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RESEARCH PAPER

## The use of Bioptron light (polarized, polychromatic, non-coherent) therapy for the treatment of acute ankle sprains

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### ABSTRACT

**Purpose** The purpose of this study was to investigate the efficacy of Bioptron light therapy for the treatment of acute ankle sprains. **Method** A parallel group, single-blind, controlled study was carried out in patients with grade II acute ankle sprains. Patients were randomly allocated into two treatment groups ( $n = 25$  for each). Both groups received cryotherapy, and the test group also received Bioptron light therapy. All treatments were performed daily for 5 d. Evaluations included self-reported pain via a visual analogue scale, degree of ankle edema, and ankle range of motion via goniometry carried out before the treatment and at the end of the treatment. **Results** The test group showed the largest magnitude of improvement for all evaluations at treatment five, and the between-group differences observed were statistically significant ( $p < 0.0005$  for each). **Conclusions** These data provide preliminary evidence of the efficacy of Bioptron light therapy supplemented with cryotherapy for the treatment of acute ankle sprains; however, larger studies are required to confirm these results.

### ARTICLE HISTORY

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Acute ankle sprains;  
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### ► IMPLICATIONS FOR REHABILITATION

- Ankle sprains are common acute injuries among professional and recreational sports players but also among people in general.
- Cryotherapy is the first-standard treatment of acute ankle sprains.
- Phototherapy such as Bioptron light has been recommended supplement to cryotherapy to reduce the symptoms of ankle sprains.
- The results of the present trial showed that using BIOPTRON LIGHT and cryotherapy the rehabilitation period of acute ankle sprains can be reduced.

## Introduction

Ankle inversion sprains (for the purpose of the study ankle inversion sprains are referred to as ankle sprains) are among the most common acute injuries in sports.[1] These injuries result in significant societal costs in terms of work absences and use of health care resources.[2] Ankle sprains are commonly caused by inversion when the ankle is in plantar flexion.[3] The main symptoms of ankle sprain are pain, swelling and loss of function. Ankle sprains are divided into three grades according to the degree of damage to the ligaments, the most common being grade II injury, which is a partial ligament tear.[4] There is still some debate regarding the management of acute ankle sprains: standard treatment for the first 4–5 d usually consists of rest, ice, compression and elevation (RICE) to reduce pain and swelling,[5] but additional treatment is often necessary.[6]

The use of light therapy to treat ankle sprains has been previously documented.[7] Low-level laser devices provide an additional treatment option in patients with acute ankle sprains, with the aim of reducing the symptoms of inflammation and improving healing.[7] Other forms of light therapy exist in addition to laser light; polarized, polychromatic, non-coherent light (in this article, the term Bioptron light will be used) has been used in Russia and Eastern Europe for many years,[8] but its use in other regions has been limited to date. The manufacturer's explanation of how Bioptron's light works is given in Table 1.[9]

However, arguments for the presence of these biochemical effects are lacking and often theoretical. Even if biochemical effects are found in laboratory models, it by no means follows that they will translate into clinically meaningful effects. The extent

**Table 1.** Manufacturer's explanation of how Biopton's light works.

Polarization	Its waves move on parallel planes. In this device, polarization reaches a degree of approximately 95%, which narrows and concentrates the beam.
Polychromy	Polychromatic light contains a wide range of wavelengths, including visible light and part of the infrared range. The wavelength of this device's light ranges from 480 nm to 3400 nm, making it able to stimulate a greater range of light-sensitive receptors in the skin. This electromagnetic spectrum does not contain UV radiation.
Incoherency	This device's light is incoherent or out-of-phase light. This means the light waves are not synchronized.
Low-energy	This device light has a low-energy density (fluence) of an average 2.4 J/cm <sup>2</sup> , which has biostimulative effects. This means the light can simulate various biological processes in the body in a positive way.

