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Application of Laserobaria 2.0_S device in the treatment of hard-to-heal wounds of mixed etiology — own experience

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Abstract

Introduction: *The formation of hard-to-heal wounds can have many causes and is most often the result of the influence of several patient health factors. Some of the most difficult to treat effectively are wounds resulting from complications of diabetes, known as diabetic foot syndrome.*

Material and methods: *Fifty-two patients (mean age 67 years ± 11.5) were eligible. All patients had chronic wounds of varied etiology in the lower limb, the previous treatment of which had not been satisfactory. Therapy parameters were selected individually; in addition to standard therapy, topical physical agents such as light therapy, pulsed electromagnetic field (PEMF), ozone therapy, and oxygen therapy were included in the treatment. Each therapeutic cycle lasted 10 consecutive days (excluding Saturdays and Sundays), and each treatment lasted approximately 1 hour.*

Results: *The analgesic effect of PEMF therapy was reported at 60% according to the VAS scale assessment. Pain was reduced from the third day of treatments, including for patients in whom pharmacological pain relief did not produce a clear improvement. Wound improvement, through granulation, after the first 10-day treatment cycle was observed in 40.5% of patients (14 k, 7 m). Four patients dropped the continuation of treatment because they did not see healing progress. Six patients dropped out of the next treatment cycle for other reasons (high cost of therapy, long distance of the clinic from home, and other socio-economic reasons).*

Conclusions: *The high efficiency of combining standard treatment with innovative physical treatments allows for better patient care, which accelerates the necessary therapeutic steps toward holistic patient treatment. The authors recommend further multicenter, randomized, blinded trials to develop the optimal dosage to maximize the therapeutic effect and shorten the time to complete wound closure.*

Keywords: diabetic foot syndrome; chronic wounds; topical physical agents; light therapy; pulsed electromagnetic field (PEMF) therapy; ozone therapy; oxygen therapy

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Introduction

The formation of hard-to-heal wounds can have many causes and is most often the result of the influence of several patient health factors. Some of the most difficult to treat effectively are wounds resulting from complications of diabetes, known as diabetic foot syndrome.

The main determinants of the development of diabetic foot ulcers are neuropathy and lower limb ischemia. As the disease progresses, there is a severe degeneration of the tissues of the lower limb, which manifests itself in swelling, severe pain, and the development of serious infections within even minor cuts and skin injuries. Tissues within the wound, as a result of impaired functioning of the blood system, are unable to effectively fight off foci of infection or conduct a proper and effective regeneration process. Such a situation promotes increased infectious colonization of the wound and further degeneration of adjacent tissues, which can eventually even lead to osteitis.

The treatment of patients with hard-to-heal extremity wounds requires a multidisciplinary team that, in inpatient, outpatient, and at home, will be able to effectively provide assistance to the patient by performing the necessary procedures, properly dressing the wound, and educating the patient and his family.

Often application of all good practices and conventional methods of treating hard-to-heal wounds is insufficient and additional measures must be taken, using the latest available methods.

The article describes the clinical experience of the wound healing process using the innovative Laserobaria 2.0_S device. The device allows for local oxygen therapy, ozone therapy, magnetotherapy, red light therapy, and UV light therapy.

In the period from July 2021 to May 2022, the Alfamedica Silesia North Medical Center provided therapy for hard-to-heal wounds of mixed etiology using a combined physical therapy method with the Laserobaria 2.0_S device manufactured by INVENTMED Sp. z o.o. for 52 patients.

The following paper presents the detailed therapeutic effects and methodology of using the Laserobaria 2.0_S device.

Material and methods

Description of the population

Fifty-two patients (mean age 67 ± 11.5 years), 23 women (mean age 68 ± 9.8), and 29 men (mean age 66 ± 12.6) in the present group were qualified for treatment with combined physical therapies. All of the patients had chronic wounds in the lower extremity, the previous treatment of which had not been satisfactory, and the persistent state of wound infection posed, in many cases, a real risk of having partial limb amputation. The etiology of the wounds varied, and a detailed breakdown by the condition is in preparation (Table 1, 2).

Table 1. Demographic description of patients

Total				
M	SD	Min	Max	N
66.8	11.5	38	91	52
Women				
M	SD	Min	Max	N
67.6	9.8	38	78	23
Men				
M	SD	Min	Max	N
66.2	12.6	45	91	29

Table 2. Distribution of patients by age groups

Age range	Women	Men
> 70	12	12
60–70	7	7
50–60	2	7
40–50	1	3
30–40	1	0

Each patient was treated with drug therapy. If necessary, the wound was treated surgically before treatment with Laserobaria 2.0_S. On each treatment day, the dressing was changed and the wound was cleaned in an outpatient setting (Fig. 1).

