

Low-Level Laser Therapy for the Treatment of Chronic Neck and Shoulder Pain

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Abstract

Background: Chronic neck and shoulder pain affect a large proportion of the general population. A previous randomized, double-blind study demonstrated the beneficial effects of low-level laser therapy (LLLT) for alleviating minor neck and shoulder pain. The objective of this randomized, double-blind, sham-controlled trial was to further evaluate the efficacy of LLLT for treating chronic shoulder and neck pain and improving upper body range of motion (ROM). *Methods:* Subjects were recruited from among adult patients seeking treatment of pain due osteoarthritis or degenerative joint disorders, chronic muscle spasms, or cervical or thoracic spine sprains or strains. Subjects were randomized to receive sham or active LLLT treatment with a single-head, low-level diode laser emitting a divergent 635-nm (red) laser light with an energy output of 1 mW (Erchonia[®] PL2000, Erchonia Corporation, McKinney, TX). Sham treatment used a similar device emitting ordinary red light. A single bilateral treatment was applied for 1 to twelve min. to the neck and shoulders. The primary outcome measure was the change in pain perception using a visual analog scale (VAS) scores immediately after treatment. The criterion for individual subject success was a 30% improvement. Overall study success was defined as $\geq 30\%$ difference between treatment groups by comparing the proportion of individual successes in each group. *Results:* Among the LLLT-treated subjects ($n = 43$), 28 (65.1%) met the individual subject success criteria while among the sham-treated subjects ($n = 43$), six (11.6%) met the individual subject success criteria ($p < 0.0001$). The difference exceeded the pre-established criteria for overall study success. Mean VAS scores decreased from 60.2 to 31.2 ($p < 0.0001$) for LLLT-treated subjects vs. a change from 60.0 to 55.1 for sham-treated subjects ($p = \text{NS}$). The mean between-group difference in post-treatment VAS scores was 24.1 points ($p < 0.005$). There was a significant improvement in ROM among LLLT-treated subjects but not sham-treated subjects. There

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were no reports of adverse events. Conclusion: LLLT is safe and effective for temporary pain relief and improving ROM for patients with chronic pain in the neck and shoulder areas due to osteoarthritis, muscle spasms and cervical and thoracic spine strain. Combined with chiropractic medicine and physical therapy, LLLT may help patients lead a normal, active, and healthy life without the need for analgesic medications. ClinicalTrials.gov Identifier: NCT00929305

Keywords: neck pain, shoulder pain, chronic pain, low-level laser therapy, photomodulation, clinical trial

Introduction

Chronic neck pain is a frequent symptom among the general population. In a random survey of 10,000 adults, 34.4% of responders reported neck pain within the last year and 13.8% reported neck pain that lasted for more than 6 months [1]. In another random survey of 1,201 adults, the lifetime prevalence of neck pain was 66.7% [2]. This was further broken down to 6-month prevalence of low-intensity and low-disability neck pain (39.7%), high-intensity and low-disability neck pain (10.1%), and significantly disabling neck pain (4.6%). A systematic search of the medical literature revealed the overall point prevalence of neck pain to be 5.9% to 38.7% (eight studies), a 1-month prevalence of 15.4% to 41.1% (six studies), and a lifetime prevalence of 14.2% to 71% (eight studies) [3]. In all three reports, women were affected by neck pain more than men.

Similar results are found for shoulder pain. A survey of 3,664 adults revealed a point prevalence of 26.4% and a 12-month prevalence of 36.8% for upper extremity disorders [arm, neck and/or shoulder pain] [4]. Chronic pain was reported by 19.0% and women were again most often affected. Among women with nonspecific neck/shoulder pain, the highest prevalence of severe tenderness occurred in the levator scapulae, neck extensors and infraspinatus (18-30%) with a lower prevalence in the upper trapezius, occipital border and supraspinatus (13-19%). In men, the prevalence of severe tenderness was highest in the levator scapulae (13-21%) and 0 to 8% in other anatomical areas [5].

In the workplace, there is some evidence for a positive relationship between neck pain and neck flexion, arm force, arm posture, duration of sitting, twisting or bending of the trunk, hand-arm vibration, and workplace design [6]. Psychosocial factors in the workplace include high quantitative job demands, poor social support, low job control, high and low skill discretion and low job satisfaction [7]. With respect to shoulder pain in the workplace, there is a positive association with heavy physical load, awkward postures such as twisted postures, forward trunk flexure, working with arms above shoulder level, repetitive movements, conducting the same activity for a prolonged period, vibration, and duration of employment [8]. High job stress and non-work-related stress reactions are consistently associated with upper extremity problems [9].

