

# Evaluating the Reliability of CBCT Airway Measurement: A Pilot Study

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## Research article

**Keywords:** CBCT, Airway, Obstructive Sleep Apnea (OSA), Sleep Disordered Breathing (SDB)

**Posted Date:** June 22nd, 2020

**DOI:** <https://doi.org/10.21203/rs.3.rs-35711/v1>

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# Abstract

## Background

Many studies have analyzed treatment effects on the airway using CBCT scans of the airway as evidence, but no study to date has been published that validates a repeatable protocol for acquiring CBCT airway measurements. Our objective is to evaluate a protocol for standardization of CBCT volume acquisition of the airway.

## Methods

Ten participants (6 females and 4 males, median age  $30.03 \pm 3.53$  years) were radiographed 2 times each (T1 and T2, the average time between T1-T2 was  $15.8 \pm 3.65$  days), for a total of 20 CBCT scans. The participants' head position was placed so that the Frankfort horizontal plane was parallel to the floor. Participants were given specific instructions regarding jaw position, tongue position, swallowing and breathing before each of the 2 scans. Minimum cross-sectional area (MCA) and total volume (TV) of each airway scan were measured between the distal most point of the hard palate (superior limit) and the superior most point of the epiglottis (inferior limit). T1 and T2 were compared to determine the repeatability of our proposed protocol for CBCT airway acquisition.

## Results

There was no statistically significant difference between T1 and T2 measurements for TV and MCA. The average difference between T1 and T2 MCA and TV measurements for each participant was  $34.18 \pm 30.55 \text{ mm}^2$  and  $2.51 \pm 2.05 \text{ cc}$ , respectively.

## Conclusions

Using our proposed standardization protocol, the measurements of MCA and TV of the airway were reliable to within  $34.18 \pm 30.55 \text{ mm}^2$  and  $2.51 \pm 2.05 \text{ cc}$ , respectively.

## Background

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder that occurs as a function of increased collapsibility of the upper airway during sleep.[1] Individuals suffering from OSA experience repetitive episodes of cessation of breathing (apnea) or partial upper airway obstruction (hypopneas).[2] The diagnosis of OSA requires five or more episodes of apnea or hypopnea per hour of sleep.[2] It is estimated that as many as 26% of adults between 30–70 years of age suffer from OSA.[3] The etiology is multifactorial and includes impaired neuromuscular tone, unfavorable craniofacial structures, and other

related factors.[1] Common risk factors for OSA include obesity, advanced age, male gender, post-menopausal status in women, race, and craniofacial dysmorphisms.[4] Untreated OSA can increase the risk of excessive daytime sleepiness, decreased scholastic and occupational performance, insulin resistance, coronary artery disease, congestive heart failure, myocardial infarction, hypertension, stroke, cardiac arrhythmia, and sudden cardiac death.[1]

The gravity of untreated OSA is undeniable; however, the orthodontist's role in the treatment of OSA remains controversial. The "White Paper: Obstructive Sleep Apnea and Orthodontics" published by the American Association of Orthodontists (AAO) task force on OSA and Orthodontics provides a comprehensive summary of OSA and its relation to orthodontics. The AAO task force concluded that no orthodontic treatments have been shown to cause or increase the likelihood of OSA; rather, some forms of orthodontic treatment have been shown to be important in the treatment of OSA.[1] Participation in the treatment of OSA is not mandatory for orthodontists; however, orthodontists are encouraged to be familiar with the signs and symptoms of OSA and are strongly recommended to screen patients for known OSA risk factors.[1] Patients with OSA risk factors should be referred to a physician for further evaluation and definitive diagnosis.[1]

Some proposed OSA screening methods involve cone beam computed tomography (CBCT) analysis of the airway.[5–9] Software such as Anatomage Invivo 6 and Dolphin 3D allow for three-dimensional visualization of the shape of the airway, measurement of the total airway volume (cc), and measurement of the cross-sectional area ( $\text{mm}^2$ ) at any level of the airway. Some clinicians contend that the minimum cross sectional area (MCA) is the bottleneck of the airway and the most common cause of airway obstruction.[5] The following guidelines for assessing the risk level of obstructive sleep apnea based on MCA have been proposed: MCA 0–50  $\text{mm}^2$  is high risk, MCA 50–100  $\text{mm}^2$  is moderate risk, and MCA 100–150  $\text{mm}^2$  is low risk for OSA.[6–8]