Description of therapeutic measures

Phototherapy — during the treatment, light is emitted with wavelengths in the red light range. This wavelength of light, according to the laws of photobiology, allows penetration through cells in highly absorbent bands. For most tissues in the body, the main chromophores are hemoglobin and melanin, which have high-absorption bands in the mentioned range [1]. Light radiation is absorbed by the skin, stimulating the skin's natural healing processes and reducing pain. Red light increases blood flow and oxygen and causes the production of oxygen free radicals acting destructively against bacteria [2]. Light therapy is very effective in treating skin ulcers caused by diabetes. Wound decontamination and the device itself are achieved by light-emitting diodes, which emit ultraviolet light. It can also be used to treat psoriatic lesions or atopic dermatitis [3].

Magnetotherapy — Magnetic fields have a beneficial effect on tissue respiration and regeneration processes. Magnetic influence at the cellular level primarily

Figure 1. An overview photo of the Laserobaria 2.0_S therapy kit

stimulates the production of calcium-dependent compounds, Calmodulin (CAM+) [4]. This is an essential cellular process for tissue growth and regeneration. Also through its anti-inflammatory and anti-oedematous effects, combined with the enhancement of beta-endorphin secretion processes, it has a strong analgesic effect, which is of great importance in pain patients. In the case of therapeutic medicine, thanks to the proper selection of the field frequency to the transmembrane impedance of the cells, effective therapeutic values oscillate around a few militesla. This feature makes it possible to construct devices that are small, safe, and convenient to use. It has also been shown that a PEMF (Pulsed Electromagnetic Field) acts on the structures of cell membranes by changing their properties, induces an immune enzymatic response, and has an effect on collagen and creatine formation [5]. The above features also translate into the high effectiveness of magnetic field therapy for osteoarticular diseases and injuries. Bones subjected to PEMF treatment knit together faster and their density increases significantly [6].

Oxygen therapy — is one of the most effective methods of delivering oxygen to all cells of the body. The use of pressure higher than atmospheric pressure deprives oxygen of its physiological barriers to penetration through tissues, allowing oxygen to penetrate poorly circulated areas, such as wounds. TOT (Topical Hyperbaric Oxygen Therapy) which is categorized as low-pressure oxygen therapy is effective for treating necrotic and gangrenous wounds. Topical oxygen therapy has several advantages over classical hyperbaric therapy in that it is safer and less expensive; due to the reduced pressure (0.5–1.3 ATA), the risk of oxygen poisoning is reduced, it facilitates the application of spot treatment, etc. Providing more oxygen to the tissue during recovery is a key element of successful therapy. In chronic wounds, a high oxygenation gradient is observed in the tissues, especially between the center of the wound and its periphery. The partial pressure of oxygen (po2) varies from 0–10 mm Hg in the center of the wound to 60 mm Hg at the wound periphery, while the po2 concentration in arterial blood averages 100 mm Hg. Providing supplemental oxygen to the treated tissue, as well as other methods to promote tissue oxygenation, accelerates the healing process. Oxygen penetrates not only red blood cells — but its concentration also increases in plasma, the lymphatic system, and cerebrospinal fluid. Oxygen therapy promotes physiological processes in the body, improving tissue regeneration and wound healing in conditions such as diabetic foot, and complications after radiation therapy of soft tissues and bone. It also promotes neovascularization or the formation of new vessels in the event of injury or disease. It reduces inflammation and has proven efficacy in a number of disease entities [7].

Ozone therapy — is among one of the most effective antiseptic methods. Ozone is the most potent bactericidal, fungicidal, and virucidal agent. It oxygenates cells, has a detoxifying effect, improves cell metabolism, improves blood circulation, reduces clumping of red blood cells, improves oxygen transport and blood flow, increases oxygen absorption by tissues, destroys fungi, bacteria, and viruses, and prevents their re-emergence [8].

Dosage and selection of therapeutic agents

Therapy parameters were selected for each patient individually, but general principles of wound management according to TIME recommendations were applied [9] and thus respectively:

— for patients who had severe pain and/or severe swelling of the limb, magnetotherapy was included;
— intensive biocidal therapy with ozone was used for patients whose wounds were at risk of infection or had a local infection-threatening systemic infection (W.A.R. Wounds at Risk score ≥ 3);
— for patients with a wound at low risk of infection (W.A.R. < 3), the limb was subjected to red light stimulation;
— oxygen therapy was used in every case.

UV light

UV light therapy is characterized by the wide variation in dosage and wavelength ranges used observed in the literature. Due to the undefined consensus on dosage and the least favourable benefit-risk ratio of other methods, UV light therapy was abandoned in the cases described. Recent meta-analyses, however, indicate that UV dosing in the low-energy range can provide therapeutic benefits with very short exposure times (< 5min) without serious side effects [10]. It is likely to be harmless for the patient to use UV light therapy (used in the UV-A device — low harm to the body), but the therapeutic value remains to be verified. The proposed dosage is 0.1 J/cm^2 with an exposure time of no more than 2 minutes at the beginning of therapy.

