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This is a Study to Evaluate and Maximize the Efficacy of the TTML 810/2000 Infrared Laser (lllt) for the Treatment of Reducing Inflammation and Pain Reduction within a Noninvasive Modality

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ABSTRACT

This modality will allow the initial observations to help dictate any and all modifications that may be beneficial for the patient. All TTML-810/2000 Laser treatments performed were successful without any complications. The photons delivered by this TTML-810/2000 initiate these healing properties when they enter into each cell mitochondria.

INTRODUCTION

Purpose of the investigation

This is a study to evaluate and maximize the efficacy of USA FDA cleared Infrared Time Machine Laser Thermal Therapeutic Device, a low-level laser therapy to evaluate and maximize the efficacy of The Time Machine Infrared Laser (LLLT) for the treatment of reducing inflammation and pain reduction within a non-invasive modality.

Name of the investigated device

Time Machine TTML- 8102000 Laser Thermal Therapeutic Device Infrared 810/830 nm, 2000 Mw.

Intended use of the investigational device

This study is to determine how effective the laser device provides pain reduction immediately after treatment. The studies were done for 1, 3 and 6 treatments.

OBJECTIVES OF THE CLINICAL INVESTIGATION

Primary objective

The focus of the laser treatment is in the decrease and/or the elimination of pain and inflammation, with patient safety and value as prime concerns. The primary area of focus is acute, chronic pain, TMJ and sports injuries. The laser is designed to increase local blood circulation and therefore initiate the healing factors which yield a decrease in pain and inflammation. This begins with the photons and its warmth entering the mitochondria.

As that activates Cytochrome C Oxidase, it yields a release of ATP, Nitric Oxide and Reserve Oxygen Species. There have been

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numerous studies on various lasers, but we feel that this can add to and/or enhance some of the current trials, with the objective of increasing patient care and desired results. The 810/830 nm will be evaluated for its efficacy on pain reduction/ elimination as well as on promoting wound healing via photobiomodulation and photobiostimulation [1]. As mentioned above, the literature has been remiss in that it does not always discuss the therapy exposure time. Our working hypothesis is that time of exposure will be an important factor in safety and efficacy to our subjects and to all future patients.

Operating of the laser device

The TTML-8102000 hand held laser device operates in continuous wave mode at a fixed frequency. The power is operated with lithium batteries. A cap covers the laser aperture and must be removed before treatment. Activating a mechanical button powers on the unit when operating by battery power. When a mechanical switch is pressed a LCD screen illuminates. The device can be operated in either of two modes which are selected by means of a mechanical switch: a timer mode where treatment time is entered by means of a mechanical switch and time is displayed on the LCD screen. The device automatically shuts off when the set time is reached. A manual mode where treatment continues until the device is manually shut off. The unit is powered down by pressing the power button [2].

Assessment of safety and efficacy

All treatments were provided in keeping with The Helsinki Accord., and approved by the Salus IRB. Our Study is within the definition of a Non-significant Risk Study. This listing requirement is appropriate as it does not fall into any of the categories of a Significant Risk device. The safety of all personnel, patients and technicians, in our Clinical Trials is of the prime focus. All known precautions are discussed with the entire staff as well as the subjects prior the onset of their therapy sessions. This includes the wearing of Laser designed eye protection goggles. On the closed door of the treatment room, there will be a caution sign posted to warn people that there is an on-going Laser treatment and that protective eye glasses are needed prior to their entering the room. The laser, when using proper protocols and safety and usage directions, has no side effects or contraindications. In 2016, The Time Machine Infrared Laser device was 510 (k) cleared to market and sale by the US FDA. As part of the FDA process, the device was tested by Intertek for safety and electrical was found to comply with all standards. As indicated on the FDA 510 (k) clearance for the laser: Conclusions drawn from the performance demonstrate that the subject device is safe and effective [3].

THE SCIENCE

What is LLLT?

Low Level Laser Therapy (LLLT), is a low intensity laser light therapy. The effect is photochemical not thermal. The light triggers biochemical changes within cells. Photobiomodulation: The healing process that the LLLT produces in our tissue cells is known as Photobiomodulation therapy and is defined as a form of light therapy that utilizes non-ionizing light sources, including lasers, light emitting diodes, and/or broadband light, in the visible (400-700 nm) and near-infrared (700-1100 nm) electromagnetic spectrum. It is a nonthermal process involving endogenous chromophores eliciting photophysical (i.e., linear and nonlinear) and photochemical events at various biological scales. This process results in beneficial therapeutic outcomes including but not limited to the alleviation of pain or inflammation, immunomodulation, and promotion of wound healing and tissue regeneration. The term photobiomodulation (PBM) therapy is now being used by researchers and practitioners instead of terms such as low level laser therapy (LLLT), cold laser, or laser therapy [4,5].

