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Polarized light therapy in the treatment of venous leg ulcers — pilot study

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Abstract

Introduction: *Venous leg ulcers are still a significant healthcare problem capable of diminishing quality of life, lengthening hospitalization, and incurring substantial costs for patients and healthcare systems. In recent years, selected physical methods have been increasingly used in the complex treatment of leg ulcers.*

Material and methods: *The study included 24 patients, 11 male (45.8%) and 13 female (54.1%) aged between 46 and 85 years (mean age: 65.25 ± 9.35 years) with venous leg ulcers lasting for 12.58 ± 7.25 months, who underwent a cycle of polarized light therapy (30 daily procedures lasting 20 minutes each). The progress in wound healing was evaluated by computerized planimetry and pain intensity was assessed with the use of a visual analog scale (VAS) before the beginning and after the completion of the therapy.*

Results: *After the end of treatment using polarized light therapy, the median (IQR) area of the treated ulcers decreased statistically significantly compared to the baseline values from 4.0 (3.25–4.45) cm to 2.25 (2.0–2.95) cm^2 ($p < 0.001$). A statistically significant reduction in the area of ulcers after the end of the treatment cycle compared to the baseline values was also observed in subgroups analyzed in terms of gender, age, BMI value, and the duration and location of the ulcer. A reduction in the ulcer surface area was achieved in all treated patients, and the average percentage change in ulcer surface area was 33.93 ± 11.32%. After completing the course of treatments, a statistically significant reduction of pain intensity on the VAS scale was also achieved, from a median (IQR) level of 6.5 (6–8) points before treatment to 2.0 (2.0–2.0) points after treatment ($p < 0.001$). A statistically significant reduction in pain intensity was also observed in analyzed subgroups in terms of gender, age, BMI value, and the duration and location of the ulcer.*

Conclusions: *In patients with venous leg ulcers, polarized light therapy has a positive effect on the intensity of the ulcer healing process in objective planimetric assessment and reduces the intensity of pain ailments.*

Keywords: venous leg ulcers; polarized light therapy; ulcer surface area; computerized planimetry; pain intensity; VAS scale

Acta Angiol

Introduction

Nowadays, phototherapy is a dynamically developing branch of physical medicine. The first light source used in treatment was natural sunlight, the so-called heliotherapy. Even though the therapeutic effects of light had no scientific justification at that time, its healing power resulting from empirical experience was the

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basis for the widespread use of light in treatment [1]. It is now known that the human body undergoing light therapy converts it into electrochemical energy, which triggers a series of biochemical chain reactions inside cells, stimulating metabolic processes and the activity of the immune system. This favors, among others, stimulating tissue regeneration processes. It is worth noting that a certain percentage of sunlight reaching the body is subject to polarization and probably, among other things, this part of it is responsible for the specific therapeutic properties of natural radiation [1, 2].

With the development of biomedical technology and engineering, the possibilities of producing artificial light sources with various physical characteristics that emit light radiation of appropriate power and wavelength, causing significant therapeutic effects in the irradiated tissues, are expanding. One of the newest light sources with therapeutic properties is the Solaris lamp emitting polarized light used in physical medicine as pilerotherapy (*Polarized Incoherent Low-Energy Radiation Therapy*) [3].

Polarized light is incoherent, polychromatic (the wavelength range covers the entire visible light region and near-infrared), with a low energy value of several dozen mW. Currently, polarized light therapy is becoming more and more widely used in various areas of medicine. This applies in particular to dermatology, angiology, cosmetology, plastic surgery, and vascular surgery. The benefits of its use also apply to the treatment of difficult-to-heal wounds, including leg ulcers [3, 4].

The problem of difficult-to-heal wounds affects approximately 20 million patients in the world [5]. In Poland, according to statistical data, chronic wounds (including venous leg ulcers) occur in over 760.000 people annually [6]. Statistics indicate that the number of patients with chronic wounds will show an increasing tendency due to the increasingly common occurrence of lifestyle diseases, which constitute significant risk factors for their development [5–7].

The complexity of the causes of difficult-to-heal wounds, including ulcers, requires an interdisciplinary approach and the implementation of comprehensive therapeutic programs using various procedures that can accelerate the healing processes. The tendency for difficult-to-heal wounds to recur requires frequent hospitalization and long-term medical care. As a result of the physical suffering caused by the wound and the limited effectiveness of the treatment, patients often experience mood disorders, leading to isolation from the environment and a significant reduction in the quality of their life [8].