A vast number of treatments have been proposed for the treatment of neck and shoulder pain with varying degrees of effectiveness, including acupuncture, biofeedback, drug treatments (analgesics, antidepressants, epidural steroid injections, muscle relaxants, non-steroidal anti-inflammatory drugs), exercise, heat or cold, manipulation, mobilization, multimodal treatment, percutaneous radiofrequency neurotomy, physical treatments, postural techniques, pulsed electromagnetic field treatment, soft collars and special pillows, surgery, traction, and transcutaneous electrical nerve stimulation (TENS) [10]. Unfortunately, many patients will continue to suffer from chronic pain symptoms following treatment. Among patients treated for nonspecific back and neck pain ($N = 314$), 52% reported pain and back-related disability after 5 years. Among them, 63% reported recurrent or continual pain [11].

Increasing evidence supports the use of low-level laser therapy (LLLT) for treating several health conditions including wound healing, inflammation and edema, and painful conditions [12]. Specifically, LLLT has been beneficial for treating pain associated with chronic joint disorders [13], musculoskeletal pain [14], and chronic low back pain [15]. The results of two systematic reviews indicate LLLT reduces neck pain [16] and provides relief for up to 22 weeks [17] although the results of another review suggests the benefits of LLLT for neck pain are inconclusive [18]. One clinical trial found LLLT was beneficial for

treating painful adhesive capsulitis of the shoulder [19]. In that study, 46 of 50 treated shoulder joints (92%) showed significant improvement at the end of the 8-week treatment period, which was maintained for up to 2 years.

Erchonia Corporation previously performed a randomized, double blind study to assess the beneficial effects of LLLT for alleviating minor neck and shoulder pain (Unpublished data on file, Erchonia Corporation, McKinney, TX). Individual subject-success criteria were defined as a 30% improvement in baseline pain immediately following treatment. Among the 50 patients treated with LLLT, 40 (80%) met or exceeded the individual success criteria by demonstrating a 30% improvement in pain severity *vs.* seven (14%) of 50 sham-treated subjects ($p < 0.05$). For most subjects, the reduction in post-treatment pain was maintained for 24 hours. No adverse events were reported. Based on these results, this LLLT device was given market clearance by the Food and Drug Administration in January 2002, making it the first LLLT device of any kind to receive such approval. The objective of the following randomized, double blind, sham-controlled trial was to further evaluate the efficacy of LLLT for the treatment of chronic shoulder and neck pain and improving upper body range of motion (ROM).

Methods

Participants

This study was performed at three study sites. Subjects were recruited from among adult patients in the investigator's practices seeking treatment of pain due osteoarthritis or a degenerative joint disorder, chronic muscle spasms, or cervical or thoracic spine sprains or strains. The origin of pain was determined by history and physical examination, medication history, and by from previous X-ray, magnetic resonance imaging, and computed axial tomography scan reports. Presenting symptoms included neck or shoulder pain described as ≥ 50 on a 100-point visual analog scale (VAS, see below) and of >30 days duration. Enrolled subjects provided signed informed consent and agreed to refrain other pain

management therapies during the course of the study.

Reasons for study exclusion included an acute painful osteoarthritis, acute muscle spasms, acute cervical or thoracic spine sprain or strain; a known herniated disc injury; an infection or wound in the planned treatment area; use of a steroid medication, narcotic, or over-the-counter analgesic within the previous 24 hours or any other prescription medication prescribed for the relief of pain within the previous 48 hours; pregnancy or lactation.

Study Procedure

Subjects were randomized to receive active or sham LLLT treatment. One investigator was responsible for administering both treatments. This investigator was the only individual present in the room during the treatment phase and did not participate in other pre- or post-treatment activities. Another investigator was responsible for conducting pre- and post-procedure evaluations, determining the pain diagnosis and enrollment eligibility. Patients randomized to the LLLT group were treated with a single-head, low-level diode laser emitting a divergent 635-nm (red) laser light with an energy output of 1 mW (Erchonia[®] PL2000, Erchonia Corporation, McKinney, TX). The sham group was treated with a similar device emitting ordinary red light. All subjects and investigators wore protective eyewear during the treatment procedure.

Study Endpoints

Prior to treatment, a pain rating was recorded for each subject using a 100-point visual analog scale (VAS) where 0 represents no pain and 100 represents worst pain imaginable. Linear range of motion (ROM) was performed to assess patient mobility in the neck-shoulder region using a universal inclinometer. Shoulder ROM was measured from a seated passive abduction. The relaxed position parallel to the side of the body through full extension above head and maximum movement is 180 degrees. Lateral neck ROM was measured in a supine position,

from anatomical position to lateral face over shoulder and maximum movement is 90 degrees. To determine mobility, motion proceeded until it was impeded by pain, muscle restriction, mechanical change, or the normal motion was unimpaired, at which point the degree of range achieved was measured and recorded. Patients were evaluated prior to treatment, immediately post-treatment and after 24 and 48 hours. Immediately following treatment, VAS and ROM assessments were repeated and subjects provided treatment satisfaction rating and perceived treatment group allocation.

