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Accuracy of both virtual and printed 3-dimensional models for volumetric measurement of alveolar clefts prior to alveolar bone grafting compared to a validated algorithm

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Accuracy of virtual 3D and 3D printed models for volumetric measurement of alveolar clefts prior to alveolar bone grafting compared to a validated algorithm: a preliminary investigation

Abstract

Objective: To determine the accuracy of virtual 3D and 3D printed models derived from cone-beam computed tomography (CBCT) scans for volumetric measurement of alveolar clefts prior to bone grafting

Design: Cohort study

Setting: University dental hospital

Participants: Fifteen subjects with unilateral cleft lip and palate

Methods: Subjects had i-CAT CBCT scans recorded at 0.2mm voxel and sectioned transversely into 0.2mm slices using i-CAT Vision (Imaging Sciences International, Hatfield, Pennsylvania).

Main outcome measures: Alveolar cleft volumes were calculated using: (1) validated algorithm (MATLAB, The Mathworks Inc, Natwik, Massachusetts), (2) commercially available virtual 3D model software (Volume Graphics Studio Max 2.2 (VGSM), Volume Graphics, Heidelberg, Germany) and (3) 3D printed models, which were micro-CT scanned and analyzed using VGSM. For inter-observer reliability, a two-way mixed model intraclass correlation coefficient (ICC) evaluated the reproducibility of identifying the cranial and caudal limits of the clefts between three observers. A

Friedman Test ($p<0.05$) determined differences between the volume methods (SPSS Statistics 19.0, IBM Corporation, New York).

Results: Inter-observer reliability was almost perfect (ICC = 0.987). There were no significant differences between the three methods ($p>0.05$) although virtual 3D models were the most precise with the smallest standard deviations and confidence intervals.

Conclusion: In this preliminary investigation, virtual 3D and 3D printed models were as precise as the validated computer algorithm for calculating alveolar cleft volumes prior to bone grafting but virtual 3D models were the most accurate and subject to further investigation could be a useful adjunct in clinical practice.

Keywords: bone grafting, 3D, CAD-CAM models, micro-CT, volumetric assessment

Introduction

Oral clefts result from the failure of facial process fusion at different stages of dentofacial development and are one of the most common congenital defects worldwide. Oral clefts affect approximately 9.92 babies per 10,000 with a six-fold and three-fold variation in the prevalence of cleft lip and palate and isolated cleft palate, respectively.[1]

Where tooth movement is precluded due to the dimensions of the cleft, alveolar bone grafting (ABG) is an integral component of treatment for patients with alveolar clefts.[2] During bone graft surgery, the alveolar defect is firmly packed with cancellous bone chips to reconstruct the alveolar crest height from donor sites including the anterior iliac crest,[2] tibia[3] and mandibular symphysis[4] or recombinant human bone morphogenetic protein [rhBMP-2 (an osteoinductive cytokine)].[5] Bone is packed under the alar base to ensure good nasal symmetry.[2]

All ABG protocols involve initial imaging to assess the need for grafting and assess the eruption status of adjacent teeth and determine the need for pre-surgical orthodontic expansion (where necessary) to manoeuvre adjacent dental crowns and roots away from the cleft; immediate pre-operative imaging to determine the size of the defect and post-operative imaging to evaluate surgical success. Whilst pre- and post-operative 2D dental, occlusal or panoramic radiographs have traditionally been compared to estimate ‘bone-fill’, interest in the use of 3D imaging to quantify the success of ABG surgery has been growing over the last 15 years. With 3D imaging it is possible to quantify the volume of the cleft and volume of bone retained after consolidation, which is important in determining success and ultimately if sufficient bone is available for canine eruption and orthodontic tooth movement. Higher success rates of around 72–95% have been reported when ABG surgery has been assessed using 2D radiographs[2,6–8] when compared to the success rates with 3D imaging of 16–55%.[9,10] This is because 2D radiographs are subject to limitations such as image enlargement, distortion, structural overlap, limited identifiable landmarks, positioning problems and the effects of these on subsequent image quality, resulting in an overestimation of success rates by around 17–25%.[11,12]

Alongside developments in 3D imaging, 3D virtual models produced with computer-aided design (CAD) software and 3D printing (CAM) hardware have opened up a range of opportunities in education, science, technology, healthcare and industry. CAD-CAM models are useful for both surgical planning and for communication between members of the surgical team and patients.[13] 3D printing has also been used to provide implant-supported cutting guides for mandibular reconstruction,[14] orthodontic appliances such as Andresen appliances, sleep apnoea appliances,[15] aligners[16] and orthognathic surgery splints.[17] Virtual 3D and 3D printed models have the potential to be useful for pre-surgical planning and intra-operative harvesting of bone for alveolar bone grafting.

The objective of this study was to compare the accuracy of virtual 3D and 3D printed models with a validated method for the quantification of the volume of alveolar clefts in-vivo from cone beam computed tomography (CBCT) scans.[18]

Null Hypothesis: There is no measurable dimensional difference between virtual 3D and 3D printed models derived from CBCT scans when evaluating the volume of alveolar clefts in comparison to the gold standard computational algorithm method.