Scientific research shows that polarized light therapy reaching the inside of cells (to a depth of about 2.5 cm) improves energy processes by stimulating the activity of mitochondria and a secondary increase in ATP production, which is then reduced to ADP and releases the energy needed for the proper conduct of basic metabolic processes in the body. This phenomenon leads to an increase in intracellular energy resources. An energy-enriched cell in this way can rebuild damaged structures more quickly, which in turn restores its proper biological activity. This is also possible thanks to local stimulation of blood circulation. Healthy cells are activated to produce cytokinins, which trigger regenerative processes by rebuilding the networks of damaged blood vessels, increasing local blood supply and collagen production by fibroblasts. Modification of the activity of immune system cells is also important, associated with reducing the release of pro-inflammatory cytokines, increasing the secretion of anti-inflammatory cytokines, and stimulating the proliferation of connective tissue cells (fibroblasts and keratinocytes). Polarized light therapy also relieves pain by increasing the excitability threshold of pain receptors and increasing the production and secretion of endogenous endorphins [3, 4, 9, 10].

Taking into account the above conditions, research has been conducted in recent years on the possibility of clinical use of polarized light in the comprehensive treatment of chronic wounds, including leg ulcers.

Aim of the study

The study aimed to evaluate the effectiveness of polarized light therapy in the treatment of venous leg ulcers using a planimetric assessment of the surface area and the pain intensity with a visual analog VAS scale.

Material and methods

The study included 24 patients, 11 male (45.8%) and 13 female (54.1%) aged between 46 and 85 years (mean age: 65.25 ± 9.35 years) with venous leg ulcers lasting 12.58 ± 7.25 months. Mean value of body mass index (BMI) was 24.9 ± 2.6 kg/m^2. All patients were hospitalized in Department and Clinic of Internal Medicine, Angiology and Physical Medicine in Bytom in the period 2017–2020. Before including the study, patients received pharmacological treatment and compression therapy without a satisfactory therapeutic effect.

The inclusion criteria for the study were as follows: venous leg ulcer located on the right or left lower limb with an area of < 5 cm^2 (due to the size of the radiator of the polarized light therapy device), age > 45 and < 85 years, lack of endovascular or surgical interventions on the vascular system, the patient's voluntary consent to participate in the study and lack of contraindications to polarized light therapy procedures. Exclusion criteria from the study included: etiology of ulcers other than venous, ulcers with an area > 5 cm^2, age < 45 years and > 85 years, deep vein thrombosis, acute lower limb ischemia, generalized infection requiring systemic antibiotic therapy, diabetes, smoking, lack of voluntary patient's consent to participate in the study.

Methodology of polarized light therapy

As part of the treatment, patients underwent 30-day cycle procedures using polarized light emitted by a Solaris lamp (Medicolux, Poland). The Solaris lamp is a broadband reflective interference polarizer emitting polarized, low-energy light radiation with a wavelength of 500–2500 nm. Thanks to a special filter, the emitted light is yellow. The function of the mentioned filter is to block the emission of harmful ultraviolet radiation.

The treatments were performed locally (in the area of the ulcer) in a semi-reclining position, using a non--contact method with an applicator placed on a stand at a distance of approximately 5 cm from the irradiated ulcer surface, illuminating the ulcer once a day in two sessions consisting of 15 treatments each performed five days a week excluding Saturday-Sunday, with a 4-week break between both sessions. The following physical parameters of the treatments were used: treatment duration — 20 minutes (10 pulses), radiation power density — 50 mW/cm^2 and radiation energy density — 3.0 J/cm^2 (Fig. 1). Since the device emits radiation with constant power, the values of therapeutic parameters used: radiation power density and radiation energy density resulted from calculations taking into account the assumed distance of the applicator from the wound surface — 5 cm (determining the size of the area of the body area irradiated) and the duration of the treatment — 20 minutes (determining on the total amount of energy delivered to a unit of area of the irradiated body area during the procedure), which are consistent with the authors' own experience and current recommendations on the use of polarized light in wound treatment [9, 11].

During a cycle of physical procedures topical pharmacological treatment was applied including for each patient: sulodexide, micronized purified flavonoid fraction, pentoxifylline, and acetylsalicylic acid in standard doses. After completion of each procedure to provide antisepsis and mechanical protection, the ulcer surface was provided with sterile hydrogel dressings Aqua-Gel (KIKGEL, Polska) and subsequent compression bandaging with the use of Codoban bandage (Tricomed, Łódź, Poland) (compression class 3) was applied for 17 hours daily on a leg in between the combined physical therapy procedures.

