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MEDICAL | SCIENTIFIC REPORT

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Mechanisms of Low Level Light Therapy.

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ABSTRACT

The use of low levels of visible or near infrared light for reducing pain, inflammation and edema, promoting healing of wounds, deeper tissues and nerves, and preventing tissue damage has been known for almost forty years since the invention of lasers. Originally thought to be a peculiar property of laser light (soft or cold lasers), the subject has now broadened to include photobiomodulation and photobiostimulation using non-coherent light. Despite many reports of positive findings from experiments conducted in vitro, in animal models and in randomized controlled clinical trials, LLLT remains controversial. This likely is due to two main reasons; firstly the biochemical mechanisms underlying the positive effects are incompletely understood, and secondly the complexity of rationally choosing amongst a large number of illumination parameters such as wavelength, fluence, power density, pulse structure and treatment timing has led to the publication of a number of negative studies as well as many positive ones. In particular a biphasic dose response has been frequently observed where low levels of light have a much better effect than higher levels. This introductory review will cover some of the proposed cellular chromophores responsible for the effect of visible light on mammalian cells, including cytochrome c oxidase (with absorption peaks in the near infrared) and photoactive porphyrins. Mitochondria are thought to be a likely site for the initial effects of light, leading to increased ATP production, modulation of reactive oxygen species and induction of transcription factors. These effects in turn lead to increased cell proliferation and migration (particularly by fibroblasts), modulation in levels of cytokines, growth factors and inflammatory mediators, and increased tissue oxygenation. The results of these biochemical and cellular changes in animals and patients include such benefits as increased healing in chronic wounds, improvements in sports injuries and carpal tunnel syndrome, pain reduction in arthritis and neuropathies, and amelioration of damage after heart attacks, stroke, nerve injury and retinal toxicity.

Keywords: biostimulation, low level laser therapy, wound healing, biomodulation, cold laser, action spectra

1. HISTORY

In 1967 a few years after the first working laser was invented, Endre Mester in Semmelweis University, Budapest, Hungary wanted to test if laser radiation might cause cancer in mice [1]. He shaved the dorsal hair, divided them into two groups and gave a laser treatment with a low powered ruby laser (694-nm) to one group. They did not get cancer and to his surprise the hair on the treated group grew back more quickly than the untreated group. This was the first demonstration of "laser biostimulation". Since then, medical treatment with coherent-light sources (lasers) or noncoherent light (light-emitting diodes, LEDs) has passed through its childhood and adolescence. Currently, low-level laser (or light) therapy (LLLT), also known as “cold laser”, “soft laser”, “biostimulation” or “photobiomodulation” is practiced as part of physical therapy in many parts of the world. In fact, light therapy is one of the oldest therapeutic methods used by humans (historically as solar therapy by Egyptians, later as UV therapy for which Nils Finsen won the Nobel prize in 1904 [2]). The use of lasers and LEDs as light sources was the next step in the technological development of light therapy, which is now applied to many thousands of people worldwide each day. In LLLT the question is no longer whether light has biological effects but rather how energy from therapeutic lasers and LEDs works at the cellular and organism levels and what are the optimal light parameters for different uses of these light sources.

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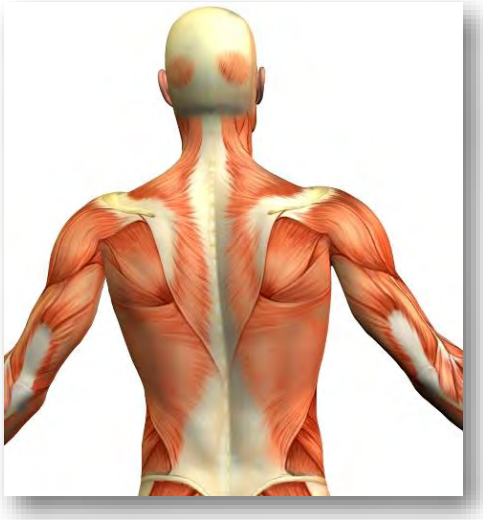

Why Class IV Laser Therapy?

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INTERNAL DOSIMETRY: COMBINING SIMULATION WITH PHANTOM AND EX VIVO MEASUREMENT

Bryan J. Stephens, PhD, Wendy Baltzer, DVM, PhD, DACVS, Phil Harrington, DC, CMLSO

Introduction

Internal dosimetry of laser therapy is far too often overlooked or "guesstimated", but is crucial information for the design of treatment protocols and prediction of biological efficacy. In vitro studies have given us a general idea of the range of biostimulatory doses, but their results do not and should not be directly extrapolated to form conclusions in vivo.

The science of dosimetry has been extensively developed in other wavelength ranges of the electromagnetic spectrum to different degrees of precision based on the danger of exposure of each. Though we do not need the sub-millimeter accuracy of the radiation oncologist who delivers ionizing radiation that can destroy individual cells, the techniques they have developed offer a sensible guide to understanding the photon transport in biological tissue. Here we employ some of these tools as we aim to bridge this gap and understand exactly how dose is distributed at depth in the body.

Materials and Methods

Wavelengths investigated were 800 nm and 970 nm at powers ranging from 0.1 - 12 Watts using the K-1200 (K-LaserUSA, Franklin, TN). First-order predictions were made from power measurements on incremental depths in water and tissue phantoms. Second-order estimates were established by Monte Carlo photon transport simulation on actual MRI data with literature-referenced values of scatter, absorption, and reflection coefficients. Finally, the most robust data came from ex vivo Si photodiode detector measurement on six canine cadavers in a variety of anatomical geometries.

2.1 First-Order Approximation

Power meter employed was the PLUS (LaserPoint, Vimodrone, Milano, Italy) using the "LD" calibration setting (quoted by the manufacturer as appropriate for the 800-900 nm range; no significant differences in sensitivity were noted for the 970 nm wavelength).

The meter was placed face-up on a stand to maintain ambient airflow through the heat sink fins. On top was placed a 2 mm thick piece of aluminum with a 1 cm diameter hole punched through that served as an aperture so that spatial independence of the detector head could be verified and radial scattering could be measured. On top of this was placed a thin plastic beaker, whose attenuation was minimal (transmission loss of 2% was measured and all the data corrected accordingly). The laser's handpiece was fixed normal to and at a distance of 12 cm from the beaker/detector interface and irradiation was carried out. In the beaker, layers of water from 0.5 - 10 cm in 0.5 cm increments were added, and the power transmission measured. At each depth of water, the detector was moved relative to the central axis of the beam (laser handpiece position kept constant) to measure transmission values at distances of 0 - 1.5 cm in 0.5 cm increments from the central axis.

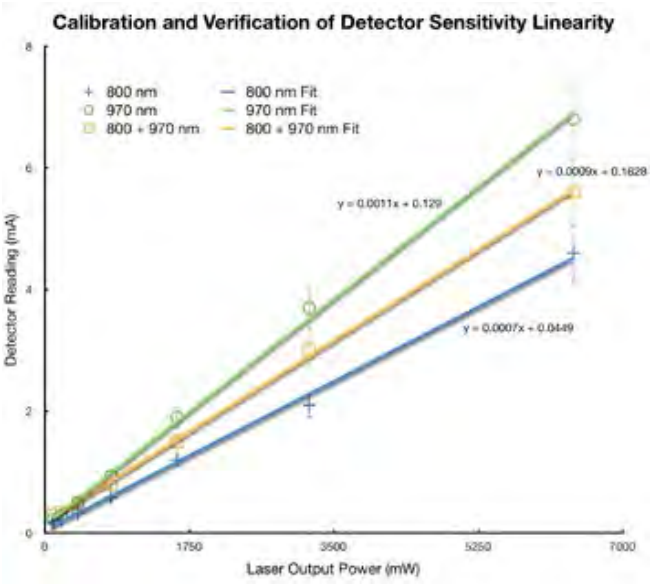

Figure 1: Measurement of Linearity of Response vs Exposed Power for the FDS-1010-CAL for each Wavelength

2.2 Second-Order Approximation

Combining techniques from radiation oncology and neurology, simulations can be performed to give the most detailed prediction of dose deposition. Radiation oncologists pre-plan their irradiations with full 3-dimensional simulations tracking accelerator head motion and collimator leaf manipulation and overlay these parameters on computed tomography images of the patient to ensure highly localized dose distributions. In fact, most linear accelerators on the market come equipped with software capable of performing such estimations, for quality assurance as well as by federal mandate. The interaction of ionizing radiation with biological matter is substantially different from infrared radiation, however, and so the core interactions can

not be modeled the same way. Neurologists started using radiation in the near-infrared (NIR) to map the oxygenation of brain tissue since gray- and white- brain matter have distinct signatures in the NIR. To this end, there have been several algorithms developed to track NIR photon transport; used here was the Monte Carlo eXtreme (MCX) [1].

Combining these resources has lead to the first Monte-Carlo simulation in laser therapy. The input parameters for the simulation are the absorption coefficient, scattering coefficient, refractive index, and anisotropy factor for each type of tissue. MRI images are used to delineate the exact location of each tissue type and a 7-dimensional matrix (three spatial and 4 parameters) can be formed. Then with enough processing time a computer can initiate a fixed number of photons, originating at any voxel in the matrix, initially traveling in any direction from that origin, and track their transport to every voxel at each time step. Run the simulation for long enough and you have a full laser therapy session modeled and the deposited dose at every voxel recorded.

2.3 Third-Order Approximation

Using a cadaver model and a sensitive photon detector system, a full ex vivo dosimetric profile can be established. Resecting various layers of dermis, fat, muscle, and connective tissue, the detector was placed at a variety of depths and the power density delivered to each depth was compared to the surface skin exposure. Normalizing these curves, an accurate model can be formulated to develop pre-planned treatment protocols and quantify the dose dependence of biological effects, post-irradiation. Used were two Si detectors (FDS-100-CAL and FDS-1010-CAL, ThorLabs, Inc., Newton, NJ) whose calibration is NIST traceable, but a power-linearity and wavelength-dependence calibration test was performed on each. Figure 1 shows the measured photocurrent vs exposed power for the full range of experimental values and their fit to a linear model.

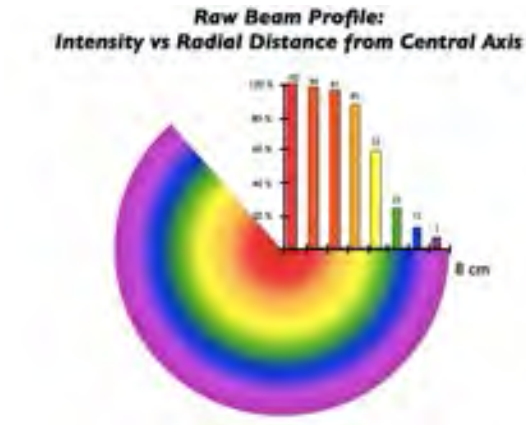

Figure 2: 2-Dimensional Beam Intensity Profile

The same aluminum aperture setup was used to test the spatial sensitivity differences on different parts of the detector wafer, with no significant differences found. This setup was also used to measure the 2-dimensional beam intensity profile, shown in Figure 2 which is clearly not uniform throughout the entire cross-section.

Results

3.1 First-Order Approximation

You can see from the full three-dimensional dose profile in Figure 3 that even in a simple water phantom at the most transparent wavelength (relative to the rest of the NIR) radiation intensity is strongly attenuated with depth. The anisotropy factor at this wavelength in water is about 0.8 which means that 80% of the scattering is directed in the forward hemisphere. This counteracts the absorption losses somewhat, but as you can see the attenuation is still quite steep.

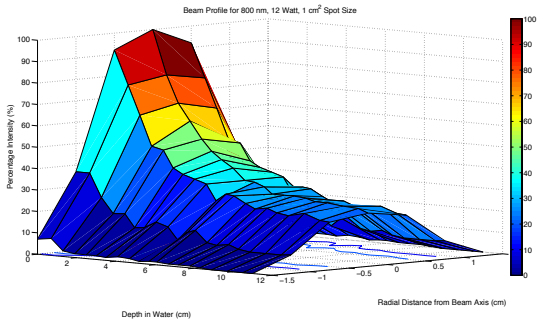

Figure 3: Measured 3-Dimensional Beam Profile in Water Phantom

3.2 Second-Order Approximation

Figure 4 shows the progression of stages in the simulation process. First, the anatomical positions of different tissue types need to be extrapolated from the MRI by a trained radiologist or surgeon. From there, the relevant literature was searched for optical properties of each tissue type at the given wavelength [2-4]. These parameters are overlaid on a contour map extracted from the MRI so that each voxel contains the absorption coefficient, scattering coefficient, anisotropy factor, and refractive index of the corresponding tissue type at the given wavelength. This particular simulation then initiated one billion photons each of which with the initial direction indicated by the red arrow and initial poistion distributed according to the measured 2-dimensional cross-sectional beam profile measured in Figure 2. The simulation then ran for fifty, 0.1 nanosecond times steps (remember radiation moves at the speed of light and so all the energy gets deposited very quickly) and recorded the absorbed dose in each voxel. Plotted are the values only in the plane of the MRI image, binned in 10% intervals, and normalized to 100% at the surface.

3.3 Third-Order Approximation

Ex vivo measurement is the most accurate, humane form of internal dosimetry estimation. Figure 5 shows the raw data taken on eight canine cadavers of a variety of breeds and in a variety of anatomical arrangements. They are plotted here for simplicity and to show the overall exponential trend in beam attenuation, but this plot does not take into account all of the different types of tissue through which the beam penetrated for each measurement.

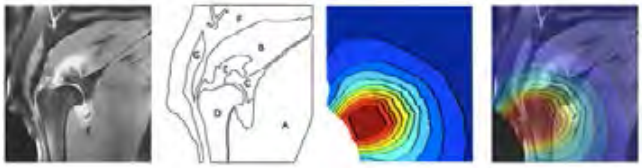

Figure 4: Stages of the Monte-Carlo Dosimetric Simulation. The different tissue types were identified as follows: A - muscle (subscapularis, teres major, latissimus dorsi, triceps) B - muscle (supraspinatus) C - bone (scapula) D - bone (humerus) E - tendon (of the supraspinatus) F - muscle and fat (omotransversarius) G - muscle (cleidobrachialis).

As you can see from Figure 4, these measurements included several combinations of skin/hair, fat, muscle, tendons/ligaments, and bone to compile a full dosimetric profile. Also, several beam paths were evaluated to acquire optimal penetration angles.

Example

The depth from the surface to the center of the joint where the detector was placed was measured (by digital caliper) to be 2.4 cm. From the curve in Figure 3, and assuming this dog to be a simple tank of water, we would predict the beam to transmit about 50% of its intensity to this depth. From an MRI-Monte Carlo simulation of this anatomical configuration, and including the estimated attenuation of skin, bone, fat, muscle, and joint tendons, we predict transmission of something more like only 5%. From the Si photodiode measurement, we find that only about 2% of the beam is transmitted to the center of the joint.

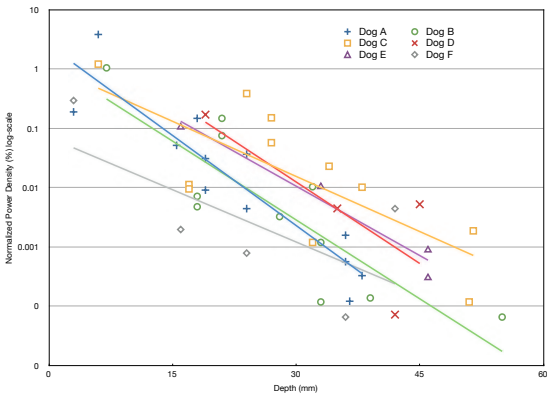

Figure 5: Generalized Penetration Data for Eight Canine Cadaver Legs

Discussion and Conclusions

As expected, the first-order experiments under-estimated the beam attenuation, but Monte Carlo results served as an accurate prediction of ex vivo observation. Dose delivered at therapeutic depths are up to 2 and 3 orders of magnitude less than those delivered to the surface. With enough data using a variety of skin, tissue, and bone thicknesses, this type of analysis will yield a full dosimetric profile.

Much more work remains to be done in quantitative internal dosimetry of laser therapy. This study, however, is a necessary step in the right direction on the path of understanding the orders of magnitude involved. Once further enlightened, we will be able to review both existing and future studies to better understand the biological effect of the delivered dose that came from the reported treatment prescriptions, and eventually converge on the optimal treatment parameters for clinical success.

Figure 6: Radiograph Examples of Anatomical Orientation of Detectors in Cadavers

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Journal of Athletic Training 2012:47(2):178–183

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original research

Limb Blood Flow After Class 4 Laser Therapy

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*Department of Applied Physiology and Kinesiology, University of Florida, Gainesville; †Palm City, FL

Context: Laser therapy is purported to improve blood flow in soft tissues. Modulating circulation would promote healing by controlling postinjury ischemia, hypoxia, edema, and secondary tissue damage. However, no studies have quantified these responses to laser therapy.

Objective: To determine a therapeutic dose range for laser therapy for increasing blood flow to the forearm.

Design: Crossover study.

Setting: Controlled laboratory setting.

Patients or Other Participants: Ten healthy, college-aged men (age = 20.80 ± 2.16 years, height = 177.93 ± 3.38 cm, weight = 73.64 ± 9.10 kg) with no current history of injury to the upper extremity or cardiovascular conditions.

Intervention(s): A class 4 laser device was used to treat the biceps brachii muscle. Each grid point was treated for 3 to 4 seconds, for a total of 4 minutes. Each participant received 4 doses of laser therapy: sham, 1 W, 3 W, and 6 W.

