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The mission of the Journal of Laser Dentistry is to provide a professional journal that helps to fulfill the goal of information dissemination by the Academy of Laser Dentistry. The purpose of the Journal of Laser Dentistry is to present information about the use of lasers in dentistry. All articles are peer-reviewed. Issues include manuscripts on current indications for uses of lasers for dental applications, clinical case studies, reviews of topics relevant to laser dentistry, research articles, clinical studies, research abstracts detailing the scientific basis for the safety and efficacy of the devices, and articles about future and experimental procedures. In addition, featured columnists offer clinical insights, and editorials describe personal viewpoints.
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Dental Lasers – Where We’ve Been, Where We Are, and Where We’re Going

Donald J. Coluzzi, DDS, Portola Valley, California

Three articles connect our past knowledge and principles to the present clinical applications:
• Mr. John Sulewski offers an overview on how dental lasers progress through the regulatory processes. John describes the mechanisms of the U.S. Food and Drug Administration and gives an update on the marketing clearances that provide the direction and confidence for our use of lasers.
• Dr. Wayne Selting writes part one of a two-part manuscript describing some fundamental concepts on how to use erbium lasers more efficiently. Wayne’s background as an electrical and biomedical engineer augments the practical clinical applications of these wavelengths.
• Mrs. Mary Lynn Smith presents four case descriptions of patients with advanced periodontal disease and how their treatment progressed. Mary Lynn concludes that her adjunctive use of certain lasers can be of benefit to even those compromised patients with their cooperation.

Two other articles continue our laser journey:
• Dr. Eugene Antenucci demonstrates how relatively simple and time-tested diode laser procedures can be employed with one of the newest dental technologies, computer-aided design and manufacturing. Gene offers clinical examples of how the laser is a necessary addition to the future of digital impressions to ensure the accuracy and clinical excellence of the fabricated restorations.
• Dr. Steven Parker offers his views on the future direction of laser education. Steven, as chair of ALD’s Education Committee, is working with that group to study new approaches to offering Standard Proficiency certification to all laser users.

I hope you enjoy this first segment of the ‘replay’ of Las Vegas.

AUTHOR BIOGRAPHY
Dr. Donald Coluzzi, a 1970 graduate of the University of Southern California School of Dentistry, is an associate clinical professor in the Department of Preventive and Restorative Dental Sciences at the University of California San Francisco School of Dentistry. He is a charter member and past president of the Academy of Laser Dentistry, and is currently the Editor-in-Chief of the Journal of Laser Dentistry. He has used dental lasers since early 1991. He has Advanced Proficiency in Nd:YAG and Er:YAG laser wavelengths. He is the 1999 recipient of the Leon Goldman Award for Clinical Excellence and the 2006 Distinguished Service Award from the Academy of Laser Dentistry, a Fellow of the American College of Dentists, and a Master of the Academy of Laser Dentistry. Dr. Coluzzi has presented about lasers worldwide, co-authored two books, and published several peer-reviewed articles. Dr. Coluzzi may be contacted by e-mail at don@laser-dentistry.com.

Disclosure: Dr. Coluzzi is a past and present presenter at various local, state, and national dental meetings. He has no financial interest in any company.
When I first encountered Ted Maiman, what attracted me was the smile on his face. He had the nicest smile I had ever seen.

That was February 13, 1984. Just that weekend Ted had been inducted into the National Inventors Hall of Fame, joining luminaries like Thomas Edison, Alexander Graham Bell, and the Wright Brothers. When we started talking I felt an immediate comfort as if I had known Ted all my life. It was magical, and as I later learned, Ted conveyed the same natural ease, warmth, and modesty to others.

It was a pleasure to feel the welcome of a large family at your annual Academy of Laser Dentistry conference last April. I appreciated your interest and could sense the pioneering spirit of ALD members. That encouraged me in sharing Ted’s personality and the laser story with you.

I had the joy of being Ted’s wife for 23 years. We were seldom separated since our fateful meeting of 1984 (Figure 1). It was always easy to be with Ted as he was a kind, generous, and gentle man. Through the years I got to better understand why Ted was successful—to understand why he had won the technological Olympics by realizing Albert Einstein’s vision of coherent light with the world’s first laser in 1960.

Several competitor groups around the world including Bell Laboratories had already set out to devise an apparatus to create coherent light. They had the top scientists and far more resources.

But they didn’t have Ted Maiman.

Ted’s family was intellectually vigorous, placing great value on education and independent thinking. Ted’s father Abe was an electrical engineer and gave Ted the love of science and invention as a small boy. Together they explored many creative ideas and often competed on such projects as who could build the best hi-fi amplifier. Ted found his father’s electronics laboratory in their basement a fun place to be.

In the home lab Ted saw his father invent the first DC-to-DC converter, known later as the vibrator, which made car radios feasible. Abe’s colleagues did not have the vision to appreciate the converter, discouraging him from patenting his invention. Abe had also developed an electronic stethoscope. Upon showing his prototype to a cardiologist, the response was, “Yes I can hear more information, but who knows what to do with it?”

Ted was witness to his father’s creative genius being ridiculed and rejected. That turned out to be a profound and positive influence on Ted’s lifelong bent not to give up on anything that seemed right to him.

And give up, Ted wouldn’t.

Ted would not give up at age 12, when he wanted to work repairing electrical appliances. Told that he was too young for that job, he accepted a job of sweeping floors to get in and then moved on to repair work. Later in life, wanting work as an electronics engineer before earning any formal degrees, Ted had to convince an employer that he was worth trying out.

Getting into Stanford’s physics department was much the same—having first to persuade Professor Willis Lamb. Dr. Lamb later received the Nobel Prize in physics after Ted finished his doctoral thesis proving the Lamb Shift by detailing fine structure splitting in excited helium atoms. This important finding led to the development of the laser.

Exit Stanford University, enter Hughes Research Laboratories, Ted’s first important job. At Hughes he was determined to extend the electromagnetic spec-
The laser's advent in 1960 has rapidly revolutionized many aspects of consumer enjoyment, industrial processes, technological advances, and medical procedures. Welcome to the age of the photon. The possibilities of lasers are limited only by our imaginations!

I can still see that maverick smile on Ted (Figure 3).

Kathleen Maiman

For Theodore Maiman's detailed autobiography and account of his laser invention, see The Laser Odyssey (www.laserinventor.com).

AUTHOR BIOGRAPHY

When I met Ted I had just finished an Emergency Medical Technicians program with the interest of becoming a physician’s assistant. Today it is my joy to have the knowledge of a myriad of laser developments to share. It is the kind of laser applications that you give to your patients, often improving their quality of life dramatically, that was Ted’s greatest satisfaction.

Ms. Maiman may be contacted through the Academy of Laser Dentistry.
Thank You, Doctor, How Much Do I Owe You?
Stuart Coleton, DDS, New York Medical College, Valhalla, New York, and Westchester University Medical Center, Valhalla, New York

J Laser Dent 2009;17(2):76-78

Editor’s note: Dr. Coleton, a periodontist, is the 2009 recipient of the Leon Goldman award for Clinical Excellence from the Academy of Laser Dentistry. While he has written many clinical articles about his specialty, this one offers a unique perspective on practice management.

SYNOPSIS
As dental practitioners, we answer a myriad of questions from our patients about treatment, from initial diagnosis to continuing care. For the emergency patient, the discussions should be shorter so that critical care can begin. After the remedial treatment, one question likely remains—“What’s the fee?” This article presents three different case scenarios and is intended to help answer that query.

Treating dental emergencies are as much a part of everyday practice as taking radiographs and returning telephone calls to patients and dental colleagues. As dentists we have formed the habit of categorizing just about everything in our offices, from paper clips to surgical instruments. Such is the case with organizing the emergency treatment we provide to our patients.

In general, emergencies can be subdivided into four groups: bleeding, pain, cosmetic discomfort, and referrals. Treatment of pain and bleeding conditions necessitate a rapid response, but cosmetic discomfort and referrals require a little bit of additional explanation. Cosmetic discomfort is usually the result of an accident necessitating medical or dental treatment. The mid-day referral may not require much time to treat but it still can wreak havoc with a carefully planned daily treatment schedule.

Many of the factors that determine the cost of preplanned dental care do not hold true for emergency treatment. This essay will discuss three typical examples of emergency care from a practice management standpoint. The first case, though cosmetic in nature, was not the result of an accident; nevertheless, it requires some conversation with the patient about etiology and treatment. The second case involving the treatment of painful oral lesions cannot factor in the cost of time, medicaments, or postoperative visits. The third case has such serious sequelae that trying to determine a fee immediately after treatment almost puts the dollar ahead of the patient’s need for immediate follow-up treatment and a careful explanation of what problems might lie ahead.

The first patient is a 42-year-old female Caucasian with 90% of her buccal gingiva pigmented very darkly (Figure 1). This pigmentation was not present at birth but became evident at age 22 when she became pregnant with her first child. Now she is 42 and her daughter is getting married in one month. She was referred by her general dentist to see whether the pigmentation could be removed. Since the melanin pigment is found in the melanocytes in the basement layer of the epithelium, it stood to reason that if I could lift the epithelium off the connective tissue of the gingiva, I could eliminate the pigmentation. In other words, a laser peel was in order.

A carbon dioxide (CO₂) laser was used at a low power setting of 2 Watts, continuous wave. With the laser tip in a highly defocused mode, I could create a bulla which could be easily peeled away from the underlying connective tissue of the gingiva, I could eliminate the pigmentation. In other words, a laser peel was in order.

Figure 1: Preoperative view of buccal pigmentation

To say the least, the patient was absolutely thrilled with the result and as I expected asked the usual question, “Thank you, Doctor, how much do I owe you?” I’ll hold my
The second patient, a 72-year-old female, was referred to our office mid-day by her dentist. She was in severe pain and could not eat or drink even the blandest of foods. Although the clinical appearance of the lesions in her mouth appeared similar to that of aphthous ulcers (Figure 4), the history of her problem was a tissue reaction to the placement of a periodontal dressing containing zinc oxide and eugenol. In any event, the goal of treatment was to denature the protein on the surface of the lesions, causing them to collapse onto the underlying connective tissue thereby forming a biologic bandage which would protect the nerves in the connective tissue from noxious stimuli.

Once again, the CO$_2$ laser was set on 2 Watts, continuous wave, and placed in a highly defocused mode. With a circular motion, the tip of the laser handpiece was brought close to the surface of the lesion. Since there was no change in the texture of the surface tissue, the tip of the laser was repositioned as before and the power was increased to 3 Watts. The procedure was repeated and as the laser tip approached to within 1 cm of the tissue surface, a graying and matting of the surface tissue occurred. Close examination of the most forward of the palatal lesions, compared it to its posterior neighbor, revealed that the posterior lesion had a shinier surface than the anterior one (Figure 4). Of course the procedure was performed without any anesthetic whatsoever so the patient could indicate any discomfort at either power setting. If any pain were felt at either setting, the procedure would have been aborted. If we were to proceed any further there would be danger of perforating the surface of the lesion, thereby exposing the underlying tissue and causing even more pain. The procedure was completed in approximately 12 to 15 minutes and the patient was able to tolerate chewing soft white bread dipped in milk. The silence in the operatory as she chewed was unbelievable but no more so than the smile on her face. I advised the patient not to keep testing the result and remain on a liquid or semi-solid diet for one week. She was instructed to call for another appointment if the symptoms returned. Once again the dreaded question was asked: “How much do I owe you, Doctor?” What do you charge for 15 minutes of your time, in the middle of a busy day and obtaining such a dramatically positive result? Once again, I’ll hold my response for later.

