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FULL PAPER

Development of a low-dose protocol for cone beam CT examinations of the anterior maxilla in children

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Objective: The aim of this study was to develop a low-dose protocol suitable for cone beam CT (CBCT) examination of an impacted maxillary canine in children by using a combination of dosimetry with subjective and objective image quality assessment.

Methods: Radiation dose and image quality measurements were made using a dental CBCT machine. An image quality phantom was used to investigate the relationship between objective image quality and dose-area product (DAP) for a broad range of exposure settings. Subjective image quality assessment was achieved using a paediatric skull phantom submerged in a water bath for the same range of exposure settings. Eight clinicians assessed each CBCT data set for nine aspects of image quality using a five-point rating scale of agreement.

Results: Acceptable image quality, defined using subjective judgements by the clinicians of the skull phantom images, was achievable with DAP values of 127 mGy cm² or greater and a polytetrafluoroethylene (PTFE) contrast-to-noise ratio (CNR) of 4.8 or greater. A cautious choice was made to recommend a low-dose protocol of 80 kV and 3 mA for implementation into clinical practice, corresponding to a DAP value of 146 mGy cm² and a PTFE CNR of 5.0.

Conclusion: A low-dose protocol for this particular CBCT machine was established which represents as much as a 50% reduction compared with manufacturer's recommendations.

Advances in knowledge: To the authors' best knowledge, this is the first study that addresses dose optimization in paediatric clinical protocols in dental CBCT. Furthermore, this study explores the relationship between radiation dose, objective and subjective image quality.

INTRODUCTION

Using X-ray exposures that are as low as reasonably achievable is a fundamental principle of radiation protection of patients. Dental cone beam CT (CBCT) is usually associated with higher levels of dose than conventional dental radiography.¹ Risk from X-ray exposure is higher for younger individuals, so it is particularly important that a priority is given to optimization of X-ray exposures for CBCT examinations in children, as highlighted by the "Image Gently" campaign and the subsequent effort within dentistry.² A recent hospital-based survey in the UK found that the most commonly performed dental CBCT examination in this age group was a localized examination of the anterior maxilla.³ This was usually for assessment of impacted canine teeth in the context of possible resorption of incisors.

Although field-of-view (FOV) dimensions are important in determining patient dose in dental CBCT, a key factor is that exposure factors (X-ray tube voltage and tube current–

exposure time product) should be adjusted to give acceptable image quality for the diagnostic task in question.^{4–6} Although some dental CBCT equipment uses automatic exposure control, most require the operator to set exposure factors manually.⁷ This is carried out using the manufacturers' suggested protocols, with the help of expert advice from a medical physicist and by the professional judgement of the operator. There are, however, limited objective data on the image quality requirements for dental CBCT. Lofthag-Hansen et al⁸ demonstrated that requirements depended on the diagnostic task and anatomical location (upper or lower jaw). Others have found that there is scope for reducing exposure factors without loss of adequate image quality in various clinical contexts.^{9–20} Low-dose protocols are a familiar optimization strategy for "medical" CT,²¹ but there is almost no comparable literature related to dental CBCT. The impact of low-dose scanning protocols on objective measurements of image quality, available on one CBCT machine, has been assessed,²² but this study did not include a subjective

image quality assessment of clinical images. A strategy for using a low-dose protocol has been presented for CBCT in the context of dental implant imaging but this did not provide any objective guidance on image quality requirements.²³ There is clearly a need to increase understanding of the relationship between objective image quality measures and clinicians' subjective image quality needs for specific clinical indications in dental CBCT.

The overall aim of this study was to develop a low dose protocol suitable for CBCT examination of impacted maxillary canines in children. The specific objectives were:

1. to measure for a broad range of X-ray tube voltage and tube current–exposure time product (mAs) combinations, objective image quality using suitable test tools, subjective image quality using a skull phantom and radiation dose.
2. to investigate the relationships between radiation dose, objective and subjective image quality.
3. to identify a practicable low-dose protocol for CBCT of impacted maxillary canines in children.

