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**IMPACT OF SHOCK WAVES ON THE SIZE
OF CALCIFICATION IN THE PRESENCE
OF CALCANEAL SPUR AND PLANTAR
FASCIITIS**

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**UTICAJ MEHANIČKOG UDARNOG TALASA
NA VELIČINU KALCIFIKACIJE KOD
PRISUSTVA PETNOG TRNA I PLANTARNOG
FASCITISA**

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IMPACT OF SHOCK WAVES ON THE SIZE OF CALCIFICATION IN THE PRESENCE OF CALCANEAL SPUR AND PLANTAR FASCIITIS

ABSTRACT

Introduction: Plantar fasciitis is a disorder of foot function associated with heel pain. In patients with plantar fasciitis, a common associated finding may be the presence of a heel spur. However, plantar fasciitis can also exist without a heel spur. A heel spur can also be asymptomatic, meaning it can persist with no signs of plantar fasciitis. One of the reasons for conducting this research is that data in the literature on the impact of shock waves on the size of calcifications in plantar fasciitis is sparse.

The aim: The aim of the research was to investigate the impact of the shock wave on the size of the calcifications and the pain intensity in the presence of a heel spur as well as the connection between the size of the heel spur and the pain intensity before and after the application of the shock wave therapy.

Material and methods: The research was conducted as a prospective study with a duration of one year. The study includes 129 subjects of both sexes, who were divided into two groups according to the randomization. In the experimental group, 67 patients were treated with shock waves, while in the control group, 62 patients were treated with classic methods of physical therapy. Treatment outcomes were monitored using VAS score and heel spur size.

Results: The size of calcifications in patients in the experimental group was statistically significantly smaller after 5 therapies compared to before treatment, and it was statistically significantly smaller after 10 therapies than after 5 therapies. In subjects from the experimental group, the VAS score values were lower after 5 treatments, while after 10 they were statistically significantly lower compared to the VAS score values at the start of treatment.

Conclusions: The application of shock waves led to a reduction in heel spurs and a reduction in pain perception in the subjects of our study. However, the reduction in heel spur size caused by the application of the mechanical shock wave was not correlated with the reduction in pain intensity.

Keywords: heel spur, fasciitis, plantar, prospective studies, heel, calcifications, mechanical shock wave, pain

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UTICAJ MEHANIČKOG UDARNOG TALASA NA VELIČINU KALCIFIKACIJE KOD PRISUSTVA PETNOG TRNA I PLANTARNOG FASCITISA

SAŽETAK:

Uvod: Plantarni fascitis predstavlja poremećaj funkcije stopala koji je praćen bolom u peti. Kod pacijenata sa plantarnim fascitisom, vrlo čest udružen nalaz može biti prisustvo petnog trna. Međutim, plantarni fascitis može postojati i bez prisutnog petnog trna. Takođe, petni trn može biti asimptomatski, odnosno može perzistirati bez znakova plantarnog fascitisa. Jedan od razloga za izvođenje ovog istraživanja je taj što su podaci u literaturi o uticaju mehaničkog udarnog talasa na veličinu kalcifikata u okviru plantarnog fascitisa oskudni.

Cilj rada: Ciljevi istraživanja bili su da se ispita uticaj mehaničkog udarnog talasa na veličinu kalcifikata i intenzitet bola kod prisustva petnog trna, kao i međusobna povezanost veličine petnog trna i intenziteta bola pre i nakon primene terapije mehaničkim udarnim talasom.

Materijal i metode: Istraživanje je sprovedeno kao prospektivna studija u trajanju od jedne godine. U studiju je bilo uključeno 129 ispitanika oba pola koji su metodom randomizacije podeljeni u dve grupe. U eksperimentalnoj grupi bilo je 67 pacijenata i oni su lečeni mehaničkim udarnim talasom, dok je u kontrolnoj grupi bilo 62 pacijenta koji su lečeni klasičnim metodama fizikalne terapije. Ishodi tretmana praćeni su VAS skorom i veličinom petnog trna.

Rezultati: Veličina kalcifikata kod ispitanika eksperimentalne grupe posle 5 terapija bila je statistički značajno manja u odnosu na pre tretmana, dok je veličina kalcifikata posle 10 terapija bila statistički značajno manja u odnosu na posle 5 terapija. Kod ispitanika iz eksperimentalne grupe vrednosti VAS skora bile su manje posle 5 tretmana, dok su posle 10 tretmana bile statistički značajno manje u poređenju sa vrednostima VAS skora na početku lečenja.

Zaključak: Primena mehaničkog udarnog talasa dovela je do smanjenja kako petnog trna tako i do smanjenja osećaja bola kod ispitanika u našem istraživanju. Međutim, smanjenje veličine petnog trna koje je uzrokovala primena mehaničkog udarnog talasa nije bilo u korelaciji sa smanjenim intenzitetom bola.

Ključne reči: petni trn, fascitis, plantarni, prospektivna studija, kalcifikati, mehanički udarni talas, peta, bol

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1. Introduction

Plantar pain is a painful condition localized in the plantar segment of the heel. The occurrence of heel pain is a complex process that includes a series of changes at the level of the osteal and soft tissue structures of the foot (Riel, et al. 2017). This pain usually develops gradually and occurs occasionally. Over time, it can become strong and continuous (Ozdemir, et al. 2004). Plantar fasciitis is cited as the most common cause of heel pain (Ahmad, et al. 2016). The other most common causes of this pain are heel spurs, medial or lateral entrapment of the plantar nerve, atrophy of the heel fat pad and/or changes in the elasticity of the fat pad, fracture of the calcaneus, tumors of the calcaneus and surrounding soft tissues, *pes planus* or *pes cavus*, and rheumatic diseases (Ozdemir, et al. 2004).

Any pain has a negative impact on the quality of life, however heel pain, regardless of the cause, additionally limits the mobility and reduces the activity of the patient (Palomo-López, et al. 2018).

The prevalence of plantar pain is around 9.6% of the population that is over 50 years old (Thomas, et al. 2019). From this, it can be concluded that every tenth inhabitant worldwide has a current health problem that, to a lesser or greater extent, affects his/her quality of life.

1.1. Plantar fasciitis

Plantar fasciitis is a disease manifesting as the occurrence of severe pain in the lower segment of the heel bone. In some cases, the pain is localized only in the region of the heel, while in other patients it can occur along the entire length of the medial longitudinal arch of the foot (Tenforde, et al. 2016). It most often occurs between the ages of forty and sixty (Tu and Bytomski, 2011).

The plantar fascia is a connective tissue structure. Similar to tendons and ligaments, it consists of elongated fibrocytes embedded in an extracellular matrix, which is composed of collagen fibers. Fibrocytes are arranged in longitudinal rows and form connections with fibrocytes from adjacent rows. In this way, groups of clearly differentiated connective tissue are formed. (Wearing, et al. 2006).

The origin of the plantar fascia is on the anterior edge of the tuber calcanei. From here the plantar fascia fans out towards the toes. Anatomically, the fibers of the plantar fascia are grouped into three portions: the medial, central, and lateral (Chen, et al. 2014). The central portion of the plantar fascia is the strongest and thickest of the three abovementioned components, and some authors only use the term plantar fascia to denote this particular segment (Ehrman, et al. 2014). This part of the plantar fascia originates from the medial part of the tuber calcanei and separates into five bundles that attach at the bases of the proximal phalanges of the toes (Chen, et al. 2014).

Different parts of the plantar fascia have different thicknesses (Chen, et al. 2014). However, many authors agree that pathological processes at the level of this fascia can lead to its thickening. This thickening is particularly important for establishing the diagnosis of plantar fasciitis, as well as in monitoring the response to treatment of this disease. The thickness of a healthy plantar fascia should not exceed 4 mm (Menz et al., 2019; Hansen, et al. 2018; McMillan, et al. 2009; Aggarwal, et al. 2020).

Pain occurring in patients with thickened plantar fascia can be explained by the occurrence of myxoid degeneration (Lemont, et al. 2003). Also, one of the explanations for the occurrence of pain is the development of neurovascular ingrowth, accompanied by hyperemia (McMillan, et al. 2013). The application of different treatment modalities for plantar fasciitis (local application of

KS, low-intensity laser, ultrasound, corticosteroids), which led to a reduction in pain and improvement of the clinical presentation of this disease, at the same time resulted in a reduction in the thickness of the plantar fascia. This fact directly connects the occurrence of pain and the increase in the thickness of this anatomical structure (Melesa, et al. 2022).

The plantar fascia has two important roles. Its first role is the effect of absorption of mechanical energy, and it involves preparing the foot to absorb the reactive forces of the surface when walking. When the foot touches the ground, the plantar fascia stretches to a limited extent. Limited stretching of the plantar fascia is enabled by the specific structure of the plantar fascia. Dorsiflexion in the ankle joint and simultaneous dorsiflexion of the proximal phalanges of the toes cause its stretching. In this way, the metatarsal joints are stabilized, which is a prerequisite for the foot to be able to absorb the reactive forces of the surface. Another role of the plantar fascia can be observed when the foot is lifted from the ground, during walking. As the result of momentum, the weight of the body is transferred to the front of the foot, which causes the heel to be lifted while the toes are extended. As a result, the plantar fascia is stretched, which raises the longitudinal arch of the foot and prepares the foot to lift off, i.e., push off from the surface. This function is called the windlass effect (Bolgia and Malone, 2004; Jeleč, et al. 2008).

Prolonged trauma causes partial and/or complete disruption of the connective fibers of the plantar fascia. The plantar fascia, as a connective structure, can resist etiological factors, such as repeated trauma, stress, pressure on its individual parts, stretching, and the like, for a long period of time. However, when these etiological factors overpower the ability of the tissue to heal, plantar fasciitis develops. Plantar fasciitis is basically a degenerative disease of the plantar fascia. The name fasciitis suggests that it is an inflammatory disease. However, at the microscopic level we find disorganization of collagen fibers, an increase in the number of fibroblasts, and minimal inflammation of the fascia. All this speaks in favor of the degenerative nature of this disorder (Ehrman, et al. 2014). Plantar fasciitis is usually unilateral, although in some cases it can occur bilaterally (Malliaropoulos, et al. 2016).

Diagnosis is usually established through clinical examination, i.e., through anamnesis and physical examination. The pain in the region of the heel at the insertion site of the plantar fascia to the heel bone is pathognomonic. The pain can occur at any time but is most intense in the morning. During the night, the foot assumes the position of slight plantar pronation. The plantar fascia is relaxed and with the first step in the morning there is a tightening and elongation of this anatomical structure, which is eventually manifested by the appearance of severe pain. This pain can also occur during the day, after rest or if the patient overburdens the foot (athletes, persons carrying heavy loads). The localization of the pain is explained by the fact that the enthesis of the plantar fascia is located exactly at the site of greatest pain. The attachment of the plantar fascia, i.e., its enthesis, suffers great strain from the weight of the body and over time a pathological process develops within it (Trojian and Tucker, 2019). As part of the physical examination, the heel can be palpated in the area of the projection of the plantar enthesis. Also, the Windlass Test can be useful in diagnosing plantar fasciitis. A positive result for this test is pain in the heel caused by dorsiflexion of the fingers in the metatarsophalangeal joints with a stabilized ankle joint. The specificity of this test is 100%, while the sensitivity is 32% (De Garceau, et al. 2003).

Pain in the heel of the foot within differential diagnosis can also occur due to various diseases of neurological, bone and soft tissue structures (Goff and Crawford, 2011; Thompson, et al. 2014). If necessary, additional diagnostics can be performed with X-ray imaging of the feet, ultrasound or MRI examination (Drake, et al. 2022).

It is debatable whether plantar fasciitis occurs more often in men or women. Men are more likely to engage in heavy physical work that exposes the plantar fascia to increased strain. On the other hand, in women, we encounter altered biomechanics of gait as the result of wearing high-heeled shoes (Kirkpatrick, et al. 2017). When it comes to the age of the patients, plantar fasciitis is

more common in the elderly. This is explained by altered gait mechanics, with older adults taking a greater number of shorter steps (Scott, et al. 2007).

Risk factors for the occurrence of plantar fasciitis are the following: body mass index > 27 kg per m^2 , excessive running, intrinsic tightness of the foot and calf muscles, leg length discrepancy, occupations that require prolonged standing or walking, *pes cavus* (high foot arch), *pes planus* (excessive foot pronation), reduced ankle dorsiflexion, and a sedentary lifestyle (Goff and Crawford, 2011).

For a long time, calcaneal spurs were thought to be one of the causes of plantar fasciitis. At present, the understanding of this problem is somewhat different, and the most acceptable theory for the formation of calcaneal spurs is the theory of vertical compression, which will be discussed in one of the subsequent chapters. The fact that these two diseases can be seen simultaneously in a large number of patients sparked the idea of their causal relationship. However, it is most likely that these diseases develop independently of each other. What is definitely true is that these two diseases have similar etiological factors.

1.2. Calcaneal spur

The calcaneal spur was first mentioned in literature in 1900 (Menz et al., 2019). It is believed that the formation of a calcaneal spur is an adaptive mechanism, i.e., the organism's reaction to continuous compression to the heel (Johal and Milner, 2012). There is no exact definition of this structure. However, it is described as a bony growth in the area of the medial end of the tuber calcanei, where the plantar fascia attaches to the heel bone (Kirkpatrick, et al. 2017; Alatassi, et al. 2018). Anatomically, some authors believe that the calcaneal spur lies deep in the plantar fascia, at the site of its attachment to the calcaneus, while others believe that the calcaneal spur is located above the plantar fascia, more precisely at the origin of the flexor digitorum brevis muscle (McCarthy and Gorecki, 1979). Some studies describe the calcaneal spur to be localized at the site of the origin of the abductor hallucis muscle (Forman and Green, 1990). In order to distinguish a calcaneal spur from a cortical irregularity of the heel bone, a criterion was adopted according to which a bone structure larger than two mm is considered a calcaneal spur (Prichasuk and Subhadrabandhu, 1994; Davis, et al. 1994). In their study, Moroney et al. reported that the prevalence of calcaneal spurs was 12.4%. They also pointed out that this prevalence increases with age, the female sex, obesity, diabetes mellitus, and osteoarthritis (Moroney, et al. 2014). In young and middle-aged people, the frequency of calcaneal spurs ranges from 11%, in India, to 21%, in USA. In Europe, the prevalence of heel spurs is around 17%. In the population older than 62 years, the frequency of calcaneal spurs is up to 55%. However, calcaneal spurs are found in as many as 59% – 78% of patients who complain or have complained of heel pain, and in 81% of patients suffering from osteoarthritis (Menz, et al. 2008; Kirkpatrick, et al. 2017). The more frequent presence of calcaneal spurs in the elderly is explained by the change in gait pattern, as well as the shortening of the stride length (Scott, et al. 2007). In their review article, Kirkpatrick et al. reported that, in one study, 98.4% of subjects with calcaneal spurs were over 40 years of age. This means that less than 2% of subjects with calcaneal spurs in this study were under the age of 40 years (Kirkpatrick, et al. 2017).

A calcaneal spur can be simple or irregular in appearance. A simple heel spur has a triangular appearance. The base of the triangle is located next to the calcaneal tuberosity, while the apex is oriented towards the forefoot, i.e., towards the toes. A simple heel spur has well-defined smooth cortical borders and well-developed trabeculae. An irregular spur, as its name suggests, has an irregular structure, ill-defined borders and no clear trabeculae (Rubin and Witten, 1963; Kirkpatrick, et al. 2017).

When the study of calcaneal spurs became more intensive, it was first believed that these bony structures were the cause of plantar fasciitis. However, some authors agreed that the presence of calcaneal spurs in patients with plantar fasciitis resulted from the same risk factors (Moroney, et al. 2014). It often happens that there are no signs of a calcaneal spur in a patient and that its presence is discovered incidentally, when examining the heel for some other reason (Johal and Milner, 2012). The question as to why calcaneal spurs occur in some patients but not for others, it's unclear. What is known is that the occurrence of calcaneal spurs depends on numerous other factors, such as gender, age, the presence of a certain pathology, occupation, lifestyle, and many others (Velagala, et al. 2022).

There are two theories attempting to explain the origin of calcaneal spurs. Initially, the theory of traction by the plantar fascia was developed. According to this theory, when there is an increased tension of the plantar fascia at the site of its attachment to the heel bone, i.e., at the site of its enthesis, the development of an inflammatory reaction occurs. As the result of this reaction, ossification develops in the area of plantar fascia enthesis, in other words, an osteophyte is formed (Bergmann, 1990; Irving, et al. 2007; Velagala, et al. 2022). This theory has not fully been accepted because there are certain limitations to it being understood. According to this theory, the trabeculae within the structure of the calcaneal spur should be positioned horizontally, i.e., in the direction of the pulling force. They are, however, positioned vertically, which speaks in favor of the second theory (Li and Muehleman, 2007). When the tension of the plantar fascia is removed surgically, by removing the heel spur, recurrence is possible. In these patients, traction by the plantar fascia is absent but the heel spur re-forms (Tountas and Fornasier, 1996). Finally, histological examination of the removed calcaneal spurs showed no signs of inflammation (Lemont, et al. 2003; Velagala, et al. 2022).

According to the second theory, the cause lies in vertical compression. The enthesis of the plantar fascia is located in the region of the calcaneus, in the area that comes into contact with the ground and is therefore exposed to significant force. Due to increased vertical pressure, a microfracture of the calcaneus occurs, precisely at the site of this enthesis. As a protective mechanism, due to this prolonged trauma, fibrocartilaginous growths appear. Their role is to protect the calcaneus from microfissures. Accordingly, it can be concluded that the calcaneal spur represents an adaptive mechanism, i.e., a response to vertical force (Kumai and Benjamin, 2002). This theory is supported by the direction of the trabeculae, as described above, which corresponds to the direction of vertical force, as well as by the fact that calcaneal spurs are more common in obese people, as well as in people whose heels are exposed to greater strain (athletes, people who carry heavy loads, workers who work standing up for longer periods of time, etc.), (Menz, et al. 2008; Velagala, et al. 2022).

The investigation of the histological characteristics of calcaneal spurs obtained from cadavers and/or after their surgical removal, has enabled researchers to form a clearer picture, both of the histological features of these structures, as well as of the structures surrounding them. Histologically, the heel spur consists of a core, which is composed of mature lamellar bone, while intramembranous and endochondral ossification can be seen on the surface (Tountas and Fornasier, 1996; Chen and Carter, 2005). The presence of osteoclasts, as well as the irregular surface of the calcaneal spurs, suggest continuous active regeneration of bone tissue (Tountas and Fornasier, 1996; Kumai and Benjamin, 2002). When it comes to the surrounding tissue, for a long time it was believed that the calcaneal spur was completely imbedded in the enthesis of the plantar fascia. However, numerous studies indicate that the calcaneal spur is located above the plantar fascia or is only partially imbedded in it. It is mostly located in the surrounding muscles, such as the flexor digitorum brevis, the quadratus plantae, the abductor hallucis, and the abductor digiti minimi. Extremely rarely, the entire calcaneal spur is located within the plantar fascia, i.e., its enthesis (McCarthy and Gorecki, 1979; Forman and Green, 1990; Barrett, et al. 1995; Abreu, et al. 2003).

For a long time, it was believed that the intensity of pain, with an existing calcaneal spur, depended on its size. It has been proven, however, that neither the size nor the shape of the calcaneal spur shows a statistically significant correlation with symptoms before therapy (Ahmad, et al. 2016). A calcaneal spur can exist without any symptoms and be discovered incidentally during a radiological examination of the foot. Heel pain is not present in these patients. On the other hand, a radiological examination of the feet, in a certain number of patients who consult a doctor because of heel pain, can confirm the presence of a heel spur. As a possible reason as to why pain occurs in some patients with a calcaneal spur, while in others it does not, the shape and position of the calcification is proposed. A vertical calcaneal spur is believed to physically irritate the plantar fascia, whereas a horizontal and/or hooked calcaneal spur does not (Ahmad, et al. 2016).

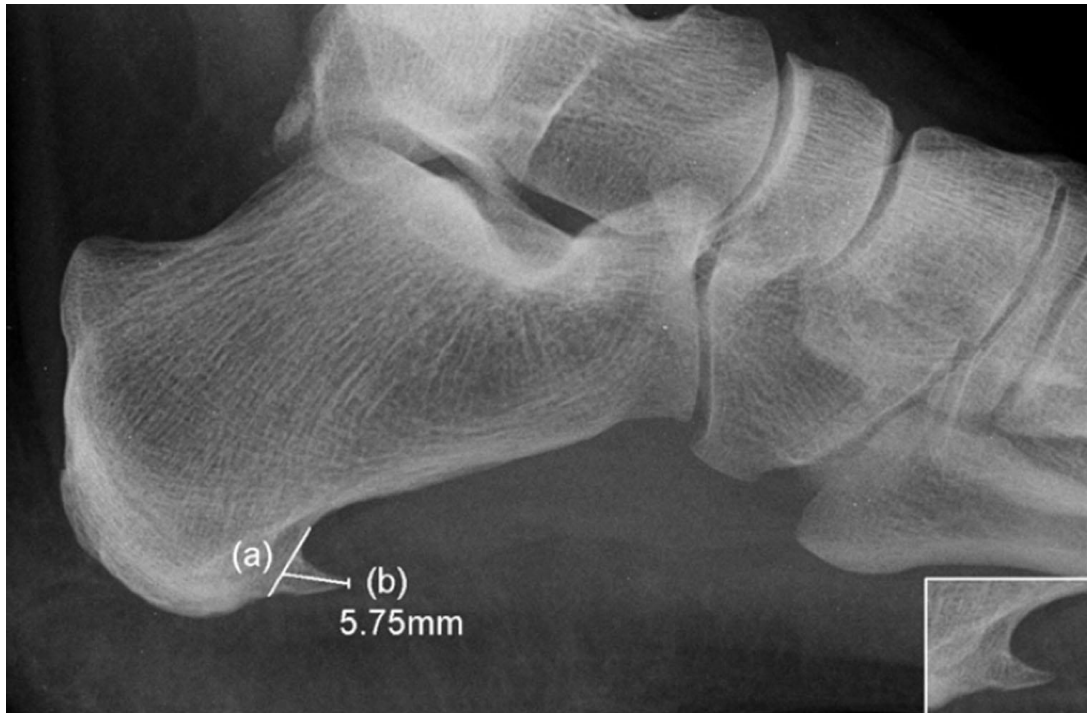


Figure 1.1. Calcaneal spur measuring technique (Johal and Milner, 2012)

There is no uniform classification of calcaneal spurs. For the purpose of easier analysis of these bone structures, some researchers were compelled to make a classification, within their own study. We have found several studies in literature, wherein the classification of calcaneal spurs was made:

- Duvries described three types of calcaneal spurs: type 1 (large and asymptomatic), type 2 (large and painful) and type 3 (small and irregular), (Duvries, 1957);
- Ozdemir et al. classified calcaneal spurs according to size: small (1 – 2 mm), medium (3 – 5 mm) and large (over 6 mm), (Ozdemir, et al. 2004);
- Johal et al. also classified heel spurs according to size: small (1 – 3 mm), medium (4 – 7 mm) and large (over 8 mm), (Johal and Milner, 2012);
- Zhou et al. classified heel spurs based on the anatomical location of the calcification: type A (located above the plantar fascia) and type B (located within the plantar fascia), (Zhou, et al. 2015);
- Ahmad et al. described three types of calcaneal spurs: type 1 (horizontal), type 2 (vertical) and type 3 (hooked), (Ahmad, et al. 2016).

