The Royal Australian and New Zealand College of Ophthalmologists

Laser Safety Protocol

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1. Introduction and purpose

Shortly after the construction and demonstration of the world's first laser system was reported in 1960, lasers were used for the treatment of ocular disease. Lasers are now in common use in various branches of medicine and also have widespread use in the community. As the eye is primarily at risk of non-therapeutic injury by lasers, ophthalmologists need to have a clear understanding of their safe use.

The purpose of this document is to update College Fellows in the safe use of medical laser systems and in the management of patients who have had accidental laser exposure.

2. Introduction to Medical Laser Systems

The three essential components of any laser system consist of the active material, e.g. argon, Nd: YAG, an external energy source which adds energy to the active material, and a cavity with mirrors at each end within which the induced energy from the active material oscillates to increase the intensity of the beam emitted from the cavity.

In commercial medical laser products the laser output operation is controlled by the operator through the use of series of electronic and optical controls on the laser and its delivery system. There is a main power switch that energises the laser system, a control that varies the output power, and a firing or operation switch that triggers the laser output (a foot or hand switch, or under micro-processor control). Stand-by switches are frequently incorporated into the equipment to avoid accidental or unintentional firing of the laser during patient preparation.

Laser beam monitoring devices vary considerably. The output power may be set at a predetermined level. The laser power may be sampled before the output end of the final delivery system and so the true output may be different from the meter reading because the delivery system changes or deteriorates with use. The output beam of a laser can be either pulsed or a continuous wave laser for safety purposes. The output of pulsed lasers can vary greatly in the duration and energy of individual pulses and can be from as short as a few femtoseconds to as long as many milliseconds. The pulses may be delivered individually or repetitively.

Because the laser light rays do not diverge as they emerge from the laser cavity the laser beam retains its brightness over distance and thus may cause accidental damage to a distant target. This problem of accidental damage at a distance is reduced as all medical lasers contain a delivery system that focuses the energy output of the laser to a tiny spot.

Beyond the focus the divergent beam becomes of low intensity over a short distance. This has given rise to the concept of nominal hazard zone, which includes laser light reflected from mirrored surfaces.

The delivery systems of ophthalmic lasers utilise a slit lamp, indirect ophthalmoscope, fibre optic probe for intra-operative laser, or an articulated arm (excimer). Class 2 helium- neon lasers have been used in diagnostic ophthalmic applications coupled to the scanning laser ophthalmoscope and to the corneal surface analyser. The delivery of laser energy to the target tissue for non-ophthalmic applications of lasers is either directly or through fibre optics.

The interaction of laser light with the target tissue depends on the wavelength of the laser light, the energy reaching the target tissue per unit area per unit time, and the absorbing characteristics of the target tissue. The interaction can be photo thermal, photo disruptive, photochemical or photo ablative. A thermal effect is characterised by a temperature rise, which is linearly related to the amount of energy absorbed. At higher temperatures there will also be mechanical effects from induced vaporisation of tissue. As the energy per unit time per unit volume at the focal point or the laser increases there is a point at which the effect becomes so intense that plasma forms.

The unstable state results in a micro-explosion (a photo disruptive effect). At very low laser intensities there is an alteration in cell organelles which alters cell function and which can be lethal to the cell (photochemical effect). The high photon energy and short pulses of the excimer laser are capable of breaking molecular bonds without causing thermal damage (photo ablative effect).

The effect on tissue of lasers in common use are (1) thermal, e.g. argon (448nm and 514nm), diode (typically 805nm), frequency double YAG (532NM), CO_2 laser (10.6 microns), Nd:YAG (1064nm), dye lasers at 585nm, (2) photo disruptive, e.g. shortpulsed Nd:YAG (1064nm), (3) photo ablative, e.g. excimer (193nm), and (4) photochemical, e.g. metal vapour lasers operating near 630nm which are used for photodynamic therapy.

