Hygiene requirements for dental laser fibers

Author_Hans-Joachim Koort, Germany


Fig. 1


Fig. 2


Fig. 3a


Fig. 3b

Fig. 1_Laser application in periodontology: The fiber is inserted into the gingiva pocket, parallelly to the long axis of the tooth to kill pathogen germs with the laser radiation by means of heat.
Fig. 2_Laser use in endodontics: The laser fiber is inserted into the root canal for disinfection.
Fig. 3a & b_Different situations with laser treatments.

_Introduction

Methods including laser application have been successfully established in the clinical work, especially in soft tissue surgery, periodontics and endodontics as well as in therapeutic applications (e.g. in photodynamic therapy) and in bleaching. Lasers can be used successfully for the decontamination of periodontal pockets (Fig. 1) and for the disinfection of root canals (Fig. 2). Although laser devices have been widely adapted to the dental needs in terms of performance parameters, design, size and mobility, only a few enhancements have been made with respect to the fibre-based systems. A situation frequently encountered is that laser fibres, although designed as single-use products, are not verified and validated to be reprocessed and reused. This situation must be regarded as very risky and, therefore, critical. A solution to this problem is the use of special single-use fibre tips. Still, a considerable amount of fibre lasers on the market neither corresponds with the requirements of the relevant standards nor do they agree with recommendations such as EN ISO 60601-2-22, EN ISO 13485 and national government guidelines. They are often neither subjected to biocompatibility (e.g. NAMSA) tests nor do they possess a proof of sterilization according to EN ISO 17664. Sometimes there is not even a certification. In cases such as these, these products must be scrutinized very carefully for their usability according to the Medical Devices Act, and their capability of being prepared for reuse. The reuse of unauthorised and undocumented products after refurbishing and reprocessing can be deemed at least negligent and at most very risky. Primarily for cost reasons, fibre systems are often used again and again after cleaning and disinfection. However, only rarely are they used with proper sterilization, independently from their suitability for recycling and reuse. To quote an expert: "What's happening during the preparation process is a large-scale experiment on people" and to quote a judge, "It is usually medical malpractice when choosing the riskier method among several alternatives. Neither economics, nor negative bid lists or budgeting can put this normative system out of power..."

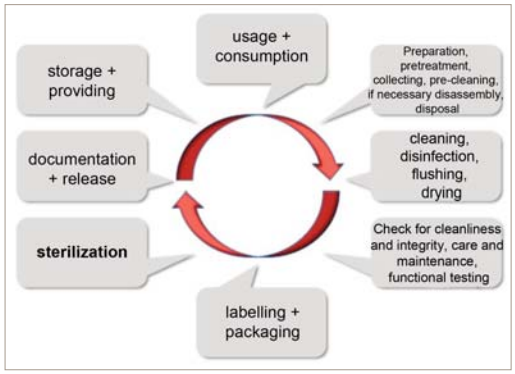


Fig. 4_Preparation does not equal sterilization alone.

_The legal situation

The Medical Devices Directive (MDD) does not explicitly distinguish between disposable products and those that can be used multiple times. However, when it comes to reprocessing, at least the statutory requirements for a validated method must be fulfilled. This is almost impossible to accomplish for most dentists in their private practice. All preparations of medical devices are based on the requirements of the MDD and other national directives, in particular the "hygiene requirements when processing medical devices". For the reprocessing of medical devices (e.g. laser fibres), therefore, only persons with specialized knowledge, appropriate training and practical work should be appointed. The marketability of reusable medical devices according to EN ISO 17664 also includes that the original manufacturer provides data on the validated preparation. A conformity declaration by the manufacturer of the respective disposable instruments consequently concerns sin-

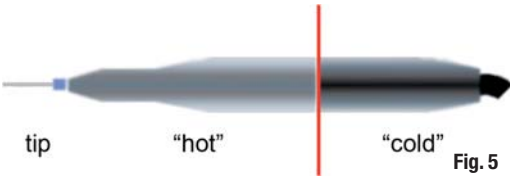
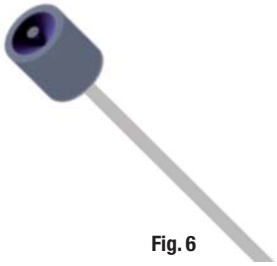
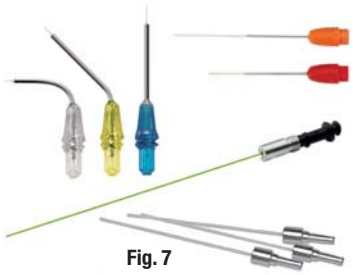