METHODS AND MATERIALS

Cone beam CT equipment

All CBCT examinations were performed using the 3D Accuitomo F170® (J. Morita, Kyoto, Japan). This equipment requires manual setting of exposure factors. 35 combinations of X-ray tube voltage (kV) and tube current (mA) were used throughout. An exposure time of 17.5 s was always used. The X-ray tube voltage options were 60, 65, 70, 75, 80, 85 and 90 kV. X-ray tube current options were 1, 3, 5, 7 and 10 mA. These combinations represent a wide range of exposures, including those recommended by the manufacturer for use in everyday clinical practice (90 kV and 4–6 mA) but extending well beyond this range. A full rotation scan (360°) with a cylindrical field-of-view (FOV) of 4 cm in diameter and 4 cm in height and a 80-µm voxel size were used at all times.

Dose measurements

For all combinations of X-ray tube voltage and tube current, dose–area product (DAP) values, expressed in mGy cm², were obtained using a DAP metre with an active diameter of 7 cm (VacuDAP; VacuTech Messtechnik GmbH, Dresden, Germany). The DAP metre sensor was positioned at the centre of the X-ray tube exit window and completely intercepted the radiation field.

Objective measurement of image quality

The SedentexCT IQ cylindrical phantom (Leeds Test Objects, Boroughbridge, UK), a dedicated dental CBCT phantom, was used, along with three of the cylindrical (35 mm diameter, 20 mm height) contrast resolution test inserts supplied with it. The three inserts were polytetrafluoroethylene (PTFE), low-density polyethylene (LDPE) and air. These were chosen as being representative of the tissues found in dental imaging: air inserts representing air cavities, PTFE representing dense bone and LDPE representing soft tissues. Each insert contains five rods of the specified material with different diameters (1, 2, 3, 4 and 5 mm) encased in a background of homogeneous polymethylmethacrylate (PMMA).

Each test insert was scanned individually to avoid possible interferences by adjacent inserts. The inserts were placed into the

phantom in a peripheral location and approximately midway in the vertical plane to ensure full containment of the primary beam in the phantom. The isocentre of the FOV was positioned at the centre of the test insert, with the test insert placed anteriorly and the bulk of the phantom placed posteriorly, to best reproduce the location of the anterior maxilla in a patient's head. The 5 mm diameter rod of the test insert was always located anteriorly to ensure consistency. All empty locations in the phantom were filled with homogeneous PMMA inserts of the same dimensions as the test inserts.

CBCT examination was performed by positioning the SedentexCT IQ phantom in the 3D Accuitomo F170 scanner in the position used for patient examinations. The phantom was exposed once for each insert, using each of the 35 combinations of X-ray tube voltage and tube current described above. CBCT data sets were exported as DICOM files into ImageJ software v. 1.45s (National Institutes of Health, Bethesda, MD). Axial images were analysed at 16-bit scale. On these images, a circular region of interest of approximately 12 mm² was drawn within the 5 mm diameter rod of each material and another in the central area of PMMA as the background, allowing measurement of the pixel values of each material. For all data sets, measurements were performed on five consecutive axial images, starting from the centre of the 5 mm diameter rod in an upwards direction. For each test insert and exposure parameter combination, the mean and standard deviation of the pixel values from the five slices were recorded. For each test insert image, the coefficient of variation was used as a measure of consistency, calculated as the standard deviation/mean of the five measurements at all combinations and materials. Contrast-to-noise ratio (CNR) for each combination was then calculated relating the mean pixel value from the rod and the background with the following formula:²⁴

$$\text{CNR} = \frac{\text{MPV}_{\text{insert}} - \text{MPV}_{\text{background}}}{\sqrt{(\text{standard deviation}_{\text{insert}}^2 + \text{standard deviation}_{\text{background}}^2)}} / 2$$

where MPV represents the mean pixel value. Thus, CNR values were obtained for each of the test insert materials and at each X-ray tube voltage/tube current–exposure time product combination.

Subjective measurement of image quality: image production

In order to produce suitable CBCT images of the anterior maxilla, as close in appearance to clinical images as possible, an anthropomorphic phantom was used. This was the design developed in a previous study.²⁵ Briefly, the phantom consists of a hollow container made of high impact polystyrene shaped to the morphology of the head and neck. Into this, a skull or mandible can be positioned and the container filled with water to simulate soft-tissue density. The polystyrene container can be fixed to a photographic tripod for stability during use.

