervention group, 52 patients were treated with ultrasound and formed the therapeutic ultrasound group and 13 patients made up the control group. Patients under 18 years old, those suffering from a systemic infection, inflammatory disease or malignant disease and those who had undergone surgery of the Achilles tendon were excluded from this study.

**Research Tools:** In the present study, the self-administered anonymous questionnaire ‘The University of Peloponnese Pain, Functionality and Quality of life Questionnaire - the UoP-PFQ’ was used on a five-point Likert scale for the lower limbs (Table 1) pre-treatment, post-treatment and at 4-week follow-up as described by Dedes et al. [21]. Briefly, the questionnaire consisted of four parts. The first part contained the demographic characteristics, whereas the second part had three sections evaluating pain, the functionality of the lower limbs and quality of life each on a five-point Likert scale. The patients completed both the first and second parts before the initiation of the treatment. The third part was completed by the orthopaedic doctor and contained specific information of 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, medication etc. Finally, the fourth part of the questionnaire was precisely the same as part two, and all the patients completed it immediately after the completion of the therapeutic intervention (post-treatment) and the 4-week follow-up.

Patients of the shockwave intervention group received radial shockwaves by using a STORZ MEDICAL Masterpulse MP200 device and applying the following settings: for the initial session the frequency was set at 21 Hz, the pressure at 1.8 bar and 2000 shocks were used to achieve analgesia. All remaining sessions were treated with 15 Hz frequency, 2 bar pressure and 3000 shocks. Patients of the therapeutic ultrasound group received pulsed ultrasound waves by using a Gymna Pulson 200 device set at 3 MHz frequency and 2 W/cm² intensity. Patients in the control group were treated with conservative therapy, which included topical application of NSAIDs in the form of gels and creams, the use of supporting straps, an exercise program, modification of activity levels, friction massage, and placing hot or cold packs on the injured part of the body.

**Statistical Analysis:** The outcomes of the study were statistically analyzed by using the IBM SPSS v.25 program. The means and standard deviations were estimated from all six questions of each parameter. Comparisons were made by performing T-tests. The difference in means and standard deviations from each group were estimated by paired-samples T-tests pre-treatment, post-treatment and 4-week follow-up. Additionally, the difference in means and standard deviations between groups were carried out for each parameter of the therapy pre-treatment, post-treatment and 4-week follow-up using independent samples T-test.

**Ethical considerations:** This study followed all fundamental ethical principles that govern the conduct of research such as full confidentiality regarding the patients’ data, the safety of the material, and anonymity of the participants. Finally, the study protocol complied with the Helsinki Declaration and was approved by the Ethical Committee of the University of Peloponnese.

**Results**

One hundred and thirty patients were diagnosed with Achilles tendinopathy (60 males and 70 females). From these, 65 patients (27 males and 38 females) constituted the shockwave intervention group, 52 patients (27 males and 25 females) constituted the therapeutic ultrasound group, and 13 patients (6 males and 7 females) made up the control group. Consequently, 43 patients of the shockwave intervention group were submitted to 3 treatments, 17 patients to 4 treatments, 4 patients to 5 treatments (once a week), whereas all the patients of the therapeutic ultrasound group (52) were submitted to 10 treatments (three times a week). All patients in the shockwave intervention group did not receive any medication during the entire course of treatment, whereas 42 patients of the therapeutic ultrasound group received oral NSAIDs. Finally, all patients in the control group used topical application of NSAIDs in the form of gels and creams.

