Light-Emitting Diode Versus Sham in the Treatment of Plantar Fasciitis: A Randomized Trial

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Abstract

Objective: The purpose of this preliminary study was to compare the application of the light emitting diode (LED) to sham LED in the treatment of plantar fasciitis.

Methods: Eighteen subjects met the inclusion criteria and were randomly assigned into 2 groups: light emitting diode or sham LED. The subjects received either the LED at 12 J/cm² or sham LED along 2 points of the plantar fascia. Subjects in both groups received a 10 minute transverse friction massage and participated in 4 plantar fascia stretching exercises. All subjects received a total of 6 treatments over 3 weeks. Progress was assessed using the lower extremity functional and analog pain scale.

Results: No significant difference was found between treatment groups ($P = .845$). There was a significant difference in pain and outcome scores over time within both groups ($P < .35$).

Conclusion: Among patients with plantar fasciitis, the use of LED did not result in greater improvement in function or pain compared with sham treatment. The findings suggest that manual intervention and passive stretching activities may have provided significant pain relief and improvement in functional outcome scores.

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Introduction

Plantar fasciitis affects more than 2 million people per year and is one of the most common foot pathologies diagnosed in the United States.^{1–7} Clinicians commonly apply local modalities, manual treat-

ments and stretching exercises in spite of a general lack of clinical evidence to prove the effectiveness of some of these methods. Authors performing a systematic review cited, “26 conservative treatments that have been recommended for the treatment of plantar heel pain.”⁶ These interventions included night splints, orthotic devices, shockwave therapy, stretching activities and local modalities.

The plantar fascia can be described as a fibrous layer of connective tissue that originates from the calcaneal tuberosity and extends as lateral slips to attach distally

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along the lateral border of the metatarsal heads.^{3,8,9} Patients often report plantar heel pain that may originate just distal to the medial tubercle of the calcaneus. Their symptoms can occur while walking, or with the first few steps after a period of non-weight bearing. The fascia is typically tender to palpation over the medial aspect of the calcaneus and longitudinal arch, while passive stretching can increase pain. The term “fasciitis” implies localized inflammation, but recent literature suggests this pathology to be more of a degenerative process.^{8,10} Degeneration of the plantar fascia can be the result of excessive loading, repetitive trauma, tears, or chronic inflammation.^{2–8} Among the various treatment options, it appears that there is limited documented effectiveness. The most effective treatment involves gastrocnemius/soleus muscle stretching.⁶

Some authors have suggested that initial treatment for plantar fasciitis begin with a temporary custom foot orthosis (TCFO) for a short period of time followed by stretching. “Overall, findings suggest that a TCFO for 2 weeks, followed by a stretching program, decreases overall pain and increases foot and ankle function in subjects with plantar fasciitis”.³

Recent evidence indicates that light therapy (phototherapy) may be beneficial in the treatment of musculoskeletal pathology.¹¹ One primary benefit of light therapy is the photobiotic effect, which has been shown to produce mitochondrion oxidative reactions. These reactions produce a single oxygenlet, a free radical, which in turn allows for a greater production of ATP for the healing tissue.¹¹

Light therapy can be used for musculoskeletal pathology, neurologic and wound care applications.¹¹ Typical phototherapy devices include laser diodes, super luminous diodes, and light emitting diodes (LED). The benefit and application of the various diodes require a knowledge base/understanding of tissue response to wavelengths, frequency, power and treatment indications. The light emitting diode is a therapeutic modality that is thought to create similar physiological effects as laser therapy in the absorbing tissues. Several sources to this point, have expressed that appropriate parameters have not been established, yet that laser and/or light therapy devices appear to be safe for clinical use.^{12–15}

The goal of this clinical trial was to determine if an application of the LED is more effective in the treatment of plantar fasciitis than a sham LED for patients receiving traditional methods of transverse friction massage and stretching of the plantar fascia.

