Essential guidelines for using cone beam computed tomography (CBCT) in implant dentistry. Part 3: Radiation dose, risks, safety, ethical and medico-legal considerations

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Summary

Clinician liability and patient risk from radiation has been a continuing concern in oral and maxillofacial imaging due to the frequency of radiographic examinations in dental practice. With the increased use of CBCT imaging in dental practice, patients will be exposed to even higher radiation doses. The purpose of Part 3 of this series is to provide an overview of: (i) radiation dose and optimization of exposure, (ii) the biological risks of irradiation, (iii) core standards for safe and effective practice, and (iv) ethical and medico-legal considerations relating to the clinical use of CBCT scanners in dental implantology. This knowledge will enhance clinicians understanding of liabilities and risks of irradiation, improve competencies to justify and optimize safe and effective use of CBCT, and know the medico-legal and ethical obligations associated with CBCT use in dental practice. Dental practitioners using CBCT have a clinical obligation to firstly, maximize potential benefits for the patient, and secondly, to ensure that radiation exposure is optimized to minimize biological risks.

Dental practitioners also have an ethical obligation to maximize diagnostic and treatment planning benefits of this technology that best serve the interests of the patient, whilst optimizing patient safety and minimizing radiation-related patient risk. As CBCT technology advances in dentistry, clinicians who embrace it should understand the potential liabilities and risks associated with the technology as well their ethical obligations towards the patient and the profession.

Introduction

The role of 3D CBCT imaging as a new diagnostic tool in modern day dentistry cannot be overemphasized and has increasingly been referred to as the new professional 'standard of care' for diagnostic maxillofacial imaging.[1,2,3] It serves as an essential diagnostic tool for clinical assessment and treatment planning and has revolutionized every aspect of how dental implant practices are performed.[4,5,6] However, CBCT technology does not come without pitfalls, liabilities and risks.

Understanding the radiation dose imparted by CBCT and potential biological risks to the patient is an important patient safety issue. Appropriate selection criteria must be used with the minimum radiation exposures that result in images of acceptable diagnostic qualities.[7,8]

As in any new technology introduced to a profession, the education lags far behind the technological advance, this is especially true of cone beam imaging.

An important basic requirement of using CBCT imaging as a diagnostic and treatment

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Figure 1: Comparison of effective radiation dose by type of X-ray used.

Figure 2: The ALARA principle – limiting patient radiation dose to "as low as reasonably achievable".

planning tool, is that practitioners should have appropriate training and competencies to ensure safe and effective use of a CBCT unit, that will best serve the patients' interests, whilst optimizing patient safety and minimizing radiation-related patient risk.

Purpose

The purpose of Part 3 of this series is to provide an overview of: (i) radiation dose and optimization of exposure; (ii) the biological risks of irradiation; (iii) radiation protection and the core standards for safe and effective use of CBCT technology; and (iv) the ethical and medico-legal considerations, pertaining to the clinical application of CBCT scanners in dental implantology. This knowledge will enhance practitioners understanding on how to maximize diagnostic and treatment planning benefits of this technology that best serve the interests of the patient, whilst optimizing patient safety and minimizing radiation-related patient risk.

Radiation dose, risks, safety considerations and optimization of exposure

Radiation dose and optimization of exposure

Among the many risks to which we are prone is the normal background radiation with a world average of about 2.4 mSv per individual and year. Medical exposures now contribute with around 20% of the average annual per head effective dose to the global population. Medical diagnostic X-ray examinations result in per head effective dose of 0.6 mSv of which dental radiology only contributes a small fraction (0.01mSv).[9,10]

Understanding the radiation dose imparted to the patient by dental radiology is an important patient safety issue. Appropriate selection criteria must be used with the minimum radiation exposures that result in images of acceptable diagnostic qualities (Fig.1).[7,8] This concept is known as ALARA (As Low As Reasonably chievable) (Fig.2).[11,12]

In general, imaging parameters (i.e. kV, mAs, and FOV size) have an effect on the effective radiation dose as well as image quality parameters (spatial resolution, contrast, noise and artefacts).[13,14] In terms of optimization of exposure, the most straightforward imaging parameter is FOV size, as larger FOVs increase radiation dose to the patient. Effective doses for different CBCT devices exhibit a wide range, but for all devices, significant dose reduction can be achieved by reducing the FOV to the actual region of interest.[15] In addition, larger FOVs increase the relative amount of scattered radiation reaching the detector, leading to an increase in noise and artefacts, thus affecting the quality of the image. Therefore, FOVs should always be kept as small as possible, covering only the area of interest.[16]