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a) Comparison of shockwave intervention group vs control group: (Table 2)
The mean of the reported pain, functional impairment and quality of life impairment showed significant reductions both after the completion of the therapy ($p<0.001$) and at 4-week follow-up ($p<0.001$). In fact, these reductions reached to zero levels at the 4-week follow-up in all three parameters tested. Patients in the control group revealed minor reductions, in all parameters tested both post-treatment and at the 4-week follow-up. Thus, the results in the shockwave intervention group were significantly improved compared to the control group, both post-treatment ($p<0.001$) and the 4-week follow-up ($p<0.001$).

b) Comparison of therapeutic ultrasound group vs control group: (Table 2)
In the therapeutic ultrasound group, the mean of pain intensity, functional impairment and quality of life impairment declined significantly post-treatment ($p<0.001$). However, at the 4-week follow-up, the results were slightly inverted towards the pre-treatment state in all three parameters tested. The results in the control group indicated minor reductions, in all parameters tested both post-treatment and at the 4-week follow-up. Thus, the results in the therapeutic ultrasound group were significantly better compared to the control group, both post-treatment ($p<0.001$) and the 4-week follow-up ($p<0.001$).

c) Comparison of shockwave intervention group vs therapeutic ultrasound group: (Table 2)
In comparison, the results in the shockwave intervention group were significantly better than those of the therapeutic ultrasound intervention group both post-treatment ($p<0.001$) and at 4-week follow-up ($p<0.001$) in all three parameters tested.

Discussion
The outcomes of the present study indicate that radial shockwave therapy achieved significant improvements in pain, the functionality of lower limbs and quality of life after the completion of the therapeutic intervention and the 4-week follow-up in patients with Achilles tendinopathy. Accordingly, significant improvements in pain, functionality, and quality of life were also observed when patients were treated with therapeutic ultrasound, but these findings were less pronounced compared to ESWT. Thus, the present study clearly indicated that radial ESWT is more effective than therapeutic ultrasound in pain alleviation and improvements in both functional ability of lower limbs and quality of life for Achilles tendinopathy.

Many studies have investigated the effect of shockwave therapy in the treatment of Achilles tendinopathy. In a randomized control study, Rasmussen et al. [22] revealed significant improvements on functional recovery as assessed by the AOFAS score when patients were treated with ESWT versus placebo after the completion of the therapy with better results seen at the 8- and 12-week follow-up. However, the reduction in pain did not reach significance level giving as an explanation for the poor effect on pain due to the early recovery at a full level of activity. For the ESWT treatment protocol, they used 2,000 shocks, 0.12 to 0.151 mJ/mm² and 50 Hz for four sessions in total once a week. Lakshmanan and O’Doherty [23] treated Achilles tendinopathy by giving 3 radial shockwave sessions with one week apart. At each session, 2,000 impulses of radial shockwaves were delivered targeting the painful area of the Achilles tendon under 2.5 bar pressure and a frequency of 6-10 Hz. The results showed a significant decrease in pain ($p<0.001$) as evaluated by VAS score, and a significant improvement in functionality ($p<0.001$) as assessed by VISA-A score post-treatment.

In a randomized control trial, Rompe et al. [24] treated 50 patients with chronic recalcitrant insertional Achilles tendinopathy comparing the effect of eccentric exercise versus low-energy radial ESWT. Three sessions of low energy ESWT using 2,000 shocks once a week (0.1 mJ/mm², 8 Hz) were administered. Low energy ESWT therapy was found superior to eccentric loading at four-month follow-up, and these results remained stable at the one-year follow-up. Similarly, Rompe et al. [25] also showed an improvement in the VISA-A scale, which assesses pain, function and activity of Achilles tendon both after the completion of the therapy and the 4-month follow-up and these outcomes were better when ESWT was used together with eccentric loading than the eccentric loading alone. Similarly, Mansur et al. [26] treated patients suffering from insertional tendinopathy with radial shockwaves (2,000 to 3000 pulses, 7 to 10 Hz frequency and 1.5 to 2.5 bar of intensity) together with an eccentric exercise protocol where they found significant improvements on VAS, AOFAS and VISA-A scores after the 24-week follow up. Vulpiani et al. [27] also presented a significant improvement on pain ($p<0.001$) and subjective clinical evaluation two months after the end of treatment where the pain decreased further, and this improvement continued until 12 months post-treatment. Furthermore, Pavone et al. [28] also treated 40 patients suffering from chronic insertional Achilles tendinopathy with 4 sessions of low-energy ESWT at a 2-week interval by using 800 shocks per session (4 Hz, 14 KeV) together with eccentric exercises. At the 12-month follow-up, 65% of the patients got back to normal activities without any pain complaints, 27.5% of the patients also got back to normal activities despite the pain experienced (VAS score 2-4), and only 7.5% of the patients still complained of pain with a VAS score higher than 4. Thus, therapy with low-energy ESWT together with eccentric exercises is effective in both reducing pain as evaluated by VAS score and function recovery as assessed by AOFAS score.