Methods

This preliminary double blind, randomized controlled trial was performed with 18 subjects twice a week for three weeks. The protocol was reviewed and approved by the University of Hartford, Human Subjects Committee. Subjects were recruited using an electronic flyer posted in the University newsletter. A total of 26 subjects, 8 males and 18 females between the ages of 21 to 65 volunteered to participate in the study. Subjects were provided formal instruction regarding possible treatment outcomes, expected sensations from the applied modalities and a description of the soft tissue mobilization techniques used in this study. All subjects signed written consent.

Each subject presented with symptoms of plantar heel pain and was evaluated by a physical therapist to confirm the diagnosis of plantar fasciitis. Diagnosis was based on subjects reporting heel pain in the area of the medial calcaneal tubercle, general fascia pain and symptoms that increase in weight bearing especially the first few steps in the morning.¹³ Six subjects withdrew from the study due to scheduling conflicts, while 2 did not meet the inclusion criteria.

Subjects were excluded from the study if their symptoms were the result of trauma within the last six months or those who reported having experienced foot fractures within the last four months. Subjects who presented with contraindications to light therapy which included: participation in radiation therapy within the last 6 months, acute swelling or inflammation, an undiagnosed mass or growth along the treatment area, those taking a prescribed anti-inflammatory medication at the time of the study, having had a steroidal injection within the last 3 weeks, or those who having a sensitivity to light.¹⁶

The remaining 18 subjects were randomly assigned into two treatment groups. All subjects received transverse friction massage and a plantar fascia stretching program along with either the LED or sham LED. Group 1 received LED at 12 J/cm² in two positions¹⁶ along the fascia and Group 2 received sham modality in the same treatment positions. Sham LED was a light emitting diode treatment with an opaque cover over the diode to block transmission of the light to the tissue. Subjects were blinded as to whether they were receiving the real-time modality or sham. Clinicians who were involved in data collection and those who performed the transverse friction massage were also blinded to which modality the subjects had received. Subjects completed the analog pain scale and lower extremity functional scale (LEFS) at the initial visit, at the start of the fourth visit and at the

Fig. 1. The subject passively extended the great toe while applying pressure to the fascia with their fingers.

Fig. 2. The subject leaning against the wall with the knee extended and heel remaining in contact with the floor.

completion of the sixth visit to assess their progress. All subjects participated in a total of six treatment sessions over three weeks.

The LED used in this study was the Intellect transport® Light Therapy unit from the Chattanooga Group, that was calibrated prior to the study. A 19-diode cluster was used in this study, containing six 625 nm, 10 mW diodes, seven 850 nm 25 mW diodes, and six 950 nm 15 mW diodes.

The clinical protocol that was delivered to both treatment groups involved a 10 minute transverse friction massage while placing the plantar fascia in a position of stretch then the patient performed stretching exercises. The stretching program consisted of four commonly used fascia stretching activities that were derived from the literature.^{1–4,6} Subjects performed 3 repetitions of each exercise, holding each repetition for 30 seconds. During the first stretch, the subjects passively extended their great toe while applying pressure to fascia (Fig 1). The next stretch targeted the gastrocnemius with the subjects leaning against the wall with the knee extended and heel remaining in contact with the floor on the affected limb (Fig 2). The soleus stretch was performed in the same standing position; however the knee of the affected limb was flexed (Fig 3). During the final stretch the subject was instructed to place his or her great toe on the wall and lean forward to stretch the fascia directly (Fig 4).^{13,17–19}

Group 1 received LED that was applied over the two most painful points on each subject's plantar fascia. The parameters chosen for this intervention were 12 J/cm² applied for 4.56 minutes, over each treatment point. Following the LED application, subjects in Group 1 received the transverse friction massage and participated in the passive stretching exercises.

Group 2 received sham LED at the same 12 J/cm² over the two most painful points of the plantar fascia; however the diode had an opaque covering preventing

the light from reaching the skin. This group also received the transverse friction massage and was instructed in the passive stretching exercises.

Both groups were encouraged to continue their normal activity level and continue the stretching protocol at home at least twice daily. The home stretching program was not mandatory, but each subject was provided pictures with written instructions if they wanted to continue their stretching at home.

