



Legal Considerations in the Use of Cone Beam Computer Tomography Imaging

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ABSTRACT Cone beam computed tomography imaging represents a paradigm shift for enhancing diagnosis and treatment planning. Questions regarding cone beam computed tomography's associated legal responsibility are addressed, including cone beam computed tomography necessity, recognition of pathosis in the scan's entire volume, adequate training, informed consent and/or refusal and current court status of cone beam computed tomography. Judicious selection and prudent use of cone beam computed tomography technology to protect and promote patient safety and efficacious treatment complies with the standard of care.

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Cone beam computed tomography, CBCT, technology was introduced to the dental profession more than a decade ago. It offers a new means of visualizing the orofacial complex to provide valuable diagnostic and treatment planning information for the dental patient. Indeed, in multiple applications of everyday dental practice, CBCT enhances diagnostic accuracy of disease detection, reveals anatomic structures that complicate treatment or allows confident identification of anatomic variants that simulate disease but do not require intervention. An increasing number of publications supporting CBCT use and the availability of CBCT scanners in universities, private dental offices and dental radiographic laboratories has facilitated the availability of CBCT imaging for the diagnosis and treatment planning of the dental patient. It can be argued that in many

ways CBCT technology has transitioned from a paradigm shift in orofacial imaging to a standard of care for dental practice for diagnosing or managing some conditions.¹

California courts define the standard of care as that level of skill, knowledge, and care that a reasonably careful dentist should possess and use for diagnosis or treatment.² Reasonably careful dentists comply with the standard of care in using CBCT to maximum advantage for diagnostic accuracy in radiographic interpretation and treatment planning.

In conjunction with the advantages and opportunities from the application of new technologies in patient care, responsibilities and obligations for proper use of such technologies also emerge. Pertinent legal questions and answers for CBCT technology are categorized below in questions involving diagnosis, training, utilization, and patient involvement.

Diagnosis

Q: Is a dentist legally obligated to recognize or diagnose all disease evident in a CBCT examination if it is not in the field of interest for which the CBCT was ordered?

A: Multiple dentists and dental organizations have expressed the belief that similar to conventional radiographs, the responsibility of the clinician is not limited to only the field of interest being diagnosed and/or treated. As recommended in a leading dental radiology textbook, "Practitioners should avoid limiting their attention to one particular region of the film, all aspects of each film should be examined systematically."³ The executive board of the American Academy of Oral and Maxillofacial Radiology, AAOMR, the professional organization representing oral and maxillofacial radiologists in the United States, recommends that dentists should be competent to identify abnormalities and suspicious areas of pathosis existent in the entire CBCT scan or refer the images to a specialist for final interpretation.⁴ The American Association of Orthodontist's Council on Scientific Affairs surveyed various university-based radiology departments and concurs with the AAOMR's executive committee's conclusion that a CBCT scan should be read in its entirety.⁵

There are several legal perspectives to this question. First, is the treating dentist legally responsible to recognize and/or diagnose disease in the structures that fall within the scope of the dentist's license as defined by the California Dental Practice Act but outside the dentist's area of interest?⁶ The California Dental Practice Act defines dentistry to include "diagnosis or treatment, by surgery or other methods of disease and lesions" of the "jaws or associated structures."⁷ Accordingly, such diagnosis or treatment may include all necessary related proce-