The presence of a calcaneal spur is most easily determined by a lateral x-ray of the heel. Diagnosis of this disease is possible using other visualization methods, such as ultrasound and NMRI (Drake, et al. 2022). There is no universal technique for measuring calcaneal spur size.

However, several authors have described a technique for measuring the size of these bony outgrowths. On the lateral radiograph of the heel, two lines are important. The first line (Figure 1.1. line a) represents the margin of the heel bone and passes through the base of the calcaneal spur. The second line (Figure 1.1. line b) represents the length of the calcaneal spur expressed in millimeters. This line originates at the apex of the heel spur and extends downwards to the previous line that represents the margin of the calcaneus (Johal and Milner, 2012; Hayta, et al. 2016).

1.3. Treatment of plantar fasciitis and calcaneal spurs

Treatment for plantar fasciitis and heel spurs is similar. In both cases, it is pain that brings the patient to the doctor. Therapy for these patients is based on eliminating pain and restoring foot function. Treatment of heel pain is often long-term. It is often necessary to apply several therapeutic procedures. Therapy can be divided into conservative and surgical (Trojian and Tucker, 2019). Patients who complain of heel pain are always first treated with conservative therapy. Symptoms improve in about 80% of patients with plantar fasciitis within 12 months (Buchbinder, 2004). However, 10%–20% of patients require additional therapy (Thomas, et al. 2010). Conservative treatment consists of rest, modification of physical activity, ice massage, application of non-steroidal anti-inflammatory drugs, stretching and strengthening exercises, and heel braces. It is also recommended to adapt the treatment to the patient's symptoms, lifestyle and activity level (Schneider, et al. 2018).

Numerous studies have shown that the application of exercises aimed at stretching the plantar fascia has produced good results (Trojian and Tucker, 2019) Counterstrain exercises can lead to immediate improvement of symptoms in plantar fasciitis (Wynne, et al. 2006). By reducing the strain on the plantar fascia, foot braces reduce the symptoms of plantar fasciitis (Baldassin, et al. 2009). These prostheses, in fact, provide support to the medial arch and thereby reduce foot pronation (Landorf, et al. 2006). Acupuncture is another method in the treatment of plantar fasciitis. This is a traditional Chinese method wherein thin needles are inserted at the site of the trigger points (Zhuang, et al. 2013). Due to the stimulation of certain trigger points, biochemical changes occur within the tissues, resulting in improved blood. All of this ultimately results in the reduction of pain (He and Ma, 2017). Night splints keep the foot and ankle in dorsiflexion. In this way, the foot is prevented from spontaneously assuming the position of plantar flexion. During plantar flexion of the foot, the plantar fascia is shortened. With the first steps in the morning or after a long period of rest, the plantar fascia stretches, resulting in pain. Night splints prevent the occurrence of this pain (Banerjee, et al. 2012, Lee, et al. 2012).

The use of corticosteroids has proven to be one of the methods successful in treating plantar fasciitis. However, corticosteroids are drugs that have a number of side effects. Therefore, the use of these drugs should be limited to as few applications as possible, and when it comes to the method of application, it is justified to administer them locally. Applied locally, as an injection in the region of the heel of the foot, they can cause rupture of the plantar fascia, atrophy of the skin and of the fat pad of the heel (Schulhofer, 2013; Lee, et al. 2014; Thompson, et al. 2014). Rupture of the plantar fascia can result in loss of the longitudinal medial arch of the foot (Kim, et al. 2010).

Ultrasound is also used in the treatment of plantar fasciitis. It increases the level of cellular activity and circulation in the treated tissue (Baker, et al. 2001). In this way, it removes pain and limited mobility, and reduces disability in patients (Akinoglu, et al. 2017). Low-intensity laser therapy can be used alone or in combination with other conservative treatment modalities (Melesa, et al. 2022). The low-intensity laser acts on the metabolism of serotonin, which is a powerful pain suppressant. Also, it stimulates the process of the regeneration of fibrous tissue (Yinilmez Sanmak, et al. 2018).

Plantar fasciitis is a disease which, in a certain number of cases, can resolve on its own or with applied conservative therapy. If patients still have symptoms after a year, it is necessary to consider surgical treatment. Percutaneous and endoscopic methods of accessing the plantar fascia differ. The open procedure requires the patient to stay in bed for a longer period of time and it takes the patient longer to return to their normal everyday activities. Therefore, in today's world, the endoscopic method is more acceptable (Cottom and Baker, 2016). Plantar fasciotomy can be partial and/or complete (Thomas, et al. 2010). Adverse effects that may occur are the following: infection, arch destabilization, midfoot pain, heel pain, and loss of arch height (Trojian and Tucker, 2019).

1.4. Mechanical shock waves

Mechanical shock waves are sound waves that propagate through a medium. By spreading through the medium, these waves cause it to deform, i.e., change its density. Extracorporeal mechanical shockwave therapy is a non-invasive form of treatment developed from extracorporeal shock wave lithotripsy. Mechanical shock waves are used in urology for lithotripsy, i.e., stone disintegration. For all other indications, mechanical shock waves are used to induce regenerative changes in tissues (Auersperg and Trieb, 2020).

Historically speaking, mechanical shock waves for the treatment of musculoskeletal diseases originated as a modification of extracorporeal shockwave lithotripsy. The possibility of stone destruction in urolithiasis has encouraged the idea of treating calcifications in musculoskeletal diseases (Notarnicola and Moretti, 2012). The first research related to the application of mechanical shock waves for the treatment of musculoskeletal diseases was carried out in Germany and Bulgaria. However, the desire to introduce mechanical shock waves in the treatment of musculoskeletal diseases was accompanied by a lack of evidence on the effectiveness of this therapy. All this had the effect that, in 1999, funding for this type of treatment by health insurance funds in Germany was discontinued (Auersperg and Trieb, 2020). This was followed by three multicenter studies, initiated by the German Society for Orthopedics and Trauma Surgery. The final results of these studies indicated better mechanical shockwave treatment outcomes, as compared to placebo, which enabled mechanical shock waves to remain a therapeutic option for treating musculoskeletal diseases (Haake, et al. 2002; Haake, et al. 2003; Gerdesmeyer, et al. 2003). Numerous studies followed, whose results suggested that the application of this type of therapy successfully led to a reduction in pain, in patients with plantar fasciitis and other diseases of the musculoskeletal system. Owing to these results, the US Food and Drug Administration also approved the use of mechanical shock waves in the treatment of musculoskeletal diseases (Notarnicola and Moretti, 2012).

A mechanical shock wave is characterized by a large amplitude of positive pressure (10 – 100 MPa), a short pressure rise time ($< 1 \mu\text{s}$), and a small amplitude of negative pressure (1 – 10 MPa) (Rompe, et al. 2007).

There is a number of devices for the production (induction) of mechanical shock waves. Electrohydraulic devices were in use first. With the development of this treatment method, piezoelectric and then various electromagnetic devices (with a flat coil or a cylindrical coil) were developed. All of the abovementioned devices are intended to produce focused mechanical shock waves (Auersperg and Trieb, 2020). In the meantime, the so-called radial devices, which use compressed air or electromagnetic forces to propel a "projectile" within the device, have been developed. The "projectile" reaches high speed and transfers its energy to the applicator, which is in contact with the skin. In this way, mechanical shock waves are transmitted to the tissue via the applicator (Auersperg and Trieb, 2020). Radial devices generate waves whose energy is highest at the point of entry into the treated part of the body. The waves generated in this way spread radially

in all directions and their intensity decreases the deeper they penetrate into the tissue (Auersperg and Trieb, 2020).

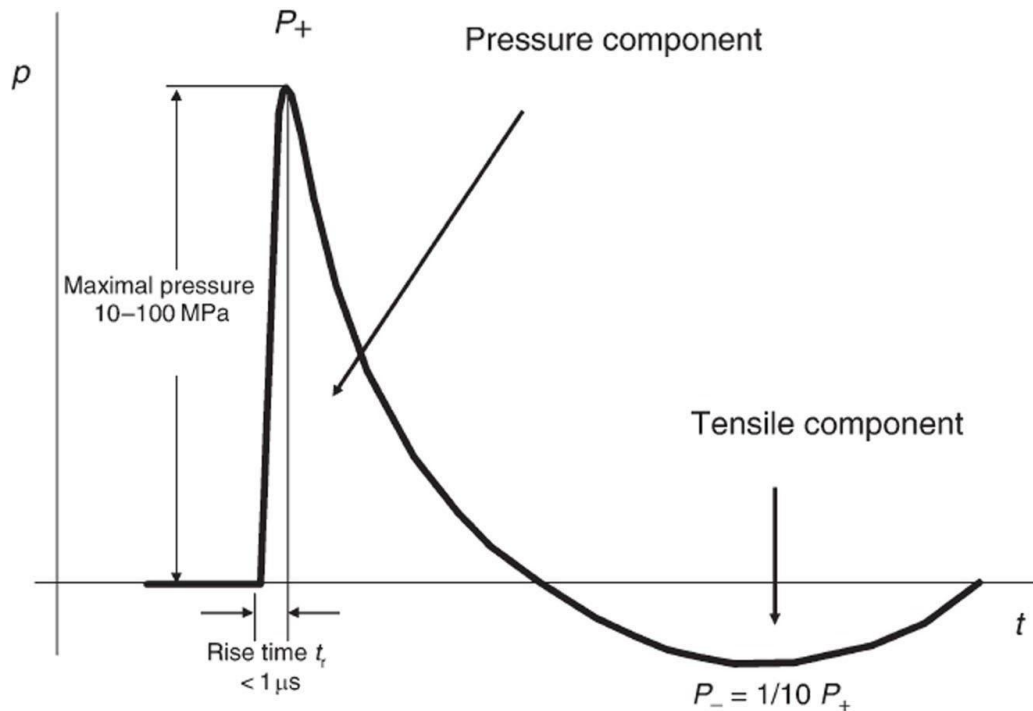


Figure 1.2. Graphic representation of a typical mechanical shock wave (Rompe et al., 2007)

The waves produced by focused mechanical shockwave devices are very different from the waves produced by radial devices. Namely, radial devices produce pressure pulses that do not have the characteristics of a standard mechanical shock wave created in one of the devices for the induction of a focused mechanical shock wave. Also, the rise time and the maximal pressure of the radial wave are much smaller (Auersperg and Trieb, 2020).

The common feature of all focused mechanical shock waves is that they carry the greatest energy in the focus. However, focused mechanical shock waves differ from each other depending on the type of apparatus where they are induced. The quality of electrohydraulic generated mechanical shock waves differs greatly from the quality of shock waves induced in electromagnetic and/or piezoelectric devices (Auersperg and Trieb, 2020). Numerous studies using mechanical shock waves describe results that sometimes contradict each other. The question arises as to whether the reason for the difference in efficiency lies, in fact, in the difference in the quality of differently induced mechanical shock waves. The answer to this question has not yet been found, but the fact remains that impulses do differ from each other (Auersperg and Trieb, 2020).

Radial mechanical shock waves have the point of highest pressure and of highest energy flow density outside the tissue, i.e., at the tip of the applicator. On the other hand, focused mechanical shock waves have the point of highest pressure and highest energy flow density in the center of the focus, in other words, within the treated tissue. These facts are the main reason why radial mechanical shock waves are better tolerated than focused mechanical shock waves (Chang 2012, Eslamian, et al. 2016).

When the use of mechanical shock waves in the therapy of diseases of the musculoskeletal system began, it was considered that the use of higher energy waves gave better results. However, it was observed very early on that lower intensity waves caused tissue regeneration without damaging it (Rompe, et al. 1998). Depending on the energy they carry, i.e., depending on the energy flux

density, mechanical shock waves can be divided into the following categories (Chow and Cheing, 2007):

- low energy mechanical shock waves (energy flux density less than 0.1 mJ/mm^2)
- mechanical shock waves of medium energy (energy flux density $0.1 - 0.2 \text{ mJ/mm}^2$)
- high energy mechanical shock waves (energy flux density higher than 0.2 mJ/mm^2).

The biological effects, i.e., the effects of mechanical shock waves on tissue, do not depend only on energy flux density, but on other factors as well. One of the frequently mentioned factors that can affect the effectiveness of this type of therapy is the application of anesthesia. Initially, mechanical shock waves were applied with anesthesia. For this purpose, general, regional or local anesthesia was used (Lohrer, et al. 2010). However, the monitoring of VAS score results showed that anesthesia reduced the effectiveness of mechanical shock waves (Rompe, et al. 2005; Wang, et al. 2019). In their meta-analysis, Wang et al. reported that the use of low-intensity mechanical shock waves, without local anesthesia, in the treatment of plantar fasciitis, was effective and led to a significant reduction in pain. Conversely, they stated that the application of the same therapy for the same indication with the simultaneous use of local anesthesia did not lead to a reduction in pain (Wang, et al. 2019). On the one hand, the use of anesthesia ensures the painless application of mechanical shock waves of higher intensity, while on the other hand, as can be seen from numerous studies, it reduces their effectiveness. Due to the reduction in the effectiveness of this type of therapy, it is recommended that the application of anesthesia depends on the intensity of the applied energy, i.e., that mechanical shock waves of higher energy levels are applied under local anesthesia (Lohrer, et al. 2016). Today, the use of local anesthesia is not recommended when applying mechanical shock waves in the therapy of soft tissue diseases (Schmitz, et al. 2015), while, at the same time, it is considered useful for bone-related indications (Schaden, et al. 2015). Mechanical shock waves that cause pain during application lead to the release of neuropeptides which promote local and central trophic effects for increasing the metabolism in bradytrophic tissues (Klonschinski, et al. 2011; Schmitz, et al. 2015). In their study, Klonschinski et al. state the following: "mechanical shock waves dose-dependently activate and sensitize primary afferent nociceptive C-fibers, but activation and sensitization are prevented if local anesthesia is applied" (Klonschinski, et al. 2011). One of the important advantages of using radial mechanical shock waves, compared to the use of the first generation of focused mechanical shock waves, is that this type of therapy does not require the use of anesthesia. Unlike focused mechanical shock waves, this type of shock waves can be delivered to tissue without the administration of any form of anesthesia (Chang, et al. 2012; Eslamian, et al. 2016).

The mechanism of how mechanical shock waves act on tissue is complex and is explained by mechanotransduction. Namely, mechanical energy causes changes inside the cell, more precisely, changes in the cellular skeleton. In other words, mechanical energy causes changes in the cell which are reflected in the release of mRNA from the nucleus, which further affects various cellular structures, such as mitochondria, the endoplasmic reticulum, intracellular vesicles, etc., so that the enzymatic response leads to an improvement in the healing process (Wang, et al. 2003, Auersperg and Trieb, 2020). In animal experiments, it has been proven that mechanical shock waves induce oxygen and free radicals, which further promote the production of certain growth factors (Wang, et al. 2004, Auersperg and Trieb, 2020). This type of therapy reduces the expression of matrix metalloproteinases and pro-inflammatory interleukins. Mechanical shock wave also increases the synthesis of growth factors and the release of anti-inflammatory cytokines, thus stimulating the tissue recovery process (De Girolamo, et al. 2014). Over time, mechanical shock waves reduce pain and improve organ function by, among other things, leading to intense axon stimulation and a reduction in the number of unmyelinated sensory fibers. Also, by increasing angiogenesis, they lead to tissue revitalization (Chang, et al. 2012).

Fast healing with the use of mechanical shock waves is not possible. Healing with this type of therapy takes time (Auersperg and Trieb, 2020).

The indications for the application of mechanical shockwave therapy are numerous (DIGEST Guidelines, 2019):

1. Tendinopathies in the upper extremities: *Tendinosis calcarea*, radial epicondylopathy, ulnar epicondylopathy, and *Morbus Dupuytren*;
2. Tendinopathies in the lower extremities: trochanteric pain syndrome, plantar fasciitis, Achilles tendon tendinopathy, patella tip syndrome, tibial stress syndrome, hamstring tendinopathy, and *Morbus Ledderhose*;
3. Cartilage and bone: arthrosis, *Osteochondrosis dissecans*, bone marrow edema syndrome, pseudarthrosis, and stress fractures;
4. Skin: extracorporeal shock wave therapy on the skin and extracorporeal shock wave therapy on cellulite;
5. Myofascial pain therapy;
6. Urology: extracorporeal shockwave therapy of urological diseases.

Regardless of such a large number of indications, the application of mechanical shock waves has shown the best results in the treatment of certain orthopedic diseases. Some of the conditions in which the role of this type of therapy has been more intensively studied are as follows: non-union of bone fractures, calcifying tendinitis of the shoulder, lateral epicondylitis of the elbow, plantar fasciitis, and inflammation of the Achilles tendon (Wang, et al. 2003).

The application of mechanical shock waves is quite safe and there are only a few known side effects that can occur with the application of this therapy. These side effects are the appearance of pain during the procedure and the appearance of minor hematomas. The way that this therapy produces pain has been described earlier in this segment of the study. Contraindications for the application of mechanical shock waves are as follows: coagulopathy, the presence of an embryo or fetus, and severe infections (Auersperg and Trieb, 2020).

From all that has been described above, plantar fasciitis has a high frequency in the general population. Just like plantar fasciitis, a calcaneal spur can also often be the cause of heel pain. Each of these diseases separately, or in many cases together, greatly affect the quality of life in patients. In addition to the pain present, patients also have limited mobility, which makes daily activities even more difficult. As a result, patients are forced to take long-term rest, treatment and absence from work. As we have seen, there is a number of therapeutic options, but in a certain number of cases, patients do not respond appropriately to therapy, which is why in such cases it is necessary to resort to surgical treatment. All therapeutic procedures carry certain costs. Some of them are cheaper and some are more expensive. Also, being absent from work leads to additional costs that are not negligible. Because of all this, it is necessary to help the patient heal and return to their normal way of life, as soon as possible.

On the other hand, the application of mechanical shock waves for therapeutic purposes has not been fully explored. It is a relatively new therapeutic option, which, based on current knowledge, is expected to have a bright future. Patients tolerate it well, it is non-invasive, easy to perform, and relatively inexpensive. Because of all the above, we believe that studies such as ours would greatly contribute to the development of this therapeutic method.

2. Aims and Objectives

The aims and objectives of this thesis were as follows:

1. to investigate the impact of the mechanical shock wave on calcification size, in case of a calcaneal spur;
2. to investigate the impact of the mechanical shock wave on pain intensity, in case of a calcaneal spur;
3. to investigate the association between the size of the calcaneal spur and pain intensity, before and after shockwave therapy application

3. Material and methods

3.1. Study design

The research was conducted as a prospective study, at the Clinic for Physical Medicine and Rehabilitation of the Clinical Center of Serbia, Faculty of Medicine, University of Belgrade, lasting one year. The study included 129 subjects of both sexes, treated at the aforementioned clinic, in the period between January 1, 2021, and December 31, 2021. The patients were divided into two groups. The experimental group comprised 67 patients, while the control group had 62 patients. Patients in the experimental group were treated with mechanical shock waves, while patients in the control group were treated with standard methods of physical therapy (cryotherapy, drug electrophoresis, magnetotherapy, laser therapy and transcutaneous electrical nerve stimulation – TENS). The Ethics Committee of the Faculty of Medicine, University of Belgrade, approved the execution of this study.

Before starting the study, all patients were given anamnestic data related to the current disease and other diseases that were present in patients. Anamnestic data referred to the current disease as well as to other diseases present in the patients. The data from the anamneses were extensive and precise, with the aim of giving the examiner a clear picture of the complaints for which the patient sought treatment. . From the data obtained, we obtained precise data on the onset and course of the disease. The data obtained from the anamnesis were as follows:

- personal information (sex, year of birth, occupation, place of residence);
- the leg that the patient was complaining of;
- whether the complaints lasted all day or occurred periodically;
- whether the complaints were more pronounced in the morning, during the day or at night;
- whether the complaints affected the mobility of the patient;
- whether walking was difficult;
- duration of complaints prior to visiting the doctor;
- whether, in the meantime, the patient had been taking any drugs, systemically and/or locally;
- whether the patient contacted the doctor for the first time on that occasion or whether he/she had already sought help;
- whether the patient had received any advice from a doctor on a prior occasion;
- whether the patient had put ice on the leg, and if so, who had recommended this to him/her;
- the time when the diagnosis of the patient's pathology was established and by which diagnostic method;
- who decided on the type of diagnostic method applied to determine the size of the calcification;
- according to the patient's opinion, which etiological factor was the cause of the resulting condition;
- whether the complaints occurred after some strenuous activity, such as sports or some other similar activities (track and field, playing tennis, etc.);
- whether a change of footwear had preceded the occurrence of the first complaints;
- whether the patient was overweight (body weight, body height, body mass index – BMI);
- whether a foot injury had preceded the occurrence of the first complaints;
- whether the patient had any foot deformities, such as flat feet (*pedes plani*);
- whether the patient was being treated for diabetes mellitus;
- whether the patient was being treated for any heart disease;

- whether the patient had any malignant diseases;
- whether the patient had had an injury or was treated for a fracture of the leg affected by plantar fasciitis;
- whether the patient had had a knee or hip prosthesis fitted, especially if it was on the side affected by plantar fasciitis.

After anamnesis and clinical examination, the treatment protocols with mechanical shock waves and standard methods of physical therapy were explained in detail to all subjects who met the inclusion criteria and who did not have any exclusion criteria. Also, the patients were familiar with the biological effects, contraindications and side effects of both of the above-mentioned therapies. After this, the respondents opted for one of the two treatment methods.

The inclusion criteria were as follows:

- sensation of pain in the heel of the foot;
- an established diagnosis of plantar fasciitis – first episode;
- radiologically confirmed existence of a calcaneal spur;
- patients above the age of 18 years.

The exclusion criteria were as follows:

- previous existence of plantar fasciitis;
- persons under the age of 18 years;
- absence of a calcaneal spur on X-ray images of the heel;
- previous long-term use of corticosteroids and/or NSAIDs and/or analgesics due to the treatment of other diseases;
- previous injury to the leg affected by plantar fasciitis;
- existence of a contraindication for the application of mechanical shockwave therapy (presence of a metal implant in a patient, malignant tumor in the region of the foot, osteomyelitis in the region of the foot, hemiplegia, hemiparesis, polyneuropathy of various etiology, and an implanted pacemaker);

The size and exact position of the calcaneal spur was determined for all subjects included in the research, using ultrasound or x-ray diagnostics. The size of the calcaneal spur was measured a second time after the fifth mechanical shockwave treatment or after the first cycle of standard physical therapy. The size of the calcaneal spur was measured for the third time after 10 mechanical shockwave treatments, i.e., after the second cycle of physical therapy.

