How Not To Promote Laser Therapy

By Jan Tunér, DDS
Lars Hode, DrSci (Swedish Laser Medical Society)
Peter A Jenkins, MBA (Australian Medical Laser Association)

"We can talk to the cells, but we must learn their language."
Tiina Karu

This challenging statement has been met with enthusiasm as well as with incredulity. Taking command of the cells by the use of light is still not part of mainstream medicine, in spite of strong scientific evidence. It is now obvious that we can indeed talk to the cells even though we are still rather poor in understanding their language The scepticism about this method has many explanations. In this article, we will focus on one of them – marketing tricks.

The collected evidence about the many advantages of laser phototherapy is rapidly increasing. The knowledge about the basic mechanisms as well as about the optimal dosage intervals has improved dramatically in recent years. It should be easy to sell laser equipment to all kinds of therapists just using the available scientific knowledge – which is truly amazing in and of itself. But this is not always the case. Too many manufacturers deliver poor equipment and training, and too many of them use sales gimmicks in order to make their equipment look unique. It is not that the devices they're selling are incapable of producing therapeutic effects. They are; even a $10 lecture pointer has some therapeutic potential. It is that they are simply NOT capable of delivering upon many (in some cases, most) of the claims that are made about them, whether those claims be about the range of treatable indications, therapeutic outcomes, depth of penetration, speed of treatment, method of application, or patented waveforms, etc.. Such sales techniques and outright dishonesty are confusing for consumers and risk draining the therapy of the credibility it deserves. Let us look at some examples!

"An extraordinary claim requires extraordinary proof."
Marcello Truzzi

Sales trick 1: Soliton waves
One laser manufacturer in the USA claims that their lasers produce "soliton waves" by "piggy-backing one wavelength upon another", and that these "penetrate deeper into the body than is possible with any other type of laser". This sounds impressive and unique, but it is a sales trick, no more, no less. No therapeutic laser on the market produces solitons. And, even if it were possible and financially viable to do so, what evidence is there to support this manufacturer's claims of therapeutic benefit?

Sales trick 2: Scalar waves
The husband-and-wife "inventors" of the Scalar Wave Laser claim to have developed the "most advanced low level laser technology with state of the art quantum scalar waves" that supposedly employs a "unique approach to accessing the quantum neutral unified field state" to "dissolve cellular memory, normalize body systems, optimize anti-aging capabilities, and activate the glands and higher dimensional subtle body that yogis and mystics have tapped into throughout the ages". This is, of course, a complete fabrication, a crackpot theory. No laser equipment designed for laser phototherapy is producing scalar waves and again, even if such waves existed, there is no evidence whatsoever that they should have a positive or negative effect of cell functions.

Penetration
For many indications, some degree of light penetration through tissue is an advantage. The penetration of laser light into different types of tissue is surprisingly poorly investigated, but enough is certainly known to refute the claims of some manufacturers. There are two extremes oft found in the marketing claims, one that photons can penetrate clothes and even the entire body at very low powers, the other that very high power output is needed to reach very deep-lying targets. Both claims are characterised by gross exaggeration, demonstrating either complete ignorance or deliberate misapplication of the science of optics.

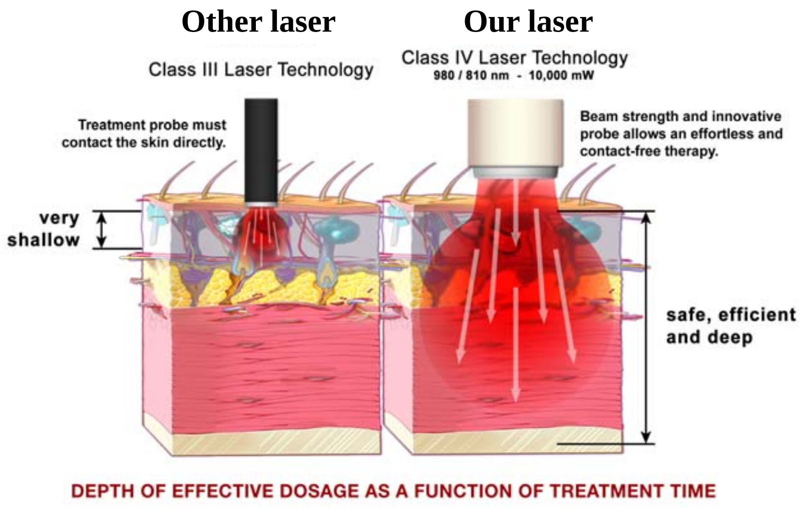
Sales trick 3: Treating through clothes
One particular manufacturer claims that their device, emitting a very low intensity thin line of red laser light, can be used to treat patients effectively through their clothing. Yet it is obvious to anyone who wears a shirt in the sun that clothes are a very effective blocker of light. And the skin barrier in itself reduces the amount of light going below the dermis. A simple experiment on the penetration of 650 nm 20 mW red laser light through different types of textiles can be watched on the following Youtube presentation: http://www.youtube.com/watch?v=MkGJvvWD1vw.

