IV-1 Guidelines for Safe Clinical Laser Applications

B. Fuchs, C. Philipp, H.-P. Berlien

Contents

Introduction

Given the continuous development of new lasers and application techniques, laser safety does not represent a static problem, but has to be adapted to these changes. National and international organizations like the ISO (International Organization for Standardization) and the IEC (International Electrotechnical Commission) deal with questions of laser safety and have therefore issued a number of recommendations and guidelines, which are continuously being brought up to date. A great number of these decisions were first taken regarding the industrial use of lasers and were transferred to medical use later, whereby specific medical requirements have only occasionally been considered. Furthermore, safety guidelines mostly try to protect medical staff – the patient's safety is not always taken into consideration. It is the aim of this chapter to point out typical hazards in using medical lasers in daily routine for both staff and patient and to give practical advice as to how to avoid risks and accidents.

Medical lasers belonging to the classes 3A, 3B and 4 (see below are allowed to be used only within laser protection areas, which are defined as locations where the intensity of laser light can exceed the limit for the maximally tolerable irradiation, i. e. which does not lead to any damage of skin or eye (this limit varies between different lasers and depends on the wavelength, power, pulse rate and other settings). Therefore the laser protection area must not necessarily include the whole operating unit, but only the operating theatre.

A laser protection area can be separated from the operating theatre by a protective curtain (see Fig. 1). Here, protective glasses must be available for the staff before entering that part of the theatre where laser irradiation is applied. If any laser is in use, this should be indicated by a visual warning system outside the operating theatre.

H.-P. Berlien et al. (eds.), *Applied Laser Medicine*

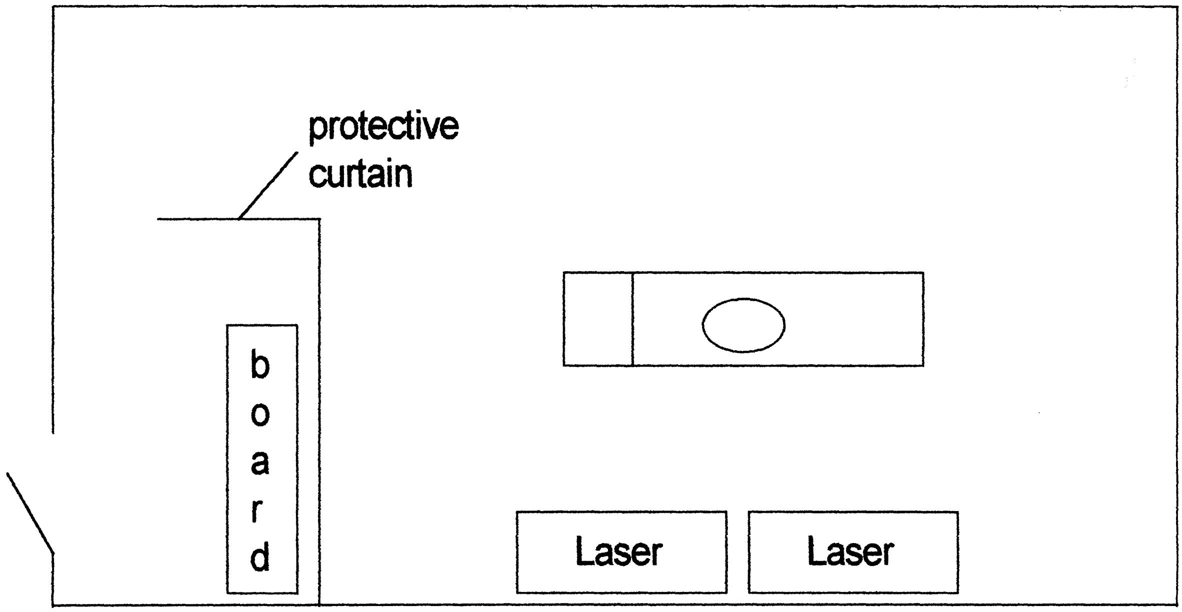

Fig 1. Arrangement of an operating theatre with an integrated laser safety area. Laser protective glasses can be kept on the board

In contrast to open laser surgery, where protective glasses must always be worn, the laser area in endoscopic or interstitial procedures can be defined as inside the patient, if

- the fibre is inside the patient`s body,
- the fibre is protected against bending and
- *video*endoscopy is performed in endoscopic procedures.

