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APPLICATION OF DEEP OSCILLATION THERAPY IN THE TREATMENT OF PERIPHERAL ARTERIAL DISEASES

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Abstract. Application of deep oscillation therapy in the treatment of peripheral arterial diseases. Trybulski R., Biolik G., Kuczmik W., Ivasyk N., Tyravska O. Intermittent claudication is a common symptom of peripheral arterial disease, affecting up to 50% of patients over the age of 50, which is characterized by pain, discomfort, and cramping in the leg muscles during physical activity. Intermittent claudication is a common symptom of lower extremity arterial disease (LEAD), which significantly impacts patients' quality of life and drives healthcare costs. Current treatments for intermittent claudication are often inadequate, leading to a need for more effective treatments. Developing new treatments is critical to improve outcomes for patients and address the public health implications of LEAD. This study's aim was to present the impact of comprehensive physiotherapy, conducted independently, with the supervision of a physiotherapist, for 14 weeks, on a patient with intermittent claudication caused by peripheral arterial disease. The therapy included bicycle training in a form of physical therapy at home, combined with deep oscillation therapy. Deep oscillation therapy involved the use of an electrostatic field with a frequency of 5 to 250 Hz. The field was applied following the lymphatic drainage methodology. In the discussed case, a statistically significant and favourable increase in the measured variables was observed, such as the increase of bone-brachial index from 0.65 to 0.8, the increase of tissue perfusion, measured by laser Doppler flowmetry, from 12.3% to 61%, depending on the measurement site, and the increase in pain-free walking distance by 451%. TcPO₂ measurement in the affected leg increased from 31 to 48 mmHg. The use of physical therapy at home combined with deep oscillation showed improvements in pain-free walking distance, Ankle Brachial Index, and other measures in patients with peripheral arterial disease. Deep oscillation therapy demonstrated potential analgesic effects but also raised concerns about possible nerve damage. The study indicated that physical therapy at home might serve as an alternative to supervised exercise therapy, but it had limitations like a small sample size and lack of direct comparisons.

Реферат. Застосування глибокої осциляційної терапії в лікуванні захворювань периферичних артерій. Трибульський Р., Біолік Г., Кучмік В., Івасик Н., Тиравська О. Переміжна кульгавість є поширеним симптомом захворювання периферичних артерій, що уражає до 50% пацієнтів старше 50 років і характеризується болем, дискомфортом і судомами в м'язах ніг під час фізичної активності. Переміжна кульгавість є поширеним симптомом захворювання артерій нижніх кінцівок, яке значно впливає на якість життя пацієнтів і призводить до витрат на охорону здоров'я. Сучасні методи лікування переміжної кульгавості часто є неадекватними, що призводить до необхідності більш ефективного лікування. Розробка нових методів лікування має вирішальне значення для покращення результатів для пацієнтів і полегшення наслідків захворювання для громадського здоров'я. Мета цього дослідження полягала в тому, щоб представити вплив комплексної фізіотерапії, що проводилася самостійно під наглядом фізіотерапевта протягом 14 тижнів, на пацієнта з інтермітуючою кульгавістю, спричиненою захворюванням периферичних артерій. Терапія включала тренування на велосипеді у формі домашньої лікувальної фізичної культури (ЛФК) в поєднанні з глибокою осциляційною терапією. Глибока осциляційна терапія передбачала використання електростатичного поля з частотою від 5 до 250 Гц. Поле було застосовано за методикою лімфодренажу. У цьому випадку спостерігалось статистично значуще та сприятливе збільшення вимірних змінних, таких як збільшення щиколотково-плечового індексу з 0,65 до 0,8, підвищення тканинної перфузії, вимірної за допомогою лазерної доплерівської флоуметрії, з 12,3% до 61% залежно від місця вимірювання та збільшення дистанції безболісної ходьби на 451%. Вимірювання TcPO₂ на ураженій нозі зросло з 31 до 48 мм рт.ст. Використання домашньої фізичної терапії в поєднанні з глибокою осциляцією показало поліпшення в дистанції безболісного ходьби, індексу голілково-плечового тиску та інших показників у пацієнтів з периферійною артеріальною хворобою. Терапія глибокою осциляцією демонструвала потенційні анальгетичні ефекти, але також викликала питання щодо можливого ушкодження нервів. Дослідження показало, що домашня фізична терапія може служити альтернативою наглядовій фізичній терапії, але має обмеження, такі як мала вибірка та відсутність прямих порівнянь.

The treatment of intermittent claudication caused by lower extremity arterial disease (LEAD) is a pressing issue that needs urgent attention. Intermittent claudication is a common symptom of LEAD, and can significantly reduce patients' quality of life by limiting their physical activity and mobility. Intermittent claudication still is a significant driver of healthcare costs, due to the need for diagnostic tests, medical treatments, and surgical interventions. Moreover, current treatments for intermittent claudication are often inadequate, and many patients continue to experience symptoms despite treatment. Therefore, it is critical to study and develop new and more effective treatments for this condition in order

to improve outcomes for patients and address the significant public health implications of LEAD.