Following treatment, subjects were asked to assess their level of treatment satisfaction with respect to their overall improvement in pain using a scale ranging from Very Satisfied to Not at All Satisfied and were asked to indicate their perceived group assignment. Subjects were also evaluated 24 and 48 hours after treatment. At that time, they were asked to grade their physical activity from Very Physically Active to Not at All Physically Active and provide a list of all specific physical activities they performed during the previous 24- and 48-hour periods. Participants were asked to refrain from using any analgesic medications until the 48-hour post-procedure evaluation was completed and to report the use of and rescue medications.

Intervention

Immediately following VAS and ROM assessments, a single LLLT or sham treatment was applied at the sagittal suture along the bilateral cerebral cortex down the cervical anterior and posterior muscles, and towards the shoulders and torso anterior and posterior muscles; bilateral shoulders during passive external rotation of the shoulder encompassing the anterior muscles of the shoulder and pectoralis group while the arm of the patient was bent; bilateral cervical muscles and trapezius muscles during passive lateral flexion of the cervical spine with the subject's head originating in the neutral position; and bilateral sternocleidomastoid and scalene muscles during passive ROM. Each site

was treated for 1 minute providing a total treatment time of 12 minutes.

Primary Endpoint

The primary efficacy outcome measure was the change in subject VAS scores immediately after treatment. The criterion for individual subject success was a 30% improvement. Overall study success was defined as $\geq 30\%$ difference between treatment groups by comparing the proportion of individual successes in each group. This overall study success criterion was determined to be clinically meaningful by the U.S. Food and Drug Administration. The intention-to-treat population included all randomized subjects with a baseline VAS score. The last observation carried forward method was used to impute missing data.

Ethics

The protocol used in this study adhered to the Good Clinical Practice guidelines of the International Conference on Harmonization [20]. The protocol and all related documents were approved by a commercial institutional review board (Western Institutional Review Board®, Puyallup, WA). Each subject provided informed consent prior to participating in any study-related activities. ClinicalTrials.gov Identifier: NCT00929305.

Results

One hundred subjects were screened and 86 were enrolled and completed the study. Among the enrolled subjects, 55 (64%) were diagnosed with pain from multiple origins and 31 (36%) with pain from a single origin. Reported pain was distributed across five locations including the left and right neck, back of the neck, and right or left shoulders with no significant differences between groups seen in Table 1. The mean (SD) duration of pain at enrollment for sham-treated subjects was 82.9 (86.1) months, which was significantly longer than 61.7 (77.2) months for LLLT-treated subjects ($p < 0.05$).

Table 1. Pain Location for Each Treatment Group

	LLLT Group N = 43	Sham Group N = 43
Pain Location, n (%)		
Right Neck	21 (48.8)	22 (51.2)
Left Neck	17 (39.5)	17 (39.5)
Back of Neck	19 (44.2)	26 (60.5)
Right Shoulder	24 (55.8)	19 (44.2)
Left Shoulder	18 (41.9)	21 (48.8)