Ozone therapy

Ozone is administered at the beginning of treatment to clear the limb of biofilm and, in particular, inactivate viruses within the wound. Sealing the treatment chamber at the beginning of the treatment also allows ozone to remain inside the chamber after ozone therapy until the chamber is unsealed or ozone is displaced by oxygen. This approach makes it possible to extend the effective duration of ozone exposure for another several minutes (the half-life of ozone is 20 minutes) [11] (Table 3).

Flow rate: 3.5 l/min, capacity: 400 mg/h

Table 3. Duration of ozone therapy, number of treatments

Number of treatments	57
Average time	15
Median	15
Min	5
Max	30

Pulsed electromagnetic field

Based on previous experience using magnetic fields and taking advantage of the possibility of almost free shaping of magnetotherapy parameters, the following device setting parameters were used (Table 4, 5).

Table 4. Dosage of slow-variable magnetic field

	Bipolar	Unipolar
Triangle 4 mT, 5 Hz	12	13
Triangle 4 mT, 10 Hz	3	2
Triangle 4 mT, 15 Hz	0	2
Triangle 4 mT, 20 Hz	1	0
Triangle 4 mT, 40 Hz	4	3
Triangle 2 mT, 60 Hz	0	1
Sinus, 4.3 mT, 5 Hz	1	0
Sinus, 4.3 mT, 10 Hz	1	0
Sinus, 4.3 mT, 40 Hz	2	0

Table 5. Magnetic field trapping time

Treatment time with PEMF	[min]
Medium	14
Median	12
Maximum	20
Minimum	10

A total of 45 sessions (450 treatments) were performed using magnetic fields. Settings that showed wide therapeutic efficacy were: 4 mT, 5 Hz, triangular waveform, and bipolar.

Oxygen therapy

Oxygen with a concentration above 90% and a maximum pressure of 500 Pa or 1000 Pa above atmospheric pressure was supplied to the therapy chamber. During oxygen therapy, an atmosphere of increased pressure and increased oxygen concentration was maintained in the chamber. After the end of oxygen therapy, pressure equalization occurred, but it can be assumed with a high degree of probability that an elevated oxygen concentration was maintained in the chamber (Table 6, 7).

Concentration > 98%

Table 6. Oxygen dosage by time

	Pressure [Pa]	Time [min]
Average	570	34
Median	500	30
Min	500	10
Max	1000	60

Table 7. Distribution of maximum pressure dosage

	Number of treatments
500 Pa	61
1000 Pa	10

Red light

The Laserobaria 2.0_S device allows omnidirectional irradiation of the limb being treated inside the therapy chamber. The unique arrangement of the irradiation panels inside the chamber, along with its finish in a way that maximizes light reflection, makes it one of the few devices available on the market that effectively delivers light radiation evenly over the entire surface of the limb being treated (Table 8).

Radiation area: 1435 cm^2

Radiation power: 2000 mW

Table 8. Red light dosage

	Dose [J/cm^2]	Time [min]
Average	0.85	10
Median	0.84	10
Min	0.42	5
Max	1.67	20

Number of red light treatments performed: 35

Combination of physical therapeutic agents

In addition to medical contraindications to the use of selected therapeutic agents, the duration of the procedure is also an important limitation. For financial reasons, standardization of the medical service, and patient convenience, the duration of a single treatment should not exceed one hour. Therefore, in some cases, choices had to be made between therapies, to maximize the duration of the most appropriate form in a given case.

The general rule of thumb for combining therapeutic agents is similar effects of agents. So, for example, ozone can combine with UV light therapy, for maximum biocidal effect. Magnet therapy and red light therapy accelerate the process of angiogenesis and increase blood flow, so both therapies will act complementarily and work well in combination with oxygen therapy.

For reasons of time constraints, therapy should be planned in such a way as to maximize the duration of effect of the therapeutic agents prescribed to the patient, by appropriately arranging the sequence of successive therapies.

In all the cases described above, regardless of the choice of individual therapies, they were performed in the following order: ozone therapy, magnetotherapy, oxygen therapy, and red light therapy (Table 9, Fig. 2).