Lower extremity arterial disease and its related symptoms are an important and ongoing topic of research in the medical community. As reported by A. Jawień et al. [1], in Poland, each year about 40,000 patients present for the first time with early symptoms of LEAD. P. Nowakowski et al. [2] proposed innovative revascularization methods for these patients, which were effective and radical. However, they did not address the cause and pathogenesis of peripheral arterial disease (PAD), which is also important in preventing a relapse. For numerous patients who suffer from mild to moderate claudication, the pri-

mary method of treatment continues to be lifestyle change [3]. Despite its importance, lifestyle change often yields disappointing results in terms of compliance [4]. J. Kapusta and R. Irzmański [5] reported physical therapy at home (PTH) to be the preferred choice in patients with chronic intermittent claudication caused by LEAD, but further research was needed to better understand the potential benefits of PTH.

Deep oscillation (DO) was studied by J. Pogorzelska et al. [6] in the context of burn scars treatment. The authors concluded that the therapy was effective, but further research was needed. The effects of DO on the cardiovascular system were not explored. A. Opuchlik et al. [7] brought up the use of DO in the context of treating secondary lymphedema. It was stated that the technique had wound-healing and anti-inflammatory properties. However, the technique did not get much attention and was mentioned among many others. DO was also researched by R. Belmonte et al. [8], who concluded it to be effective in reducing pain in patients with lymphedema. The analgesic effect was not addressed specifically, which is why it needed further research.

The present study intended to delve into the topic of analgesia in a more comprehensive manner than previous studies and to offer a deeper understanding of the subject. This study aimed to showcase the positive impact of DO therapy on enhancing the parameters and overall quality of life for patients with PAD. The goal of this study was to introduce a promising and cost-effective non-invasive treatment option for PAD.

MATERIALS AND METHODS OF RESEARCH

The study was conducted at the Provita Medical Center. The study used the individual case study method. The following techniques were used: interview, analysis of medical records, observation, measurement of the bone-brachial index (BBI), determination of the pain-free walking distance (PFW) and of subjective fatigue according to the Modified Borg Dyspnea Scale (MBS). Medical Outcomes Study Short Form-36 (SF-36) was used to evaluate the patient's quality of life [9-11]. The study was approved by the Bioethics Committee of the Upper Silesian Academy. The research adhered to the principles outlined in the Helsinki Declaration, ensuring the ethical conduct of the study. Informed consent was obtained from the single participant prior to his involvement in the research.

The following physiotherapeutic methods were used: walking training, cycling training, and DO therapy. The Shapiro test was used to confirm the normal distribution of the examined variables. The significance of differences among the variables examined was analysed using one-way analysis of

variance (ANOVA). The significance level was assumed: $\alpha=0.05$. Tuckey's post-hoc multiple comparison tests were used to check which trials had significant differences. The research material was developed using the Statistica package ver. 10 by StatSoft (license number: SPV10-2023-XYZ-5678). The computer application Excel of the Office package ver. 2010 from Microsoft was also used.

The patient: male, 67 years old, 88 kg. In 2022, the patient underwent amputation of the left thigh due to critical ischemia. At the beginning of the study, the patient had progressing PAD of the lower right limb. Atherosclerosis was diagnosed 12 years ago.

Comorbidities: post-COVID-19 status (2020), post-NSTEMI status (2013), hypertension. Doppler flow test for the lower right limb performed at the beginning of the study showed signs of moderate arterial obstruction.

The patient was subjected to the daily physiotherapy algorithm for 10 weeks, then the same parameters were assessed for the next 4 weeks without the use of DO therapy. This system is called PTH. DO therapy involved lymphatic drainage for 30 minutes twice a day, using an 8cm-diameter head. The methodology of drainage with the use of DO followed the principle of maintaining the direction: along the course of the vascular system to the lymph nodes, always moving from the proximal to the distal parts. Drainage was performed by moving the head in a circular pattern, adjusting to the pace of lymphangion contractions, which ranges from 8 to 14 times per minute [7, 12, 13], and to the properties of the subcutaneous tissue. Physiotherapy was performed according to the presented scheme (Fig. 1, 2). For this study, the patient's wife was taught to perform the described DO therapy independently, controlling the way it was implemented every 7 days (PTH).

A BM-66 model of pedometer and the SmartHealth application were used to measure PFW. The SonoScape S60 ultrasound apparatus with a 4-16MHz linear transducer and a 1-7MHz convex transducer was used to assess BBI and Doppler scan. The BBI index was calculated by the formula:

$$\text{Right BBI} = \frac{\text{Highest systolic pressure in Right Foot}}{\text{Highest systolic pressure in Both Arms}} \quad (1)$$

The following measurement points were determined on the right lower limb for laser Doppler flowmetry (LDF): Point 1 – the middle part of the dorsum of the foot (F-foot); Point 2 – the middle part of the medial head of the gastrocnemius muscle (GCN); Point 3 – middle part of the biceps femoris muscle (BF); Point 4 – middle part of the rectus femoris muscle (RF). It should be noted that LDF was measured in a relative unit of PU (Perfusion Unit) [14]. The

PeriFlux 6000 system was used for transcutaneous oximetry (TcPO₂). All the measuring equipment had the approvals appropriate for their class of application. All the measurements were performed at the beginning and every 7 days until the end of

treatment. The LDF tests were carried out in a sitting, fully relaxed position, at a fixed time. All the mentioned measurements were performed by a trained physiotherapist and angiologist.

