eMedical Research
Volume 2
Article ID: 100005

Research Article

A Randomized, Double-Blind, Sham-Controlled Study Evaluating the Effectiveness of a Low-level Laser Device for Treating Lower Back Pain

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Received: November 05, 2019; **Accepted**: February 05, 2020; **Published**: February 15, 2020

Abstract

Background: Low back pain is the leading cause of disability with a high lifetime prevalence. The use of low-level lasers has demonstrated beneficial effects for treating a range of painful musculoskeletal conditions including low back pain. The objective of this study was to determine the effectiveness of a low-level laser device for providing temporary acute relief of minor episodic chronic low back pain of musculoskeletal origin.

Methods: This was a randomized, double-blind, sham-controlled study performed in an outpatient clinic setting. Subjects were randomized to receive treatment with the active or sham laser device. Subjects received eight 20-minute treatments to the lower back region over a 4-week period consisting of two procedures per week, 3 to 4 days apart. The low-level laser device was a Class 2 device comprised of three independent 17 mW, 635 nm red laser diodes (Erchonia® FX-635™; Erchonia Corporation, Melbourne, FL). The primary efficacy assessment was the change in visual analog scale (VAS) pain scores. The predefined outcome measure was the proportion of subjects achieving a ≥ 30% change in VAS pain scores at a 2-month follow-up assessment. Overall study success was predefined as a ≥ 35% between-group difference in the proportion of subjects achieving treatment success.

Results: 72.4% of subjects treated with the low-level laser achieved a ≥ 30% decrease in low back pain VAS scores *vs.* 27.6% of sham-treated subjects (44.8% difference; $p<0.005$). The mean decrease in low back pain VAS scores was 34.2 points for subjects treated with the laser *vs.* 11.0 points for sham-treated subjects (23.4-point difference; $p<0.001$).

Conclusion: Low-level laser is an effective means for reducing episodic chronic low back pain of musculoskeletal origin. Based off the results of this randomized, double-blind, sham-controlled study the Food and Drug Administration (FDA) cleared the Erchonia® FX-635™ for indication of use to provide relief of chronic low back pain (K180197).

Keywords: *low-level laser therapy, low back pain, chronic pain, clinical trial*

Introduction

Globally, low back pain (LBP) is the leading cause of disability [1] with a lifetime prevalence reported to be as high as 84% [2]. The point prevalence has been shown to increase with advancing age, from 4.2% among individuals 24 to 39 years old to 19.6% among those 20 to 59 years old [3]. It is among the ten leading causes of years lived with disability in every country surveyed [4]. In the United States, LBP has a point prevalence of approximately 12%, a 1-month prevalence of 23%, a 1-year prevalence of 38% and a lifetime prevalence of 40% [5]. Among all types of disorders in the

United States, low-back pain ranks third for disability-adjusted life-years and first by years lived with disability [2]. Although more common among the elderly, LBP also affects children and adolescents [6-8].

In addition to disability, LBP contributes to anxiety, depression, sleep disturbances, poor quality of life, and increased healthcare costs [9] and can have a negative effect on employment and family responsibilities [5]. Not surprisingly, LBP constitutes a major economic problem in many countries. In many instances, the cause of LBP is unknown, but several risk factors have been suggested, including heavy lifting, poor body mechanics and exposure to whole-body vibration [2,10,11]. Contributing factors include obesity, smoking, lack of exercise, advancing age, and lifestyle factors [5,12].

Non-pharmacologic interventions for treating LBP include spinal manipulation, physical therapy and acupuncture [13,14]. Physical activity and exercise may improve pain severity and physical function [9]. In patients with chronic LBP with an inadequate response to nonpharmacologic therapy, treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy may be considered [15].

Opioids appear to have short-term efficacy for treating chronic LBP with much less evidence supporting long-term use [16], possibly due to tolerance [17] and may not provide additional benefits over the use of NSAIDS alone [18]. Half of patients treated with opioids discontinue using them due to lack of efficacy or adverse events [19] including constipation, nausea, sedation addiction, and overdose-related mortality [17]. There is conflicting evidence regarding the use of antidepressants [20].

