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Brief Report

Treatment of Carpal Tunnel Syndrome with Polarized Polychromatic Noncoherent Light (Bioptron Light): A Preliminary, Prospective, Open Clinical Trial

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ABSTRACT

Objective: **Our aim was to assess the efficacy of polarized polychromatic noncoherent light (Bioptron light) in the treatment of idiopathic carpal tunnel syndrome.** ***Background:*** **Carpal tunnel syndrome is the most common compression neuropathy, but no satisfactory conservative treatment is available at present.** ***Method:*** **An uncontrolled experimental study was conducted in patients who visited our clinic from mid-2001 to mid-2002. A total of 25 patients (22 women and three men) with unilateral idiopathic carpal tunnel syndrome, mild to moderate nocturnal pain, and paraesthesia lasting >3 months participated in the study. The average age of the patients was 47.4 years and the average duration of patients' symptoms was 5.2 months. Polarized polychromatic noncoherent light (Bioptron light) was administered perpendicular to the carpal tunnel area. The irradiation time for each session was 6 min at an operating distance of 5–10 cm from the carpal tunnel area, three times weekly for 4 weeks. Outcome measures used were the participants' global assessments of nocturnal pain and paraesthesia, respectively, at 4 weeks and 6 months.** ***Results:*** **At 4 weeks, two patients (8%) had no change in nocturnal pain, six (24%) were in slightly less nocturnal pain, 12 (48%) were much better in regard to nocturnal pain and five (20%) were pain-free. At 6 months, three patients (12%) were slightly better in regard to nocturnal pain, 13 (52%) were much better regarding nocturnal pain, and nine patients (36%) were pain-free. At 4 weeks, four patients (16%) had no change in paraesthesia, five (20%) were slightly better, 13 patients (52%) were much better, and three patients (12%) were without paraesthesia. At 6 months, two patients (8%) had no change in paraesthesia, two (8%) were slightly better, 14 (56%) were much better, and seven (28%) were without paraesthesia.** ***Conclusions:*** **Nocturnal pain and paraesthesia associated with idiopathic carpal tunnel syndrome improved during polarized polychromatic noncoherent light (Bioptron light) treatment. Controlled clinical trials are needed to establish the absolute and relative effectiveness of this intervention.**

INTRODUCTION

CARPAL TUNNEL SYNDROME (CTS) is a compression neuropathy of the median nerve at the level of the carpal tunnel and is by far the most common of all peripheral nerve entrapments.[1] The CTS patient often presents with symptoms of nocturnal pain and numbness, weakness, or clumsiness in holding small objects as well as paraesthesia in the median nerve distribution of the hand.[2,3] Despite many suggested causes of CTS, the most common presentation is idiopathic, with no discernible underlying pathology.[4] The most likely explanation is an overuse phenomenon of the hand, as in those who perform work with repetitive motions.[2,3] Other cases of CTS result from trauma and from metabolic and endocrinal abnormalities.[5] The

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Table 1. Manufacturer's Explanation of How Bioptron'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 ultraviolet 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^2, 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.php

Phalen test and Tinel sign are two commonly used provocative tests to help in the clinical diagnosis of CTS, but these two tests are not absolutely diagnostic despite being positive in about two thirds of patients with this syndrome.[6] Electrophysiological studies measuring median nerve function are the only objective way to show the nerve deficit.[1,6,7]

Benefit from nonsurgical treatment, however, seems to be limited. Conservative treatments such as splints, injections, gliding exercises, and ultrasound have been used to reduce nocturnal pain and paraesthesia associated with CTS, although this has produced variable outcomes. For example, splints, carpal bone mobilization, and median nerve mobilization have been shown to be ineffective,[8–10] and results with gliding exercises and ultrasound have been conflicting.[11–14]

Polarized, polychromatic, noncoherent light (in this article, the term Bioptron light will be used) has recently appeared on the market for the treatment of a wide range of medical conditions including CTS. The manufacturer's explanation of how Bioptron's light works is given in Table 1.

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 of clinical use of Bioptron light is not known, although novel modalities such as this are attractive to practitioners working in rehabilitation settings. We were unable to find any studies on the clinical effectiveness of Bioptron light for CTS. This preliminary, prospective, open trial reports our experience with the use of Bioptron light to manage nocturnal pain and paraesthesia associated with idiopathic CTS.

