ZOOM INTERNATIONAL LASERS LLC

# High Power - Class IV Laser Therapy

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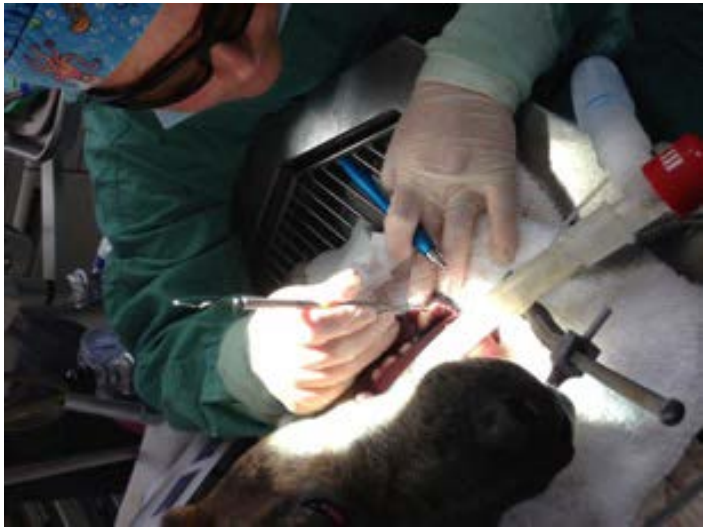
# Lasers in Medicine

**Surgical Lasers:**

- Are used to cut, coagulate, and evaporate tissues.
- This type of laser replaces the scalpel of the surgeon.



# Lasers in Medicine

- Therapeutic Lasers are used for the stimulation of cell function.
- The biological effect is photochemical not thermal, as is the case with surgical lasers.

# A meta-analysis of the efficacy of laser phototherapy on pain relief.

Fulop AM[1], Dhimmer S, Deluca JR, Johanson DD, Lenz RV, Patel KB, Douris PC, Enwemeka CS.

Clin J Pain. 2010 Oct;26(8):729-36. doi: 10.1097/AJP.0b013e3181f09713.

**Abstract**

**OBJECTIVE:**

Laser phototherapy has been widely used to relieve pain for more than 30 years, but its efficacy remains controversial. To ascertain the overall effect of phototherapy on pain, we aggregated the literature and subjected the studies to statistical meta-analysis.

**METHODS:**

Relevant original studies were gathered from every available source and coded. Articles that met preestablished inclusion criteria were subjected to statistical meta-analysis, using Cohen's d statistic to determine treatment effect sizes.

**RESULTS:**

Fifty-two effect sizes were computed from the 22 articles that met the inclusion criteria. The resulting overall mean effect size was highly significant; d = +0.84 (95% confidence interval = 0.44-1.23). The effect size remained significant even when a high outlying d value was conservatively excluded from the analysis; d = +0.66 (95% confidence interval = 0.46-0.86). The fail-safe number associated with the overall treatment effect, that is, the number of additional studies in which phototherapy has negative or no effect on pain needed to negate the overall large effect size of +0.84, was 348.

**DISCUSSION:**

These findings warrant the conclusion that laser phototherapy effectively relieves pain of various etiologies; making it a valuable addition to contemporary pain management armamentarium.

# Who is using HPLT

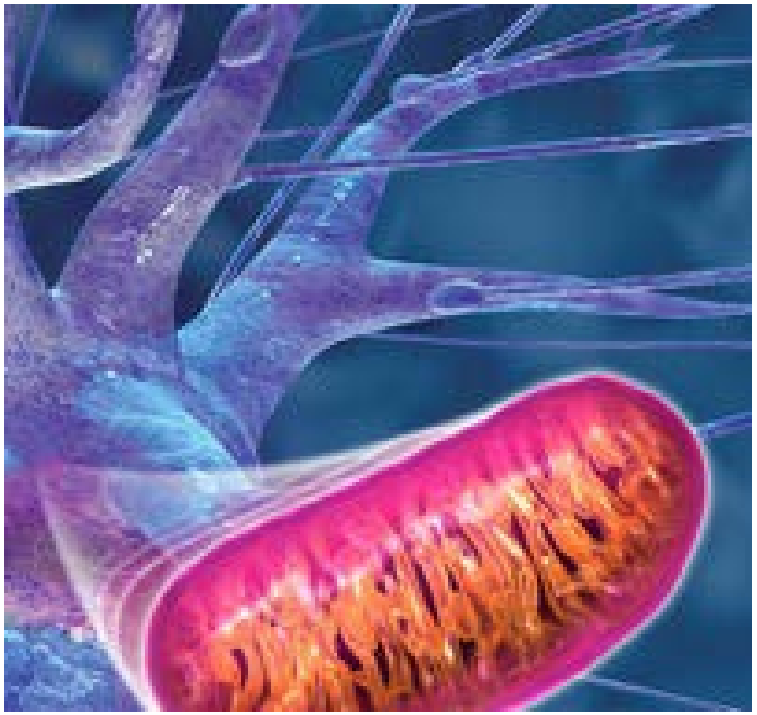
- Pain Management Specialists, Orthopedists,
- Neurologists, Interventional Pain Management
- Doctors, Physical Medicine and Rehab,
- Physiatrists and Family Practice Physicians
- Chiropractors and Physical Therapists
- Podiatrists, Naturopaths and DOM's
- MLB, NBA, NFL and College Sports Teams
- Medical and Veterinary Colleges
- The United States Military and VA Hospitals
- Veterinarians – Equine and Small Animal