Fig. 5


Fig. 6


Fig. 7

gle-use only. Risk assessment and classification of the medical device must be made before the treatment, stating whether, how often and by what measures the device, e.g. a laser fibre, can be reprocessed. Procedures which were validated accordingly to the manufacturer's information must therefore be applied for the reprocessing of semi-sterile or sterile medical devices. This validation should be appropriate with regard to the medical device, its risk assessment and classification. It should furthermore be established in agreement with generally accepted engineering standards, as well as the current state of science and technology. This means that processes applied in the preparation of laser fibres must be documented. They also have to be repeatable in order to ensure that the objectives to be achieved by each preparation process can be reached before re-application. Manual cleaning and disinfection procedures must be performed with proven efficacy and documented according to standard operating procedures. The disinfection procedures must demonstrate bactericidal, fungicidal and virucidal effects.

_Problem and solution

The used laser fibre can be assumed to become microbiologically contaminated in the oral cavity. Direct contact with the tissue can result in soiled fibres, changing the optical properties of the fibre tip by cracks and erosion, thus diminishing their quality. Typical problems which may occur in laser fibres are shown in figure 3a: The tip of a laser fibre is covered by combustion products, with the fibre acting upon further use like a hot soldering iron. As a result, the surrounding tissue will be affected by the heat much stronger than planned by the dentist. Figure 3b shows coagulum and tissue residuals at the laser fibre, which, if not immediately removed and without cleansing of the fibre tip, may quickly burn down to the glass fibre. Proper use and care in terms of a strict hygiene therefore must play an important role when using laser fibres. The patient's safety and benefit must always and above any economic considerations be regarded as imperatives. More stringent hygiene directives with the respective laws and regulations, increased control practices, high costs and the commitment to run a quality management system in the dental practice are requirements which must be met. Moreover, they make single-use items, such as disposable fiber tips for laser applications in dentistry, worth considering. Each preparation of fibres, including those fibres which are explicitly declared for reuse, must be critically assessed in terms of patient safety. Due to the high requirements for validation and verification measures, necessary qualifications of the dentist and his or her assistant as well as the time of preparation, the alleged costs of disposable products are relativized (Fig. 4). International regulations often allow the preparation of single-use products, but this permission is usually tied to high standards, which are usually hard to meet by any dentist owning a private practice. In addition, special tools are required for the preparation of laser fibres. In this regard, the fact that preparation tools such as fibre stripping devices or ceramic/diamond knifes cannot be sterilized in most cases should be considered. Thus, the preparation can take place only in a non-sterile area.

A solution to these problems can be found in the use of single-use fibre tips. Combinations of hygienic compliant hand pieces with matching disposable fiber tips are required, as shown in figures 5 and 6. A hand piece such as this consists of two parts: The "cold" part is permanently fixed to the laser device and can be disinfected. The "hot" part should be cleaned by machine and can ideally be autoclaved. Finally, to transmit the laser radiation to the tissue, short fiber tips are added. These tips should be designed as single-use products, sterile and individually packaged and documented by the manufacturer. Some producers have recognized these problems and have already developed hand pieces and fiber tips (Fig. 7). A final solution – in terms of patient safety, hygiene, as well as a reasonable price-performance ratio – will probably be achieved within the next few years. In the future, the acceptance of laser applications in dentistry can be assumed to increase greatly._

_contact laser

Hans J. Koort
MedLas Consult
Auf der Schleide 18
53225 Bonn, Germany

ceo@medlas.com
www.medlas.com

Fig. 5 _Hygienic compliant hand piece.
Fig. 6_Schematic drawing of a fiber tip as a single-use product.
Fig. 7_The tips available on the market are not quite perfect yet, however, they lead the right way. Tips made by Biolase (USA), elexxion, Hager & Werken, Sirona (Germany).