Representatives of this company also claim that these photons go right through our bodies. Whilst it is possible for very high-energy particles such as neutrinos and for x-rays, being very different waves, to penetrate through our bodies, the low energy photons produced by therapeutic lasers are physically incapable of penetrating through that much tissue.

Recent research is hinting that low power and long exposure is better than high power and short time for tissue regeneration, and, seemingly underlining this statement, this same company has presented research papers showing success using their lasers in the clinical setting (without clothes). Serious users of this approach report treatment times in excess of 15-20 minutes, which may produce a systemic effect by irradiating blood through superficial blood vessels. Well enough, but this does not involve photons penetrating the body, and certainly will not work through clothes. Mixing science with pseudoscience is pseudoscience.

Sales trick 4: Class IV laser therapy
The international system of laser classification is concerned only with the risk for eye injury and, at higher powers, skin damage. It has nothing at all to do with suitability for laser treatment, nor does it mean a generational change nor ensure any improvement in efficacy. Many different parameters are considered in eye risk evaluation (laser wavelength, beam diameter, beam divergence, exposure time, pulsing vs continuous emission, type of pulsing and more). Actually there are Class I lasers that are higher powered than many Class IV instruments! So, there is no sense in or reason for, other than deception, the term “Class IV laser therapy”.

For example, some manufacturers claim that their Class IV lasers (e.g. 10-60 W, 980 nm laser) offer superb penetration through tissue (from 6-to-9 inches according to one manufacturer), and that the so-called “weak” class IIIB lasers (e.g. 500 mW, 808 nm laser) hardly penetrate the surface skin barrier at all. However, in the chosen example below, the very opposite is the truth! Due primarily to its absorption by water in the tissue, 980 nm penetrates less than 808 nm, and this is not compensated by the higher power. At around 808 nm we actually have the best penetration into tissue, and increasing power only increases the depth of penetration marginally. With the higher superficial absorbance of the 980 nm laser there will be considerable heating, and, while heat is fine for many conditions, it is not of what photomedicine is constituted.



The picture to the left supposedly illustrates the superiority of a Class IV laser. Although the illustrations and explanations vary, there is more than one laser company using the same flawed argument to promote high-powered lasers.

It is also interesting to note the use of the term "Class IV technology". There is no specific "technology" that enables a manufacturer to choose a laser emitter that produces more than 500 mW, thus the term "Class IV technology" is simply used to infer a differential benefit that does not exist. Apart from power, the only differences between Class IIIB and IV lasers are the potential hazards and, usually, the price.

For more detailed information about the penetration of laser light, we recommend that you read our article "Penetration of light" in Laser World (www.laser.nu).

Sales trick 5: Claimed output vs. actual output

Two recent papers have considered the same thing: The power of therapeutic lasers in use. Both studies are from Brazil and the outcome is alarming, although don't think that this is a problem only in Brazil! Certainly, many laser manufacturers are responsible and are producing equipment of a high standard. But too many are not! Read the abstracts below, and take heed!

Photomed Laser Surg. 2009;27(4):633-639. ***Radiant power determination of low-level laser therapy equipment and characterization of its clinical use procedures.*** *Guirro RR, Weis LC.* Department of Biomechanics, Medicine and Rehabilitation of the Locomotor System, School of Medicine of Ribeirão Preto, University São Paulo, Ribeirão Preto, SP, Brazil. rguirro@fmrp.usp.br

The main objectives of this study were to characterize low-level laser therapy (LLLT) and the physical therapy clinical procedures for its use. There are few scientific studies that characterize the calibration of LLLT equipment. Forty lasers at 36 physical therapy clinics were selected. The equipment was characterized through data collected from the owner manuals, direct consultation with the manufacturers, and a questionnaire answered by the users. A digital potency analyzer was used to calibrate released mean potency. Qualitative data were presented throughout the descriptive statistics and quantitative data were analyzed by the Wilcoxon/Kruskal-Wallis and Fisher tests (significance, $p < 0.05$). RESULTS: The laser equipment was either GaAs (70.5%) or HeNe (23.5%), and 60% was analog and acquired over 5 years ago. The majority of the equipment was used 10-15 times per week and the most frequent density level used was 2 to 4 J/cm(2). Protective goggles were available in only 19.4% of the clinics evaluated. The association between the analyzed categories demonstrated that a lower mean potency was correlated both with equipment acquired over 5 years ago and analog technology. The determined mean potency was lower than the one claimed by the manufacturer ($p < 0.05$). In 30 cases, the analyzed equipment presented a potency between 3 microW and 5.6 mW; in three cases, the potency was >25 mW; and in seven cases, potency was nonexistent. CONCLUSION: The analyzed equipment was out-dated and periodical maintenance was not conducted, which was reflected in the low irradiated potency.

