RESEARCH ARTICLE

Implementation of a modified quality assurance protocol for CBCT machines within UT health San Antonio School of Dentistry

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Objectives: To implement the quality control assurance protocol (including the re-establishment of baseline data from 2016) to monitor the stability of image quality of CBCT machines located within the UT Health San Antonio School of Dentistry.

Methods and materials: Five CBCT machines ProMax 3D Mid® (Planmeca Oy, Helsinki, Finland), 3D Accutomo XYZ Slice View Tomograph® (Model MCT-1, Type EX-1F8; Fushimi-ku, Kyoto: J. Morita Mfg. Corp), Veraviewepocs 3D (Model R100; Fushimi-ku, Kyoto: J. Morita Mfg. Corp), PreXion3D Excelsior® (PreXion, San Mateo, CA), and i-CAT FLX Series® (Imaging Sciences International, Hatfield, PA) were tested for Artifact, Contrast-to-Noise Ratio, Noise, Spatial Resolution, and Contrast Resolution using a custom insert configuration in the SEDENTEXCT IQ phantom.

Results: Four-scan benchmark mean values for Artifact, Contrast-to-Noise, Noise, Spatial Resolution, and Contrast Resolution were determined for the five machines tested with associated alert and action level thresholds calculated.

Conclusion: This newly developed QA protocol established image quality baseline values. Recommended tests, frequency, and actions levels have been updated and control charts established for future trend analysis to enable proper implementation of a QA protocol monitoring CBCT machines at UT health San Antonio.

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Introduction

Patients and providers expect radiographic imaging to be consistently of the best quality while limiting exposure risk to acceptable levels. In fact, the National Council of Radiation Protection & Measures (NCRP) specifically addresses how to ensure such imaging stability in a process termed quality assurance (QA), also known as quality control (QC).¹ The NCRP defines QA as “the mechanisms to ensure continuously optimal functioning of both technical and operational aspects of radiologic

procedures to produce maximal diagnostic information while minimizing patient radiation exposure.”¹ The inherent benefits of a proper QA protocol are improved diagnosis as well as decreased retakes, both of which save time, exposure, and money. Contrary to QA/QC programs, Radiation Safety is a separate program in that it has no direct effect on image quality but instead consists of steps typically taken by a radiation safety officer at a less frequent time interval to ensure patients, staff, and the doctor are as safe as possible from the effects of ionizing radiation.²

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As referenced in the NCRP definition, the “mechanism” by which providers can ensure stable image quality is trend analysis—a process made possible using control charts constructed over time. The basis for such methodology is found in statistical-based textbooks whereby baseline data are established and then compared against using subsequent data collected.³ As the American College of Radiology aptly points out, the goal of such control chart methodology is to ensure the *consistency* of image quality over time as opposed to comparison to manufacturers’ data points that use proprietary phantoms testing numerous parameters more appropriate for initial testing and post-calibration verifications.⁴ Intrinsically, this means benchmark data points can be collected by the provider using a commercial phantom when image quality is subjectively acceptable; then, image quality of follow-up scans (using the same phantom and machine settings) should be compared to these baseline values at a suitable periodicity defined by the manufacturer or state regulations.

Objective image quality as measured by various computer programs has long been the way to establish quantitative and semi-quantitative standards for radiographic machines. In 2017, a European Federation of Organizations for Medical Physics International Working Group cooperated with the International Atomic Energy Agency and the European Society for Radiotherapy and Oncology to develop a book detailing cone-beam CT (CBCT) QC measures.⁵ Importantly, this book extensively examined six different commercially available phantoms “to unify the test parameters for image quality evaluation...in all types of CBCT systems.” The six parameters covered in this book were Uniformity (Artifacts), Geometric Precision, Voxel Density Values, Noise, Low Contrast resolution (contrast-to-noise ratios or CNRs), and Spatial Resolution.⁵

In regards to the six commercially tested phantoms, three manufacturers produced them (Quart GmbH, QRM GmbH, and Leeds Test Objects) and at least one of each of manufacturer’s phantoms was able to measure all six of the abovementioned parameters.⁵ Our institution has one of these, the SEDENTEXCT IQ phantom. In 2016, this same phantom was used in the initial development of a CBCT QA protocol for four machines that since has not been fully implemented since its development.⁶ Subsequently, one machine has been replaced and an additional one added before the Texas Department of State Health Services (Tx DSHS) *proposed* a revised version of regulation §289.232 (Radiation Control Regulations for Dental Radiation Machines) that would necessitate an updated QA protocol in terms of requiring certain parameters tested for dental digital imaging and mandating the periodicity of the measurements.⁷ Therefore, the aim of this current study was to implement an updated QA protocol to ensure consistent image quality of the five CBCT machines located within our clinic.

