LASERS : ASPECTS OF EFFECTIVENESS AND SAFETY*

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SUMMARY

The use of laser therapy by physiotherapists has shown a marked increase in popularity over recent years. Effectiveness and safety of lasers is essential. The results of an investigation by the CSIR of some infrared lasers is reported, highlighting, e.g., that all that **SAYS** laser may not **BE** laser. New legislation that will ensure that lasers conform with the minimum requirements to be safe and effective products, is discussed. The risk of laser radiation and product/premises licenses as a means of ensuring safe use of lasers, are explained.

OPSOMMING

Die gebruik van laserterapie deur fisioterapeute het oor die laaste paar jaar baie toegeneem. Effektiwiteit en veiligheid van lasers is noodsaaklik. Die resultate van 'n ondersoek wat deur die WNNR op enkele infrarooi lasers gedoen is, en aandui dat nie alles wat laser **SÊ** dit noodwendig **IS** nie, word bespreek. Nuwe wetgewing wat sal verseker dat lasers aan die minimum vereistes voldoen om veilige, effektiewe produkte te wees, word bespreek. Die gevare van laserbestraling en produk/perseellisensies as 'n manier om veilige gebruik van lasers te verseker, word verduidelik.

INTRODUCTION

Lasertherapy is fast becoming a popular modality in physiotherapy. This form of phototherapy has been gaining ground in proportion to the increased marketing of various lasers in South Africa over the last couple of years.

Safety and effectiveness is of great importance in performing our professional service. When a new treatment modality is introduced, ensuring effectiveness and safety may however be difficult, for two main reasons.

Firstly, control over the electronic equipment/products according to set standards of safety and reliability initially may not exist. Such control may only be instituted after some time and could possibly take years.

Secondly, lack of relevant information, training, understanding of the uses, potential dangers, method of application, and estimating the proper dosage is a problem. It is not uncommon for physiotherapists in private practice and hospitals to start using a new modality when the only information available is from manufacturer's brochures, manuals, etc. It usually takes some time for workshops to be held on the subject for qualified physiotherapist. It may also take some time for the subject to be included in the undergraduate curriculum. Scientific research may often be very sparse, even non-existent. This is certainly the case for laser therapy.

This paper deals with the effectiveness and safety of laser equipment and their safe use. The results of an investigation of some infrared lasers as well as regulatory control of laser products and its implications for South African physiotherapists are discussed.

DEFINITION

A laser is a device which emits optical radiation (radiation in the ultraviolet, visible and infrared regions of the electromagnetic spectrum) with unique characteristics due to the process of Light Amplification by the Stimulated Emission of Radiation (for which LASER is an acronym)[1]. Such radiation is typically monochromatic (of a single wavelength or lying within a very narrow wavelength band), of high energy and power density, coherent (all waves being in phase) and unidirectional (parallel; having minimal divergence)[1,2].

MEDICAL USE OF LASERS

In medicine lasers are either used for bringing about definite thermal changes and/or destruction of tissues[2], or for its biostimulatory effects[3,4,5].

High power (hot) lasers are used in various medical applications, including surgery, ophthalmology and dermatology. The carbon dioxide (CO_2) laser (wavelength 10,6 *fm*) is used for surgical cutting and coagulation. The argon laser (wavelength 488/514 nm) is used in ophthalmic surgery for "welding" detached retinas. The neodymium-yttrium-aluminium-garnet (ND-YAG) laser (wavelength 1064 nm) is used for arresting haemorrhage and destroying tumours [2,3,5].

Biostimulation is achieved by laser treatment with a dose rate that causes no immediate detectable temperature rise in treated tissue and no macroscopically visible change in tissue structure[6]. This is termed "low level laser therapy" (LLLT) by Ohshiro and Calderhead [7]. Other terms used in connection with biostimulation are cold/soft/mid laser.

LASER SOURCES: LASER WAVELENGTHS

Most commercial instruments use a laser source which is wither a small helium-neon (He-Ne) (gas) laser with a continuous wave (cw) power, or a diode laser which may be cw or pulsed[5,6].

A He-Ne laser produces optical radiation at a wavelength of 632.8 nm (visible red light)[5], whereas the combination of elements that make up a semiconductor laser diode determines the wavelength of the radiation which is produced[2,5]. Gallium Arsenide (GaAs) and the gallium aluminium arsenide (GaAlAs) diodes are both commonly used and produce invisible infrared (IR) light. Wavelengths in the near infrared region, e.g. 904 nm, is relatively common for physiotherapeutic use.