For the purpose of the current study, a child skull, assessed as being approximately 9–10 years of age, was obtained from the collection of the Centre for Comparative and Clinical Anatomy at the University of Bristol. The age was estimated according to the guidance of Al Qahtani *et al.*²⁶ The maxilla contained an

unerupted right canine tooth. The skull was soaked in water for 48 h before use to displace air from the trabecular spaces. The skull was then positioned in the polystyrene container ready for imaging.

First, scout images were taken to centre the FOV on the unerupted right maxillary canine tooth, after which the CBCT examination was performed. The phantom was exposed to the same 35 combinations of exposure parameters as used previously. In addition, scans were performed using the highest and the lowest possible exposure (highest: 90 kV, 8.0 mA, 30.5 s, full rotation: 360°; lowest: 60 kV, 1.0 mA, 4.4 s, partial rotation: 180°). These two scans were performed to obtain reference image data sets of the highest and the lowest image quality possible with the CBCT device being used. The highest exposure settings produced an image with the highest image contrast and spatial resolution and the lowest noise available by the machine. However, the lowest exposure settings resulted in an under-exposed image with poor contrast, compromised spatial resolution and high-noise levels. All exposures were taken in one session to avoid the introduction of differences in positioning between examinations.

Seven CBCT data sets were chosen randomly from the 35 and duplicated within the study sample to allow assessment of observer repeatability. Thus, there were 42 CBCT image data sets available for observations and 2 CBCT image data sets available for reference. The 42 CBCT image data sets were allocated random numbers. Figure 1 shows an example scan from the study.

Subjective measurement of image quality: observations

For the observation of the images, a new Dell Ultrasharp U2312HM 23 inch LED monitor (Dell Corporation Ltd, Bracknell, UK) was used, with a luminance of 352 cd m^{-2} , a dynamic contrast ratio of 10000:1 and a resolution of 1920×1080 pixels. All these technical specifications are within the range given by the UK Health Protection Agency for diagnostic purposes of dental CBCT images.⁵ Prior to the first use, a Society of Motion Picture and Television Engineers test pattern was used to configure the

monitor. Images were viewed using i-Dixel One Volume Viewer software provided by the manufacturer (J Morita USA, Irvine, CA).

Eight observers were recruited, consisting of three dental and maxillofacial radiologists and five orthodontists. They were requested to evaluate the 42 CBCT data sets in turn and to answer a questionnaire on each. All observers had previous experience in the use of the viewing software. The observers were given a standardized short verbal introduction individually by the first author about the study immediately before the beginning of the scoring session. Observations were performed with no time restrictions. The room for the image evaluations had standardized conditions of low environmental noise and lighting, with only a desktop lamp remaining illuminated so that the observers could read the questionnaire and record their responses. The observers were free to scroll through the three orthogonal reconstructions (axial, coronal and sagittal), to perform secondary reconstructions if they wished, to adjust contrast and brightness freely and to observe the volume-rendered image. The observers were blinded to the exposure protocols and were not informed of the presence of the duplicate cases. Observers were informed that the clinical scenario for all the CBCT data sets was the evaluation of the position and morphology of the right maxillary canine and possible root resorption of the adjacent teeth. Each observer completed a nine-point questionnaire for each CBCT data set. This was composed of six statements regarding the identification and visibility of anatomical features, two about the usefulness of the CBCT images for the specific diagnostic task and one directly addressing the acceptability of the overall image quality:

1. A clear delineation of the cortical bone plates can be seen.
2. A clear trabecular bone pattern can be seen.
3. A clear differentiation between enamel and dentine can be seen.
4. A clear image of the pulp chamber and root canal can be seen.
5. A clear image of the periodontal ligament space can be seen.
6. A clear image of the lamina dura can be seen.
7. The volume rendering is acceptable for clinical purposes.

Figure 1. Screenshot of a cone beam CT scan of the skull phantom used in the study. Clockwise, from the upper left, these are coronal, sagittal, volume-rendered and axial.

