The Radiation Protection Implications of the Use of Cone Beam Computed Tomography (CBCT) in Dentistry – What You Need To Know

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This report from HPA Radiation Protection Division reflects understanding and evaluation of the current scientific evidence as presented and referenced in this document.

Introduction

Dental Cone Beam CT (CBCT) scanners are now being installed and used in a rapidly increasing number of dental practices within the UK. Although the evidence base for their use is growing, there is currently little guidance available for dentists to inform them of the different radiation protection requirements for this type of radiography equipment. Suitable guidance is urgently needed to ensure that appropriate radiation safety measures are in place for the protection of staff and patients, and to advise practices using CBCT scanners with respect to radiation safety legislation. Working procedures and precautions that are well-established for conventional dental x-radiography equipment will in many circumstances not be adequate for CBCT.

In response to this, the Health Protection Agency's Radiation Protection Division has convened a working party (WP) to look into the radiation protection issues associated with CBCT equipment. In addition to HPA's own expertise in radiation protection the WP draws on the expertise of consultant dental radiologists, national bodies with regulatory roles in dentistry, dental surgeons with experience of working with CBCT scanners, enforcing authorities and medical physicists with experience of CBCT. The work of the WP mirrors the work being done on a Europe-wide scale under the SEDENTEXCT project¹, but this project will not publish formal guidance until 2011. The WP expects to publish its formal guidance for the UK later this year, following a consultation exercise, in a freely available web-based format. However due to the increasing popularity of CBCT equipment and the current vacuum of guidance, the WP agreed that it was necessary to make dentists using or planning to install CBCT equipment aware of the most important issues, as soon as possible. The aim of this article is to explain what these issues are and how to deal with them, in advance of the formal guidance. Briefly, the issues of greatest importance from a radiation safety perspective are as follows:

- the selection of equipment
- establishment of a suitable QA programme
- consultation with a Radiation Protection Adviser (RPA) and Medical Physics Expert (MPE) for the necessary advice on radiation protection
- training requirements
- referrals

In January 2009 the European Academy of Dental and Maxillofacial Radiology (EADMFR) published its 'Basic Principles for Use of Dental Cone Beam CT²' that lists 20 important aspects of the use of CBCT with a very similar aim to this article, and is recommended to the reader.

¹ SEDENTEXCT ('Safety and Efficacy of a New and Emerging Dental X-ray Modality') see http://www.sedentexct.eu/home

² See http://www.sedentexct.eu/basicprinciples

The terms operator³, referrer⁴ and practitioner⁵ mentioned in this article are used as defined by the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER). Both IRMER and the Ionising Radiations Regulations 1999 (IRR99) are referred to where appropriate, throughout the article.

Radiation doses and risks from dental CBCT examinations

The following table lists typical doses to patients from x-ray examinations from a conventional panoramic unit, two types of dental CBCT scanner and a medical CT scanner. To put the numbers into context, the annual average radiation dose to a member of the UK population is 2,700 microsieverts (μ Sv). The dose from a conventional panoramic radiograph is equivalent to that which would be received from a few days' exposure to natural background radiation, and carries an additional lifetime risk of cancer of one in a few million. The dose and attendant risk from a dental CBCT scan is, from the table, in a range from a few times to a few tens of times that of a panoramic radiograph.

Examination	Effective patient dose (µSv)	Dose as a multiple of the dose from a typical panoramic exam
Panoramic	24 ⁶	1
Small FOV* CBCT	48 – 652 ⁷	2 – 27
Large FOV* CBCT	68 – 1073 ⁷	3 – 45
CT scan (dental program)	$534^7 - 2100^8$	22 – 88

* FOV = Field of view

Selection of cone beam CT equipment

Within the dental practice the employer or legal person, usually the principal dentist(s), carries the responsibility for complying with IRR99 and IRMER, including the duty of considering the restriction of radiation doses to patients when selecting x-ray equipment

recommendations regarding dose calculation. J Am Dent Assoc 2008 Sep;139(9):1237-43

³ Any person who is entitled, in accordance with the employer's procedures, to carry out a practical aspect of radiography.