Rev Bras Fisioter. 2010;14(4):303-308. ***Calibration of low-level laser therapy equipment.*** *Fukuda TY, Jesus JF, Santos MG, Cazarini Junior C, Tanji MM, Plapler H.* Physical Therapy Sector, Irmandade Santa Casa de Misericórdia de São Paulo (ISCMSP), São Paulo (SP), Brazil. tfukuda10@yahoo.com.br

Despite the increase in the use of low-level laser therapy (LLLT), there is still a lack of consensus in the literature regarding how often the equipment must be calibrated. For the evaluation, a LaserCheck power meter designed to calibrate continuous equipment was used. The power meter was programmed with data related to the laser's wavelength to gauge the real average power being emitted. The LLLT devices were evaluated in two ways: first with the device cooled down and then with the device warmed up for 10 minutes. For each condition, three tests were performed. The laser probe was aligned with the power meter, which provided the real average power being emitted by the LLLT device. All of the data and information related to the laser application were collected with the use of a questionnaire filled in by the supervising therapists. RESULTS: The 60 devices evaluated showed deficit in real average power in the cooled-down and warmed-up condition. The statistical analysis (ANOVA) showed a significant decrease ($p<0.05$) in the real average power measured in relation to the manufacturer's average power. On average, the most common dose in the clinics was 4 J/cm², and the most desired effects were healing and anti-inflammatory effects. According to the World Association for Laser Therapy (WALT), 1 to 4 J of final energy are necessary to achieve these effects, however only one device was able to reach the recommended therapeutic window. CONCLUSION: The LLLT devices showed a deficit in real average power that emphasized a lack of order in the application of this tool. The present study also showed the need for periodical calibration of LLLT equipment and a better technical knowledge of the therapists involved.

Pulsing

There are principally two types of pulsing in laser phototherapy – chopped (switched) or super pulsed. A chopped beam is a continuous beam that is electronically (or mechanically) switched between on and off. During the moments when it is on it has typically the same output power as in continuous mode, but as it is not on all the time, the average output power is less than when it is continuous. The average power is a function of the continuous wave power and the duty cycle (the ratio of the "on" time of the beam to the total emission ("on" + "off") time, usually expressed as a percentage). Typical laser types are most of the gas lasers (such as the HeNe laser) and all semiconductor (diode) lasers (except the GaAs laser).

The GaAs laser was the first semiconductor laser in the world. In order to generate laser light, the current density in the GaAs semiconductor crystal had to be extremely high. As a consequence of the high electric current the output power of this semiconductor laser is very high. Typical peak power is in the order of many watts. However, when an electric current is conducted through a material heat is generated, and with the necessary high current in this laser the crystal will burn up immediately unless the time of current conduction is extremely short, i.e., super-pulsed GaAs lasers cannot work continuously. The maximal pulse time for this laser is in the order of 100 to 200 nanoseconds and, after each such pulse, a long cooling time is needed, usually about a thousand times longer than said pulse time. This form of pulsing is called super pulsing and, although the peak power is very high, the average output of super-pulsed lasers is comparatively low. Typically the GaAs laser produces its maximum emission at 904 nm.

Sales trick 6: The 904 nm trick

Restating the above, even though the peak power of the super-pulsed GaAs laser may be very high, it lasts for an extremely short time compared to the pulse cycle, resulting in an average output power that is usually a thousand times lower than the peak power. For clinical use, it is the average power that counts. The energy (dose) delivered from pulsed lasers is always the average output power multiplied by the exposure time. The average power is the important output of the laser.

Some manufacturers prefer to label these lasers as "very strong" and state only the peak power which then can be in the order of 100 watts. This sounds impressive, but typically these lasers emit 10-100 mW average power, and this is what counts for the treatment. The GaAs lasers are quite useful in physiotherapy, but care has to be taken.

