EVALUATION OF THE EFFECTIVENESS OF PLATE-RICH CONCENTRATE TREATMENT FOR PLANTAR FASCIA ENTHESOPATHY IN RUNNERS

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DOI. 10.51371/issn.1840-2976.2022.16.1.17 Original scientific paper

Abstract

The plantar fascia plays a very important role in the function of the foot during walking and running. It is the most functional element of the medial part of the foot. This disease is one of the most common causes of pain in the heel area in adults. There are many methods and regimens for treating patients with plantar fascia enthesopathy, including non-surgical-orthoses, stretching, taping, iontophoresis, NSAIDs, ESWT, laser, steroid injections, botulinum toxin type A, and surgical-fasciotomy. These methods do not bring high treatment effectiveness. Therefore, it was decided to conduct studies evaluating the effectiveness of an innovative method of treating these diseases. The research involved a group of 54 patients with diagnosed plantar fascia enthesopathy who practiced running sports (at least once a week, over 30 minutes).The first group consisted of 34 persons who were treated with a PRP injection and a specific rehabilitation program. The second group consisted of 20 people as a control group with diagnosed plantar fascia enthesopathy, matched for sex and age, subjected to an identical rehabilitation protocol, and not treated with PRP. The effectiveness of the treatment of patients with the use of a platelet-rich concentrator was assessed experimentally. The study consisted in monitoring a selected group of patients with a disease for which the proposed therapy was applied. The control group consisted of people with the same diseases without the study therapy. Pain sensations were recorded according to VAS scale and quality of life -EQ-5D, percentage index of the foot function index, limb stability index. The obtained statistical data indicate a downward trend in all parameters of the results obtained after the therapy in relation to the data from before the therapy, which proves the effectiveness of the studied therapy. For the parameter defining pain when touching in the group studied before the therapy, the median value was 4, and after the therapy the value was 0.
The downward trend was also maintained with the percentage value of the foot function index (sum_FFI_%) at the value of 42% before the therapy, reaching 1% after the therapy . In the control group, the values also maintained a downward trend in the value of the function index was obtained at the level of 44% with the result after treatment at the level of 9%. Among the treatments currently in use for plantar fascia enthesopathy, there is no single most effective method. The therapeutic method presented in the study showed statistically better results than commonly used therapies for this disease. The use of therapy with an autogenous platelet-rich concentrator in the treatment of plantar fascia enthesopathy with a selected rehabilitation program shows a significant advantage over all natural methods. It gives good effectiveness in healing this type of diseases, and in combination with rehabilitation, it brings measurable therapeutic benefits.

Keywords*: plantar fascia enthesopathy, platelet-rich plasma treatment, plantar fascia rehabilitation*

Introduction

Enthesopathies are painful lesions of the tendon attachments of muscles to the bones. The essence of the disease is the release of single tendon fibers from the pathological changed substrate of cartilage or periosteal bone deprived of the bone. The displacement of the torn fibers together with the cartilage or bone cells deep into the tendon causes pathological bone formation. They are so-called enthesophytes, i.e. specific bony outgrowths. These types of changes in the plantar fascia area are often called plantar fasciitis, due to the inflammation of the proximal plantar fascia area and the tissues surrounding the fascia, causing pain that makes it difficult to walk. The very name "plantar fasciitis" indicates the inflammatory background of the disease. However , histopathological studies indicate that the degenerative process (mucous degeneration, micro-tears, necrosis of collagen fibers) dominates here. Plantar fascia enthesopathy most commonly affects people between the ages of 40 and 60. It is one of the most common causes of pain in the heel area in adults. It is estimated that these patients constitute about 1% of people visiting an orthopedic doctor. Factors that increase the risk of its occurrence are: obesity, work requiring long