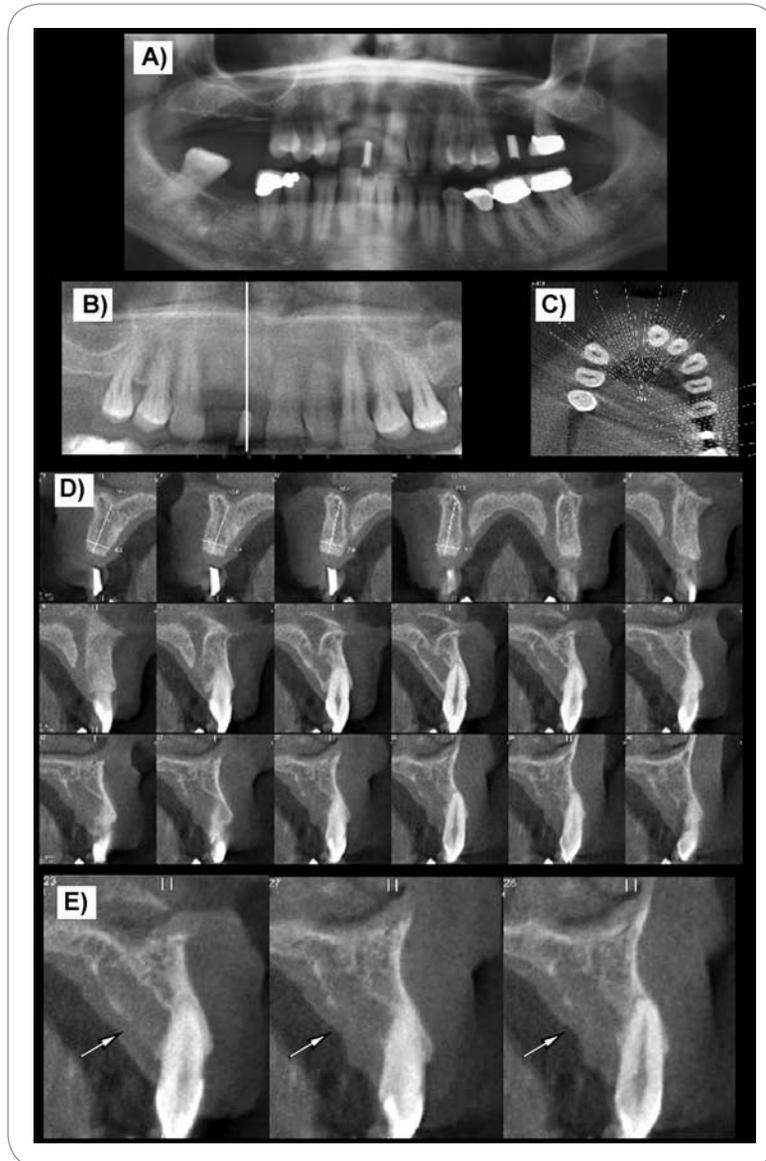


FIGURE 1. (A) Cropped conventional panoramic radiograph of patient A, prior to implant placement. Two radiopaque markers at the areas of prospective implants are in place. (B) "Panoramic" CBCT reconstruction showing the opaque marker at the area of the anterior maxilla. (C) An axial slice through the maxillary teeth showing the position and number of transaxial slices through the implant areas. (D) A series of transaxial slices through the area of teeth Nos. 8-10. Bone width and height measurements at the area of the marker demonstrate sufficient quantity and adequate quality for implant placement. Adjacent to the marker and lingual to teeth Nos. 9 and 10 an irregular radiolucency is observed. There is erosion of the palatal cortex of the maxilla with no tooth displacement and minimal bone expansion. (E) Selected magnified transaxial sections through the area of the lesion. This radiographic presentation is consistent with malignant disease or infection. Biopsy of the lesion demonstrated metastatic malignancy of unknown origin.

dures that may include a CBCT as an "other method" of diagnosing disease in "associated structures." **FIGURES 1A-D** illustrates an unanticipated incidental finding of metastatic malignancy in the anterior max-

illa detected in an asymptomatic implant patient. This finding completely changed the treatment planning of the patient.