Under these conditions, the use of protective glasses is not required. Furthermore, to prevent risks, it is advisable to have the laser in Stand by position whenever possible. Questions of laser safety concern not only the direct but also the *reflected* laser beam from a material's surface, which can also be dangerous. The amount of reflected irradiation differs between infrared and visible light: while black surfaces hardly reflect visible light, they can behave like a mirror with infrared light. Furthermore, shiny metals and smooth, unpolished metal surfaces are good reflectors for infrared rays, but non-metal surfaces (e.g. ceramic) are bad ones, even if they appear shiny.

The practical significance of this phenomenon is, in general, limited to the operating area and mostly concerns surgical instruments (e.g.,tweezers) in close proximity to the laser beam. If such close contact between the laser beam and surgical instruments is expected, laser-resistant tools should be chosen.As, on the other hand, the power of a diffusely scattered beam is reduced fourfold if the distance is doubled, the reflection of a metal infusion stand, for instance, is hardly significant.

With respect to the laser apparatus, the actual power emitted should be continuously controlled by an internal checkup system. If a significant deviation is measured, an alarm should be set off followed by an automatic inactivation of the faulty system components. Furthermore, an acoustic signal is helpful if laser irradiation is being applied. According to the accident prevention guidelines, medical lasers are used only under the control of an authorized laser safety representative, who must supervise all aspects of laser safety and should therefore have a broad practical and theoretical knowledge of laser medicine.

Specific Risks Using Medical Lasers

Specific risks using medical lasers and their importance are summarized in Table 1.

Risks to the Surgeon

Laser therapy is applied to effect controlled damage to tissue. To realize this, the laser, its parameters, the application technique and specific tissue characteristics must be adjusted.

The most important risks when using medical lasers are related to the surgeon, and include insufficient personal experience, wrong indication of the operative procedure and wrong decisions regarding the laser and its parameters. Trainee programs and literature reviews can minimize these risks.

Table 1. Potential risks when using medical lasers

No personal experience
Wrong indication
Wrong laser
Wrong parameters
Eye hazards
Ignition of combustible materials
Earthquake destroys operating room
Electrical hazard
Intoxication by smoke
Intoxication by laser agents
Skin hazards to staff

The laser beam can lead to the ignition of combustible materials such as surgical drapes and/or other protective covers, tubes, cuffs, catheters, disinfectants (for instance ethanol) and anaesthetic gases (O_2, N_2O etc.).

With surgical drapes, protective covers and tubes, the risk of ignition is relatively high if the surgeon has to operate inclose proximity to these materials. Under these circumstances laser-resistant equipment, as offered by several companies, should be used. In all other cases, laser-resistant materials are not necessary for every operation, as the risk of ignition is, in general, quite low (if the surgeon is aware of this problem and experienced), so that the high costs of this specific equipment are not warranted.

Changes in the flammable characteristics of combustible materials (e.g., compress,swab) can be effected by rinsing with water.

Smoke Intoxication

Toxic smoke can develop from heating or vaporization of tissue, plastics or other materials. In the case of a virus infection of the tissue, the smoke can even contain living particles, if the tissue is only removed by pulsed lasers but not vaporized. Therefore all hazardous fumes and vapours must be adequately expelled from the operating area until no smell can be defected.

Eye Hazards

Direct, reflected or scattered laser light can lead to damage to the eyes during open laser surgery. The range of damage can vary between different lasers and applications modes. Where as ultraviolet or far-infrared irradiation (10 600 nm) is mostly absorbed in the cornea or the lens, infrared or visible light can pass the lens and is focused on the retina.