Figure 2. Contrast-to-noise ratio for the polytetrafluoroethylene (PTFE) (a), low-density polyethylene (LDPE) (b) and air test inserts (c) at all combinations of tube current (mA) and tube voltage (kV). Data were fitted with second-order polynomials.

8. The amount of noise in the images is acceptable for clinical purposes.
9. I am content that the image quality is acceptable for clinical purposes.

For these, a five-point rating scale of agreement was available for observer responses:

1. Strongly disagree.
2. Disagree.
3. Neither agree nor disagree.
4. Agree.
5. Strongly agree.

In making their responses, observers were encouraged to refer frequently to the reference “best” and “worst” quality CBCT data sets.

Data analysis

With regard to the subjective assessment of image quality recorded using the questionnaire, responses to the nine questions were dichotomized, with values 4 and 5 considered as a positive result (response in agreement with the statement) while 1, 2 and 3 were considered as negative (disagreement).

Intraobserver and interobserver agreement was calculated by using the kappa test with the scale for strength of agreement

Table 1. Dose-area product in mGy cm^2 measurements at each combination of X-ray tube voltage and tube current (mA). Exposure time was 17.5 s for all tube current-exposure time product (mAs)

Tube current		Tube voltage (kV)						
mA	mAs	60	65	70	75	80	85	90
1	17.5	26	31	36	43	49	55	61
3	52.5	77	92	109	127	146	164	184
5	87.5	128	154	182	212	243	273	306
7	122.5	179	214	255	297	340	382	428
10	175	266	322	384	450	517	582	655

described by Altman.²⁷ Intraobserver agreement was calculated for the complete group and also considering the radiologist and orthodontist observers separately. Interobserver agreement was evaluated separately for each question. Only observers with intraobserver kappa values exceeding 0.4, corresponding to moderate, good or very good agreement,²⁷ were included for subsequent analysis. Those who failed to attain this level of intraobserver agreement were excluded from further analysis, following previously established practice.^{28–30}

In order to identify a low-dose protocol which provided adequate image quality at the lowest DAP value, the observations of the remaining observers needed to be combined, bearing in mind the likelihood of imperfect agreement between them in response to individual questionnaire statements. For each exposure setting combination, the image quality was defined as acceptable when a majority of the observers agreed or strongly agreed with at least four out of the first six questionnaire statements, dealing with anatomical features, and all three of the remaining statements. This combined image quality assessment, hereafter referred to as the “integrated image quality”, was used as the dependent variable for subsequent statistical analysis.

Binary logistic regressions were performed to evaluate the CNR values from each test insert material from each of the combinations of X-ray tube voltage/tube current–exposure time product to determine which, if any, was more related to integrated image quality.

All statistical analysis was performed using IBM SPSS® Statistics v. 20.0 (IBM Corp., Armonk, NY; formerly SPSS Inc. Chicago, IL). In all cases the significance level was set at $p < 0.05$.

RESULTS

Dose measurements

DAP measurements for each combination of X-ray tube voltage and tube current are shown in Table 1. The data show the expected trends in DAP according to exposure settings.

Objective measurement of image quality

The coefficient of variation for measurements was 1% or lower. CNR values for each of the three test inserts are shown in Figure 2a–c.

Subjective measurement of image quality

Reliability, measured as interobserver agreement in response to the nine questionnaire statements, was found to be 0.50 (moderate

agreement). Intraobserver agreement ranged from fair to moderate ($\kappa = 0.21$ – 0.66). The individual intraobserver percentage agreement and kappa values are shown in Table 2. Three observers, all orthodontists, failed to attain kappa values exceeding 0.4 and their observations were excluded from further analysis. The mean intraobserver agreement of the remaining five observers was 0.61 (good).

Table 3 is a diagrammatic representation of the questionnaire responses of these five observers. As can be seen, the responses formed a complex picture, but the definition of integrated image quality provided a clear threshold, as shown by the thick line in the Table. There were 24 possible combinations of X-ray tube voltage and tube current which were consistent with acceptable integrated image quality. By comparing this with Table 1, it can be seen that acceptable integrated image quality was obtained with DAP values of 127 mGy cm^2 (75 kV and 3 mA) or greater.