Second, is it within the scope of the dentist's license to recognize and/

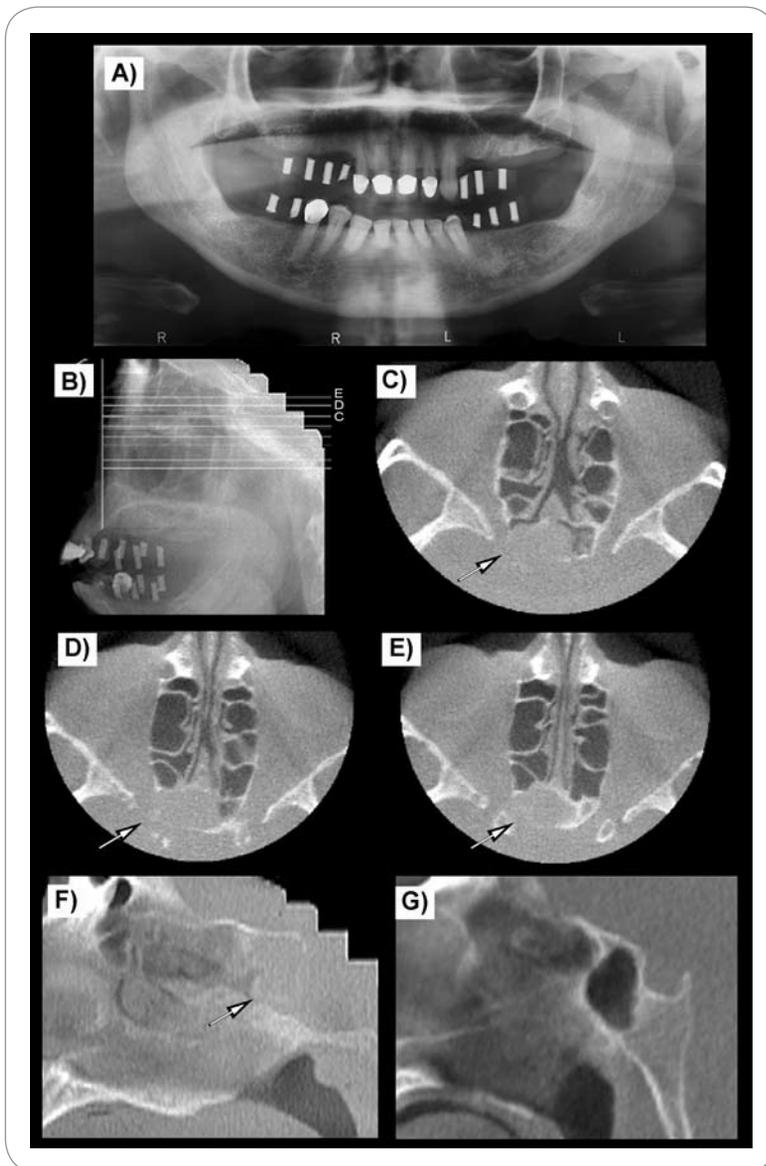


FIGURE 2. (A) Conventional panoramic radiograph of patient B prior to implant placement. Twelve radiopaque markers at the areas of prospective implants are in place. The facial structures are unremarkable. (B) Detail of scout view from CBCT. The radiopaque markers are seen at the area of the jaws. The position of axial slices through the midface and base of the skull area is marked. (C, D and E) Three representative axial slices through the base of the skull. Note opacification of the sphenoid sinus and destruction of the sphenoid sinus walls and floor of the sella turcica (arrows). (F) Sagittal slice at the midline, through the skull base. Destruction of the sella turcica and complete opacification of the sphenoid sinus are seen (arrow). (G) Sagittal slice at the midline, through the skull base of a normal individual is provided for comparison with (F). The lesion in patient B was subsequently determined to be a pituitary gland tumor.

or diagnose pathosis outside the dental alveolar complex? The answer to this question has not yet been definitively decided by a California appellate court. In the interim, it is a general legal

principle to always prudently err on the side of caution and presume a dentist is obligated to recognize pathosis in the entirety of the CBCT scan as peer-reviewed literature recommends.^{4,5,8,9}

FIGURES 2A-F illustrate such a case where a pituitary tumor causing destruction of the sella turcica and sphenoid sinus was discovered as an unexpected incidental finding in the CBCT scan of an implant patient. As with the malignancy in **FIGURE 1**, a dentist would not be required to diagnose the pituitary tumor as the cause of the destruction but rather recognize a suspected abnormality or pathosis, which mandates referral for final diagnosis and any needed treatment.