standing, intensive running sports, flat feet, dorsiflexion reduction in the ankle joint, most often resulting from calf muscle contracture. In 1/3 of cases, the disease affects both feet. Therefore, this problem appears much more frequently in runners. It accounts for 7-9% of all diseases occurring in this group of athletes. Pain in this group increases the next day after training. Moreover, the disease more often affects the elderly and overweight among all people practicing running. There are many methods and regimens for treating patients with plantar fascia enthesopathy. The current, most commonly used methods are: non-surgical - orthoses, stretching, taping, iontophoresis, NSAIDs, ESWT, laser, steroid injections, botulinum toxin type A, and surgical - fasciotomy. Nevertheless, none of these methods is characterized by high effectiveness and specificity of treatment. In connection with the above, it was decided to conduct research evaluating an innovative method of treatment. It is based on the administration of multiple platelet growth factors (PRP), isolated from the body's own blood. Therapy with the use of autogenous growth factors is complemented by rehabilitation. It is an integral and necessary element of the treatment with platelet-rich plasma (PRP).

Methods

The effectiveness of the treatment of PRP patients was assessed experimentally by conducting in-depth monitoring of a selected group of patients with the analyzed disease using the selected therapy in relation to the monitored people with the same diseases (control group) without the implementation of this therapy.

The study included a group of 54 patients with diagnosed plantar fascia enthesopathy who practiced running sports (at least once a week, over 30 minutes). Participants for the study were selected using a double-blind database of 200 patients with analyzed ailments, creating two therapeutic groups participating in the study. The first was a group of 34 people, the participants of which underwent a PRP (platelet rich plasma) treatment. The median age of the patients was 38 years (patients were in the range 27-51). The female to male ratio was 24:10. The first symptoms of the disease appeared 6-12 months ago, most of them started treatment from that moment. Three weeks after the administration of PRP, the study group underwent a rehabilitation protocol. The second group consisted of 20 people (control group) with diagnosed plantar fascia enthesopathy, matched for sex and age, subjected to an identical rehabilitation protocol, and not subjected to PRP surgery. In the selection of participants, the double-blind technique was used, taking into account the decisions and voluntary consent to participate in the research by a randomly selected person. The studies were conducted in accordance with the standards contained in the Helsinki Declaration of 2013, and the results of the studies were prepared in accordance with the recommendations of the ICMJE.

In the study group, from each patient about 20-40 ml of venous blood (a randomly selected Biomet kit was used) was collected, which was then placed in sterile test tubes and centrifuged for 12 minutes (3200 rpm). After centrifugation, the plasma fraction with a high concentration of platelets and growth factors was pipetted off (Fig.1).Then, about 2 ml of such a concentrate was administered as an injection, under ultrasound control, into the damaged area. The use of ultrasound in this method is very important, because the precise administration of the concentrate allows the maximum local action of the factors to be achieved. Three weeks after the administration of PRP, the study group underwent a unified rehabilitation protocol. Rehabilitation included exercises directly related to the post-treatment area and exercises aimed at restoring muscle balance, improving central stability, and re-educating kinesthetic sensation. The lists presented in the table required verification by an experienced therapist in order to select activities tailored to the individual capabilities of patients, so that they did not increase pain even to a minimal extent.

The research (in the rehabilitation protocol) adopted pain assessment using Visual Analog Scale (VAS). The scale in VAS includes 10 pain levels, from 0 to 10, with 0 being pain deficient and 10 being the worst pain imaginable. the scale has been calibrated on a 10 cm measuring tape. The Numerical Rating Scale (NRS) was used to assess the stability of the lower limb. The scale in the NRS was calibrated on a 10 cm measuring tape - from 0 to 10, where 0 denoted complete instability in standing on one limb, and a value of 10 denoted stable standing on one limb.

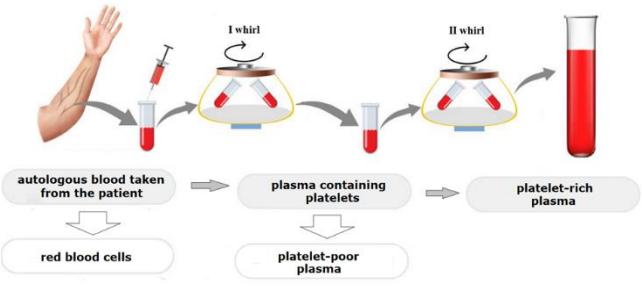

Fig.1 Scheme for obtaining PRP

Pain sensations were recorded according to VAS scale and quality of life -EQ-5D, percentage index of the foot function index, limb stability index.

