**Original Article** 

# **Comparison of Radial Extracorporeal** Shockwave Therapy versus Ultrasound Therapy in the Treatment of Rotator Cuff Tendinopathy

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#### Abstract

Introduction: People suffering from rotator cuff tendinopathy exhibit reduced mobility due to pain. The pain and the limited functionality affect negatively the overall quality of life.

Aim: The present study aimed to investigate the intensity of pain, the functionality of the upper limbs and the quality of life of patients with rotator cuff tendinopathy by using two different therapeutic modalities, shockwave and ultrasound, whose outcomes were assessed pre-treatment and post-treatment as well as after a 4-week follow-up.

Materials and methods: Out of the total sample of 115 patients with rotator cuff tendinopathy, 56 patients constituted the shockwave intervention group, 47 patients constituted the therapeutic ultrasound group and 12 patients made up the control group. The self-administered questionnaire "The University of Peloponnese Pain, Functionality and Quality of Life Questionnaire, UoP - PFQ" was used where the intensity of pain, functionality and quality of life of the upper limbs were evaluated on a five-point Likert scale, pre-treatment, post-treatment and at a 4-week follow-up.

Results: The pain intensity was reduced and both the functionality and quality of life were improved after shockwave therapy post-treatment (p<0.001) and at a 4-week follow-up (p<0.001) compared with those found after the treatment. Similar improvements in all three parameters were also observed after ultrasound treatment but the outcomes were not as pronounced as in the shockwave group.

Conclusion: Both radial shockwave and ultrasound therapies were found to be effective in the treatment of rotator cuff tendinopathy, the statistical analysis showing that radial shockwave therapy was superior to the ultrasound therapy post-treatment and at the 4-week follow-up.

#### **Keywords**

musculoskeletal injuries, shockwave therapy, tendinopathy, rehabilitation, ultrasound therapy,

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#### INTRODUCTION

Rotator cuff tendinopathy is defined as pain and tenderness of the shoulder followed by hypersensitivity above the head of the humerus<sup>1</sup> leading to inflammatory and degenerative lesions of the rotator cuff tendons of the shoulder and the long head of the biceps.

The incidence of shoulder tendinopathy is related to performing activities involving extended arm lifts, repetitive shoulder flexion and repetitive and dynamic movements of the arms. The risk of injury is particularly high when repetitive activities are performed above the shoulder height, due to the load on shoulder tendons.<sup>2</sup>

The most common symptom of rotator cuff tendinopathy is shoulder pain which is usually related to movement, muscular weakness, and mobility reduction. As symptoms progress, pain can become constant and can prevent patients from sleeping on the affected shoulder. Rotator cuff tendinopathy causes intense pain on the upper external side of the shoulder, with possible reflection on the lateral side of the shoulder and the arm. Active movement, especially abduction, increases the pain. Tenosynovitis of the head of the long biceps causes pain on the anterior side of the shoulder with possible reflection on the arm. Resistance to bending also causes pain. In addition to pain, patients may experience a worsening of their ability to perform movements that require the rotation, flexion or abduction of the shoulder.<sup>3</sup>

The symptoms of rotator cuff tendinopathy, shoulder pain in particular, can be relieved by using conservative therapies such as analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), a corticosteroid injection locally, physical therapy including ESWT, laser therapy and ultrasound therapy, whereas surgical treatment must be used as the last resort when other conservative therapies have failed.<sup>4-7</sup>

Therapeutic ultrasound is a commonly used modality by many physiotherapists for treating many forms of tendinopathies and muscle injuries including rotator cuff, plantar fasciitis and lateral epicondylitis among others. Therapeutic ultrasound is targeted at the tissues by both its thermal and non-thermal effects. The thermal effects aid pain relief by increasing the temperature of the local tissue, increasing the blood flow locally, reducing the local swelling and initiating the resolution of the chronic inflammatory state. The non-thermal effects stimulate the tissue repair process via cavitation and acoustic microstreaming.<sup>8,9</sup>

Extracorporeal shockwave therapy (ESWT) is an innovative modality which has gained popularity in the last decade in the treatment of various painful musculoskeletal diseases, especially when other conservative treatments have failed. The mechanism by which ESWT produces its effects is still not elucidated. ESWT is believed to induce neovascularization at the bone-tendon junction, it releases growth factors such as eNOS (endothelial nitric oxide synthase), PCNA (proliferating cell antinuclear antigen) and VEGF (vascular endothelial growth factor), which improve blood supply and increase cell proliferation leading to tissue regeneration, whereas its analgesic effect is achieved by inhibiting the activation of the serotonergic system and the peripheral denervation.<sup>10-12</sup>

#### AIM

The present study aimed at comparing the efficacy of the therapeutic ultrasound used regularly in physical therapy practices and extracorporeal shockwave therapy, a relatively new physical therapy modality, both of which can be used in the conservative treatment of the rotator cuff tendinopathy. Additionally, this is the first study which compares extracorporeal shockwave therapy and ultrasound therapy investigating pain reduction and both shoulder function and quality of life improvements during this comparison.