Main Outcome Measure(s): The dependent variables were changes in blood flow, measured using venous occlusion plethysmography. We used a repeated-measures analysis of variance to analyze changes in blood flow for each dose at 2, 3, and 4 minutes and at 1, 2, 3, 4, and 5 minutes after treatment. The Huynh-Feldt test was conducted to examine differences over time.

Results: Compared with baseline, blood flow increased over time with the 3-W treatment ($F_{3,9} = 3.468$, $P < .011$) at minute 4 of treatment (2.417 ± 0.342 versus 2.794 ± 0.351 mL/min per 100 mL tissue, $P = .032$), and at 1 minute (2.767 ± 0.358 mL/min per 100 mL tissue, $P < .01$) and 2 minutes (2.657 ± 0.369 mL/min per 100 mL tissue, $P = .022$) after treatment. The sham, 1-W, and 6-W treatment doses did not change blood flow from baseline at any time point.

Conclusions: Laser therapy at the 3-W (360-J) dose level was an effective treatment modality to increase blood flow in the soft tissues.

Key Words: therapeutic modalities, circulation, musculoskeletal injuries

Key Points

- Using a class 4 laser in a human clinical model, we found a protocol-response effect: a 3-W protocol at a 50% duty cycle applied to the biceps brachii muscle was the most effective for increasing blood flow to the distal forearm.
- Laser therapy is an effective, noninvasive treatment modality to improve blood flow and perhaps tissue healing in the clinical setting.

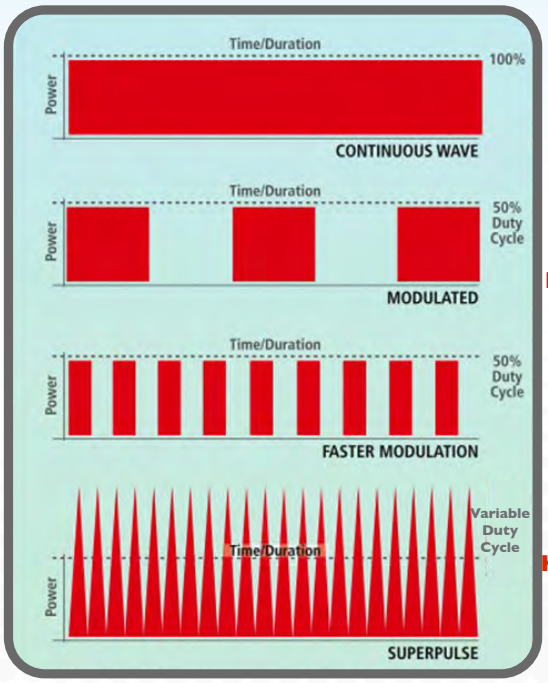
The use of laser as a clinical modality has increased greatly over the past decade. Positive effects of laser therapy for the treatment of acute and chronic musculoskeletal disorders include pain control[1,2] and improved tissue repair.[3,4] However, the underlying mechanisms and clinical effectiveness of laser therapy remain poorly understood.

Lasers are classified by power level and their ability to produce eye injury. These power and beam characteristic ratings are established by the American National Standards Institute and the International Electrotechnical Commission. Most therapeutic lasers available for use in clinical practice are classified as 3B or 4. Class 3B lasers emit power of 5 to 500 mW, whereas class 4 lasers emit power of more than 500 mW. A few therapeutic laser manufacturers offer divergent-beam power outputs greater than 10000 mW. Class 3B level emitting lasers are known as low-level, low-intensity, and cold lasers because they generate no significant thermal effect in the superficial tissue during irradiation. Class 4 lasers are known as high-power and hot lasers because they can produce rapid increases in superficial tissue temperatures when maximum permissible exposure limits are exceeded. Recent trends in laser therapy show a preference for class 4 lasers in patient care settings.[5] Class 4 lasers can emit greater photonic energy in a shorter period of time than class 3B lasers without producing an appreciable rise in tissue temperature under normal treatment protocols.[5] This higher power becomes important when treating injuries to deeper tissues such as ligaments, muscles, tendons, and cartilage.

Authors of most published clinical studies on laser therapy to treat musculoskeletal injuries have used class 3B low-power lasers. Several published reports[6,7] have questioned the ability of low-power lasers to effectively transmit energy beyond the skin into deep musculoskeletal tissues. Excessive beam scattering and attenuation within the skin limit the potential biostimulative effects of laser in the deeper target tissues because of several factors related to dosimetry, such as subthreshold optical power, insufficient treatment durations, and varied treatment frequencies.[8,9] Therefore, it is relevant and timely to study the dosimetric responses of specific infrared wavelengths of high-power class 4 lasers and their ability to modulate the physiologic effects that are conducive to healing.

Positive therapeutic effects of laser have been attributed to increased blood flow in soft tissues and, coincidentally, the

Continuous Wave (CW), Frequency Modulated, or SuperPulse

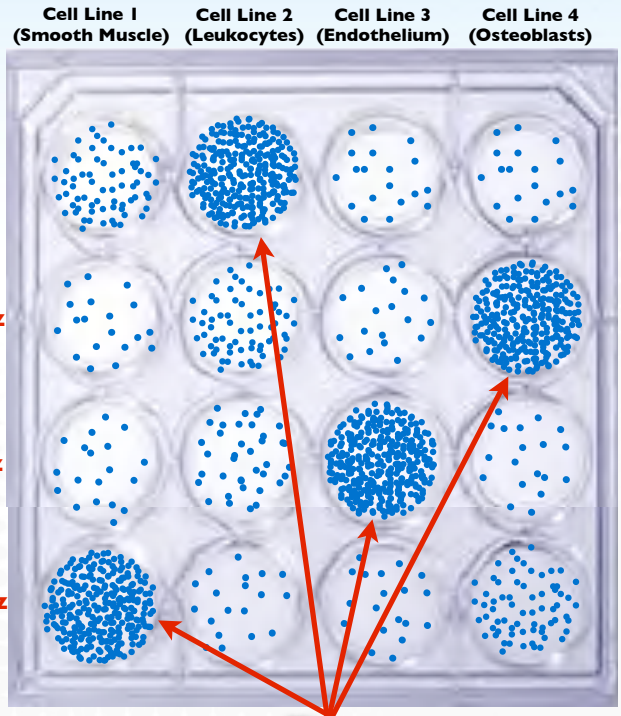


CW

Low Hz

Mid Hz

High Hz



Different Tissue Types Respond to Different Frequencies

Lasers in Surgery and Medicine 42:450–466 (2010)

Effect of Pulsing in Low-Level Light Therapy

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Background and Objective: Low level light (or laser) therapy (LLLT) is a rapidly growing modality used in physical therapy, chiropractic, sports medicine and increasingly in mainstream medicine. LLLT is used to increase wound healing and tissue regeneration, to relieve pain and inflammation, to prevent tissue death, to mitigate degeneration in many neurological indications. While some agreement has emerged on the best wavelengths of light and a range of acceptable dosages to be used (irradiance and fluence), there is no agreement on whether continuous wave or pulsed light is best and on what factors govern the pulse parameters to be chosen.
Study Design/Materials and Methods: The published peer-reviewed literature was reviewed between 1970 and 2010.
Results: The basic molecular and cellular mechanisms of LLLT are discussed. The type of pulsed light sources available and the parameters that govern their pulse structure are outlined. Studies that have compared continuous wave and pulsed light in both animals and patients are reviewed. Frequencies used in other pulsed modalities used in physical therapy and biomedicine are compared to those used in LLLT.
Conclusion: There is some evidence that pulsed light does have effects that are different from those of continuous wave light. However further work is needed to define these effects for different disease conditions and pulse structures. Lasers Surg. Med. 42:450–466, 2010.

Key words: low level light therapy; photobiomodulation; frequency; pulse duration; duty cycle; clinical trials

INTRODUCTION

Since the introduction of low-level laser (light) therapy in 1967, over two hundred randomized, double-blinded, and placebo-controlled phase III clinical trials have been published from over a dozen countries. Whereas there is some degree of consensus as to the best wavelengths of light and acceptable dosages to be used, there is no agreement on whether continuous wave (CW) or pulsed wave (PW) light is more suitable for the various applications of LLLT. This review will raise (but not necessarily answer) several questions. How does pulsed light differ from CW on the cellular and molecular level, and how is the outcome of LLLT affected? If pulsing is more efficacious, then at what pulse parameters is the optimal outcome achieved? In particular, what is the ideal pulse repetition rate or frequency to use?

PULSE PARAMETERS AND LIGHT SOURCES

There are five parameters that could be specified for pulsed light sources. The pulse width or duration or ON time (PD) and the pulse Interval or OFF time (PI) are measured in seconds. Pulse repetition rate or frequency (F) is measured in Hz. The duty cycle (DC) is a unitless fractional number or %. The peak power and average power are measured in Watts.

Pulse duration, pulse repetition rate, and duty cycle are related by the simple equation:

$$DC = F \times PD$$

Peak power is a measure of light intensity during the pulse duration, and related to the average power (measured in Watts) by:

$$\text{Average power} = \text{Peak power} \times F \times PD$$

Alternatively,

$$\text{Peak power} = \frac{\text{Average power}}{DC}$$

Conflict of Interest: Luis De Taboada is an employee and stockholder in Photothera, Inc. that does phototherapy for stroke. James Carroll is owner of THOR Photomedicine a company that makes phototherapy devices.
Contract grant sponsor: NIH; Contract grant number: R01AI050875; Contract grant sponsor: Center for Integration of Medicine and Innovative Technology; Contract grant number: DAMD17-02-2-0006; Contract grant sponsor: CDMRP Program in TBI; Contract grant number: W81XWH-09-1-0514; Contract grant sponsor: Air Force Office of Scientific Research; Contract grant number: FA9950-04-1-0079.
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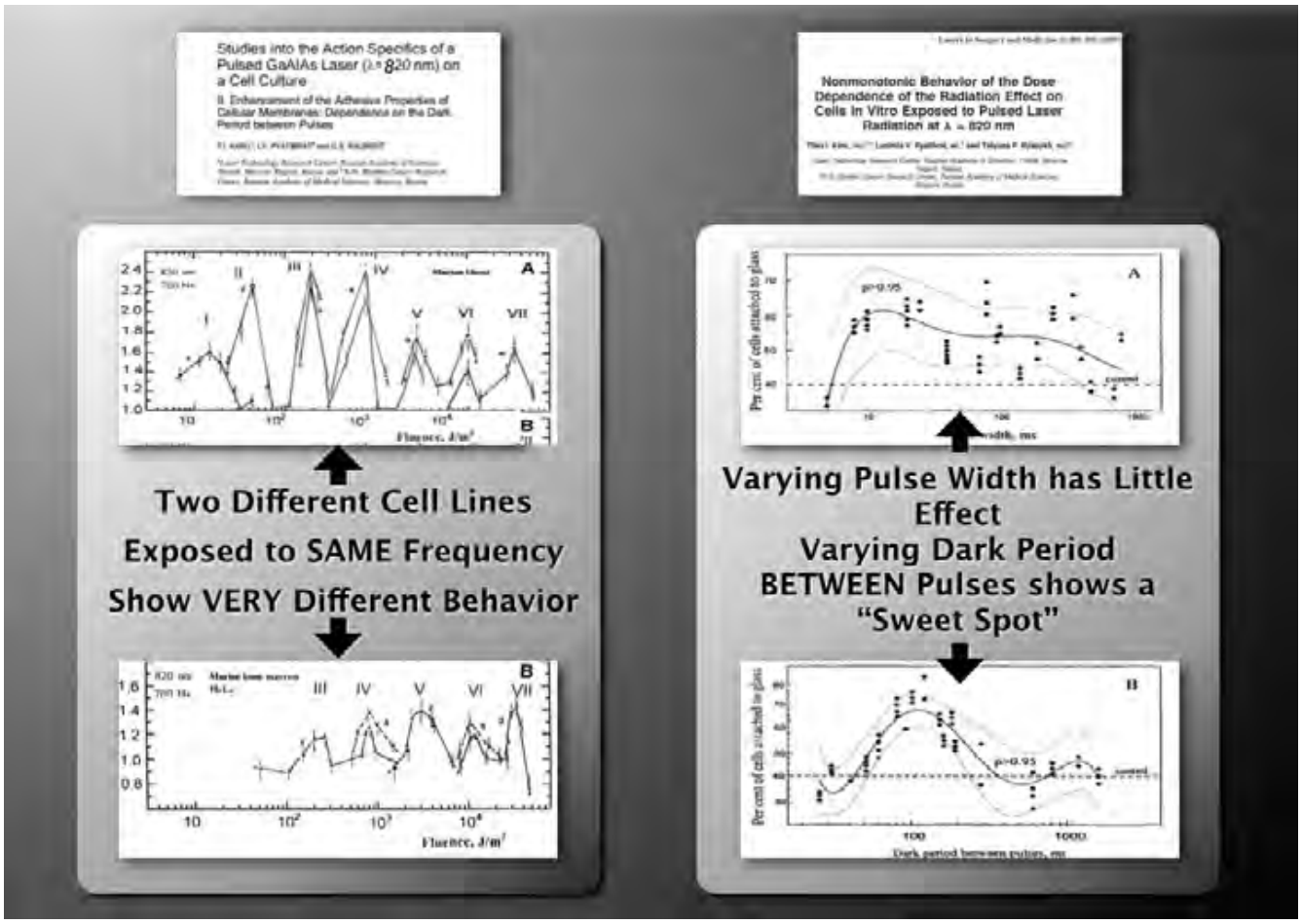
HOW DO WE KNOW



This slide is a graphical illustration of the idea that different cell types respond to different frequencies (and parameters, in general). Not every in vitro study measures "stimulation" by increased proliferation. Some measure adhesion to the glass, others spinning flagellum, others different biochemical secretions. And if you scour all the papers you'll find that the peak of stimulation occurs with different parameter sets. The closest thing to a truly side-by-side analysis is the Karu paper (attached).

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Studies into the Action Specifics of a Pulsed GaAIAs Laser (λ=*S20* nm) on a Cell Culture

II. Enhancement of the Adhesive Properties of Cellular Membranes: Dependence on the Dark Period between Pulses

T.I. KARU[*]', LV. PYATIBRAT[a] and G.S. KALENDO[b]

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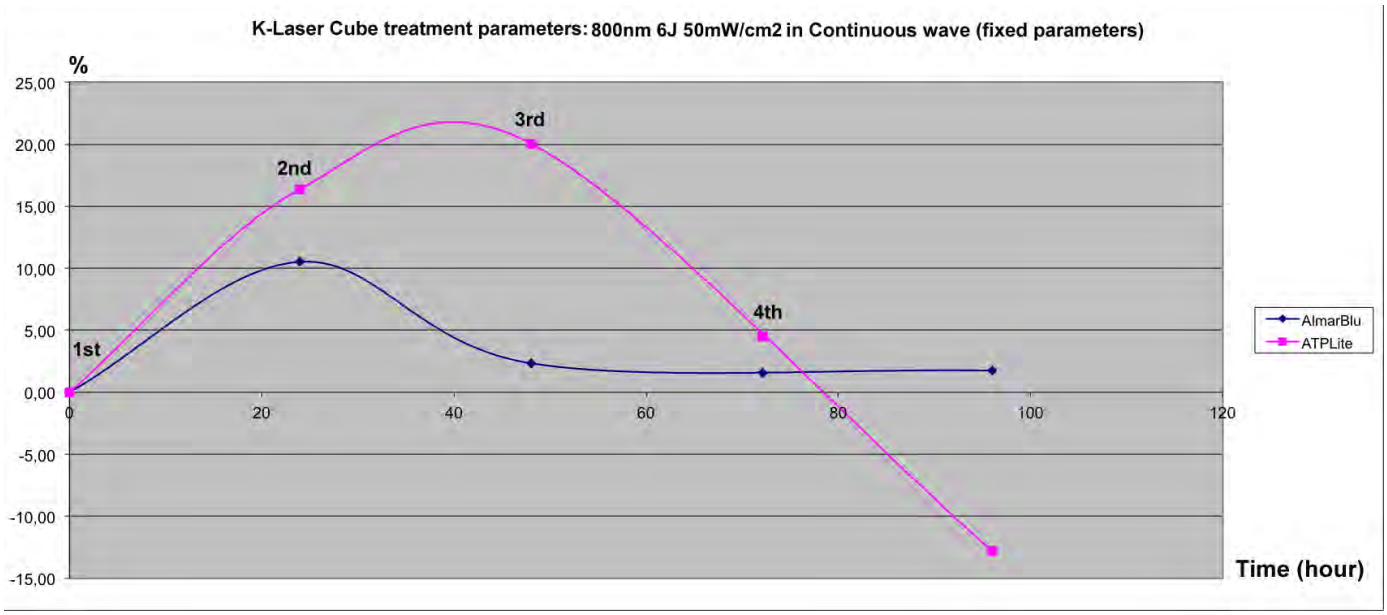
Based on the number of cells attached to glass, changes are studied in the adhesive properties of cellular membranes 30 min. after irradiating a HeLa cell suspension with a pulsed GaAIAs laser (λ. = 820 nm. dose 60 J/m^2. pulse repetition frequency 0.1, 0.2, 0.5, 1.0, 2.5, 10, 50 or 100 Hz, duty factor 5, K), 20, 40, 70 or 95%). It is demonstrated that irradiation causes the number of the cells attached to the glass substrate to increase, but only when the duration of the dark period between pulses is in the range 50-200 ms (maximum increase at 100 ms).