CBCT imaging of the airway is viewed skeptically because of the static nature of CBCT scans vs. the dynamic nature of the airway. The shape and size of the airway is greatly affected by head position, tongue position, position of the mandible, breathing, and swallowing. One case study demonstrated that the MCA changed 87  $\text{mm}^2$  by moving the patient's tongue from a retruded position on the soft palate to the most anterosuperior position of the hard palate (198  $\text{mm}^2$  vs 285  $\text{mm}^2$  respectively,  $n = 1$ ).[5] It is not difficult to imagine that simply swallowing during an exposure might introduce a similar discrepancy. Another case study showed that changing the head posture can influence the MCA by as much as 200  $\text{mm}^2$  (75  $\text{mm}^2$  vs 275  $\text{mm}^2$ ,  $n = 1$ ).[5]

Studies have assessed the intraexaminer and interexaminer reliabilities of upper airway linear, area, and volumetric measurements in CBCT scans;[10–12] however, no standardized protocol has been proposed or proven to date that repeatedly replicates the size and shape of the airway in consecutive scans of the same patient. The purpose of this pilot investigation is to evaluate the inclusion of CBCT scans to improve airway evaluation of orthodontic patients by determining if a standardized protocol can deliver reproducible CBCT scans of the airway.

## Methods

The A.T. Still University, Arizona IRB committee approved the present study (IRB #2018 – 172). The board determined our protocol to be of minimal risk to our participants. Written consent was obtained from all participants. CBCT images were captured using an i-CAT FLX CBCT unit in the “3D Ceph Quick Scan +” setting. This setting gave us the necessary field of view (FOV) to capture the upper airway while exposing our participants to the least amount of radiation possible. The “3D Ceph Quick Scan +” setting consists of a volume size of 16 cm x 13 cm, voxel size of 0.6 mm, scan time of 4.8 seconds, and Dose Area Product (DAP) of 99.2 mGy cm<sup>2</sup>. The effective dose of each scan was 11.4 µSv.[13] Each participant of the study was informed of the effective dose of radiation they would incur and consented to voluntarily participate in the study. All CBCT scans were read and interpreted for incidental findings.

The participants in this study consisted of 10 orthodontic residents (6 females and 4 males), with an average age of 30.03 ± 3.53 years. Participants volunteered to participate in the study. No other inclusion criteria were employed for the study; however, participants with any events that might affect the anatomy of their upper airway were excluded (maxillofacial surgery, extensive orthodontic treatment, growth, significant change in weight, etc.).

Each of 10 participants provided 2 CBCT scans (T1 and T2), for a total of 20 CBCT scans. T1 represents the initial scan and T2 represents the scan taken roughly two weeks later (average time between T1-T2 was 15.8 ± 3.65 days). Recognizing the importance of head position, tongue position, mandibular position, swallowing and breathing, our participants were given the following instructions immediately before each of their two scans (after having their heads positioned so that the Frankfort horizontal plane was parallel to the floor): “Please bite together so that your upper and lower back teeth are touching. Gently place your tongue on the roof of your mouth, with the tip of the tongue touching the back of the upper front teeth. Please swallow, inhale deeply followed by a deep exhale, and hold your breath. When I see you exhale, I will activate the 4.8 second CBCT scan. Please hold your breath until the CBCT unit completes its scan. Do you have any questions?”[14]

Three-dimensional volume rendering and airway analysis were completed using InVivo 6 software (Anatomage Inc, San Jose, California) (Fig. 1). The distal most point of the hard palate defined the superior border of the airway while the most superior point of the epiglottis defined the inferior border. The uvula defined the anterior border, separating the upper airway from the oral cavity. 3D voxels less than or equal to -400.0 Hounsfield units (H.U.), located within the anatomic boundaries previously described, were considered part of the airway and were included in measurements.

The total volume (TV) and minimum cross-sectional area (MCA) of each scan was measured twice, at a two-week interval, by the same examiner. Each scan was measured twice at each time point, and the means of the TV and MCA measurements were used for reliability analyses. Means and standard deviations of the measurements are provided. Intra-examiner reliability was calculated using a two-way random-effects (consistency) model based on a single measurement. This pilot study was not powered

to test any hypotheses. Pearson correlation coefficients were also calculated to provide an estimate of the strength of the linear relationship between the measurements across scans.

