

# The Power and Penetration Myth

Erchonia Corporation

## Low Level Laser Therapy:

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The understanding of how the human body functions in conjunction with low level laser therapy (LLLT, 3LT®, cold laser) is an advancing paradigm in modern wellness approaches. These transformative changes are encouraging a clearer understanding of the mechanism of how each new invention affects each system.

3LT® is not excluded from the advancing medical technology that requires continual scientific evidence of the mechanism before we can thoroughly comprehend the magnitude of the neurological and physiological changes taking place. Nevertheless, 3LT® is one of the few devices that have published, peer-reviewed double blinded controlled studies dating back over twenty years and many “clinicians and researchers are unaware of the extensive research that has been done in field of biophysics, bionics, photobiology and quantum biology during the past eighty years”<sup>1</sup> that aid in clarity of the mechanism of laser applications.

The first milestone made in the United States for 3LT® was a FDA approval in 2002. With this approval came a new classification of therapeutic devices, referred to as NHN,<sup>2</sup> which is a category for non-heating modalities for adjunctive use in pain therapy commonly known as biostimulation, which we will address later. The first market clearance (510k approval) was issued for the treatment of neck and shoulder pain. Since this accomplishment, the FDA has issued 510(k) clearances in the NHN category for the treatment of carpal tunnel and post surgical pain based on clinical data and cellular/molecular research.

Unfortunately, other laser companies have not adhered to such standards of their therapeutic devices and have filed what is referred to as ‘substantial equivalence’ against a laser previously granted market clearance by acceptable completion of clinical trial data. A ‘substantial equivalence’ submission to the FDA is authored by the company or a representative of the company that is intending to obtain market clearance without conducting clinical trials. The substantial equivalence document shows the device attempting to obtain market clearance being compared against a device that already has been awarded market clearance by comparison of features and components. The company submitting a substantial equivalence document, using the features and components comparison as a catalyst, then authors a narrative explaining why the device they are vying for fits in the same category of therapeutic applications of the laser or laser(s) being compared to. Laser Classification is a regulated feature of a laser device and is a component of comparison in a substantial equivalence submission. As recently quoted in Tunér and Hodes’s article Confounders and magicians,<sup>3</sup> classification of laser devices are determined by “...the possible risk for eye injuries and has nothing to do with the efficiency in treatment... The classification is not only a question of output power; it has to do with wavelength, divergence of the beam, emission area, pulsing etc.” The FDA approval process is extremely complex; this brief explanation is simply a highlight of the proceedings of receiving a laser approval and also to show that the considerations of the approval are independent of the advertising and marketing which follow.

The most recent flux of laser advertising has led to a great deal of confusion pertaining to the field. Much of this confusion about the use of therapeutic lasers stems from attempting to look at laser effects from a Newtonian mechanistic perspective that has now been supplanted by non-linear dynamics and quantum physics. Oftentimes we assume things natural from current knowledge to fit within a paradigm of healing. If this was the only approach, new and innovative applications would never be developed. The latest trend in the development and what is commonly mistaken for proper applications of low level laser therapy, are the influx in approvals for topical heating devices (ILY).<sup>4</sup> These devices have an associated low level laser component, with the removal of the collecting lens from a high powered laser, but are not low level lasers. **The problem is that when you remove the collecting lens out of configuration it ceases to be a focused laser. This in essence is now just a concentrated heat lamp, which gleams to the understanding of why market clearance was so easily obtainable.**

By far one the most difficult concepts of laser is the energy density or fluency, this component is what in large part relates to a non linear approach to understanding the applications. In the market place it is the focal point of sales in the approach that depth of penetration is somehow related to this component.

**Let's look at common myths in laser therapy pertaining to power and how it correlates to penetration.** Several articles have **claimed**, in this publication and other journals that you need more power to penetrate the tissue and that high power lasers are putting an end to low level lasers. *The science of 3LT® has proven this to be untrue in many studies which will be referenced in this article.* It is important to take into consideration that the FDA gave market clearance to the first high power therapeutic laser in 2004 (two years after the first low level laser); the approved device is manufactured by a company that filed substantial equivalence from a heat lamp (ILY) and in turn was given approval for topical heating and muscle relaxation not depth of penetration like the manufacturer claim. To date there **have been no other 510(k) market clearances granted to any other "high powered laser" based on their own clinical trial.** Low level lasers have endeavored in more substantial clinical, cellular & molecule trails that have not only been expensive to undertake, but time consuming; this is in part the reason why there are still very few indications for low power lasers.

