LaserTouchOne™
the future of pain relief

White Paper

A Clinical Study Evaluating the LaserTouchOne™ Compared to TENS and LLLT Medical Devices in Treating Chronic Neck and Shoulder Pain

WHITE PAPER

A Clinical Study Evaluating the LaserTouchOne™ Compared to TENS and LLLT Medical Devices in Treating Chronic Neck and Shoulder Pain

Abstract: The LaserTouchOne™(LTO) is a hand-held, ergonomically designed pain relief device that integrates two modalities: low level laser therapy (also referred to as cold laser) and electric stimulation. Laser Health Technologies sponsored a clinical trail to evaluate the safety and effectiveness of the LTO. The study was a 3-arm open-label randomized controlled study in which the LTO was compared to TENS and LLLT devices: The ProM-100 (TENS device) and the Quantum IV LLLT. Participants were randomly selected to receive five treatments with one of the three devices. Participants needed to have pain at least six months duration and a reported pain score of 6 on a 10 point pain/visual analog scale. It can be concluded from the data obtained during this clinical trial and presented in this study report that the LaserTouchOne™ device is safe and effective. The LTO device was successful in reducing pain by at least 2 points in 93.1% of the Completer population. This compared to 83.3% of subjects treated with the TENS device and 62.5% of subjects treated with the LLLT device. In the All Subjects population, the LTO reduced pain in 87.1 % of the population compared to 78.1% of subjects treated with the TENS device and 60.6% of subjects treated with the LLLT device.

INTRODUCTION

The sponsor of this clinical trial, Laser Health Technologies (LHT), conducted this study to evaluate the safety and effectiveness of the LaserTouchOne™ (LTO), a combination low level laser and electric stimulation pain relief device. Since the two treatment modalities combined in the LTO device represent a first-of-a-kind, the Food and Drug Administration (FDA) required the conduct of a clinical trial in which the LTO would be compared to two FDA-cleared devices: TENS and LLLT. The study was designed to be a 3-arm open-label randomized controlled study in which the LTO device is compared to TENS and LLLT devices.

DEVICES

Investigational Device: LaserTouchOne™

The LTO has a single diode red laser for delivery of the low level (cold) laser therapy, and stainless steel nose contact electrodes for delivery of the electrical stimulation. A conductive gel is used as the conduction and transmission point between the device and the study subject's skin.

Control Device: ProM-100 TENS

The ProM-100, a TENS device is provided for use with 2 or 4-electrode pads. The electrical stimulus is delivered by means of adhesive electrodes which are placed on the subject's skin alongside the areas of pain. The device is provided with two controllable output channels. The study Medical Director pre-selected the output channel and 4-electrode treatment for the TENS treatment group.

Control Device: Quantum IV LLLT

The Quantum IV, has a variety of settings for selection by the treating therapist. Both 2-laser or 4-laser diode heads are provided with the system. The study Medical Director chose the 4-laser diode head and pre-selected the LLLT settings, with all subjects in this group receiving the same settings.

STUDY DESIGN

Overview

Subjects were randomized using a 1:1:1 allocation to receive one of the three devices. A computer-generated randomization schedule was provided by LHT's contract statistician. To achieve statistical significance, it was determined that 28 study subjects would be required in each of the three groups.

Subjects who had 'self-reported' pain of at least 6 months' duration and who scored a baseline pain level of 6 or above on the 10 point pain/visual analog scale (VAS) were eligible for consideration to participate in this study. The full inclusion and exclusion criteria are listed below.

Treatment with the devices was provided at the clinical research site by trained therapists. The treatment regimen involved 5 sessions over the course of a two-week period. The study subjects recorded their pain on study forms.

STUDY OBJECTIVE

The objective of this clinical trial was to demonstrate the substantial equivalence of the LTO to the other two technologies for the purpose of supporting a 510(k) application. This required evaluating the safety and effectiveness of the LTO compared to the two selected devices –– in reducing pain level as measured on a 10-point visual analog scale (VAS) in patients with shoulder and/or neck pain that was of at least 6 months' duration, who reported a pain score of at least 6 on the 10-point VAS scale.

STUDY OUTCOMES

Primary outcome

The primary outcome was based on the proportion of treatment responders in each group. A responder was defined as a subject who had an improvement of at least two (2) points from the baseline VAS score over the course of five (5) treatments in at least one VAS measure (neck or shoulder) and no worsening in either measure.

Secondary outcomes:

a) an assessment of mean change in VAS scores for the LTO subjects compared to the two control groups;
b) an assessment of adverse events for the LTO compared to the two control groups; and
c) a 7 day post-treatment follow-up to assess possible long-term analgesic effects.

