

# Dental and legal considerations in periodontal therapy

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This chapter introduces the practitioner to basic legal principles and concepts relating to periodontal diagnosis, treatment, referral and the effects of emerging technologies on periodontal legal issues. An overview of periodontal evidence in the courtroom is also included.

The biological foundation of periodontics is crucial to successful restorative dentistry. Indeed, knowledge of the interrelationship between biological principles of hard and soft tissue management and the biomechanics of restorative design and materials are essential to optimize dental health. Similarly, legal principles provide the foundation for the interrelationship between dentistry and the law. Critical to building this legal foundation is the fiduciary obligation required by law of both the general practitioner and the periodontist to protect and preserve the patient's dental health (50). Accordingly, the patient's welfare and best dental health interest should remain paramount. Protecting the patient's interest also promotes dentistry's ethical goals. The American Dental Association (ADA) Dentist's Pledge, adopted in 1991, states, in pertinent part:

“... I understand and accept that my *primary responsibility* is to my patients, and I shall dedicate myself to render, to the best of my ability, the highest standard of oral health care and to maintain a relationship of respect and confidence. Therefore, let all come to me safe in the knowledge that their total health and well-being are *my first considerations* ...” [Emphasis added.]

Just as lawyers are advocates for their clients, dentists should be advocates for their patients' health. For instance, some courts have held practitioners liable for failing to appeal an insurance carrier's denial of patient benefits, and thereby acquiescing in providing a reduced level of patient care (51, 100, 103). Dentists are obligated to exert reasonable efforts to preserve dental health that necessarily includes the periodontium.

## Legal basics

### The standard of care

The legal standard of care may vary somewhat from state to state. However, it is generally defined as the level of care that reasonably prudent dentists in the local community ordinarily perform under similar circumstances (102). A violation of the standard of care constitutes negligence.

A common misconception about the legal standard of care is that the standard measures average dentistry in the community. However, the legal standard of care does not measure the care that only the average dentist in the community provides. If this were true, 49% of the dentists who practice below the customary practice of the average practitioner would all be practicing substandard dentistry. Instead, the legal standard of care is measured against what a reasonably prudent dentist should do, regardless of what the average dentist does or how many or how few so practice (51). Indeed, one legal case held: “We are not permitted to aggregate into a common class the quacks, the young men who have not practiced, the old ones who have dropped out of practice, the good, and the very best, and then strike an average between them” (86).

An analogous misconception is that standard of care is defined by the customary practice of most dentists. Courts disagree, and instead hold that although the majority practice often equates with the standard of care, customary practice does not conclusively establish the standard of care. A customary practice may be imprudent rather than reasonably prudent. A customarily negligent practice proves only that no matter how many do it wrong, doing so never makes it right. Negligent customary practices that violate the standard of care include the following examples:

- failure to use bacteriological monitoring of dental unit water lines and evacuation systems to verify that chemical disinfectants have eliminated waterline biofilm buildup (2, 17, 69);

- performing prescription periodontal surgery for bridge abutment teeth while ignoring periodontitis elsewhere, including adjacent or opposing teeth;
- evaluating periodontal disease control by pocket measurements alone and not considering bleeding on probing as a component of periodontal disease diagnosis (8, 11);
- diagnosing pulpal disease, but failing to consider periodontal-endodontic lesions or that successful endodontics may not salvage a tooth compromised with severe periodontitis (27, 52);
- using D speed film and round collimators rather than E speed film with rectangular collimators that provide comparable diagnostic quality and radiation reduction approaching 80% (21, 49);
- medical histories that are not currently updated (a 10-year-old medical history is an example) and/or incomplete medical histories. Failure to inquire about past fenfluramine-phentermine (fen-phen) usage is another example of not updating the medical history;
- performing periodontal screening examinations instead of comprehensive periodontal examinations before performing full-mouth restorative procedures;
- blindly abiding by the dictates of managed care plans that unreasonably limit either referrals to periodontists or frequency of periodontal maintenance procedures without advising the patient of reasonable alternatives even if they are not covered by managed care plans (46, 88); and
- recommending product advertisement benefits without critically examining such claims for puffery, researcher bias, adequacy of research data, or proven long-term efficacy (70).

Prudent practitioners adhering to the standard of care can remain current by reading the latest peer-reviewed scientific publications and attending continuing education courses. On the other hand, some negligent practitioners rely on outmoded diagnostic and therapeutic modalities by not advancing beyond their dental school training (55). A careful practitioner is neither the first nor the last to adopt emerging or new technologies but instead awaits adequate research testing and general acceptance in the profession. Publications in scientific journals should be read with a degree of critical scientific skepticism recognizing the following limitations:

- *Peer review journals.* Not all scientific publications are peer-reviewed for scientific accuracy in both research methods and conclusions.
- *Author bias.* Whether the manufacturer sponsored the research or conducted research in its own laboratories should be considered in weighing the author's objectivity. For instance, an author's conflict of interest is now listed at the beginning of research publications in the *British Medical Journal*.
- *Sampling.* A small number of subjects in a study or an inadequate demographic sample may result in low statistical power or in a sample that is not representative of the larger population. Moreover, infrequently occurring side effects are unlikely to manifest if a relatively small number of subjects are studied. For example, 7 months after the US Food and Drug Administration (FDA) licensed the popular arthritis drug Feldene, six patients died and 30 others became seriously ill (33).

### Informed consent

A dentist's duty in providing informed consent to the patient may vary from state to state. However, in general, if potential serious injury can occur, such as complications from periodontal surgery, informed consent should be obtained. A comprehensive dental lecture course is not required, but the dentist must inform the patient of: 1) the material risks compared with benefits of the proposed treatment, 2) the consequences of declining treatment, and 3) any other reasonable treatment options (50, 67). Failure to obtain adequate informed consent renders the dentist liable if a reasonably prudent patient would have declined treatment if the patient had been informed of the risks (22).

Oral informed consent information may be supplemented with written consent forms, patient literature and animated videos. Written informed consent forms are desirable but not legally required. Nevertheless, informed consent forms provide objective concrete evidence that the patient was provided legally mandated informed consent. Informed consent is a non-delegable duty that the dentist owes to the patient. Auxiliary staff may supplement the dentist's explanation to the patient. However, they may not solely provide informed consent since they do not possess a dental license nor are they trained to answer all patient questions, particularly regarding the incidence or severity of risks associated with treatment.

Despite having signed written consent forms, many legal cases have been lost on the issue of informed consent. Practical difficulty with written informed consent forms, including those available

through the American Academy of Periodontology, is that the patient may testify at trial that they did not read the form before signing nor did the dentist explain the risks associated with the treatment or procedures. The jury may conclude that the dentist did not take the time to explain particular treatment risks to the patient and instead, utilized the written form as if it were a consent-to-treatment (rather than informed consent) form. Thus, according to the patient's testimony, the dentist's legal informed consent obligation to explain in detail treatment risks, factually never occurred. If the jury believed the patient's version, informed consent never occurred. Rather, uninformed consent occurred, because the dentist failed to provide material information that a reasonable patient would want to know and/or reasonable dentists would disclose (22, 50).