Due to the fact that enthesopathies are degenerative, it seems that the use of platelet-rich plasma in this type of disease has its rationale.

The therapy with the use of PRP is complemented by appropriately selected rehabilitation. Post-treatment rehabilitation is to support the biochemical processes induced by the administration of PRP as well as to

restore the functions of the lower limb, significantly impaired by the disease process. It is also necessary to correct the pathological movement patterns in the lower limb and pelvis. Disorders within the lower limb, in their often long-term course, disturb the stereotype of gait with a change in the duration of its phases (limping). The way the whole limb is moved is changing, trick movements are created that are designed to protect against pain and, consequently, lead to overload. The function of the foot, knee and hip joints along with the rim of the lower limb is disturbed. The rehabilitation process is closely correlated with changes at the tissue level following PRP administration. Initiating the treatments earlier may disrupt the healing process by suppressing physiological inflammation or excessive mechanical stress on the tissue being formed. Therefore, the use of physical procedures in the first week after administration and kinesiotherapeutic techniques for two or three weeks is inadvisable. The aim of the first period of rehabilitation is to support repair processes by causing hyperemia, anti-inflammatory effects and techniques stimulating the proper production of collagen. The following are the physiotherapeutic techniques used in patients treated with PRP.

Implemented rehabilitation program recommended after administration of PRP to patients with plantar fascia enthesopathy

The rehabilitation protocol is based on physiotherapeutic techniques carefully selected by an experienced physiotherapist and most frequently used in plantar fascia enthesopathy studies. The individual techniques respond to the set of symptoms presented by the patient with plantar fascia enthesopathy.

The list includes exercises directly related to the post-treatment area as well as exercises aimed at restoring muscle balance, improving central stability and re-educating kinesthetic sensation. It is very important that exercise, even to a small extent, does not increase the pain (Tab. 1).

Table 1. The treatment plan

Week One:	-cryotherapy in the area of the heel tumor (time: max. 3 minutes for the treatment with nitric oxide, 15 minutes for the Cryo-cuff system) -ultrasound to the area of the plantar fascia attachment to the tuberosity of the calcaneus (time: 6 minutes, treatment every 2 days with a dose increase of 0.2 W / cm2, intermittent impulse) -magnetic field (time: 30 minutes, program after treatments on muscles and tendons of the lower limbs) - transverse plantar fascia massage and mobilization of the heel tumor -muscle energization techniques (PIR-post isometric relaxation, RI-reciprocal inhibition, stretching) of the posterior and lateral bands, i.e. the iliotibial band, hamstring muscles and calf muscles, gluteal muscles and plantar fascia. -kinesiotaping
Week two:	- anti-inflammatory treatments in the field of physical therapy (cryotherapy, ultrasound, magnetic field) -continuation of muscle energization techniques - exercises that improve deep feeling and balance (balance of the center of gravity, exercises on a variable surface with dosing the degree of difficulty, a balance platform) -exercises to strengthen weakened muscle groups, mainly mm. buttocks and calves -kinesiotaping
Week three:	-continuation of anti-inflammatory activities in the field of physical therapy -muscle energization techniques - proprioception training (especially exercises on a moving surface with a high degree of difficulty) -strengthening weakened muscle groups -taping
Recommendations for home:	-autostretching - work on the improvement of kinesthetic sensation - equivalent exercises -strengthening weakened muscle groups

The study used the "Patient's Diary", containing various questionnaires, including an epidemiological survey containing basic data on patients (age, sex, weight, height, current type of patient's activity, playing sports, first pain signal related to plantar fasciitis, treatment time, accompanying diseases, past myocardial infarction), Foot Function Index (FFI)), A survey based on the available pain rating (VAS) and quality of life (EQ-5D) scales. The questionnaire was conducted before the therapy and 3 months after

the end of rehabilitation at a follow-up visit (wk). The second research method is the measurement of limb stability using the Biodex Balance System. This measurement was also taken before and after therapy.

