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Low-Level Laser Therapy for Treating Low Back Pain: 12-Month Follow-Up

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Abstract

Low back pain is the leading cause of disability, with an estimated 632 million persons worldwide suffering and producing societal costs exceeding $100 billion annually in the United States. The use of low-level lasers (LLLT) has demonstrated beneficial effects for treating a range of painful musculoskeletal conditions, including low back pain. The Food and Drug Administration granted LLLT the first 510(k) market clearance for the treatment of chronic low back pain (K180197), based off a randomized, double-blind, sham-controlled study. The objective of the following study was to reassess the safety and efficacy of LLLT in these same subjects 12 months after receiving LLLT for chronic low back pain.

Keywords: Low-level laser therapy; Low back pain; Chronic pain; Clinical trial; Long term

Introduction

Non-specific low back pain (LBP) affects people of all ages and is a leading cause of disability. The Global Burden of Disease Study estimates that 632 million persons worldwide suffer from LBP [1] making it the leading cause of disability [2,3]. The societal costs of LBP pain exceed $100 billion annually in the United States, including health care expenditures and lost productivity [4]. Historically, non-steroidal anti-inflammatory drugs (NSAIDs) have been prescribed as first-line pharmacologic therapy for LBP, with opioids reserved for patients who do not receive benefits from NSAIDs [5]. Unfortunately, there is growing evidence that this strategy is less than optimal for treating LBP. The long-term use of NSAIDs is associated with gastrointestinal, renal, and cardiovascular toxicity [6], which is especially worrisome among the elderly [7,8]. Opioids are less efficacious than other medications while increasing potential patient harm [9] and long-term opioid use does not improve the quality of life of patients with chronic LBP [10]. Nevertheless, the overuse of opioids remains a widespread problem [2] [11,12]. One study showed that opioids and opioids combined with NSAIDs are not more effective than NSAIDs alone, [5] and patients using opioids and NSAIDs reported greater back-related disability and poorer quality of life than patients using no drug therapy [5]. In general, treatment guidelines are shifting away from drug therapy, especially the use of opioids, due to their poor efficacy and safety profile [11]. Greater use of non-pharmacologic therapies and better second-line, nonopioid pharmacologic therapies are necessary for more effective treatment of chronic LBP [3] Recommendations from the Clinical Practice Guideline of the American College of Physicians suggest clinicians and patients should choose nonpharmacologic treatment for acute or subacute low back pain. If pharmacologic treatment is desired, clinicians and patients should select non-steroidal anti-inflammatory drugs or skeletal muscle relaxants [12]Opioids should only be considered when patients fail all other treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients [13].Low-level laser therapy (LLLT), also referred to as nonthermal or cold lasers, has demonstrated benefits for a wide range of painful conditions, including musculoskeletal disorders such as LBP [14,15] neck and shoulder pain [16], and heel pain. Laser therapy can significantly reduce pain and disability and improve range of motion in patients with chronic LBP [17,18]. A low-level 635 nm red laser has been developed for treating musculoskeletal disorders (Erchonia® FX-635™; Erchonia Corporation, Melbourne, FL). A previous study demonstrated this device significantly improves pain severity and range of motion when used to treat neck and shoulder pain [19]. A similar study using the Erchonia 635 nm red laser provided a significant decrease in heel pain associated with Plantar Fasciitis, with continued improvement in pain recorded in a 12-month follow-up study [20]. Based on these promising results, a randomized, double-blind, sham-controlled study assessed the effectiveness of this laser device for providing temporary acute relief of minor episodic, chronic LBP of musculoskeletal origin. The results of that study showed that almost 75% of treated subjects (n=29) achieved a ≥30% decrease in low back pain scores (Figure 1) [21]. Based off the study success the Food and Drug Administration granted the Echonia FX635 Laser the first 510(k) market clearance for low-level laser device on the treatment for the treatment of chronic low back pain [22] The objective of the following study was to reassess the safety and efficacy of LLLT in these same subjects 12 months after receiving LLLT for LBP. The methods are briefly reviewed here.

