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LLLT: WHERE IS IT NOW?

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First of all may I thank the Publishers for the opportunity of penning this Editorial to issue 10.3 of the journal. I think that, after the success of the 2nd WALT meeting in Kansas City in early September of this year, and the successful founding at that meeting of the North American Laser Therapy Association (NALTA) under the umbrella of WALT, the growing field generalized variously as 'laser therapy', LLLT, LILT, LILI, photobioactivation or photobiomodulation (but *not*, please, 'low power laser') is at last moving forward with gathering momentum in the USA, thus catching up with the rest of the world. On the international scene (and even here in the USA), because of the growing number of first class research and well controlled clinical studies which are appearing regularly in the international literature, it is becoming harder for the sceptics to continue in their scepticism. The vast majority of papers give strong support for a real clinical effect from LLLT in both *in vivo* and *in vitro* studies, although areas of controversy remain, particularly in dosimetry and wavelength.

Of the papers which find little effect or even negative results for LLLT, on careful examination not a few of these are flawed. [*Editorial note:* By the way, something for you to look forward to: readers will find in the forthcoming issue 10.4 of *Laser Therapy* an excellent and comprehensive review paper on this subject from Tunér and Hode.] For example, as has been constantly argued in this journal, and equally constantly ignored by some researchers who ought to know better, any study using a contralateral unirradiated control on the same subject is instantly flawed, since systemic whole body effects have been shown and proved since the earliest LLLT papers in the late 1960's.

Back to parameters ... yet again! There is a lot of confusion about what actually constitutes the 'dose', although once again the science is crystal clear on the subject. Some manufacturers and researchers persist in using joules (J) as their 'unit of dosimetry', although I am happy to note that more and more are using joules

per square centimetre (J/cm^2). Some even use W/cm^2 as the 'energy density'! It is an irrefutable fact that joules on their own are only a unit of energy, that is to say power over time, and can not, indeed should not be quoted as the 'dose', which must include the incident power, the unit area over which that power is incident and the time for which that unit area is exposed: in other words, the only correct dose in laser therapy and surgery is the *energy density* (also referred to as the radiant flux) expressed in J/cm^2 . To make matters even more complicated, many researchers are extremely coy about giving their complete parameters, particularly the incident power and the irradiated area, from which the *power density* can be calculated as a parameter of primary importance when considering faithful replication of a clinical or experimental study. As my good friend and colleague Glen Calderhead has often stated, if the energy density is the dose, then the power density can be looked at as the medicine. Carrying the analogy further, if the medicine is incorrect then there is no use playing around with the dose!

Despite the controversy, or perhaps because of it, the status of laser therapy is improving rapidly almost world-wide as both a stand-alone therapeutic modality and as an adjunctive therapy with conventional therapeutic methods. The most important obstacle to the genesis of complete acceptance remains the failure of the US Food and Drug Administration (FDA) to grant marketing approval to the manufacturer of any laser therapy system. This is not the fault of the FDA, but is instead the fault of the manufacturers who have until now presented insufficiently researched proposals for clinical trial protocols, so that even FDA permission for preclinical trials of an LLLT system under an investigational device exemption (IDE) has been extremely rare.

On the international scene outwith the USA, laser therapy is well used and accepted both north and south of our US borders in Canada and Mexico. LLLT is an accepted modality under the UK national health service, and also in Spain. In Greece, moves are afoot to bring

LLLT under the Greek Government's health insurance plan. In Brazil the situation is difficult under the government insurance plans, but laser therapy is a well-accepted modality although mostly confined at present to odontology. In Argentina, LLLT is widely applied, with rapidly growing interest in sports medicine. In Japan, LLLT is accepted well in many specialties, although there are only a few Japanese manufactured systems which have full Japanese Ministry of Health certification, the equivalent of US FDA approval. In Australia, LLLT is very well accepted, particularly in physiotherapy and physical therapy. In Asia and South East Asia, particularly Singapore, India and Pakistan, LLLT is garnering much attention, especially as an adjunctive therapeutic modality in neurosurgery. The data available from Russia are vast and wide-ranging, but unfortunately mostly published in Russian and therefore unavailable to the average researcher. In many countries LLLT is used very much in veterinary medicine, even in the USA, and the potential there is staggering. In brief, the current status of LLLT is improving, and it will continue to improve. I am convinced that this journal, and the World Association for Laser Therapy, must take some of the credit for this

US Food and Drug Administration and LLLT

The greatest single step to boost credibility in LLLT will be the issuing of an FDA approval for a laser therapy system, so for the benefit of those who are unclear regarding the process, I would like to clarify the steps required for FDA to grant such approval. There are two possible avenues for FDA approval of a laser system. If a new system can be shown to be substantially equivalent to an existing approved system and can be shown in approved clinical trials to be safe and effective for the condition being treated, FDA will issue an approval referred to as the 510k, said as 'five-ten kay'. Many surgical lasers are approved under this route. However, if no similar system has approval, or the system was not in regular use prior to 1976 (the so-called 'grand-fathering' approval), then the manufacturer of the system must go for a full premarketing approval from FDA, abbreviated to 'PMA.'

Getting a PMA is a matter of the manufacturer's carefully identifying (usually three) recognized trial centers run by credible leaders in their fields; identifying appropriate target diseases or conditions; and writing a protocol around these in collaboration with FDA and with the approval of the centers' Institutional Review Boards (IRB's). The manufacturer must then request an interview with FDA at which a group of documents are lodged with FDA, such as the product description (usually including a copy of the laser system Operator's Manual), and a comprehensive argument is presented as to the safety and efficacy of the system based on the basic science and data already seen in the international peer-reviewed literature. The protocol is also presented, and with the protocol approved, the FDA will issue an investigational device exemption (IDE) and the trial can start.

Once the treatment called for in the protocol has been carried out and the data collected and analyzed, a submission is prepared and sent to FDA, hopefully showing the desired results, and petitioning for issue of a PMA. After due consideration, FDA must reply to the submission in a set period of time followed by the granting of a PMA, always provided the manufacturers have done their homework correctly.

I hope that this has clarified the situation here in the USA, and that *Laser Therapy* readers will see how the issue of the first PMA for a laser therapy system will be a milestone in our chosen field. It is true to say that many other countries look to FDA approval as a kind of stamp of acceptance, so the positive repercussions of a laser therapy-related PMA will be felt world-wide. In my opinion, we will almost certainly see at least one PMA for a laser therapy system issued in the coming year (1999), and that will really announce to the sceptics that LLLT has finally arrived. Of course, many of us have known this for some considerable time, but none the less, I am looking forward to that first approval! The light of LLLT is getting brighter, and you can certainly help increase the level and purity of this light by using the medium of *Laser Therapy* to report your clinical and scientific findings to your colleagues world-wide. We are waiting for your input!

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