Increased radiation dose risk

Patient risk and clinician liability from radiation has been a continuing concern in oral and maxillofacial imaging, due to the frequency of radiographic examinations in dental practice.[17] With the increased use of CBCT imaging in dental practice, clinicians must be made aware that patient radiation doses associated with CBCT imaging are higher than those of conventional radiographic techniques (Fig.1). Therefore, routine replacement of current radiographic techniques must be considered with great care.[18]

The average effective radiation dose for a CBCT corresponding to a small FOV is 34 μSv, medium FOV is 88 μSv and a large FOV is 131 μSv with the medium and large FOV's showing the largest variability of doses.[19] In general, CBCT imaging results in higher patient doses than standard radiographic methods used in dental practice for dental therapy but remain well below those reported for common MDCT protocols (280-1410 μSv).[15,16] The effective radiation dose for a CBCT is 2-4 times greater than for a cephalometric X-ray (<6 μSv); 3-6 times greater than a panoramic X-ray (2.7 – 24.3 μSv); and 8-14 times greater than a peri-apical x-ray (<1.5 μSv).[15, 16]

Risks have also been noted in the radiation dose needed with CBCT although it is generally believed that the radiation dose of CBCT is significantly lower than a conventional CT.[20] Effective radiation doses (μSv) of typical dento-maxillofacial applications are relatively low when compared with the worldwide annual background radiation of 200-4500 μSv.[21,22]

The effective radiation dose of CBCT can be affected to an order of magnitude by the factors: patient size; FOV; region of interest; and resolution A careful selection of all these parameters is needed to optimize diagnostic information and to reduce the patient's radiation exposure (Fig.2).[23]

Biological risks of irradiation

The biologic effects of ionizing radiation maybe divided into two categories: tissue reactions (previously called deterministic effects) and chromosomal effects (also know as stochastic effects).[24]

Tissue reactions are proportional to the dose and occur in all individuals when the dose is large enough. They result in cell death or cell malfunction, and the severity of the effects increases with the dose. Tissue reactions, such as cataract formation, skin erythema, and effects on fertility, occur only above threshold doses that are far greater than those given in dental radiology.

Chromosomal effects can be considered as "chance" (or stochastic) effects, where the magnitude of the risk is proportional to the radiation dose.[16] Chromosomal or stochastic effects include the detriment-adjusted nominal risk of cancer and hereditable effects owing to mutation of reproductive cells. The detriment-adjusted risk factor for the whole population is 5% per Sv (Sievert). In case of cancer, epidemiological and experimental studies provide evidence of radiation risk albeit with uncertainties at low doses (<100 mSv).

The probabilistic nature of stochastic effects makes the distinction between "safe" and "harmful" exposures to radiation impossible.[16,24] The biological risk from irradiation is age-dependent, being highest for the young and least for the elderly.[16] The risk for small children is three times the risk for an adult at 30 years of age.

Radiation protection – limiting the dose and risk from x-ray imaging

Radiation protection in clinical practice is based on two fundamental principles.[24]

The first principle is that of justification. The clinician has an obligation to ensure that there must be a net benefit for the individual who is being exposed, i.e. more good than harm; or potential benefits must outweigh the potential risks.[9]

The second principle is that of optimization of radiation exposure, namely it should be as low as reasonable achievable to minimize the risk of cancer or tissue effects (also known as the ALARA principle – As Low As Reasonable Achievable) (Fig.2).[9, 25]

It is obvious that cone beam computed tomography should not be carried out without proper optimization strategies in order to maintain the correct balance between cost and radiation dose, on the one hand, and information required, on the other hand. Therefore, the scanned area should not exceed the area of interest. This would substantially limit the dose of radiation, whilst justifying the use of cone beam computed tomography in preparing for implant surgery.[22] The FOV of the CBCT examination should be restricted to the region of interest (ROI) whenever possible. Patient- and equipment-specific dose reduction measures should be used at all times.[18]

Basic principles and core standards for safe and effective practice

The clinician performing or interpreting CBCT scans for implant dentistry should take into consideration current radiologic guidelines for safe and effective use of CBCT. The European Association of Dental and Maxillofacial Radiology (EADMFR) developed the following consensus-based core standards for safe and effective use of dental CBCT.[8] These basic principles are not in conflict with the current evidence-based guidelines (recommendations) as set by SEDENTEXCT, a collaborative project of the European Union.[16]

Justification

- CBCT examinations must not be carried out unless a history and clinical examination has been performed.

