

# **Low-intensity Laser Therapy, Transcutaneous Electrical Nerve Stimulation and Light Emitting Diodes in the Treatment of Chronic Pain – A Double Blind – Placebo Study**

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## Abstract

### Background

More than 100 million Americans suffer from acute and chronic pain many of them undertreated. Current methods of treatment fail to meet the needs of many of these patients; therefore, consideration of a multimodality, multidisciplinary approach is indicated. This prospective study of seventy patients with chronic pain (>3 mo.) utilized a novel device combining the synergistic effects of electrical stimulation(TENS), low level laser, and light emitting diodes(LED) to alleviate pain. The study group included both diverse locations and etiologies of pain.

### Methods

Seventy chronic pain patients were enrolled to receive 10 treatments of 30 minutes duration over a two week, double blind study period. Patients were given a numerical pain assessment before, after, and for 36 patients at one year follow-up. A placebo group consisted of 5 patients who received treatment with inactivated e-photonic elements.

### Results

Fifty-one patients completed the study with 75% reporting an average of 49% improvement in pain level. The placebo group reported a 9%

increase in level of pain. Painful areas treated included upper extremity (16 patients, 13 improved an average of 50%), lower extremity (33 patients, 26 improved an average of 49%), back (24 patients, 19 improved an average of 42%), knee (12 patients, 11 improved an average of 51%). Seventy-four percent of patients had improvement in the amount of sleep per night an average of 51 minutes. Sixteen patients were unable to sleep through the night at the first visit; 12, 75% reported sleeping all night at the last visit. Durability of the treatment was assessed at 1 year in 36 patients who reported an average pain improvement of 52%.

### Conclusion

E-photonic treatment for chronic pain in a diverse population was effective for pain relief, sleep improvement, and was durable at one year follow-up. This safe, user-friendly therapeutic device should be considered a mainstay in a multidisciplinary, multimodality approach for chronic pain management.

Key words: Chronic pain, e-photonic therapy, laser, light emitting diodes

### Introduction

At some time in their life all people are at risk of suffering from chronic pain with its attendant

psychosocial effects for both patients and their professional and lay caregivers. Pain is a uniquely personal experience tempered by ones cognitive state, emotional balance, cultural influences, and understanding of the underlying condition that causes the pain. Many patients feel hopeless, angry, or anxious, and often become severely depressed. Sadly many of the patients currently receiving pain care are undertreated or receive no treatment at all, particularly the elderly, poor, women, and minority groups [2].

Current methods of pain treatment are largely ineffective for many patients because of the lack of education of healthcare providers and patients alike regarding pain management options [2]. Opiate use has been the mainstay of therapy, but fear of opiate addiction, and widespread opiate abuse and misuse, has limited application of these effective medications over the past several years [5]. The long term benefit of opiates used for chronic pain has recently been questioned by pain management specialists [6].

Other types of pharmaceutical agents have been used, but all have significant negative side effects and few well controlled studies are available to validate their efficacy for any given condition. Alternative therapies have been effective for some groups of patients, but are not widely accepted for use in patients with chronic pain.

A new paradigm is needed for pain therapy to include multimodality and multidisciplinary approaches along with conventional treatments. Outcomes using a simple, novel device which combines the synergistic effects of three e-photonic therapeutic modalities in a diverse chronic pain population are presented. Transcutaneous electrical nerve stimulation(TENS), low level laser light, and LED light, are all proven to benefit some pain patients and were combined in a user-friendly device producing both central nervous system and local cellular effects resulting in pain control.

## Methods

### The Device

A simple wrap assembly uniquely engineered to incorporate microprocessor controlled driver circuitry to deliver precisely coordinated energy through multiple electro-current and photonic transmission components was used. A broad spectrum of energy wavelengths utilizing 24 light emitting diodes, 12 low level lasers and 8 surface conductive adhesive pads were used to create the desired tissue bio-modulation response. Technical specifications for the device are shown in Table 1.

## Structural Components of E-Photonic Device

<b>Battery</b>	Lithium-Ion 3.6v
<b>Charger</b>	Input: 220/110vac, 50/60hz Output: 9vdc, 1.5amp
<b>Velcro Wrap Assemblies; Adhesive Pads</b>	
Laser Diodes	
Quantity Per Assembly	2
Wavelength	808nm
Output Power	60mW
L.E.D.- Red	
Quantity Per Assembly	2
Wavelength	660nm
Output Power	15mW
L.E.D.-Infrared	
Quantity Per Assembly	2
Wavelength	904nm
Output Power	22mW
<b>T.E.N.S. (500-550ohm Load Impedance)</b>	
Frequency	2hz
Output Current	100mA Max.
Pulse Voltage	75vdc
Pulse Width	100uS biphasic

Table 1: Structural components of the wrap assembly for e-photonic treatment device.

