Malmö University

**MAXILLOFACIAL CONE BEAM COMPUTED
TOMOGRAPHY (CBCT)**

Malmö University, Faculty of Odontology
Doctoral Dissertation 2017

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MAXILLOFACIAL CONE
BEAM COMPUTED
TOMOGRAPHY (CBCT)

Aspects on optimisation

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To my family (E.M.L)

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LIST OF ARTICLES

The thesis is based on the following studies, which will be referred to in the text by their Roman numerals (I – IV). All articles are reprinted with permission from the copyright holders and appended to the end of the thesis.

- I. Effective dose of cone beam CT (CBCT) of the facial skeleton: a systematic review. Al-Okshi A, Lindh C, Salé H, Gunnarsson M, Rohlin M. Br J Radiol. 2015; 88(1045):20140658.
- II. Using GafChromic® film to estimate the effective dose from dental cone beam CT and panoramic radiography. Al-Okshi A, Nilsson M, Petersson A, Wiese M, Lindh C. Dentomaxillofac Radiol. 2013; 42(7):20120343.
- III. Dose optimization for assessment of periodontal structures in cone beam CT examinations. Al-Okshi A, Theodorakou C, Lindh C. Dentomaxillofac Radiol. 2017; 46(3):20160311.
- IV. Reliability of assessment of root lengths and marginal bone level in CBCT and intraoral radiography: a study of adolescents. Al-Okshi A, Paulsson L, Rohlin M, Ebrahim E, Lindh C. To be submitted to European Journal of Orthodontics.

THESIS OUTLINES

ABBREVIATIONS

3D	Three-dimensional
2D	Two- dimensional
AAPM	American Association of Physicists in Medicine
AEC	Automatic exposure control
Al	Aluminum
ALADA	As low as diagnostically acceptable
ALARA	As low as reasonably achievable
ART	Alderson Radiation Therapy phantom
ATPS	Apical third of periodontal space
BW	Bitewing radiography
CBCT	Cone-beam computed tomography
CCD	Charge-coupled device
CEJ	Cemento-enamel junction
CI	Confidence interval
CIRS	Computerized Imaging Reference Systems
CNR	Contrast-to-noise ratio
CRD	Centre for Reviews and Dissemination
CT	Computed tomography
DAP	Dose-area product
DICOM	Digital Imaging and Communications in Medicine
DLP	Dose length product
DMFR	Dento-maxillofacial radiology
DNA	Deoxyribonucleic acid
DRL	Dose reference level
ED	Effective dose
ESD	Entrance surface dose
ICC	Intra-class correlation coefficient

FOV	Field of view
FPD	Flat panel detector
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
k	Kappa value
kV	Kilovoltage
LDPE	Low-density polyethylene
mA	Milliampere
mAs	Milliampere second
MBC	Marginal bone crest
MBL	Marginal bone level
MDCT	Multiple detector computed tomography
MEDLINE	Medical Literature Analysis and Retrieval System Online
MeSH	Medical Subject Headings
mGy	Milligray
MPR	Multi-planar reconstruction
MPV	Mean pixels value
MSCT	Multi-Slice Computer Tomography
OSL	Optically stimulated luminescent
OSLD	Optically stimulated luminescent dosimeter
PA	Periapical radiography
PMMA	Polymethyl methacrylate
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSP	Phosphor storage plates
PTFE	Polytetrafluoroethylene
ROI	Region of interest
SD	Standard deviation
s	Second
SEDENTEXCT	Safety and Efficacy of a New and Emerging Dental X-ray Modality
SPSS	Statistical Package for the Social Sciences
Sv	Sievert
TLD	Thermoluminescent dosimeter
TMJ	Temporomandibular joint
VGA	Visual grading analysis

DEVICES AND SOFTWARES REFERRED TO IN THE THESIS

Devices/ software	Manufacture
GafChromic® XR-QA	ISP Corp., Wayne, NJ
Veraviewepocs® 3De	J. Morita MFG Corp., Kyoto, Japan.
ProMax® 3D	Planmeca, Helsinki, Finland
ProMax®	Planmeca, Helsinki, Finland
NewTom® VGi	Quantitative Radiology, Verona, Italy.
NewTom® VG	Quantitative Radiology, Verona, Italy.
NewTom® 9000	Quantitative Radiology, Verona, Italy.
NewTom® 3G	Quantitative Radiology, Verona, Italy.
PSP with ProMax panoramic unit	DX-S digitizer; Agfa HealthCare, Mortsel, Belgium.
RANDO® phantom	The Phantom Laboratory, Salem, NY
Epson® Perfection 4990 Photo flatbed scanner	Seiko Epson Corp., Nagano, Japan.
3D Accuitomo® 170	J. Morita MFG Corp., Kyoto, Japan.
3D Accuitomo®	J. Morita MFG Corp., Kyoto, Japan.
3DX® multi-images micro CT	J. Morita MFG Corp., Kyoto, Japan.
VacuDAP meter	VacuTec Messtechnik GmbH, Dresden, Germany.
SedentexCT IQ cylindrical phantom	Leeds Test Objects Ltd, Boroughbridge, UK.

Image J® software	National Institutes of Health, Bethesda, MD.
i-Dixel software	J. Morita MFG Corp., Kyoto, Japan.
BARCO® monitor	MFGD 1318; BARCO, Kortrijk, Belgium.
Planmeca® ProX	Planmeca; Helsinki, Finland
Kavo®, Gendex 765 DC	Kavo; Biberach/Riss, Germany
Planmeca® Intra	Planmeca; Helsinki, Finland
Sirona ®– HELIODENT DS	Sirona Dental Systems, Bernsheim, Germany
ProSensor®	Planmeca; Helsinki, Finland
Schick 33®	Sirona Dental, Salzburg, Austria
Sigma CCD ®	GE/Instrumentarium Imaging, Tuusula, Finland
Kodak® 9000	Carestream Health
CIRS® – ATOM phantom	CIRS Inc., Norfolk, VA
QUART DVT phantom	QUART GmbH, Zorneding, Germany
i-CAT® FLX	Imaging Sciences, Hatfield PA
Scanora® 3D	SOREDEX
Galileos®	Sirona Dental Systems
Iluma®	IMTEC Imaging
AAPM CT - Performance Phantom	CIRS Inc., Norfolk, VA
Dinnova3	HDXwill Inc., Seoul, Korea

ABSTRACT

Maxillofacial Cone Beam Computed Tomography (CBCT) has become a common modality for imaging of the facial skeleton. The increased, and sometimes inappropriate, use of this modality and the fact that radiation doses from CBCT examinations are generally higher than those from conventional radiography will result in an increase in the radiation dose and radiation-associated risk to which patients are exposed. Therefore, the radiation protection principles, justification and optimisation of protection, recommended by the International Commission on Radiological Protection (ICRP) should be applied. Justification of clinical indication is the most important aspect of reducing radiation dose with CBCT scanning. In terms of optimisation, the examination should be performed exposing the patient to the lowest possible radiation dose whilst simultaneously obtaining the image quality required for the diagnostic task. The overall objective of this thesis was to clarify some aspects of optimisation for CBCT examinations.

STUDY I comprised a systematic review with the aim to estimate effective dose of CBCT of the facial skeleton with focus on measurement methods and scanning protocols that were used when measuring and estimating the radiation dosage and effective doses range. The review adhered to the preferred reporting items for systematic reviews (PRISMA) statement. Three electronic databases were searched and 38 studies ultimately met the inclusion criteria. Heterogeneity in measurement methods and scanning protocols between studies made comparisons of effective doses of different CBCT units and scanning protocols difficult.

A model with minimum data set on important parameters based on this observation of heterogeneity was proposed. Few studies related effective dose to image quality and consequently the review revealed a need for studies on radiation dosages related to image quality.

STUDY II demonstrated the feasibility of GafChromic® film XR-QA2 (ISP Corp., Wayne, NJ) as a dosimeter when performing measurements of the effective dose from three different CBCT units and comparing doses from 3 common dental clinical situations. The CBCT units used were Veraviewepocs 3De® (J Morita MFG Corp., Kyoto, Japan), ProMax® 3D (Planmeca, Helsinki, Finland) and NewTom VGi® (Quantitative Radiology, Verona, Italy). Depending on availability, medium and smaller field of view (FOV) scanning modes were used. Additionally, radiation doses from the three CBCT units were compared with radiation doses from three digital panoramic units. GafChromic XR-QA2 films were placed between selected layers of the head and neck of a tissue-equivalent human skull (RANDO® phantom; The Phantom Laboratory, Salem, NY). The effective dose was estimated using the 2007 ICRP formalism.

The lowest effective dose of a CBCT unit was observed for ProMax 3D, FOV 4 X 5 cm (10 µSv), the highest for NewTom VGi, FOV 8 X 8 cm—high resolution (129 µSv). The range of effective doses for panoramic units measured was 8-14 µSv.

STUDY III investigated the relationship between dose and image quality for 3D Accuitomo® 170 CBCT scanner (J. Morita, Kyoto, Japan) using 12 different scanning protocols for assessment of periodontal structures. The SedentexCT IQ phantom (Leeds Test Objects Ltd, Boroughbridge, UK) was used to investigate the relationship between contrast-to-noise ratio (CNR) and dose–area product (DAP). Subjective image quality assessment was achieved using a small adult skull phantom (RANDO®; The Phantom Laboratory, Salem, NY) for the same range of exposure settings. Five independent raters assessed the images for three anatomical landmarks using a three-point visual grade analysis. Objective and subjective image quality was evaluated and correlated to radiation dose.

By altering tube potential and current for the 360° rotation protocol, the conclusion was reached that assessment of periodontal structures

can be performed with a smaller dose without substantially affecting visualisation.

STUDY IV comprised a clinical study of ten adolescents with the aim of evaluating the reliability of measurements of root lengths and marginal bone levels in CBCT images, and periapical (PA) and bitewing radiographs (BW). Six raters performed all available measurements.

CBCT was the most reliable imaging method for root length measurements while reliability for marginal bone level measurements was about the same for all methods.

POPULÄRVETENSKAPPLIG SAMMAFATTNING

Inom odontologisk såväl som inom medicinsk radiologi sker en snabb utveckling av nya tekniker. Nya metoder för att kunna diagnosticera och följa sjukdomsförlopp över tid introduceras. Cone-Beam Computed Tomography (CBCT) är en sådan ny teknik, som introducerades inom odontologin under sent 1990-tal. Tekniken innebär att man får en avbildning av kroppen i genomskärning i tre mot varandra vinkelräta plan. Efter en långsam start med få fabrikanter och typer av CBCT-maskiner har antalet tillverkare och modeller ökat och en snabb spridning av tekniken har skett. CBCT kan ge en utökad och bättre diagnostisk information än konventionell röntgenteknik, men till priset av högre stråldos. Eftersom utveckling av nya tekniker liksom försäljning av ny apparatur går snabbare än forskning som undersöker nyttan med de nya teknikerna, är det angeläget att vetenskapligt utvärdera i vilken utsträckning nya tekniker är till nytta för de patienter som undersöks. Alla undersökningar som görs med röntgenstrålning ska vara berättigade och optimerade dvs utföras med lägsta möjliga stråldos för en specifik klinisk frågeställning. Därför är det viktigt att forskning som rör nya tekniker beaktar olika aspekter av optimering av undersökningar som utförs vid olika kliniska indikationer. Denna avhandling behandlar några aspekter av hur undersökningar med CBCT kan optimeras.

I det första delarbetet gjordes en systematisk granskning av den vetenskapliga litteratur som publicerats då det gäller hur stora stråldoser som en undersökning med CBCT av tänder, käkar och ansiktsskelett ger upphov till, samt hur dessa stråldoser beräknas. För

att hitta all relevant litteratur gjordes en sökning i tre databaser vilket resulterade i att över 700 publikationer identifierades. Efter en första genomgång kvarstod 38 publikationer som handlade om dosmätningar vid CBCT undersökningar av tänder, käkar och ansiktsskelett. Få studier beskrev i tillräcklig omfattning hur stråldoser beräknats, vilka protokoll och mätmetoder som använts. Likaså var beskrivningen av hur stråldoser relateras till kvalitén på de röntgenbilder som undersökningen resulterade i, mestadels knäpphändig. Det behövs mer forskning som beskriver hur beräkningar av stråldoser sker samt hur man kan använda den lägsta möjliga stråldosen för att uppnå den kvalitén på röntgenbilderna som är optimal för en given klinisk frågeställning. En modell för vilka parametrar som är nödvändiga vid rapportering av uppmätt stråldos för CBCT undersökningar av tänder, käkar och ansiktsskelett föreslås.

Syftet med det andra delarbetet var att testa en metod för att beräkna stråldos, som inte tidigare använts i nämnvärd utsträckning för odontologiska undersökningar. Denna metod innebär att en röntgenkänslig film placeras i ett fantom som är sammansatt av material vilka simulerar biologisk vävnad. Stråldosen från tre CBCT apparater från olika tillverkare beräknades för tre olika kliniska frågeställningar. Därutöver jämfördes de uppmätta stråldoserna från de tre CBCT apparaterna med doser från tre konventionella röntgenapparater som ger två dimensionella bilder av tänder och käkar sk panoramaröntgenbilder. Stråldoserna från CBCT apparaterna varierade beroende på strålfält, samt energi och mängd av röntgenstrålning för de olika undersökningarna och var generellt högre än de uppmätta stråldoserna från panoramaröntgenapparaterna.

I det tredje delarbetet var målet att relatera stråldos till bildkvalitet för en specifik klinisk frågeställning och en specifik CBCT apparat. Stråldoser uppmättes med en DAP-meter och bildkvalité utvärderades såväl fysikaliskt (objektivt) som subjektivt. För beräkning av den objektiva bildkvalitén användes ett fantom som tagits fram i ett tidigare EU-finansierat projekt (SEDENTEXCT) och för bedömning av den subjektiva bildkvalitén användes ett fantom som var sammansatt av material liknande biologisk vävnad. Från resultaten av denna studie kunde ett undersökningsprotokoll föreslås för undersökning av tänder och omgivande vävnad som ger den bästa bildkvalitén med lägsta möjliga stråldos.

I det fjärde delarbetet användes röntgenbilder tagna på unga individer som skulle genomgå behandling för att korrigera snedställda tänder. En sådan tandreglerings behandling kan ge upphov till vissa icke önskvärda sidoeffekter så som förkortade tandrötter och/eller att den benvävnad som omger tänderna till viss del blir förstörd. Det kan därför vara viktigt att utföra röntgenundersökningar på denna patientgrupp både innan behandlingen påbörjas och vid uppföljningar av behandlingen. Syftet med denna studie var att undersöka hur olika bedömare identifierar och mäter anatomiska strukturer (tandrötter och den benvävnad som omger tänderna) i röntgenbilder från CBCT undersökningar och jämföra med mätningar i röntgenbilder från två konventionella tekniker. Sex bedömare granskade röntgenbilderna och utförde mätningarna. Resultatet visar att i röntgenbilder från CBCT undersökningen var det lättare att identifiera de anatomiska strukturerna än i röntgenbilderna från de konventionella teknikerna. Likaså var samstämmigheten mellan och inom bedömare högst för CBCT undersökningen då det gäller mätning av rötternas längd. Då det gäller mätning av benvävnaden runt tänderna fanns ingen skillnad mellan de olika teknikerna.

Sammanfattningsvis visar denna avhandling att det saknas studier av hög kvalitet då det gäller mätning av stråldos relaterat till optimal objektiv och subjektiv bildkvalitet för givna kliniska frågeställningar. Vidare förslås en modell som innehåller nödvändiga parametrar för att rapportera uppmätt stråldos vid undersökning med CBCT av tänder, käkar och ansiktsskelett. Ett protokoll för CBCT undersökning av tänder och omgivande benvävnad som ger bästa möjliga bildkvalitet med minsta möjliga stråldos föreslås liksom vilka aspekter som bör beaktas i vetenskapliga studier för röntgenologisk kartläggning av icke-önskvärda effekter av tandregleringsbehandling.

INTRODUCTION

There is a wide variety of imaging modalities available for use in the field of dentistry and for the benefit of oral healthcare. In general dental practice, intraoral radiography, such as bitewing and periapical radiography, is a valuable tool for the diagnosing of various dental conditions. For more advanced examinations of the dento-maxillofacial region conventional and Computed Tomography (CT) have been used for more than 40 years and Cone Beam Computed Tomography (CBCT) for about 25 years. CBCT was described in 1982 for angiographic applications (Robb et al., 1982) and in the late 1990s for examinations of the dento-maxillofacial region (Mozzo et al., 1998; Arai et al., 1999). Since then, the technique has become widespread within the fields of both dental and maxillofacial radiology. As is the case with many new and emerging technologies within healthcare, there is a lack of evidence demonstrating the benefits to the patient. The marketing and selling of new equipment simply outpaces the research in the field. When investigating the effects of diagnostic imaging to the patient, many aspects have to be taken into consideration such as those presented in the six-tiered hierarchical model by Fryback & Thornbury (1991). The objective of this thesis was to clarify some of these aspects.

Imaging techniques in dental and maxillofacial radiology

Intraoral radiography is the most basic, and often only, imaging technique required for examining dental pathology. There are two main categories: periapical projections and bitewing projections (Boeddinghaus & Whyte, 2008). The tube shift or buccal object rule can be used to determine the anatomical relationship between different structures.

Panoramic radiography produces a single tomographic image that includes both the maxilla and the mandible as well as facial structures. The x-ray source and receptor rotate around a central point or plane, the image layer, in which the object is located (Paatero, 1954). There are a number of advantages associated with panoramic imaging e.g. the image provides an excellent overview of the facial bones and teeth, the examination is convenient for the patient, and it involves a low patient radiation dose (White & Pharoah, 2008). As all teeth and supporting tissues are shown on one image it also has an ancillary use for patient education. A panoramic image is sufficient for many dental purposes but supplementary periapical radiographs may be indicated when periapical pathology is evaluated (Rohlin & Akerblom, 1992).

Lateral and postero-anterior cephalograms are the standard radiographs obtained with a cephalostat. They are mainly used for orthodontic assessment. The images can be used to evaluate dental and skeletal relationships as well as asymmetries (Boeddinghaus & Whyte, 2008).

The drawbacks of these techniques are that the three dimensional (3D) structure of an object is imaged two dimensionally (2D) which causes a loss of depth information. Technological advances in radiological imaging have moved the technique from film radiography towards digital 3D (Boeddinghaus & Whyte, 2008; White & Pharoah, 2008; Robinson et al., 2005). This has been achieved through the use of conventional tomography (Tanimoto et al., 1989), computed tomography (Boeddinghaus & Whyte, 2008) and, more recently, by CBCT (Arai et al., 1999).

Cone Beam Computed Tomography

The technical development of CBCT scanners, such as the introduction of high quality digital flat panel detectors (FPD), powerful computers for rapid image reconstruction, and the modern X-ray tube design of these scanners, along with their relatively small size, have made CBCT scanners suitable for use in dentistry and maxillofacial specialties (Mozzo et al., 1998; Arai et al., 1999; Hashimoto et al., 2003). A CBCT scan can be performed with the patient in three positions: sitting, standing, or supine. During scanning the patient's head is stabilised with a head holder or chin cup.

Imaging is accomplished using a rotating gantry to which an X-ray source and detector are fixed and that revolves around the patient's head. During rotation, multiple – from 150 to more than 600 – sequential projection images of the FOV are acquired (Scarfe & Farman, 2008). When the basis projection frames have been acquired, data is processed to create the volumetric data set. This process is called reconstruction and it has two stages: sonogram formation and reconstruction using the Feldkamp algorithm. The Feldkamp algorithm is the first and most widely used back projection algorithm for volumetric data acquired using a CBCT (Mozzo et al., 1998; Arai et al., 1999). Reconstructed slices can be recombined into a single volume for visualisation. Depending on technical aspects such as exposure parameters (FOV, rotation angle and voxel size), the reconstruction time differs between scanners. Posterior-anterior and lateral scout views – when available – are sometimes used to determine the correct location of the imaging area.

✎ The literature on dose levels of CBCT is difficult to grasp and interpret owing to the diversity of CBCT units and the different approaches taken within studies of radiation dosimetry.

Technical aspects

In order to maximise patient benefit and minimise radiation risk, the complexity of modern CBCT equipment requires an insight into the various trade-offs involved. It is essential to understand the various technological factors and scan parameters that influence dose.

The exposure factors, kilovoltage (kV), and the current (mA) or tube current-exposure time product, (mAs) can be fixed in some scanners, whereas in other they can be changed according to patient size (European Commission, 2012). The dental CBCT scanners use tube current between 1 and 32 mA, and tube voltage between 40 and 120 kV (Kiljunen et al., 2015). Most dental CBCT scanners use adjustable kV between 60 and 90 kV, and a few use 120kV as a fixed potential difference. Automatic exposure control (AEC), which is implemented in medical CBCT scanners, is for the most part not available in dental CBCT scanners.

Scanning time is defined as the time it takes to complete the entire examination (5-40 seconds) (Nemtoi et al., 2013) and exposure time is the time during which X-rays are generated. Some scanners provide continuous radiation exposure instead of pulsed X-ray beam exposure. Some dental CBCT scanners use 360° rotation; others use a smaller trajectory arc of between 180° and 220°.

CBCT scanners use a collimated narrow cone-shaped X-ray beam instead of a wider fan or cone beam, resulting in a scan range with a restricted field of view (FOV) in the axial dimension (Scarfe & Farman, 2008). The dimensions of the FOV are primarily dependent on the detector size and shape, beam projection geometry and the ability to collimate the beam. Some CBCT scanners allow the FOV to be selected to suit the particular examination area. The more recent models also allow stitched or blending FOVs (Scarfe et al., 2012).

Earlier CBCT scanners employed image intensifiers and charged couple device (CCD) cameras in the image detector hardware. Digital FPD have replaced and expanded image intensifiers and CCD technology (Scarfe & Farman, 2008) as FPDs have greater sensitivity to X-rays and the potential to reduce patient dose (Kalender & Kyriakou, 2007).

Dental CBCT scanners use voxel (element of a 3D CBCT reconstruction matrix) size between 75 and 600 µm (Kiljunen et al., 2015). The voxel size is one factor affecting the spatial resolution, and it is important to distinguish between theoretical spatial resolution based on the given voxel size and actual spatial resolution based on all imaging chain components such as beam projection geometry, scatter, detector motion blur and fill factor, focal spot size, number of basis images and reconstruction algorithm (Scarfe et al., 2012).

With the rapid increase in the number, models and scanning options of dental CBCT, it is urgent to prioritise technical and clinical research in order to close knowledge gaps and to generate CBCT examinations with a dose as low as diagnostically acceptable.

Dose measurement

Radiation dose may be expressed as effective dose (ED), measured in units of Sievert (Sv) but is more usually expressed as the micro-Sv (μSv). ED takes into account the type of radiation and the sensitivity of each organ or tissue being irradiated. A summation of organ doses due to varying levels and types of radiation produce an overall calculated effective dose.

While the ED is an impossible quantity to measure in vivo, it is possible to determine it from laboratory studies or computer modelling. This can be used to estimate radiation risk. ED permits a comparison of different types of examinations.

According to Thilander-Klang & Helmrot (2010) there are a number of ways to determine the ED, such as entrance surface dose (ESD), organ dose, dose area product (DAP), dose length product (DLP) and dose simulation programs.

Thermoluminescent dosimeters

The traditional way of estimating ED in dental and maxillofacial radiology is by measuring organ doses using thermoluminescent dosimeters (TLDs) and anthropomorphic head and neck phantoms, which contain real skull or bone-equivalent material (Ludlow et al., 2008; Pauwels et al., 2012; Qu et al., 2010; Ludlow & Walker, 2013). The dosimeters are placed inside the phantom in small cavities, which have been drilled in a regular pattern in every slice of the phantom. The main advantages of these TLDs are fair to good tissue equivalent composition, small dimensions, and flexibility in shape (Kron, 1999; IAEA, 2007).

Radiochromic films

Radiochromic films, initially intended for dose measurement in radiotherapy (sensitive only to extremely high doses; $\sim 10^3$ Gy), are now also available with higher sensitivity for X-ray diagnostic purposes as GafChromic® XR-QA, XR-QA2 and XR-CT (Brady et al., 2010). There are some advantages of GafChromic® films compared to TLDs, such as easy preparation and adjustable size of the film. The reading process and the digitisation procedure for a set of three film sheets takes a few seconds, whereas around 1 min or more is necessary for the reading of one TLD. Furthermore, the GafChromic® film will

present a continuous “analogue”-like dose distribution, where the limit for spatial resolution is set by the pixel size when digitising the image in the flatbed scanner. The film is not sensitive to visual light and can therefore be handled in ambient light.

✍ In rotating irradiation geometry with collimated radiation fields, the dose distribution will show more or less steep dose gradients. This is a significant problem if you want to map or sample the dose distribution with a reasonable degree of accuracy using TLDs. This encouraged us to test Gafchromic® film.

Dose area product

DAP in dental and maxillofacial radiology is mainly used in panoramic radiography (Helmrot & Alm Carlsson, 2005). DAP is defined as an average of the air kerma in Gray (Gy) multiplied by the corresponding X-ray beam cross exposed area in (cm²) and is expressed as Gy.cm².

Also, DAP can be used to establish a reference dose for dental radiography (Tierris et al., 2004; Thilander-Klang & Helmrot, 2010) and to compare dose of different imaging modalities and radiation optimisation purpose (Huda, 2010). DAP can be used to compare different scanning protocols of CBCT scanners for dose optimisation purposes.

Dose optimisation

Dose optimisation is one of the principles of radiation protection for patients and workers recommended by ICRP (ICRP, 2007). It can be defined as keeping doses as low as reasonably achievable (ALARA), taking into account economic and societal factors (ICRP, 2007). Dental and maxillofacial radiologists have part of the responsibility for the dose optimisation of CBCT examinations. The decision to use CBCT instead of any other modality should be based on consultation between practitioner and specialists in the field.

✍ Many studies have examined radiation dose of CBCT. However, the SEDENTEXCT report indicates that there is room for optimisation in order to keep the radiation dose as low as reasonably achievable. The use of CBCT scanners have increased dramatically, but published evidence supporting the principle of optimisation is low (Kim et al., 2009; European Commission, 2012).

Factors influencing radiation dose

Tube voltage (kV)

The kilovoltage (kV) is the potential difference between anode and cathode that accelerates the electrons in the X-ray tube between them. The tube voltage determines the energy (quality) of the X-ray beam and quantity of X-ray photons (Langland et al., 2002). Higher kV may result in a decrease in effective dose (Geijer et al., 2009) but an increase in scatter. The influence of kV on the radiation is complex and also depends on the scanned area and patient size (McCollough et al., 2009). Jadu et al. (2010) showed that reducing kV from 120 to 100 kV resulted in a 30% reduction of ED and in a 60% reduction when reducing it from 120 to 80kV. Palomo et al. (2008) achieved a 38% reduction of ED by using 100 kV instead of 120kV.

Tube current-exposure time product (mAs)

The product of the tube current (mA) and the exposure time (s) determines the number of X-ray photons. It is directly proportional to absorbed dose when other factors remain constant (Shaw, 2014; Kalender, 2011). Increasing the exposure time of MSCT as well as of CBCT increases the dose (Loubele et al., 2008a; Schilling & Geibel 2013). Jadu et al. (2010) reported that, reducing mA from 15 to 10 mA resulted in a 37% reduction of effective dose. Palomo et al. (2008a) noted a linear relationship between mAs and ED.

Field of View (FOV) and Collimation

The size of the FOV is associated with the patient's dose (Hirsch et al., 2008; Okano et al., 2009; Roberts et al., 2009; Lofthag-Hansen et al., 2010; Pauwels et al., 2012; Schilling & Geibel 2013; Jadu et

al., 2010). Pauwels and co-workers (Pauwels et al., 2012) investigated the difference in dose due to variability in FOV size, tube output, and exposure factors, and found that the FOV is one of the main determinants of the effective dose. A smaller FOV results in lower radiation doses when other exposure factors held constant. A large fixed FOV is inappropriate for dental diagnostic tasks (teeth or jaw) (European commission, 2012).

Filtration

Most CBCT scanners are equipped with aluminum filtration while some dental scanners are equipped with copper filtration alone or in addition to aluminum. An increase of filtration reduces the dose as lower energy X-ray photons are removed. Ludlow (2011) demonstrated that an increase of 0.4 mm copper filtration (kV change by 10-16 kV) resulted in a 44% reduction of effective dose for both large and medium FOV for one CBCT scanner. Qu et al. (2010) demonstrate the same result for another CBCT scanner. In terms of image quality, using heavy filtration result in lower intensity and higher energy of the X-ray beam, which means that the image reconstruction suffers less from beam-hardening artifact.

Receptor technology

Image intensifier-based CBCT produces a spherical FOV. Flat panel detector-based CBCT produces a cylindrical FOV. Scanning both temporomandibular joint (TMJ) and chin anatomy will require a spherical volume diameter that is approximately 25% larger to cover the same anatomy, resulting in an increase of dose (Ludlow et al., 2015).

Voxel size

Pixel size has an indirect effect on patient dose as a higher dose is required to achieve the same signal-to-noise ratio as pixel size is decreased (Ludlow, 2009). Qu et al (2010) showed that the use of small voxel size “low-dose resolution” option on one CBCT machine substantially reduced patient dose by 10% when compared with “normal-dose resolution”. Schilling and Geibel showed that to reduce the resolution of 0.3 mm voxel size instead of 0.125mm voxel size of one CBCT scanner resulted in a reduction of the ED by 50% (Schilling & Geibel, 2013). Grunhied et al. (2012) reported that the

ED ranged from 67.7 to 69.2 μSv for standard resolution and 127.3 to 131.3 μSv for high resolution.

Number of projections

For some CBCT scanners the changing number of basis images is under the control of the operator. A high number of projections are associated with increased radiation dose. Sur J et al. (2010) reported that the reduction of the scan arc from 360° to 180° resulted in a 50% reduction in patient radiation dose with adequate diagnostic quality for implant planning in the upper jaw. Schilling and Geibel showed that performing the scan with a rotation of 180° instead of 360° resulted in a reduction of the ED by 50 % (Schilling & Geibel, 2013).

With the growing concerns about CBCT radiation risk, various CBCT reducing dose strategies have been developed. Thus, the benefit-risk ratio of CBCT examinations can be maximised with optimised CBCT using these strategies for different diagnostic tasks.

Image quality

Image quality can be defined as the effectiveness with which an image can be used for its intended diagnostic task (Vennart, 1997). As with any new medical technology, it is important to assess the quality of images obtained by CBCT in order to address the inherent question concerning radiation dose optimisation. There is a wide spectrum of methods for assessment of image quality, some of them focusing on the physical characteristics of the imaging system and others on subjective assessment of image quality (Tingberg, 2000).

Physical characteristics of the imaging system

The imaging characteristics of a system for diagnostic radiology can be studied using various physical test phantoms. The physical measurements are used to evaluate imaging properties (equipment and detectors) as well as dosimetric characteristics of the imaging process. Image noise, contrast resolution, spatial resolution and artifacts are key parameters in the objective image quality assessment (Workman & Brettle, 1997).

Contrast-to-noise ratio CNR

Contrast-to-noise ratio (CNR) is mainly used for optimisation purposes in combination with radiation doses and can be defined as the ratio between lesion or structure contrast and image noise.

The most important factor affecting contrast is the photon energy, which is controlled by kV and beam filtration. Lower photon energy leads to more differential attenuation between adjacent tissue (higher contrast) and vice versa. Other factors to be considered are the lesion's atomic number, scatter, and image display system (Huda, 2013). Noise occurs due to reduced photon number that incident on image detector and describes the limitation of the ability to visualise lesions or structure. It is mainly affected by mAs. Increasing the number of photons reduces the noise and vice versa.

For CBCT, there are many other factors affecting the contrast and noise, such as system geometry, focal spot size, FOV, object size, and voxel size. The CNR of the 3D Accuitomo® CCD scanner has been reported as being more than 50% lower than that in MSCT, but is still adequate for diagnostic tasks (Peltonen et al., 2007). For the same scanner it has been reported that the best CNR was achieved with the highest mAs and kV (Peltonen et al., 2009).

Subjective image quality

As the physical measurement (objective image quality evaluation) is not enough to predict diagnostic performance of an imaging system, the evaluation of image quality must include psycho-physical, environmental, and system considerations (Martin et al., 1999).

One method of observer performance-based image quality evaluation is visual grading analysis (VGA), which is based on the visibility of clinically important normal anatomical or pathological structures. As the observer's grading takes into account the contribution of technical capacity, image processing, display, and the reader's experience, the validity is assumed to be high (Ludewig et al., 2010). The validity of a VGA study can be assumed to be high if the selection of anatomical structure is based on their clinical relevance and the observers are experienced radiologists (Båth, 2010). VGA can be relative to reference image (all images are compared and graded against reference image) or absolute without reference image (all images are compared and graded against each other).