The prudent practitioner should make a chart entry noting that the patient was informed of the risks of treatment, and consented to treatment, even though an informed consent form is signed. The following chart entry is suggested as an example.

Doctor explained implant risks, benefits, and alternatives to patient. Patient agreed to treatment and stated: "The doctor has answered all of my questions." (Dental assistant's initials, entry date.)

**IMPLANT INFORMED CONSENT QUESTIONNAIRE®**

In order to help your understanding of implant benefits, risks, and alternatives, please answer the following questions by checking the true box if the statement is correct and the false box if the statement is incorrect. In the event that your answers suggest the need for further explanation, the implant surgeon will review materials with you and answer any questions. Please feel free to ask any question so that you may feel comfortable with your implant decision and aid your understanding.

	True	False
1. Implant success is guaranteed.	<input type="checkbox"/>	<input type="checkbox"/>
2. Acceptable tooth replacement alternatives to implants do not exist.	<input type="checkbox"/>	<input type="checkbox"/>
3. Infection cannot occur as the implant surgery area heals.	<input type="checkbox"/>	<input type="checkbox"/>
4. A surgical implant risk is numbness of the lower lip or chin which is usually temporary but, on rare occasions, permanent.	<input type="checkbox"/>	<input type="checkbox"/>
5. Since implants are artificial, daily oral hygiene care after implant placement is unnecessary.	<input type="checkbox"/>	<input type="checkbox"/>

I understand that I may ask the doctor any question I may have regarding implants and implant surgery. All of my questions, if any, were answered to my satisfaction.

Dated: \_\_\_\_\_ Time: \_\_\_\_\_ \_\_\_\_\_  
Patient's signature

Dated: \_\_\_\_\_ Time: \_\_\_\_\_ \_\_\_\_\_  
Witness

**Fig. 1. Implant questionnaire used to confirm informed consent**

Utilizing a written informed consent form, confirmed by an assistant's chart entry that the dentist did inform the patient, will enhance the likelihood of the dentist winning the credibility contest as to whether or not the dentist provided adequate informed consent. Since patients should not be sedated before signing, as an added precaution, the time of the patient's signature may be added to the informed consent form or noted in the chart. The times sedation was begun and surgery completed should also be included.

Another verification method use to confirm informed consent is to have the patient complete a questionnaire such as the implant questionnaire illustrated in Fig. 1. Juries are likely to believe objective evidence, such as a patient completed questionnaire in the patient's own handwriting, more so than an undocumented oral dentist-patient risk disclosure discussion. Note that the questionnaire cannot be accurately completed unless it is actually read because, except for question 4, all of the answers are false. Most patients probably assume from common experience that the majority of the answers are likely to be true. If the patient incorrectly answers any of the questions, it is recommended that the patient be given a further explanation and asked to retake the questionnaire test. It should be an office policy not to proceed with treatment unless the patient is able to correctly answer all questions. Both the incorrect and correct answers should be saved in the patient's chart to document that the patient's misperceptions were corrected. Animated videos are also helpful risk management tools and can be replayed to the jury with freeze-framed pertinent risk disclosures. After first viewing and discussing with the treating dentist, the patient and witness should sign the appropriate form to confirm that it aided the patient's understanding of the proposed procedure and all patient questions were answered by the treating dentist.

If implants are being considered, the patient should understand that implants are not guaranteed and that there may be risks such as failure or permanent paresthesia if the implant is placed in to either the inferior alveolar or mental nerve. The best informed consent is no defense if the dentist incorrectly selected an oversized implant or utilized inadequate pre-operative imaging, This is because informed consent refers to non-negligent risks and does not include reasonably avoidable negligent risks. It should also be emphasized that any patient's consent to negligent care is voidable if it is contrary to public policy (96). Fig. 2A demonstrates preoperatively a bridge abutment molar apex approximating

the superior border of the mandibular canal. Although no paresthesia existed prior to extraction, a computed tomographic scan is indicated because it is unknown whether the molar apex lies directly over the inferior alveolar nerve or is located lateral to the area. Fig. 2B is the postoperative radiograph showing an implant directly impinging upon the inferior alveolar nerve with resultant permanent paresthesia.

### Duty to refer

A general dentist has a duty to refer a patient to a specialist in situations where other reasonably prudent dentists would make such referral under similar circumstances. The general dentist who declines to make a referral, choosing instead, as a generalist, to perform the needed procedure or treatment, will be held to the specialist's standard of care (43, 44). Specialists may be held to a higher standard of care (30). Although there are approximately 5000 periodontists in the United States, the majority of periodontal therapy is accomplished by general practitioners. A dental license gives a dentist the right to perform all dental procedures, but few dentists possess the knowledge, training, and skill to perform every procedure within the standard of care. Knowledge and training are gained in dental school to practice at a minimally competent level. Expert competency skill often requires at least 5 years of clinical experience supplemented by continuing education courses.

The duty to refer is not confined to general dentists. Specialists frequently encounter conditions that are best treated by a specialist in another discipline. In such cases, the specialist should refer. The ADA recognizes eight specialty areas: periodontology, dental public health, endodontics, oral pathology, oral and maxillofacial surgery, orthodontics and dental facial orthopedics, pediatric dentistry and prosthodontics. The ADA Principles of Ethics and Code of Professional Conduct permits general dentists to advertise advanced education credentials for treatment of periodontal disease. However, the generalist must also include "general dentist" in the advertisement to avoid misleading patients by inferring that the advertising general dentist is a specialist (25, 89).

The absence of specialists in a particular geographic locale does not relieve a dentist of the legal duty to refer. Travel inconvenience for the patient is not a valid reason for failing to refer patients to a specialist. Irrespective of travel cost or inconvenience, it is the patient's decision whether or not

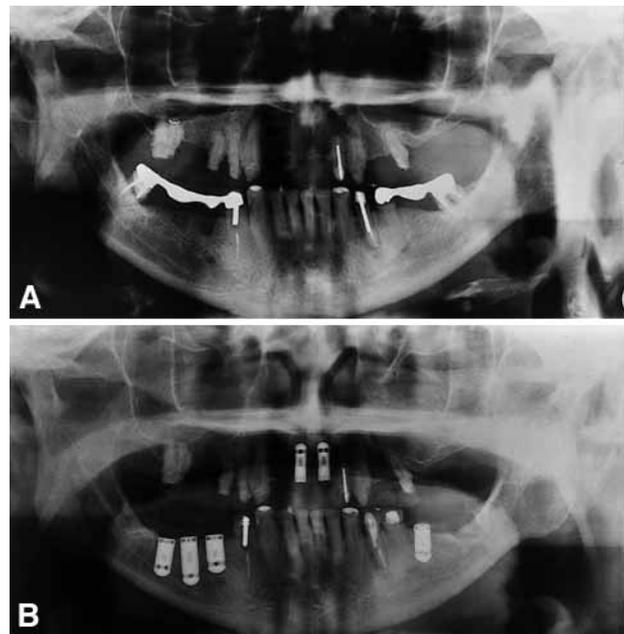


Fig. 2. **A.** Preoperative radiograph showing apex of mandibular right molar located close to inferior alveolar nerve. **B.** Postoperative radiograph showing implant impingement on the inferior alveolar nerve resulting in permanent paresthesia.

to comply with the dentist's referral to a specialist. The dentist's records should reflect reasonable post-referral attempts to determine whether the patient received the recommended treatment, including any patient reminder cards that were mailed regarding the importance of referral follow-through and the consequences of not following the dentist's referral recommendations. Thorough records should document: a) the patient's pretreatment condition, b) patient reminder phone calls, and c) letters, e-mail, or facsimile to other health care practitioners and any dental insurance carrier.

