Everything You Need To Know About Class 3 vs. Class 4 Laser

Low Level Laser Therapy (LLLT) is a fast growing field of medicine recognized by every major industrialized nation in the world, offering painless, non-invasive and highly effective drug-free solutions. Able to treat a plethora of neural muscular skeletal conditions, LLLT is often the only solution that is available to the highly trained practitioner to control disease when conventional therapies have come up lacking.

Unfortunately, LLLT is yet to achieve universal recognition by the medical community due to the confusion in the marketplace caused by the many poorly designed clinical studies in the published literature promulgated by researchers who lack the formal training in the rigors of proper scientific and clinical study methodologies. These unscientific and poorly designed clinical studies do more harm than good for the LLLT field, as the large number of patients who could substantially benefit from this modern miracle called LLLT are denied the service because their attending practitioners remain unconvinced of the technology. I have used many different laser devices over the past 20 years in my career and I must say that no two lasers are created equal. The best therapeutic laser I have used is one from one of the oldest and most respected cold laser manufacturers in the world; namely, Theralase Inc., based out of Toronto, Canada. The Theralase TLC-1000 laser system is Health Canada, FDA and European Union approved as a class 3B superpulsed therapeutic medical laser device. The Theralase's advanced LLLT proprietary technology encompasses potent and complementary bioregulatory mechanisms achieved using visible red 660 nm and near infrared superpulsed (NIR) 905 nm laser light.

The Theralase superpulsed laser has the distinction of being one of the fastest in the world – delivering pulses at 200 billionths of a second, producing average powers of 100 mW and peak powers up to 50,000 mW per diode. These unique parameters result in a higher concentration of light energy (I_0), or photon density at tissue depth versus any known competitive technology, without the risk of burning tissue.

While continuous wave (CW) and standard pulsed lasers (PW) are limited to less than 1 to 2 cm of therapeutically effective depth of penetration, the Theralase superpulsed (SP) NIR laser technology is able to demonstrate therapeutic effect at up to 10 cm below the tissue surface. This allows Theralase's superpulsed technology to target deep tissue structures such as: bones, tendons, ligaments and cartilage. In the literature, Theralase's 905 nm superpulsed technology has been proven to be more effective than a 905 nm CW laser treatment1, thus it is the superpulsing of the Theralase technology which creates this difference.

In conjunction with its 905 nm superpulsed technology, Theralase combines 660 nm continuous wave technology leading to a synergistic therapeutic effect operating via direct photochemical and photophysical cellular events. The therapeutic optical windows of 660 nm and 905 nm laser light utilised by Theralase's LLLT technology correspond with the absorption and the action spectra optical windows of the key mitochondria chromophores, such as cytochrome c oxidase and the cellular membrane lipids. Moreover, it is apparent that 660 nm and 905 nm light have an impact on the mitochondrial chromophores via independent and nitric oxide mediated photochemical and photophysical mechanisms.1,2,3 Hence the combination of 660 nm and 905 nm light is proven to have an additive biologic effect compared to any individual wavelengths. This biologic effect is further amplified by these two wavelengths activating and targeting the proximal and distal therapeutic mechanisms, in tissues, which induce bioregulatory responses that effectively modulate local and systemic pathologic manifestations in the Theralase LLLT treated patients.

According to Brown et al., mitochondria produce and consume nitric oxide (NO) and NO stimulates mitochondrial biogenesis, apparently via the upregulation of nucleotides like ATP and transcriptional factors like nuclear factor kappa B (Nf-kB).[4]

Therefore, it can be strongly suggested that the Theralase LLLT induced NO can reprogram cellular function, mainly via oxidative stress and changes of mitochondrial temperature gradient due to a process similar to selective photothermolysis, and thus initiate a cascade of local and systemic therapeutic signalling1. These signal transduction pathways may lead to increased cell activation and traffic, modulation of regulatory cytokines, growth factors and inflammatory mediators and expression of protective anti-apoptotic proteins.[5][6]

The results of these molecular and cellular changes in animals and humans integrate such benefits as: increased healing in chronic wounds, improvements in sports injuries and carpal tunnel syndrome, pain reduction in arthritis and neuropathies, amelioration of damage after heart attacks, strokes or nerve injury and alleviation of chronic inflammation and toxicity.[7][9]

There is certainly more than one reaction involved in the primary mechanisms of LLLT and there is reason to believe that all of these processes occur simultaneously when a tissue is irradiated. Experimental data clearly supports the use of 660 nm and 905 nm laser light as the best choices, based on their role in the modulation of redox mitochondrial function, changes in the properties of terminal enzymes and the cellular signalling that are critical steps in the bioregulatory mechanisms of LLLT.

In closing, I must report that there is a perplexity in the literature pertaining to the direct photoacceptor or the light absorbing chromophore for near infrared light (NIR). Manufacturer's marketing materials are particularly rich with assumptions about the prime molecular photoacceptor and mechanisms of the light within the 800 to 880 nm range; however, the clinical literature shows no strong evidence that cytochrome c oxidase has strong absorption in the 800 to 880 nm range. Therefore, although photobiological effects in the 800 to 880 light range are ascribed to light absorption by mitochondrial cytochrome c oxidase, the low absorbance in this region makes scientists highly question it.[7][9]

Class 3B versus Class 4 Lasers

There is a slew of false information in the public domain regarding the effectiveness and cellular mechanisms activated during class 4 laser light irradiation. Many class 4 laser manufacturers are intentionally or unintentionally misleading healthcare practitioners into believing that higher power and longer near infrared wavelengths equate to deeper tissue penetration and better clinical efficacy. Nothing could be further from the truth. Particularly disturbing are claims made by manufacturers of Class 4 laser technologies emitting in the 808, 880, 970 and 980 nm wavelengths.