3. Classification of Lasers

The classification of a laser gives an indication of its potential hazard. Laser product classification is based on the maximum level of laser safety radiation that is accessible during conditions of normal operation.

The laser product classes are outlined below, together with a brief description of the protection requirements that should normally be satisfied for each product class. Except for classes 2 and 2M, the emitted radiation may be visible or invisible.

a) Class 1 lasers are normally safe under reasonably foreseeable conditions of use either because of the inherently low emission of the lasers themselves, or because they are totally enclosed and human access to higher levels of internal laser radiation is not possible during normal operation.

   Protection requirements for Class 1: Ensure that conditions for Class 1 operation are maintained. If access to levels of laser radiation in excess of the limits for Class 1 could occur, for example during servicing of an embedded laser product, or in the case of an expanded-beam laser by using external optics to reduce the size or divergence of the emitted beam then the protection requirements of the appropriate higher class apply.

b) Class 1M lasers exceed the permitted accessible emission limits for Class 1 but, because of the geometrical spread of the emitted radiation, cannot cause harmful levels of exposure to the unaided eye. The safe limit for ocular exposure can be exceeded and injury can occur if magnifying viewing instruments are used. Hazardous exposure can also occur if the dimensions of the laser beam (its diameter or divergence) are reduced by the use of optical components in the beam path.

   Protection requirements for Class 1M: Avoid the use of magnifying viewing aids or instruments (such as binoculars, telescopes, microscopes and magnifying lenses, but not spectacles or contact lenses). Avoid placing optical devices in the emitted beam that could cause the concentration of the laser radiation to be increased. Do not direct the beam into areas where other people may be present if there is a likelihood of the people in those areas using magnifying viewing aids or instruments looking directly into the beam.

c) Class 2 lasers emit low levels of visible radiation (that is, at wavelengths between 400nm and 700nm) which are safe for the skin but which are not inherently safe for the eyes. Eye protection is normally afforded by natural aversion responses to bright light including the blink reflex and therefore accidental eye exposure is normally safe. However, such lasers may be harmful where the natural aversion response is overridden or influenced e.g. in the anaesthetised patient

   Protection requirements for Class 2: Avoid staring into the beam (i.e. deliberate viewing of the laser source) or pointing the beam at other people.

d) Class 2M lasers emit levels of visible radiation that exceed the permitted accessible emission limits for Class 2, but because of the geometrical spread of the emitted radiation, protection of the unaided eye is normally afforded by natural aversion responses to bright light. However, the aversion response may not provide sufficient protection and injury can occur if magnifying viewing instruments are used. Hazardous exposure can also occur if the dimensions of the laser beam (its diameter or divergence) are reduced by the use of optical components in the beam path.

   Protection requirements for Class 2M: Avoid the use of magnifying viewing aids or instruments (such as binoculars, telescopes, microscopes and magnifying lenses, but not spectacles or contact lenses). Avoid placing optical devices in the emitted beam that could cause the concentration of the laser radiation to be increased. Avoid staring into the beam (i.e. deliberate viewing of the laser source) or pointing the beam at other people.

e) Class 3R lasers have a level of accessible emission up to five times the limit for Class 1 (if invisible) or Class 2 (if visible). The maximum permissible exposure may be exceeded but the risk of injury is low.

   Protection requirements of Class 3R: Prevent direct eye exposure to the beam or pointing the beam at other people.

f) Class 3B lasers have a level of accessible emission, which can be harmful to the eyes, whether magnifying viewing aids are used or not. Class 3B lasers can also be harmful to the skin at output levels approaching the upper limit of this class.

   Protection requirements for Class 3B: Prevent eye (and in some cases skin) exposure to the beam. Guard against unintentional beam reflections.

g) Class 4 lasers have a level of accessible emission, which can be harmful to both the eyes and skin. Diffuse reflections of the laser radiation may also be hazardous. The laser emission can also be sufficient to ignite material, on which it impinges, and to generate harmful radiation or fume hazards by interaction with target materials.