Treatment records should also reflect discussions with the patient about the reasons for referral (including chief complaint), as well as the patient's decision to seek or reject the referral. If the referral is refused, the reason should be recorded. A dentist may be exonerated at trial if a referral was made but declined. However, the dentist will still be held responsible if evidence of progressive disease was not discussed with the patient and if the earlier refused referral was not renewed. This is because a patient may reconsider a prior referral refusal if new information regarding a changed clinical condition is provided. The patient may testify at a malpractice trial that periodontal disease was only described by the dentist as a potential risk for premature tooth

loss. A potential risk that becomes increasingly manifest as a worsening condition should be disclosed to the patient since both the patient and dentist's assessment of risk may change during the course of ongoing therapy.

A referring dentist is not responsible for the specialist's outcome of treatment if the specialist acted without the referring dentist's treatment participation or control. However, the referring dentist may be liable for the specialist's care if the referring dentist participates in or controls the specialist's treatment. For example, joint consultation between the periodontist and generalist may be required to determine the appropriate pathway of insertion when utilizing surgical stents or to avoid premature occlusal loading of implants before adequate osseointegration. Therefore, a general dentist who co-treats a patient with a periodontist in an implant reconstruction case could be held jointly liable.

## Record keeping

### Written records

Record keeping is an essential component of the standard of care. Licensing boards have disciplined both generalists and periodontists for failure to adequately document baseline periodontal measurements prior to surgery rather than relying on periodontal sounding measurements only at the time of surgery.

Comprehensive periodontal care requires more than a periodontal screening examination but, rather, a complete full-mouth assessment including full mouth radiographs, clinical attachment levels, radiographic assessment, bleeding on probing, mobility and furcation classification (7, 9, 12). Without baseline measurements, the practitioner cannot adequately assess at re-evaluation visits whatever periodontal disease has remained stable, improved or progressed. Bitewing radiographs are inadequate since the entire tooth, including evaluation of apical pathology, is not evident. Panoramic films are not adequate for comprehensive full-mouth evaluation since overlap, magnification and lack of detail obscure an adequate evaluation, particularly interproximally (42, 64). Furthermore, if baseline full-mouth periapical and bitewing radiographic surveys are not available, the practitioner cannot adequately determine whether subsequent radiographic changes are new or pre-existing.

The American Academy of Periodontology does not endorse the use of any specific charting system. Periodontal record standards are listed in its Guide-

lines for Periodontal Therapy (4). Acceptable charting should be capable of being easily read without undue study. Insurance carriers are within their rights to request further information if charting is poorly documented. Although useful, photographs and diagnostic casts are not standard elements of a comprehensive periodontal examination and create added patient financial burden (6). In summary, the three rules of record keeping are: document, document and document.

### Electronic records

Electronic records are acceptable and within the standard of care but risk skepticism from a jury regarding their authenticity because it is a common perception is that electronic records may be easily altered (95). Electronic signatures are now valid for federal claim forms including Medicare. Ink life is related to both paper and ink quality. Permanent ink made from pigments should have a useful life of at least 30 years. Documents printed on ink-jet printers often fade after a few months. Furthermore, ink-jet ink is made from dyes and lasts a maximum of 10 years (104). Laser printers produce more permanent output because the carbon and plastic toner is melted onto the page. To avoid a claim of electronic record falsification, it is suggested that a facility that is a member of a professional record management association be used for maintenance of backup data. The survival of computer storage media such as zip disks or plastic CD-ROMs is 30 years, and it is important to store copies on media and in a format that lasts. Otherwise, there is a great danger that it will not be usable in 10 or 20 years. For example, the floppy disks utilized with the first desktop computers are virtually unusable today because their sizes and digital formats are no longer in use. Therefore, it is important to save both software and hardware that can read old data. Electronic records are more vulnerable than paper records to the destructive effects of smoke and heat despite storage in a vault designed to be impervious to fire damage. On the other hand, storage vaults for electronic records are specifically designed for electronic record storage and maintain a constant temperature and humidity to preserve record longevity. A record storage company should be used that has a log-in and log-out system that can verify each date that electronic backup records were deposited and retrieved.

Weekly, or at least monthly, backup tapes or disks should be placed in a vault and not retrieved unless necessary for an audit or subpoenaed to document

record authenticity. The requesting party or agency can have the stored tapes or disks sent to a neutral third party for inspection. This preserves the chain of custody when records are sent from a records storage company to a third party for inspection. Proving that the original storage and subsequent retrieval dates occurred without any intervening data removal protects the integrity and trustworthiness of electronically preserved data from allegations of tampering. Computer data should be periodically printed out. The date and initials of the person printing out such data should be placed on each printout page. As an additional precaution, the same writing instrument that ink dated the periodically printed data should be stored with the printout. If the data is subsequently questioned, a forensic ink expert can age-date the ink of the printout to verify the computer data's authenticity and original creation date.

### **Falsified records**

The tort of spoliation arises from falsification of potential trial evidence, which can include dental records. Intentional record falsification with intent to deceive can potentially result in punitive damages for which professional liability insurance carriers will not reimburse or indemnify the falsifying dentist. It can also result in evidentiary sanctions at trial, including a specific jury instruction that such conduct may be regarded as evidence of a guilty conscience and the awareness of a defense weakness that the jury may consider adversely against the falsifying party (26, 31, 78, 92–94). Falsification of records may also incur an investigation of a dental licensing board for disciplinary purposes (24). Examples of record falsification include: a) creation or substitution of chart entries, belated form creation, such as a periodontal pocket charting form, or even an entire new set of records, b) alterations to records such as adding or changing chart entries regarding periodontal pocket depths or specialty referrals, (c) adding entries between lines and (d) back-dating entries.

As a practical matter, a jury will distrust any person who falsifies records. A dentist lacks trustworthiness and credibility if fraudulent record alteration is exposed at trial. Good dentists usually keep good records (16, 97). Poor dentists often maintain poor records. However, falsified records are in an entirely different category. A defense attorney would rather defend poor records than altered records. For example, it can be argued in defense that, despite poor record keeping, the undocumented diagnosis, treatment or referral occurred. On the other hand, falsi-

fied records infer that the dentist was hiding or concealing his or her negligence or that treatment was never performed. Some insurance carriers will not renew professional liability insurance policies in the event that record falsification is detected.