✎ As it is a complicated and time consuming task that requires multi-professional work, there are few studies that relate patient exposure to clinically satisfactory image quality (optimise CBCT scanning protocols for intended clinical task). Evidence for clinical practice is still low.

Efficacy of diagnostic imaging

The appropriate choice of a radiographic modality is based on the understanding of technical aspects and other aspects related to the diagnostic outcomes of the modality. To provide a way of understanding and comparing of imaging modalities, Fryback and Thornbury (1991) proposed a conceptual model to be applied to all diagnostic technologies – not just diagnostic imaging technology. The hierarchical model on efficacy of diagnostic technology categorised at six levels “extends from basic laws of physics, through practical clinical use, to more general patient outcome and societal issues” (Fryback & Thornbury, 1991):

- Level 1- Technical efficacy
- Level 2- Diagnostic accuracy efficacy
- Level 3- Diagnostic thinking efficacy
- Level 4- Therapeutic efficacy
- Level 5- Patient outcome efficacy
- Level 6- Societal efficacy

Level 1 is the level at which the objective image quality of diagnostic imaging (raters not included) is measured. For CBCT, resolution, noise, DAP and CNR are included in this level. Level 2 is the level at which the performance of diagnostic imaging (raters included) is assessed and can be performed on images of either anthropomorphic phantoms or images of patients. The goal of a diagnostic method is to establish a connection between the physical characteristics of the method and the diagnostic outcome of the system for a given, clinically relevant task. To take this into account the next levels (Level 3-6) of Fryback and Thornbury’s model (1991) include the therapeutic impact and the patient outcomes of diagnostic methods.

New radiographic imaging modalities are increasingly used and there is not always a reference standard available. In such situations, agreement and reliability studies can address the amount of error inherent in a diagnosis or score and the rater agreement may represent an “upper boundary” for diagnostic accuracy efficacy (Kottner et al., 2011)

Periodontal structures and root resorption

Periodontal disease or conditions can be initially assessed by clinical examination and radiography to assess hard tissue status. Diagnostic information on the marginal bone level has usually been obtained from 2D radiography (periapical and/or panoramic) (Björn et al., 1969; Albandar et al., 1985; Salonen et al., 1991). However, there are shortcomings associated with these 2D imaging methods even when efforts are made to obtain periodically identical radiographs or to compensate for image distortions. A systematic review focusing on the adverse effects of the marginal bone tissue after orthodontic treatment concluded that “orthodontic treatment can cause a reduction of bone level between teeth; the scope of this reduction, however, is so small that it lacks clinical relevance. This conclusion was based on what occurs at the mesial and distal sites of the roots (SBU, 2005). Using CBCT (Lund et al., 2012a) it was found that bone height decreases on the buccal and lingual surfaces of incisors after orthodontic treatment indicating the usefulness of 3D imaging for scientific analyses of changes of the marginal bone tissue.

There is no published evidence regarding the influence of exposure parameters (mAs, kV and rotation angles) on radiation dose and subjective and objective image quality measurements for dental CBCT on periodontal diagnostic tasks of small adults.

Most research on the adverse effects of orthodontic treatment has tended to focus on external root resorption (ERR). As for marginal bone level measurements the most commonly used method to study ERR has been periapical or panoramic radiography. When considering length measurements, CBCT images have been found to be at least as accurate as periapical radiographs for tooth-and root length measurements (Sherrard et al., 2010). For repeated measurements of root lengths of a dry skull, errors ranged between 0.19 – 0.32 mm for one observer (Lund et al., 2010).

✎ Evidence regarding the intra- and inter-rater reliability of root length and marginal bone level assessment using intraoral radiography and CBCT is limited.

GENERAL AIM

The overall aim of this thesis was to investigate some aspects of the optimisation of CBCT imaging based on image quality and radiation dose taking the reliability of measurements into consideration. This is in line with the recommendations from the European Commission Radiation Protection report No 172 on Cone Beam CT for dental and maxillofacial radiology (evidence-based guidelines) that priority should be given to research focusing on relating image quality to diagnostic tasks and patient dose optimisation.

SPECIFIC AIMS

The specific aims of the studies on which the present thesis are based were to:

- Estimate effective dose of CBCT of the facial skeleton with focus on measurement methods and scanning protocols – Systematic review.
- Demonstrate the feasibility of GafChromic® XR-QA2 (ISP Corp., Wayne, NJ) as a dosimeter when performing measurements of the effective dose from three CBCT scanners and to compare the doses from examinations of three common dental clinical situations.
- Compare the radiation doses for three digital panoramic units with the doses for the CBCT scanners.
- Investigate the relationship between dose and image quality for a dedicated dental CBCT scanner using different scanning protocols and to set up an optimal imaging protocol for assessment of periodontal structures.
- Evaluate the reliability of measurements of root lengths and marginal bone levels in bitewing (BW) and periapical radiographs (PA) and in CBCT images.

MATERIALS AND METHODS

Systematic review – STUDY I

Reporting and undertaking guidelines

The literature review was conducted in accordance with the preferred reporting items for systematic reviews (PRISMA) Statement (Moher et al., 2009) and the guidelines of the Centre for Reviews and Dissemination for undertaking reviews in healthcare (Akers et al., 2009).

Review questions

With regards to CBCT of the facial skeleton, the review questions were as follows:

- Which methods and scanning protocols were used when measuring and estimating the radiation dosage?
- What are the effective doses?

Literature searches

The searches were designed with the help of university librarians. The following electronic databases were searched: MEDLINE® using PubMed as search engine, the Web of Science and the Cochrane Database of Systematic Reviews in The Cochrane Library. The search in MEDLINE was based on MeSH terms and free-text terms. The searches in Web of Science and The Cochrane Library (the Cochrane Database of Systematic Reviews) were performed using free-text terms. An additional hand search was carried out using the reference lists of retrieved systematic reviews.

Study selection

The inclusion criteria were as follows:

- Publication type: original study or systematic review.
- CBCT unit: regarding brand and version, FOV dimensions and degree of rotation, X-ray beam type (pulsed or continuous radiation).
- Anatomical region: facial region, further detailed and described in studies of FOVs ≤ 10 cm.
- Material: equipment to measure radiation dosage (dosimeters and read-outs).
- Outcomes: data on effective dose based on ICRP 60—1990 (ICRP, 1991) or ICRP 103—2007 (ICRP, 2007).
- Language: abstract in English and full-text publication in English, German, or Japanese.

Data extraction and data synthesis

We developed a model with components that were considered important when performing studies of radiation dosages in CBCT (Figure 1) and a data extraction sheet. Information was extracted from each study on (i) the CBCT unit(s), (ii) method to measure and estimate radiation dosages, (iii) scanning protocol, (iiii) object and (v) radiation dosages. When the information provided by the CBCT unit was insufficient, the manufacturer's website was searched for such information.

The effective doses for three heights of FOV (≤ 5 cm, 5.1–10.0 cm and >10 . cm) were compiled in a spreadsheet. Median values, 25 and 75 percentiles, and the range for effective dose values were calculated using software (Microsoft Office Excel® 2010; Microsoft Corporation, Redmond, WA).

Figure 1. A model presenting the steps for data extraction with different parameters important when analysing radiation dosages in cone beam CT (CBCT) of the facial skeleton. FOV, field of view; ICRP, International Commission on Radiation Protection.

Imaging modalities

Panoramic units

Three panoramic units were used in STUDY II: ProMax[®] was used with a photostimulable phosphor plate system (PSP), ProMax 3D[®] was used with a CCD and Veraviewepocs[®] 3De was used with a FPD. The parameters for each panoramic unit were fixed at the recommended settings for an average adult patient (Table 1).

CBCT scanners

The CBCT units chosen for STUDY II were Veraviewepocs[®] 3De, ProMax[®] 3D, and NewTom[®] VGi. All CBCT units used FPDs. The exposure parameters and protocols used are given in Table 1.

In STUDY III & IV all CBCT images were obtained with a 3D Accuitomo[®] 170 unit. In Study III using 12 scanning protocols for a range of tube voltages (kV), tube currents (mA), and trajectory arcs. The unit was equipped with a calculated DAP value monitor. The exposure parameters and protocols are shown in Table 1.

Equipment for intraoral radiography

In STUDY IV PA and BW radiographs were obtained in four radiographic departments. The dental X-ray units, exposure parameters, and imaging systems are shown in Table 1. For all radiographic examinations, the patients were oriented with the same plane setting provided by the main author as a part of study protocol.

Table 1. Technical parameters of selected radiographic modalities were used

STUDY	Unit's name	Region of interest	FOV Width X height cm	Exposure parameters			Notes
				kV	mA	s	
CBCT scanners							
STUDY (11)	Veraviewepocs® 3De	Upper jaw impacted canine	4 X 4	80	5	9.5	Continuous radiation
		Lower jaw molar	4 X 4	80	5	9.4	Continuous radiation
	NewTom® VGi	TMJ, bilateral	12 X 8	110	5.3	3.6	Pulsed radiation Normal resolution
		TMJ, unilateral	8 X 8	110	6.1	3.6	Pulsed radiation Normal resolution
		TMJ, unilateral	8 X 8	110	17.2	5.4	Pulsed radiation High resolution
	ProMax® 3D	Upper jaw impacted canine	4 X 5	84	10	12	Pulsed radiation

STUDY (III)	3D Accuitomo® 170	Mandible and maxilla	8 x 8	80	3	9	Protocol 1 - 180° rotation
				80	5	9	Protocol 2- 180° rotation
				80	9	9	Protocol 3- 180° rotation
				90	3	9	Protocol 4- 180° rotation
				90	5	9	Protocol 5- 180° rotation
				90	9	9	Protocol 6- 180° rotation
				80	3	17.5	Protocol 7- 360° rotation
				80	5	17.5	Protocol 8- 360° rotation
				80	9	17.5	Protocol 9- 360° rotation
				90	3	17.5	Protocol 10- 360° rotation
				90	5	17.5	Protocol 11- 360° rotation
				90	9	17.5	Protocol 12- 360° rotation
STUDY (IV)	3D Accuitomo® 170	Mandible and maxilla	8 x 8	80	3	17.5	
Panoramic units							
STUDY (I)	Veraviewepocs® 3De	Standard panorama	-	78	10	7.4	Level 3 of autoexposure used for adults Continuous exposure
	ProMax® 3D		-	66	9	16	Level 3 of autoexposure used for adults Pulsed exposure
	ProMax®		-	74	12	16	Continuous exposure

Periapical and bitewing radiography							
STUDY (IV)	Planmeca® ProX	-	-	60	7	0.125	ProSensor® Effective area 36 x 26.1 mm ² Pixel size 30 x 30 µm ²
	Kavo, Gendex® 765 DC	-	-	65	7	0.25 (PA) 0.125 (BW)	ProSensor® Effective area 36 x 26.1 mm ² Pixel size 30 x 30 µm ²
	Planmeca® Intra	-	-	60	8	0.160	Schick 33® Effective area 25.6 x 36 mm ² Pixel size 15 x 15 µm ²
	Sirona® HELIODENT DS	-	-	60	7	0.16	Sigma® CCD Pixel size 39 x 39 µm ²

Phantoms

The phantom for organ dose measurement used in STUDY II was a sliced RANDO® of a small adult skull surrounded by soft tissue-equivalent material. GafChromic® films were placed between four selected levels in the phantom for each radiographic technique to record the distribution of the absorbed radiation dose. For detailed information regarding placement of the films, see Table 2.

The SedentexCT IQ cylindrical phantom for objective image quality measurements was used in STUDY III. The phantom is 176mm in height and 160mm in diameter. We used four contrast resolution inserts with different materials (Table 2). The phantom was mounted on a rigid tripod and scanned once to take an image of each contrast resolution insert. The target inserts were placed at the periphery as the FOV is positioned more towards the periphery of the patient's head.

For assessments of subjective image quality in STUDY III the examination of the upper and lower jaw together (FOV 8 X 8 cm) was performed on a RANDO® adult skull phantom. The phantom was set on the phantom table of the unit and was centred with the

jaws in the imaging area and scanned once to obtain an image of each scanning protocol. Twelve scans were performed, 1 scan for each of the exposure scenarios in Table 2.

Table 2. Phantom’s type and name and inserts used in Study II and III

STUDY	Phantom type	Phantom name	Inserts	Place of insert	Notes
STUDY II	Phantom for organ dose measurement	RANDO® (Sliced phantom)	GafChromic film	Phantom levels 3-4-5-6	CBCT- Upper jaw impacted canine
				Phantom levels 5-6-7-8	CBCT- Lower jaw molar
				Phantom levels 4-5-6-7-8	CBCT- TMJ, bilateral
				Phantom levels 4-5-6-7-8	CBCT- TMJ, unilateral
				Phantom levels 4-5-6-7-8	CBCT- TMJ, unilateral
				Phantom levels 3-4-5-6	CBCT- Upper jaw impacted canine
				Phantom levels 5-6-7-8	Panorama
STUDY III	Objective image quality phantom	SedentexCT IQ cylindrical phantom (Leeds Test Objects Ltd, Boroughbridge, UK)	Aluminium (Al), Polytetrafluoroethylene (PTFE), Low density polyethylene (LDPE) Air	Phantom level 4 at periphery	
	Subjective image quality phantom	(RANDO®; The Phantom Laboratory, Salem, NY) Unsliced phantom	No insert		

Patient sample

In STUDY IV ten adolescents (mean age 13.4; range 12-17) were examined with CBCT of both the upper and lower jaws (16-26 and 36-46), PA radiography (12-22), and posterior BW radiography (16-26 and 36-46) during March 2016 and March 2017. Table 3 presents patients and teeth selected for measurements of root lengths. Table 4 presents patients and teeth selected for measurements of marginal bone level.

The subjects were enrolled in a prospective clinical trial of orthodontic treatment from two orthodontic clinics. The radiographic examination was part of the clinical trial and no additional radiographs were performed for the present study.

Table 3. Patient distribution and number of sites available for measurement of root lengths in CBCT and periapical radiography (PA) for each of six raters.

Patient no.	1 + 3 + 5 + 7 + 9						2 + 4 + 6 + 8 + 10					
Tooth	16	15	14	13	12	11	21	22	23	24	25	26
Root	P	DB										P MB
CBCT	5	5	5	5	5		5		5	5	5	5
PA					5	5	5	5				
CBCT	5	5	5		5		5		5	5	5	5
Root	M											D
Tooth	46	45	44	43	42	41	31	32	33	34	35	36
Patient no.	2 + 4 + 6 + 8 + 10						1 + 3 + 5 + 7 + 9					

P= palatal, DB= disto-buccal, MB=mesio-buccal D= distal, M= mesial

Table 4. Patient distribution and number of sites available for measurements of marginal bone level in CBCT, periapical (PA) and bitewing (BW) for each of six raters.

Patient no.	1 + 3 + 5 + 7 + 9						2 + 4 + 6 + 8 + 10					
Tooth	16	15	14	13	12	11	21	22	23	24	25	26
Root	P	DB									P	MB
CBCT	14	9	18	19	20		19		19	20	15	10
BW	10	10	10	5				5	10	10		10
PA					10	10	10	10				
BW	10	10	10	5				5	10	10		10
CBCT	15	20	20		19		20		20	20		15
Root	M											D
Tooth	46	45	44	43	42	41	31	32	33	34	35	36
Patient no.	2 + 4 + 6 + 8 + 10						1 + 3 + 5 + 7 + 9					

P= palatal, DB= disto-buccal, MB=mesio-buccal D= distal, M= mesial

Dose measurements

In STUDY II measurements were performed using GafChromic® XR-QA2 films that were scanned with a flatbed scanner. To be able to translate the blackening of the film to absorbed dose, the film has to be calibrated before dosimetric application. (For detailed information of calibration see STUDY II).

A piece of film that did not undergo any irradiations was scanned together with the other films and used for background subtraction. These images were read with Image J®, following background subtraction, and converted to black-and-white 8 bit images. The mean pixel values were measured in each film square using rectangular regions of interest (ROIs). The mean pixel values were used to construct a dose-response diagram. The equation of the dose-response curve was used for converting the net pixel value distributions found in the phantom measurements to the absorbed dose distribution.

After loading with GafChromic® XR-QA2 films, the phantom was exposed several times to provide a reliable measurement. Later, these values were divided by the number of exposures to provide one individual value for each region. For the skin (entrance) dose measurements, TLDs were used.

An Epson® Perfection 4990 PHOTO scanner was used. The Image J programme was used for converting the net pixel value distributions found in the phantom measurements to the absorbed dose distributions.

The mean absorbed dose to organs (parotid gland, oral mucosa, extra-thoracic airways, bone surfaces, red bone marrow, skin, brain and thyroid gland) and tissue types that were irradiated were estimated by superimposing ROIs on the dose distribution matrices and calculating the mean value inside each ROI. This was repeated for all film sheets in the phantom. The equivalent dose for an organ/tissue was calculated as the product of the mean absorbed dose to that organ/tissue and the fraction of that organ/tissue that was irradiated. The ED was then estimated as the sum of the organ/tissues' equivalent dose multiplied by their tissue-weighting factor according to the International Commission on Radiological Protection (ICRP) 2007 recommendations.

In STUDY III DAP values for all scanning protocols expressed in mGy.cm², were obtained by DAP meter. At the same time, the automatically calculated DAP values were recorded from the CBCT unit console. DAP values were obtained five times for each scanning protocol in order to evaluate the consistency of the unit performance.

Objective measurements of image quality

For measurements of the contrast-to-noise ratio (CNR) metric of image quality for the images of the IQ phantom in STUDY III, the images were transferred as DICOM files from the CBCT workstation computer to the Image J software. By using Image J® tools, a circular region of interest (ROI) was drawn inside the big rod of each insert and the same ROI was drawn for PMMA as a background. For each ROI, the mean grey value and standard deviation (SD) were measured in triplicate and the average was used for CNR calculation. CNR for each scanning protocol was calculated using the following formula:

$$CNR = \frac{(MPV(insert) - MPV(PMMA))}{\sqrt{(SD^2(insert) + SD^2(PMMA))/2}}$$

Where MPV is the mean pixel value and SD is the standard deviation.

Subjective measurements of image quality

In STUDY III and STUDY IV 22 CBCT volumes, (12 from phantom and 10 from patients) were stored in DICOM format, and prepared and assessed with i-Dixel® software on a workstation. A BARCO® 18.10 greyscale liquid crystal display monitor was used with a luminance of 400 cd/m² and resolution of 1280 X 1024 pixels. The illumination in the observation room was dim (below 50 lux as recommended by American Association of Physicists in Medicine Task Group 18) and kept constant (Samei et al., 2005). The reading distance was approximately 60 cm. There were no restrictions on observation time and zooming was allowed.

In order to achieve standardised comparisons in STUDY III, reformatted images were pre-prepared by the researcher in charge of the project and these images were assessed in random order to avoid potential bias. To get the same anatomical section, an adjustment of the xyz images of all protocols according to the same level was performed. Following this, the centre of each tooth in the axial view was marked to create a curved multiplanar reformation, which includes oblique, curved planar reformation (distortion-free panoramic images), and serial transplanar reformation (providing cross-sections).

The visibility of three dental anatomical landmarks was assessed by five raters using visual grade analysis with all images graded separately within each protocol. The following landmarks were assessed: the apical third of periodontal space (ATPS), the cemento-enamel junction (CEJ), and the marginal bone crest (MBC) of all upper right and lower left quadrant teeth, 17–11 and 37–31, respectively. For multirooted teeth in the upper jaw, the palatal roots were chosen; for multi-rooted teeth in the lower jaw, the distal root was chosen. Altogether, 168 sites for assessment were available in each protocol (14 teeth x 3 anatomical landmarks x 4 sites). A three-point rating scale (0 = hardly visible, 1 = partly visible and 2 = well visible) was used to assess the visibility. In addition, the raters measured the distance between the CEJ and MBC at all sites. Grading of landmarks and measurements were performed using panoramic reformatted images for mesial and distal sites and using multiplanar reformatted (sagittal plane) images for buccal and palatal/lingual bone sites. All images were evaluated at 1-mm slice thickness. Prior to the first session of observation, all raters attended a training session. The aim was to familiarise the

raters with the imaging display software and scoring scale. At the first observation session, all the included images were read. In order to calculate intra-observer agreement, a second observation session was held for a random selection of teeth (21%). This session was held more than 3 weeks after the first session in order to minimise reader recall bias.

In STUDY IV selection of CBCT images was performed by a radiologist with experience of CBCT scans using i-Dixel® software. The collection of intraoral radiographs was selected by one of the authors (AA) from available images from the same patients as the CBCT images had been obtained. After linear measurement calibration the measurements were derived using Image J® software by six raters.

Prior to performing the measurements all raters attended a 10-minute educational presentation given by the main author showing examples of root lengths and marginal bone levels measurement procedure on intraoral and CBCT images. During the session, the raters were given examples of a procedure similar to what they were expected to measure in the study sample. The aim was to familiarise the readers with the Image J® software and measurement procedure. Among available sites the raters identified, step by step, the sites possible to measure and carried out the measurement. All measurements were recorded in millimeters and were rounded to one decimal place. The patient information was masked from all images.

The following definitions were used for the measurements:

- Root length: distance between the mid-point between the cemento-enamel junction (CEJ) and root apex,
- Marginal bone level: distance between CEJ and alveolar bone crest (ABC).

In order to calculate intra-rater reliability, a second session was made for a representative selection of sites in CBCT images (48% of sites available and measured in the first session), all sites measured by all raters in the first session by all raters in PA and BW (PA 73% and BW 51% of sites available in the first session). The replicate measurements were performed by three raters (2 dental and maxillofacial radiologists and 1 orthodontist). First session of measurement was performed over 9 weeks, second session was held more than 3 weeks after the first session in order to minimise rater recall bias.

Data analyses

In STUDY III inter- and intra-rater agreement of subjective image quality assessment was calculated by using the kappa (k) test as described by Altman (Altman, 1991). Levels of agreement on k values were interpreted as suggested by Altman: $k = 0.81$ – 1.00 , excellent; $k = 0.61$ – 0.80 , good; $k = 0.41$ – 0.60 , moderate; $k = 0.20$ – 0.40 , fair; $k < 0.20$, poor.

Evaluation of subjective image quality was based on calculations of observations where all included observers had given a grade of 1 or 2 on the visual grade analysis scale for all assessments of an anatomical landmark. Assessments where a grade of 0 was given for any site by any observer were excluded.

In the next step, the same calculation was made for each protocol and landmark, where the subjective image quality was scored in percentage. The threshold for acceptable (optimal) image quality was thereafter determined by excluding all images assessed below the half-value of the highest image quality scoring for all anatomical landmarks in all tooth aspects (mesial, distal, buccal and lingual/palatal) together, taking all observer assessments into account.

Binary logistic regression analysis was performed to evaluate the CNR values from each test insert material from each scanning protocol to determine which, if any, was more related to acceptable (optimal) subjective image quality. Optimisation was based on the relation between objective and subjective image quality with exposure level (DAP value) taken into consideration.

Inter-measurement agreement for the five observer measurements of the distance between CEJ and MBC was calculated using intra-class correlation coefficient (ICC 2.1). The ICC value was interpreted according to Landis and Koch (Landis & Koch, 1977) as ICC < 0.20 = slight agreement, ICC 0.21 – 0.40 = fair agreement, ICC 0.41 – 0.60 = moderate agreement, ICC 0.61 – 0.80 = substantial agreement and ICC 0.81 – 1.0 = almost perfect agreement.

All statistical analyses were performed using IBM SPSS® Statistics v. 22.0.

In STUDY IV all results were collected in a computer database for statistical analysis. When analysing the reliability of each method we used the intra-class correlation coefficient (ICC 2.1) with 95% confidence intervals (CI). All statistical analyses were performed using IBM SPSS® Statistics v. 22.0.

RESULTS

Systematic review – STUDY I

Study selection

The number of records identified, excluded, and included are shown in Figure 2. After a review of titles/abstracts, 674 were found to not meet the inclusion criteria. The full text of the remaining 67 publications was examined, and 38 of these met the inclusion criteria. The majority of the included studies were published from 2008 onwards. Most studies were published in 2008 and 2012.

Methods and scanning protocols used to measure and estimate radiation dosages

The methods used to measure radiation dosages varied across the studies. The following methods were used: thermoluminescent dosimeter (TLD) 100 (25 studies), TLD-100H (8 studies), optically stimulated luminescence dosimeter (OSLD) (2 studies), radiochromic film (2 studies), ionisation chamber (2 studies), magnesium orthosilicate doped with terbium ($\text{Mg}_2\text{SiO}_4\text{:Tb}$; TLD-MSO-S) (1 study), lithium borate ($\text{Li}_2\text{B}_4\text{O}_7$)-TLD (1 study) and photoluminescence glass (1 study).

Also, the type of phantom, the number of slices, dosimeters and exposures of each dosimeter varied across studies. In most studies, a commercially available anthropomorphic phantom including an adult male skull was used. A phantom that included a female skull was examined in three studies and a paediatric phantom (corresponding to a 10 years of age) in two studies. In two studies the phantom was developed at the institution (University of Göttingen, Göttingen, Germany) where the study was performed. Only in one study (Ludlow & Walker, 2013) was the phantom repositioning between scans

described in enough detail to ascertain reproducibility. The method for distribution of dosimeters as described by Ludlow et al. (2006) was applied in most studies. The number of phantom slices ranged between 7 and 10 and the number of TLDs was about 24 in most studies. The number of exposures of dosimeters ranged between 1 and 10, except for 1 study that used 34 exposures (Okano et al., 2009). In seven studies there was no information about the number of TLDs, and in one-third of the studies there was no information supplied about the number of exposures of dosimeters.

Complete technical specifications of the CBCT unit were only provided in one study (Ludlow & Walker 2013). Supplementary information, such as the degree of rotation or trajectory arc, filtration and detector specifications, was to some extent available on the manufacturers' websites. *(For detailed information of the above see Table 2, study I.)*

Figure 2. Flow chart according to the preferred reporting items for systematic reviews (PRISMA) statement presenting the study selection process with number of publications identified, excluded, and included for systematic review of effective dose of cone beam CT (CBCT) of the facial skeleton.

What are the effective doses of cone beam CT examinations of the facial skeleton?

As presented in Figure 3, effective dose was influenced by the height of the FOV. The reduction of the median effective dose of FOVs with height 5.1–10.0 cm compared with that of FOVs with height >10 cm was 38%. The reduction of the median effective dose of FOVs with height ≤ 5 cm compared with that of FOVs with height 5.1–10.0 cm was 59%. There was a wide range between the highest and lowest doses of each FOV height (Figure 3).

As presented in Figure 4, there was a variation in reported dose estimates for the same CBCT unit with the same FOV dimensions.

Effective dose was related to image quality in six studies expressed as objective image quality or subjective image quality. As presented in (Table 2, study 1), the effective dose of CBCT was compared with those of other imaging modalities in eight studies. Eight studies presented risk estimations and did so mainly as comparisons with background radiation.

Figure 3. Box-and-Whisker diagram of effective doses (μSv) of CBCT-units with three heights of fields of view (FOV).

Figure 4. Effective doses (μSv) of different versions of the same cone beam CT unit with the field of view of $8 \times 8 \text{ cm}^2$ presented in studies published 2008–13.

Dose measurement

The absorbed organ doses and effective doses for medium FOV (TMJ) protocols in STUDY II are shown in Table 5. The effective dose ranged between $45 \mu\text{Sv}$ and $129 \mu\text{Sv}$. The highest absorbed dose was in the parotid salivary gland. The effective dose of the examination with high resolution was nearly three times as high as that for normal resolution with the same FOV ($8 \times 8 \text{ cm}$). Table 6 also shows the results for the small FOV protocols. The effective dose ranged between $10 \mu\text{Sv}$ and $22 \mu\text{Sv}$.

The dosimetric results of panoramic imaging are shown in Table 5. Effective doses ranged between $8 \mu\text{Sv}$ and $14 \mu\text{Sv}$. The unit with the highest effective dose was the ProMax using a PSP as a receptor; the unit with the lowest effective dose was the ProMax 3D.

As seen in Table 5, the mean measured DAP values in STUDY III were 268.0 mGy cm^2 (SD 52.03) for the lowest exposure parameter setting (Protocol 1) and 1935.8 mGy cm^2 (SD 526.99) for the

Table 5. Absorbed organ dose (mGy) and effective dose (mSv) for CBCT and panoramic scan protocols (STUDY II)
And Dose-area product (DAP) values measured in mGy cm² for CBCT (STUDY III)

Study	Unit's name	Region of interest	FOV Width X height cm	Organ absorbed dose (mGy)							Effective dose (μSv)	Dose are product (DAP) (mGy.cm ²)		Protocol no.	
				Parotid glands	Oral muco- sa + extra- thoracic airways	Brain	Bone surfaces	Red bone marrow	Skin	Thyroid		Measured DAP	Calculated DAP		
(II)	Veraviewepocs® 3De	Upper ca- nine	4 X 4	1.890	0.120	0.001	CBCT scanners				21	-	-		
		Lower molar	4 X 4	0.900	0.600	NS	0.108	0.036	0.015	0.050	-	-			
		Two TMJ	12 X 8	2.400	2.300	0.230	0.122	0.048	0.074	0.020	-	-			
	NewTom® VGi	One TMJ	8 X 8	2.130	1.800	0.150	0.102	0.040	0.062	0.020	-	-			
		One TMJ	8 X 8	5.200	5.200	0.420	0.306	0.120	0.186	0.040	12.9	-			
		Upper ca- nine	4 X 5	0.840	0.070	0.001	0.040	NS	0.012	0.001	10	-	-		
	3D Accuitomo® 170	Mandible and maxilla	-	-	-	-	-	-	-	-	-	268.0 ± 2.03	308		1
-			-	-	-	-	-	-	-	-	-	444.8 ± 1.16	510	2	
-			-	-	-	-	-	-	-	-	-	768.0 ± 9.38	914	3	
-			-	-	-	-	-	-	-	-	-	342.0 ± 3.20	407	4	
-			-	-	-	-	-	-	-	-	-	563.4 ± 5.46	673	5	
-			-	-	-	-	-	-	-	-	-	983.4 ± 17.04	1210	6	
-			-	-	-	-	-	-	-	-	-	526.0 ± 5.23	599	7	
(III)	Veraviewepocs® 3De	Standard panorama	-	-	-	-	-	-	-	-	-	853.6 ± 13.18	992	8	
			-	-	-	-	-	-	-	-	-	-	1505.6 ± 22.6	1780	9
			-	-	-	-	-	-	-	-	-	-	664.4 ± 11.21	791	10
			-	-	-	-	-	-	-	-	-	-	1097.8 ± 15.87	130	11
			-	-	-	-	-	-	-	-	-	-	1935.8 ± 26.99	2350	12
			Panoramic units										-	-	-
			0.017										-	-	-
(II)	Veraviewepocs® 3De	Standard panorama	-	0.700	0.240	0.002	0.017	0.005	0.001	0.020	11	-	-		
			-	0.650	0.156	0.001	0.009	0.003	0.001	0.013	8	-	-		
			-	1.000	0.240	0.002	0.014	0.004	0.001	0.020	14	-	-		

highest exposure parameter setting (Protocol 12). Compared with the calculated DAP values that were recorded from the unit console, the unit tended to overestimate DAP values ranging from a minimum of 12% to a maximum of 17% depending on exposure scanning parameters.

Objective measurement of image quality

With increased mAs in STUDY III, CNR was improved. The CNR improvement of different inserts in the SEDNTEXCT phantom is associated with an increase in the radiation dose. When using the same exposure parameters, the 360° scan has a higher CNR than the 180° scan (Figure 5).

Subjective assessment of image quality

STUDY III

The scoring of image quality for different scanning protocols is seen in Figure 5. The scoring of image quality essentially depends on the anatomical landmarks. There is no standard scanning protocol that is optimal for all anatomical landmarks.

Rater agreement

Inter-rater agreement for scoring subjective image quality varied between $k = 0.11$ and $k = 0.32$ when taking all anatomical landmarks into account. The agreement principally depends on the anatomical landmark and tooth aspect. Higher values of agreement were seen when assessing the CEJ on the distal aspect of teeth.

Kappa values for intra-rater agreement were moderate for rating the images ($k = 0.44$ – 0.51).

ICC for measurements between CEJ and MBC for all observers were 0.52 mesially [95% confidence interval (CI) 0.12–0.78], 0.57 distally (95% CI 0.16–0.81), 0.85 buccally (95% CI 0.76–0.90) and 0.95 in lingual/palatal bone sites (95% CI 0.90–0.97).