# Biological Effects of Therapeutic Lasers

- Laser therapy aims to bio-stimulate injured and dysfunctional tissues.
- Clinical studies and trials of Class III & IV laser technology indicate the following beneficial effects of light therapy on tissues and cells.

# Cellular Effects of Laser Energy

- Chromophores are components of molecules which absorb light.
- The stimulation of chromophores on mitochondrial membranes incites the production of ATP.
- Leading to a biological cascade of events.



# Wound Healing Effects of Laser Energy

- **Faster Wound Healing** – Laser significantly increases fibroblast and collagen production which are essential for tissue repair.
- **Improved Vascular Activity** – Increased capillary production leads to faster wound closure.
- **Greater Tensile Strength** – Surgical repaired wounds heal with greater tensile strength, including skin, tendon, ligament and fascia.
- **Scar Tissue Reduction** – Wounds heal with less scar tissue formation.

# Wound Healing


*PRE-LASER AND AFTER TWO MONTHS OF TRADITIONAL THERAPY*


*AFTER TWO 5 MINUTE LASER THERAPY TREATMENTS AT 7.5 WATTS*

# Wound Healing

**Clinical Translation of the Previous Slide as it Pertains to the Spine**

- Decreased inflammation of disc, nerve roots and the cauda equine
- Increase microcirculation of spinal structures
- Accelerate healing of annular defects
- Decreased formation of abnormal/non-functional scar tissue
- Decreased scar tissue and non-osseous hypertrophic changes
- Reduce pain associated with prolotherapy injection
- Decrease or even eliminate need for epidurals

# Wound Healing

## Clinical Translation of the Previous Slide as it Pertains to the Lower Extremities

- Decreased inflammation of nerve tissue
- Accelerated reinervation of nerve fibers
- Increase blood flow and microcirculation of tissue structures
- Accelerate healing of open wounds
- Decreased formation of abnormal/non-functional scar tissue

# All Lasers are Not Created Equally

Although all therapeutic lasers bio-stimulate tissue, that is where the similarities end.

**Laser Therapy is all about Physics!**

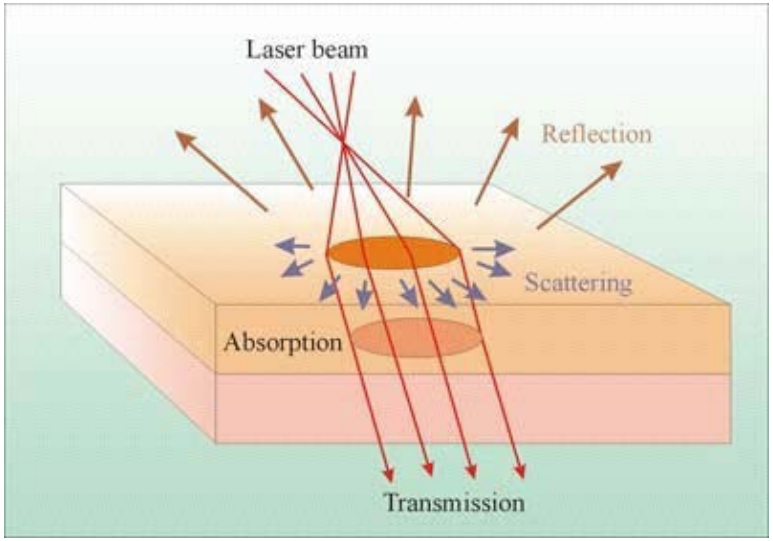
# Energy Medicine and Therapeutic Laser Physics

- The therapeutic dosage of laser energy is measured in Joules
- Dosage is a function of the lasers power output
- For every one watt of continuous laser power output, one joule of laser energy is delivered per second of time
- For a pulsed laser the energy delivery depends on the duty cycle.
- Duty cycle tells us what percentage of time the laser is on or actively firing. If the duty cycle is 50% then the laser at 1 watt only delivers 0.5 Joules/Second. For any given time period a continuous wave laser delivers twice as much energy than a pulsed laser with a 50% duty cycle

# How Laser Light Penetrates Tissue

- As light energy hits the surface of the skin and subsequent deeper layers, some of it is scattered and some of it is absorbed and some is reflected
- At each tissue interface less energy is available to pass further through to the next layer because of the effects of absorption, reflectance and transmission