The relationship between subjective and objective image quality

Binary logistic regression, performed to measure the relationship between the CNR for each of the test insert materials and integrated image quality as the dependent binary variable (acceptable or unacceptable integrated image quality), showed that there was no statistically significant relationship between integrated image quality and LDPE CNR values ($p = 0.975$) or between integrated image quality and air CNR values ($p = 0.980$). A significant positive relationship was found, however, between integrated image quality and the PTFE CNR value (odds ratio: 29.11, $p < 0.001$).

By examination of the PTFE CNR values in Table 4 in conjunction with Table 3, it can be seen that acceptable integrated image quality was obtained with a PTFE CNR of 4.8 or greater.

Optimized exposure protocol

The results allowed us to identify a threshold for DAP and PTFE CNR which provided acceptable integrated image quality for the skull phantom in this laboratory study. Bearing in mind that clinical CBCT examinations may be faced by factors which can reduce image quality, such as metal-related artefacts and minor patient movement, a cautious approach was agreed by the researchers when defining a combination of X-ray tube voltage and tube current–exposure time product suitable for introduction into clinical practice.

A decision was made to select a tube voltage of 80 kV and a tube current of 3 mA for the low-dose protocol, while giving the operator freedom to adjust the latter by $\pm 0.5 \text{ mA}$ on the basis of

Table 2. Intraobserver agreement of the eight observers for responses to the image quality questionnaire, measured using kappa and percentage agreement

Observer	1	2	3	4	5	6	7	8
Clinical speciality	O	O	O	O	O	R	R	R
Kappa	0.21 ^a	0.24 ^a	0.30 ^a	0.42	0.54	0.59	0.41	0.66
% Agreement	71	67	64	79	84	83	76	84

O, orthodontist; R, radiologist.

^aObservers with only fair agreement.

Table 3. Diagrammatic representation of the subjective image quality assessments made by the five observers

Integrated image quality		Tube voltage (kV)						
mA	mAs	60	65	70	75	80	85	90
1	17.5	+	+	+	++	+	++	+
3	52.5	+	+	++	+++	+++	+++	++++
5	87.5	++	+++	++++	++++	++++	++++	++++
7	122.5	+++	+++	++++	++++	++++	++++	++++
10	175	+++	++++	++++	++++	++++	++++	++++

Each table cell represents a combination of X-ray tube voltage (kV) and tube current-exposure time product (mAs). Four crosses correspond to agreement with all six statements, three to agreements with four or five of the statements, two with agreement between one and three of the statements and one with no agreement with the statements. The grey highlighted cells indicate that the image quality was acceptable for clinical purposes. The threshold for “integrated image quality”, shown by the thick line, indicates combinations of tube voltage and tube exposure-time product for which there was agreement on at least four of the first six statements and all of the remaining three statements.

their judgement of patient size. This decision was made taking into consideration the objective and subjective image quality results, the pre-optimized clinical protocol and the input from the Medical Physics Expert for the University Dental Hospital of Manchester, the oral radiologists and radiographers. The skull used in the phantom was estimated as being at the younger end of the likely age group for CBCT examinations, meaning that subjects requiring slightly higher exposures would be anticipated in clinical practice. Consequently, this led to the cautious consensus decision not to reduce the tube voltage to 75 kV but to use 80 kV without risk of compromising image quality. The 80 kV and 3 mA combination corresponded to a DAP value of 146 mGycm² and a PTFE CNR of 5.0, corresponding to approximately a 50% reduction compared with the midpoint of the exposure range recommended by the manufacturers. Figure 3a,b shows images from the study taken using these combinations of tube voltage and tube current.

DISCUSSION

This study aimed to identify a low-dose protocol for CBCT examination of impacted maxillary canines in children. Although optimization of exposure is of particular importance in the paediatric age group, no previous research has addressed this specifically. A low-dose CBCT protocol was presented by Harris *et al*²³ implant dentistry, but this presented general principles rather than precise exposure guidelines and is obviously aimed at adults. The need of clinicians using dental CBCT

is to be able to identify a specific exposure protocol that will deliver a balance between acceptable image quality and the lowest achievable patient dose.