- CBCT examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.
- CBCT examinations should potentially add new information to aid the patient's treatment management.
- CBCT should not be repeated routinely on a patient without a new risk/benefit assessment having been performed.
- When accepting referrals from other dentists for CBCT examinations, the referring dentist must supply sufficient clinical information to allow the CBCT practitioner to perform the justification process.
- CBCT should only be used when conventional (lower dose) radiography does not provide adequate information for the question at stake.
- CBCT images must undergo a thorough clinical evaluation of the entire image data set.
- Where it is likely that the evaluation of the soft tissues will be required as part of the patient's radiological assessment, the appropriate imaging should then be conventional CT or MR, rather than CBCT.

Optimization

- CBCT examinations must use the smallest volume size (FOV that is compatible with the clinical situation.
- Where CBCT equipment offers a choice of resolution, the resolution compatible with adequate diagnosis and the lowest achievable dose should be used.
- A quality assurance programme must be established and implemented for each CBCT facility, including equipment, techniques and quality control procedures.
- Aids to accurate positioning, i.e. light beam markers, must always be used.

Quality standards and assurance

- All new installations of CBCT equipment should undergo a critical assessment and detailed acceptance tests before use to ensure that radiation protection for staff, members of public and patients are optimal.
- CBCT equipment should undergo regular routine tests to ensure that radiation protection for both practice/facility users and patients has not deteriorated.

Staff protection

- For staff protection from CBCT equipment, the guidelines in Section 6 of the European Commission document: 'Radiation Protection 136. European Guidelines on Radiation protection in Dental radiology' should be followed.[27]
- A qualified expert should oversee the installation and use of CBCT to ensure that staff doses are as low as reasonably achievable and that all relevant national requirements are met.[16]
- CBCT equipment should be installed in a protected enclosure and the whole of the enclosure designated a controlled area., The provision of personal monitoring should be considered.[16]

Training and competence

- All those involved with CBCT must have received adequate theoretical and practical training for the purpose of radiological practices and relevant competence in radiation protection.
- Continuing education and training after qualification are required, particularly when new CBCT equipment or techniques are adopted.
- Dentists responsible for CBCT facilities who have not previously received adequate theoretical or practical training should undergo a period of additional theoretical and practical training that has been validated by an accredited academic institution.
- For dento-alveolar CBCT images of teeth, their supporting structures, the mandible, and the maxilla up to the floor of the nose (e.g. 8cm x 8cm FOV), clinical evaluation should be made by a specially trained Dento-Maxillo-Facial Radiologist, where this is impracticable, an adequately trained general dental practitioner.
- For non-dento-alveolar small FOV (e.g. temporal bone) and all craniofacial CBCT images (FOV extending beyond the teeth, their supporting structures, the mandible, including TMJ and the maxilla up to the floor of the nose), clinical evaluation should be made by a specially trained Dento-Maxillo-Facial Radiologist or by a Medical Radiologist.

Ethical and medico-legal considerations

As CBCT technology advances in dentistry, clinicians who embrace it should understand the potential liabilities and risks associated with the technology as well their ethical obligations towards the patient and the profession.

Competency and serving the best interest of the patient

Given that a single CBCT scan uses ionizing radiation at levels exceeding any current two-dimensional dental imaging modalities, it is timely to recommend the development of rigorous training standards in maxillofacial CBCT imaging in the interests of our patients who deserve to have imaging performed by competent clinicians.[27]

Furthermore, there is mounting concern among oral and maxillofacial radiologists, based on issues of quality and patient safety, that dentists with inadequate training and experience should not perform interpretation of extended field of view diagnostic imaging studies using CBCT. [27] The view has also been expressed by The American Association of Oral and Maxilla-Facial Radiology (AAOMR) that non-radiologist dentists should not be excluded from performing CBCT imaging, provided they have appropriate and documented training and experience.[27]

If dentists or non-radiologist dental specialists decide to examine their own volumes, then they are held to the same standard of care as an oral maxillofacial radiologist and required to find and report any unusual conditions or incidental findings that may reside in that volume. This is a significant responsibility, one that might require additional training for some dentists.[28]

Unfortunately, many dentists who acquire a CBCT unit for their practice are not adequately trained to fully understand and take advantage of their machine's capabilities. Common errors include a scan with an FOV that is too large or too small. A larger FOV than is necessary has at least 2 deleterious effects. It results in a less optimal image (the larger the FOV, the greater the scatter and the less detailed the image) and a greater patient dose. Although increased scatter and dose are not likely to result in liability, a wider FOV than is necessary does have medico-legal implications as far as interpretation of the image is concerned.[17] The potential liability issue that arises is that the dentist is responsible for reading the entire scan. Thus, even though the maxilla and skull were not required in this case, once they are included in the scan, the dentist is responsible for pathology missed in either location.[17]

