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Efficacy of polarized light therapy versus monochromatic infrared energy in the treatment of venous leg ulcer

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***Abstract*---**Purpose: To evaluate the effects of polarized light therapy versus monochromatic infrared energy in the treatment of venous leg ulcers. Methods of evaluation: - (Measurement of the ulcer surface area (USA) and the ulcer volume measurement (UVM). Methods: Forty patients suffering from stage 2 lower limb venous ulcers were selected randomly from the vascular and general surgeries departments of Kasr-El-Aini Hospital. These patients were divided randomly into two equal groups in number: One was treated with the polarized light therapy (BLT) besides the regular ulcer care (topical and general medications as well as the intermittent surgical curettage) for three months, while the other was treated with the monochromatic infrared energy (MIRE) therapy, medical treatment and the and the regular ulcer care (topical and general medications as well as the intermittent surgical curettage) for three months or till healing, their ages were ranged from 50 to 65 years. Results: Results showed that both the BLT and MIRE were effective in enhancing the healing of the lower limb venous ulcers as manifested by the highly significant decreases in ulcer surface area (USA) and ulcer volume measurement (UVM). MIRE was more fruitful in decreasing the USA but not significant as BLT in decreasing the UVM. Conclusion: Both were nearly equivalent and significantly effective in enhancing the healing of the lower limb venous ulcers as manifested by the highly significant decreases in

USA and UVM. The monochromatic infrared energy (MIRE) was more fruitful in decreasing the USA but not significant as BLT in decreasing the UVM

***Keywords*---**Polarized light therapy (BLT), Monochromatic infrared energy (MIRE), Venous ulcers.

Introduction

Venous ulcers are wounds that are thought to occur due to improper functioning of valves in the veins usually of the legs. They are the major cause of chronic wounds, occurring in 70% to 90% of chronic wound cases. Venous ulcers are costly to treat, and there is a significant chance that they will reoccur after healing; up to 48% of venous ulcers had recurred by the fifth year after healing. Venous ulcers are an immense problem among the older and obese population. There are many studies about the aetiology, natural history, and epidemiology of skin breakdown. There is relatively little information about factors that stimulate the repair of body tissues after break down, [2,3,6,8,9,10].

Chronic lower limb ulcers are usually managed by general practitioners with the more difficult cases referred to a dermatologist or surgeon. Many of these ulcers represent a complication of varicose veins or a late complication of deep venous thrombosis. The majority of the rest are caused by arterial insufficiency or diabetes and a few by vasculitis (angiitis) or ulcerating tumours. In developed countries, infection rarely plays a primary role. In intractable cases, persistent ulceration may be due to a combination of factors such as the local trauma, diabetic neuropathy and obliterative atherosclerosis. Lower limb ischemia is chronic and it ranges in severity from minimal to critical. The condition is often referred to as chronic arterial insufficiency (CAI) or simply as a peripheral vascular disease (PVD). Acute lower limb ischemia usually occurs suddenly and often threatens the viability of the limb. The symptoms and signs of arterial insufficiency depend on the degree of ischemia and there are three main clinical presentations: intermittent claudication, rest pain, and critical ischemia, [2,3,11,12,17,18].

Vascular disorders of the lower limb are caused mainly by atherosclerosis, arterial thromboembolism, aneurysms, complications of diabetes mellitus, and thromboembolic and varicose disorders of the venous system, in some patients especially the elderly, a variety of causes may interact. Accurate initial diagnosis of vascular disorders depends largely on skilled clinical evaluation rather than special investigations. Symptoms and signs are best interpreted in the light of the underlying pathophysiological processes. The principal symptoms and signs of lower limb vascular disease are pain, changes in skin texture, changes in skin colour and temperature, ulceration and swelling. Complications of the obliterative atherosclerosis are the luminal narrowing and the embolism arising, lumen narrowing by atherosclerotic plaques, chronic ischaemia and sudden occlusion by the superimposed thrombus affecting the aorta and large distributing vessels, which is more common in diabetes, particularly type II, [1,11,12,17,18,19,29].

