

# **Laser Therapy Applications for Chronic Joint Pain**

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## **ABSTRACT**

A randomized placebo controlled clinical trial to evaluate an adjunct treatment modality for pain associated with knee disorders utilizing a therapeutic (non-surgical) laser is presented. The Theralase TLC 1000 laser was used as an adjunctive modality to standard treatment for knee pain using chiropractic techniques. The primary endpoint was measured by the Visual Analog Scale assessment of pain levels on a scale of 0 - 10. The success criteria for an individual patient in this study was an improvement of 30% or more in the Visual Analog Scale (VAS) from baseline to 12<sup>th</sup> treatment and/or an improvement of 20% or more in the VAS from baseline to 30 day follow-up evaluation. The data obtained in the study demonstrated that the Theralase TLC 1000 therapeutic laser provided significant relief and improvements in all the primary evaluation criteria.

**Keywords:** laser therapy, chronic pain, joint pain.

## OVERVIEW AND INTRODUCTION

Pain, especially its chronic form, is a complex process, which deeply affects a person's life, forcing alterations in professional, private, social and other aspects of everyday activities. Knee pain is the third most frequent ache reported today after low back pain and headache, and followed by neck pain, toothache and stomach ache. Although pain and dysfunction from osteoarthritic pain trouble 40 per cent of adults in the Western world (Darby 1983; Shane and Grant 1987), no successful cure for osteoarthritis has been found to date.

Common methods of treatment for osteoarthritis of the knee include joint surgery, medication, electrotherapy, muscle strengthening and external mechanical load reducing devices (Calabro 1986). The impact of a successful clinical trial in the treatment of chronic non-pathological knee pain using therapeutic means that are conservative and with no side effects is quite significant.

The objective of the research was to assess the effectiveness of laser therapy in the treatment of chronic knee pain. In particular, the research study was focused on measuring the effectiveness of laser therapy using a combination of pulsed and continuous wave laser diodes. The researchers use the Theralase TLC 1000 therapeutic laser for this purpose. The characteristics of these laser diodes and the TLC 1000 therapeutic laser is introduced in the Clinical Study Laser Device section.

Specifically, the research study addressed the following question:

*Do treatments with the Theralase TLC 1000 laser instrument, as an adjunctive therapy, produce significant reduction in chronic pain in the knee joint?*

The primary outcome measure was based on the Visual Analog Scale (VAS) score. It is measured as the percent reduction in VAS score between the baseline value and the 30-day post treatment VAS score.

The research study consisted of a multi-site placebo controlled (single blind) randomized clinical trial. Three private clinics in the Virginia cities of Richmond and Charlottesville were used to conduct the treatments. The 124 participants were randomly assigned to either of the "laser active" or "laser sham" group as described in the Experimental Study section.

The next section gives a brief overview, with a clinical emphasis, of laser physics and the applications of therapeutic lasers. The section Therapeutic Lasers presents details on the different types of therapeutic lasers currently available in the medical market. The therapeutic laser used in the research study is described in the section The Clinical Study Laser Device. The specifics of the research study protocol, methodology and statistical results are presented in the Experimental Study section.

## OVERVIEW OF LASER TECHNOLOGY FOR CLINICIANS

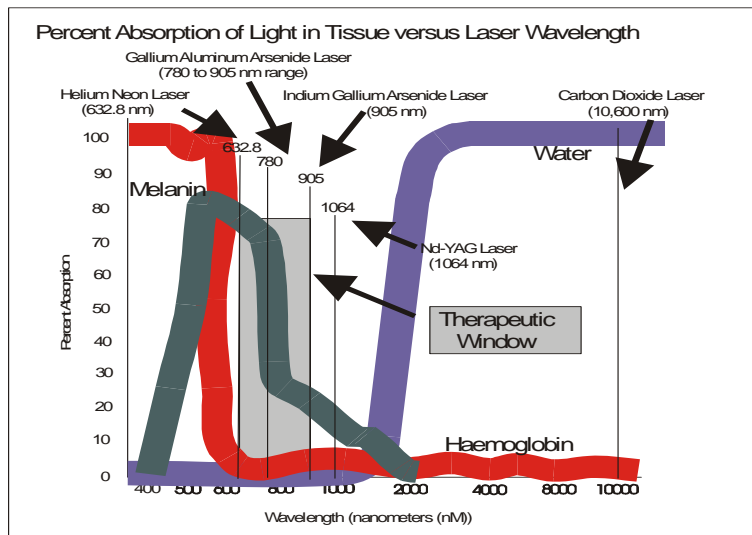
In 1917, Albert Einstein established the physical principle of Light Amplification by Stimulated Emission of Radiation (LASER), thus paving the way for the development of the laser (Simunovic 2000). In June 1960, Dr. Theodoro H. Maiman, an electrical engineer, constructed the world's first laser using a ruby crystal, now known as the ruby laser (Tuner and Hode 1999). In 1965, doctors Sinclair, Knoll and Mester pioneered the way for therapeutic lasers, through their research with human tissue (Mester, Mester and Mester 1985). These lasers do not cut or destroy tissue, but biostimulate the tissue creating a therapeutic effect. Non-invasive or non-surgical lasers are also called "soft" or "cold" lasers.