The analysis of the obtained results regarding measurements of the surface area of treated ulcers and the intensity of pain was carried out in relation to the patients' gender and age, BMI values, duration of ulcers, and the location of ulcers on a specific lower limb.

Figure 1. Polarized light therapy in a 71-year-old female patient diagnosed with a venous ulcer of the right lower leg resulting from venous insufficiency

Before the beginning of the therapeutic cycle, every patient attended a surgical and angiological consultation and in case of the presence of necrotic tissue or purulent infiltration in the ulceration area, surgical wound debridement was also performed.

Planimetric assessment of ulcer surface area

To assess ulcerations high-resolution digital photographs were used in the study. Computer software for planimetric assessment of the ulceration surface area was used for digital image processing. The program automatically calculated the size of the wound surface and perimeter area and after the scaling process gave the result in square centimeters. To maintain high accuracy, all measurements were performed by one specialist experienced in this method [12].

Measurement of pain intensity

The level of pain intensity was assessed using a Visual Analogue Scale (VAS). The patients were instructed to score their pain intensity on a numeric scale in a range from 0 (absence of pain) to 10 (worst possible pain) [13].

The trial was conducted by the Declaration of Helsinki (1964) and its protocol was approved by the Local Bioethical Commission of the Medical University of Silesia in Katowice, Poland (permission no.: KNW/2022/KB1/102/I/16). All qualified patients signed a written informed consent for participation in this study.

Statistical analysis

Statistical analysis was performed with the use of a Statistica 13 package (Statsoft, Kraków, Poland). The Shapiro-Wilk test was used to test the normality of data. There were non-normal distributions of data. The results are presented as median and interquartile range. The Mann-Whitney U test and Wilcoxon test were used to compare two unmatched and matched groups of non-parametric data respectively. The level of statistical significance was set at $p < 0.05$.

Results

The results of the measurements of ulcer surface area before and after treatment with the use of polarized light therapy for the total group of patients as well as in subgroups concerning gender, age, BMI, disease duration, and localization of ulcer with statistical evaluation are presented in Table 1.

After completing the course of treatments using polarized light, a statistically significant reduction in

Table 1. Results of the planimetric assessment of the ulcer surface area before and after the course of polarized light treatments for the entire group of examined patients and in individual subgroups, considering gender, age, BMI, duration of the disease, and location of the ulcer, along with statistical evaluation

	N (%)	Ulcer surface area [cm²]		**p
		Before treatment	After treatment	
		Median*(IQR)	Median*(IQR)	
Total group	24 (100%)	4.0 (3.25–4.45)	2.25 (2.0–2.95)	**< 0.001**
Gender				
Male	11 (45.83%)	3.6 (3.0–4.5)	2.1 (1.9–2.9)	**0.003**
Female	13 (54.16%)	4.0 (3.6–4.4)	2.4 (2.1–3.0)	**0.001**
***p		0.400	0.622	
Age [years]				
< 65	12 (50%)	4.0 (3.3–4.35)	2.25 (2.0–2.85)	**0.002**
≥ 65	12 (50%)	3.8 (3.05–4.5)	2.45 (1.95–2.95)	**0.002**
***p		0.644	0.953	
Body mass index (BMI) [kg/m²]				
18.50–24.99 (normal weight)	13 (54.16%)	3.6 (3.0–4.0)	2.0 (1.9–2.1)	**0.001**
25.00–29.99 (overweight)	11 (45.83%)	4.2 (4.0–5.0)	2.8 (2.4–3.4)	**0.003**
***p		**0.027**	**0.016**	
Ulcer duration [months]				
< 12	12 (50%)	3.8 (3–4.55)	2.65 (2.05–3.05)	**0.002**
≥ 12	12 (50%)	4.0 (3.6–4.1)	2.1 (1.95–2.7)	**0.002**
***p		0.908	0.326	
Localization of ulcer				
Left leg	12 (50%)	4.0 (3.6–4.5)	2.1 (1.95–2.95)	**0.002**
Right leg	12 (50%)	3.85 (3.0–4.45)	2.5 (2.05–2.95)	**0.002**
***p		0.750	0.386	