Polarized light from low-power lasers and non-laser devices has been used as a non-invasive therapy in the treatment of various musculoskeletal disorders, acceleration of wound healing and treatment of skin ulcers, although the polarized light is known to have numerous photo-biostimulation effects including cell proliferation, enhanced collagen synthesis, changes to the circulatory system and anti-inflammatory actions, the precise mechanism of its action remains unclear. The available non-laser optical devices are the Bioptron products which emit a wide beam of polarized, non-coherent, polychromatic, low-energy light that contains wavelengths from the visible spectrum (480-700nm) and infrared radiation (700-3400nm); this range provides optimal penetration and stimulation of the tissues without the risk of DNA damage, [7,14,21,23,26].

Bioptron light therapy device emits light that is polarized, polychromatic, non-coherent and of low energy. The light emitted has a wide range of wavelengths (480-3400nm) and differs from laser light, which is monochromatic (of narrow wavelength), coherent, polarized and of high or low energy. A possible risk of burns is present with the laser therapy, while not possible with the Bioptron light therapy. User skills are essential in laser therapy, but not essential with the Bioptron light therapy. Higher costs are present with the laser therapy, but not with the Bioptron light therapy, in addition, treatment of large area is available with the Bioptron light therapy, [7,21,23,26,27].

Monochro¬matic Infrared Energy/ (MIRE™) through infrared light-emitting diodes. These diodes are mounted in flexible Therapy Pads, and emit infrared light at a wavelength of 890 nm, increasing local circulation and reducing pain, stiffness and muscle spasm where applied. Anodyne® Therapy Systems that delivers Monochro¬matic Infrared Energy/ (MIRE™) received clearance from the US FDA in 1994, obtained CE Marking in 2005, and are compliant with the ISO 13485 International Standard. Monochro¬matic Infrared Energy/ (MIRE™) is a non-pharmacological treatment for acute and chronic wounds, including ulcers, diabetic wounds, abdominal wounds, and traumatic wounds, it is primarily used for more complex chronic wounds. It has been suggested that Monochro¬matic Infrared Energy/ (MIRE™) is best suited for the management of large, stage 2 and stage 3 ulcers with inadequate or poor granulation tissue and heavy exudates,[4,5,13,15,16,22,24,25,28].

Material and Methods

Subjects

This study was carried out Forty patients suffering from stage 2 lower limb venous ulcers were selected randomly from the vascular and general surgeries departments of Kasr-El-Aini Hospital. These patients were divided randomly into two equal groups in number: One was treated with the BLT therapy besides the regular ulcer care (topical and general medications as well as the intermittent surgical curettage) for three months, while the other was treated with the MIRE therapy, medical treatment and the and the regular ulcer care (topical and general medications as well as the intermittent surgical curettage) for three months or till healing, their ages were ranged from 50 to 65 years. Group (A): (the first study group) (Bioptron light therapy group): This received the Bioptron light

therapy and the regular ulcer care (topical and general medications as well as the intermittent surgical curettage) for three months. Group (B): (the second study group) (MIRE group): This received the monochro¬matic Infrared Energy/ (MIRE™) and the regular ulcer care (topical and general medications as well as the intermittent surgical curettage) for three months Measurements were conducted before starting the treatment as a first record and at the end of the treatment as a second (final) record. Measurements were conducted before starting the treatment as a first record and at the end of the treatment as a second (final) record.

Instrumentation

In this study, the measuring tools and equipment were the Ulcer surface area (USA) measurement in cm2, Ulcer volume measurement (UVM) in Cubic cm, while the therapeutic equipment was Bioptron Compact III light therapy system (PAG-860) and the Anodyne® Therapy Systems-Model,[4,5,7,13,14, 15,21].

Procedures
Evaluation
Measurement procedures:

A- Measurement of ulcer surface area (USA) in cm2:
The measurement of the ulcer surface area was conducted by tracing methods according to the following steps: A sterilized transparency film was placed on the wound or ulcer area. The ulcer parameter was traced by using the fine-tipped transparency marker. Each ulcer area was traced three times to establish measurement reliability. After tracing, the transparency film face, which faces the ulcer wound, was cleaned with a piece of cotton and alcohol. The carbon paper was placed over the metric graph paper 1mm2. The traced transparency film was placed over a carbon paper with a white paper in between and transcribed the tracing on metric graph paper. The number of square millimetres on the metric graph paper within the ulcer wound was traced and counted to determine the ulcer wound area. This area was converted to cm2; the mean of the three trials was calculated and considered as a wound surface area (USA). The measurements of ulcer surface area were conducted pre-treatment and at the end of treatment after 2 months,[1, 3,9,12,17,18].