Bland-Altman plots were constructed based on mean differences (T1 – T2) to assess TV and MCA measurement reliability (Figs. 2A and 2B). The average of paired differences would be zero if no bias existed between the measurements. Standard errors of measurement (SEM), along with 95% confidence intervals, were also calculated for TV and MCA. The SEM is an estimate of how much repeated measures tend to be distributed around a “true” score.

An alpha of 0.05 (two-tailed) was used as the criterion for statistical significance. Data were analyzed using SPSS version 25 (IBM Corporation, Armonk, New York, USA).

## Results

### Airway Measurements

Two of the 10 participants produced a CBCT scan in which the airway was completely constricted (MCA = 0.0 mm<sup>2</sup>) at one location along the airway in the defined region (Fig. 3). The MCA of these two scans was not considered in the analysis (Table 1). The TV on these scans was calculated as the sum of the volumes superior and inferior to the constriction, and therefore was included in the analysis. The average difference between T1 and T2 measurements of MCA and TV was 34.18 ± 30.55 mm<sup>2</sup> and 2.51 ± 2.05 cc, respectively (Tables 2 and 3).

Table 1  
Summary of Measurements

Participant ID	Total Volume T1, cc	Total Volume T2, cc	Minimum Cross-Sectional Area T1, mm <sup>2</sup>	Minimum Cross-Sectional Area T2, mm <sup>2</sup>
1	9.75	17.35	159.65	241.60
2	11.05	11.00	156.20	161.70
3	9.10	11.80	60.65	97.25
4	9.60	10.50	101.05	101.85
5	14.90	13.75	201.45	147.70
6	5.85	8.80	26.25	89.60
7	4.45	1.95	(43.70)	(0.00)
8	25.00	22.05	226.90	228.60
9	11.75	10.15	175.90	146.10
10	9.85	7.20	(96.90)	(0.00)

Table 2

Individual absolute difference of Total Volume &amp; Minimum Cross-sectional Area between T1 &amp; T2

Participant ID	$\Delta$ Total Volume, cc (T1-T2)	$\Delta$ Minimum Cross-Sectional Area, mm <sup>2</sup> (T2-T1)
1	7.60	81.95
2	0.05	5.50
3	2.70	36.60
4	0.90	0.80
5	1.15	53.75
6	2.95	63.35
7	2.50	(43.70)
8	2.95	1.70
9	1.60	29.8
10	2.65	(96.90)
Mean	2.51	34.18
SD	2.05	30.55
SD, Standard deviation.		

Table 3

Descriptive Statistics for Airway Measurements (N = 10).

<i>Descriptive Statistics for Airway Measurements (N = 10)</i>						
Variable	M	SD	Range	Minimum Value	Maximum Value	
Total Airway Volume, cc (T1)	11.13	5.67	10.45	4.45	14.90	
Total Airway Volume, cc (T2)	11.46	5.48	20.1	1.95	22.05	
Total Airway Volume Mean Absolute Difference, cc (T2-T1)	2.51	2.05	7.55	0.05	7.60	
Minimum Cross-Sectional Area, mm <sup>2</sup> (T1)	138.51	69.69	200.65	26.25	226.90	
Minimum Cross-Sectional Area, mm <sup>2</sup> (T2)	151.80	57.88	152.00	89.60	241.60	
Minimum Cross-Sectional Area Absolute Mean Difference, mm <sup>2</sup> (T2 - T1)	34.18	30.55	81.15	0.80	81.95	

The SEM's for TV and MCA were 2.28 cc and 28.81 mm<sup>2</sup>, respectively. This translates into the expectation that for TV = 11.26 cc, and SEM = 2.28 cc, there is a 95% probability that the true value falls within the

range of 6.75 cc to 15.72 cc. For an MCA of 152.04 mm<sup>2</sup>, and SEM = 28.81 mm<sup>2</sup>, there is a 95% probability that the true value falls within the range of 95.57 mm<sup>2</sup> to 208.51 mm<sup>2</sup>.

## Reliability

Intraclass correlation coefficients (ICC) were calculated for airway volume and cross-sectional area measurements taken 14 days apart. This approach estimated the proportion of variance of an observation due to between-subject variability in the true scores. The ICC for total airway volume was, ICC = .823 (95% CI: .437 to .953) and the ICC for cross-sectional area was, ICC = .748 (95% CI: .163 to .944). Both of these values represent good reliability. Test-retest reliability, expressed using Pearson correlation coefficients, was,  $r = .82$ ,  $p < .001$ , for total airway and,  $r = .76$ ,  $p < .001$ , for cross-sectional area.