The benefits of the of the Erchonia® FX-635 low-level laser therapy (3LT) for treating painful musculoskeletal conditions has been demonstrated and recently received FDA 510(k) for providing relief of nociceptive musculoskeletal pain. The clearance was based off collective clinical performance of over 200 subjects on various musculoskeletal pain conditions including neck, shoulder, low back and plantar fasciitis [21]. A randomized, double-blind, placebo-controlled study assessed the beneficial effects of low-level laser device for alleviating minor neck and shoulder pain [22]. Among the 50 patients treated with 3LT, 40 (80%) achieved a ≥ 30% improvement (reduction) in pain severity *vs.* seven (14%) of 50 sham-treated subjects ($p<0.05$). A subsequent double-blind, sham-controlled trial assessed the efficacy of 3LT for treating pain related to osteoarthritis or degenerative joint disorders, chronic muscle spasms, or cervical or thoracic spine sprains or strains [23]. Among the 43 subjects treated with 3LT, 28 (65.1%) achieved a ≥ 30% improvement in pain scores *vs.* six (11.6%) sham-treated subjects ($p<0.005$). Laser-treated subjects also achieved significant improvement in range of motion ($p<0.0001$). A Placebo-controlled, randomized, double-blind, multicentre study that evaluated the clinical utility of low-level laser therapy for the treatment of unilateral chronic fasciitis. the group participants demonstrated a mean improvement in heel pain with a visual analog scale score of 29.6 compared with the placebo subjects, who reported a mean improvement of 5.4, a statistically significant difference ($p<0.001$) [24].

Based on these promising results, the objective of the following randomized, double-blind, sham-controlled study was to determine the effectiveness of 3LT for providing temporary acute relief of minor episodic chronic LBP of musculoskeletal origin.

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, and also individuals responding to local recruitment flyers and print ads. Qualifying subjects received financial compensation for completed study compliance and participation.

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. Low back pain was of musculoskeletal origin stemming

from benign musculoskeletal problems involving lumbar sprain, strain or stretch injury to the ligaments, tendons, and/or muscles of the low back in the absence of nerve root compromise.

Diagnosis included a history of initial LBP onset occurring after one or more of the following events: known injury, such as an accident or fall; overexertion of a muscle, such as after unusual amounts of exercise or unaccustomed activity, or sustained positioning (strain injury); or sudden force or movement exerted upon ligaments, such as unusual turning or twisting (sprain injury). Subjects complained of at least two of the following: pain and/or loss of function such as inability to turn, twist or bend normally; pain located along lower back and upper buttocks which may radiate into surrounding tissue; pain that worsens with activity; painful muscle spasms that can worsen with activity or at night while asleep; or history of prior back injury.

Diagnosis was further based on a physical examination which revealed at least three of the following features: inability or difficulty straightening into normal posture while standing; activities such as sitting, standing, walking or driving are limited, difficult or impossible; palpation of muscles in lower lumbar area reveals local tenderness and muscle spasm while lying in prone position; change in sensation and/or motor function of knees and ankles; raising straight leg from supine position produces sciatica; or upon observation, there is no notable posture, spinal alignment or other back deformities. Other factors included a history of taking over-the-counter or prescription muscle relaxants or anti-inflammatory medications, and if available, review of medical records and confirmatory diagnostic testing, such as X-ray, MRI or CAT scan reports.

The presenting LBP was episodic chronic, defined as ongoing over ≥ 3 preceding months, with pain 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, 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.

Subjects with LBP known to be caused by the following etiologies were excluded from study participation: mechanical (apophyseal osteoarthritis, thoracic or lumbar spinal stenosis, spondylolisthesis), inflammatory (ankylosing spondylitis, rheumatoid arthritis, infection), neoplastic (primary or metastatic bone tumors, intradural spinal tumors), metabolic (osteoporotic fractures, osteomalacia, chondrocalcinosis) or psychosomatic conditions (tension myositis syndrome). Other exclusion criteria included the use of the muscle relaxants cyclobenzaprine, diazepam or meprobamate within the prior 30 days, use of the muscle relaxants carisoprodal or metaxalone within the prior 7 days, initiation of the antidepressants duloxetine or a tricyclic or serotonin-selective reuptake inhibitor within the prior 30 days, systemic corticosteroid therapy or narcotics within 30 days; infection, wound or other external trauma to the planned treatment area; prior back or spine surgery; history of alcohol or other substance abuse; pregnancy, breast feeding, or planning pregnancy prior to the end of the study; participation in a clinical study or other type of research during the past 30 days.