After the researchers explained the study design to them in detail, all of the subjects gave their written consent for inclusion in the study, i.e., they signed their informed consent. Patients from the experimental and control groups who started the study, remained in the study until its conclusion, which means that there were no individuals dropping out of the study. Attrition of the groups was not recorded.

The technique of therapy application differed in the experimental group and the control group.

3.2. Experimental group

Patients in the experimental group were treated with focused mechanical shock waves. The device used in the research for the application of this type of therapy was MASTERPLUS MP 200, serial number: BS 2058, 2011STORZ MEDICAL, Switzerland. This type of apparatus is able to

generate focused or radial mechanical shock waves. The device consists of a compressor, a control (display) panel and an amplifier in the shape of a gun. Various options for the quality of shock waves can be set via the control panel, while the set characteristics of mechanical shock waves can be monitored in real time via the display on the control panel. The frequency of the shock waves, the number of shock waves and their strength can be monitored on the display. The frequency of mechanical shock waves, which can be prescribed using this device, ranges from 1 to 30 hertz (Hz), the number of shocks ranges from 10 to 2,200 per one treatment, while the range of the strength of the shock waves is from 1 to 25 bars.



Figure 3.1. The device used in the study

Each patient was individually informed and prepared for the application method, as well as for the mechanical shockwave application technique itself. The application of mechanical shock waves basically does not cause pain. However, a thin layer of contact gel or malposition (bad angle) of the amplifier can cause pain. Therefore, all patients were warned to report any pain. In order to

fully apply the therapy to the patients, without pain, a sufficient amount of the contact gel, as suggested by the device manufacturer, was used. In case the patient still reported pain during the application of therapy, the angle between the surface of the skin where the mechanical shock wave was being applied and the amplifier was corrected.



Figure 3.2. The amplifier of the device used in the study

The application of therapy to the sole of the foot was carried out via an amplifier for focused mechanical shock waves. The procedure consists of having a bare foot patient lie down on his stomach. A roller is placed under the knee, which provides a relaxing position for the lower leg and foot. The amplifier is placed at a right angle in relation to the skin of the sole of the foot. The point of contact between the amplifier and the skin should be located in the region of the heel of the foot, at the point of greatest pain, which is previously determined by palpation.

The therapy parameters are set via the control panel of the device. In our study, 1,600 shock waves were used, at a frequency of 10 Hz and with a shock strength of 1.6 bars. Mechanical shockwave therapy was performed for seven days. The planned number of treatments was ten. In case of the detection of changes on the patient's skin or in case of the patient's expressed desire, it was possible to stop the treatment earlier. However, all patients in the experimental group ended up having 10 treatments, which means that the treatment lasted a total of 10 weeks.



Figure 3.3. Application of focused mechanical shock waves

3.3. Control group

The subjects of the control group were treated with standard physical therapy methods. The treatment protocol for this group of patients included: cryotherapy, drug electrophoresis, magnetotherapy, laser therapy and transcutaneous electrical nerve stimulation (TENS).

The initial procedure was cryotherapy. It involved applying ice to the sole of the foot along the plantar fascia for five to ten minutes. The ice massage was performed from heel to toe, without strong pressure and observing the recommended duration of the massage. If the patient complained of pain and discomfort after a few minutes of cryotherapy, the massage was stopped. The following day cryotherapy was continued for as many minutes as the patient was comfortable with.

The treatment that was administered next, within the treatment protocol for these patients, was drug electrophoresis. Electrophoresis electrodes were placed along the length of the sole so that the cathode was positioned distally, on the toes, while the anode was placed on the calcaneal part of the plantar fascia attachment. Here, in addition to the effect of the medicine, the effect of the poles of the galvanic current was also achieved. In the acute phase of treatment, when the patients were in severe pain, dexazone and novocaine were administered, as the goal was to relieve the patient's pain, as soon as possible. Drug electrophoresis was applied for 15 to 20 minutes, depending on the drug applied and the surface area of the electrodes that were used.

The next therapy administered according to the treatment protocol was magnetotherapy. A low frequency alternating magnetic field was applied. The method of application was to place the antennas transversely on the foot, by placing one antenna on the dorsal and the other on the plantar side of the foot. The application lasted 20 minutes, with a frequency of 10 Hz and a magnetic field strength of 40 gauss.

Laser therapy followed. Laser biostimulation was applied, with a laser probe that measured one centimeter in diameter. The therapy was applied at the point of attachment of the plantar fascia to the heel bone, as well as along the plantar fascia, at five points in a row. The application time per point was five minutes, with a frequency of 100 Hz.

The last treatment in the series was transcutaneous electrical nerve stimulation. Conventional TENS therapy was applied, lasting 10 minutes, with electrodes placed longitudinally along the plantar fascia.

This protocol was applied for ten days in patients belonging to the control group. It should be noted that cryotherapy was discontinued after five days. In a certain number of patients of this group, the pain completely subsided after a series of ten days of combined physical therapy, and they did not continue the treatment. For those subjects whose pain did not decrease even after a series of ten treatments, a ten-day break was made. After the break, another cycle of therapy was administered for the same duration. Cryotherapy was not prescribed in the new cycle of treatment, because the patient's complaints were already in the subacute phase of the disease.

3.4. Technique of outcome measurement

In our study, treatment outcomes were monitored through calcaneal heel spur size and through pain intensity. Regardless of the group they belonged to, all patients underwent the identical protocol of outcome follow-up.

The size of the calcaneal spur was measured in all patients, at the beginning of the study. To this end, ultrasound or X-ray diagnostics were applied. The size of the calcaneal spur was then measured at the end of the study. In the patients belonging to the experimental group, the size of the calcaneal spur was also measured after five treatments had been applied.

Pain intensity was determined using the Visual Analogue Scale (VAS) for pain. VAS was determined in all patients, at the beginning of the study. The same measurement was repeated after the end of treatment. In the experimental group, patients were subjected to one more measurement, i.e., establishing VAS after the fifth mechanical shockwave treatment.

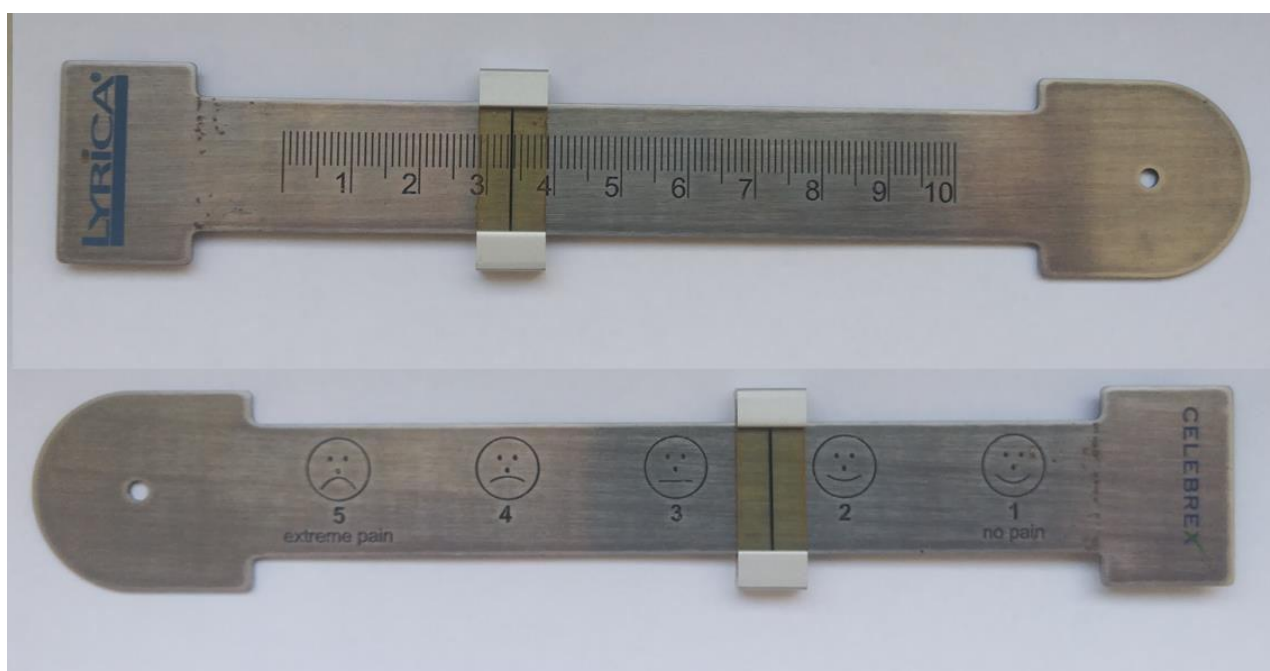


Figure 3.4. VAS scale used in the study

The VAS scale for measuring pain intensity is divided into divisions ranging from 0 to 10. Within this scale, 0 represents the absence of pain, while 10 represents maximum pain. Before being interviewed about the intensity of pain, all patients were informed about which marks were for the highest and which were for the lowest pain. Figure 3.4 shows the VAS scale used in our research. On one side of this scale there are numbers from 0 to 10, while on the other side there are five different facial expressions. The graphic facial expressions are marked with numbers from 1 to 5. The state without pain corresponds to the facial expression marked with number 1, while extreme pain is represented by the facial expression marked with number 5. Facial expressions corresponding to numbers 2, 3 and 4 represent transitional states of pain that are between the above-mentioned two states. Using the VAS scale designed in this way, it is quite simple to quantify pain in patients. However, testing with the VAS scale was only started when each individual patient fully understood the way in which this scale was used.

3.5. Statistical data processing

Depending on the type of variables and the normality of the distribution, the data description is presented as n (%), arithmetic mean \pm standard deviation, or the median (range, min – max). Among the methods for testing statistical hypotheses, the following were used: t-test, Mann-Whitney test, chi-square test, Fisher's exact probability test, the Friedman test and the Wilcoxon test. Quantile regression was used to model the relationship between dependent variables (difference between pre-post median values for calcification size and VAS) and potential predictors. To model the relationship between binary outcomes and potential predictors, logistic regression was used. Statistical hypotheses were tested at a statistical significance level (alpha level) of 0.05.

The results are presented tabularly and graphically. All data were processed in the IBM SPSS Statistics 22 (SPSS Inc., Chicago, IL, USA) software package.

4. Results

4.1. Subjects

Table 1. Distribution of study subjects, by groups

Group	n	%
Experimental group	67	51.9
Control group	62	48.1
Total	129	100.0

Of the total number of subjects involved in the study, 67 (51.9%) belonged to the experimental group, while 62 (48.1%) were in the control group.

4.2. Sex structure

Table 2. Distribution of study subjects, by sex

Sex	Experimental group		Control group		Total	
	n	%	n	%	n	%
Male	32	47.8	34	54.8	66	51.2
Female	35	52.2	28	45.2	63	48.8
Total	67	100.0	62	100.0	129	100.0

Of a total of 129 subjects, 66 were male and 63 were female. There were 32 (47.8%) men in the experimental group and 34 (54.8%) men in the control group. There were 35 (52.2%) women in the experimental group and 28 (45.2%) women in the control group. Such a distribution of men and women did not demonstrate statistically significant differences in the sex structure of the groups ($\chi^2=0.646$; $p=0.422$).

4.3. Age structure

Table 3. Distribution of study subjects, by age

Age (years)	mean	SD	med	min	max	p-value
Experimental group	55.3	10.5	54.0	36.0	88.0	0.123
Control group	51.8	14.3	55.0	20.0	76.0	

The average age of the subjects in the experimental group was 55.3 ± 10.5 years, while the average age of the controls was 51.8 ± 14.3 years, which is not a statistically significant difference ($t=1.555$; $p=0.123$).

A comparison of the experimental group and the control group showed that these two groups were not statistically significantly different with regards to size, sex structure, and age structure.

4.4. Method of diagnosis

Table 4. Distribution of study subjects in the experimental group and the control group, by diagnostic method

Diagnostic method	Experimental group		Control group		Total	
	n	%	n	%	n	%
US	64	95.5	49	79.0	113	87.6
X-ray	3	4.5	13	21.0	16	12.4
Total	67	100.0	62	100.0	129	100.0

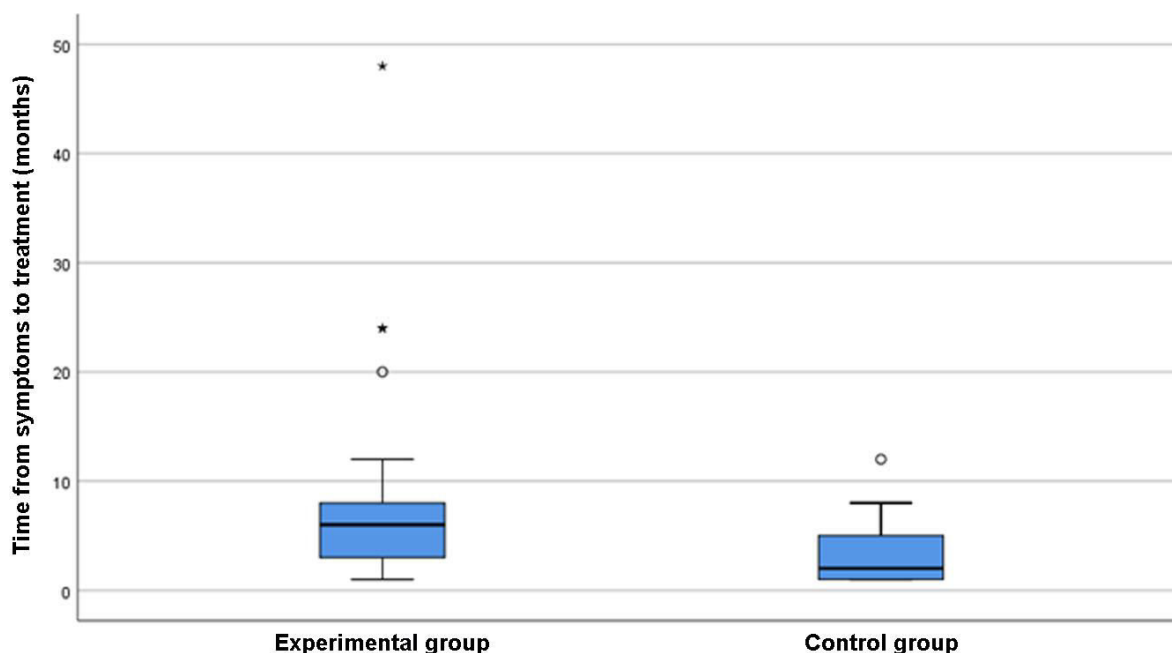
In the experimental group, the diagnosis was established with US in 64 (95.5%) patients, while X-ray was used to establish the diagnosis in three (4.5%) subjects. In the control group, the diagnosis was established with US in 49 (79.0%) subjects, while in 13 (21.0%) patients it was established with the use of X-ray. There is a statistically significant difference ($\chi^2=8.059$; $p=0.005$) in the method of diagnosis between the experimental group and the control group.

4.5. Time from onset of symptoms to beginning of treatment

Table 5. Time elapsed (months) from onset of symptoms to the beginning of treatment of experimental and control group subjects

Time from symptoms to treatment (months)	mean	SD	med	min	max	p-value
Experimental group	7.3	7.6	6.0	1.0	48.0	<0.001
Control group	3.3	2.6	2.0	1.0	12.0	

The median time from the onset of symptoms to the beginning of treatment of the subjects in the experimental group was six months (range: 1-48 months), while it was two months in the control group (range: 1-12 months), which is a statistically significant difference ($U=1120.5$; $p<0.001$). The subjects of the experimental group began treatment significantly later.



Graph 1. Time elapsed (months) from the onset of symptoms to the beginning of treatment of experimental and control group subjects

4.6. Pain during mechanical shock wave application

Most of the subjects felt no pain during mechanical shock wave application. Only 7 (10.4%) subjects reported feeling pain during the application of this form of treatment.

4.7. Affected leg

Table 6. Distribution of study subjects, by leg affected with plantar fasciitis

Affected leg	Experimental group		Control group		Total	
	n	%	n	%	n	%
Right	45	67.2	30	48.4	75	58.1
Left	22	32.8	32	51.6	54	41.9
Total	67	100.0	62	100.0	129	100.0

In the experimental group, 45 (67.2%) subjects had an affected right leg, while in 22 (32.8%) subjects the left leg was affected. In the control group, 30 (48.4%) subjects had their right leg affected, while 32 (51.6%) subjects had an affected left leg, which is a statistically significant difference ($\chi^2=4.665$; $p=0.031$).

4.8. Etiology

Table 7. Distribution of study subjects, by plantar fasciitis etiology

Etiology	Experimental group		Control group		p-value
	n	%	n	%	
	Change of footwear	31	46.3	20	
Track and field sports	24	35.8	18	29.0	0.411
Tennis	40	59.7	29	46.8	0.141
Obesity	18	26.9	16	25.8	0.891
<i>Pedes plani</i>	24	35.8	23	37.1	0.880
Previous foot injury	13	19.4	15	24.2	0.510

Change of footwear, as an etiological factor in the development of plantar fasciitis, was present in 31 (46.3%) subjects of the experimental group and 20 (32.8%) subjects of the control group. There was no statistically significant difference in the change of footwear, as an etiological factor in the development of plantar fasciitis, in experimental and control group subjects ($\chi^2=2.421$; $p=0.120$).

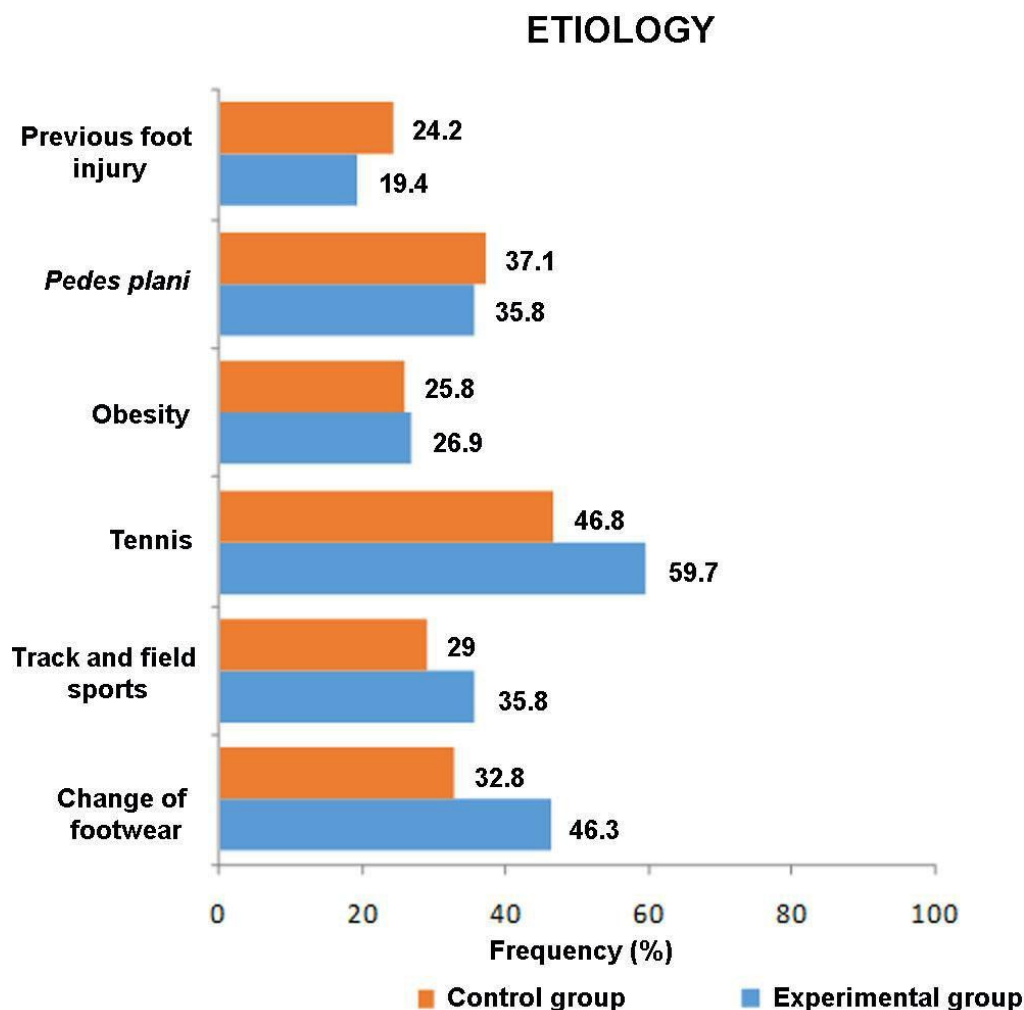
Engaging in track and field sports, as an etiological factor in the development of plantar fasciitis, was present in 24 (35.8%) subjects of the experimental group and 18 (29.0%) subjects of the control group. There was no statistically significant difference regarding the involvement in track and field sports, as an etiological factor in the development of plantar fasciitis, in experimental and control group subjects ($\chi^2=0.676$; $p=0.411$).

Playing tennis, as an etiological factor in the development of plantar fasciitis, was present in 40 (59.7%) subjects of the experimental group and 29 (46.8%) subjects of the control group. There was no statistically significant difference with regards to playing tennis, as an etiological factor in the development of plantar fasciitis, in experimental and control group subjects ($\chi^2=2.163$; $p=0.141$).

Obesity, as an etiological factor in the development of plantar fasciitis, was present in 18 (26.9%) subjects of the experimental group and 16 (25.8%) subjects of the control group. There was no statistically significant difference in obesity, as an etiological factor in the development of plantar fasciitis, in experimental and control group subjects ($\chi^2=0.019$; $p=0.891$).

Pedes plani, as an etiological factor in the development of plantar fasciitis, was present in 24 (35.8%) subjects of the experimental group and 23 (37.1%) subjects of the control group. There was no statistically significant difference in relation to *pedes plani*, as an etiological factor in the development of plantar fasciitis, in experimental and control group subjects ($\chi^2=0.023$; $p=0.880$).

Previous foot injury, as an etiological factor in the development of plantar fasciitis, was present in 13 (19.4%) subjects of the experimental group and 15 (24.2%) subjects of the control group. There was no statistically significant difference in relation to previous foot injury, as an etiological factor in the development of plantar fasciitis, in experimental and control group subjects ($\chi^2=0.435$; $p=0.510$).



