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PU	Public	**X**
PP	Restricted to other programme participants (including the Commission)	
RE	Restricted to a group defined by the consortium (including the Commission)	
CO	Confidential, only for members of the consortium (including the Commission)	

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Abstract:
The aim of Work Package 1 (WP1) is to develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies. As a first step in this process, a systematic review was conducted of scientific literature related to CBCT in dentistry. The systematic review (Deliverable D1.1) yielded the evidence required to allow the development of provisional evidence-based guidelines for CBCT.

D1.1 (previously reported 30.1.09) provided completed data extraction/quality assessment forms for each identified item of literature, in duplicate. During the assessment of the studies, each paper had been coded as to study design and potential risk of bias (high risk of bias (-), moderate risk of bias (+), low risk of bias (++). These forms were tabulated into Evidence Tables according to major topic categories (Dose and Risk, Diagnostic Reference Levels, Optimisation, Quality standards, Cost/Benefit Analysis, Diagnostic Accuracy Studies). Literature in the Diagnostic Accuracy category was further sub-divided into the main sub-categories of clinical dentistry. The Guideline Development Panel (GDP), established in the first part of WP1, met for a two-day meeting in March 2009. GDP members were divided into pairs and topics for guideline development were allocated to each pair, reflecting their expertise. GDP members were asked to review the Evidence Tables, along with copies of the original papers if required, and to formulate and grade provisional recommendations. When producing the provisional recommendations, members of the GDP were asked to consider:

- Volume of evidence
- Applicability of the findings to clinical practice
- Generalisibility of the results presented to the guideline's target population
- Consistency of the results (highlighting any major inconsistencies)
- Clinical impact (e.g resource implications, balance of risk/benefit)

Each provisional recommendation was linked, where applicable, to the relevant research evidence. It was graded according to an adaptation of the SIGN grading system. To aid in the development of clinical referral criteria, GDPs were asked to consider two questions:

- Can CBCT be recommended for *routine* clinical use for this application?
- Can CBCT be recommended for *selected* use for this application?

A set of 53 recommendations were developed by the GDP. These were collated as a draft Provisional Guideline document (v1.0), along with summaries of the literature. This was released for internal review and externally to selected independent

international experts. Some corrections and minor modifications were made to the draft document before public release of the Provisional Guideline document (v1.1). Guidelines are 'living documents', and require regular update if they are to provide the target population with a relevant and comprehensive recommendations. The searches are updated on a monthly basis and any new studies identified will be subjected to appraisal as before. Where new, high quality research is identified, their impact on the recommendations will be examined, and amendments to the initial guidelines made on a six-monthly basis, looking forward to Definitive Guideline development by month 40 of the project.

RADIATION PROTECTION: **CONE BEAM CT FOR DENTAL AND MAXILLOFACIAL RADIOLOGY**

Provisional guidelines 2009

(v1.1 May 2009)

SEDENTEX CT

RADIATION PROTECTION:
CONE BEAM CT FOR DENTAL AND MAXILLOFACIAL RADIOLOGY

Provisional guidelines
(v1.1 May 2009)

A report prepared by the SEDENTEXCT project
www.sedentexct.eu

2009

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PREFACE

SEDENTEXCT is a collaborative project which aims to acquire of the key information necessary for sound and scientifically based clinical use of Cone Beam Computed Tomography (CBCT) in dental and maxillofacial imaging. In order that safety and efficacy are assured and enhanced in the 'real world', a parallel aim was to use this information to develop evidence-based guidelines dealing with justification, optimisation and referral criteria for users of CBCT. The aim of this document is to provide such evidence-based guidelines to professional groups involved with CBCT in dental and maxillofacial imaging, including:

- Dental and Maxillofacial Radiologists
- Dentists working in primary care and their assistants
- Radiographers/ Imaging technicians
- Medical Physicists
- Equipment manufacturers and suppliers

The core guidance in preparing the document has been from the two relevant Council Directives of the European Union:

- Directive 96/29/Euratom, of 13 May 1996, laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (Basic Safety Standards Directive)
- Directive 97/43/Euratom, of 3 June 1997, on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (Medical Exposures Directive)

Beyond these sources, the detailed guidelines have been prepared by systematic review of the currently available literature. No exposure to X-rays can be regarded as completely free of risk, so the use of CBCT by practitioners implies a responsibility to ensure appropriate protection.

These are *provisional* guidelines and will be updated in the duration of the SEDENTEXCT project (2008-2011) as new research improves our understanding of CBCT and its appropriate use. Guidelines are not a rigid constraint on clinical practice. Local variations may be required according to national legislation and healthcare provision and practice.

I hope that the document will be of help to professional groups and contribute to optimizing the use of ionizing radiation in dental imaging.

K. HORNER
SEDENTEXCT project Co-ordinator

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SEDENTEXCT PROJECT MEMBERS

The SEDENTEXCT consortium is a multidisciplinary team of seven partners, exploiting the synergies between medical physicists, dentists and dental radiologists, dental clinicians, experts in guideline development and industry. In each centre, excluding the industrial partner, there is both dental and medical physics expertise. The Table below lists the participants.

Participant	Individuals
University of Manchester, UK	Keith Horner *(SEDENTEXCT Project Co-ordinator)* Gillian Armitt *(SEDENTEXCT Project Manager)* Vivian Rushton Hugh Devlin Stephen Birch Anne-Marie Glenny Chrysoula Theodorakou Anne Walker Mohammed Islam Helen McEvoy Gareth Hughes
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GUIDELINE DEVELOPMENT PANEL MEMBERS

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Thanks are also due to the entire SEDENTEXCT team for their contributions and advice on this document.

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- Helen McEvoy for library services.
- Mohammed Islam for website services.
- Linda Norman for secretarial support.

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- Hans-Göran Gröndahl
- Keith Isaacson
- Kevin O'Brien
- Stuart White

FOREWORD

One objective of the SEDENTEXCT project has been to review the current literature on CBCT and to derive useful guidelines that will clarify those clinical situations in which this imaging technique would be found to be beneficial to both the clinician and the patient.

The method chosen was systematic review of the literature. The literature available for formal review was, however, limited in quantity. Because of this, the Guideline Development Panel also reviewed the many case reports/ series and non-systematic reviews available.

Of particular note is the proliferation in CBCT equipment manufacturers and models; **research evidence for one CBCT machine may not apply to other equipment**. As a consequence, caution is needed in generalising research findings. Many of the recommendations made are “Best Practice” rather than carrying any formal evidence grade, based upon the informed judgement of the Guideline Development Panel. It is important, therefore, to remember that these are *provisional* guidelines. We hope that, by the end of the SEDENTEXCT project, sufficient high quality evidence will have accumulated to allow us to develop guidelines that are more “evidence-based”.

Please remember that the literature reviewed does not take account publications in the three months prior to the development of these guidelines. The time required for review and guideline development means that we will always lag behind. In a rapidly changing research scene, we will be updating these guidelines regularly during the project to take account of this.

Your feedback will be appreciated. The mechanism for providing this will be via the project website at www.sedentexct.eu

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1: INTRODUCTION AND GUIDELINE DEVELOPMENT

1.1 Imaging in dentistry and the dental and maxillofacial specialties

Radiology is essential to dentists for determining the presence and extent of disease in patients for whom a thorough patient history and examination has been performed. It also has roles in treatment planning, monitoring disease progression and in assessing treatment efficacy.

However, an integral part of radiology is exposure of patients and, potentially, clinical staff to X-rays. No exposure to X-rays can be considered completely free of risk, so the use of radiation by dentists is accompanied by a responsibility to ensure appropriate protection. Unlike most medical imaging, dentists use radiology to a relatively greater extent on children and young adults, so the need for judicious use is paramount.

The advent of CBCT has been an enormous advance in dental imaging. It is a type of imaging technology that is entirely new to dentists. All stakeholders have a responsibility to deliver this technology to patients in a responsible way, so that diagnostic value is maximised and radiation doses kept as low as reasonably achievable.

1.2 Guideline development

1.2.1 Aim

The aim was to develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies.

The development of the provisional guidelines has been through a systematic assessment of the current research literature. These provisional guidelines are seen as a 'living' document, into which any new, emerging evidence will be incorporated by repeated iteration of the process. A later version of the guidelines will be supplemented with a Delphi technique to obtain a formal consensus on areas lacking high quality research evidence. These "validated" definitive guidelines will be available in the Spring of 2011.

As well as providing recommendations on the use of CBCT in clinical practice, the guidelines will be used to identify gaps in research. An over-arching research strategy will be developed to encourage the development of subsequent

research projects which will be formative in the update of future evidence-based guidelines for the use of CBCT.

1.2.2 Methodology

The provisional guidelines have developed following the methods outlined by the Scottish Intercollegiate Guidelines Network (SIGN) where appropriate.

Guideline development panel and scope of the CBCT guidelines

A multidisciplinary guideline development panel (GDP) was established. The GDP included a variety of stakeholders, including dentists, dental radiologists, medical physicists and oral and maxillofacial surgeons. The membership was derived from colleagues attending the first SEDENTEXCT meeting held in Leuven in January, 2008. The GDP confirmed the areas that were to be addressed in the guidelines as:

- Dose and Risk
- Diagnostic Reference Levels
- Optimisation
- Quality standards
- Cost/Benefit Analysis
- Diagnostic Accuracy Studies

Members of the GDP were divided into sub-groups and assigned to topic areas on the basis of their personal expertise and skills. In those topics which have commonality, at least one member of each team worked on both sub-groups. An Information Officer (Helen McEvoy, University of Manchester, UK) and Project Coordinator (Gillian Armitt, University of Manchester, UK) provided overall support to all sub-groups. The sub-groups were responsible for identifying the key questions to be addressed, screening and data extraction of relevant identified papers, grading of the scientific content of papers and the development of initial recommendations. The overall administration of the guidelines was shared by the SEDENTEXCT Work package 1 Lead and the Project Coordinator in Manchester, UK.

Identification of the literature

An initial search of the FDI guideline database (www.fdiworldental.org) the National Guidelines Clearing House (www.guidelines.gov/index.asp) and MEDLINE (OVID) was undertaken to identify existing guidelines. In addition, scoping searches for scientific papers on the identified topic areas were conducted using MEDLINE (OVID). The development of the search strategies was seen as an iterative process and this initial ‘scoping search’ was undertaken to gain an overview of the volume of literature; identify further questions that may need to be addressed; establish the research methodologies used within each area and also to identify further search terms for refining the search strategy.

The final search strategy was developed for MEDLINE (OVID, 1950 onwards), using a combination of free text and controlled vocabulary (Table 1.1). This search strategy was adapted accordingly and the following databases searched:

- EMBASE (1980 onwards)
- The Cochrane Central Register of Controlled Trials (Central)
- Web of Science
- Scopus
- UK Clinical Research Network
- Clinical Trials.gov
- Register of Controlled Trials (www.controlled-trials.com)
- NICE guidelines (www.nice.org.uk)

Every attempt was made to include both unpublished literature (by contacting experts in the field and through searching SIGLE (until 2005) (opensigle.inist.fr/) and FADE (www.fade.nhs.uk/)) and non-English language articles. All searching was undertaken by an experienced Information Officer and the results imported into Endnote (version 9) for coding. Two members of the GDP screened the titles and abstracts and coded the articles according to the six key areas:

- Dose and Risk
- Diagnostic Reference Levels
- Optimisation
- Quality standards
- Cost/Benefit Analysis
- Diagnostic Accuracy Studies

At this stage, it was noted that much research in this area comes from case-series and case-reports. In order to gain an understanding of how CBCT is being used in clinical practice, it was felt important to gather information from these studies and a formal assessment of them was undertaken by two GDP members using a proforma adapted from Ramulu et al (2005).

Reference details of those articles considered potentially relevant to the subject area were passed back to the Project Co-ordinator and the full article retrieved.

Data extraction/quality assessment

All identified studies and predefined data extraction/quality assessment forms were distributed to the relevant sub-groups by the Project Coordinator, via the SEDENTEXCT website intranet. Members of each sub-group undertook data extraction and quality assessment independently, with each article being assessed in duplicate. Members of the sub-groups were asked to 'flag-up' any records identified in their search results which might also be of relevance to other topic areas. During the assessment of the studies, each paper was coded as to study design and potential risk of bias (high risk of bias (-), moderate risk of bias (+), low risk of bias (++)). This information was used to aid the grading of any recommendations.