B- Ulcer volume measurement (UVM) in Cubic cm:
The patient was positioned in a relaxed position with the ulcer directed upward. The ulcer was traced on the transparent paper and placed over the metric graph paper to have the longest length and width. A disposable measuring tape was directed into the deepest point of the ulcer to record the ulcer depth. (Width X length X depth) was calculated to have the volume of the ulcer, [1,2,8,11,19,29].

Treatment procedures:
All patients in the two groups; (A) and (B) received the same traditional treatment (topical and systemic medications and intermittent surgical curettage to the ulceration) plus the same nursing care, same dressing and the same described diet.

Group (A) Steps of the BLT treatment procedures

1-Position of the patient: Supine lying position is appropriate for the lower limb ulcers. 2-Wound preparation: the wound was cleaned at first. Some abscesses were opened and pockets of pus were drained via the surgeon, and necrotic tissue was removed, scrubbing the wound with a soft toothbrush followed by hydrogen peroxide, saline rinse and betadine. 3- BLT device preparation: the plug of the BLT unit was inserted into the main current supply; the on/off switch was switched on. Then set the treatment parameters of BLT. 4- BLT application: point the light beam at the area to be treated, holding the device at the right angle (90°) perpendicular to the surface of the venous ulcer and maintaining a distance of 10 cm from the surface of the venous ulcer and applying the BLT for about 20 minutes. 5-frequency of application: 20 minutes session was applied day after day (three times/week) for three months. 6- Unplug the device after use and it is advisable to prolong the BLT for one or two weeks if wound closure occurred before the end of the treatment period (three months) to strengthen the treated area, [7,21,27].

Steps of the MIRE treatment procedures in the second study group (B) (MIRE group):
This group was treated with the essentials of foot ulcer care medications and traditional wound care, besides the MIRE therapy. The wound was cleaned at first. Some report abscesses were opened and pockets of pus drained, and necrotic tissue was removed by scrubbing the wound with a soft toothbrush followed by hydrogen peroxide, saline rinse and betadine. The Anodyne® Therapy System, Model 480 consists of the Main Control Unit, Therapy Pads, Attachment Straps, Velcro Strips and the Carrying Case.

Setting up the Anodyne® Therapy System:

Step 1: Place the Main Control Unit securely on a table or cart to prevent it from falling and endangering the patient. Be sure there is an electrical outlet close to the System. **Step 2:** Visually inspect both the power cord and the Therapy Pads to ensure that no exposed wires are present, as exposed wires may be unsafe and can cause electrical shock. **Step 3:** Plug the cord into the power transformer on the back of the System and an active electrical wall outlet. Be sure the electricity to the outlet is turned on. **Step 4:** Plug the ends of the cords of the Therapy Pads into the Therapy Pad Connectors on the front of the Control Unit. Be sure they are inserted firmly into the Connectors. **Step 5:** Turn on the Control Unit using the On/Off Switch on the top of the System. **Step 6:** Turn the Energy Control Dials to the right. The Energy Control Indicators should show 10 energy bars on each side when all Therapy Pads are properly connected. If all 10 bars do not illuminate, wait a few minutes and retry. **Step 7:** The System is now ready to be used with patients. Place the Therapy Pads on the area to be treated, being sure to place a clear plastic barrier between the Pads and the patient's skin. **Step 8:** Always turn this System OFF between each session using the On/Off Switch. **Step 9**: frequency of application: One session was applied day after day (three times/week) for three months or till healing,[5,13,15,16,22].

Data analysis:

Measurement of the ulcer surface area (USA) and ulcer volume measurement (UVM) were measured pre-treatment as a first record and after three months of intervention as a second final record in both groups. Collected data were fed into the computer for statistical analysis; descriptive statistics such as mean, standard deviation, minimum and maximum were calculated for each group. The t-test was done to compare the mean difference between the two groups before and after application and within each group. Alpha point of 0.05 was used as a level of significance,[20,30].

