

Statement on Lasers in Dentistry ADA Council on Scientific Affairs

Introduction

Applications for and research on lasers in dentistry continues to expand since their introduction to the dental profession. Dental laser systems are cleared for marketing in the United States via the Food and Drug Administration (FDA) Premarket Notification [510(k)] process. The primary purpose of this Statement is **to provide comments** and **a science-based perspective** on several increasingly popular uses for dental lasers. These topics include: Sulcular Debridement (sometimes termed *Laser Curettage*), Laser-Assisted New Attachment Procedure (LANAP), Reduction of Bacteria Levels in periodontal pockets (sometimes termed *Pocket Sterilization*), Laser-facilitated Wound Healing, Laser Root Planing, Aid in the Diagnosis of Caries (Laser Fluorescence), and other Hard Tissue Applications including endodontics. The statement also provides a brief overview of the FDA's 510(k) process and educational options for dental laser systems.

FDA 510(k) Clearance

All dental lasers currently available on the U.S. market have been issued 510(k) clearances by the FDA. 510(k) submissions are reviewed and processed by the Center for Devices and Radiological Health (CDRH) in the FDA. The review team determines if the product under review meets relevant criteria for "substantial equivalence" to a *predicate device* (The term "predicate" is used to describe any device that is marketed for the same use as the new device, even if the actual technologies are not the same).

The FDA includes in its review dental laser system specifications and safety mechanisms in relationship to already cleared devices. **For new indications for use the FDA may request additional safety and effectiveness data in support of the clearance for market.** Given the many factors that are appropriate to evaluate when using lasers in biological systems, the Council feels that the 510(k) process alone is not inherently sufficient to scientifically demonstrate safety, efficacy, or effectiveness for marketed dental laser applications in all cases. Properly designed preclinical and clinical studies are often needed to demonstrate safety, efficacy and clinical effectiveness for specific products and uses.

The number and type of studies necessary to obtain 510(k) clearance varies widely for the various types of devices used in dentistry. The Council encourages dental practitioners to cautiously consider claims of safety and efficacy that are purely based on the product having been cleared for market by the FDA through the 510(k) process. It is appropriate and prudent for the practitioner to request detailed information from the manufacturer about the scientific evidence that forms the basis for the marketed use. This information will help the dentist to discuss the benefits and risks of the treatment options with patients. Another source of information for clinicians to learn more about the available evidence on a specific topic or clinical question is the ADA's Evidence-Based Dentistry Web page (<http://ebd.ada.org/>) developed by the ADA Center for Evidence-Based Dentistry.

There are currently more than twenty cleared indications for use for dental lasers in the United States. Dental lasers obtaining 510(k) clearance may be labeled, promoted, and advertised by the manufacturer for only those specific indications for use for which the devices have been cleared for marketing. Dental laser manufacturers must seek FDA 510(k) clearance for each laser product and each specific indication for use. Not every laser is cleared for every conceivable use. Therefore, FDA marketing clearances apply to certain products that are specific to the manufacturer and product. For any specific laser device, the specific indications for use, as marketing clearances, can be found in the professional information section of the operator's manual for the device.

Additional uses for dental lasers are considered "off label use." Within the scope of a license to practice, dentists may choose to use lasers or other products "off label." Practitioners should consider off label use in light of possible benefits and risks, patient needs, and the available scientific evidence. The Council recommends that dentists read and understand the specific indications for use for each device.

Practitioners may also access the FDA Web site

(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>), call the FDA or consult with the manufacturer for specific and up-to-date information about cleared indications for use.

Laser Education

It is the position of the Council that practitioners obtain proper training on the use of dental laser devices, and that dentists use the devices within their licensed scope of practice, training and experience. Guidance for the profession for safe dental laser use is provided by American National Standards Institute Standard Z136.1 Safe Use of Lasers and Z136.3 Safe Use of Lasers in Health Care Facilities. Specific training is also available from manufacturers, and via independent providers of continuing education, including professional organizations and academic institutions. Continuing education programs/presenters should address and disclose possible conflicts of interest. At the present time, the ADA's Commission on Dental Accreditation does not include laser education in its accreditation standards for dental education programs. However, proposed educational standards are available (e.g., Curriculum Guidelines and Standards for Dental Laser Education¹).

Sulcular Debridement (Curettage)

The dental literature indicates that when used as an adjunct to meticulous root planing, mechanical or chemical curettage (i.e., the intentional removal of the epithelial lining of the sulcus) offers no consistent benefit beyond scaling and root planing alone with respect to gain of the periodontal attachment. As such, curettage was deemed several years ago to be of no known clinical value. Accordingly, the ADA code for curettage was omitted from the CDT-4 code listing. There is little convincing clinical evidence that adjunctive laser curettage produces a result superior to adjunctive mechanical or chemical curettage, or even scaling and root planing alone. Current evidence suggests that therapies intended to arrest and control periodontitis depend primarily on effective root debridement.