Table 1.1: Search strategy developed for use in the SEDENTEXCT project

1	cone beam computed tomography .mp
2	volumetric radiography. mp
3	volumetric tomography.mp
4	digital volumetric tomography.mp
5	digital volumetric tomography.mp
6	digital volume tomography
7	cbct.mp
8	qcbct.mp
9	cone-beam ct.mp
10	cone beam imaging .mp
11	cone-beam.mp
12	volume ct.mp
13	volumetric ct.mp
14	or/1-13
15	(dental or dentistry).mp [mp=title, original title, abstract, name of substance word, subject heading word]
16	exp dentistry/
17	(intra-oral or intraoral).mp [title, original title, abstract, name of substance word, subject heading word]
18	oral surgery.mp. or exp surgery, oral/
19	endodontics$.mp. or exp endodontics
20	orthodontics$. mp. or exp orthodontics
21	(periodontic$ or periodontology).mp.or exp periodontics/
22	exp dental caries/
23	maxillofacial.mp
24	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25	14 and 24

Production and grading of recommendations

The results from the assessment of all identified articles were tabulated to produce 'Evidence Tables'. A meeting of members of the GDP was held to discuss the Evidence Tables and to formulate and grade provisional recommendations. When producing the provisional recommendations, members of the GDP were asked to consider:

- Volume of evidence
- Applicability of the findings to clinical practice
- Generalisibility of the results presented to the guideline's target population
- Consistency of the results (highlight any major inconsistencies)
- Clinical impact (e.g resource implications, balance of risk/benefit)

Each provisional recommendation was linked, where applicable, to the relevant research evidence. It was graded according to an adaptation of the SIGN grading system (Tables 1.2 and 1.3).

Table 1.2: Grading systems used for levels of evidence [adapted from Scottish Intercollegiate Guidelines Network (SIGN), 2008].

1++	High quality meta-analyses/systematic reviews of randomised controlled trials (RCTs) or RCTs (including in vitro studies) with a very low risk of bias
1+	Well conducted meta-analyses/systematic review of RCTs, or RCTs (including in vitro studies) with moderate risk of bias
1-	Meta-analyses/ systematic reviews of RCTs, or RCTs (including in vitro studies) with high risk of bias
2++	High quality systematic reviews of case-control or cohort studies; High quality non-randomised trials, case-control or cohort studies with a very low risk of confounding, bias, or chance and high probability that the relationship is causal
2+	Well conducted non-randomised trials, case-control or cohort studies with a moderate risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Non-randomised trials, case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case series, cross-sectional surveys
4	Expert opinion

Table 1.3: Grading systems used for levels of evidence [adapted from Scottish Intercollegiate Guidelines Network (SIGN), 2008].

Grade	
A	At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+
GP	Good Practice (based on clinical expertise of the guideline group)

Two additional gradings are used in this document:

- A grade of "**ED**" is applied where a statement is directly derived from The Council of the European Union Directive 96/29/Euratom of 13 May 1996 (laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation) or Council Directive 97/43/Euratom of 30 June 1997 (on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure).
- A grade of "**BP**" is applied where a statement was identical to, or directly derived from, a "Basic Principle" of use of dental CBCT, as developed by consensus of the European Academy of Dental and Maxillofacial Radiology (see Section 3 of this document).

Update of provisional guidelines
This document is the first version of the guidelines (v1.0). It is acknowledged that guidelines should be 'living documents', and require regular update if they are to provide the target population with a relevant and comprehensive recommendations. The searches are updated on a monthly basis and any new studies identified will be subjected to appraisal as before. Where new, high quality research is identified, their impact on the recommendations will be examined, and amendments to the initial guidelines made on a six-monthly basis.

Dissemination of guidelines
The provisional and definitive guidelines will be widely disseminated throughout and beyond the European Union and will be easily accessed from a dedicated website. This will allow interested groups worldwide to rapidly access this information. Feedback from users of the provisional guidelines is encouraged via the SEDENTEXCT website. Comments received will be reviewed at each six-monthly update (or earlier if deemed necessary). It is envisaged that input from users will aid uptake of the guidelines.

1.3 References

Ramulu VG, Levine RB, Hebert RS, Wright SM. Development of a case report review instrument. J Clin Pract 2005; 59: 457-461.

Scottish Intercollegiate Guidelines Network (SIGN). A guideline developers' handbook. Edinburgh: SIGN; 2004 May 2002. Report No: 50.

2: RADIATION DOSE AND RISK

2.1: X-rays

X-rays are a type of electromagnetic (EM) radiation. EM radiation also includes visible light, radio waves, microwaves, cosmic radiation, and several other varieties of 'rays'. All can be considered as 'packets' of energy, called photons, which have wave properties, most importantly a wavelength and frequency. EM radiation can vary in wavelength from 10^{-13} to 10^{3} m with X-rays having a small wavelength of 10^{-9} to 10^{-13}m. The importance of this is that small wavelengths mean high energy, deeper penetration though matter and high energy transfer to the matter. When X-rays hit atoms this energy can be transferred, producing ionisation of atoms.

2.2: Radiation damage

When patients undergo X-ray examinations, millions of photons pass through their bodies. These can damage any molecule by ionisation, but damage to the DNA in the chromosomes is of particular importance. Most DNA damage is repaired immediately, but rarely a portion of a chromosome may be permanently altered (a mutation). This may lead ultimately to the formation of a tumour. The latent period between exposure to X-rays and the clinical diagnosis of a tumour may be many years. The risk of a tumour being produced by a particular X-ray dose can be estimated; therefore, knowledge of the doses received by radiological techniques is important. 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 (Longstreth et al, 1993; Preston-Martin & White, 1990), salivary gland (Preston-Martin & White, 1990; Horn-Ross et al, 1997) and thyroid (Hallquist et al, 1994; Wingren et al, 1997) tumours for dental radiography.

The effects described above are believed to have no threshold radiation dose below which they will not occur (European Commission, 2001). They can be considered as 'chance' (stochastic) effects, where the magnitude of the risk is proportional to the radiation dose. There are other known damaging effects of radiation, such as cataract formation, skin erythema and effects on fertility, that definitely have threshold doses below which they will not occur. These threshold doses vary in size, but all are of a magnitude far greater than those given in dental radiography. Thus, except in extraordinary circumstances, these deterministic effects are given no further consideration.

2.3: Radiation dose

The terms ‘dose’ and ‘exposure’ are widely used but often misunderstood. ‘Doses’ may be measured for particular tissues or organs (e.g. skin, eye, bone marrow) or for the whole body, while ‘exposure’ usually refers to equipment settings (time, mA, kV). A commonly used measure of dose in surveys is ‘entrance dose’, measured in milliGrays (mGy).This has an advantage of being fairly easily measured by placing dosimeters on the patient’s skin. Diagnostic reference levels (DRLs), based upon entrance dose surveys, may be set as standards against which X-ray equipment can be assessed as part of quality assurance.

In these Guidelines, however, radiation dose is expressed as *effective dose*, measured in units of energy absorption per unit mass (joules / kg) called the Sievert (more usually the microSievert, μSv, representing one millionth of a Sievert). Effective dose is calculated for any X-ray technique by measuring the energy absorption in a number of ‘key’ organs/tissues in the body. Each organ dose is multiplied by a weighting factor that has been determined as a reflection of its radiosensitivity. These are added together, so that the final figure is a representation of ‘whole body’ detriment. While effective dose is an impossible quantity to measure *in vivo*, it is possible to determine it from laboratory studies or computer modelling. This can then be used to estimate radiation risk.

Many studies have measured doses of radiation for dental radiography, but only some have estimated effective dose. Much published work on conventional dental radiographic techniques pre-dates the recent revision of tissue weighting factors by the ICRP (ICRP 2007). This revision altered the existing tissue weighting factors and specific weighting factors were added for salivary glands, brain, gall/bladder, heart, lymphatic nodes, oral mucosa and prostate. As salivary glands, brain and oral mucosa are often irradiated during dental x-ray examinations, this means that studies using old weighting factors might give very different results to those using the new factors. Furthermore, variation in the technical parameters of the X-ray equipment and image receptors used in studies means that care should be taken when comparing dose estimations from different studies. Because it is a relatively new technique, most dental CBCT dosimetry research has used the more recent tissue weighting factors. Nonetheless, it is still important to recognise that the doses reported for one CBCT machine may be quite different to another and that ranges of dose are more appropriate to use than absolute figures.

2.4: Radiation risk

Radiation detriment can be considered as the total harm experienced by an irradiated individual. In terms of stochastic effects, this includes the detriment-adjusted nominal risk of cancer and hereditable effects. The probability of radiation-induced stochastic effects for the whole population is 5.7×10^{-2} Sv^{-1}.

Table 2.1 was taken from (ICRP 2007) and it gives the breakdown of this summed figure into its constituent elements. Hereditable effects are believed to be negligible in dental radiography (White 1992) and this is also true for CBCT.

Risk is age-dependent, being highest for the young and least for the elderly. Here, risks are given for the adult patient at 30 years of age. These should be modified using the multiplication factors given in Table 2.2 (derived from ICRP 1990). These represent averages for the two sexes; at all ages risks for females are slightly higher and those for males slightly lower.

Beyond 80 years of age, the risk becomes negligible because the latent period between X-ray exposure and the clinical presentation of a tumour will probably exceed the life span of a patient. In contrast, the tissues of younger people are more radiosensitive and their prospective life span is likely to exceed the latent period.

Table 2.1: Detriment-adjusted nominal risk coefficients for stochastic effects

Detriment ($10^{-2}Sv^{-1}$)	
Cancer	5.5
Hereditable effects	0.2
Total	5.7

Table 2.2: Risk in relation to age. These data are derived from (ICRP 1990) and represent relative attributable lifetime risk based upon a relative risk of 1 at age 30 (population average risk). It assumes the multiplicative risk projection model, averaged for the two sexes. In fact, risk for females is always relatively higher than for males.

Age group (years)	Multiplication factor for risk
<10	x 3
10-20	x 2
20-30	x 1.5
30-50	x 0.5
50-80	x 0.3
80+	Negligible risk

2.5: Doses and risks with CBCT

The literature review conducted by the SEDENTEXCT project included 11 studies in which dosimetry for CBCT was performed and in which effective dose was calculated using tissue weighting factors taken from ICRP (2007). Table 2.3a shows the reported effective doses for a range of dental CBCT units along with comparative data for conventional imaging techniques. Table 2.3b presents the effective dose for conventional imaging and MSCT imaging. The majority of studies were based on thermoluminescent (TLD) dosimetry techniques using anthropomorphic phantoms. They showed significant variation in methodology, especially with respect to the type of phantom used and TLD number and positioning. The effect of the number and position of the TLD dosimeters on the accuracy of the assessment has not been assessed.

Life is a risky business. Among the many risks to which we are prone, we are all constantly exposed to normal background radiation, which averages about 2400 μSv (European Commission, 2001) each year (average world figures). Medical exposures (of which dental radiology contributes a small fraction) add substantially to this figure, with wide variation from country to country. With this in mind, a panoramic radiograph may be associated with an effective dose the same as 1-5 days' additional background radiation, while the dental CBCT risk could result in an effective dose equivalent to a few days up to a couple of months of background radiation, depending on the type of the machine and clinical protocol used.

The radiation dose and risk from dental CBCT are generally higher than conventional dental radiography (intraoral and panoramic) but lower than conventional CT scans of the dental area. Dose is dependent on equipment type and exposure settings, especially the field of view selected

C

Research studies should be performed to assess organ and effective doses using scientifically accurate and precise methodologies, paying special attention to paediatric dosimetry

GP

Table 2.3a: The range of effective dose from dental CBCT in μSv. Studies are divided into those in which "dento-alveolar" CBCT (fields of view smaller than the facial region) and "craniofacial" CBCT, in which the field of view routinely includes at least the maxilla and mandible. CBCT technology is a rapidly developing field and manufacturers are regularly bringing out new models or up-grading existing models. Consequently, the doses quoted in the table might not apply to newer versions of CBCT equipment with the same name.