# MATERIALS AND METHODS

#### **Research Population**

A total of 115 patients with rotator cuff tendinopathy who were seen at an orthopedic clinic from February 2015 to August 2017 by the physicians included in the current study. Out of the total sample, 56 patients were treated with radial shockwaves and constituted the shockwave group (group A), 47 patients were treated with therapeutic ultrasounds and constituted the ultrasound group (group B), and 12 patients made up the control group (group C).

The exclusion criteria were as follows: a) patients under the age of 18, b) patients with a systemic infection or inflammatory rheumatic disease, c) patients with malignant diseases, d) people who had undergone surgery of the shoulder or neck.

#### **Research Tools**

For the purposes of this research study, the self-administered questionnaire 'The University of Peloponnese Pain, Functionality and Quality of life Questionnaire - the UoP-PFQ' was used on a five-point Likert scale, pretreatment, post-treatment and during the 4-week follow-up as described by Dedes et al.<sup>13</sup>, which consisted of four parts. Briefly, the first and second parts were completed by the patients of all three groups before the initiation of the therapy (pre-treatment). The first part contained the demographic characteristics whereas the second part (**Table 1**) was divided into three sections, one for the estimation of the perception of pain upon precise movements on a five-point Likert scale where 0= no pain and 4= severe pain intensity. The second section assessed the functionality of the upper limbs upon specific movements, on a five-point Likert scale where 0= no difficulty and 4= extreme difficulty. The third section examined the quality of life by assessing the difficulties in performing specific daily tasks on a five-point Likert scale where 0= no difficulty and 4= extreme difficulty. The third part of the questionnaire was completed by the physician and included information 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, medication, etc. Finally, the fourth part of the questionnaire was identical to part two and it was completed by the patients of all three groups post-treatment and at the 4-week follow-up. The internal consistency of the questionnaire (Cronbach's alpha coefficient) was tested and found equal to 0.88.

Patients of group A received radial shockwaves by using a STORZ MEDICAL Masterpulse MP200 device with the following parameters: in the first session, a high frequency of 21 Hz, a pressure of 1.8 bar and 2000 shocks were used to achieve analgesia, whereas in the case of the remaining sessions, the frequency was set at 15 Hz, the pressure at 1.8 bar and 1500 shocks in order to carry out the therapy. Patients in group B received therapeutic ultrasound waves by

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

	Shoulder						
Pain	Opening the arms						
	Wiping the table						
	Hanging a curtain						
	Cleaning windows						
	Scratching the back						
	Washing the car						
Functionality	Opening the arms						
	Doing circular movements with the hands						
	Lifting up the hands						
	Moving the hands in circular movements when raised						
	Touching the back						
	Touching the back of the neck						
Quality of life	Stretching with extended hands						
	Cleaning the table						
	Picking up an object from a high shelf						
	Cleaning the windows						
	Scratching the back						
	Washing hair						

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).

using a Gymna Pulson 200 device set at a frequency of 3 MHz and intensity of 2 W/cm<sup>2</sup>. Patients of group C were treated with conservative therapy, which included the local application of NSAIDs in the form of gels and creams, the use of supporting straps and an exercise program for the tendinopathy, modification of activity levels, friction massage, and the placement of hot or cold packs on the injured part of the body.

#### **Statistical analysis**

The statistical analysis was performed using the IBM SPSS v. 25 programme. It provided outcomes regarding the frequencies, the means and the standard deviations of the answers on each question of the questionnaire. Then, there was a calculation of the means and the standard deviations of the answers of the six questions which compose each parameter. Finally, the core of the statistical analysis provided the final results, performing t-tests. Specifically, a paired sample t-test was used to find the difference of the means and the standard deviations in each group, before, after the treatment and follow-ups for each parameter and therapy. Then, an independent sample t-test was performed for the difference of the means and the standard deviations between groups, before, after the treatment and follow-ups for each parameter and therapy.