Subjective and objective image quality relationship

Logistic regression performed to measure the relationship among the CNRs for each of the test insert materials and optimal image quality showed that there was a very high correlation between the four different inserts. This means that there was a statistically significant relationship between all inserts and optimal image quality ($p = 0.951-1$). An examination of the CNR values and optimal image quality in Figure 5 showed that the optimal image quality was obtained with a CNR of Protocols 2, 3, 6, 12, 8 and 11 in ascending order.

Optimisation

When taking into consideration the protocols resulting in overall optimal subjective image quality (Protocol number 2, 3, 8, 6, 11 and 12) together with the CNR values of all inserts, it was concluded that Protocols 3, 8 and 11 had the highest overall scoring with regards to image quality (Figure 5). We decided to exclude Protocol 3, as this protocol displayed lower image quality assessment scores for some landmarks than Protocols 8 and 11 did. After consulting the two radiologists and one medical physicist, we selected Protocol 8 (80 kV/5 mA/360° or 17.5 s) as the optimised protocol for this diagnostic task. The main objective was not to achieve the highest CNR values but rather to keep the radiation dose as low as possible as there was only a slight difference in CNR values between Protocol 8 and Protocol 11.

Protocol no.	1	4	2	7	5	10	3	8	6	11	9	12
mA	3	3	5	3	5	3	9	5	9	5	9	9
mAs	27	27	45	52.5	45	52.5	81	87.5	81	87.5	157.5	157.5
kV	80	90	80	80	90	90	80	80	90	90	80	90

Figure 5. Dose–area product (DAP), contrast-to-noise ratio (CNR) and scoring image quality in the percentage of different scanning protocols. Scanning protocols have been reordered according to DAP values. Al, al minium; ATPS, apical third of periodontal space; CEJ, cementoenamel junction; LDPE, low-density polyethylene; MBC, marginal bone crest; PTFE, polytetrafluoroethylene.

STUDY IV

Measurability

Ten patients were recruited. For the first measurement session, the number of measured sites varied among the imaging methods, the raters, and the item measured (root length/marginal bone level). With regards to root length 600 sites were available for measurement in CBCT images and 120 sites in PA images. In CBCT images all sites for root length measurements were measured by all raters and all but one root in a PA radiograph. For marginal bone level measurements 2,112 sites were available in CBCT mages, 840 in BW images and 240 in PA images. Taking all observers into account, all sites were measured by all observers in CBCT images and with regards to BW images, 719 sites were measured; the corresponding number for PA images were 189 sites (Table 6).

Rater reliability

ICC of CBCT measurements of *root length* for all raters was 0.88 (CI 0.85 - 0.98) (Figure 6). Depending on which tooth was measured in CBCT, ICC ranged between 0.27 and 0.96, being the highest for mandibular left second premolars and the lowest for maxillary right cuspids (Figure 7). ICCs of teeth 11 and 22 in CBCT were 0.88 (CI 0.67 – 0.98) and 0.76 (CI 0.45 – 0.97), respectively. The corresponding ICCs for PA were 0.64 (CI 0.28 – 0.94) and 0.68 (CI 0.35 – 0.95) (Figure 4). Pairwise inter-rater reliability ICCs for root length measurements of all measured teeth in CBCT were above 0.85 (range 0.85 - 0.91) and below 0.84 (range 0.44 - 0.84) in PA for maxillary anterior teeth (Figure 8).

Table 6. Number of available and measured sites in CBCT, periapical (PA) and bitewing (BW) radiographs for measurements of root lengths and marginal bone level for each rater.

Rater	Root lengths				Marginal bone level						
	CBCT			PA		CBCT		PA		BW	
	Available sites	Measured sites	Available sites	Available sites	Meased sites	Available sites	Measured sites	Available sites	Measured sites	Available sites	Measured sites
1	100	100	20	19	352	352	40	28	140	115	
2	100	100	20	20	352	352	40	31	140	124	
3	100	100	20	20	352	352	40	31	140	122	
4	100	100	20	20	352	352	40	27	140	118	
5	100	100	20	20	352	352	40	38	140	120	
6	100	100	20	20	352	352	40	34	140	120	
Total	600	600	120	119	2112	2112	240	189	840	719

Figure 6. Inter-rater reliability expressed as intra-class correlation coefficient with confidence interval for the measurements of root lengths and marginal bone level in CBCT, periapical radiography (PA) [for maxillary incisors] and bitewing radiography (BW) [for premolars and molars].

P= palatal, DB= disto-buccal, MB=mesio-buccal D= distal, M= mesial

Figure 7. Inter-rater reliability expressed as intra-class correlation coefficient and confidence intervals for measurements of root lengths in CBCT and in periapical radiography (PA) [for 11, 22].

Figure 8. Pairwise inter-rater reliability expressed as intra-class correlation coefficient with confidence intervals for measurements of root lengths and marginal bone level in CBCT, periapical radiography (PA) [for maxillary incisors] and bitewing radiography (BW) [for premolars and molars].

Intra-rater reliability ICC for each of the three raters varied depending on imaging method (Figure 9). For measurements in CBCT of selected teeth, ICC was the highest ranging with numbers between 0.82 and 0.92. ICC ranged between 0.47 and 0.84 for measurements of upper anterior incisors in PA. For measurements in CBCT of 11 and 22, ICC was 0.72 and 0.94, respectively. Corresponding ICC for measurements in PA ranged between 0.38 and 0.94.

Figure 9. Intra-rater reliability expressed as intra-class correlation coefficient with confidence intervals for measurements of root lengths and marginal bone level in CBCT, periapical radiography (PA) [for maxillary incisors] and bitewing radiography (BW) [for premolars and molars].

With regards to *marginal bone level measurements* in CBCT, ICC was 0.4 (CI 0.32 - 0.47) for all raters (Figure 6). For measurements of upper anterior incisor in PA, ICC was 0.38 (CI 0.19 – 0.6) and 0.4 (CI 0.25 - 0.55) for measurements in BW images (Figure 2). Figure 4 presents pairwise ICCs for the measurements using the different methods. For CBCT, ICCs were below 0.68 (range 0.34-0.68). For PA of upper anterior incisors ICCs were below 0.66 (range 0.12- 0.66) and for BW images they were below 0.66 (range 0.2-0.66).

Intra-rater reliability for ICC varied depending on imaging method and among the three raters (Figure 9). For measurements in CBCT, ICC was comparable for the three raters, ranging between 0.56 and 0.57. For measurements of level of upper anterior incisors in PA, ICC ranged between 0.3 and 0.62 and in BW there was a wide range for ICC of between 0.35 and 0.8.

DISCUSSION

Main results

The systematic review in STUDY I revealed that key methodological details of radiation dose measurement methods and scanning protocols were missing in studies on estimation of effective dose of CBCT examinations of the facial skeleton.

STUDY II demonstrated the feasibility of using radiochromic films for dental CBCT and panoramic dosimetry. The results should be interpreted with care owing to the complex relationship between image quality, size of the scanned volume, and absorbed dose to different tissues. The main purpose of this study was to test GafChromic® film dosimetry rather than to compare the clinical performance of investigated panoramic and CBCT scanners.

In STUDY III, we performed dosimetry, objective measurements, and subjective assessment of image quality, all on the same material and the same machine. This study contributes to the field of dose optimisation for dental CBCT.

As shown in STUDY IV CBCT presents high measurability, high reliability for root length measurements among six raters and for repeated measurements by the same rater.

Systematic review

Narrative reviews have been criticised as they tend to use unsystematic and subjective ways in which to extract, analyse, and interpret data that can be problematic because of the lack of reporting guidelines and other types of biases (Mulrow, 1987). According to the Cochrane Collaboration, a systematic review is defined as “a review of the evidence on a clearly formulated question that uses systematic and

explicit methods to identify, select and critically appraise relevant primary research, and to extract and analyze data from the studies that are included in the review” (Higgins et al., 2008). Because of their systematic structure, both systematic reviews and meta-analyses have been ranked as the “highest level of evidence” (Greenhalgh, 2010).

It has, however, been reported (Moher et al., 2007) that the quality is somewhat varied and the reporting is insufficient in systematic reviews in general. Systematic reviews in the field of radiology are not an exception from this general rule (Tunis et al., 2013). To overcome this problem, the literature review (STUDY I) was conducted in accordance with the preferred reporting items for systematic reviews (PRISMA) Statement (Moher et al., 2009) and the guidance of the Centre for Reviews and Dissemination for undertaking reviews in healthcare (Akers et al., 2009). We did not, however, implement any quality evaluation, as there is no validated tool for these types of publications, as is the case for quality evaluation of diagnostic studies. If the model proposed in Figure 1 had been used as a quality tool all but one study would have been excluded, as technical data of the CBCT scanners was insufficiently described and reported.

A few systematic reviews have been published aiming to answer questions regarding radiation dose of dental CBCT in general (De Vos et al., 2009; Lorenzoni et al., 2012; European Commission, 2012; Ludlow et al., 2015), but none has been published regarding the methods and scanning protocol used during measuring and estimation of radiation dosage.

Effective dose (ED) and dose measurements

In general, radiation dose measurement is a principal tool for optimisation. Depending on the X-ray modalities, there are many dose quantities used to measure patient radiation dose (IAEA, 2011). The ED is one of the most commonly used dose quantities. There are a number of ways to estimate the ED. All of them include assumptions, which result in limitations and uncertainties (Thilander-Klang & Helmort, 2010).

The ED corresponds to the risk that a uniformly distributed dose with the same value in the whole body would represent. It gives a general indication of the level of risk for the X-ray examination in question. It takes into account different organs’ sensitivities to induction of severe late effects and is the preferred quantity for

comparing the detrimental effects from different exposure situations to large populations (ICRP, 2007).

ED of small FOVs that is estimated by using TLDs and a phantom largely depends on the position of the phantom inside the CBCT scanner. Any change in vertical position will influence the organ absorbed dose and ED. Using the same small FOV, the ED of the lower jaw is higher than that of the upper jaw. This is mainly due to the higher equivalent dose for the thyroid gland involved in the lower jaw scan (Rottke et al., 2013; Al-Okshi et al., 2013; Pauwels et al., 2012; Schilling & Geibel, 2013). A 10° inclination of the Frankfurt plane results in a 92% difference in measured dose for the thyroid surface (Ludlow, 2009). This highlights the importance of thyroid shields and careful positioning of the FOV.

By using 14 CBCT scanners with recommended exposure parameters from the manufactures, Pauwels et al. (Pauwels et al., 2012) estimated the ED of these scanners. The ED dose range was found to be between 19 µSv and 368 µSv. Rottke et al. (Rottke et al., 2013) estimated the ED of 10 CBCT scanners with the lowest and highest exposure parameters for each scanner. With similar results the ED dose range was found to be between 17.2 µSv and 396 µSv. In both studies, the ED values were mainly dependent on the size and position of FOV.

The EDs of the ProMax® 3D-CBCT estimated in our study (STUDY II) were lower than those previously reported (European commission, 2012; Ludlow & Ivanovic, 2008; Pauwels et al., 2012). However, the main explanation for the lower measured doses is likely to be the increase in copper filtration of the X-ray beam and the difference in FOV. The study by Ludlow and Ivanovic (Ludlow & Ivanovic, 2008) was based on an early version of the ProMax® 3D-CBCT unit. In the beginning of 2008 those units were equipped with an additional 0.5mm of copper filtration to reduce the dose.

We also found that the ED for Veraviewepocs® 3De-CBCT (21 µSv) was higher than that for the ProMax® 3D-CBCT (10 µSv) for the upper jaw using a small FOV. Again, the most likely explanation for this is probably an increase in the copper filtration of the X-ray beam for the ProMax® 3D unit and a short exposure time of 2.8–8.3 s, combined with a pulsed output. The ProMax® 3D unit used was an upgraded unit of the version that was manufactured in 2011.

From the results (STUDY II), the effect of FOV positioning can be observed. Comparing an upper jaw canine region with a lower jaw molar region scan from the Veraviewepocs® 3De-CBCT, it is clear that there were large differences regarding the absorbed dose for the parotid salivary glands and oral mucosa. The dose to the thyroid was very low because it was outside the primary beam for all protocols. The NewTom® VGi provides two levels of resolution of the same FOV (8 X 8 cm²), high and normal. When the high resolution was selected, the calculated ED was 129 µSv. If the normal resolution is chosen, the ED can be reduced to about 35% of that with high resolution.

We measured (STUDY II) the absorbed dose during panoramic exposure with three digital panoramic units equipped with different detectors. EDs ranged between 8 µSv and 14 µSv. When PSP, CCD, and FPD units were compared, the ED of the panoramic unit using the PSP receptor (14 µSv) was higher than those of the CCD and FPD units (8–11 µSv). When the exposure settings are considered the panoramic machine (ProMax®) with the highest dose uses 74 kV, the highest tube current (12 mA), and the longest exposure time (16 s). The ProMax® 3D-panoramic, yielding the lowest dose, operates at the low tube current (9 mA). Differences in the doses measured depended not only on the tube potential, mA, and filter but also on the actual exposure time, i.e. if the X-rays are continuous or pulse. The size of the radiation field also plays a significant role. Ludlow et al. (Ludlow et al., 2008) evaluated a ProMax® (CCD based) panoramic machine operated at 68 kV and 13 mA with a 16 s exposure time and found an ED of 24.3 µSv using the ICRP 2007 tissue weights. In our study, an effective dose of 14 µSv was found. Difference in the type of dosimeter, variation in exposure settings and phantom composition and position can account for these differences.

One known factor influencing ED is the dimension of the FOV. If all other factors affecting the dose remain constant, a larger FOV results in a higher dose. The dose range for the same FOV height was wide (STUDY I), which is in line with the results presented in another review (Bornstein et al., 2014) and the overlap for different FOV heights indicates that several factors influence the ED. This was further highlighted in our synthesis of the results of six studies of the same CBCT scanner with the same FOV dimensions (STUDY I). The positioning of FOV with heights ≤10 cm was shown to influence

dose in the way that exposure of the posterior part of the lower jaw resulted in higher effective dose than the anterior part of the upper jaw did. This is because salivary gland and thyroid tissues receive little exposure when the FOV is centred on the anterior upper jaw.

Implication for patient care

■ *Results on ED of different diagnostic tasks and CBCT brands are available and can guide clinicians when selecting scanning parameters and to communicate with the patients. (STUDY I & II)*

Thermoluminescent dosimeters (TLD)

Most studies of dose distribution measurements in dental and maxillofacial radiography are based on TLDs. This was also the case for CBCT studies.

In our systematic review (STUDY I) TLD-100 was used in most studies. This is probably owing to the fact that TLD-100 is not only used in the field of dosimetry but also for monitoring personnel radiation doses, which means that the method is a well-established clinical routine. The main advantages of the TLD-100 are good sample-to-sample uniformity, almost tissue-equivalent, and simple calibration procedures using common radionuclide sources. According to Al Najjar et al. (Al Najjar et al., 2013) TLDs may be less accurate in the lower dose range than OSLDs, which were used in two recent studies (Ludlow & Walker, 2013; Lukat et al., 2013). The results of the study by Ludlow and Walker (Ludlow & Walker, 2013) showed, however, that TLDs and OSLDs yielded differences of <2% in the calculation of ED in CBCT.

Position and number of TLDs, skull size and type (actual skull or not), and the shape of soft tissue simulating material of the phantom play an important role in measurement of organ absorbed dose by this method.

TLDs have the advantage of being quite sensitive and can measure the absorbed dose down to at least 0.5 mGy with sufficient accuracy. However, they also have some major drawbacks:

- They must be handled with extreme care and the whole dose measuring procedure, including calibration, is very time consuming.

- Their energy dependence in the diagnostic energy range will result in their response being dependent on the amount of scatter at the measurement point. As the amount of scatter varies within a dosimetric phantom, the uncertainty of the dose values will increase.
- The dosimeters are $3 \times 3 \times 1 \text{ mm}^3$. In an irradiation geometry where the dose gradients are as steep as 25% per mm, it is obvious that the positioning of the radiation field in relation to the dosimeters can significantly affect the dose values measured. There are no standards regarding the number and the distribution of measuring points.

In rotating irradiation geometry with collimated radiation fields, the dose distribution will show more or less steep dose gradients. This is a major problem if you want to map or sample the dose distribution with a reasonable degree of accuracy.

Different types of dosimetry phantoms have been used with TLDs, e.g. RANDO® phantom (Rottke et al., 2013; Davies et al., 2012; Rampdo et al., 2014; Librizzi et al., 2011; Palomo et al., 2008; Ludlow & Ivanovic, 2008), Alderson Radiation Therapy phantom (ART) (Kim et al., 2014; Schilling & Geibel, 2013; Jeong et al., 2012, Qu et al., 2010; Pauwels et al., 2012) and CIRS ATOM® (Theodorakou et al., 2012; Ludlow & Walker, 2013). Most of these phantoms are transected horizontally into slices. They vary in size, location of TLDs and simulation-constructive materials.

The nature and size of the phantom (used with TLDs), the number of sections, and the position and extension of the organs inside the phantom varied across the studies of CBCT. In most studies of CBCT, an adult RANDO® phantom was used but the attenuation varies as each RANDO® phantom is constructed around a real human skull or synthetic bone material. Some studies use a paediatric phantom corresponding to patients aged 10 years (Theodorakou et al., 2012; Ludlow & Walker, 2013). This is notable as CBCT is increasingly replacing two-dimensional imaging modalities, such as cephalometry and panoramic radiography, in adolescents aged 10–18 years undergoing orthodontic treatment (Alqerban et al., 2009; Hidalgo-Rivas et al., 2014). As the justification for giving an increased dose to this young patient group is unclear, there is an urgent need to estimate EDs in relation to diagnostic tasks when examining these patients.

Radiochromic film

Recent studies have shown that it is possible to use ordinary office flatbed document scanners for radiochromic film scanning (Boivin et al., 2011; Thomas et al., 2003) . The film response depends on the film type, batch number, and scanning parameters. As for any radiation dosimetry system, uncertainties exist (Devic, 2011).

In STUDY II, the attenuation of the film was determined experimentally and was found to be two times higher than that of the soft tissue. Thus, the film thickness of 25 mm corresponds to 50 mm of soft tissue, which is negligible for the dose measurement geometry. However, the dose measurement can be affected if the central beam of the X-ray field coincides with the film plane. Here, there are primary photon paths directed along the film plane, which will lead to underestimation of the absorbed dose because of the higher attenuation in the film. We experimentally determined the underestimation to be in the of 10%. This will, however, only occur if the central axis of the radiation field coincides with the film plane. We have deliberately avoided this in all measurement situations.

As is the case for every dosimetry system, during the process of converting the measured dosimeter response (netOD in the case of film) into dose, there are many sources of uncertainties (Fig 10) (Devic, 2011).

Figure 10. Sources of uncertainties of GafChromic® film dosimetry system.

Dose Area Product (DAP)

In STUDY III, radiation doses were measured in terms of DAP, as it is practicable means of representing patient dose. Furthermore, DAP has been recommended for establishing achievable doses or diagnostic reference levels when established and relates reasonably well with ED (European commission, 2012; Holroyd & Walker, 2010). Even though the central point of the scan is not always in the centre of the clinical ROI and patient dose measurements could be both underestimated and overestimated, DAP can be used to assess dose reduction strategies and compare the results from different CBCT units (Lofthag-Hansen, 2010, Goulston et al., 2016).

In the literature, conversion coefficients for the estimation of EDs in 2D dental radiology are reported (Looe et al., 2008), and CBCT (Kim et al., 2014) from DAP values. However, in a review article it was stated that the reliability of DAP for risk estimation can be questioned (Ludlow et al., 2015). In the study in question a 7.5-fold range in the ratio of ED/DAP values was calculated from the adult

head phantom data encompassing a large number of measurements on CBCT scanners of different beam energies.

A reduction of kV (STUDY III) from 90 kV to 80 kV of the same mAs reduced mean DAP values (20–22%). The 180° rotation angle scan provided a significant reduction (50%) in the radiation dose compared with the 360° rotation angle scan of the same kV and mA. A substantial reduction (82%) in DAP value can be achieved by combining rotation angle and kV (27mAs or 52.5mAs instead of 81mAs or 157.5mAs).

The DAP values (STUDY III) indicated by the CBCT unit consoles were overestimated by 12–17% when compared with measured values. This can be explained by the fact that the values indicated by the CBCT unit consoles are determined computationally, based on X-ray tube output and field size settings. Therefore, calibration of CBCT unit DAP systems is important for a reliable analysis of diagnostic reference levels. Another explanation could be that the output of the machine is incorrect and that the stated peak tube potential is less than the actual unit peak tube potential.

Implication for patient care

■ *The proposed scanning protocol in study (III) improved image quality at low tube voltage (80-kV) and this may be an effective strategy for reducing patient radiation dose for periodontal CBCT examinations. (STUDY III)*

■ *The proposed scanning protocol can be used in other institutions to guide their optimisation process for the same diagnostic task. (STUDY III)*

Dose optimization

The guiding principles of radiation protection for patients and workers recommended by ICRP (ICRP, 2007) are:

1. Justification: the radiological examination of patients must be clinically indicated, and should do more good more than harm.
2. Optimisation of protection: the radiological examination must be performed with doses that are As Low As Diagnostically Acceptable (ALADA), consistent with clinical purposes, taking

into account economic and societal factors. An appropriate justification and optimisation is to a great extent dependent on the X-ray modality used and the diagnostic task.

3. Dose limitation: dose limits are applicable for workers (radiologists and technologists) and for the public.

Dose reference levels (DRLs) have been used to promote optimisation and have shown good results, particularly for medical CT. For CBCT, the DRL was not practical due to the wide range of doses collected from different CBCT scanners with different FOVs (Holroyd & Walker, 2010). A DAP value of 250 mGycm² for the placement of an upper first molar implant of an adult has been established as an achievable dose and a potential DRL (European commission, 2012). Other than this there are no DRLs found in the literature for CBCT. Because there is a dramatical increase in the use of CBCT and different CBCT scanners, it is highly recommended to establish DRLs for different diagnostic task.

From an optimisation point of view, the FOV is the most important exposure factor affecting patient dose (exposed area) and image quality (scatter radiation amount). In the case of CBCT with manual selection of kV and mAs, the adjustment of kV-mAs according to the patient's size and diagnostic task is highly recommended for dose optimisation.

Image quality

Even though studies have been performed on reducing exposure factors without loss of adequate image quality for different diagnostic tasks, few studies and limited data are currently available on both physical factors (objective) and subjective image quality related to the radiation dose of CBCT (Lofthag-Hansen, 2010; Bamba et al., 2013; Al-Okshi et al., 2015).

Objective image quality

There are different types of physical phantoms used for dental and maxillofacial CBCT objective image quality assessment (Loubele et al., 2008b; Suomalainen et al., 2009, Watanabe et al., 2011).

In comparison to CT, Cohnen et al. (Cohnen et al., 2002) assessed the image quality of CBCT NewTom® 9000 as mean image noise by

using a non-commercial program, and concluded that image noise was similar in both modalities. Faccioli et al. (Faccioli et al., 2009) used an AAPM CT performance phantom to estimate CBCT and MSCT image quality as high and low contrast resolution, uniformity, and noise and concluded that CBCT provide a lower level of image quality but still sufficient for diagnostic task with the advantages of lower radiation compared to MSCT.

For four different CBCT scanners, Suomalainen et al. (Suomalainen et al., 2009) assessed the image quality in the parameters of CNR and modulation transfer function (MTF), and found that the lowest corrected CNR were measured for the two 3D Accuitomo® scanners, with the FPD version providing a 30% higher CNR-corrected than the CCD version.

Ludlow and Walker (Ludlow & Walker, 2013) used QUART® DVT phantom to calculate CNR for different exposure setting of i-CAT® FLX CBCT and found that when voxel size and FOV were held constant, an increase in CNR was seen with increasing energy and milliamperes.

Pauwels and coworkers (Pauwels et al., 2011) evaluated the SEDENTEXCT IQ phantom and reported that it showed promising results for objective CBCT image quality assessment. The same phantom was used in another study to evaluate CBCT units and found to be useful for basic image quality parameters (Bamba et al., 2013).

Image noise, contrast resolution, spatial resolution, and artefacts are key parameters in objective image quality assessment. The quality of CBCT images, with the same spatial resolution, is fundamentally described by two parameters (indexes): contrast and noise.

Pauwels et. al. (Pauwels et al., 2014) used a SEDENTEXCT IQ phantom with four different inserts [air, low-density polyethylene (LDPE), polytetrafluoroethylene (PTFE) and aluminum (Al)] to measure CNR of CBCT images performed using different exposure setting of 3D Accuitomo® 170, and concluded that the best optimal contrast at a fixed dose was found at the highest available kV setting. Hidalgo Rivas et al. (Hidalgo Rivas et al., 2015) investigated 3D Accuitomo® 170 CBCT examinations of the anterior maxilla in children and images were classified as acceptable/not acceptable related to a number of different diagnostic tasks and different exposure conditions.

It was found that using 80kV and 3mA reduced dose without compromising the CNR value.

In STUDY III, we used CNR measurements for objective image quality assessment. There are many factors affecting the contrast and noise parameters of image quality of CBCT units such as system geometry, focal spot size, FOV, object size, exposure parameters (kV, mAs), number of projections, and voxel size. In the present study, we used the same geometry, FOV, object size, and voxel size during all scans.

For the different protocols, we used the same quality of X-ray beam by using different peak energy (80 kV or 90 kV). Theoretically, for CT increased kV will lead to a decreased contrast resolution, as a result of the difference in attenuation coefficient between different structures, and an increase of noise, as a result of decreased quantum detection efficiency of the X-ray converter, i.e. more scatter interaction and less photoelectric effect with higher kV. Concurrently, decreased kV will lead to increased noise as a result of decreased fluence transmitted to the image detector. This finding was also observed in STUDY III. The standard scanning mode of 3D Accuitomo® 170 has fixed frames per second (30 frames/s), i.e. it has 270 and 525 basis images for 180° (9 s) and 360° (17.5 s), respectively. In the less basis images (less exposure time), the effect on the images manifests as more noise. For example, when comparing full rotation 360° and half-rotation 180° protocols of the same kV and mA, the average decrease in CNR value of PTFE inserts was 30–34% for half-rotation protocols.

Subjective image quality

Physical measurement expressed as objective image quality is not enough to predict the diagnostic performance of an imaging system clinically and the evaluation of image quality must include psychophysical, environmental, and system considerations (Martin et al., 1999)

In the literature there are many studies assessing subjective image quality of dental CBCT scanners (Hashimoto et al., 2006; Liang et al., 2010; Lofthag-Hansen et al., 2011; Shelley et al., 2011; Alqerban et al., 2011; Kamburo lu et al., 2011) but few studies correlate objective and subjective image quality (Choi et al., 2015; Hidalgo Rivas et al., 2015) Table 7.

Table 7. Summary table of some CBCT subjective image quality studies

Study	CBCT	Objective	Raters (NO. + Prof)	Rating	ROI	Conclusion	Notes
Hashimoto et al. 2006	3DX multi- image micro-CT + 4 MDCT	Dried maxilla	5 dentists	5-point scale	6 anatomical landmarks + overall image.	3DX was superior to MDCT	
Loubele et al. 2008b	CBCT + MSCT	One formalized maxilla	postgraduates in oral imaging			CBCT was superior for small bony structures and inferior for cortical bone and the gingiva.	
Liang et al 2010	5 CBCT (Accuitomo 3D, i-CAT, NewTom 3G, Galileos, Scanora 3D) + MSCT (Somatom Sensation 16)	One dry mandible	5 dentist	5-point scale.	Visibility of 11 anatomical landmarks + overall image noise	The Accuitomo system was superior to MSCT and all other CBCT systems in depicting anatomical structures while MSCT was superior to all other CBCT systems in terms of reduced image noise.	
Lofthag et al 2011	3D Accuitomo + 3D Accuitomo FPD	Posterior part of the jaws on a skull phantom	7 radiologists (3 with >20 years of experience and 4 with <10 years)	6-point scale	Periapical diagnosis Implant planning	The exposure parameters should be adjusted according to diagnostic task. For this particular CBCT brand a rotation of 180° gave good subjective imagequality	(DAP) value was determined
Shelley et al 2011	3 CBCT (3D Accuitomo 170 + NewTom VG + Kodak 9000 3D) + lateral cephalometric +spiral tomography + transsymphyseal	Mandible in water phantom	10 dentist	6 statements on 5-point scale	Symphysal region	Small volume, high resolution CBCT provided images with the highest scores for subjective image quality.	

Alqerban et al 2011	6 CBCT (3D Accuitomo-XYZ + Scanora 3D +Galileos 3D Comfort + Picasso + ProMax 3D + Kodak 9000 3D)	Child cadaver skull in the early mixed dentition	12 (8 orthodontic residents, 2 orthodontic instructors, and 2 radiologists	5-point rating scale for visibility + 5-point scale for resorption	Visibility of 4 landmarks + overall image noise + presence of a resorption in the lateral incisor	CBCT systems tested showed variable image qualities No significant differences between CBCTs in the detection of the severity of root resorption.	
Kamburo lu et al 2011	4 CBCT (Veraviewepocs 3D + lluma,+ Kodak,+ Vatech)	3 cadaver mandibles	5 raters	4-point scale	visibility of 10 specific structures	The Veraviewepocs 3D has the highest quality images for most of the assessed features, whereas the lluma low- resolution scan has the lowest	
Choi et al 2014	Dinnova3 CBCT	Real skull phantom + SedentexCT IQ phantom	5 Radiologists	6- point scale for visibility + acceptable and unacceptable for classification	Visibility of three anatomic landmarks + classification according to diagnostic tasks (periapical diagnosis and implant planning)	MTF and CNR values have a significant association with subjective image quality	Higher MTF and CNR values were required in the periapical diagnosis compared with the implant planning of the mandible.
Hidalgo Rivas et al 2015	3D Accuitomo 170	Real skull phantom + SedentexCT IQ phantom	8 (3 radiologists + 5 orthodontists)	9 statements on 5-point scale	impacted maxillary canine	Acceptable image quality was achievable with DAP values of 127 mGycm2 or greater and a polytetrafluoroethylene (PTFE) [CNR] of 4.8 or greater.	Dose-area product (DAP) value was determined + CNR

In STUDY III, we performed dosimetry, objective measurements and subjective assessment of image quality, all on the same material and the same machine. We consider this to be strength of the study. We chose to evaluate subjective image quality by assessments of images of a skull phantom and a variation of exposure settings in order to find the lowest exposure settings for the specific diagnostics tasks. The reason for choosing standard observation environment was that one of the tasks of this study was to investigate observer agreement, where agreement is defined as the degree to which two or more observers achieve identical results under similar assessment conditions (Kottner et al., 2011). The reason for choosing five observers was that different observers might have different prior experience. In STUDY IV, we performed measurement reliability study on 10 real patients in four different clinical practices, all CBCT images taken by the same machine model. We consider this to be strength of the study. As in study III, we chose standard observation environment. Six raters with different profession and experience have been involved.

Efficacy of diagnostic imaging

The widespread use of CBCT in dental practice raises the questions regarding the benefits of this modality as a diagnostic imaging. These benefits can be estimated by diagnostic efficacy. One of misconception about diagnostic efficacy of diagnostic imaging as well as CBCT that commonly seen, is to describe diagnostic efficacy as high image quality (European Commission, 2012. Fryback and Thornby (1991) developed a diagnostic efficacy model with six levels presented in introduction. This model has been used to evaluate diagnostic efficacies of CBCT (Kim et al, 2009; European Commission, 2012). Most of diagnostic efficacy studies of CBCT are mainly focous on the first two levels (technical efficacy and diagnostic accuracy efficacy).

In level 2, according to the study's purpose, the study can be divided into (Zhou et al., 2002; Obuchowski, 2004) (Table 8):

- Phase I- Exploratory phase
- Phase II- Challenge phase
- Phase III- Advanced phase

Table 8. Characteristics of different phases of diagnostic test evaluation

	Phase I	Phase II	Phase III
	Exploratory phase	Challenge phase	Advanced phase
No. of patient	10-15	50-200	Hundred collected prospectively
Characteristics of patients	Well known diseased vs. healthy volunteers	Difficult cases of diseased vs. difficult cases mimicking diseased	Cases represent the target population
Main objective of the study	Differentiate between two groups of patient	Examine the failure of investigated test	Estimate the performance for well-defined target population and compare it with other tests
No. of raters	2 or 3	5-10	More than 10 raters from different institutions

In phase I, the included patients are “the sickest of the sick” and the “weldest of the well” (Zhou et al., 2002). If the investigated test fails to differentiate between two included groups there is no point in taking the tests further. For inter-rater variability assessment, at least two raters must be included. In this phase with limited diagnostic ability there is no need to use a lot of resources. Methodologically speaking this type of study is weak and overestimates accuracy (Zhou et al., 2002).