REGULATORY COMPLIANCE, DEVICE CONTROL, ETHICAL REVIEW AND INFORMED CONSENT

The FDA has categorized the LLLT and TENS medical devices as Class II products, which obtain clearance for marketing through the 510(k) pre-market notification pathway. Clinical trial regulations found in 21 CFR 812 state that an NSR clinical trial may be conducted without FDA's approval of an IDE application. However, Institutional Review Board (IRB) approval is required and was obtained. This study was conducted in accordance with the principles of Good Clinical Practices and according to the abbreviated requirements of the IDE regulations.

Each subject who was enrolled and randomized into the study had consented to participation by signing the IRB-approved Informed Consent form.

All study devices were controlled in a secure location and obtained by the therapists as subjects were scheduled for treatment sessions.

STUDY CONDUCT

The clinical research site selected to conduct this clinical trial was the Pivotal Research Center in Peoria, AZ. This clinical site was selected

because of its access to a large population of potential study subjects and because of its proximity to the study Medical Director. Laser Health Technologies contracted the services of an independent clinical research associate (CRA) to perform on-site monitoring of the study.

SCREENING

Pivotal Research Center's call center was used to pre-screen potential qualified subjects. More than 1,000 individuals were pre-screened to assess their eligibility based on the primary entry criteria. Of those individuals, 102 potential subjects were invited to Pivotal's research facility for formal screening.

ENROLLMENT

Potential subjects were assessed according to the study's protocol entry criteria. Subjects who met all the entry (inclusion and exclusion) criteria were fully informed of the study, provided opportunities to ask questions, and after signing the Informed Consent form, were randomized according to the randomization log generated for the study. 96 subjects were enrolled and randomized to participate in the study.

Inclusion Criteria:

- >18 years of age
- Both males and females are eligible for study participation
- Self-reported neck and/or shoulder pain lasting for >6 months.
- Baseline pain level of 6 or above on a 10-point Visual Analog Scale
- Willing and able to follow protocol required visits
- Willing and able to read and sign IRB approved informed consent and HIPAA authorization for use and disclosure of PHI
- Willing to be randomized to one of the three treatment groups

Exclusion Criteria:

- Recent (within last 6 months) surgery on spine or shoulders
- Known tumor or malignant cancer diagnosis
- Has a demand-type cardiac pacemaker or other implantable active device, known heart arrhythmias, or a history of seizures
- Pregnant or currently breast-feeding
- Currently uses other electrical stimulation device
- Significant change in pain medication in 4 weeks

STUDY PROCEDURES

The treatment sessions were provided at the Pivotal clinical research facility under the direction of Louise Taber, M.D., one of Pivotal's Medical Directors, who served as this study's Principal Investigator. The study treatment regimen required 5 sessions of 10-minute treatments, which were scheduled with each study subject to occur within a two-week period of time.

Subjects recorded their own pain scores on the Pain Assessment case report form (CRF) prior to, and following, each treatment session. If both neck and shoulder areas were treated, these were recorded separately. The baseline was the score recorded prior to the 1st treatment and the final pain score, used for the primary outcome, was the score recorded following the 5th treatment session. Adverse events were assessed and if any existed, they were recorded at each study visit on a CRF.

Follow-Up

One week (± 2 days) following the 5th treatment session, the clinical site coordinator telephoned the study subjects, who were asked to state their current pain score(s). This follow-up pain score was obtained to assess whether there was a longer-term analgesic effect of the treatments, and was specified in the protocol as a secondary

outcome of the study.

STUDY POPULATIONS

Intent-to-treat (ITT) population

The intent-to-treat population is comprised of all randomized subjects. Subjects were evaluated as if they received the treatment to which they were randomized regardless of which treatment was actually received.

Per Protocol (PP) or Completers population

This represents the subset of subjects who received the study treatment to which the subject was randomized, were eligible, were compliant, and who completed all five treatments within the required time frame.

RESULTS

Intent to Treat population (All Subjects)

The Intent to Treat population consisted of 96 subjects, 45 males and 51 females between the ages of 19 and 81 (median age of 38), who enrolled and were randomized into one of the three study groups (31 in the investigational LTO group, 33 in the LLLT group and 32 in the TENS group). This population group is referred to as All Subjects or Intent to Treat.