First, the term "sulcular debridement" is an old FDA regulatory term imposed on the laser manufacturers by the FDA beginning in 1997 and does not accurately reflect the clinical condition being treated—periodontal curettage. Additionally, we feel this is a misrepresentation of the literature. The literature states that here is no "additional" value to periodontal curettage, since the unintended effects of S/RP includes periodontal curettage.

Excerpt from the AAP Position Statement on Gingival Curettage, dated 2002.
<http://www.perio.org/resources-products/pdf/38-curettage.pdf>

"Short- and long-term clinical trials have confirmed that gingival curettage provides no additional benefit when compared to SRP alone in terms of probing depth reduction, attachment gain, or inflammation reduction.4-7 After comparing SRP alone to curettage plus SRP, it was concluded that curettage 'did not serve any additional useful purpose.'" Underline emphasis added.

Furthermore, the studies in the 2002 position statement do not take into account recent finding published in the peer reviewed literature since the paper was published 7 years ago.

"Recently, a method of curettage with a dental laser has been proposed. The goals of laser curettage are epithelial removal, as with previous methods, and, in addition, bacterial reduction. A short-term study reported that Nd:YAG laser treatment did not produce statistically significant bacterial reduction.²⁰ This was subsequently confirmed in a multicenter study of laser curettage, which reported that bacterial reduction was not often achieved.^{21,22} Only 1 of the 3 centers reported an advantage in bacterial reduction over SRP alone.²² One pilot and follow-up study did report bacterial reduction with a diode laser; however, the laser treatment was repeated, while the SRP was not.^{23,24} These findings indicate that despite advances in technology, gingival curettage, as a clinical procedure, fails to consistently provide any advantage over SRP alone for the treatment of chronic periodontitis."

Studies conducted over the past 7 years have added to the scientific body of evidence and should be included in any discussion on laser "curettage". See Kamma, J, et all The Effect of Diode Laser (980 nm) Treatment on Aggressive Periodontitis: Evaluation of Microbial and Clinical Parameters in Photomedicine and Laser Surgery, Volume 27, Number 1, 2009 pp 11-19

Laser-Assisted New Attachment Procedure

A 2007 publication compared the probing depth, attachment gain, and type of attachment from traditional mechanical therapy of advanced chronic periodontitis vs. traditional mechanical therapy that included two intrasulcular applications of Nd: YAG; one aimed at removing the sulcular epithelium and another said to “seal” the pocket.² In this study, histology was performed on 6 pairs of single-rooted teeth at 3 months. Laser-treated pockets tended to show greater probing depth reductions and clinical attachment gains than non-lased pockets. Based on measurements from notches placed in periodontally involved root surfaces before treatment, lased teeth showed evidence of new cementum while 5 of the 6 control teeth showed a long junctional epithelial attachment. This study concluded that the Laser Assisted New Attachment Procedure™ (LANAP) can be associated with cementum-mediated new connective-tissue attachment and apparent periodontal regeneration of diseased root surfaces in humans.

It is not accurate to state that the therapy included “intrasulcular applications” to remove “sulcular epithelium”. This study reviewed moderate periodontal disease, and as such periodontal pocket applications of the Nd:YAG were investigated.

The following paragraph is mere opinion and speculation, and misrepresents the study, the scientific findings and the conclusion of the author.

Although the Council is optimistic regarding the potential for lasers to enhance effectiveness in treating periodontitis, dentists should note that this study provides no more than pilot validation for this treatment concept. The study was not blinded, and the sample size was small thereby limiting extrapolation of the results to the general population. Further, pre-treatment notches in the teeth were difficult to place, hard to know exactly where they were placed and are difficult to clearly detect on histological specimens. Moreover, the advanced periodontal destruction initially present in these 6 test teeth make it difficult to extrapolate these results to cases of early and moderate chronic periodontitis, where the anatomic environment, laser energy distribution and clinical outcome may differ substantially. It is also unclear what laser-based “sealing” of a treated periodontal sulcus is and, if real, what benefits it might provide. Additional clinical data from properly designed clinical trials with adequate sample sizes are still required before it can be known to what extent LANAP is safe and effective across the spectrum of patients with chronic periodontitis. The Council therefore cautions clinicians to weigh the available evidence for LANAP when considering the options available for treatment of the periodontal diseases.

