Some Current Legal Issues that May Affect Oral and Maxillofacial Radiology: Part 1. Basic Principles in Digital Dental Radiology

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ABSTRACT

Developments in oral and maxillofacial radiology affect almost every aspect of dentistry: some change the legal framework in which Canadian dentists practise; some re-emphasize established standards of care, such as the dental radiologist's mantra, ALARA (using a dose that is as low as reasonably achievable) and viewing images in reduced ambient lighting. Developments in the legislation that regulates the use of radiology, such as Health Canada's Safety Code 30 for radiation safety in dentistry and the Healing Arts Radiation Protection Act, also affect the practice of dental radiology. Some technical developments, such as charge-coupled devices and photostimulatable phosphors, are already well-known to the profession. Teleradiology, currently used in hospitals, but unfamiliar to most dentists (especially those working in urban communities), may soon have an impact on dentistry when it is used for Canada's electronic health record, now under development. In this first of 2 articles about dental digital technology, we discuss the legal impact of developments in oral and maxillofacial radiology on dental practice and patient care.

For citation purposes, the electronic version is the definitive version of this article: www.cda-adc.ca/jcda/vol-73/issue-5/409.html

ALARA, or as low as reasonably achievable, is the oft-cited, still valid[1] mantra for protecting patients from exposure to too much radiation because no accepted minimum safe dose of radiation exists.[2–4] The most important way to reduce the radiation dose is to determine whether a clear clinical indication for each exposure exists,[5] and to make each exposure under optimal conditions, minimizing the need for repeated exposures.

In addition to the professional requirement that dentists use their skill and knowledge with due care and attention in the best interests of their patients at all times, various documents itemize what dentists are expected to do to minimize the radiation dose and thus the risk of damage to patients. These expectations are usually found in the codes of conduct issued by the provincial dental colleges. Contravention of these codes could lead to disciplinary and/or civil proceedings.

The provinces have various laws and regulations that minimize patients' exposure to radiation, contravention of which could result in administrative or even criminal proceedings in the truly grossest cases. Very few cases

of dental malpractice (negligence) have been reported in the Canadian Legal Information Institute's database of cases heard in superior courts. All seem to have arisen from unsuccessful treatment (silicone-based TMJ implant[6]) or some other matter such as limitation periods[7] and human rights (HIV patient refused treatment[8]). It is impossible to determine the impact that radiology has had on the vast majority of cases that were settled out of court or otherwise disposed of.

Dental regulatory bodies have qualified and controlled the extent of their members' practice, including radiology, unilaterally or with provincial legislation (e.g., British Columbia's Health Professions Act). One of the better-known pieces of provincial legislation that has had an impact on radiology in dental practice is Ontario's own rigorous regulations, the Healing Arts Radiation Protection (H.A.R.P.) Act,[9] which is consistent with Health Canada's Safety Code 30,[10] the federal government document that regulates radiation hygiene and practice in dentistry. This federal document has little legal force unless the provinces adopt it. However, only British Columbia has adopted it in its entirety.

One strategy to reduce the radiation dose is to use thyroid collars, which is required by law in Ontario and British Columbia; long position-indicating devices (formerly called cones); rectangular collimation; and faster-speed film (i.e., E or F speed). Another strategy is to convert to digital radiography.[11] In this first of 2 articles on dental digital technology, we discuss the legal impact of developments in oral and maxillofacial radiology on dental practice and patient care.

Going Digital

A number of recent publications provide an overview of digital radiology. Petrikowski[12] discusses its introduction to the dental office. van der Stelt,[13] Farman[14] and Kantor[15] explain and discuss the role of digital radiography in dental practice. Wenzel maintains an up-to-date list of old and new brands on her homepage (www.odont.au.dk/rad/).

Prospective buyers of a digital radiology system may be swayed by the apparent comparability between a particular digital system and intraoral film, the gold standard of dental radiology. One such point is spatial resolution. Similar to film, some systems now claim to be able to resolve in excess of 20 line pairs per millimetre.[16,17] However, the buyer must check that this resolution is real, not merely theoretical, especially for systems with lower spatial resolutions.