### The Study Population

After obtaining informed consent, 70 patients suffering from chronic pain (at least 3 mo.) were enrolled in the study. A widely diverse pain location and various types of pain syndromes were represented. Five patients received placebo treatment in a double blind manner by placement of the wrap assembly over the painful location without e-photonic therapy. All other patients received ten daily 30 minute treatments with a pretreatment numerical pain assessment and the same post treatment evaluation [2]. Long term follow up was obtained by telephone contact at one year post treatment in thirty-six patients.

### Results

Characteristics of the study population are shown in Table 2. There was no significant difference between those who completed the treatment protocol and the total group. All five of the placebo group experienced either no benefit or increased pain and dropped out of the study without completion. Fifty one patients completed the study with 75% reporting an average decrease in pain level of 49%. Painful areas treated were divided into four categories: upper extremity, lower extremity, back, and knee. Results of treatment of these areas are shown in Figure 1. All locations had nearly 80% of patients improved by almost 50% in pain

level. The diverse nature of diagnoses of the subjects treated is shown in Table 3. Although the numbers in some categories were too small

to draw conclusions, some of these individual patients had a dramatic response to the e-photonic treatment protocol.

### Characteristics of Patients in Study Group

	Began Study	Completed Study
N	70	51
Age (mean)	57.5	59.1
Male	32	25
Female	38	30
Hypertension	12	11
BMI (mean)	30.2	30.4
Arthritis	2	2
Fibromyalgia	2	2
Migraine	1	0
Neuropathy	12	8
Foot & Leg Pain	26	24
Back Pain, Sciatica	26	17
Devices	1	1
Lupus	1	1
Stroke	1	1
Lymphedema	1	0
Other	20	17

Table 2: Characteristics of patients in the study group showing no difference in those who began the study and those who completed the study.

### Study Population by Diagnosis

Diagnosis	# Treated	# Improved	% Improvement	% Population
Arthritis	2	2	76.47%	3.23%
Fibromyalgia	2	1	85.71%	3.23%
Neuropathy	5	5	31.82%	8.06%
Foot & Leg Pain	20	18	52.27%	32.26%
Back Pain, Sciatica	16	14	46.58%	25.81%
Carpal Tunnel	1	1	81.25%	1.61%
Devics	1	1	66.67%	1.61%
Lupus	1	1	69.23%	1.61%
Stroke	1	1	72.73%	1.61%
Other	13	10	58.21%	20.97%
n	62	54		

Table 3: Diversity in diagnoses of the study population and percentage improvement.

Subject's improvement in pain levels varied by the anatomical areas treated. See Table 4.