In phase II, it is important to compare the accuracy of investigated test with others and determine the relation between accuracy and patient features (patho-clinical features). In this phase the included cases may not represent the real prevalences of different groups of the target population.

In phase III, the included cases represent the disease prevalence. The sensitivity and specificity in phase III are more reliable than in phase I & II (Obuchowski, 2004). Therefore it is important to demonstrate the external validity in these phase studies. The main drawback of studies with one rater is that there is no rater difference assessment.

In level 2 (diagnostic accuracy efficacy), a reference standard can be looked upon as the best available method to establish a diagnosis and accuracy is a keystone in assessing diagnostic methods. When a reference standard is hard to obtain, agreement and reliability studies can be used to address the objectivity of the imaging result. In other words, the measure of reliability is useful in determining the extent to which the inaccuracy of a system is due to decision-making errors. It can serve as an indication of the upper bound of accuracy (Swets & Pickett, 1982). Unfortunately, reliability and agreement studies are generally neglected and do not appear in the different stages of evaluating studies of diagnostic methods (Kottner et al., 2011)) or in interventional studies where diagnostic methods are used to evaluate outcomes. The analyses of measurement and decision-making errors of the imaging methods applied are fundamental in studies on treatment outcomes. For example in studies of orthodontic treatment, the measurement errors of baseline and follow-up examinations should be less than the assessed change of root length and marginal bone level. Furthermore, rater performance, particularly when several raters are involved in a study, is important to know.

In STUDY III & IV, we investigated the rater agreement and measurement reliability as a part of diagnostic efficacy evaluation. The evaluation in STUDY III was as a part of optimization process on phantom. The number of raters was 5 raters with different professions and experience. The measurement reliability study in STUDY IV was conducted on real patients with 6 raters with different profession.

Reliability and agreement

In general, the reliability of the information obtained by medical imaging depends on several factors such as the image quality, the method used to assess the images and the skills of those interpreting the information. New radiographic imaging modality is increasingly used when reference standard validation is not available. In such situations, only agreement and reliability studies can address the objectivity of the imaging result.

There were differences between the reliability for root length measurements in CBCT and PA images of the maxillary anterior incisors, as indicated by non-overlapping CIs around the ICCs. These differences were large in magnitude and, therefore, may be meaningful

for scientific evaluations of orthodontic treatment, which often are based on assessment of the maxillary anterior incisors. Although ICC was lower for marginal bone level measurements by PA compared with CBCT and BW, the CIs overlapped, indicating a lack of difference. Overall ICCs for measurements of the marginal bone levels were lower than those for root length measurements. These results may depend on that correct identification of the CEJ and marginal bone outlining is difficult. The low ICCs for both inter-and intra-rater reliability for PA images of the maxillary anterior incisors could be expected since the anatomy of the borderline of the marginal bone tissue and the projection in this region may result in a vague image. The low ICCs for BW of the premolars and molars were more unexpected as BW often is recommended as an accurate and reliable imaging method for the assessment of the marginal bone tissue.

Our results on ICCs for marginal bone level measurements in CBCT were lower. One reason may be that the sample consisted of growing individuals and the eruption of specifically the molars was not complete resulting in a diffuse outlining of the marginal bone tissue. In radiographic follow-up examinations of orthodontic treatment, the identification of the CEJ and marginal bone tissue may be even more difficult due to artifacts of metallic orthodontic appliance.

Our results on high measurability in CBCT for measurements of root lengths and marginal bone level as well as high reliability for root length measurements add further to the results of previous studies that CBCT may be the best choice of imaging method for scientific analyses of outcomes of orthodontic treatment. Even if CBCT is more expensive than intraoral radiography, CBCT could be more consistent to identify changes related to interventions.

Implication for research and patient care

■ *CBCT shows higher measurability and reliability for root length measurement when compared to periapical radiographs, which is important to take in consideration for research studies and for practitioners and radiologists. (STUDY IV)*

CONCLUSIONS

- Although there are several studies on ED of CBCT of the facial skeleton, the quality of the evidence is low regarding how different diagnostic tasks and appropriate image quality should be matched with different scanning protocols in order to adhere to the ALADA principle.
- To increase the quality of evidence a minimum data, as presented in STUDY I the model presented in Figure 1, has to be reported in future studies on optimisation and image quality of CBCT.
- GafChromic® film can be utilised to map the dose distribution and measure the absorbed organ/tissue dose of CBCT and panoramic radiography.
- The use of small FOV and standard resolution reduces the dose when compared with larger FOVs of the same ROI or higher resolution.
- For a dedicated CBCT (3D Accuitomo® 170) unit, changing the rotation angle from 360° to 180° degrades the image quality.
- By altering tube potential and current for the 360° rotation protocol, assessment of periodontal structures can be performed with a smaller dose without significantly affecting visualisation.
- CBCT was the most reliable imaging method for root length measurements while reliability for marginal bone level measurements was about the same for the CBCT, PA and BW images.

FUTURE RESEARCH

- According to the grading of recommendations assessment, development and evaluation principle (GRADE), the quality of evidence is low when there is a limitation to the study quality, important inconsistency of estimates of effects across studies and an uncertainty about important consequences. As this is the case for effective dose in CBCT, further research is very likely to have an impact on our confidence in the estimates of effective doses.
- The need for standardised reporting in CBCT dosimetric studies could help improve the accuracy and transparency of publications and the efficiency of literature searching.
- Further studies may to standardised method to use Gafchromic® film for organ absorbed dose measurement, especially determining the extension of radiosensitive organ in different phantom level could help in using this method.
- Further studies may assess the impact of exposure parameters of CBCT scanners for indications for different age, sex and diagnostic tasks, especially exposure time and kV as these factors could help in instable patient and different patient's size.
- Further studies should investigate the diagnostic accuracy and higher level of diagnostic efficacy of CBCT for analysis of changes of roots and marginal bone tissues. The results of such studies may elucidate more adverse effects of orthodontic treatment than have been previously acknowledged.

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APPENDIX A:

Dose definitions

The absorbed dose, D , is the basic physical dose quantity, and it is used for all types of ionizing radiation. It is defined as the mean energy imparted per unit mass by ionizing radiation (ICRP 103). The equivalent dose in an organ or tissue takes into account the different biological damage potential of different types of radiation and can be calculated by the formula

$$H_{T,R} = Q \times D_{T,R}$$

where $D_{T,R}$ is the mean absorbed dose from radiation R absorbed in a unit mass of tissue T , and Q is a radiation quality factor that depends on the type and energy of that radiation (ICRP 103). The unit of equivalent dose is Sievert (Sv) and as the quality factor for x-rays is 1, 1Gy corresponds to 1Sv.

To assess the probability of health detriment from low doses of ionizing radiation, the International Commission on Radiation Protection (ICRP) proposed a theoretic quantity in 1977 (ICRP 1977) as effective dose equivalent and finally it is known as effective dose in 1990 (ICRP 1990). The effective dose, E , is defined by a weighted sum of tissue equivalent doses as:

$$E = \sum_T w_T \sum_R w_R D_{T,R}$$

PAPERS I-IV

I

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FULL PAPER

Effective dose of cone beam CT (CBCT) of the facial skeleton: a systematic review

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Objective: To estimate effective dose of cone beam CT (CBCT) of the facial skeleton with focus on measurement methods and scanning protocols.

Methods: A systematic review, which adhered to the preferred reporting items for systematic reviews (PRISMA) Statement, of the literature up to April 2014 was conducted. Data sources included MEDLINE[®], The Cochrane Library and Web of Science. A model was developed to underpin data extraction from 38 included studies.

Results: Technical specifications of the CBCT units were insufficiently described. Heterogeneity in measurement methods and scanning protocols between studies made comparisons of effective doses of different CBCT units and scanning protocols difficult. Few studies related doses to image quality. Reported effective dose varied across studies, ranging between 9.7 and 197.0 µSv for field of views (FOVs) with height ≤5 cm, between 3.9

and 674.0 µSv for FOVs of heights 5.1–10.0 cm and between 8.8 and 1073.0 µSv for FOVs >10 cm. There was an inconsistency regarding reported effective dose of studies of the same CBCT unit with the same FOV dimensions.

Conclusion: The review reveals a need for studies on radiation dosages related to image quality. Reporting quality of future studies has to be improved to facilitate comparison of effective doses obtained from examinations with different CBCT units and scanning protocols. A model with minimum data set on important parameters based on this observation is proposed.

Advances in knowledge: Data important when estimating effective dose were insufficiently reported in most studies. A model with minimum data based on this observation is proposed. Few studies related effective dose to image quality.

Since introduction in the late 1990s, cone beam CT (CBCT) has become a common modality to image the facial skeleton. There is currently a large variety of CBCT units on the market,^{1,2} and technical improvements are made continuously, such as the development of the field of view (FOV) from one fixed size to several sizes as well as stitched FOVs in the more recent models.

The use of CBCT has increased dramatically, but published evidence supporting informed clinical decision-making is weak.³ As is the case with emerging healthcare technologies, it will take some time to produce evidence on the cost-effectiveness of CBCT for different diagnostic tasks including “costs” in terms of radiation dosages. Meanwhile, the use of CBCT and choice of scanning protocol has to rely on good practice related to the image quality needed for the actual diagnostic task and the amount of radiation exposure to the patient. The literature on dose levels of CBCT is, however, difficult to grasp and interpret owing to the

diversity of CBCT units and different approaches taken in radiation dosimetry.

The aim of this systematic review was to estimate the effective dose of CBCT of the facial skeleton with focus on measurement methods and scanning protocols used. Such a review can be beneficial when aiming to perform CBCT examinations with a radiation exposure as low as diagnostically acceptable (ALADA).³ A review may also highlight both strengths and weaknesses in study design to date and can thereby support sound study design in future research.

METHODS AND MATERIALS

The literature review was conducted in accordance with the preferred reporting items for systematic reviews (PRISMA) Statement⁴ and guidance of Centre for Reviews and Dissemination for undertaking reviews in healthcare.⁵ The following steps were defined: (i) review questions, (ii) literature searches, (iii) study selection and (iv) data extraction and synthesis.

REVIEW QUESTIONS

Regarding CBCT of the facial skeleton, the review questions were as follows:

- Which methods and scanning protocols were used when measuring and estimating the radiation dosage?
- What are the effective doses?

The following terms were based on Medical Subject Headings (MeSH):

- CBCT/instrumentation: CT modalities that use a cone- or pyramid-shaped beam of radiation.
- Facial bones: the facial skeleton, consisting of bones situated between the cranial base and the mandibular region. While some consider the facial bones to comprise the hyoid (hyoid bone), palatine (hard palate), zygomatic (zygoma) bones, mandible and maxilla, others include also the lacrimal and nasal bones, inferior nasal concha and vomer but exclude the hyoid bone.
- Radiation dosage as stated above defined according to MeSH.
- Thermoluminescent dosimetry as stated above defined according to MeSH.

The following terms not included in MeSH were defined as:

- Dental CT: CBCT used for the oral and maxillofacial region.
- Effective dose according to International Commission on Radiation Protection (ICRP) publication 103:⁶ the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body.
- Material to measure radiation dosages: dosimeters and read-outs.
- Scanning protocols: exposure parameters and phantom features.

LITERATURE SEARCHES

The searches were designed together with university librarians. The search strategies are presented in Table 1. The following electronic databases were searched: MEDLINE[®] using PubMed as search engine, the Web of Science and the Cochrane Database of Systematic Reviews in The Cochrane Library. The search in MEDLINE was based on MeSH terms and free-text terms. The searches in Web of Science and The Cochrane Library (the Cochrane Database of Systematic Reviews) were performed using free-text terms. Additional hand search was carried out using the reference lists of retrieved systematic reviews.

STUDY SELECTION

Eligibility assessment of half of the retrieved titles and abstracts was performed independently by two authors, and two other authors assessed the other half of the titles and abstracts. When at least one of the authors regarded a record as having met the inclusion criteria, it was ordered and read in full text. Reviewers were not blinded to authors and institutions of the records during the study selection process.

The inclusion criteria were

- Publication type: original study or systematic review.
- CBCT unit: described regarding brand and version, FOV dimensions, degree of rotation, X-ray beam type (pulsed or continuous radiation).
- Anatomical region: facial region, further detailed and described in studies of FOVs ≤ 10 cm.
- Material: equipment to measure radiation dosage (dosimeters and read-outs).

- Outcomes: data on effective dose based on ICRP 60—1990⁷ or ICRP 103—2007⁶
- Language: abstract in English and full-text publication in English, German or Japanese.

DATA EXTRACTION AND DATA SYNTHESIS

We developed a model with components that were considered important when performing studies of radiation dosages in CBCT (Figure 1) and a data extraction sheet. Information was extracted from each study on (i) the CBCT unit(s), (ii) method to measure and estimate radiation dosages, (iii) scanning protocol, (iii) object and (iv) radiation dosages. When information of the CBCT unit was insufficient, information was searched for on the manufacturer's website. Together, the authors pilot tested the data extraction sheet on five included studies. The authors had different professional backgrounds and experience: one radiophysicist, two specialists (>25 years' experience) and two trainees in oral and maxillofacial radiology. One author

Table 1. Search strategies and number of publications retrieved from MEDLINE[®], the Web of Science and the Cochrane Library

Indexing terms	Publications (n)
MEDLINE	
#1 Cone Beam Computed Tomography (MeSH)	3150
#2 Cone Beam Computed Tomography	4968
#3 Dental CT	4727
#4 Radiation Dosage (MeSH)	67,196
#5 Radiation Dosage	110,803
#6 Thermoluminescent Dosimetry (MeSH)	2873
#7 Thermoluminescent Dosimetry	3274
#8 = #1 OR #2	4968
#9 = #8 OR #3	9226
#10 = #4 OR #5	110,803
#11 = #6 OR #7	3274
#12 = #10 OR #11	112,099
#13 = #9 AND #12	737
Web of Science	
Topic = (Radiation Dosage) OR Topic = (Thermoluminescent Dosimetry) AND Topic = (Cone Beam Computed Tomography)	3000
Refined by: Web of Science Categories = (DENTISTRY ORAL SURGERY MEDICINE)	92
The Cochrane Library	
There are 6 results from 783,686 records for your search on "Radiation Dosage OR Thermoluminescent Dosimetry AND Cone Beam Computed Tomography in title abstract keywords in Trials"	6

MeSH, Medical Subject Headings.

Search conducted on the 22 April 2014.

Figure 1. A model presenting the steps for data extraction with different parameters important when analysing radiation dosages in cone beam CT (CBCT) of the facial skeleton. FOV, field of view; ICRP, International Commission on Radiation Protection.

extracted data from included studies, and the other authors checked the extracted data independently. Disagreement was resolved by discussion.

Effective doses for three heights of FOV (≤ 5 cm, 5.1–10.0 cm and > 10.0 cm) were compiled in a spreadsheet. Median values, 25 and 75 percentiles, and range for effective dose values were calculated using software (Microsoft Office Excel® 2010; Microsoft Corporation, Redmond, WA).

RESULTS

Study selection

Figure 2 shows the number of publications identified, excluded and included. Of the retrieved publications, 674 were discarded because, after reviewing the abstracts, it appeared that these publications did not meet the inclusion criteria. The full text of the remaining 67 publications was examined, and 38 met the inclusion criteria. Three systematic reviews were excluded because their research question was different to that of the present review, but an additional three studies were identified and included by checking the reference lists of these reviews. Most included studies were published from 2008 onwards, the number of studies being the highest in 2008 and 2012.

Methods and scanning protocols used to measure and estimate radiation dosages

The methods used to measure radiation dosages varied across the studies (Table 2). The following methods were used: thermoluminescent dosimeter (TLD) 100 (25 studies), TLD-100H (8 studies), optically stimulated luminescence dosimeter (OSLD) (2 studies), radiochromic film (2 studies), ionization chamber (2 studies), magnesium orthosilicate doped with terbium (Mg_2SiO_4 ;

Tb; TLD-MSO-S) (1 study), lithium borate ($\text{Li}_2\text{B}_4\text{O}_7$)-TLD (1 study) and photoluminescence glass (1 study). Also, the type of phantom, the number of slices, dosimeters and exposures of each dosimeter varied across studies (Table 2). In most studies, a commercially available anthropomorphic phantom including an adult male skull was used. A phantom that included a female skull was examined in three studies and a paediatric phantom (corresponding to a person 10 years of age) in two studies. In two studies, the phantom was developed at the institution (University of Göttingen, Göttingen, Germany) where the study was performed. Only in one study⁴⁰ was the phantom repositioning between scans described in enough detail to ascertain reproducibility. The method for distribution of dosimeters as described by Ludlow et al²⁷ was applied in most studies. The number of phantom slices ranged between 7 and 10 and the number of TLDs was about 24 in most studies. The number of exposures of dosimeters ranged between 1 and 10, except for 1 study using 34 exposures.⁴⁴ In seven studies, there was no information about the number of TLDs, and in one-third of the studies there was no information about the number of exposures of dosimeters.

Complete technical specifications of the CBCT unit were described in only one study.⁴⁰ Supplementary information, such as the degree of rotation or trajectory arc, filtration and detector specifications, was partly accessible on the manufacturers' websites.

What are the effective doses of cone beam CT examinations of the facial skeleton?

Effective doses and individual study characteristics are presented in Supplementary Tables A–C. In seven studies, ICRP 1990 and

Figure 2. Flow chart according to the preferred reporting items for systematic reviews (PRISMA) statement⁴ presenting study selection process with number of publications identified, excluded and included for systematic review of effective dose of cone beam CT (CBCT) of the facial skeleton.

ICRP 2007 weights were presented so that the effect of the change from 1990 weights to 2007 in effective dose calculations could be estimated. The increase of the estimated effective dose using 2007 compared with 1990 was on average 173% (range, 58–350) for FOVs with height ≤ 5 cm, 164% (range, 64–276) for FOVs 5.1–10.0 cm and 76% (13–180) for FOVs with height > 10 cm.

As presented in Figure 3, effective dose was influenced by the height of the FOV. The reduction of the median effective dose of FOVs with height 5.1–10.0 cm compared with that of FOVs with height > 10 cm was 38%. The reduction of the median effective dose of FOVs with height ≤ 5 cm compared with that of FOVs with height 5.1–10.0 cm was 59%. The maximum effective dose of the smallest FOVs overlapped the median dose of the FOVs with height 5.1–10.0 cm and the same applied to the FOVs of medium and large heights (Figure 3). The ranges between the highest and lowest doses of each FOV height were wide (Figure 3). As presented in Figure 4, there was a variation in reported dose estimates for the same CBCT unit with the same FOV dimensions.^{10,14,20,25,35,39} As the description of technical parameters of the CBCT units examined was incomplete, it was difficult to evaluate which components of the CBCT units that produced the different results on effective doses in these studies. Besides, different phantoms, dosimeter types and number, exposure parameters and protocols were applied in these studies (Figure 4).

In addition to the size, the positioning of the FOV influenced the effective dose. The dose of FOVs of < 10 cm was higher for examination of the lower jaw than for the upper jaw^{23,30} and for examinations with the FOV positioned on the posterior part of the lower jaw than for the anterior part of the upper jaw.^{14,38,45} The effective dose was reduced by 43% when 0.4-mm copper filtration was added in examinations with FOV heights 9 and 18 cm.¹⁸

Effective dose was related to image quality in six studies (Table 2) expressed as objective image quality^{21,32,39,40} or subjective image quality.^{17,19} As presented in Table 2, the effective dose of CBCT was compared with those of other imaging modalities in eight studies: CT,^{13,16,24,25,37,44} panoramic radiography^{16,25,31,37,44,45} and cephalometry.³⁷ Risk estimations were presented in eight studies^{12,18,23,25,27,30,35,45} mostly as comparisons with background radiation.

DISCUSSION

This systematic review revealed that key methodological details of measurement methods and scanning protocols were missing. We did not implement any quality evaluation in this systematic review, as there is no validated tool for this publication type, as is the case for quality evaluation of diagnostic studies. If the model proposed in Figure 1 had been used as a quality tool, all but one study⁴⁰ would have been excluded, as technical data of the CBCT units was insufficiently described.

Table 2. Methodology for measurements and estimation of the radiation dosage in cone beam CT (CBCT) of the facial skeleton

Study	Dosimeter		Object		Radiation dosage presented as: – Organ absorbed dose – Effective dose – Weighting factor to estimate effective dose (ICRP 60 ⁷ — 1990; ICRP 103 ⁶ —2007)	Comments
	Number (n)	Exposures of each dosimeter (n)	Phantom – Type (manufacturer) – Size	Slices used (n)		
TLD-100						
Kim et al ⁸	22	NA	– ART head and neck phantom (Radiology Support Devices, Inc., Long Beach, CA) – Adult male	9	– Equivalent organ absorbed dose – Effective dose – ICRP 2007	Conversion coefficients from the DAP
Schilling and Geibel ⁹	24	– Prescan 50 – Scan 3	– Alderson RANDO® ART-210 (Radiology Support Devices, Inc.) – Adult male	9	– Organ absorbed dose – Effective dose – ICRP 1990, 2007	Organ absorbed dose from middle ranges for each unit
Rotke et al ¹⁰	48	10	– RANDO head phantom (The Phantom Laboratory, Salem, NY)	8	– NA – Effective dose – ICRP 2007	
Davies et al ¹¹	72	10	– RANDO head (The Phantom Laboratory) – Adult male	7	– NA – Effective dose – ICRP 1990, 2007	
Grünheid et al ¹²	24	3	– RANDO (The Phantom Laboratory) – Adult male	7	– NA – Effective dose – ICRP 2007	
Jeong et al ¹³	3 × 25	NA	– ART (Radiology Support Devices, Inc.) – Adult	16	– Organ absorbed dose – Effective dose – ICRP 2007	Compared with CT with low-dose technique
Pauwels et al ¹⁴	147; 152	NA	– Two ART head and neck phantom (Radiology Support Devices, Inc.) – Adult male	11	– Organ absorbed dose – Effective dose – ICRP 2007	
Rampado et al ¹⁵	50	10	– RANDO head phantom (The Phantom Laboratory)	9	– NA – Effective dose – ICRP 2007	
Sözgin et al ¹⁶	21	NA	– RANDO head phantom	NA	– NA – Effective dose – ICRP 2007	Compared with panoramic radiography and CT

(Continued)

Table 2. (Continued)

Study	Dosemeter		Object		Radiation dosage presented as: – Organ absorbed dose – Effective dose – Weighting factor to estimate effective dose (ICRP 60 ⁷ —1990; ICRP 103 ⁹ —2007)	Comments
	Number (n)	Exposures of each dosimeter (n)	Phantom – Type (manufacturer) – Size	Slices used (n)		
Librizzi et al ¹⁷	78	3	– RANDO (The Phantom Laboratory)	NA	– Organ absorbed dose – Effective dose – ICRP 2007	Image quality assessed as presence or absence of erosion of temporomandibular joint by two radiologists
Ludlow ¹⁸	24	9 or 10	– RANDO (Nuclear Associates, Hicksville, NY) – Adult	7	– Organ absorbed dose – Effective dose – ICRP 1990, 2007	Doses with and without 0.4-mm copper filtration
Carrasfello et al ¹⁹	42	NA	– RANDO (Alderson Research Laboratories, Inc., New York, NY)	10	– NA – Effective dose – ICRP 1990	Subjective image quality: analysed spongy bone, teeth, surrounding structure and soft tissues Assessed on five-point scale by two observers
Qu et al ²⁰	63	5	– ART phantom, model ART-210 (Radiology Support Devices, Inc.) – Adult male	7	– Organ absorbed dose – Effective dose – ICRP 1990, 2007	
Faccioli et al ²¹	46	NA	– RANDO (Alderson Research Laboratories, Stanford, CN) – NA	NA	– Organ absorbed dose – Effective dose – ICRP 2007	Image quality assessed as high and low contrast resolution, uniformity and noise
Loubele et al ²²	NA	10	– Two RANDO (Alderson Research Laboratories, NY) – Male	20	– NA – Effective dose – ICRP 2007	
Roberts et al ²³	72	10	– RANDO – Adult	8	– NA – Effective dose – ICRP 1990, 2007	
Coppentrath et al ²⁴	Unclear	NA	– RANDO	NA	– Organ absorbed dose – Effective dose – ICRP 1990	Compared with CT
Ludlow and Ivanovic ²⁵	24	3	– RANDO (Nuclear Associates) – Adult male	7	– NA – Effective dose – ICRP 1990, 2007	Compared with CT and average panoramic dose

(Continued)

Table 2. (Continued)

Study	Dosemeter		Object		Radiation dosage presented as:	Comments
	Number (n)	Exposures of each dosimeter (n)	Phantom (manufacturer) – Size	Slices used (n)		
Palomo et al ²⁶	10	1	– RANDO head phantom (The Phantom Laboratory)	7	– Organ absorbed dose – Effective dose – ICRP 1990, 2007	
Ludlow et al ²⁷	24	3	– RANDO (Nuclear Associates) – Adult male	7	– NA – Effective dose – ICRP 1990, 2005 draft recommendations	
Wörtche et al ²⁸	NA	NA	– RANDO	NA	– NA – Effective dose – ICRP 2005 draft recommendations	
Tsilakis et al ²⁹	25	NA	– RANDO (Alderson Research Laboratories, CN)	NA	– NA – Effective dose – ICRP 1990, ICRP 1990 + salivary glands	
Ludlow et al ³⁰	NA	10	– RANDO (Nuclear Associates) – Small adult	7	– NA – Effective dose – ICRP 1990, ICRP 1990 + salivary glands	
Mah et al ³¹	NA	2	– Humanoid, tissue-equivalent dosimetry phantom (Humanoid Systems Inc., Torrance, CA)	NA	– Organ absorbed dose – Effective dose – ICRP 1990	Compared with panoramic radiography and CT
Cohen et al ³²	26	2	– RANDO	13	– NA – Effective dose – NA	Image quality assessed as mean image noise
TLD-100H						
Davies et al ¹¹	72	10	– RANDO (The Phantom Laboratory) – Male	7	– NA – Effective dose – ICRP 1990, 2007	
Pauwels et al ¹⁴	147; 152	NA	– Two ART head and neck phantom (Radiology Support Devices, Inc.) – Adult male	11	– Organ absorbed dose – Effective dose – ICRP 2007	Different numbers of TLDs used for two phantoms

(Continued)

Table 2. (Continued)

Study	Dosemeter		Object		Radiation dosage presented as:	Comments
	Number (n)	Exposures of each dosimeter (n)	Phantom – Type (manufacturer) – Size	Slices used (n)		
Qu et al ³³	3 chips Positioned at 21 locations (3 × 21)	5	– Anthropomorphic ART-210 (Radiology Support Devices, Inc.) – Adult male	7	– NA – Organ absorbed dose – Effective dose – Weighting factor to estimate effective dose (ICRP 60 ⁷ –1990; ICRP 103 ⁹ –2007)	Evaluated influence of thyroid collars
Qu et al ³⁴	63	5	– Anthropomorphic ART-210 (Radiology Support Devices, Inc.) – Adult male	7	– NA – Organ absorbed dose – Effective dose – ICRP 2007	Different oral and maxillofacial regions with and without thyroid collar
Theodorakou et al ³⁵	10 years: 104 Adolescents: 140	NA	– ATOM® model 702-c, 706-c (Computerized Imaging Reference System Inc., Norfolk, VA)	10 years: 10 Adolescent: 11	– Organ absorbed dose – Effective dose – ICRP 2007	
Loubele et al ²²	NA	10	– Two RANDO (Alderson Research Laboratories, NY) – Male	20	– NA – Organ absorbed dose – Effective dose – ICRP 2007	TLD-100H used for organs and tissues expected to receive low dose
Hirsch et al ³⁶	48	5	– Anthropomorphic (developed at University of Göttingen, Göttingen, Germany)	16 sites	– Mean absorbed dose – Effective dose – ICRP 2007	
Silva et al ³⁷	48	5	– Anthropomorphic (developed at University of Göttingen)	NA	– NA – Organ absorbed dose – Effective dose – ICRP 2007	Compared with panoramic radiography, lateral cephalometry and CT
TLD-MSO-S						
Okano et al ³⁸	132	2	– RANDO – Female body phantom	All	– Organ absorbed dose – Effective dose – ICRP 1990, 2007	
Lithium borate (Li ₂ B ₄ O ₇)-TLDs						
Suomalainen et al ³⁹	26	NA	– RANDO (Nuclear Associates) and RSVP Phantom™ (The Phantom Laboratory, Salem, NY)	NA	– Organ absorbed dose – Effective dose – ICRP 1990, 2007	Image quality assessed as CNR and MTF

(Continued)

Table 2. (Continued)

Study	Dosemeter		Object		Radiation dosage presented as: – Organ absorbed dose – Effective dose – Weighting factor to estimate effective dose (ICRP 60 ⁷ — 1990; ICRP 103 ⁶ —2007)	Comments
	Number (n)	Exposures of each dosimeter (n)	Phantom – Type (manufacturer) – Size	Slices used (n)		
Optically stimulated luminescence dosimeter						
Ludlow and Walker ⁴⁰	24	2–12 exposures	– ATOM Max model 711 HN and ATOM model 706 HN (Computerized Imaging Reference System Inc.) – Adult male and 10-year-old child	9	– Equivalent organ dose – Effective dose – ICRP 2007	Image quality assessed as contrast, homogeneity, CNR, MTF, polymethylmethacrylate voxel and noise, Nyquist frequency
Lukat et al ⁴¹	25	3	– RANDO (Alderson Research Laboratories, CT) – Male	7	– Equivalent organ dose – Effective dose – ICRP 2007	
Ionization chamber						
Vassileva and Stoyanov ⁴²	Not applicable	NA	– NA	NA	– NA – Effective dose – ICRP 1990, 2007	Air kerma–area product
Lofthage-Hansen et al ⁴³	Not applicable	NA	– For CTD1100: CT head dose phantom type 76-414 (Victoreen Instruments, Cleveland, OH)	NA	– NA – Effective dose – NA	Measurement of radiation exposure Effective dose based on CTD1100 Effective dose based on DAP Patient examinations
Photoluminescence glass						
Okano et al ⁴⁴	155	3D Accutomo (J Morita Mfg. Corp., Kyoto, Japan): 100 CB Mercuray (Hitachi Medical Corp., Tokyo, Japan): 50	– RANDO (Alderson Research Laboratories, CT) – Female	34	– Organ absorbed dose – Effective dose – ICRP 1990, 2007	Compared with panoramic radiography and CT 34 slices from skull to pelvic bones

(Continued)

Table 2. (Continued)

Study	Dosemeter		Object		Radiation dosage presented as: – Organ absorbed dose – Effective dose – Weighting factor to estimate effective dose (ICRP 60 ⁷ —1990; ICRP 103 ⁶ —2007)	Comments
	Number (n)	Exposures of each dosimeter (n)	Phantom – Type (manufacturer) – Size	Slices used (n)		
Radiochromic film						
Al-Okshi et al ⁴³	3–4 sheets	10–50	– RANDO (The Phantom Laboratory) – Small adult	6	– Organ absorbed dose – Effective dose – CRP 2007	Compared with panoramic radiography
Rampado et al ¹⁵	50 pieces Width, 5 mm Length, 25 mm	10	– RANDO (The Phantom Laboratory)	9	– NA – Effective dose – ICRP 2007	Compared TLD with Gafchromic film (International Specialty Products Corp., Wynn, NJ)

CNR, contrast-to-noise ratio; CTDI, CT dose index; DAP, dose-area product; ICRP, International Commission on Radiation Protection; MTF, modulation transfer function; NA, information not available; TLD, thermoluminescent dosimeter.

TLD-100 was used in most studies, probably owing to the fact that TLD-100 is not only used in the field of dosimetry but also for monitoring personnel radiation doses, which means that the method is a well established clinical routine. The main advantages of the TLD-100 are good sample-to-sample uniformity, nearly tissue equivalent and simple calibration procedures using common radionuclide sources. According to Al Najjar et al,⁴⁶ TLDs may be less accurate in the lower dose range than OSLDs, which were used in two recent studies.^{40,41} The results of the study by Ludlow and Walker⁴⁰ showed, however, that TLDs and OSLDs yielded differences of <2% in the calculation of effective dose in CBCT. Radiochromic film, used in two studies,^{15,45} is, compared with TLDs, easier to adjust on the phantom in relation to the radiation field and present a continuous “analog”-like dose distribution, where the limit for spatial resolution is set by the pixel size when digitizing the image in the flatbed scanner.⁴⁵ CT dose index (CTDI) or the dose-area product (DAP) in combination with a conversion factor was used in one study.⁴⁷ When used for CBCT dosimetry, both CTDI and DAP have been criticized. CTDI underestimates the dose by failing to measure scatter radiation to tissues outside the scan region.²⁵ DAP value represents only the surface dose and effective doses based on DAP conversion factor have been found to be inaccurate for small FOVs.⁴³ As revealed by this review, radiation dosages have been measured and estimated with dosimetric methods used in conventional dental radiography, such as intraoral and panoramic radiography, and in CT. There are, however, significant differences between these imaging modalities, for example, dose distribution and scanning geometry, which entail a different approach to measurements of the radiation for CBCT. The shortcoming of the CTDI concept is well known, and the International Atomic Energy Agency⁴⁸ and American Association of Physicists in Medicine⁴⁹ have proposed recommendations on new CTDI type measurements but, as of yet, there is not any new dosimetry standard established.