The LEFS is a questionnaire used to measure a subject's ability to perform everyday tasks. The percentage function is determined by dividing the total score by 80, multiplying by 100. The higher the percentage, the greater the functional score.

The data was analyzed in SPSS using paired *t* test with a Bonferroni correction of $\alpha = .016$. The Bonferroni correction was used to adjust for the treatment and sham group comparisons of the analog pain scores and LEFS scores over time as well as the within group comparisons over time.

Results

There were no significant improvements in functional outcome scores and analogue pain scores between the 2 treatment groups $P = .845$. However, using a paired *t*-test with a Bonferroni correction of $\alpha = .016$, there was a significant improvement in functional outcome scores and reported pain levels within the treatment groups $P < .035$. Both groups reported a decrease in pain level, the most notable change in pain being reported between week 2 and the end of the study. Functional outcome scores also indicated the highest level of improvement during the second and third week of treatment.

LEFS scores improved from initial reports (59% of daily function) during week 1 to 71% of daily function

Fig. 3. The subject leaning against the wall with the knee of the affected limb was slightly flexed and heel remaining in contact with the floor.

at the completion of the study. Analog Pain Scale indicated an average pain level during week 1 across groups as 3.9/10. Final reports of pain following the last intervention averaged a 2.3/10.

Discussion

Use of local modalities to decrease pain and improve patient outcomes is common practice among healthcare practitioners. This study compared the use of a LED vs. sham LED in the treatment of plantar fasciitis, when used in conjunction with manual treatment and a stretching program. While improved functional outcome scores and decreased pain levels were reported across both groups, there were no significant differences found between LED and sham LED. At this point, it appears the modality had no effect on functional outcomes and reported pain scores.

The comparison within treatment groups over time indicates that the evidence based treatment of a 10 minute friction massage and stretching exercises may have been essential in the treatment of plantar fasciitis. Across both groups, subjects reported improvements in function and pain levels that were noteworthy. Unfortunately without a no-treatment control group for comparison, time may have played a factor in tissue healing.

The parameters used in this study attempted to address the sub-acute inflammatory nature of this pathology. The final literature search at the completion of the data collection yielded a few sources that suggested that plantar fasciitis is more of a degenerative

Fig. 4. The subject placed her great toe on the wall and leaned forward to stretch the fascia directly.

pathology.²⁻⁸ This information may have future implications on the parameters chosen in the treatment of plantar fasciitis.

Limitations

Use of an LED has been suggested for superficial pathologies including local wound healing. It appeared that plantar fasciitis, which is palpable, would be considered a superficial pathology. The LED used in the study was a 19 diode cluster with a maximum power of 325 mW. Secondary to the physical nature of the diodes used, the penetration of the photons is only a few millimeters into the tissue. The parameters used may have not been a high enough dosage to have an effect on the skin and fascia of the foot. This would suggest that the photons generated did not reach the tissue at fault, rendering it ineffective. The LED is also considered to be divergent, non-directional, non-coherent and polychromatic.¹⁶ As the light diverges across the tissue its intensity decreases. The LED's energy becomes diffuse and non-directional making it difficult to directly target the tissue at fault.

Additional limitations to this study include the small number of subjects ($n = 18$). A larger sample size might have produced significant results between groups.

The LEFS, while a reliable and valid indicator of functional improvement for the lower extremity, may not have been sensitive enough to indicate more precise improvements in foot/ankle function. Furthermore, subjects were encouraged to perform the stretching activities at home, but were not required. Therefore the study design did not include follow-up for the home program.

Further research is needed in the areas of light therapy/laser/LED modality application and tissue response. While LED application has been determined to be safe, further study on parameter selection is needed before its overall effectiveness can be determined.

Conclusion

Among patients with plantar fasciitis, the use of LED did not result in greater improvement in function or pain compared with sham treatment. The findings suggest that manual intervention and passive stretching activities may have provided significant pain relief and improvement in functional outcome scores.

Funding Sources and Conflicts of Interest

An internal University grant was awarded to purchase the light emitting diodes used in this study. There were no conflicts of interest with the corresponding author and co-authors in the production of this manuscript. No conflicts of interest were reported for this study.

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