The third case involved a patient who was referred some six years ago to my office by her dentist who had recently finished the placement of a full crown on tooth #13. The dentist reported that 3 weeks after permanent cementation was completed, the patient returned to his office with a chief complaint of mild discomfort and bleeding upon brushing in the upper left part of her mouth. His clinical examination revealed what appeared to be granulation tissue between teeth #12 and 13. Using local anesthetic, he had curetted the area, suspecting that there might be some excess cement subgingivally. The patient returned with the same complaint and clinical picture in 10 days. It was then that he decided to make the referral.

Upon close examination of this 55-year-old Caucasian female, I noted that the full extent of the gingival lesion was from the mesial aspect of tooth #11 to the buccal aspect of #13 (Figure 5), but this large affected area could not be due to the placement of the crown. The surface of the tissue was erythematous and granulated. The speed at which the tissue re-grew after initial removal aroused my suspicions so I decided to biopsy the area. I discussed my suspicions with the patient, advising her that my procedure would most likely
result in significant tissue recession and the possible need for additional restorative dentistry. The patient agreed to the biopsy.

The CO$_2$ laser was set at 6 Watts, continuous wave, in a focused mode and a buccal specimen of tissue was removed and sent for histologic examination (Figure 6). The patient returned for a postoperative evaluation in 1 week. The clinical picture showed unusual healing of a granulomatous nature (Figure 7). The biopsy report was delivered by phone in 2 days, a departure from the usual written report in 7 to 10 days, and the diagnosis was squamous cell carcinoma. Histologic specimens closely followed (Figure 8). I called the patient immediately after receiving the phone report and asked her to come in to see me the next day. At that visit I explained the findings to her and advised her that most if not all of her questions could only be answered after further examination by an oral surgeon. The proper referrals were made while she was still in my office, and her state of mind did not generate any questions about fees. However, every year at Thanksgiving I receive a card with a handwritten note, “Thank you for saving my life.” I have received six cards so far.

While in graduate school I attended the closest thing to a patient management lecture I had in four years. This doctor was far ahead of his time. He told us that there were two ways to be paid for our work, in shekels or in warm fuzzies; and when we felt better receiving the warm fuzzies than the scheckles, we were truly professionals. Well, every Thanksgiving, when I receive that card, I feel those warm fuzzies running up and down my arm, very much as I do right now as I write this.

So how do I answer my patients’ question as to fees? As I stand with the patient at the reception desk, I palm a few of my professional cards and hand them to the patients. I ask them to put them in their purse or wallet and should a family member or friend have need of my services, please remember me and give them one of my cards. I can guarantee that by using this method in 38 years of treating patients, I have never lost one cent. On the contrary, I’ve practiced my profession proudly.

**AUTHOR BIOGRAPHY**

Dr. Stuart Coleton is a Diplomate of the American Board of Periodontology and the American Board of Oral Medicine. He is chief attending periodontist at Westchester Medical Center University Hospital and holds the rank of assistant professor in dental medicine at New York Medical College. He is a past president of the Academy of Laser Dentistry and is a Recognized Course Provider. He has been certified as having Advanced Proficiency, Educator, and Mastership status in lasers by the Academy of Laser Dentistry. His areas of special expertise are periodontal diagnosis and treatment as well as oral medicine. He has taught didactic and clinical laser therapy to both dental and medical general practice residents. Dr. Coleton may be contacted by e-mail at Scoleton@aol.com.

**Disclosure:** Dr. Coleton is a stockholder in Lantis Laser, Inc.
President John F. Kennedy once stated, “There is always inequity in life. Some men are killed in a war, and some men are wounded, and some men never leave the country, and some men are stationed in the Antarctic and some are stationed in San Francisco…” After graduating from the University of Illinois College of Dentistry in 1970, as luck would have it, I spent two years active duty with the U.S. Naval Reserve in San Francisco, while many of my friends were deployed to less desirable places like Vietnam.

Twenty years later, fortune shone upon me again when I attended my first course on using lasers for dental care. The course was presented by Dr. Jerry Kohen in Windsor, Ontario just across the border from Detroit. Dr. Terry Myers dropped in at Jerry’s office to greet us and answered our numerous questions about what he perceived would be the impact of lasers on dental care. I refer to Terry as the godfather of lasers in dentistry. As most of you know he and his late brother Bill, an ophthalmologist, adapted an Nd:YAG laser as the first device dedicated for use in dentistry.

I questioned Terry about what plans were in place for additional training and possible certification in the clinical use of lasers. He informed me of a study club that had met on two previous occasions and would be meeting again in October 1990 in Boston. That October, I purchased my first Nd:YAG laser and three days later I left for Boston to attend the meeting. At that session, sponsored by American Dental Laser (ADL), a commercial company, several significant events occurred. Terry challenged the group to consider organizing as an independent entity free of unilateral commercial support. Because there were other laser companies in the marketplace and surely many more to come in the future, it behooved us to form our own Academy. I remember suggesting that perhaps we could come up with an amount of seed money to start the organization and we would be acknowledged as Charter Members. Someone proposed that two organizations be formed—an international group and a North American group. Thus, at a meeting in Puerto Vallarta, Mexico in February 1991, the groundwork was laid for the International Academy of Lasers in Dentistry and the North American Academy of Laser Dentistry. At this time I began my commitment to organized laser dentistry, when I was elected to be Secretary of the North American Academy.

One of my most memorable experiences occurred in July of 1992, when a group of dentists, academicians, and manufacturer’s representatives met at the University of California San Francisco School of Dentistry where we created the *Curriculum Guidelines and Standards for Dental Laser Education*. Dr. Myers’ desire for a certification program was set in place. In April of 1993, I received my Category II (Standard Proficiency) certification in the Nd:YAG laser wavelength.

In the late 1980s and early 1990s a group of dentists who were using CO₂ lasers formed the American Academy of Laser Dentistry. It was not long before all the academies determined it would be best to merge—forming the Academy of Laser Dentistry (ALD) in 1993. About this time, I was asked to serve as a member of the Board of Directors. By October 1993, we had our first conference in Chicago. At that conference, I received my Mastership (Advanced Proficiency), again in Nd:YAG. I am proud to say that my wife, Elaine, and I have been in attendance at every conference since.

The first educator course was given in San Francisco in October 1998. That weekend a group of us also revised the *Curriculum Guidelines*. One of the most gratifying aspects of my association with ALD has been participating in its mission of educating and certifying dental professionals. Through my involvement in teaching laser courses as well as assisting in the certification process, I have had the opportunity to train and meet people from around the world.
These experiences have returned big dividends. Not only do I learn a lot from these colleagues, Elaine and I have become friends with people from all over the United States and internationally.

After working my way up the chain of command in the Academy, it was my privilege to serve as President in 2000. I feel fortunate to have had some great mentors preside before me. At the last conference in Las Vegas, I was so pleased that so many of the Past Presidents were in attendance, where we participated in a Past Presidents panel. One notable exception was our late friend Dr. Eugene Seidner (1997 President). During the discussion Dr. Alan Goldstein commented that the future of ALD is in our young people. Several years ago, a student scholarship was established in Gene’s name. I would like to challenge all Academy members to make a contribution toward this important program.

I want to thank the members and the Board of ALD for the honor of receiving the Distinguished Service Award. To be included in the company of so many accomplished people is truly flattering. Like the loyal Chicago Cubs fan that I am, each year I look forward to the next baseball season and the next ALD conference with much optimism. Every ALD conference has exceeded my expectations. At the end of each of the annual sessions, I think about the phrase most quoted by Cubs fans, “Wait until next year.” Of course, what I mean is that I know where I’m going with lasers next year; the beloved Chicago baseball fans are only hoping.

**AUTHOR BIOGRAPHY**

Dr. Dennis Pietrini is a 1970 graduate of the University of Illinois College of Dentistry. He served on active duty with the U.S. Navy Dental Corps from 1970 to 1972 at Hunter’s Point Naval Shipyard in San Francisco. In 1972, he started a private general dentistry practice in River Grove, Illinois, moving to his current location in Franklin Park in 1978. He has been on the active staff of Gottlieb Memorial Hospital since 1972, serving as Chairman of the Department of Oral Medicine, a member of the Credentials Committee, and as the Chairman of the hospital’s Laser Safety Committee. Dr. Pietrini has Advanced Proficiency in Nd:YAG, is a Certified Dental Laser Educator, and a Recognized Standard Course Provider. He is the past president of the Academy of Laser Dentistry and the co-founder of the former Midwest Laser Dental Study Club. Dr. Pietrini may be contacted by e-mail at dr.pietrini@laserdentist.com.

**Disclosure:** Dr. Pietrini has no stock, teaching assignments, or active commitments with any laser company.
Clearing the FDA Hurdle, from Initial Device Application through Regulatory Approval to the Clinical Operatory: An Update on Dental Laser Marketing Clearances

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This article presents a brief overview of the role of the U.S. Food and Drug Administration (FDA) as it relates to dentistry, and describes how medical devices, including lasers, enter the U.S. marketplace; presents a timeline of milestones in dental laser marketing clearances; examines how one can search the FDA Web site for marketing clearance information; discusses the concepts of off-label use, adverse events, and risk management; and summarizes other national regulatory agencies and worldwide efforts toward harmonizing regulations.

ROLE OF THE U.S. FOOD AND DRUG ADMINISTRATION

The history of the FDA dates from 1906 when Congress passed the modern food and drug law which made it illegal to distribute misbranded or adulterated foods, drinks, and drugs. Over the years additional legislation expanded the responsibilities of the agency. Overall, its mission is to promote and protect the public health by helping safe and effective products reach the U.S. market. It also monitors products for continued safety once they are in use, and helps the public get accurate, science-based information needed to improve health.

The FDA is mandated to conduct a number of activities in fulfillment of its mission. It reviews new products, monitors safe manufacturing and handling and new risks, uses standards and regulations to define requirements, conducts research to provide the basis for regulatory decisions, corrects problems, and enforces the law.

The FDA has a number of regulated product areas under its purview, ranging from foods and medicines, biologics (such as vaccines and blood products) and medical devices, electronic devices that emit radiation (such as microwave ovens and cellular phones), to animal drugs and devices, cosmetics, and product labels. This article will concentrate on one of those areas, medical devices.

Legislation has added new definitions to and requirements of the Federal Food, Drug and Cosmetic Act since its inception in 1906. Of special note are the Medical Device Amendments of May 28, 1976 which defined a medical device for the first time from a regulatory standpoint, specified 1700 generic types of devices and 19 medical specialties, and required premarket review of devices.

Under Section 201(h) of the Food, Drug and Cosmetic Act, a medical device was defined as a device that:
• is used for diagnosis, cure, mitigation, treatment, or prevention of disease or condition
• affects the structure or function of the body
• does not achieve its intended use through chemical reaction
• and is not metabolized to achieve effect.

A number of products fit that definition, including dental floss, endoscopes, replacement heart valves, examination gloves, and, of course, lasers.

FDA’S ROLE IN THE REGULATION OF MEDICAL DEVICES

The FDA’s Center for Devices and Radiological Health (CDRH) is the branch of the agency charged with oversight of medical devices. The Center helps ensure that medical devices are “reasonably” safe and effective, regulates what manufacturers can claim about their products, requires manufacturers to abide by defined Good Manufacturing Practices and Quality System legislation. The FDA does not control the practice of medicine or dentistry.