Source: [www.bioptron.com/characteristics/index.php9](http://www.bioptron.com/characteristics/index.php9)

of clinical use of Biopton light is not known, although novel modalities, such as this are attractive to practitioners working in rehabilitation settings. Previous trials assessed the effectiveness of this treatment in lateral epicondylitis [10–12] and in carpal tunnel syndrome.[13] To date, there are no previously published reports investigating the efficacy of Biopton light therapy in the treatment of acute injuries, such as ankle sprains; therefore, the aim of this study was to assess the clinical effectiveness of Biopton light in the management of acute ankle sprains.

## Materials and methods

### Participants

This was a single-centre, parallel group, single-blind, controlled study carried out over a period of 9 mo, and was approved by the Local Ethics Committee. Following the receipt of a patient information sheet and thorough discussions with the investigators, each study participant gave written informed consent.

Patients suffering from an ankle sprain injury were examined and evaluated in the Rheumatology and Rehabilitation Center, Athens, Greece between February 2012 and October 2012. All patients lived in Athens, Greece and were native speakers of Greek. All patients were either self-referred or were referred by their physician or physiotherapist. Patients aged 18–35 y were included in this study if they presented with a grade II ankle sprain (confirmed by the Ottawa ankle rules) [14] that had been present for at least 24 h but less than 96 h, and had participated in sports activities at least three times per week during the past 2 y. The main exclusion criteria consisted of the presence of any of the following: bone fracture, grade III ankle sprain (complete ligament tear), history of previous sprain in either ankle and/or multiple injuries.[7] Low back pain with sciatic symptoms, signs of degeneration in lumbar spine and/or hips and/or knees neurological impairment, diabetes mellitus, and/or participation in other clinical trials were also exclusion criteria.[6,7]

### Treatment allocation

The patients were randomly divided into two treatment groups by the method of drawing lots: that is, the patient who was assigned to Group 1, the test group, receiving cryotherapy plus Biopton light therapy, the patient who was assigned to Group 2, the control group receiving cryotherapy only.

### Experimental protocol

Three investigators were involved in the study: a specialist rheumatologist (IS) evaluated the patients to confirm the diagnosis of ankle sprain; the primary investigator (DS) administered the treatments; and a specialist physiotherapist in orthopedic injuries (KP), who was blinded to the patients' treatment group allocation, performed all assessments at baseline and during the study period, at follow-up. All treatments were administered at the Rheumatology and Rehabilitation Center by a qualified physiotherapist with a certificate in orthopedic medicine on Cyriax principles (DS).

Patients in both treatment groups received cryotherapy for acute ankle sprain (grade II). The mode of cryotherapy was standardized across groups based on Bleakley et al. [15] protocol and consisted of melting iced water (0 °C) in a standard sized pack.[16,17] Plastic ice bags (20 cm × 20 cm) were completely filled with water, placed in a freezer and removed when frozen. Before application, the packs were held under hot water for 30 s and wrapped in a single layer of standardized towelling (moistened until just dripping wet). Standard ice application consisted of 20 min of continuous ice treatment performed every 2 h for 5 d. This duration of treatment has been recommended in the literature [18,19] and is also commonly used in the clinical setting.[19] Subjects were responsible for ice pack preparation, and all treatments were self-administered. At the time of the trial, subjects were given a verbal explanation of the correct procedure for ice pack preparation and application, which was supplemented with step by step written instructions. Patient compliance was monitored using a treatment diary, which was



Figure 1. The optical medical light therapy device used in this study (BIOPTRON 2, BIOPTRON AG, Switzerland) emits light, that is, polarized, polychromatic, non-coherent, and of low energy.

returned to the secondary researcher one week after the injury.