#### **Ethical considerations:**

This research study was conducted following all the fundamental ethical principles. Particularly, full confidentiality and anonymity of the participants were ensured and the results obtained were used only for the purposes of this study. Finally, the study protocol was in compliance with the Helsinki Declaration and was approved by the University's Ethics Committee (Faculty of Human Movement and Quality of Life Sciences).

# RESULTS

Rotator cuff tendinopathy was diagnosed in 115 patients, 55 men (47.8%) and 60 women (52.2%). Out of these, 56 patients were treated with shockwaves (26 men and 30 women), 47 patients were treated with therapeutic ultrasound waves (23 men and 24 women) and 12 patients constituted the control group (6 men and 6 women). 40 patients of the shockwave group were submitted to 3 shockwave treatments and 16 patients to 4 shockwave treatments (once a week), while all 47 patients of the ultrasound group were submitted to 10 ultrasound treatments (three times a week). Finally, all 12 patients from group C used the local application of NSAIDs.

a) Comparison of group A versus group C (Table 2): The mean of the reported pain, functional impairment and quality of life impairment were significantly reduced (p<0.001) in group A immediately after the treatment and these reductions were even more pronounced after the 4-week follow-up (p<0.001) compared to post-treatment values. In group C, only minor reductions in all three parameters were observed immediately after the treatment and at the 4-week follow-up. Therefore, the results obtained from group A were significantly better compared to those in group C both after the treatment (p<0.001) and at the 4-week follow-up (p<0.001).

(p<0.001) in group B immediately after the treatment and at the 4-week follow-up. Thus, the results obtained from group B were significantly better compared to those in group C both after the treatment (p<0.001) and at 4-week follow-up (p<0.001).

**c) Comparison of group A versus group B (Table 2):** The results obtained in group A by assessing the pain intensity, functionality impairment and quality of life impairment were significantly better than those from group B

**b)** Comparison of group B versus group C (Table 2): The mean of pain intensity, functional impairment and quality of life impairment were significantly diminished

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

SHOULDER (ROTATOR CUFF)	Ultrasound group (n = 47)	Control group (n=12)	Shockwave group (n= 56)	<i>p</i> -value* US vs Control	<i>p</i> -value* Shockwave vs Control	<i>p</i> -value* Shockwave vs US
Pain						
Pre-Treatment						
mean±SD	2.75±0.45	$2.53 \pm 0.20$	$2.80{\pm}0.47$	0.098	0.053	0.595
Post-Treatment						
mean±SD	0.89±0.09	2.36±0.21	$0.18 \pm 0.40$			
<i>p</i> value**	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
4-Week Follow-up						
mean±SD	0.98±0.22	$2.46 \pm 0.21$	$0.01 {\pm} 0.05$			
<i>p</i> value***	0.010	0.011	0.010	< 0.001	< 0.001	< 0.001
Functional impairment						
Pre-treatment						
mean±SD	2.69±0.47	2.51±0.17	2.73±0.48	0.205	0.128	0.128
Post-Treatment						
mean±SD	0.87±0.17	$2.32{\pm}0.15$	$0.29 \pm 0.45$			
<i>p</i> value**	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
<u>4-Week Follow-up</u>						
mean±SD	0.99±0.18	2.38±0.16	$0.01 {\pm} 0.05$			
<i>p</i> value***	< 0.001	0.100	< 0.001	< 0.001	< 0.001	< 0.001
Quality of life impairment						
Pre-treatment						
mean±SD	2.72±0.47	2.72±0.16	2.73±0.47	0.99	0.957	0.957
Post-treatment						
mean±SD	0.88±0.19	$2.43 \pm 0.17$	0.28±0.37			
<i>p</i> -value**	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
4-Week Follow-up						
mean±SD	0.98±0.21	$2.36 \pm 0.22$	$0.01 \pm 0.03$			
<i>p</i> value***	< 0.001	0.053	< 0.001	< 0.001	< 0.001	< 0.001

\*Comparisons between ultrasound and control groups, shockwave and control groups, and shockwave and ultrasound groups at pretreatment, 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.

both immediately after the treatment (p<0.001) and at the 4-week follow-up (p<0.001).

# DISCUSSION

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 of patients suffering from rotator cuff tendinopathy after the completion of the therapeutic intervention and at the 4-week follow-up. Significant pain reduction and improvement in functionality and quality of life were also observed in the ultrasound group, but these findings were less pronounced than those in the group treated with shockwaves. The control group presented only minor improvements post-treatment and at the 4 week follow-up.