Good Manufacturing Practice (GMP) requirements of the Food, Drug and Cosmetic Act specify that domestic or foreign manufacturers have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States.

Also relevant for entry into the marketplace is the ISO 13485 standard, published in 2003, that has been adopted by many countries. The ISO standard specifies the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
PATHWAYS TO THE U.S. MARKET
Under FDA regulation, three pathways to the U.S. marketplace exist for medical devices: A so-called Premarket Notification 510(k), which applies to virtually all medical and dental lasers in the commercial marketplace. This designation is for devices deemed to be “substantially equivalent” to predicate devices that were legally marketed prior to the Medical Device Amendments of 1976. Other pathways include Premarket Approval or PMA, in cases where no predicate devices exist, and the De Novo Process for low-risk in vitro diagnostic devices for which no predicate exists.

Substantial Equivalence means a device has the same intended use and has the same technological characteristics of a predicate device, or it has the same intended use and has different technological characteristics, but does not raise any new questions of safety and effectiveness, and is at least as safe and effective as the predicate device.

The FDA requires 510(k) applications be submitted when a device is introduced to the market for the first time, when a significant modification is made to a previously cleared device, and when the indications for use are changed for a previously cleared device.

Considerable information is required when submitting a 510(k) application, including the submitter and contact information, the common and proprietary name of the device, a listing of the indications for use and identification of the marketed devices to which equivalence is claimed, and proposed labels, including promotional material.

If the device is not identical to a predicate device, then additional information must be submitted related to performance data that may be bench, animal, and/or clinical in nature, as well as sterilization, software and hardware information.

The FDA requires clinical data accompany approximately 10% of all 510(k) submissions when there is an important difference with a predicate device, such as a new indication for use or new technology. The data must be collected under rigorous Investigational Device Exemption (IDE) regulations.

An IDE permits the investigational device to be used in a clinical study in order to collect required safety and effectiveness data. Additionally, investigational use includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. Clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

Clinical evaluation of medical devices that have not been cleared for marketing requires:
- an IDE approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must be approved by FDA as well;
- informed consent from all patients included in the study;
- labeling for investigational use only;
- monitoring of the study;
- required records and reports.

MILESTONES IN DENTAL LASER MARKETING CLEARANCES
With this background in mind, a timeline of milestones in laser dentistry can be constructed by listing significant 510(k) marketing clearances for specific devices and clinical indications for use. May 3, 1990 is chosen as the starting point, the date when the first laser designed specifically for general dentistry was cleared by the FDA for intraoral soft tissue surgery. Other lasers had been used previously by otolaryngologists and oral surgeons, but the dLase 300 pulsed Nd:YAG dental laser system, manufactured by Sunrise Technologies and distributed by American Dental Laser, was the first laser instrument in dentistry.

Other clearances followed. An HGM argon ion laser was cleared for curing of composite materials on June 24, 1991; an ILT Genesis carbon dioxide laser for tooth whitening on December 18, 1995; American Dental Technologies’ PulseMaster Nd:YAG laser for sulcular debridement on March 10, 1997.


KaVo received clearance for its DIAGNodent device to aid in the diagnosis of dental caries on February 22, 2000. A Biolase Technologies device, the Waterlase, was cleared for tooth preparation to obtain access to the root canal (January 18, 2002), and for cutting of oral osseous tissue (bone) (February 12, 2002).

One year later, on February 3, 2003, the Biolase Waterlase received clearance for apicoectomy, and the Millennium Dental Technologies PerioLase device was cleared for laser-assisted new attachment procedure on July 26, 2004.

On February 12, 2008, Biolase received clearance for its Waterlase for root canal disinfection, and the KaVOL Key Laser III device was cleared for removal of subgingival calculus in periodontal pockets on July 10, 2008.

SEARCHING FOR MARKETING CLEARANCE INFORMATION
How does one find out about FDA marketing clearances for lasers? A simple way is to search the online database “510(k)s – Premarket Notifications (PMN)” on the FDA.
approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.”

**“CLEARED” VS. “OFF-LABEL” USE**

If a medical or dental practitioner chooses to use a device for an application that is not named in the “Indications for Use” statement, what does this mean? What are the implications of performing “cleared” vs. “off-label” procedures?

According to the FDA, good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices according to their best knowledge and judgment. If physicians use a product for an indication that is not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product’s use and effects. Use of a marketed product in this manner when the intent is the “practice of medicine” does not require the submission of an Investigational Device Exemption, Investigational New Drug Application, or review by an Institutional Review Board (IRB). Nevertheless, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.

Another source, the Physician’s Desk Reference or PDR, refers to off-label use of pharmaceuticals. The PDR states in part:

“...The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses in treatment regimens or patient populations that are not included in approved labeling... The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling...”

The PDR does NOT indicate what should happen should something go wrong under such circumstances.

**ADVERSE EVENTS**

In FDA terms, the “something went wrong” is known as an “adverse event” which is defined as death, or serious injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent damage or impairment.

A key phrase in the adverse event regulatory language is “caused or contributed to.” This means that the medical device may have been a factor in death or serious injury because of device failure, malfunction, improper or inadequate device design, manufacture, labeling, or user error.

The Safe Medical Devices Act of 1990 specified the procedures for reporting adverse events. By law, user facilities and manufacturers must report deaths and serious injuries to the FDA. A user facility is defined in the legislation as a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility that is not a physician’s office. By extension, one can also presume that the term “physician’s office” includes “dental operatory.”

When it comes to adverse event reporting, the FDA requires manufacturers to report deaths and serious injuries to the FDA; the agency requires distributors to report deaths and serious injuries to the FDA and to the manufacturer. The FDA requires user facilities to report deaths to the FDA, and serious injuries to the manufacturer. Meanwhile,
individual private practices are encouraged to voluntarily report adverse events to the FDA and are strongly recommended to report adverse events to the manufacturer.

**USERS’ ROLE IN RISK MANAGEMENT**

Another way of looking at the topic of Adverse Events is “Risk Management.” A 2003 World Health Organization publication outlined the user’s role in risk management. Foremost among the list of responsibilities is for the user to secure and follow adequate training. The user is also responsible for monitoring safety and performance of the device on a continuous basis, ensuring regular calibration and maintenance, sharing information and problems, and assuring appropriate waste disposal.

**OTHER REGULATORY AGENCIES**

The preceding discussion dealt exclusively with the U.S. Food and Drug Administration. Of course, similar regulatory agencies exist in other countries, for example:

- Canada – Health Canada (Device License)
- European Community – Medical Devices Sector (CE Mark)
- United Kingdom – Medicines and Healthcare products Regulatory Agency (MHRA)
- Australia – Therapeutic Goods Administration (ARTG Number)
- Japan – Pharmaceutical and Medical Safety Bureau (Approval or Notification).

The common theme of each of these agencies is protection of the public health. Each of them regulates how a medical device is brought into the marketplace.

In general, like the FDA, each of the agencies mentioned requires a statement of indications for use for a medical device. However, the extent of supporting data differs from one agency or region to another. At times, published literature is sufficient, at other times clinical studies are required.

Over the past several decades, any company wishing to sell medical lasers in these regions had to comply with a dizzying array of governmental regulations before it was allowed entry into the marketplace. A need was recognized to minimize regulatory barriers, facilitate trade, and improve access to new technologies. In 1993, an effort was initiated to achieve greater uniformity between national medical device regulatory systems, with the goal of enhancing patient safety and increasing access to safe, effective, and clinically beneficial medical technologies. That year, the Global Harmonization Task Force (GHTF) was founded with representation from the European Union, United States, Canada, Australia, and Japan. The effort continues today.

**REFERENCES**

1. Numerous sources were consulted for information relating to the U.S. Food and Drug Administration, including several derived from the FDA’s Web site, www.fda.gov. Among the sources are:
   
   
   
   c. “Off-Label” and Investigational Use of Marketed Drugs, Biologics and Medical Devices, www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116355.htm


**AUTHOR BIOGRAPHY**

A graduate of the University of Michigan, Mr. John Sulewski serves as the director of education and training for The Institute for Advanced Dental Technologies. As a consulting editor for the *Journal of Laser Dentistry*, he is also a member of the Academy of Laser Dentistry’s scientific sessions, certification, conference, ethics, communications, safety, science, and research, and awards committees. Having been involved in the laser dentistry field since 1989, Mr. Sulewski is a past recipient of the Academy’s distinguished service award, has obtained Advanced Proficiency in Nd:YAG and diode lasers as a Laser Safety Officer, and is a University of California Certified Dental Laser Educator. He is a member of the Academy of Laser Dentistry, the American Society for Laser Medicine and Surgery, and SPIE – The International Society for Optical Engineering. Mr. Sulewski may be contacted by e-mail at john.sulewski@we-inc.com.

**Disclosure:** Mr. Sulewski is director of education and training of The Institute for Advanced Dental Technologies. He has served as a consultant for American Dental Technologies; Continuum Biomedical; Incisive, LLC; and Millennium Dental Technologies.
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### U.S. FDA Marketing Clearances by Wavelength

**Carbon Dioxide**
- Intraoral Soft Tissue Surgery (Ablating, Incising, Excising, Coagulating)
- Aphthous Ulcer Treatment
- Tooth Whitening
- Sulcular Debridement
- Coagulation of Extraction Sites
- Laser-Assisted New Attachment Procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)

**Argon**
- Intraoral Soft Tissue Surgery (Ablating, Incising, Excising, Coagulating)
- Curing of Composite Materials
- Tooth Whitening
- Illumination for Caries Detection
- Illumination for Endodontic Orifice Location
- Soften Gutta Percha

**Ho:YAG**
- Intraoral Soft Tissue Surgery (Ablating, Incising, Excising, Coagulating)
- Caries Removal, Cavity Preparation, Tooth Etching
- Sulcular Debridement
- Treatment of Herpetic Lesions
- Pulpotomy as Adjunct to Root Canal Retreatment
- Tooth Preparation to Obtain Access to Root Canal, Pulp Extirpation, Root Canal Debridement and Cleaning, Root Canal Preparation including Enlargement
- Cutting, Shaping, Contouring and Resection of Oral Osseous Tissues (Bone)
- Apicoectomy Surgery
- Osteotomy, Osseous Crown Lengthening, Osteoplasty
- Root Canal Disinfection after Endodontic Instrumentation

**Er,YAG**
- Intraoral Soft Tissue Surgery (Ablating, Incising, Excising, Coagulating)
- Caries Removal, Cavity Preparation, Enamel Roughening
- Aphthous Ulcer Treatment
- Sulcular Debridement
- Pulpotomy as Adjunct to Root Canal Retreatment
- Tooth Preparation to Obtain Access to Root Canal, Pulp Extirpation, Root Canal Debridement and Cleaning, Root Canal Preparation including Enlargement
- Cutting, Shaping, Contouring and Resection of Oral Osseous Tissues (Bone)
- Apicoectomy Surgery
- Osteotomy, Osseous Crown Lengthening, Osteoplasty
- Root Canal Disinfection after Endodontic Instrumentation

**Nd:YAP**
- Intraoral Soft Tissue Surgery (Ablating, Incising, Excising, Coagulating)
- Pulpotomy as Adjunct to Root Canal Retreatment
- Tooth Preparation to Obtain Access to Root Canal, Pulp Extirpation, Root Canal Debridement and Cleaning, Root Canal Preparation including Enlargement
- Cutting, Shaping, Contouring and Resection of Oral Osseous Tissues (Bone)
- Apicoectomy Surgery
- Osteotomy, Osseous Crown Lengthening, Osteoplasty
- Root Canal Disinfection after Endodontic Instrumentation

**Diode**
- Intraoral Soft Tissue Surgery (Ablating, Incising, Excising, Coagulating)
- Aphthous Ulcer Treatment
- Sulcular Debridement
- Removal of Filling Materials as Adjunctive Treatment During Root Canal Procedures
- Pulpotomy as Adjunct to Root Canal Retreatment

**Diode-Pumped 2.01-micron**
- Intraoral Soft Tissue Surgery (Ablating, Incising, Excising, Coagulating)
SYNOPSIS
This article is the first of a two-part manuscript, and will offer some basic understanding of how erbium lasers interact with dental hard tissue. The points covered below include discussions about the thermal events, energy and power calculations, and how the laser radiation is delivered to the target tissue.