Moreover, full-volume scan assessment is in accord with dentistry's paramount ethical obligation to always protect the patient's best interest to preserve patient health and safety.¹⁰ Consultation with specialists, such as oral and maxillofacial radiologists, oral and maxillofacial surgeons, oral pathologists, or medical specialists as warranted can aid in this task.¹¹ Clinical findings, as well as pertinent medical and dental history, are useful to help evaluate CBCT examination findings and should be included when a referral to a specialist is made to aid a CBCT interpretation. Peer-reviewed literature and numerous dental specialties who support the concept that a dentist must identify suspicious conditions within the entirety of a CBCT scan may provide the greater weight of expert opinion to any future court ruling that a dentist practices within the scope of the practitioner's dental license when identifying abnormalities in the CBCT's scan entire volume and/or referring for a final diagnosis.^{4,5,8,9,12,13}

Third, is the treating dentist legally responsible to identify a lesion in structures other than the orofacial complex, if this dentist is also practicing under a medical license? Although no California appellate court has ruled in such a case, the answer is probably "yes," since the medical license extends responsibility for care to these structures.

Q: Once an abnormality is identified on a CBCT, who is legally responsible to diagnose, treat, or refer this condition?

A: The responsible dentist is the one who orders the CBCT examination. For instance, suppose a generalist refers a patient to a surgical and prosthetic specialists for implant placement and prosthetic restoration. In this scenario, only the treating specialist who orders the CBCT examination is liable. If the generalist also incidentally uses the CBCT for either diagnosis or treatment planning, then the generalist may also be liable.

A general dentist's identification of disease is ordinarily a final diagnosis. This would include, for instance, an endodontic lesion necessitating root canal therapy that the generalist may treat or refer to an endodontist. However, if the generalist can only identify but not diagnose the abnormality, a referral should be made to determine a final diagnosis. By analogy, a dental hygienist is trained to recognize but not diagnose dental disease but yet must obtain a diagnosis for suspected pathosis or refer.

Q: If a treating dentist refers a CBCT scan to a board-certified oral and maxillofacial radiologist for diagnosis of the whole imaged volume and it is later determined that a lesion was detectable but missed by both, is the treating dentist protected from liability?

A: Although referring to a competent radiologist specialist to interpret a CBCT substantially reduces the likelihood of a missed finding, misdiagnoses can occur. The radiologist is principally responsible for any misdiagnosis. The fact that a radiology specialist did not identify the pathosis substantially reduces the potential liability of the referring dentist who reasonably relied upon the radiologist's specialized training and expertise.

Q: Is the treating dentist legally responsible for identifying the anatomical course of the inferior alveolar nerve canal, IANC, on a CBCT reconstruction if an X-ray lab provides a tracing or images with the outline of the IANC?

A: Yes. A dental lab technician is not legally permitted to diagnose. A dentist must either confirm or reconfigure the drawn IANC. Therefore, the X-ray lab should not only provide an estimate of the IANC course as drawn but also additionally provide the same image absent the X-ray lab's drawing. The dentist can then make the final diagnosis of the IANC location including the ascending IANC portion, mental foramen, any anterior loop of the mental nerve and anomalies such as a bifid canal. Just as the dentist is responsible for evaluating the quality of the dental lab's prosthesis prior to restoration cementation, so is the dentist responsible for identifying the precise location of vital structures within the CBCT for diagnosis and treatment planning.

Training

Q: Suppose the dentist received no training in dental school in recognizing lesions located superior or posterior to the maxillary sinus. Is the dentist still legally responsible to recognize disease outside the scope of the dentist's academic training?