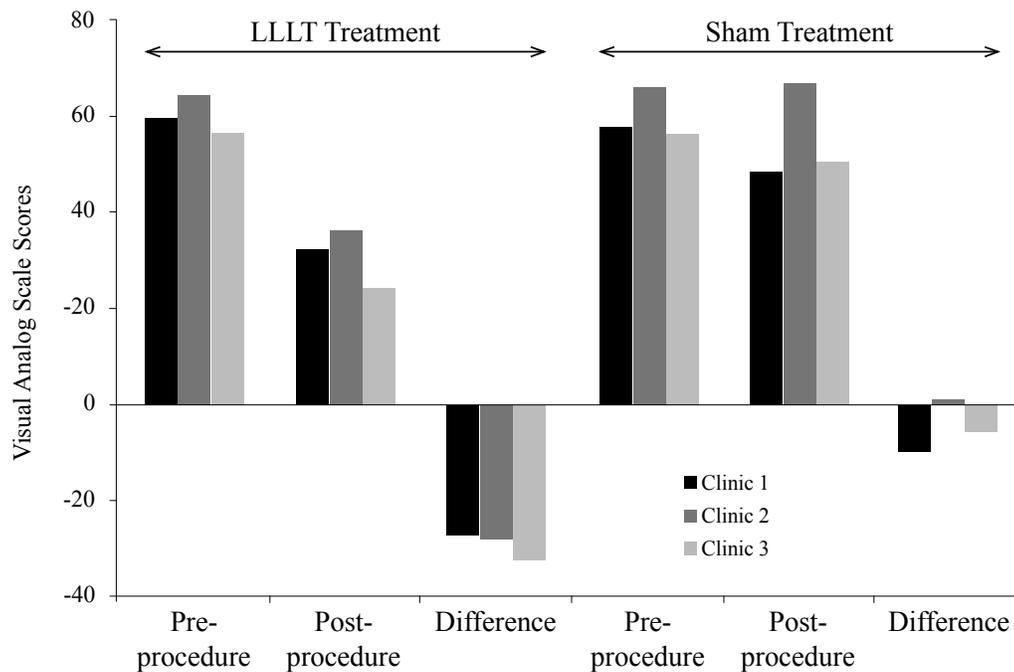


Figure 1. Change in Mean Pain Scores by Treatment Site

Primary Endpoint

Among the 43 LLLT-treated subjects, 28 (65.1%) met the individual subject success criteria vs. six (11.6%) sham-treated subjects ($p < 0.0001$). This difference of 53.5% exceeded the pre-established overall study success criteria by 23.5%. Mean VAS scores decreased by 29.0 points from 60.2 to 31.2 ($p < 0.0001$) while the sham-treated group decreased by 4.9 points from 60.0 to 55.1 ($p = NS$). The mean between-group difference in post-treatment VAS scores was 24.1 points ($p < 0.005$). These improvements were observed at each participating study site as represented in Figure 1.

The significant improvement in VAS scores was independent of the anatomical area treated (for each, $p < 0.0001$; represented in Figure 2). In contrast, improvement in VAS scores among sham-treated subjects occurred only in the back of the neck ($p < 0.05$). When subject results were analyzed by pain duration, significant improvements were observed for all groups, but decreased with increasing pain duration, the results represented in Table 2). Data assessing 24- and 48-hour post-procedure degree of pain on the VAS were not significantly different between test and sham group participants. In addition, when comparing immediate and 24- and 48-hour post-procedure VAS rating, there were no significant differences observed between immediate, 24- and 48-

hour post-procedure VAS ratings (as seen in Figure 3). The lack of different between LLLT- and sham-treated subjects may be due to the use of over-the-counter and/or prescription medications. During the 24- and 48-hour evaluation periods, a significantly greater number of sham-treated subjects consumed rescue medications ($p < 0.005$; shown in Table 3).

Comparison of mean pre- and post-procedure ROM values for LLLT group participants demonstrated a significant improvement for the right side of the neck from 72.7 to 65.7, for the left side of the neck from 74.9 to 66.6, for the right shoulder from 144.2 to 128.9, and the left shoulder from 143.7 to

130.3 (for each, $p < 0.0001$). There was no significant improvement in ROM for any anatomical area among sham-treated subjects.

Among the enrolled subjects, 76 participated in the satisfaction survey. Among subjects in the LLLT group, 89.5% reported being Very Satisfied or Somewhat Satisfied compared to 34.3% of subjects in the sham group ($p < 0.0001$). Conversely, 23.7% of sham-treated subjects were Not Very Satisfied or Not at All Satisfied compared to 2.6% of LLLT-treated subjects.

There were no reports of adverse events.

Table 2. Change in Visual Analog Pain Scale Scores among LLLT-Treated Subjects

Mean Pain Duration (months)	Pre-Treatment	Post-Treatment	Difference (%)	Significance
1-12 (n = 14)	59.0	23.9	35.1 (59.5)	$p < 0.0001$
13-36 (n = 11)	60.7	28.1	32.6 (53.7)	$p < 0.0001$
37-96 (n = 9)	61.3	35.9	25.4 (41.4)	$p < 0.005$
>96 (n = 9)	60.3	41.7	18.6 (30.8)	$p < 0.01$

Table 3. Use of Post-Procedure Rescue Medications

Medication	24 Hours Post-Treatment		48 Hours Post-Treatment	
	LLLTT (n = 35)	Sham (n = 36)	LLLTT (n = 35)	Sham (n = 35)
Over-the-counter	11.1%	20.0%	2.8%	27.3%
Prescription	14.3%	17.1%	11.4%	17.6%