Dentists are presented with a bewildering array of detectors and receptors. Some guidance, however, can be found in the literature. For example, Farman and Farman[16] recently compared 18 detectors used in dentistry. Wenzel's current review of the literature[18] (which approached the rigour required for a systematic review[19]) reported a dearth of literature about new receptors that continually enter the market, likely because of the lengthy process of publishing reports about their accuracy and usefulness in international journals. Reports describing their clinical performance are also lacking, in part because in vivo studies are not suitable for evaluating diagnostic accuracy because their results cannot be confirmed with histopathology.[20] New detectors must undergo a laboratory accuracy test before any clinical use.

Legal Implications of Going Digital

The purported facility for fraud with digital radiology is no greater than that with analogue images.[21] Although there has been no legal ruling about digital dental images in malpractice cases, digitized fingerprints are admissible in criminal cases in the United States, and digital dental radiographs were admitted into evidence for identification purposes after the World Trade Centre and Oklahoma terrorist attacks, and the Columbia shuttle disaster.[22]

Since the image quality of radiographs used for identification purposes is not equivalent to that required for treatment planning, any system purchased for a dental office should be able to produce appropriate image quality and be completely secure. The system should prohibit erasure or alteration of images, other than the preprocessing that occurs automatically to deal with the effects of defective pixels.

Digital Display

Digital display must have the resolution to display digital radiographs of diagnostic quality to prevent misdiagnosis.[23] The criterion standard for image quality of the radiographic image is still film, particularly for spatial resolution,[15] when it is viewed on a standard illuminated viewer under reduced ambient lighting. Translation to digital technology requires similar viewing conditions, but must ensure that the monitor specifications are compatible with the optimal display of the image captured by the receptor.[24]

Copies

Because copies of radiographs can become a legal issue, hard copies of digital radiographs must be of diagnostic quality. That means that the software used must enable this process[24] and the printer must meet the technical standards set out by the National Electrical Manufacturers Association.[25] Moreover, the original analogue images, even if they are scanned, must be retained for legal purposes, since scanned or photographed copies do not produce images of diagnostic quality.[26]

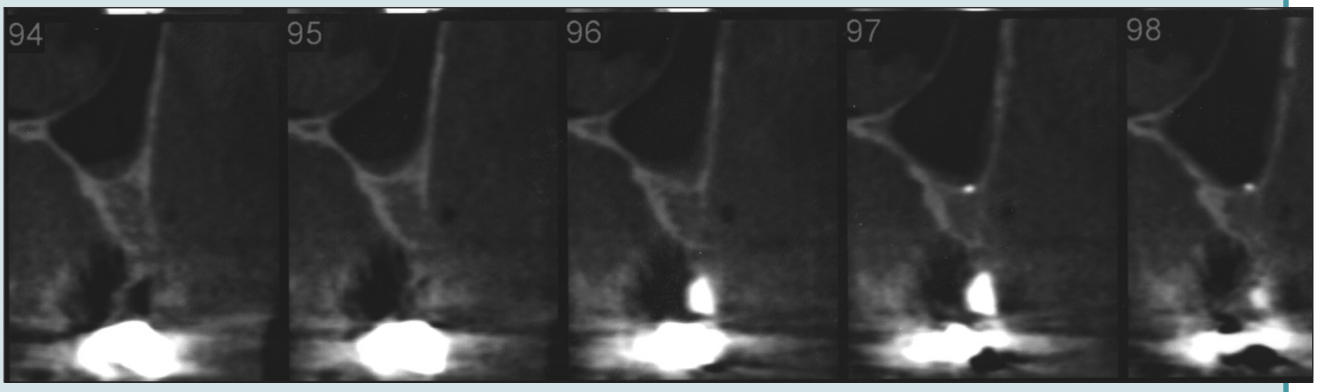

Figure 1: Cross-sectional images of a potential implant site made with a cone-beam computed tomography unit (iCAT). Note the stent placed on the edentulous gap on the upper left. The middle 5 consecutive cross-section images of the 30 sections through the edentulous ridge are shown. The images display marked variation in height and width, and degree of cortication over consecutive slices. The opacities on the crest of the ridge represent gutta-percha markers embedded within the stent. These markers help the surgeon translate the image to his or her patient. The stent ensures optimal placement of the resultant implant, both to minimize complications that arise from malpositioning, some of which are serious, and to ensure ultimately the fabrication of the restoration (a fixed bridge or removal overlay-style prosthesis).