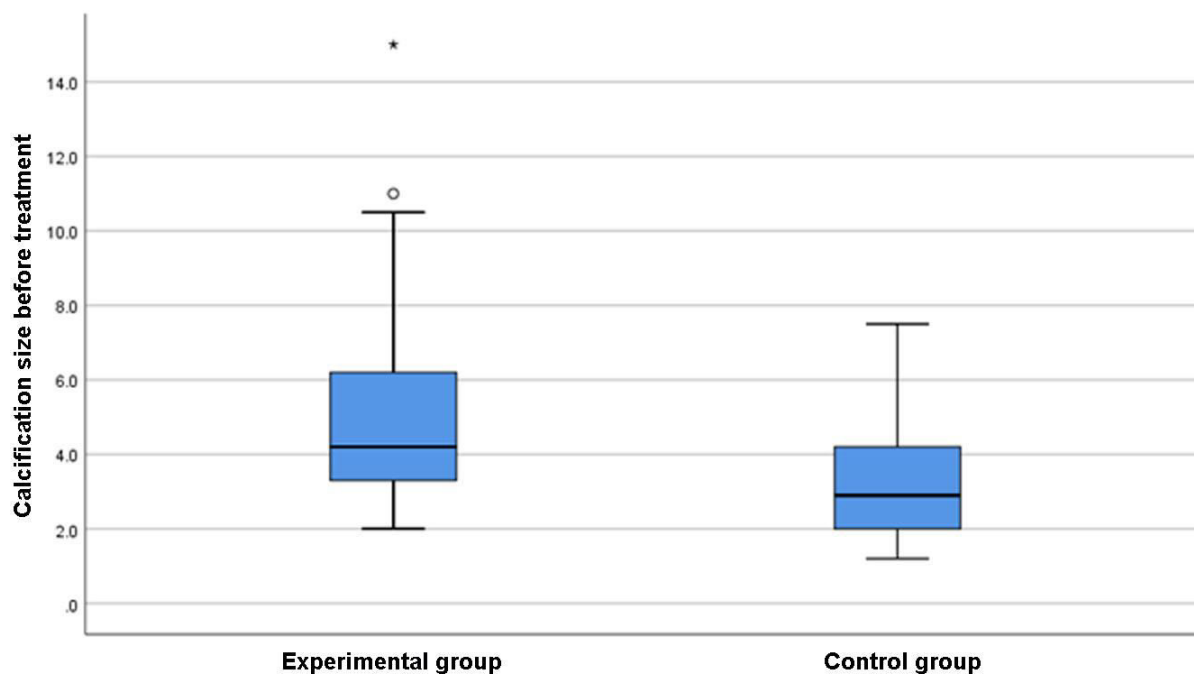
Graph 2. Distribution of study subjects, by etiology of plantar fasciitis development

4.9. Calcification size before treatment

Table 8. Calcification size before treatment, in millimeters

Calcification size (before treatment)	mean	SD	med	min	max	p-value
Experimental group	5.0	2.5	4.2	2.0	15.0	<0.001
Control group	3.3	1.5	2.9	1.2	7.5	

The median calcification size before treatment, in subjects belonging to the experimental group, was 4.2 mm (range: 2.0-15.0 mm), while it was 2.9 mm (range: 1.2-7.5 mm) in the control group subjects. There is a statistically significant difference (U=1098.0; p<0.001) in the size of the calcification before therapy, in experimental and control group subjects. Subjects belonging to the experimental group had significantly higher calcification values before treatment.



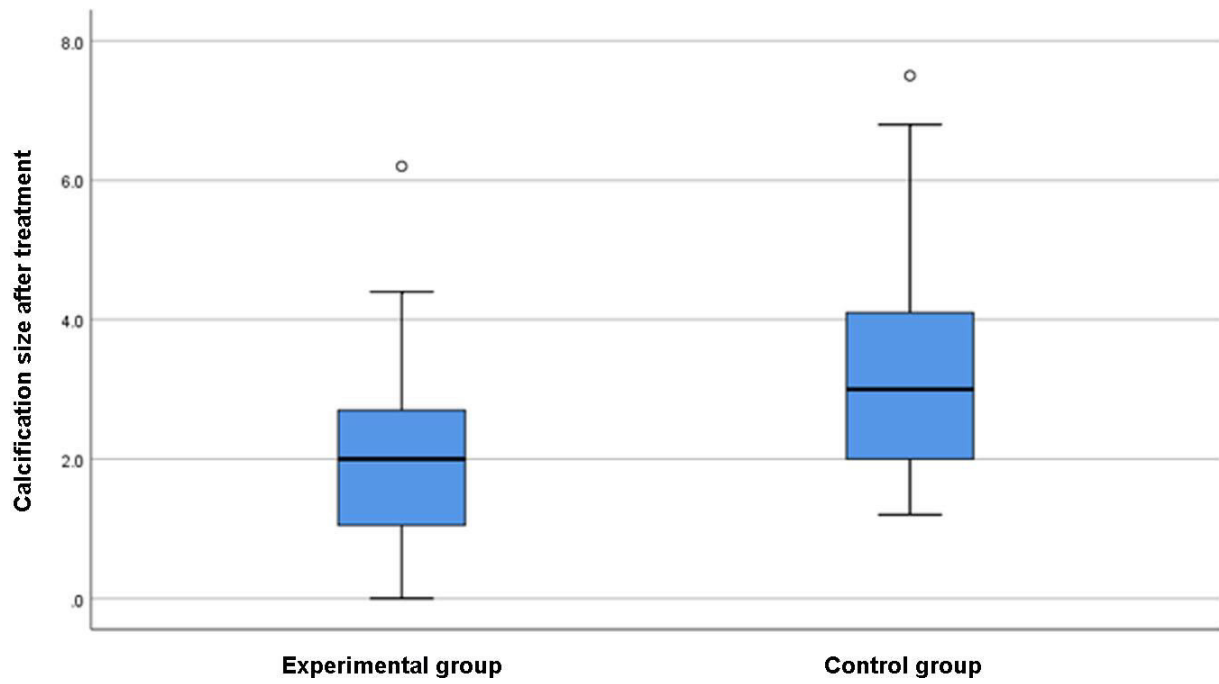
Graph 3. Calcification size before treatment

4.10. Calcification size after treatment

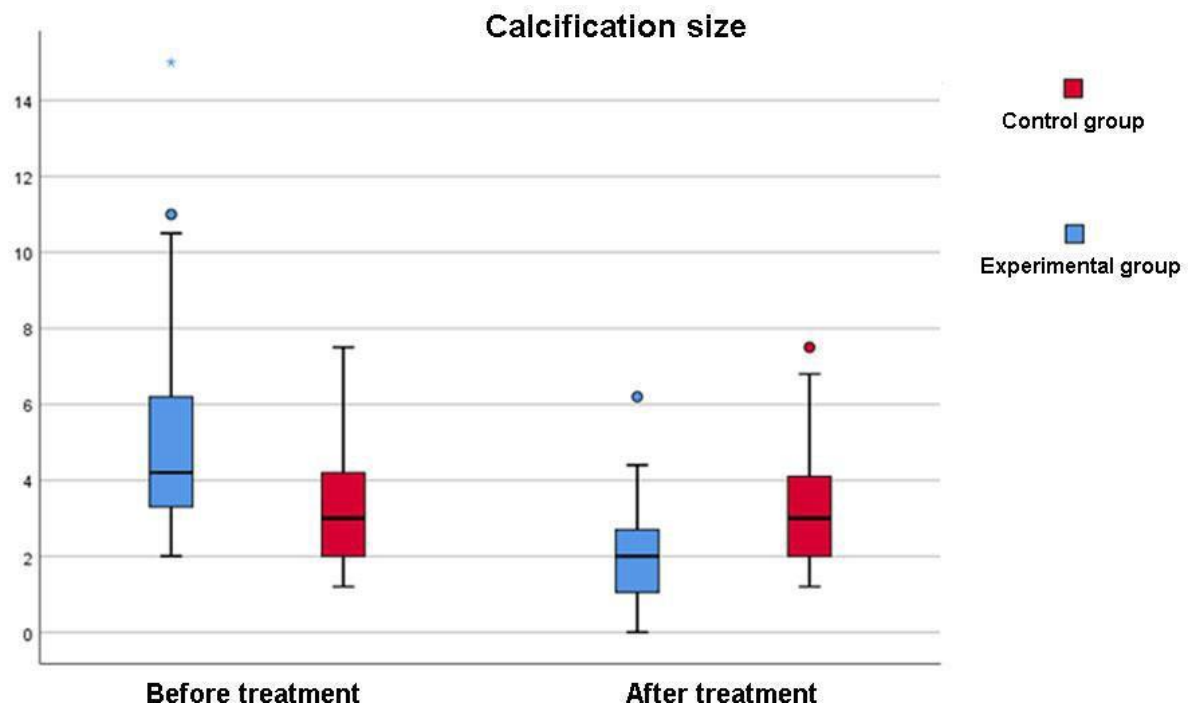
Table 9. Calcification size after treatment, in millimeters

Calcification size (after treatment)	mean	SD	med	min	max	p-value
Experimental group	2.0	1.2	2.0	0.0	6.2	<0.001
Control group	3.3	1.5	3.0	1.2	7.5	

The median calcification size after treatment, in subjects belonging to the experimental group, was 2.0 mm (range: 0.0-6.2 mm), while it was 3.0 mm (range: 1.2-7.5 mm) in the control group subjects. There is a statistically significant difference in calcification size (U=1023.0; $p < 0.001$). Subjects belonging to the control group had significantly higher calcification values after treatment.



Graph 4. Calcification size after treatment



Graph 5. Calcification size before and after treatment

4.11. Calcification size in the experimental group

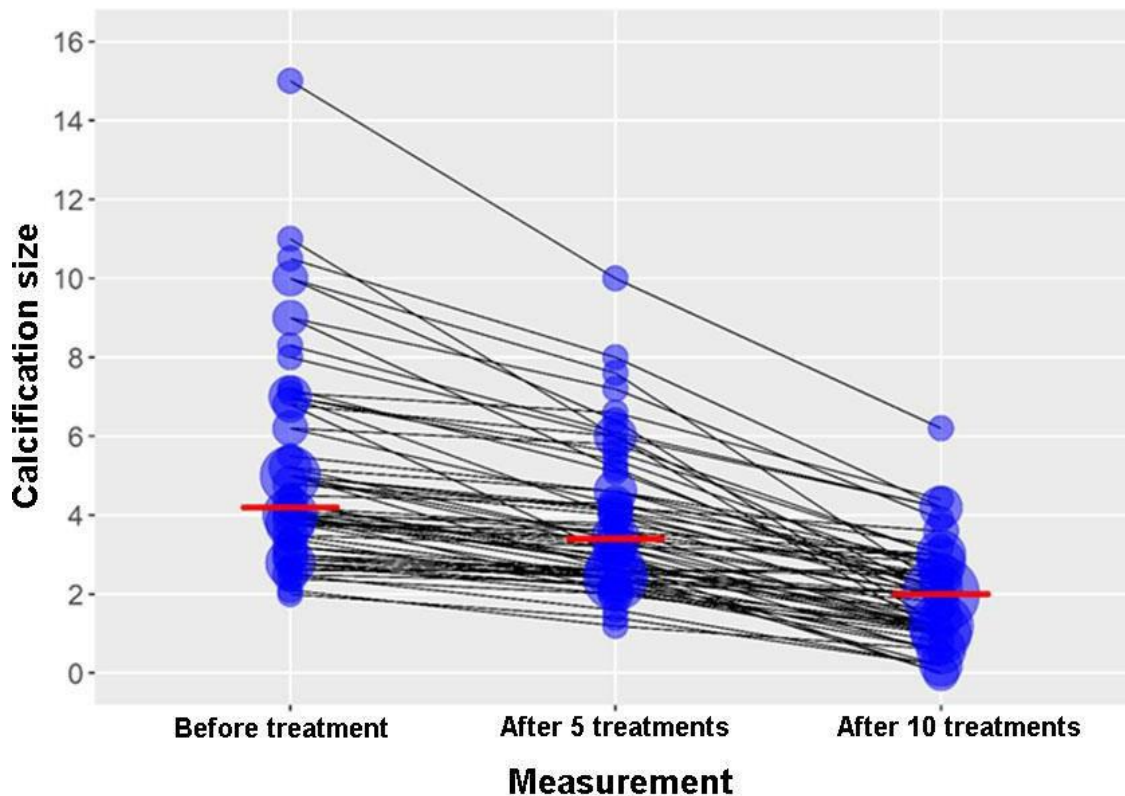
Table 10. Calcification size in experimental group subjects – before treatment, after five treatments, and after ten treatments, in millimeters

Calcification size	mean	SD	med	min	max	p-value
Before treatment	5.0	2.5	4.2	2.0	15.0	
After five treatments	3.8	1.7	3.4	1.2	10.0	<0.001
After ten treatments	2.0	1.2	2.0	0.0	6.2	

Calcification size values in experimental group subjects, during the observation period, are presented in Table 10.

There is a statistically significant difference in the values of calcification size during the observation period ($\chi^2=132.0$; $df=2$; $p<0.001$). A statistically significant reduction in calcification size over time was registered.

There is a statistically significant difference in calcification size after ten treatments, as compared to the calcification size before treatment ($p<0.001$) and after five treatments ($p<0.001$). There is also a statistically significant difference in calcification size after five treatments, as compared to calcification size before treatment ($p<0.001$).



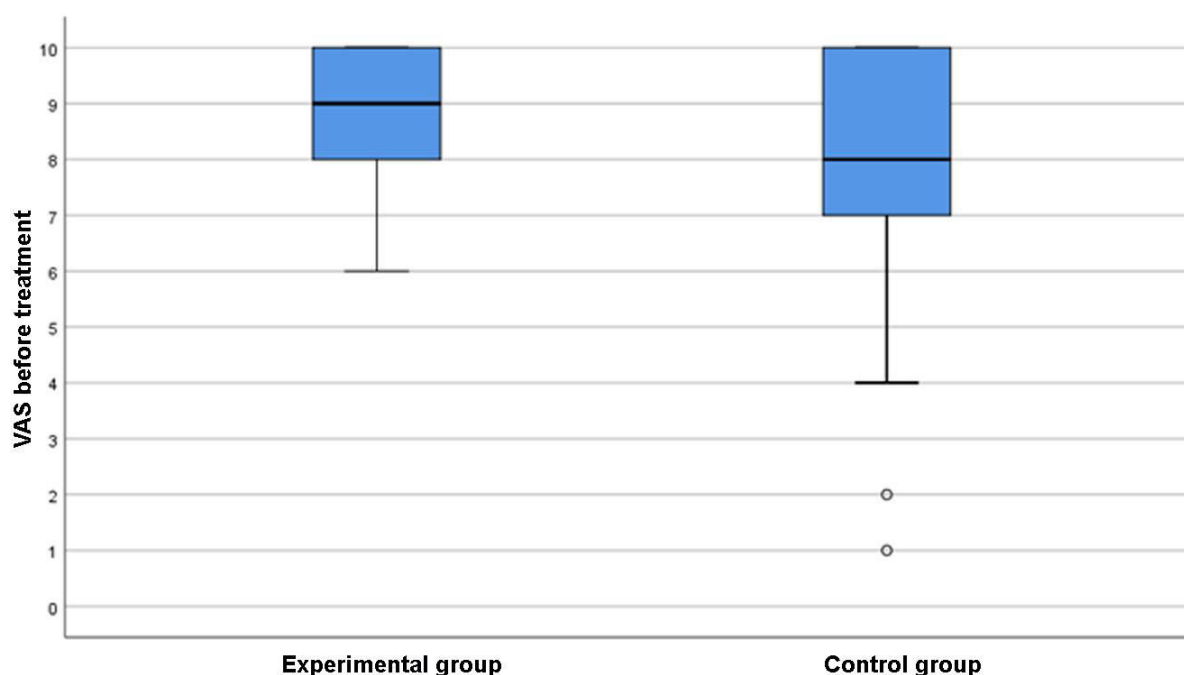
Graph 6. Values of calcification size in experimental group subjects – before treatment, after five treatments, and after ten treatments

4.12. VAS before treatment

Table 11. VAS values before treatment

VAS (before treatment)	mean	SD	med	min	max	p-value
Experimental group	8.7	1.1	9.0	6.0	10.0	0.038
Control group	7.9	2.0	8.0	1.0	10.0	

The median VAS before treatment, in the experimental group subjects, was 9.0 (range: 6.0-10.0), while it was 8.0 (range: 1.0-10.0), in the control group subjects. There is a statistically significant difference ($U=1647.5$; $p=0.038$) in VAS values before treatment in the experimental group and the control group. The subjects of the experimental group had significantly higher VAS values before treatment.



Graph 7. VAS values before treatment

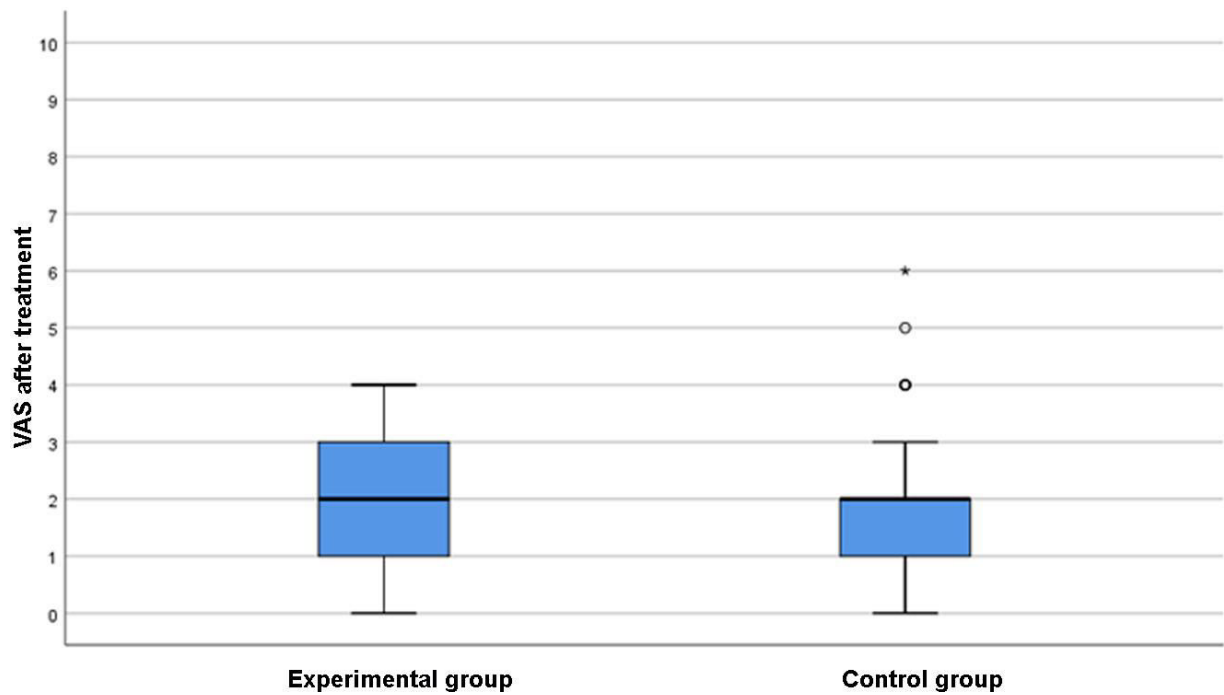
4.13. VAS after treatment

Table 12. VAS values after treatment

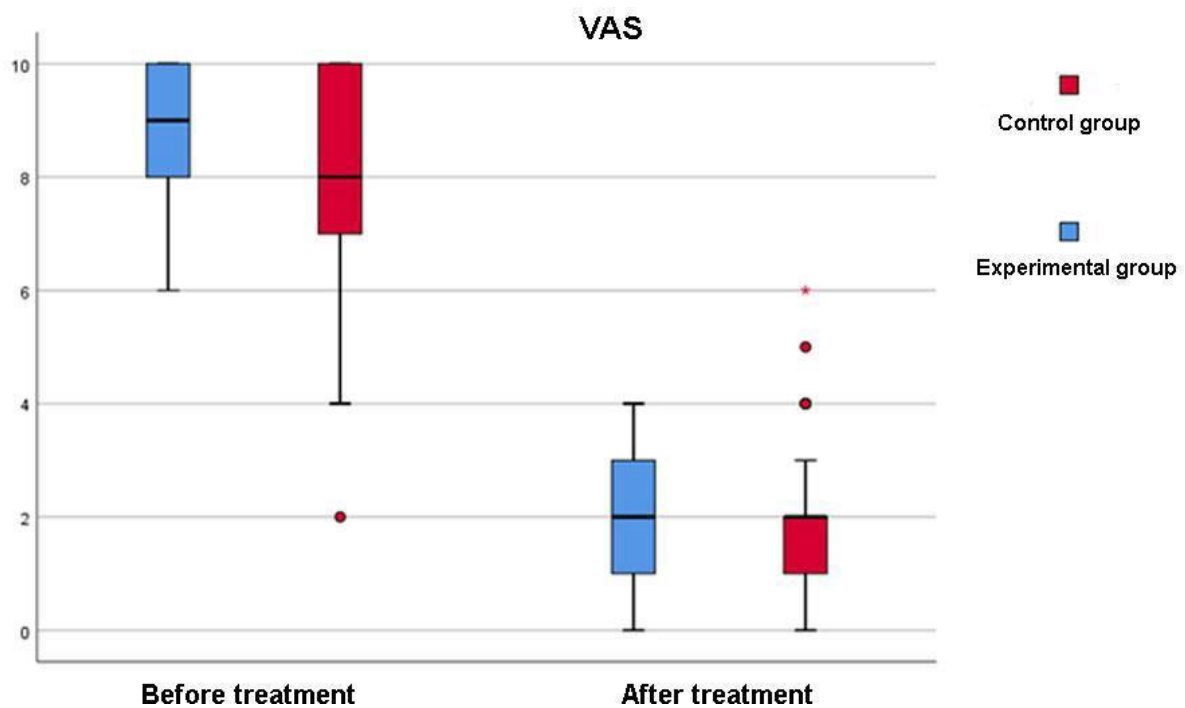
VAS (after treatment)	mean	SD	med	min	max	p-value
Experimental group	1.9	1.2	2.0	0.0	4.0	0.537
Control group	1.8	1.3	2.0	0.0	6.0	

The median VAS after treatment, in experimental subjects, was 2.0 (range: 0.0-4.0), and it was also 2.0 (range: 0.0-6.0) in control group subjects. There was no statistically significant

difference ($U=1889.0$; $p=0.537$) in VAS values after treatment in experimental and control group subjects.