A: Yes. A reasonably careful dentist must keep current with continuing education. California State Board continuing education, C.E., requirements for license renewal are only a licensing standard that does not mandate, with few exceptions, any particular C.E. credits such as dental radiology.¹⁴ A reasonably careful dentist should keep current in all fields of dentistry in which the clinician practices and particularly when employing new technology, which requires training and skill for adequate utilization.



FIGURE 3. CBCT sagittal reconstruction demonstrating a dental implant penetrating through both the superior and inferior cortical borders of the inferior alveolar nerve canal.

Numerous authors increasingly opine that dentists using CBCT should be held to the same standard as a board-certified oral and maxillofacial radiologist.^{5,8,9,12} By analogy, dentists extracting horizontally impacted wisdom teeth are held to the same standard as oral and maxillofacial surgeons.^{13,15} Similarly, generalists are held to the same standard as an endodontist performing root canal therapy because endodontists set the standard of care in endodontics.¹⁶

Q: Should a general dentist use a CBCT for diagnosis or treatment planning without training?

A: No. Virtually any new sophisticated technology requires training. Also, the standard of care requires a dentist to possess a requisite degree of learning and skill.² A dentist cannot exercise reasonable skill and learning if the dentist does not first possess the requisite learning and skill that the standard of care requires. Learning includes not only didactic classes but also hands-on training. The third dimension of a CBCT requires training to assess moving on the computer static sequential imaging series. By analogy, a dentist should not employ laser technology or perform implant surgery without a minimum amount of hands-on training.¹⁷ **FIGURE 3** demonstrates a case of implant placement within the IANC, seen on a postimplant placement CBCT image. Interestingly, the dentist had obtained a medical CT prior to implant placement. Apparently, these CT images were misinterpreted. As a consequence, the preoperative height of the alveolar ridge implant site was overestimated.

A dentist's legal and ethical obligation is to always protect the patient's best interest.^{10,18} Instead of doing no harm (*primum non nocere*), an undiagnosed disease harms the patient if not treated at the earliest time since treatment delayed denies optimal therapy with improved prognosis. A dentist who acquires a CBCT and fails to assess the entire scan volume is not exercising the dentist's best judgment but rather is practicing blindly.

Q: What constitutes adequate training to interpret CBCT examinations?

A: As with any new technology, the best training is hands-on training. With CBCT, such training should not be limited to the technical issues of patient positioning, image reconstruction and multiplanar sectioning, but should expand to the recognition of normal anatomy and anatomic variants that might complicate treatment or simulate disease, as well as to the identification and interpretation of pathosis. A certificate of training is helpful to prove to a jury that the dentist achieved minimum competence to interpret CBCT scans. An example of circumstantial evidence of a gross departure from the standard of care would be that despite a preoperative CBCT the implant was placed through the entire diameter of the IANC. Indirect circumstantial evidence may infer that either the dentist's CBCT training program was inadequate or that the dentist violated the principles taught in the CBCT course. Circumstantial evidence is entitled the same weight of proof as direct evidence.¹⁹ Alternatively, an expert may opine that such an extreme degree of IANC penetration ordinarily does not occur except for probable operator negligence.²⁰ This legal doctrine of *res ipsa loquitur* means the facts speak for themselves.

One of the defenses to dental negligence is that the dentist made a reasonable

judgment error.²¹ A dentist's best judgment should not be impaired because of ignorance or by failure to become current with ever improving CBCT technology.

Utilization

Q: Is every patient likely to benefit from a CBCT examination?