Results

As shown in table (1) and figure (1), the mean value of the USA in cm^2 before treatment was (13.400 ± 1.033) in the (polarized light therapy group), while after treatment was (3.400 ± 0.535) in cm^2. These results revealed a highly significant decrease in the USA in cm^2 ($P < 0.0001$). While in the MIRE group, the mean value of the USA in cm^2 before treatment was (13.405 ± 0.551) in cm^2, while after treatment was (2.200 ± 0.311) in cm^2. These results revealed a highly significant decrease in the USA in cm^2 ($P < 0.0001$).

Table (1)
Comparison of the mean values of the ulcer surface area (USA) measurement in cm2 of the 2 records before and after treatment in both groups

	Before treatment		After treatment		Mean difference	T-value	P.value	Level of significance
	Mean	**SD**	**Mean**	**SD**				
BLT Group	13.400	1.033	3.400	0.535	10.0000	38.44	0.0001	Highly significant decrease
MIRE Group	13.405	0.551	2.200	0.311	11.2050	79.20	0.0001	Highly significant decrease

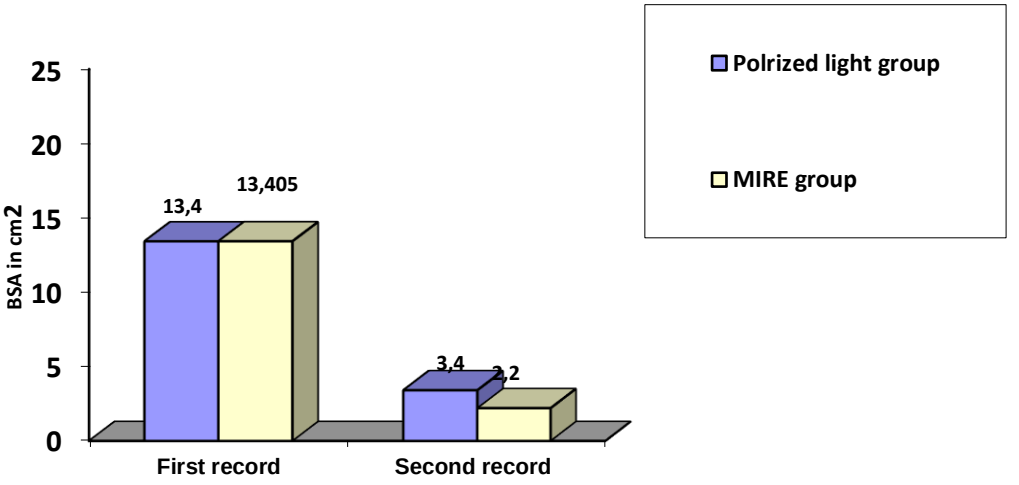

Fig (1): Bars representing the mean values of the ulcer surface area (USA) measurement in cm2 of the 2 records before and after treatment in both groups.

As shown in table (2) and figure (2), the mean value of the UVM in Cubic cm before treatment was (20.80 ± 5.90) Cubic cm in the polarized light therapy group, while after treatment was (5.661 ± 1.650) Cubic cm. These results revealed a highly significant decrease, (P > 0.0001), while in the MIRE group, the mean value of the UVM in Cubic cm before treatment was (20.75 ± 5.88) Cubic cm, but after treatment was (5.100 ± 1.090) Cubic cm, these results revealed a highly significant reduction in the UVM in Cubic cm (P < 0.0001).

Table (2)
Comparison of the mean values of the ulcer volume measurement (UVM) in Cubic cm before and after treatment in the two groups

	Before treatment		After treatment		Mean difference	T-value	P.value	Level of significance
	Mean	SD	Mean	SD				
BLT Group	20.80	5.90	5.661	1.650	15.1390	11.05	0.0001	Highly significant decrease
MIRE Group	20.75	5.88	5.100	1.090	15.6500	11.70	0.0001	Highly significant decrease