**LASER TISSUE INTERACTIONS**



# Physiological Effects
# Light – Tissue Interactions

- 65% of laser energy is absorbed in the skin and subcutaneous tissue layers with the following having a high affinity for absorption:
  - Hemoglobin in blood
  - Melanin in skin, hair, moles, etc.
  - Water (present in all biological tissue)
- In order to overcome those factors one must start with large quantities of energy on the skin

# Therapeutic Laser Penetration

- Prime Determinants of Laser Penetration and Concomitant Tissue Stimulation are:
  - Power – measured in watts or milliwatts
  - Wavelength – measured in nanometers
  - Power Density – measured in mw / cm2
  - Frequency – continuous wave versus pulsing

# Importance of Power Density

- Since approximately 65% of the energy delivered is lost in the epidermis
- If you don't start with enough energy on the skin, there will not be enough to stimulate cell healing in deeper tissues
- If you do not have sustained power density over a long enough period of time treatments may be ineffective

mitochondria and they trigger an increase in Cytochrome C Oxidase and Adenosine Tri-Phosphate, 2 key chemicals required in the healing process. About 70% of the therapy lasers on the market operate in this range. Several studies have shown almost unbelievable results in experiments with rats in the regeneration of damaged tissue [1].

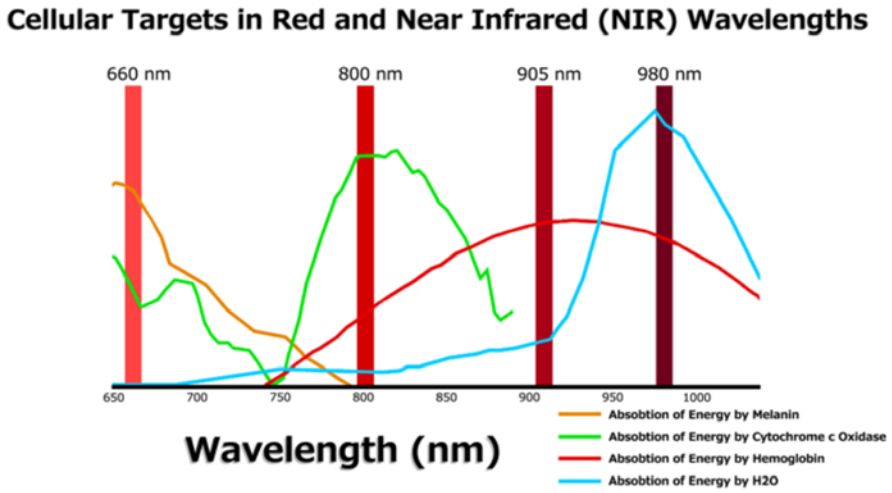
## 905nm Super Pulsed Lasers

All 905nm lasers are superpulsed. Laser diodes that operate in this range must be pulsed (turned on and off) to keep the diode from overheating. This wavelength is also very popular because superpulsing the laser eliminate the risk of eye damage. This wavelength is unique because it interacts primarily with the iron in hemoglobin. When a 905nm laser interaction with the iron in hemoglobin, it oxygenates the area. Oxygen is another key chemical in the healing process so that some conditions might get the best result with a super-pulsed laser. This is the most common wavelength for home systems because they are the safest systems.

## 980nm Lasers

As we near 980nm, we approach the peak interaction of light with $H^2O$ in the body. Although some of the energy is also interaction in the hemoglobin and performing the same function as a 800 to 850nm laser, the bulk of the energy goes to creating thermal gradients in the $H^2O$ that increase circulation and blood flow. The increase in circulation allows the bodies natural healing process to accelerate. This is also the most popular wavelength for high-end pain control lasers and many doctors feel that 980nm system provide the highest level of pain control. If you would like to see the downside to 980nm, just search for "980nm surgical lasers" and will see how they market 980nm system as great for surgery because so much of the energy converts into heating water in tissue . This is great for laser surgery but less than ideal for therapy.

The following graph is based on research by K-Laser®. Although this is not and independent analysis, it seem to explain why all the different technologies work and how they are working in different ways.



