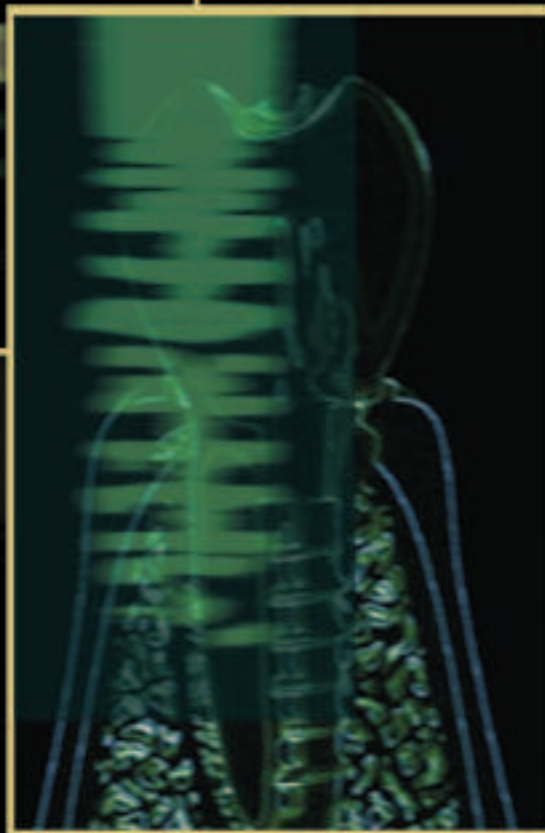
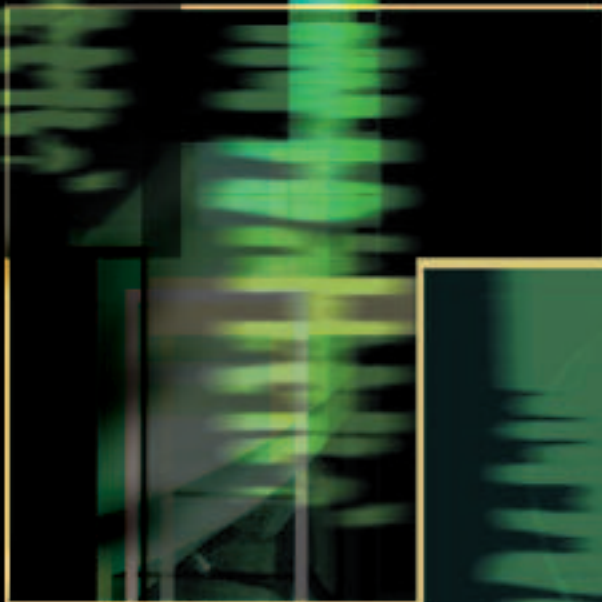


**Recommended
CE Training Protocols
to Meet the Legal Standard
of Care for Implant Placement**





September, 2007

The proliferation of training courses and training centers throughout the country promoting 1-3 day courses as being fully adequate to begin placing implants could result in significant problems for patients and practitioners alike. Many of these problems would not occur if course participants were being informed of the legal standard of care for implant placement, which would enable them to make fully informed decisions regarding their course of study and how they wish to incorporate implants into their practices.

Therefore, acting in the best interests of patients, the profession and the implant industry, the IDIA organized a committee, which included malpractice defense attorney Arthur W. Curley J.D., to develop recommendations for training guidelines to meet the legal standard of care for implant placement. We have based these guidelines on those already established in the U.K., the collective experience of several surgical specialists and restorative dentists, and the knowledge and understanding of the legal ramifications in the United States. These guidelines were subsequently reviewed by numerous general dentists, prosthodontists and surgical specialists who were independent of the committee.

It is not our intention to dictate the structure of CE courses or to establish a specific curriculum for surgical implant placement training programs. Rather we seek to provide guidelines for evaluating CE courses to determine whether they cover the recommended areas of study to meet the legal standard of care.