Concomitant medications were allowed for the treatment of non-pain-related disorders, such as hypertension, diabetes, gastroesophageal reflux disease, hypothyroidism and hypercholesterolemia.

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 pre-programmed series of breaks. The device utilizes internal mechanics that collects 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 spiralling 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 scans the three areas simultaneously, the estimated amount of total energy delivered is 0.0865 J/cm^2. The light-emitting diode (LED) sham device produced 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). Since this study was completed, this low-level laser device has been cleared by the Food and Drug Administration for the treatment of chronic low back pain [25].

Procedures

Eligible subjects entered a 2-day pre-treatment Washout Phase and abstained from non-study related medications for low back pain and began using the as-needed study rescue medication acetaminophen 325 mg tablets (Tylenol®; McNeil Consumer Healthcare, Fort Washington, PA) which continued until the end of the post-treatment evaluation phase. Upon waking on these 2 days, subjects recorded their pain severity using the 0-100 VAS scale and completed the daily diary documenting study compliance. Subjects were then randomized to receive treatment with the active or sham device in double-blind fashion. Each subject received eight 20-minute treatments applied to the lower back region with their assigned treatment over a consecutive 4-week period consisting of two procedures per week, 3 to 4 days apart.

Outcomes measures

Baseline measures included location and duration of LBP, prior therapies, concomitant medication, demographics and base-line characteristics. Efficacy assessments included VAS pain scores, Oswestry Disability Index (ODI) questionnaire, Range of Motion (ROM) measures, diary record of rescue pain medication use, and a subject satisfaction survey. The ODI is a reliable and valid scale suitable for measurement of disability in patients with low back pain [26] and the VAS is often used to assess changes in low back pain [27,28]. Subjects were instructed not to record a VAS score within 6 hours after taking pain relief rescue medication. Subjects completed diary entries daily. VAS scores and an AE evaluation was performed after each treatment session and the ODI questionnaire was completed weekly. The ODI questionnaire, ROM assessment, and subject satisfaction survey were also performed after the final treatment. At 1-month post-treatment, VAS scores, ODI questionnaire, ROM and AE assessments were repeated. Safety measures included subject and investigator reports of adverse events (AEs). The study endpoint evaluation occurred at 2 months post-treatment and included VAS scores, ODI questionnaire, ROM and AE assessments and subject's satisfaction survey.

Efficacy endpoint

The goal of this study was to determine if treatment with 3LT was more effective than sham treatment for alleviating LBP. The primary efficacy measure was predefined as the between-group difference in the proportion of subjects achieving a clinically meaningful decrease in self-reported baseline LBP VAS scores of ≥ 30% at the 2-month follow-up evaluation at the 0.05 level. The clinical relevance of a 30% change in VAS score was previously established by the U.S. Food and Drug Administration Division of Surgical, Orthopedic and Restorative Devices through numerous pre-investigational device exemption (IDE) reviews. The results of these studies were subsequently used to successfully support related pain-reduction indications for similar light therapy devices [24].

Overall study success was predefined as a ≥ 35% difference in the proportion of individual subject successes between procedure groups.

Statistical analysis

A *t*-test for independent samples was used to analyze between-group differences in demographics and baseline characteristics. A Fischer's Exact Test for two independent proportions was used to analyze primary efficacy, and an

ANCOVA analysis was used to analyze the mean change in low back pain VAS scores. As every randomized subject completed all study visits and procedures and had all study measurements recorded through the final evaluation, only an intent-to-treat analysis was performed for primary outcome success.

Ethics approval and consent to participate

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 Indentifier NCT01835756. All subjects provided signed informed consent prior to participating in any study-related activities.

Results

Demographics

The 58 participating subjects were randomized to the active (n=29) and sham treatment groups (n=29). All subjects completed the study according to protocol. Demographics and baseline chacteristics of enrolled subjects are summarized in Table 1. A *t*-test for independent samples revealed no statistical significances between-group differences for any parameter. Prior prescription and non-prescription medications used by subjects to manage LBP are summarized in Table 2 and prior traditional and alternative therapies are summarized in Table 3.