Practitioners should have appropriate training in operating a CBCT unit and competence in interpreting images. This training and competence should be maintained through continuing dental education courses. Such training should include a thorough review of normal maxillofacial anatomy, common anatomic variants, and imaging signs of diseases and abnormalities. This is particularly important for CT and CBCT imaging because of the complexity of structures within the expanded FOVs.[7]

Clinicians who do not have adequate experience in interpreting a CBCT scan, should rather refer the scan to a specialist Radiologist or Radiographer for reviewing, or refer the patient to a specialist Oral and maxillofacial Radiologists for the CBCT scan and reviewing.

Ethical obligation of beneficence

The practice of dentistry exposes practitioners at each patient encounter to an ethical obligation of beneficence; namely, will the image serve the patient's best interests? Practitioners are obliged ethically and morally to measure the benefit from using a CBCT scan versus the potential risk from radiation before a decision is made to take a CBCT scan.[16] Dentists may also have legal responsibilities and duties that overlap with ethical considerations to some degree.[29]

When a patient undergoes an x-ray examination, millions of photons pass through their body. These can damage any molecules by ionization, but damage to DNA in the chromosome, although rare, is of particular importance because a chromosome can be permanently altered in the process, ultimately leading to the formation of a tumor.[16] While doses and risks for dental radiology are small, a number of epidemiological studies have provided some limited evidence of an increased risk of brain,[30,31] salivary glands,[32] and thyroid tumors,[33] for dental radiographs.

Any radiation exposure entails a risk to the patient. Under normal circumstances, however, the risk from dental radiography is very low.

The basic premise that justifies the use of CBCT is that the benefits provided by the radiographic examination must far outweigh the potential risks associated with radiation exposure.[16] Such benefits may be in the form of increased diagnostic efficacy, enhanced treatment planning or better therapeutic outcomes.[9, 34]

The clinician has an obligation to ensure that appropriate measures are taken at all instances to limit radiation dose and risk to the patient through justification and optimization processes. A CBCT examination should at all times add new information to aid the patient's treatment.[16] The as low a dose as is reasonably achievable principle (ALARA Principle) must also be applied taking into account any alternative techniques that might achieve the same objectives.[9]

Informed patient consent

Reporting the findings in a CBCT volume is probably the most essential process in the total diagnostic evaluation of a patient, even if it is something as simple as implant planning.[28] It is the responsibility of health care providers to acquire information data from patients to best determine the health status of patients and if treatment is indicated and to provide a basis for treatment planning and informed patient consent.[28]

The CBCT report therefore becomes an important component of information for the patient to make informed decisions about their health or dental care and treatment and to facilitate giving informed consent standard of care. A CBCT could give the clinician the opportunity to visualize, plan and explain more clearly the situation to the patient. Hence, the standard of care by definition involves that, in all the cases where it is required and possible, the CBCT or some three dimensional technique should be offered to the patient. In the case that the patient declines after being informed of the risks, benefits, and alternatives, then informed refusal should be obtained and documented.[2]

Medico-legal issues on reviewing and reporting

The interpretation of CBCT images remains one of the most vexing problems and greatest source of liability for practitioners who take their own scans.[17] The use of CBCT carries with it medico-legal risks of which the dental practitioner should be aware. These include licensing and malpractice liability concerns.[17]

The quality, accuracy, and use of the CBCT report or findings are subject to medico-legal scrutiny, and knowledge of such issues determines whether or not a primary provider or a secondary radiology reader evaluates the image data and issues the final report.[28] If a dental practitioner owns a CBCT machine and takes scans not only for his or her own patients, but also for those referred from outside, he or she must ensure that in the latter situation they do not lack malpractice coverage in the event of a lawsuit. Some malpractice carriers have explicit limitations and will defend a dental practitioner for CBCT related diagnostic issues only if the suit is brought by one of the dentist's own patients. If a patient who was referred from outside solely for a CBCT scan and brings a lawsuit for a misdiagnosis, then malpractice coverage can be denied.[17]

When examining a CBCT scan, the dental practitioner has the legal responsibility to examine every cross-section to ensure that no pathosis is overlooked. The accepted standard of care is that the dentist reviewing / reading the CBCT is obligated to read the entire scan that is included in the FOV.[35] Dentists cannot read only part of the scan that is related to the area of interest where an implant will be placed. Reviewing practitioners cannot afford to miss an important finding or fail to communicate these findings to referring clinicians. For those individuals to examine their own data, this is also true. No clinician would be in trouble for misdiagnosing a condition or problem, but that same clinician is definitely placing himself or herself at risk for not examining the volume for these occult findings.[28]