A substantial number of studies have shown that there is scope for lowering exposure factors in dental CBCT examinations without an unacceptable loss of image quality.^{9–20} Most of these have been aimed at the use of CBCT in implant dentistry, while others have investigated the impact on diagnosis of simulated root resorption and periapical pathosis. Only two studies have specifically looked at orthodontic-related applications of CBCT.^{10,22} In most cases, “image quality” has been assessed only subjectively or by assessment of diagnostic accuracy, while others have made objective measurements but not related these to subjective judgements of image quality. None of these studies has performed dosimetry, subjective assessment and objective measurement of image quality, all on the same material.

It is important to recognize that the many different models of dental CBCT equipment, produced by several independent manufacturers, vary enormously in their technical specifications.⁷ Consequently, research results presented for one piece of equipment cannot be translated to others easily. An obvious example is presented by the CBCT machine used in our current study. Researchers have shown that the use of the 180° rotation option available on the 3D Accuitomo scanner can be used to lower exposure factors without affecting diagnostic performance.^{12,13} As

Table 4. Contrast-to-noise ratio (CNR) values for the polytetrafluoroethylene (PTFE) test insert at all combinations of tube current (mA) and tube voltage (kV)

CNR PTFE		Tube voltage (kV)						
mA	mAs	60	65	70	75	80	85	90
1	17.5	1.3	1.4	1.8	2.1	2.7	3.0	3.0
3	52.5	2.8	3.5	3.9	4.8	5.0	5.7	5.9
5	87.5	4.2	5.1	5.5	6.2	6.9	7.7	8.0
7	122.5	5.2	6.2	7.1	7.7	8.4	8.6	9.4
10	175	6.5	7.4	8.2	9.0	10.0	10.7	11.3

Figure 3. Coronal images from cone beam CT scans performed at (a) the mid-point of the exposure range recommended by the manufacturers [90 kV, 5 mA, dose-area product (DAP) 306 mGy cm²] and (b) using the selected low dose protocol (80 kV, 3 mA, DAP 146 mGy cm²).

this option is not universally available on dental CBCT equipment, however, it cannot be advised as a general means of lowering patient dose. Similarly, Ludlow and Walker²² performed a comprehensive evaluation of radiation dose and objective measurement of image quality for the iCAT® FLX machine (Imaging Sciences International, Hatfield, PA), including some low dose programmes (QuickScan and QuickScan+) but these findings are only relevant to that piece of CBCT equipment. The challenge of dealing with the widely varying technical specifications and performance means that the “holy grail” of dose optimization would be to identify an objective measure of image quality for each diagnostic task which can be transferred from one piece of CBCT equipment to another. This would be of enormous value to clinicians, medical physics experts and manufacturers of CBCT equipment. In this study, we identified that acceptable image quality was obtained with a PTFE CNR of 4.8 or greater. A further step in this research would be to repeat the research on alternative models of CBCT equipment to determine whether this threshold of image quality can be used more widely when establishing exposure protocols.

In the present study, radiation doses were measured as DAP. An alternative might have been to measure absorbed dose or effective dose using thermoluminescent dosimeters, but the quantity of effort required to perform such measurements for the 35 combinations of X-ray tube voltage and tube current–exposure time product used in the study was considered excessive. Furthermore, DAP has been recommended for establishing Dose Reference Levels (DRLs) for dental CBCT^{4,31} and thus our results relate directly to measurements performed by medical physics experts when conducting commissioning and routine equipment testing. Although no DRLs are currently established due to insufficient dose audit data, an “achievable dose” has been proposed of 250 mGy cm² for an adult scan in the posterior maxilla,³¹ and this proposal was adopted in European guidelines.⁴ Both documents also recommended a paediatric achievable dose scenario of imaging for a single impacted maxillary canine in a 12-year-old male, but without being able to set an achievable dose level. The findings in the current study, in which acceptable image quality was achieved at and above a threshold DAP value of 146 mGy cm², may provide some useful data for establishing a paediatric achievable dose level for dental CBCT. It should be noted that,

recently, Ludlow et al¹ presented an argument that dose–height product is a preferable dose index to DAP because it relates better to effective dose. While this may be correct, this does not invalidate a study such as ours, where effective dose was not considered.