# 980 vs 808 Power Density

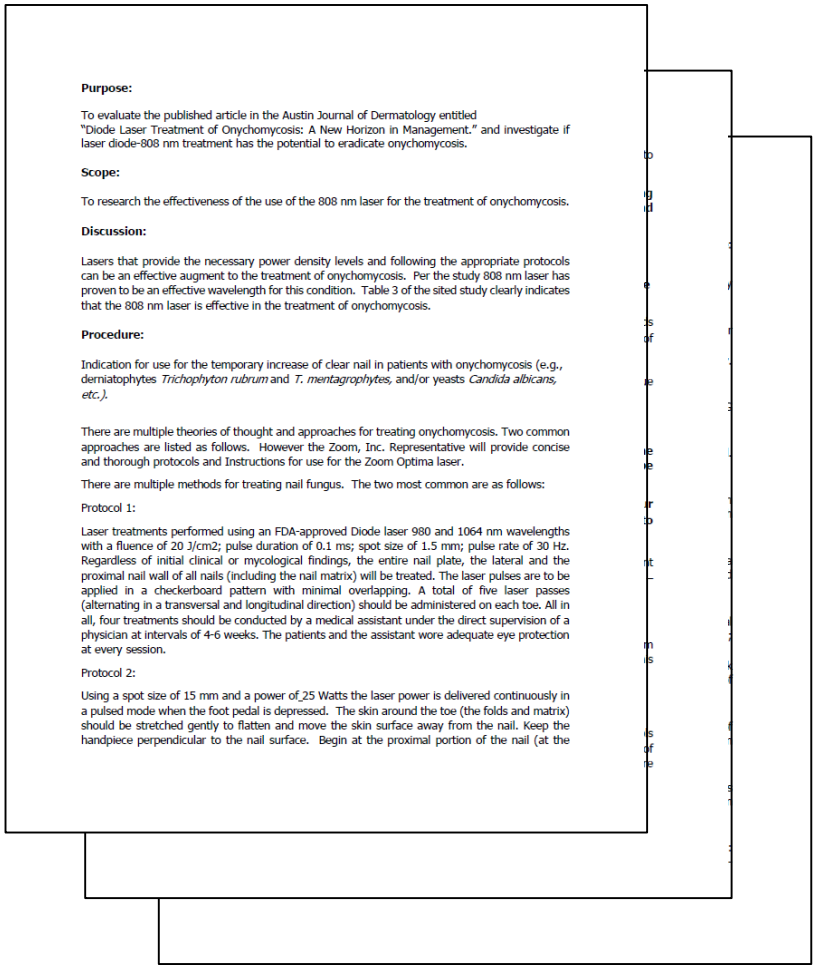
- Less heat with 808
- Can move slower then 980 over skin
- 808 absorbs into mitochondria
- Equals greater biostimulation
- Less treatment time with 808

**Purpose:**
To evaluate the published article in the Austin Journal of Dermatology entitled

“Diode Laser Treatment of Onychomycosis: A New Horizon in Management.” and investigate if laser diode-808 nm treatment has the potential to eradicate onychomycosis.

**Scope:**
To research the effectiveness of the use of the 808 nm laser for the treatment of onychomycosis.

**Conclusion:**
The anticipated clinical results using an 808 nm laser diode with the appropriate clinical protocols should result in similar clinical effects as those of the 980 and 1064 nm wavelength lasers of approximately 70 to 80 percent clearance after the full treatment regimen and protocols are followed and completed.



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**Scope:**

To research the effectiveness of the use of the 808 nm laser for the treatment of onychomycosis.

**Discussion:**

Lasers that provide the necessary power density levels and following the appropriate protocols can be an effective augment to the treatment of onychomycosis. Per the study 808 nm laser has proven to be an effective wavelength for this condition. Table 3 of the sited study clearly indicates that the 808 nm laser is effective in the treatment of onychomycosis.

**Procedure:**

Indication for use for the temporary increase of clear nail in patients with onychomycosis (e.g., derniatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans, etc.).*

There are multiple theories of thought and approaches for treating onychomycosis. Two common approaches are listed as follows. However the Zoom, Inc. Representative will provide concise and thorough protocols and Instructions for use for the Zoom Optima laser.

There are multiple methods for treating nail fungus. The two most common are as follows:

Protocol 1:

Laser treatments performed using an FDA-approved Diode laser 980 and 1064 nm wavelengths with a fluence of 20 J/cm2; pulse duration of 0.1 ms; spot size of 1.5 mm; pulse rate of 30 Hz. Regardless of initial clinical or mycological findings, the entire nail plate, the lateral and the proximal nail wall of all nails (including the nail matrix) will be treated. The laser pulses are to be applied in a checkerboard pattern with minimal overlapping. A total of five laser passes (alternating in a transversal and longitudinal direction) should be administered on each toe. All in all, four treatments should be conducted by a medical assistant under the direct supervision of a physician at intervals of 4-6 weeks. The patients and the assistant wore adequate eye protection at every session.

Protocol 2:

Using a spot size of 15 mm and a power of 25 Watts the laser power is delivered continuously in a pulsed mode when the foot pedal is depressed. The skin around the toe (the folds and matrix) should be stretched gently to flatten and move the skin surface away from the nail. Keep the handpiece perpendicular to the nail surface. Begin at the proximal portion of the nail (at the

Timothy J. Shea
President, CEO
The SCCR Consulting Group

# Sponge Theory

- In order to get penetration you must create significant energy density to overcome absorption in the superficial layers of the skin. With low power density and even with pulsed Class IV lasers, it is like pouring small amounts of water onto a large sponge (the dermis and subcutaneous tissues) and expecting the water to leak through. In order to do so, you must saturate the superficial layers of the sponge with enough water (energy) to soak the sponge (superficial tissue structures) so as you pour more water (energy) over the sponge it will start to penetrate or leak through. This it what is needed and why it is important to deliver a high amount of laser on the skin especially if you want to reach deep seated pathologies.