Unfortunately, all of these claims turn out to be fancy sales gimmicks, as they have not the standing in the clinical or scientific journals to support their claims. The clinical and scientific

facts are clear that because of the very high absorption of NIR laser light by water at wavelengths greater than 950 nm, 99% of the energy produced at this wavelength or above is absorbed before penetrating the dermis of the skin, leading to a high risk of thermal damage and a low depth of penetration. Promoting that a laser is a class 4 laser states absolutely no information about the wavelength of the device, but simply informs the purchaser about the risk of thermal tissue damage. A CO2 laser (wavelength = 10,600 nm), for example, is a common class 4 laser that is absorbed in the first 10 microns (0.0004 inches) of tissue, thus primarily in the epidermis. The same holds for the excimer (XeCl, wavelength = 308 nm) laser which is also absorbed in the epidermis. At 970 and 980 nm, the depth of penetration is less than 300 microns (< 0.01 inches), thus total absorption is achieved within the dermis of the skin. For any given wavelength, the tissue properties are determined by the scattering and absorption coefficients of the specific tissue structures resident in the tissue. These scattering and absorption coefficients determine the penetration depths and ultimately govern the overall depth of penetration of a laser beam. Now a Class 4 laser typically has higher incident power and larger treatment area, but the depth of penetration is superficial and is restricted to a few hundred microns at best (i.e.: the top layer of the dermis). Even with higher incident powers and large treatment areas there is no biochemical effect due to lack of cellular mechanism activation; therefore, the thermal effects of a class 4 laser are the only mechanism of action remaining. Once the thermal effects of tissue have been exceeded, tissue damage is imminent.

Certain manufacturers use the limited knowledge of their customers to claim that a Class 4 laser has greater efficacy than a class 3B laser. This is unsubstantiated rubbish. Laser classification is only used according to IEC-825 guidelines to determine the possible risk for eye and skin damage and has nothing to do with the efficiency in treatment. Laser classification is determined by not just a question of optical output power, but also wavelength, divergence of the beam, emission area, pulsing parameters, exposure rates, et cetera. Regarding Class 4 high power lasers, it has not been proven in the scientific and clinical literature that high power is better than low power, in fact the opposite has been proven to be true. As I have mentioned above, there is a therapeutic “optical” response window between 600 and 950 nm and a biphasic dose response curve governed by the Arndt-Schulz law, within which the positive bioregulatory effects occur.

The use of LLLT in animals and humans almost exclusively involves light in the range above 600 nm and below 950 nm with the maximum effective “optical window” ranging from 650 nm to 930 nm.[10]

As an example, a class 4 laser emitting 880 and 970 nm laser light at 10 W average power with a beam surface area of 10 cm^2 producing a radiant exposure of 1000 mW / cm^2, thus exceeding the safe exposure limits known as the Maximum Permissible Exposure limits (“MPE”), which range from 200 mW to 500 mW / cm^2 depending on wavelength. Therefore, these devices need to be treated as thermal invasive devices, period!

The use of class 4 lasers have a high potential of delivering non optimal treatment doses of energy due to their lack of penetration and excessive MPE; thus presenting a greater risk of burning patients, particularly with dark hair follicles. Let’s say that you wish to deliver energy to a tissue surface of 1 cm^2 with a dose of 10 joules/cm^2 of energy. With a 10 Watt laser this takes one second of treatment time. If however you wished to deliver 2 to 4 joules of energy to the same surface area, which is a more common therapeutic dose, this would take 0.2 to 0.4 seconds. Most Class 4 manufacturers treat up to 5 minutes with their technology, thus they have exceeded the therapeutic dose of tissue not only in wavelength by being outside the optical window, but also in power by exceeding the MPE by 20 times and the therapeutic dose by 500 times. This logic suggests that too much power and the wrong wavelength simply equates to the expense of more money without the requisite return in better clinical effects. I therefore regard lasers with output powers exceeding 500 mW as unnecessarily strong and downright dangerous to conduct LLLT treatments.

Class 4 lasers for phototherapy is not new and not innovative, as such lasers have been on the market for years but have been approved strictly for surgical applications; such as: general surgery and tissue ablation for port wine stains, spider veins, et cetera. Just advertising the advantage that a laser is class 4 and hence, is a better instrument then a class 3B laser is akin to claiming that the Chrysler 600 is a better vehicle than the Mercedes Benz 500, just because the number is higher.

The above criticism is directed towards the gross generalizations and false claims of vendors of Class 4 lasers who purport their use for therapeutic purposes, not against the use of class 4 lasers

for their eligible claims in laser surgery and tissue ablation. One thing remains certain, current scientific and clinical research proves that class 3B lasers are best suited for therapeutic applications and class 4 lasers are best suited for tissue destruction.

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