The nature and size of the phantom, number of sections and the position and extension of the organs inside the phantom varied across the studies. In most studies, an adult RANDO® anthropomorphic phantom was used but the attenuation varies as each RANDO phantom is constructed around a real human skull or synthetic bone material. A specific phantom has been developed (SedentexCT IQ CBCT Phantom; Leeds Test Object Ltd, Boroughbridge, UK) that has been shown to be valid for assessment of image quality parameters.⁵⁰ There were only two studies using a paediatric phantom corresponding to patients aged 10 years.^{35,40} This is notable as CBCT is increasingly replacing two-dimensional imaging modalities, such as cephalometry and panoramic radiography, in adolescents aged 10–18 years undergoing orthodontic treatment. As the justification for an increased dose to this young patient group is unclear,¹ there is an urgent need to estimate effective doses in relation to diagnostic tasks when examining these patients.

One known factor influencing effective dose is the dimension of the FOV. If all other factors affecting the dose remain constant, a larger FOV results in a higher dose. The dose

Figure 3. Box and whisker diagram of effective doses (μSv) of cone beam CT units with three heights of fields of view. ICRP, International Commission on Radiation Protection.

range for the same FOV height was wide, which is in line with the results presented in the review by Bornstein et al⁵¹ and overlapped for different FOV heights indicating that several factors influence the effective dose. This was further highlighted in our synthesis of the results of six studies of the same CBCT unit with the same FOV dimensions.^{10,14,20,25,35,39} The positioning of FOV with heights ≤ 10 cm was shown to influence dose such that exposure of the posterior part of the lower jaw resulted

Figure 4. Effective doses (μSv) of different versions of the same cone beam CT unit with the field of view of $8 \times 8 \text{ cm}^2$ presented in studies published 2008–13. ART, Radiology Support Devices Inc., A Carson, CA; ATOM®, Computerized Imaging Reference System, Norfolk, VA. ICRP, International Commission on Radiation Protection; TLD, thermoluminescent dosimeter.

in higher effective dose than did the anterior part of the upper jaw,^{14,38,45} because salivary gland and thyroid tissues receive little exposure when the FOV is centred on the anterior upper jaw.

Since effective dose was related to image quality in few studies, it is difficult to assess how the dose can be reduced and still achieve the diagnostic aims of a CBCT examination. Image quality of rotation of 180° and 360° was compared in examinations of the posterior parts of the jaws, and it was concluded that "a rotation of 180° gave good subjective image quality, hence a substantial dose reduction can be achieved without loss of diagnostic information".⁵² It remains, however, to produce more evidence on how the reduction of the scan arc from 360° to 180° in combination with other factors will influence image quality for different diagnostic tasks. As stated by Ludlow and Walker,⁴⁰ "As optimization and dose reduction become more of a focus for CBCT manufacturers, the effect on image quality will need close attention."

Our review has limitations. Although the literature search was performed with some language limitation and only in databases, not in reference lists of included studies, some studies were probably missed. However, the search was in accordance with assessment of multiple systematic reviews (AMSTAR),⁵³ which proposes a search of at least two electronic sources. As the definition of facial skeleton in MeSH guided the study selection, studies of the soft tissues and surrounding regions

of the facial skeleton were excluded. Key methodological data of measurement methods and scanning protocols were missing, which made data extraction difficult and might have induced bias. Heterogeneity between how effective doses were measured and calculated in the included studies is likely to have an effect on our calculations of the median values for different FOV heights.

In conclusion, although there were many studies on effective dose of CBCT of the facial skeleton, the quality of the evidence is low on how different diagnostic tasks and appropriate image quality should be matched with different scanning protocols to accord with the ALADA principle. According to grading of recommendations assessment, development and evaluation (GRADE),⁵⁴ the quality of evidence is low when there is a limitation to the study quality, important inconsistency of estimates of effects across studies and an uncertainty about important consequences. As this is the case for effective dose in CBCT, further research is very likely to have an impact on our confidence in the estimates of effective doses. For estimations, and in particular comparisons of effective doses of different CBCT units and scanning protocols, a more complete reporting is required. A minimum data, as presented in the model presented in Figure 1, has to be reported in future studies on optimization and image quality of CBCT examinations.

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Table A. Effective dose and risk estimation of Cone Beam CT (CBCT) – Small field of view (FOV) (height ≤ 5 cm; examination of localized region)

1 st Author Year ^(ref)	CBCT						Results		Comments		
	Model Name/ Manufacturer	FOV Height (cm) Width (cm)	kVp	mAs	Exposure parameters		Degree of rotation (°)	X-ray emission (pulsed, continuous)		Object Phantom Examined region	Effective dose (mSv; μSv)
Al-Okshi 2013 ⁽⁴⁵⁾	Veraviewepoc 3De J Morita Mfg Corp.	Height: 4 Width: 4	80	5	-	9.5	180*	Continuous	Adult Maxilla Impacted canine	μSv (ICRP) 21 (2007)	Days of per capita natural background (2.08 mSv per day) Excess cases of faal cancer in 1 million people
		Height: 5 Width: 4	80	5	-	9.5	180*	Continuous	Adult Mandible Molar	μSv (ICRP) 22 (2007)	
	ProMax 3D Planmeca Oy	Height: 4 Width: 4	84	10	-	12	200*	Pulsed EET =7 s*	Adult Maxilla Impacted canine	μSv (ICRP) 10 (2007)	
		Height: 5 Width: 3.7	68	6.3	-	NA	360*	Pulsed *	Child TMJ	μSv (ICRP) 9.7 (2007)	
Lukat 2013 ⁽⁴¹⁾	Kodak 9000 3D Carestream Health	Height: 5 Width: 3.7	70	8	-	NA	360*	Pulsed *	Adolescent/ small adult TMJ	μSv (ICRP) 13.5 (2007)	NA
		Height: 5 Width: 3.7	70	10	-	NA	360*	Pulsed *	Adult TMJ	μSv (ICRP) 20.5 (2007)	
Schilling 2013 ⁽⁹⁾	3D eXam KaVo Dental	Height: 4 Width: 16	120	5	-	7.4	360**	Pulsed *	Adult Maxilla	μSv (ICRP) 25.6 (1990) 67.6 (2007)	NA
		Height: 4 Width: 16	120	5	-	3.7	360**	Pulsed *	Adult Maxilla	μSv (ICRP) 12.3 (1990) 32.8 (2007)	
		Height: 4 Width: 16	120	5	-	7.4	360**	Pulsed *	Adult Mandible	μSv (ICRP) 29.2 (1990) 76.3 (2007)	

		Height: 4 Width: 16	120	5	-	3.7	360°*	Pulsed *	Adult Mandible	µSv (ICRP) 14.3 (1990) 37.7 (2007)		
Jeong 2012 ⁽¹³⁾	Implagraphy, Vatech 3D EXAM, Kavø	Height: 5 Width: 8 Height: 5 Width: 10	80	3.5	66.5	-	-	-	Adult Mandible	µSv (ICRP) 83.09 (2007)	NA	
		Height: 3 Width: 4	80	4	-	17	360°*	Continuous*	Maxilla Incisor Left molar	µSv (ICRP) 111.6 (2007) 6 (1990) 27 (2007) 7 (1990) 30 (2007)		
Okano 2012 ⁽³⁸⁾	3DX multi-image micro CT J Morita Mfg Corp.	Height: 3 Width: 4	80	4	-	17	360°*	Continuous*	Mandible Incisor Left molar	µSv (ICRP) 15 (1990) 47 (2007) 21 (1990) 59 (2007)	NA	
		Height: 3 Width: 4	80	4	-	17	360° *	Continuous*	TMJ Left side	µSv (ICRP) 8 (1990) 14 (2007)		
		Height: 3 Width: 4	80	2	-	0.5	360° *	Continuous*	Scout Left lower molar	µSv (ICRP) 1 (1990) 1 (2007)		
Pauwels 2012 ⁽¹⁴⁾	3D Accutomo 170 J Morita Mfg Corp.	Height: 4 Width: 4	90	-	87.5	-	360°*	Continuous*	Mandible Molar	µSv (ICRP) 43 (2007)		
	Kodak 9000 3D Carestream Health*	Height: 5 Width: 3.7	70	-	107	-	360°*	Pulsed * EET = 11 *	Maxilla Anterior	µSv (ICRP) 19 (2007)	NA	
		Height: 5 Width: 3.7	70	-	107	-	360°*	Pulsed * EET = 11 *	Mandible Molars	µSv (ICRP) 40 (2007)		
	PaX-Uni 3D	Height: 5 Width: 5	85	-	120	-	220 / 360 *	Pulsed*	Maxilla Anterior	µSv (ICRP) 44 (2007)		
Theodorako u 2012 ⁽³⁵⁾	Kodak 9000C 3D Carestream Health*	Height: 5 Width: 3.7	70	-	5.6	-	360°*	Pulsed * EET = 11 *	10-yr Maxilla Anterior	µSv (ICRP) 16 (2007)	Percentage attributable lifetime mortality risk	
		Height: 5 Width: 3.7	70	-	106.8	-	360°*	Pulsed * EET = 11 *	Adolescent 3 rd molar	µSv (ICRP) 24 (2007)		
	3D Accutomo 170	Height: 4	90	-	87.5	-	360	Continuous*	10-yr	µSv (ICRP)		

	J Morita Mfg Corp.	Width: 4 Height: 4 Width: 4 Height: 4 Width: 4 Height: 3 Width: 4	90	-	87.5	-	360	Continuous*	Maxilla Anterior Adolescent 3 rd molar	28 (2007) μSv (ICRP) 32 (2007) μSv (ICRP) 31.05 (1990) 49.92 (2007) μSv (ICRP) 18.18 (1990) 29.62 (2007) μSv (ICRP) 127 (2007) μSv (ICRP) 197 (2007)		
Okano 2009 ⁽⁴⁴⁾	3D Accutomo J Morita Mfg Corp.	Width: 4 Height: 4 Width: 4 Height: 4 Width: 4 Height: 3 Width: 4	80	5	-	18	360	Continuous*	Mandible Molar area	μSv (ICRP) 31.05 (1990) 49.92 (2007) μSv (ICRP) 18.18 (1990) 29.62 (2007)	NA	Effective dose compared to MDCT and Panoramic radiography
Qu 2010 ⁽²⁶⁾	ProMax 3D Planmeca Oy	Width: 4 Height: 4 Width: 5 Height: 4 Width: 5	84	16	-	12	200*	Pulsed * EET =7 *	Adult Anterior	μSv (ICRP) 127 (2007) μSv (ICRP) 197 (2007)	NA	
Loubele 2009 ⁽²²⁾	Accutomo 3D XII® J Morita Mfg Corp.	Width: 3 Height: 3 Width: 4 Height: 3 Width: 4	60-80	1-10	-	18	360*	continuous	Maxilla Front Premolar Molar	μSv (ICRP) 29 (2007) 44 (2007) 29 (2007) μSv (ICRP) 13 (2007) 22 (2007) 29 (2007)	NA	Table with comparison of effective doses of other radiographic modalities
Suomalainen 2009 ⁽³⁹⁾	3D Accutomo CCD J Morita Mfg Corp.	Width: 3 Height: 3 Width: 4 Height: 4 Width: 4	80	4	-	17.5	360*	Continuous*	Adult 3 rd molar	μSv (ICRP) 27 (2007) μSv (ICRP) 30.24 (2005) recommenda on μSv (ICRP) 20.02 (2005) recommenda on	NA	Table with effective doses of various studies of CBCT
Hirsch 2008 ⁽³⁶⁾	Veraviewepocs 3D J Morita Mfg Corp.	Width: 4 Height: 4 Width: 4 Height: 4 Width: 4	80	4	-	NA	180	Continuous* EET =9.4 *	Adult Maxilla Anterior	μSv (ICRP) 20.02 (2005) recommenda on	NA	
Loftag-Hansen 2008 ⁽⁴³⁾	3D Accutomo J Morita Mfg Corp.	Width: 4 Height: 4 Width: 4 Height: 3 Width: 4	80	4	-	NA	360	Continuous*	Adult Maxilla Anterior	μSv (ICRP) 20.02 (2005) recommenda on	NA	DAP value determined on data from 90 patients examinations
	Accutomo 3D J Morita Mfg Corp.	Width: 3 Height: 3 Width: 4 Height: 3 Width: 4	80	5-6	-	17.5-18	360*	Continuous*	Maxilla Cusps	μSv (based on DAP value) 21-25 μSv (based on DAP value)	NA	
		Width: 3 Height: 3 Width: 4 Height: 3 Width: 4	75-80	3-6	-	17.5-18	360*	Continuous*	Maxilla 2 nd premolar	μSv (based on DAP value) 21-25 μSv (based on DAP value)	NA	

	Height: 3 Width: 4	75–80	3–6.5		-	17.5– 18	360°*	Continuous*	+1 st molar Mandible 3 rd molar	11–25 μSv (based on DAP value) 11–27	
Accutomo 3D FPD J Morita Mfg Corp.	Height: 4 Width: 4	75	4–5	-	17.5– 18	360°*	Continuous*	Maxilla Cuspids	μSv (based on DAP value) 21–26		
	Height: 4 Width: 4	75	4–6	-	17.5– 18	360°*	Continuous*	Maxilla 2 nd premolar +1 st molar	μSv (based on DAP value) 21–31		
	Height: 4 Width: 4	75–80	4–5	-	17.5– 18	360° *	Continuous*	Maxilla 3 rd molar	μSv (based on DAP value) 21–29		

*= Information extracted from website; NA = Information not available; EET = Effective exposure time; FOV = Field of view; TMI = Temporomandibular joint; DAP = Dose Area Product;
KAP = Kerma-Area Product

(Continued)

Table B. Effective dose and risk estimation of Cone Beam CT (CBCT) – Medium field of view (FOV) (height = 5.1–10 cm, examination of single and inter arch)

1 st Author Year ^[ref]	CBCT					Object	Results		Comments	
	Model Name/ Manufacturer	FOV Height (cm) Width (cm)	kVp	mAs	s		Degree of rotation(°)	Beam type (pulsating, continuous)		Effective dose (mSv;µSv)
Kim 2014 ⁽⁸⁾	Alphard VEGA Asahi Roentgen Ind. Co	Height: 5.1 Width: 5.1	80	9	-	17	Continuous*	Adult Maxillary incisor	µSv (ICRP) 22.34 (2007)	NA
		Height: 5.1 Width: 5.1	80	9	-	17	Continuous*	Adult Maxillary molar	µSv (ICRP) 25.26 (2007)	
		Height: 5.1 Width: 5.1	80	9	-	17	Continuous*	Adult Mandibular molar	µSv (ICRP) 93.67 (2007)	
		Height: 5.1 Width: 5.1	80	6	-	17	Continuous*	Maxillary incisor	µSv (ICRP) 20.10 (2007)	
		Height: 5.1 Width: 5.1	80	6	-	17	Continuous*	Maxillary molar	µSv (ICRP) 20.20 (2007)	
		Height: 5.1 Width: 5.1	80	6	-	17	Continuous*	Mandibular molar	µSv (ICRP) 61.51 (2007)	
		Height: 8 Width: 8	110	6.1	-	3.6	Pulsed	Adult One TMJ	µSv (ICRP) 45 (2007)	
		Height: 8 Width: 8	110	17.2	-	5.4	Pulsed	Adult One TMJ	µSv (ICRP) 129 (2007)	
Al-Okshi 2013 ⁽⁶⁾	NewTom VGi Quantitative Radiology	Height: 8 Width: 12	110	6.1	-	3.6	Pulsed	Adult Two TMJ	µSv (ICRP) 56 (2007)	Days of per capita natural background (2.08 mSv per day) Excess cases of fatal cancer in 1 million people
		Height: 8 Width: 8	90	3	-	2	Pulsed	Adult Dental	µSv (ICRP) 5.3 (2007)	
		Height: 8 Width: 8	90	3	-	2	Pulsed	Child Dental	µSv (ICRP) 6.8 (2007)	
Ludlow 2013 ⁽⁶⁾	i-CAT FLX Imaging Sciences	Height: 6	90	3	-	2	Pulsed	Adult	µSv (ICRP)	NA

[illegible]

Schilling 2013 ⁽⁹⁾	3D eXam KaVo Dental	Width: 16							Mandible	61.3 (2007)
		Height: 6	120	5	-	3.7	360		Child	µSv (ICRP)
		Width: 16							Mandible	73.2 (2007)
		Height: 8	120	5	-	3.7	360		Adult	µSv (ICRP)
		Width: 16							Both arches	69.8 (2007)
		Height: 8	120	5	-	3.7	360		Adult	µSv (ICRP)
	Pan eXam Plus 3D KaVo Dental,	Width: 8							Dental	85.1 (2007)
		Height: 6	120	5	-	4.7	360		Adult	µSv (ICRP)
		Width: 16							Maxilla	65.0 (2007)
		Height: 6	120	5	-	4.7	360		Adult	µSv (ICRP)
		Width: 16							Mandible	126.5 (2007)
		Height: 8	120	5	-	4.7	360		Adult	µSv (ICRP)
NA	3D eXam KaVo Dental	Width: 16							Both arches	148.1 (2007)
		Height: 8	120	5	-	7.4	360*		Adult	µSv (ICRP)
		Width: 16							Maxilla	67.6 (1990)
		Height: 8	120	5	-	2	360*		Adult	µSv (ICRP)
		Width: 16							Maxilla	18.4 (1990)
		Height: 8	120	5	-	7.4	360*		Adult	µSv (ICRP)
	Pan eXam Plus 3D KaVo Dental,	Width: 8							Maxilla	48.4 (1990)
		Height: 8	120	5	-	3.7	360*		Adult	µSv (ICRP)
		Width: 8							Maxilla	22.8 (1990)
		Height: 6.4	90	13	-	0.12	360*		Adult	µSv (ICRP)
		Width: 7.8							Pre-scan	0.4 (1990)
		Height: 6.1	90	10	-	2.3	360*		Adult	µSv (ICRP)
Schilling 2013 ⁽⁹⁾	Pan eXam Plus 3D KaVo Dental,	Width: 4.1							Maxilla	11.7 (1990)
		Height: 6.1	90	8	-	6.1	360*		Adult	µSv (ICRP)
		Width: 4.1							Maxilla	23.8 (1990)
		Height: 6.1	90	10	-	2.3	360*		Adult	µSv (ICRP)
		Width: 4.1							Mandible	79.2 (2007)
		Height: 6.1	90	10	-	2.3	360*		Adult	µSv (ICRP)

Davies 2012 ⁽¹⁾	i-CAT Next Generation Imaging Sciences	Height: 6.1 Width: 4.1	90	8	-	6.1	360*	Pulsed*	Adult Mandible	49.3 (ICRP) μSv (ICRP) 48.8 (1990) 114.8 (2007)	No presentation of FOV- width
		Height: 6.4 Width: 7.8	90	10	-	4.7	360*	Pulsed*	Adult Maxilla	μSv (ICRP) 27.4 (1990) 79.3 (2007)	
		Height: 6.4 Width: 7.8	90	6.3	-	12.5	360*	Pulsed*	Adult Maxilla	μSv (ICRP) 38.0 (1990) 124.9 (2007)	
		Height: 6.4 Width: 7.8	90	10	-	4.7	360*	Pulsed*	Adult Mandible	μSv (ICRP) 39.3 (1990) 109.6 (2007)	
		Height: 6.4 Width: 7.8	90	6.3	-	12.5	360*	Pulsed*	Adult Mandible	μSv (ICRP) 68.4 (1990) 183.7 (2007)	
		Height: 6	120	2.1	-	8.9	360	Pulsed* EET = 2-7.2 *	Adult Mandible	μSv (ICRP) 35 (1990) 58 (2007)	
Grunheid 2012 ⁽¹²⁾	i-CAT Next Generation Imaging Sciences	Height: 6	120	1.4	-	26.9	360	Pulsed* EET = 2-7.2 *	Adult Mandible	μSv (ICRP) 69 (1990) 113 (2007)	No presentation of FOV- width
		Height: 6	120	2.1	-	8.9	360	Pulsed* EET = 2-7.2 *	Adult Maxilla	μSv (ICRP) 18 (1990) 32 (2007)	
		Height: 6	120	1.4	-	26.9	360	Pulsed* EET = 2-7.2 *	Adult Maxilla	μSv (ICRP) 35 (1990) 60 (2007)	
		Height: 8	120	-	8.9	8.9 scan time	360*	Pulsed* EET = 2-7.2 *	Maxilla + mandible	Dose as % annual background in the US Probability of fatal cancer per 1 million people 65 (2007)	
		Height: 8	120	-	37.07	26.9 scan time	360*	Pulsed* EET = 2-7.2 *	Maxilla + mandible	μSv (ICRP) 134.2 (2007)	
		Height: 7.1	85	6	102	-	NA	NA	Adult	μSv (ICRP)	
Jeong	AZ3000CT, Asahi	Height: 7.1	85	6	102	-	NA	NA	Adult	μSv (ICRP)	NA

2012 ⁽¹³⁾	Width: 7.9	80	5	-	17	360*	Continuous*	Mandible	332.4 (2007)		
Okano 2012 ⁽³⁶⁾	Height: 6 width: 10.2	80	5	-	17	360*	Continuous*	Adult Maxilla + Mandible	μSv (ICRP) 146 (1990) 203 (2007)	NA	
	Height: 5.1 width: 5.1	80	8	-	17	360*	Continuous*	Adult Several teeth	μSv (ICRP) 34 (1990) 86 (2007)		
Pauwels 2012 ⁽¹⁴⁾	Height: 10 Width: 5	90	-	87.5	-	360*	Continuous* EET=5.4-30 *	Adult Maxilla	μSv (ICRP) 54 (2007)	NA	
	Height: 6 Width: 16	120	-	18.5	-	360*	Pulsed*	Adult Mandible	μSv (ICRP) 45 (2007)		
	Height: 8 Width: 15	90	-	108	-	360*	Pulsed* EET=10.8 *	Adult Dento- alveolar	μSv (ICRP) 92 (2007)		
	Height: 8 Width: 12	110	-	43	-	360*	Pulsed* EET=3.9-9 *	Adult Dento- alveolar	μSv (ICRP) 265 (2007)		
	Height: 7 Width: 12	85	-	127	-	360*	Continuous *	Adult Dento- alveolar	μSv (ICRP) 123 (2007)		
ProMax 3D Planneca Oy	Height: 7 Width: 12	85	-	91	-	360*	Continuous *	Adult Dento- alveolar	μSv (ICRP) 81 (2007)	NA	
	Height: 8 Width: 8	84	-	169	-	200*	Pulsed* EET=7*	Adult Dento- alveolar	μSv (ICRP) 122 (2007)		
	Height: 8 Width: 8	84	-	19.9	-	200*	Pulsed* EET=7*	Adult Dento- alveolar	μSv (ICRP) 28 (2007)		
	Height: 10 Width: 7.5	85	-	30	-	360*	Pulsed* EET=2.25-6 *	Adult Dento- alveolar Mandible	μSv (ICRP) Dentoalveolar .46 (2007) Mandible: 47(2007)		
								Maxilla	Maxilla:		

	Veraviewpos 3D J Morita Mfg Corp.	Height: 8 Width: 8	70	-	51	-	180*	Continuous * EET = 9.4*	Dento- alveolar	45 (2007) µSv (ICRP) 73(2007)		
Qu 2012B ⁽³⁴⁾	DCT – PRO DCT Pro (VATECH, Co., Ltd.)	Height: 7 Width: 16	90	7	-	Scan time 15	360	Continuous*	Mandible	NA	38.7% dose reduction 41.5% dose reduction	
Theodorakou u 2012 ⁽³⁵⁾	i-CAT Next Generation Imaging Sciences	Height: 6	120	-	18.5	-	360*	Pulsed* EET=2-7.2 *	10yrs Mandible	µSv (ICRP) 63 (2007)	No presentation of FOV - width	Percentage attributable lifetime mortality risk
		Height: 6	120	-	18.5	-	360*	Pulsed* EET=2-7.2 *	Adult Mandible	µSv (ICRP) 49 (2007)		
		Height: 6	120	-	18.5	-	360*	Pulsed* EET=2-7.2 *	10yrs Maxilla	µSv (ICRP) 43 (2007)		

Ludlow 2011 ⁽¹⁶⁾	ProMax 3D Planmeca Oy	Height: 6	120	-	18.5	-	360*	Pulsed* EET=2-7.2 *	Adult Maxilla	µSv (ICRP) 33 (2007)	Effective dose compared to Panoramic radiography	Number of days of per capita background radiation Probability of x in a million fatal cancer	
		Height: 8	84	-	16.8	-	200*	Pulsed * EET=7*	10yrs Maxilla and mandible	µSv (ICRP) 24 (2007)			
		Height: 8	84	-	19.6	-	200*	Pulsed * EET=7*	Adult Maxilla and mandible	µSv (ICRP) 18 (2007)			
		Height: 5	90	5	-	17.5	360	Continuous* EET=5.4-30 *	Adolescent Maxilla	µSv (ICRP) 70 (2007)			
	3D Accuion 170 J Morita Mfg Corp.	Height: 5	90	5	-	17.5	360	Continuous* EET=5.4-30 *	10yrs Mandible	µSv (ICRP) 214 (2007)			
		Height: 10	90	5	-	17.5	360	Continuous* EET=5.4-30 *	10yrs Maxilla and mandible	µSv (ICRP) 237 (2007)			
		Height: 10	90	5	-	17.5	360	EET=5.4-30 *	Adolescent Maxilla and mandible	µSv (ICRP) 188 (2007)			
		Height: 9 Width: 15	80	-	86.4	-	360*	Pulsed* EET=10.8 *	Small adult Maxilla + mandible	µSv (ICRP) 76 (2007)			
	Kodak 9500 Carestream Health*	Height: 9 Width: 15	85	-	108	-	360*	Pulsed* EET=10.8 *	Medium adult Maxilla + mandible	µSv (ICRP) 98 (2007)			
		Height: 9 Width: 15	90	-	108	-	360*	Pulsed* EET=10.8 *	Large Adult Maxilla + mandible	µSv (ICRP) 166 (2007)			
		Height: 5 Width: 8	84	16	-	12	200*	Pulsed*	Adult Maxilla	µSv (ICRP) 127 (2007)			
		Height: 5 Width: 8	84	16	-	12	200*	Pulsed*	Adult Mandible	µSv (ICRP) 197 (2007)			
Ou 2010 ⁽²⁰⁾	ProMax 3D Planmeca Oy	Height: 8 Width: 8	84	8	-	12	200*	Pulsed*	Adult Maxilla + Mandible	µSv (ICRP) 102 (2007)	NA		
		Height: 8	84	10	-	12	200*	Pulsed*	Adult	µSv (ICRP)			

		Width: 8								Maxilla + Mandible	169 (2007)		
		Height: 8 Width: 8	84	12	-	12	200*	Pulsed*	Adult Maxilla + Mandible	Adult Maxilla + Mandible	μSv (ICRP) 216 (2007)		
		Height: 8 Width: 8	84	14	-	12	200*	Pulsed*	Adult Maxilla + Mandible	Adult Maxilla + Mandible	μSv (ICRP) 272 (2007)		
		Height: 8 Width: 8	84	16	-	12	200*	Pulsed*	Adult Maxilla + Mandible	Adult Maxilla + Mandible	μSv (ICRP) 298 (2007)		
		Height: 8 Width: 8	84	8	-	2.8	200*	Pulsed*	Adult Maxilla + Mandible	Adult Maxilla + Mandible	μSv (ICRP) 30 (2007)		
		Height: 8 Width: 8	84	16	-	12	200*	Pulsed*	Adult Maxilla + Mandible	Adult Maxilla + Mandible	μSv (ICRP) 306 (2007)		
		Height: 8 Width: 8	84	8	-	8.4	200*	Pulsed*	Adult Maxilla + Mandible	Adult Maxilla + Mandible	μSv (ICRP) 87 (2007)		
Loubele 2009 ⁽²²⁾	i-CAT Imaging Sciences	Height: 8	120	3-8	-	20 or 40	360*	Pulsed*	Adult Maxilla	Adult Maxilla	μSv (ICRP) 20s: 45 (2007) 40s: 77 (2007)	NA	Effective doses compared to other radiographic exams No presentation of FOV - width
		Height: 8	120	3-8	-	20 or 40	360*	Pulsed*	Adult Mandible	Adult Mandible	μSv (ICRP) 20s: 34 (2007) 40s: 64 (2007)		
		Height: 8	120	3-8	-	20 or 40	360*	Pulsed*	Adult Extended FOV	Adult Extended FOV	μSv (ICRP) 2x20s: 82 (2007)		
Okano 2009 ⁽⁴⁴⁾	3D Accuitemo J Morita Mfg Corp.	Height: 6 Width: 6	80	5	-	18	360*	Continuous *	Mandible Molar	Mandible Molar	μSv (ICRP) 66.08 (1990) 101.46 (2007)	NA	Effective dose compared to MDCT Panoramic radiography
Roberts	i-CAT Next	Height: 6	120	3-8	-	NA	360*	Pulsed*	Mandible	Mandible	μSv (ICRP)	Dose as %	Effective

Ludlow 2008 ⁽²⁵⁾	CB MercurRay Hitachi Medical Corp.	Height: 10 Width: 10	120	-				3 rd molar Adult Maxilla	52-77 µSv (ICRP) 156 (1990) 407 (2007)	Background radiation Probability of increase fatal cancer in a million	Effective dose compared to panoramic radiography
		Height: 8 Width: 8	84	-	72	-	191	Small adult Maxilla Mandible	µSv (ICRP) 151 (1990) 488 (2007)		
	ProMax 3D Planmeca Oy	Height: 8 Width: 8	84	-	96	-	191	Large adult Maxilla Mandible	µSv (ICRP) 203 (1990) 652 (2007)		
		Height: 7.6 Width: 8.1	90	-	76	-	360	Maxilla Mandible	µSv (ICRP) 66 (1990) 189 (2007)		
	Pexion 3D TeraRecon Inc	Height: 7.6 Width: 8.1	90	-	148	-	2 x 360	Maxilla Mandible	µSv (ICRP) 154 (1990) 388 (2007)		
		Height: 8 Width: 13	110	3.2	-	18	360	Adult Mandible	µSv (ICRP) 34.7 (1990) 74.7 (1990+Salivar y Gland)		
Ludlow 2003 ⁽³⁰⁾	NewTom unit 1 Quantitative Radiology	Height: 8 Diameter: 13	110	3.2	-	18	360	Adult Maxilla	µSv (ICRP) 19.9 (1990) 41.5 (1990+Salivar y Gland)	Probability of increase fatal cancer in a million	

*= Information extracted from website; NA = Information not available; EET = Effective exposure time; FOV = Field of view; TMJ = Temporomandibular joint; DAP = Dose Area Product;
KAP = Kerma-Area Product

(Continued)

Table C. Effective dose and risk estimation of Cone Beam CT (CBCT) – Large field of view (FOV) (Height $\geq$ 10 cm, examination of maxillo- and craniofacial region)