Results

The recorded data are tabulated with the division into the first research group (PRP intervention and an appropriately selected rehabilitation model) and the second control group (appropriately selected rehabilitation model without PRP intervention), which were homogeneously selected. All the obtained test results presented in the table were subjected to the Mann-Whitney U test in order to determine averaged values (Tab. 2-3).

Table 2 List of abbreviations used in Tables 3

TP_before	Touch Pain before (pain when touching before treatment)
TP_after	Touch Pain after (pain when touching at the control visit 3 months after the end of rehabilitation,
MPbefFS_before	Morning Pain before First Steps before the theraphy pain in the morning before getting out of bed before therapy
MPbefFS_after	Morning Pain before First Steps after theraphy (at follow-up visit after 3 months) pain in the morning before getting out of bed at a follow-up visit after 3 months
FFI%_before	Percentage index of Foot Function Index before therapy
FFI%_after	Percentage ratio of the Rate Function Index at the control visit after 3 months
Biodex TL_before	Biodex Treated Limb before (limb stability index measured with the Biodex platform before therapy)
Biodex TL_after	Biodex Treated Limb after (limb stability index measured with the Biodex platform at the 3-month follow-up visit
Biodex_change	change in the limb stability index in relation to the state before and after the therapy measured with the Biodex platform

Table 3. Descriptive statistics of the assessed parameters

Parameter		TP_before	TP_after	MPBefFS_before	MPBefFS_after	FFI%_before	FFI%_after	Biodex TL_before	Biodex_TL_after
The first test group	n	34	34	34	34	34	34	34	34
	mean	5.3	0.8	3.5	0.3	41%	11%	2.9	2.3
	95% CI	4.3	0.3	2.8	0.0	36%	5%	2.4	2.1
	+95% CI	6.3	1.3	4.3	0.7	45%	17%	3.3	2.6
	Median	4.0	0.0	4.0	0.0	42%	1%	2.5	2.4
	Min	0.0	0.0	0.0	0.0	5%	0%	0.3	0.4
	Max	10.0	4.0	8.0	4.0	65%	41%	6.8	3.4
	sd	2.9	1.4	2.2	1.0	12%	17%	1.3	0.7
Test U M-W	P	0.069	0.004	0.017	0.00001	0.013	0.001	0.013	0.012
Second st	n	20	20	20	20	20	20	20	20
	mean	5.7	1.1	4.5	1.5	44%	11%	3.5	2.7

udy group control	95% CI	4.3	0.6	3.7	1.1	37%	7%	2.8	2.3
	+95 % CI	7.1	1.6	5.3	1.9	51%	16%	4.3	3.1
	Median	4.5	1.0	4.0	1.0	44%	9%	3.0	2.5
	min	0.0	0.0	1.0	0.0	12%	3%	1.3	1.4
	max	10.0	4.0	9.0	4.0	68%	32%	6.8	4.3
	Sd	2.9	1.0	1.8	0.9	15%	9%	1.6	0.8

Based on the collected data from the questionnaires and during diagnostic tests, using the Biodex Balacne System SD both before the applied therapies and after the therapy, it was decided to analyze whether there was a significant statistical change. For this purpose, a pair test was carried out by verifying the equality of the medians using the Wilcoxon test. The results are statistically significant with $p < 0.05$.

The statistical analyzes show that the assessed parameters changed in relation to the values before and after the therapy (Tab. 2) both in the study group and in the control group. For the parameter pain on touching (TP) in the group studied before the therapy, the median was 4, and after the therapy was 0, so in this case the pain relief is observed. When observing the parameter pain in the morning before getting out of bed (MPbefFS), the median also drops from 4 to 0. The downward trend is also maintained for the value FFI%(percentage index of Foot Function Index), before = 42%, after = 1%. In the control group, the downward trend of selected parameters is also maintained and they are as follows: TP_before = 4.5 after = 1, MPbefFS_before = 4 after = 1, while the percentage ratio of the Rate Function Index, i.e. FFI_% before = 44% after = 9 %. The improvement is also evidenced by the comparison of limb stability before and after the therapy, measured with the Biodex Balance System. The stability index in the test and control groups also decreased. In the study group it was 2.5 before the treatment, and for after (control visit after 3 months it was 0.1 lower and amounted to 2.4 (the higher the stability index, the less stable the limb). A slightly larger difference in stability was observed in the control group. The stability index dropped from 3.0 before treatment to 2.5 after treatment. Analysis of the graphs showing the assessed parameters (TP, MPbefFS, FFI%) before the therapy and at the control visit (Fig. concerning parameters was observed in the study group (Fig. 3, 4, 5). In the study on the BIODEX platform, patients in the control group (Fig. 2).