Although it is difficult to directly compare the outcomes from other studies due to the different shockwave devices used or the different dosage of energy flux employed in these studies along with the different time periods used in the follow-ups, in the present study, shockwave treatment showed similar results with other studies in the literature about patients with rotator cuff tendinopathy. Thus, several studies have revealed the benefits of ESWT for the treatment of rotator cuff tendinopathy.

Ioppolo et al.14 reported that both the high and low energy of ESWT (>0.28 and <0.28 mJ/mm<sup>2</sup>, respectively) are significantly effective in the improvement of shoulder function as tested by the Constant Murley Scale (CMS) and in pain reduction by using the VAS score at both 3and 6-month follow-ups. However, the results from the high energy ESWT were found to be more pronounced. Gerdesmeyer et al.<sup>15</sup> in a randomized controlled trial, also noticed that both the high and low energy of ESWT resulted in a significant improvement of the shoulder function measured by the Constant Murley Score and in pain alleviation at the 6-month follow-up compared with the sham treatment and that the high-energy ESWT was superior to the low energy shockwave therapy. Another randomized controlled study performed by Schofer et al.<sup>16</sup> also assessed the high versus low energy shockwave therapy for rotator cuff tendinopathy. They reported a statistically significant improvement in both treatment groups in respect to pain as measured by the VAS score and shoulder function by the Constant Murley score at 12 weeks and 1 year after the therapy, but no significant difference was observed between the high and low energy treatment groups. Furthermore, Albert et al.<sup>17</sup> tested the efficacy of the high versus low energy ESWT on individuals with calcifying rotator cuff tendinitis. They reported that high energy ESWT improved shoulder pain and function as measured by the Constant Murley Score at the 3-month follow-up, whereas no significant change was observed using the low energy ESWT.

Cacchio et al.<sup>18</sup> used the University of California-Los Angeles UCLA Shoulder Rating Scale to evaluate shoulder function after ESWT treatment versus placebo where they found significant improvements in the treatment with ESWT at the 6-month follow-up. Carulli et al.<sup>19</sup> treated individuals with calcific tendonitis of the shoulder where 3 shockwave sessions at monthly intervals were administered using 2400 shockwaves with an intensity of >0.20 mJ/mm<sup>2</sup> for each session. The study reported a significant improvement in pain as evaluated by NRS and in shoulder function as assessed by the Constant Murley Score at 1-, 6-, and 12-month follow-ups. Similar findings were also observed by other studies where significant improvements in pain reduction and shoulder function in the ESWT group were noted compared to the sham group as measured by the Constant Murley Score after the treatment and the various lengths of follow-ups.<sup>20-22</sup>

Sanzo<sup>23</sup> applied radial shockwave therapy involving 3 weekly sessions each session consisting of 2000 shockwaves at an intensity of 2.5 bars and 10-15 Hz administered to patients suffering from chronic rotator cuff tendinopathy. Patients suffering from chronic rotator cuff tendinopathy were assessed according to their shoulder pain based on both the VAS scale and P4 scale and the shoulder functionality on the Upper Extremity Functional Scale (UEFS) questionnaire. The results revealed that radial shockwave therapy significantly improved shoulder function and reduced shoulder pain three months post-treatment. Similarly, the effect of radial shockwave therapy for treating patients with chronic rotator cuff tendonitis was also tested by Li et al.<sup>24</sup> in a randomized placebo-controlled trial. The Shockwave group received 3000 pulses of 0.11 mJ/mm<sup>2</sup> at a frequency of 15 Hz and a pressure of 3 bars. Compared to the placebo, radial ESWT showed greater efficacy in shoulder pain relief with regard to the NRS score and in shoulder function as measured by using the CMS and SST scores at 4 weeks and 8 weeks after treatment. Conversely, radial shockwave therapy for the treatment of chronic rotator cuff tendinitis was performed by Kolk et al.<sup>25</sup> in a randomized double-blind placebo-controlled trial. The ESWT group received 3 sessions, 10-14 days apart, each session with 2000 pulses of 0.11 mJ/mm<sup>2</sup> at a frequency of 8 Hz and a pressure of 2.5 bars. The outcome was assessed using a VAS scale for pain, and the CMS and Simple Shoulder Test (SST) for shoulder function and the results were recorded pretreatment and three and six months after treatment. The VAS, CMS and SST scores improved significantly three and six months after treatment in both the ESWT and placebo groups and thus the study was not able to prove a beneficial effect of the ESWT.