   Protection requirements for Class 4: Prevent eye and skin exposure to the beam, and to diffuse reflections (scattering) of the beam. Protect against beam interaction hazards such as fire and fume.

4. Laser Injury

The mechanisms of non-therapeutic injury by lasers are the same as the therapeutic mechanisms indicated above. They affect mainly the eye and also the skin. Whether or not injury occurs is related to (1) the wavelength of the laser system, (2) the energy emitted per unit area per unit time, and (3) the absorption properties of the target tissue.

The ocular tissues at risk include the retina, cornea and lens. The high brightness of a laser light source makes it far more dangerous to view than a conventional light source. The laser will always focus to a much smaller spot than will any other conventional or non-coherent source of light. Because of the focusing properties of the eye, the macula, especially the fovea, is at high risk of injury and substantial loss of vision can result. Also, because the wavelengths 400 – 1400nm are transmitted through the ocular media, lasers operating at these wavelengths are particularly dangerous to the retina. This spectral region is referred to as “the retinal hazard region”. It is also important to remember that the area where the laser is imaged on the retina may not be the only site of damage as both heat flow and mechanical transients travelling outward can result in damage to a large area of the retina. This increases the amount of damage to the retina and the loss of visual function. Following laser damage, retinal repair processes are limited to resorption of haemorrhage and resolution of oedema and adjacent tissues. Accidental exposure away from the central macula may not result in loss of acuity, but may cause loss of visual field and the victim will note a scotoma. The cornea and lens absorb wavelengths outside the retinal hazard region. The cornea is at risk of injury over a wide range of ultraviolet and infrared parts of the spectrum and the lens can be damaged by the wavelengths UVA, UVB between 295 – 320, IRA and IRB between 1 – 2 microns.

5. Personnel at Risk

Those persons at risk of injury include the patient, the surgeon, any bystanders including surgical assistants and service personnel. All laser systems should be serviced according to the manufacturer's instructions to reduce the risk of accidental exposure and non-therapeutic injury.

6. Patient

Laser surgery regulations do not apply to the exposure of the patient at the target site for surgery. However, accidental exposure of the patient from misdirection of the laser beam should be of concern and the tissues at risk are the eye especially and also the skin. Ignition of patients' airways including endotracheal tubes can cause death and flammable gases and materials (endotracheal tubes, drapes, etc) must be avoided.

7. Surgeon

This risk to the surgeon is reduced when he/she views the target tissue through the delivery optics, which should be fitted with an appropriate safety mechanism for eye protection. However, with hand held delivery systems the surgeon must wear appropriate eyewear.

8. Other Theatre Personnel

Surgical assistants including nurses are at risk of exposure to misdirected laser beams especially in the operating room and especially from reflected beams.

9. Service Personnel

Service personnel are particularly at risk when they gain access to the collimated laser beam from the laser cavity or by opening up the delivery optics.

10. Rules for the Safe Use of Medical Laser Systems

The safe use of these lasers depends upon strict adherence to the following rules:

a. Lasers should be operated only by staff that are trained in their use, aware of the dangers and hazards involved, familiar with the manufacturers operating instructions, and have knowledge of laser safety.

b. Both the laser operator and owner should ensure the laser is serviced as suggested by the manufacturer and the laser is working optimally. In institutions where there is a designated laser safety officer a report should be made to the laser safety officer of any laser, which is apparently faulty when this is first noticed.

c. The laser operator should ensure (i) persons assisting the laser procedure are fully conversant with the safe performance of their duties, and (ii) the safety of any visitors who may be present.

d. All assisting or observing personnel should be positioned to minimise the risk from beam reflection and scattering. This area will vary for different lasers.

e. During the laser procedure the laser operator and all assisting and observing personnel who are at risk of ocular injury should wear appropriate protection (the viewing system of a medical laser system should be fitted with appropriate eye protection).

f. The laser should not be switched on unless directed towards the patient or a suitable barrier opaque to the wavelength of the laser.