Bland-Altman charts for the two measurements, across 14 days (Figs. 2A and 2B) show the magnitude of differences across the two measurements plotted against the mean scores for the two. The mean differences in measurements were + 0.33 cc for TV, and + 13.29 mm<sup>2</sup> for MCA. For TV, 9 of the 10 measurements (90%) fell within the 95% limits of agreement. For MCA, all measurements fell within these limits of agreement. The charts exhibited no evidence of error bias based on the size of the airway passage, that is, the extent of error across the 14-day measurements showed no recognizable pattern across airway sizes.

## Discussion

In this pilot study, airway measurements showed a strong and statistically significant linear relationship between T1 and T2 using our standardization protocol; however, statistical significance and clinical significance are not synonymous. Previous suggestions that patients with MCA 100–150 mm<sup>2</sup>, MCA 50–100 mm<sup>2</sup>, or MCA 0–50 mm<sup>2</sup> have low, moderate, or high OSA risk, respectively, must take into consideration the variability that exists in the acquisition and measurement of MCA in a CBCT volume. [6–8] For example, a patient with a measured MCA of 90 mm<sup>2</sup> would receive a moderate OSA risk assessment using such a scale. The variability of the MCA measurement (SEM = 28.81) suggests that the patient could produce a second measurement as low as 33 mm<sup>2</sup> (extreme risk) or as high as 146 mm<sup>2</sup> (low risk) and still be within the expected (95%) margin of error. This demonstrates that there is the potential for a large clinically significant difference between our T1 and T2 measurements.

While there was a lot of variability between T1 and T2, our study had a high positive correlation coefficient. This suggests that participants with relatively larger airways at T1 still had relatively larger airways at T2 when compared to the other participants. The same is true for participants with relatively smaller airways. For example, if a CBCT volume captured using our protocol shows a patient has an MCA of 300 mm<sup>2</sup> (which would be considered relatively large), it is probable that this given patient would still demonstrate a relatively large airway if measured a second time, using our protocol.

The findings of our study support the American Association of Orthodontists task force on Obstructive Sleep Apnea and Orthodontics in that “three-dimensional imaging of the airway should not be used to diagnose sleep apnea or any other sleep-related breathing disorders because such imaging currently does not represent a proper risk assessment technique or screening method.”[1] While the variability of MCA and TV measurements is significantly large clinically to the point that their inclusion in proposed screening protocols is ill-advised, there may still be valuable information in a CBCT volume measurement of the airway. All CBCT images should be thoroughly read and any incidental findings, including those relating to the airway, should be reported and the appropriate referrals should be made when applicable. [1] For example, 3-dimensional radiographs, and even 2-dimensional cephalograms to an extent, are effective tools for identifying enlarged tonsils and adenoids.[15] When in doubt, it is better to err on the side of caution and make a referral to the appropriate specialist; however, no diagnosis or risk level assignments should be made based on CBCT findings relative to the airway.

OSA is a complex, multifactorial disorder that is dependent on more than simply the anatomical dimensions of the airway. No irrefutable correlation between airway dimensions and sleep apnea has been presented.[1,16,17] CBCT volumes are static images of a dynamic object and do not provide information to evaluate the volumetric changes in the airway during the breathing cycle. As stated by the AAO task force on OSA and Orthodontics, “CBCT provides no information on neuromuscular tone, susceptibility to collapse, or actual function of the airway.”[1] CBCT volumes are routinely taken with patients upright and awake, which may not correlate to the airway size and shape of the same patient supine and asleep. Lastly, CBCT volumes do not provide any information on neuromuscular tonicity or airway function. The goal of our study is to establish a standardization protocol to improve the reproducibility of CBCT airway measurements; application of this information to OSA is beyond the scope of this study but may be considered in future studies.

Our pilot study is limited by a small sample size (N = 10). Future investigations should aim to include larger and more diverse samples to replicate the findings from this pilot study. While the findings of our study may be limited in their application, we hope they will encourage continued research in the field of CBCT measurement of the airway as well as an understanding of the limitations of both previous and future studies utilizing CBCT measurements of the airway.

The findings of our study are also limited to acquisition using the i-CAT FLX CBCT unit in the “3D Ceph Quick Scan +”. We chose to use the shortest scan time to reduce the risk of movement or inability of the participant to hold their breath throughout the scan. A longer scan time may be more limited in reproducibility as it would become increasingly difficult for the participant to maintain the same position of the breathing cycle. Shorter scan times may be more accurate in the future but were not available to us to perform this study.