### **Facsimile**

Undocumented oral communication offers limited credibility because memory fades, but records remember. If one communicates with a dental specialist or a physician, where time is of the essence, one should consider fax communication followed by mailing of the original document. Printouts of fax documents should be preserved to verify that the fax was sent to a specific phone number at a particular date and time. As with other records, fax copies should be stored in the patient file and the sending party should initial and stamp the document with the date and time of the fax transmission.

### **Physician consultation**

If the patient's medical history suggests a need for medical consultation before proceeding with treatment, a current updated physician approval with a verified consultation that the patient may proceed with periodontal or restorative treatment should be obtained. Telephone calls to the physician's office, including date, time, phone call participants and any limitations or conditions for treatment should be documented in the patient's chart. If time is limited, physician's recommendations can be faxed to the dentist's office, because it is preferable to have the physician's written approval for treatment whenever it is reasonably possible to do so.

### **Extraction diagrams**

When tooth extraction is being recommended, the use of the tooth numbers and diagrams of the teeth to be extracted on referral slips, charts, and informed consent forms should be considered. Teeth to be extracted may be indicated on the diagram and tooth numbers can be checked against the diagram. This verifies that the correct teeth will be extracted and reduces the risk of an incorrect or wrongful extraction. It is important to indicate on the referral form whether teeth have drifted into new positions, such as extract tooth number 2 in the number 3 position. Duplicate referral forms serve as an important documentary backup so that a copy may be kept with both the generalist and the specialist.

## Comparative (patient) negligence

The patient is a co-therapist in preventing and managing periodontal disease. Therefore, a patient is legally obligated to follow a dentist's responsible advice, instructions and specialty referrals. A noncompliant patient who fails to act prudently may be adjudged negligent in court. Depending on the patient's degree of culpability and state law regarding proportional or comparative negligence between dentist and patient, any patient negligence may diminish or eliminate the dentist's responsibility for the dentist's negligence. For example, a patient who blames a dentist for failing to diagnose and treat periodontal disease may be found partially or entirely culpable for failing to follow the dentist's instructions to brush and floss, return for maintenance recall appointments and/or comply with referral to a periodontist. On the other hand, deep periodontal pockets may not be amenable to patient home care techniques since the toothbrush and/or floss usually extends subgingivally only 1–2 millimeters and the patient alone cannot adequately prevent calculus formation in deeper pockets (15, 98). Therefore, frequent professional periodontal maintenance visits are required, regardless of the patient's daily plaque control levels.

A dentist who fails to prescribe prophylactic antibiotics for a patient in accordance with current American Heart Association guidelines for the prevention of infective endocarditis may be judged negligent for failing to adequately obtain a medical history. However, the dentist's negligent conduct may be reduced or eliminated if the patient negligently fails to accurately complete a written medical history that would alert the dentist to the need for prophylactic antibiotic therapy. This defense might be argued if the patient's cardiologist advised the patient to inform the treating dentist of valvular heart disease but the patient failed to do so. On the other hand, the dentist should not rely solely on the patient's memory but should consult with the patient's physician prior to performing invasive procedures for patients with a heart murmur. Evaluation of heart murmurs solely by auscultation is notoriously unreliable compared to technological methods that are now available such as echocardiograms (3). Therefore, for patients with a history of a heart murmur who have not had a recent echocardiogram, the use of prophylactic antibiotics may be indicated until a new echocardiogram is evaluated by the patient's cardiologist.

When patient noncompliance is recorded, any en-

tries should be professional. An abbreviated entry such as "G.M." for "garbage mouth" may be regarded by a jury as unprofessional. Similarly, a chart entry of "PI," for "punctually impaired" that refers to being habitually late for appointments is borderline. Appropriate chart entries include factual circumstances such as "patient late 20 minutes" or "failed appointment" if patients fail to keep appointments without canceling or rescheduling.

## Government agency approval affecting the standard of care

The mere fact that a dentist complies with all governmental regulations, such as using FDA-approved products, does not alone assure that the dentist complied with the standard of care. Government standards are minimal standards and prudent dentists complying with the standard of care frequently exceed such standards. Furthermore, governmental testing of devices or products does not test all conceivable clinical uses. For example, it is unlikely that implant research submitted for FDA marketing approval would include testing of implant length for varying anatomical conditions. Such testing would place research subjects at risk for penetration and injury to anatomic structures such as the inferior alveolar nerve or maxillary sinus. Research review boards would not approve human clinical studies that deliberately expose patients to potential permanent injury. Instead, implant studies primarily demonstrate efficacy or usefulness for the intended purpose of tooth replacement.

The FDA relies on the integrity of the drug manufacturer to report and accurately assess adverse incidents. If there is an unusually high incidence of adverse results with a particular device or drug after marketing, the manufacturer is obligated to advise the FDA. As a result, the FDA may consider additional warning labeling or withdrawal of the product from the market (20). The FDA Modernization Act modified the research requirements for obtaining marketing approval of products (99). Consequently, mounting case reports of adverse events reported to the FDA by individual practitioners, rather than the drug manufacturer, have increasingly become important sources of information to alert the FDA of the need for labeling changes or product withdrawal (32). In summary, when assessing the efficacy of a drug or device for patient use, prudent practitioners should consider all sources of knowledge, including pertinent peer-reviewed scientific literature as well as FDA approval.

## **Malpractice litigation**

A patient who sues a dentist must prove that the dentist: 1) violated the standard of care (that is, either negligently failed to provide treatment or provided negligent treatment), and 2) caused injury to the patient. All states have time limits for filing dental negligence actions and state statutes vary widely, but generally range from 1 to 6 years. It is usually longer for minors, and certain exceptions may extend the statute of limitations including evidence of fraud, intentional concealment or delayed manifestations of disease. Therefore, although records should be maintained indefinitely, or until 3 years after the patient's death, storage for 7 years is all that is necessary or practical in the vast majority of instances for non-active patients.

The mere fact that a dental negligence lawsuit is filed does not mean that the case will result in a trial. Over 95% of cases are resolved without a trial. Most cases settle out of court before trial, but some are dismissed because the lawsuit was not filed on time or the patient could not prove the case. Many factors affect resolution of cases that do not end up in trial and the dentist generally must give explicit consent to the insurance carrier to settle any professional malpractice claim (23). Dental negligence actions generally require proof by expert witness testimony (that is, another dentist). The patient's prior dental history may be significant in assessing whether the dentist who is being sued is responsible for all the dental treatment that the patient presently requires (that is, whether the dentist caused injury, which is known, legally, as causation). The proceedings and results of jury trials are not generally published unless the judgment is appealed and the reviewing court issues a reported decision that becomes available to the public. Even then, an appellate decision may discuss legal, rather than dental issues. Trial verdicts are sometimes, but not always, reported in trial verdict publications. Combined with the fact that most cases are settled out of court, all of these factors makes actual lawsuit data difficult to obtain. Professional liability insurance carriers maintain their own confidential data of litigation incidents that they are reluctant to publicize.