Dental CBCT unit	Effective dose (μSv)		References	
	Dento-alveolar	Craniofacial	Dento-alveolar	Craniofacial
NewTom	41-75	30-78	Ludlow et al 2003	Ludlow et al 2006 Okano et al 2009 Silva et al 2008 Ludlow et al 2003 Ludlow et al 2008 Mah et al 2003 Tsiklakis et al 2005
Accuitomo/ Veraviewepocs	11-102		Okano et al 2009 Loftag-Hansen et al 2008 Hirsch et al 2008 Loubele et al 2008	
Galileos		70-128		Ludlow et al 2008
Promax	488-652		Ludlow et al 2008	
Prexion	189-388		Ludlow et al 2008	
i-CAT	34-89	48-206	Roberts et al 2009 Loubele et al 2008	Ludlow et al 2006 Roberts et al 2009 Loubele et al 2008 Ludlow et al 2008 Mah et al 2003
CB MercuRay	407	283-1073	Ludlow et al 2008	Ludlow et al 2006 Okano et al 2009 Ludlow et al 2008
Illuma		98-498		Ludlow et al 2008

Table 2.3b: Effective dose from conventional dental imaging techniques in μSv

	Effective dose (μSv)	References
Intra-oral radiograph	<8.3*	European Commission 2004*
Panoramic radiograph	2.7 - 23	Ludlow et al 2006 Okano et al 2009 Silva et al 2008 Palomo et al 2008 Garcia-Silva et al 2008
CT maxillo-mandibular	180 - 2100	Ludlow et al 2006 Okano et al 2009 Silva et al 2008 Loubele et al 2005
CT maxilla	1400	Ludlow et al 2006

*no data available calculated subsequent to ICRP2007

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3: BASIC PRINCIPLES

3.1: Background

The SEDENTEXCT project aims to acquire key information necessary for sound and scientifically based clinical use of Cone Beam Computed Tomography (CBCT). As part of this aim, the project set an objective of developing evidence-based guidelines for dental and maxillofacial use of CBCT. Early in 2008, it became apparent that there was an urgent need to provide some basic guidance to users of CBCT because of concerns over inappropriate use. These concerns were voiced by the European Academy of DentoMaxilloFacial Radiology (EADMFR), an organisation whose objective is to promote, advance and improve clinical practice, education and/or research specifically related to the specialty of dental and maxillofacial radiology within Europe, and to provide a forum for discussion, communication and the professional advancement of its members. EADMFR has a membership exceeding 300 individuals whose special interest is imaging of the dental and maxillofacial region. It is multi-disciplinary, including dental radiologists, medical physicists, radiographers and scientists. It includes both academics (teachers and researchers) and clinicians. In view of the mutual aims of EADMFR and SEDENTEXCT, a decision was taken to collaborate in the development of a set of “Basic Principles” for the use of dental CBCT, based upon existing standards. These standards include fundamental international principles, EU Directives (Council of European Union, 1996, 1997) and previous Guidelines (European Commission 1994).

3.2: Methodology

The detailed methodology followed in the preparation of these guidelines is fully described elsewhere (Horner et al, 2009). Briefly, a Guideline Development Panel was formed to develop a set of draft statements using existing EU Directives and Guidelines on Radiation Protection. The draft statements covered Justification, Optimisation and Training of CBCT users. These statements were revised after an open debate of attendees at the 11th EADMFR Congress on 28th June 2008. A modified Delphi procedure was then used to present the revised statements to the EADMFR membership, utilising an online survey in October/November 2008. Consensus of EADMFR members, indicated by high level of agreement for all statements, was achieved without a need for further rounds of the Delphi process.

A set of 20 “Basic Principles” on the use of Dental CBCT were thus established. These act as core standards for EADMFR and are central to this Guideline publication.

3.3: The "Basic Principles"

1	CBCT examinations must not be carried out unless a history and clinical examination have been performed
2	CBCT examinations must be justified for each patient to demonstrate that the benefits outweigh the risks
3	CBCT examinations should potentially add new information to aid the patient's management
4	CBCT should not be repeated 'routinely' on a patient without a new risk/benefit assessment having been performed
5	When accepting referrals from other dentists for CBCT examinations, the referring dentist must supply sufficient clinical information (results of a history and examination) to allow the CBCT Practitioner to perform the Justification process
6	CBCT should only be used when the question for which imaging is required cannot be answered adequately by lower dose conventional (traditional) radiography
7	CBCT images must undergo a thorough clinical evaluation ('radiological report') of the entire image dataset
8	Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than CBCT
9	CBCT equipment should offer a choice of volume sizes and examinations must use the smallest that is compatible with the clinical situation if this provides less radiation dose to the patient
10	Where CBCT equipment offers a choice of resolution, the resolution compatible with adequate diagnosis and the lowest achievable dose should be used
11	A quality assurance programme must be established and implemented for each CBCT facility, including equipment, techniques and quality control procedures
12	Aids to accurate positioning (light beam markers) must always be used
13	All new installations of CBCT equipment should undergo a critical examination and detailed acceptance tests before use to ensure that radiation protection for staff, members of the public and patient are optimal
14	CBCT equipment should undergo regular routine tests to ensure that radiation protection, for both practice/facility users and patients, has not significantly deteriorated
15	For staff protection from CBCT equipment, the guidelines detailed in Section 6 of the European Commission document *'Radiation Protection 136. European Guidelines on Radiation Protection in Dental Radiology'* should be followed
16	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
17	Continuing education and training after qualification are required, particularly when new CBCT equipment or techniques are adopted
18	Dentists responsible for CBCT facilities who have not previously received 'adequate theoretical and practical training' should undergo a period of additional theoretical and practical training that has been validated by an academic institution (University or equivalent). Where national specialist qualifications in DMFR exist, the design and delivery of CBCT training programmes should involve a DMF Radiologist
19	For dento-alveolar CBCT images of the teeth, their supporting structures, the mandible and the maxilla up to the floor of the nose (eg 8cm x 8cm or smaller fields of view), clinical evaluation (*'radiological report'*) should be made by a specially trained DMF Radiologist or, where this is impracticable, an adequately trained general dental practitioner
20	For non-dento-alveolar small fields of view (e.g. temporal bone) and all craniofacial CBCT images (fields of view extending beyond the teeth, their supporting structures, the mandible, including the TMJ, and the maxilla up to the floor of the nose), clinical evaluation (*'radiological report'*) should be made by a specially trained DMF Radiologist or by a Clinical Radiologist (Medical Radiologist)

3.4: References

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4: JUSTIFICATION AND REFERRAL CRITERIA

4.1: Introduction

As with any X-ray exposure, CBCT entails a risk to the patient. It is essential that any X-ray examination should show a net benefit to the patient, weighing the total potential diagnostic benefits it produces against the individual detriment that the exposure might cause. The efficacy, benefits and risk of available alternative techniques having the same objective but involving less (or no) exposure to X-rays should be taken into account.

All CBCT examinations must be justified on an individual basis by demonstrating that the benefits to the patients outweigh the potential risks. CBCT examinations should potentially add new information to aid the patient's management

ED BP

In order that the justification process can be carried out, it is essential that selection of CBCT is based on the individual patient's history and a clinical examination. The 'routine' use of CBCT on patients based on a generalised approach rather than individual prescription is unacceptable. A 'routine' (or 'screening') examination is defined as one in which a radiograph is taken regardless of the presence or absence of clinical signs and symptoms.

CBCT should not be selected unless a history and clinical examination have been performed. "Routine" imaging is unacceptable practice

ED BP

Choosing CBCT for a patient should also be based upon consideration of the prevalence of diseases, their rates of progression and the diagnostic accuracy of CBCT, compared with traditional techniques, for the application in question. Consulting guidelines facilitates the process of selecting radiographs. Such guidelines, called 'referral criteria' or 'selection criteria' exist for both medical and traditional dental imaging. Radiographic Referral Criteria have been defined as:

> "*descriptions of clinical conditions derived from patient signs, symptoms and history that identify patients who are likely to benefit from a particular radiographic technique".*

As with any guideline, these are not intended to be rigid constraints on clinical practice, but a concept of good practice against which the needs of the individual patient can be considered. The term 'referral criteria' is appropriate for medical practitioners, where radiography is usually arranged by referral to a specialist in radiology. With CBCT, this situation may also apply, with the dentist referring to a hospital department or to a dentist-colleague. When acting as a referrer, the dentist should ensure that adequate clinical information about the patient is provided to the person taking responsibility for the exposure.

When referring a patient for a CBCT examination, the referring dentist must supply sufficient clinical information (results of a history and examination) to allow the CBCT Practitioner to perform the Justification process

ED BP

Guidelines have been devised for a range of uses of CBCT that became apparent during the course of the systematic review. Following the original SEDENTEXCT project aims and objectives, priority is given to paediatric uses.

4.2: The Developing dentition

Many children seek orthodontic treatment. For children in the mixed dentition stage, where there are abnormalities in eruption pattern, tooth position or signs of crowding, radiographs may be required to determine the presence, absence, position and condition of teeth. Most orthodontic appliance treatment takes place at around 12-13 years of age, at which stage radiographs may be necessary to confirm the presence, absence, position and condition of teeth as an aid to treatment planning.

Justification of X-ray examinations in children is especially important because of the higher risks associated with exposure in children (see section 2.4). Traditional radiological examination of children undergoing orthodontic assessment relies on a panoramic radiograph, supplemented by a lateral cephalometric radiograph in specific circumstances. Intra-oral radiographs are also used according to patient-specific needs. In recent years, however, the availability of CBCT has led to this technique being used by some clinicians as a means of radiological examination.

For assessment of facial bone shape, position and inter-relationships, there must be a high accuracy of measurements made with CBCT. Several studies have addressed this, usually using direct calliper measurement of dried skulls as a reference standard. Differences between CBCT-derived measurements and the reference standard appear to be small and are unlikely to be clinically significant (Lascala et al 2004; Marmulla et al 2005; Ludlow et al 2007; Mischkowski et al 2007; Moshiri et al 2007; Peck et al, 2007; Ballrick et al 2008; Loubele et al 2008; Periago et al, 2008; Stratemann et al 2008; Suomalainen et al 2008). Studies are not, however, available for all CBCT machines on the market.

The applications of CBCT in assessment of the developing dentition for orthodontics will be considered under two broad headings: localised applications to answer a specific question and generalised application for examination of the entire dento-facial region.

4.2.1 Localised applications of CBCT for the developing dentition

Unerupted tooth localisation
A frequent application of CBCT is for assessment of the position of an unerupted tooth, particularly where the tooth is impacted. In such cases, an integral aspect of the assessment is often the accurate identification of any resorption of adjacent teeth. Such a situation is most often seen where maxillary canines are ectopic and incisor roots are suspected of having undergone resorption. Traditional radiological assessment relies upon the use of parallax movement between images taken with different perspectives. In some specialised centres, conventional CT has been used for this purpose, so some studies have concentrated on this comparison of performance.

Teeth are relatively large objects, having good contrast with the surrounding bone. It is obvious that a three-dimensional imaging technique with acceptable measurement accuracy and little distortion will identify position of teeth with high diagnostic accuracy. As such, it is not surprising that no formal study has been performed that compares diagnosis of unerupted tooth position using CBCT and conventional radiographs. Such studies would be “proving the obvious”. The literature on this use of CBCT, therefore, is mainly case reports and series (see Table 4.1) and those of Liu et al (2007, 2008) are highlighted in view of their scale. Despite the self-evident advantage of CBCT in tooth localisation, it is important to consider the impact upon management of patients, the increased radiation dose and the likely higher cost of CBCT examinations. Conventional radiography has served orthodontists well over many years, and the GDP concluded that there is a need for research demonstrating changed (and improved) management of patients before routine use of CBCT for this purpose could be considered. The exception to this may be where current practice is to use MSCT for localisation of unerupted teeth. Conventional CT has been shown to alter management of a significant proportion of children with impacted

maxillary canines (Alqerban et al, 2009), so it seems likely that the same would be true for CBCT. In such cases, CBCT is likely to be preferred over MSCT when dose is lower. In any case, radiological examination of maxillary canines is not usually necessary before 10 years of age.