Other Hazards

Some lasers use toxic materials as lasing medium (e.g., poisonous dyes, halogens in the case of the excimer laser). In the case of an accident, these substances can leak out of the laser and cause health injuries. Moreover, such substances must be disposed of according the producer`s guidelines.

The application systems used must be controlled again after finishing the procedure. Parts of the bare fibre, for instance, are not toxic, but can lead to a foreign body reaction. Further components of the LIT-Tapplicator (e.g., the glass dome of the fibre) may seriously damage the affected tissue.

Many lasers require a high-voltage power supply. Charged condensers can be dangerous even if the laser is disconnected from the electrical supply. Pulsed lasers may, additionally interfere electromagnetically with other electronic medical equipment. Electric hazards often go unnoticed.

Injuries to the skin during laser therapy mostly affect the staff and can lead to burns.Uncontrolled movements of the laser by the surgeon, reflected laser light or inattentiveness of the staff may be the reasons. As the irradiation of non-anaesthized skin is, in general, quickly noticed because of pain, the affected area is quickly removed from the laser beam, so that serious injuries are prevented.

Nevertheless, unintended skin injuries to the patient can be very serious, as anaesthesia interrupts this pain-feedback system. A typical complication is necrosis of the skin of the cheek during Nd: YAGlaser therapy of the enoral mucous membrane with ice-cube cooling at the same site; here, the mucous membrane is protected by the ice cube, but the skin on the outside can be heated and damaged. Control of the skin temperature is therefore essential during this procedure. Heat conduction must also be taken into consideration if the surgeon is using metal tools to protect or clamp a special area of tissue.

Radiation Hazards

Besides the risk of damaging eyes and skin after exceeding a critical limit of irradiation (so-called maximally tolerable irradiation), there are two other important hazards of irradiation. Depending on the wavelength, mutation of DNA can be induced, whereby UV light is more dangerous, because the absorption maximum of DNA is about 260 nm. Further, the intended therapy result will not be achieved if the surgeon chooses the wrong parameters or laser. An overdose can lead to increased side effects and injury to surrounding healthy tissue; but even an underdose may also result in a higher percentage of side effects, as the irradiation time has to be prolonged to reach the desired therapy effect, resulting in potential injury to surrounding tissue.

Classes of Lasers

According to their potential danger, lasers are divided into four classes:

- Class 1 — Lasers of this class are definitely or constructionally safe (power <0.39 mW).
- Class 2 — These lasers emit visible rays (400–700 nm) of low power (<1 mW). Eye protection is ensured by the blink reflex.
- Class 3A — The emitted power of these lasers is less than 5 mW and includes all wavelengths. Looking directly into the beam with optical aids (e.g., a binocular microscope) can be dangerous.
- Class 3B — With these lasers, looking direct by into the laser beam is dangerous close to the outlet of the applicator/handpiece.
- Class 4 — Lasers of this class emitting irradiation of more than 0,5 W represent a danger for the eyes due to diffuse reflections and/or direct by looking into the beam.

All medical lasers belong to the classes 3 and 4.

Laser Protective Glasses

The eyes of both staff and patient must be protected when working with high-energy laser systems. For the patient, it has proven to be of advantage to occlude his/her eyes completely with compresses and adhesive stripes (e.g., Leukosilk) instead of glasses. Especially in operations in the face, glasses may hinder the surgeon or can slip out of place. The staff and the surgeon however, should wear goggles or glasses, which must be chosen with respect to the relevant wavelength as well as to the type and intensity of the irradiation.

According to the DIN 58215, protective glasses are characterized by the following four numbers and letters:

1	2	3	4
WL	LP	IC	St

1. The first number describes the wavelength WL, against which the protective glasses provide protection (e.g., 1060 nm for the Nd:YAGlaser).
2. The second complex gives information about the level of protection LP. Thus, L3A, for instance, means that the intensity of the first-mentioned wavelength is reduced by 10^3. The capital letter A allows all types of lasers to be used with these glasses, D is for continuous and I for pulsed lasers only.
3. The third part is reserved for the index code IC of the manufacturer.
4. Finally, the last complex describes the relevant standard St, (e.g., DIN) for these glasses.