Table 1 Settings for each machine tested in the QA protocol

Machine	Tube voltage (kVp)	Amperage (mA)	Time (s)	FOV (cm x cm)
Planmeca Promax 3D Mid	90	8	12	10 × 10
Morita 3D Accuitomo	90	7	17.5	8 × 8
PreXion3D Excelsior	110	2.4	7.7	10 × 8
Morita Veraviewepocs 3D R100	90	8	9.3	10 × 8
i-CAT FLX Series	120	5	4.1	16 × 10

FOV, field of view; QA, quality assurance.

Method and materials

CBCT machines

20 baseline scans (4 for each machine) were acquired using the following 5 CBCT machines: ProMax 3D Mid[®] (Planmeca Oy, Helsinki, Finland), 3D Accuitomo XYZ Slice View Tomograph[®] (Model MCT-1, Type EX-1F8; Fushimi-ku, Kyoto: J. Morita Mfg. Corp), Veraviewepocs 3D (Model R100; Fushimi-ku, Kyoto: J. Morita Mfg. Corp), PreXion3D Excelsior[®] (PreXion, San Mateo, CA), and i-CAT FLX Series[®] (Imaging Sciences International, Hatfield, PA). Once the phantom inserts (described below) were verified centered within the field of view (FOV using scout images, the four scans per machine were acquired within a half-hour period on the same day. Settings were unique for each machine and corresponded to the default settings associated with the selected FOV (Table 1).

SEDENTEX-CT IQ Phantom

The SEDENTEXCT IQ phantom used was developed by Leeds Test Objects Ltd. (Boroughbridge North Yorkshire, United Kingdom) for CBCT quality assurance testing and was centered on a tripod in each CBCT machine tested in this protocol (Figure 1). The phantom is a polymethyl methacrylate (PMMA) cylinder with a 16 cm diameter.⁸ The phantom can be filled with six rows of testing inserts arranged as seven columns in a circular pattern with one in the center. The custom arrangement of eight inserts used for this QA protocol were arranged as seen in Figure 2.

Image Analysis

For each machine, four baseline scans at the same machine-specific settings were taken after multiple scout images verified the two columns of inserts were centered and level within the FOV. As per the user’s manual, native axial slices of the DICOMS were exported “...using the thinnest slice thickness and smallest slice interval available.”⁸ Mean values of Artifact, Noise, CNR, Spatial Resolution, and Contrast Resolution were calculated for each machine using axial images within the ImageJ software (National Institutes of Health, Bethesda, MD) as follows:

Figure 1 Example of SEDENTEXCT IQ phantom setup on tripod.

Artifact (via beam hardening artifact insert)

To determine the correct axial slice, a slice 30 slices superior to the inferior edge of the aluminum rods was selected. “Plot profile analysis” was done whereby a line was drawn connecting the peripheral edges of the insert that was parallel and 2mm away from the three rods as seen in [Figure 3](#). The center group of peaks and valleys on the resulting gray value plot were examined noting the maximum peak and most-minimum of the two valleys defining the center group. The difference between these maximum and minimum values were defined as the artifact.

Noise (via Center of the phantom)

To determine the correct axial slice, the approximate center of the phantom was found and defined as the point when only PMMA was visible as seen in [Figure 4](#). “Histogram analysis” was done whereby an 8.8 x 8.8 mm circle was drawn between the two insert columns of interest. The mean and standard deviation of the resulting histogram was recorded as the Contrast_{Control} and Noise_{Control}, respectively. Noise_{Control} values were defined as the Noise.