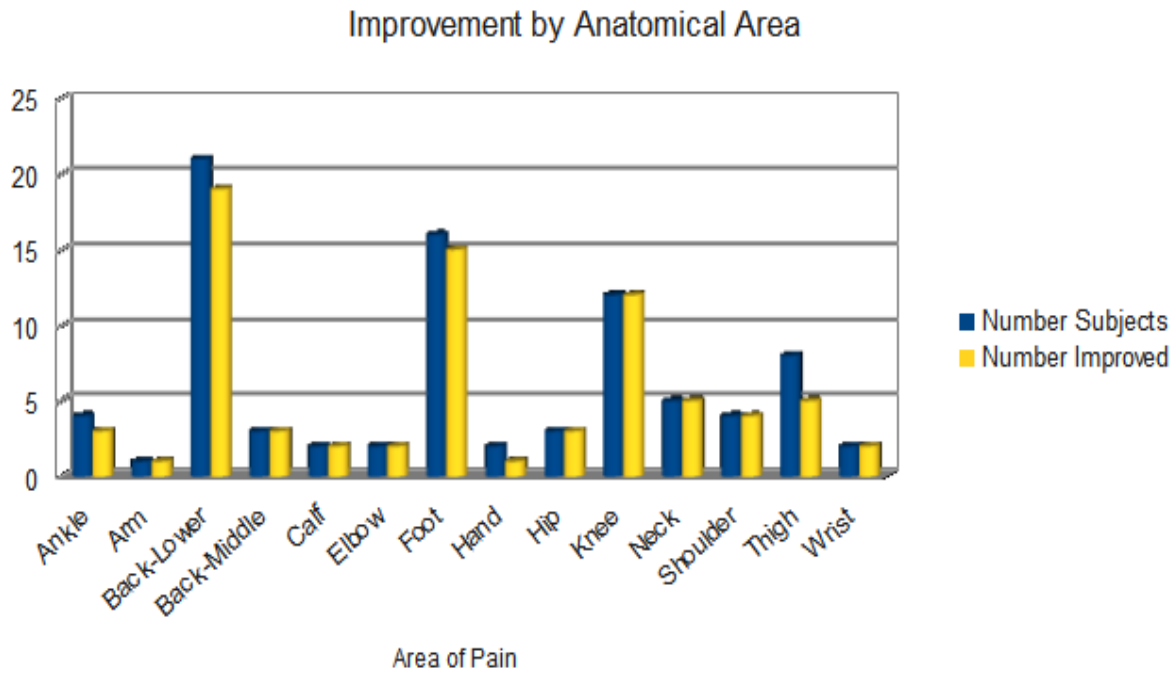


Table 4. Improvement by anatomical area.

Follow up at one year in 36 patients is shown in Table 5. Patients reported an average improvement of 62% after the initial treatment

and 52% at one year which attests to the durability of the e-photonic treatment.

#### One Year Follow-up Results of E-Photonic Therapy

Diagnosis	Number	Percent Improvement During Study	Percent Improvement Year Later
Arthritis	2	76.47%	64.71%
Fibromyalgia	1	85.71%	42.86%
Neuropathy	3	28.00%	56.00%
Foot & Leg Pain	12	50.00%	58.87%
Back Pain Sciatica	9	42.31%	63.46%
Carpal Tunnel	1	81.25%	87.50%
Devics	1	66.67%	66.67%
Lupus	1	69.23%	46.15%
Other	6	52.63%	44.74%
N	36	62%	52%

Table 5: Comparison of improvement after initial study and follow up at one year.

Seventy-four percent of patients increased their amount of sleep an average of 51 minutes per night. Of the 16 subjects who reported not sleeping through the night at the beginning of the study, 12 (75%) reported sleeping all night at the last visit. At each visit the subjects were asked to indicate the time of day their pain level was at its worst. Of the subjects, 68.6% responded that their pain was worse in the

evening and nighttime. At each visit the subjects were asked to indicate the time of day their pain level was at its least. Of the subjects, 63.8% indicated that it was least during the morning and afternoon. Results are listed in Table 6. NOTE: These findings are particularly relevant to supporting the deployment of the device as a take-home model.

Total Reported Pain Levels and Indicated Time

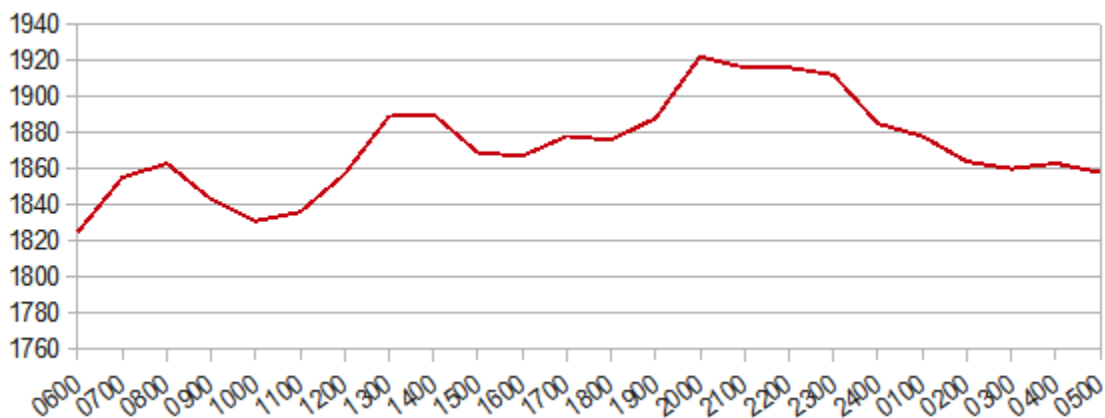


Table 6: Comparison of pain levels according to time of day.

