RISK MANAGEMENT IN LASER TECHNOLOGY
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No description of any modern medical device is complete without assessment of its risks, and laser technology is no exception. Broadly speaking, laser risk assessment can be classified into the following categories:

1. Risks inherent to laser technology

The primary cause of laser hazards is the extremely high concentration of laser light contained in a very small diameter beam, used at its focal point. The concentration of energy is higher than that of solar energy. Therefore, everyone in contact with the laser, including the patient, is a potential victim. To mitigate the risks, national laser safety standards have been drawn up.

2. Safety regulations

In Europe, as a result of harmonization, all countries in the EC must adopt the same product standards. For lasers, this is EN 60825-1:1994, and the English language version is BS EN 60825-1:1994\textsuperscript{12}. This provides equipment specifications, including the laser classification described below. The main advantage of this classification system is that it provides the user with an easy way of knowing whether any special precautions are required. Almost all surgical lasers fall under Class 4. A useful document, which provides hospital laser users with advice on safety, is the Guidance on the Safe Use of Lasers in Medical and Dental Practice, 1995, issued by the Medical Devices Agency for the Department of Health in the UK\textsuperscript{11}. This document recommends the appointment of a laser protection adviser (LPA), who is knowledgeable in the evaluation of laser hazards. One of the duties of the LPA is to ensure that local rules are drawn up for each specific application of a laser. A laser protection supervisor (LPS) should also be appointed whose responsibility it is to ensure that the local rules are observed. It is a sensible precaution that all laser users should be approved by the LPS in consultation with the LPA. All laser users should sign a statement that they have read and understood the local rules.
3. Faulty equipment

The surgical outcome will be sub-standard if the equipment is in poor condition. To prevent this, a trained technician should carry out a biannual inspection and maintenance. Many of these potential hazards are the result of a lack of proper maintenance and, therefore, are completely unjustified.

4. Laser plumes

During a surgical laser procedure, laser-generated air contaminants (LGACs) are released into the operating theatre as surgical smoke or plumes. Surgical smoke pollution can also occur when the thermal destruction of the tissue is undertaken with an electrosurgery device or other surgical power instruments. The plume is heavier than the air and thus remains in the vicinity of the operating site, obscuring it completely. No further surgery can be carried out until the plume is removed.

Apart from obscuring the surgical field, it also has an unpleasant smell, not unlike burning flesh. Initially, it was believed that the rise in temperature was high enough to destroy all viable particles, but now it is thought that some tissue at the periphery of the plume may be ejected into the air without being raised to a high temperature. Therefore, LGACs are not entirely benign products with simply a nuisance value. The smoke plume contains particles, toxic gases such as benzene, hydrogen cyanide, formaldehyde, carbonized tissue, and biological fragments from human tissue. Particles of blood, viruses, DNA, bacteria, water, and carbon dioxide have been demonstrated in plumes. The presence of abdominal smoke during laparoscopy caused increased levels in methaemoglobin, resulting in the reduced oxygen-carrying capacity of the blood, and HIV DNA was detected in the culture of a plume on the 14th day. Garden et al. (1988) studied the contents of a plume produced during vaporization of infected verrucae and concluded that intact viral DNA was present. Papillomavirus DNA was demonstrated to be infectious. There is the possibility that active viruses may be present in CO2 laser plumes, but studies have shown that the use of appropriate smoke evacuators virtually eliminates any risk to the operator (Ferenczy et al., 1990). A study performed during the laser treatment of laryngeal papillomas was unable to find HPV
DNA (Abramson et al., 1990)\textsuperscript{16}. In laboratory experiments, viable bacteria have been found in plumes (Walker et al., 1986; Byrne et al., 1987)\textsuperscript{17}. The use of a standard surgical mask does not provide adequate protection to the theatre personnel, since the size of the particles ranges from 0.1-0.8 μm, too small to be effectively filtered by such a mask. Masks designed to filter out viralsized particles cease to operate effectively as the pores become blocked.

A standard, centrally operated suction facility is primarily designed for sucking out liquids, rather than gases or particulate matter. Therefore, it cannot cope with the amount of smoke generated and can get clogged up if used to evacuate laser plumes. A dedicated smoke evacuator for the effective removal of LGACs from the operating theatre consists of suction unit, filter, hose, and inlet nozzle. It is worthwhile testing the evacuator before purchase to ensure that it is powerful enough to keep the field clear. A capture velocity of about 100–150 feet per minute at the inlet nozzle is required. A high efficiency particulate air (HEPA) or ultra-low penetration air (ULPA) viral trap capable of removing particles >0.2 μm with 99.9% efficiency is incorporated into the unit in the form of a disposable filter, and should be replaced according to the manufacturer’s instructions, since it can pose a possible biohazard. An on-line sump is useful for trapping any liquids sucked out during the laser procedure. A suction cannula held at a distance of 2 cm from the target is only capable of removing 50% of smoke. For adequate removal, the suction cannula needs to be held as close as 1 cm from the target. However, this may not always be possible. A dual suction unit, one with low volume and high velocity, the other with high volume and low velocity, can be used effectively in such circumstances. It has been shown that increasing the oxygen concentration in a zone around the target significantly reduced the concentration of toxic gas byproducts. Similar results were obtained by spraying the zone with a water spray. Increasing the concentration of oxygen could be undesirable when lasering the laryngeal pathology, since this may promote potential anesthetic tube ignition.
5 Fire hazards

The most significant and serious hazard is anesthetic tube ignition. If a laser is being used in close proximity to the tube, there is a serious risk of an airway fire since the high oxygen saturation in the tube encourages combustion. Even if the laser is not being used in close proximity to the tube, it is still at risk of ignition from a reflected beam. A particular hazard exists when the CO₂ laser is being used, since its beam is collimated and thus has high irradiance over a distance.