For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth) where the current imaging method of choice is MSCT, CBCT may be preferred because of reduced radiation dose

GP

External resorption in relation to unerupted teeth

As stated above, it is often the case that assessment of unerupted tooth position also involves assessment of the presence or absence of resorption in adjacent teeth. This application of CBCT has been considered in several case series and non-systematic reviews (Table 4.1). A recent review (Alqerban et al, 2009) has also considered this aspect in detail for the maxillary canine. Nonetheless, there is a paucity of studies that look at diagnostic accuracy of CBCT for detection of resorption cavities in this situation, but some information can be obtained from studies on different clinical aspects of resorption. Hahn (2009), in an animal study and using a prototype imaging system, found some limitations in specificity in diagnosing artificial external cavities on roots, while Liedke et al (2009) found that voxel size was influential in diagnostic performance using an iCAT CBCT unit. In external review of the draft Guidelines, one orthodontist expressed the view that only extensive resorption has treatment implications and that this would be visible on a conventional intraoral radiograph. In view of the lack of evidence for treatment implications of three-dimensional images, more research is needed in this area

For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth) where the current imaging method of choice is conventional dental radiography, CBCT may be used when the information cannot be obtained adequately by lower dose conventional (traditional) radiography

C

For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth), the smallest volume size compatible with the situation should be selected because of reduced radiation dose. The use of CBCT units offering only large volumes (craniofacial CBCT) requires very careful justification and is generally discouraged

GP BP

Table 4.1: Orthodontic applications of CBCT identified and reviewed

Application of CBCT for orthodontics	Reference
Cleft palate assessment	Müssig et al 2005 Hamada et al 2005 Wörtche et al 2006
Tooth position and localisation	Chaushu et al, 2004 Kau et al 2005 Nakajima et al 2005 Walker et al 2005 Liu et al 2007 Liu et al 2008 Mussig et al 2005
Resorption related to impacted teeth	Kau et al 2005 Liu et al 2008
Measuring bone dimensions for mini-implant placement	Gracco et al 2006 King et al 2006 Gracco et al 2007 Gracco et al 2008 Kim et al 2007
For rapid maxillary expansion	King et al 2007 Rungcharassaeng et al 2007
3-dimensional cephalometry	Garrett et al 2008 Baumrind et al 2003
Surface imaging integration	Swennen & Scutyser 2006 Lane & Harrell 2008
Airway assessment	Maal et al 2008 Aboudara et al, 2003 Kau et al 2005 Ogawa et al 2007
Age assessment	Shi et al 2007
Investigation of orthodontic-associated paraesthesia	Erickson et al 2003

Cleft palate

MSCT is an accepted method of assessing clefts prior to surgery, despite the significant radiation dose. The use of CBCT in this application has been the subject of several non-systematic reviews and descriptive studies (Müssig et al 2005; Hamada et al 2005; Wörtche et al 2006; Korbmacher et al 2007). The GDP found this application to be the simplest to support, in view of the established use of three-dimensional images and the potentially lower dose of CBCT.

Where the current imaging method of choice for the assessment of cleft palate is MSCT, CBCT may be preferred where radiation dose is lower. The smallest volume size compatible with the situation should be selected because of reduced radiation dose

GP BP

Temporary orthodontic anchorage using "mini-implants"
Several studies have used CBCT to measure the available bone thickness for placing "mini-implants" for temporary orthodontic anchorage (Gracco et al 2006; King et al 2006; Gracco et al 2007; Gracco et al 2008; Kim et al 2007; King et al 2007). It was not clear when reviewing these studies whether the aim was to measure bone thickness (using CBCT as a convenient method of assessment) or whether CBCT was being proposed as a routine diagnostic tool. In view of this, the GDP did not feel able to make a recommendation.

4.2.2 Generalized application of CBCT for the developing dentition

Large volume (craniofacial) CBCT, imaging at least the entire facial skeleton, is currently being used as a routine tool for orthodontic-related radiological assessment by some clinicians, particularly outside Europe. In view of the radiation doses involved and the (largely) paediatric age group of patients, this practice requires critical consideration. The European Guidelines on Radiation Protection in Dental Radiology (European Commission, 2004) highlighted the research performed, prior to the introduction of CBCT, which shows that clinical indicators and algorithms can reduce the numbers of radiographs without compromising patient treatment. Various studies have shown that radiographic information changes diagnosis and treatment plans in a minority of patients. A flow-chart to support clinical decision making on the need for lateral cephalograms was included in the British Orthodontic Society Guidelines of 2002 and in a recent new edition (Isaacson et al 2008). Similar algorithms for selecting radiographs for orthodontic patients have been presented in European Guidelines (European Commission, 2004).

The Panel felt that much of the literature on using large volume CBCT for routine orthodontic diagnosis and treatment was strong on hyperbole and short on evidence of significant clinical impact. There is evidence that cephalograms synthesised from CBCT volume datasets are accurate (Cattaneo et al 2008; Kumar et al 2007; Kumar et al 2008), but this does not justify using CBCT as a primary investigation. No evidence was identified to support the routine use of

large volume CBCT at any stage of orthodontic treatment. The use of three-dimensional cephalometry has been presented by some authors as a means of improved diagnosis and management, but the evidence for this opinion is absent. As such, the GDP could not recommend CBCT use for this purpose. GDP could, however, see the potential value of large volume CBCT for assessment of patients with complex craniofacial deformity requiring surgical or combined surgical/orthodontic intervention at 16 years or over as part of planning for the definitive procedure. Serial “monitoring” of skeletal growth should be discouraged.

Large volume CBCT should not be used routinely for orthodontic diagnosis
GP

For complex cases of skeletal abnormality, particularly those requiring combined orthodontic/surgical management, large volume CBCT may be justified in planning the definitive procedure, particularly where MSCT is the current imaging method of choice
GP

Research is needed to define robust guidance on clinical selection for large volume CBCT in orthodontics, based upon quantification of benefit to patient outcome
GP

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4.3: Restoring the adult dentition

4.3.1: Dental caries diagnosis

The use of CBCT as part of caries detection and diagnosis has been the subject of only a few laboratory research studies on extracted teeth. Nonetheless, the relative ease of obtaining a valid reference standard means that the studies provide useful evidence of diagnostic value. It is important to recognise that much of the research has been performed using “limited” CBCT (small volumes with specific equipment) and that results are not transferable to all CBCT machines, as pointed out by Haiter-Neto et al (2008). One study (Kalathingal et al, 2007) used a customised assembly of an intraoral X-ray set with a rotating table, so could not be included in the systematic review, although the results may still be relevant. Most studies have been focused upon proximal caries diagnosis rather than occlusal caries, with one exception. One practical challenge to using CBCT for caries detection in the clinical situation, not addressed in the laboratory studies, is that metallic restorations may produce artefacts that would reduce diagnostic accuracy.

The current evidence suggests that limited CBCT has a similar diagnostic accuracy to conventional radiography for the detection of caries in posterior teeth *in vitro*, but that the representation of caries depth may be superior (Akdeniz et al, 2006; Haiter-Neto et al 2008; Tsuchida et al 2007). The Panel concluded that the evidence did not support the routine use of CBCT for caries detection and diagnosis, but that care should be taken when reporting CBCT examinations to look for caries where teeth are included in the images.

CBCT should not be used as a routine method of caries detection and diagnosis

B

Where CBCT images include the teeth, care should be taken to check for caries when performing a clinical evaluation (report)

GP

4.3.2: Periodontal assessment

The diagnosis of periodontal diseases depends on a clinical examination. This may be supplemented by radiological examination if this is likely to provide additional information that could potentially change patient management or prognosis. Radiographs do not have a role in diagnosis of periodontal disease,

but are used as a means of demonstrating the hard tissue effects of periodontal disease, particularly the bony attachment loss. As pointed out in previous guidelines, there is no clear evidence to support any robust recommendations on selection of radiological examinations. Those guidelines recommended that "existing radiographs, e.g. bitewing radiographs taken for caries diagnosis, should be used in the first instance".

Conventional radiographs have significant limitations in demonstrating the periodontal attachment of teeth. Two-dimensional images do not show irregular bone defects or buccal/lingual attachments clearly. The attraction of a three-dimensional image is, therefore, considerable. The literature on periodontal uses of CBCT is small and the Panel identified only a few studies for formal assessment in the review. Some case studies were also considered. Limited volume CBCT can provide accurate depiction of periodontal bone defects with good dimensional accuracy in laboratory studies (Mengel et al, 2005; Pinsky et al 2005; Mol & Balasundaram 2008), but with the latter study showing a less impressive performance for CBCT in the anterior regions. Interestingly, however, one study reported no significant differences in linear measurements between bone sounding, conventional radiography and CBCT (Misch et 2006), although buccal/lingual measurements could not be made by radiography. This lack of statistically significant difference between conventional and CBCT images was also reported in another laboratory study (Vandenberghe et al 2007). In a large ex vivo study, however, CBCT measurement accuracy was significantly better than intraoral radiography when cross-sectional images were used, but not when a panoramic reconstruction was employed (Vandenberghe et al 2008). The same study showed that CBCT was superior to intraoral radiography for crater and furcation defect imaging, reflecting case reports and non-systematic review opinion (Ito et al 2001; Kasaj & Willershausen 2007; Naitoh, 2006).

Overall, the literature related to use of CBCT in periodontal imaging is small, laboratory-based and involves a limited number of CBCT systems. The impact of three-dimensional images upon management decisions and treatment impact in clinical practice has not been considered.

CBCT should not be used as a routine method of imaging periodontal bone support

C

CBCT may be useful in selected cases of infra-bony defects and furcation lesions, where clinical and conventional radiographic examinations do not provide the information needed for management.

C

Where CBCT images include the teeth, care should be taken to check for periodontal bone levels when performing a clinical evaluation (report)

GP

4.3.3: Assessment of periapical disease

Diagnosis of periapical inflammatory pathosis is a common and important task for dentists. A number of case reports and non-systematic reviews have highlighted the value of CBCT for identification of periapical lesions in selected cases (Nakata et al, 2006; Cotton et al, 2007; Patel et al, 2007). The research studies addressing this aspect of use of CBCT are limited by the difficulty of obtaining a true reference standard in clinical studies. Because of this difficulty, the studies formally reviewed included those where the design was limited to a comparison of diagnostic yield between CBCT and traditional radiographic techniques (Loftag-Hansen et al, 2007; Estrela et al, 2008; Low et al, 2008). In one case, CBCT itself was used as the reference standard and the conclusion of this study was that “CBCT was proved to be accurate to identify apical periodontitis” (Estrela et al, 2008a). Similar results were reported by Estrela et al (2008b). Clearly, no test method can be shown to be superior to the reference standard, so this conclusion is flawed. These comparative studies found a higher number of periapical lesions apparently revealed by CBCT. While this gives some reassurance of diagnostic value, such studies do not take account of possible false positive diagnoses with CBCT.

While clinical studies with no reference standard suffer from the risk of overestimating the diagnostic validity of CBCT for periapical diagnosis, laboratory studies, in which periapical bone defects are mechanically prepared, may offer a more objective test. One study judged to be of high quality showed that CBCT was superior to periapical radiography in diagnostic accuracy (and in other measures of diagnostic utility) where artificial periapical lesions were prepared in pig jaws (Stavropoulos & Wenzel, 2007). Clearly, there are some reservations regarding the direct applicability of these results to the human situation.

One small study (Simon et al, 2006) looked at grey scale values of large periapical radiolucencies and assessed whether cysts and granulomas could be differentiated. The authors suggested that “CBCT may provide a more accurate diagnosis than biopsy and histology”. This is clearly not correct, as properly performed histopathology is always the correct reference standard. The results suggested that CBCT had high sensitivity for diagnosis of cysts but limited specificity (i.e. over-diagnosis of cysts).

In conclusion, there are several studies showing that CBCT identifies more periapical lesions on posterior teeth than traditional radiography, but these studies did not assess real diagnostic accuracy as they did not have a valid reference standard. There is no information in the literature about the ability of CBCT to identify subtle periapical inflammatory changes such as lamina dura loss or subtle periodontal ligament changes.

CBCT should not be used routinely for identification of periapical pathosis

GP

CBCT may be considered for periapical assessment, in selected cases, when conventional radiographs give a negative finding when there are contradictory positive clinical signs and symptoms

GP

Where CBCT images include the teeth, care should be taken to check for periapical disease when performing a clinical evaluation (report)

GP

4.3.4: Endodontics

Conventional endodontic imaging relies on intraoral radiography. In multi-rooted teeth and more complex cases (e.g. suspected root perforations; resorptions and atypical canal systems) intraoral radiographs at different beam angulations are used to achieve a range of perspectives and allow parallax localisation. Panoramic radiography does not provide the necessary image detail, while MSCT is impracticable for dentists and hard to justify on the basis of radiation dose. Endodontic treatment requires images in three phases of management: diagnosis, during treatment (working length estimation, master cone check image) and in post-treatment review. Endodontic treatment itself includes orthograde treatment and surgical endodontic procedures.

The three-dimensional images from CBCT appear to offer a valuable new method of imaging root canal systems, and there are several non-systematic reviews in the literature that give a favourable perspective (Cotton et al, 2007; Nair et al, 2007; Patel et al 2007). Endodontics requires, however, a high level of image detail, and it is important to remember that available CBCT systems offer different resolution capabilities and, at best, spatial resolution is less than introral radiography. Furthermore, because endodontic treatment is a single tooth procedure, CBCT systems incapable of reducing the field of view to suitable dimensions will expose areas to radiation without patient benefit.