### **Examples of periodontal negligence litigation**

The following are examples of this author's litigated periodontal cases, offered as a litigation sampler but not an exhaustive list:

### **Failure to diagnose, treat, or refer**

In this author's experience, non-recognition of periodontitis was the common denominator in periodontal litigation lawsuits until approximately 1990. Before 1990, negligent practitioners' charts typically lacked full-mouth radiographs, periodontal probing measurements, or documentation that the patient was ever diagnosed, adequately treated or referred to a periodontist. Although diminishing in number, because of increased dentist and patient awareness of the importance of maintaining a healthy periodontium, cases involving periodontal neglect still occur. In litigation, dental records are crucial because the patient may claim that the patient was never advised of periodontal disease and therapeutic options. Dental record entries that document periodontal diagnosis, treatment recommendations or advice, treatment, referrals, patient refusals and any patient plaque control deficiency are essential to defend a claim of periodontal neglect.

### **Soft tissue mismanagement**

When soft tissue management continuing education courses in the late 1980s and early 1990s began instructing dentists on diagnosing, treating, and maintaining periodontal disease, the focus of periodontal litigation changed. Although the generalist increasingly began diagnosing periodontitis, in some instances the soft and hard tissues were mismanaged despite frequent periodontal maintenance recalls. This was because reevaluations were infrequently or inadequately performed to assess soft tissue management of disease control. Consequently, periodontitis progressed undetected. With the exception of acute periodontal abscess formation, periodontitis is usually slowly progressive. Inadequate periodontal maintenance may result in gingival recession and cosmetic gingival defects that are particularly noticeable when a patient smiles (18). Although the amount of gingival recession may only be a few millimeters, the strategic preservation of the interdental papillae for aesthetics, particularly in a patient with a high lip line, is essential. Photographs of a patient who was frequently maintained with regular recalls are illustrated in Fig. 3. However, spot periodontal probing was only done in limited areas rather than full-mouth probing. Recall radiographs were bitewing only. Periodontitis developed and then probably progressed slowly during the last 5 years of the generalist's soft tissue mismanagement. A cosmetic defect due to loss of the maxillary in-



**Fig. 3. A.** Close-up of wedding picture of plaintiff. **B.** Appearance of interdental gingiva 10 years after A. Periodontitis developed and then probably progressed slowly during the last 5 years of the generalist's soft tissue management. The cosmetic defect due to loss of the interdental papillae resulted in a US \$67,500 settlement.

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#### Placing implants without adequate imaging

Implant placement should avoid vital structures, which can often be prevented with pre-placement imaging studies such as computed tomographic scan or, at the very least, panoramic images. Fig. 4 is a panoramic radiograph that demonstrates implants placed into the inferior alveolar nerve, resulting in permanent paresthesia and dysesthesia of the inferior alveolar nerve. The patient was a dentist's mother, which emphasizes that family members should receive the same standard of care and therapy as non-family patients. To assess location of surrounding structures and assess bone density, the prudent practitioner should obtain adequate imaging studies prior to implant placement.

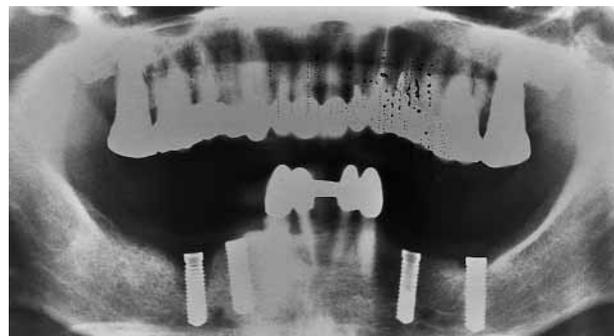
#### Ill-fitting crowns

Over-contoured crowns, deficient (open or overhanging) margins, inadequate embrasure spaces, and invasion of the biological width (length) space can either initiate or aggravate periodontal disease. Experts demonstrate these clinical deficiencies to a jury by showing objective findings including chart, radiographic and photographic evidence. Occasionally, punitive damages have been assessed where crown marginal defects are so numerous and obvious that the jury concluded it was not a case of negligent inadvertence but rather a conscious and deliberate disregard of the patient's health, safety and welfare. Failing to immediately replace permanently cemented defective crowns places patients at a high degree of risk for causing or contributing to periodontitis and/or caries (90). Consequently, punitive damages may be awarded if the dentist acts intentionally to fraudulently conceal negligence such as deliberately permanently cementing crowns that the dentist knows are defective.

#### Periodontal practice in the courtroom

##### Admissibility of expert opinion testimony

Periodontal practice increasingly is evidence-based rather than relying on less scientifically valid anecdotal or case report evidence (45, 53, 66, 85). Federal courts (and state courts that follow federal guidelines) have increased their judicial scrutiny regarding admissibility of expert opinion testimony. US Federal District Court judges act as gatekeepers of such evidence, deciding whether an expert's scientific testimony passes the muster of admissibility into evidence to separate scientific wheat from unscientific chaff. Typically, an expert's deposition is taken before



**Fig. 4.** Radiograph illustrating implants placed into the inferior alveolar nerve resulting in permanent paresthesia and dysesthesia

trial. The trial judge may review the deposition transcript to assess whether the expert's opinion fulfills minimum legal standards for evidence admissibility. The judge may consider four non-exclusive factors in determining whether expert opinion testimony is admissible evidence, as follows:

- whether it has been or can be tested;
- whether it has been subjected to peer review or publication;
- whether it has a known or potential error rate; and
- whether it is generally accepted by the relevant scientific community (29).

If the expert's opinion possesses an adequate evidence-based foundation to support the expert's opinion, that expert's opinion testimony is admitted into evidence for jury consideration. If not adequately supported scientifically, the expert's opinion may be excluded, in whole or in part, from the jury's deliberations. Recently, the United States Supreme Court extended the federal judge's gatekeeper responsibilities to include all expert testimony and not just scientific expert testimony (56).

Depending on each state's statutes and case law, state court judges either follow the lead of federal courts or act more liberally in admitting expert opinion testimony (80, 84). For example, rather than strictly enforce an exclusionary rule, state court judges may act more liberally than federal judges in permitting expert witness opinion testimony to be admitted into evidence, leaving the decision as to whether to believe or disbelieve the expert to the jury's decisional wisdom. If expert opinions consist mostly of guesses or statements of mere possibilities, instead of reasonable dental probabilities (that is, more likely to occur than not), the jury may regard such speculative testimony as lacking sufficient scientific strength to be worthy of belief.