- Low power or pulsed Class IV lasers just cannot provide the energy necessary to overcome the absorptive capabilities of the superficial skin layers and that is why they fail to deliver a positive outcome when trying to reach deep-seated pathologies.

# How Much is Enough

49-73 mw/cm$^2$ for cell stimulation[1]

**EFFECTS OF INFRARED LASER EXPOSURE IN A CELLULAR MODEL OF WOUND HEALING**

**Mark D. Skopin and Scott C. Molitor, Department of Bioengineering, University of Toledo, Toledo OH**

*This study shows an optimal wavelength (980nm) and power density range for wound healing and tissue stimulation*

# Translation

*It is important to comprehend that as laser energy penetrates through the body, more and more energy is absorbed at each tissue interface, so by the time you start reaching deeper structures there may not be enough therapeutic energy to cause adequate tissue stimulation unless you start with a sufficient amount of energy on the skin. This is the reason why low power lasers as well as pulsing lasers with low power output fail to deliver when treating deep seated pathologies.*

# Other Factors Affecting Lasers Penetration

- Duty Cycle – 100%
  - Laser is firing continuously
  - Duty Cycle – 50%
- Laser is firing 50% of the time. This will not only cut energy delivery but it will also affect ability to penetrate.
- Pulsing – Lasers that pulse also do not emit continuous energy
- Zoom Laser can operate at 100% continuous wave output or pulse the laser energy while still maintaining a high average power output. Maintaining a high power output is key to treating deep seated pathologies.

# Penetration of Laser Light at 808 and 980 nm in Bovine Tissue Samples

Donald E. Hudson, BSEE, Doreen O. Hudson, BS, CET, [...], and Brian D. Richardson, BA, JD

Additional article information

## Abstract

***Objective:*** The purpose of this study was to compare the penetration of 808 and 980 nm laser light through bovine tissue samples 18–95 mm thick. ***Background data:*** Low-level laser therapy (LLLT) is frequently used to treat musculoskeletal pathologies. Some of the therapeutic targets are several centimeters deep. ***Methods:*** Laser light at 808 and 980 nm (1 $W/cm^2$) was projected through bovine tissue samples ranging in thickness from 18 to 95 mm. Power density measurements were taken for each wavelength at the various depths. ***Results:*** For 808 nm, 1 $mW/cm^2$ was achieved at 3.4 cm, but for 980 nm, 1 $mW/cm^2$ was achieved at only 2.2 cm depth of tissue. ***Conclusions:*** It was determined that 808 nm of light penetrates as much as 54% deeper than 980 nm light in bovine tissue.

## Introduction

LOW-LEVEL LASER THERAPY (LLLT) is a light therapy frequently used to treat musculoskeletal pathologies. Some of the therapeutic targets can be several centimeters deep, such as the piriformis and psoas muscles, hip joints, intervertebral discs, and the spinal cord. Byrnes et al.[i] found that near infrared light in the range 770–850 nm penetrates deeper through Sprague–

# Why Therapeutic Lasers Fail

- **Under-penetration** – The typical low level or cold laser or weak or pulsed Class IV laser does not concentrate the laser energy sufficiently to allow for adequate penetration
- **Under-dosage** – The typical low level or cold laser or weak or pulsed Class IV laser does not deliver enough energy to adequately stimulate deep-seated inflammatory conditions
- Zoom Laser protocols are successful because they call for delivery of significantly larger amounts of therapeutic energy than industry standard protocols

# The Key to Better Outcomes

- Higher the power output of laser energy, the Greater the Penetration
- The Faster the Therapeutic Outcome, the Quicker the Patient Returns to Normal
- This is the main reason we keep advancing our technology and developing more powerful lasers

# Why More Power is Better

- More power equates to deeper penetration, faster delivery of the proper therapeutic dosage, and ultimately better outcomes
- A 30 watt laser will not only penetrate deeper, it will put more therapeutic energy to the target pathology
- It will do this 3X faster than a 10 watt laser and 5X faster than a 12 watt laser with a duty cycle of 50%

# Why More Power is Better

- Maximum power output per wavelength is one of the most important factors in favorable treatment outcome. A 30 watt laser will not only penetrate deeper, it will put more therapeutic energy to the target pathology
- With a dual wavelength laser, laser beam penetration is reduced by 50%; with a 50% duty cycle setting and dual wavelengths, laser penetration is equal ¼ of the stated power output of the laser.
- With multiple-wavelength lasers (3 wavelengths or more), laser beam penetration is reduced even more significantly. If a 50% duty cycle setting is paired with a three-wavelength laser, beam penetration is equal to 1/6 of the stated laser power output.
- Do other medical laser manufacturers know this fact!? Probably not.