Keywords: Adhesion; dark period between pulses; GaAIAs laser; low-power laser therapy

INTRODUCTION

It is known that the sensitivity of eukaryotic cells to continuous-wave (CW) and pulsed laser radiation of one and the same wavelength and dose may be different (Karu *et al,,* 1996a and b, 1997; Karu 1998). In these


K-Laser Cube treatment parameters: 800nm 6J 50mW/cm2 in Continuous wave (fixed parameters)
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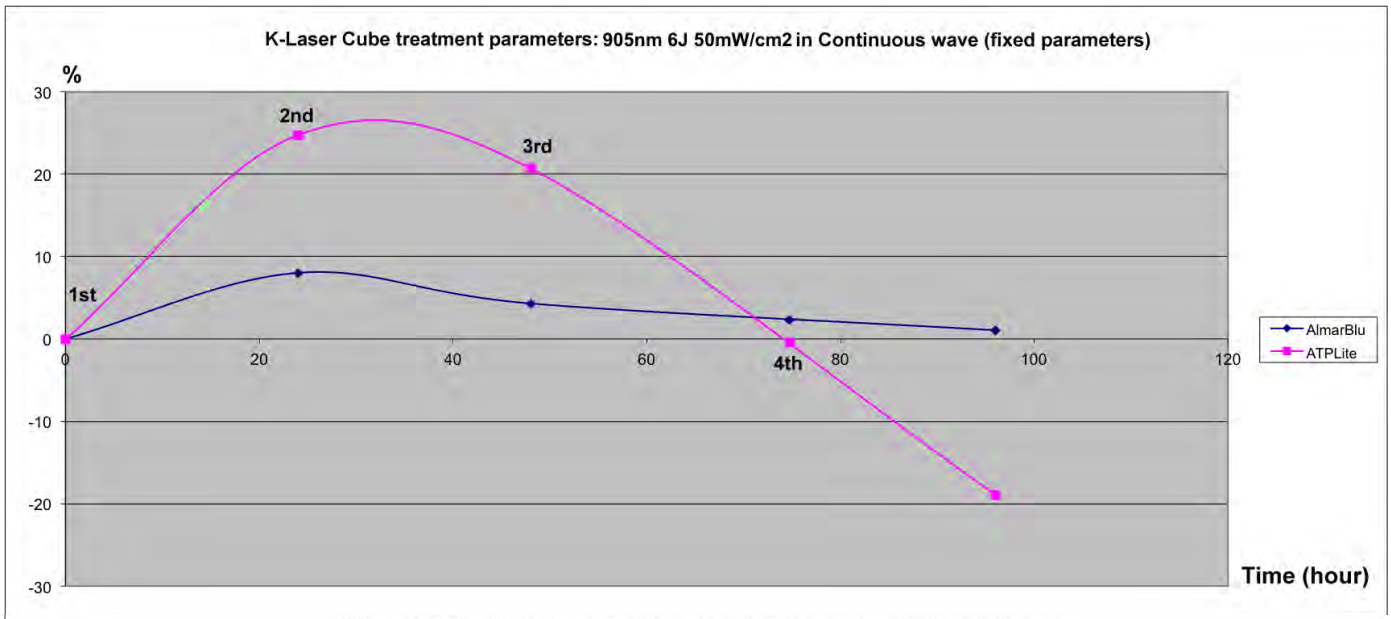
K-Laser Cube treatment parameters: 905nm 6J 50mW/cm2 in Continuous wave (fixed parameters)
%
30
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60
80
100
120
1st
2nd
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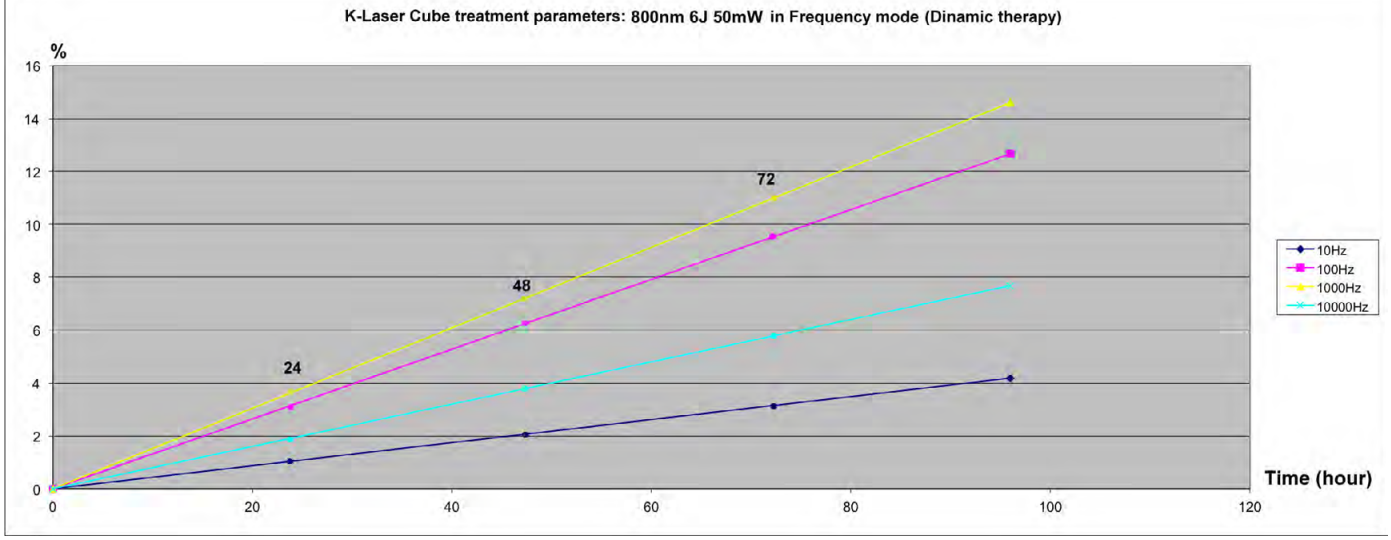
4th
AlmarBlu
ATPLite
Time (hour)


K-Laser Cube treatment parameters: 800nm 6J 50mW in Frequency mode (Dinamic therapy)
%
16
14
12
10
8
6
4
2
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40
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1000Hz
10000Hz
Time (hour)

Lasers in Surgery and Medicine 41:271–276 (2009)

Effect of Low Level Laser Therapy (830 nm) With Different Therapy Regimes on the Process of Tissue Repair in Partial Lesion Calcaneous Tendon

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Background and Objective: Calcaneous tendon is one of the most damaged tendons, and its healing may last from weeks to months to be completed. In the search after speeding tendon repair, low intensity laser therapy has shown favorable effect. To assess the effect of low intensity laser therapy on the process of tissue repair in calcaneous tendon after undergoing a partial lesion.

Study Design/Materials and Methods: Experimentally controlled randomized single blind study. Sixty male rats were used randomly and were assigned to five groups containing 12 animals each one; 42 out of 60 underwent lesion caused by dropping a 186 g weight over their Achilles tendon from a 20 cm height. In Group 1 (standard control), animals did not suffer the lesion nor underwent laser therapy; in Group 2 (control), animals suffered the lesion but did not undergo laser therapy; in Groups 3, 4, and 5, animals suffered lesion and underwent laser therapy for 3, 5, and 7 days, respectively. Animals which suffered lesion were sacrificed on the 8th day after the lesion and assessed by polarization microscopy to analyze the degree of collagen fibers organization.

Results: Both experimental and standard control Groups presented significant values when compared with the control Groups, and there was no significant difference when Groups 1 and 4 were compared; the same occurred between Groups 3 and 5.

Conclusion: Low intensity laser therapy was effective in the improvement of collagen fibers organization of the calcaneous tendon after undergoing a partial lesion. Lasers Surg. Med. 41:271–276, 2009. © 2009 Wiley-Liss, Inc.

Key words: calcaneous tendon; diode laser; lesion tendon; low level laser therapy; physical therapy; repair tissue

INTRODUCTION

The calcaneous tendon is one of the most frequently injured tendons in human beings, followed by digital flexors, due to overuse, trauma caused by firearm wounds, and sharp objects [1].

Owing to the slow pace of healing, the rupture of the calcaneous tendon is considered a serious injury, and it has drawn the attention of several researchers [2].

Spontaneous rupture of the calcaneous tendon occurs between 2 and 6 cm of its insertion into the calcaneous bone. Histological examination has suggested that such tendons had already undergone primary degeneration [3] and showed important alterations in the type of collagen fibers [4].

In order to observe blood supply to the calcaneous tendon, CARR & NORRIS (1989) [5] verified that the number of blood vessels varies along the length of the tendon and their highest concentration occurs in the calcaneous insertion and up to 4 cm above it, considering that neoangiogenesis is a vital part of the healing process, as it restores normal circulation and carries more cells and nutrients to the injured location, thus limiting ischemic necrosis and allowing tissue repair [6].

Due to its low blood supply, the calcaneous tendon is a structure that can take weeks or even months to heal completely [2,7].

During the period of the lesion, it is customary for the patient to remain immobilized in order to prevent a new rupture, which could generate countless functional complications, including ultra-structural and biomechanical alterations in the tendon [8,9].

Such complications, caused by prolonged immobilization, can be minimized by shortening the duration of the tendon repair [3].

Trying to accelerate tendon repair, several physical agents such as ultrasound [10], electrical stimulation [11], and low level laser therapy [12] have shown beneficial effects.

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Lasers in Surgery and Medicine 28:216–219 (2001)

Effects of Laser Irradiation on the Spinal Cord for the Regeneration of Crushed Peripheral Nerve in Rats

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Background and Objective: The purpose of the present study was to examine the recovery of the crushed sciatic nerve of rats after low-power laser irradiation applied to the corresponding segments of the spinal cord.

Study Design/Materials and Methods: After a crush injury to the sciatic nerve in rats, low-power laser irradiation was applied transcutaneously to corresponding segments of the spinal cord immediately after closing the wound by using 16 mW, 632 nm He-Ne laser. The laser treatment was repeated 30 minutes daily for 21 consecutive days.

Results: The electrophysiologic activity of the injured nerves (compound muscle action potentials—CMAPs) was found to be approximately 90% of the normal precrush value and remained so for up to a long period of time. In the control nonirradiated group, electrophysiologic activity dropped to 20% of the normal precrush value at day 21 and showed the first signs of slow recovery 30 days after surgery. The two groups were found to be significantly different during follow-up period ($P < 0.001$).

Conclusion: This study suggests that low-power laser irradiation applied directly to the spinal cord can improve recovery of the corresponding insured peripheral nerve. Lasers Surg. Med. 28:216–219, 2001.

Key words: peripheral nerve injury; compound muscle action potentials; low-power laser; spinal cord irradiation; rats

INTRODUCTION

Treatment of injuries to peripheral nerves has always constituted an important medical problem, and, although recovery does eventually occur in most cases, it is a very slow and frequently incomplete process [1]. Peripheral nerves are highly vulnerable to pressure. The amount of damage done depends on the specific nerve involved, the magnitude and type of pressure and the length of time the nerve is compressed. If the amount and duration of compression are slight, most nerves will recover either immediately or shortly after trauma. But if the pressure is intense and/or the duration is long, recovery is prolonged and often partial. One of the causes of nerve compression is the crush injury. The usual results after such an injury are degeneration of the axons and retrograde degeneration of the corresponding neurons of the spinal cord, followed by a very slow regeneration. Understandably, therefore, numerous attempts have been made to enhance and/or accelerate the recovery of injured peripheral nerves. One of the methods studied is the use of low-power laser irradiation to enhance the recovery of peripheral nerve injuries. The use of low-power laser irradiation in the treatment of experimental peripheral nerve injuries was reported by Rochkind in 1978 [2]. More recent publications describe the effect of low-power laser irradiation applied directly or transcutaneously to the crushed peripheral nerve alone [3–7] or to the crushed nerve and the corresponding segments of the spinal cord [8]. The results showed that low-power laser irradiation increases the recovery of the crushed sciatic nerve of rats [3,4,7] and decreases retrograde degeneration of the neurons in the corresponding segments of the spinal cord [6,7]. In this study, the recovery of the crushed sciatic nerve of rats after low-power laser irradiation applied to the corresponding segments in the spinal cord alone was studied.

MATERIALS AND METHODS

The present study was carried out on 17 Sprague-Dawley rats of uniform age (3 months) each weighing approximately 300 g. The rats were divided into two groups and were anesthetized intraperitoneally with diluted Nembutal 15 mg/kg weight. The right thigh along the sciatic nerve and the dorsolumbar region of the spine were shaved.

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Lasers in Surgery and Medicine 42:494–502 (2010)

Irradiation at 830 nm Stimulates Nitric Oxide Production and Inhibits Pro-Inflammatory Cytokines in Diabetic Wounded Fibroblast Cells

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Background and Objective: Wound healing in diabetic patients remains a chief problem in the clinical setting and there is a strong need for the development of new, safe, reliable therapies. This study aimed to establish the effect of irradiating diabetic wounded fibroblast cells (WS1) in vitro on pro-inflammatory cytokines and the production of nitric oxide (NO).
Materials and Methods: Normal, wounded and diabetic wounded WS1 cells were exposed to an 830 nm laser with 5 J/cm^2 and incubated for a pre-determined amount of time. Changes in cellular viability, proliferation and apoptosis were evaluated by the Trypan blue assay, VisionBlue^{TM} fluorescence assay and caspase 3/7 activity respectively. Changes in cytokines (interleukin—IL-6, IL-1β and tumour necrosis factor-alpha, TNF-α) were determined by ELISA. NO was determined spectrophotometrically and reactive oxygen species (ROS) was evaluated by immunofluorescent staining.
Results: Diabetic wounded WS1 cells showed no significant change in viability, a significant increase in proliferation at 24 and 48 hours ($P<0.001$ and $P<0.01$ respectively) and a decrease in apoptosis 24 hours post-irradiation ($P<0.01$). TNF-α levels were significantly decreased at both 1 and 24 hours ($P<0.05$), while IL-1β was only decreased at 24 hours ($P<0.05$). There was no significant change in IL-6. There was an increase in ROS and NO ($P<0.01$) 15 minutes post-irradiation.
Conclusion: Results show that irradiation of diabetic wounded fibroblast cells at 830 nm with 5 J/cm^2 has a positive effect on wound healing in vitro. There was a decrease in pro-inflammatory cytokines (IL-1β and TNF-α) and irradiation stimulated the release of ROS and NO due to what appears to be direct photochemical processes. Lasers Surg. Med. 42:494–502, 2010.

Key words: IL-1β; IL-6; lasers; NO; ROS; TNF-α

INTRODUCTION

The process of wound healing is a highly co-ordinated process that involves a series of overlapping events controlled by a variety of cells, growth factors, cytokines and metabolic enzymes released at the wound site. Dysregulation of this co-ordinated event leads to impaired wound healing; an abnormality which is frequently seen in conditions such as diabetes. There are many causes of chronic wounds, with diabetes, pressure ulcers and venous stasis as the three most common causes [1]. Impaired wound healing is an incapacitating complication of diabetes often necessitating amputation and poses a serious challenge in clinical practice.

Growth factors and cytokines such as interleukin-1-beta (IL-1β), IL-6 and tumour necrosis factor-alpha (TNF-α) have diverse modes of action and are released during wound repair [2]. IL-1β and TNF-α are both well-known pro-inflammatory cytokines and have similar functions or effects; however, they do not share chemical or structural resemblance and their effects are interceded by specific receptors. Together with IL-1, TNF-α is the first cytokine known to be upregulated during the inflammatory phase of wound healing and contributes to the oxidative stress within the wound by generating reactive oxygen species (ROS) [3]. IL-6 is induced during acute phase reactions and usually expressed in response to or together with IL-1 and TNF-α [4]. However, contradictory effects have been reported [5]; it suppresses TNF-α, IL-1 and IL-12. Its vital role in wound healing is its ability to cause cell differentiation and proliferation. TNF-α is the most critical accelerator of diabetes [6].

ROS and reactive nitrogen species (RNS) act as molecular messengers during cell signalling; however, they have a biphasic effect, being both beneficial and detrimental depending on their concentration. ROS and RNS are generated during wound healing and are important mediators in this carefully controlled process, however in chronic wounds there is an uncontrolled production of these molecules. Nitric oxide (NO) is significantly reduced in chronic ulcers and impaired healing of diabetic wounds is

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Lasers in Surgery and Medicine 44:726–735 (2012)

Low-Level Laser Therapy (808 nm) Reduces Inflammatory Response and Oxidative Stress in Rat Tibialis Anterior Muscle After Cryolesion

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Background and Objective: Muscle regeneration is a complex phenomenon, involving coordinated activation of several cellular responses. During this process, oxidative stress and consequent tissue damage occur with a severity that may depend on the intensity and duration of the inflammatory response. Among the therapeutic approaches to attenuate inflammation and increase tissue repair, low-level laser therapy (LLLT) may be a safe and effective clinical procedure. The aim of this study was to evaluate the effects of LLLT on oxidative/nitrative stress and inflammatory mediators produced during a cryolesion of the tibialis anterior (TA) muscle in rats.

Material and Methods: Sixty Wistar rats were randomly divided into three groups ($n = 20$): control (BC), injured TA muscle without LLLT (IC), injured TA muscle submitted to LLLT (IRI). The injured region was irradiated daily for 4 consecutive days, starting immediately after the lesion using a AlGaAs laser (continuous wave, 808 nm, tip area of 0.00785 cm^2, power 30 mW, application time 47 seconds, fluence 180 J/cm^2; 3.8 mW/cm^2; and total energy 1.4 J). The animals were sacrificed on the fourth day after injury.