Patients in Group 1 (test group) also received Biopton light therapy, via the BIOPTRON 2 (Figure 1) optical device (BIOPTRON AG, Wollerau, Switzerland; for 10 min once daily for 5 d. The equipment used was non-invasive. The physical parameters of the light output from this optical medical device were as follows: wavelength 480–3400 nm, light spot size 254 cm<sup>2</sup>, and specific power density 40 mW/cm<sup>2</sup>. During active light exposure, the energy output of the device (energy density) was 2.4 J/cm<sup>2</sup> /min (that is, 24 J/cm<sup>2</sup> /10 min session).[9] During each light exposure the patient was seated and fitted with darkened eye wear, the treatment area (lower leg and foot) was exposed, carefully cleaned (by wiping with a sterile gauze soaked in clean water) and dried, then the optical medical device was powered up and used to ‘paint’ the exposed area with Biopton light for 10 min.[9] During light exposure, the optical medical device was positioned via a support floor stand to be approximately at right angles to the skin surface, and at a distance of approximately 10 cm from the treatment area.[9] A “beep” signified the end of the 10 min treatment.

Communication and interaction (verbal and non-verbal) between the therapist and patient was kept to a minimum, and behaviours sometimes used by therapists to facilitate positive treatment outcomes were purposefully avoided (e.g. patients were given no indication of the potentially beneficial effects of any of the treatments given, nor were they given any feedback on their performance in the pre- and post-treatment assessments).

During the study period, all patients were instructed to reduce weight bearing as much as possible on the affected side, and were not permitted to take any form of anti-inflammatory medication. Patient compliance with these requests was monitored using a treatment diary.

### **Outcome measures**

The primary efficacy outcome was assessed via self-reported degree of pain using the 10 cm visual analogue scale (VAS; ranging from 0 to 10, where 0 indicates ‘no pain’ and 10 indicates the ‘worst pain imaginable’). This form of assessment was considered most appropriate because of its high level of repeatability when used serially on the same patient.[20] Secondary outcomes included an assessment of ankle edema using the figure of eight method (ankle circumference using eight ankle/foot landmarks), and an assessment of ankle range of motion using goniometry. The figure of eight method has been shown to be a highly reliable [21,22] and valid [22] tool for measuring the girth of both healthy and oedematous ankles. The assessment of ankle range of motion using goniometry has demonstrated validity and reliability in patients with acute ankle sprains.[7] Patients were assessed before treatment, and at the end of the final (fifth) treatment. Assessments were made by the same examiner (KP) and carried out in the same order. A drop-out rate was also used as an indicator of treatment outcome. Reasons for patient drop-out were categorized as follows: (1) a withdraw without reason; (2) did not return for treatment; and (3) request for an alternative treatment.

### **Statistical analysis**

Based on methodology from a previous study using Biopton light therapy from a BIOPTRON optical medical device in the treatment of lateral epicondylitis,[10] a sample size of 25 subjects per group was deemed sufficient to demonstrate statistical clinical significance for all outcome measures on musculoskeletal injuries, such as ankle sprains.[23] Based on previous published data, clinical effects of 20% were reported as clinically

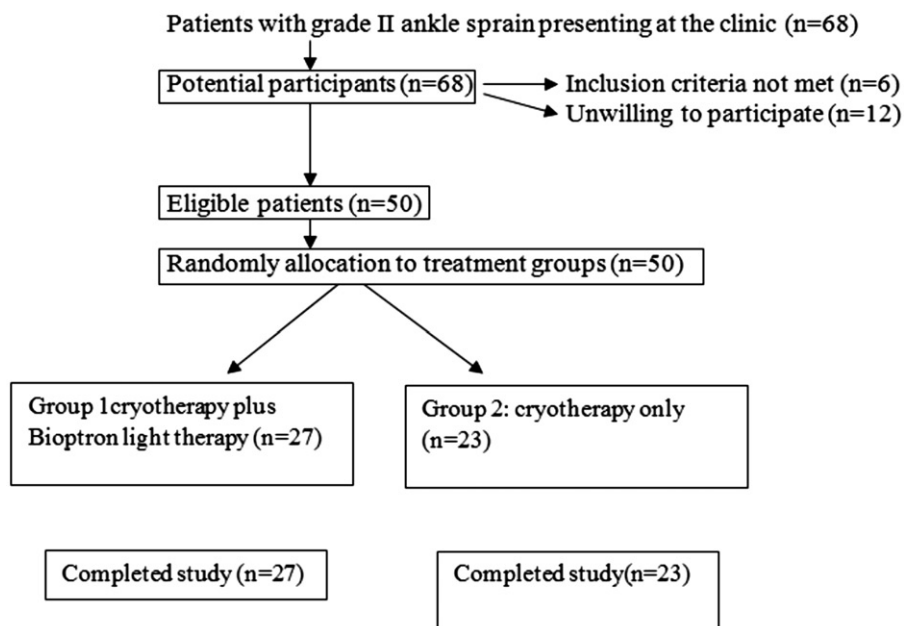


Figure 2. Study flowchart.