The literature review identified only a few studies that even partially satisfied the criteria for formal review. One study (Matherne et al, 2008), that ostensibly studied the use of CBCT to identify root canal systems in vitro, in fact made a comparison with intraoral radiography using CBCT as the reference standard. For the reasons mentioned in previous sections, this was not an assessment of diagnostic accuracy as it did not take account of false results and the possibility that intraoral radiography might have provided the “true” information in some cases. The study of Hannig et al (2006) showed that their flat panel-based volume computed tomography system could produce detailed volumetric data about root canal systems, but there was no reference standard and their system is a prototype. CBCT, using the small volume Accuitomo CBCT unit, was shown to reveal about 10% more root canals than intraoral radiographs in two clinical studies (Loftag-Hansen et al, 2007; Low et al, 2008) without a reference standard, all in molar teeth. The impact of CBCT on management decisions has not been addressed in any detail, although one study on posterior teeth (Loftag-Hansen et al, 2007) reported that CBCT added additional clinically relevant information in 70% of cases. Research is needed to establish objectively the diagnostic accuracy of CBCT in identifying root canal anatomy and to quantify its impact on management decisions.

There is no literature regarding the use of CBCT during endodontic treatment or as part of post-treatment review. With regard to the latter, however, one laboratory study (Soğur et al, 2007) has shown that CBCT gave inferior images of the homogeneity and length of root canal fillings compared with intraoral radiographs.

On empirical grounds, the use of CBCT as part of planning and performing surgical endodontic procedures seems capable of justification. Apart from case reports, however, the assessable literature was limited to one study (Rigolone et al, 2003), looking at maxillary first molar teeth in the context of surgical access to the palatal root. While this was a descriptive study only, it considered the potential treatment planning value of understanding the three-dimensional relationships of anatomical structures, including the maxillary sinus. Further research is needed to consider the impact on management (surgical time, outcomes of treatment) before an evidence-based recommendation can be made.

In summary, the current evidence suggests that limited volume CBCT may reveal more root canals than conventional radiography in molar teeth. The research available did not warrant any evidence grading stronger than “Good Practice”. There is substantial volume of case report material that suggests usefulness for several endodontic applications, as shown below:

Table 4.2: Endodontic uses of CBCT

Endodontic applications of CBCT	Reference
Differentiation of pathosis from normal anatomy	*Cotton et al, 2007*
Relationships with important anatomical structures	*Cotton et al, 2007*
Aiding management of dens invaginatus and aberrant pulpal anatomy	*John, 2008* *Siraci et al, 2006*
External resorption	*Maini et al, 2008* *Cohenca et al, 2007* *Walter et al, 2008* *Patel et al, 2007* *Patel & Dawood, 2007*
Internal resorption	*Cotton et al, 2007*
Lateral root perforation by a post	*Young 2007*
Accessory canal identification	*Cotton et al, 2007* *Nair et al, 2007* *Patel & Dawood, 2007*
Surgical management of fractured instrument	*Tsurumachi et al, 2007*
Aiding surgical endodontic planning	*Patel et al, 2007* *Patel & Dawood, 2007*

It seems likely from these case reports and non-systematic reviews that CBCT will have several valuable applications in *selected* cases. The absence of high quality studies available for this systematic review underlines the need for further research in this important area of dental practice.

CBCT should not be used routinely for endodontic diagnosis

GP

CBCT may be justifiable for selected cases, where intraoral radiographs provide information on root canal anatomy that is equivocal or inadequate for planning treatment, most probably in multi-rooted teeth

C

CBCT may be justifiable for selected cases, where endodontic treatment is complicated by concurrent factors, such as resorption lesions, combined periodontal/endodontic lesions, perforations and atypical pulp anatomy

C

CBCT may be justifiable for selected cases when planning surgical endodontic procedures. The decision should be based upon potential complicating factors, such as the proximity of important anatomical structures

D

4.3.5: Dental trauma

Trauma to teeth and alveolar bone is a fairly common event faced by dentists in clinical practice. Some case reports and non-systematic reviews have included comments about the potential role of CBCT in assessment of dental injuries, as shown below:

Table 4.3: CBCT in dento-alveolar trauma

Application of CBCT for dento-alveolar trauma	Reference
Root fractures	Terakado et al 2000 Cohenca et al 2007a Cotton et al 2007 Nair et al, 2007 Patel & Dawood 2007
Luxation injuries	Cohenca et al 2007a Patel et al 2007
Avulsion	Walter & Krastl 2008
Root resorption as a post-trauma complication	Cohenca et al 2007b Walter et al, 2008

There were no research studies that could be subjected to formal review by the Panel. The case report and non-systematic review evidence for value of CBCT in diagnosis of root fracture must be tempered by considering the resolution limitations compared with conventional radiography.

While it seems likely that CBCT could be valuable in diagnosis of dento-alveolar injuries, in the absence of any research evidence, the Panel cold not develop any guidance other than a “Good Practice” point.

The role of CBCT in more significant trauma is considered under “Surgical applications”, below.

CBCT may be justifiable in the assessment of dento-alveolar trauma in selected cases, where conventional radiographs provide inadequate information for treatment planning

GP

4.3.6: References

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4.4 Surgical applications

Surgery of the dental and maxillofacial region encompasses minor procedures (oral surgery) that may be performed in dental practices and major surgery (maxillofacial surgery) that would always be carried out by specialists, often in a hospital environment.

4.4.1 Exodontia

There is no literature related to the use of CBCT as part of the pre-extraction assessment of erupted teeth and there seems no good reason to suggest its use for this purpose. The literature concentrates on unerupted teeth, principally lower third molars.

A number of case series and non-systematic reviews have been published on the use of CBCT for pre-surgical assessment of impacted third molars (Heurich et al 2002; Nakagawa et al 2002; Danforth et al 2003; Friedland et al 2008; Neugebauer et al 2008). There were also two studies that were formally assessed in the systematic review (Nakagawa et al 2007; Tantanapornkul et al 2007) although the first of these was flawed in using CBCT itself as a reference standard. Using a surgical validation, cone-beam CT was significantly superior to panoramic images in predicting neurovascular bundle exposure during extraction of impacted mandibular third molar teeth, with impressive sensitivity (Tantanapornkul et al 2007). This evidence, combined with the general opinion expressed in case reports and the known consequences of neural damage during lower third molar surgery, allowed the GDP to make a recommendation.

Where conventional radiographs suggest a close relationship between a mandibular third molar and the inferior dental canal, and when a decision to perform surgical removal has been made, CBCT is justified

B

The literature on surgical removal of other tooth types is very small, although some of the orthodontic literature related to impacted maxillary canines is also relevant here (see Section 4.2.1). It seems likely that CBCT may have a role in pre-surgical assessment of any unerupted tooth where conventional radiographs fail to give the information required.

GDP agreed that it was important to emphasise the need to use the smallest field of view consistent with the information required, consistent with the Basic Principle No.9 (Section 3).

CBCT may be justified for pre-surgical assessment of an unerupted tooth in selected cases where conventional radiographs fail to provide the information required

GP

4.4.2 Implant dentistry

In investigating an implant site, a surgeon requires information on bone volume and quality, topography and the relationship to important anatomical structures, such as nerves, vessels, roots, nasal floor, and sinus cavities (Harris et al 2002).

In 2002, a Working Group of the European Association of Osseointegration (EAO) devised consensus guidelines on imaging for implant dentistry (Harris et al 2002). They did not include any comment on CBCT. They did, however, describe criteria for use of "cross-sectional imaging" (at that time, spiral tomography and conventional CT).

The EAO guidelines made the following key points:

- Clinicians should decide if a patient requires cross-sectional imaging on the basis of the clinical examination, the treatment requirements and on information obtained from conventional radiographs.
- The technique chosen should provide the required diagnostic information with the least radiation exposure to the patient.
- "Standard" imaging modalities are combinations of conventional radiographs.
- Cross-sectional imaging is applied to those cases where more information is required after appropriate clinical examination and standard radiographic techniques have been performed.

The EAO guidelines presented valuable information on the special clinical situations in implant dentistry when cross-sectional imaging is required (Table 4.4). The guidelines go on to explain that cross-sectional imaging is of principal value in pre-operative assessment and treatment planning, but that it is not part of a "routine protocol" for post-operative examinations "unless there is a need for assessments in situations where some kind of complications have occurred, such as nerve damage, postoperative infections in relation to nasal and/or sinus cavities close to implants" (Harris et al 2002).

Table 4.4: Special indications for cross-sectional imaging (adapted from Fig. 2b in Harris et al 2002).

Maxilla	Single tooth	a. incisive canal b. descent of maxillary sinus c. clinical doubt about shape of alveolar ridge
	Partially dentate	a. descent of maxillary sinus b. clinical doubt about shape of alveolar ridge
	Edentulous	a. descent of maxillary sinus b. clinical doubt about shape of alveolar ridge
Mandible	Single tooth	a. clinical doubt about position of mandibular canal b. clinical doubt about shape of alveolar ridge
	Partially dentate	a. clinical doubt about position of mandibular canal or mental foramen b. clinical doubt about shape of alveolar ridge
	Edentulous	a. severe resorption b. clinical doubt about shape of alveolar ridge c. clinical doubt about position of mandibular canal if posterior implants are to be placed

While these criteria for cross-sectional imaging are subjective in nature, relying heavily on subjective “clinical doubt”, they do offer useful guidance. The GDP had neither the remit nor the expertise to reconsider the EAO guidelines. With the advent of CBCT, which has different dose implications and different capabilities, the EAO may wish to reconsider their 2002 guidelines entirely. New information on the importance of anatomic and neurovascular variations and the availability of access to CBCT may also influence a change of guidelines. As such, GDP decided to make an unusual recommendation, to an external body.

GDP recommends that the European Association for Osseointegration reviews its 2002 consensus guidelines on the use of imaging in implant dentistry to take into account the availability of CBCT

GP

There is a substantial literature related to the use of CBCT in dental implantology. This is not surprising as implant treatment planning has been the most frequent use of conventional CT in dentistry. Studies on geometric accuracy for linear measurements, of obvious importance in implant planning, show high accuracy (Kobayashi et al 2004; Lascala et al 2004; Marmulla et al 2005; Ludlow et al 2007; Loubele et al 2007 and 2008), although one study gave a poorer figure for accuracy (Suomalainen et al 2008). One systematic review was available, although this mixed CBCT and conventional CT in its analysis (Lou et

al 2007). The literature related to geometric accuracy in relation to orthodontic measurements is probably also applicable here (see Section 4.2). Overall, the evidence suggests that CBCT has sufficient geometric accuracy for linear measurements in implant dentistry. Interestingly, however, one study compared ridge mapping with CBCT, using a direct surgical measurement as a reference standard, and found that CBCT was less consistent than ridge mapping and that it did not add any additional information (Chen et al 2008). Apart from geometric accuracy, an important aspect is the ease of visualisation of important structures on CBCT. Angelopoulos et al (2008) showed that CBCT reformatted panoramic images outperformed conventional panoramic images in subjective quality of visualisation of the mandibular canal, while Loubele et al 2007 demonstrated better subjective image quality for important structures for CBCT compared with MSCT . Mengel et al (2006) showed promising results for visualisation of peri-implant defects in an animal study.

The EAO guidelines emphasise the importance of relating accurately the image data to the surgical situation: *"The diagnostic information can be enhanced by the use of appropriate radiopaque markers or restorative templates. However, this information cannot be transferred exactly to the surgical site as long as no intraoperative navigation is used"* (Harris et al 2002). Several papers have been published relating to the accuracy of implant placement using surgical guides manufactured using CBCT datasets (Fortin et al 2002; Fortin et al 2003; Sarment et al 2003; van Steenberghe et al 2003; Nickenig & Eitner 2007; van Assche et al 2007). These studies suggest that, within specified limits of error, CBCT is an effective means of providing data for the manufacture of surgical guides in implant dentistry.

There are a large number of publications (case studies; non-systematic reviews; descriptive studies) that illustrate the use of CBCT in implant dentistry. Many of these were consulted during the review by members of the GDP to help build the body of knowledge in developing the guidelines (Almog et al 2006; Blake et al 2008; Bousquet & Joyard 2008; Fan et al 2008; Ganz 2005; Ganz 2006; Ganz 2008; Garg 2007; Guerrero et al 2006; Hatcher et al 2003; Moore 2005; Peck & Conte 2008; Sato et al 2004). These publications make it clear that CBCT is being used widely for implant dentistry. As such, GDP make the following recommendations:

The use of CBCT is not recommended as a routine imaging technique for all implant cases

GP

CBCT is justified for cross-sectional imaging prior to implant placement as an alternative to existing cross-sectional techniques where the radiation dose is shown to be lower

D

The advantage of CBCT with adjustable fields of view, compared with conventional CT, becomes greater where the region of interest is a localised part of the jaws, as a similar sized field of view can be used

GP

While the emphasis has been on assessment of bone quantity, there is interest in bone quality assessment using CBCT. Bone density evaluation of implant sites is feasible using conventional CT (de Oliveira et al 2008). Since Barone et al (2003), a number of studies have, however, tried to derive Hounsfield Units (HUs) from CBCT. Aranyarachkul et al (2005) found good correlations between CBCT-derived HUs and CT-derived values. Lagravère et al (2006, 2008) were able to derive a predictable relationship between HU values and materials of different densities. Lee et al (2007), however, found only moderate correlations between drilling resistance torque and HU values. Quantitative CT for bone density in medical practice requires extremely careful calibration and quality assurance, a process that may not be practicable in dental practice. In reality, however, that degree of accuracy may not be needed for surgical decision-making. Current work by members of the SEDENTEXCT consortium suggests that density values from CBCT are variable and not reliable. The GDP considered that, in view of the wide variety of CBCT units and software available, they could not make a recommendation in support of quantitative bone quality assessment from CBCT.