CNR (via Pixel Intensity insert)

To determine the correct axial slice, a slice 10 slices superior to the superior edge of the Aluminum disk was

Figure 2 Sagittal image of custom insert setup. The left column on this image is on the periphery of the phantom and consists of the Pixel Intensity, Contrast Resolution (Aluminum), Contrast Resolution (Air), Contrast Resolution (Delrin) inserts. The right column on this image is in the center of the phantom and consists of the Beam Hardening Artifact, Spatial Resolution (Z-axis), Line Spread Function, and Spatial Resolution (XY axis) inserts.

selected—this axial slice position was the approximate center of the PTFE disk as seen in [Figure 5](#). “Histogram analysis” was done whereby an 8.8 x 8.8 mm circle was drawn in the center PTFE disk. The mean and standard deviation of the resulting histogram was recorded as the Contrast_{PTFE} and Noise_{PTFE}, respectively. CNR was then calculated using the following equation⁹:

$$\frac{\text{Contrast}_{\text{PTFE}} - \text{Contrast}_{\text{Control}}}{\sqrt{\text{Noise}_{\text{PTFE}}^2 + \text{Noise}_{\text{Control}}^2}} \quad (1)$$

Spatial Resolution (via Spatial Resolution (Z-axis) insert)

To determine the correct axial slice, a slice 30 slices superior to the inferior edge of the aluminum strips was selected. “Plot profile analysis” was done whereby a line was drawn connecting the peripheral edges of the insert and perpendicular to the aluminum strips as seen in [Figure 6](#). Starting from right-to-left, each group of peaks was subjectively analyzed on the gray value plot. The last group of peaks where three distinct peaks could be distinctly visualized was defined as the limiting spatial resolution (lp/mm).

Contrast Resolution (via Contrast Resolution inserts)

To determine the correct axial slice, a slice 30 slices superior to the inferior edge of the Aluminum, Air, and Delrin rods in each insert was selected as seen in [Figure 7](#). For all three inserts, the presence of each

Figure 3 Beam hardening artifact analysis of artifact insert consisting of “a line of three 5.0mm diameter rods of Titanium suspended in PMMA”⁸: (A) Plot profile line placement; (B) Gray value plot with an example of maximum and minimum values within the center group of peaks indicated with arrows. PMMA, polymethyl methacrylate.

column was subjectively determined. The minimum column diameter visualized was defined as the limiting contrast resolution (mm).

Statistical analysis

The motivation for the statistical approach for new QA protocol lies in the control chart methodology outlines in Statistical Quality Control.³ As such, the goal was to establish performance-monitoring thresholds for each machine based on the four-scan baseline data collected in the manner described above. With the baseline mean values ($\bar{Y}$) determined, standard deviations (s) around the means were calculated. Because the scan sample size (n) was small, a normal distribution could not be assumed; thus, standard error was calculated ($s/\sqrt{n}$). Then, “alert levels” and “action levels” were defined as

seen in Equations (2) and (3), respectively, to be used in subsequent three-month interval measurements:

$$\bar{Y} \pm 2 \cdot s/\sqrt{n} \quad (2)$$

$$\bar{Y} \pm 3 \cdot s/\sqrt{n} \quad (3)$$

Results

For each machine, four-scan benchmark means for Artifact, CNR, Noise, Spatial Resolution, and Contrast Resolution were calculated and displayed in [Figures 8–12](#). Alert and action levels for single-scan follow-up measurements were established (graphically

Figure 4 Control Area Analysis (for CNR calculations) between the second and third rows of inserts: (A) Histogram circle placement; (B) Histogram with Mean and Standard Deviation—defined as Noise. CNR, contrast-to-noise ratio.

Figure 5 Sample Area Analysis (for CNR calculations) of the PTFE Disk within the Pixel Intensity insert: (A) Histogram circle placement; (B) Histogram with Mean and Standard Deviation. CNR, contrast-to-noise ratio.

indicated by green and red lines, respectively). Equations 2 and 3 were used to define alert and action levels for the Artifact and CNR parameters; Equation 2 was used to define alert levels for Noise. For Spatial Resolution, any decrease in lp/mm was defined as an alert level while any reading less than 1.0 lp/mm was defined as action level. For Contrast Resolution, a decrease of one column visualized was defined as an alert level while any decrease of greater than one column visualized was defined as action level.

Discussion

The QA protocol listed above was developed for the school to comply with the proposed changes to the Tx DSHS regulation §289.232 (Radiation Control Regulations for Dental Radiation Machines). As such, the minimum parameters designated to be tested by the

state of Texas will be "...spatial resolution, noise, artifacts and contrast...".⁷ Furthermore, the state proposes that image testing be done "...using a commercially purchased testing tool..." and should be at intervals "...not to exceed three months."⁷ Two things are noteworthy about these proposed changes. First, unlike the six parameters the FOMP-European Society for Radiotherapy and Oncology-International Atomic Energy Agency CBCT Protocol recommended for CBCT QA, the state of Texas decided not to include Geometric Precision and Voxel Density Values parameters.^{5,7} While no explanation is given as to why the state made these extra parameters optional, their inclusion would have been difficult in the design of this new one-scan QA protocol due to FOV size limitations (detailed below). Second and directly related to the first, because previous state-testing requirements had no timing requirements other than the time and date had to be recorded when

Figure 6 Spatial Resolution analysis of insert consisting of alternating Aluminum/polymer line pairs in the XY axis: (A) Plot profile line placement; (B) Gray value plot read from right-to-left it corresponds to 5.0, 4.0, 2.8, 2.5, 2.0, 1.7, and 1.0 lp/mm.