Storage and Compression of Images

Adopting digital technology does not alleviate the problem of long-term storage of all analogue films. The length of time that records must be retained varies among the provinces: for example, Ontario requires retention of records for 10 years, whereas Nova Scotia requires their indefinite retention.[24]

Fundamentally, the storage of electronic dental records must accurately preserve the original content of the record (e.g., text, image or chart) and visual display.[24] The record must include complete information about the creation or any modification of the record (author, date, time and exact source of the record, such as workstation). The format must be read only and protected from unauthorized alteration, loss, damage or any other event that might make the patient information it contains inaccessible.

Although not much of an issue for a single practitioner, the storage of images may present a much greater challenge for a large group practice that uses cone-beam computed tomography (CBCT) data for implants and orthodontic cephalometry. Intraoral images account for only hundreds of bytes of storage and panoramic radiographs for only a few thousands. The very large image files required for CBCT data quickly exhaust even a very generous storage capacity.

Compression of image files is one alternative to acquiring more storage. Two systems are used for compression, lossless and lossy. CBCT iCAT (Imaging Sciences International, Hatfield, Penn.) files are automatically losslessly compressed, reduced to a third without loss of data. Lossy compression, however, involves an irrevocable loss of data. Although Eraso and others[27] reported that loss of image quality is not a factor unless the file size is reduced to 4% or less, research results are insufficient to recommend lossy compression for any image file. Fidler and others,[28] who systematically reviewed the literature on lossy compression, reported that the amount of information lost is difficult to express and standardize. Until lossy compression has been definitively tested, all data contained in an image file should be considered sacrosanct and should be preserved.

For CBCT, the best spatial resolution currently achievable is 0.1 mm voxel size, which is less than the spatial resolution necessary for detecting disease and the features that are observable on intraoral images. Observing these details for an appreciably larger field of view requires an increased radiation dose that may be comparable to that for a spiral computed tomography image (with poorer spatial resolution). When referring clinicians have clear clinical reasons for this greater resolution, this increased dose may be justified.

Imaging for Implantology

A position paper[29] by the American Academy of Oral and Maxillofacial Radiology recommends the use of cross-sectional imaging as part of preimplant planning (**Fig. 1**) to enhance successful outcomes and reduce the number and seriousness of complications. Cross-sectional imaging ranges from conventional tomography (preferably complex rather than linear motion, which is most likely to distort the image) through spiral computed tomography to CBCT. Failure to use cross-sectional imaging can result in complications, such as malpositioning of the implant into the inferior dental nerve or into the submandibular space, which is poorly tolerated and may

Figure 2: An image made on a photostimulatable phosphor (PSP) plate displaying widespread and severe damage to the PSP. This PSP should have been discarded long before it reached this state.

rupture the lingual artery, provoking a potentially life-threatening event. Placement of implants in the anterior arch can cause a substantial hemorrhage in the highly vascularized floor of the mouth and result in life-threatening airway events.[30]

Reduction in Chemical Hazards

Digitization can reduce chemical and environmental hazards, and may reduce the risk of damage that can lead to "occupier liability" suits. Digitization does not involve the use of processing chemicals, which are a potential health and environmental hazard, and digitization eliminates the need for removing and recycling silver.

However, digital radiography is not entirely free of solutions and disposables, as one might gather from the trade shows. To deal with the legal requirement for microbiological hygiene, appropriate disinfectants and barrier methods must be used.