Methods

Study subjects

Study subjects were male or female, ≥18 years old, and recruited from among each investigators' pool of patients seeking treatment for LBP or responding to local recruitment flyers and print ads. Each subject was required to have primary pain located in the left, right, or both sides of the lower back, defined as the area between the lowest rib and the crease of the buttocks, physical examination, and medication use. The presenting LBP was episodic chronic, defined as ongoing over ≥three preceding months, with LBP having occurred on ≥15 days of each preceding month, and each episode lasting ≥24 hours followed by a subsequent period of ≥24 hours without pain. Other inclusion criteria included a self-reported score of ≥40 on the 100-point Visual Analog Scale (VAS) pain scale; ability to refrain from consuming analgesic,

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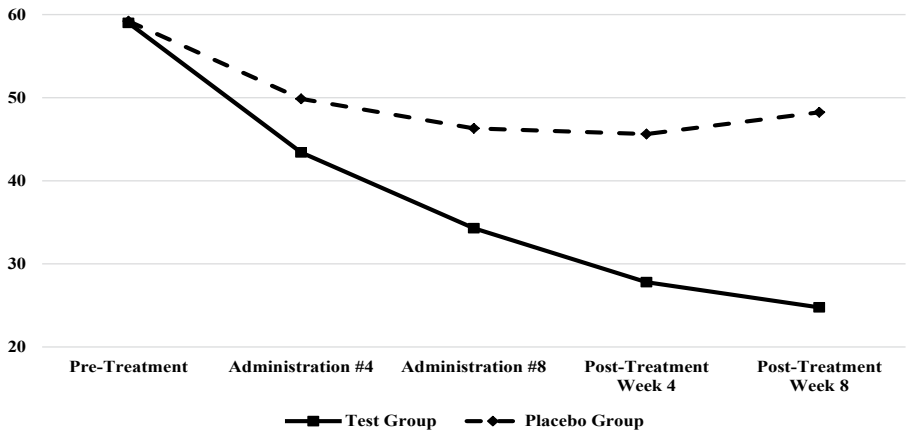

Figure 1: Change in visual analog scale pain scores

Among laser-treated subjects, VAS scores progressively decreased from pre-procedure through endpoint evaluation, indicating the cumulative treatment effect of the laser. Among sham-treated subjects, there was a slight initial placebo effect with low back pain ratings returning to near baseline levels by endpoint.

A series of Student t-tests for independent samples were performed to evaluate the significance of the difference in mean VAS ratings between test and placebo group subjects at each of the evaluation points. From completion of treatment administration #8 through to post-treatment week 8 evaluation, the difference in mean VAS ratings between treatment groups was statistically significant:

- End of treatment administration #8: t=-2.04; p<0.05.
- Post-Treatment Week 4: t=-2.64; p<0.05
- Post-Treatment Week 8: t=-3.49; p<0.001

anti-inflammatory or muscle relaxing medications throughout the study except for the study-related pain relief medication; refraining from other therapies for managing LBP, such as physical therapy, occupational therapy and hot or cold packs, chiropractic care or acupuncture; and ability to complete a daily patient diary. Concomitant medications were allowed for the treatment of non-pain related disorders. Outcome Assessment Tools

The Visual Analog Pain Scale (VAS) is one of the three most commonly used scales for assessing chronic pain. The visual analog scale (VAS) used in this clinical study was a 0-100 mm horizontal line. It is a simple scale that consists of a line anchored at one end by a label such as "NO PAIN" and at the other end "WORST POSSIBLE PAIN". The subject was instructed to mark a single spot only on the line that visually represents the level of feet pain. The measurement of the VAS markings was only to be performed by the study principal investigator.

The Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to quantify disability for acute or chronic low back pain. The ODI is currently considered the gold standard of low back functional outcome tools for measuring degree of disability and estimating quality of life in a person with low back pain. The self-completed questionnaire evaluated the patient's perceived level of disability in 10 everyday activities of daily living concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each topic category is followed by 6 statements describing different potential scenarios in the patient's life relating to the topic. The patient then checked the statement which most closely resembles their situation.

The subject's ROM measurements for flexion, extension, left lateral flexion and right lateral flexion was taken using a goniometer and following the American Medical Association Guides (2nd and 4th editions) recommendation using measurements of thoracolumbar and lumbar range of movement, respectively, to estimate the percentage of impairment in patients with chronic low back pain. These measurements evaluate the mobility of the lumbar spine from both an articular and a muscular standpoint.