Figure 7 Contrast Resolution analysis of inserts, each consisting of 5.0, 4.0, 3.0, 2.0, and 1.0mm diameter rods suspended in PMMA: (A) Aluminum; (B) Air; (C) Delrin. PMMA, polymethyl methacrylate.

image quality measurements were completed, there was a high motivation in the development of this new QA protocol to make it as efficient and simple as possible so as to ensure compliance at this accelerated periodicity.^{7,10}

Initially, the SEDENTEXCT user manual was referenced but it became apparent that the image-testing capacity of the phantom far exceeded the new requirements of the Tx DSHS; thus, use of all of the features of the phantom would negate the efficiency goals of this new QA protocol.⁸ Furthermore, the 16cm diameter of the phantom would require a 17 x 20cm FOV to fully visualize the 12 possible inserts spread throughout the entire phantom.⁸ Given that only one of the five machines in the school had such a large FOV, a compromise via a custom arrangement of inserts was sought that could be consistently visualized in a single scan using the smallest-largest FOV in the school. As a result, the 8 x 8 cm FOV in the 3D Accuitomo XYZ Slice View Tomograph[®] was the limiting FOV size. Through trial-and-error, it was determined that a maximum of eight inserts arranged in two columns—one in the center of the phantom and one on the periphery—was the necessary compromise (Figure 2).

Additional limitations related to FOV sizes and insert choices had to be accounted for. First, as shown in Table 1, there was substantial variation in FOV size options. Voxel sizes and standard machine settings differed between machines. For this reason, it was highly inappropriate to compare the baseline results listed in Figures 8–12. Second, these smaller-than-the-phantom FOVs meant scanning of the PMMA base (where the Noise calculations are typically done) was not possible without taking four extra scans for each machine, thus doubling the time requirements for scanning and nearly doubling the time for image analysis. Therefore, a compromise had to be made and it was finding a part of the phantom that was consistently PMMA-only similar to the base. As seen in Figure 4, this happened to be between the second and third rows of inserts. Because this area can be consistently found, this was determined to be an acceptable compromise when it came to Noise measurements. It should be noted that the advantage to this mid-phantom location is that it easily avoids the extra “...artifacts caused by use of a high-density phantom stand (e.g. a tripod).”⁸ The final FOV-related limitation led to the decision to use a center + periphery, instead of a periphery +

Figure 8 ProMax 3D Mid[®] Results.

Figure 9 3D Accuitomo XYZ Slice View Tomograph® Results.

periphery, positioning of insert columns within the phantom. Initially, it was desired to place each column on the periphery to ensure symmetry in case position-within-the-phantom effects were significant. However, experience showed it was difficult to quickly center the columns axially within the FOV if one was not in the center of the phantom; thus, in an effort to be more efficient, a center + periphery position was chosen. Since two columns were being imaged, the user's manual recommendation to "place the isocenter at the mid-point between the two columns" was followed and any unknown positioning effects will be negated by repeating the exact same column arrangement in subsequent 3-month scans to ensure consistency in measurements.⁸ In regard to insert limitations, the FOV-size-restraint already mentioned meant that four inserts had to be eliminated from the available 12. Thus, a determination had to be made on which to include to still meet the proposed Tx DSHS regulation changes. As such, Point Spread Function, Edge Spread Function, Contrast Resolution (PTFE), and Contrast Resolution (LDPE) inserts were excluded since they were redundant to the ones included in Figure 2. With that said, it should be noted that the included Line Spread Function and Spatial Resolution (XY axis) inserts seen in Figure 2 were not included in the data

analysis and will not be included in future trend analysis. Both of these inserts could not be analyzed using the ImageJ software; the first (LSF) because ImageJ lacked modulation transfer function capabilities and the second (Spatial Resolution (XY axis)) because of the inability to import DICOMS in anything other than axial views thus preventing line pair visualization seen in coronal and sagittal views using a viewing software (Figures 2 and 13).