INTRODUCTION
Clinical lasers aid us in providing optimal treatment for our patients. As with any device, they work effectively only if basic principles of use are followed meticulously. For example, when using a high-speed handpiece, we ensure that the air pressure is set correctly, water flow is adequate, the bur is sharp, and our manipulation does not stall bur rotation or cause overheating of the tooth. Similar considerations, such as water spray, beam placement, and laser parameters, are necessary to use a dental laser efficiently without causing tissue damage.

The erbium family of lasers (Er,Cr:YSGG at 2780 nm and Er:YAG at 2940 nm) ablate both enamel and dentin efficiently under routine clinical situations. However, ablation efficiency is dramatically affected by a complex interaction of several parameters including proximity of the laser tip to the tissue surface, beam divergence, irrigation flow rate, laser energy level, pulse repetition rate, tip angulation, and tip condition. A series of studies was conducted to explore the relative importance of each of these factors.

METHODS AND MATERIALS
Recently extracted third molars were subjected to laser ablation using an Er:YAG laser (DELight, HOYA ConBio, Fremont, Calif.) with a wavelength of 2940 nm. An 80-degree, 600-micron diameter quartz tip was used with air and water spray. Tip-to-tissue distance was precisely controlled with a custom spacer as shown in Figure 1. A series of studies were conducted over the last four years on at least 100 different tooth specimens.

Suction was placed at approximately 1 cm from the surface to remove excess water during ablation without causing the surface to become dehydrated. Specimens were washed, dried, and weighed before and after treatment on a precision analytical balance (Sartorius CP64, Sartorius AG, Goettingen, Germany) with an accuracy of 0.1 milligram. Weight loss due to ablation was recorded, and mean and standard deviations were calculated.

Ablation of enamel was performed on the facial or lingual surface where the enamel structure is predictable. Root dentin was ablated, avoiding the apical third where dentin might not be fully formed. Dentin and enamel were ablated for 30 seconds under a variety of conditions in different studies.

FUNDAMENTAL CONCEPTS
The information here will be...
presented in the form of fundamental concepts describing the erbium laser’s interaction with dental hard tissues. While the studies discussed here were conducted with the aforementioned erbium:YAG laser, in the author’s experience, most of the conclusions can be generally applied to all erbium lasers. Although the following concepts are discussed individually for clarity, they are strongly interrelated.

1. **Er:YAG and Er,Cr:YSGG laser wavelengths interact with biological tissues in a similar fashion but with significant differences.**

The basic laws of physics apply to all erbium lasers. Ablation of enamel, dentin, and bone occurs through the explosive removal of tissue in a thermechanical event. Because laser energy of erbium wavelengths is very highly absorbed by water, the target tissue is rapidly superheated. When the steam pressure within the tissue exceeds the structural strength of the overlying material, micro-explosions occur, ejecting particles of fractured material, as shown in Figure 2. Considerable pressure is needed to fracture enamel and dentin so temperatures much higher than water’s normal boiling point of 100°C must be generated, a fact confirmed by Hibst and Keller. Ablation of enamel has been reported to occur at temperatures of 300°C to 400°C using Er:YAG and 800°C for Er:YSGG. (Note: A number of articles compare two erbium wavelengths, but many of those laboratory studies use an Er:YSGG laser with a wavelength of 2790 nm. The commercially available equivalent, manufactured by Biolase Technologies in Irvine, Calif., uses an Er,Cr:YSGG active medium with a wavelength of 2780 nm. In this author’s opinion, the 10-nm difference is insignificant for the concepts presented here.)

While explosion is dependent on the total amount of energy deposited in the tissue, it is critically dependent on energy absorption and pulse width. Although absorption coefficients for water are commonly used in ablation discussions (Er:YAG = 13,000 cm⁻¹ and Er:YSGG = 5,250 cm⁻¹, approximately), water is only a part of enamel (3% by weight, 12% by volume) and dentin (12% by weight, 25% by volume). Majaron et al. found an absorption coefficient for the Er:YAG laser of 150 mm⁻¹ for enamel and 200 mm⁻¹ for dentin. Perhavec and Diaici found the corresponding coefficients for the Er,Cr:YSGG laser were about three times lower. Therefore, they calculated Er:YAG energy penetration of 7 μm in enamel and 5 μm in dentin. Similarly, Er,Cr:YSGG energy penetrates 21 μm in enamel and 15 μm in dentin. Other authors report absorption coefficients for enamel at 480 cm⁻¹ for Er:YSGG and 800 cm⁻¹ for Er:YAG with corresponding absorption depth of 25 μm for Er:YSGG and 12 μm for Er:YAG.

It is apparent from these widely varying numbers that no consensus has been reached on values for absorption coefficient or the resultant energy penetration depth at the two commonly used erbium wavelengths. What is important is the concept of significantly higher absorption and, therefore, lower penetration depth for the Er:YAG laser compared to the Er,Cr:YSGG laser. The impact of these values on ablation is borne out in clinical application. Dispersing the energy through a larger volume creates a less vigorous explosion and more thermal diffusion. Two studies that used extracted teeth show Er:YAG to be more efficient than Er,Cr:YSGG in ablation rates and speed. While efficiency is not necessarily the most important determining factor in laser ablation, it minimizes the negative effects of thermal diffusion as discussed in the next concept.

2. **Diffusion of thermal energy is harmful and inefficient.**

Thermal relaxation is a very important factor to consider in soft tissue ablation but is detrimental in hard tissue applications. The concept of thermal relaxation asserts that energy will diffuse into surrounding tissue, moderating temperature changes at the target site and, thus, minimizing harmful effects. It assumes that the energy will be carried away to some noncritical location. In fact, for dental hard tissue, the opposite effect – thermal confinement – is both desirable and necessary.

All infrared laser radiation entering hard tissue is converted into heat or thermal energy and, ideally, most of that heat causes ablation. In a tooth, heat must not dissipate toward the pulp since even a small temperature rise can cause cell death. Zach and Cohen found that an increase in pulpal temperature of 5.6°C caused...
necrosis in 15% of teeth and an increase of 16.7°C caused necrosis in 100% of them. If thermal energy diffuses into surrounding enamel or dentin, it leads to dehydration and lowered ablation. Osseous tissue can also be damaged by heat; the collagen tissue begins to denature and coagulate at temperatures above 60-80°C.

The concept of thermal confinement asserts that, if incident energy is completely contained in a small volume of enamel, explosive ablation will occur. During this process, energy is ejected in the vapor and exploded particles, leaving little to affect the surrounding tooth structure. The shorter the pulse, the less the energy will diffuse before being ejected. Water coolant causes rapid diffusion of the remaining energy out of the tooth.

Table 1, compiled from data in the study of Perhavec and Diaci, illustrates the thermal effects of pulse width employed by the two different erbium wavelengths. As pulse width increases, surface temperature, residual heat (thermal energy remaining after the ablation event), and the depth to which the thermal energy penetrates increase. The percentage of incident energy that remains in the tooth after ablation more than triples as the pulse width increases from 150 µsec to 1400 µsec. Of course, the two erbium devices in the study have inherently different pulse durations; nevertheless, while these are different lasers, the trend is strongly suggested by different pulse widths within the Er,Cr:YSGG laser.

<table>
<thead>
<tr>
<th>Tooth Substance</th>
<th>Laser Type</th>
<th>Surface Temperature Change (°C)</th>
<th>Residual Heat (% of pulse energy)</th>
<th>Penetration Depth of Residual Heat (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enamel</td>
<td>Er:YAG</td>
<td>150 µsec</td>
<td>104</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Er,Cr:YSGG 500-700 µsec</td>
<td>176</td>
<td>9</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>Er,Cr:YSGG 1200-1400 µsec</td>
<td>200</td>
<td>13</td>
<td>30</td>
</tr>
<tr>
<td>Dentin</td>
<td>Er:YAG</td>
<td>150 µsec</td>
<td>64</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Er,Cr:YSGG 500-700 µsec</td>
<td>236</td>
<td>7</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Er,Cr:YSGG 1200-1400 µsec</td>
<td>251</td>
<td>9</td>
<td>22</td>
</tr>
</tbody>
</table>

This table shows that as pulse width increases, all three variables also increase significantly. Results are compiled from data by Perhavec and Diaci.

3. Hydroxyapatite does not contribute to ablation when erbium lasers are used.

While hydroxyapatite is a major secondary absorber of erbium energy, in the author’s opinion, it does not contribute to ablation; in other words, the primary erbium laser-tissue interaction is with water, as mentioned above. The mineral can absorb energy and then transfer the heat into the enamel or dentin, promoting dehydration and structural change. If sufficient energy is absorbed to raise the temperature to about 1100°C melting of the enamel will occur. It should be pointed out that erbium lasers are not indicated for enamel melting and their proper use will prevent that from occurring; moreover, some experimental carbon dioxide lasers are being studied for therapeutic enamel melting and recrystallization.

A simple experiment illustrates this point. Directing Er:YAG laser energy at a dried extracted tooth with no water spray using 240 mJ at 25 pps from a distance of 10 mm results in subablative irradiation. After about 10 seconds the tooth becomes too hot to hold, having reached approximately 200°C measured with an infrared pyrometer (Model MS6530, Precision Mastech Enterprises Co., Ltd., Shenzhen Huayi, Kowloon, Hong Kong, China). No ablation has occurred but a significant amount of energy has been absorbed. Moving even closer (5 mm) causes melting, charring, and overheating of the enamel, but still no true explosive ablation.

4. Emitted fluence is not uniform over the surface of the tip.

The spatial profile of the laser beam is not well understood. It is often, erroneously, assumed to be homogeneous with energy output uniform across the entire laser tip, commonly referred to as a “Top Hat” output. While this beam profile can be achieved with lenses, it is not the normal output from an optical resonator.

Most lasers emit in the “fundamental transverse mode” also called the “TEM00 mode.” This output is Gaussian in cross section (a symmetric “bell curve” shape) as it leaves the resonator. By the time the light is emitted, imperfections in the laser tip and the fiber-optic delivery system cause variation from this theoretical output, as shown in
Figure 3: Actual 3-dimensional output profile of an Er:YAG quartz tip analyzed with an Ophir Spiricon beam analyzer (Model SP503U, Ophir-Spiricon Inc., Logan, Utah). The vertical axis indicates relative energy density while the white ring represents an ideal Top Hat output. (Photo courtesy of Frank Yung, DDS)

Figure 3: The tip surface is further altered by damage during use.7

Significant amounts of subablativ energy are deposited into tissue on the fringes of the output, causing heating and dehydration instead of the desired ablation.