CLINICAL PROTOCOL

Overview

This study uses The Time Machine 810 nm, 2,000 mW Infrared Laser for patients suffering from sports injuries [6,7], chronic and acute pain [8-11]. Within the medical community, typical treatment protocols for pain include ice, over-the-counter and prescription pain medications, steroids, anti-inflammatory drugs and surgery of which many have possible risks and side effects. All natural effective treatments that carry low risk of side effects and addictions can offer a pain solution for people that have limited treatment options. It is of our interest to study our low-level laser therapy (LLLT) device for the treatment of inflammation, pain reduction within a non-invasive modality.

Subject selection

The origin of pain was determined by history and physical examination, medication history, and by from previous X-ray, magnetic resonance imaging, and diagnostics and imaging presented by the subjects. Subjects will be recruited for this study from the Investigators private practice, referring Doctors, referring Physical Therapy, and to a large degree, from word of mouth. There will not be brochures handed out or any magazine nor newspaper advertisements. Subjects that are selected will have pain from acute or chronic conditions that will include sports injuries. The financial participation in this study was kept low and merely to cover the overhead.

Study treatment procedures

Once a person has been selected and agrees to be part of this Clinical Trial, the Investigator and/or his designee will review the

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Informed Consent document, in keeping with the Declaration of Helsinki. This study was performed at one study site. Subjects were recruited from among adult patients in the investigators practice seeking treatment of pain due to muscle pain, sports injuries, body and hand pain, jaw and face pain. Several subjects were treated for recent wounds. Our study included 70 patients. 6 patients each were treated with 6 sessions. 26 patients each had one treatment. 38 remaining patients were treated with 3 sessions. Numeric Rating Scale was used to determine pain levels. The NRS is an 11-point scale that measures pain intensity from 0 (no pain) to 10 (worst possible pain) and qualitatively is as good as the Visual Analog Scale (VAS). It is easier to administer than VAS since a pen/pencil is not required to mark a response, and can be administered verbally over the phone in patients with limited mobility thereby increasing the compliance **(Figure 1)**.

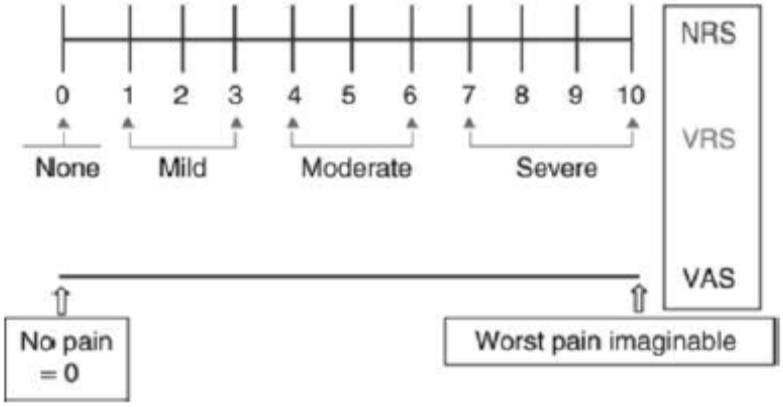

Figure 1: The NRS is an 11-point scale that measures pain intensity from 0 (no pain) to 10.

The device used for all patients in this study was the TTML;-810/2000, Infrared 810/830 nm, 2,000 mW. For documentation and result comparison, wound patients had "pre" and "post" study photos recorded. Larger regions were visually divided into 10 square cm areas and each area was then assured to receive this therapy. The treatment time was 8 minutes per area as defined by the Time Machine treatment protocol. An extra 1 to 3 minutes was added to the more severe patients. This was an Adaptive Clinical Study, which allowed for small time changes in the therapy sessions as may be seen beneficial during their sessions. For non-facial areas, the overall treatment area was again visually divided so as to assure the full coverage necessary. The TTML-810 Infrared laser will be most effective, using these treatment parameters (wavelength, power, power density, pulse parameters, energy density, total energy and time) need to be within certain ranges. The medical laser community agrees that the best penetrating wavelengths are in the range of 760–850 nm and may achieve a skin penetration 3 to 4 cm which is the optimal penetration for laser treatments.

Study details

Group one: 26 subjects (1 treatment)

Group two: 38 subjects (3 treatments)

Group three: 6 subjects (6 treatments)

These included subjects with sports injuries, acute or chronic pain/inflammatory conditions. 26 subjects in this study had a reduction of pain after one 8-minute treatment. 38 subjects in this study were for reduction of pain after three 8 min treatments. 6 subjects in this study were to determine the reduction of pain after six 8-minute treatments.

Primary/Secondary study endpoints

The primary endpoint is the achievement of success in the subjects primary goals of their therapy, as agreed by the Investigator, to be evaluated at the end of the treatment session [12]. That will give us a distinct visualization of the degree of success accomplished by the laser exposure times. The actual on-going results will be analyzed after each session. A secondary endpoint will be the lack of pain, redness and/or itching as the trials progress to the sixth session.