Medico-legal assurance

In today's society, adequate and appropriate records and documentation has become essential for medical aid reimbursements as well as to prevent legal recourse. Having performed the CBCT scans provides the dental practitioner with the necessary information to prove the procedure was performed above the standard of care. Having this documentation can help prevent any litigation that may occur in association with negative outcomes that could not be avoided. CBCT technology provides that supporting documentation that is needed for insurance reimbursement as well as for legal purposes. Using the CBCT for evaluating patients who wish to receive dental implants is essential to protect the patients as well as the practitioner. There are legal cases in which health care providers have been sued because of implant failure. Implant failure can still occur no matter the technology used; however, with the CBCT the dentist can provide the most precise information to prove his/her reasoning if questioned in the future about why he/she chose to place dental implants.

Standard of care

One important term in the medico-legal area is "standard of care", which generally is defined as what a rational and judicious health professional would do or should have done. In the area of dentistry, it is supposed that the dentist meets or exceeds the standard of care. Presenting all the possible alternative treatments as well as all the techniques available to the patient makes this successful protocol that follows the standard of care principle. The failure to practice the "standard of care" could be considered in a court of all as professional negligence, also called malpractice. In this regards, CBCT has been qualified as a standard of care technology.[2] The standard to which the dental profession is held both by the public and among us transcends legal (standard-of-care) and technical (gold standard) definitions. The professional standard for CBCT is appropriate care: to choose CBCT imaging for each patient "wisely" based on selection criteria derived from the best available evidence.[29]

Self-referred and overprescription of CBCT's

Dental practitioners in general, have commonly self-referred radiographic procedures, and many dental procedures require immediate radiography be available.[36] Approximately 150 Dental CBCT units have been purchased in South Africa. These systems currently vary in price from approximately ZAR575,000 to more than ZAR2,500,000.

Charges range from approximate R650 to R3500 per scan. Depending on the number and price charged for each CBCT imaging procedures performed, a rush to achieve return on investment could well lead to unethical over-prescription of procedures. Such over prescription could have impacts both on healthcare costs and also on the radiation exposure load to the patient.[36]

Hillman[37], in studying physicians' utilization and charges for outpatient diagnostic imaging found that self-referral resulted, depending on physician specialty, in 1.7 to 7.7 times more frequent performance of imaging examinations than radiologist-referral. This difference was statistically significant ($p < 0.01$) across all presentations. Within all physician specialties, self-referral uniformly led to greater utilization of diagnostic imaging than radiologist-referral, with mean imaging charges per episode of medical care 1.6 to 6.2 times greater when self-referral applied.While self-referral can have economic implications, as mentioned above there is another side to this matter, namely, the question of training and experience to accurately interpret the diagnostic images that are made. As the tissues included in the imaged volume need to be read to maximize the diagnostic yield potential relative to the exposure given, it can be questioned whether all individuals who presently own CBCT systems are trained to a level of competency to evaluate the images that they produce. Referral of these images for reading by specialists in oral and maxillofacial radiology might be necessary, but this in itself can also add to the cost of healthcare.[36]

Conclusions

CBCT has become the new standard of care as imaging modality for diagnosis and pre-surgical planning in implant dentistry. However, CBCT it is not without its potential pitfalls, limitations, risks and liabilities. The potential diagnostic and presurgical treatment planning benefits are undisputed. However, due to additional radiation exposure, dental practitioners have an obligation to ensure that every CBCT scan is justified and to optimize exposure to radiation by always using the smallest FOV that is possible for that area of interest.

Practitioners taking CBCT's should ensure that they have appropriate training in operating radiographic equipment and competent in interpreting images. This training and competence should be maintained through continuing dental education courses. Clinicians who embrace CBCT technology should understand the potential liabilities and risks associated with the technology and to ensure that they meet the requirements for licensing, adequate training and competencies and malpractices liability coverage from their malpractice insurance carries.

When mastered, use of cone beam makes it indispensable diagnostic and pre-surgical treatment planning and communication tool in implant dentistry and therefore improved patient care and satisfaction. However, as with all clinical procedures, the selection of CBCT as an imaging modality should be guided and justified by patient symptoms, findings of the clinical examination and the information needed to allow a proper diagnosis and presurgical treatment planning. With this technology, adequately trained clinicians can enhance their practice and best serve the interests of their patients.

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