5. As the distance between the laser tip and the target tissue increases, the fluence decreases precipitously.

One of the most important concepts to understand is the effect of beam divergence on laser-tissue interaction. Erbium laser energy is transported efficiently from a resonating chamber, through a fiber-optic delivery system bundle, and finally through a quartz or sapphire tip to be delivered directly to the tooth surface. Once the energy leaves the application tip, it diverges rapidly, as seen in Figure 4a.

Beam divergence for the laser used in this study is reported in the manufacturer’s specifications as 230 mrad or 13.2 degrees (26.4-degree beam spread). Simple mathematical calculations (fluence = total energy/area, where area changes as a function of the square of the radius) show that fluence or energy density decreases precipitously in a very short distance, as seen in Table 2. At 2 mm tip-to-tissue distance, fluence has decreased by 68% from its level at the tip surface. At 3 mm, it has decreased by 78%, making tip-to-tissue distance a critical factor in laser use.

Manipulation of laser beam divergence is routinely done in industry to achieve a desired effect. In laser pointers, a focusing lens is used to collimate the output, minimizing divergence and allowing spot size to remain largely unchanged at long distances, as seen in Figure 4b. While this is essential to pointer function, it is rarely done with clinical lasers. A focused beam with constant spot size could cause as much damage/ablation at 2 meters as it does at 2 millimeters – an undesirable outcome. Instead, manufacturers use divergence to create a safe working environment.

Laser beams can be more extensively focused with optics, creating a small spot size at a single point with a diverging beam beyond, as shown in Figure 4c. The result is similar to starting a fire with a magnifying glass by focusing the sun’s energy on paper. The enormous energy densities produced are ideal for melting, cutting, and fusing metals but are not appropriate for biological tissues where the intention is to remove a relatively broad swath of tissue by explosive ablation.

Table 2: Decrease in Energy Density with Increased Tip-to-Tissue Distance

<table>
<thead>
<tr>
<th>Tip-to-Tissue Distance (mm)</th>
<th>Spot Area (mm²)</th>
<th>Fluence (% of contact value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 (contact)</td>
<td>0.2827</td>
<td>100</td>
</tr>
<tr>
<td>0.5</td>
<td>0.4012</td>
<td>70</td>
</tr>
<tr>
<td>1.0</td>
<td>0.5424</td>
<td>52</td>
</tr>
<tr>
<td>2.0</td>
<td>0.8860</td>
<td>32</td>
</tr>
<tr>
<td>3.0</td>
<td>1.3134</td>
<td>22</td>
</tr>
</tbody>
</table>

This table shows the theoretical decrease in energy density (fluence) with distance at a commonly stated beam divergence of 13.2°.
In a variation on this concept, some dental laser manufacturers (Fotona d.d., Ljubljana, Slovenia, EU; and Biolase Technology, Irvine, Calif.) now offer a noncontact “tipless” handpiece which focuses the laser beam in a zone about 2 mm long, located a few millimeters from the tip. An example is shown in Figure 4d.

Were it not for the next concept of ablation threshold, beam divergence would be of little consequence. If the spot area is tripled, as occurs at 2 mm tip-to-tissue distance vs contact (see Table 2), the fluence would be one-third but the total energy would be the same. Therefore, ablation would be one-third as deep but cover three times the area for the same total ablation. Ablation threshold is the primary reason that this does not hold true.

6. Energy is needed to reach the ablation threshold.

Ablation threshold is defined as the minimum energy density required to initiate an explosive removal process. Below this level, all energy is absorbed as heat and dissipated into surrounding areas. As mentioned above, there is an amount of energy needed to bring the water contained in the tissue to a boil and further energy is required to create the pressure necessary for fragmentation of the enamel or dentin particles.

Apel et al. found a fluence of 9-11 J/cm² using the Er:YAG laser and 10-14 J/cm² using the Er:YSGG laser as the ablation threshold of enamel. For purposes of our discussion a threshold value for enamel of 10 J/cm² will be assumed. Measuring energy in joules/cm² has little meaning in our dental context with 600-micron diameter tips. A more appropriate measurement system translates 10 J/cm² into 100 mJ/mm². With a 600-µm tip (0.2827 mm²), the total threshold energy required per pulse would be 28 millijoules if the tip were placed in contact with the enamel.

In contact: Threshold energy = 100 mJ/mm² x 0.2827 mm² = 28.27 mJ.

At a 3-mm distance, the total threshold energy has increased to 131 millijoules per pulse.

At 3 mm: Threshold energy = 100 mJ/mm² x 1.31 mm² (spot area at 3 mm) = 131 mJ.

Table 3 shows the effect of tip-to-tissue distance on total energy that must be supplied before ablation can begin.

When water spray interposes, absorption and scattering will occur, significantly modifying the beam profile and affecting the energy density actually reaching the tooth surface. Any part of the beam that does not exceed the levels in Table 3 will not cause ablation.

7. Tip-to-tissue distance has a profound effect on ablation.

As a result of the previous two fundamental concepts, actual clinical ablation of any tissue by any erbium laser is highly dependent on tip-to-tissue distance. Only energy above that needed to reach threshold can be used for ablation. As tip-to-tissue distance increases, spot size also increases through beam divergence and total threshold energy increases as described above. If the energy illuminates twice the area, twice as much energy must be expended to reach the threshold.

Majaron et al. showed in their in vitro study that having a gap between the tip and tissue increased enamel ablation significantly. They suggest an optimal gap of 0.3 to 0.6 mm for enamel. Theoretically, this would allow debris to exit the gap and allow more water in to flush accumulated debris. As the distance exceeds 1 mm, decreases in energy density as well as absorption by and refraction from interposed water will exceed the advantages of debris clearance.

The theoretical calculations in Table 2 and Table 3 suggest significant effect on ablation by increasing tip-to-tissue distance. This theory is supported by empirical results as shown in Figure 5. Beyond 3-mm tip-to-tissue distance all ablation ceases. A deceptive “popping sound” still occurs but it only represents explosion of intervening water.

8. Peak power is more important than average power.

One watt of average power is one joule of energy delivered over one second. The energy may be delivered evenly throughout that second or turned on and off any number of times. The term “peak power” creates an image of an ultimate level that is rarely achieved. It is, in fact, the power emitted any time that the laser pulse is on.

The currently available erbium

<table>
<thead>
<tr>
<th>Tip-to-Tissue Distance (mm)</th>
<th>Total Threshold Energy (mJ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 (contact)</td>
<td>28</td>
</tr>
<tr>
<td>0.5</td>
<td>40</td>
</tr>
<tr>
<td>1.0</td>
<td>54</td>
</tr>
<tr>
<td>2.0</td>
<td>88</td>
</tr>
<tr>
<td>3.0</td>
<td>131</td>
</tr>
</tbody>
</table>

This table shows the theoretical total ablation threshold energy per pulse in enamel at different tip-to-tissue distances based on a threshold of 10 J/cm² per Apel et al.
Lasers offer pulse durations ranging from 50 µsec to several hundred µsec. These short pulse widths create high peak power, since the calculation divides the energy per pulse by the pulse duration. This “peak power” can be in the hundreds or thousands of watts, although the average power may be in single digits. For example, in a 250-µsec pulse at 25 pulses per second and 240 mJ/pulse that is commonly used to ablate enamel with an Er:YAG laser, the average power would be 6 watts (0.24 J/pulse x 25 pulses/sec = 6.0 J/sec = 6 watts). Since 240 mJ is delivered during the pulse “on time” of 250-µsec duration, peak power is 960 watts (0.24 J / 0.000250 sec = 960 watts).

If pulse width were narrowed to 100 µsec, peak power with the same 240 mJ of energy would be increased to 2,400 watts (0.24 J / 0.00001 sec = 2,400 watts).

9. Ablation is directly proportional to pulse repetition rate.

Currently available dental lasers offer the ability to adjust the pulse repetition rate from as few as 3 to as many as 50 pulses per second. If both pulse width and energy per pulse are kept constant, increasing the pulse repetition rate will increase total energy and, thus, ablation rate. Figure 6 shows a linear increase in ablation with increased pulse rate. These results suggest that there is no “optimal” pulse rate. However, the pulse duration as well as the pulse repetition rate must be kept in mind so that ablation proceeds efficiently as well as safely.35

CONCLUSION

The fundamental concepts discussed here provide a basis for making scientifically supported clinical decisions. The next part of this paper will explore the effect of commonly encountered clinical variables on ablation efficiency through practical experiments.

AUTHOR BIOGRAPHY

Dr. Wayne Selting holds a bachelor’s degree in electrical engineering and a Master’s degree in biomedical engineering from Marquette University, as well as a Doctor of Dental Surgery degree from Creighton University. He is the former chief of biomedical engineering for the U.S. Army Institute of Dental Research in Washington, DC and a former consultant on Biomedical Engineering to the Army Medical Research and Development Command. Dr. Selting has been a special lecturer on the faculty of the U.S. Army Dental Postgraduate School and the George Washington University. He now maintains a laser and cosmetic practice in Colorado Springs, Colorado and conducts independent research on dental lasers. Dr. Selting may be contacted by e-mail at wselting@aol.com.

Disclosure: Dr. Selting has no commercial relationships relative to this paper.

REFERENCES


The Pending Zone: Managing the Compromised Periodontal Patient

Mary Lynn Smith, RDH, McPherson, Kansas

INTRODUCTION

Patients with advanced periodontal disease often find themselves in a “Pending Zone.” Restorative or prosthetic treatment is postponed because the patient has not chosen to take the next step of treatment or the next step may be clinically unclear. Periodontal infection therapy during the interim is valuable and could change the course of treatment. How the patient’s oral health is managed in the “Pending Zone” is determined by the patient’s desires and commitment to treatment, the treatment options and possible results, and continued evaluation throughout treatment.

Open communication will help define success for both the patient and clinician. Most patients know their dental condition is compromised by the time they come for an evaluation. Some have a preconceived idea of needed treatment but have little understanding of other possible options. The periodontally compromised patient in particular needs treatment goals clarified. Because the bone loss is severe, treatment may be a progression of steps. Periodontal therapy, as one of the steps, is meant to stabilize the current disease by reducing the inflammatory processes and eliminating active infection. Preserving comfort and function, as well as providing time to determine the desired course of treatment, are also essential objectives. The following critical areas should be considered when shaping treatment: esthetics, quality of life, compromised health issues, function, treatment prognosis, patient compliance/motivation, and required treatment time. Inviting honest discussion about dental concerns, hopes, and fears builds the relationship needed between the patient and clinician. When expectations are matched, trust and harmony result.

Excellent treatment planning builds on the foundation of comprehensive clinical evaluation yet pivots on the patient’s ideas of successful treatment. Components of the comprehensive evaluation are:

- Radiographs
- Periodontal charting (pocket depths, recession, clinical attachment loss, hemorrhaging, furcations, and mobility)
- Restorative charting
- Temporomandibular joint and occlusal relationship evaluation
- Risk assessment for caries and periodontal disease
- Pathogenic testing
- Systemic health issues that may require collaboration with the patient’s physician and additional testing (HbA1C [glycated hemoglobin, for diabetes], CRP [C-reactive protein assay, for inflammation], genetic testing).

Additional considerations for designing treatment include:

- What are the patient’s physical tolerances (i.e., length of appointments, pain threshold, anxieties)?
- Is sedation desired (i.e., IV sedation, conscious sedation, nitrous oxide)?
- What kind of anesthetic is needed (i.e., local anesthesia, topical anesthesia)?
- How can scheduling be accommodated by the patient and practice?