meaningful in placebo or non-controlled studies measuring pain relief and functional outcomes in response to physiotherapeutic interventions.[24] In this study, baseline variance for pain and functional outcomes was set at 25%, in line with previously published data in this field.[25] Power calculations suggested that a sample size of 25 patients per group was sufficient to detect a 20% change in outcome measures, assuming variance was equivalent to 25%, with 80% power and a significance level of 5%. The formula that used to estimate the appropriate sample size was:

$$N = \frac{16\sigma^2}{d^2} \quad (1)$$

where  $\sigma^2$  = the variability of the data and  $d^2$  = the effect size. For example in our trial  $\sigma = 25$  and  $d = 20$ . Therefore, the above formula is  $N = 16(25^2)/(20^2) = 16 \times 625/400 = 25$ .

Differences between groups were determined using the independent *t*-test. The difference within groups between baseline and end of treatment was analysed with a paired *t*-test. A 5% level of probability was adopted as the level of statistical significance. SPSS 20 statistical software was used for the statistical analysis (SPSS Inc., Chicago, IL).

## Results

A total of 68 patients who were eligible for inclusion visited the Rheumatology and Rehabilitation Center within the trial period. Of these, 12 patients were unwilling to participate in the study, and a further six

Table 2. Baseline characteristics of study participants.

Characteristic	Group 1 (test group) <i>n</i> =27	Group 2 (control group) <i>n</i> =23
Sex, male: female	19:8	16:7
Mean age (SD), years	27.92 (4.23)	27.96 (4.25)
Ankle sprain details:		
Dominant ankle affected	90%	92%
Duration of sprain	50 h	47 h

SD: standard deviation.

patients did not meet the inclusion criteria described above; thus, the remaining 50 patients were randomly allocated to one of the two treatment groups (Figure 2). Patients in Group 1 (test group) received cryotherapy plus Biopton light therapy, via the BIOPTRON 2 optical medical device. Patients in Group 2 (control group) received cryotherapy only. There were no significant between-group differences in mean age or the mean duration of symptoms (Table 2). All 50 patients completed the study.

### Primary efficacy outcome

Baseline self-reported pain score using VAS was 6.64 for the whole sample ( $n=50$ ). There were no significant differences between the groups in baseline VAS score (Table 3). At treatment 5 (i.e. day 5), there was a decrease in VAS score from baseline of 2.20 units in the test group and 1.28 units in the control group with the baseline ( $p < 0.0005$ , paired *t*-test) (Table 4). There were significant differences in the magnitude of improvement

Table 3. Pain, edema and range of motion before treatment and at the end of treatment.

	Pain (cm) (CI)		Edema (cm) (CI)		Range of motion-dorsiflexion (degrees) (CI)		Range of motion-plantarflexion (degrees) (CI)	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Treatment 0	6.66 (6.89–6.46)	6.62 (6.79–6.41)	62.88 (63.04–62.79)	62.62 (62.8–62.51)	10.90 (11.05–10.78)	10.65 (10.81–10.49)	34.40 (34.68–34.24)	34.15 (34.33–34.05)
Treatment 5	4.46 (4.62–4.30)	5.34 (5.48–5.28)	60.21 (60.39–60.03)	61.10 (61.24–60.98)	8.90 (9.06–8.77)	9.55 (9.68–9.41)	32.60 (32.77–32.54)	33.25 (33.43–22.13)

Group 1, cryotherapy, and Biopton Light.  
Group 2, cryotherapy only.

between the groups at treatment 5 ( $p < 0.0005$  independent  $t$ -test) (Table 4).