Graph 8. VAS values after treatment



Graph 9. VAS values before and after treatment

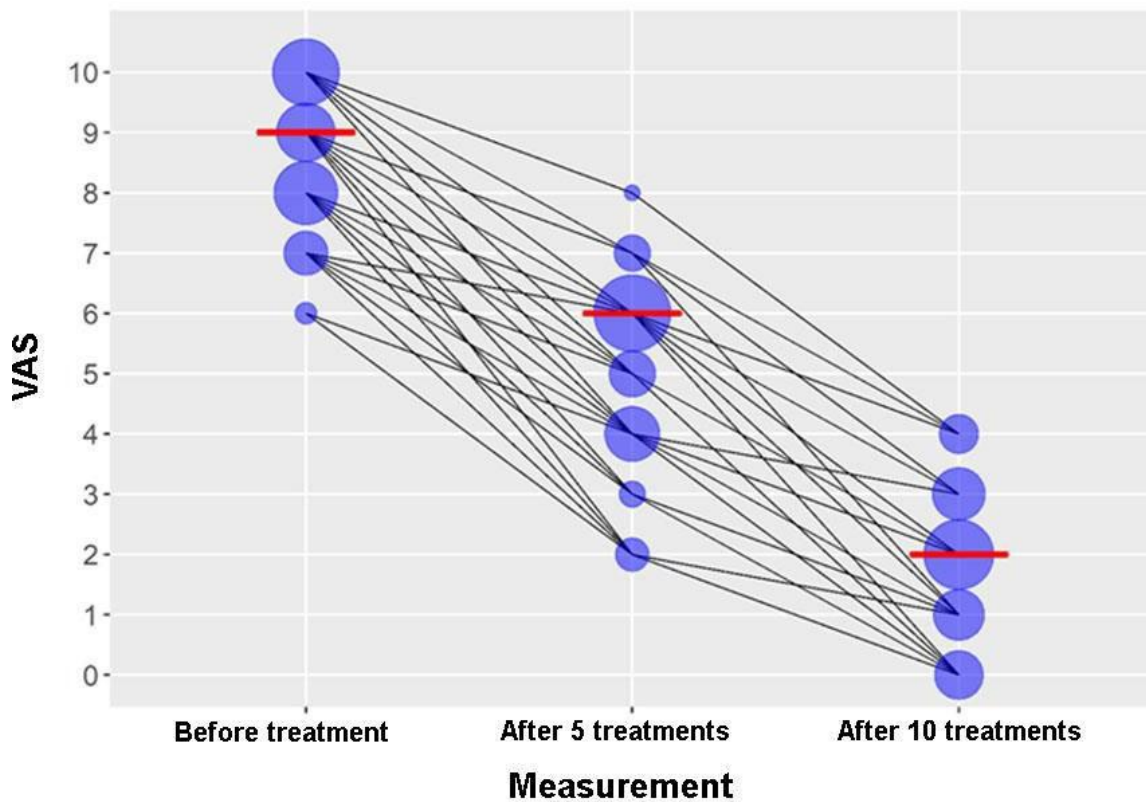
4.14. VAS in the experimental group

Table 13. VAS in experimental group subjects – before treatment, after five treatments, and after ten treatments

VAS	mean	SD	med	min	max	p-value
Before treatment	8.7	1.1	9.0	6.0	10.0	0.024
After five treatments	5.1	1.4	6.0	2.0	8.0	
After ten treatments	1.9	1.2	2.0	0.0	4.0	

VAS values for experimental group subjects during the observation period are presented in Table 13.

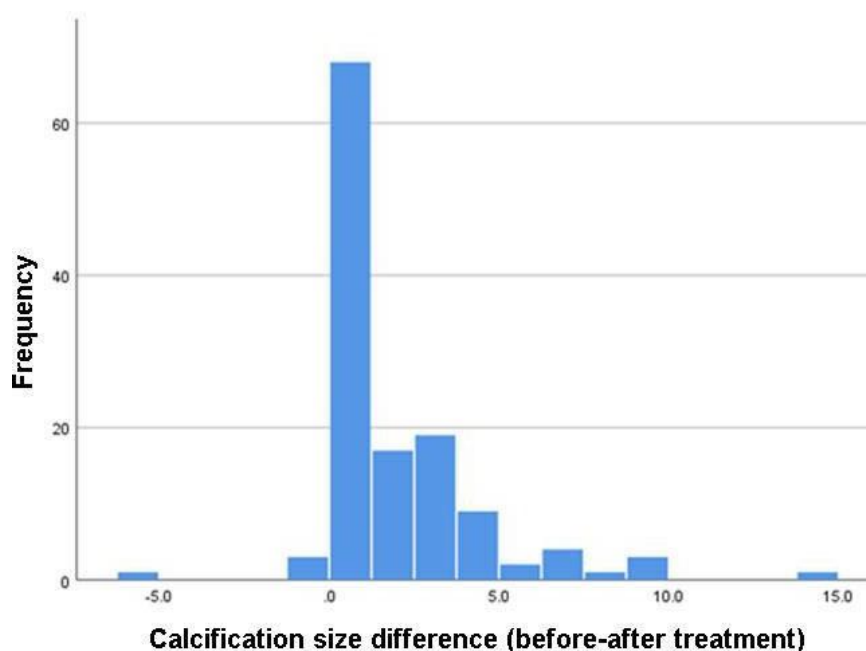
There is a statistically significant difference in VAS values during the observation period ($\chi^2=7.429$; $df=2$; $p=0.024$). A statistically significant drop in VAS values was registered over time. There is a statistically significant difference in VAS values after ten treatments, as compared to VAS values before treatment ($p=0.040$). However, there is no statistically significant difference in VAS values after five treatments, as compared to VAS before treatment ($p=0.231$), nor a statistically significant difference in VAS values after ten treatments, as compared to VAS after five treatments ($p=1.000$).



Graph 10. VAS values in experimental group subjects – before treatment, after five treatments, and after ten treatments

4.15. Difference in calcification size before-after treatment

The median calcification size difference before-after treatment was 0.5 (range: 6.2-14.0).



Graph 11. Values of calcification size difference before-after treatment

Table 14. Quantile regression, with the calcification size difference after-before treatment as the dependent variable

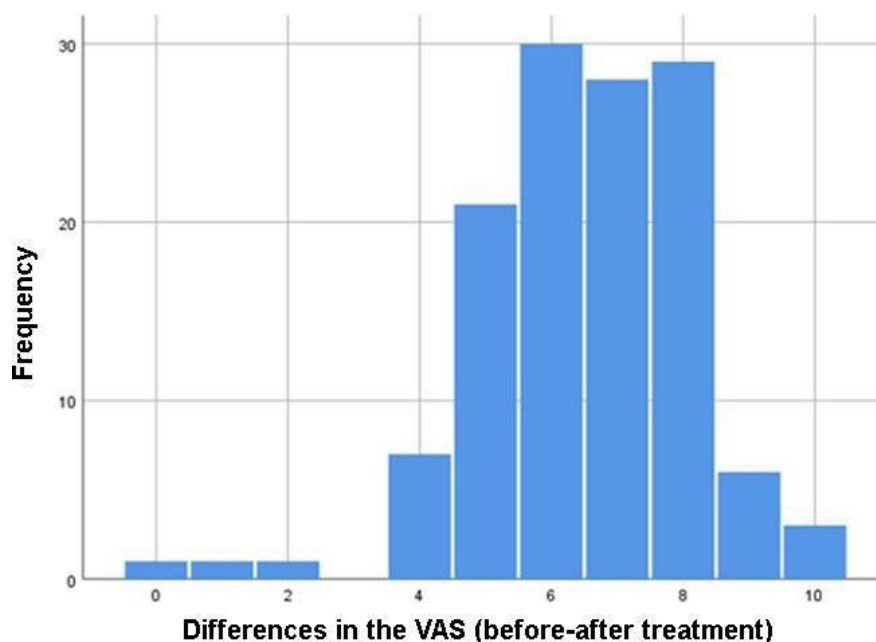
Variables	Univariate analysis		Multivariate analysis	
	B	p	B	p
Group (Experimental group/Control group)	2.700	<0.001	2.700	<0.001
Men/Women	-0.400	0.412		
Age	0.026	0.194		
Time from symptoms onset to treatment	0.140	< 0.001		

With the difference in calcification size before-after treatment, as the dependent variable, those variables which were statistically significant in the univariate models, at the level of significance of 0.05, were included into the multivariate quantile regression model.

The experimental group, as compared to the controls (B=2.700; p<0.001) is a statistically significant predictor of greater calcification size reduction.

4.16. Difference in VAS before-after treatment

The median difference in VAS before-after treatment was 7 (range: 0 – 10).



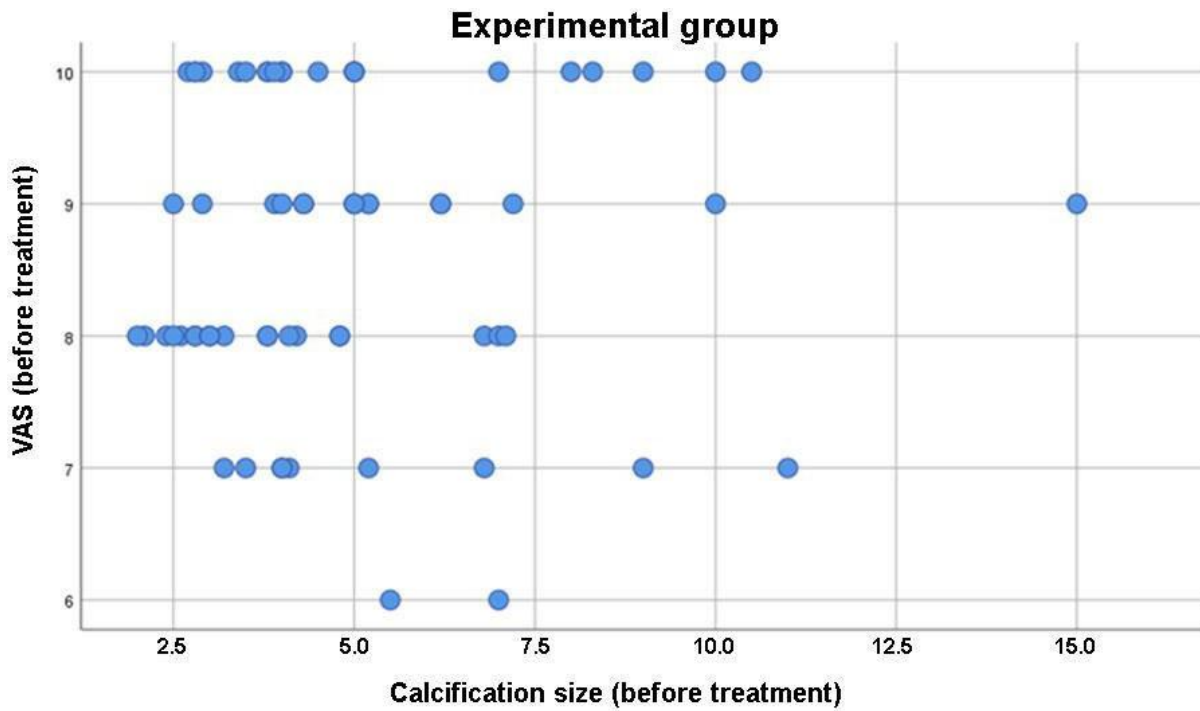
Graph 12. The differences in VAS values before-after treatment

Table 15. Quantile regression with the difference in the VAS before-after treatment as the dependent variable

Variables	Univariate analysis		Multivariate analysis	
	B	p	B	p
Group (Experimental group/Control group)	1.000	0.006		
Men/Women	0.000	1.000		
Age	<0.001	1.000		
Time from symptoms onset to treatment	0.000	1.000		

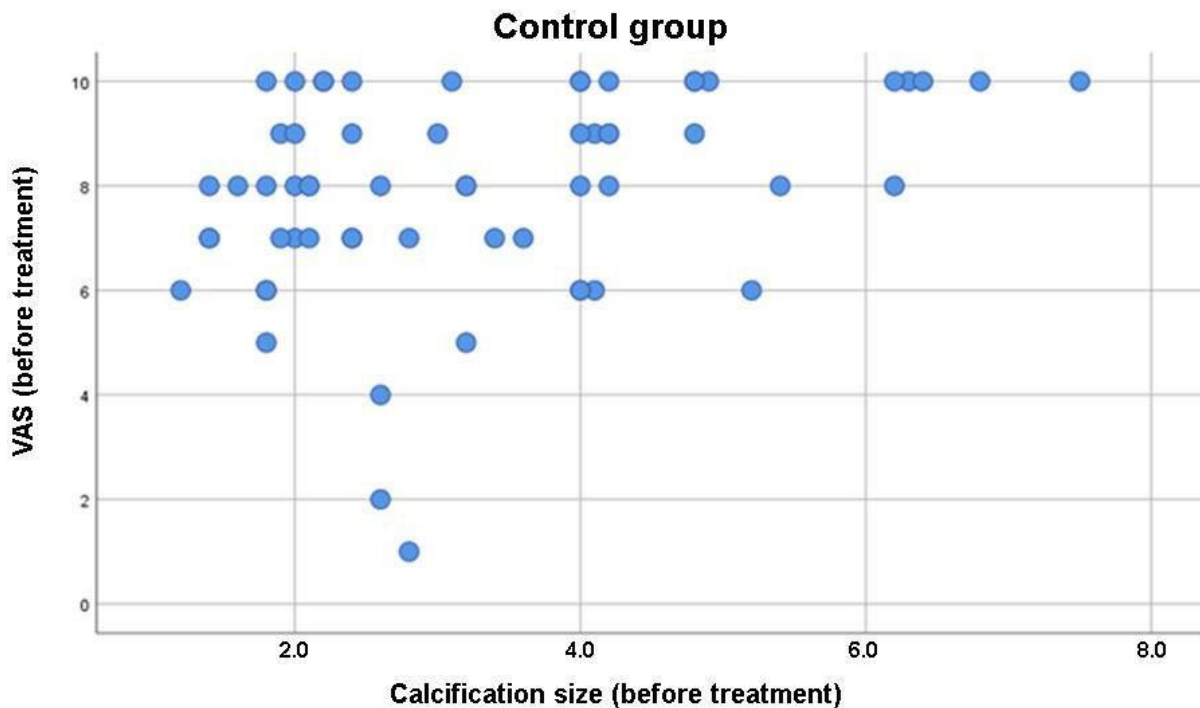
The experimental group, as compared to the controls (B = 1.000; p = 0.006) is a statistically significant predictor of greater VAS reduction, from univariate models.

4.17. Association between calcification size and VAS



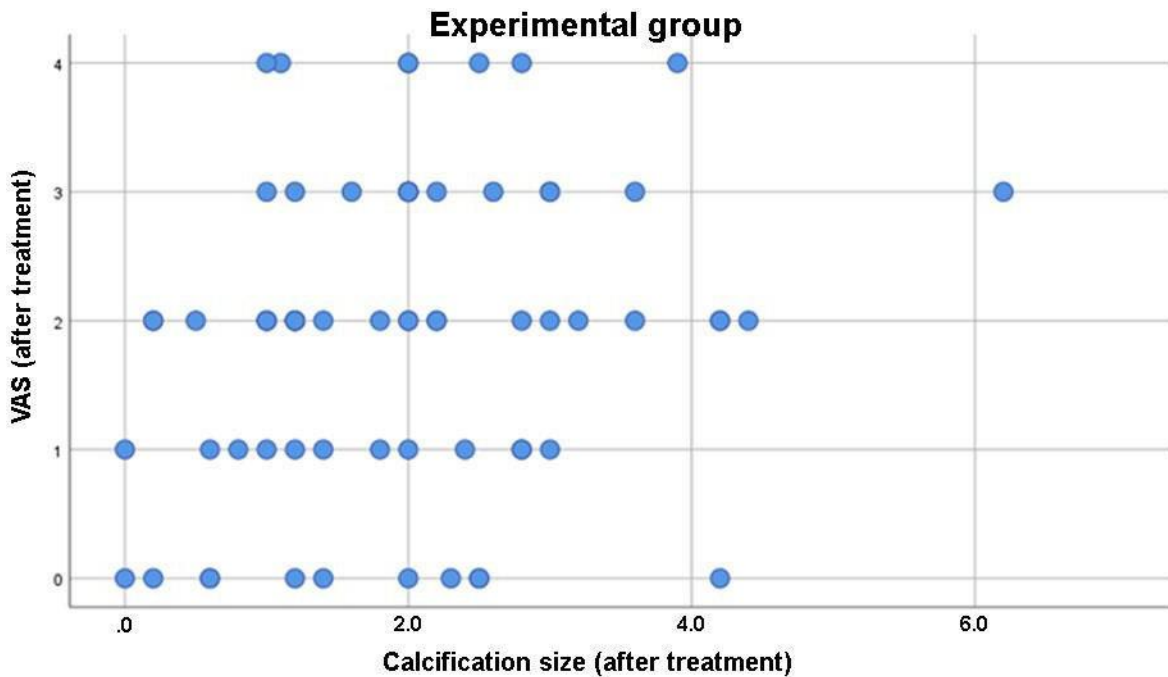
Graph 13. Association between calcification size before treatment and VAS before treatment, in the experimental group

In the experimental group, there is no statistically significant association between calcification size before treatment and VAS before treatment ($r_s=0.51$; $p=0.682$).



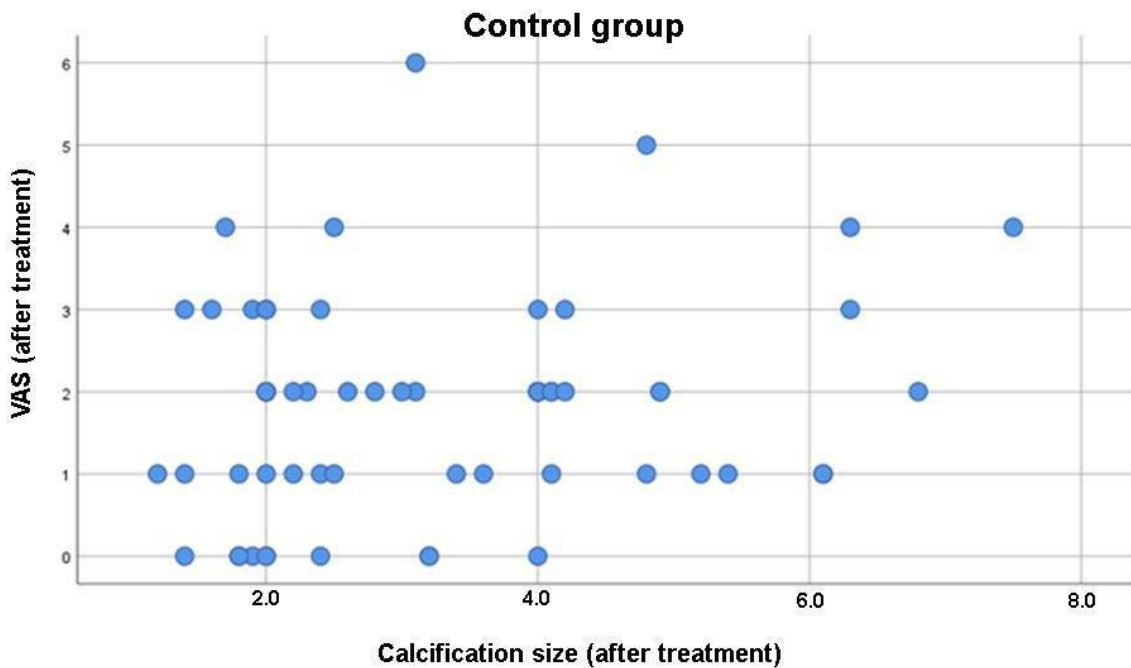
Graph 14. Association between calcification size before treatment and VAS before treatment, in the control group

In the control group, there is a statistically significant positive association between calcification size before treatment and VAS before treatment ($r_s=0.37$; $p=0.003$). A larger calcification size before treatment is associated with higher values of VAS.



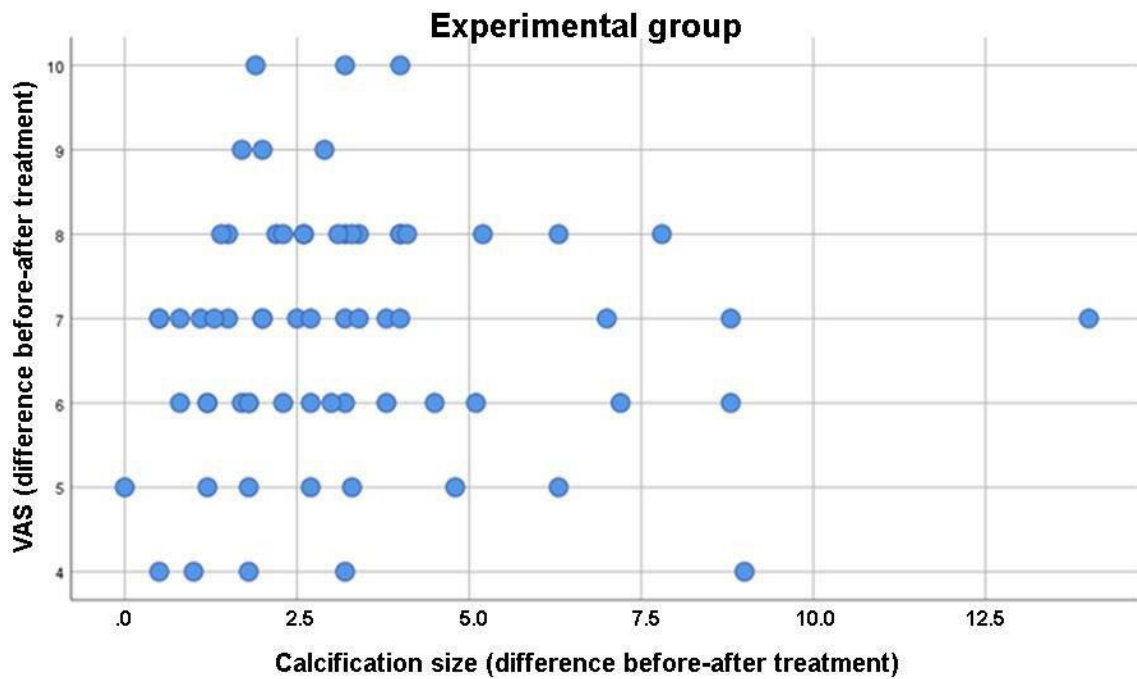
Graph 15. Association between calcification size after treatment and VAS after treatment, in the experimental group

In the experimental group, there is no statistically significant association between calcification size after treatment and VAS after treatment ($r_s=0.23$; $p=0.066$).