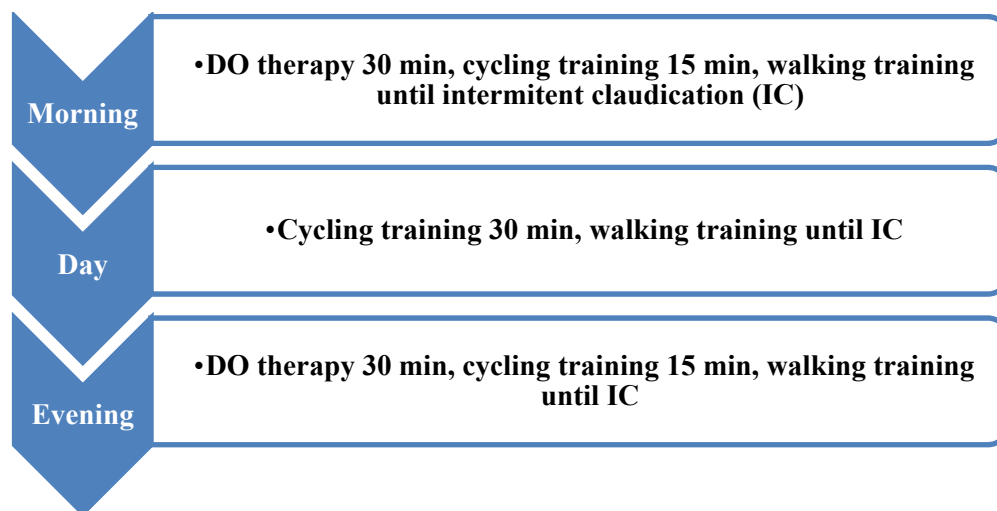


Fig. 1. Diagram (PTH) 1–10 weeks

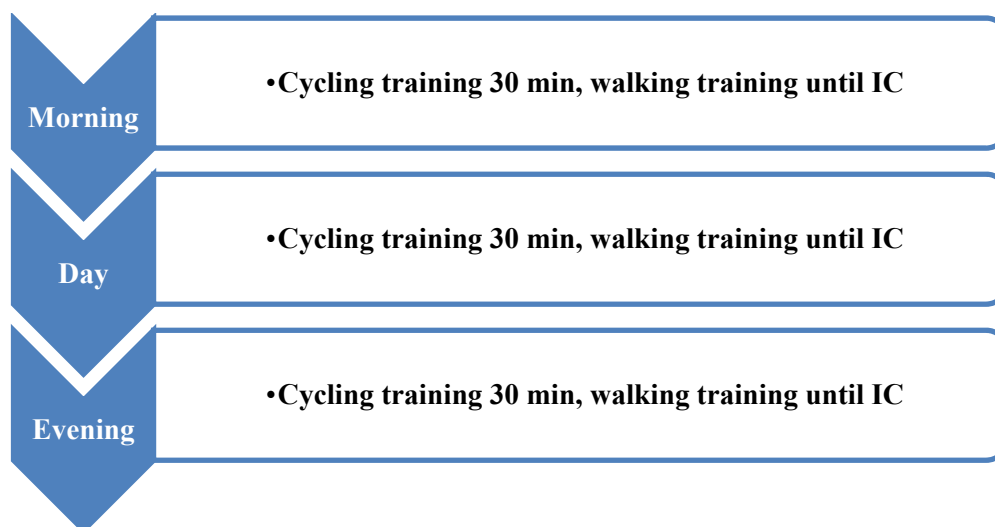


Fig. 2. Diagram (PTH) 11–14 weeks

RESULTS AND DISCUSSION

In this study, the authors analysed the efficacy of a 14-week physical therapy program in a patient with peripheral arterial disease (PAD). The therapy program included deep oscillation therapy, physical exercise, and lymphatic drainage. The data collected in this study indicated that the combination of Deep Oscillation therapy and controlled physical activity (in the background of the patient's usual pharmacotherapy) significantly improved skin microcirculation in the limb affected by PAD (measured by LDF).

Analysis of the data revealed that the patient, being administered the proposed treatment, demonstrated a statistically significant improvement in arterial blood flow, as measured by bone-brachial index (BBI) values. There was also observed a significant increase in pain-free walking distance and the overall subjective well-being of the patient. Based on these findings, it was inferred that the suggested therapy is an effective conservative treatment for PAD.

In this study, the laser Doppler flowmetry was used to measure the patient’s skin microcirculation. Laser Doppler flowmetry is a continuous non-invasive method used for measuring capillary blood flow in the tissues, which is an important indicator of

cardiovascular health. LDF measurements were taken in four points on the leg, and the measurements in all of them showed a tendency to increase, especially in the first 10 weeks. PU changes for all points (p1-4) during 14 weeks are shown in the diagram (Fig. 3).