Table 1. Demographics and Baseline Characteristics

	Test (n=29)	**Sham (n=29)**
Mean Age, years (SD)	46.4 (17.1)	44.7 (13.0)
Gender		
Male	13	14
Female	16	15
Race/Ethnicity		
Caucasian	22	18
Hispanic	1	7
African American	3	2
Asian	3	2
Pain Location		
Right Side	2	3
Left Side	5	2
Both Sides	21	24
Mean Pain Duration, months (SD); min, max	86.4 (80.5); 9, 240	92.7 (82.7); 3, 276
Mean Pain Severity on 100-Point VAS (SD)	59.0 (11.8)	59.2 (13.2)
Mean Oswestry Disability Index % Score (SD)	26.3 (11.1)	28.9 (9.7)
0-20: minimal disability	8	7
21-40: moderate disability	18	19
41-60: severe disability	3	3
61-80: crippling back pain	-	-
81-100: bed-bound or exaggerated symptoms	-	-
Mean Range of Motion Measures, degrees (SD)		
Flexion	76.6 (28.8)	75.3 (32.3)
Extension	22.5 (9.7)	22.0 (10.2)
Right Lateral Flexion	23.0 (11.4)	21.6 (10.3)
Left Lateral Flexion	23.3 (10.2)	21.3 (10.5)
SD: Standard Deviation; VAS: Visual Analog Scale		

Table 2. Prior Medications Used to Manage Lower Back Pain[†]

Nonprescription	**Test (n=29)**	**Sham (n=29)**
Acetaminophen	7	5
Ibuprofen	13	18
Acetaminophen/aspirin/caffeine	0	1
Naproxen	3	2
Magnesium salicylate	0	1
Aspirin	1	0
Prescription	**Test (n=29)**	**Sham (n=29)**
Acetaminophen/Hydrocodone	1	8
Cyclobenzaprine	3	3
Acetaminophen	0	4
Ibuprofen	1	4
Naproxen	2	1
Percocet	1	1
Metaxalone	1	1
Tramadol	1	1
Meloxicam	0	1
Hydrocodone	0	1
Prednisone	0	1
Oxycodone	0	1
Codeine	1	0
Gabapentin	1	1
Phenytoin	1	0
Diazepam	0	1

[†]Some subjects used more than one medication.

Table 3. Prior Therapies Used to Manage Lower Back Pain[†]

Traditional	**Test (n=29)**	**Placebo (n=29)**
Physical therapy	8	11
Ice packs	2	5
Hot pads	3	7
Occupational	-	1
Traction	-	1
Alternative	**Test (n=29)**	**Placebo (n=29)**
Chiropractic	11	15
Massage	4	12
Acupuncture	2	4
Reflexology	-	3
Yoga/Stretching	1	1
TENS	-	2

[†]Some subjects used several therapies

Primary efficacy measure

At the end of the study, 72.4% of subjects treated with 3LT achieved a ≥ 30% decrease in baseline LBP VAS scores *vs.* 27.6% of subjects treated with the sham device, a difference of 44.8% ($p<0.005$). The mean decrease in LBP VAS

scores was 34.2 points for subjects treated with the laser *vs.* 11.0 points for subjects treated with the sham device, a difference of 23.4 points ($p<0.001$) (Table 4 and Figure 1).

Table 4. Mean Lower Back Pain VAS Scores

Evaluation Visit	Test (n=29)	Sham (n=29)
Pretreatment	59.0	59.2
Treatment 4	43.4	49.9
Treatment 8	34.3	46.3
Post-treatment Week 4	27.8	45.6
Post-treatment Week 8	24.8	48.2