A: No. The dentist is obligated to determine when a CBCT is necessary to complement conventional 2-D images. Reasonable and careful judgment is a necessary prerequisite in selecting patients for any radiograph including CBCT. Only after obtaining a thorough dental and medical history and

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performing a detailed clinical examination, the dentist should carefully assess the necessary radiographic procedures required. Prudent practice requires the practitioner to justify radiation exposure based upon likely patient benefit exceeding ionizing radiation risk and the financial cost.²² Optimization for radiation hygiene safety is premised on three justification principles as follows²³:

1. Imaging will probably do more good than harm.
2. The radiological procedure will likely improve diagnosis and/or treatment.
3. Alternative imaging with less or no radiation and/or prior imaging is equivocal or unavailable.

Using a CBCT scan for screening purposes, without appropriate clinical indications, should be avoided. Unnecessary

or overutilization may create conflicts of interest, particularly if a specific CBCT unit is installed in the dental office and scans are made indiscriminately. Indeed, physicians who own their own medical CT facility are five to seven times more likely to order CT scans than those who refer to outside facilities.²⁴ The practitioner is always obligated to protect the patient's best interest regardless of the practitioner's financial interest.^{10,18} The patient is entitled to information about different options, including a discussion of conventional imaging, CBCT and CT in terms of radiation dosage, fields of view, resolution, and cost. The adequately informed patient has the ethical and legal right to make the final decision in compliance with the principle of patient autonomy.^{10,25}

Q: Is the type of CBCT unit used important from a legal perspective?

A: CBCT scanners can be categorized according to the field of view, FOV, as large, medium, and small FOV units. A large FOV can include intracranial structures, the base of the skull, paranasal sinuses, cervical spine, neck, and airway. A small FOV is typically limited to the maxilla or mandible, exposes fewer anatomic structures, produces less scatter, creates fewer artifacts and in general provides a higher resolution image. Thus, the smallest FOV of a CBCT available that covers the area of interest should be chosen. (See previous articles and references within this issue of the *Journal*).

An additional benefit of using the smallest FOV scan for the diagnostic task is that fewer anatomic structures will be visualized, thus minimizing the necessity to detect any incidental abnormalities outside the area of interest. Therefore, a small FOV limits legal liability of unidentified pathosis outside the dentist's treating field of interest since such disease outside the dental alveolar complex is less likely to be depicted in the scan.

Q: Can the dentist be liable for not ordering a CBCT or other volumetric examination?

A: If conventional intraoral or panoramic radiographs provide the diagnostic information for appropriate treatment planning, CBCT imaging should not be used. However, CBCT or other 3-D evaluation should always be considered when 2-D imaging is equivocal in providing a final diagnosis. This is particularly important in cases where a treatment complication requiring immediate corrective care is suspected and/or if the patient is unresponsive to treatment.

For example, postoperative anesthesia or paresthesia eight hours following implant placement near the IANC or its anterior loop should direct the practitioner to consider a CBCT to aid in the diagnosis of any potential IANC or anterior loop penetration, if periapical or panoramic radiographs are inconclusive. Similarly, CBCT imaging can provide valuable diagnostic information in cases of persistent or enhanced pain or paresthesia after endodontic treatment or suspicion of endodontic treatment complications such as perforation, fractures, short fills, missed or apically transported root canals, and endodontic overfills into the IANC. Such complications would be difficult to evaluate accurately with 2-D imaging.

FIGURE 4 demonstrates a case of endodontic perforation with resulting sodium hypochlorite injury to the lingual gingiva (**FIGURE 4A**). A periapical image made after a root canal treatment was aborted midendodontic treatment because acute severe pain did not reveal the perforation (**FIGURE 4B**). However, the lingual perforation is clearly evident on the CBCT image (**FIGURE 4C**) and on the postextraction photographs (**FIGURE 4D**). This case demonstrated that periapical 2-D imaging did not identify endodontic perforation as the probable cause of lingual tissue sloughing, while CBCT imaging provided objective circumstantial evidence of