1 st Author Year ^(ref)	Model Name/ Manufacturer	CBCT					Object	Results		Comments
		FOV Height (cm) Width (cm)	kVp	mAs	ms	Degree of rotation (°)		Beam type (pulsating, continuous)	Effective dose (mSv, μ Sv)	
Kim 2014 ⁽⁸⁾	Alphard VEGA (Asahi Roentgen Ind. Co)	Height: 10.2 Width: 10.2	80	8	-	17	Continuous*	Adult Maxilla	μ Sv (ICRP) 145.85 (2007)	NA
		Height: 10.2 Width: 10.2	80	8	-	17	Continuous*	Adult Mandible	μ Sv (ICRP) 184.33 (2007)	
		Height: 10.2 Width: 10.2	80	4	-	17	Continuous*	Adult Maxilla	μ Sv (ICRP) 68.51 (2007)	
		Height: 10.2 Width: 10.2	80	4	-	17	Continuous*	Adult Mandible	μ Sv (ICRP) 85.10 (2007)	
		Height: 15.4 Width: 15.4	80	9		17	Continuous*	Adult Maxilla	μ Sv (ICRP) 303.66 (2007)	
		Height: 15.4 Width: 15.4	80	9	-	17	Continuous*	Adult mandible	μ Sv (ICRP) 288.48 (2007)	
		Height: 15.4 Width: 15.4	80	5	-	17	Continuous*	Adult Maxilla	μ Sv (ICRP) 163.23 (2007)	
		Height: 15.4 Width: 15.4	80	5	-	17	Continuous*	Adult Mandible	μ Sv (ICRP) 158.49 (2007)	
		Height: 17.9 Width: 20	80	6	-	17	Continuous*	Adult	μ Sv (ICRP) 183.07 (2007)	
		Height 17.9 Width 20	80	4		17	Continuous*	Adult	μ Sv (ICRP) 123.02 (2007)	
		Height: 11 Width: 16	90	3	-	2	Pulsed	Adult Arches + TMJ	μ Sv (ICRP) 8.8 (2007)	
		Height: 11 Width: 16	90	3	-	2	Pulsed	Child Arches + TMJ	μ Sv (ICRP) 13.3 (2007)	
Ludlow 2013 ⁽⁴⁰⁾	i-CAT FLX Imaging Sciences	Height: 13 Width: 16	90	3	-	2	Pulsed	Adult Standard	μ Sv (ICRP) 11.4 (2007)	Arches= jaws Ceph. = cephalometry

[illegible]

		Height: 17 Width: 23	120	5	-	7.4	360	Pulsed	Adult Extended FOV	µSv (ICRP) 136.2 (2007)		
Lukat 2013 ⁽⁴¹⁾	CB MeruRay Hitachi Medical Corporation.	Width: 22.86	100	10	-	9.6	NA	NA	Adult TMJ Bilateral	µSv (ICRP) 223.6 (2007)	NA	
Rottke 2013 ⁽⁴⁶⁾	Kodak 9500 Carestream Health*	Height: 18.4 Width: 20.6	90	10	-	NA	360*	Pulsed*	Maxilla Mandible	µSv (ICRP) 151 (2007)		
	Galileos Comfort Sirona Dental Systems	Height: 15 Width: 15	85	7	-	NA	210	Pulsed*		µSv (ICRP) 51 (2007)		
		Height: 15 Width: 15	85	7	-	NA	210	Pulsed*	Maxilla Mandible	µSv (ICRP) 95 (2007)	-	
	PaX-Duo 3D	Height: 12 Width: 8.5	90	10	-	NA	360*	Pulsed*		µSv (ICRP) 228 (2007)		
	3D eXam	Height: 20 Width: 16	120	5	-	NA	360*	Pulsed*		µSv (ICRP) 23 (2007)		
		Height: 17 Width: 23	120	5	-	NA	360*	Pulsed*		µSv (ICRP) 156 (2007)		
Schilling 2013 ⁽⁴⁹⁾	3D eXam KaVo Dental	Height: 17 Width: 23	120	5	-	0.12	360*	Pulsed* EET =2-7.2 *	Adult Pre-scan	µSv (ICRP) 1.7(1990) 3.1(2007)	NA	
		Height: 17 Width: 23	120	5	-	3.7	360*	Pulsed* EET =2-7.2 *	Adult Maxilla	µSv (ICRP) 56.4(1990) 72.0(2007)		
		Height: 13 Width: 16	120	5	-	3.7	360*	Pulsed* EET =2-7.2 *	Adult Maxilla	µSv (ICRP) 62.7(1990) 106(2007)		
		Height: 17	120	2.1	-	8.9	360*	Pulsed*	Adult Full head	µSv (ICRP) 47 (1990) 78 (2007)	NA	
Davies 2012 ⁽¹¹⁾	i-CAT Next Generation Imaging Sciences	Height: 13	120	2.1	-	8.9	360	Pulsed*	Adult Mandible maxilla	µSv (ICRP) 44 (1990) 77 (2007)		
Grinheid 2012 ⁽¹²⁾	i-CAT Next Generation	Height: 17	120	-	18.54	9	360*	Pulsed*	Maxilla and mandible	µSv (ICRP) 69.2 (2007)	Dose as % annual	No presentation

	Imaging Sciences											Maxilla and mandible	μ Sv (ICRP) 64.7 (2007) μ Sv (ICRP) 127.3 (2007) μ Sv (ICRP) 131.3 (2007)	background in the US Probability of fatal cancer per 1 million people	of FOV-width
		Height: 17 Width: 17	120	-	18.54	9	360*	Pulsed*	Maxilla mandible	Maxilla mandible	Maxilla mandible	Maxilla mandible			
Okano 2012 ⁽³⁸⁾	Alphard VEGA ASAHI ROENTGEN IND. CO., LTD.*	Height: 10.2 Width: 10.2	80	5	-	17	360*	Continuous*	Adult Maxilla + Mandible + nose	μ Sv (ICRP) 171 (1990) 238 (2007)					
		Height: 15.4 Width: 15.4	80	5	-	17	360*	Continuous*	Adult Full face + TMJ	μ Sv (ICRP) 335 (1990) 413 (2007)					
		Height: 17.9 Width: 20	80	5	-	17	360*	Continuous*	Adult Full head	μ Sv (ICRP) 244 (1990) 323 (2007)					
		Height: 15 Width: 15	85	-	28	-	220*	Pulsed*	Maxillo- facial	μ Sv (ICRP) 84 (2007)					
Pauwels 2012 ⁽¹⁶⁾	Galileos Comfort Sirona Dental Systems	Height: 13 Width: 16	120	-	18.5	-	360*	Pulsed*	Maxillo- facial	μ Sv (ICRP) 83 (2007)					
	i-CAT Next Generation Imaging Sciences	Height: 14 Width: 21	120	-	76	-	360 or 190*	Continuous*	Maxillo- facial	μ Sv (ICRP) 368 (2007)					
	Iluma Elite IMTEC Imaging	Height: 18 Width: 20	90	-	108	-	360*	Pulsed*	Maxillo- facial	μ Sv (ICRP) 136 (2007)					
	Kodak 9500 Carestream Health*	Height: 23 Width: 23	110	-	10.4	-	360*	Pulsed*	Maxillo- facial	μ Sv (ICRP) 83 (2007)					
	NewTom VG Quantitative Radiology	Height: 15 Width: 15	110	-	8.8	-	360*	Pulsed*	Maxillo- facial	μ Sv (ICRP) 194 (2007)					
	Scanora 3D Soredex	Height: 13.5 Width: 14.5	85	-	48	-	360*	Pulsed*	Maxillo- facial	μ Sv (ICRP) 68 (2007)					

	SkyView Cefla Dental Group	Height: 17 Width: 17	90	-	51	-	190 or 360*	Pulsed*	Maxillo- Facial	µSv (ICRP) 87 (2007)		
										µSv (ICRP) - Without collar around the neck: 95.3 (2007) - With one collar loosely on the front of the neck: 91.8 (2007) - With two collars loosely on the front and back of the neck: 84.5 (2007) - With one collar tightly on the front of the neck: 82.0 (2007) - With two collars tightly on the front and back of the neck: 79.1 (2007)		
Qu 2012A ⁽³³⁾	NewTom 9000 Quantitative Radiology	Height: 15 Width: 15	110	3.5	-	NA	360	Pulsed	Height from nasal root to inferior border of the mandible Maxilla + mandible	NA		
Qu 2012B ⁽³⁴⁾	DCT – PRO DCT Pro (VAITECH, Co., Ltd)	Height: 19 Width: 20	90	7	-	NA	360*	Continuous*	Maxilla + mandible	µSv (ICRP) Without collar	NA	

										around the neck: 254.3 (2007) With one collar tightly around the front neck. 208.5 (2007) With two collars tightly around the front and back neck: 219.1 (2007)	(18.0% reduction) Scan time 1.5
Rampado 2012 ⁽¹⁵⁾	NewTom VG 3D Quantitative Radiology	Height:10.5 Width: 15	110	2.2	-	3.6	360*	Pulsed*	Adult Maxilla Mandible	µSv (ICRP) Film dose : 107 (2007)	Compare two dosimeter types
		Height:10.5 Width: 15	110	2.2	-	3.6	360*	Pulsed*	Adult Maxilla Mandible	µSv (ICRP) TLD dose : 117 (2007)	
Szczyn 2012 ⁽¹⁶⁾	Kodak 9500 Carestream Health* NewTom FP Quantitative Radiology	Height: 18.4 Width: 20.6	90	10	-	10.8	360*	Pulsed*	Maxilla Mandible	µSv (ICRP) 118.65 (2007)	NA
		Height: 13 Width: 17	110	2.7	-	5.4	360*	Pulsed*	Maxilla Mandible	µSv (ICRP) 84.45 (2007)	
Theodoraku 2012 ⁽¹⁵⁾	i-CAT Next Generation Imaging Sciences	Height: 13	120	-	18.5	-	360*	Pulsed*	Maxillo-facial	µSv (ICRP) 10yr-old: 134 (2007) Adolescent: 82 (2007)	No presentation of FOV-width mortality risk
	NewTom VG Quantitative Radiology	Height: 11	110	-	Auto	-	360*	Pulsed*	Dental	µSv (ICRP) 10yr-old: 114 (2007) Adolescent: 81 (2007)	
	3D Accutomo 170 J Morita Mfg. Corp.	Height: 12	90	5	-	17.5	360	Continuous*	Maxillo-facial	µSv (ICRP) 10yr-old:	

Librizzi 2011 ⁽¹⁷⁾	CB MercuRay Hitachi Medical Corp.	Width: 30.48	120	-	150	-	360*	Continuous*	TMJ Bilateral	282 (2007) Adolescent: 216 (2007)	Each TMJ was imaged with the TMJ in the center of the image field.
		Width: 22.86	120	-	150	-	360*	Continuous*	TMJ Bilateral	µSv (ICRP) 916 (2007)	
		Width: 15.24	120	-	150	-	360*	Continuous*	TMJ- Single	µSv (ICRP) 548 (2007)	
		Width : 15.24	120	-	150	-	360*	Continuous*	TMJ- Bilateral	µSv (ICRP) 279 (2007)	
		Height: 18 Width: 21	80	-	86.4	-	360*	Pulsed*	Small adult Maxilla and mandible	µSv (ICRP) 93 (2007)	
Ludlow 2011 ⁽¹⁸⁾	Kodak 9500 Carestream Health*	Height: 18 Width: 21	85	-	108	-	360*	Pulsed*	Medium adult Maxilla and mandible	µSv (ICRP) 163 (2007)	Effective dose compared to panoramic radiography Compare doses with/without copper filtration 0.4mm
		Height: 18 Width: 21	90	-	108	-	360*	Pulsed*	Large adult Maxilla and mandible	µSv (ICRP) 260 (2007)	
		Height: 20 Width: 13.2	120	-	23.87	-	360*	Pulsed*	Maxilla Mandible	mSv (ICRP) 0.11 (1990)	
Carrafiello 2010 ⁽¹⁹⁾	i-CAT Imaging Sciences	Height: 14 or 18*	120	3.8	-	40	360	Continuous*	Maxilla Mandible	mSv (ICRP) 126 (1990) 157 (2007)	standard adult Measured KAP = 184
Vassileva 2010 ⁽⁴²⁾	Iluma Ultra IMTEC Imaging	Height: 14 or 18*	120	3.8	-	20	360	Continuous*	Maxilla Mandible	mSv (ICRP) 74 (1990)	low-dose adult

Author	Imaging System	Height: 14 or 18*	120	1	-	20	360	Continuous*			94 (2007)	Measured KAP = 110 paediatric Measured KAP = 54
Faccioli 2009 ⁽²¹⁾	Illuma Ultra IMTEC Imaging	Height: 14 Width: 15	120	-	-	20	360	Continuous*	Maxilla Mandible	msSv (ICRP 37 (1990) 46 (2007)	NA	Effective doses compared to other radiographic exams
	QR-DVT 9000	Height: 15 Width: 15	110	-	226.13	-	-	NA	Temporal bone	msSv (ICRP) 0.11 (2007)		
Loubale 2009 ⁽²⁶⁾	i-CAT Imaging Sciences	Height: 13	120	10.6	-	10	360*	Pulsed	Maxilla Mandible	µSv (ICRP) 48 (2007)	NA	Effective doses compared to other radiographic exams
	i-CAT Imaging Sciences	Height: 13	120	39.5	-	40	360*	Pulsed	Maxilla Mandible	µSv (ICRP) 77(2007)		
	NewTom 3G® Quantitative Radiolog	Height: 15.24	110	9	-	36	360*	Pulsed	Maxilla Mandible	µSv (ICRP) 57 (2007)		
	NewTom 3G® Quantitative Radiolog	Height: 30.48	110	9	-	36	360*	Pulsed	Maxilla Mandible	µSv (ICRP) 30(2007)		
Roberts 2009 ⁽²⁵⁾	i-CAT Next Generation Imaging Sciences	Height: 13	120	3-8	-	N/A	360*	Pulsed*	Maxilla + mandible	µSv (ICRP) 39.5 (1990) 110.5 (2007)	Dose as % annual background dose in UK	Effective dose compared to panoramic and as multiple of full FOV
		-Full FOV:	120	3-8	-	-	360*	Pulsed*	Maxilla + mandible	µSv (ICRP) 92.8 (1990) 182.1 (2007)	Risk of fatal malignancy	
Coppenrath 2008 ⁽²⁴⁾	NewTom DVT QR 9000 Quantitative Radiology	Height: 15 Width: 13	110	4.1- 4.7		N/A	360*	Pulsed*	Maxilla Mandible	msSv (ICRP) -Female:0.095 (1990) -Male : 0.093 (1990)	NA	
Ludlow 2008 ⁽²⁵⁾	NewTom 3G® Quantitative Radiology	Height: 19 Width: 19	110	-	8.09	-	360	Pulsed*	Maxilla Mandible	µSv (ICRP) 42 (1990) 68 (2007)	Background	Effective dose compared to panoramic
	CB Mercuray Hitachi Medical Corporation	Height: 19 Width: 19	120	-	150	-	360	Continuous*	Maxilla Mandible	µSv (ICRP) 806 (1990) 1073 (2007)	Probability of increase fatal cancer in a million	
		Height: 19 Width: 19	100	-	100	-	360	Continuous*	Maxilla Mandible	µSv (ICRP) 464 (1990) 569 (2007)		

	i-CAT Next Generation Imaging Sciences	Height: 17 Width: 23.2	120	-	19	-	360	Pulsed*	Maxilla Mandible	µSv (ICRP) 37 (1990) 74 (2007)	
		Height: 19 Width: 19	120	-	20	-	360	Continuous*	Maxilla Mandible	µSv (ICRP) 50 (1990) 98 (2007)	
		Height: 19 Width: 19	120	-	125	-	360	Continuous*	Maxilla Mandible	µSv (ICRP) 252 (1990) 498 (2007)	
		Height: 15 Width: 15	120	-	150	-	360	Continuous*	Maxilla Mandible	µSv (ICRP) 264 (1990) 560 (2007)	
	CB Mercuray-Hiachi Medical Corporation	Height: 13 Width: 16	120	-	19	-	360	Pulsed*	Maxilla Mandible	µSv (ICRP) 29 (1990) 69 (2007)	
		Height: 13 Width: 17	120	-	19	-	360	Pulsed*	Maxilla Mandible	µSv (ICRP) 36 (1990) 87 (2007)	
	i-CAT Classic Imaging Sciences	Height: 15 Width: 15	85	-	21	-	210	Pulsed*	Maxilla Mandible	µSv (ICRP) 28 (1990) 70 (2007)	
		Height: 15 Width: 15	85	-	42	-	210	Pulsed*	Maxilla Mandible	µSv (ICRP) 52 (1990) 128 (2007)	
	Galileos Sirona Dental Systems	Height: 30.48	110–120	2.5, 10, 15	-	NA	360	Continuous*	Full head	µSv (ICRP) 62–656 (1990) 72–761 (2007)	
		Height: 22.68	110–120	2.5, 10, 15	-	NA	360	Continuous*	both dental arches, the condyles, and the nose	µSv (ICRP) 54–601 (1990) 61–680 (2007)	
Palomo 2008 ⁽²⁶⁾	CB Mercuray-Hiachi Medical Corporation	Height: 15.24	110–120	2.5, 10, 15	-	NA	360	Continuous*	both arches with anterior soft tissue, condyles as possible	µSv (ICRP) 47–535 (1990) 53–603 (2007)	NA No presentation of FOV-width

Silva 2008 ⁽³⁷⁾	NewTom 9000 Quantitative Radiology	Height: 23	110	5.4	-	NA	360*	Pulsed*	Maxilla & mandible	µSv (ICRP) 56.2 (2007)	NA	No presentation of FOV- width
	i-CAT Imaging Sciences,	Height: 13	120	23.87	-	NA	360	Pulsed*	Maxilla Mandible	µSv (ICRP) 61.1 (2007)		
Ludlow 2006 ⁽²⁵⁾	NewTom 3G Quantitative Radiology	Height : 30.48	110	1.5	-	5.4	360*	Pulsed*	Maxilla Mandible	µSv (ICRP) 44.5 (1990) 58.9 (2005)	Background radiation	Effective dose compared to panoramic radiography No presentation of FOV- width
	MeruRay Hitachi Medical Corporation	Height : 30.48	120	15	-	10	360*	Continuous*	Maxilla Mandible	µSv (ICRP) 846.9 (1990) 1025.4		
		Height : 30.48	100	10	-	10	360*	Continuous*	Maxilla Mandible	µSv (ICRP) 476.6 (1990) 557.6 (2005)		
		Height : 22.68	100	10	-	10	360*	Continuous*	Maxilla Mandible	µSv (ICRP) 288.9 (1990) 435.5 (2005)		
		Height : 15.24	100	10	-	10	360*	Continuous*	Maxilla Mandible	µSv (ICRP) 168.4 (1990) 283.3 (2005)		
	i-CAT Imaging Sciences	Height :30.48	120	5.7		6.6	360	Pulsed*	Maxilla Mandible	µSv (ICRP) 143.8 (1990) 193.4 (2005)		
Height :22.68		120	5.7		6.6	360	Pulsed*	Maxilla Mandible	µSv (ICRP) 68.7 (1990) 104.5 (2005)			
Wortche 2006 ⁽²⁸⁾	NewTom, QR DVT 9000 Quantitative Radiology	Height: 10 Width: 12	110	5.4	-	NA	360	Pulsed*	Maxilla Mandible	mSv (ICRP) 0.342 (1990)	NA	

Tsiklakis 2005 ⁽²⁵⁾	NewTom DVT 9000 Quantitative Radiology	Height: 15 Width: 13	110	3.4	-	17	360°	Pulsed*	Maxilla Mandible	mSv (ICRP) -Non- shielding 0.035(1990) -Non- shielding 0.064 (1990+ salivary gland) -Shielding 0.023 (1990) -Shielding 0.052 (1990+salivar y gland)	NA	
Ludlow 2003 ⁽³⁰⁾	NewTom QR DVT 9000 unit 1 Quantitative Radiology	Height: 15 Width: 13	110	3.2	-	18	360°	Pulsed*	Mandible & Maxilla	µSv (ICRP) 36.9 (1990) 77.9 (1990+Salivar y Gland)	Probability of increase fatal cancer in a million	
	NewTom QR DVT 9000 unit 2 Quantitative Radiology	Height: 15 Width: 13	110	4.2	-	18	360°	Pulsed*	Mandible & Maxilla	µSv (ICRP) 42.1 (1990) 91.5 (1990+Salivar y Gland)	Days of annual background radiation dose per capita in USA	
Mah 2003 ⁽³¹⁾	NewTom 9000 Quantitative Radiology	Height: 13	110	3.5	-	18	360°	Pulsed	Full head	µSv (ICRP) 50.27 (1990)	NA	No presentation of FOV- width

*= Information extracted from website; NA = Information not available; EET = Effective exposure time; FOV = Field of view; TMJ = Temporomandibular joint; DAP = Dose Area Product;

KAP = Kerma-Area Product

II

RESEARCH

Using GafChromic film to estimate the effective dose from dental cone beam CT and panoramic radiography

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Objectives: To demonstrate the feasibility of GafChromic[®] XR-QA2 (ISP Corp., Wayne, NJ) as a dosimeter when performing measurements of the effective dose from three cone beam CT (CBCT) units and to compare the doses from examinations of three common dental clinical situations. A second aim was to compare the radiation doses for three digital panoramic units with the doses for the CBCT units.

Methods: The CBCT units used were Veraviewepocs 3De[®] (J Morita MFG Corp., Kyoto, Japan), ProMax[®] 3D (Planmeca, Helsinki, Finland) and NewTom VGi[®] (Quantitative Radiology, Verona, Italy). GafChromic XR-QA2 films were placed between the selected layers of the head and neck of a tissue-equivalent human skull (RANDO[®] phantom; The Phantom Laboratory, Salem, NY). The exposure parameters were set using the automatic exposure control function of the units. Depending on the availability, medium and smaller field of view (FOV) scanning modes were used. The effective dose was estimated using the 2007 International Commission on Radiological Protection formalism.

Results: The lowest effective dose of a CBCT unit was observed for ProMax 3D, FOV 4 × 5 cm (10 µSv), the highest for NewTom VGi, FOV 8 × 8 cm—high resolution (129 µSv). The range of effective doses for digital panoramic machines measured was 8–14 µSv.

Conclusions: This study demonstrates the feasibility of using radiochromic films for dental CBCT and panoramic dosimetry.

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Keywords: radiation dosage; cone beam computed tomography; film dosimetry

Introduction

Panoramic radiography has long been a common diagnostic imaging technique in dentistry owing to its low dose and large area for evaluation, which includes bone and teeth in the same image.¹ Cone beam CT (CBCT) is a more recent technology that has significant potential for a number of clinical situations requiring CBCT imaging.² Although CBCT provides additional information, it may result in higher radiation doses than conventional imaging procedures, such as intraoral and panoramic.^{2,3}

Although the absorbed doses from oral and maxillofacial radiology procedures are usually low, no exposure to radiographs can be regarded as completely free of risk. The measurement of absorbed organ doses is needed to estimate the effective dose associated with diagnostic radiographic imaging. The traditional way of determining the effective dose in oral and maxillofacial radiology is by measuring the organ doses using thermoluminescent dosimeters (TLDs) and head phantoms.^{3–6}

In rotating irradiation geometry with collimated radiation fields, the dose distribution will show more or less steep dose gradients. This is a major problem if you want to map or sample the dose distribution with a

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reasonable degree of accuracy using TLDs. The geometry drawback encouraged us to choose a method with higher spatial resolution for mapping the dose distributions in a phantom. The GafChromic® XR-QA film (ISP Corp., Wayne, NJ) is designed specifically as a quality assurance (QA) tool for radiology and dosimetry applications. In combination with flatbed document scanners,⁷ it has been used for measuring medical⁸ and dental⁹ CBCT doses and CT doses.^{10,11} Some of the characteristics of this film have been studied: energy dependence⁸ and angular dependence.¹⁰ One of the advantages of this film is that it provides a high-resolution image with no chemical processing.¹² The film is not sensitive to visual light and can therefore be handled in ambient light. Ionizing radiation induces polymerization within the active layer of the film, changing its reflectance and making it appear darker. The darkening of the film is dependent on the radiation exposure received. The darkening of the film occurs instantaneously as the reaction immediately creates a polymer dye complex within the active layer of the film.¹³

The aim of this study was to demonstrate the feasibility of the GafChromic film as a dosimeter for use in rotating dental radiography and apply this technique for estimation of the effective doses from three CBCT units and three panoramic units.

Materials and methods

Cone beam CT units

The CBCT units selected for this study were Veraviewepocs 3De® (J Morita MFG Corp., Kyoto, Japan), ProMax® 3D (Planmeca, Helsinki, Finland) and NewTom VGi® (Quantitative Radiology, Verona, Italy). All CBCT units used flat panel detectors (FPDs) based on similar principles, i.e. a scintillating CsI layer and a light-sensitive silicon photodiode matrix. Exposure parameters and protocols used are given in Table 1.

Panoramic units

The panoramic machines selected for this study were Veraviewepocs 3De (J Morita MFG Corp., Kyoto, Japan), ProMax 3D and ProMax (Planmeca) ProMax was used with a photostimulable phosphor plate system (PSP) (DX-S digitizer; Agfa HealthCare, Mortsel, Belgium), ProMax 3D was used with a charge coupled device detector (CCD) and Veraviewepocs 3De was used with the same FPD as for the CBCT mode. The parameters of voltage (kV), tube current (mA) and exposure time (s) for each scan of the CBCT and panoramic units were fixed at the units' manufacturer-recommended settings for an average adult patient (Table 1).

Phantom and the GafChromic film XR-QA2

The phantom (RANDO®; The Phantom Laboratory, Salem, NY) was a small adult skull surrounded by soft tissue-equivalent material (Figure 1). Using the positioning aid provided for the scanner, the phantom was positioned mimicking a typical patient examination.

GafChromic films were placed between four selected levels in the head and neck of the phantom for each radiographic technique to record the distribution of the absorbed radiation dose. For detailed information regarding placement of the films, see Table 1.

Measurements were performed using GafChromic XR-QA2 films that were scanned with an Epson® Perfection 4990 Photo flatbed scanner (Seiko Epson Corp., Nagano, Japan). To be able to translate the blackening of the film to absorbed dose, the film has to be calibrated before dosimetric application. The dose-response curve of the GafChromic film was determined using an ionization chamber (Radcal 10X6-6®, a Radcal model 9660 ion chamber digitizer and a Radcal model 2186 electrometer; Radcal Corp., Monrovia, CA). A standard X-ray tube for medical radiology (A-196®, Varian Medical Systems, Inc., Salt Lake City, UT) with a standard collimating device (Svendx SX100-MF; Santax Medico A/S, Aarhus, Denmark) was used for irradiation. The ionization chamber was placed on top of a 255-cm-thick

Table 1 Technical parameters of selected CBCT and panoramic exposure protocols and sites in which GafChromic® XR-QA2 films were placed in the phantom

CBCT units	Protocol	FOV sizes (d) × (h) cm	kV	mA	s	Phantom levels	Number of exposures
Veraviewepocs 3De®	Upper jaw impacted canine region	4 × 4	80	5.0	9.5, NP	3-4-5-6	10
	Lower jaw molar region	4 × 4	80	5.0	9.4, NP	5-6-7-8	10
NewTom VGi®	TMJ, bl: normal resolution	12 × 8	110	5.3	3.6, P	4-5-6-7-8	30
	TMJ, ul: normal resolution	8 × 8	110	6.1	3.6, P	4-5-6-7-8	30
	TMJ, ul: high resolution	8 × 8	110	17.2	P5.4, P	4-5-6-7-8	20
ProMax® 3D	Upper jaw impacted canine region	4 × 5	84	10.0	12, P	3-4-5-6	50
Panoramic units							
Veraviewepocs 3De	Panorama, standard, level 3	—	78	10.0	7.4, NP	5-6-7-8	20
ProMax 3D	Panorama, standard, level 3	—	66	9.0	16, P	5-6-7-8	30
ProMax	Panorama, standard	—	74	12.0	16, NP	5-6-7-8	20

bl, bilateral; CBCT, cone beam CT; FOV, field of view; Level 3, level 3 of autoexposure used for adults; NP, not pulsed radiation; P, pulsed radiation; TMJ, temporomandibular joint; ul, unilateral. GafChromic XR-QA2 film is manufactured by ISP Corp., Wayne, NJ; Veraviewepocs 3De units by J Morita MFG Corp., Kyoto, Japan; NewTom VGi by Quantitative Radiology, Verona, Italy; and Promax 3D and Promax by Planmeca, Helsinki, Finland.

Figure 1 RANDO® phantom head (The Phantom Laboratory, Salem, NY)

styrofoam slab to minimize the backscatter. A Raysafe® (Unfors Raysafe AB, Billdal, Sweden) semi-conducting detector was placed adjacent to the ionization chamber for use as an exposure monitor when the film was irradiated. The detector was connected to a Raysafe Xi electrometer.

The output (mGy/mAs) of the X-ray tube was determined using 60 kV, 80 kV and 120 kV X-ray tube

potentials. The ionization chamber was thereafter removed and replaced with pieces of the GafChromic film that were irradiated with absorbed doses (in air) up to 200 mGy. It was found that the dose-response curve for 60 kV, 80 kV and 120 kV coincided. Owing to the very small spectral dependence of the ion chamber used for the output measurements, the calibration was not sensitive to tube potential, and the same calibration curve could thus be used for all three CBCT units. This is in agreement with what was found for the GafChromic XR-CT film.¹⁴ This film has identical physical properties and an identical calibration curve to the GafChromic XR-QA film. The film used in this study is a new version, XR-QA2, which has a slightly higher sensitivity. According to our results, there is no reason to believe that the spectral dependence should differ from that of the XR-CT film, indicating that their atomic compositions are very similar. A piece of film that did not undergo any irradiations was scanned together with the other films and used for background subtraction. The pieces of films were scanned to an ordinary 24-bit red-green-blue (RGB) image; a 24-bit RGB image was used for simplicity reasons to train inexperienced operators. No colour channel selection or suppression was used, and images were stored as 24-bit RGB images. These images were read with Image J® (see <http://rsbweb.nih.gov/ij/>), following background subtraction, and converted to black-and-white 8-bit images. The mean pixel values were measured in each film square using rectangular regions of interest (ROIs). The mean pixel values were used to construct a dose-response diagram. The equation of the dose-response curve (Figure 2) was used for converting the net pixel value distributions found in the phantom measurements to the absorbed dose distribution.

Before the GafChromic films were positioned for the CBCT scans, a scout image was taken to ensure correct positioning of the phantom and that the field of view

Figure 2 Dose-response calibration curve. The x-axis is the film response represented by the net pixel value change and the y-axis is the corresponding absorbed dose

(FOV) included the whole anatomical ROI. The dose measurements did not include the scout images. After loading with GafChromic XR-QA2 films, the phantom was exposed several times (Table 1) to provide a reliable measurement. Later, these values were divided by the number of exposures to provide one individual value for each region.

For the skin (entrance) dose measurements, TLDs were used. The TLDs were calibrated using a secondary standard ^{60}Co beam and a pre-defined, reproducible geometric set-up with a plexiglass phantom containing the dosimeters. Prior to the dose measurements in the clinical situation, the dosimeters were annealed at 400°C for 10 min. For every group of 20 dosimeters, 4 were used for reference irradiation in the ^{60}Co beam and 2 were used for background correction, leaving 14 dosimeters available for clinical dosimetry. The dosimeters were read in a Thermo Scientific Harshaw 5500 TLD[®] reader (Thermo Fisher Scientific Inc., Reading, UK). The signal was corrected for the dosimeter's higher sensitivity to diagnostic X-ray energies, and was thereafter converted to the absorbed dose.

Scanning system

An Epson Perfection 4990 PHOTO scanner was used. Warming up the scanner provided a more stable light source and more consistent optical density readings.¹⁵ The films were scanned in the same orientation, and within the region of the scanner, which had been previously determined to be the most uniform in sensitivity. The Image J programme was used for converting the net pixel value distributions found in the phantom measurements to the absorbed dose distributions.

Dose estimations

The mean absorbed dose to organs (parotid gland, oral mucosa, extrathoracic airways, bone surfaces, red bone marrow, skin, brain and thyroid gland) and tissue types that were irradiated were estimated by superimposing ROIs on the dose distribution matrices (Figure 3) and calculating the mean value inside each ROI. This was repeated for all film sheets in the phantom.

The equivalent dose for an organ/tissue was calculated as the product of the mean absorbed dose to that organ/tissue and the fraction of that organ/tissue that was irradiated. For the skin surface of the exposed head and neck, we used a simple model. The irradiated area in CBCT imaging, which represented the irradiated skin surface of the head and neck area, was Y (cm^2) and the total skin surface area was 1.9 m^2 ($19\,000 \text{ cm}^2$).¹⁶ The fraction of the skin area was assumed to be $Y/19\,000$. The estimation of fraction of the irradiated bone surface was based on the total bone area ($100\,000 \text{ cm}^2$)¹⁷ and bone area irradiated for each protocol. Owing to higher attenuation in the bone, a conversion factor for $D_{\text{bone}}/D_{\text{soft-tissue}}$ of 4 was used. The fraction of the red bone marrow irradiated (cervical vertebrae and the mandibular ramus) was assumed to be 2% for the temporomandibular joint (TMJ) lower jaw and panoramic protocol

Figure 3 Region of interests on the dose distribution matrices; (a) vertebra, (b) parotid gland and (c) mandible

and $<1\%$ for the upper jaw scan.¹⁶ The brain fraction estimation is just a crude estimation depending on the radiation geometry of each protocol. The fractions of organs irradiated in each protocol are shown in Table 2. The effective dose was then estimated as the sum of the organ/tissues' equivalent dose multiplied by their tissue-weighting factor according to the International Commission on Radiological Protection (ICRP) 2007 recommendations.¹⁸

Result

For CBCT units, the results were split up by dividing the units into two categories: medium FOV (used for TMJ) and small FOV (used for maxillary impacted canine and mandibular molar area). This allows for a better comparison between protocols, as different FOV sizes are used for different subsets of patients.