The use of physical phantoms is common in dental CBCT image quality assessment.^{32–35} The SedentexCT IQ phantom Pauwels et al³⁶ was used in this study for objective measurement of image quality because it was specifically designed for dental CBCT and was readily available to us. However, the SedentexCT IQ phantom represents an adult head with no paediatric equivalent phantom being available at the time of the study.

Five measurements in the same scan were performed to ensure consistency of values. The coefficient of variation showed very small differences (1% and less), similar to those reported in a previous study (from 1.0% to 1.3%).³⁶ Thus, fewer measurements ought to be practicable and reliable in any future study.

CNR encapsulates contrast and noise in one equation, which is most important when measuring image quality from a physical perspective and when evaluating the relationship between X-ray tube voltage, tube current–exposure time product and image quality.^{37,38} It is known that, in CT, a reduction in X-ray tube voltage increases contrast and noise,³⁹ a finding which was observed in the present CBCT study. The relationship between CNR and X-ray tube voltage, as illustrated in Figure 2a–c, can be approximated to a second-order polynomial relationship, with values rising with increased X-ray tube voltage and tube current. For a fixed X-ray tube current–exposure time product, contrast falls with increasing X-ray tube voltage, as expected due to the decrease in proportion of photoelectric interactions. Noise increases with decreasing X-ray tube voltage due to reductions in scatter interactions and the number of unattenuated photons reaching the detector. However, the CNR values increase with X-ray tube voltage which implies that noise is the driving parameter for CNR for this task.

A trend towards progressively greater CNR values was observed as the combinations of X-ray tube voltage and tube current–

exposure time increased. This trend was shown for all test insert materials evaluated. These greater values have been shown to be related to an improved image quality.²² Different CNR values were found for the three materials due to their different attenuation properties. Different densities have been reported to affect the distribution of pixel values, with a wide variability across CBCT machines for air and aluminium.³⁶ Thus, pixel values can be different depending on the test insert material and may not be comparable between different insert material scenarios or even between machines.⁴⁰

Although objective measurement of image quality is essential in studies such as this, the decision on acceptability or rejection of image quality for clinical purposes must rest with observers. The nine-point questionnaire used to make the subjective assessments was developed after discussion amongst the researchers and took into account the methodology of previously published studies. Six anatomical features were used here, taking into account the approach used in previously published work.^{8,41,42} Most of these anatomical features were related to the teeth, while others were related to surrounding tissues. Ideally, we would have included a question regarding the presence or absence of root resorption, a common diagnostic question in the context of impacted maxillary canine teeth. There was no identifiable resorption of any tooth in the skull used in the study and, as this was on loan, preparing an artificial root defect was not possible. Regardless of this, however, to introduce this variable in a meaningful way would have probably meant duplicating all exposure variables so that some image data sets included a resorption defect and others did not. This would have greatly increased the burden upon observers performing assessments and was considered unfeasible.

A five-point rating scale was used for observer assessments, following the approach of many previous studies. In our questionnaire, the middle of the scale was a neutral option (neither agree nor disagree with the statement) and at the time of dichotomising these data, a negative connotation was given to it, as previously reported for subjective image quality studies in oral radiology.⁴³ Thus, the possibility of having a positive result was reduced to two options out of five. This decision represented a cautious approach, with the intention of images being scored positively only when observers had made a definite positive response. It could be argued that as all responses were dichotomized for data analysis, a simple yes/no question would have been appropriate, but a multiple option questionnaire was designed so that the observers could feel more freedom to score the images.

Eight observers were recruited to perform subjective image quality assessments, a number typical for other studies on CBCT image quality. Of these, we excluded three observers after the data collection was completed based on their intraobserver repeatability. The decision to exclude observers whose data is judged to be unreliable is in accord with previous researchers.^{28–30} It was clear during the analysis that the observers did not give identical results and that selection of a clearly defined threshold was challenging. For example, some cases were considered as having acceptable image quality despite being judged as having unacceptable levels of noise and/or

the 3D images as being not acceptable for clinical diagnosis. Therefore, the “integrated image quality” parameter was introduced as an attempt to redefine subjective image quality in a way that reconciled the various judgements made by the observers. An alternative method of integrating observer judgements might have produced different results in terms of threshold for integrated image quality. However, this would have required a level of subjective decision about which items to include and exclude.