1. This study was, at the time, the 4th largest human histology – with a control group – in the prestigious, peer-reviewed periodontal scientific literature. To call it a “pilot validation” or a small sample size is an attempt to minimize the significance of the findings.
2. It is a completely false representation to state that the “study was not blinded”. The study was blinded to the patient (proximate teeth were treated in all but one case), blinded to the calibrated clinical examiner, and blinded to the histologist.
3. It is disingenuous to state the sample size was small. This was a human histological study that involved the block sectioning of the study along with bone. Human Investigation Review Boards (“IRBs) regard human experimentation very seriously. IRBs regard block section removal of teeth even more rigorously. Consequently, (IRBs) bone block sections of human tooth/bone histology is not performed on the same numbers of patients and teeth, as a clinical study comparing established treatment method and that does not involve intention creation of bony defects
4. The placement of the pre-treatment notches were fully explained in the peer-reviewed manuscript in the December 2007 issue of the [International Journal of Periodontics and Restorative Dentistry](#) (IJPRD). Yukna, RA; Carr RL; Evans, GH: Histologic Evaluation of an Nd: YAG Laser-Assisted New Attachment Procedure in Humans. Int J Perio Rest Dent 27(6):577-587, 2007
5. It is absolutely baffling what the Council can possibly mean in the statement regarding extrapolation to early and moderate chronic periodontitis, when considering the beneficial outcomes from advanced periodontitis. This statement is more argumentative than enlightening.
6. Similarly argumentative is the Council's comments on the creation of a stable fibrin clot (referred to as a “seal” by the Council). If the authors do not understand the benefits of creating a stable

fibrin (1st connective tissue) clot, then one must question the expertise of the Council and its members in wound healing 101.

Reduction of Bacteria Level

Lasers, as a group, have inconsistently demonstrated the ability to reduce microorganisms within a periodontal pocket. It appears from the literature that mechanical root debridement remains a priority to attain improvements in clinical attachment levels. However, limited new data suggest that clinical outcomes may be enhanced by the adjunctive use (following root debridement) of a bactericidal irrigant activated by a cold laser.³

See reference to Kamma et al above.

Laser Wound Healing

Methods using low-powered lasers to improve wound healing have been noted for many years but the reported results have been mixed. While the risk of thermal damage from low-powered lasers appears minimal, the Council considers the application of laser energy purely for the purpose of improved wound healing to be controversial and not well supported by clinical studies.

Laser Root Planing

Erbium lasers show potential for effective root debridement. The Er:YAG laser has been shown, *in vitro*, to remove calculus⁴ and to negate endotoxin.⁵ Clinical data also exist that suggest the Er:YAG laser can result in a superior calculated clinical attachment gain compared with mechanical scaling and root planing alone.⁶ The Council views such developments as encouraging. Additional well-designed comparative studies would be helpful to clinicians in confirming these results.

The Council states no concern over the lack of human block section histology for this wavelength, and states positively the “clinical data” can result in a “superior” calculated (but not histologically demonstrated) clinical attachment gain.

Aid in the Diagnosis of Caries

Laser fluorescence may be a useful adjunct in the detection of early enamel caries.⁷ The level of energy used in this application poses little risk to the patient and offers potential benefits. Presently, one product available commercially in the United States is based on this laser technology, using a diode laser at 655-nm wavelength. Other adjunctive caries detection products available in the United States do not use laser technology.

Hard Tissue Applications

The vast majority of the lasers cleared for market since the last Council Statement on Lasers in 1998 that are intended for hard tissue applications, such as the ablation of caries, enamel, and dentin, are either the Er:YAG (2.94 μm) or the Er,Cr:YSGG (2.78 μm) laser. In general, the Council believes these applications to be reasonable based upon supporting *in vitro* and *in vivo* studies. Some clinical studies exist that report equivalency to traditional hard tissue removal methods.⁸ However other studies question the reliability of bonding to dentin surfaces prepared with an Er,Cr:YSGG laser⁹ or suggest that Er:YAG laser-cut preparations in enamel and dentin are equivalent to air-abrasion preparations with respect to resin bond strengths.¹⁰ The ability to perform cavity preparations with the Er:YAG and Er,Cr:YSGG lasers without local anesthetic, where possible and where appropriate, is viewed positively by the Council. The shallow penetration of the Er: YAG and Er, Cr: YSGG lasers reduce the thermal risk to the pulp in comparison to other more penetrating laser wavelengths. While the Council acknowledges that the Er:YAG and Er, Cr:YSGG lasers represent an alternative method of removing enamel, dentin and caries, clinicians are encouraged to be cautious and to be aware of the benefits and risks involved in the removal of hard tissue and caries using lasers and traditional cavity preparation methods.

Endodontics

The primary goal for endodontic therapy is cleansing, shaping and sealing the root canal system. Lasers are cleared for pulpotomy, blood flow measurements, apicoectomy, and illumination of the endodontic

orifice and for softening gutta percha. Currently, there are no devices that can accurately measure the pulpal blood flow. Lasers used as an adjunct have been shown to aid in the cleansing of the root canal space. *In vitro* evidence indicates that lasers are equivalent to conventional rotary instrumentation for shaping the coronal and middle thirds, but inferior for shaping the apical 1/3 of the root canal system. There is no evidence that lasers provide a superior seal or higher clinical success rate than conventional instrumentation.

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