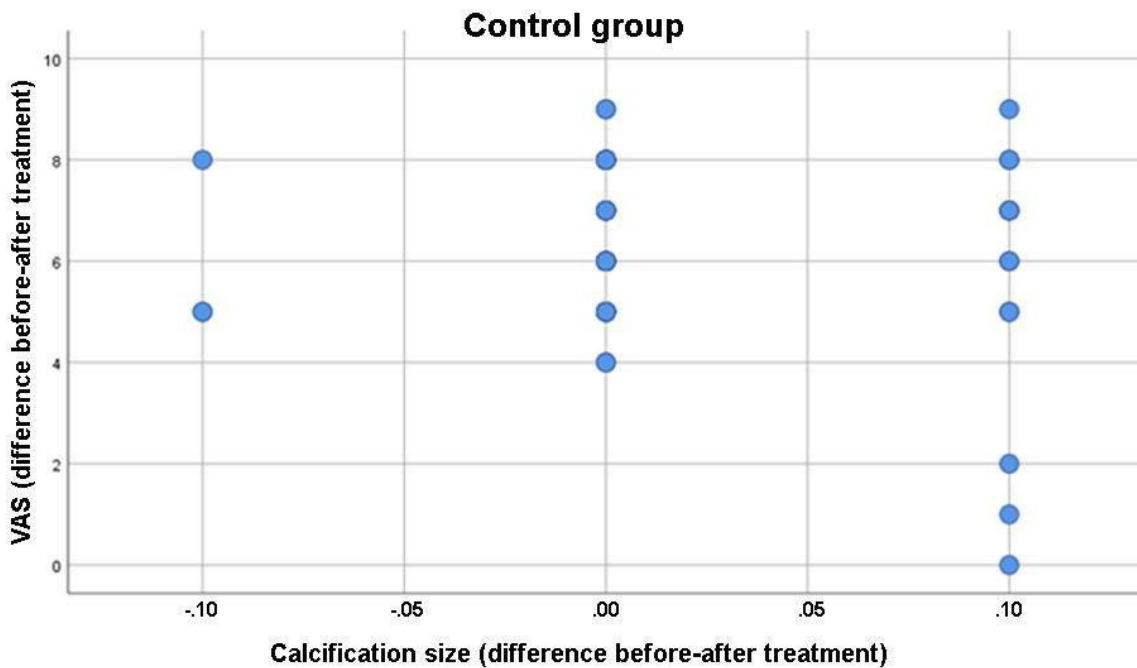
Graph 16. Association between calcification size after treatment and VAS after treatment, in the control group

In the control group, there is no statistically significant association between calcification size after treatment and VAS after treatment ($r_s = 0.19$; $p = 0.156$).



Graph 17. Association between the difference in calcification size before-after treatment and the difference in VAS before-after treatment, in the experimental group

In the experimental group, there is no statistically significant association between the difference in calcification size before-after treatment and the difference in VAS before-after treatment ($r_s=0.12$; $p=0.328$).



Graph 18. Association between the difference in calcification size before-after treatment and the difference in VAS before-after treatment, in the control group

In the control group, there is no statistically significant association between the difference in calcification size before-after treatment and the difference in VAS before-after treatment ($r_s=0.003$; $p=0.981$).

4.18. Treatment outcome

Table 16. Distribution of study subjects, by treatment outcome

Treatment outcome	n	%
Improvement	80	62.5
No improvement	48	37.5
Total	128	100.0

Of the total number of subjects involved in the study, improvement after treatment was registered in 80 (62.5%) patients.

4.19. Treatment outcome by group

Table 17. Distribution of study subjects in relation to treatment outcome, by group

Group	Improvement		No improvement		Total	
	n	%	n	%	n	%
Experimental group	66	82.5	1	2.1	67	52.3
Control group	14	17.5	47	97.9	61	47.7
Total	80	100.0	48	100.0	128	100.0

Improvement was registered in 66 (82.5%) subjects of the experimental group and in 14 (17.5%) subjects of the control group, which is a statistically significant difference ($\chi^2=77.773$; $p<0.001$).

4.20. Treatment outcome by sex

Table 18. Distribution of study subjects in relation to treatment outcome, by sex

Gender	Improvement		No improvement		Total	
	n	%	n	%	n	%
Male	38	47.5	27	56.3	65	50.8
Female	42	52.5	21	43.8	63	49.2
Total	80	100.0	48	100.0	128	100.0

Improvement was registered in 38 (47.5%) male subjects and 42 (52.5%) female subjects, while no improvement was found in 27 (56.3%) male subjects and 21 (43.8%) female subjects, which is not a statistically significant difference ($\chi^2=0.919$; $p=0.338$).

4.21. Treatment outcome by age

Table 19. Distribution of study subjects in relation to treatment outcome, by age

Age (years)	mean	SD	med	min	max	p-value
Improvement	55.2	11.4	54.5	30.0	88.0	0.123
No improvement	50.8	14.0	54.0	20.0	73.0	

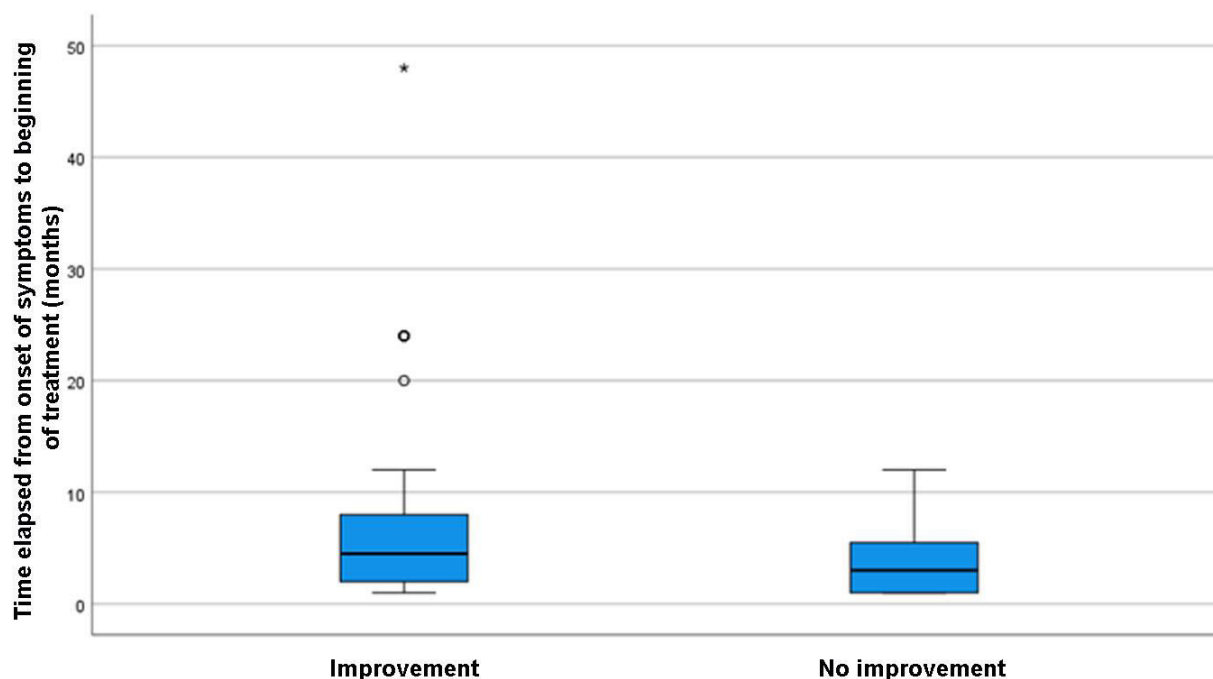
The average age of subjects showing improvement was 55.2 ± 11.4 years, while in subjects showing no improvement the average age was 50.8 ± 14.0 years, which is not a statistically significant difference ($t=1.927$; $p=0.056$).

4.22. Treatment outcome by time elapsed between onset of symptoms and beginning of treatment

Table 20. Distribution of study subjects in relation to treatment outcome, by time elapsed from onset of symptoms to beginning of treatment

Time elapsed from onset of symptoms to beginning of treatment (months)	mean	SD	med	min	max	p-value
Improvement	6.5	7.2	4.5	1.0	48.0	0.002
No improvement	3.4	2.6	3.0	1.0	12.0	

The median time elapsed from the onset of symptoms to the beginning of treatment, in subjects showing improvement, was 4.5 months (range: 1-48), while in subjects showing no improvement, it was 3 (range: 1-12), which is a statistically significant difference ($U=1297.0$; $p=0.002$). The subjects showing improvement started treatment significantly later.



Graph 19. Distribution of study subjects in relation to treatment outcome, by time elapsed from onset of symptoms to beginning of treatment

4.23. Treatment outcome by affected leg

Table 21 Distribution of study subjects in relation to treatment outcome, by affected leg

Affected leg	Improvement		No improvement		Total	
	n	%	n	%	n	%
Right	48	60.0	27	56.3	75	58.6
Left	32	40.0	21	43.8	53	41.4
Total	80	100.0	48	100.0	128	100.0

Improvement was registered in 48 (60.0%) subjects with an affected right leg and in 32 (40.0%) subjects with an affected left leg, while no improvement was registered in 27 (56.3%) subjects with an affected right leg and in 21 (43.8%) subjects with an affected left leg, which is not a statistically significant difference ($\chi^2=0.174$; $p=0.677$).

4.24. Treatment outcome by etiology of calcaneal spur development

Table 22. Distribution of study subjects in relation to treatment outcome, by etiology

ETIOLOGY	Improvement		No improvement		p-value
	n	%	n	%	
	Change of footwear	34	42.5	16	
Track and field sports	30	37.5	12	25.0	0.145
Tennis	46	57.5	23	47.9	0.292
Obesity	22	27.5	11	22.9	0.566
<i>Pedes plani</i>	28	35.0	19	39.6	0.603
Previous foot injury	17	21.3	11	22.9	0.825

Change of footwear, as an etiological factor in calcaneal spur development, was present in 34 (42.5%) subjects with improvement and in 16 (34.0%) subjects without improvement, which is not a statistically significant difference ($\chi^2=0.887$; $p=0.346$).

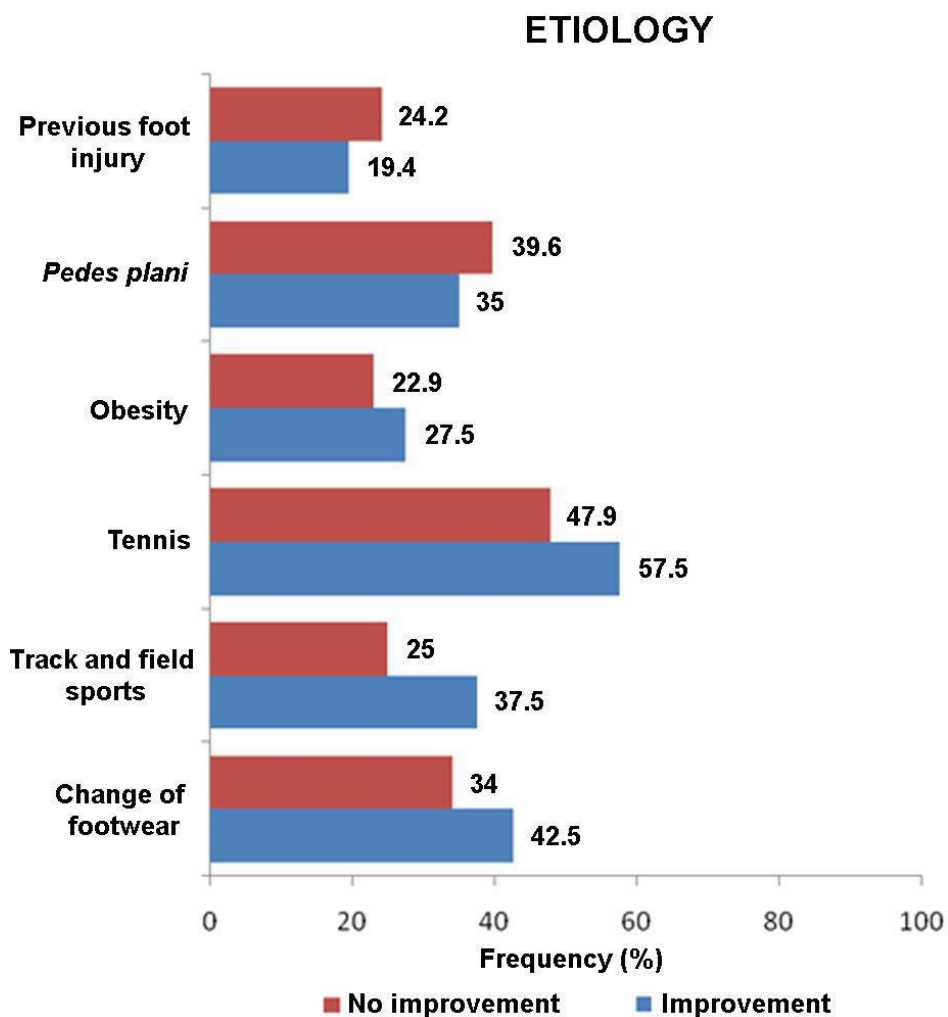
Involvement in track and field sports, as an etiological factor in calcaneal spur development, was present in 30 (37.5%) subjects with improvement and in 12 (25.0%) subjects without improvement, which is not a statistically significant difference ($\chi^2=2.126$; $p=0.145$).

Tennis playing, as an etiological factor in calcaneal spur development, was present in 46 (57.5%) subjects with improvement and in 23 (47.9%) subjects without improvement, which is not a statistically significant difference ($\chi^2=1.109$; $p=0.292$).

Obesity, as an etiological factor in calcaneal spur development, was present in 22 (27.5%) subjects with improvement and in 11 (22.9%) subjects without improvement, which is not a statistically significant difference ($\chi^2=0.329$; $p=0.566$).

Pedes plani, as an etiological factor in calcaneal spur development, was present in 28 (35.0%) subjects with improvement and in 19 (39.6%) subjects without improvement, which is not a statistically significant difference ($\chi^2=0.271$; $p=0.603$).

Previous foot injury, as an etiological factor in calcaneal spur development, was present in 17 (21.3%) subjects with improvement and in 11 (22.9%) subjects without improvement, which is not a statistically significant difference ($\chi^2=0.049$; $p=0.825$).



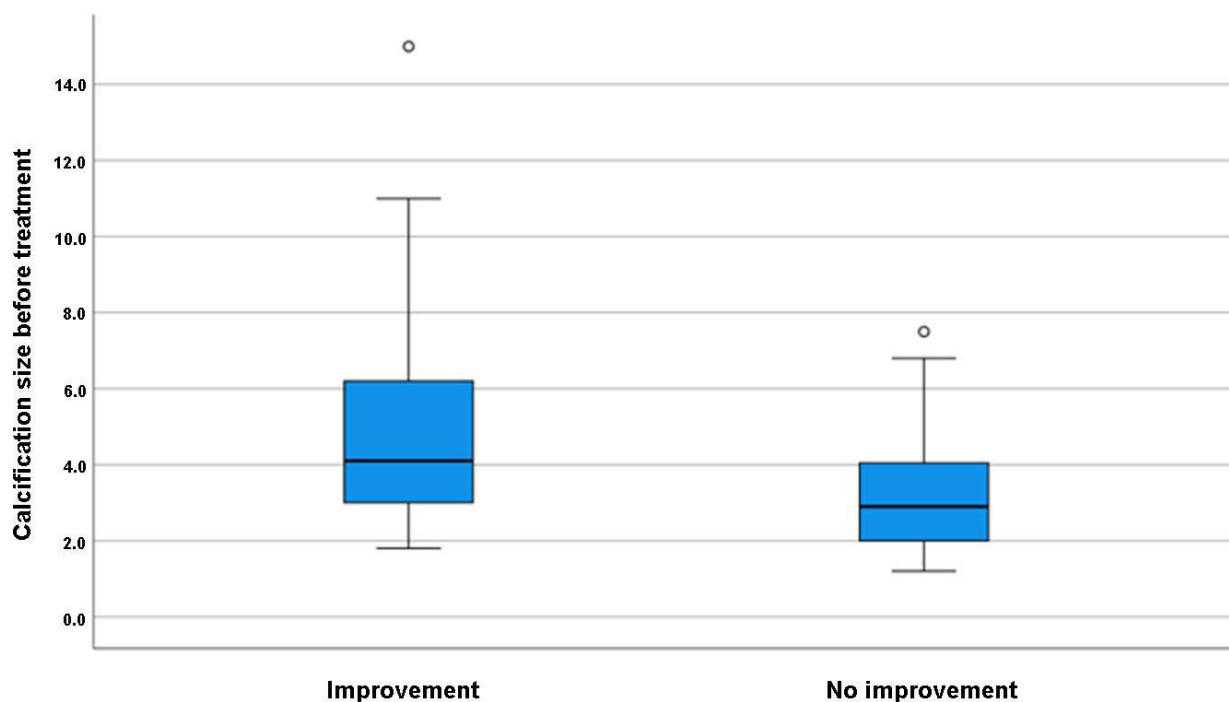
Graph 20. Distribution of study subjects in relation to treatment outcome, by etiology

4.25. Treatment outcome by calcification size before treatment

Table 23. Distribution of study subjects in relation to treatment outcome, by calcification size before treatment

Calcification size (before treatment)	mean	SD	med	min	max	p-value
Improvement	4.8	2.4	4.1	1.8	15.0	<0.001
No improvement	3.2	1.5	2.9	1.2	7.5	

Median calcification size before treatment in subjects showing improvement was 4.1 mm (range: 1.8-15.0 mm), while it was 2.9 mm (range: 1.2-7.5 mm) in patients who showed no improvement, which was a statistically significant difference (U=1076.5; p<0.001). Subjects who showed improvement had significantly higher calcification values before treatment.



Graph 21. Distribution of study subjects in relation to treatment outcome, by calcification size before treatment

4.26. Multivariate logistic regression with the „no improvement” outcome as the dependent variable

The multivariate logistic regression model included those predictors of unfavorable outcome (no improvement) which, in the univariate logistic regression models, were statistically significant at the level of significance of 0.05.

The model contains three predictors presented in Table 24, which were compared in 128 subjects, of whom 48 had an outcome of significance. The entire model (with all the predictors) was statistically significant ($p < 0.001$).

Table 24. Multivariate logistic regression with the outcome „no improvement” as the dependent variable

Independent variable	B	p	OR	95% confidence interval	
				lower	upper
				limit	limit
Group (control vs. experimental)	5.283	<0.001	197.06	20.64	1880.96
Time from symptoms onset to treatment	0.023	0.777	1.02	0.87	1.20
Calcification size before treatment	- 0.200	0.272	0.82	0.57	1.17

In the multivariate logistic regression model, the statistically significant predictor of an unfavorable outcome (“no improvement”) was the type of treatment ($B=5.283$; $p<0.001$), whose odds ratio was $OR = 197.06$. This shows that subjects belonging to the control group had an almost 200 times higher chance of an unfavorable treatment outcome, with the control of all other factors in the model.

5. Discussion

Plantar fasciitis is a functional foot disorder, which is associated with pain in the heel, i.e., increased sensitivity of the middle aspect of the *tuber calcanei*. Functionally speaking, plantar fasciitis is most commonly associated with decreased dorsiflexion of the foot (Melesa, et al. 2022). The diagnosis of this disease is very often confirmed on clinical examination and is relatively easy to establish (Troijan and Tucker, 2019). A characteristic symptom of this condition is pain at the site of plantar fascia insertion to the medial calcaneal tubercle. One of the important characteristics of this pain is that it is the most intense in the morning or after a long rest (Lee, et al. 2003; Toomey, 2009; Wang, et al. 2019). Additional diagnostic procedures are usually not necessary, but will be performed in patients who do not respond to therapy and in those with chronic pain (Ehrman, et al. 2014). In patients with pain in the heel, the presence of a calcaneal spur can be confirmed on an X-ray image, while US can clearly confirm plantar fascia thickening (Menz et al., 2019; Drake, et al. 2022). Both of these abnormalities, each on its own, or both of them together, may be associated with pain in the heel (Ahmad, et al. 2016; Menz et al., 2019).

In our study, all of the patients had a calcaneal spur. The inclusion criterion was that the patient was suffering from plantar fasciitis in conjunction with a calcaneal spur. In most cases, the presence of a calcaneal spur was confirmed with US. In less than 5% of the subjects from the experimental group and in around 20% of the subjects belonging to the control group, the presence of the calcaneal spur was confirmed with an X-ray image. In all other subjects, the presence of a calcaneal spur was confirmed with US. The difference in the method of establishing the diagnosis between the experimental and the control group was statistically significant.

Ultrasound, as a diagnostic method, has an exceptionally important role in diseases of the foot. Changes occurring in patients with pain in the heel of the foot, which require additional imaging diagnostics, are the following: thickening of the plantar fascia, partial or complete rupture of the plantar fascia, abnormalities of the heel fat pad, calcaneal spur, increased hyperemia of the plantar fascia, and abnormalities in the bones of the foot (Drake, et al. 2022). Thickening of the plantar fascia is one of the most important changes found in plantar fasciitis (Hansen, et al. 2018; Drake, et al. 2022). Ultrasound is most commonly used for determining its thickness. The thickness of the plantar fascia can also be measured with MRI. However, when measuring the plantar fascia using MRI, incorrect, i.e., larger measurements may be obtained. This may happen as the result of maloriented scans, i.e., if the scan is at an oblique angle in relation to the plane of maximal thickness (Drake, et al. 2022). Partial or complete rupture of the plantar fascia, as well as changes related to the heel fat pad can clearly be seen on US and/or MRI examination (Sabir, et al. 2005). For diagnosing plantar fascia hyperemia, the appropriate method is Doppler ultrasound (McMillan, et al. 2013), while US elastography is the appropriate method for investigating the elasticity of the plantar fascia (Lee, et al. 2014). Lateral X-ray of the heel is usually the method of discovering a calcaneal spur. With all the advantages of the US examination, it must also be noted that its successfulness also greatly depends on the doctor performing it. This method cannot reveal edema of the calcaneal bone marrow, which can be the cause of pain in the heel in a certain number of cases (Ehrman, et al. 2014). Diagnosis of this change is possible with the use of MRI (Sutera, et al. 2010). The application of laboratory diagnostics in patients with plantar fasciitis is not customary. This type of diagnostics is performed only in case of suspected association between the pain and some other disease, such as rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, gout, etc. (Thomas, et al. 2010).

In all the subjects in our study, the calcaneal spur was localized unilaterally. In 75 (58%) subjects, it was located on the right side, while in 54 (42%) subjects it was localized on the left side. If we observe each group separately, we find that, in the experimental group, the calcaneal spur was

located on the right foot twice as often (45 or 67.2% calcaneal spurs were on the right side, as compared to 22 or 32.8% calcaneal spurs on the left side), while in the control group, the calcaneal spurs were almost equally distributed in the right leg (30 or 48.4% calcaneal spurs) and in the left leg (32 or 51.6% calcaneal spurs). The difference between the control group and the experimental group, regarding right or left localization of plantar fasciitis, was statistically significant.