Durability of Imaging

Photostimulatable phosphor (PSP) detectors should be considered semi-disposable to ensure that a legally adequate standard of image quality is maintained. Bedard and coauthors[31] determined that PSP detectors were so damaged after 50 uses that they should be replaced. **Figure 2** displays a severely damaged PSP, which should have been withdrawn from service. The image quality for PSP also requires that the exposed PSPs be loaded into the scanner in reduced ambient light in a dim room.[32] Akdeniz and colleagues[33] recommend that PSPs be scanned within 10 minutes of exposure to avoid loss of quality.

Integration with a Digitized Patient Record System

Integrating digital radiology with a digitized patient record system offers clear advantages: it streamlines office processes, enhances efficiency and minimizes errors, reducing the risk of legal liability.

Radiation Dose

Digital radiography is thought to routinely require less radiation than film to produce the same image; however, the reduction in radiation dose occasioned by changing to digital radiography may have been overstated.[13] Since it permits dentists to choose the image they prefer for diagnosis, it may require a longer exposure than that considered adequate for diagnosis. In a study comparing the radiation doses needed for the preferred image for digital radiography with those for E speed film, Berkhout and others[34] found that the reduction in dose may be minimal or none. Doses required for digital radiology are lower than those required for D speed film, which is still used by some dentists. However, the comparative ease of generating an immediate image, particularly with solid-state receptors (CCDs or CMOS), increases the number of retakes and thus increases radiation exposure.[35]

Teleradiology

Teleradiology should be defined as the formal transmission of images within a secure local area network and not as transmission by ordinary email. Email transmission is not secure, nor are the attached images diagnostic, particularly if they were lossy compressed. Teleradiology lacks standards for an interoperable, manufacturer-independent protocol for secure teleradiology,[36] and does not permit clients access to their images stored in the local area network's Digital Imaging and Communication in Medicine (DICOM) server.[37] Tachibana and others[38] designed a DICOM network-attached server (DICOM-NAS) that allows eligible clinical clients to access their images that are temporarily stored on the DICOM-NAS. Such temporary storage greatly improves security.

Although the physical record is deemed the property of the dentist, the information contained within it belongs to the patient. Therefore, any sharing of a patient's records, including images, with a third party, requires the patient's express consent.[39]

Canada Health Infoway has been commissioned to "develop a more integrated patient-focused system that tracks the patient's journey across the care continuum."[40] It plans to have an interoperable electronic health record in place across 50% of Canada, by population, by the end of this decade.[40] The electronic health record will contain diagnostic imaging elements that will reduce travel and archiving costs, delays in diagnosis and radiation dose by reducing redundant and repeat imaging. It will also facilitate expert interpretation and reduce the risk of missed pathology.[41]

Conclusions

Modern digital radiology, if clinically indicated and carefully executed, should minimize the legal hazards of dental practice. It should retain and store all captured images without loss of data, and minimize the scope for fraud.

Although medicine has used digital radiology without any appreciable legal repercussions, dentistry may not necessarily fare as well. Medicine, with a few exceptions, in particular mammography, which has only very recently become digitized,[42] does not require the high spatial resolution that is necessary for dentistry. This requirement has legal implications for dentists. Since they act as their own radiologists, they must display a high level of diagnostic acumen, and the technical specifications of their radiographic equipment must be at least the same, if not higher, than those of the equipment that medical radiologists use.

Until now, digital radiology has not been a major issue in dental cases heard in a superior court, where the use of digital radiology is most likely to be reported. This recent technical advance into an area that has been monopolized by medicine means that dentistry will be held to the generally accepted technical standards of the practice in medicine, sooner rather than later. These standards will affect not only the specifications of the detectors, but also the image display and CBCT (the principle subjects of part 2 of this 2-part series).

In addition to the issues discussed in this article, other issues could directly or indirectly have legal ramifications for dental practice. For example, manufacturers or their suppliers are usually required to apply for Health Canada's approval for each product, and provincial regulations and competent authorities may impose further restrictions. Therefore, careful inquiry of federal or provincial authorities should be made before the purchase any radiographic equipment.

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Acknowledgement: *We are grateful to Dr. Babak Chehroudi, clinical professor, department of oral and biological sciences, University of British Columbia, for providing us with Figure 2.*

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The authors have no declared financial interests.

This article has been peer reviewed.

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