Therapeutic lasers work by supplying energy to the body in the form of non-thermal photons of light. The body is able to absorb this external energy on a cellular level and transform light energy into chemical energy, which the body uses to accelerate the normal healing rate of tissue for a wide range of ailments.

### Wavelength

The three main components of tissue that affect the absorption of laser photons are water, hemoglobin and melanin. The absorption curves for these three substances versus the laser wavelength will determine the precise impact that a particular laser will have on tissue.

Laser photons have the unique properties of monochromaticity, (a single wavelength), coherence (travels in a straight line) and defined location (concentrated beam). These properties are what allow lasers to penetrate the skin surface, non-invasively, delivering energy directly to the cells which the cells in turn convert into chemical energy.



T. Ohshiro, a leading expert on therapeutic lasers, testifies to the effectiveness of the 905nm diode. He states that the peak of tissue penetration is around 900 nm and that this fact would appear to make the GaAlAs diode system the most effective LLLT (Low-Level Laser Therapy) system for penetrating to the desired depth (Ohshiro and Calderhead 1988).

## Power

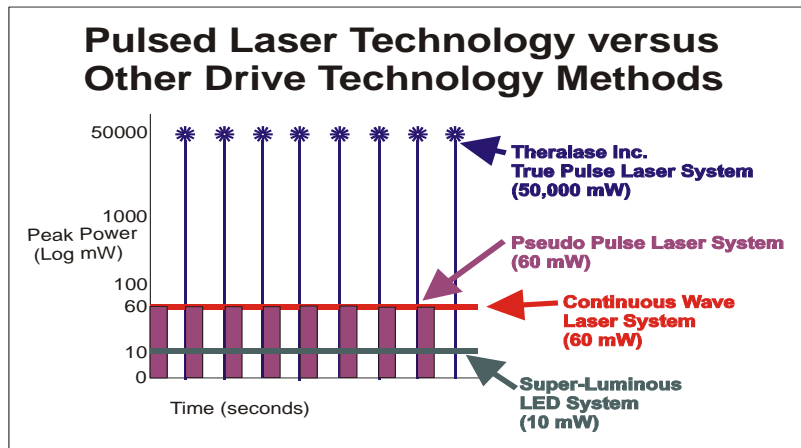
The power of a laser determines how much energy is initially delivered to the tissue surface and along with the wavelength, the power at any given depth of penetration. Biostimulation of the cells is achieved with a minimum amount of power and energy delivered to the target tissue at a particular depth (the “biostimulatory threshold”). Energy density at surface (Joules / centimeter<sup>2</sup>) is equal to the power of the laser in Watts multiplied by the treatment time in seconds, divided by the surface area irradiated in square centimetres.

$$\text{Surface Energy Density} = \frac{\text{Power X Time}}{\text{Surface Area}}$$

The energy of the laser beam will be reduced as it passes through the treatment layers. The choice of wavelength and power of the laser, the quantity and quality of interlaying tissues and the target tissue depth will all have beam attenuating effects.

## Continuous versus Pulsed Wave Laser Technology

A true pulsed laser such as the Theralase therapeutic laser uses a peak power of 50 Watts (50,000 mW) delivering this energy in pulses of an extremely small fraction of a second (200 billionth's of a second) to produce a maximum average power output of 100 mW per infrared diode.



A true pulsed laser system has peak powers that are typically between 100 to 5,000 times greater than the peak power of a continuous wave (CW) system of the same average power rating. Typical CW lasers have powers between 10 mW and 500 mW. The Theralase laser system achieves much greater tissue penetration than CW lasers by delivering powerful but extremely short bursts of energy versus a continuous output, which has difficulty penetrating different tissue densities.