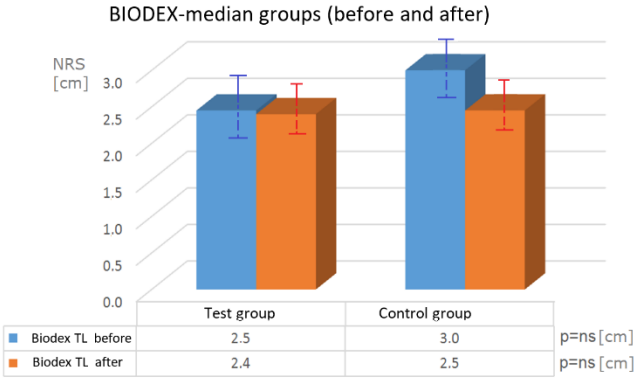

Fig. 2 Comparison of limb stability on the biodex platform before and after therapy at the control visit in the study and control groups

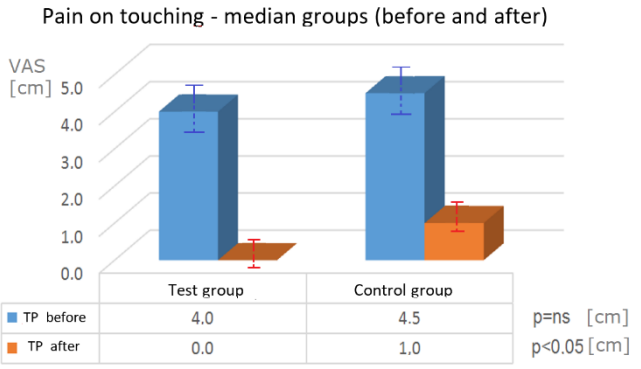

Fig. 3 Change in the bpd parameter before and after the therapy at the control visit in the study and control groups

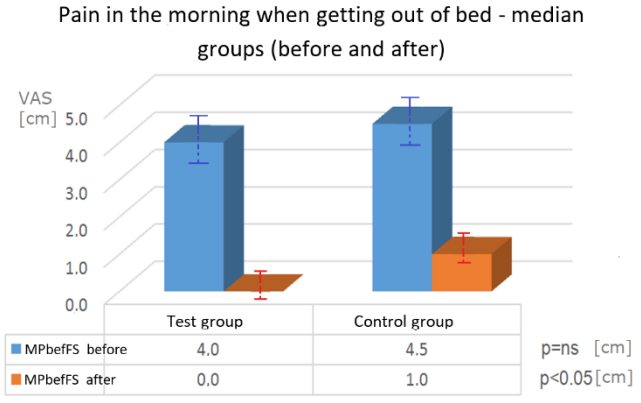

Fig. 4 Change in the BPD parameter before and after the therapy at the control visit in the study and control groups

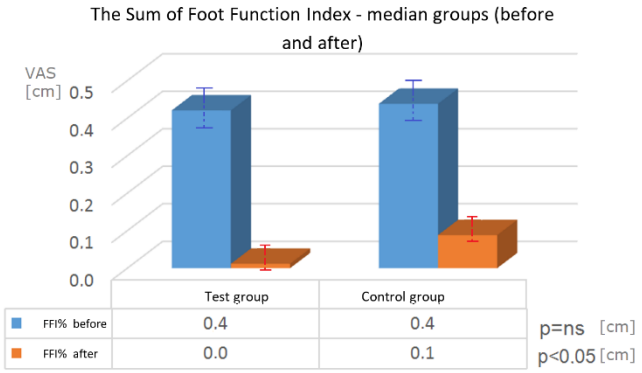

Fig. 5 Change in the parameter sum FFI% before and after the therapy at the control visit in the study and control groups.

