

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

Journal of Pain & Relief
2019; Vol. 9; No. 1; 1000347

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The Food and Drug Administration granted low-level laser therapy (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.

The study used 58 subjects who were randomized to the active (n=29) and sham treatment groups (n=29).

Outcome measures were the current level of low back pain measured with the visual analogue scale (VAS), Oswestry Disability scores, and overall patient satisfaction with treatment outcomes:

- The "Blinded" Visual Analogue Pain Scale (VAS) "is one of the three most commonly used scales for assessing chronic pain."
- The Oswestry Disability Index (ODI) is "used by clinicians and researchers to quantify disability for acute or chronic low back pain."

The low-level laser used in this study was a 635 nm red laser, developed for treating musculoskeletal disorders by Erchonia® FX-635™; Erchonia Corporation, Melbourne, FL.

The low-level laser used in this study is a Class 2 device comprised of three independent 17 mW, 635 nm red laser 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/cm².

The sham device emitted the same light wavelength (color), but the light was not coherent (it was non-laser LED).

KEY POINTS FROM THIS ARTICLE:

- 1) "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."

- 2) "Non-specific low back pain (LBP) affects people of all ages and is a leading cause of disability."
- 3) "The use of low-level lasers (LLL) has demonstrated beneficial effects for treating a range of painful musculoskeletal conditions, including low back pain."
- 4) There is growing evidence that non-steroidal anti-inflammatory drugs (NSAIDs) and opioids are "less than optimal for treating LBP."
- "The long-term use of NSAIDs is associated with gastrointestinal, renal, and cardiovascular toxicity."
 - "Opioids are less efficacious than other medications while increasing potential patient harm and long-term opioid use does not improve the quality of life of patients with chronic LBP."
- 5) "Low-level laser therapy (LLL), also referred to as nonthermal or cold lasers, has demonstrated benefits for a wide range of painful conditions, including musculoskeletal disorders such as LBP, neck, shoulder pain, and heel pain."
- "Low-level laser refers to lasers emitting red or near-infrared light with power in the range of 0.001 to 500 mW."
- 6) "Laser therapy can significantly reduce pain and disability and improve range of motion in patients with chronic LBP."
- 7) Previous Erchonia non-thermal laser studies have demonstrated:
- Significant improvement in pain severity and range of motion when used to treat neck and shoulder pain.
 - Significant decrease in heel pain associated with plantar fasciitis, with continued improvement in pain recorded in a 12-month follow-up study.
 - Effectiveness for providing temporary acute relief of minor episodic, chronic LBP of musculoskeletal origin.
 - "Almost 75% of treated subjects achieved a $\geq 30\%$ decrease in low back pain scores."
 - "Based off the study success the Food and Drug Administration granted the Erchonia FX635 Laser the first 510(k) market clearance for low-level laser device for the treatment of chronic low back pain."
- 8) Inclusion criteria:
- Visual Analogue Scale (VAS) pain score of ≥ 40 on the 100-point scale.

- The ability to refrain from consuming analgesic, anti-inflammatory or muscle relaxing drugs throughout the study.
- Refraining from other therapies for managing LBP, such as physical therapy, occupational therapy, hot or cold packs, and chiropractic care or acupuncture.

9) “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.”

- “It is the absorbed light that exerts a photochemical effect in the damaged cells.”
- “With respect to photochemistry, the primary site of light absorption is mitochondrial *cytochrome c oxidase*.”
- The application of LLLT to humans induces a “significant increase of *cytochrome c oxidase* and oxygenated hemoglobin concentration at the treatment site.”
- Excitation of *cytochrome c oxidase* increases the production of mitochondrial products such as ATP.

10) “LLLT is being used to reduce pain, inflammation, edema, and enhance healing of various types of injuries.”

11) “The results of our work indicate LLLT is an effective treatment for low back pain and a safer alternative to opioids and NSAIDs.” **[Key Point]**

12) LLLT is “an effective alternative to opioids and nonsteroidal anti-inflammatory medications for treating low back pain.” **[Key Point]**

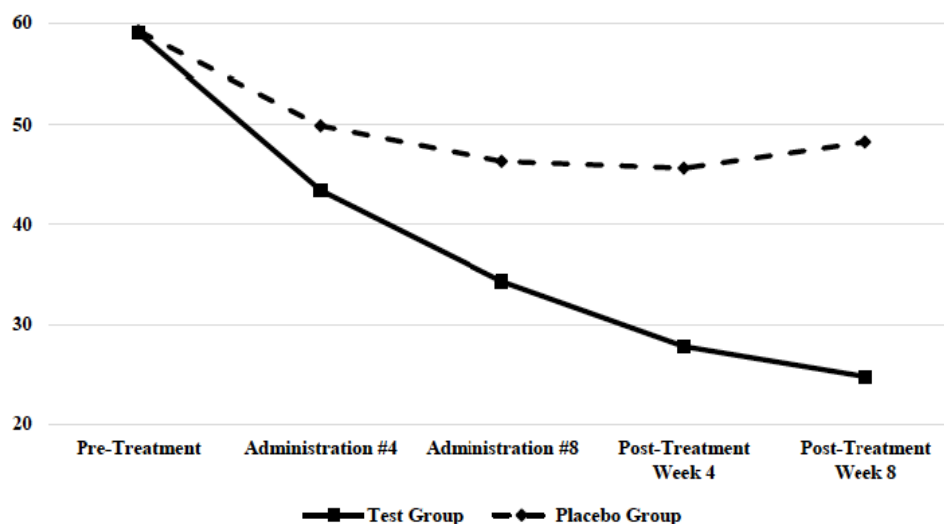


Figure 1: Change in visual analog scale pain scores

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.