In a study by Bagciera and Yilmaz, of the 40 subjects involved in the study, 19 (47.5%) had a calcaneal spur. Right localization was found in 12 (63%) subjects, while left localization was found in 7 (37%) subjects, which is similar to our study (Bagcier and Yilmaz, 2020). Krol et al. had similar results. Of a total of 55 subjects who completed this randomized clinical study, in 31 (56.4%) patients, the calcaneal spur was localized on the right side, while in 24 (43.6%) subjects it was localized in the left leg (Krol, et al. 2021). As opposed to these results, Ahmad et al. more frequently found, in the subjects involved in their study, a calcaneal spur on the left side. Of the total of 109 subjects, a calcaneal spur was found in the right leg in 50 (45.9%) subjects, while it was present in the left leg in 59 (54.1%) subjects (Ahmad, et al. 2016). A calcaneal spur was more often found on the left side, in a study by Yalcin et al. Of the 108 subjects in this study, in 63 (58.3%) patients the calcaneal spur was found in the left leg, while in 45 (41.7%) patients it was localized in the right leg (Yalcin, et al. 2012). In a study by Hayta et al., the number of calcaneal spurs on the right and on the left was almost equal. Of 80 calcaneal spurs, 39 (48.7%) were localized on the right, while 41 (51.3%) were localized on the left (Hayta, et al. 2016). It is not uncommon for a calcaneal spur to occur bilaterally. Of the 530 participants involved in one study, a calcaneal spur was found in 185 (35%) patients, of whom 89 (48%) had the spur in one leg, while as many as 96 (52%) of them had bilateral spurs (Menz, et al. 2019). A similar situation can be seen in a study by Badil Guloglu and Yalcin. In 35 (56.4%) subjects, out of a total of 62 included in the study, there was a calcaneal spur both on the left and on the right side (Badil Guloglu and Yalcin, 2021).

As already said, the easiest and most precise method of determining the presence and size of the calcaneal spur is lateral X-ray imaging of the calcaneus (Drake, et al. 2022). The length of the calcaneal spur is represented by a line connecting the apex of the calcaneal spur and its base. The base of the calcaneal spur is formed by an imaginary line between the calcaneus and the calcaneal spur (Ozdemir, et al. 2004; Johal and Milner, 2012; Hayta, et al. 2016). In our study, the mechanical shock wave affected the size of the calcaneal spur. At the beginning of the study, the calcaneal spurs in experimental group subjects were statistically significantly larger, as compared to the calcaneal spurs in the control group. However, at the end of the study, the calcaneal spurs in the experimental group subjects were statistically significantly smaller, as compared to the control group. This difference occurred as the result of the application of mechanical shockwave treatment, which significantly reduced the size of the calcaneal spurs in the experimental group, while the alternative treatment applied in the control group had almost no effect on the size of the calcaneal spurs. The calcification size, prior to the application of mechanical shockwave therapy in the subjects of the experimental group, ranged from 2 mm – 15 mm. The median calcification size in this group was 4.2 mm.

In literature, however, we can find examples with much larger calcaneal spurs. Alatassi et al. presented a case of a 23-year-old young man, in whom the calcaneal spur was as long as 23.3 mm. The young man sought medical help exclusively due to the pain he was experiencing in the region of the heel of the foot. The function of the foot was preserved, without visible deformities. He was advised to undergo surgical treatment due to the size of the calcaneal spur, which he declined and opted for conservative treatment. Systemic application of anti-inflammatory drugs and pads for the heel, physiotherapy, and finally the application of a night splint, led to the reduction of pain in this patient (Alatassi, et al. 2018).

In a prospective study involving 435 patients with the diagnosis of plantar fasciitis, Lee et al. found a calcaneal spur in 283 (65%) patients. The largest calcaneal spur was 18 mm long, while the smallest one was just 1 mm in size. Most of these spurs ranged from 2 mm to 5 mm in length. The

study subjects were divided into two groups. The experimental group was treated with mechanical shockwave therapy, while the control group was treated with placebo. Unfortunately, during the execution of this study, there was no absolute control over the radiological findings. Therefore, conclusions could not be made regarding the exact reduction in the size of the calcaneal spurs. However, by evaluating the results, three months and one year after the application of shockwave therapy, it was noted that none of the calcaneal spurs had disappeared completely, but that none of them had grown in size either (Lee, et al. 2003).

With the aim of performing a detailed analysis of the histological structure, but also of the exact position of calcaneal spurs, a group of Australian researchers conducted a study involving five patients. The youngest patient was 27 years old, while the oldest one was 48 years old. Apart from the pain in the heel of the foot, which had been present in the patients for several years, as well as the presence of the calcaneal spur, no other comorbidity was noted in these patients. The size of the calcaneal spurs in these patients, which were surgically removed, ranged from 6 mm to 9 mm. The average size of the calcaneal spurs in this study was $7.1 \text{ mm} \pm 1.1 \text{ mm}$, which places them in the category of large calcaneal spurs. It is interesting to note that in two of the subjects, the calcaneal spur had fractured, which was clearly visible on the X-ray images. In one more patient, fracture of the calcaneal spur was registered during surgery. In all of these patients, the body mass index (BMI) was above 30, which is why one of the conclusions of this study points towards the possible association between excess body mass and the presence of a calcaneal spur (Smith, et al. 2007).

Calcaneal spurs can be classified according to size, shape and position (Ozdemir, et al. 2004; Johal and Milner, 2012; Zhou, et al. 2015; Ahmad, et al. 2016). In their study, Ozdemir et al. classified calcaneal spurs, according to size, into the following groups: small calcaneal spurs (1 mm – 2 mm), medium-sized calcaneal spurs (3 mm – 5 mm), and large calcaneal spurs (measuring more than 6 mm). Of a total of 67 examined heels of the foot, calcaneal spurs were present in 44 cases. There were 27 (61%) small, 15 (34%) medium-sized, and only two (5%) large calcaneal spurs. The withdrawal of symptoms, i.e., the alleviation of pain upon the administration of conservative treatment (NSAIDs, contrast foot baths, stretch exercises, and footwear modification), was statistically significantly more evident in patients with small and medium-sized calcaneal spurs ($< 5 \text{ mm}$), as compared to patients with large calcaneal spurs ($> 5 \text{ mm}$). Also, these authors stated that large calcaneal spurs reduced the elasticity of the heel fat pad to a greater extent, however without a statistically significant difference, which they further explained by a small sample size (Ozdemir, et al. 2004). This is definitely an interesting finding, since literature data suggests that a change in the thickness of the heel fat pad, as well as the reduction of its elasticity, may be the cause of pain in the heel (Ozdemir, et al. 2004; Drake, et al. 2022; Velagala, et al. 2022).

In patients with plantar fasciitis, the presence of a heel spur is very often observed. However, plantar fasciitis may exist without the presence of a calcaneal spur. Also, a calcaneal spur may be asymptomatic, i.e., it can persist without any signs of plantar fasciitis. Frequently, a calcaneal spur is an incidental finding of lateral X-ray imaging of the ankle (Osborne, et al. 2006). Johal and Milner proved a link between the occurrence of plantar fasciitis and a calcaneal spur. In their study, they formed two groups of subjects. The experimental group was composed of 19 patients with plantar fasciitis, while the control group was also composed of 19 subjects – patients who had sought medical assistance due to ankle ligament injury. In the experimental group, calcaneal spurs were identified in 17 (89%) patients. Most of these spurs were 2 mm – 10 mm long, while their mean length was 6.59 mm. In the control group, X-ray imaging confirmed the presence of six calcaneal spurs, which means that they occurred in 32% of the subjects in this group. The range for most calcaneal spurs was 3 mm – 9 mm, with a mean value of 5.08 mm. When analyzing the frequency of the occurrence of calcaneal spurs, the authors of this study concluded that there was a statistically significantly higher prevalence of calcaneal spurs in the experimental group than in the control group. Unfortunately, the said study did not provide an answer as to whether this is a causal association (Johal and Milner, 2012).

According to the classification of calcaneal spurs in relation to their size, as defined by Ozdemir et al. (Ozdemir, et al. 2004) and Johal and Milner (Johal and Milner, 2012), calcaneal spurs from our study would be classified in the group of medium-sized calcaneal spurs.

A study similar to ours was carried out by a group of authors from the Sivas Cumhuriyet University (Sivas, Turkey). The aim of their research was to investigate the impact of radial mechanical shock waves on the size of the calcaneal spur and on the intensity of pain in patients with plantar fasciitis. The study involved a total of 80 patients with clinically and radiologically confirmed presence of a calcaneal spur. The inclusion criteria for the study were that patients had no other comorbidities and that they had not been taking therapy (analgesics, NSAIDs, corticosteroids) during the preceding three months. Prior to the application of mechanical shock wave therapy, the size of the calcaneal spurs and the intensity of pain were measured. VAS was used for measuring the intensity of pain. After that, two radial mechanical shockwave treatments were applied within the space of seven days. Three months after the second treatment, measuring was repeated, upon which the results were evaluated. The size of the calcaneal spurs prior to treatment ranged from 4.0 mm to 7.6 mm, with a mean length of $5.7 \text{ mm} \pm 1.0 \text{ mm}$. The repeated measuring revealed that a statistically significant reduction in the size of the calcaneal spurs had occurred. Their size ranged from 0.4 mm to 6.8 mm, while the mean length was $4.4 \text{ mm} \pm 0.9 \text{ mm}$ (Hayta, et al. 2016).

When comparing these results with the ones from our study, it is evident that a statistically significant reduction in calcification was registered in both studies. However, in the study by Hayta et al., this reduction was less pronounced. This difference in results can be explained by the fact that, in our study, a greater number of treatments was applied. The fact that the reduction in the size of the calcification was significantly greater after five treatments, as compared to the beginning, and that this reduction was significantly greater after ten treatments, as compared to after five treatments, speaks in favor of this explanation. In other words, in our study, a constant reduction of the calcaneal spur size can be noted with the rise in the number of treatments. In the same study, Hayta et al. proved that the application of the mechanical shock wave also led to statistically significant reduction in pain intensity. At the beginning of the study, VAS was 8.3 ± 1.4 (range: 5 – 10), while when measuring was repeated, three months after the final treatment, this score was 4.6 ± 2.2 (range: 2 – 10). Such a difference in VAS was statistically significant. However, the authors of the above-described study did not succeed in proving the existence of a significant correlation between calcaneal spur size values and VAS values, before and after treatment (Hayta, et al. 2016).

The results of our study also coincide, to a great extent, with the results of the afore described study by Hayta et al (Hayta, et al. 2016). The application of mechanical shock waves decreased the sensation of pain in the subjects participating in our study. VAS values were lower in subjects after five treatments, while after ten treatments, they were statistically significantly lower, as compared to the VAS values at the beginning of treatment. However, similarly to Hayta et al., we also failed to prove the association between the size of the calcaneal spur and VAS, before and after shockwave therapy (Hayta, et al. 2016). In other words, we cannot claim that the reduction in the size of the calcaneal spur leads to the reduction in pain intensity. We showed that the mechanical shock wave led to a reduction in the size of the heel spur and to a reduction in the intensity of pain, but whether these two phenomena are cause-and-effect related, based on the obtained results, we cannot claim.

In their study, Yalcin et al. also failed to prove a correlation between the clinical outcome and the radiological finding. The study included 108 patients and was aimed at investigating the impact of radial mechanical shock wave therapy on plantar fasciitis symptoms and the size of the calcaneal spur. One of the inclusion criteria was radiologically proven presence of a calcaneal spur. Patients who met all the inclusion criteria were treated with five radial mechanical shockwave treatments, which were spaced seven days apart. VAS, a questionnaire on patient satisfaction with the applied therapy, and a lateral X-ray of the heel were used to assess the treatment outcome. The

X-ray was used to monitor the size and position of the calcaneal spur. Measuring was performed prior to the beginning of therapy and after the last application of shock wave therapy. VAS values were statistically significantly lower after the application of the therapy. Namely, 66.7% of the subjects stated that they no longer felt any pain, 15.7% of them stated that the intensity of pain had been cut by half, while 17.6% of the subjects said that the pain intensity was the same as before the applied therapy. Radiological analysis determined that none of the calcaneal spurs had disappeared completely. However, lateral X-ray imaging revealed a reduction in the dimensions of the calcaneal spurs in 23 (21.3%) patients and the reduction of the calcaneal spur angle in 19 (17.6%) patients. Just like our results and the results obtained by Hayta et al., the results of this study also failed to prove a correlation between the reduction in the size of the calcaneal spurs and the evident reduction of the intensity of pain (Yalcin, et al. 2012).

Many studies have proven a strong association between mechanical shockwave therapy and the reduction in pain intensity, in patients with plantar fasciitis. As already stated, the results of our study also coincide with these results, to a great extent, and contribute to the understanding of this association.

Numerous studies, which investigated the impact of shockwave therapy on plantar fasciitis symptoms, compared the effects of this type of treatment with the effects of other treatment options for this disease. In a randomized clinical study, Eslamian et al. proved a significant association between mechanical shockwave therapy and pain intensity reduction. In the mentioned research it was included 40 patients diagnosed with plantar fasciitis, who, for a period longer than two months, had not responded to physical therapy, NSAIDs, stretch exercises, and pads for the heel. The study did not include patients whose anamnesis contained information on procedures and diseases related to the osteoarticular system, expectant mothers, nor patients who, due to plantar fasciitis, had been receiving corticosteroid therapy in the preceding six months or physical therapy in the preceding three months. The subjects were divided into two groups, with 20 patients each. The subjects of one group were treated five times with radial mechanical shockwave treatments, spaced three days apart. The subjects of the other group were treated with a single dose of corticosteroids. The drug was administered via injection in the region of the greatest intensity of pain in the heel. Pain intensity, in the morning and during the day, was assessed on the basis of VAS, while foot function was assessed with the Foot Function Index. Measuring was performed before treatment, and four and eight weeks after treatment. A calcaneal spur was confirmed in 7 (35%) patients of the experimental group and in 10 (50%) patients of the control group. A significant correlation between the presence of a calcaneal spur and the reduction of pain, i.e., Foot Function Index, was not determined in either of the groups. However, results showed that the application of mechanical shockwave therapy had led to statistically significant reduction in both the morning and evening VAS, four and eight weeks after the application of the therapy. The Foot Function Index also showed significant reduction after the application of mechanical shockwave therapy. Similar results were obtained in the control group as well. The only difference was that the Foot Function Index showed better results in the experimental group and that patients expressed a greater level of satisfaction with the application of shockwave therapy, as compared to the administration of the corticosteroid injection (Eslamian, et al. 2016). The above-described study proved the positive effect of radial mechanical shockwave application in the treatment of plantar fasciitis.

Very similar results were obtained by Lai et al. in their study, the difference being that they used focused mechanical shockwave therapy. We also used focused mechanical shock waves, in our study. Within the said study, this group of researchers compared the effects of the application of focused mechanical shock waves with the effects of corticosteroids, in patients with plantar fasciitis. A total of 110 patients, who met the inclusion criteria, were divided into two equal groups, using the randomization method. The subjects in the first group were treated with focused mechanical shockwave therapy, twice within the space of 14 days. The subjects in the second group were treated with a single corticosteroid injection, applied locally in the region of the heel of the

foot. A total of 47 subjects from the first group and a total of 50 subjects from the second group completed the study. The following parameters were monitored: plantar fascia thickness, VAS, and the modified scores (scores related to pain and functionality). Measuring was performed prior to treatment, four weeks, and twelve weeks after corticosteroid injection application, i.e., after the application of the first mechanical shockwave treatment. The evaluation of the obtained results indicated that both of the strategies applied yielded beneficial results. However, the application of mechanical shockwave therapy was more efficient, as compared to local corticosteroid application. This was especially noticeable after twelve weeks. Of all the parameters analyzed, only plantar fascia thickness did not show a better result in the group of patients treated with focused mechanical shockwave therapy (Lai, et al. 2018). The two studies described above show that the application of both radial and focused mechanical shock waves is equally efficient, or that is slightly more efficient, as compared to corticosteroid application. When the fact that corticosteroid application carries the risk of numerous adverse effects, as well as the possibility of plantar fascia rupture, is taken into consideration, it is quite clear why the preferred treatment should be the application of mechanical shockwave therapy (Schulhofer, 2013; Lee, et al. 2014).

The effectiveness of mechanical shockwave therapy in the treatment of plantar fasciitis has also been compared to the effectiveness of botulinum toxin treatment. In a study carried out by Roca et al., out of a total of 103 patients who were candidates for inclusion in the study, 29 patients responded well to the treatment of first choice (physical therapy and radiation therapy), which is why they were not included in the study further. This indicates that a little over a quarter of the patients had an appropriate response to the treatment of first choice, i.e., that in a majority of the patients it was necessary to apply another form of treatment. The subjects who met the inclusion criteria were randomly allocated into two groups, with 36 subjects each. The patients in the experimental group received one treatment of focused mechanical shockwave therapy, while the control group was treated with a single dose of botulinum toxin. Treatment outcomes were measured with VAS (in the morning, during the day, and during exercise), the Roles and Maudsley score, the European Quality of Life scale, and with plantar fascia thickness. Measuring was performed before treatment, as well as one to two months after treatment was administered. A calcaneal spur was detected in 83.3% of the patients in the experimental group and in 72.2% of the patients in the control group. In our study, a calcaneal spur was present in all of the subjects, since one of the inclusion criteria was the presence of a calcaneal spur. Data on the frequency of a calcaneal spur in plantar fasciitis are found in numerous studies. However, data on the presence of a calcaneal spur in 72% – 83% of subjects of the control group and the experimental group within the study by Roca et al. are one of the largest that we have found in literature. The superiority of mechanical shockwave therapy over botulinum toxin, which was proven in this study, was reflected in pain management. In two of the five applied pain scales, a statistically significant difference was found, while in the three remaining scales, a tendency in favor of mechanical shockwave therapy was noted. By comparing plantar fascia thickness after therapy and the thickness before treatment, a reduction was noted. This change was present in both treatment modalities, but it did not attain statistically significant values (Roca, et al. 2016).

In a randomized clinical study, Sanmark et al. investigated the effect of mechanical shockwave therapy and low-level laser therapy in patients with plantar fasciitis. Of a total of 46 patients, 34 patients met the inclusion criteria. The randomization method was applied to divide these patients into two groups, with 17 subjects in each group. Mechanical shock wave therapy was applied three times in all the subjects of the first group, with the treatment sessions spaced seven days apart, while in the patients of the second group, low-level laser therapy was applied, three times a week, over a period of four weeks. The following were used for assessing the effects of both treatment modalities: plantar fascia thickness, VAS, and the Foot Function Index. All measuring was performed prior to the beginning of treatment, immediately after the last treatment session, and a month after the final treatment session. Plantar fascia thickness was measured with ultrasound. It

is generally accepted that plantar fascia thickness in patients with plantar fasciitis is ≥ 4 mm (McMillan, et al. 2009; Hansen, et al. 2018; Drake, et al. 2022). In the group of patients treated with mechanical shockwave therapy, the median plantar fascia thickness at the beginning of therapy was 4.7 mm, while a month after the final treatment it was 3.8 mm. In the group of patients who received low-level laser therapy, these values were 4.6 mm and 4.0 mm, respectively. Both forms of therapy led to a statistically significant reduction in plantar fascia thickness, with this reduction being more pronounced in the patients treated with mechanical shockwave therapy. The situation was similar regarding the Foot Function Index. Both forms of therapy significantly reduced it, however, this reduction was more pronounced in the group of patients treated with mechanical shockwave therapy. With regards to VAS, the patients treated with low-level laser therapy showed a somewhat better result. However, both treatments caused statistically significant reduction of this score (Yinilmez Sanmak, et al. 2018).

The aim of the study carried out by Akinoglu et al. was to compare the acute effects of radial mechanical shockwaves and ultrasound, in patients with plantar fasciitis. The study involved only women who met the inclusion criteria for this study. The subjects, 54 in all, were randomly divided into three groups of equal size. Each of the groups was prescribed a program of exercise to be carried out at home. In addition to the exercises at home, the patients from the first group had three shockwave treatments, spaced seven days apart; the patients from the second group received ultrasound treatment twice a week, until they received a total of seven treatments; while the patients from the third group, which were used as controls, received no other treatment except the home exercises. The results of the applied therapy were measured with VAS, the Foot Function Index, the American Orthopedic Foot and Ankle Society (AOFAS) score, the one-leg stand test, the functional reach test, as well as the test of ankle proprioception. Measuring was performed before the beginning of any therapy, as well as four weeks after the initial treatments. Upon evaluating the obtained results, the authors of this study concluded that both mechanical shockwave and ultrasound therapy were efficient methods for pain reduction and improvement of foot functionality, when combined with exercise. Additionally, the authors agreed that a similar future study, involving also men, would greatly contribute to an even better understanding of the effects of shockwave therapy and ultrasound therapy on the symptoms of plantar fasciitis (Akinoglu, et al. 2017).

Analyzing the literature related to plantar fasciitis treatment, we have also found studies investigating the effectiveness of mechanical shockwave therapy and acupuncture (Cotchett, et al. 2010). Acupuncture is an ancient, traditional treatment method, originating in China. This therapeutic method has been in use for over 3,000 years and is performed by penetrating the skin with thin needles, at the site of the acupuncture points (Zhuang, et al. 2013). It is most commonly used for alleviating pain, in combination with other forms of treatment. In their study, Bagcier et al. investigated whether acupuncture can improve the effectiveness of mechanical shockwave therapy. Subjects diagnosed with plantar fasciitis and who met the inclusion criteria for the study were divided into two groups. Each group had 20 patients. One group was treated with mechanical shock waves, while the other group was treated with mechanical shock waves and acupuncture. The patients from both groups were treated with mechanical shockwave therapy, three times, with the treatment sessions spaced seven days apart, under the same conditions. After each mechanical shockwave treatment session, patients from the second group underwent acupuncture in the gastrocnemius muscle trigger acupuncture points. To evaluate the effectiveness of the therapy, the morning VAS, the VAS at rest and during activity, pain assessment with a pressure algometer and the Foot Function Index were used. All measurements were performed before treatment and one month after the last treatment. In both groups, a statistically significant decrease in all values measured one month after treatment was observed, as compared to the values measured before the beginning of therapy. Mechanical shockwave therapy was clearly effective in reducing pain, in patients with plantar fasciitis. This result coincides with the results we obtained in our research. However, in the group where acupuncture was also applied, this reduction was even more

pronounced. The values of the morning VAS, the VAS at rest and during activity, as well as the values of the Foot Function Index, were statistically significantly lower in the group in which acupuncture was applied, as compared to the group treated only with mechanical shock waves. Since there was no group that underwent acupuncture alone, it remains an open question as to whether under these conditions acupuncture alone would lead to a statistically significant reduction in pain (Bagcier and Yilmaz, 2020). Moosaei Saein et al. partially answered this question in their research, suggesting that the application of acupuncture alone reduces pain in patients with plantar fasciitis (Moosaei Saein, et al. 2022).

By comparing the results of our study with the results of other clinical studies which dealt with the effects of mechanical shock waves and the effects of other therapeutic modalities, such as the local application of corticosteroid injections, low-level laser therapy, ultrasound, botulinum toxin and acupuncture, we came to the conclusion that the effects of the application of mechanical shockwave therapy, are, if not better, then at least the same, as compared to the above-mentioned therapeutic options.