*(IQR) — Interquartile Range (Q1-Q3), **p — Wilcoxon test, ***p — Mann-Whitney U test; N — number of patients

the area of treated ulcers was achieved with a median (IQR): 4.0 (3.25–4.45) cm to 2.25 (2.0–2.95) cm^2 ($p < 0.001$). A statistically significant reduction in the area of ulcers after the completion of treatment with polarized light compared to the baseline values was also observed in individual subgroups of patients, analyzed according to gender: gender (male: $p = 0.003$, female: $p = 0.001$), age range (< 65 years): $p = 0.002$, ≥ 65 years: 0.002), BMI (normal weight: $p = 0.001$, overweight: $p = 0.003$), ulcer duration (< 12 months: 0.002, ≥ 12 months: $p = 0.002$) and ulcer location at a specific lower limb (left: 0.002, right: $p = 0.002$).

Only in the subgroup analyzed according to body weight in overweight patients, the ulcer surface area was statistically significantly larger compared to the subgroup of patients with normal body weight both before the start of treatment with polarized light (median 4.2 (4.0–5.0) cm^2 vs. 3.6 (3.0–4.0) cm^2; $p = 0.027$) and after its completion (median 2.8 (2.4–3.4) vs. 2.0 (1.9–2.1); $p = 0.01$). However, no statistically significant differences were found between the values of the ulcer surface area between patients in the remaining subgroups, both before and after the treatment with polarized light (Table 1).

Complete healing of the ulcer was achieved in no patient, and the percentage change in the ulcer surface area after polarized light therapy compared to the baseline values before treatment was on average 33.93 ± 11.32%. There was no increase in the ulcer surface area after treatment in any patient.

There were no statistically significant differences in the mean percentage change in the ulcer surface area between patients in individual patient subgroups, analyzed according to gender, age range, BMI value, ulcer duration, and location of the ulcer on a specific lower limb.

The results of measurements of pain intensity with the use of the VAS scale, before and after the end of a cycle of polarized light therapy procedures for the total group of patients as well as in subgroups concerning gender, age, BMI, ulcer duration, and localization of ulcer, with statistical evaluation are presented in Table 2.

After completing the treatment cycle of using polarized light, there was a significant reduction in the intensity of pain experienced on the VAS scale, from a median of 6.5 (6.0–8.0) points before treatment to 2.0 (2.0–2.0) points after treatment ($p < 0.001$). A statistically significant reduction in the intensity of pain after completing treatment with polarized light compared to the baseline values was also observed in individual subgroups of patients, analyzed according to gender (male: $p = 0.003$, female: $p = 0.001$), age group (< 65 years: $p = 0.002$, ≥ 65 years: $p = 0.001$), BMI value (normal weight: $p = 0.001$, overweight: $p = 0.003$), ulcer duration (< 12 months: 0.001, ≥ 12 months: $p = 0.002$) and ulcer location on a specific lower limb (left: $p = 0.001$, right: $p = 0.002$).

Only in the subgroup analyzed according to the location of the ulcer in patients with an ulcer located on the left lower limb, the intensity of pain assessed on the VAS scale before the start of treatment with polarized light was statistically significantly higher compared to the subgroup of patients with an ulcer located on the right lower limb (median 8.0 (6.0–8.0) points vs. 6.0 (5.0–7.0) points; $p = 0.035$), while after the end of treatment, the pain intensity did not show statistically significant differences between patients with different ulcer locations. However, there were no statistically significant differences between the intensity of pain assessed on the VAS scale between patients in the remaining subgroups, both before and after the start of treatment with polarized light (Table 2).

In 2 patients, complete relief of pain was achieved, and in the remaining patients, the intensity of pain was reduced by more than 50% of the baseline values, and the percentage change in the intensity of pain was on average 70.76 ± 11.3%.

There were no statistically significant differences in the mean percentage change in pain intensity between patients in individual patient subgroups, analyzed according to gender, age range, BMI value, duration of ulceration, and location of the ulcer on a specific lower limb.

Treatments using polarized light were well tolerated by patients who reported no side effects during or after treatment.