Table 3 gives the absorbed organ doses and effective doses for medium FOV (TMJ) protocols. The effective dose ranged between $45 \mu\text{Sv}$ and $129 \mu\text{Sv}$. The highest absorbed dose was in the parotid salivary gland. The effective dose of the examination with high resolution was nearly three times higher than that for normal resolution with the same FOV ($8 \times 8 \text{ cm}$). Table 3 also shows the results for the small FOV protocols. The effective dose ranged between $10 \mu\text{Sv}$ and $22 \mu\text{Sv}$.

Table 2 Estimated fraction of tissue irradiated by primary and scattered radiation for CBCT and panoramic scan protocols

Tissue	Fraction irradiated		TMJ: normal resolution 12 × 8		Upper jaw impacted canine region 4 × 4	
	Lower jaw molar region 4 × 4		TMJ: normal resolution 8 × 8		Standard panoramic	
	TMJ: high resolution 8 × 8		4 × 5			
	Primary/scattered	Primary/scattered	Primary/scattered	Primary/scattered	Primary/scattered	Primary/scattered
Parotid glands	0.70/0.30	1.00/0.00	1.00/0.00	0.70/0.30	1.00/0.00	
Oral mucosa + extrathoracic airways	1.00/0.00	1.00/0.00	1.00/0.00	1.00/0.00	1.00/0.00	
Brain	0.10/0.90	0.00/1.00	0.20/0.80	0.10/0.90	0.10/0.90	
Bone surfaces	0.01/0.99	0.02/0.98	0.02/0.98	0.01/0.99	0.02/0.98	
RBM	<0.01/>0.99	0.02/0.98	0.02/0.98	<0.01/>0.99	0.02/0.98	
Skin	0.01/0.99	0.01/0.99	0.03/0.97	0.02/0.98	0.02/0.98	
Thyroid	0.00/1.00	0.00/1.00	0.00/1.00	0.00/1.00	0.00/1.00	

CBCT, cone beam CT; RBM, red bone marrow; TMJ, temporomandibular joint.

The dosimetric results of panoramic imaging are shown in Table 3. The highest absorbed doses were found in the parotid salivary glands (0.65–1.0 mGy). Effective doses range between 8 µSv and 14 µSv. The unit with the highest effective dose is the ProMax using a PSP as a receptor; the unit with the lowest effective dose is the ProMax 3D. The effective dose was 1.8 times higher in ProMax than in ProMax 3D.

For comparison purposes, the effective doses were also calculated as multiples of the average dose of panoramic radiograph of the same study and as a percentage of the average annual dose of 760 µSv in Sweden from natural background radiation.¹⁹ Moreover, the excess cases of fatal cancer in 1 million people irradiated was calculated using a risk coefficient of $5.5 \times 10^{-2} \text{ Sv}^{-1}$ (Table 4).

The highest excess cases were associated with the scan protocol used for the TMJ—high resolution, whose effective dose is about 62 days of exposure to background radiation. The lowest fatal cancer excess cases of the CBCT scans were associated with the ProMax 3D upper impacted canine protocol. Its effective dose corresponds to approximately 5 days of exposure to natural background radiation. On the other hand, the effective dose

of panoramic radiography was between 4 and 7 days of natural exposure.

Discussion

The results of this study should be interpreted with care owing to the complex relationship between image quality, size of the scanned volume and absorbed dose to different tissues. The main purpose of this study was to develop and test GafChromic film dosimetry rather than to compare the clinical performance of imaging devices.

There are a number of ways to estimate the effective dose. All of them include assumptions, which result in limitations and uncertainties.²⁰

The effective dose corresponds to the risk that also a uniformly distributed dose with the same value in the whole body would represent. It gives a general indication of the level of risk for the X-ray examination in question. It takes into account different organs' sensitivities to induction of severe late effects and is the preferred quantity for comparing the detrimental

Table 3 Absorbed organ dose (mGy) and effective dose (µSv) for CBCT and panoramic scan protocols

Tissue	CBCT-small FOV			CBCT-medium FOV			Panorama		
	Veraviewepocs® 3De	Veraviewepocs 3De	ProMax® 3D	NewTom VGi®	NewTom VGi	NewTom VGi	Veraviewepocs 3De	ProMax 3D	ProMax
	Upper jaw (4 × 4)	Lower jaw (4 × 4)	Upper jaw (4 × 5)	TMJ NR (12 × 8)	TMJ NR (8 × 8)	TMJ HR (8 × 8)	Standard	Standard	Standard
Parotid glands	1.890	0.900	0.840	2.400	2.130	5.700	0.700	0.650	1.000
Oral mucosa + extrathoracic airways	0.120	0.600	0.070	2.300	1.800	5.200	0.240	0.156	0.240
Brain	0.001	NS	0.001	0.230	0.150	0.420	0.002	0.001	0.002
Bone surfaces	0.065	0.108	0.040	0.122	0.102	0.306	0.017	0.009	0.014
RBM	NS	0.036	NS	0.048	0.040	0.120	0.005	0.003	0.004
Skin	0.017	0.015	0.012	0.074	0.062	0.186	0.001	0.001	0.001
Thyroid	0.001	0.050	0.001	0.020	0.020	0.040	0.020	0.013	0.020
Effective dose	21	22	10	56	45	129	11	8	14

CBCT, cone beam CT; FOV, field of view; HR, high resolution; NR, normal resolution; NS, not significant; RBM, red bone marrow; TMJ, temporomandibular joint.

Veraviewepocs 3De units are manufactured by J Morita MFG Corp., Kyoto, Japan; NewTom VGi by Quantitative Radiology, Verona, Italy; and Promax 3D and Promax by Planmeca, Helsinki, Finland.

Table 4 Effective dose and risk as multiple of average panoramic images, days of natural background dose in Sweden and risk of cancer

Unit/protocol	Effective dose (μSv)	Dose as multiple of average panoramic radiograph ^a	Days of per capita natural background (2.08 μSv per day)	Excess cases of fatal cancer in 1 million people ^b
Veraviewepocs 3De [®] /upper jaw	21	1.9	10	1.2
Veraviewepocs 3De/lower jaw	22	2.0	11	1.2
ProMax [®] 3D/upper jaw	10	0.9	5	0.6
NewTom VGi [®] /TMJ, NR (12 $\times$ 8)	56	5.1	27	3.9
NewTom VGi/TMJ, NR (8 $\times$ 8)	45	4.1	22	2.5
NewTom VGi/TMJ, HR (8 $\times$ 8)	129	11.7	62	7.1
Veraviewepocs 3De/panorama	11	1.0	5	0.6
ProMax 3D/panorama	8	0.7	4	0.4
ProMax/panorama	14	1.3	7	0.8

Veraviewepocs 3De units are manufactured by J Morita MFG Corp., Kyoto, Japan; NewTom VGi by Quantitative Radiology, Verona, Italy; and Promax 3D and Promax by Planmeca, Helsinki, Finland.
HR, high resolution; NR, normal resolution; TMJ, temporomandibular joint.
^aAverage of three units: ProMax, ProMax 3D, Veraviewepocs 3De (11 μSv).
^bBased on the same study—calculated by using a risk coefficient of $5.5 \times 10^{-2} \text{ Sv}^{-1}$.

effects from different exposure situations to large populations.¹⁸

Most studies of dose distribution measurements in oral and maxillofacial radiography are based on TLDs.³⁻⁶ The dosimeters are placed inside a phantom in small cavities, which have been drilled in a regular pattern in every slice of the phantom. TLDs have the advantage of being rather sensitive and can measure the absorbed dose down to at least 0.5 mGy with sufficient accuracy. They also have some major drawbacks, namely:

- (1) They must be handled with extreme care, and the whole dose measuring procedure, including calibration, is very time-consuming.
- (2) Their energy dependence in the diagnostic energy range will result in their response being dependent on the amount of scatter at the measurement point. As the amount of scatter varies within the phantom, the uncertainty of the dose values will increase.
- (3) The dosimeters are $3 \times 3 \times 1 \text{ mm}^3$. In an irradiation geometry, where the dose gradients are as steep as 25% per mm, it is obvious that the positioning of the radiation field in relation to the dosimeters can heavily affect the dose values measured.

Radiochromic films, initially intended for dose measurement in radiotherapy, are now also available with higher sensitivity for X-ray diagnostic purposes as GafChromic XR-QA, XR-QA2 and XR-CT. There are some advantages of GafChromic films compared with TLDs, such as easy preparation and adjustable size of the film. The reading process and the digitization procedure for a set of three film sheets take a few seconds, whereas around 1 min or more is necessary for reading one TLD. Furthermore, the GafChromic film will present a continuous “analog”-like dose distribution, where the limit for spatial resolution is set by the pixel size when digitizing the image in the flatbed scanner.

Recent studies have shown that it is possible to use ordinary office flatbed document scanners for radiochromic film scanning.^{7,21} The film response depends on

the film type, batch number and scanning parameters. As for any radiation dosimetry system, uncertainties exist.¹²

The attenuation of the film was determined experimentally and was found to be two times higher than that of the soft tissue. Thus, the film thickness of 25 μm corresponds to 50 μm of soft tissue, which is negligible for the dose measurement geometry. However, one situation that can occur and can affect the dose measurements is when the central beam of the X-ray field coincides with the film plane. Here, there exist primary photon paths directed along the film plane, which will lead to underestimation of the absorbed dose because of the higher attenuation in the film. We have experimentally determined the underestimation to be in the order of 10%. This will, however, only occur if the central axis of the radiation field coincides with the film plane. We have deliberately avoided this in all measurement situations.

In all settings of different units, the salivary gland tissue received the highest amount of radiation exposure. The salivary gland tissue tends to be in the centre of the imaging field and receives nearly constant exposure during the rotation of the gantry. This is a major reason for the increased effective dose seen when using the newest ICRP 2007 guidelines,¹⁸ as the salivary gland tissue had not been previously included in the calculations.

The effective doses of the ProMax 3D-CBCT estimated in the present study were lower than those previously reported.²⁻⁴ However, the main explanation for the lower measured doses is likely to be the increase in copper filtration of the X-ray beam and the difference in FOV. A study by Ludlow and Ivanovic²² was based on an early version of the ProMax 3D-CBCT unit. Beginning in 2008, those units were equipped with an additional 0.5 mm of copper filtration to reduce the dose. We also found that the effective dose for Veraviewepocs 3De-CBCT (21 μSv) is higher than that for the ProMax 3D-CBCT (10 μSv) for upper jaw at small FOV. Again, the greatest contribution to the lower measured doses is probably an increase in the copper filtration of the X-ray beam for the ProMax 3D unit and a short exposure

time of 2.8–8.3 s, combined with a pulsed output. The ProMax 3D unit used was an upgraded unit of the version that was manufactured in 2011. In the newest model, manufactured in 2012, some parameters are changed for three-dimensional exposure; however, the mAs is constant and the dose should not be affected.

From the results, the effect of FOV positioning can be observed. Comparing an upper jaw canine region with a lower jaw molar region scan from the Veraviewepocs 3De-CBCT, it is clear that there were large differences regarding the absorbed dose for the parotid salivary glands and oral mucosa. On the other hand, the dose to the thyroid was very low because it was outside of the primary beam for all protocols.

The NewTom VGi provides two levels of resolution of the same FOV (8×8): high and normal. When the high resolution was selected, the calculated effective dose was 129 μ Sv. If the normal resolution is chosen, the present study shows that the effective dose can be reduced to about 35% of that with high resolution. When comparing the effective dose from a study by Ludlow,²³ it can be seen that a higher effective dose for high resolution (172 μ Sv) and a normal resolution (51 μ Sv) of the same FOV were found than those in this study (129–45 μ Sv). Also, the effective dose of FOV (12×8) normal resolution (56 μ Sv) is lower when compared with the study by Ludlow (69 μ Sv).²³ Difference in dosimetry and variation in phantom position can again account for these differences.

The absorbed dose produced by a CBCT unit is dependent on the imaging parameters used (tube potential, mAs); pulsed beam vs continuous beam; amount, type, and shape of beam filter; full 360° rotation vs partial rotation; limited vs full FOV; and resolution setting. Some of these factors, such as type of beam and filtration, are unique to a specific unit, whereas other factors, such as FOV, are under the control of the operator. In general, smaller FOV, lower radiation dose⁵ and a shorter scanning time all result in a lower total dose of radiation.

Also, the dose levels are lower in a CBCT scan when compared with multislice (CT) scanners.²²

We measured the absorbed dose during panoramic exposure with three digital panoramic units equipped with different detectors. Effective doses ranged between 8 μ Sv and 14 μ Sv. When PSP, CCD and FPD units were compared, the effective dose of the panoramic unit using the PSP receptor (14 μ Sv) was higher than those of the CCD and FPD units (8–11 μ Sv).

When the exposure settings are considered, the panoramic machine (ProMax) with the highest dose uses 74 kV, the highest tube current (12 mA) and the longest exposure time (16 s). The ProMax 3D-Panoramic, yielding the lowest dose, operates at the lowest tube current (9 mA). Differences in the doses measured depend not only on the tube potential, mA and filter but also on the actual exposure time, i.e. if the X-rays are continuous or pulse. The sizes of the radiation field also play a significant role.

Ludlow et al³ evaluated a ProMax (CCD based) panoramic machine operated at 68 kV and 13 mA with a 16 s exposure time and found an effective dose of 24.3 μ Sv using the ICRP 2007 tissue weights. In our study, an effective dose of 14 μ Sv was found. Difference in the type of dosimetry, variation in exposure settings and phantom composition and position can account for these differences.

The use of CBCT for diagnosis, dental implant planning and orthodontic treatment is a subject of intense discussion among dental practitioners. The risk associated with exposing a patient to higher levels of radiation must be weighed against the improvements in patient care and the information that is gained through the use of CBCT. This issue must be carefully considered.

In conclusion, GafChromic film can be utilised to map the dose distribution and measure the absorbed organ/tissue dose of CBCT and panoramic radiography. The use of small FOV and standard resolution reduces the dose when compared with larger FOVs of the same ROI or higher resolution.

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III

RESEARCH ARTICLE

Dose optimization for assessment of periodontal structures in cone beam CT examinations

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Objectives: To investigate the relationship between dose and image quality for a dedicated dental CBCT scanner using different scanning protocols and to set up an optimal imaging protocol for assessment of periodontal structures.

Methods: Radiation dose and image quality measurements were made using 3D Accuitomo 170 (J. Morita, Kyoto, Japan) dental CBCT scanner. The SedentexCT IQ phantom was used to investigate the relationship between contrast-to-noise ratio (CNR) and dose-area product. Subjective image quality assessment was achieved using a small adult skull phantom for the same range of exposure settings. Five independent observers assessed the images for three anatomical landmarks using a three-point visual grade analysis.

Results: When correlating the CNR of each scanning protocol to the exposure parameters used to obtain it, CNR decreased as these parameters decreased, especially current-exposure time product. When correlating to subjective image quality, the CNR level remained acceptable when 5 mA and 17.5 s or greater was selected and 80 kV could be used without compromising the CNR.

Conclusions: For a dedicated CBCT unit, changing the rotation angle from 360° to 180° degrades image quality. By altering tube potential and current for the 360° rotation protocol, assessment of periodontal structures can be performed with a smaller dose without substantially affecting visualization.

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Introduction

CBCT has become an important imaging technique in dental and maxillofacial radiology and replaces, or adds to, conventional radiography in several diagnostic tasks in the maxillofacial area. The increased use of CBCT and the fact that radiation doses from CBCT

examinations are generally higher than those from conventional radiography will result in an increase in the radiation dose to which patients are exposed.^{1,2} This is a matter of concern and must be taken into consideration especially for paediatric patients, as they are more sensitive to radiation than adult patients.^{3,4}

It is not only the use of CBCT that has increased dramatically in recent years; the number of CBCT units available from different manufacturers has also significantly increased.⁵ The many scanning options offered

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by these new units make it a challenge to choose the optimal scanning protocol parameters to achieve sufficient image quality for a given diagnostic imaging task. The recent advances in CBCT technology have suggested several dose reduction strategies, such as decreasing the field of view (FOV) dimensions and tube current–time product (mAs).⁶ However, when scanning radiation dose decreases, the image quality might be degraded and it is therefore important to perform the examination using doses that are as low as diagnostically acceptable (ALADA), while still being consistent with the diagnostic imaging task.^{7,8}

Even though studies have been performed on reducing exposure factors without loss of adequate image quality for different diagnostic tasks, few studies and limited data are currently available on both physical factors (objective) and subjective image quality related to the radiation dose of CBCT.^{9–11} Hidalgo Rivas et al¹² suggested a low-dose protocol for CBCT examinations of the anterior maxilla in children and images were classified as acceptable/not acceptable related to a number of different diagnostic tasks and different exposure conditions. In a study by Choi et al,¹³ the relationship between physical factors and subjective image quality was investigated but without any dose measurements.

Diagnostic information on the marginal bone tissue as well as on the periodontal space along the roots has usually been obtained from periapical and/or panoramic radiographs.^{14–16} With the introduction of CBCT, a possibility to detect these structures in the buccolingual direction also has opened up and CBCT has been used to evaluate the alveolar bone level and periodontal space in order to eliminate the image distortion and tissue overlapping of two-dimensional radiography.^{9,17–19} Even though CBCT is not recommended as a routine method for imaging the periodontal bone tissue, its use might be indicated in situations where clinical and conventional radiographic examinations do not provide the information needed for management,²⁰ as well as for evaluating the long-term effects of treatment.^{21,22} The aim of this study was therefore to investigate the relationship between dose and image quality for a dedicated CBCT scanner using different scanning protocols and to set up an optimal imaging protocol for periodontal structure examination.

Methods and materials

CBCT equipment and scanning protocols

All CBCT images were obtained with a 3D Accuitomo 170 (J. Morita, Kyoto, Japan) unit, using 12 scanning protocols for a range of tube voltages, tube currents (mA) and trajectory arcs. The X-ray tube voltage options were 80 kV or 90 kV and the X-ray mA options were 3 mA, 5 mA or 9 mA. Full-rotation (360°) or

half-rotation (180°) scans were used. A standard acquisition mode with an FOV of 8 cm (diameter) × 8 cm (height) and 160-μm voxel size was chosen. Details of the scanning protocols are shown in Table 1. The unit was equipped with a calculated dose–area product (DAP) value monitor.

Dose measurements

For all scanning protocols, DAP values, expressed in milligray square centimetre, were obtained by attaching an ion chamber of a DAP meter (VacuDAP meter; VacuTec Messtechnik GmbH, Dresden, Germany) to the centre of the beam output and at the same time, the automatically calculated DAP values were recorded from the CBCT unit console. The DAP meter with an active area of 14.7 × 14.7 cm fully intercepted the investigated FOV. DAP values were obtained five times for each scanning protocol in order to evaluate the constancy of the unit performance.

Objective measurement of image quality

The SedentexCT IQ cylindrical phantom (Leeds Test Objects Ltd, Boroughbridge, UK), a dedicated dental CBCT image quality phantom, was used. The phantom is 176 mm in height and 160 mm in diameter. There are five contrast resolution inserts with different materials [aluminium (Al), polytetrafluoroethylene (PTFE), low density polyethylene (LDPE), air and delrin]. The Al insert simulates dentin density, the PTFE insert simulates dense bone, the low-density polyethylene insert simulates soft tissues and air simulates air cavities. All the inserts were placed at the same level of the phantom and the rest of the phantom columns were filled with poly methyl methacrylate (PMMA) inserts for simulating the total mass of a head. The phantom was mounted on a rigid tripod and scanned once to take an image of each contrast resolution insert. The target inserts were placed at the periphery, as the FOV is positioned more towards the periphery of the patient head. More specifications and images of this phantom can be found at www.leedstestobjects.com.

To measure the contrast-to-noise ratio (CNR) metric of image quality for the images of the IQ phantom, the images were transferred as digital imaging and communications in medicine files (DICOM) from the CBCT workstation computer to the Image J (National Institutes of Health, Bethesda, MD) software. By using Image J tools, a circular region of interest (ROI) was drawn inside the big rod of each insert and the same ROI was drawn for PMMA as a background. For each ROI, the mean grey value and standard deviation (SD) were measured in triplicate and the average was used for CNR calculation. Care was taken to ensure that all measurements, from different scanning protocols, were performed in the same order and number of image series.

CNR for each scanning protocol was calculated using the following formula:

$$CNR = \frac{(MPV(insert) - MPV(PMMA))}{\sqrt{(SD^2(insert) + SD^2(PMMA))/2}},$$

where MPV is the mean pixel value and SD is the standard deviation.

Subjective assessment of image quality

The examination of the upper and lower jaw together (FOV 8 × 8 cm) was performed on a RANDO skull phantom (RANDO®; The Phantom Laboratory, Salem, NY) consisting of a human skull and upper cervical vertebrae. In order to simulate a small male adult patient, the additional material used in the phantom had a density equivalent to that of a biological tissue.

The phantom was set on the phantom table of the unit and was centred with the jaws in the imaging area and scanned once to obtain an image of each scanning protocol. A radiographer trained to work with CBCT imaging positioned the phantom so as to reproduce as closely as possible the real clinical conditions. 12 scans were performed, 1 scan for each of the exposure scenarios in Table 1. These alterations were performed without moving the phantom in order to ensure maximum consistency throughout the imaging process.

12 CBCT volumes were stored in DICOM format and assessed with i-Dixel software on a workstation. A BARCO (MFGD 1318; BARCO, Kortrijk, Belgium) 18.1" greyscale liquid crystal display monitor was used with a luminance of 400 cd/m² and resolution of 1280 × 1024 pixels. Subjective evaluation of image quality was performed over a period of 8 weeks by five observers with different professions and experience. Two were specialists in dental and maxillofacial radiology with 25 and 30 years' experience in radiology, respectively. One observer was a specialist in orthodontics with 8 years' experience and the two remaining observers were trainees in dental and maxillofacial radiology and oral surgery, respectively. All observers were familiar with CBCT images. To ensure a standardized comparison, the observers were not allowed to adjust brightness and contrast settings or the reconstruction views. The observers were aware of the purpose of the study but were blinded to the volume acquisition parameters and dose-related data. In order to get standardized comparisons, reformatted images were pre-prepared by the researcher in charge of the project and these images were assessed in random order to avoid potential bias. To get the same anatomical section, firstly an adjustment of the xyz images of all protocols according to the same level was performed. After that, the centre of each tooth in the axial view was marked to create a curved multiplanar reformation, which includes oblique, curved planar reformation (distortion-free panoramic images) and serial transplanar reformation (providing cross-sections) (Figure 1).

The observation room illumination was dim (below 50 lux as recommended by American Association of Physicists in Medicine Task Group 18) and kept constant.²⁵ The reading distance was approximately 60 cm. There were no restrictions on observation time and zooming was allowed.

The visibility of three dental anatomical landmarks was assessed using visual grade analysis with all images graded separately within each protocol. The following landmarks were assessed: the apical third of periodontal space (ATPS), the cementoenamel junction (CEJ) and the marginal bone crest (MBC) of all upper right and lower left quadrant teeth, 17–11 and 37–31, respectively. For multirooted teeth in the upper jaw, the palatal roots were chosen; for multirooted teeth in the lower jaw, the distal root was chosen. Altogether, 168 sites for assessment were available in each protocol (14 teeth × 3 anatomical landmarks × 4 sites). A three-point rating scale (0 = hardly visible, 1 = partly visible and 2 = well visible) was used to assess the visibility (Figure 1). In addition, the observers measured the distance between the CEJ and MBC at all sites. Grading of landmarks and measurements were performed using panoramic reformatted images for mesial and distal sites and using multiplanar reformatted (sagittal plane) images for buccal and palatal/lingual bone sites. All images were evaluated at 1-mm slice thickness.

Prior to the first observation, all observers attended a training session. The aim was to familiarize the observers with the imaging display software and scoring scale. At the first observation session, all the included images were read. In order to calculate intraobserver agreement, a second observation session was held for a random selection of teeth (21%). This session was held more than 3 weeks after the first session in order to minimize reader recall bias.

Data analysis

Interobserver and intraobserver agreement of subjective image quality assessment was calculated by using the kappa (*k*) test as described by Altman.²⁶ Levels of agreement on *k* values were interpreted as suggested by Altman: *k* = 0.81–1.00, excellent; *k* = 0.61–0.80, good; *k* = 0.41–0.60, moderate; *k* = 0.20–0.40, fair; *k* < 0.20, poor.

Evaluation of subjective image quality was based on calculations of observations, where all included observers had given a grade of 1 or 2 on the visual grade analysis scale for all assessments of an anatomical landmark. Assessments where a grade of 0 was given for any site by any observer were excluded. An example of assessments performed by all observers of the anatomical landmark ATPS is shown in Table 2. It was possible to assess 4 sites on each of the 14 teeth for the ATPS in each protocol, resulting in 56 possible assessments of this landmark for each observer. Only the sites where no observer graded 0 were taken into account. As shown in Table 2, only three sites had no 0 grading in Protocol 1 and for Protocol 8, the corresponding figure was 7.

Table 1 CBCT technical specification, dose-area product (DAP) values measured in mGy cm² and examples of images for different scanning protocols

Protocol number	1	2	3	4	5	6
kV	80	80	80	90	90	90
mA	3	5	9	3	5	9
s				9		
Rotation angle				180°		
Frames per second				30		
Basis images				270		
Calculated DAP (mGy.cm ²)	308	510	914	407	673	1210
of unit console						
Measured DAP (mGy.cm ²)	268.0 ± 2.03	444.8 ± 1.16	768.0 ± 9.38	342.0 ± 3.20	563.4 ± 5.46	983.4 ± 17.04
of DAP meter						
SEDENTEXCT phantom images
Rando phantom images
Protocol number	7	8	9	10	11	12
kV	80	80	80	90	90	90
mA	3	5	9	3	5	9
s				17.5		
Rotation angle				360°		
Frames per second				30		
Basis images				525		
Calculated DAP (mGy.cm ²)	599	992	1780	791	1310	2350
of unit console						
Measured DAP (mGy.cm ²)	526.0 ± 5.23	853.6 ± 13.18	1505.6 ± 22.6	664.4 ± 11.21	1097.8 ± 15.87	1935.8 ± 26.99
of DAP meter						
SEDENTEXCT phantom images
Rando phantom images

kV, tube potential; mA, tube current; s, second.

Hence, image quality scoring for Protocols 1 and 8 was calculated to be 5.35% (3/56) and 12.5% (7/56), respectively. In the next step, the same calculation was

made for each protocol and landmark (Figure 2), where the subjective image quality was scored in percentage. The threshold for acceptable (optimal) image quality

Figure 1 Reformatted panoramic (a) and cross-sectional (b, c) images used for visual grading analysis of anatomical landmarks scoring and measurements of the distance between the marginal bone crest (MBC) and the cemento-enamel junction (CEJ). D, apical third of periodontal space; E, CEJ; F, MBC; G, distance between MBC and CEJ.

was thereafter determined by excluding all images assessed below the half-value of the highest image quality scoring for all anatomical landmarks in all tooth aspects (mesial, distal, buccal and lingual/palatal) together, taking all observer assessments into account (Figure 2). Binary logistic regression analysis was performed to evaluate the CNR values from each test insert material from each scanning protocol to determine which, if any, was more related to acceptable (optimal) subjective image quality. Optimization was based on the relation between objective and subjective image quality with exposure level (DAP value) taken into consideration.

Intermeasurement agreement for the five observer measurements of the distance between CEJ and MBC was calculated using intraclass correlation coefficient (ICC 2.1). The ICC value was interpreted according to Landis and Koch²⁷ as ICC < 0.20 = slight agreement, ICC

0.21–0.40 = fair agreement, ICC 0.41–0.60 = moderate agreement, ICC 0.61–0.80 = substantial agreement and ICC 0.81–1.0 = almost perfect agreement.

All statistical analyses were performed using IBM SPSS® Statistics v. 22.0 (IBM Corp., New York, NY; formerly SPSS Inc., Chicago, IL).

Results

Dose values

As seen in Table 1, the mean measured DAP values were 268.0 mGy cm² (SD = 2.03) for the lowest exposure parameter setting (Protocol 1) and 1935.8 mGy cm² (SD = 26.99) for the highest exposure parameter setting (Protocol 12). When comparing full-rotation (360°) and half-rotation (180°) protocols of the same tube potential

Table 2 Example of how optimal image quality was calculated, applied on the anatomical landmark apical third of periodontal space (ATPS) and the different sites (mesial, distal, buccal lingual) of this landmark that were assessed

ATPS sites		Mesial					Distal					Buccal					Lingual				
		Observer					Observer					Observer					Observer				
Protocol number	Tooth	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
1	11	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	2	2	2	2	2
1	12	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	13	1	0	0	1	0	1	0	0	1	0	0	0	0	0	0	0	1	1	1	0
1	14	1	1	1	0	1	1	1	1	0	1	0	0	0	1	0	0	0	0	1	0
1	15	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
1	16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	17	0	1	0	0	1	0	1	0	0	1	0	0	0	0	1	0	0	0	0	0
1	31	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2	1	1	1	0	1
1	32	0	0	0	0	0	0	0	1	0	0	2	2	0	2	1	1	0	0	1	1
1	33	1	0	0	0	0	1	0	0	0	0	2	2	1	2	2	1	0	1	1	1
1	34	1	1	0	0	1	1	1	0	0	1	1	1	0	1	1	1	0	0	2	1
1	35	1	1	0	1	1	1	1	0	1	1	1	1	0	1	1	1	1	0	1	1
1	36	1	2	0	1	1	1	1	0	1	0	1	1	0	1	1	1	0	0	0	1
1	37	0	1	0	0	0	0	0	0	0	0	1	1	0	0	0	1	1	0	0	0
8	11	1	0	0	0	0	1	0	0	0	0	1	1	1	1	0	2	2	2	2	2
8	12	1	0	0	0	0	1	0	0	0	0	1	1	0	0	0	1	0	0	1	0
8	13	2	1	1	1	2	1	1	1	2	1	1	1	0	1	0	1	2	1	2	2
8	14	1	1	0	0	1	1	1	0	0	1	1	1	0	1	2	1	0	0	0	1
8	15	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0	1
8	16	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0
8	17	0	0	0	0	0	0	0	0	0	0	1	1	0	1	1	1	0	0	0	1
8	31	1	0	0	0	0	1	0	0	0	0	2	2	1	1	2	2	0	0	1	2
8	32	1	0	0	1	0	1	0	0	0	0	2	2	1	2	2	1	0	0	1	1
8	33	1	0	0	1	0	1	0	0	1	0	1	1	0	1	1	1	0	0	0	0
8	34	1	1	0	1	1	1	1	0	1	1	2	2	1	1	2	1	1	0	0	1
8	35	1	1	0	1	1	1	1	0	1	1	1	1	0	0	0	1	1	0	0	0
8	36	1	1	0	1	1	1	1	0	1	0	2	2	0	0	0	1	0	0	0	0
8	37	1	0	0	0	0	1	0	0	0	1	1	1	0	1	1	1	0	0	1	1

All observer assessments in Protocols 1 and 8 are shown. The sites where no zero (0) was assessed by any observer are given in bold.

(kV) and mA, the average decrease in DAP value was 50–52% for half-rotation protocols. Compared with the calculated DAP values that were recorded from the unit console, the unit tended to overestimate DAP values ranging from a minimum of 12% to a maximum of 17% depending on exposure scanning parameters.

Objective image quality measurements

The measured data on DAP and CNR for different scanning protocols are seen in Figure 3. With increased mAs, CNR is improved, and this improvement in CNRs of different inserts is associated with an increase in the radiation dose. The CNR values of different inserts vary in range because of the different densities of the inserts. When using the same exposure parameters, the 360° scan has a higher CNR than the 180° scan.

Subjective image quality assessments

The scoring of image quality for different scanning protocols is seen in Figure 3. The scoring of image quality essentially depends on the anatomical landmarks. There is no standard scanning protocol that is optimal for all anatomical landmarks.

Interobserver agreement varied between $k = 0.11$ and $k = 0.32$ when taking all anatomical landmarks into account. The agreement principally depends on the

anatomical landmark and tooth aspect. Higher values of agreement were seen when assessing the CEJ on the distal aspect of teeth (Figure 4). Kappa values for intraobserver agreement were moderate for rating the images ($k = 0.44–0.51$).

ICC for measurements between CEJ and MBC for all observers were 0.52 mesially [95% confidence interval (CI) 0.12–0.78], 0.57 distally (95% CI 0.16–0.81), 0.85 buccally (95% CI 0.76–0.90) and 0.95 in lingual/palatal bone sites (95% CI 0.90–0.97). Also, ICC for each observer varied depending on which aspect of the tooth was measured (Figure 5).