## Types of Laser Delivery Systems and Applications

Probes are typically cylindrical in shape; battery powered and contains 1 to 3 low-power CW laser diodes. They are used in the superficial treatment of wound peripheries, small joints and acupuncture points.

Clusters are applicator heads that contain many CW or pulsed laser diodes that are of various or uniform wavelengths, powers etc.. Clusters that contain multiple red CW laser diodes are used in the superficial treatment of wounds and dermatological conditions. Clusters that contain multiple NIR pulsed laser diodes are used to treat wound beds, large joints and deep anatomical structures. Clusters that use a combination of wavelengths and power technologies, like the Theralase TLC 1000 device for deep musculoskeletal applications, can be optimized to effect particular conditions.

Scanners are technologies that allow large areas to be automatically covered (or “painted”) by the laser instrument. This is accomplished by firing the laser beam(s) through a series of moving mirrors and projecting the beam(s) through the treatment region.

## Basic Procedures in Laser Therapy

For a laser system to provide optimal penetration through the skin it must be at an incident angle of 90 degrees (perpendicular to the skin). Additionally, laser probes and clusters should be in direct contact with the skin. This will minimize any reflection from the skin's surface and allow the best penetration into the tissue. The Theralase TLC1000 therapeutic laser system's design facilitates that each and every probe is always in direct contact with the skin surface, thus minimising surface reflection.

## **THE CLINICAL STUDY LASER DEVICE**

The TLC 1000 Therapeutic Medical Laser System (Figure 1) is a Class 3B medical laser system. Applications of the Theralase laser technology in Canada and in Europe have demonstrated its efficacy in the relief of pain associated with soft tissue conditions. The TLC 1000 Therapeutic Medical Laser has been approved for therapeutic and medical uses in many European countries, Japan, Canada, and also in many East European countries.

The System consists of a TLC 1000 laser controller unit with internal TLC 1001 battery, TLC 900 multiple laser probe, TLC 154 external power supply, TLC 155 hospital grade power cord, TLC 901 laser safety glasses, Operator's Manual and a carrying case.



**Figure 1. The Complete TLC 1000 Therapeutic Laser System**

The TLC 900 laser probe consists of a cluster of five 905 nanometer near infrared (NIR) laser diodes and four 660 nanometer red laser diodes. The laser probe is capable of emitting laser energy in the NIR with a maximum of 100 mW average power per diode and in the visible range with an average power of 25 mW per diode.

The TLC-900 multiple laser probe is used in direct contact with tissue in order to emit photons of non-invasively into the tissue according to a pre-programmed protocol.

The TLC 1000 laser controller and TLC 900 multiple laser probe have the following characteristics:

**Input:**

- Input power, 110 to 120 VAC
- Frequency, 50/60 Hz

Output:

- Maximum average power, 100 milliwatts per NIR diode, 25 milliwatts for visible diode
- Frequency, 0-10,000 Hertz
- Wavelength, 905 nanometers for NIR diodes, 660 nanometers for visible diodes
- Beam Spot Size, 0.01 centimeters<sup>2</sup>
- Pulse Duration, 200 nanoseconds
- Energy Density, 600 Joules/cm<sup>2</sup>/min per 5-probe cluster
- Class, 3B laser diodes
- Weight, 2 kilograms
- Dimensions, 23.3 cm x 13.4 cm x 8.8 cm

## **EXPERIMENTAL STUDY: CHRONIC KNEE PAIN**

The clinical study conducted was a randomized, single blinded placebo controlled to evaluate an adjunct treatment modality for pain associated with knee disorders utilizing the TLC 1000 Therapeutic Medical Laser System. The TLC 1000 laser was used as an adjunctive modality to standard treatment for knee pain using chiropractic techniques. The chiropractic treatment techniques were consistently applied as a baseline therapy to all participants regardless of their laser assignment into either group A or B. The baseline chiropractic treatment consisted of adjustments as taught in CCE accredited schools of chiropractic.

Chronic knee pain is one of the most common reasons for visits to a family practitioner. Chronic knee pain can be related to disease such as osteoarthritis or associated with overuse or untreated injuries to muscles, ligaments, or tendons (The Philadelphia Panel 2001). Walker and Stelian and colleagues (Walker 1995; Stelian, et al 1992) observed beneficial effects in randomized controlled trials of low level laser irradiation in the treatment of knee pain associated with osteoarthritis.