A clear stair-like line separating acceptable from unacceptable image quality with increasing exposure parameters indicates the dynamic range that can be used to reduce the dose without compromising image quality. This is in agreement with other studies for implant planning and endodontic tasks in adults.⁸ 24 out of the 35 exposure setting combinations gave an acceptable level of “integrated image quality”, including a DAP as low as 127 mGy cm².

The relationship between objective measurements of image quality and clinical image quality is difficult to establish;^{1,3–35,44,45} objective image quality may not be linearly related to subjective image quality. The CNR image quality metric was used to determine the lowest combination of tube voltage/tube current–exposure time product possible without compromising contrast. The integrated image quality indicated the 75 kV and 3 mA as the lowest dose protocol. However, when evaluating the CNR values for all test insert materials, 80 kV and 3 mA (DAP value: 146 mGy cm²) were judged to be a pragmatic choice for a low-dose protocol for the reasons discussed above. An acceptable image quality and tolerable levels of CNR reduction were found.

Only CNR values from the PTFE test insert were significantly related to bone tissue from the SedentexCT IQ phantom ($p = 0.975–0.980$). This may indicate that PTFE could be used as the only material for investigation of the relationship between image quality and CNR, at least for the particular CBCT machine and clinical task evaluated here. However, further studies would be required to confirm whether the same results are found in other contexts.

There has been some uncertainty about whether tube current–exposure time product alone should be used to alter exposure in CBCT or whether adjustment of X-ray tube voltage is also appropriate. While tube current–exposure time product has a simple linear relationship with number of X-ray photons, X-ray tube voltage changes both number and energy (mean and maximum) of X-ray photons in a more complex way with increasing energy leading to a proportional fall in photoelectric effects and an increase in Compton scatter.

The study of Pauwels *et al.*⁴⁶ is of particular interest to ours because they investigated the impact of changing tube voltage and tube current–exposure time product on CNR, using the same CBCT scanner and image quality phantom as we did. The conclusion of Pauwels *et al.*⁴⁶ was that the highest contrast was found at the highest available X-ray tube voltage setting for this CBCT machine (90 kV) and that low-dose protocols should use tube current reduction. A key difference between their study and ours is that we incorporated subjective image quality assessment of a skull

phantom. The subjective image quality results of our study indicated that the optimum CNR was achieved at a lower tube voltage than the maximum. Furthermore, our study showed that acceptable image quality was achieved at a PTFE CNR value of 5.0. Pauwels et al⁴⁶ results indicate that a PTFE CNR of 5.0 can be achieved with a lower tube voltage than 90 kV, e.g. 80 kV and 4.5 mA or 85 kV and 3.75 mA without a dose penalty. Our study has shown that a specific CNR can be achieved with a range of combinations of tube voltage and tube current/exposure time product, which is in line with Pauwels et al⁴⁶ results.

CONCLUSION

The present study demonstrated that the radiation dose can be decreased while maintaining the image quality as an adequate level for the studied diagnostic task. The standard clinical protocol was reduced from 90 kV to 80 kV and from 4–6 to 3 mA with some flexibility in tube current–exposure time product according to the radiographer's judgement. This decision was made after careful consideration of both objective and subjective

image quality results, which were taken into consideration by the Medical Physics Expert for the Hospital, along with the oral radiologists and radiographers. CNR values were shown to be reduced slightly when reducing tube voltage, while dose reduction observed was considerable. This change allowed a dose reduction of approximately 50% when considering the manufacturer's recommended protocols. Further reductions to 75 kV and 3 mA, despite having shown an acceptable image quality from a subjective perspective, showed a higher CNR value reduction (19–27%). This may not be acceptable for real clinical practice, especially when scanning young people when other sources of image quality degradation, such as movement and metal-related artefacts, may be present. The results of a clinical trial which followed the introduction of the low-dose protocol will be reported in a future publication.

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