Our study is limited by the age of our participant population; findings cannot be extrapolated to an adolescent population that may experience significant airway changes between acquisition time points. Any airway study of an adolescent population that fails to provide a meaningful control group for

comparison should immediately be viewed with skepticism. It is normal for the size of the airway to increase during growth while the size of lymphatic tissues that could obstruct the airway decrease in size. Any treatment performed at the same time as this expected growth and reduction could erroneously indicate positive treatment effects if changes from growth are not considered. It is also necessary to appreciate that the comparison of a pre-treatment CBCT volume of a 7-year-old and a post-treatment CBCT volume of the same patient two years later at the age of 9 will be limited by the ability of that 7 and 9-year-old patient to cooperate equally at both points of time. Future CBCT-airway studies should consider application of our proposed standardization protocol. While there is still variability in our protocol, it provides more certainty than no attempt at standardization. Future research with a larger sample size or innovative technology may be able to improve upon our study and produce more repeatable and clinically insignificantly different measurements.

## Conclusions

Using our standardization protocol, the mean absolute differences between measurements of consecutive scans of the same patient for MCA and TV were  $34.18 \pm 30.55 \text{ mm}^2$  and  $2.51 \pm 2.05 \text{ cc}$ , respectively. Correlation between anatomical airway dimensions and sleep apnea remain uncertain and further research is needed.

## Abbreviations

AAO  
American Association of Orthodontists  
CBCT  
Cone beam computed tomography  
DAP  
Dose area product  
MCA  
Minimum cross-sectional area  
OSA  
Obstructive Sleep Apnea  
SEM  
Standard errors of measurement  
TV  
Total volume

## Declarations

## Ethics approval and consent to participate

The A.T. Still University, Arizona IRB committee approved the present study (IRB #2018 – 172). The board determined our protocol to be of minimal risk to our participants. Written consent was obtained from all participants.

### **Consent for publication**

Not applicable

### **Availability of data and materials**

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

### **Competing interests**

The authors declare that they have no competing interests

## **Funding**

Not applicable

## **Authors' contributions**

1. Brent L. Jorgensen: contributed to leading the research; reviewing the literature prior to starting the research/manuscript; editing and finalizing the figures; presenting the research in the form of a PowerPoint and poster presentation and to receive feedback to improve on the manuscript; writing, reviewing, editing the manuscript; coordinated work between all authors and edited their contributions to the manuscript.
2. Jae Hyun Park: contributed to supervising the research; coming up with ideas to start and expand on the research; improving illustration, tables, figures; reviewing and editing the research as an author/editor; final approval of the manuscript; corresponding author.
3. R. Curtis Bay: contributed to IRB process; contributed statistical analysis; specializes in SPSS and analysis; advising on and contributing to the statistical analysis of the manuscript; evaluated data collection; ensured that the claims made by the manuscript are supported by the findings.

## **Acknowledgements**

The authors would like to acknowledge Ivan Halim for his assistance in this study. The authors would also like to thank the participants of this study.