The ability of the laser diode (depending on their composition) to emit at different wavelengths together with their low cost (relative to the He-He tubes of higher power ranges), small size and robustness has made this type of laser medium very popular with the manufacturers of biomedical laser systems. It must however be noted that not all diodes are made with the same optical properties or the same method of manufacturing so a variation of quality of beam radiance, divergence, wavelength bandwidth) is expected[3]. It is important that manufacturers provide adequate radiation specifications of the laser product.

CREDIBLE LASER

To reproduce the clinical results that is reported in the lit-

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erature, it must be ensured that the characteristics of the laser radiation is identical. For instance, a narrow bandwidth of wavelengths is supposed, together with the expected high intensity due to the process of amplification.

In the past it was assumed that potentially hazardous electronic products, e.g. lasers, would be imported almost exclusively from recognised manufacturers that maintain internationally accepted norms for safety and effectivity. More recently, however, more and more products of less well known and even unknown origin, including locally manufactured products, have appeared on the South African market, often not complying with the required standards[8].

CSIR INVESTIGATION

Against this background, the Division of Production Technology of the CSIR was commissioned by the University of Stellenbosch during 1989 to investigate by means of radiometric measurements the characteristics of five near infrared radiation sources (laser diodes) used in physiotherapy (table 1.). The devices were characterised with regard to spectral properties, radiant power and beam divergence.

MAKE	MODEL	SERIAL NO	OPERATION	CLASS
Lasdac (2 probes)	No Model No.	No serial no.	Continuous	IIIb
Laserex	LTU 904	2176	Pulsed	I
Mesolaser	IRO1	820709	Pulsed	IIIb
LAWO	AL607/4	8908745	Continuous	IIia
Medical Electronics	LSI2030	01655M	Continuous	I/IIIb according to power

TABLE 1: DETAILS OF EQUIPMENT INVESTIGATED

Spectral properties

On the basis of the relatively broad band of wavelengths (895 *q* 75 nm) of one of the two proves of the Lasdac, it was concluded that it was an ordinary light emitting diode (LED) (or infrared emitting diode) as distinguished from a laser diode[9]. The advertisement of this probe as a laser diode would be misleading.

This indicates that quite a number of physiotherapists who had bought Lasdac laser units during or before 1989 were not/are not treating with true laser when using the 895 nm probe. Clinical effects could therefore not be ascribed to laser radiation. Reports of comparative results using the two different probes may be of interest.

It has also come to light that the peak wavelength of some of the products (mesolaser, Lasdac) differs from that which is stated by the manufacturer[10,11](table 2). This may be of importance when reporting on clinical research, or when comparing the effects of radiation of different wavelengths.

Radiant power

Table 3 shows approximate average power measured for each source in comparison to the manufacturer's specifications.

The measured average power of the Mesolaser (a pulsed source) differs from that calculated by the formula Pav = f x pw x Pp, where Pav = average laser power in watts, f = pulse frequency in hertz, pw = pulse width in seconds, Pp = peak power in watts[2,5]. This is apparently because the pulse width is actually less than 200 ns[9,10]. This would indicate that output measurements are vital when reporting research results.

Another interesting observation is that most of the radiation sources tested, excluding the LAWO, showed a lack of power stability, especially just after switch-on, when drops in output power in excess of 10% were observed. In assessing the dosage this observation should be noted.

Source	Peak wavelength (nm)	Measured spectral bandwidth $\Delta\lambda$ (nm)[†]	Conditions[4]
Lasdac			
Probe 1	895(v 880)	75	Set to square wave ("pulse" mode), and a frequency of 30/s (although found to be independent of frequency).
Probe 2	820	6,5	Equipment appears to malfunction in continuous mode The power setting had no effect.
Laserex	912,5	2,5	Set to "Hi", i.e. repetition frequency of 5000/s.
Mesolaser	915[2]	6[2]	Set to a repetition frequency of 5000/s, and the "30W" peak power setting.
	916[3](v 904)	4,5[3]	
LAWO	783,5	2	Set to D (continuous mode). Set to 5mW power.
Medical Electronics	786	1,5	This unit has no continuous mode, only "Polyfrequency". Alpha frequency disabled.