Withdrawn or lost to follow-up

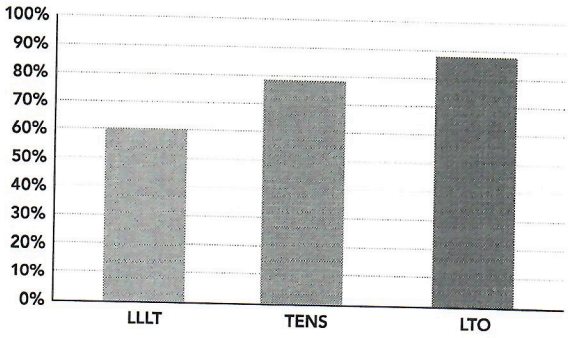
Three subjects (one each LTO, TENS and LLLT) withdrew consent or were terminated after the first treatment for personal reasons, such as inability to comply with the treatment regimen. Two subjects (an LTO and a TENS) were lost to follow-up after the second treatment session.

Per Protocol (Completer)

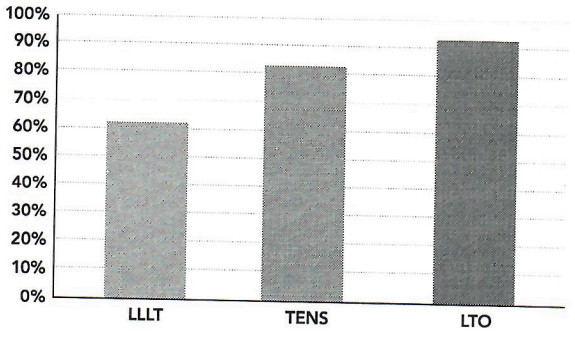
The study's Per Protocol or Completer population consisted of 91 subjects: 29 in the investigational LTO group, 32 in the LLLT group and 30 in the TENS group.

Primary Outcome

This study was designed to show that the LTO device performed as least as well as the two currently marketed devices. The LTO device was successful in reducing pain by at least 2 points in 87.1% of the All Subjects population. This compared to 78.1% of subjects treated with the TENS device and 60.6% of subjects treated with the LLLT device



The same comparisons were performed on the Completer population. The LTO device was successful in reducing pain by at least 2 points in 93.1% of the Completer population. This compared to 83.3% of subjects treated with the TENS device and 62.5% of subjects treated with the LLLT device.



Secondary Outcomes

The LTO device group showed greater reductions in pain from baseline level compared to both of the other device groups. For neck pain,

there was a 1.5 point greater reduction in the LTO group than the TENS group and a 2.2 point greater reduction than the LLLT group. For shoulder pain, there was a 0.4 point greater reduction in the LTO group than the TENS group and a 2.1 point greater reduction than the LLLT group.

Success rates were also compared based on pain reported at the final phone-based follow-up that occurred one week after the 5th -week final treatment for both the All Subjects and Completer populations. In these comparisons there was very little difference (<1%) in success rates between the LTO and TENS groups, but the success rate of the LTO was 13.4% greater than the LLLT device in patients who had received the full treatment regimen.

There were no serious adverse events or serious unexpected device-related adverse events.

Conclusion

This study confirms research data suggesting that low level laser therapy (1) as well as micro current electrical stimulation (2) aids in the increase of ATP production as well as protein synthesis, and facilitates tissue repair. The combination of the two therapies has now been clinically proven to be 93 percent effective in decreasing pain in study patients who received the full treatment regimen The LTO is portable, effective, simple and safe to use as frequently as needed, often eliminating the need for pain medication.

More than 86 million people live with chronic pain, impacting their quality of life and making simple tasks such as lifting a child or swinging a golf club nearly impossible. Include those who suffer from acute pain, and 50 percent of the population lives with pain. The LTO is an unique, clinically proven and FDA-cleared device that can help patients regain their active, pain-free lifestyles.

References

1. Pereira AN, Eduardo CP, and Matson E et al. Effect of low power irradiation on cell growth and procollagen synthesis of culturedfibroblasts. Lasers in Surgery and Medicine. 2002. 31(4): 263-267.

Bjerring P, Clement M, and Heickendorf L et al. Dermal collagen production following irradiation by dye laser and broadband light source. Journal of Cosmetic Laser Therapy. 2002, June;4(2):39-43

Medrado AR, Pugliese LS, and Reis SR et al. Influence of low level laser therapy on wound healing and its biological action upon myofibroblasts. Lasers in Surgery and Medicine.
2003. 32(3): 239-244.

2. Cheng, Ngok, "The Effects Of Electrical Current On ATP Generation, Protein Synthesis And Membrane Transport In Rat Skin," Clinical Orthopedics and Related Research, 171 (Nov.-Dec. 1982) 264-271

A full report is on file with the company