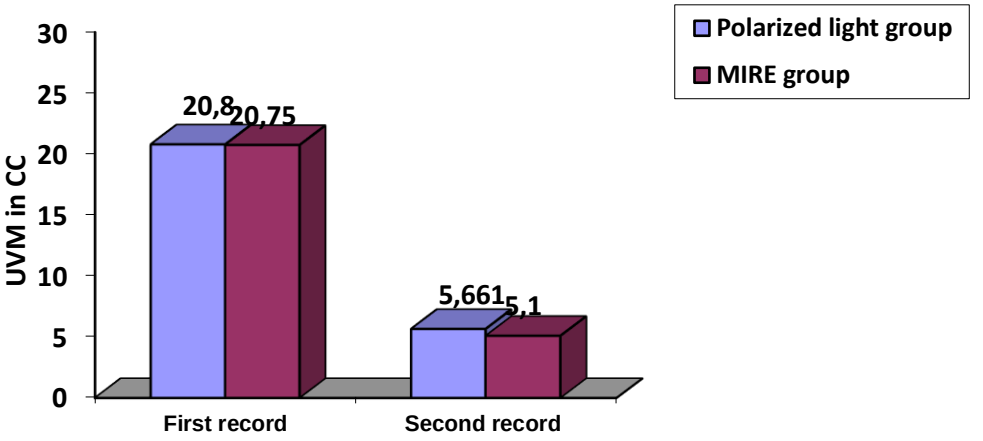

Fig (2): Mean values of the UVM in Cubic cm of the 2 records in both groups.

Discussion

Venous ulcers, as with all superficial ulcers, are a breakdown of the cutaneous and subcutaneous tissues. The venous part of the title indicates the aetiology of the ulcer. With increased venous pressure from venous insufficiency, there is also increased pressure in the microvasculature, resulting in oedema. As such, there is decreased perfusion of tissues, with the absence of nutrition and build-up of toxic metabolites. These factors reduce the resistance of the tissues, rendering them susceptible to breakdown from minor trauma. The most common site for a venous ulcer is just proximal to the medial malleoli, as this is where the ankle vessels perforate, locally increasing the venous pressure. Venous ulcers usually present as shallow, irregular to oval in shape, with macerated borders. Size varies from a pinhead to extensively covering the distal-medial aspect of the leg. The base may be granulated, however, it is usually covered in slough and a serious or haemoserous exudate, [1,2,3,8,9].

There is a relationship between pressure and time indicating that higher pressures require a shorter time to cause ulcerations than lower pressures. Tolerance to high tissue pressures depends on the patient's health, and the amount of damage is proportional to the extent of the pressure and the time it is applied. In high-risk patients the amount of pressure and duration of time before damage occurs are short. venous insufficiency impaired mobility Chronic ambulatory hypertension in the area eventually leads to subcutaneous fat necrosis and fibrosis, so that orders of time and magnitude were reduced easily lead to ulcers. Leg ulcers occur relatively commonly in the late middle and old age, arising in association with chronic venous insufficiency (80% of cases), chronic arterial insufficiency (5% to 10%), or peripheral sensory neuropathy; in some patients, a combination of these factors exists. leg ulcers are associated with significant long-term morbidity and often do not heal unless the underlying problem(s) is corrected [3, 6, 8,10,12].

A chronic leg ulcer is a lesion that has failed to heal after 1 month. But this definition is arbitrary and embodies the notion of delayed healing. The definition of chronic venous ulcer that was used in this study was the presence of venous abnormality in a limb with a chronic ulcer. The most common type of chronic wound among the ambulatory elderly is thought to be the venous leg ulcer. Venous leg ulcers have been estimated to afflict between 0.2% and 1% of the total population and between 1% and 3%of the elderly population in the United States and Europe. Unfortunately, these estimates are primarily from studies that are more than 20 years old, [1,3, 8,9,11].

Bioptron light therapy system is a medical device, with expanding clinically proven efficacy both in the treatment of wounds and pain conditions as well as in the treatment of selective skin disorders, it employs a combination of infrared and visible light wavelengths considered to be beneficial in the treatment of different types of problems and injuries. Both visible and infrared light have been shown to affect different positive changes at the cellular level. Bioptron light therapy device emits light that is polarized, polychromatic, non-coherent and of low energy, the light emitted has a wide range of wavelengths (480-3400nm) and differs from laser light, which is monochromatic (of narrow wavelength), coherent, polarized and of high or low energy. A possible risk of burns is present with the laser therapy, while not possible with the Bioptron light therapy. User skills are essential in laser therapy, but not essential with the Bioptron light therapy. Higher costs are present with the laser therapy, but not with the Bioptron light therapy, in addition, treatment of a large area is available with the Bioptron light therapy, [7, 14,21,27].