The companies marketing these high powered laser devices proclaim that they have more power and penetrate deeper than 3LT® devices (NHN). There is no research that proves these devices are more effective than a \$600 heat lamp, not to mention they have the exact same marketing claims and can cost up to \$50,000. There is also a question to the long term safety of these devices which has not been proven otherwise according to published research available. In evaluating the reference material of high powered lasers, almost every study referenced has been done with low level, low energy lasers, not high powered devices. New research published in *Lasers in Surgery and Medicine* in January 2006<sup>5</sup> states that "with as little as 10 joules you can cause damage to the DNA of the cell and decrease cell viability". The laser used in the aforementioned study was a **3mW** laser with a divergent beam and this article also stated "that since the laser used was a 3mW divergent beam it is not as harmful as a narrow parallel beam." The research proves that even a low level laser can potentially cause damage if over treated; it would take only 1 second at 10 watts to over-stimulate to a level that can cause damage.

**Another myth is that high power lasers have biostimulation effects.** Tiina Karu's new text titled, Ten Lectures on Basic Science of Laser Phototherapy, highlighted a study by Rochkind et al (1988), where it was found that 540nm and 632.8nm had a strong effect on the action potential of the nerve and 904nm, as well as CW radiation at 660nm, 830nm, 880nm and 950nm had no effect.<sup>6</sup> Since these wavelengths are not affecting the nerve through biostimulation they try and affect the nerve through heat which has a completely different consequence. In a statement made in Jan Tunér and Lars Hode

2002 Laser Therapy book, “biostimulation based on current clinical research is .5 to 1 J/cm<sup>2</sup> on an open wound and 2-4 J/cm<sup>2</sup> through overlaying skin.”<sup>7</sup> For a patient to receive the maximum of 4 joules required for biostimulation they would only need to treat the patient for 1 second with a 4 watt laser and 0.5 seconds with a 10 watt laser. This is in agreement with the Arndt-Schulz Law which states “weak stimuli excite biologic activity and strong stimuli retard this activity.”<sup>8</sup> High powered lasers are used for tissue ablation, hair removal, acne, etc. The companies that produce these high powered lasers remove the collecting lens on these devices to prevent the device from burning the skin. In addition they have to manually scan (back and forth) the patient with these devices to keep from burning the tissue. The mechanism in which they are heating the skin proves that they are not penetrating deeper; according to Tunér and Hode article, *Confounders and magicians*<sup>3</sup> where they state “because 980nm has a lower penetration capacity, more energy is absorbed in the upper part of the skin and the risk for overheating is greater.” They also state anything over “1 watt is excessive” in laser therapy.<sup>7</sup>

An additional article available in this publication titled *Basic Principles of Low level Laser Therapy*<sup>9</sup> stated “super pulsing allows for deeper penetration,” the laser they were referencing was a 10 to 100 watt laser used at relatively low power which is conflicting with laser classifications due to the fact that it references a class IV laser which is not considered low power. These Class IV lasers are the same lasers used for resurfacing and tissue ablation without the focusing lens and the reason they super pulse them is because they are targeting a specific chromophore on the surface of the skin in which research has proven to be a topical treatment, that if left on the skin it would burn or ablate the subject. The author goes on to state “that it is well suited for medium and deep tissue, such as joints and tendons,” but offers no research or references.