In our study, focused mechanical shock waves were used, whose effectiveness in reducing pain in patients who were treated with this type of therapy we have proven. However, we can note that, in addition to this type of mechanical shockwave therapy, a large number of researchers have used radial mechanical shock waves in their studies. There are certain differences between these two types of waves, and they arise from the source where they are generated (Galecka Szczerba, et al. 2019; Auersperg and Trieb, 2020). In a systematic review by Schmitz et al., publications that were in the PEDro database, up to the time when this extensive research was carried out, were analyzed. A total of 37 controlled clinical trials were identified that investigated the use of mechanical shockwave therapy in plantar fasciitis. In 27 studies, focused mechanical shock waves were used, in nine studies radial mechanical shock waves were applied, while in one study both types of mechanical shockwave therapy were used. Improvement, attributed to mechanical shockwave therapy, was present in 31 of a total of 37 controlled clinical studies (Schmitz, et al. 2015). As can be seen, few studies directly compare the impact of radial and focused mechanical shock waves.

In order to check whether there is indeed a difference when applying one of the mentioned types of mechanical shock waves, Lohrer et al. conducted a randomized clinical study. Patients who met all the inclusion criteria were divided into two groups. The group of patients treated with focused mechanical shockwave therapy had a total of 20 subjects, wherein 16 (80%) of them had a calcaneal spur confirmed by radiographic findings. The group of subjects in which radial mechanical shock wave therapy was applied included 19 patients, of whom 17 (89.5%) patients had calcaneal spurs. Mechanical shockwave therapy was applied three times, with the treatment sessions spaced seven days apart. Each patient received 2,000 impulses (frequency: 10 Hz) per session. The energy flux density of the focused mechanical shock waves was 0.20 mJ/mm^2 , while the energy flux density of the radial mechanical shock waves was 0.17 mJ/mm^2 . The above-stated density of the energy flux corresponded to an impact strength of three bars. The patients in our study were exposed to focused mechanical shock waves, with each patient receiving 1,600 impulses in one session, at a frequency of 10 Hz and a shock strength of 1.6 bars. In the aforementioned study, the impact of the applied therapy was evaluated based on the Foot Function Index. Also, in order to objectively assess the influence of different types of mechanical shock waves, the authors applied neuromuscular performance tests. To this end, the following were performed: single-leg jumps, single-leg long jumps, the single-limb stance test, as well as isokinetic testing. In this way, it was possible to objectively assess how pain affects function. Measuring was performed before the start of therapy, as well as two and 12 weeks after the last therapy. The overall results showed a slight superiority of focused mechanical shock waves as compared radial mechanical shock waves. The result adjusted for age subgroups indicated, as the authors put it, a “more than slight” superiority of focused mechanical shock waves over radial mechanical shock waves (Lohrer, et al. 2010).

A group of Polish researchers conducted a similar study. Their aim was to compare the therapeutic effects of radial and focused mechanical shock waves. One of the inclusion criteria for the study was that the subjects had radiological confirmation of the presence of a calcaneal spur. This criterion was the same as in our study. The subjects included in our study, both those from the control group as well as those from the experimental group, had a calcaneal spur confirmed by X-ray or ultrasound. A total of 66 patients met all the criteria for inclusion in this study and they were divided into two groups, with 33 patients in each. However, due to the long duration of the research, there was an attrition of study subjects. After three months, 30 patients remained in each group. After six months, the group treated with focused mechanical shock waves had 27 patients, while the group treated with radial mechanical shock waves was left with 28 subjects. All patients who were treated with focused mechanical shockwave therapy received, during one treatment, 2,000 impulses, at a frequency of 4 Hz and an energy flux density of 0.4 mJ/mm^2 . Patients treated with radial mechanical shockwave therapy received, during one treatment, 2,000 impulses, at a frequency of 8 Hz and an energy flux density of 0.38 mJ/mm^2 (5 bars), and then another 2,000 impulses, with an energy flux density of 0.23 mJ/mm^2 (2.5 bars). There was a total of five treatments, spaced seven days apart. The following were used to assess the effectiveness of mechanical shockwave therapy: Foot Function Index, analysis of ground reaction force during walking, temporal gait parameters, and absolute symmetry index, calculated on the basis of the data from the above listed analyzes. Measuring was performed before the beginning of therapy, as well as one, three, six, twelve, and twenty-four weeks after the end of the therapy. The authors of this research concluded, based on the obtained results, that the application of both focused and radial mechanical shock waves is an effective method in the treatment of symptomatic calcaneal spurs. A more detailed analysis of the Foot Function Index shows slightly better results in the application of radial mechanical shock waves, as compared to the application of focused mechanical shock waves. The Foot Function Index proved to be the only appropriate method for evaluating the effectiveness of the therapy, as compared to the other selected tests in this study. Its results were the best in both groups of subjects after 24 weeks, which justifies the long follow-up of patients. This result suggests long-term positive effects of applying mechanical shock waves in the treatment of plantar fasciitis accompanied by the presence of calcaneal spurs (Krol, et al. 2021).

As evident from everything noted so far, mechanical shock waves show great success and good results in the treatment of plantar fasciitis. However, studies such as the study by Krol et al. (Krol, et al. 2021), which follow the long-term effects of mechanical shockwave therapy, are rare. The largest number of studies follow the effects of this therapy immediately after its application or during a short period after it has been completed. Mechanical shockwave therapy is effective, in terms of reducing pain and improving function during short- and medium-term follow-up, but its effectiveness in the long term has not been sufficiently investigated (Malliaropoulos, et al. 2016). This is also the case with our study. VAS showed a significant improvement, however, measuring was performed immediately before the application of therapy, after the fifth, as well as after the tenth treatment session.

In order to determine the long-term effects of the application of mechanical shock waves, Ibrahim et al. conducted a study wherein they followed-up the subjects for two years after the application of therapy. The study included 50 subjects who met all the inclusion criteria, while 77% of them had calcaneal spurs. Subjects were randomly divided into two groups of 25 patients each. The experimental group was treated with radial mechanical shock waves, while the control group was treated with placebo. The placebo was applied over a clasp on the heel so that the waves could not enter the tissue. Patients were unaware of the existence of the clasp between the applicator and the heel. The only one who had this information was the doctor who performed the therapeutic procedure. During one treatment, 2,000 impulses were applied to the patients, at a frequency of 8 Hz and energy flux density of 0.16 mJ/mm^2 , which corresponded to a pressure of 3.5 bars. Radial mechanical shockwave therapy was applied twice, with an interval of seven days between the

treatment sessions. Treatment outcomes were measured with VAS and the modified Roles and Maudsley scale. Measuring was performed before the start of the study, as well as one, three, six, twelve and twenty-four months after the final treatment. No attrition of the study groups after the first year was recorded. After the second year, two subjects left the experimental group and one patient dropped out of the control group. The results of measuring VAS, at every point in time planned for this, indicated the existence of statistically significant differences in these values in favor of the patients treated with mechanical shock waves, as compared to the placebo. The results of the measurements after the first and after the second year are especially important, because they indicate the long-term effects of mechanical shockwave therapy. The authors of this study suggest that the use of mechanical shock waves in patients with plantar fasciitis is effective and safe and leads to significant long-term pain reduction without side effects (Ibrahim, et al. 2017).

Clearly, a longer period of follow-up of subjects in the studies would provide more data on the long-term effects of mechanical shock wave application. However, the longer the follow-up period, the greater the possibility of subjects dropping out. In studies where the subjects were followed-up for a six months or longer, attrition was recorded. As an example, we can cite the following studies: Krol et al. (66 patients started the study; 55 patients completed the study) (Krol, et al. 2021), Ibrahim et al. (50 patients started the study; 47 patients completed the study) (Ibrahim, et al. 2017), Malliaropoulos et al. (68 patients started the study; 64 patients completed the study) (Malliaropoulos, et al. 2016). Attrition of subjects represents a big problem for completing research and drawing final conclusions. Therefore, this emerges as one of the possible reasons why the researchers opted for a shorter period of follow-up of the subjects in their studies.

According to the official guidelines of the International Society for Medical Shockwave Treatment (ISMST), treatment of plantar fasciitis with radial or focused mechanical shock waves should be performed up to five times, with intervals between sessions of one to two weeks (DIGEST Guidelines, 2019). In keeping with the recommendations, in our study, the interval between two applications of mechanical shockwave therapy was seven days. In the largest number of clinical studies that we analyzed, the interval between treatments was seven days (Lohrer, et al. 2010; Malliaropoulos, et al. 2016; Galecka Szczerba, et al. 2019; Badil Guloglu and Yalcin, 2021). The shortest interval between two mechanical shockwave applications was three days (Eslamian, et al. 2016), while the longest was 14 days (Lai, et al. 2018). In our study, we applied a total of 10 treatments. Within the design of the study, we planned to perform at least five cycles of therapy with an interval of seven days between them, and, if no adverse effects of mechanical shockwave therapy were to occur, to continue the therapy for up to 10 cycles. Since there were no adverse effects reported, there was no reason not to continue the therapy up to the intended 10 applications. Measuring was performed after the fifth and after the tenth therapy, which proved to be quite useful. Comparing the results of measuring, we noticed that the reduction of the calcaneal spur as well as the reduction of VAS were more pronounced after ten applied therapies, as compared to five applications of mechanical shock wave therapy.

In the largest number of studies, regardless of whether the effect of focused or radial mechanical shock waves was investigated, there were three to five applications of the therapy (Lohrer, et al. 2010; Eslamian, et al. 2016; Bagcier and Yilmaz, 2020; Krol, et al. 2021). There are rare studies wherein mechanical shockwave therapy was applied only once (Roca, et al. 2016) or twice (Ibrahim, et al. 2017; Lai, et al. 2018). The largest number of applied treatments that we have found in the literature was 11 (Malliaropoulos, et al. 2016). Malliaropoulos et al. analyzed the application of radial mechanical shockwave therapy in patients with plantar fasciitis using an individualized treatment protocol. The individualized treatment protocol included adjusted values of the mechanical shockwave properties (number of impulses, impulse frequency and pressure), as well as adjusting the number of sessions to each patient, especially depending on the response to therapy. Out of a total of 68 patients, 9 (13%) patients had four sessions, 10 (15%) patients received 5 treatments, 21 (31%) patients received 6 treatments, 5 (7%) patients had 7 treatments, 17 (25%)

patients had 8 sessions, two (3%) patients received 9 treatments, three (4%) patients received 10 treatments, and one (1%) had 11 sessions. The interval between applications in all patients, regardless of the number of applications, was seven days. The longer the symptoms lasted before going to the doctor, the more treatments were administered to the patients. One of the most important results obtained in this study is establishing a positive and moderate correlation between the duration of pain before the start of mechanical shockwave therapy and the number of sessions. In other words, the later the application of this type of therapy started, the more sessions were necessary for the successful treatment of patients. Also, the number of treatments to which the patient was exposed depended on the strength of the mechanical shock waves. Patients who chose weaker shock waves due to pain had a greater number of sessions. The results of this research indicate that therapy with more sessions of lower energy waves was just as effective as therapy with fewer sessions of higher energy waves (Malliaropoulos, et al. 2016). This indicates that the energy delivered to the tissue is critical to successful mechanical shockwave treatment (Chow and Cheing, 2007). However, the increased flow of energy into the tissue in a short period of time leads to increased pain and local swelling. This would mean that the application of high-energy mechanical shock waves may cause more pain at the application site, as compared to the application of low-energy mechanical shock waves (Rompe, et al. 2005). In order to avoid pain at the site of mechanical shockwave application, local anesthesia can be applied. However, the use of local anesthesia may reduce the effectiveness of mechanical shockwave therapy (Wang, et al. 2019).

In our study, about 10% of the patients who received mechanical shockwave therapy reported pain during the application. No local anesthetic was used during the application. The impact strength of the mechanical shock waves used in our research was 1.6 bars. This strength corresponds to the lower cut-off value for medium-intensity mechanical shock waves, or the upper cut-off value of low-intensity mechanical shock waves (Chow and Cheing, 2007).

In their study, Lee et al. wanted to investigate whether a lower number of high-energy mechanical shockwave sessions or a greater number of low-energy mechanical shockwave sessions would have better effects in the treatment of plantar fasciitis. Sixty patients who met all the inclusion criteria were included in the study and were randomly divided into two equal groups. One group was treated with 1,000 impulses, with energy flux density of 0.08 mJ/mm^2 , and this group was designated as the low-energy group. The second group was treated with 1,000 impulses, with energy flux density of 0.16 mJ/mm^2 , and this group was designated as the medium-energy group. The low-energy group was treated with six mechanical shockwave sessions, while the medium-energy group was treated with three mechanical shock wave sessions. The interval between sessions was seven days. Treatment outcomes were monitored based on pain intensity, foot function, and plantar fascia thickness. Measuring was performed for both groups before the beginning of treatment, seven days, one month, and three months after the last treatment. After three sessions, the medium-energy group showed better results, with regards to the reduction of pain intensity and the improvement of foot function, as compared to the low-energy group. However, after six sessions, the low-energy group showed similar results, in terms of pain intensity and foot function improvement, as the medium-energy group did after three sessions. Pain during the application of mechanical shockwave therapy was not registered in any patient. This can be explained by the relatively low energy flux density in both of the groups analyzed. As one of the conclusions of this research, it is stated that mechanical shock waves of medium energy led to the same effect as mechanical shock waves of low energy, but with twice as few sessions (Lee, et al. 2013). The results of the meta-analysis by Wang et al. are predominantly consistent with previous results. This group of authors also agreed that mechanical shock waves of medium energy showed the greatest efficiency, regardless of whether radial mechanical shockwaves or focused mechanical shock waves were applied (Wang, et al. 2019).

The time from the onset of symptoms of plantar fasciitis to the moment of presentation to the doctor can play a significant role in the prognosis of this disease. In their study, Malliaropoulos

et al. reported that VAS, one year after the end of treatment, correlated with the duration of pain before treatment. Also, this group of authors stated that the percentage of recurrence in their research was 8%, after one year, and that the three main factors contributing to recurrence were female gender, the duration of pain before the start of therapy, and the number of mechanical shockwave sessions (Malliaropoulos, et al. 2016). On the other hand, there are studies that do not find a clear connection between the duration of pain before treatment and clinical outcomes (Yalcin, et al. 2012; Chuckpaiwong, et al. 2009). In our study, the time from the onset of symptoms to the moment when the patient reported to the doctor ranged from one month to as long as four years, in the experimental group. In the control group, similarly to the experimental group, the subjects reported, at the earliest, one month after the onset of complaints, while, at the latest, they reported twelve months after the onset of symptoms. This difference between the observed groups was statistically significant. The time from the onset of symptoms of plantar fasciitis to the moment the patient presents to the doctor may range from a few months to several years. The longest period of the persistence of symptoms before the beginning of treatment that we have found in the literature was 120 months (Ozdemir, et al. 2004; Yalcin, et al. 2012).

The mechanism of calcaneal spur formation is not fully understood. There are several theories that have been developed over time attempting to explain the origin of this disorder. Current knowledge gives most precedence to the theory of vertical compression (Menz, et al. 2008). Why some people are more prone to developing this condition than others, depends on their sex, age, occupation and lifestyle (Velagala, et al. 2022). The majority of studies that have dealt with the analysis of calcaneal spurs and plantar fasciitis agree with the fact that this pathology is more often present in the female population. In our research, in the experimental group, there were several more women compared to men, while in the control group it was the opposite, i.e., there were six more male respondents, as compared to female respondents. These differences were not statistically significant. However, looking at the entire population of respondents in our research, we find that there were more men than women, which is in contrast to numerous other studies. The more common occurrence of calcaneal spurs in women is explained by altered foot biomechanics due to wearing high heels (Toumi, et al. 2014).

The change in gait of the geriatric population also contributes to the increased incidence of the development of calcaneal spurs (Velagala, et al. 2022). In the clinical studies that we have reviewed, we found that plantar fasciitis, with or without calcaneal spurs, was more common in the elderly. Plantar fasciitis is extremely rare in people under the age of 20. This disease most often occurs between the ages of 40 and 60 years (Tu and Bytomski, 2011). In our research, the average age of subjects in the experimental group was 55 years, while in the control group it was almost 52 years, which was not a statistically significant difference. Analyzing the data from our study, we find that the youngest respondent was 20 years old, and he was in the control group, while the oldest respondent was 88 years old, and he was in the experimental group.

6. Conclusions

Based on the results obtained, we have reached the following conclusions:

1. In our study, the application of mechanical shockwave therapy led to the reduction of the size of calcaneal spurs. This reduction was statistically significant as soon as the first five treatments had been completed. After 10 treatments, the calcaneal spurs were statistically significantly smaller, as compared to the calcaneal spurs after five treatments. Mechanical shockwave therapy successfully reduced the size of calcaneal spurs in our subjects.

2. The application of a mechanical shockwave therapy reduced the sensation of pain in the subjects participating in our study. VAS score values were statistically significantly lower in subjects after 10 treatments, as compared to the VAS score values at the beginning of treatment. The VAS score after five treatments, compared to the VAS score at the beginning of the treatment, was lower, however, it did not reach statistically significant values. Mechanical shockwave therapy reduced the intensity of the pain, but a greater number of treatments is required for the full effect to be achieved.

3. The correlation between the size of the calcaneal spur and the intensity of pain, before and after the application of mechanical shockwave therapy, in our study, was not statistically significant. Namely, the reduction in the size of the calcaneal spur, resulting from the application of mechanical shock waves, did not correlate with the reduction in pain intensity.

4. Mechanical shockwave therapy successfully led to a decrease in the size of the calcifications, as well as to a decrease in pain intensity. However, for a better effect, the application of more treatments should be considered. Our results suggest that with an increase in the number of treatments, the size of the calcaneal spurs and the pain intensity would decrease to a greater extent.

5. From all that has been stated above, we can conclude that mechanical shockwave therapy is an effective way of treating plantar fasciitis which is accompanied by calcaneal spurs.

7. Literature

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Published works from the thesis

1. Ivana Topalović, Dejan Nešić, Sindi Mitrović, Vera Miler Jerković, Ljubica Konstantinović, " The Efficacy of Focused Extracorporeal Shock Wave Therapy and Ultrasound Therapy in the Treatment of Calcar Calcanei: A Randomized Study", BioMed Research International, vol. 2023, Article ID 8855687, 8 pages, 2023 <https://doi.org/10.1155/2023/8855687>
2. Ivana Topalović, Dejan Nešić. Application of mechanical shock wave in the treatment of calcified tendinopathies- Medical youth, March 2022; Vol 73, 1pg 7-11 doi: 10.5937/mp73-35808

Biography

Ivana Topalovic was born on July 1, 1983 in Belgrade. She finished elementary school in Belgrade with a grade of 5.00. She finished high school in America, in the state of Virginia.

In 2001, Norfolk Collegiate School. In March 2009, she graduated from the Faculty of Medicine (teaching in English), and six months later she passed the state exam.

In 2010, she enrolled in specialist academic studies in the field of physical medicine and rehabilitation and graduated in 2012. In 2012, she received a specialization in physical medicine and rehabilitation, which she completed in January 2017 with a passed specialist exam with a score of ten. . In 2012, she enrolled in doctoral studies, passed the mandatory exams, and her doctoral dissertation which was approved by the decision of the Council of Scientific Fields of Medical Sciences of the University of Belgrade dated September 14, 2021 (No. 61206-2533/4-21) with a topic 'Impact of shock waves on the size of calcification in the presence of calcaneal spur and plantar fasciitis'.

Work experience

From 2009-2012, she was employed in spec. Ord. for physical medicine and rehabilitation PHYSICAL.

Now she works in the same workplace under a part-time contract.

Since 2018, she has been a member of the Board of Education and Science of the Belgrade Regional Medical Chamber

Teaching experience

Since 2012, she has been permanently employed at the Sports and Health College, where she still works. Elected as a lecturer at the same school in 2014 for the subject Clinical physical therapy in neurology and surgery with orthopedics and traumatology. She is in the same workplace now.

Scientific papers

1. Health and physical activity Popovic O., Lazic B., Topalovic I 2013 poster and award at the Belgrade Health Festival
2. The effectiveness of shock wave therapy in calcified tendinitis, final thesis on specialist academic studies, defended in 2012 at the Faculty of Medicine in Belgrade
3. Application of physical therapy in the treatment of pressure ulcers Popovic O, Matanovic D, Topalovic I 2014 Congress on wound healing Belgrade
4. Delaying the onset of muscle pain in athletes with an energy crisis and treatment options; Filipovic D, Vukusic K, Topalovic I. Sport, Science and Practice, Vol.6 N 1& 2, 2016 st 31-4
5. Fibromyalgic syndrome - novelties in understanding' Filipović D, Vukušić K, Topalović I. Sport, Science and Practice vol8, No1, 2018 70-81
6. Ivana Topalovic. Effects of five- and ten-week application of mechanical shock waves on the reduction of pain caused by chronic lateral epicondylitis, Serbian Medical Journal of the Medical Chamber. September 2020 vol11 no1 pg 49-56

7. Ivana Topalovic, Dragana Matanovic, et al. Effects of the Shock Wave Therapy Application in Treatment of Heel Thorn: Calcar Calcanei. Clin Image Case Rep J. 2020; 2(2): 115. Impact factor 3.75
8. Ivana Topalović, Dejan Nešić. Application of mechanical shock wave in the treatment of calcified tendinopathies - Medical youth, March 2022; Vol 73, 1 pg 7-11 doi:10.5937/mp73-35808
9. Invited lecture 'Physical therapy after infection with Covid 19'. The knowledge brought to us by the Covid 19 pandemic. National congress with international participation - October 2021
10. Invited lecture: Treatment of tendinopathies within the Post-Covid syndrome. Infections and challenges in diagnosis and treatment, National Congress with international participation on April 8, 2023, Belgrade
11. Invited lecture: Rehabilitation of the respiratory system in patients with post-covid Syndrome. Infections and challenges in diagnosis and treatment, National Congress with international participation on April 8, 2023, Belgrade
12. Ivana Topalović, Dejan Nešić, Sindi Mitrović, Vera Miler Jerković, Ljubica Konstantinović, "The Efficacy of Focused Extracorporeal Shock Wave Therapy and Ultrasound Therapy in the Treatment of Calcar Calcanei: A Randomized Study", BioMed Research International, vol. 2023, Article ID 8855687, 8 pages, 2023. <https://doi.org/10.1155/2023/8855687>

образец изјаве о истоветности штампане и електронске верзије докторског рада

Изјава о истоветности штампане и електронске верзије докторског рада

Име и презиме аутора IVANA TOPALović

Број индекса 2017/5124

Студијски програм BIOLOGIJA SKELETA
LETICAJ MEHANIČKOE UDARNOE TALASA NA VELIČIMLL

Наслов рада KALCIFIKACIJE KOD PRIBLISSTVA PETHOE TRNA I PLANTARHOE
FASCITICA

Ментор PROF. DR. DEJAN MEŠIĆ

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Потпис аутора

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