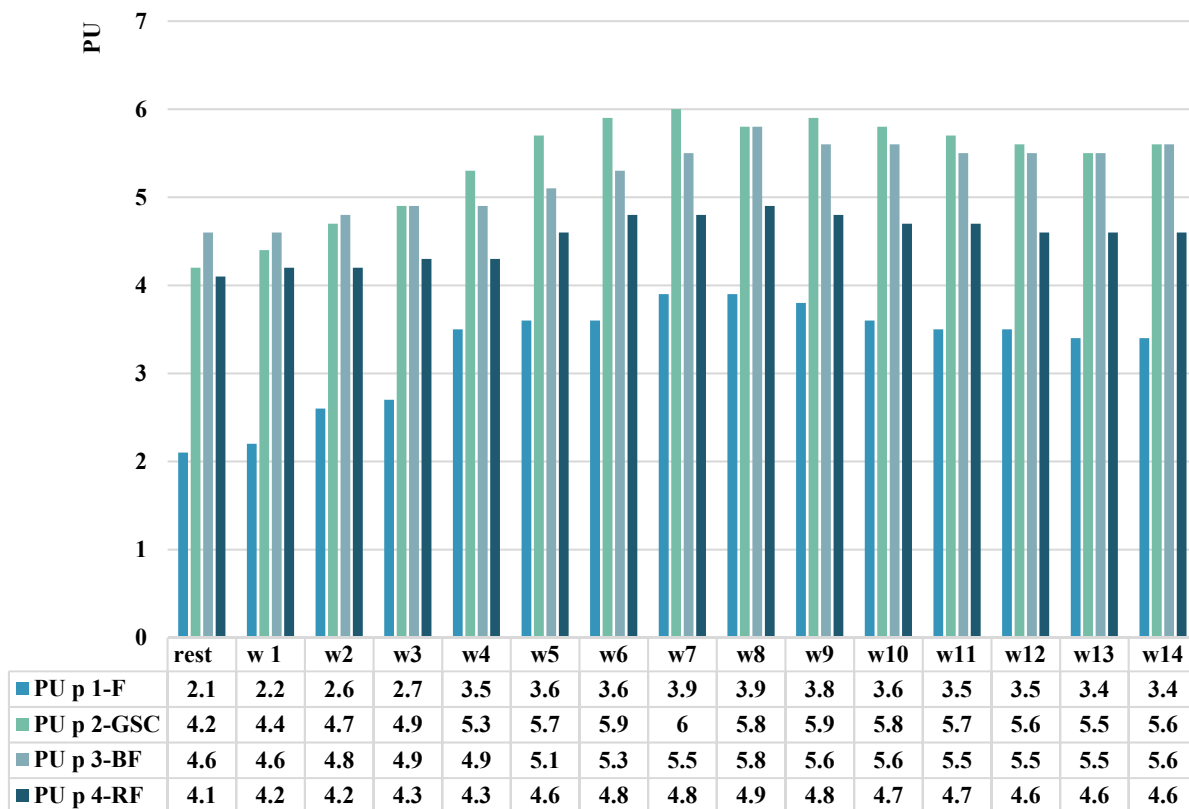


Fig. 3. LDF measurements from all points

The greatest increase was seen until the 8th-10th week of therapy. After the end of DO therapy, a slight but statistically significant decrease in the PU index was observed. This indicated that specifically the use of DO therapy positively affected microcirculation in the patient with PAD.

The presented PU variables for individual points showed the greatest percentage changes in measurements on the middle part of the dorsum of the foot (p1, 61%), The readings for the middle part of the medial head of the gastrocnemius muscle increased by 31%, 19.5% for biceps femoris, and 12.3% for rectus femoris.

Along with the LDF measurements, the BBI readings were recorded to see the effectiveness of treatment not only on microcirculation but also on the magistral blood flow. BBI variables showed a statistically significant increase in the BBI index, as well as only a slight decrease after the end of the 10 weeks of DO therapy. Specifically, the mean BBI score increased from 0.65 to 0.82 in the first 10 weeks

of treatment. The BBI measured at the beginning of the study corresponds to moderate/severe peripheral artery disease, while at the peak of the proposed treatment, with the use of both DO and physical activity, BBI readings indicated mild PAD. In addition, simultaneous maintenance of walking and cycling training for the 10-14th weeks was noted. These readings, of course, were accompanied by other measurements, such as Doppler scanning, LDF and PFWD. BBI changes are shown in the diagram (Fig. 4).

In this study, the authors used pain-free walking distance as one of the indicators to measure the efficacy of the therapy. Pain-free walking distance is a standard and objective method used to evaluate the functional capacity of individuals with peripheral artery disease. With physical therapeutic factors integrated into the treatment program, the PFWD measurements showed (Fig. 5) a significant improvement in the patient’s functional capacity over the course of the therapy sessions.