4.4.3 Bony pathosis

Occasionally, a dentist may be presented with a patient with an unusual bony lesion. Cysts, tumours and a wide range of esoteric lesions can present in the jaws causing symptoms and/or clinical signs; some may only be detected by chance on conventional radiography. There are numerous case reports of bony lesions that have been imaged using CBCT (Abdelkarim et al 2008; Araki et al 2006; Araki et al 2007; Barragan-Adjemian et al 2009; Closmann & Schmidt 2007; Fullmer et al 2007; Guttenberg 2008; Harokopakis-Hajishengallis &Tiwana 2007; Kumar et al 2007; Nakagawa et al 2002; Quereshy et al 2008; Rodrigues &

Estrela 2008; Rozylo-Kalinowska & Rozylo 2001; Scherer et al 2008; Schulze et al 2006; Smith et al 2007; Ziegler et al 2002). While these are too wide ranging in pathoses and are case reports/series rather than formal studies, it seems reasonable to predict that CBCT will have a useful role in the assessment of bony pathosis of the jaws. GDP felt that it was important, however, that unless dentists are treating patients themselves (as opposed to referral to an oral surgeon) it is probably correct to leave the choice of imaging to the surgeon who intends to treat the patient. Similarly, if there is any suspected soft tissue extension of the lesion, then conventional CT or MR may be a more appropriate investigation.

Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than CBCT

BP

4.4.4 Trauma

The management of significant maxillofacial trauma is outside the normal working practice of a dentist and limited to specialist/ hospital practice. Fractures are conventionally imaged using plain radiography or conventional CT, depending on custom and practice. Generally speaking, as stated by Schoen et al (2008), "when radiographs do not show clearly the degree of displacement, type of fracture or degree of comminution, for example, in suspected fractures of the condylar head, CT or cone-beam CT is indicated". There were no studies identified as suitable for formal systematic review, but several case studies/ case series were identified that demonstrated the effective use of CBCT for orbital floor fractures (Zizelmann et al 2007; Drage & Sivarajasingam 2008), mandibular fracture (Ziegler et al 2002), intraoperative imaging of fractures of the mandible (Heiland et al 2004a; Scarfe 2005; Pohlenz et al 2007; Pohlenz et al 2008) and zygomatic fractures (Heiland et al 2004a; Heiland et al 2007; Pohlenz et al 2007) and postoperative imaging of zygomatic fractures (Heiland et al 2004b). GDP felt that there was a need for diagnostic accuracy studies of CBCT for the common fracture types (mandibular and maxillary), Consequently, a low grading for the following recommendation was applied:

For maxillofacial fracture assessment, where cross-sectional imaging is judged to be necessary, CBCT may be used as an alternative imaging modality to conventional CT where radiation dose is shown to be lower and soft tissue detail is not required

D

In foreign body detection and localization, CBCT is suitable for imaging high attenuation materials, but not as effective as conventional CT for lower attenuation objects (Stuehmer et al 2008; Eggers et al 2007).

4.4.5 Orthognathic surgery

This application is closely allied to orthodontics and the evidence presented in Section 4.2 regarding measurement accuracy is also relevant here. Whereas in Section 4.2.2 the GDP did not support the routine use of CBCT for orthodontic assessment, the patients likely to be candidates for orthognathic surgery (with significant facial deformity) are more likely to benefit from cross-sectional imaging.

Some additional papers were reviewed under this heading (Enciso et al 2003; Cevidanes et al 2005; Boeddinghaus & Whyte 2008; Hoffman & Islam 2008; Metzger et al 2008; Quereshy et al 2008; Swennen et al 2009) and overall, GDP were able to make two recommendations:

CBCT should not be used routinely for imaging the craniofacial skeleton

GP

CBCT may be used, in selected cases, where only bone information is required, for obtaining three-dimensional datasets of the craniofacial skeleton

C

4.4.6 Temporomandibular joint

The overwhelming majority of patients with symptoms and signs related to the temporomandibular joint (TMJ) are suffering from myofascial pain/dysfunction or internal disc derangements. Bony abnormality is not seen in the former and only occasionally in the latter. In such cases, radiographs do not add information of relevance to management. Where imaging of the TMJ disc is needed, Magnetic Resonance Imaging is the method of choice.

Other pathoses encountered in the TMJ include osteoarthrosis and rheumatoid arthritis. In both these conditions, there are often bony changes that may be detectable on conventional radiographs and CBCT. When considering the justification for CBCT, however, the clinician should consider whether the information obtained will alter the management of the patient. The identification of bony erosions, remodelling or deformity may be purely documentary and have no impact on treatment strategy.

The available evidence included three diagnostic accuracy studies with valid reference standards (Hilgers et al 2005; Honda et al 2006; Honey et al 2007) and nine case series/ non-systematic reviews (Zhao et al 2003; Honda et al 2004; Tsiklakis et al 2004; Honda & Bjornland 2006; Sakabe et al 2006; Kijima et al 2007; Krisjane et al 2007; Meng et al 2007; Lewis et al 2008). There was also one systematic review of imaging of TMJ erosions and osteophytes which considered CBCT evidence (Hussain et al 2008).

Custom oblique multi-planar reformatted CBCT reconstructions using iCAT provided accurate and reliable linear measurements of TMJ dimensions (Hilgers et al 2005). CBCT images provide similar diagnostic accuracy to conventional CT for condylar osseous abnormality (Honda et al 2006) and greater accuracy than panoramic radiography and linear tomography in the detection of condylar cortical erosion (Honey et al 2007). Case report and non-systematic reviews also suggested a possible role for CBCT in arthrography and in the evaluation of developmental anomalies.

While there is good evidence for the accuracy of CBCT for detection of osseous abnormalities of the TMJ, the GDP were not prepared to suggest routine use of CBCT for examination of the TMJ in the absence of evidence about its impact upon treatment decisions. GDP concluded that CBCT could be considered as an alternative to conventional CT, when radiation dose with CBCT is known to be lower.

Where the existing imaging modality for examination of the TMJ is conventional CT, CBCT should be considered as an alternative where radiation dose is shown to be lower

B

4.4.7 References

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5: EQUIPMENT FACTORS IN THE REDUCTION OF RADIATION RISK TO PATIENTS WITH CBCT

The literature review in section 2.4 showed that the effective dose may vary significantly between different manufacturers and exposure settings. In this section, the significance of selection of appropriate exposure settings in limiting doses while maintaining the image quality at acceptable clinical levels (optimisation) is reviewed.

5.1: X-ray tube voltage and mAs

The kilovoltage (kV) of an X-ray tube is the potential difference between anode and cathode during operation. The tube voltage determines the energy of the X-rays. Lower tube voltages give lower energy X-rays and thus increase the dose to the skin of the patient (Horner 1994). Increasing the kV results in a decrease in skin and effective dose (Geijer et al 2009). A higher kV increases the scatter which results in deteriorating the image quality and also results in a lower contrast between soft and hard tissues. The kV in dental CBCT is either fixed or can be varied depending on the CBCT unit (Ludlow et al 2006; Lofthag-Hansen et al 2008; Silva et al 2008; Okano et al 2009; Roberts et al 2009).

The product of the tube current measured in milliamperes (mA) and the exposure time measured in seconds (s) only affects the number of photons emitted by the X-ray tube and not their energy. Increased mAs increases dose, but the penetration of the beam and image contrast remain the same.

There is a lack of studies that attempt to optimise these two exposure factors for different CBCT units and clinical protocols.

Research studies should optimise the tube kiloVoltage and mAs for a range of dental CBCT units and for a range of protocols

GP

5.2: Field of View and collimation

CBCT units can be characterised by their Field of View (FOV). The FOV is usually a cylindrical volume and determines the shape and size of the reconstructed image. FOVs may vary from a few centimetres in height and diameter to a full head reconstruction. Several CBCT units offer a range of FOV, whilst a fixed FOV is provided by other units. Some CBCT machines offer the option to collimate the beam to the minimum size needed to image the area of interest. The size of the FOV is associated with radiation dose to the patient and staff (Hirsch et al 2008; Okano et al 2009; Roberts et al 2009). Reducing the size of the X-ray beam to the minimum size needed to image the object of interest is, therefore, an obvious means of limiting dose to patients, as well as improving image quality by scatter reduction.

CBCT equipment should offer a choice of volume sizes and examinations must use the smallest that is compatible with the clinical situation if this provides less radiation dose to the patient

BP

5.3: Filtration

Aluminium filtration is an established component of medical X-ray equipment. Filtration removes lower energy X-ray photons which results in skin dose reduction but also results in contrast loss. Dental CBCT units are equipped with several mm of Al filtration (Ludlow et al 2006; Loftag-Hansen et al 2008; Silva et al 2008; Okano et al, 2009; Roberts et al 2009;2-6). Further studies on optimising filtration in terms of material and thickness should be performed.

Research studies on optimisation of filtration for dental CBCT units should be performed

GP

5.4: Digital detector

Dental CBCT units are equipped with digital receptors where the image is captured and formed. Digital detectors offer diagnostic image of high image quality in terms of spatial and contrast resolution.

Two types of digital detectors have been used for dental CBCT units (Hashimoto et al 2003; Ludlow et al 2003; Araki et al 2004; Pasini et al 2007; Loubele et al 2008; Ludlow& Ivanovic 2008; Roberts et al 2009). The first type involves conventional image intensifiers (II). They consist of an input window, input phosphor, photocathode, vacuum and electron optics, output phosphor and output window. The input phosphor converts the X-rays to optical photons which then are converted to electrons within the photocathode. The electrons are accelerated and focused by a series of electrodes and then strike the output phosphor which converts the electrons to light photons which are then captured by various imaging devices. Most modern image intensifiers have cesium iodide for the input phosphor because it is a very efficient material in absorbing X-rays.

The second type, flat panel detectors (FPDs), are composed of an x-ray detection layer and an active matrix array (AMA) of thin film transistors (TFT). The X-ray detector consists of a layer of a cesium iodide phosphor which converts the X-ray photons to light photons. The intensity of the light emitted by the phosphor is a measure of the intensity of the incident X-ray beam. The AMA has a photosensitive element which produces electrons proportional to the intensity of the incident photons. This electrical charge is stored in the matrix until it is read out and it is converted into digital data sent to the image processor. FPDs have greater sensitivity to X-rays than IIs and therefore have the potential to reduce patient dose. They have higher spatial and contrast resolution and fewer artefacts than IIs but, in general, IIs are cheaper than FPDs.

Dental CBCT units equipped with either flat panel detectors or image intensifiers need to be optimised in terms of dose reduction before use

GP

5.5: Voxel size

The volume element (voxel) represents a three-dimensional (3D) quantity of data and it can be pictured as a 3D pixel. The reconstructed image area or FOV consists of a number of voxels. A FOV of 29 mm in height and 38 mm in diameter consists of 240 and 320 voxels respectively, with a voxel being a cube with a side length of 0.119mm (Hashimoto et al 2003). The voxel size may vary between 0.1 mm to 0.42 mm (Hashimoto et al 2003; Loubele et al 2008; Liedke et al 2009). A smaller voxel size is associated with better spatial resolution but with a higher radiation dose to the patient. Liedke et al (2009) showed that the best protocol in terms of diagnostic performance for assessment of simulated resorption cavities and lower X-ray exposure was a medium voxel size, not the smallest voxel size.

CBCT equipment should offer a choice of voxel sizes and examinations must use the size most compatible with the clinical situation if this provides less radiation dose to the patient. Research studies should be performed to assess further the relationship between voxel size, image quality and radiation dose for a range of dental CBCT units and clinical protocols

C

5.6: Number of projections and reconstruction algorithm

The rotation of the X-ray tube and the detector around the patient's head produces multiple projection images. The total number of acquired projections depends on the rotation time, frame rate (number of projections acquired per second) and on the completeness of the trajectory arc. A high number of projections is associated with increased radiation dose to the patient, higher spatial resolution and greater contrast resolution. Brown et al (2009) have shown that increasing the number of projections does not influence the linear accuracy of CBCT. Reducing the number of projections, while maintaining a clinically acceptable image quality, results in patient dose reduction. Further research studies should look into the effect of the number of acquired images on the relationship between radiation dose and image quality.