DR. DAVID ANSON
DR. JAY BEAGLE
DR. BRUCE JOHNSON
DR. PAUL KORB
DR. ALDO LEOPARDI
DR. LARRY LYTLE
DR. JAY MALMQUIST
DR. ELGAN STAMPER
DR. RICH STUART
DR. CLARK TAYLOR
DR. JEFFERY THOMAS
DR. STEPHEN WHEELER

It is our hope that this working set of guidelines, will be supported and distributed by all of the major implant companies, which would eventually lead to an industry standard for company sponsored training programs. We believe that this will effectively preserve the highest standards in implant dentistry, which will ultimately protect the patients and the profession.

Additionally, it is recognized that the practice of implant dentistry is changing as new materials and techniques are developed and that it will be necessary to review these training guidelines at least every two years, and if necessary, modify them accordingly

Finally, we wish to thank Scott Root, President and CEO of Astra Tech and Steve Schiess, President of Biomet 3i for their commitment to preserving the integrity of implant dentistry and for taking the lead role in the industry to support the creation and distribution of training guidelines for the benefit of the profession and the entire implant industry. We also wish to thank Lifecore and Neoss for participating in the distribution of these guidelines.



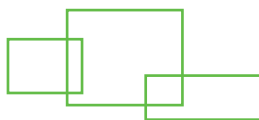
INTRODUCTION:

In designing any continuing education program intended to train dentists on the safe and successful placement and maintenance of dental implants, the nature of the procedure must be kept in perspective. Above all, the placement of dental implants is a surgical procedure, with all the attendant risks, benefits and alternatives associated with any surgery. In maintaining that perspective, the distinction between residency trained specialists and dentists without post-graduate surgical residency training must also be considered.

From a legal perspective, any licensed dentist can perform any dental procedure. However, when a general dentist begins to perform procedures that are primarily performed by dental specialists, due to either complexity or difficulty, the law holds all such practitioners to the standard of care expected of specialists providing similar procedures on a regular basis. The test of the standard of care is not so much a dentist's ability to begin or initiate treatment, rather it is the experience and ability of the dentists to quickly recognize and treat all of the various potential complications.

Most implants are placed by specialists who have attended residency programs. Those programs taught not only the techniques of dental implant surgery, but also how to diagnose the complex or unusual cases, predicting and diagnosing the potential for complications and most importantly providing timely and effective treatment for such complications.

It is the very nature of surgical residency programs that they have a disproportionate number of unusual patients, cases and complications associated with dental implant patients. Indeed, what might be rare in the typical dental office is more commonplace in a residency program. Therefore a training program, even a two day weekend course, must keep that perspective in mind and employ risk management education.



RECOMMENDED AREAS OF STUDY FOR CE PROGRAMS TO MEET THE LEGAL STANDARD OF CARE:

1) PATIENT SELECTION:

As medical management of patients and diseases has become more complex, so has the need to be aware of the potential impact and complications of dental surgery. The standard of care now requires frequent, at least annual, updates of not only the patient health history data, but also the very forms they fill out. With such updated information the doctor can and should be able to predict the potential for reactions or complications, common or rare and to prepare accordingly. Depending upon the patient, obtaining and documenting medical clearance for surgery may be required. Failure to do so could be considered substandard care or failure to practice at the level of a specialist. *(continued next page)*



2) PATIENT EDUCATION & DOCUMENTATION:

All dental implant patients are entitled to know the risks, benefits, and alternatives to any number of recommended treatments for the replacement of missing teeth. Dentists should understand informed consent and informed refusal and how to obtain it and document it prior to implant placement.

N.B. This segment of the recommended training protocols is covered in the Standard of Care program developed by the Institute for Dental Implant Awareness and its legal consultant, Mr. Arthur Curley. This program can be viewed as the prototype for development of the patient education and documentation segment of CE programs, or simply incorporated into CE programs.