Discussion

The currently used treatment methods include: non-surgical - orthoses, stretching, taping, iontophoresis, NSAIDs, ESWT, laser, steroid injections, botulinum toxin type A, as well as surgical - fasciotomy. The research conducted so far indicates the lack of satisfactory therapeutic effects in the treatment of plantar fascia enthesopathy. Landorf et al. Studied the effectiveness of orthoses in the treatment of the described disease. Investigating a group of 135 people, he divided the patients into 2 groups. The first group wore soft orthosis simulating braces and the second group wore semi-rigid plastic orthoses for three months. Studies have favored semi-rigid orthoses, but no significant statistics have been shown to demonstrate a positive effect of orthoses in plantar fascia enthesopathy. The effectiveness of orthoses and night splints was also assessed by Roos et al. He conducted studies on a group of 43 patients with an average age of 46 years. He used FAOS (Foot and Ankle Outcome Scale) for the assessment. The results of the studies were similar for both groups and indicated a short-term treatment effect. Similar conclusions were reached in their studies by Powell et al. and Batt et al. [31-33]. Winemiller et al. in turn investigated the effect of active, bipolar, magnetic, shock-absorbing insoles and foam insoles on pain in the area of the plantar fascia. 101 patients were enrolled in the study over 8 weeks. There were no significant differences between the two types of insoles and their impact on reducing heel pain, which means that it has been proven that magnetic insoles do not bring greater benefits to the therapy than ordinary foam insoles [13, 16]. Another method that has been tested is ESWT Shockwave Therapy. Haake et al. Assessed the effectiveness of ESWT on 272 patients. Each of the study participants did not respond to standard treatments.

The study groups were: ESWT and the placebo group. The observation period was 12 weeks. Based on the results, it was concluded that ESWT is an ineffective method of chronic pain treatment. ESWT was also the subject of studies by Speed et al. 88 patients with plantar fasciitis lasting more than 3 months were examined. Patients were treated with ESWT and ESWT simulations once a month for 3 months. Three indicators were assessed: pain during the day, pain at night, and pain accompanying the first steps in the morning. Patients were asked to fill in questionnaires before treatment, 1 month, 3 months after the end of treatment. There were no statistically significant differences between the two groups. Similar conclusions were reached by Buchbinder who subjected 166 patients to conductive ultrasound of ESWT and placebo for 6 weeks. Based on the results of this study, it was proved that ESWT did not lead to any greater benefit than placebo. Kudo et al. Repeated the research on ESWT on 114 patients diagnosed with plantar fasciitis, persistent area 6 months, not subject to standard treatment methods. Patients who used other therapies in parallel were excluded from the study. The research of Kudo et al. Proved a decrease in pain at the first steps in the morning. The VAS scale was used for the measurement. Kudo et al. Demonstrated the beneficial effects of ESWT in the treatment of refractory plantar fascia enthesopathy. In search of an effective method of treating plantar fasciitis, Babcock et al. Decided to administer to a group of 97 patients (with symptoms for over 6 months) botulinum toxin type A (BTX-A). One group was injected with BTX-A and the other with saline. BTX-A gave satisfactory results in 3-8 weeks in various tests. Babcock et al. Found that BTX-A increases the level of pain in patients with plantar fasciitis. On the other hand, Wheeler et al While studying the reduction of pain in muscles and tendons, concluded that the analgesic effect of BTX-A did not differ from placebo. When standard treatments fail, injections of steroids become the treatment of choice. The effectiveness of this method was tested by Crawford et al. In a group of 106 patients, who were divided into 4 groups depending on the drug administered: prednisolone with lignocaine, prednisolone with lignocaine after tibial blockade, lignocaine alone, lignocaine after tibial blockade. Pain reduction was demonstrated after 1 month, but no significant difference was noted after 3 months. Crawford et al. Proved that steroid injections have a strong analgesic effect, but only in the short term. Gaudeman, who assessed the effect of steroid iontophoresis in a group of 40 people, made similar observations. The results of the study were similar - iontophoresis with