Nonsurgical periodontal infection therapy may occur as a series of appointments coordinated with restorative treatment or in a separate treatment phase with an expanded treatment design or full-mouth debridement within 24 hours. The severity of periodontal disease and the amount and
quality of calculus affect the treatment planning as well.

The following cases illustrate various treatment paths chosen by patients. Each case was discussed thoroughly in a consultation. Patients were counseled that they had the option to stop or change the course of treatment at any time. The dentist, hygienist, and patient continually evaluated and qualified success according to criteria discussed in the consult prior to treatment. The results indicated the next treatment phase.

**CASE 1**

The first patient had a general attitude of “get ‘em out and get on down the road!” He is a 57-year-old who presented with a missing maxillary anterior bridge and wanted upper teeth replaced by the weekend. He was not interested in periodontal therapy, yet he wanted to maintain his lower teeth as long as possible. He chose to have the maxillary arch restored with implant-supported bridges (Figure 1). The plan was for him to return for hygiene care every 3 months.

He returned sporadically over the next 2 years (Figure 2). With further deterioration, he was ready for treatment of the mandibular arch—ex Extractions and implants with an abutment-supported denture (ANKYLOS® SynCone®, Dentsply Friadent, Mannheim, Germany) (Figure 3). He falls into the “Mr. Noncompliant” category and comes every so often for dental visits.

**CASE 2**

The second patient, 54 years old, wanted to know her options. She felt sure she would have to wear dentures but was hesitant. Her concerns were centered around the fact she is a performing artist and a denture is likely to change her speech as well as resonance when singing. There were immediate treatment needs to address prior to considering periodontal treatment if she were to opt for delaying dentures (Figure 4). Challenges of her case were numerous. The posterior teeth were in bilateral crossbite and the anterior teeth in an open bite (Figure 5); the amount of bone loss was extensive; her daily care was fair; and she smokes approximately 1/4 to 1/2 pack per day. Her stress was elevated due to unemployment. The patient wanted to try to saving her teeth and was undaunted by the proposed treatment plan.

Teeth #2 and 18 were extracted, and even though several teeth were fractured, the next priority was to begin minimizing the inflammation and infection of soft tissues rather than undertake restorative treatment. The patient agreed to nonsurgical laser-assisted periodontal therapy followed by maxillary surgery after primary resolution. The pretreatment periodontal chart is shown in Figure 6, and therapy was completed in one day for a total treatment time of 5 hours. The following month, teeth #6-11 were splinted prior to surgery. The flap surgery and open debridement employed a laser, manual and ultrasonic instrumentation. The lower arch was debrided with manual and power instrumentation and decontaminated with a laser. A micropulsed 10,600-nm CO₂ laser (Smart US20D, DEKA Laser Technologies, Inc., Carlsbad, Calif.) was used throughout treatment. A 400-micron ‘periodontal tip’ was used with parameters of 50 Hz and an
average power range of 1.7-2.0 W. Follow-up biofilm removal and laser decontamination followed at intervals of 10-14 days until complete. After 12 weeks full periodontal assessment was charted. Areas of redebridement and additional laser decontamination follow-up were needed. Supportive care consisted of 8-week intervals to provide evaluation of daily biofilm removal, professional ultrasonic biofilm removal, and laser decontamination.

This case began with 81 bleeding-on-probing sites, 107 pockets measuring 4 mm or greater, and all 23 teeth exhibiting pocketing. At one year, the patient experienced improvements of 88% in bleeding, 57% in pocketing, and 17 of 23 teeth with pocketing. See Table 1.

The patient is pleased she has gained better health with therapy. When considering the current panoramic radiograph (Figure 7) and other imaging data (not shown), the maxillary arch still seems hopeless. The patient’s choice is to continue short-interval hygiene appointments and pursue upper extractions and a denture as the next step.

**CASE 3**
The third patient is one whose teeth have been extracted one at a

<table>
<thead>
<tr>
<th>Table 1 (Case 2)</th>
<th>Bleeding</th>
<th>Periodontal Pockets (≥ 4 mm)</th>
<th>Number of Teeth Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>81</td>
<td>107</td>
<td>24 of 24</td>
</tr>
<tr>
<td>12 Months Later</td>
<td>10</td>
<td>46</td>
<td>17 of 23</td>
</tr>
<tr>
<td>% Improvement</td>
<td>88%</td>
<td>57%</td>
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<table>
<thead>
<tr>
<th>Table 2 (Case 3)</th>
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<th>Periodontal Pockets (≥ 4 mm)</th>
<th>Number of Teeth Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>89</td>
<td>131</td>
<td>25 of 25 (all teeth present affected)</td>
</tr>
<tr>
<td>4 Months Later</td>
<td>43</td>
<td>90</td>
<td>25 of 25</td>
</tr>
</tbody>
</table>

Nd:YAG laser (PulseMaster 600IQ, American Dental Technologies, Corpus Christi, Texas) was used with a 400-micron fiber. Laser bacterial reduction was accomplished at parameters of 30 mJ and 60 Hz (1.8 W) followed by coagulation with parameters of 100 mJ and 20 Hz (2.0 W).

Prior to laser-assisted therapy, data showed improved parameters, as shown in Table 2.

Supportive care continued approximately every 10 to 12

---

Figure 6: Periodontal probe chart of Case 2 at initial presentation (pocket depths on first line, next to tooth icons) and one-year postoperative results (pocket depths on second line)

Figure 7: One-year post-treatment panoramic radiograph of Case 2. Note molars with hopeless prognosis (teeth #2, 14, 15, 18, and 31) have been extracted and with good osseous repair. There is some radiographic evidence of bone fill in some of the existing pockets, compared to Figure 4.

Figure 8: Anterior view of Case 3 at initial presentation

Figure 9: Initial radiographs of Case 3 at initial presentation
weeks. A year later, another tooth had been extracted and full retreatment using a different laser wavelength was completed. Data improved, as seen in Table 3.

Supportive care continued approximately every 10-12 weeks for a total of 7 months of laser-assisted treatment. Fifteen months after the start of treatment, another tooth had been extracted and full re-treatment using a different laser wavelength (the CO₂ described above) was completed. Eighteen months after initial treatment, the CO₂ was used again. Data improved.

Even more interesting is how the pocket depths were changing. Pockets depths changed (see Table 4).

He continues supportive care at approximately 10 weeks and is currently maintaining fairly well (Figures 10-11). An implant has been placed in the tooth #13 area. Tooth #12 is the next planned extraction. Other areas showing advanced compromise are being treated periodontally and being monitored. Implants are being strategically placed in order to eventually support a maxillary denture.

**Case 4**

The last case is one motivated by the patient’s immediate health concerns and emotional dread of moving into dentures. She knew her dental health was extremely challenged with significant disease, but she was hoping for “just one more year.” At 63 years old, she originally presented with pain on tooth #10, which was extracted. A graft was placed in preparation for an implant, but failed. Her general health was showing compromise through repeated sinus infections, urinary tract infections, and chronic fatigue. Antibiotics almost always caused a yeast infection. With her return visit, radiographs were taken (Figure 12); the surgical site of tooth #10 was examined, and she agreed to an evaluative hygiene visit. She was able to discuss her dental future and wanted options. She wanted to buy time, even if it were only 12 months, if there were a possible treatment option. Esthetics were not as much of a concern as her health and function. She chose maxillary full-flap surgery and debridement using manual and ultrasonic instrumentation and laser decontamination. Her treatment was scheduled in 3 sessions—upper right, upper left, and lower arch. The previously described micropulsed CO₂ laser was used throughout her treatment. Continued home care refinement, ultrasonic biofilm removal, and laser decontamination were completed every week for 4 weeks. Figure 13 shows her smile at this point. Then 6-week appointment intervals were scheduled for the next year. These appointment services alternated a reinfection assessment appointment type (plaque management evaluation

### Table 3 (Case 3)

<table>
<thead>
<tr>
<th></th>
<th>Bleeding</th>
<th>Periodontal Pockets (≥ 4 mm)</th>
<th>Number of Teeth Involved</th>
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<tr>
<td>15 Months Later</td>
<td>53</td>
<td>87</td>
<td>24 (one tooth extracted)</td>
</tr>
<tr>
<td>18 Months Later</td>
<td>31</td>
<td>59</td>
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### Table 4 (Case 3)

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<th>4-mm sites</th>
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<tr>
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<td>40</td>
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<td>12</td>
<td>11</td>
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</tr>
<tr>
<td>TO:</td>
<td>38</td>
<td>13</td>
<td>4</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>
and ultrasonic biofilm removal with laser decontamination) and a supportive care appointment type (complete periodontal maintenance including laser decontamination). At one year, appointments continued with supportive care at 10-week intervals.

After 2.5 years, the improvement has been significant. She states that her health has improved with no urinary tract infections, only 1 sinus infection, and a return of normal energy. Esthetics are less than ideal in this case; however, the patient’s lip line shows minimal crown length, and the tissue tone is acceptable (Figure 14). She has no sensitivity and minimal mobility on localized teeth. The maxillary periodontal chart is shown in Figure 15 and the mandibular arch in Figure 16. Periodontal data shows improvements, as seen in Table 5.

Plans are being made for restorative treatment, beginning on the lower right. She continues her supportive periodontal care at 12-week intervals. She has absolutely no regrets for pursuing this treatment path.

**CONCLUSION**

Periodontally compromised patients may or may not have to pursue restorative or prosthetic treatment right away. Varying levels of care may be provided while other treatment is pending. It is critical that the patient be educated on periodontal treatment options and prognosis. The dentist, hygienist, and patient need to continually evaluate, qualify, and quantify success according to criteria discussed in the consult prior to treatment. The results indicate the next treatment phase. Identifying what is success in the patient’s eyes is significant. Success is not always resolving pocket depths. Sometimes success is bringing the patient to a healthier state in order for them to take the next step. The hygienist is an integral part of this transition. Patients who understand the treatment options and related prognosis prior to beginning therapy usually continue with recommended treatment.

**Table 5 (Case 4)**

<table>
<thead>
<tr>
<th></th>
<th>Bleeding</th>
<th>Periodontal Pockets (≥ 4 mm)</th>
<th>Number of Teeth Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>56</td>
<td>95</td>
<td>22 of 23 (96%)</td>
</tr>
<tr>
<td>30 Months Later</td>
<td>4</td>
<td>8</td>
<td>8 of 21 (38%)</td>
</tr>
<tr>
<td>% Improvement</td>
<td>93%</td>
<td>92%</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 14**: Two-and-one-half-year post-treatment view of Case 4

**Figure 15**: Maxillary periodontal chart of Case 4. Initial pocket depths at presentation are on the first line, next to tooth icons, and 2.5-year post-treatment measurements are on the second line. Significant pocket reduction has taken place, and almost all of the bleeding and inflammation areas have been eliminated.

**Figure 16**: Mandibular periodontal chart of Case 4. Initial pocket depths at presentation are on the first line, next to tooth icons, and 2.5-year post-treatment measurements are on the second line. Similar to the maxillary arch shown in Figure 15, all pockets have been reduced; and the bleeding areas are almost all eliminated.
AUTHOR BIOGRAPHY
Ms. Mary Lynn Smith is a registered dental hygienist, working clinically for more than 14 years. She achieved Standard Proficiency for the Nd:YAG (1,064 nm) and diode (810 nm) laser wavelengths in 2003 and Advanced Proficiency in Nd:YAG in 2007. Ms. Smith has contributed to the dental community through articles and speaking to fellow hygienists on care of implants, periodontal therapies, and laser-assisted hygiene techniques and principles. She currently resides in McPherson, Kansas, and is employed by Jon Julian, DDS and Brian Kynaston, DDS. Ms. Smith may be reached by e-mail at mlsrdh@swbell.net.