Discussion

Albert Einstein defined insanity as doing the same thing over and over expecting a different result. Unfortunately, many people who suffer from chronic pain find themselves being treated in a manner that isn't working well, but for many reasons inadequate pain relief is the result. The report in 2011 by the Institute of Medicine (IOM) is a comprehensive review of the complex nature of chronic pain care and a clear indictment of how badly we are short changing our patients by being unwilling to change our treatment protocols to include multidisciplinary and multimodality forms of treatment [5]. The IOM estimates that some 110 million patients

suffer from chronic pain at a cost of \$560-630 billion in treatment, debility, and lost productivity far exceeding the cost of cancer, COPD, diabetes, and other common ailments which are receiving far more attention. Many pain patients relate needing simple things such as hope for pain relief, a good night's sleep, and to wake in the morning without lingering opioid side effects.

The current study offers new evidence of efficacy using a novel device to provide significant pain relief for patients with a variety of pain locations and having very diverse diagnoses. E-photonic therapy combining the central nervous system effects of TENS, with the photobiologic cellular effects of laser and LED light is a new and refreshing approach to a

very difficult problem which has remained a major health issue for millions of Americans [6],[4]. Although alternative methods of pain management have been used in the past, their widespread utilization for large numbers of patients has been limited. Most pain management facilities are not equipped to offer such treatments as massage therapy, hydrotherapy, acupuncture, psychotherapy, yoga or combinations of alternative medical treatments. Most limit their practice to interventions, injection therapy, surgery, or purely pharmacological treatment.

Pain management strategies which include all available choices are needed in order to move toward a more consistent, comprehensive methodology for chronic pain patients. Unfortunately, little research is available for development of “best practices” for these complex patients and consequently no definite recommendations are available for the unique nature of many of these patients. Chelminski, et al developed a program in which they evaluated pain, mood, and functional limitation related to pain before and 3 months after a carefully monitored opioid treatment regimen with good results in those patients who completed the study [1]. Many patients in their study and other studies as well, were noncompliant with the protocols which limited the value of these studies for application in a large population.

The user friendly nature of the e-photonic device used in the present study makes it useful for most patients in the outpatient clinic setting, in physical therapy offices, home health services, or even at home with application by family members or by the patients themselves. As there are no negative side effects, the device can be used as frequently as needed to achieve desired pain relief.

The mechanisms of therapeutic use of low level laser and LED were reviewed by Hamblin, et al

in 2006 [4]. This comprehensive review of what is known about the cellular biologic response to these modalities offers insight to the potential mechanism of action for the e-photonic device used in this study. An effective wavelength of 600-950 nm has been identified as the window for a cellular, photobiologic response which enhances wound and tissue repair, relief of inflammation, relief of acute pain and neuropathic pain, decreased edema and increased microcirculation. Although data from our outpatient clinic are anecdotal, an increase in skin temperature has been consistent in the treated area suggesting an increase in microcirculation and cellular metabolism possibly in response to increased adenosine triphosphate (ATP) production, increased nitric oxide production, as well as increased vasoactive substance formation. Accelerated wound healing of stasis ulcers of the lower extremities as well as some ischemic lesions has also been observed. Application of e-photonic therapy for multiple sclerosis, Devic’s disease, arthritis, diabetic neuropathy, phantom limb pain, and fibromyalgia has yielded remarkable results in preliminary studies at our center. The broad spectrum of usefulness of e-photonic combination therapy is currently being explored and further studies are in progress. It is remarkable that a 49% reduction in pain level was observed in this study compared to a 20-25% decrease previously reported in multidisciplinary pain treatment centers [3].

Additional studies are needed to assist those who treat chronic pain patients in developing safe, comprehensive approaches to relieve this devastating clinical problem. It is imperative that we caregivers accept the mandate of the IOM to develop and execute improved methods of treatment for our patients in order to not only offer relief to them , but also to diminish the huge financial burden to our health care system and our society. Will we accept the challenge?

## Conclusions

1. E-photonic therapy in management of chronic pain has been shown to be effective in a diverse population of patients.
2. A nearly 50% decrease in pain level following a short treatment regimen which lasted for up to 1 year is remarkable when compared to other treatments.
3. The user-friendly device used in this study lends its usefulness to a broad array of clinical applications.
4. E-photonic therapy should be considered an essential component of multidisciplinary, multimodality treatment for chronic pain patients

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