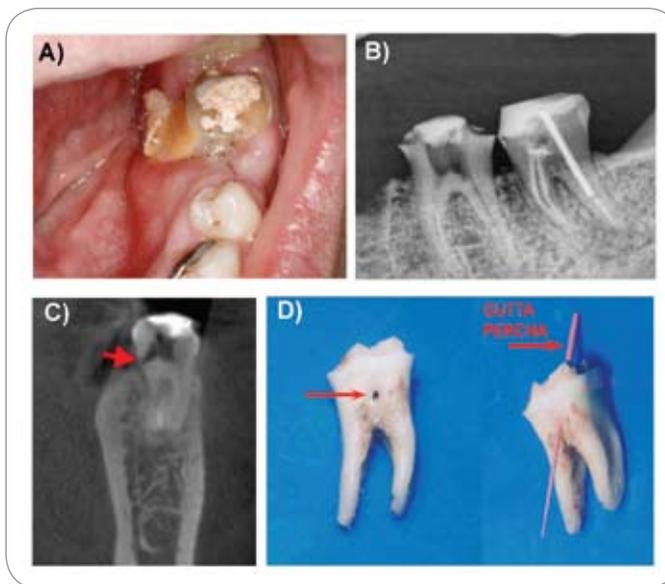


FIGURE 4. (A) Clinical picture demonstrating soft-tissue sloughing of lingual gingiva after application of sodium hypochlorite during endodontic treatment of No. 19. (B) Midtreatment periapical radiograph erroneously demonstrating unperforated root of No. 19. (C) CBCT cross-section showing perforation of the lingual surface of No. 19 at the cervical area (arrow). (D) After extraction of No. 19, the perforation is clearly seen (arrows). A gutta percha cone has been inserted in the perforation through the coronal surface of the tooth.

the perforation portal of entry for irrigating bleach diffusing through the perforation lingually into the underlying tissues.

Q: Are CBCTs necessary for all implant placements?

A: The 2000 position paper from the American Academy of Oral and Maxillofacial Radiology opined that cross-sectional imaging, which today may include CBCT, before implant placement should be performed for all implants.²⁶ However, other experts may disagree whether CBCTs are necessary in all instances, particularly if there is a wide margin of safety distance between the proposed implant depth and vital structures along with ample ridge height and width for prosthetic alignment. Thus, reasonable dentists may have reasonable differences of opinion. Moreover, a CBCT may not be geographically accessible, although medical CTs are widely available.

There is general consensus that for implant surgery a 2 mm safety zone between the maximum implant drill depth and superior border of the IANC should be maintained.²⁷⁻²⁹ A CBCT should be consid-

ered if this safety zone distance cannot be accurately estimated with 2-D imaging. With only a periapical film, the mental foramen is clearly shown only half the time and is anatomically accurate within 1 mm between the alveolar crest and the superior crest of the IANC only 17 percent of the time.³⁰

CBCT is preferred over medical CT since CBCT delivers considerably less radiation and provides comparable diagnostic accuracy of bone and teeth. A medical CT's superiority for soft-tissue analysis compared with a CBCT is usually not needed for implant placement.

Should a complication arise following implant placement when a preoperative CBCT and surgical guide were not used, a CBCT may become necessary for postoperative evaluation of whether the implant is malaligned or impinging upon or penetrating into vital structures.² A CBCT can then aid the decision to remove or partially retract before osseointegration occurs. CBCT also aids in diagnosing cause of postoperative neuropathic pain or paresthesia including endodontic overfills into the IANC.

Patient Involvement

Q: When medical CT is chosen instead of CBCT, is informed consent regarding comparative radiation safety required?