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## Figures

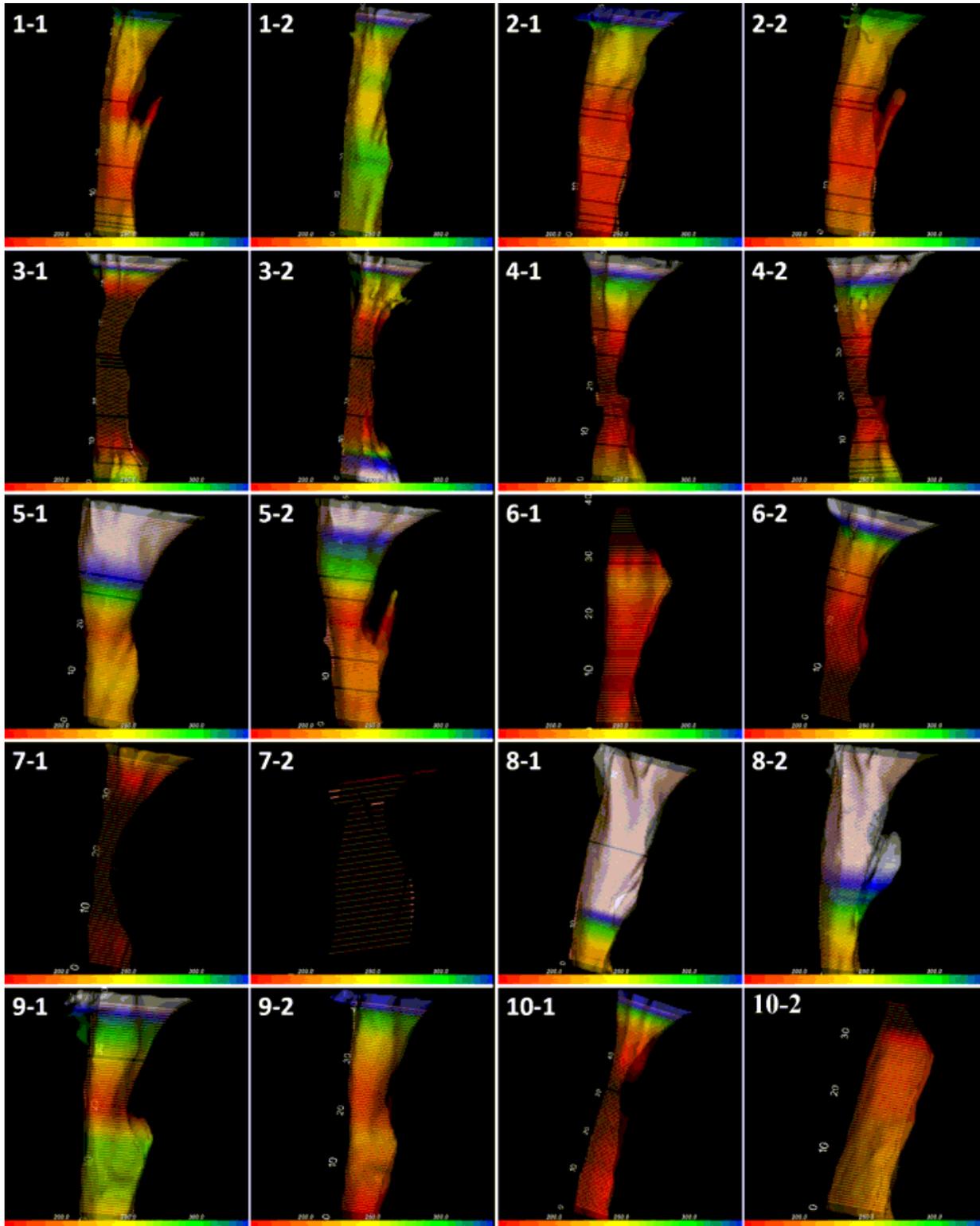
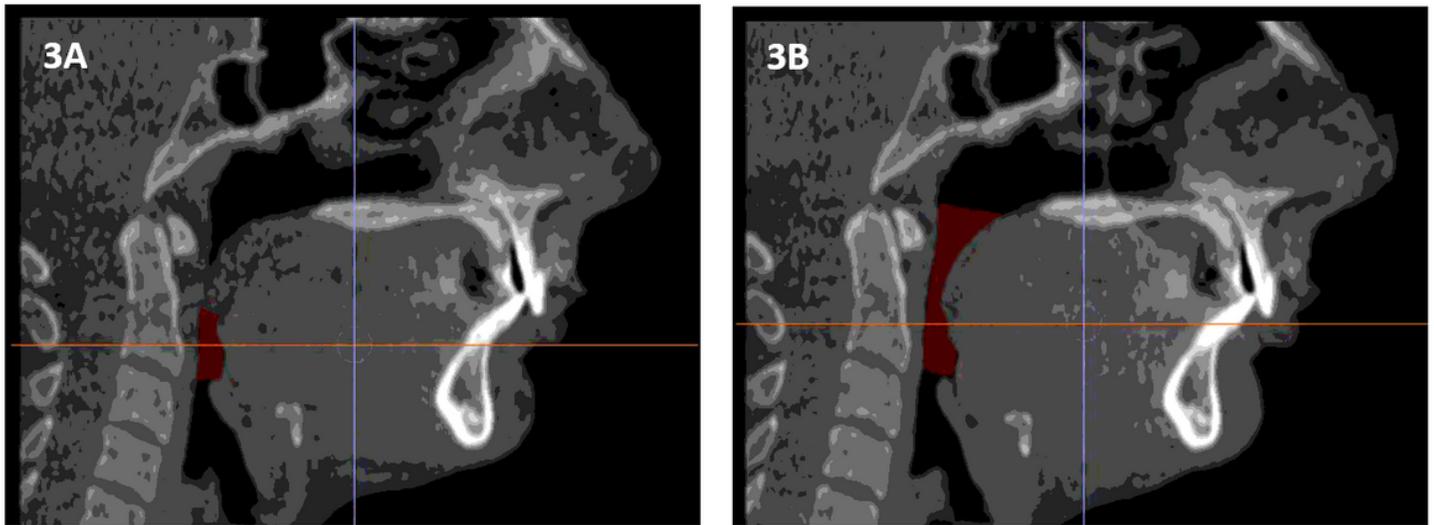