Merely because an expert opinion is offered in testimony, the jury is not bound by such opinion. The jury is free to disregard the opinion and consider it as scientifically unsound and, therefore, not credible. A contrary expert opinion may appear to the jury as possessing the greater weight of truth. The jury decides which side's evidence preponderates in favor of being the more credible expert opinion evidence. Thus, the jury's verdict ultimately decides which side's expert opinion prevails, recognizing that reasonable minds may disagree. Since the plaintiff has the legal burden of proof, if the evidence is equally balanced between plaintiff and defendant, the defense prevails since the plaintiff has not sus-

tained the burden of proof. A witness who possesses greater credentials does not automatically achieve the greater weight of credibility among competing expert opinions. Instead, the jury listening to the evidence may believe a particular expert's opinion is not scientifically well supported or that the witness may be biased and, therefore, untrustworthy of belief.

The therapeutic options for periodontal treatment are constantly evolving as new treatment methods and new drugs become available. Moreover, new products may be relatively unproven by long-term clinical trials in the rush to market. Thus, admitting the testimony of expert witnesses may be problematic if the underlying periodontal science appears promising, but still remains unproven and not generally accepted by the scientific community. Merely because a device is new or is promoted in a new application does not always equate its use with prudent practice. A case in point is laser surgery or subgingival curettage in which Nd:YAG or diode laser is utilized to vaporize intrasulcular pockets (79). The risks of laser damage to cementum (72, 101) may exceed other benefits. The American Academy of Periodontology regards such laser use as experimental (13, 54), and such usage currently lacks general acceptance in the relevant scientific community. On the other hand, an example of improved technology is utilization of magnifying operating glasses with telescopes or binocular magnification. This technological advancement aids detection of residual calculus, marginal breakdowns, fit of implant connecting bars, and examination of furcation areas. Unaided 20–20 vision is no longer the state of the art for comprehensive full mouth evaluations. Fiber-optic lighting, which is available in a variety of instrumentation including disposable periodontal probes, can also assist to help detect residual calculus in a root concavity.

### **Demonstrative evidence**

Demonstrative evidence is evidence that demonstrates an expert's opinion in visual or audio form or both. Jurors are accustomed to receiving information in a visual format augmented by audio, such as television or movies. Most experts enhance their opinions before a jury by illustrating their testimony with paper or blackboard drawings, enlarged textbook drawings and/or customized generic drawings by medical illustrators. The experts who are best received by a jury are often educators or lecturers who are teach complex concepts by breaking the subject

down into simplified terms. For instance, a teaching expert can illustrate various periodontal organisms and their relative pathogenicity using phase-contrast microscopy projected on a screen for jury viewing.

Since a trial functions as a persuasion contest between opposing views of evidence, graphic forms of evidence can be effective and persuasive communication aids. In ascending order of simplicity to complexity, the following are examples of demonstrative evidence utilized by periodontal expert witnesses:

- generic models and drawings of teeth, mouth and jaws;
- chalk drawings on a blackboard;
- drawings on paper utilizing colored felt pens;
- enlargements of charts and radiographs utilizing blowups, overhead projectors, or enlargement of radiographs;
- videotapes;
- dental and medical illustrations drawn by a professional illustrator;
- electronic illustrating pads with video projectors; and
- computer-generated animations (34, 35).

Projection of slide-mounted individual radiographs on a screen represents a virtual no-cost method of enlarging original radiographs for a jury. Illustrating changes between preoperative and postoperative conditions with a screen pointer is also helpful by directing the jury's attention to specific pathology. Illustrations need not be precise in every detail or accurate to scale if the purpose is merely to educate the jury by illustrating generic anatomy or a scientific principle. For example, a current bacterial plaque sample can be introduced in evidence if it is only for the purpose of demonstrating microflora activity of plaque, rather than specifying that a particular patient possessed identical microflora on a particular date.

Modern visual evidence encompasses audiovisual exhibits that recognizes and incorporate the pace of rapidly accelerating technological changes. For instance, video depositions, in whole or in part, can be played back to the jury either to present direct evidence or to discredit a witness with a prior inconsistent statement (37). If the witness is incapacitated, but is still necessary at trial, real-time video may be utilized from the witness's distant location or hospital bed (36). Computer-generated animation provides improved communications regarding complex subjects such as dental implantology or treatments such as bone or connective tissue augmentation procedures.

An experiment demonstrating a scientific principle is admissible into evidence if it simulates the incident at issue or demonstrates an abstract scientific principle. So long as it is fair, accurate and not misleading, experimentation proof constitutes admissible evidence (47). Persuasive physical exhibits may be introduced in evidence, as the Roman Antony did in his use of Caesar's bloodstained toga and slashed body to arouse the Roman mob.

### **Concealment of scientific evidence**

Rather than admit a defective product was marketed and recall the product, corporations sometimes have destroyed or concealed scientific evidence that later exposes them to liability, and punitive damages. A recent example is when fenfluramine (Pondimin) was introduced into the United States market in 1973. Sales remained flat until the 1990s. In 1992, a researcher, with drug manufacturer support, published a study of the dietary benefits of fenfluramine and its chemical cousin dexfenfluramine (Redux). Pondimin sales began to skyrocket the following year. By June 1994, the drug manufacturer had reports of 41 cases of potentially fatal pulmonary hypertension associated with fenfluramine (Pondimin), whereas the labeling only mentioned four (75). By 1994, the FDA recommended stronger warnings about the risk of pulmonary hypertension, including a black box warning highlighting the risk. Although the FDA repeated its recommendation for a stronger drug warning to the drug manufacturer in 1996, it was not done. In early 1997, a Mayo Clinic study linked potentially fatal heart valve damage to fenphen and in September of 1997, the FDA recommended that it be withdrawn from the market (14). In litigation against the manufacturer, the court considered ordering the manufacturer to preserve all documents, including computer backup tapes and E-mails. If the drug manufacturer subsequently violated the court's order and destroyed such documents, the judge would likely instruct the jury that, if the destruction was done with consciousness of guilt, the jury could consider the destruction of evidence in judging the manufacturer's credibility. In this fen-phen example, the manufacturer settled the case before the jury reached its verdict (61). Later, in the first case to be decided by a jury, the verdict was US \$23 million (62) and in another case, five plaintiffs were awarded a total of US \$150 million (77). Shortly thereafter, U.S. District Judge Louis Bechtel tentatively approved a US \$3.75 billion class action settlement against American Home Products who

made the fenfluramine, the “fen” in fen-phen under the brand name, Pondimin, and a similar drug, Redux.

## Litigation myths

Trial lawyers and personal injury lawsuits are the favorite whipping-boy targets for tort reform. Typical myths surrounding litigation are disputed by evidence-based facts that demonstrate that the need for tort reform is unfounded.

### Myth no. 1

Personal injury lawsuits, which include dental negligence actions, are clogging the courts, causing a litigation “explosion”.