Practical Advice on How to Avoid Laser Hazards

To minimize the risk of laser hazards as described in the preceding sections, a clinical laser checkup should be performed before putting the apparatus into operation. The following five-step procedure is recommended:

1. The fibre (260/400/600 µm must be compatible with the adapter/laser. If resterilizing a fibre, its size and resterilization cycle should be recorded.
2. The fibre must be checked for visible defects or contamination before use.
3. The adapter/fibre must be checked for optical permeability. A simple test to control the optical permeability of the fibre is to put one end of the fibre against a light source and to look at the opposite end: if one can see a bright light, the fibre can be used. To clean the adapter, only compressed air, acetone or high by concentrated alcohol (97%) are allowed, used with a dust-free tissue.
4. The complete laser system must then be checked for its optical permeability and the quality of the pilot beam.
   First, the fibre should be carefully connected without touching the surface of the fibre or adapter.

Then the pilot beam is activated; this should appear circular and regular at different positions of the fibre handpiece. The entire length of the fibre must also be controlled for any lateral emergence of the pilot laser,which would indicate a partial or complete break of the fibre. In this case,shortening the fibre is necessary or a new one must be used.
5. Finally, the laser system can be put into operation. Calibration of a focusing handpiece may be performed, if necessary. If the surgeon notices that the efficiency of the laser system is too low, the fibre applicator should first be checked once again, then the power can be gradually increased.

For the practical aspects of laser safety in daily routine, seven golden rules are helpful in preventing hazards to staff and patients.

Laser Safety in Daily Clinical Routine

Protective measures for the patient must always be adapted to the current treatment situation, and can have the character of a recommendation only. Additionally, they must be established only by those responsible for patient treatment.

To combine laser protective measures for the staff with optimal treatment, the interests of the patient and the prevention of accidents, the following seven golden rule have proved invaluable in years of experience.

1. Keep the laser in the standby mode.
2. Keep distance.
3. Wear glasses in the laser area.
4. The laser is not a pointer.
5. Do not lase instruments.
6. Do not lase combustible materials.
7. Check your system.

1. Keep the Laser in the Standby Mode

Accidents can occur at the moment that the fibre or handpiece is put down "only shortly" and the surgeon or another person steps on the foot switch accidentally. Severe injuries can result because during such a break in treatment the OP staff no longer recognize the danger of a laser irradiation, and remove their protective goggles. In addition, fire can be caused, as the applicators are frequently put down on medical textiles. At the end of a laser operation the laser should be switched from ready to standby mode.

2. Keep Distance

In contrast to industrial lasers, during the use of fibres and handpieces in most medical lasers a beam divergence exists (exception: focusing handpieces); the power density of the laser irradiation decreases with the square of the distance. The setting of a sufficient safety distance is, as with X-rays, the most important precaution to prevent injuries of any kind through laser irradiation. Moreover, no person should be present in the surgical operating room who is not directly participating. This is also important for reasons of hygiene. Laser surgigal applications are not to be confused with a laser show!

3. Wear Glasses in the Laser Area

With all open laser procedures in medicine, the wearing of protective glasses is prescribed in the laser area. The laser area in endoscopic or interstitial procedures can be defined as inside the patient if:

- the laser is in standby mode (whenever possible)
- and in the ready mode only if:
  - the fibre is inside the body,
  - the fibre is protected against bending.

Videoendoscopy is obligatory for endoscopic procedures.

Protective glasses are effective against laser radiation only when the emitted wavelength lies within the specific wavelength spectrum for which they are intended. This can be determined by reading the label, usually on the side of the glasses.No glasses give protection against all laser wavelengths – this would correspond to a black eye shield, which is needed to look directly into the laser beam with the eye unprotected. Before beginning a laser operation, the surgeon must ensure that all employees and the patient have the appropriate eye protection. For the patient the best solution is to cover the eyes with a medical compress fastened with Leukosilk.