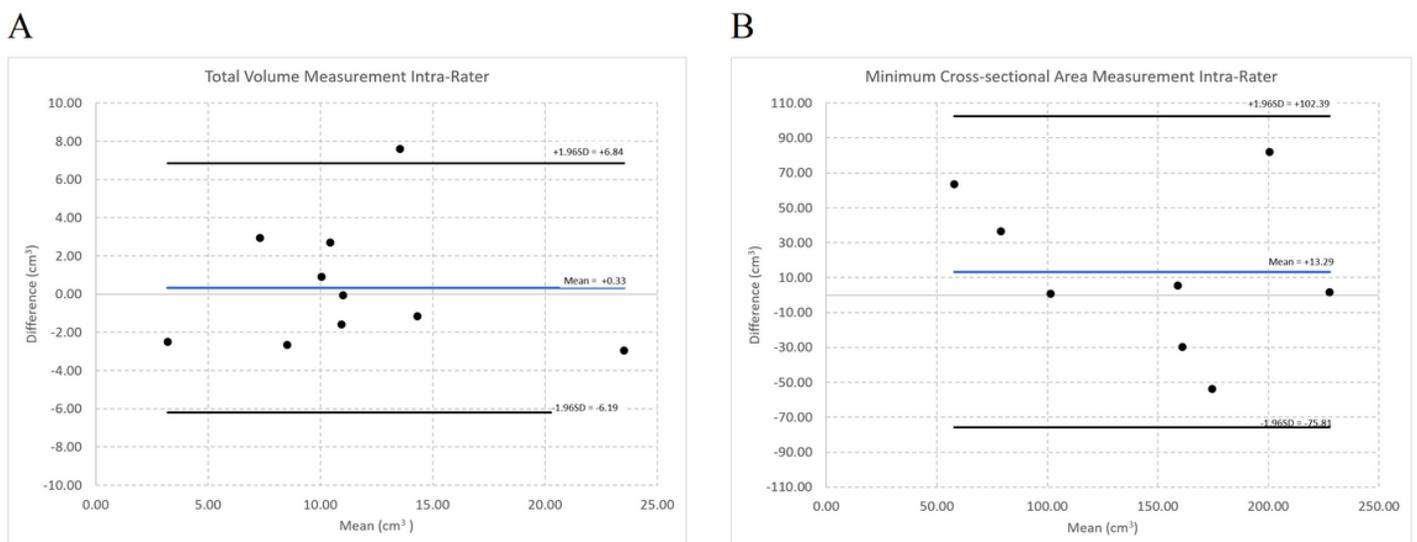
Figure 1

Composite graphic showing all 20 airway reconstructions. The images are labeled “Participant ID”-“Scan #” (i.e. 1-1 is Participant 1, Scan 1). All reconstructions use the same color scale with red being the most constricted portion of the airway and blue/white being the largest cross-sectional area, proportional to the scale.



**Figure 2**

Both Participant 7 and Participant 10 produced airway scans in which there was a complete airway constriction (MCA = 0 mm<sup>2</sup>) between the superior and inferior borders of the airway. For such scans, the TV was measured by adding the areas above and below the constriction and the MCA was considered 0 mm<sup>2</sup>. Fig 3A: Participant 7, Scan 1. TV = 4.45 cc, MCA = 43.7 mm<sup>2</sup>. Fig 3B: Participant 7, Scan 2. TV = 1.95 cc, MCA = 0.0 mm<sup>2</sup>.