In some super-pulsed lasers the average output changes with the set pulse frequency, so that low pulse repetition rates deliver very low average outputs. This means that with such lasers, with low frequency settings, the treatment time may be impractically long in order to deliver a reasonable dose. One manufacturer, for example, promotes its super-pulsed lasers as having 25,000 mW or 50,000 mW of power, and offers the user a small number of preset 'programs' which, essentially, only adjust the pulse frequency and, therefore, the average output power. One of these 'programs' sets a frequency of 5 Hz. To calculate the average power one must only know the Peak Power, the Pulse Frequency and the Pulse Duration. As mentioned previously, the pulse duration (i.e., the 'width' of each pulse of energy) of most GaAs devices is 100-200 nanoseconds (0.0000001 – 0.0000002 sec). If we use the manufacturer's 'highest' power option (50,000 mW), select their 5 Hz program, and assume the longest possible pulse duration (0.0000002 sec) for our calculation, we arrive at an Average Output Power of only 0.050 mW, or fifty millionths of one Watt. With this very low average power it will take twenty thousand seconds (5.6 hours) for this manufacturer's laser to deliver one Joule. Impractically long, perhaps?

Other super-pulsed lasers employ "pulse trains", which enable the average output to be maintained at a constant level over all frequencies. The importance of checking upon this is obvious when it comes to acquiring a GaAs laser.

Sales trick 7: False super pulsing

One manufacturer claims that its dual-wavelength (800 nm and 970 nm) high-powered Class IV laser has better penetration due to its 'Intense Super Pulse' emission. However, these diode lasers are not super pulsed, they are "chopped", and chopping does not offer increased penetration. In this case chopping the output simply reduces the tissue-heating effect of the high power laser by both reducing the average power and also allowing time for the tissue to thermally relax (i.e., dissipate heat) between each pulse of light.

Frequencies

The biological differences between super-pulsed and chopped emissions are likely to be fundamental. Is pulsing then of interest? The in vitro studies by e.g. Tiina Karu clearly show that the type of pulsing is of importance. However, in these situations one type of cell and one type of reaction is studied. In the clinical situation, many types of cells are irradiated and a multitude of events happen. So is pulsing then of any clinical importance? The answer is that we do not know. This is well presented in the recent literature review by Hashmi et al, http://www.ncbi.nlm.nih.gov/pubmed/20662021. Some lasers are pulsed to allow for heat dissipation, but that has nothing to do with biostimulation. Chopping is an option in some continuous lasers and users should be aware of the fact that suggested pulse repetition rates are only setting options; we do not know if the different pulse repetition rates provide different biological results. Many "recommended" frequencies employed in therapeutic lasers are, in fact, carried over from other fields and modalities, especially electrical stimulation. Nogier's frequencies, for example, are often incorporated into laser therapy protocols for both humans and animals; yet their original application was in humans only, specifically auricular therapy delivered by electrical stimulation. Due largely to the impact of pulse frequency upon the average power of the first therapeutic diode laser, the GaAs, Nogier's original frequencies (there are seven, ranging from 1.14 Hz to 146 Hz) are even presented at a higher "harmonic" so as to achieve a higher average output power, further increasing the disparity between their original intended application and their current use. Despite this, and the fact that there have been no studies undertaken to compare or confirm the efficacy of the original or higher-harmonic laser-delivered frequencies in humans or animals, these and other frequencies are provided as an integral part of many different therapeutic laser devices and their pre-programmed protocols.

Sales trick 8: Pre-programmed machines
There are many variations of so called pre-programmed lasers on the market. Some offer ‘starter’ protocols that employ simple variations of power, frequency and time, making these parameters known to the user and even affording them the option of changing them as their knowledge and experience improves. Others, however, provide the user with nothing more than a choice of letters or numbers that represent different “proprietary programs”, ensuring that the user is kept completely in the dark as to what they’re actually doing. Such programs may consist of various frequencies and exposure times, often in automatically-changing combinations of such; for instance, 20 seconds of 500 Hz + 40 second of 120 Hz + 10 second of 1500 Hz. The user is informed only that that “program” is supposed to be the best for e.g. headache, and that another program and time/frequency combination is the best for arthritis, etc.

The buyer of such an instrument trusts that the constructor of the instrument knows that this is a fact. However, there are no such optimal time/frequency combinations scientifically proved to be better than others. Also - how can a setting for “arthritis”, for example, be the same for a finger joint as well as for a knee? Who can verify the pulse repetition rates recommended? Such preset protocols will generate nothing more than vaguely satisfactory outcomes, at best; neither what your patients expect of you, nor what you should expect of a clinical tool that has, most likely, cost you thousands of dollars.