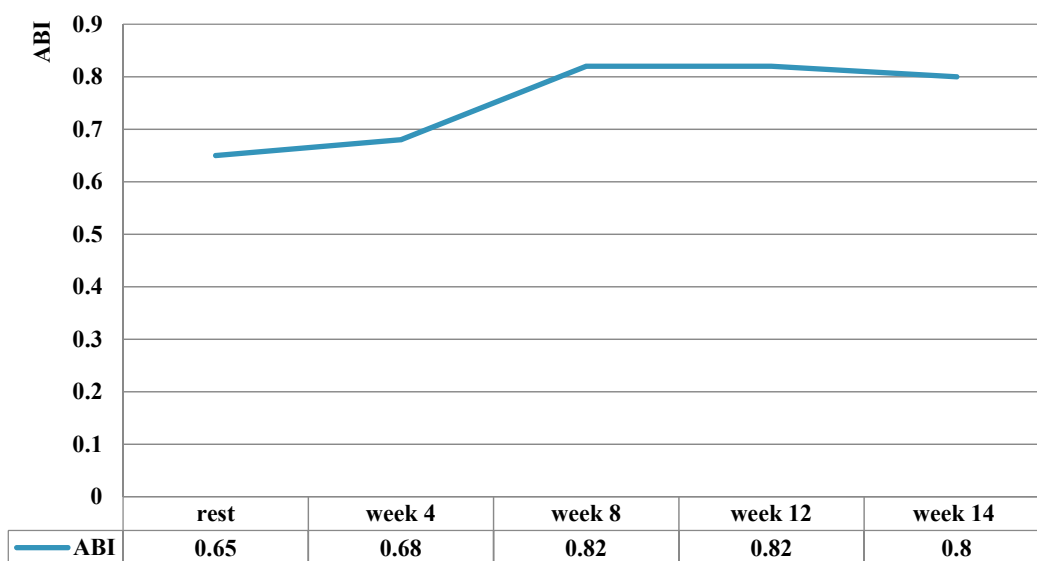


Fig. 4. BBI changes over 14 weeks

The changes observed in PFWD were the most significant. The patient increased his walking distance without intermittent claudication by 451%. Despite the discontinuation of DO therapy (while maintaining a constant training rhythm) the PFWD values did not decrease radically during 4 weeks. This improvement was important because it directly influenced the patient's life quality. Individuals with PAD often experience limited physical activity due to their condition [15], which in turn worsens the symptoms, creating a vicious circle. The increase in PFWD could directly suggest the patient's higher capability to perform therapeutic physical exercise. However, the radical increase in PFWD could be explained by multiple factors. Physical activity is effective as a standalone treatment. It has been shown

[16] that physical exercise can be an effective therapeutic intervention for atherosclerosis. Over-exercising, however, was proven to have the opposite effect. In this study, the exercises were controlled. The other factor that could explain the progress in PFWD was the analgesic effect of oscillation therapy [17]. The patient experienced some degree of pain relief, as was noted when the measurements were taken, and could walk longer distances without unpleasant sensations. Also, the patient's adaptation to his prosthetic should have been taken into account. Nonetheless, the implementation of DO therapy was an important factor in improving the patient's condition. The decline of all measurements after the 10th week of the study, when DO was discontinued, confirmed this conclusion.

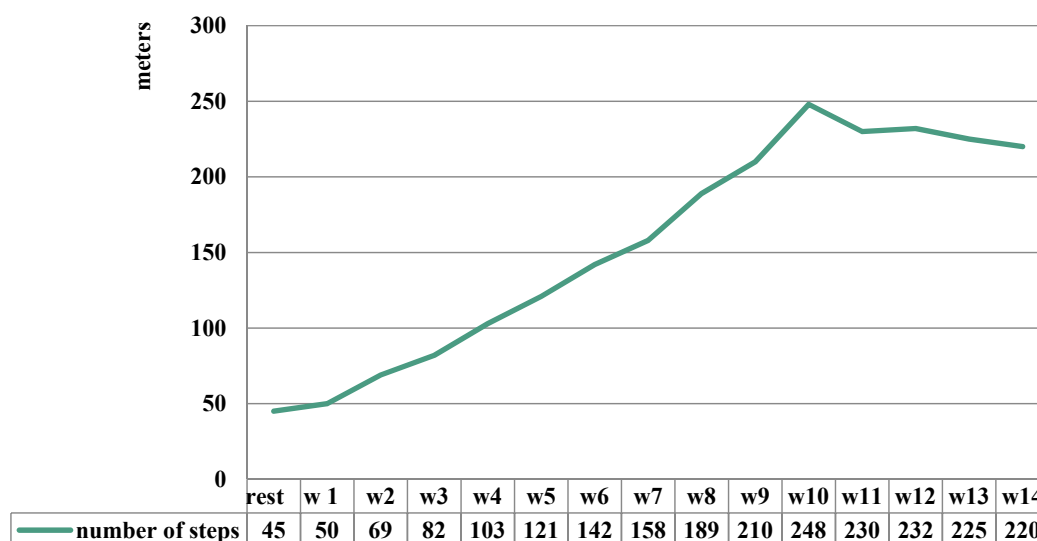


Fig. 5. PFWD changes

In addition to the mentioned methods, the authors used the Modified Borg Dyspnea Scale to measure the patient's subjective fatigue. During the exercises, the patient recorded his subjective state for the study. The results can be seen in Figure 6.

The Borg Scale is a commonly used tool for measuring perceived exertion during physical activity. This study used the Borg Scale to assess the patient's perceived exertion during the physical activity sessions (cycling, walking).