Light is a form of energy and has wave-like properties; the difference between the various colours of light is determined by their wavelength. Light has been used as a healing tool since ancient times. Scientists now have a better understanding of which components of natural light are useful in the stimulation of healing. This has led to the development of optical devices to produce various types of medically useful light such as the Bioptron light therapy (BLT) system. BLT devices emit light containing a range of wavelengths that correspond to visible light plus infrared radiation, both of which have been reported to stimulate biological reactions and importantly no harmful ultraviolet radiation is present in the BLT,[7,14, 21,23,26].

Anodyne Professional Therapy System is a MIRE device that received marketing clearance from the U.S. Food and Drug Administration (FDA) in 1994 through the 510 (k) process. Wound healing involves a highly complex set of physiological processes regulated by many different cellular and humeral factors; MIRE therapy stimulates the endogenous purification by removal of infectious microorganisms and cell debris via the following; increasing stimulation of macrophages, increasing bacterial phagocytosis activity and bacterial phagocytosis capacity by increasing formation of the scavenger cells, increasing stimulation of neutrophils, increasing number of neutrophils and phagocytosis activity. MIRE therapy stimulates the higher quality of granulation by revascularization and collagen production via the following sequence; release of mediators leading to release of cytokines (IL1 and IL VI) and release of growth factors, the release of cytokines (IL1and IL VI) leads to stimulation of fibroblasts, increase collagen production,

stimulation of keratinocytes, increasing formation of epithelium, stimulation of endothelium cells and stimulation of the angiogenesis,[4, 5,13,16,22,25]. The findings of the present study showed that there was a highly significant decrease between the means of the second record USA (2) (after 3 months of the polarized light therapy application) and the first record USA (1) (pre-application) ($P < 0.0001$).

Findings of the present study showed that there was a highly significant decrease between the means of the second record USA (2) (after 3 months of the MIRE application) and the first record USA (1) (pre-application) ($P < 0.0001$). Findings of the present study showed that there was a highly significant decrease between the means of the second record UVM (2) (after 3 months of the polarized light therapy application) and the first record UVM (1) (pre-application) ($P < 0.0001$). The results of this study indicated that there was a highly significant decrease between the means of the second record UVM (2) (after 3 months of the MIRE application) and the first record UVM (1) (pre-application) ($P < 0.0001$). These significant differences, between the first study group (Polarized light therapy group) and the second study group (MIRE group), which were in the form of a highly significant decrease in the USA and UVM, were consistent with those observed and recorded by Abbade and Lastoria, 2005; Adam and Clark, 2006; Allison et al., 2010; Aydin et al., 2009; Ballyzek et al., 2005; Barrick and Campbell, 2009; Brem et al., 2004; Bulk, 2006; Burke, 2005; Chung et al., 2006; Clifft et al., 2005; Depuydt et al., 2009; ECRI Institute, 2010; Eiffel, 2008; Heinen et al., 2006; Hoeksema et al., 2002; Iordanou et al., 2007; Irving and Hargreaves, 2009; Jianping et al., 2005; Kochman, 2004; Kubasova et al., 2005, 2006 and 2008; Li et al., 2008; Liu et al., 2005; Medenica and Lens, 2003 and 2004; Monstrey et al., 2003 and 2004; Moro et al., 2012; Nather et al., 2007 and Volkert et al., 2005.

Both the polarized light therapy and monochromatic infrared energy (MIRE) in the treatment of lower limb venous ulcers had a valuable healing effect. The results of this study support the expectation that both the polarized light therapy and monochromatic infrared energy (MIRE) were effective in enhancing the healing of the lower limb venous ulcers as manifested by the highly significant decreases in ulcer surface area (USA) and ulcer volume measurement (UVM). The monochromatic infrared energy (MIRE) was more fruitful in decreasing the USA but not significant as the polarized light therapy (BLT) in decreasing the UVM.

Conclusion

Application of the polarized light therapy and monochromatic infrared energy (MIRE) in the treatment of lower limb venous ulcers had a valuable healing effects. The results of this study supports the expectation that both the polarized light therapy and monochromatic infrared energy (MIRE) were effective in enhancing healing of the lower limb venous ulcers as manifested by the highly significant decreases in ulcer surface area (USA) and ulcer volume measurement (UVM). The monochromatic infrared energy (MIRE) was more fruitful in decreasing the USA but not significant than the polarized light therapy (BLT) in decreasing the UVM.

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