A: If a procedure involves the risk of serious injury, a patient is entitled to be informed of these risks. Dental literature from 15 years ago stated that there was no proven biologic harm from routine dental X-rays.³¹ Current literature does not exclude the possibility of harm from diagnostic exposures.³² Imaging procedures with ionizing radiation are an important source of exposure resulting in the combined cumulative effects of natural background and ionizing radiation. The linear nonthreshold hypothesis holds that any ionizing radiation has a potential carcinogenic effect, regardless of dose level.^{23,33-37}

Notwithstanding, in one study the majority of ER physicians and almost half the radiologists did not appreciate any cancer potential from CT radiation.³⁸ Thus, the radiation protection principle of ALARA, as low as reasonably achievable, is relevant to all radiation exposures. In the 1980s, the annual average per capita radiation dose from medical procedures was 0.54 mSv.³⁹ Today, it is 3.2 mSv in the United States and between 0.7 mSv and 2.0m mSv in Europe.³³ Increased use of medical CT and nuclear medicine examinations accounts for most of the increased radiation exposure.^{17,23,28,31,34,35,40,41} The effective dose from CT and CBCT examinations can vary widely but typically CBCT exposures are 10 percent or less of a medical CT examination.⁴²

For many common clinical applications such as implants or orthodontics, CBCTs offer diagnostic efficacy comparable to medical CT at a fraction of the exposure. For small volume issues such as endodontic, TMJ, or single-implant placement applications, high-resolution CBCT is superior to medical CT.¹² Accordingly,

the patient is entitled to be informed of the CBCT's advantage over CTs for accuracy, lower radiation, and likely lower costs. Thus, a patient may elect to travel a greater distance to obtain a CBCT rather than obtain a geographically convenient CT at a closer medical CT facility. The informed consent doctrine requires the patient being advised of their options so the patient may make the final decision.²⁵

Q: Is the dentist responsible if the patient refuses a specialist referral after a suspicious lesion is identified on the CBCT?

**A DENTIST HAS THE
right to refuse treatment
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and should do so.**

A: California informed refusal law requires that the patient be informed of the consequences of their refusal.⁴³ The chart and also, preferably, an informed refusal form should document that the undiagnosed condition may include malignancy, life-threatening or disfiguring tumors. Most patients will probably reconsider a necessary referral rather than sign an informed refusal form that advises them of the consequences of a refusal. As an extra abundance of caution, the patient could copy the informed refusal form in their own handwriting and sign their entire name. Depending upon the patient's financial circumstances, the dentist may wish to absorb the consultation fee for a specialist's diagnosis.

A dentist has the right to refuse treatment if a patient refuses necessary diagnostic imaging or referral, and should

do so. An exception may occur if the dentist is in the middle of treatment that places the dentist and patient relationship at risk of abandonment if treatment is discontinued.⁴⁴ An abandonment claim can be reduced, if not eliminated, if complete and accurate diagnostic images are obtained before initiating treatment rather than after a complication arises.

Conclusion

Dentists should use CBCT as an advanced diagnostic tool to aid diagnosis and treatment planning when indicated. The dentist should obtain hands-on learning to appreciate the diagnostic information contained in the CBCT image or refer the patient to an expert. Dentists have a legal and ethical obligation to provide and protect the patient's best interest as their primary goal in patient care.^{10,18} A reasonably careful dentist complying with the standard of care should always weigh the benefits versus risks of proposed treatment. Because CBCT examinations offer substantial diagnostic benefits, low radiation harm risk and modest financial cost, the benefit/risk balance is generally in favor of making the examination when appropriate clinical indications exist.

The dentist should judiciously justify ordering CBCT scans and, when they are needed, use the smallest field of view appropriate to the task. The dentist should also consider the patient's lifetime accumulation of medical/dental X-ray dosage in accordance with reasonable and careful radiation safety precautions embodied in the ALARA principle.⁴¹ CBCT scans should not be ordered when alternative modalities offer equal efficacy with lesser or no ionizing radiation or when they would be unnecessarily repetitive. CBCT imaging, when justified, often provides improved diagnostic information compared to conventional

imaging that can lead to significant therapeutic benefits. As a general maxim, a dentist should not be the first nor the last to adopt new technology. At this stage in the evolution of CBCT technology, a dentist will certainly not be the first nor should a dentist be the last to include CBCT among their judicious choices of diagnostic armamentarium. ■■■■

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