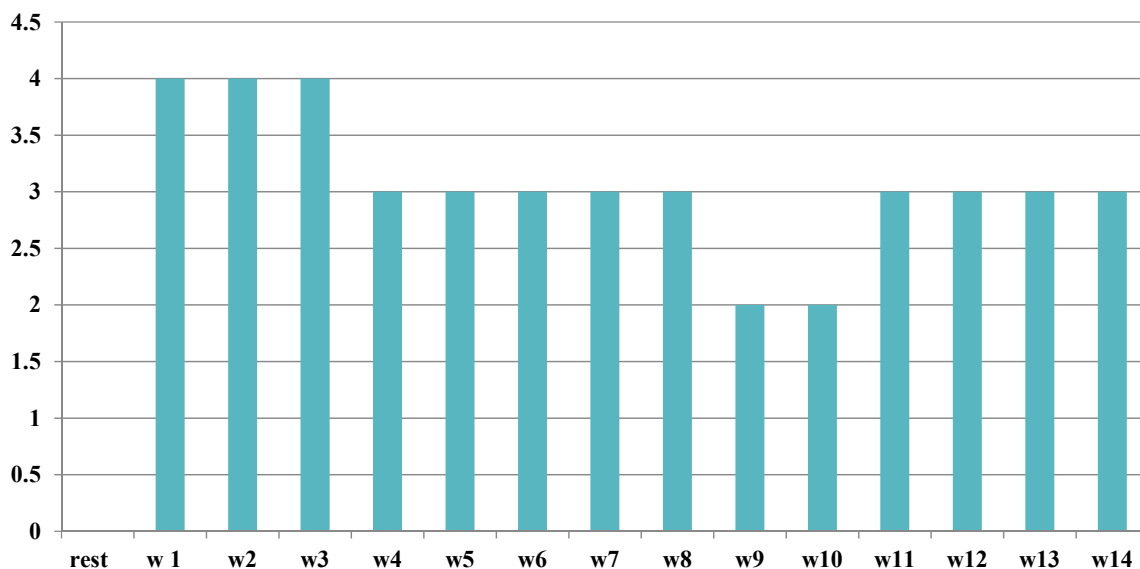


Fig. 6. Evaluation of subjective fatigue with the Borg Scale

The results of the Borg Scale measurements showed a significant improvement in the patient's subjective fatigue over the course of the therapy sessions. At the beginning of the study, the patient reported high levels of perceived exertion, indicating that physical activity was difficult and demanding for him. However, as the therapy progressed, the patient's perceived exertion decreased significantly (from 4 to 2 points by the MBS), indicating that the exercises were becoming easier for him to perform. This improvement suggested that the patient's physical capacity and fitness level have increased. Additionally, the improvement in perceived exertion was also an indication that the patient's cardiovascular fitness improved as a result of the therapy. This was because the Borg Scale is based on the relationship between perceived exertion and heart rate, and a decrease in perceived exertion meant that the patient's heart rate was able to adapt to the demands of exercise therapy. The Borg Scale readings also correlated well with the results obtained from the other measurements taken during the study.

Significant improvements were also observed in the TcPO₂ measurements of the patient. TcPO₂ is a non-invasive method that reflects the balance between oxygen delivery and oxygen consumption by the tissue. At the initial evaluation, the tcpO₂ level in

the patient's right leg was 31 mmHg, indicating severe tissue ischemia. After 10 weeks of treatment, the TcPO₂ measurement in the same leg had increased to 48 mmHg, which was close to the normal range (mild ischemia). The measurements comparison can be seen in Figure 7.

Finally, the patient's quality of life was evaluated using the Medical Outcomes Study Short Form-36 (SF-36) questionnaire, as can be seen in Figure 8.

The SF-36 measures eight domains of health, including physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. The physical health aspects were the most important for this study. The patient's scores on the physical functioning, role-physical functioning, bodily pain and general health subscales of the SF-36 all showed significant improvements after the therapy program. These results indicated that the suggested therapy not only improved the patient's physical fitness and functional capacity, but also had a positive impact on the patient's overall quality of life. The SF-36 evaluation was only performed at the beginning and the end of the study, so the exact changes through the 14 weeks were not recorded.