Discussion

The treatment of ulcers is still a serious medical problem all over the world. Although many risk factors have been identified and many new treatment strategies have been introduced, in many cases the possibility of full recovery of difficult-to-heal wounds is very limited. Objective clinical observations in this area are difficult due to differences in the characteristics of patients and the selection and dosage of treatment methods in individual studies. In many cases, pharmacological treatment is not fully effective and requires many modifications. The tendency to recur during the first 3 months of treatment of leg ulcers is almost 70%, which requires frequent hospitalizations and long-term medical care. Due to the complex etiopathogenesis of chronic wounds, the most beneficial therapeutic effects are achieved by a comprehensive, multidirectional treatment model that considers the synergistic effect of individual therapeutic methods [7, 8, 14].

Table 2. Results of the assessment of the intensity of pain on the VAS scale, before and after the course of polarized light treatments for the entire group of examined patients and in individual subgroups, considering gender, age, BMI, duration of the disease, and location of the ulcer, along with statistical assessment.

	N (%)	VAS score (points)		**p
		Before treatment	After treatment	
		Median *(IQR)	Median *(IQR)	
Total group	24 (100%)	6.5 (6–8)	2.0 (2.0–2.0)	**< 0.001**
Gender				
Male	11 (45.83%)	7.0 (5.0–8.0)	2.0 (1.0–3.0)	**0.003**
Female	13 (54.16%)	6.0 (6.0–8.0)	2.0 (2.0–2.0)	**0.001**
***p		0.706	0.643	
Age [years]				
< 65	12 (50%)	6.5 (6–7.5)	2.0 (2.0–2.5)	**0.002**
≥ 65	12 (50%)	7.0 (5.0–8.0)	2.0 (1.5–2.0)	**0.001**
***p		0.908	0.707	
Body mass index (BMI) [kg/m^2]				
18.5–24.99 (normal weight)	13 (54.16%)	7.0 (5.0–8.0)	2.0 (2.0–2.0)	**0.001**
25.0–29.99 (overweight)	11 (45.83%)	6.0 (6.0–8.0)	2.0 (2.0–2.0)	**0.003**
***p		0.542	0.976	
Disease duration [months]				
< 12	12 (50%)	7.5 (6.0–8.0)	2 (2–3)	**0.001**
≥ 12	12 (50%)	6.0 (5.5–7.5)	2 (1–2)	**0.002**
***p		0.214	0.119	
Localization of ulcer				
Left leg	12 (50%)	8.0 (6.0–8.0)	2.0 (1.5–2.5)	**0.001**
Right leg	12 (50%)	6.0 (5.0–7.0)	2.0 (2.0–2.0)	**0.002**
***p		**0.035**	0.976	

*(IQR) — Interquartile Range (Q1-Q3), **p — Wilcoxon test, ***p — Mann-Whitney U test; N — number of patients

Treatment methods often used as part of comprehensive therapy include physical medicine, which in many cases can support routine pharmacological treatment and compression therapy, leading to complete healing of ulcers. These methods also include polarized light [4, 9].

In the presented study polarized light therapy was used, which resulted in an improvement in the effectiveness of ulcer healing, consisting of a statistically significant reduction in their surface area in an objective planimetric assessment. This improvement concerned both the entire group of treated patients and the results obtained in individual subgroups, taking into account the patient's gender and age, BMI, duration of ulcers, and the location of ulcers on a specific lower limb.

The beneficial effects on ulcer healing are probably due to the described biological effects of polarized light therapy. The wound healing process consists of three successive stages: reaction, regeneration, and reconstruction. During the regeneration stage, capillaries bud and form new vessels; fibroblasts proliferate and secrete increased amounts of collagen, bacteria multiply in dead tissue, macrophage activity increases, and epithelial cells and myofibroblasts migrate. In the remodeling stage, the activity of fibroblasts and macrophages is reduced, but collagen fibers begin to reorganize. Thanks to the mechanisms indicated above, tissue regeneration processes are stimulated [11, 15].

In the studied group of patients, a statistically significant reduction in the intensity of accompanying pain was also achieved, both in the entire group of treated patients and in individual subgroups. Literature data show that polarized light affects specific neural structures, causing, among others, reducing the excitability of pain receptors and stimulating the production and secretion of endorphins responsible for alleviating the feeling of pain [16].

In the available literature, the authors found only a few studies presenting the results of clinical trials devoted to the use of polarized light therapy in the treatment of venous leg ulcers.

In the work of Medenica et al. from 2003, the effectiveness of polarized light therapy in the treatment of 25 patients with venous leg ulcers was assessed. All patients received polarized light therapy applied to the ulcers once a day for four weeks. At the end of four weeks of treatment, an increase in the ulcer area with advanced healing was observed in 24 ulcers (99%) [17].