#### *Fact*

Between 1984 and 1996, civil filings increased by 31% compared with criminal filings, which increased by 41%; juvenile filings, which increased by 64%; and domestic relations filings, which increased by 74% (58). Furthermore, there is no medical malpractice or products liability explosion. In 1992, medical cases comprised only 2.4%, and product cases only 1.7%, of all civil cases. Filings for newer torts, such as sexual harassment, doubled between 1991 and 1997, and are changing the litigation landscape (91). Moreover, there is not one juried empirical study demonstrating a crisis in the field of tort law (40, 82). State supreme courts in Ohio, Indiana, Oregon, and Illinois have recently struck down, as unconstitutional, tort “reform” laws as improper legislative intrusion upon the exclusive authority of the judiciary (28). The real culprit clogging the courts is business litigation that comprises more than one-third of all civil cases in state courts. Businesses file ten times as many lawsuits as injured consumers. Businesses suing each other over contract disputes comprise the single largest category of lawsuits filed in federal court.

### Myth no. 2

Undeserving personal injury plaintiffs recover millions in frivolous lawsuits.

#### *Fact*

Most personal injury lawsuits are anything but frivolous and often accomplish a great deal by bringing

about measurable safety improvements or exposing consumer fraud. Jury verdicts have forced safety improvements in drugs, cars, tractors, industrial equipment, children’s pajamas and other unsafe or defective products.

News media reports of large verdicts often distort facts and contain omissions. No case has been more distorted than the McDonald’s scalding coffee case and the claim that the plaintiff contributed to her injury by holding the hot coffee in her lap. What the media omitted was when the cup of coffee spilled in plaintiff 79-year-old Stella Liebeck’s lap, she suffered third-degree burns over 6% of her body – including her inner thighs, buttocks, and genital and groin area, requiring 8 days of hospitalization, painful skin grafts, and debridement. Contrary to some reports, she was not driving her automobile, nor was it moving, during the spill. Instead, she was sitting in her parked car attempting to remove the coffee cup’s lid to add cream and sugar. McDonald’s knew its coffee had scalded consumers prior to Ms. Liebeck’s incident. McDonald’s had received more than 700 prior burn claims. Notwithstanding, McDonald’s maintained a policy requiring coffee be kept at 180°F to 190°F (much hotter than coffee from other competing fast food outlets) even though McDonald’s knew that a burn hazard existed with liquids served above 140°F. Overheating the coffee resulted in greater profits by increasing the number of servings per coffee pound. McDonald’s refused plaintiff Stella Liebeck’s demand for US \$20,000 to pay her medical expenses. The jury’s punitive damages verdict of \$2.7 million was reduced by the trial judge to \$480,000 and, thereafter, plaintiff settled for an even lesser sum. However, the verdict sent a clear message to McDonald’s, and the temperature of its coffee was immediately lowered to that of its competitors (59, 60, 87).

### Myth no. 3

Professional malpractice suits are forcing “defensive” practices and thereby driving up the cost of medical and dental services.

#### *Fact*

According to a 1992 report by the Congressional Budget Office, malpractice insurance premiums account for less than 1% of total health care costs.

About 8% of diagnostic procedures are ordered because of physicians’ conscious fear of liability, according to a 1994 report by the Office of Technology

Assessment, the nonpartisan Congressional research agency. In its 1994 report, the office noted that “a high percentage of defensive medical procedures are ordered to minimize the risk of being wrong when the medical consequences of being wrong are severe.”

According to the 1995 World Competitiveness Report, issued by two Swiss groups, the United States has the most competitive economy in the world. Consumer protection laws in the United States enhance American competitiveness by motivating companies to manufacture the safest and highest quality products. Liability costs for U.S. corporations decreased 37% in the past 5 years according to an Ernest & Young study of Risk and Insurance Management (74).

## Emerging legal issues in periodontics

As noted elsewhere in this chapter, periodontology has undergone remarkable technological changes in recent years. While providing new tools for preventing, diagnosing, and treating periodontal disease, this developing technology imposes a burden on the practitioner to remain prudently knowledgeable about new periodontal therapies. For example, computer technology will play an increasing role in monitoring prescriptions for drug interactions. In one study, computer alerts resulted in one-fourth of the prescriptions being changed after prescribing physicians were notified of potential inappropriate use in an elderly population (19, 73). Practitioners must constantly upgrade their knowledge through journal reading and continuing education courses. Although the standard of care may not require the practitioner to always practice the latest therapies, the practitioner should be sufficiently knowledgeable to provide adequate informed consent for patients who require sophisticated therapy. The prudent practitioner in the 21st century will be increasingly technologically knowledgeable in order to provide optimal patient care and avoid malpractice claims.

## Changing therapies

### Drugs

A dentist is obligated to provide reasonable care and reasonable treatment options for patients. A dentist is not a guarantor of success or of perfect outcome. Newer drugs and periodontal therapies may aid di-

agnosis or treatment, but dentists are not obligated to incorporate every new product or procedure in their practice. New products are often introduced into the marketplace without long-term studies that prove efficacy. Moreover, statistically significant proof of efficacy does not necessarily mean that a drug has a clinically significant effect (48). Regardless of statistical proof resulting from clinical trials, practitioners must make decisions regarding the value of any new drug in terms of its clinical significance for their patients. As a general maxim, the general dentist should not be the first or the last to adopt new treatment methods. Ultimately, the marketplace determines general acceptance based upon proven reliability.

### Surgical versus nonsurgical therapy

Choosing between nonsurgical versus surgical periodontal therapy involves a choice between well-recognized and proven efficacious therapies. However, assuming the practitioner is equally competent in providing both forms of therapy, it is the patient's option to decide between surgical or nonsurgical therapy (10). If the generalist is not reasonably or adequately trained in providing comprehensive periodontal surgical therapy, the patient should be provided with the option of referral to a periodontist. Regardless of the training of the general dentist, the patient should be provided with the pros and cons of each treatment method since it is the patient's prerogative to choose a treatment. The informed consent doctrine requires the reasonable dentist to make reasonable disclosures to the patient of the risks, benefits, and alternatives of reasonably available therapies, as well as the consequence of doing nothing. Limitations of nonsurgical therapy include the dentist's inability to mechanically adequately debride the entire root surface adjacent to deep pockets and gain access to tortuous root configurations such as root concavities and furcation areas. Moreover, it is difficult for both patient and therapist to maintain deep pockets because of access limitations. On the other hand, surgical therapy also has risks and limitations. Regardless of whether nonsurgical or surgical therapy is chosen, patients must be monitored during periodontal maintenance recall examinations to re-evaluate whether the periodontal disease is controlled and to determine if new diseased sites are emerging.

Studies demonstrating the efficacy of nonsurgical therapy have included very thorough and meticulous scaling and root planing performed by periodontists

or periodontal hygienists in university-based centers. This is not the same treatment as a superficial 30-minute prophylaxis performed by a general dentist or a hygienist in a private general practice. Circumstantial evidence of a poorly maintained patient circumstantially includes residual subgingival calculus, excessive bleeding on probing and progressive bone loss that was undetected because only bitewing radiographs were taken. In such a case, the patient was compliant with regular recalls, but the dentist was noncompliant with the standard of care.