3) DIAGNOSIS & TREATMENT PLANNING:

The current standard of care for diagnosis is much more than merely determining that a missing tooth can be replaced with a dental implant. Based upon patient selection, not only must potential for complications be considered, but the use of current diagnostic and planning tools, to reduce such risks, should be considered. In particular, depending upon patient anatomy and general medical conditions, tools such as 3D imaging and alternative implant systems must be considered, and if appropriate, offered to the patient. The process should include a discussion of the benefits of such tools and if the patient should decline use, then informed refusal should be obtained and documented.

4) PRE-SURGICAL WORK-UP:

The long term success of implant surgery depends in large part on the success of the prosthetics. Planning for placement and occlusion should include a discussion of the tools to maximize success, ranging from stents to computer guided surgery. Those options must be discussed with the patient and the choice documented.

5) SURGERY:

Surgical placement of dental implants involves much more than simply knowing the techniques used to insert implants in training mandibles. Dentists placing implants should have an understanding of the anatomic variations in morphology that affect implant placement, such as undercuts in the mylohyoid area and canine fossae, the proximity of the maxillary sinus, floor of the nose and mandibular nerve. It is critical to understand buccal plate integrity, most importantly in the esthetic zone, and how to maintain it, when to delay implant placement, grafting techniques and when to refer to a specialist. Dentists should also have an understanding of the variations necessary in the surgical protocol that are required in areas of poor bone density and competency in treating the problems that occur.

Additionally, dentists placing implants should have an understanding of the complications occurring from the aforementioned morphological variations, as well as competency in treating these complications, which require surgical decisions and management at the time of surgery and not necessarily post-operative. This would include placing short implants, or aborting surgery, treating dehiscence and fenestration problems, especially in the esthetic zone, GBR techniques and block grafting techniques and when to refer, and management of wound dehiscence and/or infection. Even if dentists hope to place implants in

a flapless manner, they should be familiar with flap design and techniques as this may be necessitated if areas of dehiscence or fenestration are encountered during surgery. Other important considerations include the management and treatment of implant failures and the resulting defects as well as the parameters of care that incorporate risk management principles. For example, in the case of mandibular implants, manufacturers have set forth guidelines regarding the approximation of implants to the mandibular canal.

6) COMPLICATIONS:

Evaluation and documentation of the post operative status of a dental implant surgery patient should be an essential part of any implant surgery training program. This would include regular evaluation of the healing and/or periodontal status, implant integration, neurological or sinus status, imaging evaluation, and patient overall status. It is important to be exposed to both didactic and clinical examples of a wide range of potential complications, including but not limited to those outlined above (section 5), techniques for early recognition, evaluation, treatment, or referral. Part of that process must include documentation of the process, including tests performed or considered, consultations, and referrals.

7) MANAGEMENT/MAINTENANCE:

Finally, dentists should understand the maintenance of healthy implants and their post-operative assessment. Documentation is essential from a risk management perspective and should include periodic consideration for soft tissue analysis (probing, texture, color, etc.), bone status (occlusion, TMJ, mobility, etc.) and function.



ADDITIONAL RECOMMENDATIONS FOR PLACEMENT OF IMPLANTS WITH MAJOR BONE AUGMENTATION AND/OR MODIFICATION OF ANATOMICAL STRUCTURES:

The placement of dental implants with bone augmentation or modification of anatomical structures demands a high level of surgical experience. Therefore, prior to advancing to complicated implant surgery (major bone grafting or sinus lift procedures) dentists should have completed comprehensive CE programs as outlined above and should also have extensive experience placing implants. In addition, dentists should attend courses which specifically train in these techniques, including the potential immediate and long-term complications. Ideally, dentists should be mentored by experienced surgical specialists prior to performing these procedures. *(continued next page)*



OTHER RECOMMENDATIONS:

Since implant dentistry is prosthetically driven, it is recommended that dentists should be proficient in the treatment planning and restoration of both fixed and removable implant cases, prior to undertaking surgical training for implant placement. This would include:

- An understanding of advanced restorative procedures
- Recognition of technical and cosmetic limitations of implant dentistry in certain situations

It is also suggested that dentists be prepared to attend courses on a regular basis to update and reinforce knowledge of implant dentistry; have an established protocol for dealing with complaints and maintain appropriate malpractice insurance coverage for surgical procedures.