While the proposed Tx DSHS changes were the driving force in shaping the development of this new QA protocol, one may note that an extra analysis was detailed above that was not mentioned in the new state directive: CNR. CNR is a widely used measurement that is easy to interpret and nearly as easy to calculate because the same procedure is used to calculate Noise. Given this high yield of image quality information for minimal effort, it was determined the small amount of extra time required to complete the analysis was worthwhile. However, because the analysis required the use of the Pixel Intensity insert that was located on the superior edge of the 8 x 8 cm FOV, the middle disk (PTFE) was chosen as the sample area for the CNR calculations to avoid the sometimes vertically-cutoff Delrin disc (Figure 13).

Figure 10 PreXion3D Excelsior® Results.

Figure 11 Veraviewepocs 3D (Model R100) Results.

In regards to the alert and action levels, a number of decisions were made in order to properly implement a control chart methodology for this new QA protocol.³ The fundamental decision made was that in order to monitor the performance of the machines via trend analysis, 3 month interval measurements for each of the five machines will be taken (as detailed in the Methods section *except that only a single scan will be required*). These new measurements will be compared to the four-scan benchmark means, alert, and action levels established in the Results section thus giving the user an indication about the consistency of the performance over time. If the alert or action levels for a particular parameter are violated, the following rules will be applied. If alert level met, one more scan needs to be taken for the machine and the parameter will be re-calculated. If the new calculated parameter is not outside the alert level, the machine is determined to be operating satisfactorily; however, if the parameter is still outside the alert level, the machine will require corrective action defined by the action level. If an action level is reached, the machine should be immediately taken out of service, the manufacturer called, and a calibration should be performed. Once complete, a new four-scan benchmark series of QA measurements as detailed in the Methods section shall

be undertaken meaning (a) the machine will have new means, action, and alert levels and (b) new control charts for trend analysis will need to be constructed. Figure 14 provides an example of a theoretical control chart displaying how trend analysis is possible with the control charts that have now been constructed.

Regarding the quantitative measurements of Artifact, CNR, and Noise, application of the alert and action level equations was straightforward noting that only alert levels were calculated for Noise. The reason for this difference is that Noise is a nested variable within the multifaceted CNR calculation. As a result, CNR is inherently a more stable parameter to track than Noise while at the same time giving an indication of Noise. Nevertheless, alert levels needed to be established for Noise because if the CNR values started to drift towards action levels, investigation into the variables within its calculation would be unproductive without predetermined alert levels. Concerning the semi-quantitative measurements of Spatial Resolution and Contrast Resolution, because there are such large intervals in the measurements of each, more practical alert and action levels had to be defined as listed in the Results section. Furthermore, regarding Spatial Resolution, it was noted that nearly all the mean values were at the minimum for the test object used (1.0 lp/

Figure 12 i-CAT FLX Series® Results.

Figure 13 Arrows indicating the vertical limitations of the 8 x 8cm FOV: (A) Delrin disc cut-off; (B) Artifact rods cut-off.

mm). In light of the fact that these mean values represented the lower half of the range of acceptable spatial resolution of CBCT machines, action levels were set at <1.0 lp/mm.¹¹

In summary, the baseline mean values were based on four measurements taken for each parameter of

scans taken at the same time. The statistician-backed recommendation for future parameter measurements (at intervals of every three months per the Texas state regulations) is to be based on a single scan, the results of which will be compared to four-measurement-mean-value baselines. This control chart methodology

Figure 14 Example of a control chart with the four-scan mean established in this QA protocol and theoretical data entries after seven single-scan measurements taken every three months. Note that trend analysis in this theoretical case reveals that artifact is drifting close to the upper alert level (green line). QA, quality assurance.

is pictorially shown in Figure 14 whereby a theoretical example of a control chart is given. It can be seen how the four-scan means for each parameter established in this QA protocol can be compared to separate single-scan measurements taken at three-month intervals (in the case of Figure 14, a random number of seven future theoretical measurements was chosen). In other words, this theoretical trend analysis displays how a future operator will be able to identify that the artifact parameter measurements are drifting close to the upper alert level—a powerful feature not easily recognized without graphically displaying the data.

Conclusion

This newly developed QA protocol established Artifact, Spatial Resolution, Noise, CNR, and Contrast

Resolution baseline values of image quality assessment. Recommended tests, frequency, and actions levels have been updated and control charts established for future trend analysis to enable proper implementation of a QA protocol monitoring CBCT machines at our institution.

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