Subjective and objective image quality relationship

Logistic regression performed to measure the relationship among the CNRs for each of the test insert materials and optimal image quality showed that there was a very high correlation between the four different inserts. This means that there was a statistically significant relationship between all inserts and optimal image quality ($p = 0.951–1$). An examination of the CNR values in Figure 3 and optimal image quality in Figure 2 showed that the optimal image quality was obtained with a CNR of Protocols 2, 3, 6, 12, 8 and 11 in ascending order.

Figure 2 Scoring image quality percentage for different anatomical landmarks and optimal image quality threshold. APTS, apical third of periodontal space; BL, buccolingual/palatal; CEJ, cementoenamel junction; MBC, marginal bone crest; MD, mesiodistal.

Optimization

Taking the protocols resulting in overall subjective image quality (Protocol number 2, 3, 8, 6, 11 and 12) into consideration together with the CNR values of all inserts, it was concluded that Protocols 3, 8 and 11 had the highest overall scoring with regard to image quality (Figure 3). We decided to exclude Protocol 3, as this protocol showed lower image quality assessment scores for some landmarks than Protocols 8 and 11. After consulting the two radiologists and one medical physicist, we selected Protocol 8 (80 kV/5 mA/360° or 17.5 s) as the optimized protocol for this diagnostic task. The main objective was not to achieve the highest CNR values but rather to keep the radiation dose as low as possible, as there was only a slight difference in CNR values between Protocol 8 and Protocol 11.

Discussion

One conclusion of a recent systematic review was that more research is needed concerning the image quality and radiation dose of different machine types and for different diagnostic tasks.²⁸ In this study, we performed dosimetry, objective measurements and subjective assessment of image quality, all on the same material and the same machine. We consider this to be a strength of the study. The diagnostic tasks chosen were the assessment of the periodontal space at the apical third of the root, the MBC and the CEJ. The apical third of the root is the area of interest for root resorption detection and radiography is the

only possible method by which to detect it, which is mostly performed as intraoral, periapical radiography. However, this technique has its shortcomings as do panoramic and lateral cephalometric radiography.^{29–31} It has been concluded that CBCT can provide more valid and accurate information about root resorption caused by orthodontic treatment than any other radiographic technique.^{20,22}

Furthermore, a number of studies have been performed to investigate whether CBCT provides more information when used to evaluate marginal bone loss than periapical radiographs.³² Studies have shown that CBCT images do provide additional information that might benefit diagnostic outcome.^{33,34} Identification of the CEJ, the third diagnostic task in this study, was chosen because the CEJ is a landmark often used as a starting point or an end point for measurements of root length as well as of marginal bone level.

Taking the above into consideration, it can be hypothesized that CBCT examinations for the assessment of periodontal structures might increase in quantity for both adult and young adult patients and that there is a need to identify specific scanning protocols that will deliver a balance between acceptable image quality and the lowest achievable patient dose. The CBCT unit used in this study offers four scanning modes; standard, high fidelity, high resolution and high-speed imaging mode. The main difference between them is the exposure time. As recommended by the manufacturer, we used the standard mode for all scanning protocols. The reason for choosing an FOV of 8 × 8 cm was the intention to capture all teeth in both the upper and lower jaw during

Protocol no.	1	4	2	7	5	10	3	8	6	11	9	12
mA	3	3	5	3	5	3	9	5	9	5	9	9
mAs	27	27	45	52.5	45	52.5	81	87.5	81	87.5	157.5	157.5
kV	80	90	80	80	90	90	80	80	90	90	80	90

Figure 3 Dose-area product (DAP), contrast-to-noise ratio (CNR) and scoring image quality in the percentage of different scanning protocols. Scanning protocols have been reordered according to DAP values. AL, aluminium; ATPS, apical third of periodontal space; CEJ, cementoamel junction; LDPE, low-density polyethylene; MBC, marginal bone crest; PTFE, polytetrafluoroethylene.

Figure 4 Kappa values for interobserver agreement for the visual grade analysis of different anatomical landmarks and tooth aspects. ATPS, apical third of periodontal space; b, buccal aspect; CEJ, cemento enamel junction; CI, confidence interval; d, distal aspect; l, lingual/palatal aspect; m, mesial aspect; MBC, marginal bone crest.

the same scanning. In addition to the FOV, the radiation exposure of CBCT is influenced by the exposure parameters (mAs, kV) that affect the quantity and quality of incident radiation beam and therefore radiation dose. Most CBCT units use 90 kV when scanning adult patients, as this provides an acceptable combination of X-ray penetration and image contrast resolution. A few CBCT units like i-CAT use 120 kV as a fixed potential value with filtration equivalent to 10 mm of aluminium. Higher kV may be used for specific diagnostic tasks when reduced a beam-hardening artefact is needed. For paediatric patients, a low kV (80 kV or less) may be used to minimize the patient dose. In this study, we used 80 kV and 90 kV with three levels of mA related to possible adult patient sizes (3 mA, 5 mA and 9 mA).

In addition to FOV reduction, the use of a partial rotation can also be used to further optimize patient dose.³⁵ Some CBCT units use 360° rotation; others use a smaller trajectory arc of between 180° and 220° as the coverage of 180° and the cone angle is sufficient for tomographic image reconstruction.³⁶ Images produced by partial rotation may, however, have more noise and reconstruction artefacts.³⁷ For some diagnostic tasks on specific CBCT units, partial rotation can be used to reduce radiation dose while maintaining sufficient image quality.^{38,39} 3D Accuitomo 170 includes a standard rotation with a 360° (17.5 s) as well as a 180° (9 s) rotation to reduce scan time and, thereby, patient dose.

In the present study, radiation doses were measured in terms of DAP, as it is the most practicable means of

Figure 5 Intraclass correlation coefficient (ICC) plot for the measurements between the cemento enamel junction and marginal bone crest of different tooth aspects by different observers. CI, confidence interval.

representing patient dose. Furthermore, DAP has been recommended for establishing achievable doses or diagnostic reference levels when established and relates reasonably well with effective dose.^{20,40} Even though the central point of the scan is not always in the centre of the clinical ROI and patient dose measurements could be both underestimated and overestimated, DAP can be used to assess dose reduction strategies and compare the results from different CBCT units.^{9,28}

Pauwels et al⁴¹ evaluated the SEDENTEXCT phantom and reported that it showed promising results for physical CBCT image quality assessment. The same phantom was used by Bamba et al¹⁰ to evaluate three different CBCT units and the authors stated that the basic image quality parameters could be well assessed by this phantom. Image noise, contrast resolution, spatial resolution and artefacts are key parameters in objective image quality assessment. The quality of CBCT images, with the same spatial resolution, is fundamentally described by two parameters (indexes): contrast and noise. Accordingly, we used CNR measurements for objective image quality assessment. There are many factors affecting the contrast and noise parameters of image quality of CBCT units such as system geometry, focal spot size, FOV, object size, exposure parameters (kV, mAs), number of projections and voxel size. In the present study, we used the same geometry, FOV, object size and voxel size during all scans.

Physical measurement expressed as objective image quality is not enough to predict the diagnostic performance of an imaging system clinically and the evaluation of image quality must include psychophysical, environmental and system considerations.⁴² In our study, we chose to evaluate subjective image quality by assessments of images of a skull phantom and a variation of exposure settings in order to find the lowest exposure settings for the specific diagnostics tasks. The reason for choosing standard observation environment was that one of the tasks of this study was to investigate observer agreement, where agreement is defined as the degree to which two or more observers achieve identical results under similar assessment conditions.⁴³ A further step would be to investigate observer performance on images of patients in a real clinical situation. The reason for choosing five observers was that different observers may have different prior experience.

A reduction of kV from 90 kV to 80 kV of the same mAs reduced mean DAP values (20–22%). The 180° rotation angle scan provided a significant reduction

(50%) in the radiation dose compared with the 360° rotation angle scan of the same kV and mA. A substantial reduction (82%) in DAP value can be achieved by combining rotation angle and kV (27 mAs or 52.5 mAs instead of 81 mAs or 157.5 mAs). The DAP values indicated by the CBCT unit consoles were overestimated by 12–17%, when compared with measured values. This can be explained by the fact that the values indicated by the CBCT unit consoles are determined computationally, based on X-ray tube output and field size settings. Therefore, calibration of CBCT unit DAP systems is important for a reliable analysis of diagnostic reference levels. Another explanation would be that the output of the machine is incorrect and that the stated peak tube potential is less than the actual unit peak tube potential.

For the different protocols, we used the same quality of X-ray beam by using different peak energy (80 kV or 90 kV). Theoretically, for CT, increased kV will lead to a decreased contrast resolution, as a result of the difference in attenuation coefficient between different structures, and an increase of noise, as a result of decreased quantum detection efficiency of the X-ray converter, *i.e.* more scatter interaction and less photoelectric effect with higher kV. Concurrently, decreased kV will lead to increased noise as a result of decreased fluence transmitted to the image detector. This finding was observed in this study also. The standard scanning mode of 3D Accutomo 170 has fixed frames per second (30 frames/s), *i.e.* it has 270 and 525 basis images for 180° (9 s) and 360° (17.5 s), respectively. In the less basis images (less exposure time), the effect on the images manifests as more noise. For example, comparing full-rotation 360° and half-rotation 180° protocols of the same kV and mA, the average decrease in CNR value of PTFE inserts was 30–34% for half-rotation protocols.

The result of this study cannot be generalized to all clinical situations and/or CBCT units. For a specific clinical situation and CBCT unit, patient dose reduction is possible without a clinically relevant reduction in image quality.

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IV

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RELIABILITY OF ASSESSMENT OF ROOT LENGTHS AND MARGINAL BONE LEVEL
IN CBCT AND INTRAORAL RADIOGRAPHY: A STUDY OF ADOLESCENTS

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Summary

Background: Orthodontic treatment may negatively affect roots and alveolar bone. Cone Beam Computed Tomography (CBCT) offers the possibility to evaluate adverse effects in detail.

Objectives: To evaluate reliability of measurements of root lengths and marginal bone levels in CBCT images, and periapical (PA) and bitewing (BW) radiographs.

Methods: Ten adolescents, enrolled in a clinical trial of orthodontic treatment, were examined with CBCT of both jaws (16-26 and 36-46), PA (12-22), and posterior BW radiography (16-26 and 36-46). Six raters measured root length and marginal bone level in preselected CBCT images and in available PA and BW images. Three raters repeated their measurements of a random selection of sites. Reliability was expressed as intra-class correlation coefficient (ICC 2.1) with 95% confidence intervals (CI).

Results: The number of sites that were measured among sites available for measurements, varied among the imaging methods, the raters and what was measured (root length/marginal bone level). Interrater reliability for root length measurements in CBCT, ICC was 0.88. ICCs for measurements of teeth 11 and 22 in CBCT were 0.88 and 0.76, respectively. Corresponding ICCs for PA were 0.64 and 0.68. For marginal bone level measurements in CBCT interrater reliability was 0.4, for measurements in PA of upper anterior incisors, 0.38 and in BW 0.4. Intra-rater reliability for root length measurements in CBCT was high ranging between ICC 0.82 and 0.92. For measurements in CBCT of 11 and 22, ICC was 0.72 and 0.94, respectively, and corresponding ICC for measurements in PA, ranged between 0.38 and 0.94.

Conclusion: CBCT was the most reliable imaging method for root length measurements while reliability for marginal bone level measurements was about the same for the methods.

Introduction

In the field of orthodontics, the use of radiographic imaging as an aid in the diagnosis, treatment planning and analysis of the treatment outcomes is well established. Therapeutic interventions, such as orthodontic treatment, may have beneficial as well as adverse treatment effects. Most research on adverse effects of orthodontic treatment has focused on external root resorption (ERR) (1-4). In most clinical studies periapical or panoramic radiography have been used to analyze ERR. There are, however, shortcomings associated with these two-dimensional (2D) imaging methods, even when efforts are made to obtain periodically identical radiographs or to compensate for image distortions. Moreover the buccal and palatal root surfaces, which have been found to exhibit ERR after expansion, are difficult to visualize in 2D images (5, 6).

As Cone Beam Computed Tomography (CBCT) technology is quickly evolving, it is now possible to reduce the radiation dose without degrading the overall image quality by means of decreasing the field of view (FOV) and tube potential (kV) (7). CBCT, as a three-dimensional (3D) imaging method, can easily overcome the drawbacks of 2D imaging in the assessment of adverse effects of orthodontic treatment as the CBCT technique makes it possible to obtain thin tomographic images in any direction. Despite changes in tooth/root position CBCT can therefore offer the possibility to assess root and bone tissue changes over time.

Considering root length measurements, CBCT images were found to underestimate root lengths of porcine teeth in an experimental study by less than 0.3 mm as compared to an average of 2.6 mm for periapical radiographs (8). The authors concluded that CBCT is at least as accurate as periapical radiography for tooth and root length measurements. For repeated measurements of root lengths of a dry skull, errors ranged between 0.19 – 0.32 mm for one observer (9). Furthermore, in a study of patients treated with fixed appliance, slanted root resorption was found on buccal and palatal root surfaces as revealed by CBCT (10).

Less research has been directed towards adverse effects of the marginal bone tissue after orthodontic treatment. According to a systematic review of orthodontic treatment and its adverse effects (11), "orthodontic treatment can cause a reduction of the bone level between teeth; the scope of this reduction, however, is so small that it lacks clinical relevance". This conclusion was based on studies using bitewing radiographs and limited to what occurs at the mesial and distal sites of the roots. Using CT (12) and CBCT (13), it was found that bone height decreases on the buccal and lingual surfaces of incisors after orthodontic treatment indicating the usefulness of 3D imaging for scientific analysis of changes of the marginal bone tissue.

When assessing root and bone tissue changes over time, the diagnostic accuracy of the imaging method is dependent on both accuracy and rater performance (14). Investigating the agreement between and within raters provides information about the amount of error inherent in a diagnosis or score and the rater agreement may represent an "upper boundary" for diagnostic accuracy efficacy (15). Knowledge on reliability is a prerequisite for further investigations into the prognostic value of orthodontic treatment. To the best of our knowledge, the intra- and inter-rater reliability of root length and marginal bone level assessments have not been studied for intraoral radiography and CBCT. The aim of this study was therefore to evaluate the reliability of measurements of root lengths and marginal bone levels in bitewing (BW) and periapical radiographs (PA) and CBCT images.

Methods

This is a prospective rater-based study of reliability of root length and marginal bone level measurements in CBCT, periapical (PA) and bitewing (BW) images in adolescents. It was conducted, analyzed and reported in accordance with the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) (15). An initial study protocol was prepared, including data-collection, raters and statistical analyses. The protocol was discussed and accepted by the raters. The Regional Ethical Review Board, Lund, Sweden, gave ethical approval (Dno: 2014/647).

Sample

Ten adolescents (mean age 13.4; range 12-17) were examined with CBCT of both jaws (16-26 and 36-46), PA radiography (12-22), and posterior BW radiography (16-26 and 36-46) during March 2016 and March 2017. The male female ratio was 1:1. Table 1 presents patients and teeth selected for measurements of root lengths. In case of a premolar with two apices, the buccal roots were used. In Table 2, patients, teeth and sites selected for measurements of the marginal bone level are shown.

The subjects were enrolled in a prospective clinical trial of orthodontic treatment from two orthodontic clinics. The inclusion criteria were adolescents with permanent teeth, crowding and tooth displacement. Adolescents with craniofacial syndromes, previous orthodontic treatment, ongoing sucking habits and persisting primary teeth were excluded as well as patients with crowding and tooth displacement treated with extraction. The radiographic examination was part of the clinical trial and no additional radiographs were performed for the present study.

Radiographic equipment and data processing

CBCT images were obtained with a 3D Accuitomo[®] 170 (J. Morita, Kyoto, Japan) unit, using the same scanning protocol and operating at 80 kV and 3 mA. Option of 360 revolution of the x-ray source and standard acquisition mode with a FOV of 8 cm (diameter) x 8 cm (height) and 160- μ m voxel size were used to examine the upper and lower jaw together.

PA and BW radiographs were obtained in four radiographic departments. The dental X-ray units, exposure parameters and imaging systems are shown in Table 3. Intraoral radiographs were obtained with a rectangular positioning device. The X-ray units were equipped with electronic timers. For all radiographic examinations, the patients were oriented with the same plane setting provided by the main author as a part of study protocol. Normal quality criteria for intraoral radiography were used, and, wherever possible, unacceptable radiographs were repeated.

Prior to the radiographic examinations, one of the authors (CL) checked the radiographic equipment for the following parameters: tube voltage, exposure time (reproducibility and linearity), low contrast and spatial resolution. Radiation dose for different exposure times were recorded.

Ten CBCT volumes were stored in Digital Imaging and Communications in Medicine file (DICOM) format and prepared with i-Dixel software on a workstation. A BARCO (MFGD 1318; BARCO, Kortrijk, Belgium) 18.10 greyscale liquid crystal display monitor was used with a luminance of 400 cd/m² and resolution of 1280 x 1024 pixels.

Raters and ratings (measurements)

Six raters were selected to ensure a diverse level of professional experience: two were specialists in dental and maxillofacial radiology with 25 and 30 years' experience in radiology, respectively, two were specialists in orthodontics with 10 years' experience each, one was trainee in orthodontics and one rater was a general dentist. The raters were aware of the purpose of the study and blinded to each other's measurements. Selection of CBCT images was performed by a radiologist experienced with CBCT scans using i-Dixel software. Sites in intraoral radiographs were selected by one of the authors (AA) from available intraoral images from the same patients.

After linear measurement calibration the measurements were derived from the CBCT images and PA and BW images, using Image J software (National Institute of Health, Bethesda, MD). The reading room illumination was dimmed (below 50 lux as recommended by American Association of Physicists in Medicine Task Group 18) (16) and kept constant. The reading distance was approximately 50-60 cm. There were no restrictions on reading time and zooming was allowed. All images were assessed in the same order: CBCT, PA, and BW.

All raters first attended a 10-minute educational presentation given by the main author showing examples of root lengths and marginal bone levels measurement procedure on intra-oral and CBCT images. During the session, the raters were given examples of the procedure similar to what they were expected to

measure. The aim was to familiarize the readers with the Image J software and measurement procedure. Among available sites the raters identified, step by step, the sites possible to measure and accomplished the measurement. All measurements recorded in millimeters and were rounded to one decimal. The patient information was masked on all images.

The following definitions were used for the measurements:

- Root length: distance between the mid-point between the cemento-enamel junction (CEJ) and root apex (Figure1),
- Marginal bone level: distance between CEJ and alveolar bone crest (ABC) (Figure 1).

In order to calculate intra-rater reliability, a second session was made for a representative selection of sites in CBCT images (48% of sites available and measured in the first session), all sites measured by all raters in the first session by all raters in PA and BW (PA 73% and BW 51% of sites available in the first session). The replicate measurements were performed by three raters (2 dental and maxillofacial radiologists and 1 orthodontist). First session of measurement was performed over 9 weeks, second session was held more than 3 weeks after the first session in order to minimize rater recall bias.

All results were collected in a computer database for statistical analysis. For analyzing the reliability of each method, intra-class correlation coefficient (ICC 2.1) with 95% confidence intervals (CI) was calculated. All statistical analyses were performed using IBM SPSS® Statistics v. 22.0 (IBM Corp., New York, NY; formerly SPSS Inc., Chicago, IL).

Results

Measurability

Ten patients fulfilled the inclusion criteria. All rater assessments were included for final analysis. For the first measurement session, the number of sites that were measured varied among the imaging methods, the raters and what was measured (root length/marginal bone level). Taking all raters into account 600 sites

were available for root length measurements in CBCT images and 120 sites in PA images. In CBCT images, all sites were measured by all raters and all but one in a PA image. For marginal bone level measurements, 2112 sites were available in CBCT images, 240 in PA and 840 in BW images. All sites were measured by all raters in CBCT images, 189 (79%) in PA and 719 (86%) in BW images (Table 4).

Root length measurements

Inter-rater reliability

Overall ICC for all teeth measured in CBCT images for all raters was 0.88 (CI 0.85 - 0.98) (Figure 2). Depending on which tooth that was measured in CBCT, ICC ranged between 0.27 and 0.96, being highest for mandibular left second premolars and lowest for maxillary right cuspids (Figure 3). ICCs of teeth 11 and 22 in CBCT were 0.88 (CI 0.67 – 0.98) and 0.76 (CI 0.45 – 0.97), respectively and corresponding ICCs for PA were 0.64 (CI 0.28 – 0.94) and 0.68 (CI 0.35 – 0.95) (Figure 3). Pairwise inter-rater reliability ICCs for root length measurements of all measured teeth in CBCT were above 0.85 (range 0.85 - 0.91) and below 0.84 (range 0.44 - 0.84) in PA for maxillary incisors (Figure 4).

Intra-rater reliability

ICC of the three raters was comparable for CBCT but varied between the raters for PA images (Figure 5). For measurements in CBCT, the ICC was high ranging between 0.82 and 0.92. ICC ranged between 0.47 and 0.84 for measurements of maxillary incisors in PA.

For measurements in CBCT of 11 and 22, ICC was 0.72 and 0.94, respectively. Corresponding ICC for measurements in PA, ranged between 0.38 and 0.94.

Marginal bone level measurements

Inter-rater reliability

ICC for all raters was 0.4 (CI 0.32 - 0.47) for measurements in CBCT, 0.38 (CI 0.19 – 0.6) in PA images of maxillary anterior incisors and 0.4 (CI 0.25 - 0.55) in BW images of premolars and molars (Figure 2).

As presented in Figure 4 pairwise ICCs varied among the pairs of raters and the highest ICCs were around 0.66 for the measurements by the three methods. ICCs ranged between 0.34 and 0.68) for CBCT, between 0.12 and 0.66 for PA of maxillary incisors and between 0.2 and 0.66 for measurements in BW images of premolars and molars.

Intra-rater reliability

ICC varied depending on imaging method and among the three raters (Figure 5). For measurements in CBCT, ICC was comparable for the three raters, ranging between 0.56 and 0.57. For measurements of maxillary anterior incisors in PA and of premolars and molars in BW, ICC varied among the raters: PA range 0.3 - 0.62 and BW range 0.35 - 0.8.

Discussion

In this study, CBCT presented high measurability, high reliability for root length measurements among six raters and for repeated measurements by the same rater. For root length measurements of maxillary anterior incisors in PA images, measurability was high, inter-rater reliability was lower than that for CBCT and intra-rater reliability varied among the three raters. Measurability of the marginal bone level was high for CBCT. For PA images of maxillary anterior incisors, measurability was lower of measurements of the marginal bone level than those of root lengths. Reliability for measurements of the marginal bone level was lower than of root length for CBCT and PA. Whilst intra-rater reliability was about the same for the three raters in CBCT, it varied in PA and BW images.

The assessed sites were selected from images, which were part of an orthodontic trial. No additional radiographs were performed for the present study resulting in that a limited number of sites were imaged by both CBCT and intraoral radiography. Therefore, measurability and reliability could be compared among the diagnostic modalities for only some sites.

The diagnostic tasks chosen were measurements of root length and marginal bone level of adolescents as 25 to 30 % of these age groups receive orthodontic treatment that may lead to root resorption and changes of the marginal bone tissues. A meticulous assessment of the roots and marginal bone tissue prior to the treatment start provides an important baseline to evaluate changes that may occur and may guide treatment approaches (1, 2). Root shortening or change of root length, which have been studied in several investigations of patients receiving orthodontic treatment has been interpreted as an indicator of root resorption.

The two CBCT models used offered four predefined scan modes with possibilities to changes of mA- and kV-settings and dimensions of field of view (FOV). As recommended by Al-Okshi et. al. (17), we used standard mode – full rotation with 80kV and modified mA from 5 to 3 according to patient age (size). The size of FOV influences the image as large FOV may reduce contrast to noise ratio resulting in less visibility of anatomical structures. Even so we chose an 8 x 8 cm² FOV to capture the teeth in the upper and lower jaw during the same scanning. Another influential factor on visibility of anatomical structures is the voxel size - the smaller voxel size the higher spatial resolution (18). For the CBCT unit used in this study the choice of resolution options for FOV 8 x 8 cm² is 160µm. Higher resolution mood is available only for FOVs 4 x 4 cm² and 6 x 6 cm².

Uninterpretable results, expressed as measurability in this study, are produced with varying frequencies depending on the imaging modality but also on the sample and diagnostic task. These results are reported to a limited extent and in some studies the number of sites impossible to assess are simply removed from the analysis. This may lead to biased analyses of diagnostic modalities under investigation as well as to

incorrect reports of outcomes of clinical studies. Thus, it is important to report uninterpretable results or the opposite *i.e.* the number of measurable sites so that the impact of these results can be evaluated.

Ideally, an imaging modality should make assessments of all intended sites possible. Our study presented differences in measurability among the imaging methods and diagnostic tasks. All available sites for root length measurements were possible to measure in CBCT and in PA images, whilst the number of sites assessed for the marginal bone level differed in that all sites were measurable in CBCT by all raters but not in PA and BW images. These results are important to take into account when planning clinical trials and interpreting results on adverse effects of orthodontic treatment.

A reference standard can be looked upon as the best available method to establish a diagnosis and accuracy is a keystone in assessing diagnostic methods. When a reference standard is not available, agreement and reliability studies can be used to address the objectivity of the imaging result. In other words, the measure of reliability is useful in determining the extent to which the inaccuracy of a system is due to decision-making errors. It can serve as an indication of the upper bound of accuracy (19).

Unfortunately, reliability and agreement studies are generally neglected and do not appear in the different stages of evaluating studies of diagnostic methods (15) or in interventional studies where diagnostic methods are used to evaluate outcomes. The analyses of measurement and decision-making errors of the imaging methods applied are fundamental in studies on treatment outcomes. For example in studies of orthodontic treatment, the measurement errors of baseline and follow-up examinations should be less than the assessed change of root length and marginal bone level. Furthermore, rater performance, particularly when several raters are involved in a study, is important to know.

There were differences between the reliability for root length measurements in CBCT and PA images of the maxillary anterior incisors, as indicated by non-overlapping CIs around the ICCs. These differences were large in magnitude and, therefore, may be meaningful for scientific evaluations of orthodontic treatment, which often are based on assessment of the maxillary anterior incisors. Although ICC was lower for marginal bone level measurements by PA compared with CBCT and BW, the CIs overlapped,

indicating a lack of difference. Overall ICCs for measurements of the marginal bone levels were lower than those for root length measurements. These results may depend on that correct identification of the CEJ and marginal bone outlining is difficult. The low ICCs for both inter-and intra-rater reliability for PA images of the maxillary anterior incisors could be expected since the anatomy of the borderline of the marginal bone tissue and the projection in this region may result in a vague image. The low ICCs for BW of the premolars and molars were more unexpected as BW often is recommended as an accurate and reliable imaging method for the assessment of the marginal bone tissue.

Our results on ICCs for marginal bone level measurements in CBCT were low. One reason may be that the sample consisted of growing individuals and the eruption of specifically the molars was not complete resulting in a diffuse outlining of the marginal bone tissue. In radiographic follow-up examinations of orthodontic treatment, the identification of the CEJ and marginal bone tissue may be even more difficult due to artifacts of metallic orthodontic appliance.

Our results on high measurability in CBCT for measurements of root lengths and marginal bone level as well as high reliability for root length measurements add further to the results of previous studies that CBCT may be the best choice of imaging method for scientific analyses of outcomes of orthodontic treatment. Even if CBCT is more expensive than intraoral radiography, CBCT could be more consistent to identify changes related to interventions. For clinical praxis, on the other hand, intraoral radiographs may be still the method of choice, as clinicians make preventive measures like the use of lower forces, resting periods and decrease of the treatment time not until root resorption from 2 mm up to 1/3 of the root length is diagnosed (20).

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Table 1. Patient distribution and number of sites available for measurement of root lengths in CBCT and periapical radiography (PA) for each of six raters.

Patient no.	1 + 3 + 5 + 7 + 9						2 + 4 + 6 + 8 + 10					
Tooth	16	15	14	13	12	11	21	22	23	24	25	26
Root	P	DB									P	MB
CBCT	5	5	5	5	5	5	5	5	5	5	5	5
PA					5	5	5	5				
CBCT	5	5	5		5		5		5	5	5	5
Root	M											D
Tooth	46	45	44	43	42	41	31	32	33	34	35	36
Patient no.	2 + 4 + 6 + 8 + 10						1 + 3 + 5 + 7 + 9					

P= palatal, DB= disto-buccal, MB=mesio-buccal D= distal, M= mesial

Table 2. Patient distribution and number of sites available for measurements of marginal bone level in CBCT, periapical (PA) and bitewing (BW) for each of six raters.

Patient no.	1 + 3 + 5 + 7 + 9						2 + 4 + 6 + 8 + 10					
Tooth	16	15	14	13	12	11	21	22	23	24	25	26
Root	P	DB									P	MB
CBCT	14	9	18	19	20	20		19		19	20	15
BW	10	10	10	5					5	10	10	10
PA					10	10	10	10				
BW	10	10	10	5				5	10	10	10	10
CBCT	15	20	20		19		20		20	20	20	15
Root	M											D
Tooth	46	45	44	43	42	41	31	32	33	34	35	36
Patient no.	2 + 4 + 6 + 8 + 10						1 + 3 + 5 + 7 + 9					

P= palatal, DB= disto-buccal, MB=mesio-buccal D= distal, M= mesial

Table 3. Dental X-ray units, exposure parameters and imaging systems used for periapical and bitewing radiography

Place	X-ray unit (name and exposure parameters)	Imaging system (name, effective area , pixel size)
Dental school	Planmeca ProX (Planmeca; Helsinki, Finland) 60kV, 7mA, 0.125 s	ProSensor® (Planmeca; Helsinki, Finland) Effective area 36 x 26.1 mm ² Pixel size 30 x 30 µm ²
Hospital - 1	Kavo, Gendex 765 DC (Kavo; Biberach/Riss, Germany) 65kV, 7 mA, 0.25s for periapical and 0.125s for bitewing radiography	ProSensor® (Planmeca; Helsinki, Finland) Effective area 36 x 26.1 mm ² Pixel size 30 x 30 µm ²
Hospital - 2	Planmeca Intra (Planmeca; Helsinki, Finland) 60kV, 8mA, 0.160 s	Schick 33 (Sirona Dental, Salzburg, Austria) Effective area 25.6 x 36 mm ² Pixel size 15 x 15 µm ²
Private clinic	Sirona – HELIODENT DS (Sirona Dental Systems, Bernsheim, Germany) 60kV, 7 mA, 0.16 s	Sigma CCD (GE/Instrumentarium Imaging, Tuusula, Finland) Pixel size 39 x 39 µm ²

Table 4. Number of available and measured sites in CBCT, periapical (PA) and bitewing (BW) radiographs for measurements of root lengths and marginal bone level for each rater for the first rating session

Rater	Root lengths				Marginal bone level					
	CBCT		PA		CBCT		PA		BW	
	Available sites	Measured Sites	Available sites	Measured sites	Available sites	Measured sites	Available sites	Measured sites	Available sites	Measured Sites
1	100	100	20	19	352	352	40	28	140	115
2	100	100	20	20	352	352	40	31	140	124
3	100	100	20	20	352	352	40	31	140	122
4	100	100	20	20	352	352	40	27	140	118
5	100	100	20	20	352	352	40	38	140	120
6	100	100	20	20	352	352	40	34	140	120
Total	600	600	120	119	2112	2112	240	189	840	719

Figure 1. Cross-sectional CBCT images (A, B), intraoral periapical (C,D) and intraoral bitewing (E) images used for measurements of root length (g) and marginal bone level (f).

Figure 2. Inter-rater reliability expressed as intra-class correlation coefficient with confidence interval for the measurements of root lengths and marginal bone level in CBCT, periapical radiography (PA) [for maxillary incisors] and bitewing radiography (BW) [for premolars and molars].

Figure 3. Interrater reliability expressed as intra-class correlation coefficient and confidence intervals for measurements of root lengths in CBCT and in periapical radiography (PA) [for 11, 22].

P= palatal, DB= disto-buccal, MB=mesio-buccal D= distal, M= mesial

Figure 4. Pairwise interrater reliability expressed as intra-class correlation coefficient with confidence intervals for measurements of root lengths and marginal bone level in CBCT, periapical radiography (PA) [for maxillary incisors] and bitewing radiography (BW) [for premolars and molars].

Figure 5. Intrarater reliability expressed as intra-class correlation coefficient with confidence intervals for measurements of root lengths and marginal bone level in CBCT, periapical radiography (PA) [for maxillary incisors] and bitewing radiography (BW) [for premolars and molars].

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