**Figure 3**

A: Bland-Altman Chart for Total Volume. B: Bland-Altman Chart for Minimum Cross-sectional Area

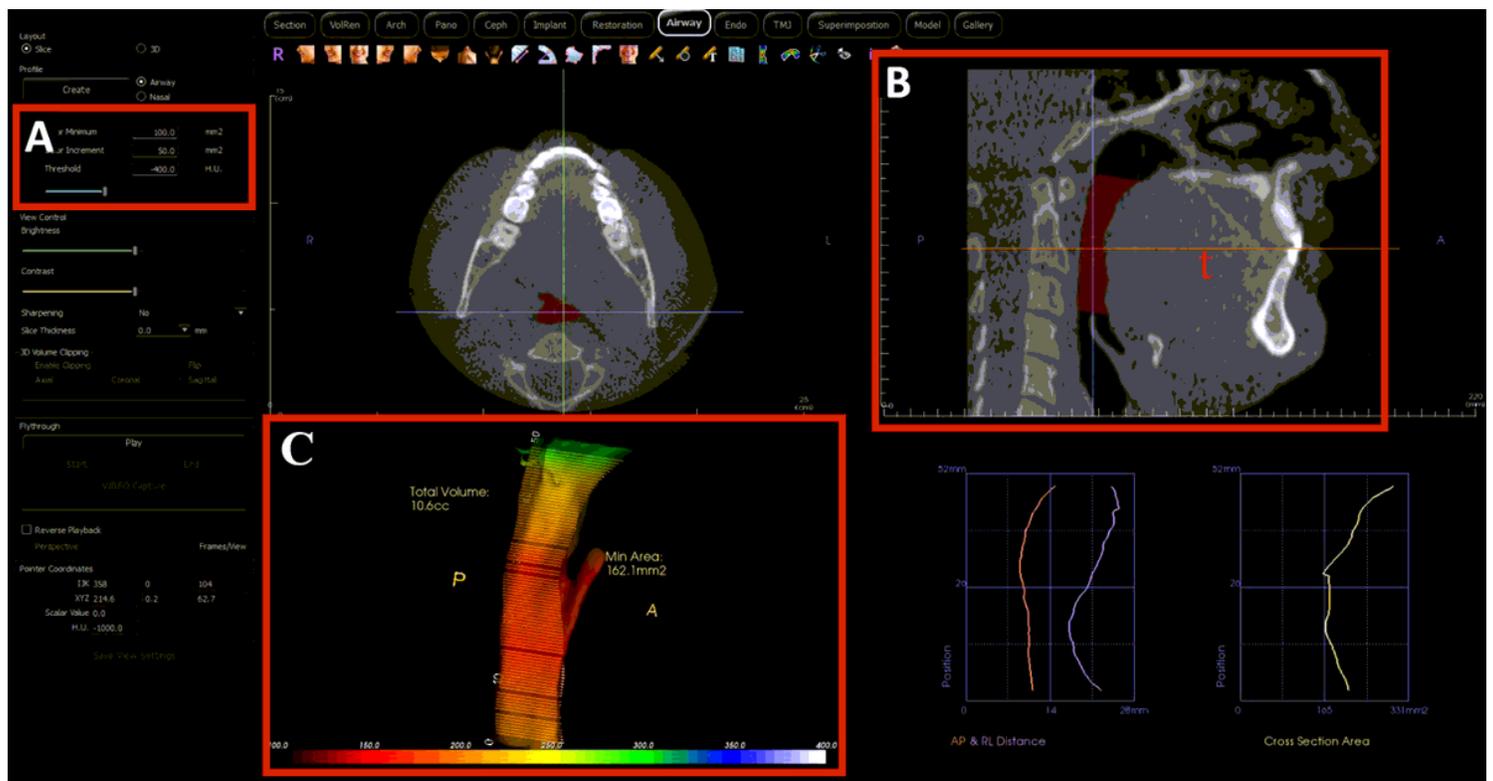


Figure 4

Screenshot of Participant B, scan 2, using InVivo 6 (Anatomage Inc, San Jose, California). In box A, the user selects the threshold that the software uses to define which voxels are considered airway. This threshold is determined by selecting the maximum radiographic density to be considered air, represented in Hounsfield Units (H.U.). Increasing (a more positive or less negative number) the threshold value results in a smaller software-constructed airway; decreasing the threshold increases the software-constructed airway. For this study, the threshold was set to -400.0 H.U. for all CBCT volumes. The color scale does not affect TV and MCA measurements and was irrelevant to this study. In box B, the user defines the upper and lower limits of the airway. In this study, the upper limit was defined by extending the line created by the hard palate into the airway space and selecting the point of that line that bisects the airway anteroposteriorly. Box C provides both a graphic and numeric representation of the airway.