To make it possible to choose the correct protective goggles before entering the laser area, it is helpful to note to laser wavelength used in the operating room. In contrast to open laser applications, wearing of laser protection glasses is not necessary in endoscopic or interstitial laser treatment, if the laser area is shifted into the body cavity of the patient. Then it is a laser of the class I like a CD-Player. This is the case,

- If the laser fibre of a ready-mode laser is in the body of the patient.
- Further the fibre must be protected against kinking; this can result due to a fibre break caused by

escaping radiation. A beam visible outside an endoscope indicates a damaged fibre, which should be replaced.

- Finally, videoendoscopy is obligatory in endoscopic operations. Over the optical fibre bundles of the endoscope no laser irradiation can be transmitted back and can lead to eyehazards. The real risk exists, however, if an awkward movement at the instrumentation channel, near the ocular, causes a fibre break. If videoendoscopy is not possible, laser protective glasses must be worn. The use of a so-called ocular protection filter is senseless.If the unprotected eye of the surgeon is directed to the fibre break, it can lead to an eye hazard in spite of the high divergence, because of the small distance only a few millimetres. The risk in fact arises not from reflection of laser irradiation through the endoscope but from the fibre break near the ocular of the endoscope. The ocular protection filter protects against a risk that does not exist, but does not protect, however, against the actual risk of a fibre break near the eye.
- Videoendoscopy has two important advantages:
  1. If the head of the endoscope can be held far away from the eye, the distance is so great that in the case of a fibre break at the place of insertion, no direct irradiation of the eye occurs; the break can be recognized immediately and the laser irradiation stopped.
  2. With relaxed working, the risk of a fibre break clear is reduced. If videoendoscopy is not possible, only the surgeon needs to wear protective glasses.

4. The Laser Is Not a Pointer – the Staff Is Not Your Target

Even in darkened rooms the visible pilot beam of a laser has a certain optical fascination, but it should not be confused with the medical laser, which has a laser pointer and can only indicate the operation area. Laser irradiation must be completed before the handpiece is removed. At the end of the operation or in the case of interruption, the applicator must be deposited in a safe place. In addition, neither the laser beam nor the pilot beam should be focused directly on the eyes of an employee, even if protective goggles are worn. Employees are not a target! Note that these regulations for clinical safety are valid only because a medical laser is a checked controlled laser unit. Check it!

5. Do not lase instruments

Not only the direct laser beam can lead to eye hazard or tissue damage, but also the reflected one. Polished instruments, metallic surfaces or even ceramic tiles can serve as mirrors. Thus black surfaces reflect no visible light, but infrared light, however, very well. So it becomes understandable that only blackening instruments offers no protection against reflection because the reflection of infrared wavelengths is not prevented and the reflected pilot beam is not visible, so that nobody can recognize where the reflected beam strikes the tissue. Additionally, blackened instruments absorb visible light and can become very hot.

Because of the beam divergence, and in contrast to industrial use, where lower energy densities are involved all reflections outside the operating area are of no importance. In the direct environment of laser applications the reflected beam shows the same power density as the initial laser beam and represents a source of danger. This risk can be reduced by using instruments with a rough and metallic surface because then a diffuse reflection of the light occurs. Such instruments are very expensive and only necessary if the beam path repeatedly hits the surface of the instruments.

6. Do not Lase Combustible Materials

All combustible materials can be ignited by different causes (laser/HF surgery, light cord etc.). The industry offers a whole palette of products and materials with higher laser safety and less fire risk after exposure to laser light. However their routine use is not necessarily economically justifiable in most cases. Normally, it is sufficient if medical textiles or compresses in the direct environment of the operation area are moistened with saline solution. To counter the risk of a tube fire, the most effective protection is to keep the tube away from the direct beam path and from the operating area. This should not, however mean hiding the tube under a mountain of medical compresses where it cannot be located. In these cases, it is better to keep the tube in sight and under control to avoid direct irradiation. Additionally, the tube can be protected by moist cotton wool or Merozell Laserguard. In general, a nasal tube should be used where possible in pharyneal and laryngeal operations, otherwise the laser safety tube offers the best, but still however, not 100% protection, against fire. Placing is also recommended a catheter filled with 50 ml saline solution in the operating area to be able to extinguish a fire immediately. If there is a smell of burned synthetic materials, a tube fire must be assumed until the contrary is proved beyond doubt! Smoke and the smell of burned plastic are often the first warning signals of a tube fire.