Results: LLLT reduced oxidative and nitrative stress in injured muscle, decreased lipid peroxidation, nitrotyrosine formation and NO production, probably due to reduction in iNOS protein expression. Moreover, LLLT increased SOD gene expression, and decreased the inflammatory response as measured by gene expression of NF-kβ and COX-2 and by TNF-α and IL-1β concentration.

Conclusion: These results suggest that LLLT could be an effective therapeutic approach to modulate oxidative and nitrative stress and to reduce inflammation in injured muscle. Lasers Surg. Med. 44:726–735, 2012.

Key words: low-level laser therapy; photobiomodulation; muscle cryolesion; inflammatory mediators; nitrative stress; oxidative stress

INTRODUCTION

Skeletal muscle injuries are common consequences of sport and labor activities. Depending on the severity of the injury, they can affect muscle function, leading to atrophy, contracture, pain, and increased likelihood of re-injury [1–3].

Muscle repair is very complex and involves several highly organized molecular and cellular processes. Immediately following the disruption of the myofibers, neutrophils, and macrophages infiltrate to the lesion area, producing pro-inflammatory cytokines and proteases responsible for necrotic tissue removal and further propagation of the inflammatory response [4–6]. These processes

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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Efficacy of low-level laser therapy in the management of neck pain: a systematic review and meta-analysis of randomised placebo or active-treatment controlled trials

Roberta T Chow, Mark I Johnson, Rodrigo A B Lopes-Martins, Jan M Bjordal

Summary

Background **Neck pain is a common and costly condition for which pharmacological management has limited evidence of efficacy and side-effects. Low-level laser therapy (LLLT) is a relatively uncommon, non-invasive treatment for neck pain, in which non-thermal laser irradiation is applied to sites of pain. We did a systematic review and meta-analysis of randomised controlled trials to assess the efficacy of LLLT in neck pain.**

Methods **We searched computerised databases comparing efficacy of LLLT using any wavelength with placebo or with active control in acute or chronic neck pain. Effect size for the primary outcome, pain intensity, was defined as a pooled estimate of mean difference in change in mm on 100 mm visual analogue scale.**

Findings **We identified 16 randomised controlled trials including a total of 820 patients. In acute neck pain, results of two trials showed a relative risk (RR) of 1·69 (95% CI 1·22–2·33) for pain improvement of LLLT versus placebo. Five trials of chronic neck pain reporting categorical data showed an RR for pain improvement of 4·05 (2·74–5·98) of LLLT. Patients in 11 trials reporting changes in visual analogue scale had pain intensity reduced by 19·86 mm (10·04–29·68). Seven trials provided follow-up data for 1–22 weeks after completion of treatment, with short-term pain relief persisting in the medium term with a reduction of 22·07 mm (17·42–26·72). Side-effects from LLLT were mild and not different from those of placebo.**

Interpretation **We show that LLLT reduces pain immediately after treatment in acute neck pain and up to 22 weeks after completion of treatment in patients with chronic neck pain.**

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See Comment page 1875

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Introduction

Chronic pain is predicted to reach epidemic proportions in developed countries with ageing populations in the next 30 years.[1] Chronic neck pain is a highly prevalent condition, affecting 10–24% of the population.[2–5] Economic costs of this condition are estimated at hundreds of millions of dollars,[2] creating an imperative for evidence-based, cost-effective treatments. Low-level laser therapy (LLLT) uses laser to aid tissue repair,[6] relieve pain,[7] and stimulate acupuncture points.[8] Laser is light that is generated by high-intensity electrical stimulation of a medium, which can be a gas, liquid, crystal, dye, or semiconductor.[9] The light produced consists of coherent beams of single wavelengths in the visible to infrared spectrum, which can be emitted in a continuous wave or pulsed mode. Surgical applications of laser ablate tissue by intense heat and are different from LLLT, which uses light energy to modulate cell and tissue physiology to achieve therapeutic benefit without a macroscopic thermal effect (sometimes termed cold laser). LLLT is non-invasive, painless, and can be easily administered in primary-care settings. Incidence of adverse effects is low and similar to that of placebo, with no reports of serious events.[10,11]

Research into the use of LLLT for pain reduction[12,13] and tissue repair[14,15] spans more than 30 years. However, reports do not identify this therapy as a potential treatment option,[16] possibly because of scepticism about its mechanism of action and effectiveness.[17] Research from the past decade suggests that LLLT produces anti-inflammatory effects,[18–21] contributing to pain relief. Cochrane reviews of the efficacy of LLLT in low-back pain[22] and rheumatoid arthritis[23] have been unable to make firm conclusions because of insufficient data or conflicting findings. However, effectiveness depends on factors such as wavelength, site, duration, and dose of LLLT treatment. Adequate dose and appropriate procedural technique are rarely considered in systematic reviews of electrophysical agents. Research into the dose-response profile of LLLT suggests that different wavelengths have specific penetration abilities through human skin.[17,24,25] Thus, clinical effects could vary with depth of target tissue. We have shown the importance of accounting for dose and technique in systematic reviews of transcutaneous electrical nerve stimulation[26] and LLLT,[11,21] and our approach is an acknowledged means of establishing efficacy.[27]

The only systematic review focusing solely on LLLT in treatment of neck pain included four randomised controlled trials, and concluded that there was evidence of short-term benefit of LLLT at infrared wavelengths of 780, 810–830, and 904 nm.[28] A Cochrane review of physical medicine for mechanical neck disorders, since

Council on Chiropractic Guidelines and Practice Parameters

Chiropractic Management of Myofascial Trigger Points and Myofascial Pain Syndrome: A Systematic Review of the Literature

Howard Vernon, DC, PhD,[a] and Michael Schneider, DC[b]

Abstract

Objectives: Myofascial pain syndrome (MPS) and myofascial trigger points (MTrPs) are important aspects of musculoskeletal medicine, including chiropractic. The purpose of this study was to review the most commonly used treatment procedures in chiropractic for MPS and MTrPs.

Methods: The Scientific Commission of the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) was charged with developing literature syntheses, organized by anatomical region, to evaluate and report on the evidence base for chiropractic care. This article is the outcome of this charge. As part of the CCGPP process, preliminary drafts of these articles were posted on the CCGPP Web site www.ccgpp.org (2006-8) to allow for an open process and the broadest possible mechanism for stakeholder input. PubMed, Excerpta Medica Database, Cumulative Index to Nursing and Allied Health Literature, and databases for systematic reviews and clinical guidelines were searched. Separate searches were conducted for (1) manual palpation and algometry, (2) chiropractic and other manual therapies, and (3) other conservative and complementary/alternative therapies. Studies were screened for relevance and rated using the Oxford Scale and Scottish Intercollegiate Guidelines Network rating system.

Results: A total of 112 articles were identified. Review of these articles resulted in the following recommendations regarding treatment: Moderately strong evidence supports manipulation and ischemic pressure for immediate pain relief at MTrPs, but only limited evidence exists for long-term pain relief at MTrPs. Evidence supports laser therapy (strong), transcutaneous electrical nerve stimulation, acupuncture, and magnet therapy (all moderate) for MTrPs and MPS, although the duration of relief varies among therapies. Limited evidence supports electrical muscle stimulation, high-voltage galvanic stimulation, interferential current, and frequency modulated neural stimulation in the treatment of MTrPs and MPS. Evidence is weak for ultrasound therapy.

Conclusions: Manual-type therapies and some physiologic therapeutic modalities have acceptable evidentiary support in the treatment of MPS and TrPs. (J Manipulative Physiol Ther 2009;32:14-24)

Key Indexing Terms: *Myofascial Pain Syndromes; Myofascial Trigger Points; Chiropractic; Musculoskeletal Manipulations*

Ever since the seminal work of Travell and Rinzler[1] in 1952, the role of myofascial trigger points (TrPs) in myofascial pain syndrome (MPS) has become an accepted part of musculoskeletal clinical practice. Along with Simons,[2] Travell first identified the importance of myofascial pain and its localization in what they termed *trigger points*, providing the first classification of diagnostic criteria for TrPs. They also provided detailed maps of the pain referral patterns from TrPs in all the muscles of the body. Myofascial pain syndrome is currently thought to be the leading diagnosis among pain management specialists[3] and the leading diagnosis in pain patients reporting to general practitioners.[4]

Interest in myofascial tenderness extends throughout the history of chiropractic. It might be said that local paraspinal tenderness, as part of the manifestations of the "subluxation," was a central feature of chiropractic thinking from its inception. Arguably, the work of Ray Nimmo[5-7] represents

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0161-4754/$34.00

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A Pilot Study to Evaluate the Efficacy of Class IV Lasers on Nonhealing Neuroischemic Diabetic Foot Ulcers in Patients With Type 2 Diabetes

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Diabetes Care 2015;38:e152–e153 | DOI: 10.2337/dc15-0774

Diabetic foot ulcers (DFUs) represent a disabling complication of diabetes that has a devastating impact on the quality of life and predict lower-limb amputation and premature mortality (1). Despite best practice, 30–40% of DFUs do not heal within 12–20 weeks (2). Novel therapeutic agents have been tested in clinical trials, and it has been estimated that ~30–50% of patients with neuropathic DFUs receiving these new treatments have healed by 12–20 weeks (3). Laser therapy, delivered with devices emitting one or two wavelengths, has been reported as an adjunctive procedure that promotes the healing of chronic diabetic wounds by increasing the blood flow and the release of growth factors and by reducing the inflammation (4).

In this pilot study, we have been the first to investigate the efficacy of an advanced class IV laser (emitting four wavelengths) on Wagner stage 1 and 2 neuroischemic DFUs of five patients with type 2 diabetes who were nonresponsive to conventional treatment for at least 12 weeks. Laser treatment was delivered once a week prior to standard care and dressing. As a control we selected patients with similar DFUs and clinical characteristics treated within our department with standard care. In the laser-treated group, age was 58.2 ± 3.6 years (mean ± SEM; range 47–66) and mean duration of diabetes was 20.4 ± 2.1 years. At the time of enrollment, glycosylated hemoglobin (HbA_{1c}) was 9.0 ± 0.8% (74.6 ± 8.4 mmol/mol). All laser-treated patients had preserved renal function (estimated glomerular filtration rate [eGFR] 72 ± 8.3 mL/min/1.73 m^2) and moderate to severe peripheral artery disease, defined as 20–49% and 50–99% diameter reduction in at least one of the arterial segments from aorto-iliac to popliteal segments on an arterial duplex scan. The mean size of the ulcers was 2.4 ± 1.0 cm^2. The control group of six patients with type 2 diabetes received standard care and had similar ulcer duration and size; comparable glycemic control, age, diabetes duration, and eGFR; and similar degree of peripheral artery disease (Table 1). Standard care for DFUs, including antibiotic treatment, dressing, and off-loading, was similar in both groups. Within the 12-week follow-up, four of five laser-treated patients (80%) had a complete ulcer resolution (most ulcers healed after 4.6 weeks). In the control group, no ulcer healing occurred by week 12.

A limited number of small clinical trials and case studies evaluating the effects of laser devices with lower power and one or two wavelengths on DFUs have previously reported positive outcomes (4). However, because of the heterogeneity in the methodology, findings from these studies have not been consistent. The laser used in this pilot study is the first example of a high-powered device with four wavelengths concomitantly acting on multiple metabolic processes that accelerate the wound healing: stimulation of cytochrome-C oxidase, an increase in angiogenesis, and improvement in blood perfusion (5).

Taking into consideration the limitations of this proof-of-concept study, our findings indicate that laser therapy delivered by a class IV laser can significantly impact the healing process of neuroischemic DFUs refractory to standard treatment. Randomized controlled clinical trials with this new laser device in larger populations are required to confirm our results.

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K-LaserUSA had no role in the design, data analysis, or preparation of the manuscript.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. G.M. managed the patients, researched the data, and wrote the manuscript. J.K. and L.G. reviewed the manuscript and contributed to the discussion. H.R., T.A., and A.L. delivered foot care and administered laser therapy. G.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1—Patient characteristics and study outcomes

	Laser + standard treatment	Standard treatment
n	5	6
Sex (male/female)	5/0	5/1
Age (years)	58.2 ± 3.6	63.2 ± 5.1
Duration of diabetes (years)	20.4 ± 2.1	13.8 ± 3.0
HbA_{1c} [% (mmol/mol)]	9.0 ± 0.8 (74.6 ± 8.4)	8.1 ± 0.9 (65.2 ± 10.3)
eGFR (mL/min/1.73 m^2)	72 ± 8.3	65.2 ± 10.3
Duration of ulcers (weeks)	18 ± 2.3	17.3 ± 1.2
Ulcer area (cm^2)	2.4 ± 1.0	2.2 ± 0.5
Patients with complete healing in <12 weeks	4/5	0/6

Data are *n* or mean ± SEM.

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LASERS, HEAT, METAL and GROWTH PLATES

by Phil Harrington, DC, CMLSO, FASLMS

Therapy lasers have become a "go-to" modality for many chiropractors across the country. The powerful combination of clinical efficacy, lack of harmful side effects and return on investment means that therapeutic lasers will be a popular treatment modality for years to come. Not long ago, laser therapy was perceived as voodoo. But today the mechanism of action is understood; cellular targets and physiological effects identified; and a solid track record of clinical efficacy for various conditions is emerging.

From a scientific standpoint, there are topics of which some is known, but further research is required. Parameters such as ideal power and power density, wavelength and combinations of wavelengths, dosage at skin surface and at depth, as well as pulsed frequencies must be studied in vitro, in vivo (in both animal and human subjects), and in clinical trials. Advancing the knowledge base will optimize laser therapy treatments so we can give our patients the very best care possible.

Many of those lecturing on laser therapy in the chiropractic world claim expertise by quoting the number of years they have used lasers, touting conjured techniques, and reciting jargon largely fed to them by the marketing department of a therapy laser company. While these tactics may have served to successfully introduce laser therapy to our health care profession, they must be set aside for a more rigorous scientific discussion.

Like it or not, a certain knowledge of basic physics is required to have a rudimentary understanding of the modality. And an advanced knowledge of physics should be required for those lecturing and writing on the topic. Full credit should be given to those with advanced degrees in orthopedics, sports injuries, etc., but this author has observed a large number of basic science mistakes in those doctors' writing and presentations.

To advance laser therapy as a modality, as well as preserving and gaining credibility for our chiropractic profession as a whole, scientifically correct terminology and concepts must be utilized.

This article will address tissue heating and laser therapy over metal implants and growth plates.

Primum non nocere — First, do no harm. The worst-case scenario must be utilized in any examination of safety. For a therapy laser, this would mean testing the highest power available in continuous wave mode (light constantly "on"). For this test, the author used a class 4 therapy laser capable of producing 15 Watts maximum power at wavelengths (colors) of 800, 905, and 970 nanometers (nm) individually, or in any combination.

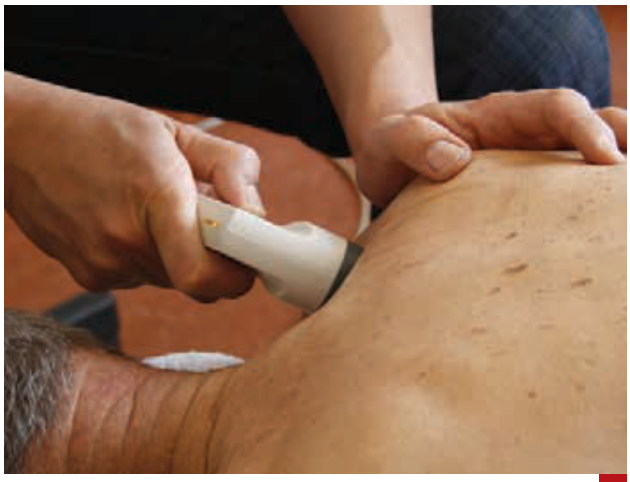
These wavelengths are in the near-infrared (NIR) region of the electromagnetic spectrum and are non-ionizing. NIR photons have much lower energy than ultraviolet or x-rays, and cannot break molecular bonds nor cause genetic damage.

There is a small peak in the absorp-

tion curve for the water molecule at 970nm. When water molecules absorb photons of light, the light energy is converted into heat, so using the 970nm wavelength alone will produce the most tissue heating.

As infrared therapy laser light penetrates into the skin and is absorbed, it attenuates and gets dimmer. This means that any tissue heating will occur from the outside-in, the skin will be warmer than any tissues deep in the body. Laser therapy is not a deep heating modality.

A therapy laser producing 15 W, CW at 970nm was run for several minutes on a human forearm. The skin temperature of the treated area was measured using a Fluke 62 Max infrared thermo-meter[1]. This test was run for four minutes, delivering 3600 Joules to an area of 200 square centimeters, a dosage of 18 J/cm^2.



Two implications of this are that even at very high power levels, therapy laser treatments are extremely safe, warming the tissues less than during a walk on a sunny day; and that no appreciable heating is occurring deep inside the body.

Human core body temperature in a normal healthy adult is 98.6˚, but ambient skin temperature is several degrees less. In our study, the starting forearm skin temperature was 95˚. During the four minutes exposure, the maximum measured skin temperature was 99˚. The subject's forearm was allowed to cool, then was exposed to direct sunlight on a summer day in Franklin, TN. After four minutes exposure, the skin temperature had increased to 102˚.

Two implications of this are that even at very high power levels, therapy laser treatments are extremely safe, warming the tissues less than during a walk on a sunny day; and that no appreciable heating is occurring deep inside the body.