Research studies should be performed to assess further the effect of the number of projections on image quality and radiation dose

GP

5.7: Shielding devices

An alternative way of reducing patient dose is by using shielding devices containing high attenuation materials, such as lead. The thyroid gland is a radiosensitive organ which may be affected by scattered radiation and, occasionally, primary beam in dental CBCT. Tsiklakis et al (2005) have observed a 20% decrease in effective dose by protecting the thyroid gland during CBCT. Further research in this area is required.

Shielding devices could be used to reduce doses to specific organs and tissues. Care is needed in positioning so that repeat exposure is not required. Further research is needed on effectiveness of such devices in dose reduction.

GP

5.8: References

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6: QUALITY STANDARDS AND QUALITY ASSURANCE

6.1 Quality assurance programme

The purpose of Quality Assurance (QA) in dental radiology is to ensure consistently adequate diagnostic information, while radiation doses are controlled to be as low as reasonably achievable.

A well-designed QA programme should be comprehensive but inexpensive to operate and maintain for the dentist and staff.
QA should address the following:

- Image quality assessment
- Practical Radiation Technique
- Patient dose
- Correct X-ray equipment function
- Image processing and viewing

The QA programme should entail surveys and checks that are performed according to a regular timetable. A written log of this programme should be maintained by staff to ensure adherence to the programme and to raise its importance among staff. A specific person should be named as leader for the QA programme.

6.2: Image Quality Assessment

Ensuring that radiological images are of consistently acceptable quality is obviously of benefit to patient and dentist alike. However there is ample research evidence showing that radiographic image quality is often less than ideal in primary dental care (European Commission 2004). While there is no literature on reject rates for dental CBCT examinations, the higher radiation doses of CBCT compared with conventional radiography, mean that high standards must be maintained.

There are no standard protocols for image quality assessment for CBCT, such as exist for conventional CT. There is a need for some standards to be set for CBCT that reflect the range of CBCT equipment types and their clinical capabilities. The SEDENTEXCT project has Quality Assurance as one of its key objectives and will work towards this over the course of the project.

Image quality standards should be developed for the clinical uses of CBCT
ED BP

6.3: Patient Dose

An objective of the QA programme is to ensure doses are kept as low as reasonably achievable. It is, therefore necessary to ensure that patient doses are monitored on a regular basis and compared to agreed standards. Standard dose levels are normally referred to as Diagnostic Reference Levels (DRLs) as described in the European Guidelines No 136 (European Commission 2004).

6.3.1 Dose quantities

Dose quantities that are to be used for the regular assessment of patient dose must be relatively easy to measure in a clinical situation. Entrance surface dose (ESD) and dose area product (DAP) are quantities that are routinely used in conventional radiology (European Commission 1999). In the field of CT, the computed tomography dose index (CTDI), and dose length product, DLP, are routinely used. Ideally, the dose quantity used should give a good correlation to the effective dose and hence overall patient risk.

Little work has yet been undertaken to establish the most appropriate quantity for setting DRLs for CBCT. Two studies have reported skin dose measurements using thermoluminescent dosimetry on RANDO type phantoms (Hashimoto et al 2003; Hirsch et al 2008). There are currently no studies reporting skin dose measurements on patients. If skin dose were to be used it is essential that work be undertaken to establish the most appropriate position for placing the dosemeters and a standard methodology be adopted. Lofthag-Hansen et al (2008) undertook a study using both DAP and CTDI to estimate effective dose but abandoned the use of CTDI due to the asymmetric dose distribution.

The use of DAP is promising as it provides one reading per exposure that gives an indication of both the dose level in the beam and the area irradiated. Some CBCT units already provide this information after each exposure. If this became universal, as CT scanners now all provide an indication of DLP, it would greatly facilitate patient dose audit. The accuracy of such readouts should be checked by the medical physics expert during routine testing.

6.3.2 Establishing DRLs

No systematic audit of patient dose for a range of different CBCT units has yet been reported. It is essential that this be undertaken before European wide DRLs are established.

6.3.3 Using DRLs

Dentists should be aware of their average doses for the different CBCT views they undertake and how these compare with the European and any national DRLs, once established.

If a DAP readout is provided on the equipment, the dentist should undertake audit of DAP readings for standard size patients, ideally with the help of a medical physics expert. If DAP is not provided it is expected that the dentist will need to seek help form the medical physics expert to establish typical patient doses. These assessments should be carried out on a regular basis, at least every 3 years or as required by national legislation.

These measurements can be seen to be a part of any QA programme adopted by the dental practice. Dose results that exceed established DRLs, or which significantly differ from previous audits, should be investigated with the help of a medical physics expert. Any resulting recommendations should be implemented.

The Panel recommend that further work be carried out to establish a measurement method (most probably DAP) for dental CBCT and to undertake further field measurements so that a European DRL can be established

GP

Manufacturers of dental CBCT equipment should provide a read-out of Dose-Area-Product (DAP) after each exposure

GP

6.4: Equipment testing

6.4.1 Maintenance and testing

The rationale for maintenance and testing of a dental cone beam CT system is similar to that of other dental systems (European Commission 2004). However, as both patient and operator dose are potentially higher, greater care is required in all aspects of an equipment QA programme.

As dental CBCT systems are digital modalities, digital information on dose or quality can be used throughout the various tests, an advantage when compared to information from film.

6.4.2 Critical examination

In general, verification of the critical examination for CBCT is similar to that performed for conventional dental equipment. As expanded in Section 7.2, the structural protection required for a dental CBCT system is greater than for conventional dental imaging equipment and greater care must be taken in the room design to ensure adequate protection for both operator and others in areas adjacent to the unit. In particular, it cannot be assumed that CBCT systems can be installed in rooms designed for intraoral and panoramic dental systems without further work being undertaken.

6.4.3 Acceptance test

The main aim of the acceptance test is to ensure the imaging system is working at an acceptable performance level for the specific clinical indications in the local practice. This should be performed by a medical physics expert.

The essential content of an acceptance test includes:

- verification of the critical examination
- testing of equipment performance parameters
- the proposal of routine test procedure and the definition of base line values for routine tests
- verification of how the systems are pre-programmed for use in practice

All acceptance testing protocols include tests of the X-ray tube output, voltage consistency and accuracy, filtration, exposure time and radiation field. These can be tested in the same way as for other modalities, like general radiology digital detector systems or conventional CT scanners. A dosimeter with wave form display may be helpful to confirm correct operation of the X-ray tube. Testing of the correct operation of any automatic exposure control device, if fitted, is also essential .

Classical tests of digital detectors (linearity, homogeneity, spatial resolution, low contrast resolution, (dark) noise, etc.) can be run if unprocessed raw data of the projective images are available. Reconstruction software can be tested indirectly via an assessment of image quality, using test objects with specific inserts. At present, there are no standardized reconstruction software tools available that would allow comparative studies among modalities. With ever more sophisticated acquisition schemes (like variable angles, off-axis radiation, tube output modulation, different FOVs, etc.) it is very unlikely that the reconstruction software will be standardized in the future.

Ultimately, a global system test should summarize all separate measurements into one or a few numbers. Phantoms are being developed for this purpose as part of the SEDENTEXCT project. When centres compare performance of their systems to others in terms of dose, it is also good practice to report an image

quality-related comparative figure. Current dental CBCT systems exhibit relatively large differences in performance between systems.

6.4.4 Routine tests

Both Medical Physics Experts and local personnel have a role in routine tests. A typical frequency for medical physics tests is yearly. Local personnel should run a series of routine tests more often as recommended by the installers of the equipment. When introducing a new modality, its operation should be monitored more frequently, until the system is working reliably at its optimal point in terms of dose and image quality. Optimisation studies may be advisable.

Routine testing may be helped with automatic procedures built into the system. These can include the evaluation of test objects against performance levels set by the company or by national or international protocols, the review of retakes (automatically stored into the system) and system self checks. Full documentation should be provided by the installers on these (automated) procedures. Exportable reports are preferable.

A simple but very sensitive test for constancy checks in digital imaging is a regular acquisition of an homogeneous block of material. Local artefacts in the digital detector induce (usually circular) artefacts in the reconstructed slices. Tube- or detector-related instabilities would produce variations in signal intensities.

After the reconstruction of the projective images into axial slices, it is important that the practitioner can make more dedicated views of the same data set. These multi planar reconstructions should be of a sufficient quality and displayed on DICOM calibrated monitors. Ambient light should be well controlled.

6.4.5 Assessment of representative patient doses

A cone beam dental system usually comes with pre-programmed settings for different types of patients (e.g. children versus adults) or clinical indications. In the absence of any patient specific tube output modulation, the pre-programmed protocols can be verified by means of dose measurements in air, at the level of the detector, or using a DAP meter. In the ideal case, the dose measurements are performed for all standard imaging sessions for which a DRL has been defined (see 6.3.1). When tube output modulation is used, dedicated phantoms may be required.

It is good practice to investigate whether the doses have been selected based upon relevant criteria. In particular, it should be verified that doses for children are significantly lower than those for adults and that separate programs are available for local pathologies as well as imaging the complete upper or lower jaw. Other settings to be tested include the correct pre-programming of lower kV, the use of tube output modulation, high versus low resolution scanning etc.

Systematic patient dose surveys are straightforward if DICOM header tags are completely filled in and if software is available to grab the dose related info automatically. The intrinsic dose information has first to be checked against measured data, has then to be expressed or recalculated into survey related quantities and can then be collected over a period of time. The Medical Physics Expert should ensure that the practitioner is aware if DRLs are exceeded.

Testing of dental CBCT should include a critical examination and detailed acceptance test when equipment is new and routine tests throughout the life of the equipment. A Medical Physics Expert should be involved and the advice of the installer sought

GP

Standard protocols and equipment should be developed for testing dental CBCT equipment

GP

6.5: References

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7: STAFF PROTECTION

The general comments on protection of staff made in the European Guidelines No 136 (European Commission 2004) are equally applicable to dental CBCT. However, as dose levels and beam energies are generally higher compared to conventional dental radiology, extra practical protection measures are required for dental CBCT. It is essential that an appropriate Qualified Expert is consulted both prior to installation and on an on-going basis.

It is essential that a Qualified Expert is consulted over the installation and use of CBCT to ensure that staff dose is as low as reasonably achievable and that all relevant national requirements are met

GP

7.1 Classification of areas

The European Guidelines No 136 (European Commission 2004) recommended that the use of distance to reduce dose was normally the only measure required for conventional dental radiography. Data on dose rates around CBCT units are not available in the literature, but information available from manufacturers indicate that the dose at 1 metre due to scattered radiation varies between 2 to 40 μSv per scan, compared with intraoral and panoramic radiography scatter doses of less than 1 μSv per exposure.

In addition, tube kiloVoltage can be as high as 120kVp, leading to scattered radiation being significantly more penetrating. This is much higher than conventional dental radiography and the increased penetration through protective shielding must also be borne in mind.

Consequently, it is recommended that CBCT equipment be installed in a purpose-built enclosure providing adequate protection to adjacent areas and the operator and that the whole of this enclosure be designated a controlled area.

CBCT equipment should be installed in a protected enclosure and the whole of the enclosure designated a Controlled Area

GP

Systematic studies of the dose due to scattered radiation in surrounding areas should be undertaken to inform decisions about shielding requirements
GP

7.2 Design of the CBCT room

7.2.1 Protection for adjacent areas

It is essential that shielding be provided to ensure dose is controlled in areas adjacent to the CBCT room. Dental CBCT units are quite compact and are likely to be fitted into relatively small areas. They have a similar footprint to dental panoramic radiography units, typically 110 x 150 cm. Most need to be fixed to a supporting wall and could be close to, at least, one other wall. When calculating shielding required, it is suggested that a minimum distance of 1m from the patient to the wall is assumed, if the true room layout is not known at the design stage.

In calculating shielding, the workload of the unit also needs to be taken into consideration. For dental practice, it is suggested that a workload of 20 scans per week be assumed, while for a hospital department the figure would be 50 scans per week. These are thought to be maximum likely values taking into account the current uses of dental CBCT. However, the clinical use of dental CBCT is still developing and workload should be kept under review.