MATERIALS AND METHODS

Patients

A total of 25 patients, 22 female and three male, with clinically suspected carpal tunnel syndrome who had been referred to our clinic over 1 year (from mid-2001 to mid-2002) were invited and subsequently completed this open, prospective, uncontrolled clinical trial. The mean age of subjects were 47.4 years (range 34–58). Carpal tunnel syndrome was diagnosed using standard electrophysiological criteria, which were motor distal latency and sensory antidrotic nerve conduction velocity. The patient population had a mean duration of CTS of 5.2 months (range 3–11).

Inclusion criteria for the study were unilateral idiopathic CTS, mild to moderate nocturnal pain, and paraesthesia lasting >3 months.[8–10,12–14] Exclusion criteria were secondary entrapment neuropathies, systemic diseases with increased risk of CTS, electroneurographic or clinical signs for axonal degeneration of the median nerve, previous treatment with physical modalities for CTS, history of steroid injections into the carpal tunnel, and regular analgesic or anti-inflammatory drugs.[8–10,12–14] All patients were asked to avoid activities that irritated the hand and to refrain from taking analgesic medication for any condition during the course of the study. Bioptron light was administered as monotherapy and patients were given no additional treatment for CTS until the 6-month follow-up assessment. Patients were able to withdraw from the study at any stage without reason and would immediately receive the standard care (polytherapy) for CTS as provided by the clinic. Patients reporting moderate or severe symptoms 2–3 months after the end of the treatment were offered an alternative form of treatment for this condition. Written informed consent was obtained by all patients, to whom no fee was to be charged, and the study was approved by the manager of the clinic.

Bioptron light treatment intervention

Patients attended the clinic three times each week over a 4-week period for each Bioptron light treatment. Bioptron light was administered by one of us (D.S.) as monotherapy and following the advice provided in the manufacturer's users guide. Patients sat upright with the arm placed on an adjacent bed with the elbow in extension and supination. The Bioptron light probe was held at a 90° angle 5–10 cm above the clean bare skin of the carpal tunnel area, as this is reported to achieve maximal penetration of light, for exactly 6 min (Fig. 1). A

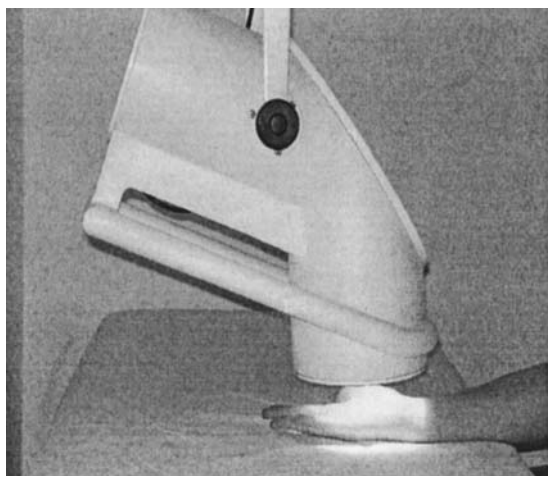

FIG. 1. Application of Bioptron light.

Bioptron 2 device (Harrier Inc.) was used to deliver the Bioptron light with the following output characteristics: rated power of halogen = 90 W; light wavelength = 480–3400 nm; degree of polarization = 95%; specific power density = 40 mW/cm^2; and energy density = 2.4 J/cm^2. A "beep" signified the end of the 6-min treatment.

Outcome measures

Outcome measures were the patient's self-report of nocturnal pain and paraesthesia respectively using a 5-point, categorical, verbal rating scale (worse pain, no change, slightly better, much better, no pain, or paraesthesia). Outcome measures were taken at the end of the treatment (week 4) and at the 6-month follow-up after the end of treatment (week 28) by a physiotherapist who was independent of the study and blind to the treatment intervention. Data were analyzed using descriptive statistics.

RESULTS

No patients requested to withdraw from the study and all patients provided data at the 6-month follow-up.

Nocturnal pain

Of 25 patients, 23 (92%) reported that their pain had improved at the end of the course of Bioptron light treatments (Table 2). Of these 23, five reported that they no longer experienced nocturnal pain and 12 reported that their nocturnal pain was "much better." At the 6-month follow-up, all patients reported that their pain had improved, with nine reporting no nocturnal pain and 13 reporting that their nocturnal pain was "much better."

Paraesthesia

Of 25 patients, 21 (84%) reported that their paraesthesia had improved at the end of the course of Bioptron light treatments (Table 3). Of these 21 patients, three reported that they no longer experienced paraesthesia, and 13 reported that their paraesthesia was "much better." At the 6-month follow-up, 23 of 25 patients reported that their paraesthesia had improved, with seven reporting no paraesthesia and 14 reporting that their paraesthesia was "much better."