Decades ago, infrared heat lamps were contraindicated for usage over open growth plates, due to concerns of early closure induced by the deep heating. After high powered therapy lasers were FDA cleared in 2003, many (including the author) cautioned against treating over open growth plates. Now that we better understand the mechanisms of action, combined with knowledge that even the highest powered therapy lasers are not creating significant heating inside the growth plates, those cautions can now be dismissed.

A study[2] by Cheetham examined the radiological and histological effects of high doses of NIR therapy laser on healthy growth plates in Wistar rats. It concluded the laser "had no significant effect on the healthy growth plates of the rat knee joint." In addition, in more than ten years clinical treatment of both human and animal juvenile patients, not a single incident of early growth plate closure or any other problem has been reported.

Chiropractors wanting to use laser therapy to treat teenage patients suffering from Osgood-Schlatter's, back pain, scoliosis or other conditions can proceed with the assurance that laser therapy will not have a harmful effect on the patient's growth plates.

Another frequent question is the use of therapy laser over metal implants in the body. Therapeutic laser light is reflected, not absorbed by metal surfaces, so no heat is generated when laser therapy is used over joint replacements, plates from broken bones, or even post-surgical metal clips.

Patients with metal implants frequently have a buildup of scar tissue resulting in reduced range of motion, chronic pain and reduced mobility. Therapeutic ultrasound cannot be used over the metal, but laser therapy can, and in combination with soft tissue mobilization the chronic scar tissue can be effectively broken up, range of motion improved and mobility restored.

Therapeutic lasers are here to stay. As further studies are conducted, equipment is refined and protocols are enhanced, clinical effectiveness will improve and return on investment will grow. Chiropractors using laser therapy can be assured the treatments can safely be used over open growth plates and metal implants.

1 *http://www.fluke.com/fluke/m2en/Electrical-Testers/Thermometers/Fluke-62-MAX-Plus.htm?PID=74272*
2 *M. J. Cheetham, S.R.Young and M. Dyson: 'Histological Effects of 820 nm Laser Irradiation on the Healthy Growth Plate of the Rat' Low Level Laser Therapy 1992; 2: 59.*

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Dynamic Chiropractic
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Physics for Chiropractors, Part 3

Can Laser Therapy Damage Tissue?

By Phil Harrington, DC, CMLSO

The laser was theorized by Einstein in 1917[1] and invented by Maiman in 1960.[2] Its unique property of light waves being coherent in space and in time led many to theorize that it could be a damaging form of electromagnetic radiation. Dr. Endre Mester conducted experiments on mice afflicted with skin cancer in 1967 and found that shaved areas grew hair more rapidly when exposed to low levels of laser light.

Thus the field of laser therapy was born and now, 42 years later, therapeutic lasers are gaining acceptance in the chiropractic profession for the treatment of chronic pain, sports injuries, musculoskeletal conditions and more. While exhibiting at a chiropractic trade show a couple years ago, a wily old doctor asked me, "How do you know you're not causing cancer?" which is an excellent question. Let's talk about laser and its effects on tissue.

Before we answer the question of whether laser therapy can damage tissue, let's review some basic physics terms applicable to laser therapy. Power is measured in Watts and is the time rate of energy delivery. Energy is measured in Joules, and time in seconds. Energy density, also known as dosage, measures the amount of energy applied per unit area in Joules per square centimeter. Power density, or irradiance, is measured in Watts per square centimeter.

Table 1. Physics Terms and Units for Therapy Lasers

Term	Description	Unit of Measurement
Power	Time rate of energy delivery	Watts, W
Energy	Ability to do work	Joules, J
Wavelength	Distance between like points of a wave	nanometers, nm
Energy Density	Dosage	Joules per square centimeter, J/cm2
Power Density	Irradiance	Watts per square centimeter, W/cm2

Wavelength is a measure of the distance between adjacent points on a light wave and is expressed in nanometers (nm). Therapy lasers use visible and near-infrared light in the range of 635 nm to 1,064 nm. Wavelength determines how deep laser energy penetrates into tissue.[3] The energy of individual photons is inversely proportional to the wavelength. Photons of ultraviolet light carry higher energy than photons of infrared light. (**See Figure 1**)

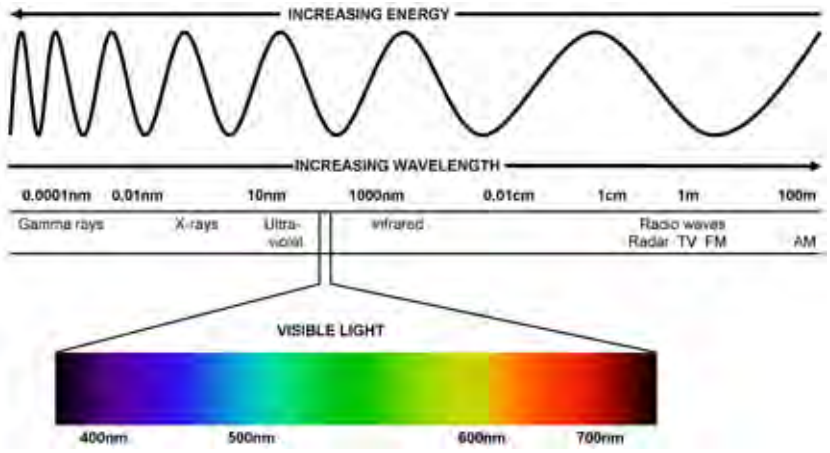

Figure 1: The electromagnetic spectrum.

All living matter is composed of molecules which are made of atoms held together by electron bonds. Ionizing radiation is energetic enough to break those bonds. High-energy photons such as gamma rays, X-rays and ultraviolet rays are capable of ionizing molecules, causing damage to cell components and DNA. Lower energy photons cannot ionize molecules, instead inducing vibration, rotation and translation within the molecule. These low-energy transfers are not capable of damaging cells or DNA.

There is a very clear wavelength limit at which the energy of individual photons becomes high enough to ionize molecules: 320 nm, which sunbathers know as UVb.[4] All electromagnetic radiation with a wavelength shorter than 320 nm (to the left of UV in Figure 1) is capable of ionizing living matter and causing cancer or other cellular damage.

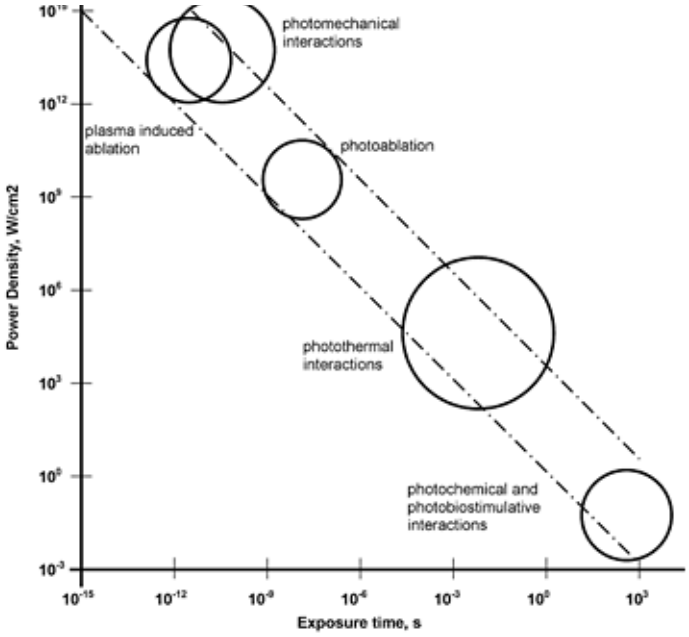

Figure 2: Map of laser-tissue interactions

showing power density versus exposure time.[7] Power density, or irradiance, measures the concentration of the laser's "brightness." Low-power densities produce beneficial photochemical and photobiological effects in tissue. Higher power densities result in thermal interactions, whereby the local temperature is elevated significantly[5].

In laser-tissue interactions the term thermal does not refer to mild warming of a few degrees, but to increases in tissue temperature above 60 degrees C, producing the effects of coagulation, vaporization, carbonization and melting.[6]

To calculate the power density of a therapy laser, divide the average power delivered by the spot size of the laser. For example, a 500 milliwatt (0.5 W) laser with a 1 centimeter diameter spot size would produce a power density of 0.6 W/cm^2, and a 10 Watt laser with a 2.5 centimeter spot size produces a power density of 2 W/cm^2. Therapy lasers deliver output powers ranging from 0.005 W to 12 W, and when used as intended operate at power densities of 2 W/cm^2 or less.

Figure 2 shows the five basic types of laser-tissue interactions plotted on a chart of power density versus exposure time. Note that the axes are logarithmic, where 10^6 = 1,000,000. The zone of action for therapy lasers is at the lower right, where power densities are less than 10 W/cm^2. Once again, in the description of laser-tissue interactions the term *thermal interaction* refers to those interactions that produce a significant (>60 degrees C) rise in temperature, not the mild increases of a few degrees that can happen with laser

therapy treatments. (**See Table 2 below**)

Table 2. Thermal Effects of Laser Radiation[8]		
Temperature		**Biological Effect**
Celsius	Fahrenheit	
37	99	Normal
39	102	(Typical maximum temperature in region of Class IV therapy laser treatment)
40	104	(Maximum suggested temperature for hot tub)
45	113	Hyperthermia
50	122	Reduction in enzyme activity, cell immobility
60	140	Denaturation of proteins and collagen; coagulation
80	176	Permeabilization of membranes
100	212	Vaporization; thermal decomposition (ablation)
> 100	> 212	Carbonization
> 300	> 572	Melting

Energy density, or dosage, measures the total amount of energy delivered per unit area and is expressed in J/cm^2. Too low a dose is ineffective, just the right dose produces the desired effect, and too high a dose can be biosuppressive. What is the right dose? Biostimulation has been reported in studies with dose ranges from 0.001 J/cm2 to 10 J/cm^2 and higher.[9]

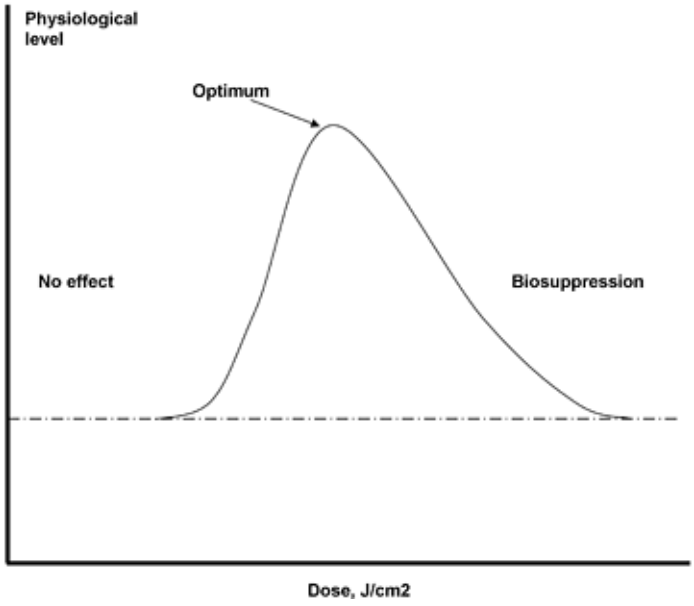

Figure 3: Dose-response curve for laser therapy.

Determining the appropriate treatment dose is a complicated issue and depends on many factors such as wavelength, power density, condition, treatment technique and more. In their text *Laser Therapy: Clinical Practice and Scientific Background*, Drs. Jan Tuner and Lars Hode suggest dosages from 1.0 to 10.0 J/cm^2 for the treatment of superficial or deep pain conditions.[10]

How much dosage is too much? One study has reported irreversible cellular and genetic damage as a result of high-energy densities.[11] In this particular study a dose of 16 J/cm2 was delivered to naked cells, whereas the maximum recommended dose in the treatment of deep pain is 10 J/cm^2. It should obvious that there is a great difference between irradiating in vitro cultures just a few cell layers thick, and living human patients.[12]

So, can laser therapy damage tissue? Yes it can, under two conditions: it is of sufficient intensity to burn (high power density); or it contains high-energy photons (short wavelength).[13]

As indicated, therapy lasers deliver power densities that produce photochemical and photobiological responses in tissue at levels significantly lower than those needed to damage tissue. The dosages recommended for laser therapy are far below those needed to damage cell cultures. Also, with their wavelength range from 635 nm to 1,064 nm, therapy lasers produce photons that do not ionize living matter. So, laser therapy does not cause cancer, or damage to skin, tissues or DNA, because therapy laser light is non-ionizing and is delivered at dosages far below those needed to cause damage.

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PRACTICAL PAIN MANAGEMENT
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Class IV Therapy Lasers: Maximizing the Primary Effects of Laser Therapy

by Dr. Julian Vickers, DC, DABCO, DACAN and Dr. Phil Harrington, DC

A rapidly growing number of progressive health care providers are adding Class IV therapy lasers to their clinics. By maximizing the primary effects of the photon-target cell interaction, Class IV therapy lasers are able to produce impressive clinical results and do so in a shorter period of time. A busy office interested in providing a service that helps a variety of conditions, is cost-effective, and is being sought out by an increasing number of patients should give a serious look at Class IV therapy lasers.

First theorized by Albert Einstein in 1916, and invented by Theodore Maiman in 1960, the laser has become one of the most beneficial inventions used in modern society. For the clinician, the most exciting use was first discovered by Hungarian physician Endre Mester, who performed experiments on cancerous tumor in rats. He found the laser didn't kill tumor cells because it was underpowered for that purpose, but rather it accelerated wound healing in the surgical sites of the experimental rats, as well as causing the shaved hair to regrow more quickly.

Therapy lasers have been used and researched extensively in Europe for more than 30 years. However, the United States Food and Drug Administration (FDA) only cleared a low level laser in 2002, and the first class IV therapy laser in 2003. Low Level Laser Therapy (LLLT) and it's known effects have already been reviewed extensively in this journal. The most important clinical and therapeutic difference between Class IV Laser therapy and LLLT is that the Class IV is able to produce a primary biostimulative effect on deeper tissues than lower powered lasers while also producing substantial secondary and tertiary effects.

The FDA approved indications for use of Class IV laser include the following: relief of muscle and joint aches, pain and stiffness; relaxation of muscles and muscle spasms; temporary increase in local blood circulation; and relief of pain and stiffness associated with arthritis.[1]

Lasers are classified by output power and hazard to the eye, with the potential for thermal injury being the guiding mechanism. The Maximal Permissible Exposure or MPE is the level of laser radiation to which a person may be exposed without hazardous effects in the eye or skin. A system of hazard classification has been developed and is part of the ANSI Standard and State Regulations, however it is usually more convenient to establish safety controls based on the laser class than use of

the exposure limits. In general, Class IIIa lasers have power output of 1 to 5 milliWatts (1-5mW), Class IIIB includes those up to 500 mW, or 0.5 Watts, and Class IV lasers include all of those above 0.5 Watts.

The classification scheme makes no distinction between the Class IV therapy lasers, cosmetic and hair removal lasers, surgical lasers, and the military laser capable of shooting down a satellite. All of theese are greater than 500 mW, and therefore all of them are Class IV. Lumping together every laser with power output greater than 500 mW is somewhat unfortunate, and has led to misunderstandings and discussions on several state physician licensing boards. One state chiropractic board first balked at the notion of its members using Class IV lasers, assuming that the intended usage was hair removal or a cosmetic procedure. However, after proper education and demonstration with a Class IV Therapy Laser, the board unanimously approved the use of such devices when used in a manner consistent with the scope of practice.

The most common Class IV therapy laser uses a Gallium-Aluminum-Arsenide (GaAlAs) semiconductor diode to produce infrared laser beams capable of deep penetration into tissue. The diodes may produce continuous wave, or pulsation frequencies of 2-10,000 Hz with a 50% duty cycle. Typically the laser diodes are housed in a control unit, and the infrared laser beams are carried by a fiber optic cable, through which coherence is maintained. The beam produced by a Class IV therapy laser is not collimated; it is allowed to naturally diffuse at a 10-12^{o} angle. Spot sizes will range from 10 to 25 millimeters in diameter, giving spot areas of 0.8 to 5 cm^2. Common power densities will range from 0.4 to 3 W/cm^2.

Wavelength is the main determinant of the laser's depth of penetration into the tissue. Hemoglobin and melanin absorb photons at lower wavelengths and water absorbs those of higher wavelengths. There is an optical window around 790 nm, where the laser photons are absorbed least by these three components and penetrate the deepest. These deep penetrating infrared lasers are ideal for pain management therapy. Other factors affecting the depth of penetration are the technical design of the laser device and the treatment technique used.

There is no exact limit with respect to the penetration of the light, as the laser light gets weaker the further from the surface it penetrates. There is a point at which the laser photon density is so low that no biological effect of the light can be measured. The biologically effective depth of an infrared therapy laser – for primary photon-tissue interactions – is conservatively stated as four centimeters.

Secondary and tertiary photobiomodulation effects will be observed much deeper, as well as systemically.

To summarize, the primary response is elicited when photons emitted by the laser reach the mitochondria and cell membranes of low lying cells such as fibroblasts where the energy is absorbed by chromophores and is converted to chemical kinetic energy within the cell. These primary effects are very predictable and are produced only by phototherapy.

Secondary reactions lead to the amplification of the primary actions. A cascade of metabolic effects results in various physiological changes at the cellular level such as changes in cell membrane permeability. Calcium is released from the mitochondria triggering changes in intracellular calcium levels which stimulates cell metabolism and the regulation of signaling pathways responsible for significant events required for wound repair such as cell migration, RNA and DNA synthesis, cell mitosis, protein secretion and cell proliferation.