Reports of in situ endotracheal ignition have been seen in the literature, sometimes with fatal consequences (Walker et al., 1986; Wenig et al., 1993). In early work with the laser, the standard precaution was to wrap the tube in aluminium tape.

However, this did not protect the inner surface or the cuff. Although the CO₂ laser is particularly dangerous in this respect, a case has also been reported in which an Nd: YAG laser caused tube ignition. The plastic tube takes less than a second to explode into fire. The rubber tube is somewhat more resistant, but will ignite. Laser-safe or laser proof tubes must be used for laryngeal surgery. Protecting the tube with wet gauze may give a false sense of security, since this dries very quickly and, in any case, may it catch fire. The use of a safe anesthetic technique is fundamental to laryngeal and oral laser surgery. It is worth remembering that, apart from the anesthetic tube, other flammable material, such as nasogastric tubes, gum shields for mouth gags, plastic tracheostomy tubes, etc., all present fire hazards. A well-rehearsed method will go a long way to preventing a fire hazard, however trivial.
6. Hazards to the eyes

The most damaging lasers are those with beams in the visible and near infrared region of the spectrum. The structures of the eye anterior to the retina are completely transparent to these wavelengths. Photocoagulation of the retina due to accidental exposure is likely to produce permanent loss of retinal function in the region struck by the laser beam. If this is in the foveal area of the retina, central vision will be seriously impaired. This is the probable outcome if a person looks directly into a laser beam. Laser radiation from short wavelength UV lasers, such as the excimer, and long wavelength infrared lasers, including the Ho: YAG and CO$_2$, is absorbed by the cornea. Though painful, this is not usually sight-threatening since the cornea has a very high capacity for repair. Anyone within the vicinity of a laser must ensure that his or her eyes are adequately protected. This generally means wearing the appropriate type of safety eye wear. It is important to realize that goggles intended for one type of laser will often not be suitable for another. It must also be appreciated that safety eye wear does not necessarily confer complete protection. Its function is to provide a last line of defense in the event of an accident. The laser goggles themselves may be damaged by exposure to the laser beam. All reasonable measures should be taken to minimize the risk of an accident by strict adherence to laser safety guidelines.
7. Non-target strikes

During laryngoscopy, non-target strike to the lips and teeth is a real possibility. The patient should be fully wet-draped. Non-target strikes can also occur in organs deep to the target tissue.

These must be suitably protected with wet gauze, suction cannula, or any other instrument that is being used for retraction, etc. Another problem can arise when the aiming beam and therapeutic beam are misaligned, with the result that the main beam is directed to an adjacent area. Before use, a simple beam alignment and power check should be carried out, using heat-sensitive paper or a wooden spatula placed on a wet towel, with the laser set to low power. Spatulas should be preserved, and used for comparison with current results. In the case of fibre deliveries, it is worthwhile checking the integrity of the fibre before use. This is simple to perform, with the aiming beam only. If there is a break in the fibre at any point, it will be evident on visual inspection.

8. Untrained medical, nursing, and technical staff

A well-organized and approved course can provide both theoretical and practical experience to all those involved in laser surgery: surgeons, nursing staff, and technicians alike.

9. Legal requirements

There are no specific legal requirements for the training and certification of laser users. In the UK, medical defense organizations do not stipulate skill acquisition as a prerequisite when defending alleged negligence due to laser usage. They simply take the view that it is easier to defend a surgeon in case of a mishap if he or she has undergone a recognized
training and holds a certificate to that effect. Likewise, academic bodies are content to award a medical or surgical qualification and leave it up to the individual to practice according to his or her own-assessed competency.

It is likely that the GMC would take a disciplinary action against any laser user who is unable to show that he/she has received an adequate training in the laser usage, should a mishap occur. Professional bodies such as the British Medical Laser Association award annual recognition to laser courses with regard to their educational content. The royal colleges require their members to undergo 50 hours of continuing medical education (CME) each year, but do not specify laser training as part of this CME. The industry could help mitigate this rather unsatisfactory state of affairs by supporting laser courses and could provide training for new purchasers or send them to suitable training courses. In national health care systems, such as the National Health Service (NHS), the employing authorities have a duty in common law to ensure that employees have adequate skill to undertake their work. They also have a duty under the Health and Safety at Work legislation to protect staff from injury arising out of inappropriate or incorrect use of laser by other members of the staff. Furthermore, under the same legislation they have an additional duty to ensure that the lasers and protection equipment are adequately maintained. However, in the private sector, there is no control, particularly for office-based laser procedures. Therefore, in the final analysis, the onus must lie on the individual to attend suitable courses.