Disclosure: Ms. Smith receives honoraria from DEKA Lasers.

Smith
Diode Lasers and Computer-Aided Design and Manufacturing (CAD/CAM) Dentistry: A Perfect Marriage of Two Advanced Technologies
Eugene L. Antenucci, DDS, FAGD, Huntington, New York
J Laser Dent 2009;17(2):100-103

SYNOPSIS
This article describes the adjunctive use of a diode laser with computer-aided design and manufacturing technology. The laser helps to create a clean, bloodless area for an accurate digital optical impression.

INTRODUCTION
Diode lasers have proven to be a highly successful technology with numerous applications in dentistry, providing practitioners and patients with a wide range of soft tissue surgical procedures. During restorative dentistry, soft tissue lasers can be used for gingival periodontal tissue management, providing good hemostasis and a reduction of bacteria. As with other soft tissue lasers, it has been reported that the diode laser offers precision during gingival contouring and that healing usually occurs uneventfully. For example, the diode laser wavelengths are routinely used for sulcular preparation prior to an impression. In the author's experience, the soft tissue can be expected to heal unremarkably, and without postoperative pain and discomfort or postoperative loss of gingival margin height.

The majority of dental impressions taken are physical impressions which utilize trays filled with materials that are injected around the prepared and unprepared teeth, and which harden following a chemical reaction after several minutes. The impressions require a laboratory procedure to create a set of hard models and a second procedure to articulate the models. Once an articulated set of models is available, the lab technician can then fabricate the desired restoration from the prescribed materials — commonly with metallic copings and a ceramic veneer. The entire restorative process from the date of preparation and impression to completion averages 2 weeks with most laboratories, during which the patient is temporized.

The introduction of chairside and laboratory-based Computer-Aided Design / Computer-Aided-Manufacturing (CAD/CAM) technology in dentistry has radically changed the paradigm and has significantly altered the manner in which dentists are able to approach the restorative workflow. It has also allowed for the introduction and utilization of nonmetallic copings which can then be veneered with ceramics, as well as monolithic ceramic restorations which are milled.

FUNDAMENTALS OF CAD/CAM
The CAD/CAM process involves acquiring an image with a digital scanning device that is linked to a computer. In restorative dental applications, the digital image replaces traditional impression-taking techniques, with the acquired image serving as the basis for designing various types of restorations. After the restoration is designed, computer software converts the information into data that is used by a milling machine to create restorations from the selected materials.

CAD/CAM has been clinically utilized in restorative dentistry since 1985 with the introduction of CEREC I by Drs. Mörmann and Brandestini. They coined the term CEREC, which stands for "computer-assisted CERamic REConstruction." CAD/CAM, however, realized a very slow start in restorative dentistry. Laboratory standards of impressions, wax-ups, castings, and ceramics were familiar and accepted by dentists and technicians. CEREC I, though an exciting concept, required a high degree of technical knowledge regarding the use of computers. Unfortunately, the technology was relatively difficult to use, and the results were not comparable to what was available by laboratories at the time. Moreover, computers were not in common use, and dentists and laboratory technicians saw no compelling reason to seriously consider CAD/CAM as a viable alternative for commonly used techniques in restorative dentistry.

Over the past several years a revolution has quietly occurred.
Computers have become widely used for dental imaging, diagnosis, education, and management; and dentists have increasingly become familiar with the use of computers and digital photographic techniques. Today the speed, memory, and capacity of computers today is high, and the relative cost is low; and that has allowed for sophisticated CAD/CAM software which is relatively simple to use.

Meanwhile, some patients are placing a high degree of value on esthetics, while trying to assess the continued controversy regarding mercury content in amalgam fillings. For practitioners, adhesive technology has matured to the point where restorations can be bonded to enamel and dentin rapidly, predictably, and with the expectation of long-term service.

The confluence of these factors has contributed to CAD/CAM’s rise to acceptance in dentistry, both in chairside restorative- and laboratory-based applications. Chairside design and in-office fabrication of restorations allows doctors to enjoy complete control over the restorative and laboratory process, with very efficiently produced, high-quality esthetic restorations.

There are several types of CAD/CAM systems in use in restorative dentistry today:

1. **In-office imaging and fabrication systems** which allow for the fabrication and delivery of single-visit restorations. Examples of these systems are CEREC AC (Sirona Dental Systems GmbH, Bensheim, Germany) and E4D (D4D Technologies, LLC, Richardson, Texas).

2. **In-office imaging-only systems** that allow dentists to replace impression materials by taking digital impressions, which are then transmitted to a commercial laboratory. The laboratory may or may not use a computer milling system for the restorations. Examples of these systems are iTero™ (Cadent, Carlstadt, N.J.) and the Lava™ Chairside Oral Scanner C.O.S. (3M ESPE, St. Paul, Minn.). CEREC AC is also marketed as an imaging-only system.

3. **Laboratory-based and centralized manufacturing facility** CAD/CAM systems. Examples are inLab-System by Sirona, Procera® (Nobel Biocare Holding AG, Zürich-Flughafen, Switzerland), and Lava by 3M ESPE. There are many laboratory-based systems in use in laboratories around the world.

**CLINICAL WORKFLOW**

The clinical workflow for CAD/CAM imaging and fabrication systems uses a plan similar to conventional indirect restorations, and is illustrated in Figure 1. The patient is anesthetized, the tooth is prepared with the carious lesion and/or defective restoration removed. The next step is to capture an optical image of the preparation. The author uses the CEREC system which requires a light spray of imaging powder to make the teeth optically reflective. (The ED4 system does not require the use of powder.) After the digital impression is completed, a bite registration is taken with conventional material and then it is captured. The optical images are displayed on the computer screen and a virtual model and die is available for custom design of the restoration. Once designed, the digital restoration is transmitted to a milling chamber. A ceramic material is selected and is then milled. The finished restoration is prepared for bonding and luted to the tooth. Adjustments to occlusion are made intraorally, and final polishing and finishing complete the process. Single restorations typically take 60 to 75 minutes from the time the patient is seated to the time the patient is...
THE ROLE OF THE DIODE LASER

For CAD/CAM to be optimally utilized, tissue and moisture at the preparation margins must be controlled. If the system employs a powder, blood and saliva will also be coated. In addition, the camera does not distinguish debris and gingiva from sound tooth structure. At this point, a diode laser is indispensable for retracting the soft tissue and managing bleeding to ensure a predictably accurate optical impression. Figures 2 and 3 illustrate the difference between an unacceptable and inaccurate impression and a usable one.

The author uses an 810-nm diode laser (Odyssey 3Watt, Ivoclar Vivadent, Amherst, N.Y.) at a power setting of 0.5 to 1.0 W at a continuous wave setting for approximately 30 seconds total time. The laser creates a circumferential trough at the restoration’s margin while providing hemostasis. Figures 4-7 illustrate the laser’s ability to provide good visibility of the margins of the preparation with excellent hemostasis in the soft tissue. The laser can also be used for contouring the marginal tissue in a crown lengthening procedure. Figures 8-12 show the laser removal of facial gingival tissue to improve the esthetics of the lateral incisor. After the veneer preparation is completed, the laser is again used to ensure hemostasis so that an accurate digital impression can be taken. The laser parameters described above were used for both procedures. The restoration is fabricated with the CAD/CAM technology and delivered. A one-year post-treatment view (Figure 12) illustrates the good-fitting restoration with healthy periodontal tissue.

SUMMARY

The use of a soft tissue laser is essential for the success of CAD/CAM technology in managing soft tissue around the margins of preparations. The author prefers using a diode laser as illustrated in this article. The utility of the laser to provide excellent hemostasis and easy contouring and troughing of the gingival tissue provide a clean and clearly visible site for an accurate digital optical impression. The computer fabrication can then
confidently proceed and the resulting restoration should be clinically successful.

**AUTHOR BIOGRAPHY**

Dr. Eugene Antenucci is a 1983 graduate of the New York University College of Dentistry. He served as a clinical instructor at the New York University College of Dentistry in the Department of Prosthodontics and Occlusion, and as an assistant clinical professor at the School of Dental Medicine at the State University of New York Stony Brook in the Department of General Dentistry. Currently, he serves as an attending dentist at Montefiore Hospital and Medical Center. Dr. Antenucci maintains a full-time private practice in Huntington, New York, where his state-of-the-art dental facility serves the patients of Huntington, and also is home to a continuing dental education training center for dentists as well as a commercial dental laboratory. Dr. Antenucci is a certified CEREC basic and advanced training instructor, and has conducted training seminars throughout the United States. He has worked with dental lasers since 1990, and with CEREC technology since 1996. Dr. Antenucci may be contacted by e-mail at laserdocc@mac.com.

**Disclosure:** Dr. Antenucci is a certified advanced and basic CEREC trainer for Patterson Dental.

**REFERENCES**

Education in Laser Dentistry: A Necessity, an Optional Extra, or an Irrelevance?

Steven Parker, BDS, LDS, RCS, MFGDP, Harrogate, United Kingdom

J Laser Dent 2009;17(2):104-105

There is a quintessentially egocentric comfort in the recollection of having graduated in dentistry – or to be more precise, successfully completed the undergraduate university curriculum in dentistry – in that there was no further need for study or examination! Sadly, or correctly, the process of learning to practice dentistry begins with graduation. Far from further study or qualification, there is the requirement of ongoing revalidation of our practicing rights and privileges, the compliance with a whole range of regulations pertaining to the physical provision of dentistry in general practice, not to mention the personal election of postgraduate education chosen to further areas of specialty or interest.

The real test of the value of certification in laser dentistry has yet to be determined; possibly through adoption of a university-based curriculum and graduation (at least one Master of Science degree in laser dentistry program is available at RWTH Aachen University in Germany1), or the consequence of a high-drama lawsuit, such value remains to be formally assigned. Until then, except currently in the States of Nevada, Arizona, and Louisiana, a dentist can purchase and use a laser for patient care without any educational requirements of licensure.

The prime tenet of the Hippocratic Oath (a possibly anachronistic declaration for medical graduates) remains “do no harm.” This may be similarly adopted by other areas of primary health care, as we all owe our patients the right to expect treatment that is within our level of competence and our scope of practice, and that is provided as an evidence-based “best option” for the presenting condition. One way in which harm can be avoided in laser use is to achieve and be able to demonstrate a meaningful level of certification.

Of course, there remains the question “what level of competence is sufficient?” Whether it is the thoughtful, expert manipulation of technique and materials that results in an exquisite dental restoration, or the compassionate expertise in treating a nervous patient, there is rightful celebration and applause for the clinician who demonstrates “mastery” of dentistry. The maxim “to know is to use – to understand is to empower” provides the distinction that sets “excellence” apart from inferior comparatives.

The use of lasers in dentistry and the development of dental implants are two modern examples of clinical practice that have challenged the hitherto conventional undergraduate curriculum. Both areas of treatment have essentially developed “outside” mainstream university teaching, both may be technically challenging, and both are best represented in the hands of the clinician who both knows and understands all aspects of the treatment modality.