dexamethasone is effective in the treatment of pain, but no more effective than placebo over a longer period of time. The effectiveness of the analgesic effect of corticosteroids was also investigated by Lee et al. Based on studies carried out on a group of 61 patients, he indicated that the strong analgesic effect was maintained shortly after administration of the drug. After six months, the pain has returned to the level from before the therapy. This result was also obtained by Tsai et al. In the conducted research. DioGiovanni et al. assessed the role of stretching in the treatment of Achilles tendon injuries and plantar fascia. In both groups there was a decrease in pain accompanying the first steps in the morning, as well as an improvement in limb function after 8 weeks of therapy, but the group with plantar fasciitis was better. DioGiovanni also investigated the effect of stretching on pain in the attachment area of the plantar fascia and heel tendon in a 2-year study on the same group of patients. The result was surprising as patients with injured Achilles tendon reached their maximum pain levels with their first steps in the morning. It was also noted that, in contrast to the results of the 8-week therapy, after 2 years there was no significant difference between the perception of pain in both groups of patients. This result may indicate errors in rehabilitation and the lack of gait re-education in a patient who is struggling with pain in the heel area for a long time. As I mentioned earlier, the aim of rehabilitation is to restore the correct stereotype of gait, muscle strength and improve flexibility so as to save the patient from relapse.The stretching effect was also investigated by Radford et al. The research group consisted of 92 people, the stretching effect was compared to mm. calves in combination with ultrasound simulation and the ultrasound simulation itself. The studies tested the effect of short-term stretching of the calf muscles, and the results of the studies did not show any benefits of this therapy (no significant difference between the two groups).

Due to the above-described lack of an effective method of treating enthesopathy of the plantar fascia, it was decided to conduct studies with the use of autogenous growth factors in the therapy of the described disease combined with carefully selected physiotherapeutic techniques to increase the effect of therapy. Treatment of enthesopathy with platelet-rich plasma has shown good results in the literature. Some rehabilitation techniques have better results when combined with each other. For example, in the study by Christopher Yelverton, Sunil Rama and Bernhard Zipfel, 2019 compare manipulation of the foot and ankle and cross friction massage of the plantar fascia; cross friction massage of the plantar fascia and gastrocsoleus complex stretching; and a combination of the aforementioned protocols in the treatment of plantar fasciitis. The results indicate that the combination of additional rehabilitation methods allows for better patient outcomes.

Conclusion

The use of platelet-rich plasma (PRP) is intended to enhance and accelerate the effects of growth factors (GF) contained in the plates, which are always universal initiators of the healing processes of almost every wound. Superior to all natural healing methods and processes, autogenous PRP is non-toxic and non-immunizing, containing known and as yet unidentified growth factors found in platelets and accelerating wound healing processes. PRP also modulates and regulates the functions of successively acting growth factors in the process of tissue formation and maturation. The action of natural growth factors contained in the platelet mass differs from the recombinant ones in that the growth factors contained in it act in a specific sequence and, on the basis of feedback, affect the processes of cell proliferation and differentiation, while a single recombinant growth factor acts on one specific renewal process, and cannot function properly in the healing wound due to the smaller, limited and unsupported activity of the associated factors.

The rehabilitation protocol is based on physiotherapeutic techniques carefully selected by an experienced physiotherapist and most frequently used in plantar fascia enthesopathy studies.The rehabilitation process is closely correlated with changes at the tissue level following PRP administration.

Statistical data show a downward trend of all the parameters tested(pain when touching, pain in the morning before first steps, %FFI, Biodex limb stability) which proves a reduction in pain and an improvement in the function of the lower limb and its stability. Patients in the study group (PRP + rehabilitation) compared to the control group (rehabilitation without PRP) had better results.[] The conducted studies showed the effectiveness of rehabilitation in the treatment of patients with plantar fascia enthesopathy. Preliminary results of the conducted research indicate a satisfactory result of the investigated method of treatment. Statistical data indicate a downward trend of all the parameters tested, which proves a reduction in pain and an improvement in the function of the lower limb and its stability. The conducted research is required to be continued for a longer period of observation, but the observed trend bodes well for the future.

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Received: 06.04.2021.
Accepted: 20.05.2022.
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