λ = Full width of half maximum

1 = The monochromator bandwidth was 1nm in all cases except for probe 1 of Lasdac, where it was 2nm Therefore the spectral bandwidth of the sources will be slightly less than the measured values

2 = Soon after switch-on

3 = After 5 minutes or more

4 = These conditions apply for all subsequent measurements except where otherwise indicated

TABLE 2: SPECTRAL PROPERTIES OF DIFFERENT SOURCES

Source	Class	Average total power	Presumed total power
Lasdac			
Probe 1	IIIb	8mW	
Probe 2	IIIb	4mW	
*Laserex	I	1mW	
*Mesolaser[3]		1mW[1]	
		20mW[2]	30mW
LAWO	IIIa	5mW	
Medical Electronics	I/IIIb	4mW	4mW

* Pulsed lasers: Peak power is in excess of 1000 times average power, as the pulse width is less than 200ns4 with a repetition rate of 5000/s.

1 On the "1W" peak power setting.

2 On the "30W" peak power setting, after being on for several minutes.

3 The lower power reading was obtained first, and actually exceeded 1mW. However, when switched from the "30W" setting down again to the "1W" setting, the value had dropped to about half, but started slowly to rise again, including thermal changes in the laser.

4 Normally just under 200ns, for both the Laserex and Mesolaser, as checked with a fast detector. However, pulses as short as 100ns were also on occasion observed with the Mesolaser, on the low power setting.

TABLE 3: RADIANT POWER

Beam divergence

Beam divergence spread was tested and documented and is applicable for all probes. Divergence and distance from the skin is of much importance with regards to determining or calculating dosage, e.g. for treatments in contact versus treatment at 1 cm from the skin. At a distance of 1 cm, according to the inverse square law, the irradiance (power/cm^2) is one tenth of the irradiance at a distance of 0,3cm.

LICENCING OF LASER PRODUCTS

Prospective buyers of laser or any other electrotherapy apparatus should take note that regulatory control of these products in South Africa was instituted on 14 April 1989. Under the Hazardous

Substances Act (Act 15 of 1973)[12], the list of electronic products declared as Group III hazardous substances (referred to as listed electronic products) was then added to include, apart from X-ray equipment, products or equipment capable of emitting ionising and non-ionising radiation, or sonic, infrasonic or ultrasonic waves[13]. Lasers, ultraviolet emitting devices, diathermy units, infrared heaters and medical ultrasound devices then became controllable under the Act, requiring users of these products to be licenced. A second set of regulations was also published[13], enabling control of the manufacturers and sellers of electronic products. They now also need to be licenced.

Since then the Department of National Health and Population Development controls the sale of Group III electronic products, by ensuring that each model of all manufacturers of a specific listed product, including lasers, conform with certain minimum standards of safety (primarily), before a licence will be issued permitting the model to be sold.

Such product licence will guarantee the safety and reliability of these expensive products to the end user. Any supplier of a laser product or other listed electronic products is now expected to display a sticker of the Dept. of National Health on the product, indicating that the product has been licenced for the purposes of sale.

SAFE USE OF LASERS

The control of lasers under the Act[10] is due to the potential health hazards, and users are required to adhere to safety precautions.

Mechanisms of injury, critical organs, contributing factors

Three primary mechanisms of injury exists for exposure to laser radiation, i.e. thermal, photochemically induced and thermo-mechanical injury[1,14]. Since laser radiation is not very penetrating (1-2 mm for wavelength 630 nm, or twice that at 800-900 nm)[6], the eye and skin are critical organs of injury. The type of biological effect, injury thresholds and damage mechanisms on these organs vary significantly with laser **power** and **wavelength** . Generally the effects of laser radiation are not different from the effects of optical radiation from a conventional source with the same wavelength range, exposure duration and irradiance[1]. Laser radiation however engenders concern due to the special properties associated with is radiation : the high intensity, or energy into one point - its concentration and directional "targeting"[14]. The eye is of special concern, since it is capable of increasing the light intensity many hundreds of times due to its focusing properties.

The harmful effects of exposure to different spectral bands of ordinary light is well known to physiotherapists. Table 4 tabulates the adverse health effects of laser radiation.