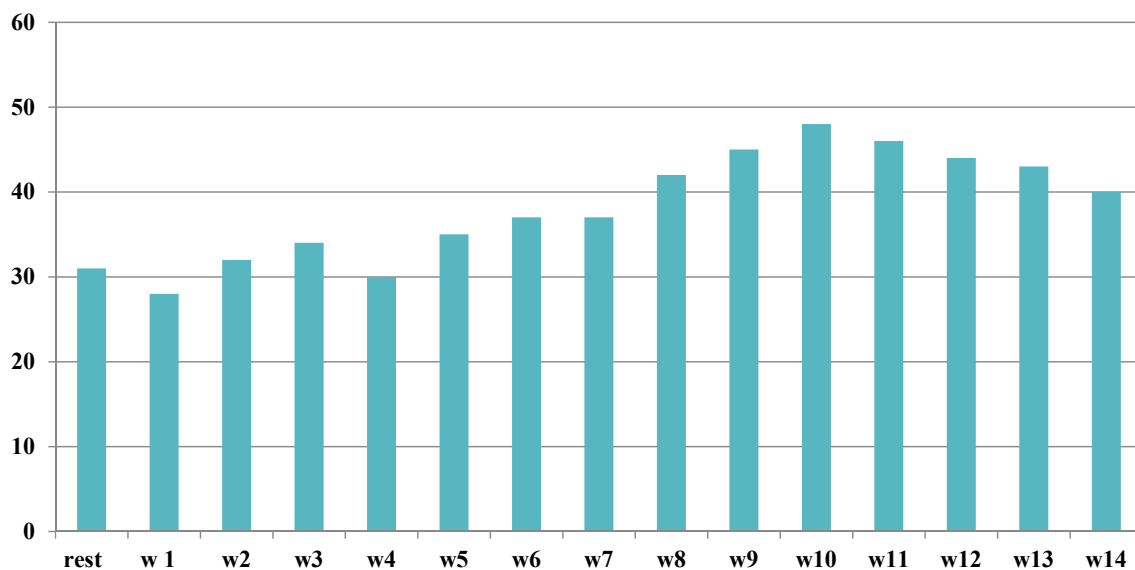
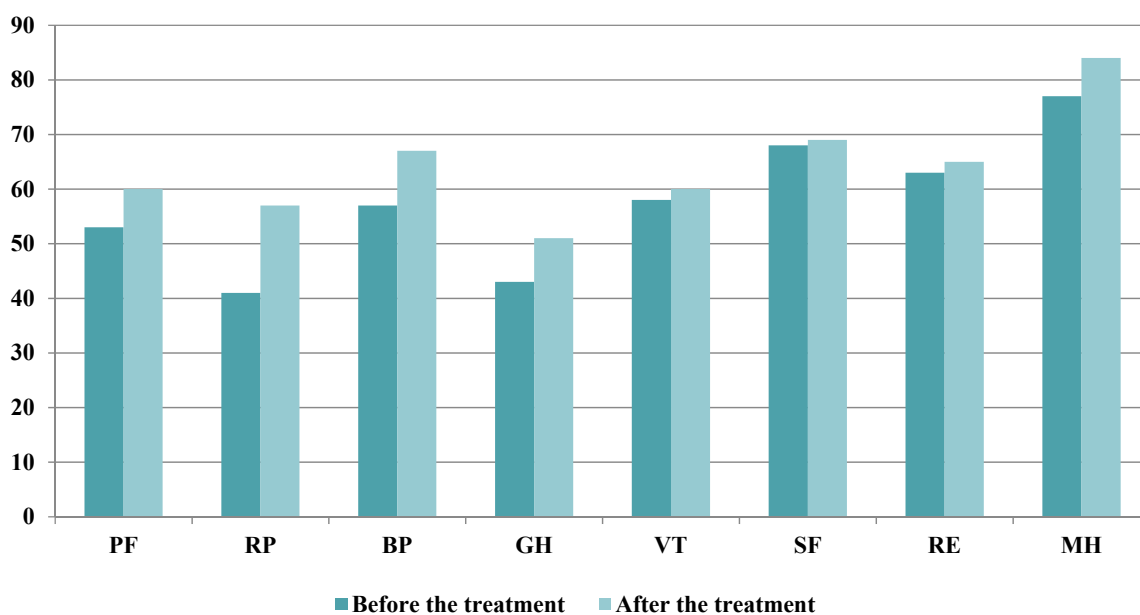


Fig. 7. TcPO₂ measurements

Additionally, after 14 weeks of treatment, an ultrasound examination was performed. Upon examination, slight positive results were observed. The ultrasound showed non-critical stenosis of the popliteal artery and calcifying plaques in the area of the bifurcation of the popliteal artery. Arteries, anterior tibial and right peroneal with numerous calcifications without signs of critical ischemia. The velocity of blood flow was increased in the femoral and popliteal

arteries, indicating improved circulation in those areas. However, despite these slight improvements, the physician noted that the stenosis in the distal part of the right popliteal artery would require additional intervention, and the patient would need to continue with their prescribed exercise and medication regimen in order to maintain and improve upon their current progress.



PF – physical functioning, RP – Role-Physical Functioning, BP – Bodily pain, GH – General Health, VT – Vitality, SF – Social Functioning, RE – Role-Emotional, MH – Mental Health).

Fig. 8. SF-36 score results

The patient himself reported experiencing fewer cramps and less pain in his leg during daily activities, particularly during walking. The patient showed great compliance and described the DO therapy as painless and helpful. No side effects were noted during the 10 weeks of using DO, but overall, it was clear that continued treatment and monitoring would be necessary to achieve more significant improvements in the patient's PAD.

The results of this study have provided some insights into the potential benefits of deep oscillation therapy as an adjunct treatment for patients with the peripheral arterial disease (PAD). Controlled physical exercise and PTH also were an important part of the treatment. In the present study, the authors observed improvements in various measurements, including BBI, pain-free walking distance, SF-36 score, Borg scale records, and TcPO₂ measurements. These findings suggested that deep oscillation therapy can be an effective non-invasive treatment option for patients with PAD. However, further research is necessary to explore the potential mechanisms underlying these observed effects and to determine the optimal dosing and frequency of deep oscillation therapy in individual cases.

When discussing the implications of the results obtained in this study, it is important to first emphasize the crucial role of physical exercise in the management of peripheral arterial disease (PAD). The importance of physical exercises as a valuable component of a treatment process for patients with chronic ischemia of the legs has an unquestionable therapeutic value, which has been confirmed in many clinical studies [18, 19, 20, 21, 22, 23]. The key element of the M. Szymczak et al. [18] research was the assessment of changes in individual variables under the influence of physical training in patients with PAD. The results obtained with the BBI measurements in the M. Szymczak's et al. study were similar to the results of the current study. Both studies demonstrated positive outcomes in terms of improving pain-free walking distances.