Furia [29] investigated the clinical outcomes of a single dose of high-energy ESWT (3,000 shocks, 0.21 mJ/mm², total energy flux density 604 mJ/mm²) for the treatment of chronic insertional Achilles tendinopathy. A significant reduction was observed in pain as assessed by Visual Analogue Scale compared to control. Twelve months post-treatment, the number of patients with improved Roles and Maudsley scores was statistically higher in the ESWT group compared to the control group.

In a recent prospective study, Taylor et al. [30] evaluated the effectiveness of ESWT in the treatment of refractory Achilles tendinopathy and found pain and function improvement among different age groups on a 24-month follow-up. However, no control was included in the study, and therefore no comparisons were made. Elmallah and Elattar [31] investigated the effect of ESWT and mesotherapy on chronic Achilles tendinopathy in athletes. Treatments were performed once a week for 4 weeks, and the outcomes were recorded pre-treatment, 4 weeks, and 12 weeks after interventions. The results showed improvements in both groups with better outcomes in the ESWT group as assessed by VAS score and AOFAS score, reaching significant differences at the 12-week
follow-up. In their meta-analysis, Al-Abbad and Simon [32] selected 6 studies to investigate the effectiveness of low-energy ESWT in treating chronic Achilles tendinopathy. Four studies reported significant improvements with ESWT in both pain scores and functional outcome for a minimum of a 3-month follow-up. Overall, they indicated that the ESWT was effective with a level of evidence I, especially when ESWT was associated with eccentric exercises. Another meta-analysis by Gerdesmeyer et al. [33] also selected 6 clinical trials and concluded that ESWT is effective in chronic Achilles tendinopathy as evaluated by pain and functional recovery. Although many studies have shown the efficacy of extracorporeal shockwave therapy in treating Achilles tendinopathy, only a few have investigated the efficacy of therapeutic ultrasound, and none has compared ESWT with therapeutic ultrasound. In a pilot study, Chester et al. [16] compared the eccentric calf muscle training with therapeutic ultrasound. The treatment protocol for the ultrasound included 2 sessions a week for 6 weeks using 3 MHz at 0.5 W/cm². The results showed pain (assessed by VAS scale) and functional (assessed by the functional index of the leg and lower limb-FILLA) improvements during the 6 weeks of ultrasound. Although pain at rest and during walking and sport had increased again at 12 weeks, function continued to improve. However, no difference in the outcomes was found between heavy eccentric loading and ultrasound for the management of Achilles tendinopathy.

Hsu and Holmes [34] used low-intensity pulsed ultrasound in the treatment of Achilles tendinopathy at maximum tendon tenderness for 20 min/day for 8 weeks total. The primary findings showed that more than half of the patients (64%) had good to excellent pain and functional improvements, whereas the rest had minimal benefits from the treatment, but none had progressive worsening of their symptoms during therapy.

Table 1: Pain, functionality and quality of life of the lower limbs as evaluated by the UoP-PFQ questionnaire pre-treatment, post-treatment and at a 4-week follow-up.