⁴ A registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposure to a practitioner.

⁵ A registered health care professional who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure.

⁶ Ludlow JB, Davies-Ludlow LE, White SC. Patient risk related to common dental radiographic examinations: the impact of 2007 International Commission on Radiological Protection

⁷ Ludlow JB. Comparative dosimetry of dental CBCT devices and 64-slice CT for oral and maxillofacial radiology. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2008;**106**:106-14

⁸ Ngan DC. Comparison of radiation levels from computed tomography and conventional dental radiographs. *Aust Orthod J.* 2003;**19**:67-75.

to purchase. The legal person must also ensure that the equipment is appropriate for its intended clinical use⁹.

CBCT equipment should not be used as a direct replacement for a panoramic or cephalometric x-ray set. If used correctly, CBCT equipment offers many advantages over conventional radiography equipment (e.g. the potential for 3D imaging and precise measurements for the placement of implants). However the use of CBCT examinations must be properly justified. If the CBCT scanner is intended to be used to obtain panoramic or cephalometric radiographs, then the equipment must also be fitted with conventional means of obtaining these views. It is not appropriate to take a CBCT examination. Conversely, if the panoramic or cephalometric view can be reconstructed from a justified CBCT radiograph then a separate panoramic or cephalometric radiograph should not be taken.

The wide range of available types and capabilities of CBCT equipment means that selecting the right model for the dentist's needs is a more complex exercise than when purchasing other types of dental x-ray equipment. However, CBCT machines can be broadly characterised by the field of view (FOV) provided. The FOV relates to the size and shape of the reconstructed image and is usually a cylindrical volume. At the time of writing, equipment is available that offers FOVs ranging from a few centimetres in height and diameter to 20 cm in height and diameter. On some equipment the FOV can be altered depending on the examination or patient, whereas other equipment is provided with a single, fixed FOV. There is a close relationship between the FOV size and the radiation dose received by the patient (however, there are many other factors that affect the patient dose such as image resolution and exposure parameters) and it is therefore important that the smallest FOV is selected for each patient whilst capturing all the required clinical information. One of the main questions to consider when purchasing equipment is what clinical examinations is the equipment to be used for? For example, if equipment is to be used for imaging only a small volume, then purchasing a machine which can only image a large FOV is not appropriate as the patient will receive a dose that is higher than necessary. Similarly, if CBCT is to be used for examinations of children, large FOV equipment would not be appropriate. However, if large FOV equipment is provided with the means to alter the size of the x-ray beam according to the region of clinical interest then the purchase of the equipment may be appropriate. but the practice's written procedures must ensure that the correct FOV is selected for This is one example of the radiation protection principle of each radiograph. optimisation and the legal requirement for keeping doses as low as reasonably practicable (ALARP).

It is also advantageous for equipment to be provided with user-variable exposure parameters (for example: operating potential, tube current, exposure time and image resolution) such that the operator of the equipment is able to adjust the settings for an individual patient, to obtain the highest possible quality diagnostic image consistent with the need to minimise the radiation dose. The range of doses delivered by similar types

⁹ IRR99. Regulation 32.

of CBCT equipment in the above table reflects the fact that not only is selecting an appropriate FOV setting necessary, but suitable exposure settings also need to be selected to ensure that patient doses are being kept as low as reasonably practicable. It should be noted also that, in keeping with other well-established diagnostic x-ray examinations, it is likely that a national reference level dose will be set for dental CBCT systems at some time in the future, based on a national survey of patient dose measurements. Dentists using CBCT scanners that deliver doses above the reference level would need to investigate ways of reducing patient doses below the reference level. CBCT scanners employing a large, fixed FOV and relatively high standard exposure factors are most likely to be in breach of a national reference level.

As described in the next section, routine quality assurance tests will need to be carried out on CBCT equipment, by the practice staff, in order to monitor and maintain the image quality performance of the equipment on a day-to-day basis. For this reason it would be advantageous for the necessary test equipment to be supplied as standard with each CBCT system.

The following are a list of suggested questions that should be asked of potential suppliers of CBCT equipment to help the practice make an informed decision as to the type of CBCT equipment model that is most appropriate to their needs:

• What are the typical patient doses?