Let’s look at the research. Every laser has a plateau where it reaches bio-inhibition (Farok Al-Watban has published this in several wound studies) or it reaches a point where the application of laser is no longer effecting the physiological structures that are targeted. This concept is well published and we have already talked about biostimulation and its peak. In review of the published research we observe results for different power outputs, the indications of such devices and the consequences of excessive use. There are numerous studies and clinical results that compare different power outputs using the same wavelength only manipulating the time treated which is measured in J/ cm<sup>2</sup>. The first example published in *Photomedicine and Laser Surgery* 2006<sup>10</sup> is a study using 685nm and 830nm laser on tissue repair in tendons on mice. In this study they used difference fluences and divided them in 6 groups, 2 placebo groups, 2 groups of 685nm laser (red) at 3 joules and 10 joules and 2 groups of 830nm (infrared) laser at 3 joules and 10 joules. Then they compared the results, the best results were with the 685nm at 3 J/cm<sup>2</sup> and the results with the greatest consequence to healing were with 830nm at 10 J/cm<sup>2</sup>. This study lends support to the fact that higher power and longer wavelengths do not lead to better outcomes. Similar findings have been published since at least 1989, when Shiroto stated that “an increase in irradiation dose may decrease biostimulatory effects.”<sup>11</sup>

As mentioned previously the first FDA market clearance was for chronic neck and shoulder pain. The laser in this study was a 5mW 635nm line generated beam (Erchonia). The treatment time was a total of one, 4 minute treatment. The results showed a difference in pain by 64% decrease in all patients treated in comparison to the placebo group, along with increased muscle strength and range of motion. The second market clearance for carpal tunnel was using a 100mW 830nm laser (Microlight). In this study they treated the patient three times a week for five weeks with each treatment for 15 minutes and at the end of the study there was a difference in pain of 6.6% between real and placebo patients. (this information was taken from company submissions to the FDA). These studies illustrate that less laser

energy produces more efficient results. These were biostimulation lasers not high powered lasers. There is no tangible information available with high powered lasers for a therapeutic indication.

**Another myth with laser therapy is depth of penetration** which seems easily disproved from the studies already noted, in addition to a 2001 MRI study by Rodrigo Neira, M.D. published in the America Journal of Cosmetic Surgery.<sup>12</sup> This study showed that an 8mW 635nm laser that was held 6 to 8 inches from the skin could emulsify deep fat (6cm) and break up the appearance of scar tissue. Dr. Rodrigo proved this by showing abdominal MRI at 0, 4 and 6 minutes on T-1 and T-2 weighted sequences. This was later confirmed in a 2004 study published by Robert Jackson, M.D. in the AJCS journal<sup>13</sup>. These results are a stark contrast to the article published in Dynamic Chiropractic titled *Basic Principles of Low Level Laser Therapy* where the author stated that “red light at 640nm has been shown to effect skin, so it might be effective in treating cuts, scars, trigger points and acupoints. Usual depth of penetration is less than 10mm.”<sup>8</sup> The author offers no research and this contradicts what the FDA gave clearance for and the two aforementioned articles prove is nothing more than a theory from the author. There seem to be many self proclaimed experts in laser therapy and the problem is none of them actually do any research. Tunér and Hode confirmed this with the author of this article they like most other so called or self professed laser experts form opinions based on what they read and who they are working for and not based on their own clinical or cellular research which they themselves have accomplished. There are countless studies, too numerous to list all in this article, that mention secondary effects using low level laser that **do not** rely on power. The fact is that there are no studies supporting high powered lasers for biostimulation and most every doctor knows that if you are heating the skin you are creating free radicals which were proven in the ASLMS study in January 2006.<sup>4</sup>



I believe every doctor should own a laser and eventually will, but there is an excess of inaccurate information from manufacturers and self professed laser experts that until more companies and laser excerpts actually do research, these articles will continue to confuse the end user. You owe it to yourself before you invest in any piece of equipment to have the manufacturer provide you research that was done with the device you are looking to purchase. If they have no research or they hand you research done by others and claim they can do the same, look else where. Just today I was called asking to provide research to a state board from a doctor that needed help because the state was telling him his device was experimental. If I had no cellular or clinical trial research to support the device he would no longer be able to use his laser, this has happened at least a half dozen times. Another consideration is if the laser manufacturer does not have liability insurance and something goes wrong you are left by yourself and in our litigious society it is almost certain, someone is going to get sued. There is a reason low powered lasers are in a class by themselves (NHN), they have proven results.

Steven Shanks has been involved with 3LT® since 1996 and was responsible for the regulatory work involved and writing of the study for the first FDA 510(k) (NHN) in 2002. He has since accomplished three additional market clearances, submitted for a 4<sup>th</sup> and is working on 5 clinical trials. He works along with several universities and private practitioners to advance the field of 3LT® through clinical and cellular research.

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