Study device

The low-level laser used in this study is a Class 2 device comprised of three independent 17 mW, 635 nm red laser diodes mounted in scanner devices with flexible arms positioned equidistant from each other (Erchonia® FX-635™; Erchonia Corporation, Melbourne, FL). The variable hertz feature of the device is a pulsed wave, defined as containing a preprogrammed series of breaks. The device utilizes internal mechanics that collect light emitted from each laser diode, which is processed through a proprietary patented lens, which redirects the beam with a line refractor. The refracted light is then bent into a spiraling circle pattern that is totally random and independent of the other diodes. The device delivers 10.2 joules to each of the three treated areas consisting of the lower spine and both hip flexors. As the device mechanically scanned the three areas simultaneously, the estimated amount of total energy delivered was 0.0865 J/cm^2. The sham device emitted light of the same color when activated. Eye protection was provided for use by the investigator and the subject (Laser Safety Industries; St. Paul, MN).

Procedures

Eligible subjects entered a 2-day pretreatment Washout Phase and abstained from nonstudy-related medications for LBP and used as-needed study rescue medication of acetaminophen 325 mg tablets (Tylenol®; McNeil Consumer Healthcare, Fort Washington, PA) which continued until the end of the post-treatment evaluation phase. During this time, subjects recorded baseline pain severity and completed daily diaries documenting study compliance. Subjects were randomized to receive treatment with the active laser or sham device. Each subject

received eight 20-minute treatments applied to the lower back region with their assigned treatment over a 4-week period consisting of two procedures per week, 3 to 4 days apart.

Ethics

The study protocol and related materials were approved by a commercial, institutional review board (Western Institutional Review Board, Olympia, WA; IRB number 20151815) and conformed to the Good Clinical Practice guidelines of the International Conference on Harmonization. ClinicalTrials.gov Identifier NCT01835756. All subjects provided signed informed consent prior to participating in any study-related activities.

Results

The original study subjects were randomized to the active (n=29) and sham treatment groups (n=29). Twenty-three subjects from the active treatment group participated in the 12-month follow-up evaluation visit. Outcome measures were the current level of low back pain, disability scores, and overall patient satisfaction with treatment outcomes.

Visual analog scale low back pain scores

The 12-month low back pain scores are shown in Table 1 and Figure 2. The mean (SD) scores at 2-months post-treatment 32.6 (29.8) had significantly decreased to 26.9 (25.4) at 12 months post-treatment ($p<0.0001$).

Oswestry disability index scores

The 12-month ODI scores are shown in Table 2. The mean scores were 15.8 (14.0) at 2 months and remained 15.7 (16.1) at 12 months, which was significantly lower than baseline ($p<0.05$).

Subject satisfaction

Using the 5-point Likert scale, subjects were asked the question, "Overall, how satisfied or dissatisfied are you with any change in the pain in your lower back following the study procedures with the study laser device?" Sixteen (16) subjects (70%) were Satisfied or Very Satisfied at 2 months post-treatment, increasing to 22 subjects (96%) at 12 months post-treatment (Table 3).

	Pre-Treatment	Treatment End	Time Post-Treatment		
			1 Month	2 Months	12 Months
Mean (SD)	60.0 (11.8)	37.6 (28.6)	28.4 (27.9)	32.6 (29.8)	26.9 (25.4)

Table 1: Mean low back pain VAS scores

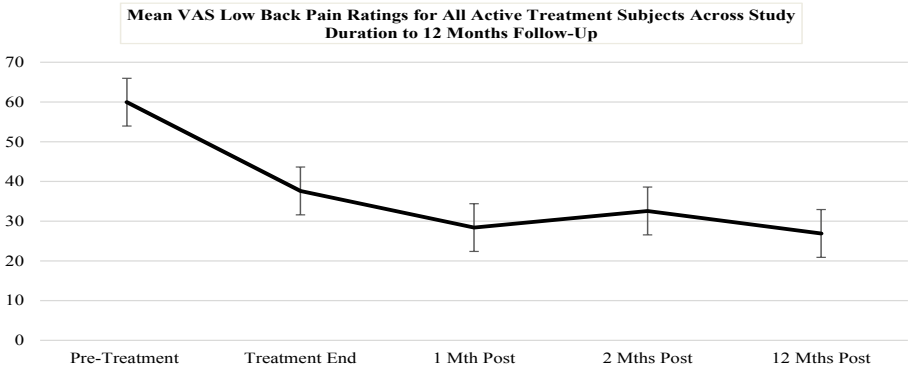

Figure 2: Mean VAS low back rating for active treatment subjects from baseline to 12-months follow-up.