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- Is the equipment provided with the means to alter the field of view?
 - If not, consider if the FOV provided is the minimum for the type of examination that will be conducted.
- Are the exposure parameters user selectable (operating potential, tube current, exposure time, resolution, etc)?
- Is a quality assurance protocol provided?
- Is suitable test equipment provided to enable all the tests discussed in the next section to be carried out?
- If required, are panoramic or cephalometric functions provided by means of separate, dedicated panoramic or cephalometric operation?
 - If not, then the equipment is not suitable to replace a dedicated panoramic or cephalometric machine.
- Does the software provided with the equipment allow me to carry out all the clinical analyses I need to, as well as carry out the all the QA test procedures discussed in the next section?

Quality assurance (QA) programme

The practice must ensure that a suitable quality assurance programme is in place for all x-ray equipment9. For CBCT equipment this will be significantly different to other forms of dental radiography equipment and the content of the QA programme should be discussed with the practice's RPA or MPE (see below). When equipment is installed the

practice should be provided with adequate information by the equipment supplier regarding the necessary testing and frequency of testing required¹⁰.

Before the equipment is put into clinical use the practice is responsible for ensuring that an Acceptance Test (sometimes called a Commissioning Test) is carried out. This test may be carried out at the same time as the Critical Examination, however, the practice is responsible for ensuring that sufficient testing has been carried out (by consultation with their RPA or MPE).

The WP guidance is likely to recommend that, as for conventional CT systems, CBCT equipment should be subjected to routine QA testing on at least a monthly basis by the dental practice. These tests are likely to include the following measurements: image noise, image density values, image uniformity, distance calibration and high contrast artefacts. Additionally it is recommended that regular checks are made on image viewing monitors including the monitor condition, distance calibration and resolution. It is intended that guidance for conducting these tests will soon be made available.

Some of these tests will require the use of test phantoms, which should be provided by the equipment supplier with the equipment to enable the tests to be carried out. The supplier should also provide details of the appropriate test procedures, and the expected results.

Unlike conventional dental radiography equipment which should be tested at intervals not exceeding 3 years, CBCT equipment should be subject to an annual full radiation safety check. This would normally be carried out by the practice's appointed RPA or MPE. This is in additional to the servicing and maintenance of the equipment which should be carried out according to the manufacturer's recommended schedule.

The results of both the routine and annual tests should be recorded in the practice's radiation protection file and compared against the baseline levels obtained at the time of installation. In the future, remedial and suspension levels are likely to be set down in national guidance, once sufficient information on the performance of CBCT systems has been collated. When these have been published, any results exceeding remedial levels should be investigated and corrected, if possible. If any results exceed suspension levels, the equipment should not be used until this has been corrected.

Radiation protection adviser (RPA)

Dental practices using any kind of x-ray equipment are legally obliged to consult a suitable RPA¹¹ for advice on compliance with IRR99. However, this is especially important when installing CBCT equipment for the first time where there is virtually no guidance or established common practice. If the practice has not yet appointed an RPA then one must be appointed prior to installing any x-ray equipment. Only those persons or organisations satisfying the criteria of competence specified by the HSE can be

¹⁰ IRR99. Regulation 31.

¹¹ IRR99. Regulation 13.

appointed as an RPA. It should be stressed that it is highly unlikely that any member of the dental practice staff will be suitable to act as an RPA; this will nearly always be an external appointment. Practices should be aware that there is a legal obligation to check that the RPA they intend to consult is "suitable".

The practice should consult its appointed RPA regarding the selection of CBCT equipment, with special attention being paid to the matters discussed above. The practice should also consult the RPA regarding the suitability of the proposed installation site for radiation protection purposes (for example, if the structure of the room will provide adequate shielding against x-rays). This is very important as many of the recommended radiation safety measures set down in the Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment (the Dental GNs)¹² for conventional dental x-ray sets will not be adequate for CBCT. The RPA will provide written advice for the practice detailing their recommendations and this will also act as evidence of the consultation.