### Secondary efficacy outcomes

Baseline edema score was 62.74 for the whole sample ( $n = 50$ ). There were no significant differences between the groups for baseline edema score (Table 3). At treatment 5, there was a decrease in edema score of 2.67 units in the test group and 1.52 units in the control group with the baseline ( $p < 0.0005$ , paired  $t$ -test) (Table 4). There were significant differences in the magnitude of improvement between the groups at treatment 5 ( $p < 0.0005$  independent  $t$ -test) (Table 4).

Baseline dorsiflexion score using goniometer was 10.77 (95% CI 10.21–11.07) for the whole sample ( $n = 50$ ). There were no significant differences between the groups for baseline dorsiflexion score (Table 3). At treatment 5, there was an increase in dorsiflexion score of 2.0 degrees in the test group and 1.1 degrees in the control group with the baseline ( $p < 0.0005$ , paired  $t$ -test) (Table 4). There were significant differences in the magnitude of improvement between the groups at treatment 5 ( $p < 0.0005$  independent  $t$ -test) (Table 4).

Baseline plantar flexion score using goniometer was 34.23 (95% CI 33.89–34.78) for the whole sample ( $n = 50$ ). There were no significant differences between the groups for baseline plantar flexion score (Table 3). At treatment 5, there was an increase in plantar flexion score of 1.8 degrees in the test group and 0.9 degrees in the control group with the baseline ( $p < 0.0005$ , paired  $t$ -test) (Table 4). There were significant differences in the magnitude of improvement between the groups at treatment 5 ( $p < 0.0005$  independent  $t$ -test) (Table 4).

### Discussion

The aim of this study was not to explain how the Biopton light acts but, rather to assess whether BIOPTRON light therapy was an effective form of intervention in patients with acute ankle sprains. Statistically significant improvements in the primary (self-reported degree of pain via VAS) and secondary efficacy outcomes (ankle edema and ankle range of motion) were observed in participants who were exposed to cryotherapy plus Biopton light therapy over a 5 d period. These findings lend support to the use of Biopton light therapy as an intervention for people with acute ankle injury as an adjunct to cryotherapy.

In the acute inflammatory phase after ankle sprain, cryotherapy is thought to decrease edema formation via induced vasoconstriction, and reduce secondary hypoxic

**Table 4.** Change in pain, edema and range of motion at the end of treatment.

	Pain (cm) (CI)		Edema (cm) (CI)		Range of motion – dorsiflexion (degrees) (CI)		Range of motion – plantarflexion (degrees) (CI)		<i>p</i> values
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	
Treatment 5	2.20	1.28	2.67	1.52	2.00	1.10	1.80	0.90	<i>p</i> < 0.0005

Group 1, cryotherapy and Biopton Light.

Group 2, cryotherapy only.

Values are mean. Values for independent *t*-test from baseline are shown.

damage by lowering the metabolic demand of injured tissues.[26,27] Although cryotherapy is the first-standard treatment of choice, for the management of acute injuries such as ankle sprains, is not applied as monotherapy. It is combined with other treatments.[28] One of these treatments is the Biopton light therapy.

It is probable that BIOPTRON light accelerates the cellular mechanisms and improves the local blood supply, and exposure to both the visible and infrared parts of the electromagnetic spectrum of BIOPTRON light may explain its potential mechanism of action. Further research is needed to investigate exactly how this occurs.[9]

Like laser therapy, Biopton light is also a low-power light source, but differs in that it is polychromatic and incoherent rather than monochromatic and coherent.[9–13] Moreover, Biopton light combines visible light at a wavelength of 480–700 nm and infrared light at a wavelength of 700–3400 nm.[9–13] In contrast, low power laser contains either visible or infrared light at one specific wavelength.[9–13] Several drawbacks have impaired the usefulness of low-power laser light in comparison to Biopton light, such as high cost, high risk, required user skills, and the small diameter of the laser beam, which allows only a limited area to be treated.[9–13]