Table 9. Occurring combinations of treatments

	Ozone + PEMF + Oxygen	Ozone + Oxygen + Red Light	PEMF + Oxygen + Red Light	Ozone + Oxygen	PEMF + Oxygen	Ozone + PEMF + Oxygen + Red Light
W	9	7	4	3	2	3
M	12	12	4	4	5	4
Total	21	19	8	7	7	7

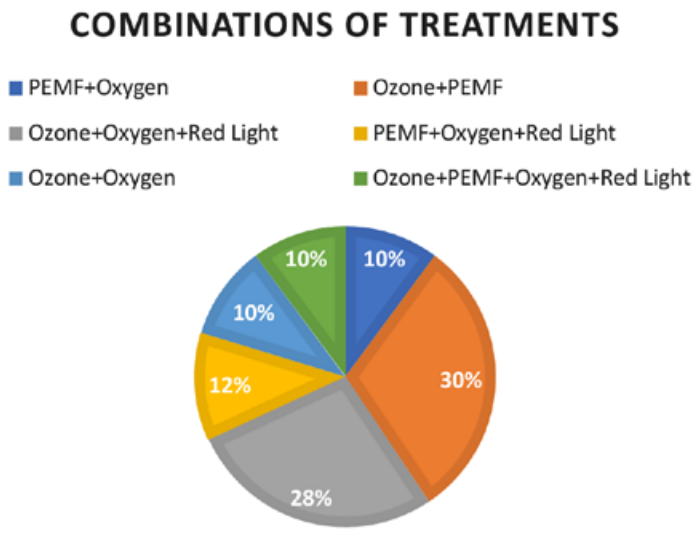

Figure 2. Graph showing the incidence of combined treatments

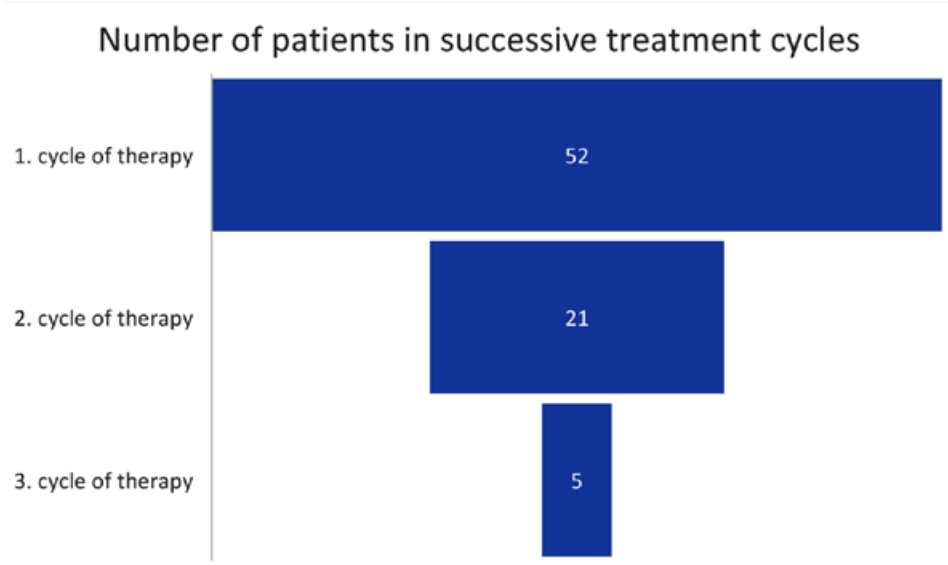

Figure 3. Graph of the number of patients in successive treatment cycles

Results

Each treatment cycle lasted 10 consecutive days (excluding Saturdays and Sundays), and each treatment lasted about 1 hour (including time for patient preparation and device disinfection).

Analgesic effect

The pain-relieving effect for the 43 PEMF therapies performed was recorded at 60% according to the VAS scale assessment. Pain was reduced from the third day of the treatments, including for patients in whom pharmacological pain relief did not produce a marked improvement.

Wound healing

Wound improvement, through granulation, after the first 10-day treatment cycle was observed in 40.5% of patients (14 k, 7 m). Of the initial group of 52 patients, 31 patients were qualified for repeat therapy. 4 people dropped out of continuing treatment because they saw no therapeutic progress. 6 people dropped out of the next treatment cycle for other reasons (high cost of therapy, long distance of the clinic from their homes, and other socio-economic reasons). The third treatment series was performed on 5 patients (Fig. 3).

Conclusions

The inclusion of the Laserobaria 2.0_S therapeutic chamber, which allows the wound to be affected by several physical therapy agents during treatment, in combination with intensified nursing care, which is meant daily cleaning and dressing of wounds, creates favorable conditions for tissue regeneration.

A dramatic and rapid improvement in the patient's well-being is noticeable, and hard-to-heal wounds often persisted for many months until therapy began to begin to heal.

The high effectiveness of the therapeutic method of combining standard treatment with innovative physical methods allows for better patient care, by relieving pain it allows for stronger compression therapy, effective infection control reduces risk factors for revascularization procedures, which accelerates the necessary therapeutic steps towards holistic patient treatment.

The authors recommend further multicenter, randomized, blinded trials to develop the optimal dosage to maximize the therapeutic effect and reduce the time to complete wound closure.

Conflict of interest

None.

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