DISCUSSION

The efficacy was predictably sufficient enough for participants to decrease and eventually refrain from needing pain medication. Those patients who were "home bound" were able to return to pre- injury activities. They were all requested to return for additional therapy if there was a recurrence. There was one return requested and granted. This was for a severe case of TMJ dysfunction and muscle spasm.

CONCLUSION

The general design will be an Adaptive Clinical Trial on healthy patients. This modality will allow the initial observations to

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help dictate any and all modifications that may be beneficial for the patient. Of all the subjects, the median subject, upon intake and before treatment, indicated an average pain level of 7 to 8 on the NRS pain scale. The 26 subjects treated with one session reported a deduction of pain with a median range of 35 to 14 of the patients in this group reported a pain reduction level of 4 and of the balance, seven subjects reporting a level 3 and five subjects reporting a level 5. The 38 patients with three sessions reported a pain reduction with a media range of 2 to 4. 23 subjects reported a pain level of 2, seven subjects a 3 and eight subjects a 4. The 6 subjects treated with 6 sessions, the pain levels reported at completion was 0 to 2 for TMJ and all wounds were successfully healed. In conclusion, all therapy sessions were completed without any complications and without any side effects. All patients reported satisfaction with their results, which met their health goals. Thus, the TTML-810/2000 can provide pain-free treatment as described in this study and succeeded in doing so with the patients safety with valued results being accomplished. Laser therapy is key to reducing inflammation and pain. Laser Therapy has had been studied for decades with strong evidence which supports its use in pain management. One of the very important aspects confirmed consistently during this Study, is that with the Infrared Laser, the subjects reported no pain, no redness, no swelling, and no downtime. The clinical trials were comprised of patients of a myriad of ages and situations. The treatment parameters have been well documented. These findings are explained on a molecular level, and are consistent with and validate the research of Hamblin in his study of Photo bio-modulation and photo bio-stimulation. The use of low levels of visible or near infrared light, as is the TMP's 810/830 nm, helps to reduce pain, inflammation and edema, and promotes the healing of wounds, deeper tissues and nerves [10]. The photons delivered by this laser initiate these healing properties when they enter into each cells mitochondria. At that sub-cellular level, a cascade of events begin that includes the release of ATP for repair and new cellular building energy, Nitric Oxide for increased micro-vascularity to provide for better oxygen, nutrients and faster elimination of toxins and by-products, and the release of growth factors and inflammatory mediators, new collagen, fibroblasts and connective tissue.

CONFIDENTIALITY

In abiding with HIPPA laws, all patient records, their participation and outcomes must be held in strict confidence. As their outcomes are the basis for our study, this will be carefully reviewed with each candidate prior to their acceptance into our Clinical Trials. We have developed a most informative Consent form for the protection of our patients as well as for our Office and our Staff. With this in mind, all information and levels of participation will remain private, and only those portions that the trials are evaluating will be published, per the subjects approval in the Informed Consent Document.

RECORDS RETENTION

Clinical Trial records will be held for at least 2 years after the cessation of the trials and the FDA is notified. The investigator is required to make the records available to the monitor, auditors, the IRB/IEC, the FDA, and other regulatory authorities. To protect the integrity of all records, there will be a duplicate history production. The individual paper patient records will be secured into a private location, not accessible to anyone except the staff who is involved with the trials. These will also be scanned periodically for computer based storage.

AUDITING

This is the responsibility of the sponsors/Investigators quality-guarantee department. This auditing will be carried out by an individual who is not a technician on this trial, and is therefore independent from the clinical research division. There will be randomly chosen auditing of the clinical research. In this clinical trial, auditing reports will be submitted directly to the Investigator. An important aspect of this auditing is that it may yield proposals to improve the current studies. As such, it may be helpful in arriving at data that will be of a high standard.

INSPECTING

This will be implemented after all the research has been completed. It will be carried out on the highest level in the Company's research team and may include the Sponsor. The outcomes may offer suggestions for any further studies and help to determine the value of the completed Clinical Trials.

ETHICAL CONSIDERATIONS

It is our prime guideline to adhere to the complete principles of Good Clinical Practice, known readily by the term GCP. The initial formulation of this was derived from the Nuremberg Code of 1947. This is defined as a standard for the design, conduct, performance, and monitoring, auditing, recording, analysis and reporting of clinical trials and studies. Our plans and actions will adhere to the FDA guidelines as it pertains to a medical device research. The overall goals of GCP are a combination of ethics and quality data. By keeping this in mind, there is protection of the rights, safety and well- being of all humans involved in our medical research. This will also help us to maintain better quality and reliability of data, as it provides the needed guidelines and standards of conduct in clinical studies. In essence, we will hold proper attention to GCP so that we can affect ethical conduct and our clinical trials. As a display of commitment to ethics and quality of our devices, we have formal current certification of FDA 510 (k) clearance.

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