The objectives of this study were to evaluate the safety and efficacy of low level laser therapy in the therapeutic treatment of knee pain. The safety aspect of the study was evaluated in terms of reported clinical complications and/or unanticipated adverse effects associated with generally accepted clinical modalities of treating knee pain. The efficacy of the study was evaluated by the assessment of pain levels via the Visual Analog Scale (VAS) measurement. Research has confirmed that a placebo effect can sometimes improve a patient's condition simply because the person has the expectation that it will help. It is not uncommonly reported in literature to have a placebo effect of up to 30% (Nordenberg 2000).

The Visual Analog Scale (VAS) has been validated worldwide and is quite reproducible and accepted by the medical community, especially, neurology and orthopedic specialists (Huskinsson 1974; Million et al 1982; McCaffery and Pasero 1999; Turk and Melzack 2001). The VAS is utilized as a primary indicator for measuring pain levels and is a landmark indicator of successful treatment of knee disorders.

The study was designed to include a total of 126 subjects equally divided into two groups at three independent study sites. Each study site was allocated forty-two sealed coded envelopes containing the coded Laser designation to be assigned in a sequential order as eligible subjects were enrolled in the study. At the end of the study four coded envelopes (1 A and 3 B) were not used, thus ending the study with a total subject enrollment of 122 subjects. Of the 122 subjects enrolled, 82.8% (101/122) completed the study with the 30 Day post treatment follow up evaluation. The dropout rate for this study was 10.7% (13/122) and the lost to follow up rate was 4.9% (6/122). There were 2 of the 122 subject files (1.6%) that were not included in the final data analyses due to discrepant/conflicting case report forms. Accountability for the total subject enrollment by individual investigative site is shown in Table 1.

**Table 1. Subject Accountability**

<b>Number of Subjects:</b>	<b>Total</b>	<b>Site 101</b>	<b>Site 102</b>	<b>Site 103</b>
Allocated	126	42	42	42
Not Used	4	0	4	0
Enrolled	122	42	38	42
Drop-Outs	13	9	2	2
Discrepant Files	2	0	2	0
Lost to Follow Up	6	0	4	2
Completed Study	101	33	30	38

Of the 122 subjects enrolled, 101 completed the 30 day follow up evaluation. Table 2 shows the break down of the subjects from initial enrollment, treatment sessions 1, 3, 6, 9, and 12 and the 30 Day post-treatment follow-up evaluation.

**Table 2. Multi-Center Patient Accountability**

(With respect to enrollment, treatment and follow up attendance)

	<b>Laser A (Active) n (%)</b>	<b>Laser B (Sham) n (%)</b>	<b>Total A + B n (%)</b>
Randomized Enrollment	62 (100%)	60 (100%)	122 (100%)
Completed Treatment 1	62 (100%)	57 (95.0%)	119 (97.5%)
Completed Treatment 3	59 (95.2%)	55 (91.2%)	114 (93.4%)
Completed Treatment 6	55 (88.7%)	49 (81.2%)	104 (85.2%)
Completed Treatment 9	55 (88.7%)	50 (88.3%)	105 (86.1%)
Completed Treatment 12	55 (88.7%)	50 (88.3%)	105 (86.1%)
30 Day Follow Up	53 (85.5%)	48 (80.0%)	101 (82.8%)
Drop-Out / Terminations	6 (9.6%)	7 (11.7%)	13 (10.7%)
Lost to Follow Up	3 (4.8%)	3 (5.0%)	6 (4.9%)
Discrepant Data Files	0 (0%)	2 (3.3%)	2 (1.6%)

A summary of the demographics and baseline values for subjects that completed the study through the 30 day follow up evaluation is provided in Tables 3. The results include the number of subjects in each treatment group, mean baseline values, gender and age range.