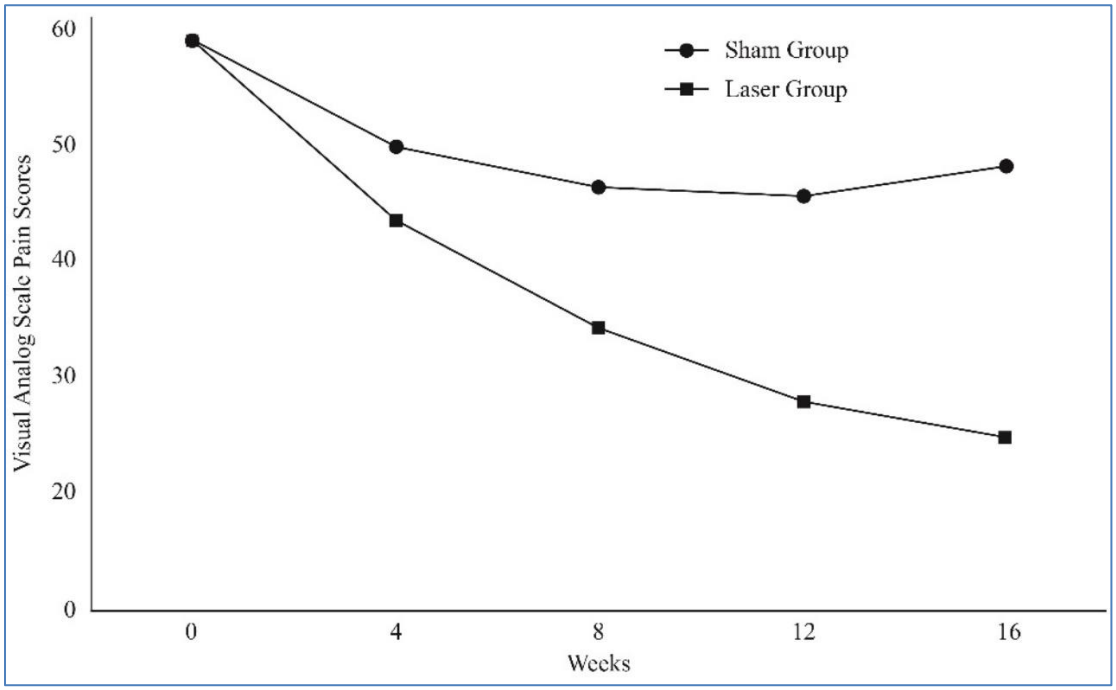

Figure 1. Changes in Visual Analog Scale Low Back Pain Scores

Among subjects treated with low-level laser therapy, there was a progressive and substantial decrease in mean low back pain (LBP) VAS scores throughout the duration of the study while the small decrease in VAS scores among sham-treated subjects was not clinically meaningful. The mean decrease in LBP VAS scores was 34.2 points for subjects treated with the laser *vs.* 11.0 points for subjects treated with the sham device, a difference of 23.4 points ($p<0.001$).

Primary safety measure

No adverse events were reported by any subject throughout the duration of the study.

Secondary efficacy measures

Oswestry disability index scores: Higher ODI Percent Total scores are associated with greater disability. A 10% change is accepted as the minimal detectable change (90% confidence) indicating clinically meaningful change in disability. Among subjects treated with 3LT, the mean (SD) scores progressively decreased from 26.3 (11.1) at baseline to 14.1 (12.2) at the end of the study, a decrease of 12.3 (10.7) points ($p<0.05$). In contrast, scores among sham-treated subjects decreased from 28.9 (9.7) at baseline to 23.7 (14.1), a decrease of 5.2 (12.6) points (P=NS) (Figure 2).