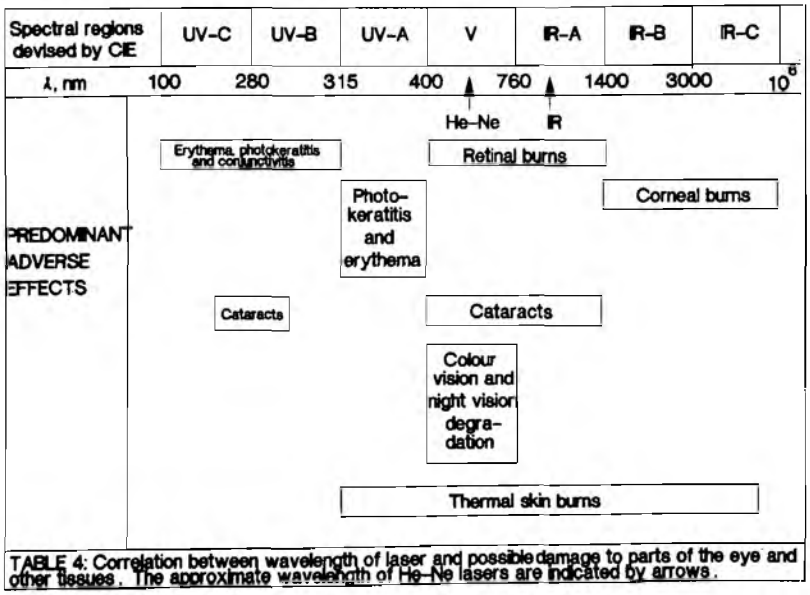

TABLE 4: Correlation between wavelength of laser and possible damage to parts of the eye and other tissues. The approximate wavelength of He-Ne lasers are indicated by arrows.

Risk according to class

Some idea of the risk/hazard associated with laser radiation can be derived from a laser's allocation to one of four designated classifications. The level of radiation to which human access is possible and its associated hazard determine the class of the product[8]. Accessible emission limits (AEL) is determined for each class. The AEL is the maximum accessible emission level permitted within a particular class computable as a function of emission duration and wavelength[1].

Each laser in class II-IV should have a yellow warning sign and explanatory label, including the laser class.

The risk for each class of laser is summarised in table 5.

CLASS I
Low power lasers. Not hazardous for the eye or skin intrinsically safe. Called "exempt" lasers.
CLASS II
Low power/low risk laser systems. Only hazardous if the viewer continuously stares into the source; safe for accidental momentary viewing due to reflex eye closure.
CLASS III
Moderate risk/medium power lasers. Can cause injury to parts of the eye; however not capable of causing serious skin injury. Safe after diffuse reflection.
CLASS IIIa
Lasers for which direct intrabeam viewing with optical aids may be hazardous, but for which the natural aversion response (eye closure) would normally protect the unaided eye.
CLASS IIIb
Hazardous for retina on intrabeam viewing, depending on exposure duration and distance; at greater distance and diffuse reflection no danger.
CLASS IV
High power lasers, high risk of injury. Can cause combustion of flammable materials, eye hazards and skin injury even from diffuse reflections. Unsafe.

TABLE 5: RISK ACCORDING TO LASER CLASS[1,4]

Practical safety measures

Most lasers used in physiotherapy are class IIIb (or lower) lasers. Even for contact or near contact (≤1cm) treatments by means of a probe it is advisable that the patient and operator wear appropriate glasses[1]. In the case of treatment near the eye or when using a laser which radiates from a distance, protection of the eye is essential [4]. Preferably no spectators should be allowed.

ELECTRONIC PRODUCT/PREMISES LICENSES

Control of the use of laser products (applicable to class IIIb and class IV lasers) is exercised according to a requirement of the licence for the purposes of the sale that the user of such products must be in possession of a valid product/premises licence before he/she uses the product [13].

In granting a premises licence the following factors are taken into consideration: Engineering controls – the product; controls such as door interlocks, filtered viewing optics, etc. Personnel protection – proper personal protective equipment, e.g. suitable eyewear, clothing and gloves. Administrative and procedural controls –7 standard operating procedures, adequate education and training of users, posting of warning signs and labels, regular maintenance and servicing of the equipment and designation of a laser safety officer.

Such premises/electronic license is a means of ensuring that the end user will comply with safety requirements when using the laser on his/her premises. Provision is made in the Regulations[13] for radiation control officers to inspect facilities and procedures to ensure safe use of the equipment[8].

All physiotherapists/hospitals/practices using laser should apply to the Department of National Health for premises licenses. A premises licence is also required for lasers purchased prior to 14 April 1989. If you are in possession of a laser, please inform the Department so that a register of laser users can be compiled. Such a register will aid the department in distribution of information, inspection/monitoring, as well as the facilitation of training/education.

Address for applications

Application should be made to the Directorate of Radiation Control, Department of National Health and Population Development, Private Bag X62, Bellville 7535. This Directorate is available as a source of information and consultation.

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Continued on page 33...