<table>
<thead>
<tr>
<th>Lower Limbs</th>
<th>Pain</th>
<th>Functionality</th>
<th>Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Walking, Standing up, Going up and down the stairs, Squatting, Getting in and out of the car, Getting up from a chair</td>
<td>Walking, Standing up, Going up and down the stairs, Squatting, Getting in and out of the car, Getting up from a chair</td>
<td>Going for a walk, Standing in a queue, Getting on/off a bus, Sitting down/ standing up, Stoopwing by bending the knees to pick up an object from the floor, Getting in or out of the bathtub</td>
</tr>
</tbody>
</table>

The ability of the patient to perform each activity was rated on a 5-point Likert scale to evaluate pain (0= no pain and 4= extreme pain), and both the functional and quality of life impairment (0= no difficulty and 4= extreme difficulty).

Table 2: Achilles tendinopathy results in pain, impairment of function and quality of life of ultrasound group (US), control group and shockwave group at pre-treatment, post-treatment and the 4-week follow-up.

<table>
<thead>
<tr>
<th>ACHILLES TENDINOPATHY</th>
<th>Ultrasound Group (n=52)</th>
<th>Control Group (n=13)</th>
<th>Shockwave Group (n=65)</th>
<th>P-value* US vs Control</th>
<th>P-value* Shockwave vs Control</th>
<th>P-value* Shockwave vs US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Pre-Treatment Mean ± SD</td>
<td>2.71±0.35</td>
<td>2.15±0.14</td>
<td>2.35±0.54</td>
<td>0.061</td>
<td>0.084</td>
<td>0.076</td>
</tr>
<tr>
<td>Post-Treatment Mean ± SD P-value**</td>
<td>1.12±0.27 &lt;0.001</td>
<td>1.95±0.13 &lt;0.001</td>
<td>0.11±0.14 &lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4-Week Follow-Up Mean ± SD P-value***</td>
<td>1.24±0.23 &lt;0.001</td>
<td>1.84±0.11 &lt;0.001</td>
<td>0.00±0.02 0.101</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Functional Impairment Pre-treatment Mean ± SD</td>
<td>2.71±0.34</td>
<td>2.14±0.14</td>
<td>2.36±0.50</td>
<td>&lt;0.001</td>
<td>0.118</td>
<td>0.076</td>
</tr>
<tr>
<td>Post-Treatment Mean ± SD P-value**</td>
<td>1.14±0.28 &lt;0.001</td>
<td>2.00±0.12 &lt;0.001</td>
<td>0.17±0.24 &lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4-Week Follow-Up Mean ± SD P-value***</td>
<td>1.23±0.27 &lt;0.001</td>
<td>1.99±0.11 0.670</td>
<td>0.01±0.04 &lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Quality of Life Impairment Pre-treatment Mean ± SD</td>
<td>2.65±0.35</td>
<td>2.29±0.14</td>
<td>2.07±0.50</td>
<td>&lt;0.001</td>
<td>0.131</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-Treatment Mean ± SD P-value**</td>
<td>1.13±0.28 &lt;0.001</td>
<td>2.07±0.09 &lt;0.001</td>
<td>0.16±0.23 &lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4-Week Follow-Up Mean ± SD P-value***</td>
<td>1.17±0.27 &lt;0.001</td>
<td>2.04±0.09 0.337</td>
<td>0.00±0.02 &lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Comparisons between ultrasound and control groups, shockwave and control groups, and shockwave and ultrasound groups at pre-treatment, post-treatment and 4-week follow-up by independent t-test.

**Comparison between pre-treatment and post-treatment within each group.

***Comparison between post-treatment and at the 4-week follow-up within each group.

Conclusions
The present study showed that both extracorporeal shockwave therapy and therapeutic ultrasound are effective in relieving pain and improving the functionality of the lower limbs and the quality of life in the short-term treatment of Achilles tendinopathy. It also exhibited that ESWT has better outcomes in all three parameters examined compared to the therapeutic ultrasound. Thus, both modalities can be used as alternative options in the management of several musculoskeletal disorders, including Achilles tendinopathy, among others, particularly after the failure of other conservative therapies. However, the study has limitations including the lack of a placebo group, the short follow-up period and optimizing the best treatment parameters. Further studies are needed to establish the most effective protocol.

References
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