SPECIFIC TOPICS THAT SHOULD BE INCLUDED IN CE PROGRAMS TO MEET THE LEGAL STANDARD OF CARE FOR IMPLANT PLACEMENT:

It is suggested that dentists who want to incorporate surgical implant placement into their practices and meet the legal standard of care should consider the following checklist when evaluating the course outlines for surgical training programs.

- † A review of the standard of care as it relates to health history data and forms, including the situations that would require medical clearance for surgery.
- † Clinical assessment of a patient's suitability for implants, and the medical conditions that could diminish a patient's candidacy for implant techniques, or complicate surgery.
- † The main implant options available and their indications and contraindications for certain patient groups.
- † The risk/difficulty factors for implants in the various zones in the mouth and potential need for referral of cases to specialists based on the difficulty of the case and the competency of the clinician. For example, since 90% of anterior cases require grafting, these cases should probably not be attempted unless there has been extensive training in bone grafting procedures. ("Why Did My Graft Fail? A Critical Evaluation of Graft Failures" Jay P. Malmquist, DMD, Academy of Osseointegration, March 9, 2007)
- † An overview of the informed consent process, including patient presentation, education and documentation, as well as the obligation to obtain informed refusal in cases where a patient declines a recommended treatment.
- † A discussion of documentation with risk management considerations in mind, including documentation of patient information, imaging, diagnosis, treatment plans, informed consents, informed refusals, surgery, process notes, referrals, consultations and recalls.

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- † The surgical anatomy of the maxilla and mandible, as well as the pathological processes that occur in the maxilla and mandible.
 - † Radiology systems and image analysis radiography of the mandible and maxilla, and how to interpret the findings from radiological examinations.
 - † A review of current diagnostic and planning tools and alternative implant systems.
 - † Surgical and prosthetic treatment planning options for various indications.
 - † A discussion on the importance of pre-surgical work-up, including stents, computer guided surgery and/or other tools that can be utilized to maximize success.
 - † Techniques for surgical placement of dental implants, ideally including treatment of patients in the presence of an experienced surgical specialist.
 - † Bone morphology, including anatomic variations that affect implant placement, including undercuts of the mylohyoid area and canine fossae, proximity of the maxillary sinus, floor of the nose and mandibular nerve, and buccal plate integrity.
 - † Treating complications that occur as a result of morphological variations, as described above, including dehiscence and fenestration problems, problems arising from variations in bone density and the patient's medical and medications history, including GBR and flap surgery to correct them.
 - † Techniques for harvesting bone from oral sites for minor augmentation during implant placement, as well as the use of exogenous bone or bone substitutes for minor augmentation.
 - † Regular evaluation of the healing and/or periodontal status, implant integration, neurological or sinus status, imaging evaluation, and patient overall status.
 - † Infection control and surgical aseptic techniques as applied to implant dentistry, as well as antibiotic use.
 - † How to identify implant failures and what constitutes and implant failure.
 - † Management and treatment of implant failures and the resulting defects.
 - † Exposure to both didactic and clinical examples of a wide range of potential complications, including but not limited to those outlined above (section 5), techniques for early recognition, evaluation, treatment, or referral, as well as documentation of the process, including imaging, tests performed or considered, consultations, and referrals.
 - † The long-term management of surgical implant patients, including soft tissue analysis, status of the bone and function.

"As a general dentist, I believe that one of the critical components of success is knowing your limitations. Focusing on what you do best and knowing when to refer and the best specialist to refer to in each situation, is essential to ensure that the patients always receive the best possible care."

Ronald G. Bollinger, D.D.S.