Tertiary effects are induced at a distance from the cells in which the secondary events occur. Energized cells communicate with each other and with nonirradiated cells through increased levels of cytokines or growth factors. This results in intercellular communication and an increase in the immune response with the activation of T-lymphocytes, macrophages and number of mast cells. An increase in the synthesis of endorphins and decrease in bradykinin results in pain relief. The tertiary effects are the least predictable because they rely on intercellular interactions and a number of environmental variables.[6]

Chromophores absorb laser photons with wavelengths between 400 and 1100 nanometers, with those in the 790 nm neighborhood being the deepest penetrating, as discussed earlier. Photons incident on tissue will reflect, absorb, transmit or scatter. With a Class IV infrared laser, the scattered photons create an egg-shaped volume of treated tissue. The effective depth of penetration is roughly four centimeters, meaning that the primary interaction of photon with target cell will occur through that depth.

Dosage refers to the amount of energy per unit area applied to the tissue surface. Energy is measured in Joules, the area in square centimeters and thus the dosage in Joules per square centimeter, J/cm^2. The power of a laser is the rate of energy delivery and is measured in Watts, or milliwatts, and one Watt equals one Joule per second. Class IV therapy lasers have power output from 0.5 to 10 Watts. As an example, a laser operating at 6 Watts continuous wave would deliver 360 Joules in one minute,

and 180 J/min in pulsed mode. If the treatment area was 50 cm^2, the dosage would be 360 J / 50 cm^2, or 7.2 J/cm^2 in continuous wave, and 3.6 J/cm^2 in pulsed mode.

Biostimulation has been reported with doses from as low as 0.001 J/cm2 to as high as 10 J/cm2. This wide range is explained by the vast differences in irradiating tissue cultures in a laboratory and treating a deep-lying condition in a clinical setting. The matter of correct dosage is very complicated, as a number of factors must be taken into account including wavelength, power density, type of tissue, condition of the tissue, acuteness or chronicity of the problem, pigmentation, treatment technique, etc. Nonetheless, there is a dosage window below which no biostimulation will occur and above which it is inhibited, most easily demonstrated in wound healing and stimulation of hair growth.[7]

Numerous studies have supported the use of higher doses of laser irradiation. In one study, irradiation of in vitro rabbit articular chondrocytes with 4-6 J/cm^2 demonstrated substantial biostimulation compared to control cultures[8]. In another, 13 J/cm^2 increased the number of chondrocytes and the thickness of the articular cartilage in immobilized rabbit knees[9]. Another study supports a dosage as high as 24 J/cm^2.[10]

Substantial amounts of the laser energy applied at the surface will be reflected, absorbed and scattered in the superficial tissues. If the target of laser therapy is several centimeters deep, a high dose at the surface will be reduced to a moderate dose in the zone of concern. At least 50% of the surface-applied energy will be lost, so a dosage of 10 J/cm^2 would be diminished to 5 J/cm^2 or less at a deep target.

Critics of high-powered laser therapy claim damage will occur in the overlying healthy tissue. It is said that surface doses of 10 J/cm^2 or more will be harmful. However, "(i)n the treatment of healthy, optimally working tissue, almost any dose can be used without noticeable macroscopic negative effects. This is the case in the use of surgical lasers cutting, evaporating and coagulating tissue, using very high power and energy densities. Right outside the destructive zone, very high levels of power density and dose occur, but this is not found to be negative."[11] In daily practice, hundreds of clinicians are safely treating thousands of patients every day with Class IV therapy lasers.

The current accepted dosage for deep-lying pain is 4-10 J/cm^2, when treated with a GaAlAs diode laser[12]. Simple calculations show that if the condition being treated is lumbar pain, the area being treated could be 100 to 400 cm^2, and even more if it is accompanied by radiculopathy. This equates to a total treatment dosage of 400 to 4000 Joules. If the treatment device was a 500 mW laser, it would take

reflected or scattered radiation during normal operation exceeds the applicable MPE[16].” The NHZ for Class IV therapy lasers is about 21 feet. Treatment with a Class IV therapy laser should never be performed in the open.

Safe operation is not difficult when the laser therapist has basic training in laser safety. Proper training and the use of wavelength specific protective goggles by everyone in the treatment room are required by the FDA. Also, one person must be designated the Laser Safety Officer for the facility. When these simple guidelines are followed the use of a Class IV therapy laser is extremely safe.

Therapy lasers have been an exciting addition to the health care treatment arsenal. The development of Class IV therapy lasers represents the next generation of light therapy. By maximizing the primary effects, Class IV therapy lasers are able to induce extremely rapid clinical responses. Progressive health care providers wanting to offer the latest technology to their clientele should investigate Class IV therapy lasers.

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Page 1 of 3

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SUMMARY OF SAFETY AND EFFECTIVENESS

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1. **DEVICE NAME (Trade/common, and classification):**

Proprietary name: K-LASER
Common/usual name: K-Laser Cube 1, K-Laser Cube 2, K-Laser Cube 3, K-Laser Cube 4
Classification name: Infrared Lamp
Classification: Class II
Regulation Nos.: 21 CFR 890.5500
Product Codes: ILY

K120604
Page 2 of 3

2. PREDICATE DEVICES:

The device under submission is substantially equivalent to the predicate devices:

K091497 (K-1200);

K061656 (Laser-D68);

The device under submission is a family of laser emit a beam of coherent light in either continuous wave or pulse mode at the following wavelengths:

K-Laser Cube 1: 905nm; peak power: 10W;

K-Laser Cube 2: 800nm, 970nm; peak power: 15W;

K-Laser Cube 3: 800nm, 905nm, 970; peak power: 20W;

K-Laser Cube 4: 905nm; peak power: 10W.

3. PERFORMANCE STANDARDS:

for Substantial Equivalent

The device conforms to the applicable requirements of 21 CFR section 1010 (Performance Standards for Electronic Products: General) and 21 CFR sections 1040.10 and 1040.11 (Performance Standards for Light-Emitting Products).

4. DESCRIPTION:

The devices under submission are a family of laser that emits a beam of coherent light in either continuous wave or pulse mode at the wavelengths previously described.

Each device is a table device, easy to transport, usable also without electrical net, thanks to a battery pack. It is composed of a touch screen for managing all the device functions, an emitter, an handpiece for the delivery of light, software and an on/off button to activate and deactivate the infrared emission.

k120604
Page 3 of 3.

5. INTENDED USE/ INDICATIONS FOR USE:

Each device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

The devices under submission share the same intended use, similar design and functional features as the predicate devices without raising any issues of safety or effectiveness. Therefore, the devices under submission are substantially equivalent to the predicate devices K091497 (K-1200), K061656 (Laser-D68).

7. SAFETY AND EFFECTIVENESS:

There are no substantive differences between the product defined in this 510(k) submission and the predicate devices. They are similar to the technologies that are currently used in other similar medical devices. They were developed and documented under Eltech's mature Quality Managerment System, under The Quality System Regulation, 21 CFR Part 820, under design/change control, and verified/validated to applicable standards/guidance documents. Besides, Eltech's Quality Assurance System is certified by CERMET, notified body n. CE 0476, according to Annex II of 93/42 EEC Directive, transposed in Italy by Dlgs. n. 46 of 24 February 1997.

The devices are safe and effective when used as indicated in specific applications under a clinician's supervision/therapy program.

Date: 25th April 2012

Signature: _____

Francesco Zanata
Eltech s.r.l. President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Eltech S.R.L.
% K-Laser USA
Mr. Richard Albright
President
1185 West Main Street
Franklin, Tennessee 37064

MAY 25 2012

Re: K120604
Trade/Device Name: K-Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: February 28, 2012
Received: February 28, 2012

Dear Mr. Albright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) PREMARKET SUBMISSION	SECTION_4: STATEMENT OF INDICATION FOR USE	Rev. 0 Sec. 4 Page 1 of 1

K120604

INDICATIONS FOR USE

Indications for Use:

K-laser Cube 1,2,3, and 4 device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120604

Santé Canada Health Canada

LN/NH: 93274

Therapeutic Products Directorate
Medical Devices Bureau
Direction des produits thérapeutiques
Bureau des matériels médicaux

Medical Device Licence

Homologation d'un instrument médical

Licence Number: 93274 ***No d'homologation:***

First Issue Date: MAY 15 2014 ***Première date de délivrance:***

Device Class/Classe de l'instrument: 3

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

K-LASER (CUBE SERIES)

Licence Type/Type d'homologation:

Group / Groupe

Manufacturer Name & Address/Nom du fabricant & adresse

ELTECH S.R.L.
VIA CASTAGNOLE, 20/H
TREVISO, TREVISO
ITALY
31100

for Barbara J. Sabourin, Director General, Therapeutic Products Directorate
Directrice générale, Direction des produits thérapeutiques

Application Number: 220580
Numéro de la demande:

Manufacturer ID: 132522
Identificateur du fabricant:

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

K-LASER (CUBE SERIES)

Device ID/No de l'instrument: 584011
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
K-LASER CUBE

K-LASER CUBE 2

Device ID/No de l'instrument: 597973
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
K-LASER CUBE 2

K-LASER CUBE 3

Device ID/No de l'instrument: 597974
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
K-LASER CUBE 3

K-LASER CUBE 4

Device ID/No de l'instrument: 597975
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
K-LASER CUBE 4

Protecting Chiropractors Ability to Utilize Therapeutic Laser Technology

K-laser USA will continue to be a proactive participant ensuring Doctors of Chiropractic access to therapeutic laser technology to help their patients with safe and drug-free therapy laser treatments.

Franklin, TN (PRWEB) March 10, 2011 -- State Medical and Chiropractic Boards are writing new rules regulating the use of laser technology; K-LaserUSA is a proactive participant in the process; Ensuring DC's access to advanced technology to help their patients with safe and drug-free therapy laser treatments.

The United States Food and Drug Administration (FDA) regulates medical devices to be sure they are safe and effective, and are honestly, accurately and informatively represented to the public. Therapeutic lasers apply a low dosage of red or infrared laser light to deliver pain management, reduce inflammation and enhance tissue healing. Photobiomodulation is the term embraced by the North American Association for Laser Therapy for this process.

Chiropractic is a health care discipline and profession that emphasizes diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system. Doctors of Chiropractic primarily use manual therapy, including manipulation of the spine, other joints, and soft tissues; but treatment may also include application of therapeutic modalities, exercises and health and lifestyle counseling.

Lasers are classified by the FDA according to their power output. Class 3a lasers have less five milliwatts of power, Class 3b are between 5 and 500 milliwatts (or half a Watt), and Class 4 lasers are more than 500 milliwatts. Class 4 lasers are utilized in therapy, surgery, hair removal and even industrial applications. The wavelength (or color) and the power density (or concentration) determines the outcome of the laser-tissue interaction. Class 4 is the highest on the classification scheme, and since 2002 the FDA has cleared therapy lasers in Classes 3a, 3b and 4.

For the past nine years, Chiropractors have been using lasers to enhance patient clinical outcomes. State Boards of Chiropractic have begun to rewrite scope of practice rules to address the utilization of therapeutic lasers. Since Class 4 lasers encompass a wide array of devices, there has been some confusion whether chiropractors could use FDA-cleared Class 4 therapy lasers.

K-LaserUSA has been a proactive participant in the process. Dr. Phil Harrington, Manager of Education and Clinical Support has supplied written testimony to the states of Maryland and Ohio, and has given personal testimony in Texas, Iowa, Washington and California.

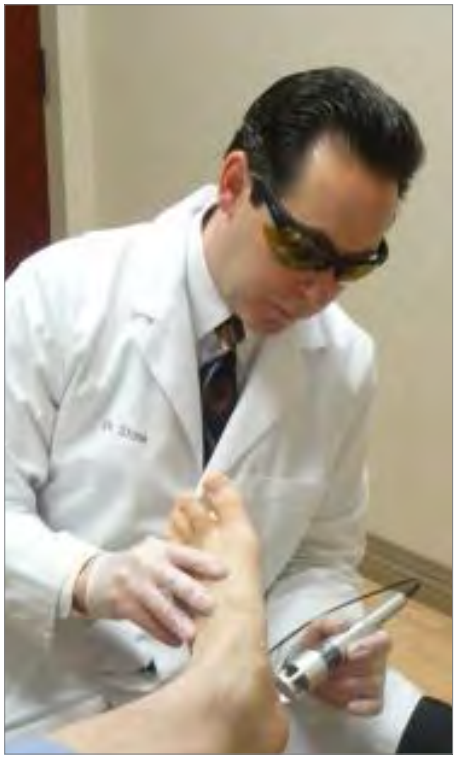
The Washington Chiropractic Quality Assurance Commission (QAC) held a meeting August 12, 2010 to discuss whether Class 4 therapy lasers should be on the list of devices approved for use by Washington Chiropractors. Dr. Harrington of K-LaserUSA was the only laser industry representative present at that meeting. At the February 24, 2011 Scope of Practice Subcommittee Meeting in Sacramento, California Dr. Harrington was one of two laser industry representatives present, and after the meeting was asked by Subcommittee Chair Dr. Hugh Lubkin to be on call as an industry expert.

K-LaserUSA will continue to be a proactive participant ensuring Doctors of Chiropractic access to therapeutic laser technology to help their patients with safe and drug-free therapy laser treatments.

DISCLAIMER

Wound cases are presented for the visual impact of healing with the K-Laser. Treating wounds is not in the scope of practice for all human K-Laser Practitioners. It is the individual practitioner's duty to determine if they may treat wounds in the clinical setting. K-Laser USA assumes no liability, duty or obligation in this matter.

CASE REPORT: HEEL PAIN



54 year old white female with a one year history of chronic left heel pain. Conservative treatment consisting two steroid injections, custom made orthotic devices, and a course of physical therapy did not relieve her pain.

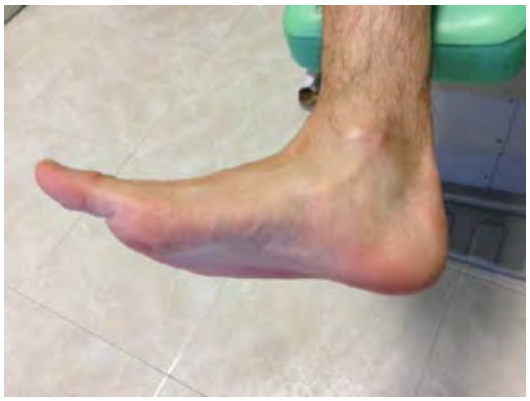
Examination revealed moderate pain to palpate the medial calcaneal tuberosity of the left foot. Due to failure of conservative treatment, soft tissue laser therapy was recommended.

Laser therapy was performed twice weekly. The K-Laser Acute Ankle Pain setting was used at 10 Watts. After a total of six treatments, the patient's heel pain was resolved and she returned to full exercise activity without recurrence of her of pain.

DR. HOWARD STONE
NORTH SHORE PODIATRY GROUP

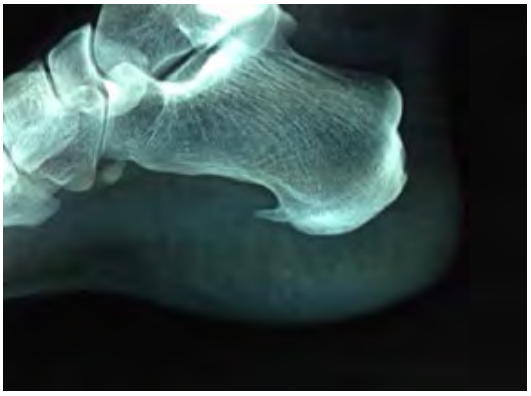
CASE REPORT:
HEEL SPUR TREATED WITH K-LASER CUBE

A.R., 35 years old male, checked in to the podiatric clinic of the Higher Learning Health Institute Claudiana in May 2014, complaining of an acute pain to the heel of the right foot when standing, and reporting an even more intense pain in the same area when putting his foot down first thing in the morning.



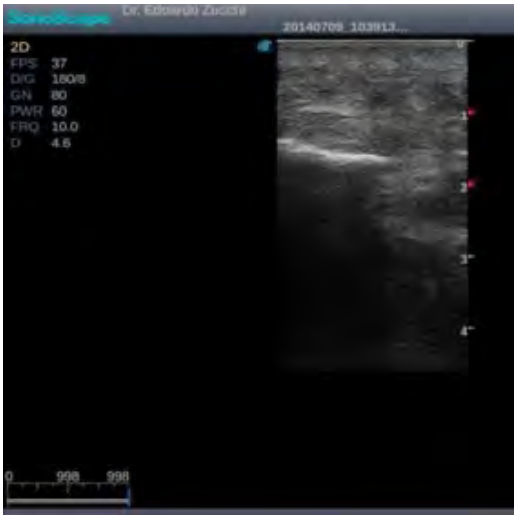
The patient had been suffering from chronic pain for 4 months now he decides to go to the clinic because of the pain intensification that causes a limitation in the usual movements and, consequently, a compensation through an antalgic gait but causing pain to the contralateral foot.

X-Ray and Ultrasound examinations confirmed the diagnosis of heel spurs.



The patient felt temporary relief by taking some NSAIDs (Nonsteroidal anti-inflammatory drugs) but he didn't resolve the problem in a definitive way.

Dr. Luca Rizzi, assisted by the third-year's students of the Master degree in Podiatry of the Higher Learning Health Institute Claudiana, knows very well the difficulties of the heel spur treatment and chooses the laser therapy's application using K-Laser Cube. First of all, the team wants to reduce the inflammation and the pain. The patient may also benefit from the biostimulating effects of laser therapy such as improved circulation and metabolic activity as well as the functioning of the nervous system, the immunoregulation and preventing the fibrotic tissue's formation.