The BIOPTRON light therapy Instructions for use states that incorrect application of Biopton light is not hazardous to a patient's health,[9] but that the effects of the Biopton light therapy are reduced if any of the following conditions apply:

- (1) It is not applied to bare skin.
- (2) It is held at an operating distance of >10cm. (The appropriate distance is 5–10 cm.)
- (3) It is not held at a 90° angle from the skin. (For the greater penetration depth, the device should be perpendicular to the treatment area.)
- (4) The light is not held steady relative to the skin.
- (5) The irradiation time is <6 min. (The appropriate irradiation time is 6 min: irradiation times >6 min do not produce better results.)
- (6) The period of treatment is <3 times per week or <1 mo.

It is important to mention that no side effects were reported during or after the treatment period. There is no UV light in the BIOPTRON light spectrum, so there is no tanning or heating effect on the skin.[9–13] Furthermore, BIOPTRON light is not harmful to the eyes, and poses no danger to pregnant women.[9–13] It is easy-to-use & can be used in the clinical setting or if required in the patient's home.[9–13] Finally, BIOPTRON light is not associated with cancer: the unsafe range for cancer risk is UV light at 250 nm, and the shortest wavelength in the Biopton spectrum is 480 nm.[9–13]

Previous trials assessed the effectiveness of BIOPTRON medical light in chronic injuries, such as lateral epicondylitis [10–12] and carpal tunnel syndrome.[13] The present trial is the first study, in which the effectiveness of BIOPTRON light was assessed in an acute injury. The most likely explanation for the lack of published research using BIOPTRON light for this application is that it has only recently become available for use in physiotherapy settings. Previously reported trials found that a course of BIOPTRON light treatment may improve patients' symptoms.[10–13] The findings of these published trials may also encourage the initiation of well-designed randomized controlled trials (RCTs) that might produce better evidence for the effectiveness of BIOPTRON light in acute and chronic injuries.

There were some limitations of the present trial. First, no placebo (sham) or no-treatment group was included in the present trial. The placebo (sham) or no-treatment group is important when the absolute effectiveness of a treatment is determined. Although, the absolute effectiveness of technique-based interventions such as BIOPTRON light is not difficult to investigate, absolute effectiveness does not provide the therapists with information as to which is the most appropriate treatment for the management of a condition, which in this case was an acute ankle sprain. Second, concomitant treatments, which patients might have been receiving outside of clinic visits were not monitored. Patients' diaries strongly suggested that patients were compliant to the study instructions, although it is possible that some patients may have given incorrect details to the investigators. For example, it was possible that patients followed the treatment but took analgesic medications

at the same time, and the improvement of symptoms may be due to those medications. Therefore, ways should be found to measure how other treatments, such as analgesic medications contribute to the improvement of symptoms. Finally, the blinding of patients and therapists would be problematic in that case, if not impossible, because patients know which treatment they are receiving and therapists need to be aware of the treatment to administer it appropriately. In addition to these weaknesses, structural changes in the ligaments related to the treatment interventions were not shown, and the short and long-term effects of BIOPTRON light treatment was not investigated. Pre- and post-therapeutic medical imaging studies, such as diagnostic ultrasound or magnetic resonance imaging (MRI) would shed further light on demonstrating such structural soft tissue changes.

Further research is needed to establish the effectiveness of BIOPTRON light in the management of acute and chronic musculoskeletal injuries, the possible mechanism of action of this treatment approach, and the cost-effectiveness of such treatment, as reduced cost is an important issue for the recommendation of any given treatment.

## Conclusion

Data from this study provide the evidence of the efficacy of cryotherapy plus Biopton light therapy in the treatment of acute ankle sprains; however, a well-designed randomized controlled study conducted by a multidisciplinary team is necessary to confirm the efficacy of this form of phototherapy supplemented with cryotherapy in patients with acute ankle sprains and to objectively evaluate recommendations for its routine use in clinical practice.

## Disclosure statement

The authors declare that there is no conflict of interest.

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