Although numerous studies have investigated the efficacy of extracorporeal shockwave therapy in the treatment of rotator cuff tendinopathy, very few have shown the efficacy of therapeutic ultrasound and none has compared shockwave therapy with ultrasound therapy for this type of tendinopathy. Ebenbichler et al.<sup>26</sup> investigated the effects of therapeutic ultrasound in the calcific tendinitis of the shoulder where they carried out 25 treatment sessions over a 6-week period. The severity of pain, the patient's ability to perform normal tasks of daily living and the active range of motion and power of the shoulder were assessed by the Constant Murley score, whereas pain was also evaluated by the VAS scale. At the end of the therapy, the results showed a greater decrease in pain and a greater improvement in the quality of life than in those treated with sham therapy, but at the nine-month follow-up the differences between these groups were no longer significant.

Ultrasound therapy of 10 sessions over a two-week period was also performed by Lioce et al.<sup>27</sup> for the treatment of shoulder diseases. The pain was evaluated using the Numeric Rating Scale (NRS) whereas the shoulder function was evaluated by both the Constant Murley Score and DASH scale. The results showed a statistically significant reduction of shoulder pain and functional limitations after the completion of the therapeutic ultrasound.

Zafar and Kumar<sup>28</sup> compared therapeutic ultrasound with laser therapy for the management of shoulder rotator cuff muscle injury. The SPADI questionnaire was used to evaluate the self-reported current level of shoulder pain and disability, whereas the shoulder ROM estimated the range of motion of the shoulder joint. Pain was also estimated according to the VAS score. Both interventions showed significant improvements in all parameters performed at both 21 days and 30 days after the interventions, but the results in the laser group were more pronounced than those of the ultrasound group. Similar findings were also observed by Santamato et al.<sup>29</sup> where both ultrasound (10 sessions over a two-week period) and laser therapies showed pain reduction, but the laser treated group experienced a greater reduction in pain compared to the ultrasound group.

# CONCLUSION

The results of the present study have shown that both the extracorporeal shockwave therapy and therapeutic ultrasound are effective modalities in relieving the pain intensity and improving the shoulder function and quality of life as regards the treatment of rotator cuff tendinopathy. However, the results of ESWT were much better when compared with ultrasound therapy. However, the present study has limitations, some of which are the lack of computerized patient randomization, the lack of a placebo group for any of the treatments due to ethical concerns since the patients had been experiencing pain and the first-line treatment had failed and finally the short follow-up period. Thus, further research and clinical trials may be necessary to elucidate the ideal parameters contributing to the efficacy of both shockwave therapy and therapeutic ultrasound.

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# Лучевая экстракорпоральная ударно-волновая терапия в сопоставлении с ультразвуковой терапией при лечении тендинопатии ротаторной манжеты

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# Абстракт

**Введение:** Люди, страдающие тендинопатией ротаторной манжеты, страдают снижением подвижности из-за боли. Боль и ограниченная функциональность негативно влияют на общее качество жизни.

**Цель:** Это исследование было направлено на изучение интенсивности боли, функциональности верхней конечности и качества жизни у пациентов с тендинопатией ротаторной манжеты с помощью двух различных терапевтических методов - ударной волны и ультразвука, результаты которых оценивались до, после лечения, а также во время 4-недельного наблюдения. Материалы и методы: Из общей группы из 115 пациентов с тендинопатией ротаторной манжеты 56 пациентов составили группу лечения ударной волной, 47 пациентов - группу ультразвукового лечения и 12 пациентов составили контрольную группу. Анкета «Боль, функциональность и качество жизни» Пелопоннесского университета (UoP - PFQ) использовалась для самостоятельного заполнения, в которой боль, функциональность и качество жизни верхней конечности оценивались с использованием пятибалльной шкалы Лайкерта до, после лечения и и во время 4-недельного наблюдения.

**Результаты:** Интенсивность боли была снижена, а функциональность и качество жизни улучшились при применении ударно-волновой терапии после лечения (р <0,001) и в течение 4-недельного наблюдения (р <0,001) по сравнению с теми, которые были обнаружены после ультразвукового лечения. Аналогичное улучшение по всем трём параметрам наблюдалось после обработки ультразвуком, но результаты были не такими выраженными, как в группе лечения ударно-волновой терапией.

**Выводы:** Как лучевая ударно-волновая, так и ультразвуковая терапия были определены как эффективные при лечении тендинопатии ротаторной манжеты, и статистический анализ показал, что лучевая ударно-волновая терапия была лучше, чем ультразвуковая терапия после лечения и через 4 недели наблюдения.

#### Ключевые слова

ударно-волновая терапия, мышечно-скелетная травма, реабилитация, ультразвуковая терапия, тендопатия