The therapeutic program includes 3 lasertherapy's sessions in a week as well as a custom orthotic insole which relieves the painful area (Schwarz ring).

The program is set for acute pain and skin type II coloration. The treatment time per session is 4:35 minutes for two times, with a pause of ten minutes between the first and the second application. The total Joule is 1200 and the average power is 6 W. The operator uses the "ENT" handpiece directing the photons' beam to the insertion area of the plantar aponeurosis.

Just after the first application the patient refers an immediate improvement that increases in the two subsequent sessions. At the end of the therapy, the pain completely disappeared.

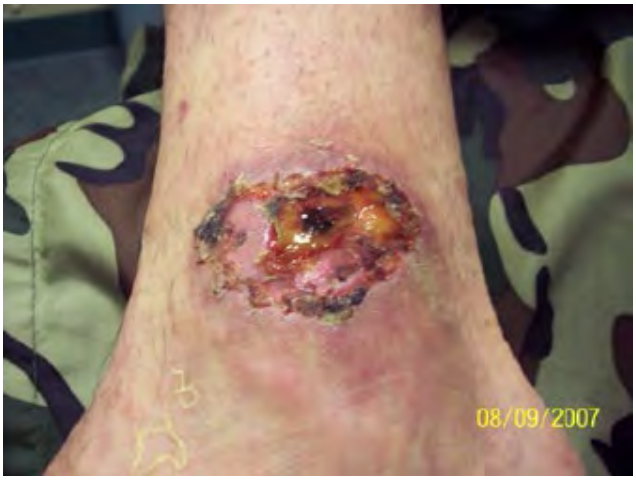
The use of the orthotic insole is important to safeguard the achieved mental and physical well-being and to prevent the relapse and any mechanical stress on the treated area.

Higher Learning Health Institute Claudiana
Via Lorenz-Böhler, 13 - 39100 Bolzano (Italy)

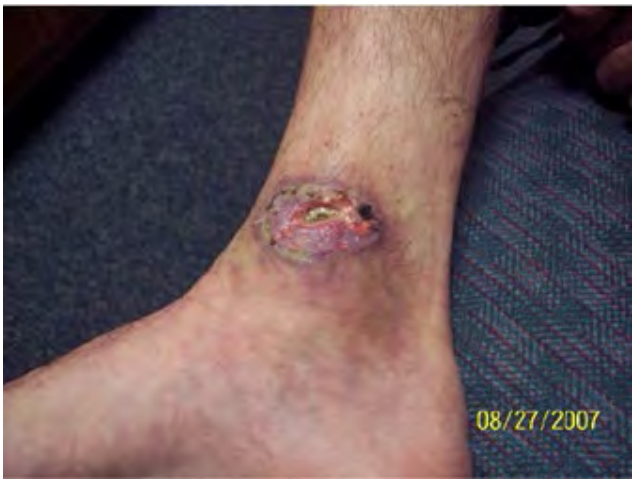
CASE REPORT: BURN

The injury occurred on July 4 ,2007 when a motorcycle fell on the patient's leg. His medial ankle was burned to the bone and he required a skin graft. On August 8, 2007 his medical doctor told him that he would require multiple skin grafts as the first one was not improving.

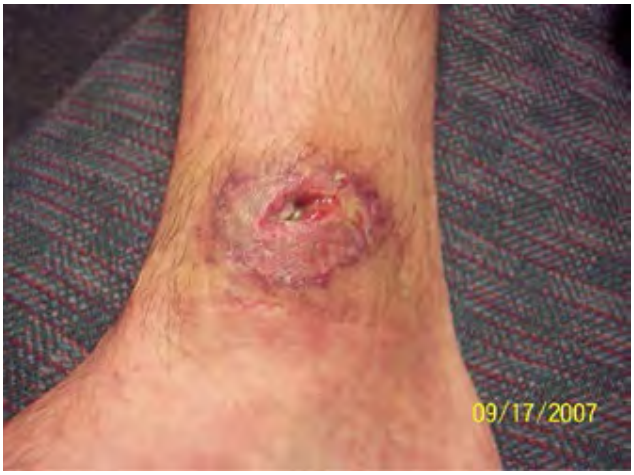
Scott chose to wait an additional 30 days after the first treatment. The K-Laser model 6D was used to relieve pain and promote healing. You'll see the results of the efficiency of the Klaser Model 6D in the following pictures.



Picture from one month and on skin graft after accident - August 9, 2007.



17 days and 4 K-Laser treatments later - August 27, 2007



39 days and 8 K-Laser treaments - September 17, 2007

J. Rod McGinnis D.C., Sacramento, CA

Case report "lateral epicondylitis"

46 year old man got a sore elbow after crossfit training.
After 2 months of calm / rest and normal physiotherapy treatment, eccentric training, stretching, acupuncture.
All he tried was with lack of efficacy, then he got K-Laser treatments.

The ultrasound scan shows M. extensor carpi radialis longus with fiber defects and increased vascularity as seen below in the positive color Doopler.

After 4 K-Laser treatments and 21 days we see perfect fiber structure throughout the muscle and there is a negative color Doopler.

MED·TECH
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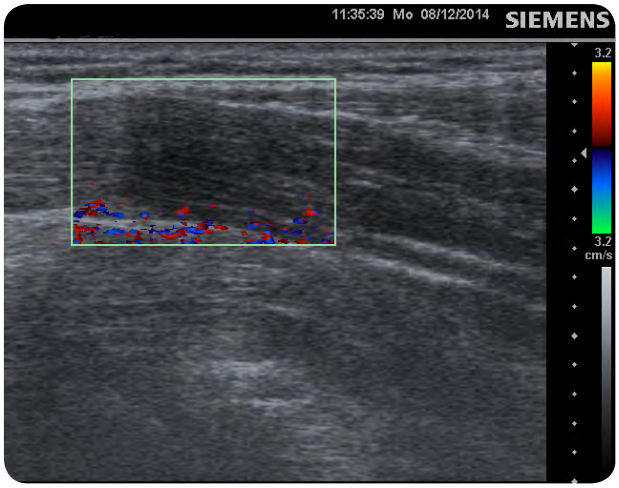
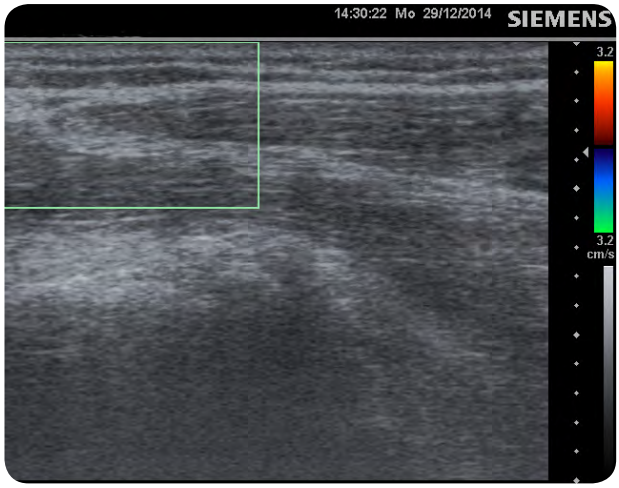
Vindinggård Ringvej 1 • DK-7100 • Vejle
+45 2929 7870 • claus@med-tech.dk
www.med-tech.dk

K·LASER USA





Case report "Fiber Blast in M. gastrocnemius"

41 year old elite tennis player with severe pain in the calf during the tennis match.

Ultrasound scan shows a rupture in M. gastrocnemius
(Cross Sectional Scanning is made 50 min. After injury)

After 5 K-Laser treatments over 3 days you see almost intact fiber structures on the scanning.

The patient played a match on day 7 after the injury.

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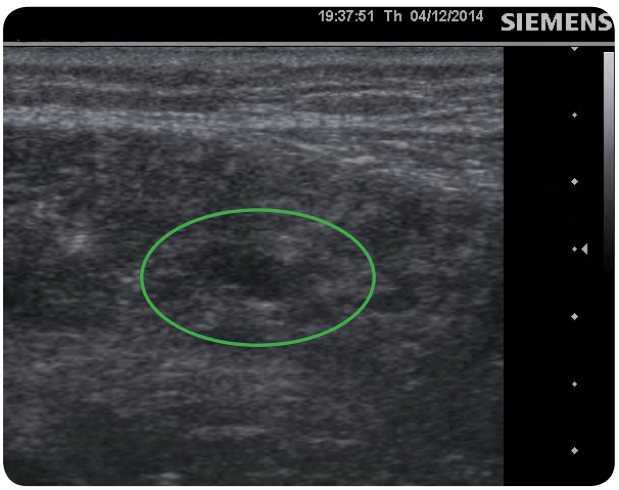
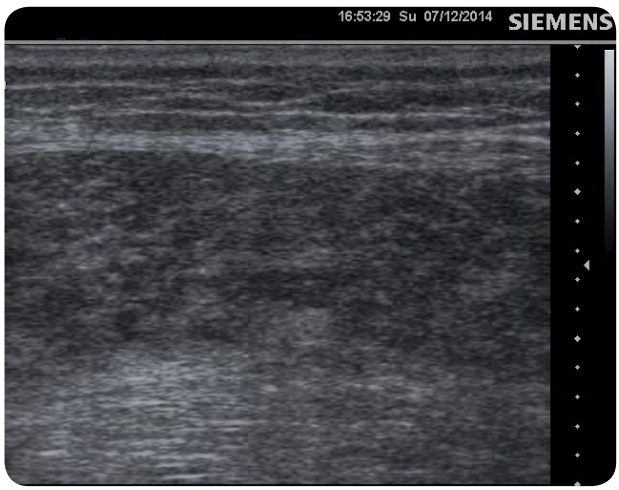
www.med-tech.dk

K·LASER USA





Case report "Fiber Blast of M. vastus intermedius"

13 year old elite hurdler with rupture in M. vastus intermedius.

Day 3 after injury, the ultrasound scan clearly shows a hole in the muscle.

Treated with K-Laser 5 times over 6 days.

6 days after the treatment the ultrasound perfect muscle fibers.

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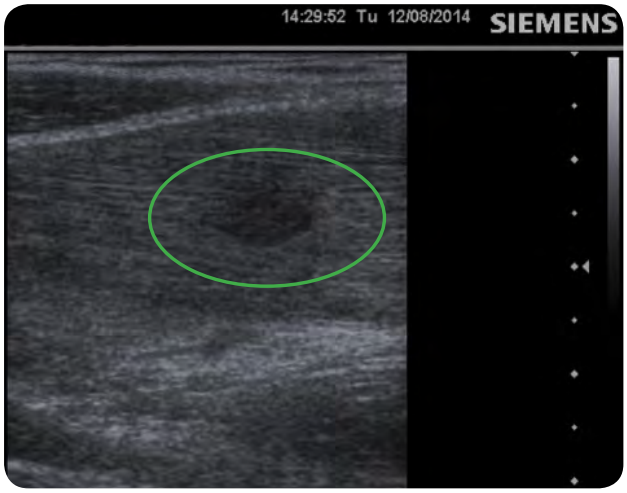
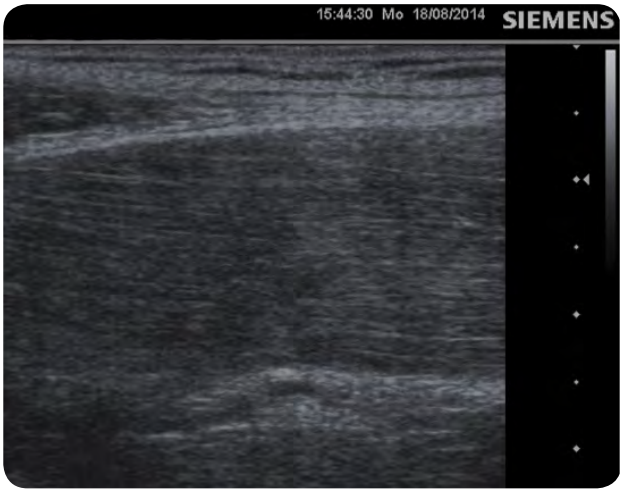
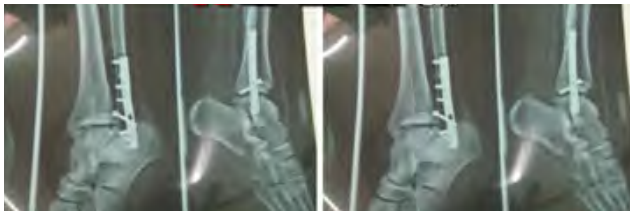
K·LASER® USA

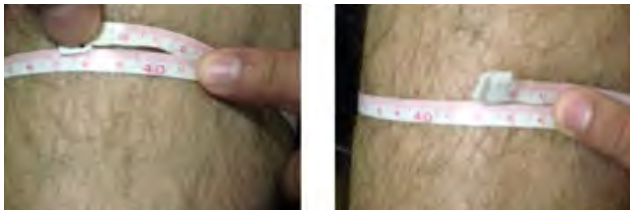


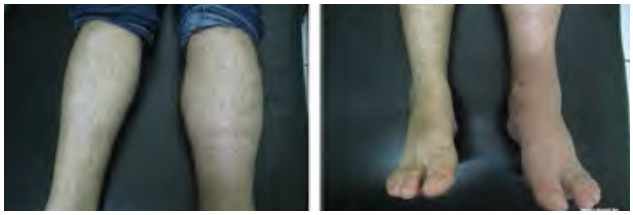


CASE REPORT: FRACTURED ANKLE

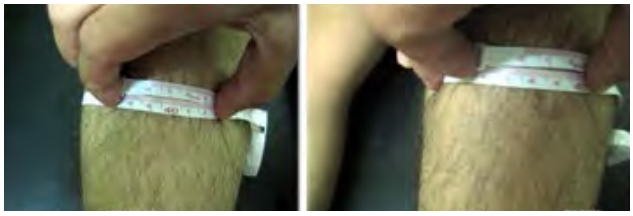


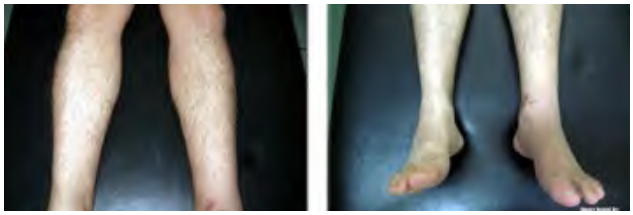
First day of physical therapy





After 8 K-Laser treatments





- Male patient, 35-years-old, suffers fractured ankle lateral malleolus of the fibula and ligament ruptures
- Deltoid on the inner face ankle and injured by abrasion medial malleolus on May 25, 2011
- The patient was surgically treated with reduction of fracture with osteosynthesis material, deltoid ligament plasty
- The patient has delayed of coagulation and therefore also slow the healing of the wound by abrasion before starting physiotherapy.

First day in physical therapy

- Patient walks with partial support up to 50% with axillary crutches
- Pain in ankle range of motion when forcing
- Range of motion; plantar flexion 40 degrees, -5 degrees dorsiflexion
- Important edema in leg, ankle and foot
- Leg metrics to evaluate edema: 39 cms diameter in right leg and 43 cms diameter in left leg - +4 cms

After 8 sessions of K-Laser therapy

- Patient with free march without crutches with light claudication
- No pain in the ankle, only a little tendinitis in the tendon of the peroneal, this caused friction on the plate osteosynthesis as the patient is performing daily activities already complete
- Range of motion: plantar flexion 45 degrees, 20 degrees dorsiflexion
- Edema is resolved
- Leg metrics to evaluate edema: 39 cms diameter in right leg; 37.5 cms diameter in left leg
- Now the left leg has a smaller diameter than the right, this is due to muscle atrophy of muscles of the leg itself with an injury of this nature

Unidad De Rehabilitacion & Terapia Laser, Mexico

Corso di Laurea Magistrale
in Odontoiatria e Protesi Dentaria
Corso di Laurea in Igiene Dentale
UNIVERSITÀ DEGLI STUDI DI TRIESTE

HPH
Azienda Ospedaliero – Universitaria
"Ospedali Riuniti" Trieste

Odontology and Stomatology Clunic: Oral Phatology and Medicine, Special Needs and Prevention in Oncology (University of Trieste)

ICGEB: International Centre for Genetic Engineering and Biotechnology

K-LASER

K-Laser designs, manufactures and markets professional laser devices worldwide for therapy, surgical, dermatology, vascular, oncology, aesthetic medicine and veterinary fields. Its products are engineered, developed and manufactured in Treviso.