# Applications of Laser Therapy

- Disc Pathologies, Spinal Stenosis, Radicular Pain, spondylolesthesis, and sacroiliac dysfunction
- Failed surgical back syndrome
- Accelerated Post Surgical, Soft and hard Tissue healing
- Arthritis (Degenerative Joint Disease)
- Foot Pain and Neuropathies... Plantar fasciitis… Achilles tendonitis ... DJD.. trauma … fractures
- Muscle, Ligament and Tendon Injuries
- Ulcerations and Open Wounds

# Relief Time

- Almost immediate pain relief first visit
- Increase ROM immediate; ie Ankle equines
- Walk into office in pain … walk out pain free

# PT vs Laser Therapy

- Laser therapy is in-office and faster
- Laser therapy is faster.
- Almost immediate pain relief
- PT 3x weekly; $150 Laser $50

# What to Look For When Purchasing a Class IV Therapy Laser

- Single wavelength laser; single wavelength is better unless it has separate controls (like Remy I)
- True CW (Continuous Wave). Laser will operate all day on CW without issues
- Highest CW Power
- In summary, my recommendation is to buy the most powerful single – continuous wavelength therapy laser you can afford over the next 5 years
- 15w for SA and 30w for Mixed or Equine practices

ZOOM LASER
Available from Foot DocPreneur

# Onychomycosis

## TREATMENT PROTOCOLS

# Eye Safety

It is required that both the clinician and the patient wear protective eye goggles.

These eye goggles are specifically designed for this specific laser and wavelength and cannot be substituted with other types of eye goggles.

# Warnings for Safe Operations

- Do not look directly into the distal end of the handpiece connected to an active laser device.
- Do no direct the laser directly into the eyes or direct the laser beam at anything other than the area to be treated.
- Do not allow any reflective object fall into or obstruct the path of the laser energy produced by the laser device.
- Do not remove the safety eye goggles until the operator has returned the laser to a safety mode.

# Warnings for Safe Operations

- Avoid the use of flammable solvents, anesthetics, oxidizing gases such as xygen or nitrous oxide.
- Always turn the laser off prior to adjusting or preparing the laser handpiece.
- Always place “Laser in Use” signs at location entrances where the laser will be used.
- Never leave the laser in Operational Mode “On” while unattended.
- Never allow untrained personnel to operate this laser unless directly supervised by a trained individual

# Contraindications

- Do not treat over a suspected tumor or any cancer
- Do not treat over active hemorrhaging
- Do not treat a patient who is currently taking drugs that have heat or light sensitive contraindications, such as, but not limited to steroids
- Do not treat over the thorax, thyroid gland, ovaries, testacies, epiphyseal lines in children or heart pacemakers
- Do no treat over the uterus or abdominal or lumbosacral points in a pregnant female
- Lack of  sensorium
- PVD
- Systemic disease that  reduces healing ability

# Avoid Treatment Over the Following Areas:

- Tattoos
- Pigmented lesions
- Moles

# Expected Adverse Events

Some patient may experience slight redness and a tingling sensation in the treated toes.

This is only temporary and should disappear within a short amount of time following the treatment.

# Protocol

- High energy protocols with three treatments – each treatment 30 days apart
- Carefully clean nails, cuticles, and adjacent tissues before beginning any laser treatment.
- In the case of abnormally thick or opaque nails, debridement prior to laser treatment may be indicated.
- No local anesthetics pre-treatment. (These can be applied as appropriate post laser treatment)
- Generally, skin cooling is not needed.
- Avoid pulse stacking or dwelling while scanning the area under treatment
- Frequently inquire about the pain level perceived by the patient.
- Take photos before each treatment or observation session.
- Post-treatment observations should be conducted at 3 month intervals.

# Protocol

- No topical agents including antifungal agents or topical anesthetic agents are indicated pre-treatment nor should be used as these may absorb the laser light and have not been shown to be of value. Topical agents may be employed post-treatment as deemed appropriate by the practitioner.
- Post-treatment the patient should be counseled on methods to avoid reinfection. These may include the use use of prescription or over-the-counter topical agents and should include discussions on the importance of frequent changes in footwear.
- Any side effects or abnormalities in plate regrowth or in the dermal tissues underlying or surrounding the nail plate should be carefully noted and referred as appropriate to a qualified clinician.

# Procedural Recommendations for Treating Nail

The nails and all adjacent areas that might come into contact with the laser light should be thoroughly cleaned pre-treatment.

The practitioner should carefully scan the laser both horizontally and vertically over each affected region under treatment, taking care to fully cover the nail plate, nail matrix and cuticle areas

# Procedural Recommendations for Treating Nail

It should be noted that the treatment region includes subcutaneous regions well below the emergence of the nail plate.

For more detailed information on treatment protocol, please consult the treatment video.