TABLE 2. PATIENTS' VERBAL JUDGMENT OF PROGRESS IN NOCTURNAL PAIN

	End of treatment (%)	*6-Month follow-up (%)*
Worse	0	0
No change	2 (8%)	0
Slightly better	6 (24%)	3 (12%)
Much better	12 (48%)	13 (52%)
No pain	5 (20%)	9 (36%)

TABLE 3. PATIENTS' VERBAL JUDGMENT OF PROGRESS IN PARAESTHESIA

	End of treatment (%)	*6-Month follow-up (%)*
Worse	0	0
No change	4 (16%)	2 (8%)
Slightly better	5 (20%)	2 (8%)
Much better	13 (52%)	14 (56%)
No paraesthesia	3 (12%)	7 (28%)

DISCUSSION

The aim of this study was not to explain how the Bioptron light acts but, rather, to find out whether this intervention is an effective treatment in patients with idiopathic CTS so that clinicians treating patients with CTS can use it.

Like laser therapy, Bioptron is also a low-power light source, but differs in that it is polychromatic and incoherent rather than monochromatic and coherent. Moreover, Bioptron combines visible light at a wavelength of 480–700 nm and infrared light at a wavelength of 700–3400 nm. In contrast, low-power laser contains either visible or infrared light at one specific wavelength. Several drawbacks have impaired the usefulness of low-power laser light in comparison to Bioptron 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.

The Bioptron light therapy booklet[15] states that incorrect application cannot be health hazardous but that the effects of the Bioptron light will be reduced if any of the following apply:

1. It is not applied to bare skin.
2. It is held at an operating distance of >10 cm. 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 area.
4. The light and skin should not be steady.
5. The irradiation time is <6 minutes. The appropriate irradiation time is 6 min. Irradiation times more than >6 min do not produce better results.
6. The period of treatment is <3 times per week or <1 month.

The data from this preliminary, prospective, open trial in patients with CTS suggests that a course of Bioptron light treatments given in 6-min sessions three times per week may reduce the self-reported nocturnal pain and paraesthesia when compared to baseline data. However, the absence of a no-treatment control group means that we cannot be certain that these findings were due to the Bioptron light treatment intervention itself rather than to natural fluctuations in symptoms, resolution of the CTS, or expectation of treatment success associated with receiving a medical intervention. We also cannot discount the possibility that patients reported prolonged improvement at the 6-month follow-up to please the investigator, as there was no placebo control.

However, none of the patients wanted to discontinue Bioptron light in favor of conventional polytherapy, so we believe that symptom reduction was an actual phenomenon. For this reason, the finding that a high proportion of patients report long-term improvement with Bioptron light given as a monotherapy merits dissemination, as management of CTS is often unsatisfactory. Some patients self-manage CTS in the initial stages by reducing activities of the hands for 1 or 2 months to reduce symptoms. However, this approach is effective in <10% of patients.[16] For most patients, CTS is managed in the initial stages by conservative treatment and by surgery if conventional treatment fails.[16]

Both the visible and infrared parts of the electromagnetic spectrum of Bioptron light can explain its mechanism of action. It is probable that Bioptron light accelerates the cellular mechanisms and improves the blood supply, but research is needed to investigate how this occurs.

It is important to mention that no side effects were reported during or after the treatment period. There is no ultraviolet light in the Bioptron spectrum, so there is no tanning or heat effect on the skin. It is not harmful to the eyes or to pregnant women. Finally, Bioptron light cannot cause cancer in any way, as the dangerous range for cancer risk is low ultraviolet light at 250 nm and the lowest Bioptron range is 400 nm.

The findings of our preliminary study should encourage the design of a randomized controlled trial with sufficient power to determine the effectiveness of Bioptron light against a valid placebo and conventional laser therapy. This is needed to confirm or refute the manufacturer's claims that Bioptron light has long-term effectiveness in patients with idiopathic CTS. Moreover, studies are needed to find out the analgesic effects of Bioptron light as well to investigate the role of Bioptron light treatment as physical therapy for common musculoskeletal or orthopedic conditions.

CONCLUSIONS

The efficacy of Bioptron light applied as monotherapy in the current preliminary, prospective, open clinical trial indicated a positive clinical effect on nocturnal pain relief and paraesthesia from carpal tunnel syndrome. Future placebo-controlled studies with adequate sample size and outcome measures of known validity are required to investigate the absolute and relative effectiveness of Bioptron light.

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