In another study, Pasek et al. presented the beneficial effects of the treatment of a 41-year-old woman with a right foot ulcer. The ulcer was subjected to 2 series of treatments with the use of polarized light therapy. Complete healing of the ulcer was achieved, and the intensity of the inflammatory reaction and local hyperemia of the scar was reduced. The obtained results suggest that polarized light therapy may be a useful adjunct method in the treatment of patients with leg ulcers which positively stimulates the healing of ulcers, causes the symptoms of local inflammation to disappear, and reduces the intensity of pain ailments [18].

In the work done by Allam et al., a review of the literature on the use of phototherapy in the treatment of various types of wounds in animals and humans showed that the most common types of phototherapy are low-energy laser therapy (LLLT) and ultraviolet (UV), with research from recent years, indicating that the polarization and broad spectrum of polarized light can stimulate wound healing in a similar way to a low-energy laser [9].

Feehan et al. in their research, emphasized that as the population grows and ages, it will be necessary to use non-pharmaceutical methods of wound treatment to ensure adequate care. According to the authors, polarized light therapy (PLT) will be effective in such cases, although there is currently a gap in the literature regarding the mechanisms of its action [14].

In another work, Feehan et al. evaluated polarized light therapy (PLT) on human U937 monocytic cells. Cells were analyzed for changes in the expression of genes and surface markers associated with inflammation. It was noticed that 6-hour exposure to PLT stimulated the ability to immunomodulate in human immune cells, which was probably the basis for the observed anti-inflammatory effect of this method [15].

Pinheiro et al. in their study presented a morphological and cytochemical analysis of the wound healing process in 30 Wistar rats undergoing laser therapy (wavelength 685 nm) and polarized light (wavelength 400–2000 nm). The animals were irradiated every 48 hours for 7 days. It has been shown that the use of laser or polarized light resulted in increased collagen deposition and better organization of its fibers in healing wounds, and when polarized light was used, the number of myofibroblasts in the wound also increased [19].

Durović et al. in turn, examined the effect of polarized light therapy on the healing of pressure sores. The randomized, single-blind study involved 40 patients with stage I–III pressure ulcers. Patients from the experimental group, in addition to standard wound cleaning and dressing, were additionally treated with polarized light emitted by a Bioptron lamp, while in the control group, only standard wound cleaning and dressing were used. Patients in the experimental group in which polarized light was used had statistically significantly better values of monitored pressure ulcer parameters compared to patients in the control group [20].

Although so far there are few randomized scientific studies clearly justifying the therapeutic effectiveness of therapy using polarized light, modern physiotherapy is systematically expanding its therapeutic possibilities. Every year, new indications for the use of this physical method appear, as well as recommendations that allow patients to maintain greater comfort and safety of therapy. Obtaining further, broader possibilities of using polarized light in medicine requires, first of all, a continuation of preclinical research, both on molecular and cellular models, as well as research on laboratory animals. The results obtained so far are satisfactory and will probably enable the initiation of large, randomized clinical trials soon, which will clearly verify the usefulness of preventive and therapeutic applications of polarized light, including the case of venous leg ulcers.

Limitations of the study

This pilot study has some limitations. One of the limitations is that it is a single-center study. For this reason, the results of this study do not reflect the general population. This study includes the short-term follow-up, a limited number of participants, and the absence of a control group. The obtained preliminary therapeutic effects can be explained more clearly in the future in randomized studies involving larger populations, the control group treated with compression therapy without the use of polarized light, and longer follow-up. The study also did not include a detailed analysis of previous standards of care.

Conclusions

1. The use of polarized light therapy in the treatment of patients with venous leg ulcers causes a statistically significant reduction in the surface area of treated ulcers in an objective planimetric assessment and a reduction in pain intensity regardless of age, gender, BMI value, and the duration and location of ulcers.
2. Clear confirmation of the favorable preliminary results requires conducting randomized clinical trials considering a larger patient population and a longer follow-up period, which in the future will allow for the possible inclusion of pilerotherapy in comprehensive treatment programs for venous leg ulcers.

Article information and declarations

Data availability statement: The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics statement: The trial was conducted by the Declaration of Helsinki (1964) and its protocol was approved by the Local Bioethical Commission of the Medical University of Silesia in Katowice, Poland (permission no.: KNW/2022/KB1/102/I/16). All qualified patients signed a written informed consent for participation in this study.

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