**Table 3. Demographic Characteristics for Subjects Completing 30 day Follow up**

<b>Parameter</b>	<b>Active Laser</b>	<b>Sham Laser</b>
<b>Number</b>	53	48
<b>Baseline Value VAS</b>	Mean (sd) 6.16 (2.05)	Mean (sd) 6.04 (1.89)
<b>Male</b>	31	33
<b>Female</b>	22	15
<b>Age Range</b>	30 - 80	25 - 80

## METHODS AND MATERIALS

### Outcome Measures

The primary endpoint was measured by the Visual Analog Scale assessment of pain levels on a scale of 0 - 10. The success criteria for an individual patient in this study was an improvement of 30% or more in the Visual Analog Scale (VAS) from baseline to 12<sup>th</sup> treatment and/or an improvement of 20% or more in the VAS from baseline to 30 day follow-up evaluation. The success criteria for the study as a whole was that the responder rate for VAS ( $\geq 30\%$  improvement at 12<sup>th</sup> treatment or  $\geq 20\%$  improvement at 30 day follow up) would be significantly greater in the active TLC 1000 Laser group than in the Sham Laser group.

The VAS was used to record the subject's present pain level without influencing their response by using descriptive terms of pain severity. The scale is a vertical line. At the bottom end of the scale are the words "No Pain." At the top end of the scale are the words "Worst Pain Possible.

The participant was instructed to place a line between the top and bottom ends of the line to indicate their level of pain. A linear scale of ten equal divisions is placed over the vertical line by the Biostatistician to quantify the patient response. Serial responses are compared using the results from the numerical overlay.

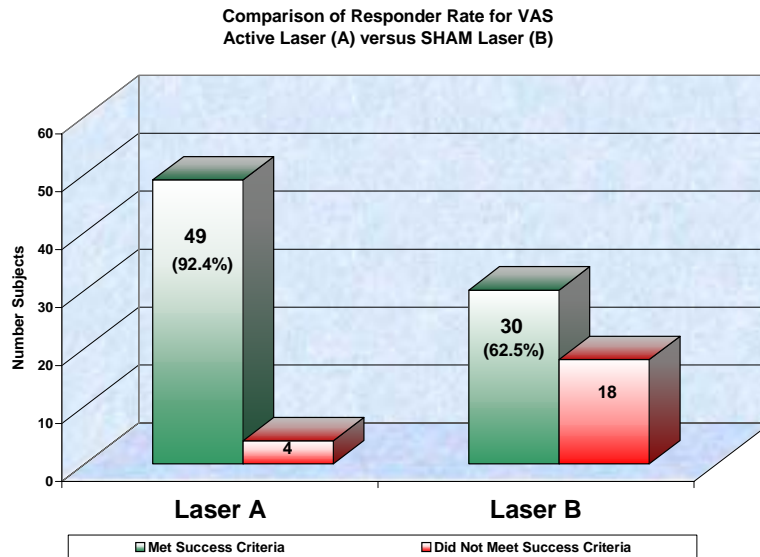
All participant data for the VAS parameters were analyzed by the analysis-of-variance (ANOVA) and the VAS parameter was analyzed by the Repeated Measures techniques. The statistical analyses were conducted utilizing SAS, Version 8. The data were analyzed to determine the differences and/or whether a significant difference exists between the pre-laser treatment and post-laser treatment data for the mean values of these parameters.

A comparison of the endpoint criteria characteristics was analyzed utilizing patient data for all patients completing the 30 day follow up evaluation. The data as seen in Tables 4 and 5 show the percent improvement in the pain level for the Active Laser (A) group of 52.9% as compared to 35.9% for the Sham Laser group between pre-treatment baseline mean values and the mean values from the 12<sup>th</sup> treatment VAS values. The data are inclusive of all participants not just those meeting the success criteria.

In addition, the successful responder rates for all patients that completed the full 12 laser treatments and the 30 day follow-up evaluations for the end-point parameter for the Active Laser group and the Sham Laser group are shown in Table 4.

**Table 4. Successful Responder Rate Active Laser vs. Sham Laser**

End-Point Parameter	Active Laser		Sham Laser	
	Number	Passed (%)	Number	Passed n (%)
VAS	53	49 (92.4%)	48	30(62.5%)



### Statistical Results

A set of t-tests (ANOVA) for independent samples and repeated measures were used to assess the efficacy of low level laser treatment for subjects with completed data through the 30 day follow up evaluation. The t-tests were performed to assess differences between active and Sham Laser groups at baseline, at each of the 1<sup>st</sup>, 3<sup>rd</sup>, 6<sup>th</sup>, 9<sup>th</sup> and 12<sup>th</sup> treatment and at the 30 day follow up intervals. The repeated measures assessed longitudinally the treatment sessions and 30 day follow intervals. Repeated measure analysis p-value = 0.04 shows that the differences of VAS scores between the Active Laser group and the Sham Laser group subjects over time are statistically significant.