Materials and methods

The Tayside Committee on Medical Research Ethics and Tayside Medical Science Centre confirmed that neither ethical approval nor Caldicott Guardian approvals were required as anonymized CBCT scans were to be used. Research and Development approval was granted by Tayside Medical Science Centre and Greater Glasgow & Clyde NHS Board. CBCT scans from 15 subjects with unilateral cleft lip and palate were identified from a consecutive series at Glasgow Dental Hospital after those with motion, beam hardening and aliasing artefacts were excluded. Subjects were scanned using an i-CAT CBCT scanner (Imaging Sciences International, Hatfield, Pennsylvania) with the following settings: 0.2mm resolution, 120kV, 37.07mAs, acquisition time 26.9 seconds, Field of View (FOV) 65mm x 65mm and 360 degrees rotation. Each scan was sectioned transversely into 2D slices of 0.2mm thickness. The cranial and caudal limits of the alveolar cleft were then determined by three observers (one dental student and two faculty Orthodontists with considerable experience of cleft care) to test inter-observer reliability. The cranial boundary corresponded to the first appearance of a measureable alveolar defect and the caudal boundary was represented by the bifurcation of the first permanent molars on the side of the cleft.

The volumes of the alveolar clefts were then calculated using: (1) validated computer algorithm (MATLAB, The Mathworks Inc, Natwik, Massachusetts), (2) commercially available 3D virtual model software [Volume Graphics Studio Max 2.2 (VSGM), Volume Graphics, Heidelberg, Germany] and (3) 3D printed models, which were micro-CT scanned and analyzed using VGSM.

Validated computer algorithm (MATLAB)

Using the protocol devised by Kasaven et al.[18] each 2D slice was converted from DICOM (Digital Imaging and Communications in Medicine) to PNG (Portable Network Graphics) format. The Matrix Laboratory [MATLAB] algorithm[18] was applied to each axial slice and summed to determine the volume of each alveolar cleft. The data from this method was used as the gold standard for comparison.

Commercially available 3D virtual model software

The 2D slices were imported into Volume Graphics Studio Max 2.2 (VGSM). To isolate the cleft, a region growing tool (Figure 1) was applied with a radius which spanned the dimensions of the cleft to be analyzed.

The software assumed that as the cleft represents a void, it should contain no grayscale values deviating significantly from zero, but as some soft tissue extended into the defect, some voxels within the cleft could not be correctly identified as belonging to the cleft resulting in discrete ‘islands’ leading to volume miscalculation. To rectify this, opening and closing functions were applied to the scans, to exclude or include these outstanding voxels respectively (Figure 2).

Finally, a polygonal masking tool was used to mark a 3D region of interest (ROI), which highlighted voxels of the segmented region not belonging to the cleft. This ROI was then subtracted from the segmented region (Figure 2) and the volume of the cleft was then determined from the segmented region (Figure 3).

3D printed models

The CBCT scans were imported into Mimics (Materialise, Leuven, Belgium) to create virtual 3D CAD models. To begin segmenting the cleft defect, firstly all bone was isolated from surrounding soft tissue by applying a thresholding tool to the scan (Figure 4). This tool defined a range of grayscale values corresponding to those of bone and highlighted only these pixels to create a ‘green mask.’ As the cleft was a defect in the bone, Cavity Fill was applied to the scans to fill all the spaces within the bone of the green mask to create a ‘yellow mask’. The yellow mask was then edited on each axial 2D slice of the CBCT scans to ensure that the cleft was clearly depicted. The green and yellow masks were rendered into 3D objects. The yellow mask was the virtual design of the 3D CAD model of the cleft defect. The virtual design was converted to STL file format and imported into CatalystEx 4.2 (Stratasys

Inc, 2011, Minnesota) where the models were automatically sliced and orientated, creating any necessary support structures. The software automatically plotted a precise deposition path for the Dimension 1200es 3D Printer (Dimension Printing, Stratasys Inc, Minnesota) to follow. The printer fed white P430 ABS*plus* plastic into an extrusion head where it was heated to a semi-liquid state and accurately deposited in a thickness of 0.254mm. After build completion, grey support structures encompassing the 3D CAD-CAM models were removed mechanically using breakaway support technology (Figure 5).

The 3D printed models were then scanned in a micro CT scanner (X-Tek BT 160 UF, Nikon Metrology X-Tek Systems Ltd, Tring, UK) at 105kV, 91A, 0.0934mm resolution, 1228 projections with 2 frames per projection with a copper filter 0.1mm thickness and tungsten target. The volume of each 3D printed model was then computed using VGSM software.

Statistical analysis

To calculate observer reliability, a two-way mixed model Intraclass Correlation Coefficient (ICC) was used to determine the reproducibility of identification of the cranial and caudal limits of the cleft between three observers for all 15 scans. Because all three observers undertook this procedure, average measures data is reported.

A Friedman Test was performed to identify significant differences between the three volume computations ($p<0.05$) (SPSS Statistics 19.0, IBM Corporation, New York).