Working to a dose constraint of 0.3mSv per year to staff in adjacent areas, shielding equivalent to up to Code 4 (1.8mm) lead will be required in the walls, although due to the significant differences in maximum operating potential and levels of scattered radiation, many installations may be satisfactorily shielded with lower requirements. It is likely that doors, which will normally be further away from the unit, could contain less protection. In addition, floor and ceiling protection needs to be considered and it is likely that ground floor windows will need blocking up. Each installation should, therefore, be assessed on a case by case basis, with the input of a Qualified Expert.

7.2.2 Room layout

The operator position should be either outside the room or be provided with additional shielding in the form of a cubicle to stand behind. The position of the operator must always ensure that they can clearly see the patient and the room entrance(s) and be able to interrupt the scan using the emergency stop, if required.

7.2.3 Exposure control

Some units require authorisation of the exposure from the computer software prior to exposure. The computer should be located close to the X-ray unit rather than over a network to avoid the possibility of authorisation of exposure without the operator being present at the CBCT control.

It is normal for the CBCT unit to require that the mains power supply be left on, as a lengthy warn up procedure will be required otherwise. If another unit is located in the same room, particular care will be needed to ensure that the wrong unit is not initiated. This may be achieved, for example, by providing exposure switches in separate locations or by placing the exposure switches in lockable boxes.

7.3 Personal Monitoring

The need for personal monitoring should be considered in the risk assessment before the equipment is brought into use, seeking the advice of a Qualified Expert if available. If the operator position is such that he/she can only initiate the exposure by standing behind adequate protective shielding, occasional monitoring is suggested (e.g. when new and then on an annual basis) but, if it is possible to operate the unit without being behind shielding, routine continuous monitoring is recommended.

The provision of Personal Monitoring should be considered
GP

7.4 Reference

European Commission. Radiation Protection 136. European Guidelines on Radiation Protection in Dental Radiology. Luxembourg: Office for Official Publications of the European Communities, 2004. Available from:
http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/136_en.pdf

8: ECONOMIC EVALUATION

Economic evaluation attempts to weigh costs and effects of alternative interventions with the goal that available resources are used to achieve maximum benefits for patients in terms of health and quality of life. In emerging technologies this is particularly important to avoid inappropriate and excessive use.

As part of the systematic review process described in this document, no literature was identified that fell under the heading “cost effectiveness” or “economic evaluation”. A few studies mentioned the costs of CBCT, usually quoting the hospital fee for a CBCT examination. Such figures do not usually reflect real costs and reflect idiosyncrasies of particular hospitals and healthcare systems.

As part of the SEDENTEXCT project, the Malmö University partner is leading the research on health economic evaluation and has commenced a broader systematic review to analyse evidence on economic evaluation in oral health care, particularly as relates to diagnostic imaging methods. Studies identified by literature search are currently being interpreted by two reviewers using a check-list for assessing economic evaluations (Drummond et al. 2005).

The findings of this separate review will be reported in future versions of this Guideline document

Economic evaluation of CBCT should be a part of assessment of its clinical utility
GP

8.1 Reference

Drummond MF, Sculpher MJ, Torrance GW, O´Brian BJ, Stoddart GL. Methods for the economic evaluation of health care programmes. Oxford: Oxford Medical Publications, 3rd ed, 2005.

APPENDIX 1: SUMMARY OF RECOMMENDATIONS

The core recommendations and statements in this document are the “Basic Principles”, described in section 3.3 (page 23). Below are listed the specific guidelines, taken from the relevant sections, with their evidence grading:

Radiation dose and risk

2.1: The radiation dose and risk from dental CBCT are generally higher than conventional dental radiography (intraoral and panoramic) but lower than conventional CT scans of the dental area. Dose is dependent on equipment type and exposure settings, especially the field of view selected.

C

2.2: Research studies should be performed to assess organ and effective doses using scientifically accurate and precise methodologies, paying special attention to paediatric dosimetry.

GP

Justification and referral criteria

4.1: All CBCT examinations must be justified on an individual basis by demonstrating that the benefits to the patients outweigh the potential risks. CBCT examinations should potentially add new information to aid the patient’s management.

ED BP

4.2: CBCT should not be selected unless a history and clinical examination have been performed. “Routine” imaging is unacceptable practice.

ED BP

4.3: When referring a patient for a CBCT examination, the referring dentist must supply sufficient clinical information (results of a history and examination) to allow the CBCT Practitioner to perform the Justification process.

ED BP

4.4: For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth) where the current imaging method of choice is MSCT, CBCT may be preferred because of reduced radiation dose.

GP

4.5: For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth) where the current imaging method of choice is conventional dental radiography, CBCT may be used when the information cannot be obtained adequately by lower dose conventional (traditional) radiography

C

4.6: For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth), the smallest volume size compatible with the situation should be selected because of reduced radiation dose. The use of CBCT units offering only large volumes (craniofacial CBCT) requires very careful justification and is generally discouraged

GP BP

4.7: Where the current imaging method of choice for the assessment of cleft palate is MSCT, CBCT may be preferred where radiation dose is lower. The smallest volume size compatible with the situation should be selected because of reduced radiation dose

GP BP

4.8: Large volume CBCT should not be used routinely for orthodontic diagnosis

GP

4.9: For complex cases of skeletal abnormality, particularly those requiring combined orthodontic/surgical management, large volume CBCT may be justified in planning the definitive procedure, particularly where MSCT is the current imaging method of choice

GP

4.10: Research is needed to define robust guidance on clinical selection for large volume CBCT in orthodontics, based upon quantification of benefit to patient outcome

GP

4.11: CBCT should not be used as a routine method of caries detection and diagnosis

B

4.12: Where CBCT images include the teeth, care should be taken to check for caries when performing a clinical evaluation (report)

GP

4.13: CBCT should not be used as a routine method of imaging periodontal bone support

C

4.14: CBCT may be useful in selected cases of infra-bony defects and furcation lesions, where clinical and conventional radiographic examinations do not provide the information needed for management.

C

4.15: Where CBCT images include the teeth, care should be taken to check for periodontal bone levels when performing a clinical evaluation (report)

GP

4.16: CBCT should not be used routinely for identification of periapical pathosis

GP

4.17: CBCT may be considered for periapical assessment, in selected cases, when conventional radiographs give a negative finding when there are contradictory positive clinical signs and symptoms

GP

4.18: Where CBCT images include the teeth, care should be taken to check for periapical disease when performing a clinical evaluation (report)

GP

4.19: CBCT should not be used routinely for endodontic diagnosis

GP

4.20: CBCT may be justifiable for selected cases, where intraoral radiographs provide information on root canal anatomy that is equivocal or inadequate for planning treatment, most probably in multi-rooted teeth

C

4.21: CBCT may be justifiable for selected cases, where endodontic treatment is complicated by concurrent factors, such as resorption lesions, combined periodontal/endodontic lesions, perforations and atypical pulp anatomy

C

4.22: CBCT may be justifiable for selected cases when planning surgical endodontic procedures. The decision should be based upon potential complicating factors, such as the proximity of important anatomical structures

D

4.23: CBCT may be justifiable in the assessment of dento-alveolar trauma in selected cases, where conventional radiographs provide inadequate information for treatment planning

GP

4.24: Where conventional radiographs suggest a close relationship between a mandibular third molar and the inferior dental canal, and when a decision to perform surgical removal has been made, CBCT is justified

B

4.25: CBCT may be justified for pre-surgical assessment of an unerupted tooth in selected cases where conventional radiographs fail to provide the information required

GP

4.26: GDP recommends that the European Association for Osseointegration reviews its 2002 consensus guidelines on the use of imaging in implant dentistry to take into account the availability of CBCT

GP

4.27: The use of CBCT is not recommended as a routine imaging technique for all implant cases

GP

4.28: CBCT is justified for cross-sectional imaging prior to implant placement as an alternative to existing cross-sectional techniques where the radiation dose is shown to be lower

D

4.29: The advantage of CBCT with adjustable fields of view, compared with conventional CT, becomes greater where the region of interest is a localised part of the jaws, as a similar sized field of view can be used

GP

4.30: Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than CBCT

BP

4.31: For maxillofacial fracture assessment, where cross-sectional imaging is judged to be necessary, CBCT may be used as an alternative imaging modality to conventional CT where radiation dose is shown to be lower and soft tissue detail is not required

D

4.32: CBCT should not be used routinely for imaging the craniofacial skeleton

GP

4.33: CBCT may be used, in selected cases, where only bone information is required, for obtaining three-dimensional datasets of the craniofacial skeleton

C

4.34: Where the existing imaging modality for examination of the TMJ is conventional CT, CBCT should be considered as an alternative where radiation dose is shown to be lower

B

Equipment factors in the reduction of radiation risk to patients in CBCT

5.1: Research studies should optimise the tube kiloVoltage and mAs for a range of dental CBCT units and for a range of protocols

GP

5.2: CBCT equipment should offer a choice of volume sizes and examinations must use the smallest that is compatible with the clinical situation if this provides less radiation dose to the patient

BP

5.3: Research studies on optimisation of filtration for dental CBCT units should be performed

GP

5.4: Dental CBCT units equipped with either flat panel detectors or image intensifiers need to be optimised in terms of dose reduction before use

GP

5.5: CBCT equipment should offer a choice of voxel sizes and examinations must use the size most compatible with the clinical situation if this provides less radiation dose to the patient. Research studies should be performed to further assess the relationship between voxel size, image quality and radiation dose for a range of dental CBCT units and clinical protocols

C

5.6: Research studies should be performed to assess further the effect of the number of projections on image quality and radiation dose

GP

5.7: Shielding devices could be used to reduce doses to specific organs and tissues. Care is needed in positioning so that repeat exposure is not required. Further research is needed on effectiveness of such devices in dose reduction.

GP

Quality standards and quality assurance

6.1: Image quality standards should be developed for the clinical uses of CBCT

ED BP

6.2: The Panel recommend that further work be carried out to establish a measurement method (most probably DAP) for dental CBCT and to undertake further field measurements so that a European DRL can be established

GP

6.3: Manufacturers of dental CBCT equipment should provide a read-out of Dose-Area-Product (DAP) after each exposure

GP

6.4: Testing of dental CBCT should include a critical examination and detailed acceptance test when equipment is new and routine tests throughout the life of the equipment. A Medical Physics Expert should be involved and the advice of the installer sought

GP

6.5: Standard protocols and equipment should be developed for testing dental CBCT equipment

GP

Staff protection

7.1: It is essential that a Qualified Expert is consulted over the installation and use of CBCT to ensure that staff dose is as low as reasonably achievable and that all relevant national requirements are met

GP

7.2: CBCT equipment should be installed in a protected enclosure and the whole of the enclosure designated a Controlled Area

GP

7.3: Systematic studies of the dose due to scattered radiation in surrounding areas should be undertaken to inform decisions about shielding requirements

GP

7.4: The provision of Personal Monitoring should be considered

GP

Economic evaluation

8.1: Economic evaluation of CBCT should be a part of assessment of its clinical utility

GP

APPENDIX 3: GLOSSARY AND ABBREVIATIONS

A (evidence grade)	At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
AMA	Active matrix array
B (evidence grade)	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+
BP (evidence grade)	Basic Principle. Consensus principle of the European Academy of Dental and Maxillofacial Radiology (section 3).
GP (evidence grade)	Good Practice (based on clinical expertise of the guideline group)
C (evidence grade)	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++
CBCT	Cone Beam Computed Tomography
CTDI	Computed tomography dose index
D (evidence grade)	Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+
DAP	Dose-Area Product
DICOM	The Digital Imaging and Communications in Medicine (DICOM) standard
DRL	Diagnostic Reference Level
DVT	Digital Volumetric Tomography
EAO	European Association for Osseointegration
ED (evidence grade)	Derived from the EC Council Directives 96/29/Euratom or 97/43/Euratom.
FOV	Field of view
FPD	Flat panel detector
GDP	Guideline Development Panel
HU	Hounsfield Unit
ICRP	International Commission on Radiological Protection
kV	kiloVoltage
MSCT	Multi-slice computed tomography. MSCT refers to “conventional medical CT”
Pixel	Picture (two-dimensional) element
QA	Quality Assurance
SEDENTEXCT	Safety and Efficacy of a New and Emerging Dental X-ray

	Modality. A project co-funded by the European Atomic Energy Community's Seventh Framework Programme (Euratom FP7, 2007-11 under grant agreement no. 212246 (SEDENTEXCT).
SIGN	Scottish Intercollegiate Guidelines Network
Sv	Sievert (unit of effective dose)
TFT	Thin film transistor
TLD	Thermoluminescent dosemeter
TMJ	Temporomandibular joint
Voxel	Volume (three-dimensional) element

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SEDENTEX CT

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