g. Appropriate room design should include opaque curtains or filters over windows, backstops, and removal of items near the laser which may give rise to specular reflection (including surgical instruments).

h. A sign on the outside of the laser room or operating room should be clearly visible to deter accidental entry of other persons during the laser procedure.

i. When the laser is in operation the number of persons should be kept to the minimum required for patient safety.

j. At the completion of treatment the laser should be in “stand-by” mode and the power reduced to zero.

k. A written record should be kept of the treatment details of the patient.

l. All suspected laser injuries either to patients or staff should be clearly documented according to the protocol “Assessment of the laser injured patient” detailed below.

11. Assessment of the Laser Injured Patient

If an accidental eye injury is suspected the following should be recorded:

a. Circumstances of injury including presence/absence of ocular protection at time of injury, laser wavelength and pulse length, distance of patient from laser source at time of injury

b. Refractive status of patient including (a) date of most recent refraction, and (b) transmission characteristics of spectacle lens, contact lens, intraocular lens.

c. Past ocular history including any history of amblyopia

d. General health

e. Medications (including any photosensitising drugs).

The examination should include:

f. Best corrected visual acuity for near and distance

g. Colour vision (e.g. Farnsworth/Munsell D-15)

h. Slit lamp examination, especially of cornea and lens

i. Fundus examination. Retinal injury is frequently initially associated with bleeding and later with pigmentary changes.

Appropriate documentation may include:

j. A fundus diagram

k. Colour photography and fluorescein angiograph

l. Automated visual field test

When lasers were first used for treatment of eye problems in the 1960s it was common to periodically examine those who routinely worked with dangerous lasers. As these routine tests failed to reveal any previously unsuspected ocular or other pathology attributed to cumulative subclinical laser injury these routine tests are now unwarranted. Today, general medical and ophthalmic examinations are not routinely prescribed for laser workers except following any incident involving laser use. This means that any incident must be followed by an ophthalmological evaluation as designated above.

12. Education and Training in Laser Safety

12.1. Laser user

There is no one single aspect of the laser safety programme more important than the training of individual laser users. In addition to the suggested rules for safe use of lasers (above), laser users should have a basic general knowledge of laser energy generation, the delivery systems of medical laser systems, and of the interaction between laser beam energy and tissues.

The syllabus for RANZCO trainees includes laser energy generation, the delivery system of ophthalmic lasers, and the interaction of laser light with tissue, especially the eye.

Further, as part of their supervised surgical training, trainees are required to be familiar with all aspects of the clinical use of ophthalmic lasers in current use, and their safe use.

12.2. Laser Safety Officer

A laser safety officer should be appointed by an institution where lasers are used to ensure a laser safety programme exists and that laser safety procedures are followed.

This person should be fully trained in laser operation, clinical application, and user safety and have appropriate and recognised qualifications. Their responsibilities include:

a. classification or the verification of classification of the laser apparatus,

b. hazard evaluation of laser work areas and the recommendation of procedures to ensure a safe working environment,

c. ensuring prescribed control procedures are in effect and periodically checked,

d. approve standard operating procedures, alignment procedures, and other safety control measures,

e. recommend or approve protective equipment and periodically check this equipment,

f. approve area warning signs and equipment labels,

g. authorise laser technicians to operate laser apparatus for maintenance and servicing purposes as necessary,

h. organise appropriate education and training authorities for all staff, and

i. investigate and report all accidents and incidents involving lasers and notify the relevant statutory authorities.

13. Further reading

1. Sliney D and Wolbarsht M “Safety With Lasers And Other Optical Sources: A comprehensive handbook: Plenum Press, New York (1980).

2. Standards Australia Ltd and Standards New Zealand. AS/NZS IEC 60825.14:2011 Safety of laser products – A user’s guide. 2011.

14. Record of Amendments

Page	Details of amendment	Date approved
Entire document	January 2011 version updated	30/06/2015