Results

Observer reliability demonstrated almost perfect agreement among the observers with an ICC value of 0.987 95% confidence interval (CI) (0.970, 0.995) for average measures. This demonstrated good reliability in the parameters chosen to identify the extremities of the cleft.

The mean volume for the MATLAB models was 575.56mm^3 95% CI (400.28, 750.83), 540.43mm^3 95% CI (401.19, 679.68) for the virtual 3D models and 662.62mm^3 95% CI (452.75, 872.49) for the 3D printed models. The differences were not statistically significant ($p=0.074$), although the virtual 3D method was the most accurate, with the smallest confidence intervals (Figure 6).

Discussion

We found no statistically significant volume differences between the methods, thus the null hypothesis was accepted. The virtual 3D model method was the most accurate of the three methods.

This is the first study that has evaluated volumetric computations of alveolar clefts derived from virtual 3D or 3D printed models using CBCT. Several non-cleft studies have evaluated the dimensional accuracy of CBCT scanning compared to micro-CT imaging finding virtual 3D models derived from CBCT scans are accurate for volumetric calculation of teeth[19] and bovine bone cavities.[20] Our results are in line with these and are comparable to other investigations of the dimensional accuracy of CAD models produced from either CT or CBCT scans.[21–23]

Although micro-CT produces high-resolution 3D images and an unprecedented level of accuracy among radiographic imaging techniques, the radiation doses are in the region of 1-15 centigray (cGy),[24] and as such the technique is only suitable for ex-vivo investigations. CBCT scans were therefore used of subjects with UCLP recruited from a bone grafting clinic at a cleft center and are a good representation of patients requiring ABG surgery. Only CBCT scans with motion, beam hardening or aliasing artefacts were excluded to minimize selection bias. There was almost perfect agreement between observers when identifying the extremities of the defect (ICC=0.987) demonstrating good reliability between the observers.

We calculated the volume of the alveolar defect and not any connecting palatal bony defect as only the former is grafted during ABG surgery. For all three methods, the algorithm failed to detect where the alveolar defect ended and any palatal defect began, as a result the boundary in these areas were manually determined, “closing off” the defect in a linear fashion. This process was a potential source of error for the volume calculations as boundary points were repositioned free-hand with no linear tools used as adjuncts to close the defect.

Whilst the virtual 3D and 3D printed methods required a threshold close to zero to determine the bony edge of the cleft, care was taken when determining this threshold for each scan to preserve all thin areas of bone required for volumetric calculation and subsequent printing, respectively. Although opening and closing functions were required with VGSM to include ‘island’ voxels, this was not a relevant source of bias. For the 3D printed, each layer of material was 0.254mm, which is smaller than the slice thickness of the CBCT scans (0.4mm), resulting in good resolution. The 3D printed models required careful post-processing to mechanically remove the support material without losing any irregular surface details on the model. They were scanned with micro-CT (resolution of 0.0934mm) to avoid any loss of detail on scanning and their volumes were automatically calculated after micro-CT scanning by the VGSM software to avoid any observer bias.

Our results indicate that virtual 3D models generated with commercially available software are more accurate than calculating the volume using a ‘slice by slice’ algorithm[18] or 3D printed models, which are inexpensive to produce. However, as only 15 subjects were included, further investigation is required. Understanding the pre-operative volume of the alveolar defect is a good indicator of the volume of bone that is needed to restore the defect at the time of surgery. Shirota et al.[25] found no significant differences between these using CT and consequently, virtual 3D models are a useful adjunct in the pre-operative planning for patients scheduled to undergo alveolar bone grafting. In particular for smaller defects, calculation of the volume of the alveolar cleft may indicate the use of harvesting sites with lower levels of post-operative morbidity. This would reduce anesthesia time and promote faster recovery and shorter hospital stays.

Although we were not able to assess the volume of the cleft at the time of surgery or at six months post-operatively due to the additional radiation dose resulting from additional CBCT scans, future studies should investigate the relationship between the volume of the alveolar defect placed during surgery and the volume of bone graft remaining after six months using the above techniques, which will help to further characterize the relationship between the volume of bone placed and graft integration success rates. In turn this could precisely determine the volume of additional bone that should be harvested to account for resorption in the post-operative period.

Conclusion

In this preliminary investigation, the virtual 3D and 3D printed models were as precise as the validated computer algorithm for the calculation of the volume of alveolar clefts prior to bone grafting but the virtual 3D model method was the most accurate and subject to further investigation, could be a useful adjunct in clinical practice.

Conflict of Interest

No

Ethics statement/confirmation of patient permission

The Committee confirmed that neither ethical approval nor Caldicott Guardian approvals were required as anonymized CBCT scans were to be used. Patient permission has been obtained.

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Figure Legends

Figure 1: Region growing tool to segment the alveolar cleft

Figure 2: Alveolar cleft after opening and closing tool applied to the scans with final segmented ROI

Figure 3: Virtual 3D model

Figure 4: Bone isolated from surrounding soft tissue by thresholding tool with yellow mask applied and edited to represent alveolar cleft

Figure 5: 3D printed model

Figure 6: Box and whisker plot for the differences between the three methods of volume calculation