	Pre-Treatment	Treatment End	Time Post-Treatment		
			1 Month	2 Months	12 Months
Mean (SD)	24.0 (10.2)	18.9 (13.4)	15.7 (15.0)	15.8 (14.0)	15.7 (16.1)
*Higher ODI Percent Total scores are associated with greater disability.					

Table 2: Mean percent total index oswestry disability index score*.

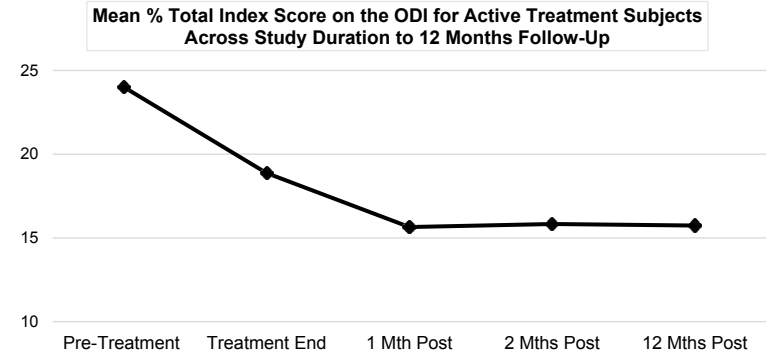

Figure 3: Total Index Score on the ODI for Active Treatment Subjects Across Study Duration to 12 Months Follow-Up.

Subject Satisfaction Ratings	Treatment End	2 Months Post-Treatment	12 Months Post-Treatment
	n (%)	n (%)	n (%)
Very Satisfied	10 (44)	11 (48)	18 (79)
Somewhat Satisfied	7 (30)	5 (22)	4 (17)
Neither Satisfied nor Dissatisfied	5 (22)	5 (22)	1 (4)
Not Very Satisfied	1 (4)	2 (8)	-
Not at All Satisfied	-	-	-

Table 3: Subject satisfaction ratings.

Discussion

The results of the original study showed subjects that had a duration of pain of 97.8 months, achieved significant improvements in VAS pain and disability scores. The present study demonstrated the durability of these results as pain scores continued to improve 17.48% from the study endpoint to 12 months post, without any additional treatments. In addition, Disability improvements were maintained, and treated subjects showed overall increased satisfaction with their treatment outcomes. As its name implies, a low-level laser refers to lasers emitting red or near-infrared light with power in the range of 0.001 to 500 Mw [23,24]. Depending on the physical characteristics of exposed tissue and the color and wavelength of the light, some tissue-directed light directed is reflected while the remaining light is absorbed and scattered [25,26]. It is the absorbed light that exerts a photochemical effect in the damaged cells. The process of photochemistry begins when a suitable molecule, known as a chromophore absorbs a photon of light with an appropriate wavelength, and an electron is raised to an excited state. Biological chromophores include haemoglobin, myoglobin, cytochromes, flavin, flavo-proteins and porphyrins [23]. With respect to photochemistry, the primary site of light absorption is mitochondrial cytochrome c oxidase (CCO) [24]. The experimental application of LLLT to human volunteers induced a significant increase of CCO and oxygenated hemoglobin concentration at the treatment site [27]. Excitation of CCO increases the production of mitochondrial products such as ATP, NADH, RNA, and an overall increase in cellular respiration.[24,28] Numerous signaling pathways are activated *via* reactive oxygen species, cyclic AMP, NO and Ca^{2+}, which activate transcription factors and increase gene expression involved in protein synthesis, cell migration and proliferation, anti-inflammatory signaling, anti-apoptotic proteins, and antioxidant enzymes [28]. LLLT is being used to reduce pain, inflammation, edema, and enhance healing of various types of injuries [24]. The results of our work indicate LLLT is an effective treatment for low back pain and a safer alternative to opioids and nonsteroidal anti-inflammatory medications.

Conclusion

The Erchonia 635 nm low-level demonstrated therapeutic durability for low back pain. Following 12 months, post-treatment subject pain scores continue to decrease by 17.48%. While overall satisfaction was increased and disability improvements were maintained. LLLT represents a side effect and an effective alternative to opioids and nonsteroidal anti-inflammatory medications for treating low back pain.

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