The literature review written by A. Afridi and F.A. Rathore [24] tried to establish what type of exercise strategy is most beneficial to patients with PAD. The analysis covered 10 studies, including 527 patients with IC. Multiple types of exercise therapy were analysed, including cycling, walking, arm ergometry, resistance training, and combinations of different exercise types. The review did not find a statistically significant difference between the mentioned exercise types and supervised exercise therapy (SET) in enhancing the PFWD in patients with IC, but alternative exercise types may be useful when supervised walking exercises are not possible. In turn,

D. Hageman et al. [25] reviewed the literature on assessing differences in the effectiveness of SET and PTH. Widespread deployment of SET is limited by a lack of infrastructure and funding. An alternative to SET is structured PTH with an element of surveillance (pedometers, exercise logs) and walking advice (WA). The review included 21 studies with 1400 patients: SET was administered to 635 participants, PTH to 320 participants, and WA to 445 participants. Moderate to high-quality evidence indicates that SET is more effective than PTH and WA in improving treadmill walking distance, including maximal and pain-free walking distance. Studies did not show clear differences in quality-of-life parameters or patient-reported functional impairments between SET and PTH. However, the evidence on that was low and very low quality, respectively.

In the current study, PTH was used as an alternative to SET due to limited resources. PTH is a feasible and cost-effective alternative to SET, as has been shown in the mentioned studies [24, 25]. To ensure the safety and effectiveness of the PTH program, the research team provided the patient and his wife with detailed instructions and demonstrations of the exercises. The progress was monitored through regular check-ins, and the patient was encouraged to report any adverse effects or concerns.

Although PTH may not be as effective as SET in improving PFWD, the current study showed that it can still provide significant benefits. The authors acknowledged that this study had limitations. The lack of supervision and guidance may have led to inconsistent exercise adherence. However, the findings of this study demonstrated the potential of PTH as a cost-effective alternative for patients who may not have access to SET. Further studies with larger sample sizes and longer follow-up periods are needed to fully evaluate the efficacy and safety of PTH in treating PAD.

To discuss the possible ways in which DO therapy may improve the condition of patients with PAD, it is important to first understand the underlying pathophysiology of the condition. PAD is characterized by atherosclerosis, which leads to stenosis or occlusion of the peripheral arteries, resulting in impaired blood flow to the lower extremities [26, 27, 28, 29, 30]. This ischemic condition can cause a range of symptoms, including pain, cramping, and weakness, as well as an increased risk of complications such as ulcers and amputations [31, 32, 33].

While the evidence on the use of physical exercises in PAD treatment is numerous and of good quality, the information and evidence available regarding the use of DO therapy are scarce. Some studies have suggested potential benefits, but the

sample sizes and study designs were small and limited, making it difficult to draw firm conclusions [34, 35]. One possible way that DO therapy may have impacted PAD symptoms is by improving micro-circulation in the affected tissues. By using a low-frequency deep oscillation technique, DO therapy was shown [36, 37, 38] to promote lymphatic and blood flow and perfusion, modulate inflammatory processes, reduce oedema and promote tissue regeneration. This could potentially improve tissue oxygenation and nutrient delivery, which helped to alleviate some of the symptoms associated with PAD [39, 40]. The presented case study confirmed the increase in the patient's exercise capacity (PFWD), blood flow (BBI) and, above all, the increase in tissue perfusion (measured by TcPO₂ and LDF) after the use of DO.

However, DO therapy is still a relatively new technique, and there has not been much research conducted on its long-term effects. As such, it is essential to approach this treatment with caution and carefully monitor patients for any adverse effects or complications that may arise. Given the limited available information and evidence, further research is needed to better understand the potential benefits and risks of DO therapy in the context of PAD. This includes larger and more rigorous clinical trials that can provide more definitive answers on the safety and efficacy of this treatment option.

CONCLUSIONS

1. It was demonstrated that the use of physical therapy at home and deep oscillation resulted in improvements in pain-free walking distance, Ankle Brachial Index, tissue perfusion (laser Doppler flowmetry) and transcutaneous oximetry levels. The deep oscillation therapy proved to have direct or indirect analgesic effects. It is advised to research this aspect carefully, to exclude the possibility of nerve damage.

2. Although there is limited evidence on the effectiveness of deep oscillation therapy, the study found that it was relatively effective at improving blood flow in the peripheral arteries of the lower limb

in a patient with peripheral arterial disease. The results suggest that deep oscillation therapy can be used in combination with other forms of therapy to achieve better outcomes in patients with peripheral arterial disease.

3. The study had some limitations, such as a small sample size and a lack of long-term follow-up. Additionally, the direct comparison of physical therapy at home and supervised exercise therapy was not performed, so it cannot be definitively concluded that physical therapy at home can be as effective as SET in combination with deep oscillation therapy.

4. The long-term effects of deep oscillation therapy on patients with peripheral arterial disease remain unknown, as well as the optimal combination and duration of the therapy. Possible side effects such as burns, skin irritation and allergic reactions can be expected. Possible risks and benefits should be researched and evaluated carefully. The possibility of interference with implanted medical devices also needs to be studied.

5. This study's findings highlight the potential of deep oscillation therapy as an adjuvant therapy option for peripheral arterial disease patients and suggest that physical therapy at home can be an effective alternative to supervised exercise therapy in resource-limited settings. Further research is recommended to explore the optimal use of these methods in the treatment of peripheral arterial disease.

Contributors:

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