One particular manufacturer has corrupted the use of the terms ‘Optical Window’ and ‘Therapeutic Window’, well-known to many within the phototherapy field, to label their preset programs as so-called ‘Therapeutic Optical Windows’ that, supposedly, deliver optimal combinations of the many different parameters that influence clinical outcomes. As an exercise, let’s consider the various device and treatment parameters and patient characteristics that affect variations in phototherapy outcomes, and determine how many iterations of these must be clinically tested and validated before one could claim, with even a hint of honesty, to have determined the optimal “Therapeutic Optical Windows” for even a handful of indications. First we take the various parameters of, say, a switched continuous wave device (e.g., output power, spot size, wavelength, pulse frequency, duty cycle). Then we add the irradiation duration, treatment technique, number of points to be treated or the area of affected tissue, and the target tissue depth. Next, toss in a handful of such patient characteristics as skin colour and tissue type and whether their condition is acute, sub-acute and chronic. Finally, consider some desirable clinical outcomes such as analgesia, reduction of inflammation, enhanced tissue repair and/or nerve tissue regeneration. Although this gives us a very simplified set of factors, we are still left with potentially billions of combinations of variables that must be subjected to clinical testing in order to support this manufacturer’s claims. In forty-something years of research into phototherapy, by hundreds of researchers, we have barely even scratched the surface in terms of determining upper and lower activity thresholds of irradiation duration and intensity, and yet we’re now supposed to believe that one company only has considered and tested every possible iteration and distilled them into nine optimal “Optical Therapeutic Windows”? Even the most credulous among us must baulk at that …

We recommend, instead, availing yourself of high-quality research published peer-reviewed journals, informative manuals and qualified seminars, rather than automatic settings. Use palpation, your own physiologic knowledge, your patients’ feedback and your experience to guide you in your choice of parameters.

High power – low power
There are two extremes on the market – those promoting very low power output and those promoting very high power output. Which is best? The answer is: none of them. There is no “one

size fits all” laser. Each one has its limitation. There is an increased awareness about the necessity to deliver fairly low doses over longer time to optimize anti-inflammatory results (Castano et al 2007, http://www.ncbi.nlm.nih.gov/pubmed/17659584 as one example). This means that, at least for healing processes, low power over long time is more effective than high power over short time, even if the total energy is the same. The same goes for stimulation of cell proliferation. For temporary analgesia of painful conditions, high power over short time can give a better momentary effect, subject to certain minimum-time and maximum-power thresholds. The optimal dose windows for musculo-skeletal indications, based upon the current scientific evidence, can be found at www.walt.nu. Conclusion: very high powered lasers are useful for treating large areas in short time and to obtain pain inhibition, but seemingly less effective for basic cell stimulation. And they do not penetrate much deeper due to the high output – in fact, the very act of making a high power laser ‘safe’ for long-duration exposures may make it less capable of penetrating as deeply as a lower-powered laser that can e.g. be applied in contact and with slight pressure to the skin. All types of medical lasers are useful within their own limitations, but the very high powered lasers are still lacking scientific documentation in spite of their increasing popularity with salesmen and their less-informed customers.

And – N.B. – high power does not mean that a laser instrument has to be in laser class IV. Let us assume that the probe has 10 laser diodes, placed at some distance from each other, each having an output of 450 mW, i.e. class III. This instrument is then a less-hazardous (by definition) class III instrument with an output of 4.5 W (4,500 mW).

Laser or LED

You will find many different configurations of phototherapy instruments in the market, some offering laser output only, some offering only LEDs, and – excluding LEDs that are provided for indication only – other devices combining both lasers and LEDs as active therapeutic components. The two latter types are sometimes deceptively called “laser” with no reference made to other emitter types; this is inaccurate, at best. Often the buyer is unaware of the distinction, thinking they have bought a true laser device. The primary reason for replacing laser sources with LED sources, or to add such, is not that LEDs are better or more efficient, but simply that they are cheaper to buy and to drive electrically. Although LED instruments can also elicit good clinical results, they are not lasers and it is technically and ethically incorrect to call them such; doing so serves only to benefit the manufacturer and/or marketer of the device, not the purchaser.

High or low price

If you are in the process of buying a laser instrument without experience of the market, you are vulnerable to the sweet arguments of the salesmen. One aspect is the price. Is high price indicating high quality and good treatment results? No. Not necessarily the opposite either. We can recommend that you acquire a power meter (separate or built-in). Also find out the service level of the company – what happens when it breaks?

Bottom line

Laser phototherapy is a wonderful tool in medicine and useful for just about any medical practitioner. The scientific evidence is considerable but differs from one indication to the other. What is already known is sufficient for piquing the interest of anyone with an open mind. So why use sales tricks when the plain truth is good enough?