7. Check Your System!

It is a frequently recurring mistake during the application of medical laser systems to increase uncritically the power or energy of the laser in the case of no or only an ineffective tissue reaction.

Before every use, lasers, and in particular the optical applicator, should be checked first. These can represent a weak point in the whole system and are especially sensitive to damage.

Before every application an inspection of the applicators should be carried out. Because this can most easily be carried by the user, he/she is responsible for this. When using flexible light guides, it is necessary:

To check the fibre for external, visible damage and dirtying (ethylene oxide dissolves plasticizers, formaldehyde oxidizes metal).

To test fibres for optical continuity when one end is held against a source of light the other end must appear bright and straight).

The pilot beam must not escape anywhere on the side of the fibre.

To check the pilot beam on a dark surface - it must be circular and under control.

During the use of rigid or inflexible application systems a test exposure should be carried out - for example on a wooden spatula to determine the correspondence of pilot and reactive beam. If the laser effect does not occur directly at the pilot beam, this means readjusting the mirrors in the articulated arm.

If the desired effect is not achieved at the tissue, first the whole system must be checked, after which the power or energy can be increased. If calibration of the applicator is carried out and a great discrepancy noted between the adjusted and the measured power, the possibility of steaming up of the focusing lense or a defect in the instrument measuring internal power should be considered. Inspection with an external power - measuring instrument can be helpful here. To depend an only one calibration for information on the correct function of a laser system would be negligent.

Medical lasers represent complex systems whose effective service depends on different qualities such as wavelength, pulse duration, etc. To be able to use this service purposefully and safely, one needs not only theoretical knowledge of optical physics, but also an appropriate training. Also from the viewpoint of insurance, participation in specific courses is absolutely recommended. In addition, practical experience should be widened, for example, by hospitations with colleagues/institutes with well-founded laser medical experience. Often there are small tips and tricks which considerably facilitate later contact with the laser and point out its potential dangers. The information from the manufacturer alone cannot replace this education and information!

The rules must be adapted to the respective situation. This adaption presupposes a thorough knowledge of both laser physics. The ensuing laser protection rules and the **typical processing situation.** On this basis it is recommended that in every functional area in which laser operations occur regulary, a responsible medical doctor be designated as local laser safety officer to determine the guidelines under local conditions and with knowledge of the specific requirements for this field. In addition, however, in particular at larger hospitals a technician should be appointed (or for example a technical department), to be responsible for compliance with structural measures, organization of regular training sessions, announcements, etc.

Further Reading

Altomare DF, Memeo V (1993) Colonic explosion during diathermy colotomy. Dis Colon Rectum, 3: 291-292

Axelrod EH, Kusnetz AB, Rosenberg MK (1993) Operating room fires initiated by hot wire cautery. Anesthesiology, (5): 1123–1126

Bailey MK, Bromley H, Allison JG, Conroy JM, Krzyzaniak W (1990) Electrocautery - induced airway fire during traceostomy. Anesth Analg, 71: 702–704

Capizzi PJ, Clay RP, Battey MJ (1998) Microbiologic activity in laser resurfacing plume and debris Lasers Surg Med, 23: 172–174

Philipp C, Albrecht H, Hug B, Berlien H-P, Müller G (1992) Significance of laser safety. Lasers in gynecology. Springer Verlag Berlin Heidelberg New York. 435-446

Rockwell RJ (1994) Laser accidents: reviewing 30 years of incidence: what are the concerns - old and new? J Laser Applic, 6: 203-211