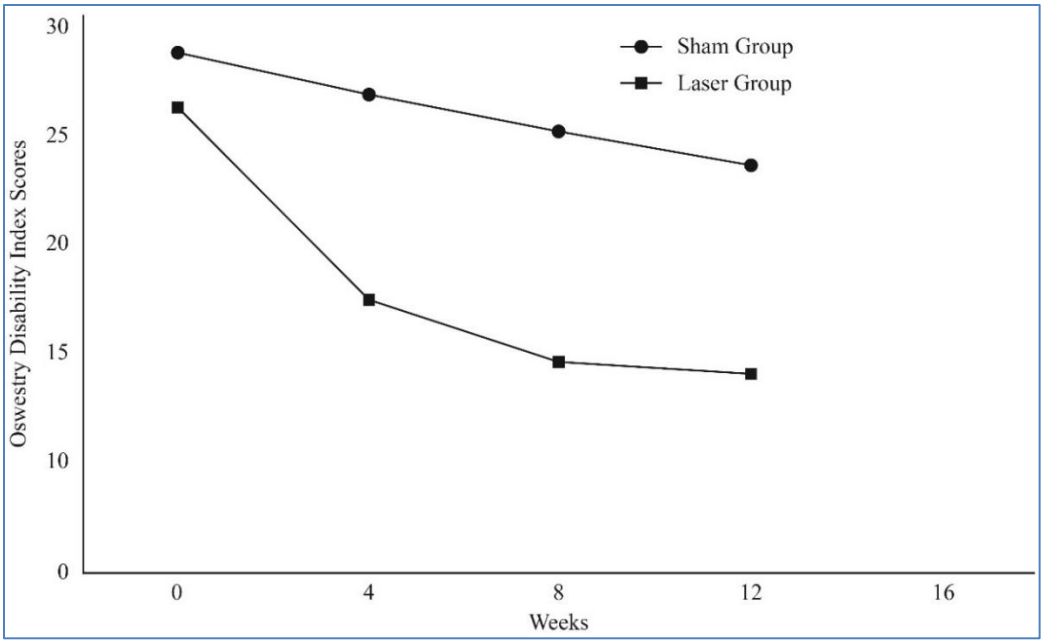

Figure 2. Changes in Oswestry disability index scores

Among subjects treated with low-level laser therapy, the mean (SD) ODI scores progressively decreased from 26.3% (11.1%) at baseline to 14.1% (12.2%) at the end of the study, exceeding the 10% minimal change indicating clinically meaningful change in disability. ODI scores among sham-treated subjects decreased from 28.9% (9.7%) at baseline to 23.7% (14.1%), a decrease of 5.2% (12.6%).

Visual Analog Scale Low Back Pain Scores: Among subjects treated with 3LT, there was a progressive and substantial decrease in mean LBP VAS scores throughout the duration of the study (Table 5). In contrast, there was a small decrease in VAS scores among sham-treated subjects which was not clinically meaningful.

Table 5: Change in Low Back Pain VAS Scores

	Active Treatment	Sham Treatment
	Mean (SD)	Mean (SD)
Baseline	59.0 (11.8)	59.2 (13.2)
After Treatment 1	51.0 (20.0)	56.7 (17.7)
After Treatment 2	46.6 (22.0)	54.9 (16.5)
After Treatment 3	42.6 (18.2)	57.1 (16.3)
After Treatment 4	43.4 (21.8)	49.9 (20.3)
After Treatment 5	41.9 (23.0)	51.0 (19.6)
After Treatment 6	38.2 (23.6)	49.0 (22.0)
After Treatment 7	31.2 (25.1)	52.5 (24.9)
After Treatment 8	34.3 (23.3)	46.3 (21.7)
Post-Treatment Week 1	32.7 (23.2)	50.6 (20.4)
Post-Treatment Week 2	36.1 (26.4)	51.6 (18.9)
Post-Treatment Week 3	32.3 (27.1)	48.1 (23.5)
Post-Treatment Week 4	27.8 (27.5)	45.6 (23.9)
Post-Treatment Week 5	28.3 (25.2)	45.9 (23.9)
Post-Treatment Week 6	28.0 (25.7)	47.1 (24.5)
Post-Treatment Week 7	30.0 (26.4)	44.3 (25.6)
Post-Treatment Week 8	24.8 (24.3)	48.2 (26.9)

Range of Motion Measurements: Mean ROM measurements obtained at Baseline, following the 4-week treatment phase, and at post-treatment weeks 4 and 8 revealed that changes in the degrees of ROM measurements for flexion, extension, right lateral flexion and left lateral flexion were negligible for both treatment groups.

Subject satisfaction

Subjects rated their satisfaction with the change in LBP at the end of the 4-week treatment phase and at post-treatment Week 8. Using the 5-point Likert scale in response to 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?," 21 subjects randomized to active treatment were satisfied *vs.* 12 sham-treated subjects at the end of the 4-week treatment phase (Table 6). At post-treatment Week 8, more subjects randomized to active treatment remained satisfied (19 *vs.* 12) while the number of dissatisfied sham-treated subjects increased.