It should be noted that although suppliers of x-ray equipment can often provide general advice on many aspects of the installation, they are unlikely to be RPAs and so cannot give the necessary formal advice regarding the radiation protection suitability of a proposed installation. This must always be obtained through formal consultation with the practice's RPA.

The equipment supplier is responsible for ensuring that a Critical Examination is carried out on the equipment, before the equipment is put into clinical use10. The purpose of the Critical Examination is to ensure that the equipment's safety and warning features are operating correctly and the installation provides sufficient protection from radiation. An RPA should be involved in the Critical Examination; however this may be either the equipment supplier's or the user's RPA.

The practice must also consult with a MPE¹³ as they are required to do for any other type of x-ray equipment. However, due to the significant differences in the use and optimisation of CBCT equipment this is especially important. The MPE is often the same person or organisation as the RPA but if so, the practice must ensure their RPA can fulfil both roles. The MPE will provide advice on the optimisation of patient dose and image quality as well as the necessary quality assurance procedures.

Training requirements

Dental CBCT is a new technique and as such, lies outside the syllabus of undergraduate dental degrees, and the current update training programmes available for dentists, dental nurses and other dental professionals.

The view of the WP is that training in the use of the equipment should take the form of at least a half-day's demonstration and practical instruction on all the hardware and

¹² HPA website. http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733764370

¹³ IR(ME)R2000. Regulation 9.

software features of the equipment. This should be provided for all members of staff who will be operating the equipment (for example, anyone who initiates an exposure or selects exposure parameters), and also any dentist (who authorises an exposure or carries out the clinical evaluation of the image or who will be responsible for the justification of individual CBCT examinations). The practical aspects of the training should include, amongst other things, factors affecting image quality and patient dose, selection of the most appropriate imaging programs and exposure factors for each patient, and the evaluation of typical images of the dento-alveolar region as it appears on CBCT images, to provide an understanding of when a particular CBCT examination is or is not suitable for an intended clinical purpose. Any person acting as a referrer is also required to undergo training; however this may be different to the training received by equipment operators or dentists.

The equipment supplier has a duty to pass on appropriate information regarding the use, testing and maintenance of the equipment to the dental practice10, and some of these aspects could be covered as part of this training, ideally provided soon after installation. Further training will, however, be needed to comply with IRMER once a core curriculum for training has been developed. The training should, as a whole, draw on the combined expertise of an applications specialist with a working knowledge of the equipment, and a dento-maxillofacial radiologist and/or specialist radiographer. It is expected that future guidance will include a requirement for verifiable CPD training time dedicated specifically to CBCT.

Most dentists will not have received training in CBCT techniques, particularly in the clinical evaluation of images in anatomical regions outside the dento-alveolar area. For this reason, any dentist who clinically evaluates CBCT images should have received appropriate training, in addition to that mentioned above, in the guidelines on making a radiological differential diagnosis, and the methods and conventions of reporting on cross-sectional imaging of the dento-alveolar region. CBCT scans obtained with a large FOV may produce images extending beyond the dento-alveolar area. Under no circumstances can a dentist ignore this image data and simply report on the conventional dental anatomical regions: the rule is, *"if it has been imaged it must be reported on!"* If the dentist does not consider that they have adequate training to clinically evaluate the complete image, they must make arrangements to ensure that the evaluation is carried out by either another dentist with suitable training, or a specialist (maxillofacial or head and neck) radiologist. Again, a core curriculum for training has yet to be developed.

Referrals for CBCT radiographs from other dental practices

The limited number of practices with CBCT equipment means that these practices may receive requests from other dental practices requesting CBCT examinations for their patients. If the CBCT dental practice receives such requests, the legal person at the CBCT practice must ensure suitable arrangements are in place to meet the requirements of IRMER, and it is recommended that this is through a service level agreement between the two dental practices. The CBCT practice should consult their

RPA or MPE to ensure that their arrangements are suitable. To achieve this, the following points should be considered:

- When requests for CBCT scans are made to another practice, the requesting dentist will be the referrer and the dentist at the practice taking the exposure will be the practitioner. This means that the dentist at the CBCT practice is responsible for determining whether the CBCT radiograph is justified based on their knowledge, the practice's own procedures and the information provided by the referrer.
- As already mentioned, CBCT equipment should not be used when other, lower dose, forms of radiographs can provide adequate diagnostic information. The practitioner must carefully justify each CBCT radiograph. CBCT should not be considered the default standard of care for any dental procedure¹⁴, including the placement of implants.
- The employer at the CBCT practice will also be responsible for ensuring that a clinical evaluation of the image data is carried out. As such, it is not appropriate that images are simply provided to the referrer without ensuring arrangements are in place for the clinical evaluation to be undertaken, including of any imaged areas that lie outside of the "dental" anatomy. It does not necessarily have to be a practitioner at the CBCT practice who carries out the clinical evaluation, but the employer at the CBCT practice is responsible for ensuring the evaluation is carried out by an appropriate person, such as a dental practitioner with suitable training in CBCT, or a medical radiologist. It is recommended that this is documented.

Radiation safety for practice staff

The Dental GNs provide advice on suitable working arrangements to ensure adequate radiation protection for staff. This guidance cannot be fully applied to CBCT equipment, where typically higher levels of radiation are observed in the radiography room whilst the equipment is operating. It is crucial that the practice's RPA is involved at an early stage in assessing the location of the equipment to ensure adequate protection is provided, even if the room was deemed adequate for using other radiography equipment. Additional considerations, that are not always necessary for conventional equipment, include:

- The provision of shielding for walls, doors, floors and ceilings beyond what is usually required for dental x-radiography
- The provision of suitable shielding for the operator
- The use of radiation warning lights outside all entrances to the radiography room
- The need to ensure the room is used exclusively for radiography
- The need to provide personal dosimetry to staff

¹⁴ *KG Isaacson et al. (2008) Orthodontic radiographs – guidelines (Third Edition).* British Orthodontic Society: London.

The practice will also need to ensure that its risk assessments and local rules accurately reflect work with CBCT, and again this will require consultation with a suitable RPA.

Miscellaneous issues

Lead aprons

The use of lead aprons for patients is not considered essential as only the patient's head should be exposed to the primary x-ray beam. There is some research¹⁵ that indicates thyroid shields could provide a dose saving in some circumstances. However the implications of this on image quality requires further study, and there is no evidence at the current time that thyroid shields should be routinely used.

Women of childbearing age

While the patient dose from a CBCT examination is generally higher than conventional dental x-rays, the dose to the abdomen of the patient, including the foetus in the case of female patients who are or may be pregnant, will be insignificant. It follows that there are no radiological reasons for delaying a CBCT examination for a female patient who may be pregnant. Nevertheless, as with any other form of dental x-ray, the dentist is free to exercise judgement regarding delaying an examination on the basis of the psychological state of the patient, should they be concerned about the potential health effects of a radiation exposure. It is not considered essential to ask every patient who may be pregnant as to their pregnancy status due to the very small doses delivered to the abdomen.

Likewise, where dental practice staff who may be pregnant work with dental CBCT equipment that has been installed and is used in accordance with the advice of a suitable RPA, it should not normally be necessary to make any alterations to their working practices in order to ensure adequate restriction of exposure to their unborn child.

Image analysis software

Images should only be clinically evaluated using software approved by the equipment manufacturer. If a person external to the practice is to carry out the evaluation (e.g. a referring dentist or radiologist), the practice taking the exposure should ensure that appropriate software is available to the referring dentist.

Conclusion

There are many radiation protection issues to be considered by any dental practice looking into purchasing CBCT equipment or those practices currently using CBCT equipment. The conventional approaches adopted for more common dental x-ray equipment are well understood by dentists and their staff, and proven to be effective.

¹⁵ K Tsiklakis et al. (2005) Dose reduction in maxillofacial imaging using low dose Cone Beam CT. *European Journal of Radiology.* **56**:413-417

However, simply extending these to apply to dental CBCT equipment will in many cases be inappropriate, inadequate or even unsafe. The importance of obtaining the right advice at the right time in order to provide an adequate level of radiation protection for both staff and patients cannot be stressed too highly; and this must be achieved by consulting a suitable RPA and MPE for advice on the issues covered in this article.

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