In summary, t-tests for independent samples and repeated measures analyses of variance demonstrated statistically significant differences and nonsignificant trends between subjects treated with the TLC 1000 Active Laser (Group A) and subjects treated with the Sham Laser (Group B). Table 5 reflects the statistical evidence in support of the efficacy of the TLC 1000 Therapeutic Medical Laser in the management of pain associated with knee disorders.

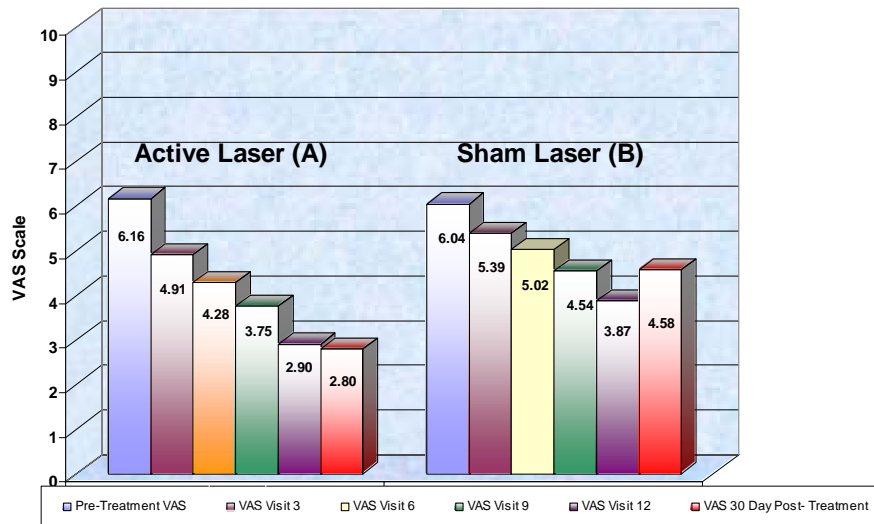
Means, standard deviations, and t-test p-values for baseline, treatment and follow up sessions are presented in Table 5. There were statistically significant differences between the Active and Sham Laser groups at Visit 12 and 30 day follow up. In addition, there were non-significant trends at baseline and treatment visits 1, 3, 6 and 9. For each of these results, the Active Laser groups mean VAS scores were lower than the Sham Laser group meal score.

**Table 5. Summary of VAS (Results of Repeat Measures Analyses)**

<b>Time Interval</b>	<b>Active Laser (<u>n</u> =47) Mean (SD)</b>	<b>Sham Laser (<u>n</u> = 46) Mean (SD)</b>	<b>p-value</b>
Baseline	6.32 (1.43)	6.61 (1.45)	
Treatment Visit 1	6.2 (2.0)	6.0 (1.9)	0.77
Visit 3	4.9 (2.2)	5.4 (2.1)	0.32
Visit 6	4.3 (2.1)	5.0 (2.6)	0.10
Visit 9	3.8 (2.3)	4.5 (2.3)	0.12
Visit 12	2.9 (2.0)	3.9 (2.8)	0.05*
Follow-up 30 Day Post Treatment	2.8 (2.4)	4.6 (2.6)	<0.01*

\*p < .05.

**Comparison of Mean VAS Scores Over Time  
Active Laser A versus Sham Laser B**



## **CONCLUSIONS**

The resulting outcome measures obtained from the clinical trial demonstrates that the TLC 1000 Therapeutic Medical Laser System provided significant relief and improvements in the primary evaluation criteria. The TLC 1000 Therapeutic Medical Laser passed the primary endpoint based on the VAS scores. The Active TLC 1000 clearly improved the pain level by reducing the VAS scores by 52.9% at the 12<sup>th</sup> Visit and 54.5% at the 30 day follow up evaluation. Utilizing the t-test and repeated measures analysis techniques, the p-values at the 12<sup>th</sup> visit and 30 day follow up for the VAS showed a statistically significant difference at the 0.05 level between the Active Laser and the Sham Laser. The p-values between the two groups were 0.05 at 12<sup>th</sup> Visit and less than 0.01 at the 30 day follow evaluation.

The reported clinical trial clearly demonstrated that the TLC 1000 Therapeutic Medical Laser provides relief from chronic pain associated with knee disorders.

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