Table 6. Subject satisfaction

	Active Treatment	Sham Treatment
End of Treatment Phase		
Very satisfied	13	5
Somewhat satisfied	8	7
Neither satisfied nor dissatisfied	7	13
Not very satisfied	0	2
Not at all satisfied	1	2
Post-treatment Week 8		
Very satisfied	13	5
Somewhat satisfied	6	7
Neither satisfied nor dissatisfied	6	9
Not very satisfied	4	6
Not at all satisfied	0	2

Covariate analyses

A Pearson correlation coefficient of r=0.585 indicated a significant, positive linear relationship between the change in ODI % total index scores and the change in VAS LBP ratings ($p<0.0001$). A series of one-way ANCOVAs for two independent samples was performed on the primary outcome measure of change in LBP VAS scores from baseline to study endpoint to adjust for the baseline covariates of age, ODI % Total Index score and ROM. The efficacy of 3LT *vs.* sham treatment was independent of subject age ($p<0.005$), subject disability ($p<0.001$) and subject ROM ($p<0.0005$).

Discussion

The results of this randomized, double-blind, sham-controlled study demonstrated the effectiveness of 3LT for relieving the pain and disability associated with minor episodic chronic LBP of musculoskeletal origin. At the end of the study, most subjects treated with the low-level laser (72.4%) achieved a ≥ 30% decrease in baseline LBP VAS scores *vs.* 27.6% of subjects treated with the sham device. This 44.8% difference between groups exceeded the ≥ 35% difference required to achieve overall study success. The mean decrease in LBP VAS scores was 34.2 points for subjects treated with 3LT *vs.* 11.0 points for subjects treated with the sham device.

Mean LBP VAS scores gradually decreased from baseline through the final evaluation for subjects treated with 3LT, suggesting a progressive and cumulative treatment effect. Additional benefit may have been achieved with treatment of longer duration. For sham-treated subjects there was an apparent placebo effect at the beginning of the study; however, VAS scores returned to near baseline values at the end of the study. The 12.3-point mean decrease in baseline

ODI % total index score far exceeded the 5.2-point mean decrease attained by sham-treated subjects, and exceeded the minimal detectable change of -10% that indicates a clinically meaningful positive improvement in the degree of disability associated with LBP. Subjects treated with 3LT also demonstrated greater satisfaction with treatment results.

Although the mechanism by which laser light decreases pain is not known with certainty, it has been studied in animal models of inflammation, hyperalgesia and neuropathic pain [29]. The analgesic and antiinflammatory effects of laser light are known to be associated with increased levels of the antioxidant glutathione, and decreased expression of P2X3 receptor subunits in C- and Aδ-fiber primary afferent neurons [30]; significant reductions in cyclooxygenase-2 (COX-2) mRNA expression [31]; endogenous opioid system activation [32]; reduced proinflammatory cytokines, such as TNF-α and CINC-1 and bradykinin receptor expression [33]; increased nitric oxide synthase activity [34]; and reduced nociceptive metabotropic glutamate receptors [35,36].

Clinically, low-level lasers have demonstrated beneficial effects for a range of painful musculoskeletal disorders [37,38] including tendinopathy [39], osteoarthritis [40], joint pain [41,42], low back pain[21,43-45] and shoulder pain [46], although evidence supporting its effect on function is sometimes lacking [21].

Conclusions

The use of low-level lasers is an effective means for reducing episodic chronic low back pain of musculoskeletal origin, progressively reducing low back pain over a 4-week treatment period and continuing to diminish it for at least an additional 8-weeks post-treatment. These improvements in pain were associated with reduced disability. Based off the results of this Randomized, Double-Blind, Sham-Controlled Study the Food and Drug Administration (FDA) the granted Erchonia® FX-635™ indication of use as an adjunct to provide relief of minor chronic low back pain of musculoskeletal origin, 510(k) # K180197. Test subjects will be followed out 12 months to determine the absolute limit of pain reduction.

Conflict of Interests

Travis Sammons is an employee of Erchonia Corporation. The other authors have no financial conflicts to disclose.

Acknowledgements

The authors acknowledge the editorial assistance of Dr. Carl S. Hornfeldt, Apothekon, Inc., during the preparation of this manuscript. This study was sponsored by Erchonia Corporation, Melbourne, FL. As the study sponsor Erchonia was responsible for device setup and training. Study was performed at (3) independent physcian sites, which compeleted CITI training (Collaborative Institutional Training Initiative) and approved through Western Institutional Review Board (WIRB).

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