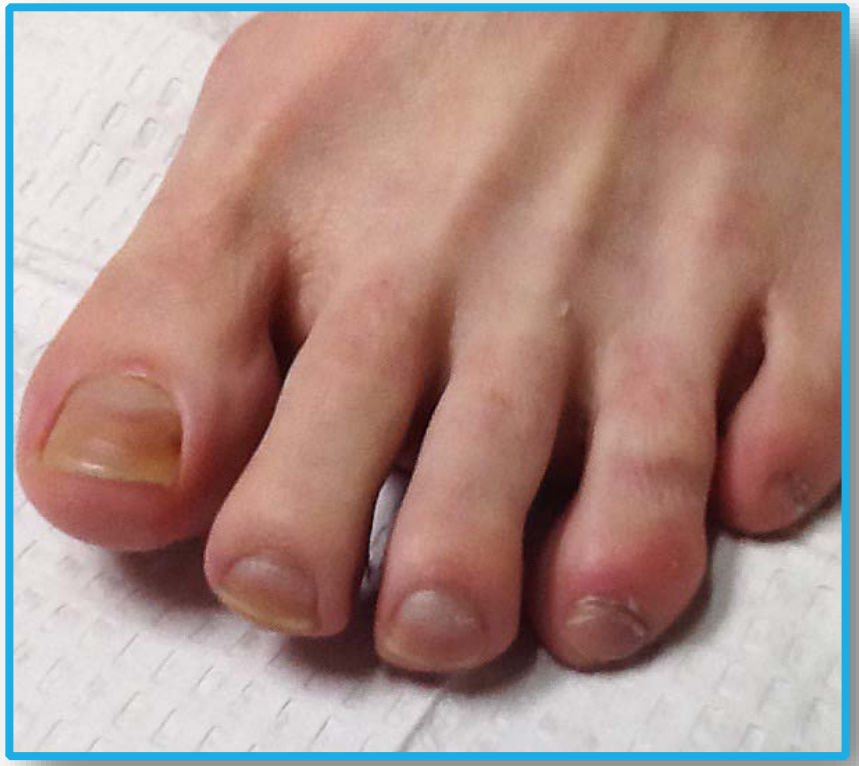
No topical agents including antifungal agents or topical anesthetic agents are indicated pre-treatment nor should be used as these may absorb the laser light and have not been shown to be of value.

# Indications for Use

The Zoom Laser is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)

# Before Treatment

# Before Treatment



# Before & After Treatment

# After Treatment

# After Treatment

# THE REMY & THE REMY II


# Laser Specifications

**Beylas Diode System**

Laser Type: GaAIAs Diode Laser

Wavelength: 810 nm – 980 nm

Maximum Power: 9 – 15 watts

Operation Mode: CW, Single or Repeat Pulse

Pulse Duration: 10us – 3s

Pilot Beam: 650 nm, Power<5mW

Control Mode: True Color Touch Screen (7”)

Transmission System: Medical Fibers with SMA905 Connector

Dimensions: 160(w) x 180(l) x 235 (h) mm

Weight: 2.1Kg

Peralas Diode System

Laser Type: GaAIAs Diode Laser

Wavelength: 810 nm – 980 nm

Maximum Power: 20/30 watts – 15 watts

Operation Mode: CW, Single or Repeat Pulse

Pulse Duration: 10us – 3s

Pilot Beam: 650 nm, Power<5mW

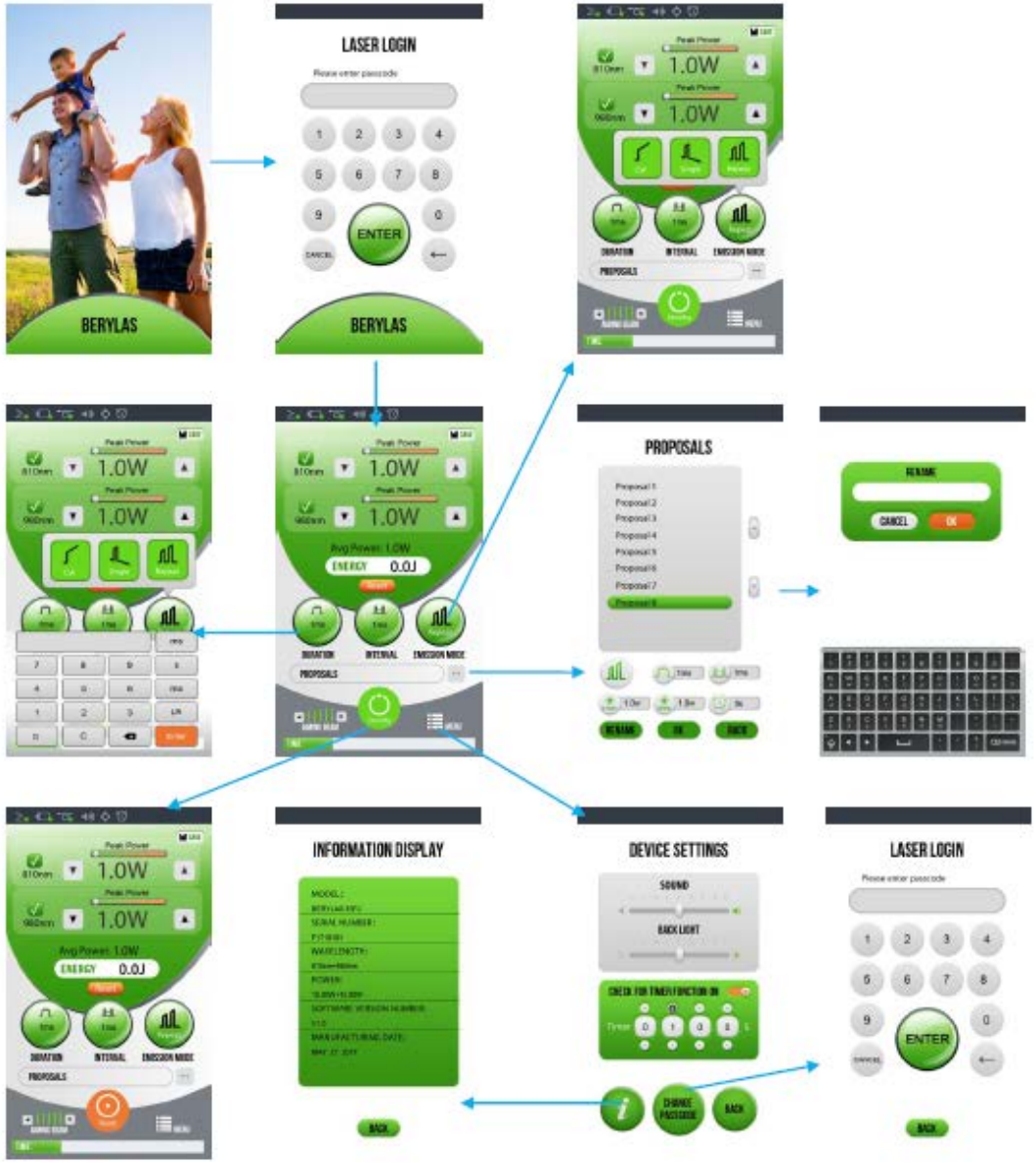
Control Mode: True Color Touch Screen (8”)