The American Journal of Pathology, Vol. 183, No. 6, December 2013

ELSEVIER

The American Journal of PATHOLOGY

ajp.amjpathol.org

ANIMAL MODELS

Effect of Class IV Laser Therapy on Chemotherapy-Induced Oral Mucositis

A Clinical and Experimental Study

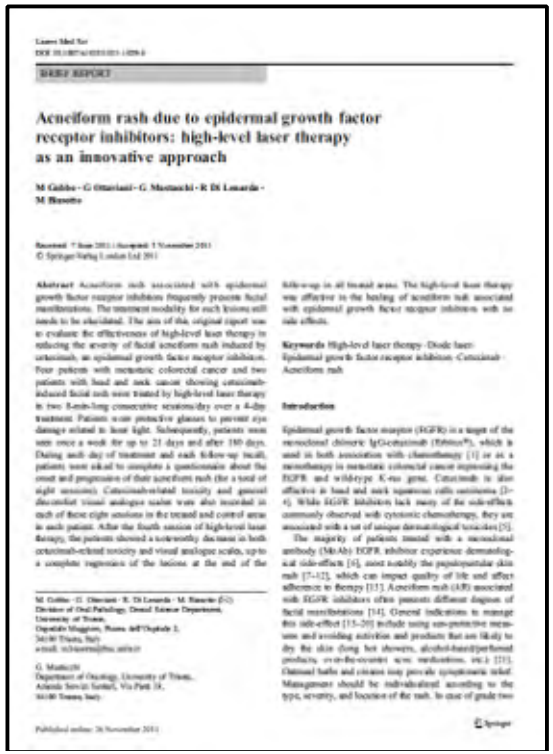
Giulia Ottaviani,* Margherita Gobbo,* Mauro Stumega,† Valentina Martinelli,† Miguel Mano,† Fabrizio Zanconati,‡ Rossana Bussani,‡ Giuseppe Perinetti,* Carlin S. Long,§ Roberto Di Lenarda,* Mauro Giacca,† Matteo Biasotto,* and Serena Zacchigna†

From the Division of Oral Pathology, Dental Science Department, and the Department of Histology and Pathology,‡ University of Trieste, Trieste, Italy; the Molecular Medicine Laboratory,† International Centre for Genetic Engineering and Biotechnology (ICGEB), Trieste, Italy; and the University of Colorado Health Sciences Center,§ Denver, Colorado*

Evaluation of nutritional status in head and neck radio-treated patients affected by oral mucositis: efficacy of class IV laser therapy

INTERNATIONAL JOURNAL OF PAEDIATRIC DENTISTRY

Class IV laser therapy as treatment for chemotherapy-induced oral mucositis in onco-haematological paediatric patients: a prospective study



Acneiform rash due to epidermal growth factor receptor inhibitors: high-level laser therapy as an innovative approach

Methotrexate-induced oral mucositis in rheumatoid arthritis disease: therapeutic strategy in a case report

Treatment of chemotherapy and radiotherapy induced mucositis

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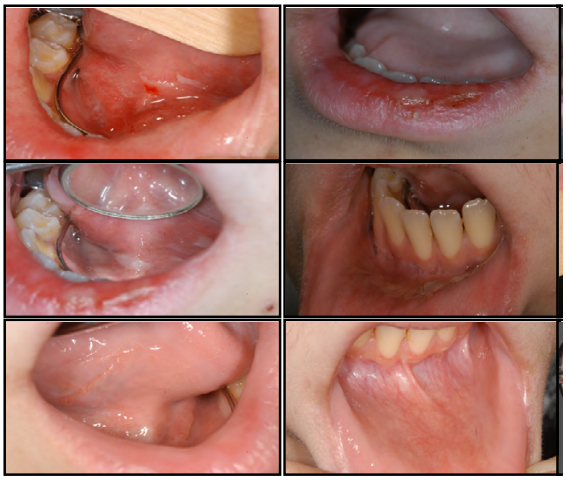

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Treatment of chemotherapy and radiotherapy induced mucositis

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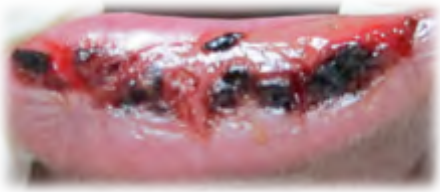

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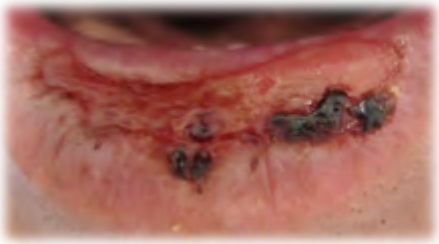

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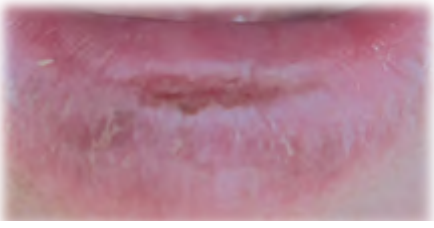
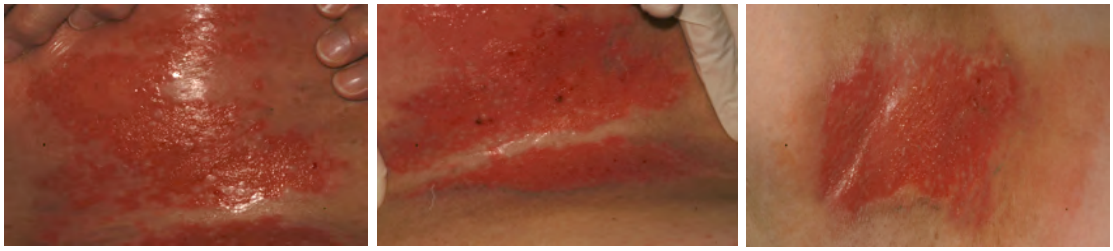


Treatment of dermatitis induced by radiotherapy in breast cancer

6 July



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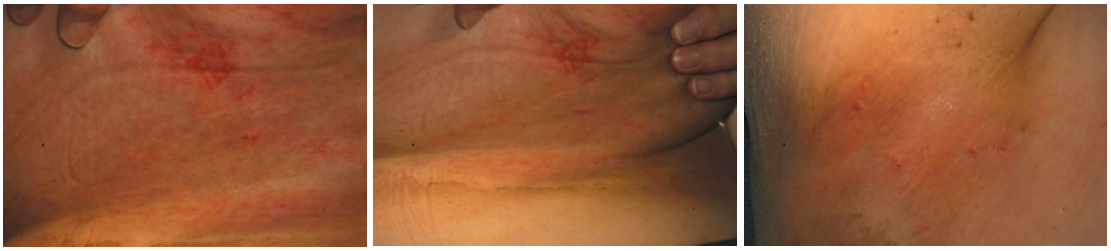

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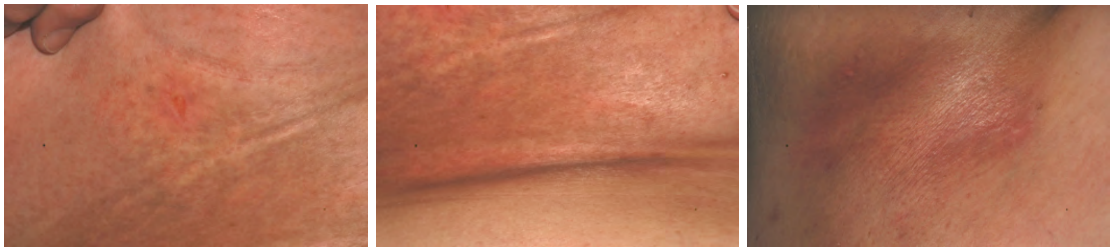

DECREASING PAIN AND INCREASING RANGE OF MOTION IN DE QUERVAIN'S SYNDROME AND TRIGGER FINGERS WITH CLASS IV THERAPY LASER ST. THOMAS' HAND THERAPY UNIT

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INTRODUCTION

Laser therapy has shown clinical success in a wide variety of musculoskeletal and wound healing scenarios as both complementary and supplementary to the standard of care. This pilot study aims to quantify the clinical efficacy of K-Laser therapy on the treatment of carpal tunnel syndrome, trigger fingers, De Quervain's tenosynovitis, and other non-specific lower brachial injuries. The future trial shall quantify both the efficacy rate (expressed as percentage of symptom-free outcomes, based on finger-locking, pain, and function) and the duration of treatment (expressed both as number of hospital visits as well as total days from initial consults) in trigger finger and De-Quervain's cases. A reduction of either of these quantities would be of substantial benefit to the patient's quality and speed of healing and National Health Service standard of care and financial budgets. Twenty-two patients with severe pain and functional hand, wrist or finger disorders were treated with K-Laser for this pilot trial.

METHODOLOGY

Firstly, therapy lasers are an engine for microcirculation. Blood is the conduit for the transport of oxygen and nutrients to the cell and waste products like lactic acid and carbon dioxide away. In the capillaries, blood flow is regulated through microscopic pressure and thermal gradients. Targeting water with radiation (most efficiently in the Near Infrared (NIR) at 970 nm), is the best way to produce the temperature gradients that will increase localized blood flow.

Once more blood reaches the tissues, haemoglobin carrying the oxygen is reduced, releasing their oxygen supply to the surrounding cells, proportional to their metabolic demand. Simultaneously, these blood cells carry the waste metabolite products away from the cells. Laser therapy can speed up this process because the haemoglobin molecule absorbs light (most efficiently in the NIR at 905 nm), this "reduction" process increases blood oxygen release to the surrounding tissue cells to be processed into cellular energy. Free oxygen passes through the cell membrane and into the mitochondria where it is processed by a chain of respiratory enzymes whose end product is ATP.

Cytochrome oxidase is the transport enzyme between the end of the respiratory chain and ATP synthase, the enzyme that produces ATP. Each back-and-forth cycle produces a molecule of ATP, and without laser, this process happens at its normal metabolic rate. Cytochrome oxidase enzyme exists in "reduced" or "oxidized" state, if it absorbs laser light (most efficiently in the NIR at 800 nm), it will alter oxidation states more rapidly. More laser light energy means greater ATP production within the cells and quicker healing by the body's tissues.

Studies using laser light energy greater than the bio-stimulatory levels can affect trans-membrane proteins bridging cell membranes. Alterations in the flow of electrolytes across these cell signaling proteins can affect inflammation, oedema and pain perception.

THE LASER

Wavelengths (nm)	Frequencies (Hz)	Power Densities (W/cm^2)	Doses Delivered (J/cm^2)
660 nm 800 nm 905 nm 970 nm	Continuous Wave + 1 - 20,000 Hz	Up to 1.6 W/cm^2	6-88J/cm^2

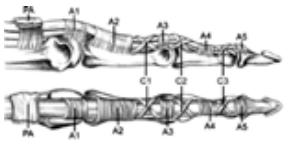
The effect of laser therapy is dose dependent. There is a broad consensus that from 2-10 J/cm2 is the optimal dose for bio-stimulation and increased healing, higher doses can have an analgesic effect. The central concept is that dose delivered at depth to the target tissue is significantly different to the dose to which the skin is exposed. To blindly extrapolate the bio-stimulatory results for a given dose delivered in vitro ,on a monolayer of cells 5 microns thick, to produce results from the same dose delivered to the skin of a patient or to treat subcutaneous soft

tissues or joints in vivo is naive and wrong by several orders of magnitude. The same rationale holds when using in vivo rat/mice studies to substantiate protocols developed for humans. Much research has been done by K-Laser and elsewhere to ascertain the optimal exposure levels that will deliver the optimal dosing of the hands and fingers in question, as well as how to modify the protocols to compensate for the variety in patient size. Research proves different tissues respond differently to different parameters, whether they be wavelengths or pulse frequencies. The laser therapy industry is relatively ignorant as to the "right" frequencies or wavelengths for any given condition, but we know that in the two conditions of this trial contain complex tissues, most notably bone, cartilage, smooth muscle, ligaments/ tendons, nerve cells and skin, each tissue type having different absorption to infra-red frequencies. K-Laser uses a variety of parameters within one treatment protocol to improve clinical efficacy. The laser does this automatically, and not randomly, but rather from a calculation of the average percentage breakdown of tissues involved and depth of treatment desired.

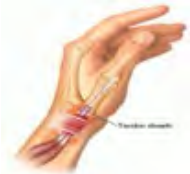
PATIENTS - INCLUSION CRITERIA

Trigger Finger - all adults aged 18 and over with single or multiple digit trigger finger disease, excluding those with a diagnosis of diabetes mellitus and all patients with a diagnosis of any form of cancer. Trigger finger in diabetics with bilateral disease- all adults aged 18 and over with symmetrical bilateral trigger finger(s) and a diagnosis of diabetes mellitus, excluding all patients with a diagnosis of any form of cancer.

De Quervains - all adults aged 18 and over with De Quervains tenosynovitis, excluding all patients with a diagnosis of any form of cancer.



Trigger Finger



De Quervains

OUTCOME MEASURES

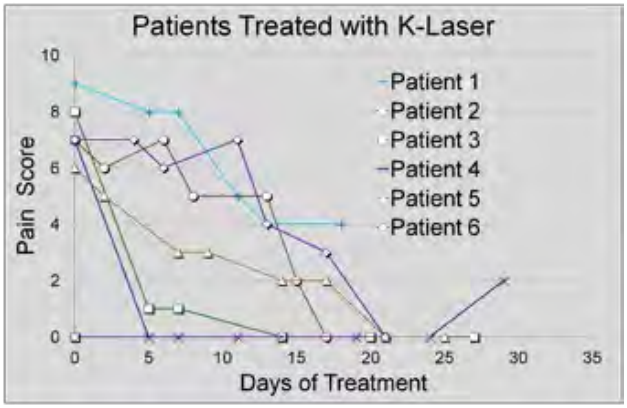
Pain - Pain was measured on a Visual Analog Scale (VAS) from 1 to 10 at every visit. Pain scores were recorded for several clinically relevant circumstances, including at night, during the day at rest, during normal daily activity, during exercise, and at full range of motion.

Range of Motion - Goniometers were used to measure full flexion and extension at every visit.

Grip Strength
Trigger Finger patients: Lateral pinch strength, Tripod pinch strength. Subjective: better / same / worse
DeQuervains patients: Pain on Finklestein test – Yes /No.
Pain on resisted MCPJ1 Extension – Yes /No.
Pain according to Visual Analogue Score

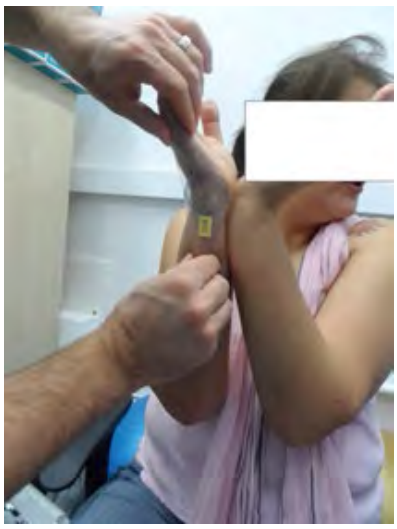
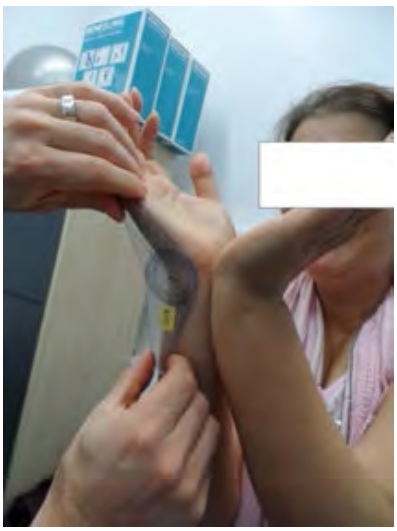
TREATMENT TECHNIQUE & FREQUENCY

RESULTS



Patient 1 Light Blue: Multiple Tendinopathy and Cervical Pain ; Patient 2 Green: Scar Sensitivity following EPL Repair Patient 3 Dark Brown: Carpal Tunnel ; Patient 4 Purple: De Quervain's Tendinitis Patient 5 Dark Blue: Ligament tear, ulnar sided wrist pain; Patient 6 Light Brown: Tenosynovitis following trauma

Patient 2: Caucasian female, 72 years old. Has area of hypersensitivity over the dorsal surface of the left hand. Post EPL surgery and tendon transfer. Tender over the MCPJ's, no scar sensitivity. Objective/Treatment: Extension + 27oMCPJ and IPJ+27o Objective Post Treatment: Left thumb extension MCPJ:+12/IPJ: +14/. Still mildly sensitive over the MCPJs, but now able to touch hand without any difficulty. Analysis: Patient very happy with outcome and keen for discharge.


Measuring Changes in Range of Motion and Grip Strength Pre and Post K-Laser Class IV Therapy

Patient 4: Caucasian female, 65 years old. 18 years ago carpal tunnel syndrome, since returning to work De Quervain's R>L pain around the lateral aspects of the thumb and wrist area. Pain R 7/10 and L 2/10. Wears splint at night and has trouble sleeping due to the pain. Opted not to have steroid injection. Had pain on Finklestein assessment after 4/52 of splinting, initially. Subjective: Patient reported that her pain has gone.She has noticed that the sharp pain has decreased after manual labour. Objective Post Treatment: Right Finkelstein's -ve; left Finkelstein's test -ve. No pain on palpation at the 1st dorsal compartment.

Patient 7: Caucasian male, 74 years old. Two years ago given two steroid injections for wrist arthritis, returned for trapeziectomy six months later. Resulted in loss of radial and palmar cutaneous medial nerve sensation and lack of grip strength. Objective Pre Treatment: Grip strength 0.66 , MCP 32o and IPJ 55o Objective Post Treatment: Grip strength 4.33, MCPJ 46o and IPJ 68o improved hand and arm sensitivity except thumb

DISCUSSION

This is a pilot study looking at the effect of the Class IV laser therapy (K-Laser) on cases that had not shown a positive or had limited response to a combination of surgery, steroidal injections, splinting and/or hand therapy exercises in St. Thomas' Hand Unit Clinic. For the simplicity of the study K-Laser therapeutic protocols were provided to patients during the study for two sessions per week for on an average a four week period, with no other therapies being provided concurrently. Despite the variety, complexity and chronicity of cases treated there was a positive response to the analgesia and functional range of motion in all but three out twenty-two cases. In addition, several patients general skin sensitivity and capillary refill time improved during the short treatment period. Further studies are required to understand the benefits of K-Laser therapy when used in conjunction to surgery and hand therapy as part of a standardised rehabilitation program.

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