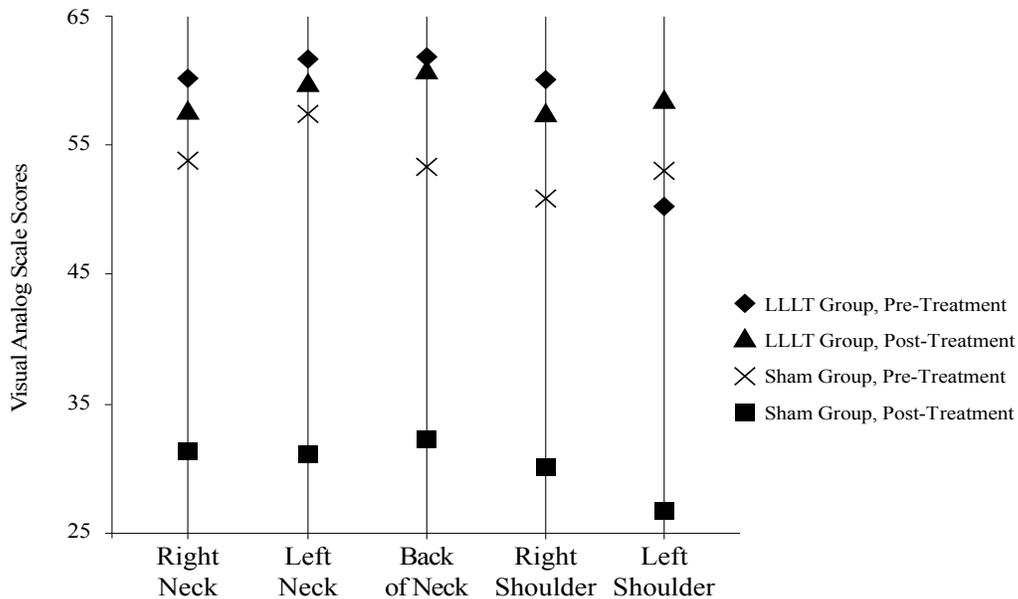


Figure 2. Pre- and Post-Treatment Pain Scores by Anatomical Area.

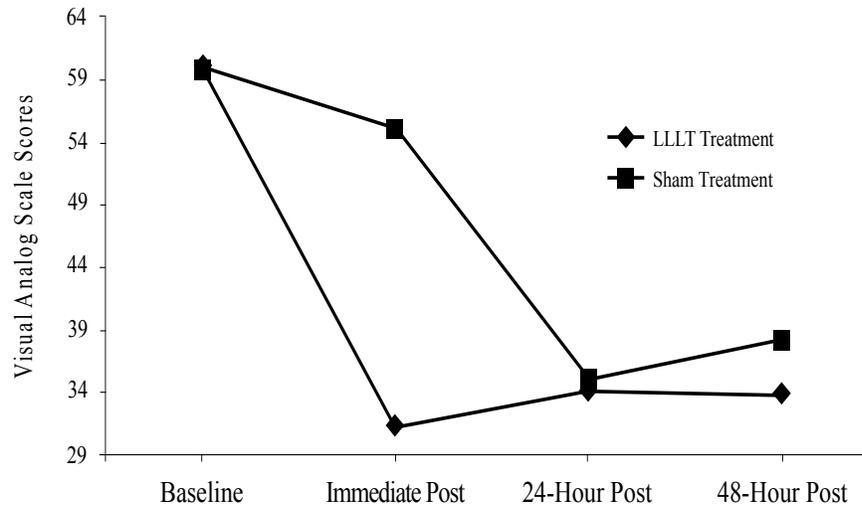


Figure 3. Mean Change in Self-Reported Visual Analog Scale Scores.

Discussion

These results are in agreement with previously unpublished data and those of other investigators demonstrating the safety and efficacy of LLLT for the treatment of painful musculoskeletal conditions [13-16]. The beneficial effects of LLLT in our study persisted for up to 24 hours while others have reported pain relief for up to 22 weeks following LLLT treatment [17]; however, subjects in most other pain studies received multiple weekly treatment sessions, sometimes for many weeks [13]. Other variables that may affect the efficacy of LLLT are light frequency, power density and energy output [13]. While the underlying mechanism whereby LLLT produces its beneficial effects remains under investigation, Chung and colleagues have provided an excellent review of what is currently known about the complex cellular effects of LLLT [12].

LLLT is not a cure for underlying painful injury or conditions and it is important for patients with these problems to seek proper medical care although it may be useful adjunctive therapy. A review of the literature indicates LLLT is already being used to improve the effectiveness of chiropractic manipulation [21, 22], physical therapy [23, 24], postoperative analgesia [25, 26] and to treat a variety of painful disorders ranging from carpal tunnel syndrome [27] to fibromyalgia [28].

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