Transmission System: Medical Fibers 400nm with SMA905 Connector

Dimensions: 305(w) x 270(l) x 145 (h) mm

Weight: 3Kg

# Touch Screen Display

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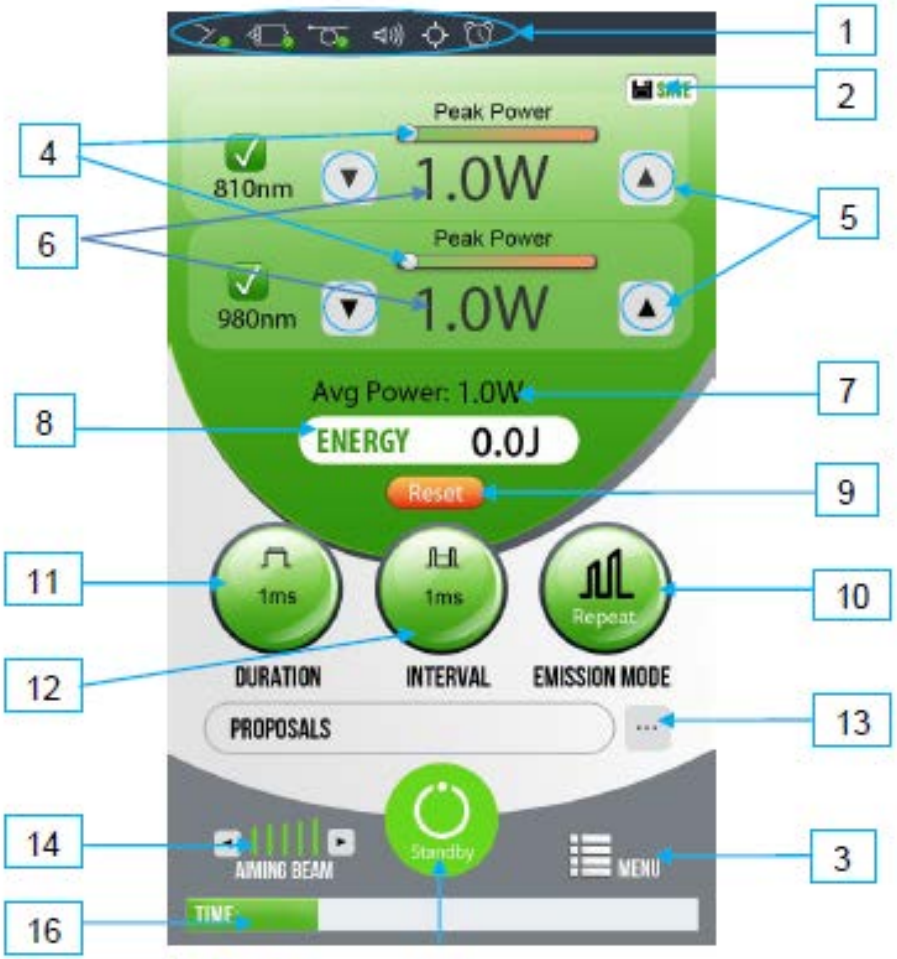
# Setting Screen



# Setting Screen (Remy II)

# Marketing Tools Provided