The American Academy of Periodontology Insurance Statement on scaling and root planing states that periodontal scaling and root planing are arduous and *time consuming* (emphasis added). Moreover, regardless of how current the dentist may be in utilizing advanced diagnostic procedures, such as microbial DNA testing of selected periodontal sites, such technology will not excuse fundamental foundational requisites of periodontal maintenance. This includes adequate root debridement, frequent periodontal maintenance, periodic reevaluation, and periodic re-instruction in patient plaque control procedures.

#### **Advanced surgical techniques and new therapeutic procedures**

Advanced surgical techniques, including regenerative grafting procedures, have enhanced the ability to maintain a healthy periodontium. Most general dentists are not trained in advanced surgical procedures, nor is it a requisite for predoctoral dental education to teach proficiency in all periodontal surgical procedures. Nevertheless, general practitioners must be aware of widely accepted new or improved procedures so patients can be advised of their availability. The patient may then elect whether or not to choose specialty consultation for such procedures. For example, by failing to monitor and intervene for progressive gingival recession due to overzealous brushing or other contributory causes, recession may progress to the extent that corrective grafting may no longer be feasible.

#### **Implants**

Many different types of implants exist and not all are approved by the FDA. Implants vary by differences in design, applications, materials, size, recommendations for timing of placement, and the need for second-stage procedures. Moreover, the standard of care in implantology frequently offers a wide range

of acceptability, depending upon the implantologist's reasonably sound judgment. Therefore, the standard of care in implant practice is difficult to define. However, certain biomechanical principles apply regardless of the implant system used. Examples of these principle include:

- Utilization of a single implant as a mid-span pier abutment in a long-span bridge is becoming less acceptable. Instead, the treatment plan should consider use of single crowns as terminal abutment teeth and the use of multiple single implants in edentulous areas (57).
- Where pretreatment films indicate close proximity of vital structures such as the inferior alveolar nerve or sinuses, the prudent practitioner should use imaging technology, such as computed tomographic scans or panographic (panoramic) film, to localize the vital structures (5).
- Splinting implants to natural teeth should be avoided in situations where occlusal forces may cause super-eruption, infraocclusion, or premature loading of implant crowns before the implant has had adequate time to osseointegrate (71, 76, 83).
- The prudent practitioner must guard against over treatment, including unnecessary extraction of treatable, periodontally diseased teeth.
- Placement of implants in nonfunctional areas should be avoided.
- Patients should be advised of reasonably acceptable alternatives. For example, a patient with a single missing tooth might be advised that it could be replaced with an implant or a three-unit fixed bridge.

#### **Periodontic and endodontic considerations**

Untreated progressive periodontitis may lead to endodontic complications. Alternatively, periodontal treatment is ineffective when the cause of the periodontitis is related to an endodontic lesion. Pulp testing should be considered when the potential for combined periodontal-endodontic lesions exists.

#### **Grafts**

Various types of graft materials including autogenous and allografts are used in periodontal therapy. The choice of which materials to use is within the scope of reasonable judgment of the practitioner. Since the patient is not in a position to scientifically weigh the relative benefits of various graft materials,

the practitioner is not required to offer patient choices in obtaining informed consent for periodontal grafting. Nevertheless, the patient should be advised if there are particular risks that are unique to a particular grafting material so that the patient may either select an alternative grafting material or decline the graft procedure altogether. For religious reasons, a patient may decline porcine or cadaver graft material and, therefore, should be so informed in advance of the procedure.

### **Risk factors**

A general dentist should be cognizant of risk factors that initiate or propagate periodontal disease. Local factors operate under the dentist's direct control such as well-adapted and fitting restorations and reducing or controlling root calculus accumulations. Other risk factors may require referral. For instance, cigarette smoking increases the risk of the occurrence and severity of disease (1). Due to the difficulty of stopping nicotine addiction, smoking cessation programs may not be successful (68). Nevertheless, patients should be advised of their availability and of the negative influence of smoking on periodontal health as well as the potential periodontal benefits of quitting. Since uncontrolled diabetes is a risk factor for periodontitis (41), referral to a physician to monitor or maintain diabetic control may be necessary. On the other hand, patients with well-controlled diabetes can be treated the same as a healthy patient (41).

### **FDA regulations**

Unlike device and drug manufacturers, individual practitioners are exempt from FDA requirements for reporting adverse incidents. Instead, voluntary reporting is encouraged (63, 65). However, despite reporting confidentiality, approximately less than ten percent of adverse incidents are ever reported by practitioners. Consequently, adverse side effects of drugs are underreported and, therefore, underappreciated. The FDA prohibits drug manufacturers from advertising a particular usage for their products unless safety and efficacy are first established by carefully controlled clinical studies. However, until 1999, the FDA regulations did not apply to individual practitioners, who were always free to prescribe off-label uses for approved drugs. In 1999, U.S. District Judge Royce Lamberth struck down, as unconstitutional pursuant to the First Amendment right of free speech, the advertising restrictions in the FDA

Modernization Act (38). Thus, the court ruled that the FDA Modernization Act, which otherwise would have permitted the FDA to regulate off-label usage (such as FDA approval before distribution of promotional materials) unduly restricted the First Amendment free speech of drug companies. Nevertheless, drug manufacturers who advertise prescription drugs directly to the public can no longer rely on the dentist as the learned intermediary to provide proper warnings of drug dosages or side effects but must do so in the public advertisement (81).

The practice of modern periodontics is increasingly evidence based (53). Off-label drug use relies upon unpublished individual practitioner predilections or anecdotal evidence which are not research based or tested. Patients risk injurious consequences because controlled studies have not established the safety of off-label usage. Such prescribing may not be illegal, but it is nonetheless imprudent if no peer-reviewed research or drug company testing has established that the benefits are proven to outweigh risk. For example, the FDA has approved chlorhexidine-containing chips for adjunctive use in scaling and root planing. The use of chlorhexidine-containing chips for treatment of acute periodontal abscesses is not a specifically labeled use. It is this author's opinion that using a chlorhexidine-containing chip to treat a periodontal abscess incurs the risk of making the condition worse by risking pocket closure at the gingival orifice of the abscess.

To avoid unknown hazards, prudent dentists should be cautious in prescribing or recommending unproven off-label drug or product use. It is generally accepted that dentists should not attempt willy-nilly off-label use, but rather should await FDA approval of expanded label use because such approval is based on carefully controlled research studies. Unfortunately, once any drug is marketed, the only limitation for drug usage appears to be the imagination of practitioner or patient.

## **Conclusion**

Good dentists who deliver dental care with reasonable competence and who substantiate their treatment with well-documented records have little to fear from litigation. As long as patients' rights and interests are protected, the dentist will be protected against legal liability. The law protects patients but also fulfills dentistry's ethical obligations to always keep the patients' best interests first and foremost.

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