One of the commonest areas of first exposure to laser use is seen in the currently popular “weekend” course on the provision of “make-over,” minimal-preparation veneers. Notwithstanding the value of such treatment, the course may present a step-by-step guide to the methodology of treatment and marketing. Often, some consideration of surgical gingival management may be presented, for which a laser is often suggested as the best instrument. From such, audience enthusiasm may result in increased sales of soft-tissue laser units, the use of which is often relegated to a gingivoplasty procedure in the hands of a possible novice practitioner. And yet, nowhere could the consequence of lack of understanding and expertise be more exposed than in the poor outcome of ill-chosen parameters in such an important cosmetic exercise.

Equally, is it acceptable for us to glibly accept that our personal “learning curve” toward self-taught expertise should be littered with a series of errors in judgment or ability, or the realization of patients who have suffered? The business of dentistry is sustained through the attraction and profitable treatment of patients, yet our core responsibility is to uphold our practicing license through the provision of competent, ethical, and proportionate treatment for our patients, within an area of expertise – not “experimentation.” An acceptable level of competence can therefore be justified and perhaps best defined as one that employs objectivity and a core of knowledge, and is measurable.

Historically, the single expression of the attempt to apply such competence has been the Curriculum Guidelines and Standards for Dental Laser Education.2 The first two lines of the document’s Statement of Purpose provide unequivocal evidence as to its importance and application: “This document
provides guidelines to assure safe and efficacious use of lasers for the health and welfare of the patient. It establishes the standards of education in the use of lasers in dentistry and defines standards for the demonstration of competency.”

This document was adopted by the Academy of Laser Dentistry (ALD) and has been endorsed by more than 100 dental and health organizations, universities, and manufacturers worldwide. It has formed the backbone of the ALD’s three main educational levels: Introductory, Standard, and Advanced. The latter two levels of competence are measurable through examinations and recognized through certification. The Academy has prided itself in its Standard Proficiency course as the standard of care in treating patients.

Other organizations have offered certification, with or without recognition of the Curriculum Guidelines, and individual laser manufacturers have provided device-specific training courses to supplement their laser products.

With multiple educational venues available, the new or inexperienced laser user may not be able to choose the best option. Moreover, standards of competence should be able to be applied to those offerings to determine their value so that the clinician can be assured of an equivalent and reciprocal certification.

The primary focus in this discussion must be the patient receiving laser therapy. That person must be assured of the dedication of his or her practitioner to the use of lasers in general and of that particular laser for a particular procedure.

The practitioner must acknowledge his or her responsibility to the patient; there must be an accumulation of appropriate knowledge pertaining to laser use in dental practice and the opportunity grasped to integrate the specific instrument within a broader range of devices / laser wavelengths. Commensurate with the requirements of continuing education, the practitioner is entitled to the opportunity to associate laser education with Continuing Education requirements or affiliation with other organizations, e.g., the Academy of General Dentistry. Additionally, there should be a dedicated, structured education pathway leading to appropriate certification.

Key to a beneficial relationship between a laser company and clinician is the metaphorical triumvirate of an excellent product, appropriate sustainable support, and evidence-based grounding in theoretical and applied knowledge of laser use. Laser manufacturers strive to temper the desire for instrument sales with responsible training, and the successful firms achieve this. However, what better endorsement of a given laser is there than the approval of a clinician who deduces excellence through detailed, science-based comparison? Correspondingly, manufacturers’ training in device-specific laser use should be ideally complemented by a broader level of background knowledge.

The Academy of Laser Dentistry has been accused of being too rigid, too dogmatic, elitist, and out of touch in a dental world that is driven by material gain. It remains one of the few organizations worldwide that offers multilevel, objective education that is designed to provide competence in laser dentistry as a whole, as opposed to single laser machines or wavelength. The Academy will continue to develop new opportunities for laser dentists and hygienists to source their education through differing routes; to eventually qualify for a measured level of competence as part of a progressive, positive framework, ultimately designed to make laser dentistry safer and more effective for the patient.

It is hoped that all clinically oriented stakeholders in laser dentistry will acknowledge their individual responsibilities within the collective need to protect the patient, and work toward this essential goal.

REFERENCES


Editor’s Note: The following three abstracts are offered as topics of current interest. Readers are invited to submit to the editor inquiries concerning laser-related scientific topics for possible inclusion in future issues. We’ll scan the literature and present relevant abstracts.

THE USE OF LASERS FOR TISSUE RETRACTION FOR IMPRESSION

In his discussion of the role of diode lasers in computer-aided design and manufacturing in restorative dentistry (pages 100-103), Dr. Eugene Antenucci describes his use of an 810-nm diode laser to prepare gingival margins and manage bleeding to achieve predictably accurate optical impressions.

As Myers and Sulewski point out, the use of a laser to circumferentially remove a portion of the inside border of the gingival-free margin of a prepared tooth for crown and bridge impressions in lieu of retraction cord can save both time and money. However, the laser-assisted tissue retraction for impression procedure is technique-sensitive. The authors indicate that some new laser dentists may become frustrated in their initial attempts at creating smooth, bloodless, open surgical areas ready for impression; they may find the margins to be rough while the sulcular area exhibits bleeding. Myers and Sulewski continue:

Assuming they used correct laser settings, the clinicians were probably moving the handpiece too slowly and applying too much force toward the gingival margin. The slower the movement, the more likely one will create small tissue tags (the roughness), and, the more force or pressure that is applied to the gingival margin with the glass or sapphire tip of the laser, the more likely that hard tip will scrape open what the laser energy just coagulated. The proper technique employs light, sweeping motions of the laser handpiece, similar to dusting fine china.

Proper adjustment of technique should enable satisfactory results (bloodless, fairly dry, and smooth) in 60 seconds or less per tooth, according to the authors. In their gingival retraction study abstracted below, the Gherlone group use a 980-nm diode laser at 2.5 to 3.5 W continuous-wave and a pulsed Nd:YAG laser at 2.5 to 4.0 W, 25 to 40 Hz, and 100 mJ.

Kutsch described the use of an argon laser, 1.0 W continuous-wave, for gingival retraction while employing suction without accessory water spray. While utilizing an 810-nm diode laser for pre-impression gingival troughing, Lee recommends that “thermal energy generation and transfer must be controlled by using the laser beam in a pulsed mode whenever possible” (compared to Dr. Antenucci who uses continuous-wave mode at 0.5 to 1.0 W), “as well as implementing the use of cooling methods such as running an air current or incorporating a water spray throughout the procedure.” Of course, care must be taken to avoid inducing subcutaneous emphysema while using pressurized air during such procedures. Lee does not specify the power settings he used.

When using an Er,Cr:YSGG laser for troughing, Scott (abstracted below) advises the use of short, brushing strokes, and indicates that the chance for bleeding increases when the wattage and/or percentage of air or water are increased beyond recommended parameters. For his case, Scott used a 6.0-mm T-4, 400-µm tapered sapphire tip and laser settings of 0.50 W and 20 Hz with 7% water and 11% air. In contrast, Colonna and colleagues used an Er,Cr:YSGG laser at 0.75 to 1.0 W, a pulse rate of 50 Hz, 30% water and 60% air, with a 600-µm quartz tip for a “margination process” during full-mouth rehabilitation with CAD/CAM technology to create smooth, readable margins.

In short, while the suggested specific operational parameters or delivery mode for laser-assisted tissue retraction may vary from clinician to clinician, depending on the instrument employed, practitioners recommend using light, brushing strokes of the fiber while keeping the power settings within the prescribed limits.

For U.S. readers, various carbon dioxide, Nd:YAG, argon, Ho:YAG, Er:YAG, Nd:YAP, Er,Cr:YSGG, diode, and frequency-doubled Nd:YAG lasers have been cleared by the U.S. Food and Drug Administration for intraoral soft tissue surgery. The literature generally
presents tissue retraction cases involving fiber-optic delivered laser systems.

As always, clinicians are advised to review the specific indications for use of their lasers and to review their operator manuals for guidance on operating parameters before attempting similar techniques on their patients.

REFERENCES


RESEARCH ABSTRACTS

COMPARATIVE STUDY ON GINGIVAL RETRACTION USING MECHANO-MECHANICAL PROCEDURE AND PULSED Nd:YAG LASER IRRADIATION

Fatma Abdel Gabbar, Cairo University, Cairo, Egypt

Sanaa F. Aboulazm, Alexandria University, Alexandria, Egypt


The aim of the present study was to study the tissue reaction and gingival healing in pulsed laser gingival retraction in comparison with chemico-mechanical gingival retraction technique. This work was applied on six patients recommended for orthodontic extraction of first premolars upper and lower. The patients were divided into three groups (two patients each), one group with laser tissue retraction, another group with ferric sulphate (13.3%), and a third group with aluminium chloride (25%). The present histologic findings revealed that with the application of pulsed Nd:YAG laser the gingival tissues showed faster healing with less hemorrhage and less inflammatory reaction in comparison with the other two groups. In conclusion it was evident that pulsed laser is a surgical device increasingly important to dentistry. The present study can support with the clinical application of laser in gingival retraction as a simple convenient, painless method.

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THE USE OF 980-NM DIODE AND 1064-NM Nd:YAG LASER FOR GINGIVAL RETRACTION IN FIXED PROSTHESSES

Enrico F. Gherlone, Carlo Maiorana, Roberto F. Grassi,

Riccardo Ciancaglini, Francesca Cattonia

Vita-Salute University, Milan, Italy; University of Milan, Italy; University of Bari Dental Clinic, Bari, Italy


Purpose: The aim of the present study was to evaluate the tissue retraction and gingival healing in pulsed laser (diode 980 nm and Nd:YAG 1064 nm lasers) gingival retraction in comparison with the conventional mechanical or surgical techniques (double cord and electro-surgery). Materials and Methods: A group of 103 adult patients, 45 women, 58 men (mean age 42, range 19 to 52 years) scheduled for fixed and implant prosthetic rehabilitation was recruited, and four impression techniques were compared: the double cord technique, the electro-surgery technique, the 980-nm diode and the 1064-nm Nd:YAG laser technique. Patient[s] were randomly placed into four groups according to impression-taking technique. Thirty impressions were taken in each group, for a total of 110 elements each. The preferred impression materials were addition silicones (polyvinyl siloxanes) (2nd generation). The outcome was measured by the bleeding index (during the impression taking and after 15 days) and gingival [recession] (after 15 and 30 days). Results: Compared to the conventional techniques, both laser techniques proved to be less aggressive in terms of absence of gingival bleeding (99.2% vs. 92.7%). There were also fewer cases of gingival [recession] than with the conventional technology (2.2% vs. 10%). Conclusion: This study suggests that the laser technique can be valuable for implant prosthetic rehabilitation. While both the conventional and laser techniques are satisfactory in achieving gingival retraction, the laser technique may be less traumatic to the periodontal tissue.

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The two-cord retraction technique is used for troughing around a crown to achieve biologic width. This technique can cause significant discomfort for the patient and offers several potential clinical disadvantages for the dentist, of which unpredictable tissue recession is the most significant. The clinical case presented in this article compares the use of the standard two-cord retraction technique with that of an 2,780-nm erbium-class dental laser to determine which method achieves an accurate, easily readable impression while respecting the biologic width. Using an erbium laser to achieve the trough prior to placing an indirect restoration results in little or no postoperative discomfort for the patient; in addition, the erbium laser reduces intraoperative complications related to tissue recession and patient discomfort while providing consistently accurate impressions.

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USE OF AN ERBIUM LASER IN LIEU OF RETRACTION CORD: A MODERN TECHNIQUE

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